

Christine A'Court, Richard Stevens, Sarah Sanders, Alison Ward, Richard McManus and Carl Heneghan

Type and accuracy of sphygmomanometers in primary care:

a cross-sectional observational study

Abstract

Background

Previous studies identified worrying levels of sphygmomanometer inaccuracy and have not been repeated in the era of digital measurement of blood pressure.

Aim

To establish the type and accuracy of sphygmomanometers in current use.

Design and setting

Cross-sectional, observational study in 38 Oxfordshire primary care practices.

Method

Sphygmomanometers were evaluated between 50 and 250 mmHg, using Omron PA350 or Scandmed 950831-2 pressure meters.

Results

Six hundred and four sphygmomanometers were identified: 323 digital (53%), 192 aneroid (32%), 79 mercury (13%), and 10 hybrid (2%) devices. Of these, 584 (97%) could be fully tested. Overall, 503/584 (86%) were within 3 mmHg of the reference, 77/584 (13%) had one or more error of 4–9 mmHg, and 4/584 (<1%) had one or more error of more than 10 mmHg. Mercury (71/75, 95%) and digital (272/308, 88%) devices were more likely to be within 3 mmHg of the reference standard than aneroid models (150/191, 78%) [Fisher's exact test $P=0.001$]. Donated aneroid devices from the pharmaceutical industry performed significantly worse: 10/23 (43%) within 3 mmHg of standard compared to 140/168 (83%) aneroid models from recognised manufacturers [Fisher's exact test $P<0.001$]. No significant difference was found in performance between manufacturers within each device type, for either aneroid [Fisher's exact test $P=0.96$] or digital [Fisher's exact test $P=0.7$] devices.

Conclusion

Digital sphygmomanometers have largely replaced mercury models in primary care and have equivalent accuracy. Aneroid devices have higher failure rates than other device types; this appears to be largely accounted for by models from indiscernible manufacturers. Given the availability of inexpensive and accurate digital models, GPs could consider replacing aneroid devices with digital equivalents, especially for home visiting.

Keywords

blood pressure determination; hypertension; general practice; quality assurance, health care.

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.^{4,6,11} 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.¹² 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,

C A'Court, GP, MA, MRCP, MRCPGP; **RJ Stevens**, BA, MSc, PhD, senior statistician; **A Ward**, BPsych, PhD, senior research fellow and director of Postgraduate Studies; **C Heneghan**, MA(Hons), MRCPGP, reader, Department of Primary Health Care, University of Oxford, Oxford. **S Sanders**, assistant practitioner, Broadshires Health Centre, Carterton, Oxfordshire. **RJ McManus**, MSc, MRCPGP, professor, Primary Care Clinical Sciences, University of Birmingham, Birmingham. **Address for correspondence** Christine A'Court, Oxford University, Department

of Primary Health Care, Old Road Campus, Roosevelt Drive, Oxford, OX3 7LF.

E-mail: christine.acourt@phc.ox.ac.uk

Submitted: 27 March 2011; **Editor's response:** 18 April 2011; **final acceptance:** 3 June 2011.

©British Journal of General Practice

This is the full-length article (published online 30 Aug 2011) of an abridged version published in print. Cite this article as: **Br J Gen Pract 2011;**

DOI: 10.3399/bjgp11X593884.

How this fits in

Mercury sphygmomanometers have been considered the 'gold standard' for blood pressure measurement, but are being phased out. Previous studies of sphygmomanometers in primary and secondary care suggested that aneroid manometers have inferior accuracy, and have not comprehensively assessed digital monitors. In this study, digital sphygmomanometers outnumbered mercury devices by 4:1, and were similar in terms of frequency and magnitude of errors and superior to aneroid devices. Much of the poor performance of aneroid sphygmomanometers could be explained by poor-quality devices provided in the context of pharmaceutical promotions, which should therefore be discarded; there is merit in replacement of aneroid devices with digital equivalents, especially for home visiting.

and at each level the true pressure was read on the pressure tester's digital display.

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 significance of errors, a 'traffic light' classification of error readings was devised, in which devices were assigned a 'green' rating if all results fell within 0–3 mmHg of the reference blood pressure (the BHS standard),⁸ 'amber' if one or more readings deviated by 4–9 mmHg, and 'red' if any of the results differed by 10 mmHg 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 604 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 mmHg of the standard across the pressure range ('green' classification), 13% (77 of 584) had one or more error of 4–9 mmHg ('amber'), and <1% (4 of 584) had one or more error ≥ 10 mmHg ('red'). Significantly fewer mercury (4/75 [5%]) and digital devices (36/308 [12%]) failed the 3 mmHg 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 mmHg of the reference standard.

