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The accuracy of blood pressure devices in paediatric renal outpatients

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1.0 INTRODUCTION

Hypertension in childhood is an uncommon condition. However, awareness of it has increased in recent years. The causes of hypertension in childhood are varied, such that a larger proportion of children with hypertension have secondary hypertension in comparison to adult hypertensive patients. Most secondary forms of childhood hypertension have a renal origin. The secondary causes of childhood hypertension consist of coarctation of the aorta, congenital renal abnormalities, bronchopulmonary dysplasia, renal artery stenosis, Wilms tumour, neurogenic tumours, renal parenchymal disease, vasculitides, and endocrine conditions. Essential hypertension, also known as primary hypertension, occurs increasingly with increasing age (Table 1.1). Older adolescents mostly have essential hypertension, a diagnosis made once a primary cause is excluded. The incidence of hypertension is not known in the paediatric population [1]

David Barker proposed that intrauterine growth retardation (IUGR), low birth weight (LBW), and premature birth are associated with the development of adult hypertension, coronary heart disease, and non-insulin-dependent diabetes. The hypothesis is derived from a cohort study that demonstrated a substantial association between middle-age hypertension, coronary atherosclerosis; and low birth weight. [2] A systematic review done by Sarki et al demonstrated the significant burden of hypertension in adults of low and middle income countries. The overall prevalence of hypertension was 32.3% (95% confidence interval [CI] 29.4-35.3). [3] This supports Barker's hypothesis.

Hypertension in children predicts adult hypertension. Childhood and adolescent hypertension contributes to premature atherosclerosis and cardiovascular disease. [4] It is therefore important to have a good approach to the diagnosis, evaluation and future monitoring of those children with hypertension.

1.1 Definitions

The Fourth Report on the diagnosis, evaluation and treatment of high blood pressure in children and adolescents, defines hypertension as: systolic blood pressure (SBP) and/ or diastolic blood pressure (DBP) persistently at the 95th percentile or more, measured on at least three occasions using auscultation to measure blood pressure (BP). Children who have systolic blood pressure at the 90th percentile are classified as having pre-hypertension as well as adolescents with a blood pressure of 120/80 mmHg or more if below the 90th percentile. A set number (140/90), is not used in the definition of childhood hypertension. Instead, the diagnostic criteria for raised BP in childhood are based on the concept that blood pressure in children is increased with age and body size. Thus, wide-ranging paediatric BP measurement data exist, based on more than 70000 children's clinic measurements. BP percentiles were then calculated for age, gender, and for seven height percentile categories in this data from the United States Task Force on high blood pressure in children and adolescents. The height percentiles for age and sex were centred on the growth charts of the Centers for Disease Control and Prevention (CDC). In other regions of the world, reference values for blood pressure have been obtained. Reference data have been compiled in Europe and Italy. The limitations encountered with these values included that the tables did not contain age, sex and height together in the European data and the study population was small in number in the Italian data. [5, 6]

1.2 Blood pressure measurements

1.2.1 Importance of BP measurements

Given the meaning of hypertension in children and with reference to the Taskforce data, it is evident that the correct and precise measurement of BP in children is vitally important. Consistent overestimation of blood pressure can lead to the expensive overtreatment of hypertension.

Conversely, blood pressure underestimation can be costly in failing to avert cardiovascular disease by the safe treatment of hypertension.

Table 1.1 Causes of childhood hypertension

System	Conditions
Renal disease	Chronic glomerulonephritis, reflux nephropathy, obstructive uropathy, polycystic kidney disease, renal dysplasia
Renovascular	Renal artery thrombosis, renal artery stenosis, Takayasu arteritis
Renal tumours	Wilm's tumour, nephroblastoma
Cardiovascular	Coarctation of aorta
Endocrine	Phaeochromocytoma, neuroblastoma, Cushing syndrome, Cushing disease, congenital adrenal hyperplasia, primary hyperaldosteronism, Liddle's syndrome
Miscellaneous	Steroids, liquorice

1.2.2 Indications

The measurement of blood pressure in children is not meant to be routine in those under the age of three years, but should be screened only under certain circumstances. These circumstances include history of prematurity, very low birth weight, previous intensive care admission as a neonate, suspected coarctation of the aorta, congenital heart disease, family history of congenital renal disease, organ transplant, malignancy, treatment with drugs known to affect blood pressure, associated systemic illnesses associated with hypertension and evidence of raised intracranial pressure. Children

three years of age and above should have their blood pressure measured at least once during every health care visit. [4, 6]

1.2.3 Blood pressure devices

In clinical settings, BP is measured using manual or automated devices. Manual devices depend on human judgment to determine the systolic and diastolic components of BP. Manual devices are also named auscultatory devices. They can either be mercury sphygmomanometers or aneroid devices. Automated devices, on the other hand, produce an SBP and DBP value by utilising electronic calculations from the mean BP. [7] The blood pressure reference tables, mentioned earlier, are based on BP measurements obtained by the auscultatory method. Therefore, the favoured method of BP measurement is auscultatory. [8]

1.2.3.1 Mercury sphygmomanometer

The gold-standard for the measurement of BP has been the mercury manometer for more than a century. It is simple and gravity-based with easy standardisation, and it has been validated against direct intra-arterial BP measurements, in a number of clinical circumstances. [9, 10] The mercury sphygmomanometer is being increasingly removed from the health care setting because of the potential risk of mercury toxicity. However, an advisory statement of the American Heart Association, in 2001, stated that inadvertent contact with mercury from BP machines in health care settings is a highly unusual occurrence. The statement also mentions that modern mercury sphygmomanometers are built to prevent accidental mercury spillage, eliminating all concern for toxicity. The mercury manometer has not been banned in the United States but has been banned in the European community. [5, 10] There was high correlation found between mercury and aneroid systolic blood pressures in a study done in youth with diabetes mellitus in 2012. [8] In another study done by Jones et al, the results were treated with reservation as only an abstract was available in the Journal of Human Hypertension published in the year 2000. [11] The study stated that aneroid manometers could not be recommended for use in place of the gold-standard mercury device. Also making this study incomplete was the lack of mention of the make and model of aneroid manometer

investigated. The Diabetes Prevention Program Outcomes Study (DPPOS) investigated the exactness of the Welch Allyn Tycos 767-Series Mobile aneroid sphygmomanometer in 2006. The study concluded that the aneroid manometer could be used as a replacement to the mercury device. [12] Both the United States guidelines and the United Kingdom National Screening Committee agreed to the use of aneroid non-mercury manometers, which have been calibrated on a semi-annual basis, if mercury manometers are unavailable. [9]

1.2.3.2 Automated devices

Automated blood pressure devices function by measuring the mean arterial blood pressure (MAP), from which SBP and DBP measurements are calculated. Automated oscillometric devices are being used increasingly in various clinical settings all over the world. The reasons for this include their ease of use and decrease in observer bias or digit preference. These devices are particularly useful when auscultation is difficult as in infants and neonates, in the intensive care setting where blood pressure monitoring is frequent or to screen patients in a busy clinical setting. [6] Automated oscillatory devices were initially designed for use during anaesthesia where accuracy is less crucial. [9] The algorithms used by the various machines differ with each company and device by device. They therefore need to be calibrated and validated from time to time in compliance with the revised British Hypertensive Society (BHS) Protocol and the Association for the Advancement of Medical Instrumentation (AAMI) as well as the European Society of Hypertension (ESH) Protocol. [5,6] The ESH protocol solely deals with validation of automated machines in adults, and therefore is not discussed further in this paper.

