

Summary Report

***NATIONAL HIGH BLOOD PRESSURE EDUCATION PROGRAM
(NHBPEP)/NATIONAL HEART, LUNG, AND BLOOD INSTITUTE***

(NHLBI) AND AMERICAN HEART ASSOCIATION (AHA)

WORKING MEETING

ON

BLOOD PRESSURE MEASUREMENT

***Natcher Conference Center
National Institutes of Health (NIH)
Bethesda, Maryland
April 19, 2002***

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National Heart, Lung, and Blood Institute (NHLBI) and
American Heart Association (AHA)
Working Meeting on Blood Pressure Measurement**

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Participants: Dr. Daniel W. Jones, M.D., Cochair, Dr. Claude Lenfant, M.D., Cochair, Dr. Lawrence J. Appel, M.D., M.P.H., Ms. Vicki Burt, R.N., Sc.M., Ms. Jean Charleston, R.N., Dr. Jeffrey A. Cutler, M.D., M.P.H., Dr. Rosalie A. Dunn, Ph.D., Dr. Bruce Friedman, D. Eng., Dr. John Graves, M.D., Ms. Carlene Grim, R.N., B.S.N., M.S.N., Dr. Clarence E. Grim, M.D., M.S., Joanne Karimbakas, M.S., Dr. Janice Meck, Ph.D., Mr. Thomas Murray, Dr. Bruce Z. Morgenstern, M.D., Dr. Ami Ostchega, Ph.D., R.N., Dr. Thomas Pickering, M.D., Dr. Edward J. Roccella, Ph.D., M.P.H., Dr. Sheldon G. Sheps, M.D., Ms. Sue Shero, R.N., M.S., Dr. Paul D. Sorlie, Ph.D., Dr. Sandy F.C. Stewart, Ph.D., Mr. Michael Wolz

INTRODUCTION

Welcome and Meeting Goals [Dr. Daniel Jones]

Dr. Jones welcomed the group to this joint meeting, sponsored by the NHBPEP/NHLBI and the AHA, and asked participants to introduce themselves and their particular interest in the topic of blood pressure (BP) measurement. The group included representatives from Government agencies, academia, and industry.

Dr. Jones stated the need for original thinking on how to improve BP measurement. He noted that the participants recognize the challenges and clinical problems that result from inadequate measurement, though they all come with their own biases about which type of measurement they prefer (e.g., mercury manometers, aneroid instruments, etc.).

Reviewing the reasons for the meeting, Dr. Jones said that the AHA convened a Writing Group to provide recommendations for BP measurement in the United States. A central issue was the dependence on the mercury manometer as the “gold standard” for BP measurement; the instrument is no longer available in some health care settings. This is creating a problem. One solution is to ask people to slow down the removal of mercury manometers in health care settings until there is a better understanding of the principles of BP measurement and alternatives. Another is to ask for a new set of standards.

The goals of the meeting are to examine the science that supports current BP measurement policies and to identify additional research needed to strengthen policies. This may lead to changes in standards by which BP is measured and how instruments are regulated, thereby leading to changes in policies to improve measurement. The Working Meeting will make recommendations to the director of the NHLBI, who suggested the meeting.

Dr. Jones listed the following questions to be addressed:

- Is the accurate measurement of BP important?
- Are mercury manometers dangerous?
- Is the use of mercury manometers forbidden?
- Are currently available aneroid and electronic instruments a reliable substitute for mercury manometers?
- Are current standards of validation of aneroid and electronic instruments adequate, or do we need new standards?
- Is there a sufficient knowledge base for establishing standards and guidelines regarding the validation of BP measurement instruments?
- Are current programs for calibration adequate, or do we need new standards and guidelines?

Possible meeting outcomes will include the following:

- Publication of a paper in the journal *Hypertension* next summer. The paper will be written by a small group and then reviewed by the entire group.
- Identification of research questions, which may lead to a Special Emphasis Panel that will further refine the research questions, leading to funding for research.
- Suggestions to manufacturers through the Association for the Advancement of Medical Instrumentation (AAMI) and other mechanisms.

History and Overview of Blood Pressure Measurement Policy Development [Dr. Sheldon Sheps]

Dr. Sheps reviewed highlights in the history of sphygmomanometry and policy development, beginning with the development of the mercury manometer and aneroid manometer in Europe in 1896 and 1897, respectively, and Korotkoff's presentation on the auscultation of arterial sounds in 1905. Janeway's book, *The Clinical Study of Blood Pressure* (1906), influenced the Northwestern Mutual Life Insurance Company to include BP measurements in physical examinations. By 1918, most life insurance companies required readings of systolic and diastolic BPs using Phase V (in Europe, Phase IV was preferred). Life insurance data for 700,000 persons were pooled, and in 1925 the Joint Committee on Mortality of the Association of Life Insurance Medical Directors and the Actuarial Society of America reported average BP by gender, age, and body build and related increased BP to mortality. Subsequent reports were provided through 1979.

The American Bureau of Standards published reports to improve BP measurement in 1917, 1921, and 1927, recognizing the need for standardization of both equipment and

measurement. In 1938, Dr. Irving Wright reported on a survey of measurement errors and also conducted a survey of medical schools and life insurance examiners, finding great variation in every aspect of measurement. In the late 1930s, the U.S. Bureau of Standards started a nationwide study of BP apparatus, and the Taylor Instrument Company developed a standard device for checking manometer accuracy.

The proliferation of coin-operated BP measurement devices 50 years later led to an NHLBI-sponsored AAMI report on manometers and the establishment of the Sphygmomanometer Committee. Specifications for manometers were developed and were promoted by the American National Standards Group. The Food and Drug Administration (FDA) delegated regulation of sphygmomanometers to the AAMI, generally accepting the manufacturers' certification that their equipment meets AAMI standards. In addition, the British Standards Institution (BSI) and the European Union produce specifications for mercury and aneroid manometers.

Dr. Sheps described the following six reports that included recommendations for human BP determinations by sphygmomanometry and summarized their changing recommendations for cuff size and technique for measuring diastolic BP (DBP).

1. The 1939 *Joint Recommendations of the AHA and the Cardiac Society of Great Britain and Ireland* recommends annual calibration, especially for aneroids, and offers recommendations for cuff size and placement, patient positioning, palpation, and specifications for taking systolic BP (SBP) and DBP. Some recommendations differed from those in the United States.
2. In 1951, the AHA asked Dr. Carl Wiggers to produce "Recommendations for Human Blood Pressure Determinations by Sphygmomanometers." This report recommends a cuff 20 percent wider than arm diameter and preferred cessation of sound for DBP. It includes a discussion of thigh cuffs, training, and literature abstracts.
3. In 1967, the AHA's Professional Education Committee (chaired by Dr. Walter Kirkendall) updated the previous report for practicing health care providers. The update includes further recommendations for cuff placement, suggests a seated position for patients, and includes sections on epidemiology, basal BP, and clinical conditions. The report describes the five phases of Korotkoff (K) sounds, the auscultatory gap, and specifications for SBP and DBP. The report regards muffling as the best index of DBP.
4. The AHA's Post Graduate Education Committee requested a report, chaired by Dr. Kirkendall and published in 1980, that includes recommendations for cuff circumference, length, and sizes by age, as well as details on care and calibration of devices, the use of the stethoscope bell, and a measurement section detailing observer/patient preparation, equipment, and technique. This report defines DBP as disappearance of sound, based on clinical trials and NHBPEP reports, but does not define high BP, or hypertension (HTN). The report dismisses kilopascals (kPa) as the unit of measurement.

5. The 1988 “Recommendations for Human Blood Pressure Determinations by Sphygmomanometers,” chaired by Dr. Edward Frohlich, emphasizes standardization of cuff size and recommends marking the cuffs to indicate the circumferences for which they can be used. It disparages the use of electronic devices and ambulatory BP in clinical care and refers to AAMI for standards. Measurement technique is detailed, with a recommendation for two or more sitting BPs at each visit and three visits to diagnose HTN. This report prompted discussion because of inconsistencies in the text and tables.
6. The sixth and current report, “Human Blood Pressure Determination by Sphygmomanometry,” published in 1993 and chaired by Dr. Dorothy Perloff, was intended “for everyone who measures BP.” This report discusses epidemiology and cuff size and placement. It disapproves of the use of the large cuff (12.5 by 35 cm) for all adults recommended by the British Hypertension Society (BHS) because use of such a cuff could lead to systematic underestimation or overestimation of blood pressure. It recommends that the width of the bladder be 40 percent of the arm circumference, and the length of the bladder be long enough to encircle at least 80 percent of the adult’s arm. The report suggests that aneroid manometers can provide accurate measurements if properly calibrated. This report underscores concern about mercury toxicity and vets automated devices, except for those used on the finger and wrist. It includes greater detail on observer and subject technique, describes errors, and includes an appendix with the classification of BP as set forth in “The Fifth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure” (JNC V).

Dr. Sheps also mentioned similar efforts in Europe, including those of the World Health Organization’s Expert Committee on Cardiovascular Disease and Hypertension (1959), the BHS (1986–1999), the European Society of Hypertension (2001), and four papers on BP measurement published in 2001 in the *British Medical Journal*.

Dr. Sheps then listed current issues and efforts. Issues include the following:

- “Standard” cuff sizes are often inconsistent and inappropriate. They are device-specific and cannot be interchanged in the electronic manometers.
- Should K5 be defined as the last sound heard or the onset of silence? This is a 2 mmHg difference.
- Environmental concerns about mercury are real; do we have reliable substitute manometers for medical environments as well as for self-use?
- If we don’t have mercury, should we revisit kPa?

