4. Black D. Investigation of the possible increased incidence of cancer in West Cumbria. Report of the independent advisory group. London: HM Stationery Office, 1984.
5. Committe on Medical Aspects of Radiation in the Environment (COMARE). Investigation of the possible increased incidence of leukaemia in young people near the Dounreay Nuclear Establishment, Caithness, Scotland. London: HM Stationery Office, 1988.
6. Alexander FE, Cartwright RA, McKinney PA, Ricketts TJ. Investigation of spatial clustering of rare disease: childhood malignancies in North Humberside. *J Epidemiol Community Health* 1990; **44**: 39–46.
7. Heath C. Leukaemia among children in a suburban community. *Am J Med* 1963; **34**: 796–812.
8. Cartwright RA, Alexander FE, McKinney PA, Ricketts TJ, Hayhoe FGJ, Clayton DGC. Leukaemia and lymphoma: an atlas of distibution within areas of England and Wales 1984–1988. London: Leukaemia Research Fund, 1990.
9. Alexander FE, McKinney PA, Cartwright RA. Radon and leukaemia. *Lancet* 1990; **335**: 1336.
10. Alexander FE, Cartwright RA, McKinney PA, Ricketts TJ. Leukaemia incidence, social class and estuaries: an ecological analysis. *J Public Health Med* 1990; **12**: 109–17.
11. Craig J. An urban-rural categorisation for wards and local authorities. London: HM Stationery Office, 1982.
12. Wrixon AD, Green BMR, Lomes PR, et al. NRPB-R-190. Natural radiation exposure in UK dwellings. London: HM Stationery Office, 1988.
13. Breslow NE, Day NE. Indirect standardisation and the multiplicative model for rates with reference to age adjustment of cancer incidence and relative frequency data. *J Chron Dis* 1975; **28**: 289–303.
14. Payne RW, Lane PW, Ainsley AE, et al. Genstat V: References manual. Oxford: Clarendon Press, 1987.
15. Linet MS. The leukaemias: epidemiological aspects. Monographs in epidemiology and biostatistics. New York: Oxford University Press, 1985.
16. Lagakos SW, Wessen BJ, Zelen M. An analysis of contaminated well water and health effects in Woburn, Massachussetts. *J Am Stat Assoc* 1986; **81**: 583–96.
17. Darby SC, Doll R. Fallout radiation doses near Dounreay and childhood leukaemia. *Br Med J* 1987; **294**: 603–07.
18. Wheldon TE. The assessment of risk of radiation induced childhood leukaemia in the vicinity of nuclear installations. *J R Stat Soc; Ser A* 1989; **152**: 327–39.
19. Greaves MF. Is spontaneous mutation the major 'cause' of childhood acute lymphoblastic leukaemia? *Br J Haematol* 1986; **64**: 1–13.
20. Greaves MF. Speculations on the cause of childhood acute lymphoblastic leukaemia. *Leukaemia* 1988; **2**: 120–25.
21. Gerrard M, Eden OB, Stiller LA. Variations in incidence of childhood leukaemia in South East Scotland (1970–1984). *Leuk Res* 1986; **10**: 561–64.
22. Cook-Mozaffari PJ, Darby SC, Doll R, et al. Geographical variation in mortality from leukaemia and other cancers in England and Wales in relation to proximity to nuclear installations, 1969–1978. *Br J Cancer* 1989; **59**: 476–85.
23. Davis S. Case aggregation in young adult Hodgkin's disease. Etiologic evidence from a population experience. *Cancer* 1986; **57**: 1602–12.
24. Yorke JA, Nathanson N, Piarigiani G, Martin J. Seasonality and the requirements for perpetuation and eradication of viruses in population. *Am J Epidemiol* 1979; **109**: 103–09.
25. Gardner MJ, Snee MP, Hall AJ, et al. Results of case-control study of leukaemia and lymphoma among young people near Sellafield nuclear plant in West Cumbria. *Br Med J* 1990; **300**: 423–29.
26. Doll R. The epidemiology of childhood leukaemia. *J R Stat Soc* 1989; **152**: 1–11.
27. Neglia JP, Robinson RL. The aetiology of childhood leukaemia. *Pediatr Clin N Am* 1988; **35**: 675–92.
28. Blair A, McDuffie HH, Dosman JA. Cancer in rural areas. *Can Med Assoc J* 1987; **136**: 924–25.
29. Donham KJ, Berg JW, Sawin RS. Epidemiological relationships of the bovine population and human leukaemia in Iowa. *Am J Epidemiol* 1980; **112**: 80–92.
30. Janicki K, Dubrowolski J, Krasnicki K. Correlation between contamination of the rural environment with mercury and occurrence of leukaemia in men and cattle. *Chemosphere* 1987; **16**: 253–57.
31. Shu XO, Linet MS, Gao RN, et al. Chloramphenicol use and childhood leukaemia in Shanghai. *Lancet* 1987; ii: 934–37.
32. Knox G. Epidemiology of childhood leukaemia in Northumberland and Durham. *Br J Prevent Soc Med* 1964; **18**: 14–24.
33. Wheldon TE. Germ cell injury and childhood leukaemia clusters. *Lancet* 1989; i: 792.
34. Pinkel D, Nefzger D. Some epidemiological features of childhood leukaemia in the Buffalo, NY area. *Cancer* 1959; **12**: 351–57.