1.2.4 Validation protocols

1.2.4.1 BHS and AAMI protocols

The BHS protocol was first compiled in 1990 as a means to evaluate the reliability of automated BP machines. It was revised in 1993 to additionally include non-ambulatory BP devices in the validation.

There are 2 major stages in the validation process. Part 1 consists of 5 phases: before-use device calibration, in-use assessment, after-use device calibration, static-device calibration, report of evaluation. Part 2 consists of validation for special categories such as the elderly, pregnant women, children, BP measurement during exercise and varying postures. Observer training takes place and a good quality stethoscope is chosen. A standard, calibrated sphygmomanometer is used as the gold-standard. Phase 1: At least 3 instruments for each device to be tested are assessed for variability. If there are differences between instruments, further testing is not continued. A y-connector is used to connect the test – instruments to a mercury device. Several deflations are done and the reading read on the test device, which should be within 3mmHg of the mercury gold-standard for 28/30 readings in order to proceed to the next phase of validation. In phase II, the three instruments of the same device are subjected to the use for which they are originally designed, receiving a minimum of 400 inflations per instrument. After-use device calibration consists of retesting the instruments for device agreement as in phase I. If discordant results are obtained for 2 or 3 devices, assessment is stopped and the device model not recommended for use. However, if none or one of the devices is discordant, validation continues to phase IV. One instrument is selected for validation. Observers are to be trained by an expert observer and assessment takes places in which 45 of 50 BP readings should not differ by > 5mmHg and 48 of 50 readings by not >10mmHg. Device validation is to occur in a warm, quiet room. In selecting subjects, children and pregnant patients are considered a special population. Subjects chosen should represent a spectrum across a wide range of BP's. Patients to be excluded are those with Korotkoff sounds persisting to nearly '0'. 85 subjects should be chosen with a wide distribution of arm circumferences and age. Cuffs that are appropriate for measured arm circumference are used. Sequential BP measurements on the same arm are to be made between the test device and the mercury gold standard. An entry BP is taken with the mercury manometer by observers 1 and 2, a partition being between them. Observer 3 takes the BP with the test device on the same subject. Subsequent BP's are measured using the mercury sphygmomanometer by observers 1 and 2 and observer 3 with the test device. A total of 3 BP pairs for analysis are obtained between test device and gold-standard for each subject by each observer and observer 3. BP measurements are to be taken 30 to 60 seconds apart to avoid the effects of venous congestion and variability,

respectively. Since children are a special group, the number required for validation is reduced to an arbitrary figure of 30 subjects. The BP measurements for analysis in the group is repeated 3 times so as to provide 90 measurements for analysis against the gold-standard. For children under 4 years, the gold-standard to be used in validation studies is intra-arterial BP measurements in contrast to mercury sphygmomanometry which may be used in children 5- 15 years of age. The required distributions of blood pressures in the study population as well as the arm circumferences are specified. Assuming normal distribution of BP readings, the proportion of differences between the test device and the mercury gold-standard differing by less than 5mmHg, 10mmHg and 15mmHg are calculated for each observer and for SBP and DBP separately. The device is graded from A-D as in table 1.2. [13] To obtain a certain grade, all three percentages should be equal to or exceed the tabulated values. The final grade for SBP and DBP separately is the grade obtained by the better observer of the two. The device- observer SBP and DBP difference, separately, is to be plotted against the mean of the device pressure and the observer pressure. Because evidence has shown that some BP machines have poorer accuracy at higher BP levels, it is recommended that pressure be analysed in ranges. However, this is to be in addition to the analysis already described above. The BP used for this part of analysis is the entry mercury measurement. Data from this analysis is only to indicate the possible trends in the accuracy of the test device.

The AAMI protocol was developed in 1987 and was revised in 1992. The methodology of comparison is similar to the BHS protocol, differing in that intra-arterial BP measurements as a standard are only to be conducted on inpatients who already have an intra-arterial line in situ for clinical management. The number in the study population for patients receiving intra-arterial measurements is a minimum of 15, and the range of BP and arm circumference may be less evenly distributed as a result. Subject selection is to be heterogeneous and may include the special population, such as children and pregnant women. For validity of a test device, AAMI standards require that it achieve a mean difference of $\leq$ 5mmHg and standard deviation $\leq$ 8mmHg. [14]

Table 1.2 Revised British Hypertension Society grading criteria

	Absolute difference between standard and test device (mmHg)		
Grade	≤ 5	≤10	≤15
	Cumulative percentage of readings		
A	60	85	95
B	50	75	90
C	40	65	85
D	Worse than C		

1.3 Current evidence

Of the literature reviewed, most of the studies assessed the accuracy of the Dinamap 8100. Only one study was a randomized crossover clinical trial. The rest were described as prospective cross-sectional studies. Heinemann et al, of the randomized crossover clinical trial, concluded that the Dinamap 8100 could assess SBP with a substantial degree of confidence. [15]

The study sample sizes were small, ranging from 3 to 193. However, all the studies were well-designed and statistically significant findings were obtained. The small numbers were compensated for, by the study methods utilized. In the study with three patients, 25 blood pressure machines from different pharmacies were compared yielding a total of 75 readings to be analysed.

Of the trials reviewed, three specifically were focused on child populations. One group of children was recruited from junior schools [16] and the other cohort consisted of pre-pubertal diabetics [17], whilst the third focused on children with chronic kidney disease [18]. The majority of studies found that automated blood pressure machines did not achieve acceptable accuracy and reliability. [10, 18, 19] From the junior school cohort, neither the Dinamap 8100 nor the Omron M1 device could be recommended for clinical use in children. Both did not meet accuracy criteria according to the BHS protocol. [16] Statistically significant differences were found in the study involving pre-pubertal diabetic cohorts, with greater differences occurring in diastolic BP readings. However, the conclusion of the study was that the automated machine, the Dinamap 8100, can be accepted in clinical practice.

This was due to its meeting accuracy criteria for the British Hypertension Society and the Association for the Advancement of Medical Instrumentation. [17] As is evident, the findings are conflicting.

In a cohort of adult medical patients, most of whom were normotensive or had stage I hypertension, systolic and diastolic blood pressure accuracy were worse in patients with blood pressures in the hypertensive levels, although these measures were based on a smaller sample of patients. The recommendation of the study was that oscillometric devices should not be used when accurate blood pressure measurements are needed for therapeutic decision-making. [21] In a study of children with chronic kidney disease, oscillometric systolic and diastolic blood pressure measurements, using the Spacelabs 90217 devices, were consistently higher than those measured by the auscultatory method (median elevations 9mmHg for systolic, 6mmhg for diastolic) [18]. The recommendation from this study and the Fourth Report is, thus, that if a blood pressure measurement is more than the 90th percentile by oscillometry, it ought to be confirmed by the auscultatory method. [4, 6]

The Dinamap Pro 100 has been validated in a study conducted in 2006. The study compared blood pressure obtained with a mercury sphygmomanometer in adult participants. The Dinamap Pro 100 underestimated BP for both systolic and diastolic BP. It did not meet criteria for SBP but met criteria for DBP according to the AAMI standards. [22]

Two studies have evaluated the Omron HEM 907. The Omron HEM 907 met the BHS criteria in a study published in the American Journal of Hypertension in 2002. [23] In a 2010 study, published in the Journal of Clinical Hypertension, the device met the AAMI criteria. Device agreement, however, decreased with increased SBP and DBP. [24]

The automated devices commonly found in the Chris Hani Baragwaneth hospital include the Dinamap Pro 100 device and Welch Allyn aneroid manometer. There are unfavourable findings for the use of automated devices in adults and children at risk for, and with high blood pressures. Underestimating or overestimating blood pressure and thus misdiagnosing hypertension would only add to the burden of disease already found in these patients. Is the use of the Omron, Dinamap devices, and aneroid

sphygmomanometer in the clinical setting justified? The aim of this study was, therefore, to assess the accuracy of blood pressure devices found in the clinical setting.