Current efforts include development of new devices to simulate mercury and enhanced aneroids, automated devices to obtain multiple readings at a single office visit, self-measurement devices that store many readings and print and send data to a server, and a more universal cuff.

Importance of Accuracy: The Costs of Errors [Dr. Clarence Grim]

Dr. Grim stressed that the key to BP control is good BP measurement. If BP measurements are not done accurately and reliably, there is a potential for great harm and great cost. Patients with truly high BP who are measured as normal are denied the proven benefits of treatment, and they will suffer premature disability and death from undiagnosed HTN.

Describing the “chain of community blood pressure control,” Dr. Grim said that if measured BP is “high,” the reading must be recognized as high, the patient must be informed, the provider must decide to treat, the patient must decide this is important, the patient must be given a goal, feedback must be given on progress, and problems must be solved to achieve the goal. In addition, the physician must make decisions based on the BP measurement—in terms of making a diagnosis, starting therapy, and increasing or decreasing treatment. In 1996, BP was measured in about half of the 734 million outpatient visits that year (about 1 million BP measurements per day). Hypertension is the major reason to see a physician for a chronic condition (31 million visits per year).

Dr. Grim observed that the life insurance industry benefits when an insured person lives a long time. Recognizing that lower BP extends life, the industry was doing palpated BPs before auscultatory techniques were available. The “Build and Blood Pressure Study: 1935–1954” and the Metropolitan Life Insurance Company in 1991 looked at the natural history of a 35-year-old white male with untreated HTN. This study showed that each 1 mm rise in DBP in this population shortened lifespan about 1 year.

Dr. Grim also pointed out the implications of small reductions in DBP for primary prevention, citing several studies that found an association between such reductions and lower risk of coronary heart disease (CHD) and stroke. For example, Cook et al. (1995) showed that a 5–6 mmHg reduction would reduce CHD by 16 percent and stroke by 38 percent. More recent analysis of longer term therapy showed reductions of 20 percent and 40 percent, respectively.

Data from the Hypertension Detection and Followup Program (HDFP) indicate that the definition of DBP determines the number of people diagnosed. For illustration purposes, if 50 million people have high DBP when the cutoff is ≥ 90 mmHg, moving the cutoff to ≥ 85 mmHg would add 27 million people to this total. The cutoff of ≥ 120 mmHg would diagnose only 1 million people with high BP.

Dr. Grim noted that many people think that an error of 5 mmHg is insignificant, but this error at the 90–95 mmHg range would miss the 21 million U.S. hypertensives. Over the next 6 years, those 21 million would have a coronary artery disease (CAD) death rate of 5 per 1,000, or 125,000 CAD deaths (Kannel, 1986). Treating BP in this group would be expected to decrease the CAD death rate by 20 percent, saving 25,000 lives (McMahon, 1990), and prevent a similar number of fatal strokes. Conversely, measuring blood pressure 5 mmHg too high would falsely classify 27 million persons as having HTN. At the cost of \$1,000 per year to treat a patient, this would add \$27 billion to the Nation’s health care bill to treat a nondisease.

Accurate BP measurement can save money—for example, by delaying renal failure. HTN (with or without diabetes) causes 80 percent of renal failure. The annual cost of treating

renal failure will soon exceed \$19 billion. Because BP control can delay the onset of renal failure by 4.5 years and each year of dialysis costs about \$50,000, controlling BP in one person potentially could save \$225,000.

Dr. Grim said that retrospective analysis has revealed serious BP measurement errors in national surveys in Finland, Norway, the United States, Australia, and England. The errors include terminal-digit bias, direction bias (a tendency to read too high or too low), falsification of data, and failure to follow the protocol for calibration and technique.

Dr. Grim then discussed problems with aneroid instruments. Five studies (from 1970 to 1997) found inaccuracies in an average of 35 percent of aneroids, suggesting that no quality assurance (QA) measures have been implemented. He described a calibration check in 86 practices in Green Bay, Wisconsin, in which no mercury manometers were used. When the aneroids were checked against a mercury manometer (using a Y tube), 35 percent were off by at least 6 mmHg; the average error was -10 mmHg; and 2 percent leaked excessively. Only 7 of 13 clinics had an equipment maintenance schedule, and none of the nursing homes or health care services knew that aneroid manometers should be inspected every 6 months. Correcting the problem would require calibrating all aneroid devices and removing all those that are off >1 mmHg. Regular annual quality control (QC) could detect 2,500 errors, while daily QC could detect 10 errors.

Dr. Grim said that an alternative is to use a mercury manometer. He noted that environmental assessments of hospital mercury waste loads have presented no evidence that manometers contribute significantly to combustion waste. He suggested that the Environmental Protection Agency (EPA) has tried to draft simple, broad laws against all persistent bioaccumulative toxins and has lost its ability to discriminate between categories of risk. Dr. Grim stated that it would appear that mercury manometers do not constitute a risk to the population and, as the absolute primary standard, they are essential to the accurate measurement and treatment of HTN.

Dr. Grim also made the following recommendations to address the lack of mandated inspection of BP measurement equipment or training for equipment operators.

- Routine inspection and calibration of office BP manometers should be implemented. How often, by whom, and at what cost remain to be decided.
- Careful training of those who use BP devices must be done and kept current.
- Legislation may be needed to assure compliance (as it does for glucose-monitoring equipment).
- Ongoing QA must be implemented.

VALIDATION

Review of Current Validation Standards and the Regulatory Process

Food and Drug Administration: Consensus Standards for Blood Pressure Monitors [Dr. Sandy Stewart]

Dr. Stewart, who is with the FDA's Office of Science and Technology, Center for Devices and Radiological Health (CDRH), reviewed the current standards for several types of BP monitors:

- **Manual blood pressure cuffs**—ANSI/AAMI SP9 (1994)
- **Automated noninvasive blood pressure (NIBP) monitors**—ANSI/AAMI SP10: 1992 for electronic or automated sphygmomanometers; IEC 60601-2-30 (1999-2012) for automatic cycling NIBP monitoring equipment
- **Invasive blood pressure transducers**—ANSI/AAMI BP22: 1994 (R) 2001 for blood pressure transducers; IEC 60610-2-34 (2000-10) for particular requirements for safety, including essential performance of invasive BP monitoring equipment

Dr. Stewart also listed future standards being developed for manual, electronic, or automated manometers. A new version of AAMI/SP10, designated AAMI/CVD-2 SP10, is just coming up for a vote. This standard will cover manual, electronic, or automated manometers and will combine the old SP9 and SP10 standards. The new version will cover all BP measurement using a cuff; update clinical validation studies to include infants and the pediatric population; and include requirements for software verification and validation as well as electromagnetic compatibility (EMC) testing.

Dr. Stewart noted that well-written consensus standards provide a solid scientific basis for objective reviews of applications, help focus on important issues and thus streamline the review process, and provide a level playing field for manufacturers. Certain standards have been formally recognized by CDRH so that they can be used in the abbreviated 510(k) process. The CDRH uses those standards as the basis for approving new devices. For example, ANSI/AAMI SP10:1992 is a standard that is recognized by the CDRH and can be used in preparing an abbreviated 510(k). However, this standard does not include EMC testing or software validation and verification, which are important components of medical device safety. Thus, a supplemental data sheet points to CDRH's National Information Policy Board (NIPB) guidance, which specifies that the manufacturer must submit EMC test data and software verification and validation along with the Certificate of Conformance to SP10: 1992. The supplemental data sheets and guidance are used even if a standard already exists because the standards may be out of date.

Dr. Stewart noted that sphygmomanometers and noninvasive blood pressure monitors (NIBPs) are pre-amendment 510(k) devices and, as such, can be approved by one of three methods: recognized standards such as SP10, substantial equivalence to a predicate device, or other standards. For NIBP monitors, SP10 is the preferred standard because it includes

statistically based clinical trial protocols as well as electrical safety, environmental, and other testing. For manual sphygmomanometers, SP9 is the preferred standard because it includes requirements for testing the cuff and includes accuracy requirements for the pressure-measuring device. In the future, the new version of SP10 will probably be the standard of choice for both manual sphygmomanometers and automated NIBP monitors.

During the question period, it was noted that some blood pressure cuffs are marketed without the FDA's approval. Dr. Stewart said that there is not enough enforcement and that companies that play by the rules should complain. It was also noted that British and U.S. standards differ and that the BHS does not look at engineering aspects of a device. Dr. Stewart pointed out that there is an effort under way to base the standards on science as well as consensus.

Association for the Advancement of Medical Instrumentation: Oscillometric Blood Pressure Measurement [Dr. Bruce Friedman]

Dr. Friedman, interim cochair of the AAMI committee, discussed several aspects of the performance of oscillometry for BP measurement. The basis of oscillometry is that the pressure volume curve changes the volume pulse. Although oscillometry assumes that blood pressure is constant over the period of measurement, that is not always the case.

Dr. Friedman described the ratio method and the deflation method. The ratio method is determined by the mean arterial pressure (MAP), based on the maximum oscillation measured by the monitor in the cuff. The largest oscillation occurs near mean pressure. Specific ratios are used to determine SBP and DBP where oscillations occur at those ratios relative to the maximum. The deflation method uses either linear or step deflation, both of which determine MAP from maximum oscillation by looking at change in slope of the oscillations' inflection point and using ratios to determine SBP and DBP. Inflection points are used in linear but not step deflation. The devices interpolate between steps.

Two artifact rejection methods are used: one uses the characteristics of the oscillometric signal (normal sinus rhythm is assumed); the other, electrocardiogram (ECG) gating, is more applicable in ambulatory monitors or in hospital settings.