Device accuracy was similar between the most common manufacturers: all errors were within 3 mmHg 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 mmHg. 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

Table 1. Manufacturers of blood pressure devices in use in 38 general practices in Oxfordshire

Type/brand	Number identified in survey (% of device type)	Number included in tests in this study	Reasons for exclusion from tests	Percentage (numbers) of tested device type classified amber/red
Mercury devices (13% of all devices identified)	79	75		5% (4/75 amber, 0/75 red)
Accoson	74 (94)	70	Four: one with bubble in mercury, stored in drawer and unclaimed, last tested 1997, presumed not in use; three labelled as out of use since previous test, but wall-mounting and cost of decommissioning precluded removal from premises	6% (4/70 amber, 0/70 red)
Other manufacturers	5 (6)	5		0% (0/5 amber/red)
Aneroid devices (32% of all devices identified)	192	191		22% (37/191 amber, 4/191 red)
Accoson	69 (36)	69		14% (10/69 amber, 0/69 red)
Welch-Allyn	46 (24)	46		15% (7/46 amber, 0/46 red)
boso	13 (7)	13		8% (1/13 amber, 1/13 red)
Other device manufacturer	34 (18)	33	One with missing part (Riester Big Ben)	18% (6/33 amber, 0/33 red)
Devices with pharmaceutical branding	23 (12)	23		52% (11/23 amber, 2/23 red)
Unknown manufacturer	7 (4)	7		43% (2/7 amber, 1/7 red)
Digital devices (53% all devices identified)	323	308	15	12% (36/308 amber, 0/308 red)
Omron	198 (61)	196	Two wrist monitors — incompatible with testers	12% (23/196 amber, 0/196 red)
A&D/boso ^a	104 (32)	103	One UB511 wrist monitor — incompatible with testers	11% (11/103 amber, 0/103 red)
Other manufacturer	11 (3)	6	Five: either incompatible with testers (3) — H21188U Wrist, KD 525, Rossmax; or mechanically failed (2) — Transtec, Prestige	17% (1/6 amber, 0/6 red)
High street pharmacist ^b	10 (3)	3	Seven: either incompatible with testers (6), or mechanically failed (1), all Lloyds Pharmacy	33% (1/3 amber, 0/3 red)
Hybrid devices (2% of all devices identified)	10	10		
A&D ^c	10 (100)	10		0% (0/10 amber/red)

^aSome A&D digital devices are branded as boso (personal communication: Mike Telford, A&D Europe). ^bThe brand name was 'Lloyds Pharmacy' on nine devices and 'Boots' one device. ^cThe A&D UM 101 meter combines aneroid and digital features (personal communication: Mike Telford, A&D Europe).

mmHg, with 89% (270 of 305) of digital devices and 84% (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

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).

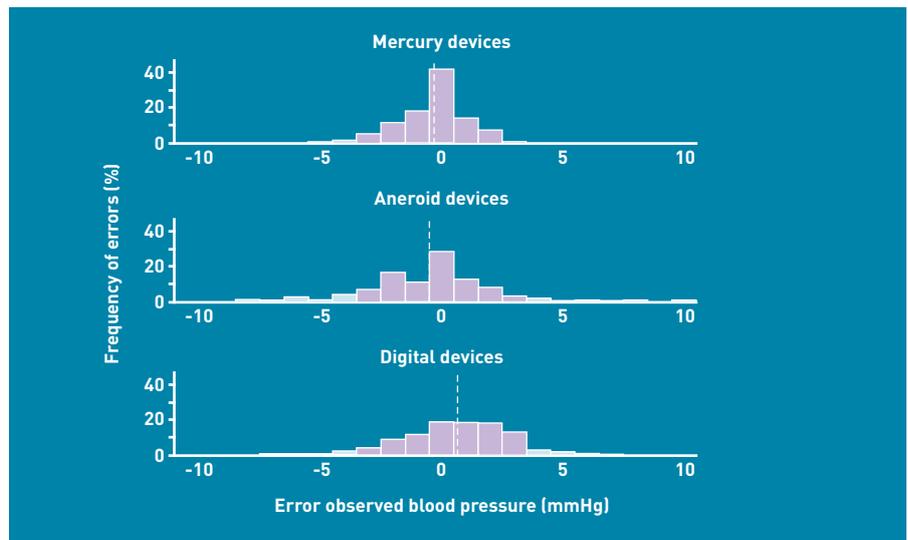
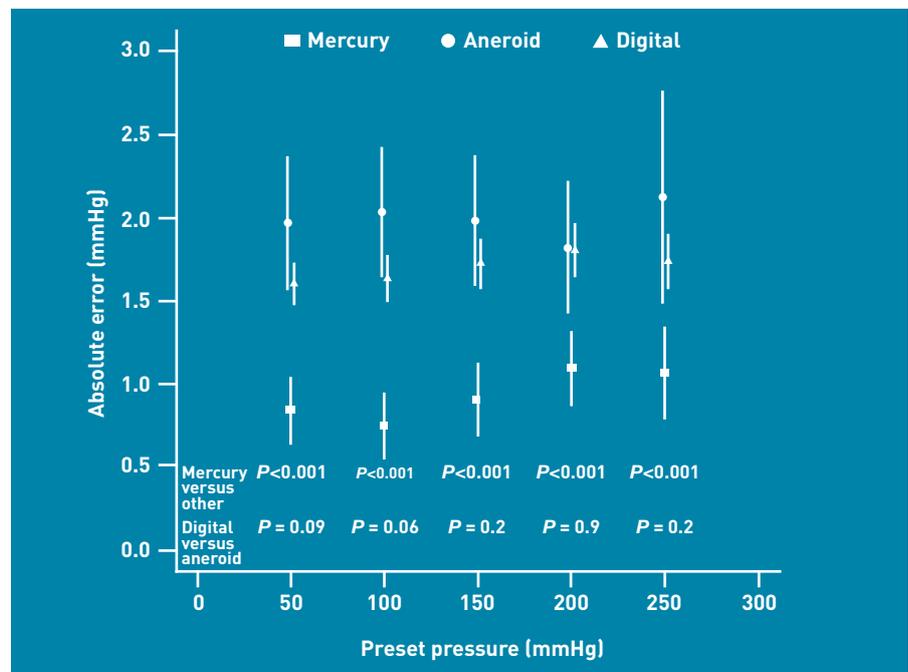


