Type and accuracy of sphygmomanometers in primary care: a cross-sectional observational study

INTRODUCTION
Hypertension is the leading risk factor for cardiovascular disease and death worldwide.1 Its diagnosis and control require accurate blood pressure measurement, which depends upon both the instrument and the technique used.2,3 Inaccurate blood pressure measurement might lead to misdiagnosis, and either unnecessary or insufficient treatment, with both ethical and public health implications.4-6 The widely accepted ’gold standard’ measuring device has been, until recently, the mercury sphygmomanometer, however, worldwide concern over increasing mercury levels led to a European Union directive that mercury sphygmomanometers be phased out.7

Several protocols exist for the validation of blood pressure devices,8,9 but these do not guarantee sustained accuracy once in use: a hospital study employing a rigorous dynamic testing protocol across the whole blood pressure range reported error readings of >10 mmHg in 50% of aneroid devices and 10% of mercury devices.10 Primary care-based studies have shown similar results but have not been undertaken since the use of electronic devices became widespread.11-13 The revised general medical services contract for UK GPs (2004) includes a recommendation to ensure medical equipment is regularly maintained, calibrated, and replaced if faulty.14 Given that reported achievement for this standard is 97%, it might be expected that most sphygmomanometers in use are now accurate.12,13

Therefore, this study aimed to assess the current state of equipment in primary care for monitoring blood pressure: the type of equipment being used, its accuracy, and, finally, the relationship between current performance and previous in-service testing.

METHOD
In January 2009, written invitations to participate in an anonymised cross-sectional survey of sphygmomanometer type and accuracy were sent to 83 practices in Oxfordshire Primary Care Trust. Participating practices were visited by a trained health technician, and practice staff identified all manometers, whether kept on site or in a doctor’s bag, or in use by staff attending the practice. Recruitment and testing were complete by July 2009.

Following pilot work confirming their equivalence, two types of pressure-testing device were deployed: the Omron PA 350 (for Omron digital devices, and any free-standing mercury, aneroid or digital device), and the more portable Scandmed 950831-2 Pressure Meter (for wall-mounted devices, and digital devices sharing the same manufacturer, A&D).14 As recommended by the British Hypertension Society (BHS),8 sphygmomanometers were inflated to 280 mmHg, then the pressure released to 250, 200, 150, 100, and 50 mmHg in turn,
The dates of previous testing were noted: devices were taken to have been tested if there was a dated label on the device, or if the practice manager reported devices as having been tested and could specify a date.

Correlation coefficients were used to examine whether errors at one pressure were correlated with errors at other pressures. To facilitate comparison with earlier studies, and communicate the significance of errors, a ‘trafficlight’ classification of error readings was devised, in which devices were assigned a ‘green’ rating if all results fell within 0–3 mm Hg of the reference blood pressure (the BHS standard), an ‘amber’ if one or more readings deviated by 4–9 mm Hg, and a ‘red’ if any of the results differed by 10 mm Hg or more. Fisher’s exact test was used to test whether this classification was associated with device type, manufacturer or branding, time since last testing, size of practice, or holder of the device. Local ethics committee advice was sought and this study was classified as service development not requiring ethical approval.

RESULTS

A total of 38 (46%) practices agreed to take part, seven of which had been involved in the pilot study. The mean practice size was 8653 patients (median 8384 patients, range 2600 to 20 000), with an average of six GPs per practice (range 1 to 12). The 664 devices identified encompassed 11 major manufacturers, and over 50 different models (Table 1). The majority of devices 323 (53%) were digital, followed by aneroid 192 (32%), mercury 79 (13%), and hybrid 10 (2%) devices. Of note, 30 (16%) aneroid devices carried no discernible manufacturer’s name, and were mostly (23/30) inscribed with the name of a pharmaceutical drug product.

A small number of sphygmomanometers (16 [2.5%: 15 digital, 1 aneroid]) could not be tested, because of either mechanical failure or absent parts rendering them unusable, or lack of compatibility with either testing device. A further four mercury devices were labelled as not in use but were retained in the practices due to lack of disposal options. These exclusions left 584 (97%) devices that were fully evaluated.