Dr. Friedman listed the following limitations of oscillometric instruments:

- Motion can increase cuff pressure, which will alter the result. Motion can also produce noise that can be interpreted as pressure oscillations.
- Arrhythmias can distort the reading. Variations in pulse pressure "distort" the oscillometric envelope.
- The monitors have not been tested in all patient populations (by age and disease). Manufacturers should state which patients and cuffs have been tested. The AAMI does not address this issue specifically.
- Manufacturers test only using their own cuffs.

Dr. Friedman noted the importance of knowing the instrument's model and serial number and its type of software (and software revision, if applicable), but he also noted that this information is sometimes not available. "Secrecy" has become less of a problem. Manufacturers should be willing to provide accuracy information (an abstract of the clinical study used for the device). Dr. Friedman added that blood pressure simulators are useful in testing, but clinical testing is needed.

Memorandum of Understanding Between the Environmental Protection Agency (EPA) and the American Hospital Association [Mr. Thomas Murray]

Mr. Murray said that one concern of the EPA's Office of Prevention, Pesticides, and Toxic Substances is the problem of chemicals that are persistent, bioaccumulative, and toxic (PBTs). Top priorities are dioxins/furans, and mercury and mercury compounds. He noted that the EPA started out as a highly regulatory agency but now increasingly focuses on prevention.

Mr. Murray reviewed the risks of mercury, stating that it is well known for its toxic effects, especially those of methyl mercury (MeHg). Long-term exposure can damage the brain, kidneys, and the developing fetus. Groups at highest risk are pregnant women, nursing infants, young children, and fish eaters (particularly among tribal nations). Efforts by the EPA and States to control mercury have led to an 85 percent reduction in its use in the United States. New controls for incinerators are expected to reduce emissions by 90 percent, and fish consumption advisories and thermometer/barometer take-back programs are designed to decrease mercury exposure. However, data from the National Health and Nutrition Examination Survey (NHANES) suggest that 10 percent of women of childbearing age have unsafe mercury levels, and an estimated 400,000 newborns per year are at risk of developmental problems from exposure to MeHg. Mr. Murray stressed the need for techniques to rid the biosystem of mercury, noting that some current efforts are only storing or recycling it. Most mercury is mined internationally and is used in many devices and consumer products. Sphygmomanometers are only one medical use of mercury, which is also used in thermometers, esophageal dilators, feeding tubes, batteries, preservatives, lab chemicals, fluorescent lights, etc.

PBTs are a global priority, and a number of international efforts and treaties have been established to deal with organic pollutants. EPA priorities include reducing the use of mercury (especially with respect to mercury-containing devices used in the medical area), reducing anthropogenic releases of mercury (e.g., through coal-fired power plants), reducing exposures through improved risk communication, ensuring safe storage and disposal of mercury waste and nonwaste elemental Hg, and investigating life cycle issues for mercury as a global commodity.

The EPA works with hospitals because hospitals generate about 2 million tons of solid waste annually, and medical waste incinerators are the fourth-largest known source of mercury emissions to the environment. Importantly, health care facilities are willing pollution-prevention partners; their benefits from involvement include reducing costs and liability and promoting community trust.

Mr. Murray described the EPA/American Hospital Association Memorandum of Understanding (MOU) that was signed in 1998. This MOU created Hospitals for a Healthy Environment (H2E), a project that asks all hospitals to pledge to virtually eliminate mercury

waste by 2005; to reduce total waste volume by 33 percent by year 2005 and by 50 percent by 2010; and to identify hazardous substances in hospitals for P2 and waste-reduction opportunities.

Other organizations participating in H2E are Health Care Without Harm (HCWH), the American Nurses Association, and the “H2E community”—more than 250 partners (hospitals, clinics, and nursing homes) representing 330 facilities. Approximately 1,000 partners are expected by the end of the year. In addition, more than 30 health care organizations, such as Kaiser Permanente, champion H2E.

H2E is a voluntary program. Patient care comes first, and change is encouraged. H2E provides tools and resources, encourages the development of effective and reliable substitutes, and gives awards to health care facilities that are leading the way to reducing mercury in their facilities. Consultants help set up new policies and procedures for no fee (a fee may be charged later). Mr. Murray stressed that full involvement is needed to ensure the success of the program, which focuses on pollution prevention and behavioral change. He provided the Web site for the H2E program, <http://www.h2e-online.org>. A listserv is also available, and a video describes the program.

Physics of Measurement and Review of Literature on Accuracy of BP Measuring Devices [Dr. Thomas Pickering]

Dr. Pickering reviewed basic principles of noninvasive BP measurement. He noted that small differences in BP are increasingly important, BP variability is high, and human factors (such as the white coat effect and poor technique) lead to unrepresentative readings and the need for automated measurements.

Dr. Pickering cited data indicating the need for multiple BP measurements. One study found that 10 readings were more accurate than just 1 or 2. Another indicated that automated BP readings taken in an office setting were closer to the ambulatory average than were readings taken by physicians or nurses.

An ideal technique should be noninvasive, accurate in all conditions (e.g., obesity or pregnancy), and automatic (to eliminate observer error). It should also provide multiple readings and be cheap and easy to use. Dr. Pickering said that aneroid and oscillometric devices are the leading contenders for replacing mercury manometers; other possibilities are a hybrid sphygmomanometer and a device based on the wideband K2 method. He mentioned the following findings about the various techniques:

- A study of wideband recording of K signals (Blank et al., 1998)—based on a filtering technique developed in collaboration with Bell Labs—found it to be more accurate than the auscultatory method. Two studies (Blank et al., 1995; Fang et al., 1995) found that the K2 method gave a closer approximation of true intra-arterial pressure than the auscultatory method, which tends to overestimate DBP and underestimate SBP. Although potentially more accurate than other noninvasive methods, the K2 method has not been developed commercially.

- A study examining the physiological basis of the auscultatory gap found that it is due to fluctuations in blood pressure. Patients with the gap are older and have more peripheral artery disease.
- A study of DBP measurement during pregnancy found that Phase IV (muffling) overestimates DBP in pregnancy. As in nonpregnancy, auscultatory SBP is lower than the K2 method. In contrast to nonpregnancy, auscultatory (Phase V) DBP is the same by both methods.
- Reports on the accuracy of aneroid devices vary and may be manufacturer-dependent. The error rate among five studies ranged from 1 percent to 44 percent.
- The oscillometric technique measures mean pressure accurately. Limitations include the fact that estimation of SBP and DBP are indirect and depend on individual algorithms. Furthermore, there may be a consistent error in substantial numbers of subjects, and error is greater in older subjects, those with stiffer arteries, and those with isolated systolic hypertension.
- A potential advantage of the hybrid sphygmomanometer is that it is based on the mercury auscultatory method but does not use mercury. (The mercury column is replaced with a transducer.) The hybrid should be acceptable to clinicians accustomed to using mercury, and the readings are equivalent to mercury readings. The device eliminates observer bias (the operator presses a button to get the results), it can be programmed to prevent excessive cuff deflation rate, and it can provide electronic output.

Dr. Pickering noted that existing BHS and AAMI validation protocols tend to lump people together as a population, but what we need to know is whether a device will work in individual patients. BHS and AAMI standards both recommend 3 readings on each of 85 individuals pooled for analysis. The mean error should be within ± 5 mmHg, and the standard deviation within 8 mmHg. A problem is that if we take three readings on one person, we expect that they will be grouped more closely together than those taken on different subjects. However, raw data from a validity study (O'Brien) of an ambulatory monitor shows a huge scatter of readings. Analysis of the data indicates a consistent error in the percentage of persons within 5 mmHg. The new protocol will try to report on individual subjects.

In summary, Dr. Pickering listed the advantages and disadvantages of different types of sphygmomanometers:

	Mercury	Aneroid	Oscillometric	Hybrid
Cuff pressure reading	Accurate	Questionable	Accurate	Accurate
SBP/DBP reading	Accurate	Accurate	Questionable	Accurate
Terminal digit preference	Yes	Yes	No	No
Individual validation needed	No	No	Yes	Yes

He concluded that there is an urgent need to find a replacement for the mercury sphygmomanometer and that the limitations of the various alternative devices will need to be addressed.

Review of Literature on Out-of-Office Devices [Dr. Lawrence Appel]

Dr. Appel presented results from an evidence-based report prepared for the Agency for Healthcare Research and Quality (AHRQ) and the NHLBI. The pre-2001 literature on ambulatory BP (ABP) and self-measured blood pressure (SMBP) was reviewed for risk prediction and treatment. The review included electronic searches of three databases and hand searches of major references, recent issues of key journals, and symposia of recent major meetings. The review looked at approximately 6,000 abstracts for eligibility and 600 potentially eligible papers. Data were abstracted from about 100 articles, and evidence tables and the report were prepared. Main eligibility criteria for including a paper were English language, sample size (from 20 to 50, depending on the research question), and the involvement of at least 2 clinic BP visits. Most of the eligible papers were in specialty journals, and there were few large-scale, multicenter studies. The quality of clinic BP measurements was poor or uncertain in most studies.

The evidence-based review included four research questions:

1. What is the distribution of BP differences between ABP, SMBP, and clinic BP, and the reproducibility of these differences?
2. What is the prevalence and reproducibility of white coat hypertension (WCH)?
3. What are the relationships of ABP, SMBP, clinic BP, and WCH with (a) subclinical outcomes in cross-sectional studies and (b) clinical outcomes in prospective studies?
4. What are the effects of treatment guided by ABP or SMBP on BP control, BP-related clinical outcomes, and other outcomes?