1.4 Study aims and objectives

Obtaining an accurate blood pressure reading is of utmost importance in the paediatric population, since childhood high blood pressure predicts adult hypertension. [4, 6] In patients with known risk factors for hypertension, such as patients with chronic kidney disease, it becomes even more important to ensure accurate vital data such as blood pressure. There are a several BP devices and device models used to measure blood pressure.

The aim of this study was to ascertain the accuracy of blood pressure devices.

The objectives of this study included:

- To assess the accuracy of Dinamap Pro 100, Omron HEM 907, and Welch Allyn aneroid sphygmomanometer found in the hospital setting

2.0 METHODS

2.1 Study Design

This was a prospective comparative cross-sectional study. Two observers simultaneously took BP measurements over a period of six weeks.

2.2 Sample Population

A convenience sample of participants was recruited from a paediatric renal clinic at Chris Hani Baragwanath academic hospital.

The inclusion criteria were:

- Paediatric renal clinic outpatient
- Age 5-18 years (these patients are more co-operative and therefore do not need intra-arterial blood pressure measurement as a gold-standard with which to compare automated blood pressure measurements)
- Written consent and assent given by parent and patient, respectively

The exclusion criteria were:

- Patients with arrhythmias
- Acutely ill patient requiring admission
- Korotkoff sounds persisting to nearly zero i.e. ≤ 40mmHg DBP on initial mercury BP reading

As per the recommendation by the British Hypertension Society (BHS) Protocol, the sample size for device validation in this special group of patients was 30 subjects. 30 subjects with 3 readings for each device in the BHS protocol, means 90 readings for each device. This was an arbitrary figure which presupposed that validation for the various devices has already been carried out in at least 85 adult subjects.

For this study, the sample size aimed for was 90. Each participant underwent a single BP reading for each test device, rather than 3 readings for 30 subjects. A total of at least 90 readings, as recommended by the revised BHS protocol, for each test device was thus obtained.

A total of 102 patients were approached for participation. 3 parents refused for their child to participate. 4 children refused to give assent for participation, and thus were excluded. Therefore, a total of 95 study participants were retained.

2.3 Data Collection

The devices that were evaluated against the gold standard mercury sphygmomanometer were the Dinamap Pro 100 (figure 2.1), Omron HEM 907 (figure 2.2), and Welch Allyn aneroid sphygmomanometer (figure 2.3). Two of these are in regular use at the renal outpatient department where the study was carried out.

The devices were calibrated using standard manufacturer's procedures by the engineering department of the hospital. All devices, at the time of data collection, had undergone in-use/ field assessment; that is in-hospital use for the specified purpose; for at least 1-3 months, as recommended by the BHS protocol.

The two observers were both medically trained staff-members and further received re-training on the manual methods of BP measurement.

BP measurements were done at the weekly paediatric renal clinic held once a week at the said hospital, in June- July 2014.

BP measurements were taken in a warm, quiet room. The arm circumference for each participant was determined, to make certain that the bladder being used would encircle at least 80% of the arm circumference. Three cuff sizes were available for measurement of blood pressure including toddler, child and adolescent sizes.

After written informed consent was acquired from the parent or guardian and assent from the minor, BP measurements were taken by the 2 observers simultaneously, as follows:

- Positioned machine on the right side of the patient, to avoid unrepresentative readings in patients who may have coarctation of the aorta
- The patient would lie supine with the arm straight at heart-level and legs uncrossed
- The appropriate cuff-size was determined by measuring the mid-arm circumference
- The appropriate cuff was fitted to the patient's arm

For the mercury and aneroid sphygmomanometers, the cuff was inflated to 30mmHg higher than the point where there is disappearance of the radial pulse. [6] The BP cuff was subsequently deflated by 2mmHg per second. Using a double-headed stethoscope on an individual participant, each observer recorded their measures corresponding to the 1st (SBP) and 5th Korotkoff sounds (DBP) for manual BP measurements, simultaneously. The BP measurements obtained by each observer were not discussed at the time of collection.

For the automated device, the observers alternated between operating the test devices. The reading was then recorded on the participant's data collection form.

The blood pressure readings were taken sequentially and randomly. The 1st reading was taken with the mercury sphygmomanometer, to classify the patient's BP category. The 2nd, 3rd, 4th and 5th readings were then taken with a minimum of 30 seconds apart (as recommended by the BHS) between the devices in a random order. The reason why each subject was subjected to one pair of measurements for each device instead of 3 as in the revised BHS protocol is because the children were not expected to tolerate as many sequential measurements. There were at least 90 readings to compare for each test device.

Each observer had a data collection sheet in which to record BP measurement values. The data collection forms were designed to record:

-The initial SBP and DBP from the 1st reading; SBP readings for each device 2, 3, 4, 5; DBP readings for each device 2,3,4,5; height in cm; the mid-upper arm circumference; age in years; the weight in kg; medical condition; antihypertensive medications and details of the measurement.

The Dinamap Pro 100 weighs about 4kg. It is attached to a stand which allows it to be relocated within the outpatient clinic where the study took place. The Dinamap needs a mains electrical supply in order to be operated, whereas the Omron HEM 907 is battery-operated, but may also use a mains electrical supply and weighs 2.07kg making it more compact than the Dinamap Pro 100. The aneroid manometer used was attached to a wall in the outpatient clinic. The study participant had to walk a short distance to have the aneroid measurement taken. After an entry pressure was taken using a mercury device, the order of device use was randomly selected for each participant. This was done by means of a manual random number generator. Study participants were all co-operative during the study. They kept still, sat with the arm at the level of the heart, except when expected to walk to the aneroid device. Of the 95 study participants, 20 needed blood pressure to be measured on the left arm for especially the Dinamap Pro100. The right-sided measurements gave an error message for some 5 study participants, however with repetition of measurements after an interval of 30 seconds, all oscillatory device measurements were obtained. None of the patients complained of discomfort during the device-measurements.

Figure 2.1 Dinamap Pro 100



Figure 2.2 Omron HEM-907



Figure 2.3 Welch Allyn aneroid manometer



2.3.1 Randomisation/ bias control

Each of the 2 observers recorded the BP readings obtained by the auscultatory method, on separate data collection forms. The reading obtained for manual BP measurements was not discussed; but they agreed openly on the automated device BP value obtained. This was to prevent bias in readings obtained by the auscultatory methods (mercury and aneroid) and allow for assessing the agreement level of the findings of the 2 observers for study outcome purposes.