Overall, 86% (503 of 584) of individual devices were within 3 mm Hg of the standard across the pressure range (‘green’ classification), 13% (77 of 584) had one or more error of 4–9 mm Hg (‘amber’), and <1% (4 of 584) had one or more error ≥10 mm Hg (‘red’). Significantly fewer mercury (4/75 [5%]) and digital devices (36/308 [12%]) failed the 3 mm Hg standard than aneroid (41/191 [21%]) (Figure 1). Compared to mercury, digital devices were no more likely to fail the BHS standard (relative risk [RR] = 2.19, 95% confidence interval [CI] = 0.80 to 5.97), but aneroid models were four times more likely to fail (RR = 4.02, 95%, CI = 1.49 to 10.8). The 10 hybrid devices were all within 3 mm Hg of the reference standard.

Device accuracy was similar between the most common manufacturers: all errors were within 3 mm Hg in digital devices manufactured by A&D/boso or Omron in 89% (92/103) and 88% (173/196) of cases respectively, and 83% (5/6) of others (P = 0.7 for difference between manufacturers). Similarly, in aneroid devices 86% (59/69) of Accoson devices, 85% (39/46) of Welch-Allyn devices, and 83% (38/46) of other recognised manufacturers (P = 0.96) had errors within 3 mm Hg. The 30 aneroid devices without a discernible manufacturer, of which 23 (77%) bore pharmaceutical advertising, were more likely to be classified as amber or red compared to other aneroid devices: 53% (16 of 30) versus 16% (25 of 161) (Fisher’s exact test P<0.001). The digital devices included three devices that bore the name of a high street retailer rather than a recognised manufacturer of manometers. A sensitivity analysis restricted to devices that were clearly from a recognised device manufacturer was therefore undertaken, in which 95% (71 of 75) of mercury devices were within 3 mm Hg of the standard.
mmHg, with 89% (270 of 305) of digital devices and 86% (136 of 161) of aneroid models now within this range ($P = 0.07$ for differences between device types).

A further sensitivity analysis evaluated absolute error across the pressure range (Figure 2). Mercury devices had a smaller error than aneroid and digital devices at every pressure ($P < 0.001$ at each pressure).

The error given by a device at any preset pressure (50, 100, 150, 200, or 250 mmHg) was predictive of the error given by the same device at other pressures, with a significant correlation coefficient ($P < 0.001$) at every level. Thus, devices that substantially over-read at any one pressure were more likely to do so at other pressures, and similarly for under-reading.

There were 17 apparently brand new devices. Of the remaining 567, 147 (26%) had been tested within the previous 6 months, 173 (31%) within the past 6 to 12 months, 97 (17%) had been tested more than 12 months ago, and 150 (26%) had no record of previous testing. Overall, no significant difference was found between testing date and accuracy of device: a ‘green’ rating (within 3 mmHg) was achieved in 87% (128/147) of devices tested in the last 6 months, 89% (154/173) of those tested within 6 to 12 months, 87% (84/97) of those tested over 12 months before, and 80% (120/150) of those never tested ($P = 0.1$).

The accuracy of a device was not related to the size of practice ($P = 0.7$) or the holder of the device — whether this was a GP, practice nurse, or district nurse, or the device was on loan to a patient ($P = 0.7$).

**DISCUSSION**

**Summary**

This study shows that the most commonly used sphygmomanometers in UK primary care are now digital devices, which outnumber mercury models 4:1. Overall, one in seven devices failed the BHS standard requiring all devices to read within 0–3 mmHg of the true value. The performance of mercury and digital models was similar and significantly better than aneroid models. This difference appears to
be explained by the presence of a group of donated aneroid sphygmomanometers with no discernible manufacturer. No significant differences were seen between devices from the commonest manufacturers, nor between those used by different professional groups, which suggests a maturing of the underlying technology. There was little evidence that previous calibration made any difference to current accuracy, although just over half had been checked within the last year.