Dr. Appel listed some of the conclusions of the review:

- Mean clinical BP exceeded SMBP and ABP (day, night, and 24-hour).
- Mean daytime ABP and SMBP appeared similar, but few studies included these data.
- Few studies assessed the reproducibility of WCH and the reproducibility of differences between clinic BP and either ABP or SMBP. The prevalence of WCH based on ABP is approximately 20 percent among hypertensives but is highly dependent on its definition and the study population (it is more common in women than men).
- There is insufficient literature to determine associations of SMBP with target organ damage. Cross-sectional and prospective studies showed an association

between ABP and left ventricular (LV) mass or albuminuria. Prospective evidence supported the idea that at least one dimension of ABP (the BP level or pattern) predicted outcome.

- WCH was associated with reduced risk of cardiovascular disease (CVD) events compared with nondipping BP, which was associated with increased risk in most cases.

The review's major findings include the following:

- **Risk Prediction:** ABP levels and patterns predict clinical outcomes. Corresponding evidence for SMBP is unavailable. Comparison of risk prediction based on ABP and clinic BP is limited, in part because of poor or uncertain quality of clinic measurements.
- **Treatment:** SMBP may improve BP control, but further trials that test interventions with contemporary devices are needed. There was insufficient literature to determine whether treatment guided by ABP reduced BP or clinical outcomes.

Dr. Appel also identified the need for research in the following areas:

- Prospective observational studies that address reproducibility of WCH, risks associated with WCH, risks associated with nondipping BP, and incremental gain from use of ABP.
- Clinical trials that determine whether treatment guided by SMBP can improve BP control and outcomes.
- Decision analyses that determine the costs and effects of strategies that integrate clinic BP, SMBP, and ABP.

Human BP Measurement Accuracy With Nonelectronic and Electronic Devices [Ms. Carlene Grim]

Ms. Grim reviewed the literature and approaches to standardized BP measurement and discussed barriers to accurate measurement. She noted that many health care providers are not aware of the existence of guidelines for BP measurement, including the latest AHA guidelines with updates on measurement in the pediatric population and pregnancy.

In a year 2000 survey of 150 physicians, 27 responded. Fifty percent of the responders said they were not familiar with AHA recommendations for BP measurement; 45 percent were aware of them but had not read them; and only 5 percent had read them cover to cover. The amount of time spent when they first learned to measure BP varied from 2 to 4 hours and as little as 10 minutes. Less than 10 percent reported the use of a standardized training videotape or audiotape, and less than 20 percent had an instructor listen with them.

Other barriers to accurate BP measurement are a belief that technology will eliminate human error, lack of standardized equipment, and debated aspects of technique such as the cutoffs for cuff bladder size and arm circumference and uncertainties about the danger of mercury in this setting.

Ms. Grim reviewed training, testing, and certification methods. She noted that in a pretest of knowledge, 2 of 3 health care providers scored less than 50 percent on a 16-question test on BP measurement, and one-quarter of M.D.s scored greater than 80 percent. On the triple stethoscope practical exercise (in which two participants listen with an instructor), 8 percent of M.D.s and 19 percent of others needed to repeat the test. Errors of interpretation included measuring SBP (the first loud, distinct, strong sound) and DBP (K4 or K5—the last sound or disappearance of sound that is 2 mmHg below the last sound). Normal variations are an absent Phase V and an auscultatory gap. Ms. Grim said that standardized BP readings force response to sounds and allow repeating the exact readings. The usual error is 10 mmHg. There is a tendency to prefer one side of the manometer, as well as problems reading “backwards” down the manometer.

To detect and correct errors, Ms. Grim recommends practice testing with stethoscopes and videotapes, comparing readings using a dual stethoscope, identifying observers who read high or low and determining the cause, checking for observer bias and differences between the readings recorded, and checking for digit bias and cutoff bias in hospital records. In one study of terminal digit bias among medical students just learning to take BPs, 53 percent had a bias to the digit 0.

Ms. Grim made the following points:

- Patient-related errors correctable by automated devices include K sound variation, arrhythmia, and patient/provider interaction. Automated devices also correct for poor eyesight, hearing, and hand-eye coordination.
- Technique-related errors include cuff selection, positioning, and preparation. Preparation and training result in optimal readings. The Children’s Heart Study showed that providers who pass a test based on videotape training measure BP well in the field.
- Equipment-related errors can be prevented by making several cuff sizes available and by making regular cuffs and automated-device cuffs interchangeable. Mercury hazard and human error are also related to equipment.
- QA in the practice setting must become routine, and steps to standardize aneroid instrument should be widely implemented.

Ancillary Issue—Cuff Size [Dr. John Graves]

Dr. Graves began by pointing out that “standard” adult cuffs are not standard—there are variations by manufacturer. He referred to the following studies of arm circumference and cuff size:

- Beavers et al. (1987) found that an arm circumference >33 cm was seen about 7 percent of the time in a general population and in 15.7 percent of 209 hypertensives in a hospital-based clinic.
- O'Brien (1993) found a mean arm circumference of 30.2 ±4 cm among Irish men and women. Use of a BHS standard cuff (12 by 35 cm) would result in 6 percent being correctly cuffed and 94 percent being overcuffed.
- Rastam et al. (1990) analyzed arm circumference in family participants in the Minneapolis Children's Blood Pressure Study and found that 38 percent of men and 18 percent of women had circumferences greater than 32 cm (considered a big arm).
- Dr. Graves' paper in *Blood Pressure Monitoring* (2001) was based on 430 consecutive hypertensives seen at the Mayo Clinic's Division of Hypertension in 1999; 61 percent (mostly of Northern European background) had arm circumferences >33 cm.
- Mayo Clinic data (2001) on out-of-office BP measurement found that 20 of 190 people had purchased the wrong cuff, even though they received direction about which cuff to buy.
- A study of nurse BP measurement by Devenhorn et al. (2001) found that only 9 of 21 nurses used the correct cuff.

Dr. Graves then reported a study he conducted with Ms. Vicki Burt, using the NHANES III Population Survey database to compare the distribution of arm circumferences in the U.S. population between the Survey's Phase I (1988–91) and Phase II (1991–94). This was the first study to identify the distribution of arm circumferences in a national population. The study found that mean arm circumference is increasing in the U.S. population—both in normotensives and hypertensives—paralleling the increase in obesity. Estimates of the percentages of all Americans by ethnicity fit by six standard cuffs indicated that certain cuffs would be best for persons with larger circumferences. There were also variations using the “large adult” cuff, indicating that the solution is not just to pick a bigger cuff.

Dr. Graves concluded that accurate blood pressure measurement in the United States increasingly will require the use of “large adult” and thigh cuffs. Manufacturers of BP measuring devices should use knowledge of arm circumference distributions to manufacture “standard arm” cuffs that better fit the U.S. population. The cuffs should be given new, nonpejorative designations to encourage the use of the appropriately sized cuff in each patient.

EQUIPMENT CALIBRATION [Dr. Bruce Morgenstern]

Dr. Morgenstern said that the issue isn't the device—it's getting people to use the devices correctly. First he addressed the blind faith that mercury manometers are accurate. He cited a study in the *Journal of Human Hypertension* (Mion et al., 1998) that cited the percentage of inaccurate mercury manometers in Brazil (21 percent) and Canada (12.6 percent), with more

than half having a nonfunctioning component. In a study of office practices in the United Kingdom (UK), all failed on at least one British standard, and 86 percent did not meet all health and safety standards. In an inner-city study in the UK, only 2.3 percent were inaccurate, and a higher percentage of aneroids were inaccurate.

Dr. Morgenstern said that mercury is toxic, persistent, and bioaccumulable. He noted that the real cost is not toxicity but what happens when there is a mercury spill. At the Mayo Clinic, which owns its own medical waste incinerator, there were 50 spills from sphygmomanometers over a 2-year period, resulting in \$26,000 in cleanup costs (spills on carpets would cost much more to clean up). The Mayo Clinic got rid of thermometers in 1992 because of state laws, and it has also replaced all mercury manometers with commercially available aneroid devices. These devices are calibrated every 6 months at three sites, using a Digimano digital gauge from Netech Corporation and a mercury column for QA. At each site, 2–3 people have been trained to test each device at 0 mmHg and 10 points between 60 and 240 mmHg. It takes 5 to 20 minutes to test each unit and 6 months to cycle through each site. The cost per site is about \$7,000 each year. Failure of the device occurs if the zero is off, the readings are ≥ 4 mmHg off the standard, or the needle does not move smoothly. Device failure rates were 1.6 percent over 3 years and 4 percent over 6 months. According to a paper by Canzenello et al. (2001), the accuracy of the aneroid devices at Mayo Clinic is within the 4-mmHg range recommended by the AAMI.

Dr. Morgenstern cited several sources on the toxicity of Hg, including a study by Markandu et al. (2000) suggesting that mercury manometers should be abandoned and a statement by the British Medical Device Agency recommending that consideration be given to the selection of mercury-free devices where appropriate. Furthermore, an AHA article states that most mercury instruments have not been adequately validated over a wide range of BP, ages, and clinical conditions to warrant routine use in hospitals and outpatient settings. It encourages the general use of mercury manometers until other instruments are better validated through the AAMI or similar organization.

Additional concerns are that automated devices may work accurately in populations but not in individuals and that automated oscillometric devices might not work in every setting for every patient. Another concern is secrecy about the algorithms.

Dr. Morgenstern noted that the draft revision of the SP10 standard for mercury manometers includes concern about leaking from the top of instrument or from the reservoir during shipment, which would affect performance and may also be a hazard. The standard gives companies the opportunity to use devices other than a mercury column for calibration. He also called attention to Sustainable Hospitals Web site, <http://www.sustainablehospitals.org>, which includes a table comparing aneroid, electronic, and mercury devices and rated electronic monitors as most reliable.

In conclusion, Dr. Morgenstern said there is no reason to fear replacing mercury manometers with manual aneroid devices. The issue is ensuring validation, calibration, and regular maintenance.