2.4 Data analysis

All data collected was entered into Microsoft Excel and subsequently exported to SPSS statistical software. Descriptive analyses were prepared for population characteristics and key measures. A frequency table was produced which gave frequencies and percentages for each sample characteristic namely whether the patient was on anti-hypertensives or not, and dialysis or not. The disease profile of the participants was analysed and presented as a bar graph. The age, weight, height and mid-upper arm circumference were analysed as means, minimum and maximum values. Confidence intervals were also given for the above characteristics.

2.4.1 Inter-observer reliability

For inter-observer reliability/ agreement, a table was made for each manual device, comparing the two trained observers' measurements. The SBP's and the DBP's were compared separately for each manual device. The number of comparisons used, the percentage of differences (≤ 5, ≤ 10, and $\leq$ 15mmHg), the average BP of both observers' readings (Mean ±standard deviation in mmHg) and the between-observer difference for SBP and DBP (Mean ± standard deviation in mmHg) were included in the table. 80% of the measurements by the observers should be within 5mmHg, and 95% within 10mmHg of each other. If this level of agreement does not exist, the study would be repeated.

2.4.2 Device agreement

Agreement between the BP devices was quantified using the statistics recommended by the revised BHS protocol. [13] The results presented were the mean and standard deviation (SD) of differences in measurements obtained between the gold-standard and test devices.

The percentage of test device measurements differing from the mercury gold-standard by $\leq$ 5mmHg, $\leq$ 10mmHg, and $\leq$ 15mmHg were calculated separately for SBP and DBP. The device was graded A, B, C, or D. To obtain a particular grade, all three percentages equalled or exceeded the charted values as seen in sample table 2.1.

The final grade for each device's SBP and DBP was the better of the grades obtained by the 2 observers. The mean differences and SD of the differences were also given to determine whether the device is within recommendations of the AAMI. These state that the mean difference should be ≤ 5mmHg and the SD ≤ 8mmHg. [14]

In addition, for each comparison, a one-sample t-test was run to determine whether there were significant differences between the test device and gold-standard mercury device measurements, assuming a perfect agreement of zero to be the test value.

2.4.2.1 Bland-Altman plots

The final grade for each SBP and DBP was the better of the grades obtained by the two observers. The better difference (device-observer), for SBP and DBP separately, was plotted using the Bland – Altman plots, against the mean of the device pressure using 91- 94 points for each test device. [13] The data used for the plots were for the better observer.

A regression analysis was then run. The mean BP was the constant and the inter-device difference was the dependent variable. The regression line was plotted on the inter-device graph and the regression equation used to predict the inter-device difference at higher and lower values of SBP and DBP. This would help determine the level of difference in device measurements at any BP value, where any difference existed.

2.4.3 BP analysis in ranges

Discrepancies in device accuracy at higher pressure levels may not become apparent if data analysis is confined to overall pressure range. Blood pressure data was also analysed in ranges: < 130/80; 130-160/80-100; >160/100. For this phase of analysis, participants' BP's were classified using BP 1,

which was the 1st mercury BP measurement. This analysis phase was not intended to determine whether the device is fit for clinical practice; this was determined by the grade for overall accuracy.

3.0 RESULTS

3.1 Population characteristics

There were 95 study participants. However, one of the participants was excluded because of a DBP that was 20mmHg. The total number of subjects used for data analysis was, therefore, 94. These were between the ages 5 to 18 years.

For comparison of the aneroid with the mercury sphygmomanometer, 91 SBP and DBP readings were used from 94 subjects because 3 readings were unobtainable with the aneroid machine. This was because, for no clear reason, Korotkoff I, and/or IV and/or V were non-recordable for the 3 participants, and by both observers. 94 data-sets for SBP and DBP were available for comparison between Dinamap Pro 100, Omron HEM 907 and the mercury device.

The mean age was 10 years 10 months. The weights were between 13kg to 81 kg, with a mean weight of 36.8kg. Heights were between 89cm to 176cm, with an average height of 136cm (see table 3.1).

The study participants had a wide array of illnesses. The disease profile of the patients is given in figure 3.1. A large proportion were nephrotic syndrome patients in remission.

The mid-upper arm circumference ranged between 14cm to 34cm, with a mean of 21.5cm. 2 of the 94 patients were on dialysis. 39 of the 94 (41.1%) were on anti-hypertensives, and the remainder, not.

3.2 Inter-observer agreement

Table 3.2 summarises agreement between the two simultaneous measurements with the mercury sphygmomanometer of the two trained observers. 94 readings were used for comparison. 92.7% of the SBP measurements and 91.6% of the DBP measurements for the mercury sphygmomanometer were within 5mmHg of one another. 98% and 99% of the differences were within 10mmHg for SBP

and DBP, respectively. For the aneroid device, 91 readings were used. 88.1% of the SBP differences were within 5mmHg and 100% within 10mmHg. For DBP, 92.4% of the differences were within 5mmHg, and 100% within 10mmHg of one another. There was thus acceptable inter-observer agreement.

Table 3.1 Study population characteristics

Characteristics	N	Minimum	Maximum	Median	95% Confidence interval for median
Age (years)	94	5.0	18.0	10	10; 11.5
Mid-upper arm circumference	94	14.0	34.0	21	20.7;22.3
Weight (kg)	94	13.0	81.0	36	33.7; 40
Height (cm)	94	89.0	176.0	135.2	132; 140