Strengths and limitations
To the authors’ knowledge, this is the first study to test sphygmomanometer accuracy in a broad range of primary care practices in the era of digital blood pressure measurement. Testing was undertaken by a single trained individual and so was unlikely to have been affected by between-observer variation, and included the vast majority of devices in use in participating practices; only 3% of devices could not be fully tested, because of either mechanical faults or incompatibility with the testing equipment. Some limitations should be noted: testing was undertaken in one geographical area that may not be representative of the country as a whole. A minority of the practices (seven) had participated in the earlier pilot study and so were likely to perform better in

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**Figure 1.** Errors in blood pressure measurements in mercury, aneroid, and digital sphygmomanometers tested at 50, 100, 150, 200, and 250 mmHg. Eleven errors 11–50 mmHg are not shown for reasons of scale (five readings from one aneroid device under-reading by 30 mmHg in all tests).

**Figure 2.** Absolute error (mean, ignoring direction of error; bars show 95% confidence intervals for the mean) in blood pressure devices when tested at 50, 100, 150, 200, and 250 mmHg.
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Implications for practice and research
This study demonstrates that despite the increased use of digital devices, there remains an improved but still unsatisfactory prevalence of inaccurate, mostly aneroid, devices. The results suggest the need for replacement of inaccurate devices with high-quality, validated devices. Given the superior objectivity offered by digital devices, memory functions, improved portability, and falling costs, perhaps the time has now come to remove aneroid devices, at least from doctors’ bags. Further studies are needed to evaluate the in-service accuracy of the newer hybrid devices, although the small sample in the present study suggested possible high accuracy. The cost of replacing unreliable manometers is likely to be dwarfed by the cost of inadequately treated hypertension, or, in overtreated patients, the cost of inappropriate prescribing and adverse events.

Comparison with existing literature
To date, mercury devices have been viewed as the ‘gold standard’ for sphygmomanometer accuracy. This study suggests that they have now been largely replaced by digital models in clinical practice, probably due to a combination of the drive to reduce mercury and the convenience of digital technology. Examination of the absolute errors observed demonstrates the superior performance of mercury models and suggests that a place for mercury devices remains, in terms of providing a reference standard. However, the clinically relevant measure of agreement (within or outside the 3 mmHg standard) highlighted by the ‘traffic light’ classification was similar for digital and mercury models.

The performance of digital devices from recognised manufacturers was consistently good, which is reassuring given their ubiquity. Many patients (and some professionals) now purchase low-cost digital devices from high street pharmacies, but it was not possible to test enough such devices in this study to assess their performance separately. In common with other investigators, a significantly higher failure rate was detected for aneroid sphygmomanometers, unless the analysis was restricted to aneroid devices from recognised manufacturers. A particularly high failure rate was found in those aneroid devices apparently received as gifts from pharmaceutical representatives. Such devices are likely to be low-cost, possibly inferior products, which have been given to clinicians under pharmaceutical industry regulations allowing donation and acceptance of inexpensive promotional items. The main advantage of aneroid sphygmomanometer devices is their portability, and one-fifth of the devices in the present study were definitely carried in a doctor’s bag. The mechanical construction of aneroid devices makes them vulnerable to physical damage, so that jolting, and the variation in temperature likely to occur in a doctor’s bag will affect their accuracy more than is the case for digital models.

Where monitors ‘failed’ on testing (over 3 mmHg deviation from the reference standard at one or more pressures), there was evidence that errors were systematic, leading to consistent over- or underdiagnosis or treatment in clinical practice. Conversely, instruments providing accurate readings at one pressure tended to be accurate across the range. Uncalibrated sphygmomanometer error potentially accounts for 20% of all undetected adult systolic hypertension. Where prevalence is low, over-detection is worse; for example, causing 63% of falsely detected systolic hypertension in 18–24-year-old females. Overdiagnosis could have an impact outside the clinical arena, due to the ‘sick patient’ effect, in which people assume a sick role and show more absenteeism after receiving a diagnosis of hypertension.

An unexpected finding was the lack of difference in performance between devices that had, or had not been tested previously. The negative findings might be due to the fact that the ‘never tested’ group included not only older devices (including the four most inaccurate devices) but also newer devices within the manufacturer’s warranty. On the other hand, within the ‘previously tested’ group, there were some manometers labelled as failing previous tests, which, worryingly, had been retained. Together, these findings emphasise that regular checks need to be acted upon but suggest that such checks could focus on just one or two pressures in a range of clinical interest, which might improve adherence to the recommendations.
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