DISCUSSION OF ISSUES AND DECISIONS [Dr. Jones and Dr. Edward Roccella]

Dr. Jones thanked the presenters and said that he sensed more common ground than he had expected. He asked them to send him their slides and abstracts, noting that the paper to be written would use these materials.

The group was asked to give preliminary votes on the questions listed earlier (see page 1). The following additional questions were raised:

- How great is the risk and environmental impact of mercury manometers? Should we encourage the development of electronic (not oscillometric) manometers as a substitute for mercury manometers?
- Should the use of mercury manometers be terminated in a short period of time or within 5 or 10 years? Should this group suggest to the EPA and the American Hospital Association that they take more time to phase out mercury devices?
- Is our current approach to BP measurement, validation, and calibration of mercury, aneroid, and electronic instruments adequate, or should we encourage stronger standards based on the science?
- Is there a sufficient knowledge base for establishing standards and guidelines regarding the validation of BP measurement instruments?
- Would national guidelines for equipment calibration resolve BP measurement issues? Would calibration overcome equipment problems associated with oscillometric devices?
- How many false positives should be acceptable with multiple readings for an individual patient: > 5 percent, > 20 percent?

Possible Recommendations

During the discussion, there was a consensus on the following recommendations (captured by Mr. Wolz on flip charts):

- Blood pressure devices should not be sold without appropriate regulatory approval.
- Blood pressure measurement devices must be manufactured with the ability to accept cuffs interchangeably from a standard set of cuff sizes.
 - The interchangeability need not extend to other brands, only within one machine.
 - Instructions must be included with the devices to allow users to match body type with appropriate cuff type.

- A system of standard cuff sizes should be developed.
- A standard system of training, certification, and recertification—perhaps linked to licenses—should be implemented and enforced.
- Send a message to the EPA (and other agencies, including state governments).
 - We support elimination of mercury from the environment.
 - We recommend a period of research to devise an adequate replacement for the mercury manometer.
- Promote calibration and maintenance programs with the NHLBI, AHA, and Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as partners.
- Develop methods to determine the accuracy of a given device when tested against a standard sample or measure.
- Develop standards based not only on group numbers but also on individual numbers—e.g., the percent of individuals whose blood pressure reading error falls outside a given multiple of the standard deviation.
- Recommend a regulated informational package insert for devices.
- Recommend that auxiliary health providers be certified to take blood pressures, perhaps with automated devices, at every visit.

Recommendations Regarding Research

- Determine the feasibility of implementing a system of standardized mercury manometers for calibration purposes.
- Find other standard measures for device calibration and testing.
- Develop methods of calibrating and standardizing oscillometric devices.
- Look at the relationships between cuff size, body size and type, and measurement error.
- Develop the standardization of cuff size.

The following issue was not decided:

- Should we encourage the development of electronic manometers as a substitute for mercury manometers?

Other Discussion Points

During the course of the discussion, participants made the following additional suggestions and comments:

- Allow limited use of mercury until research on non-mercury instruments is completed. Participants suggested allowing as much as 10–25 years or as little as 2 years. Dr. Jones suggested allowing 1.5 to 2 years for funding, followed by a period for research.
- Ask the EPA not to eliminate mercury but to allow research and hospital groups to make this decision. Develop a robust mercury manometer for calibration purposes. Calibration should look at moving columns rather than static ones. The upcoming AHA report should focus on specific calibration programs.
- Recommend that calibration be a measure for the Health Plan Employer Data and Information Set (HEDIS) and a requirement for all NIH clinical studies.
- Encourage the enforcement of current FDA standards for BP measurement devices.
- Clarify the frequency of BP measurement and who needs repeat measures. The JNC VI states that BP should be measured once every 2 years if the initial blood pressure readings are normal. Some participants suggested that the JNC should advocate measurements “at each health care encounter.”
- Report results for individuals as well as populations. Look at replicate measure by the same device and the standard. Increase the number of samples for each patient.
- Conduct research on the validity of quick BP measurements in clinics and hospitals. Determine the false negative rate.
- Conduct research to construct a model for validation standards. (The AAMI standards are a compromise.) Report validation results for both arterial and oscillatory measures.
- Report variability for individuals as well as groups. The percent error should be reported for individuals with error greater than 4 mmHg.
- Develop recommendations for a broader range of patients, such as older adults. Specify the range of clinical circumstances in which the device was tested, the subjects’ weights, and whether there were arm size requirements. Specify age >50 or end-stage renal disease. Require that people with stiff arteries be given special consideration.

- Take measurement out of the physicians' hands; use trained observers or nurses. There should be observer training, certification, recertification, and licensing for BP measurement. Take advantage of new technologies for education and certification that are available on the Internet. Use training tapes.
- Encourage insurance companies to reimburse for BP measurement devices. They should be available by prescription only (this is required by third-party payers) and should be purchased only through a blood pressure store. A regulated package insert should provide information about cuff size, etc.
- Suggest that hospitals offer free maintenance checks for measurement devices during National High Blood Pressure Education Month.

WRAP-UP

Dr. Jones thanked the participants for their efforts, which have begun to identify research questions. He said that a draft paper based on the meeting will be circulated for comment, and agencies will be contacted for their recommendations. This will result in a report to the NHLBI as well as recommendations for a Special Emphasis Panel that will lead to research. Participants may be called on to contribute to groups that would embellish the report.

Dr. Roccella added that the effort does not end here. This is an ongoing process that will lead to possibly several papers and sets of actions.

It was suggested that the group submit a short editorial or letter to *Hypertension* or another journal. Dr. Jones said that he would look into this.

ADJOURNMENT

Dr. Jones adjourned the meeting.

Attachment A

Participants

Cochair: Daniel W. Jones, M.D.
Associate Vice Chancellor for Health
Affairs
Herbert G. Langford Professor of Medicine
University of Mississippi Medical Center
Jackson, MS

Cochair: Claude Lenfant, M.D.
Director
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, MD

Lawrence J. Appel, M.D., M.P.H.
Associate Professor of Medicine
Epidemiology and International Health
Johns Hopkins Medical Institutions
Baltimore, MD

Vicki Burt, R.N., Sc.M.
Chief, Survey Planning and Development
Branch
National Center for Health Statistics
Centers for Disease Control and Prevention
Hyattsville, MD

Jean Charleston, R.N.
Project Director
ProHealth Clinical Center
Johns Hopkins Medical Institutions
Baltimore, MD

Jeffrey A. Cutler, M.D., M.P.H.
Director, Clinical Applications and
Prevention Program
Division of Epidemiology and Clinical
Applications
National Heart, Lung, and Blood Institute
Bethesda, MD

Rosalie A. Dunn, Ph.D.
Health Scientist Administrator
Heart Research Program
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Bethesda, MD

Bruce Friedman, D. Eng.
Manager, Technology Development
GE Medical Systems
Interim Cochair
AAMI Sphygmomanometer Committee
Tampa, FL

John Graves, M.D.
Assistant Professor of Medicine
Division of Hypertension, Mayo Clinic
Rochester, MN

Carlene Grim, R.N., B.S.N., M.S.N.
President
Shared Care Research and Education
Consulting, Inc.
Milwaukee, WI

Clarence E. Grim, M.D., M.S.
Professor of Medicine
Hypertension Research Clinic
Medical College of Wisconsin
Milwaukee, WI

Janice V. Meck, Ph.D.
Director of the Cardiovascular Laboratory
NASA Johnson Space Center
Houston, TX

Thomas Murray
Chief, Office of Pollution, Prevention, and
Toxics
Prevention Analysis Branch
United States Environmental Protection
Agency
Washington, DC

Bruce Z. Morgenstern, M.D.
Consultant in Pediatric Nephrology
Vice Chair for Education
Mayo Clinic
Rochester, MN

Ami Ostchega, Ph.D., R.N.
National Center for Health Statistics
Centers for Disease Control and Prevention
Hyattsville, MD

Thomas Pickering, M.D.
Professor of Medicine
Mount Sinai School of Medicine
New York, NY

Edward J. Roccella, Ph.D., M.P.H.
Program Coordinator
National High Blood Pressure Education
Program
Office of Prevention, Education, and
Control
National Heart, Lung, and Blood Institute
Bethesda, MD

Sheldon G. Sheps, M.D.
Professor of Medicine, Emeritus
Mayo Clinic
Rochester, MN

Sue Shero, R.N., M.S.
Public Health Advisor
Office of Prevention, Education, and
Control
National Heart, Lung, and Blood Institute
Bethesda, MD

Paul D. Sorlie, Ph.D.
Epidemiologist
Division of Epidemiology and Clinical
Applications
National Heart, Lung, and Blood Institute
Bethesda, MD

Sandy F.C. Stewart, Ph.D.
Research Biomedical Engineer
Hydrodynamics and Acoustics Branch
Center for Devices and Radiological Health
Food and Drug Administration
Rockville, MD

Michael Wolz
Statistician
Division of Epidemiology and Clinical
Applications
National Heart, Lung, and Blood Institute
Bethesda, MD

Attachment B

**National Heart, Lung, and Blood Institute
National High Blood Pressure Education Program
and the American Heart Association
Working Meeting on Blood Pressure Measurement**