Figure 3.1 Disease profile of study participants

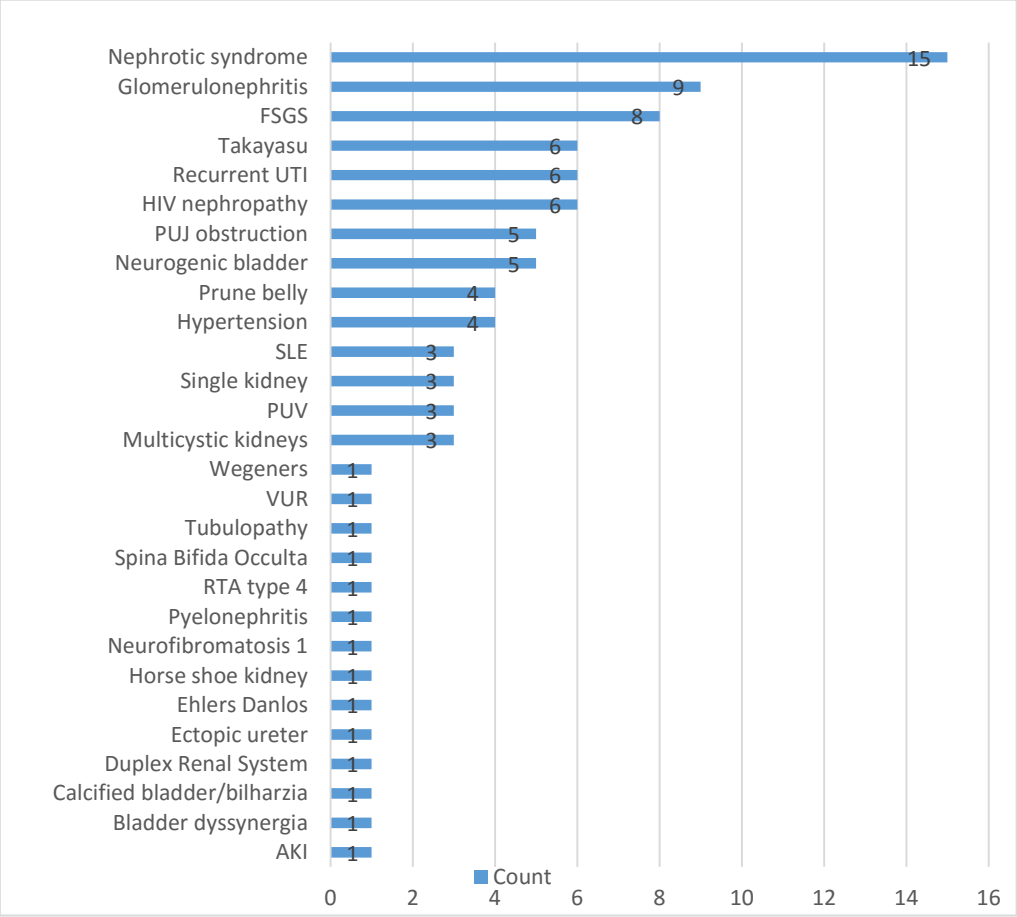

Table 3.2 Inter-observer comparison

		Percentage of differences			Average of both observers' Readings	Between-observer difference
	Number of comparisons	≤ 5mmHg	≤ 10mmHg	≤ 15mmHg	Mean ± SD	Mean ± SD
Mercury SBP	94	92.7%	98%	98%	111 ± 17	0 ± 4
Mercury DBP	94	91.6%	99.1%	99.1%	77 ± 14	1 ± 3
Aneroid SBP	91	88.1%	100%	100%	109 ± 17	0 ± 3
Aneroid DBP	91	92.4%	100%	100%	72 ± 16	0 ± 3

3.3 Inter-device evaluation

The results of the validation of the aneroid, Dinamap and Omron machines are presented in table 3.3. Results were almost similar for observers 1 and 2 as can be seen.

For each observer, there were 91 measurements of SBP and DBP with which to compare the aneroid manometer with the mercury sphygmomanometer. This was because Korotkoff I, IV and V were non-recordable for 2 participants, whereas Korotkoff IV and V were inaudible for 1 participant. There were 94 to compare the Dinamap Pro 100 with the mercury sphygmomanometer and the same number to compare the Omron HEM 907 with the mercury sphygmomanometer. For observer 1, the percentages of aneroid device SBP measurements differing from the mercury gold-standard by ≤ 5mmHg, ≤ 10mmHg, and ≤ 15mmHg were 42%, 76%, and 91%, respectively. For the DBP measurements: 36%, 73% and 76%, respectively. The percentages of Dinamap Pro 100 SBP measurements differing by the above readings were 29%, 60%, 81%. The DBP measurements differing by ≤ 5mmHg, ≤ 10mmHg, and ≤ 15mmHg were 23%, 38%, and 60%. The percentages of the Omron HEM 907 SBP measurements differing by the above readings were 51%, 80% and 90%. The DBP measurements differing by ≤ 5mmHg, ≤ 10mmHg, and ≤ 15mmHg were 31%, 56% and 74%, respectively (table 3.3).

For observer 2, the comparisons between the aneroid manometer and the standard mercury sphygmomanometer, between the Dinamap Pro 100 and the standard mercury sphygmomanometer, and between the Omron HEM 907 and the standard mercury sphygmomanometer are also given in table 3.3. The better inter-device agreement was obtained by observer 2. Better means the results obtained are more favourable towards the test device. As specified by the BHS protocol, data from the better observer is presented in the form of Blant-Altman plots.

The aneroid manometer measured 3mmHg higher for systolic blood pressure (p= 0.02) and 5mm higher for diastolic blood pressure (p <0.0001). The Dinamap Pro 100, in comparison and on average, measured 5mmHg lower for systolic pressure (p <0.0001) and 8mmHg higher for diastolic pressure (p<0.0001). The Omron HEM 907 measured, on average, 1mmHg lower for systolic blood pressure (p= 0.260) and 5mmHg higher for diastolic blood pressure (p= 0.001).

3.3.1 Correlation and regression

The number of differences between the aneroid manometer and the mercury sphygmomanometer that were ≤ 5, ≤ 10, and ≤ 15 mmHg in magnitude for systolic blood pressure and diastolic blood pressure are presented in figure 3.2. The regression equation for the difference in systolic blood pressure between the aneroid manometer and standard mercury sphygmomanometer was:

$$y = 5.18 – 0, 02 \times \text{mean SBP} (\beta = -0, 049)$$

For the diastolic blood pressure, the regression equation was:

$$y = 10, 92 – 0, 09 \times \text{mean DBP} (\beta = -0, 13).$$

Across the range of blood pressures obtained by observer 2, predicted differences between the aneroid manometer and the mercury sphygmomanometer measurements range from +2 to +4mmHg for systolic BP, and +7 to 0mmHg for diastolic BP.

The number of differences between the Dinamap Pro 100 and the sphygmomanometer that were less than 5, 10, and 15mmHg are shown for systolic and diastolic blood pressures separately in figure 3.3. The linear regressions of these differences on the mean measurement by both devices, are also shown

(dashed lines). The regression equation for the difference in systolic pressure between the Dinamap Pro 100 device and standard mercury sphygmomanometer was:

$$y = -6.11 – 0, 00934 \times \text{mean SBP } (\beta = -0, 014)$$

The regression equation for diastolic blood pressure was:

$$y = -4.49 + 0.18 \times \text{mean DBP } (\beta = 0.16)$$

Across the range of blood pressures observed, predicted differences between the Dinamap Pro 100 and the mercury sphygmomanometer measurements range from -4 to -6mmHg for systolic BP, and +5 to +15mmHg for diastolic BP.

The number of differences between the Omron HEM 907 and the mercury sphygmomanometer that were less than 5, 10, and 15mmHg are shown in figure 3.4. The linear regressions are also shown. The regression equation for the difference in systolic pressure between the Omron HEM 907 device and standard mercury sphygmomanometer was:

$$y = -4.33 + 0, 03 \times \text{mean SBP } (\beta = -0, 05)$$

The regression equation for diastolic blood pressure was:

$$y = 5.56 – 0, 00523 \times \text{mean DBP } (\beta = 0, 014)$$

Across the range of blood pressures observed, predicted differences between the Omron HEM 907 and the mercury sphygmomanometer measurements range from -2 to +1mmHg for systolic BP. The predicted difference for diastolic BP is +5mmHg throughout the range of blood pressures.