Figure 2. Absolute error (mean, ignoring direction of error; bars show 95% confidence intervals for the mean) in blood pressure devices when tested at 50, 100, 150, 200, and 250 mmHg.



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

this study. In addition, practices that decided not to participate in the study may be less interested in the topic and therefore less likely to maintain their equipment. These potential biases could lead to an overestimation of true device accuracy in practice.

Comparison with existing literature

To date, mercury devices have been viewed as the 'gold standard' for sphygmomanometer accuracy.^{8,9} 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.⁷ 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.^{8,9} 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.²

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.⁴ 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, overdetection is worse; for example, causing 63% of falsely detected systolic hypertension in 18–24 year-old females.⁵ 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.¹⁵

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.

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 manometers. 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.

Funding

This article presents independent research commissioned by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research funding scheme (RP-PG-0407-10347). The views expressed in this article are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

Ethical approval

Ethical approval was not required for this study.

Provenance

Freely submitted; externally peer reviewed.

Competing interests

The authors have declared no competing interests.

Acknowledgements

The authors wish to thank the participating practices for their willing cooperation.

Discuss this article

Contribute and read comments about this article on the Discussion Forum: <http://www.rcgp.org.uk/bjgp-discuss>

REFERENCES

1. Kearney PM, Whelton M, Reynolds K, *et al.* Global burden of hypertension: analysis of worldwide data. *Lancet* 2005; **365**(9455): 217–223.
2. McAlister FA, Straus SE. Evidence based treatment of hypertension. Measurement of blood pressure: an evidence based review. *BMJ* 2001; **322**(7291): 908–911.
3. Wan Y, Heneghan C, Stevens R, *et al.* Determining which automatic digital blood pressure device performs adequately: a systematic review. *J Hum Hypertens* 2010; **24**(7): 431–438.
4. Rouse A, Marshall T. The extent and implications of sphygmomanometer calibration error in primary care. *J Hum Hypertens* 2001; **15**(9): 587–591.
5. Turner MJ, Irwig L, Bune AJ, *et al.* Lack of sphygmomanometer calibration causes over- and under-detection of hypertension: a computer simulation study. *J Hypertens* 2006; **24**(10): 1931–1938.
6. Coleman AJ, Steel SD, Ashworth M, *et al.* Accuracy of the pressure scale of sphygmomanometers in clinical use within primary care. *Blood Press Monit* 2005; **10**(4): 181–188.
7. Directive 2007/51/EC of the European Parliament and of the Council of 25 September 2007 amending Council Directive 76/769/EEC relating to restrictions on the marketing of certain measuring devices containing mercury. http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_257/l_25720071003en00130015.pdf [accessed 12 Jul 2011].
8. O'Brien E, Petrie J, Littler W, *et al.* An outline of the revised British Hypertension Society protocol for the evaluation of blood pressure measuring devices. *J Hypertens* 1993; **11**(6): 677–679.
9. O'Brien E, Pickering T, Asmar R, *et al.* Working group on blood pressure monitoring of the European Society of Hypertension International Protocol for validation of blood pressure measuring devices in adults. *Blood Press Monit* 2002; **7**(1): 3–17.
10. Waugh JS, Gupta M, Rushbrook J, *et al.* Hidden errors of aneroid sphygmomanometers. *Blood Press Monit* 2002; **7**(6): 309–312.
11. Hussain A, Cox JG. An audit of use of sphygmomanometers. *Br J Clin Pract* 1996; **50**(3): 136–137.
12. Department of Health Investing in general practice: the new general medical services contract. London: DOH, 2003. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4071966 [accessed 11 Aug 2011].
13. NHS Information Centre. *England level data tables*. NHS Information Centre, 2009/10. <http://www.ic.nhs.uk/statistics-and-data-collections/supporting-information/audits-and-performance/the-quality-and-outcomes-framework/qof-2009-10/data-tables/england-level-data-tables>. [accessed 12 Jul 2011].
14. A'Court C, Sanders S, Ward A, *et al.* Inaccuracies in blood pressure devices in general practice. Oral presentation and proceedings of SWSAPC [Society for Academic Primary Care (South-West Region) Annual Research Meeting]. 2009.
15. Haynes RB, Sackett DL, Taylor DW, *et al.* Increased absenteeism from work after detection and labelling of hypertensive patients. *N Engl J Med* 1978; **299**(14): 741–744.