**Natcher Conference Center
NIH Campus
Bethesda, MD
Friday, April 19, 2002
8:00 a.m. to 3:00 p.m.**

Agenda

8:00 a.m.	INTRODUCTION	
	Greetings and Introductions	Dr. Claude Lenfant Dr. Daniel Jones
8:15	Goals of Meeting <ul style="list-style-type: none">• Examine the science that supports the current measurement policies• Identify additional research needed to strengthen policies	Dr. Jones
8:30	History and Overview of Blood Pressure Measurement Policy Development	Dr. Sheldon Sheps
8:50	Importance of Accuracy: The Costs of Errors	Dr. Clarence Grim
	VALIDATION	
	Review of Current Validation Standards and the Regulatory Process	
9:10	Food and Drug Administration	Dr. Sandy Stewart
9:30	Association for the Advancement of Medical Instrumentation <ul style="list-style-type: none">• Algorithms for electronic instruments: secrecy in science	Dr. Bruce Friedman
9:50	Memorandum of Understanding Between the Environmental Protection Agency and the American Hospital Association	Mr. Thomas Murray
10:10	Physics of Measurement and Review of Literature on Accuracy of BP Measuring Devices	Dr. Thomas Pickering

10:45	Midmorning Break	
11:00	Review of Literature on Out-of-Office Devices	Dr. Lawrence Appel
11:20	Human Accuracy With Nonelectronic and Electronic Devices	Ms. Carlene Grim
11:40	Ancillary Issue—Cuff Size <ul style="list-style-type: none"> • Increasing arm size • Interchangeability between manufacturers 	Dr. John Graves
12:00 p.m.	EQUIPMENT CALIBRATION <ul style="list-style-type: none"> • Status of availability of mercury instruments • Current standards and practices • The Mayo model 	Dr. Bruce Morgenstern
12:20	Lunch	
	DISCUSSION OF ISSUES AND DECISIONS	
	Questions: <ul style="list-style-type: none"> • Is the accurate measurement of blood pressure important? • Are mercury manometers dangerous? • Is the use of mercury manometers forbidden? • Are currently available aneroid and electronic instruments a reliable substitute for mercury manometers? • Are current standards of validation adequate, or do we need new standards? • Is there a sufficient knowledge base for establishing standards and guidelines regarding the validation of blood pressure measurement instruments? • Are current programs of calibration adequate, or do we need new standards/guidelines? 	Moderators: Drs. Jones and Edward Roccella
	OUTCOMES <ul style="list-style-type: none"> • Workshop proceedings published • Identified research questions • Suggestions to manufacturers 	Drs. Jones and Roccella
3:00	Adjournment	

Attachment C

Abstracts

BACKGROUND SCIENCE THAT SUPPORTS THE CURRENT MEASUREMENT POLICIES

Daniel Jones, M.D., University of Mississippi Medical Center, Jackson, MS

Europe and the United States are phasing out hospital equipment and devices containing mercury. Many institutions have removed the mercury sphygmomanometer, replacing it with various aneroid and automated devices. With the phasing out of mercury, important issues regarding blood pressure measurement have emerged.

Misdiagnosing hypertensive patients is a real possibility if blood pressure measuring devices are used without adequate attention to validation and calibration. The aneroid devices, while accurate, need to be recalibrated regularly and, without proper maintenance, will provide erroneous measures. In addition, these devices still allow for the potential of human error by requiring expertise in auscultation. Automated devices may reduce the possibility of human error, but they use different algorithms to calculate systolic and diastolic pressure, and these algorithms are usually proprietary, making it difficult to determine the accuracy of the devices. Recently it was reported one automated device was producing a zero bias. Automated devices have difficulty in providing accurate blood pressure readings as arterial stiffness increases. These devices need to be independently validated and properly maintained to provide accurate readings.

Regardless of the type of device used to measure blood pressure, selecting appropriate-sized cuffs is critical. The appropriate cuff must be used, based not only on arm size but it should also be one designed for use with the particular blood pressure measurement device chosen. Recent data from NHANES 1999 show that 61 percent of Americans are either overweight or obese. The need to select an appropriate-sized cuff becomes important every time the patient's weight significantly changes. With the increasing weight of so many Americans, data should be evaluated to determine the ideal length and width of the blood pressure cuff. Efforts should be undertaken to collaborate with industry to promote the use of proper-sized cuffs and provide information regarding the inter-changeability of cuffs produced by different manufacturers. Inaccuracies due to inappropriate cuff size or inadequate attention to validation and calibration of blood pressure measuring need to be addressed.

Because of the clear public health implications of blood pressure measurement inaccuracies, and the importance of building consensus among different groups to accept and implement a national standard, the National Heart, Lung, and Blood Institute, and the American Heart Association, will convene a Working Group on Blood Pressure Measurement. The Working Group will be charged with evaluating the current state-of-the-science that supports measurement policies and will make recommendations for additional research needed to strengthen these policies.

HISTORY OF POLICY DEVELOPMENT IN BLOOD PRESSURE (BP) MEASUREMENT—SUMMARY

Sheldon G. Sheps, M.D., Mayo Clinic, Rochester, MN

Indirect BP measurement came into general use about 100 years ago following the development of the mercury manometer by Riva-Rocci in 1896 and the aneroid manometer by Hill and Bernard in 1897. Janeway published an important monograph in 1904. Systolic blood pressure (SBP) was the only measure for several decades but estimates of diastolic pressure (DBP) evolved in the early 20th century. Korotkoff described the auscultation of arterial sounds (phases) in 1905. All the methods [auscultation, oscillometric, ultrasound, photoplethysmographic (finapres, etc.)] are derived from physiological phenomena that are mainly but not exclusively related to BP. BP estimates then are method-dependent.

Dr. J. W. Fisher, medical director of the Northwestern Mutual Life Insurance Co. was influenced by Janeway's book "the Clinical Study of Blood-Pressure" among other developments. In 1906 he initiated the inclusion of a blood pressure reading in every routine examination by their examiners. By 1918 most companies were taking blood pressures. In 1925 the first report was published of the Joint Committee on Mortality of the Association of Life Insurance Medical Directors and the Actuarial Society of America. They used 5th phase for DBP. Average BPs for gender, age and build were established. It was clear that if your pressure was less than average, you had less mortality and vice versa.

Korotkoff's presentation was rapidly disseminated. In Europe, for DBP the 4th phase was advocated while in America it was the 5th. This controversy in and outside of America was to last until the latter part of the 20th century, resolved at last in Korotkoff's favor (5th). The cuff bladder initially encircled the upper arm. The width and length remain somewhat controversial. Soon the commonly used manometers were mercury, aneroid and oscillometric.

The American Bureau of standards [aeronautic instruments section] published reports to improve blood pressure measurement standards in 1917, 1921 and a comprehensive one in 1927. Some 50 years later, the NHLBI contracted with AAMI, the Association for the Advancement of Medical Instrumentation. AAMI initiated a sphygmomanometer committee, which is composed of representatives from industry and users, mostly academics. The FDA has delegated the regulation of BP equipment to AAMI and accepts the manufacturers' certification that their equipment meets AAMI standards.

By the 1930s, it became clear to early leaders such as Irving S. Wright that standardization was necessary both for equipment and measurement. He reported on a survey of these errors in 1938. "Time does not permit a review of the volumes of literature written on the sources of error in blood pressure determinations". There was great variation in every aspect. The medical profession had little idea or influence on what was being done.

In 1939, Dr. Wright chaired a committee for the AHA on the Standardization of Blood Pressure Readings in cooperation with a similar committee of the Cardiac Society of Great Britain and Ireland chaired by Dr. Maurice Campbell. 5 subsequent US reports have been published. Until 1980, there was controversy about diastolic pressure; whether K4 or K5 was the

best phase to use. This was resolved in 1980 in favor of K5 for adults and more recently for children as well. At present bladder width is recommended to be 40% of the circumference of the limb at the point of measurement and length, sufficient to encircle at least 80% of the limb. For all who measure blood pressure, these documents describe in detail the technique, observer and subject preparation, manometers available, epidemiology and special circumstances. Recommendations have been presented by European organizations as well, notably the British Hypertension Society.

Issues remain to be resolved and will be addressed by subsequent speakers.

Reading List—AHA recommendations

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THE COST OF INACCURATE BLOOD PRESSURE MEASUREMENT

Clarence E. Grim, M.S., M.D., Medical College of Wisconsin, Milwaukee, WI

Unless blood pressure (BP) is measured accurately, the proven benefits of diagnosing and treating an unhealthy blood pressure will not be transferred to the population. Although the assessment of BP is the most cost-effective procedure in medicine, it is rarely performed according to guidelines. Measurement is cost-effective because the capital cost of equipment is low (\$250), the skills can be mastered and practiced by all health professionals (and patients) and it is the only way to detect and manage the asymptomatic, most common risk factor for premature death and disability-high blood pressure. The standards for obtaining an accurate BP are intermittently updated by the American Heart Association Council for High BP Research and published by the AHA yet most who measure blood pressure have never read these recommendations and few current training programs teach to these standards. Failure to follow these guidelines has been proven to result in errors of up to 100 mmHg. However, even errors as small as 2-5 mmHg can have astounding costs to the individual patient, to the health care system, to a research project, for government planning and for society. The cost of errors will be discussed in the terms of reading blood pressure systematically too low, systematically too high or reading imprecisely (sometimes too low and sometimes too high or reading with bias).

Patients with truly high BP, but measured as normal, are denied the proven benefits of treatment and will suffer premature disability and death because of untreated high blood pressure. An error of “only” minus 5 mmHg at the 90-95 mmHg range will miss the 21 million hypertensives in the US in this range (42% of all with HTN). Over the next 6 years these 21 million untreated HTN will experience 125,000 CAD deaths⁽¹⁾ of which at least 20% would be prevented by treatment⁽²⁾. About the same number of fatal strokes would have also been prevented. Thus a -5 mm error will cause about 50,000 preventable deaths not to mention preventing perhaps twice this many non-fatal CADs and CVAs. Aneroid devices out of calibration most often read too low.