Table 3.3 Between-device comparison of BP measurements between aneroid and mercury, Dinamap Pro 100 and mercury, Omron HEM 907 and mercury devices

	Number of comparisons	BHS	Cumulative percentage of differences			Average of readings	Between-device difference
		Grade	≤ 5	≤ 10	≤ 15	Mean ± SD (mmHg)	Mean ± SD (mmHg)
Aneroid							
Observer 1 SBP	**91**	C	**42%**	**76%**	**91%**	**108 ± 17**	**4 ± 9**
DBP	**91**	D	**36%**	**73%**	**76%**	**75 ± 14**	**5 ± 10**
Observer 2 SBP	91	C	44%	78%	96%	110 ± 17	3 ± 8
DBP	91	C	48%	75%	80%	74 ± 15	5 ± 9
Dinamap Pro 100							
Observer 1 SBP	**94**	D	**29%**	**60%**	**81%**	**114 ± 16**	**-6 ± 11**
DBP	**94**	D	**23%**	**38%**	**60%**	**73 ± 11**	**9 ± 13**
Observer 2 SBP	94	D	34%	59%	82%	114 ± 16	-5 ± 10
DBP	94	D	27%	43%	65%	72 ± 12	8 ± 14
Omron HEM 907							
Observer 1 SBP	**94**	B	**51%**	**80%**	**90%**	**112 ± 16**	**6 ± 12**
DBP	**94**	D	**31%**	**56%**	**74%**	**75 ± 13**	**2 ± 10**
Observer 2 SDP	94	B	52%	77%	91%	112 ± 16	-1 ± 10
DBP	94	D	34%	61%	77%	74± 13	5 ± 13

Table 3.4 Observer 2 Systolic blood pressure and Diastolic blood pressure minimum and maximum values with ranges, means and standard deviations

	MEAN SBP Aneroid- mercury	MEAN DBP Aneroid- mercury	MEAN SBP Dinamap Pro 100- mercury	MEAN DBP Dinamap Pro 100- mercury	MEAN SBP Omron HEM 907- mercury	MEAN DBP Omron HEM 907- mercury
Number	91	91	94	94	94	94
Mean	110	74	114	73	112	74
Std. Deviation	16.8652	13.9090	16.0351	11.4997	16.0659	12.6321
Range	91.0	77.0	76.5	54.5	77.5	60.0
Minimum	80.0	44.0	85.5	52.5	83.5	51.0
Maximum	171.0	121.0	162.0	107.0	161.0	111.0

3.3.2 BP analysis in ranges

Using the initial mercury BP reading, pressure data was analysed further according to BP range. Readings for observer 2, as the better observer, were used for this stage of analysis. This analysis only indicates a trend but has not been used to grade overall accuracy of the test devices. 62 data sets were within the specified ranges of <130/80, 130-160/80-100; >160/100. The results are presented in table 3.5.

Table 3.5 Analysis by range of BP at low, medium and high pressure levels for the better observer, observer 2

	Number of comparisons	Cumulative percentage of differences			BHS Grade
		≤ 5	≤ 10	≤ 15	
Aneroid					
Low pressure range <130/80					
SBP	49	49%	84%	100%	C
DBP	49	40%	78%	82%	C
Medium pressure range 130-160/80-100					
SBP	11	45%	91%	100%	C
DBP	11	55%	64%	91%	D
High pressure range >160/100					
SBP	2	50%	100%	100%	B
DBP	2	100%	100%	100%	A
Dinamap Pro 100					
Low pressure range <130/80					
SBP	49	37%	64%	86%	D
DBP	49	31%	51%	79%	D
Medium pressure range 130-160/80-100					
SBP	11	27%	55%	82%	D
DBP	11	18%	27%	45%	D
High pressure range >160/100					
SBP	2	50%	100%	100%	B
DBP	2	0%	100%	100%	D
Omron HEM 907					
Low pressure range <130/80					
SBP	49	49%	82%	90%	C
DBP	49	27%	55%	75%	D
Medium pressure range 130-160/80-100					
SBP	**11**	**27%**	**55%**	**82%**	**D**
DBP	**11**	**18%**	**27%**	**45%**	**D**
High pressure range >160/100					
SDP	2	50%	50%	100%	D
DBP	2	50%	100%	100%	B

a) b)

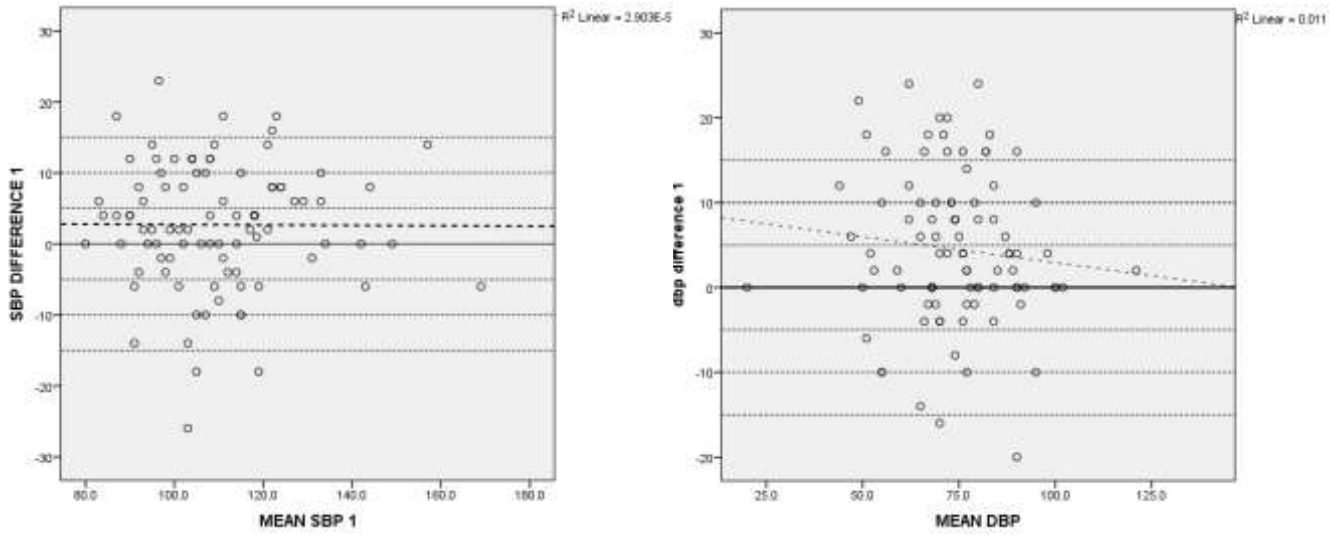

Figure 3.2 Bland-Altman plot of differences in a) SBP and b) DBP measurements between aneroid manometer and the standard mercury sphygmomanometer.
Dotted lines represent levels of difference 5, 10 and 15mmHg

a) b)