Measuring BP falsely high increases costs by treating those who do not truly have high BP. Thus an error of +5 mmHg would move 27 million people from 85-89 into the high BP range. As the estimated cost of treating one person for high BP is \$1000/yr., this will cost at \$27 billion/yr. to treat a “non-disease.” In those with HTN, a false high reading will result in more medications being used to get the BP to “goal.” Even a 2 mmHg error will misclassify about 6 million persons into the 90–95 range. Current standards permit devices ± 3 mm of the mercury standard. This seems too lenient.

Observers or machines that measure sometimes high and sometimes low confuse the provider and patient and no or sporadic treatment may result. In clinical trials, this added error increases the number of subjects to be studied to see “effects” of treatments or genes. Effective drugs may be abandoned and clues to genetic causes of hypertension missed. Indecision in diagnosing hypertension in pregnancy may result.⁽³⁾

National and international surveys and trials have frequently^(4,5,6) had problems with quality control of BP measurement due to observers and/or devices (electronic⁽⁷⁾ and non-

electronic). This has required dropping sites, diluting the power of studies estimating the burden of disease in populations and testing hypotheses.⁽⁸⁾

Practice surveys around the world report serious problems in the accuracy of sphygmomanometers (aneroids, mercury and electronic) and poor adherence to proper technique. It has been suggested that clinicians using equipment that has not been maintained and calibrated may be medically negligent.⁽⁹⁾ It appears that the most common error in the practice of medicine occurs when BP is measured. The potential for great harm to the public is clear. Efforts to improve the practice of BP measurement will likely have a major impact on the health of the population.⁽¹⁰⁾

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CONSENSUS STANDARDS FOR BLOOD PRESSURE MONITORS

Sandy F.C. Stewart, Office of Science & Technology, Center for Devices & Regulatory Health, US Food & Drug Administration, Rockville, MD

Many standards exist for blood pressure measurement, including the ANSI/AAMI SP9¹ standard for manual blood pressure cuffs, the ANSI/AAMI SP10² and IEC 60601-2-30³ standards for automated non-invasive blood pressure (NIBP) monitors, and the ANSI/AAMI BP20⁴ and IEC 60601-2-34⁵ standards for intra-arterial blood pressure transducers. Standards continue to be revised and improved to reflect the current state of the art. For example, the new version of SP10, now being finalized, will combine elements of the old SP9 and SP10. The new version will cover both manual and automated blood pressure monitors that work with a cuff, thus providing a single reference for cuff-related issues. It will also update requirements for NIBPs, providing specifications for the clinical verification studies for infants and pediatric patients (including improved statistics for these studies), and specifying testing requirements for software verification/validation and electromagnetic compatibility.

Consensus standards are an important tool in the review process at the Center for Devices and Radiological Health (CDRH). Well-written standards provide a solid scientific basis for reviewers to make decisions on new applications, thus streamlining the review process and providing a more level playing field. Certain standards have been formally recognized by CDRH, so that they can be used in the abbreviated 510(k) process. In this case, the manufacturer still performs all the required testing specified by the standard, but submits only a declaration of conformance to the standard. SP10 and IEC 60601-2-30 are two such standards. In some cases, CDRH has recognized a standard, but limits the extent of the recognition as specified in a “supplementary information sheet.” The extent of recognition may recognize or exclude part of the standard. Often the information sheet refers the manufacturer to a guidance written to provide additional details required by CDRH. Software verification/validation of NIBPs is an example of testing not included in the current SP10 that is requested to be included along with the declaration of conformance. This process of recognizing a standard but requiring additional information allows CDRH to rely on standards without being limited by the typical one-to-five year lag in scientific and technological advance that standards typically experience.

Although manufacturers may qualify NIBPs using any relevant standard, or by comparison to a predicate device, from CDRH's standpoint the SP10 standard appears to be the most comprehensive, in that it includes protocols for clinical verification studies. The new version will include protocols for neonates, infants, pediatrics, and adults. Once the new version is adopted, the NIBP guidance and supplementary data sheets for SP10 will be revisited.

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ALGORITHMS FOR ELECTRONIC INSTRUMENTS

Bruce Friedman D.Eng., Manager Technology Development, GE Medical Systems Information Technologies

The oscillometric method was developed in the late 1800's, but practical automated devices based on the oscillometric method were not available until 1976. A number of factors affect the performance of automated oscillometric monitors including: pressure control method (linear vs. stepped deflation), systolic/diastolic determination (ratios or inflection points), artifact rejection methods, and the reference standard used for accuracy testing.

Operations manuals should include any limitations for use of the device. These may include performance during arrhythmias, performance during patient motion, appropriate patient population (adult, pediatric, neonatal), cuffs approved for use.

Performance may also be affected by the hardware and software used in the monitors. Manufacturers track their products using model number, serial number, and software revision level. On most products, users can easily obtain this information. The manufacturer should then be able to supply a summary of accuracy test data.

PHYSICS OF MEASUREMENT AND REVIEW OF LITERATURE ON ACCURACY OF BP MEASURING DEVICES

Thomas Pickering M.D., D.Phil., Cardiovascular Institute, Mount Sinai Medical Center, New York, NY

Although hypertension can only be identified by measuring the blood pressure (BP), the conventionally used methods for its detection are notoriously unreliable. There are three main reasons for this: inaccuracies in the methods, some of which are avoidable; the inherent variability of BP; and the tendency for BP to increase in the presence of a physician (the so-called white coat effect). For clinical practice, the gold standard is measurements made with the Korotkoff sound technique by a physician using a mercury sphygmomanometer, but mercury is likely to be banned in the near future. This raises the issue of what will replace it. The two most widely used methods in clinical practice continue to be the auscultatory and oscillometric techniques.

The Auscultatory Technique. The Korotkoff sound method tends to give values for systolic pressure (SBP) that are lower than the intra-arterial pressure, and diastolic values that are higher, but there is no obvious superiority for phase 5 over phase 4. When both low and high frequency signals are recorded under a cuff (the K2 method) the appearance and disappearance of the high frequency component (K2) corresponds to intra-arterial SBP and diastolic pressure (DBP) (1). In people with high DBP but normal SBP when measured by the auscultatory method (known to be at low risk) the K2 method usually shows a normal DBP (2). Although potentially more accurate than other noninvasive methods, the K2 method has not been developed commercially.

The Oscillometric Technique. When the oscillations of pressure in a sphygmomanometer cuff are recorded during gradual deflation, the point of maximal oscillation corresponds to the mean intra-arterial pressure. The oscillations begin at approximately SBP and continue below DBP, so that SBP and DBP can only be estimated indirectly according to some empirically derived algorithm. One advantage of the method is that no transducer need be placed over the brachial artery, so that placement of the cuff is not critical. Other potential advantages of the oscillometric method for ambulatory monitoring are that it is less susceptible to external noise (but not to low frequency mechanical vibration). The oscillometric technique has become standard for clinical electronic blood recorders.

Alternatives to mercury. The two most popular alternatives to mercury are aneroid sphygmomanometers, and electronic oscillometric devices. The former are often inaccurate after prolonged use, and the latter may be consistently inaccurate in some patients, even though they have satisfied validation criteria. Ideally, they need to be checked on every patient. An alternative is a hybrid device which functions like a mercury sphygmomanometer but uses an electronic transducer to record the cuff pressure (3).

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AN EVIDENCE-BASED REPORT ON THE CLINICAL UTILITY OF AMBULATORY AND SELF-MEASURED BLOOD PRESSURE

Lawrence J. Appel, M.D., M.P.H., Epidemiology and International Health, Johns Hopkins Medical Institutions, Baltimore, MD

Background: The optimum technique to measure blood pressure (BP) remains uncertain, in part because clinic BP may not be representative of usual BP. Ambulatory BP (ABP) and self-measured BP (SMBP) monitoring are two techniques that record BP outside of the clinic setting and that might be satisfactory alternatives to clinic measurements.

Methods: We conducted a systematic review of the published literature on the clinical utility of ABP and SMBP. Specific goals were to synthesize evidence on:

- distributions of the differences between ABP, SMBP and clinic BP, and the reproducibility of these differences,
- the prevalence and reproducibility of white coat hypertension (WCH),
- the relationships of ABP, SMBP, clinic BP and WCH with subclinical outcomes in cross-sectional studies and clinical outcomes in prospective studies, and
- the effects of treatment guided by SMBP or ABP.

Three electronic databases were searched. Over 6,000 abstracts were reviewed. Nearly 100 articles met our inclusion criteria. Pairs of reviewers extracted data and assessed study quality.

Findings: For both systolic and diastolic BP, clinic measurements exceeded SMBP, daytime ABP, nighttime ABP and 24 hour ABP. In the few studies that compared SMBP and ABP, daytime ABP and SMBP appeared similar. The prevalence of WCH based on ABP varied considerably by definition; overall, WCH prevalence was approximately 20 percent among hypertensives. Few studies assessed the reproducibility of WCH and the reproducibility of differences between clinic BP and either ABP or SMBP. In cross-sectional studies, left ventricular mass and albuminuria were both associated with absolute ABP levels; in most studies, left ventricular mass was less in individuals with WCH than those with sustained hypertension. In each of ten prospective studies, at least one dimension of ABP predicted clinical outcomes. In two of these studies, WCH predicted a reduced risk of CVD events compared to sustained hypertension. No prospective study adequately compared the risk associated with WCH to the risk associated with normotension. In four of five studies, a non-dipping or inverse dipping pattern predicted an increased risk of clinical outcomes. The literature was insufficient to determine whether absolute SMBP levels or WCH based on SMBP was associated with left ventricular mass or proteinuria or whether SMBP measurements predicted subsequent CVD. In both cross-sectional and prospective studies, the poor or uncertain quality of clinic BP measurements precluded a satisfactory comparison of SMBP and ABP with clinic BP. In six of 12 trials, including two trials that tested contemporary devices, use of SMBP was associated with reduced BP. The availability of just two ABP trials limited

inferences about the utility of ABP to guide BP management. The vast majority of studies included both men and women, but few studies reported results stratified by gender. Few studies reported enrollment African-Americans, and race-stratified data were rarely presented. The only notable subgroup finding was a higher prevalence of WCH in women than men.