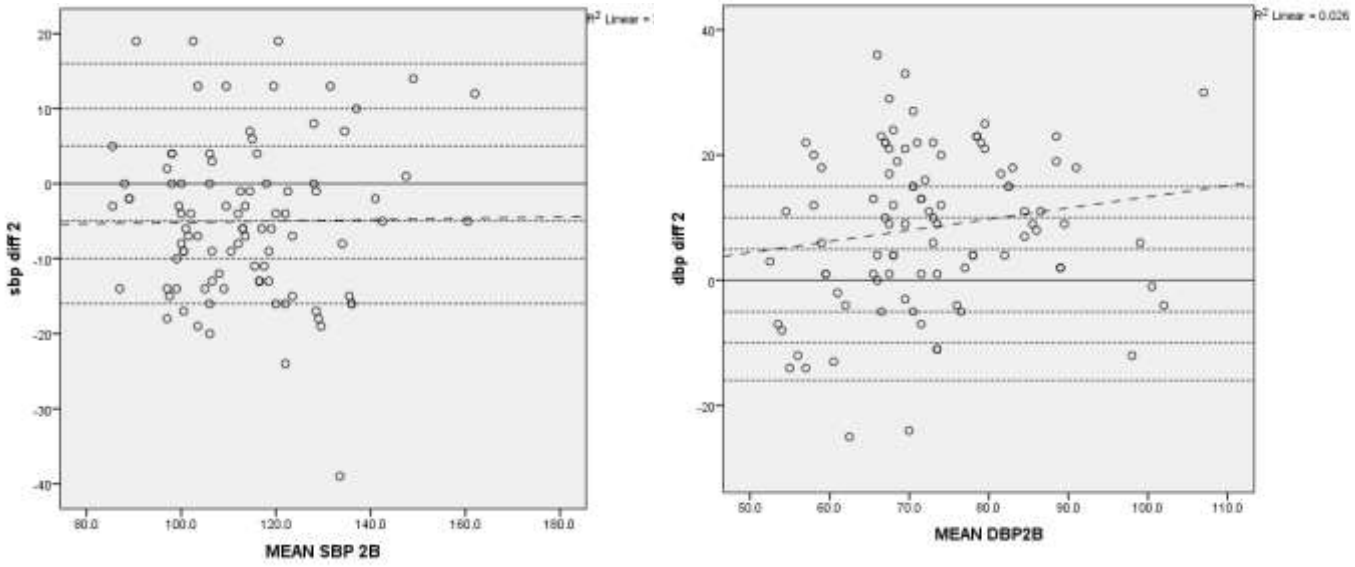

Figure 3.3 Bland-Altman plot of differences in a) SBP and b) DBP measurements between Dinamap Pro 100 and the standard mercury sphygmomanometer.
Dotted lines represent levels of difference 5, 10 and 15mmHg

a) b)

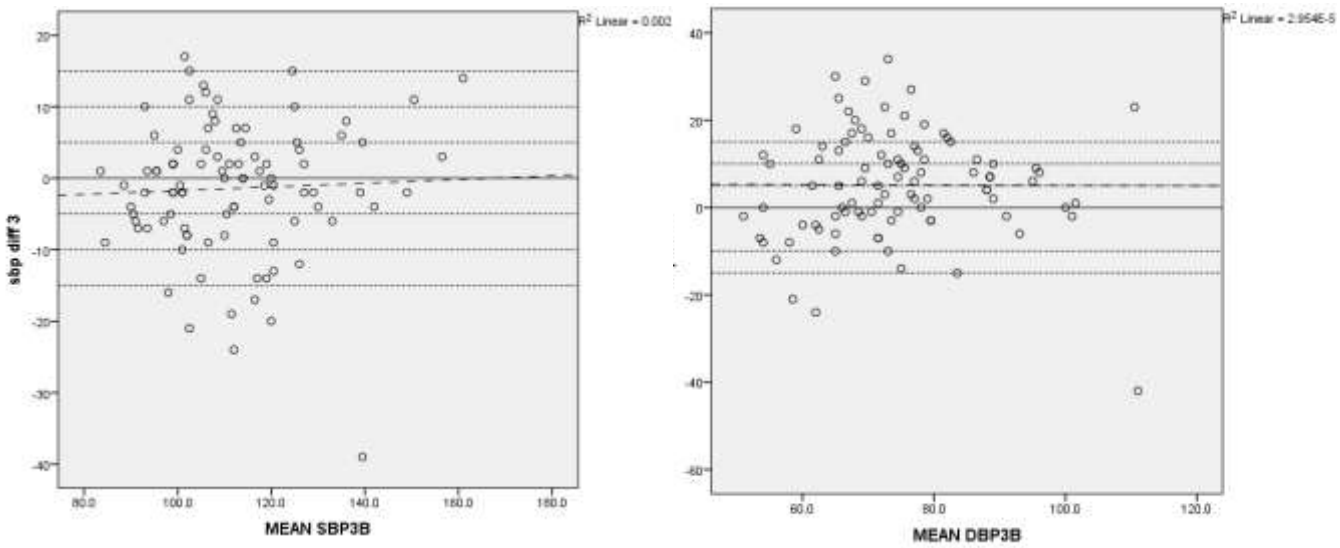

Figure 3.4 Bland-Altman plot of differences in a) SBP and b) DBP measurements between Omron HEM 907 and the standard mercury sphygmomanometer.
Dotted lines represent levels of difference 5, 10 and 15mmHg

4.0 DISCUSSION

The revised BHS protocol for the evaluation of BP measuring devices was used to assess the aneroid, Dinamap Pro 100 and Omron HEM 907 blood pressure devices. Paediatric subjects are considered a special group in the testing of BP devices for validation. There are presently limited statistics upon which to base the recommendations for validation in this special group. No pass or fail assessment is therefore proposed. [13]

The Association for the AAMI revised its national standard oscillatory devices and published these in 1993. [14]

The BHS protocol was revised in 1992 and was published in the Journal of Hypertension in the year 1993. The first protocol had focused on the evaluation of 24-hour ambulatory blood pressure measuring devices. The revised protocol addresses resting blood pressure in addition to ambulatory BP monitors.

In the quantification of BP in children above the age of three years, the standard test for identifying hypertension is by auscultating using a standard clinical sphygmomanometer and stethoscope placed over the brachial arterial pulse. [6] In infants and newborns, in whom auscultation is difficult, and in the intensive care unit, use of the automated device is preferred. [24] Evaluation of these devices in common use is thus extremely important.

The agreement between the observer 1 and observer 2 were both very good for the two manual devices (see table 3.2). The reliability of the readings obtained to compare all the devices to the mercury gold-standard is excellent in this study. Observer error was ruled out as a factor that may have confounded outcomes in our study.

The aneroid manometer received a poor grade for SBP and DBP. It obtained a grade C for SBP and C for DBP. It, however, had a small mean difference from the mercury sphygmomanometer. According to AAMI criteria, the aneroid manometer demonstrated accuracy in SBP measurement. The aneroid manometer, however, overestimates both SBP and DBP.

A Welch Allyn mounted aneroid manometer was used in our study. One of the difficulties faced during the study was the absence of a portable aneroid manometer. Patients had to walk up to the aneroid manometer within the same room, in order to have the blood pressure measured. The study population did not receive an additional period of time between sitting down and having blood pressure measured with the aneroid manometer. This may have influenced the blood pressure difference obtained between the aneroid and mercury device. This was a limiting factor in our study.

With the decreasing popularity of mercury sphygmomanometers, non-mercury auscultatory devices are considered reliable if appropriately and regularly calibrated. This is according to the UK National Screening Committee (NSC) review, and the US task force 4th report. [6, 9] The aneroid manometer has been previously formally validated using the BHS protocol, in a study done by Jones et al. [11] The results were treated with reservation as only an abstract was available in the Journal of Human Hypertension published in the year 2000. The study findings stated that aneroid manometers could not be recommended for use in place of the gold-standard mercury device. Also making this study incomplete was the lack of mention of the make and model of aneroid manometer investigated. The Diabetes Prevention Program Outcomes Study (DPPOS) investigated the accuracy of the Welch Allyn Tycos 767-Series Mobile aneroid sphygmomanometer in 2006. The study concluded that the aneroid manometer could be used as a replacement to the mercury device. The differences were quantified using probabilities and regression.