Conclusions: In cross-sectional studies, ABP levels and ABP patterns were associated with BP-related target organ damage. Likewise, in prospective studies, higher ABP, sustained BP and a non-dipping ABP pattern were associated with an increased risk of subsequent CVD events. Few studies examined corresponding relationships for SMBP. The poor or uncertain quality of clinic BP measurements precluded satisfactory comparisons of risk prediction based on ABP or SMBP with risk prediction based on clinic BP. In aggregate, these findings provide some evidence that ABP monitoring is useful in evaluating prognosis. However, evidence was insufficient to determine whether the risks associated with WCH are sufficiently low to consider withholding drug therapy in this large subgroup of hypertensive patients. For SMBP, available evidence from several trials suggested that use of SMBP can improve BP control; however, further trials are needed.

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HUMAN ACCURACY WITH NONELECTRONIC AND ELECTRONIC DEVICES

Carlene M. Grim, R.N., B.S.N., M.S.N., Sp.D.N. Shared Care Research and Education Consulting, Inc. Milwaukee, WI.

Research designed to explore and document human blood pressure (BP) error has amassed a considerable body of literature over the past seventy years. Though much of the error can be traced to a lack of awareness of standard technique and recognized guidelines, comparatively little effort has gone into correcting the deficit in basic professional education.^{1,2,3} The literature documenting the need for repeated training until mastery is extensive and ways to monitor and identify those who measure inaccurately (observers and devices) have been published.^{4,5,6} Human measurement errors are commonly identified in epidemiological studies by looking for last digit preference (terminal digit bias), occurrence of identical readings, sign difference between first and second readings, and occurrence of odd numbers.

Instrument-related human errors are frequent and easily observed in the clinical setting. They include failure to select the appropriate cuff bladder size, improperly positioning the measurement device and the subject's limb, failure to rapidly inflate the cuff above the palpated systolic, too rapid deflation rate, and failure to examine or notice when equipment is not operating properly. A popular approach to the elimination of human measurement error has been to seek an automatic device that will result in foolproof and effortless assessments.

The reality is that human BP measurement errors persist regardless of the device used to obtain the reading.^{7,8} Most professionals were never taught that small details in the way BP is measured can result in big differences in reading outcomes. BP measurement education should incorporate proven training methods^{1,2} now used primarily for epidemiological studies. With a move to electronic data records quality monitoring methods used by epidemiological studies should become standard to easily identify observers and devices that are not reading accurately and reliably.

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THE CHANGING PREVALENCE ARM CIRCUMFERENCES FROM NHANES III AND ITS IMPACT ON BLOOD PRESSURE CUFF MANUFACTURE AND PURCHASE

John W. Graves, M.D., Charles H. Darby, Kent R. Bailey, and Sheldon G. Sheps, Division of Hypertension and Department of Biostatistics, Mayo Clinic and Mayo Foundation, Rochester, MN

Accurate measurement of blood pressure is dependent upon a number of factors including the relationship between arm circumference and the length and width of the blood pressure cuff used. Blood pressure measurement using too small a cuff for the patient's arm circumference will over-estimate blood pressure while use of too large a cuff under-estimates blood pressure. JNC VI guidelines recommend that "the appropriate cuff size must be used to ensure accurate measurement. The bladder (cuff length) should encircle at least 80% of the arm. Many adults will require a large adult cuff." Two epidemiologic studies of arm circumference exist. The Minneapolis Children's Blood Pressure study found that in 1484 women the mean arm circumference was 28.5 ± 4.6 cm and amongst 940 men it was 31.6 ± 3.3 cm. More importantly, 38.1% men and 17.7% of women had arm circumferences > 32 cm.¹ O'Brien found that the mean arm circumference in a population of 1300 Irish men and women was 30.2 ± 4 cm (R-17.5–46 cm).² In clinical practice settings, Beavers³ found that 15.7% of 209 hypertensives in a hospital based clinic had arm circumference > 33 cm, while Graves⁴ found that 61% of 430 consecutive hypertensive patients seen in tertiary care clinic had arm circumference of > 33 cm.

We evaluated the changes in arm circumference that were seen in NHANES III between period one (1988–1991) and period 2 (1991–1994). The mean arm circumference increased from 31.5 cm in period one to 31.8 cm in period two ($P < 0.001$). For the hypertensive population a smaller but statistically significant change from 32.1 in period one to 32.2 ($P < 0.03$) in period two was found. The percentage of arm circumference that were 35.1 cm or greater increased from 20.1% to 23.6% ($P < 0.001$). A multivariate analysis correcting for age, sex, weight, height and period showed that the increase in arm circumference was due to the increase in weight seen between the two periods. Each 10 kg increase in weight was associated with a 2.7 cm increase in arm circumference.

The NHANES III data allows one to predict the clinical utility of different manufacturers blood pressure cuffs in the adult US population. Estimations of the numbers of adults and hypertensive adults correctly cuffed with for six major standard adult blood pressure cuffs are seen in Table 1. This information should allow manufacturers of blood pressure cuffs to optimize their product to fit the adult US population.

Table 1.

Cuff Type	Cuffed Correctly			
	All (177 million)		Htn (29.55 million)	
	M	%	M	%
Welch-Allyn	135	76.3	24.2	82
Mabis	109	63.2	14.9	50.3
Baumanometer	128.4	72.5	19.25	65
Omron	142.6	80.5	24.7	83.5
Graham-Field	82.7	46.7	10.5	35
Datascope	143.4	80.9	21.5	72.9

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MERCURY MANOMETERS, EQUIPMENT CALIBRATION, ONE INSTITUTION'S RESPONSE

Bruce Z. Morgenstern, M.D., Division of Pediatric Nephrology, Mayo Clinic, Rochester, MN

Mercury as an element used in many settings has come under increasing criticism. It has been noted to be “toxic, persistent and bioaccumable.”¹ Its use for medical devices has been eliminated in Sweden and the Netherlands. The British Medical Device Agency has recommended use of alternative devices. Several large medical groups in the United States have moved to aneroid and/or electronic devices. Despite what seems to be an inexorable move away from mercury manometers, the American Heart Association has taken a more assertive position in favor of continuing the use of mercury in manometers.² The European position is more accommodating to the loss of mercury.^{3,4} Evidence is also accumulating that mercury manometers in clinical practices are not nearly as accurate as many believe.^{3,5}

The American Heart Association and the Association for the Advancement of Medical Instrumentation (AAMI) are continuing to either advocate or allow for mercury manometers. In the proposed SP10 standard for manual sphygmomanometers, only one sentence comments on the potential toxicity of mercury. The document does not discuss the steps required to clean up a mercury spill or the proper way to discard an old and poorly functioning manometer. The immediate medical toxicities from mercury manometers are rare, but potentially quite morbid. The major hazard would appear to be the long-term environmental impact.

However, both the US and British agree that care must be taken in the transition away from mercury. Electronic sphygmomanometers have not been subjected to validated regular use in the variety of clinical circumstances in hospitals.⁴ Even though automated devices have been successfully validated, oscillometric techniques cannot measure blood pressure in all situations.⁴ The algorithms which determine how the devices report pressures are proprietary. Oscillometric devices have been the subjects of increased scrutiny.⁶ Aneroid devices are also felt to be of questionable accuracy and reliability.

The Mayo Clinic has migrated from mercury to aneroid devices in its hospitals and outpatient locations in Rochester, MN. Data have already demonstrated that aneroid devices, when properly maintained and calibrated remain quite accurate.⁷ For two of the 3 sites in Rochester, there are >1100 aneroid manometers per site that are regularly assessed for function and accuracy, using visual inspection as well as a digital pressure gauge. Over the past three years, accuracy within 4 mmHg across a range of pressure measurements has been demonstrated repeatedly (every 6 months) for >98% of the devices. In fact, only 2.7% have been rejected for all reasons (including non-zeroing and poor needle movement). Replacement of manual mercury devices by manual aneroid devices is realistic, practical and will not adversely affect measurement of blood pressure.

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**NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES)
1999–2000: TRAINING OF OBSERVERS AND STANDARDIZATION OF
MEASUREMENTS TO DECREASE ERROR IN BLOOD PRESSURE READINGS**

Ami Ostchega, Ph.D., R.N., Ronald J. Prineas, M.D., Ph.D., and Ryne Paulose, Ph.D.

Abstract

The NHANES certification program and observer training are presented. The program resulted in a major reduction in the variability of blood pressure (BP) measurement commonly due to observer and technical error. Given specific training and protocol, instruction the effects on measured blood pressure by cuff width/circumference ratio, end-digit preference, were analyzed in detail. The participants were persons aged 8 years and older who had their BP taken in the mobile examination center (N=7,416) during NHANES 1999-2000. In stepwise principal components multiple regression analysis, CW/AC ratio accounted for less than 2% of variability R^2 in all readings. With the exception of end-digit “2” for diastolic (17.6%), all other end digits were close to 20% (“0” end digit = 21% systolic and 23% diastolic). No overall observer effect was present for mean systolic BP readings. A significant observer effect ($p<.0001$) was detected for mean diastolic BP readings of <90 mmHg. However, for readings of ≥ 90 mmHg there was no significant observer effect ($p=.06$). The analysis shows that standardization and training can reduce observers’ errors.