The simple mechanics of the aneroid manometer, which uses air pressure alone to measure BP, makes it likely to be a mercury sphygmomanometer replacement. There is no risk of mercury spillage and poisoning involved, which are important advantages of the aneroid manometer in a paediatric outpatient setting.

Because of the limited number of studies that have validated the aneroid manometer using the available protocols of the BHS, AAMI and European Hypertension Society [11, 12], further studies are required to prove that the aneroid manometer indeed is a reliable replacement for the gold-standard mercury sphygmomanometer.

Dinamap Pro 100 received the worst grading of the three devices, receiving grades D for SBP and DBP. The Dinamap Pro 100 underestimates SBP by 5mmHg, on average and overestimates DBP by 8mmHg. The regression equations in figure 3.2 further highlight this.

The Dinamap Pro 100 has been evaluated in a study conducted in 2006. The study compared blood pressure obtained with a mercury sphygmomanometer. The BP was measured in random order, several times, in each of 305 adult participants. The Dinamap Pro 100 underestimated BP for both systolic and diastolic BP. The mean difference was -0.5 mm Hg ($p = 0.36$, SD = 9.8 mm Hg) for SBP and -2.9 mm Hg ($p < .001$, SD = 6.6 mm Hg) for DBP. This study was different to our study in method and findings as the BHS protocol was not used. The Dinamap Pro 100 did not pass validation for SBP but passed validation for DBP according to the AAMI criteria, contrary to not passing for SBP and DBP in our study. [22]

Additional Dinamap models that have been validated and passed validation, include the Dinamap 8100. Non-uniform conclusions prevail, however, for the Dinamap 8100 as well. In one study involving diabetic, young participants, the Dinamap passed both BHS and AAMI criteria for SBP and DBP. [17] In another study, conducted by Heinemann et al., only SDP passed validation. [15] This involved adult participants. The studies conducted on the Dinamap devices have had conflicting, yet mostly unfavourable outcomes. There is a need for further studies to measure the accuracy of these devices which are in extremely common use in paediatric outpatients' department.

The Omron HEM 907 performed better than the Dinamap Pro 100, receiving a B grade for SBP and grade C for DBP. The Omron underestimates SBP by 1mmHg, and overestimates DBP by 5mmHg with a wide standard deviation. The Omron HEM 907 met the criteria for SBP, but on the other hand, did not for DBP, according to the BHS protocol. The AAMI criteria were not met for both SBP and DBP.

The Omron range of devices is mostly used for self-measurement of blood pressure instead of the clinical environment. [20] Two studies have specifically evaluated the Omron HEM 907. The Omron HEM 907 passed the BHS criteria in a study published in the American Journal of Hypertension in

2002. [23] In a 2010 study, published in the Journal of Clinical Hypertension, the device met the AAMI criteria. Device agreement, however, decreased with increased SBP and DBP. [24]

The Omron HEM 907 in our study passed validation for SBP but not for DBP. The number of data for high-range BP was too low to make a conclusion about the correlation of the Omron device and mercury sphygmomanometer at higher blood pressures. Further studies are recommended to further assess the accuracy of the Omron HEM 907 in clinical settings, and using the BHS and AAMI protocols.

At the low-pressure range of blood pressure readings, the aneroid grade was improved to grade C vs D for DBP. The Omron HEM 907 device received a comparable grade C for DBP.

At medium- pressure ranges, the Omron HEM 907 received a worse grade of D for SBP, however at high pressure ranges, all the devices had a better grade according to the BHS protocol. The Omron did particularly well, earning an A grade for DBP and B for SBP. This finding, however, is limited by the number of data to compare, being only 2 for high-range BP, 49 for medium-pressure ranges and only 11 for low-range blood pressures.

The blood pressures of pre-adolescents cannot be classified into low, mid- or high in practice. Hence, the representation of BP in ranges is arbitrary for children. As previously mentioned, the above findings do not assist with validation but they demonstrate trends of blood pressure device accuracy at various BP ranges. Further studies with larger participant numbers will be needed to permit conclusions to be made about blood pressure machine performance at various blood pressure ranges in adults.

5.0 CONCLUSIONS

Hypertension in children is most often a sign of an underlying primary disorder. Childhood hypertension is also a predictor of hypertension in adulthood. It becomes imperative for any blood pressure machine used in paediatric patients to be accurate. The replacement of the mercury sphygmomanometer has been encouraged by the European Society of Hypertension, however there is paucity and conflicting data regarding the accuracy of aneroid and oscillatory machines which are to replace this gold-standard.

There are very few studies that have validated the aneroid manometer. In our study, the aneroid manometer demonstrated accuracy in SBP according to the AAMI criteria, but failed to demonstrate accuracy in SBP and DBP according to the BHS protocol. This finding was highly unexpected as it is an auscultatory device, like the mercury manometer and it is in such common use as a trusted replacement for the mercury device. This finding means further validation studies are needed for the aneroid manometer.

The Dinamap Pro 100 was found to have been evaluated in one study to date. In that study, DBP proved to be of acceptable accuracy, but not SBP. Our study used two international criteria, one of which was modified, and in addition correlation and regression analyses were used. The Dinamap Pro 100 was unsuccessful in demonstrating accuracy for both SBP and DBP in all three criteria. The Dinamap Pro 100 underestimates SBP and overestimates DBP. The Omron HEM 907 failed to demonstrate accuracy for DBP, but was accurate for SBP according to one of two international criteria. Neither is recommended for use in the paediatric renal outpatient clinic.

The mechanism of oscillatory BP machines involves measuring the mean BP and calculating the SBP and DBP thenceforth. It is, therefore, explicable that oscillatory machines are good for monitoring a trend in BP for an individual. However, where an accurate BP reading is required for purposes of diagnosing and treating hypertension, an abnormal BP reading needs to be confirmed using a mercury sphygmomanometer.

Further studies are recommended to evaluate the accuracy of the aneroid machine, the Omron HEM 907 and the Dinamap Pro 100 if their use is to continue in the clinical setting.

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APPENDIX A

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APPENDIX B

DATA COLLECTION SHEET

Patient number	
Diagnosis	
Antihypertensive Y/N	
Dialysis Y/N	
Age (years)	
Height (cm)	
Weight (kg)	
Mid-upper arm circumference (cm)	
SBP (mmHg)	1 /2 /3 /4 /5
DBP (mmHg)	1 /2 /3 /4 /5

APPENDIX C

R14/49 Dr Nokukhanya Swazi Mwandla

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M140146

NAME: (Principal Investigator)	Dr Nokukhanya Swazi Mwandla
DEPARTMENT:	Paediatrics Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	The Accuracy of Blood Pressure Devices in Paediatric Renal Outpatients
DATE CONSIDERED:	31/01/2014
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof Udai Kala
APPROVED BY:	Professor PE Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	30/04/2014

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX D

Plagiarism declaration for written work

I …*Nokukhanya Swazi Mwandla (Student number 699539)*…. as a postgraduate student registered for a MMed in Paediatrics, in the year 2012, at the
University of the Witwatersrand declare the following:

- I am aware that plagiarism is the use of someone else's work without their permission and or without acknowledging the original source.
- I am aware plagiarism is wrong.
- I confirm that this written work is my own work except where I have stated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or if I have failed to acknowledge the ideas or writing of others.

Signature …*N.S Mwandla*…...

Date ……*31-08-16*……