Inaccuracy of the Hawksley random zero sphygmomanometer

EOIN O'BRIEN FAINSIA MEE NEIL ATKINS KEVIN O'MALLEY

To examine the accuracy of the Hawksley random zero sphygmomanometer two studies were done with subjects with a wide range of blood pressure. When readings made by one observer on the UK model of the Hawksley sphygmomanometer were compared with readings by two independent observers on separate mercury sphygmomanometers, the Hawksley device underestimated systolic readings by a mean (SD) of 2·0 (2·4) and 0·5 (3·6) mm Hg and diastolic readings by a mean of 3·7 (2·7) and 2·8 (2·9) mm Hg. When readings made on the UK and US models of the Hawksley sphygmomanometer were compared with those made on mercury sphygmomanometers, with observers exchanging devices half way during the experiment, the UK Hawksley device underestimated systolic pressure by a mean of 3·8 (SD 3·5) mm Hg and diastolic blood pressure by 7·5 (3·8) mm Hg; and the US model by 2·6 (3·4) mm Hg for systolic pressure and 6·2 (3·7) mm Hg for diastolic pressure. There was better agreement between two observers using standard sphygmomanometers than between an observer using the Hawksley random zero sphygmomanometer and an observer using a standard sphygmomanometer. Thus the quantitative aspects of blood pressure in epidemiological and intervention studies in which the Hawksley random zero sphygmomanometer was used need re-evaluation. Moreover, the Hawksley random zero sphygmomanometer, in its present design, should not be used in hypertension research.

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Introduction

Observer bias and digit preference are well recognised as sources of error in blood pressure measurement.[1] In 1963 Garrow described a "zero-muddler for unprejudiced sphygmomanometry",[2] which was later modified[3] and produced commercially. Known as the Hawksley random

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TABLE I—COMPARISON OF HAWKSLEY RANDOM ZERO SPHYGMOMANOMETER (HRZS) WITH STANDARD SPHYGMOMANOMETER—AAMI STANDARD IN 85 SUBJECTS

Observer	Device	Mean (SD) BP (mm Hg)	Mean (SD) difference
Systolic BP			
1	Standard	154·5 (26·8)	
2	HRZS	152·5 (26·8)	−2·0 (2·4)
3	Standard	153·0 (27·5)	−0·5 (3·6)
Diastolic BP			
1	Standard	89·3 (12·1)	
2	HRZS	85·6 (12·5)	−3·7 (2·7)
3	Standard	88·4 (12·7)	−2·8 (2·9)

zero sphygmomanometer (Hawksley and Sons, Lancing, UK), this device is generally accepted as the instrument of choice for clinical and epidemiological research in hypertension. However, its accuracy has been questioned.[4,11]

Two models are on the market—the model in use in Britain and most of the rest of Europe, which has a zero that drifts between 0 and 60 mm Hg (part number 77075), and the model in use in North America, which has a zero that drifts between 0 and 20 mm Hg (part number 77076). When we assessed the UK model according to the American Association for the Advancement of Medical Instrumentation (AAMI) protocol[12] we found an inaccuracy that carries serious implications for hypertension research. To confirm that finding we assessed three UK and one US model according to the stipulations of the protocol of the British Hypertension Society (BHS).[13] Here we report on both assessments.

Methods

Evaluation of the UK model by the AAMI protocol

Observer training and assessment. 3 nurses were trained to measure blood pressure by use of the Korotkov auscultatory technique according to the guidelines of the BHS protocol[13] until at least 85% of each pair of systolic and diastolic readings made by a nurse were within ±5 mm Hg of simultaneous readings by the other 2 nurses.

Device validation. The 3 nurses measured blood pressure simultaneously. 1 used the Hawksley random zero sphygmomanometer and the remaining two read the blood pressure from the same PyMaH sphygmomanometer (the standard) (PyMaH Corporation, New Jersey, USA). The test device was connected with a T-tube connector to the standard device and to an inflatable bulb in 85 subjects, who ranged in age from 15 to 80 years. Their diastolic blood pressure ranged from 60 to 117 mm Hg and their systolic pressure from 104 to 225 mm Hg. The cuff of the device was placed on the subject's arm with the stethoscope head located over the brachial artery. The three observers recorded pressure independently and simultaneously with a triple-headed Littman stethoscope. For each patient blood pressure reading for three cuff inflations were taken and the average calculated.

Evaluation of the UK and US models by the BHS protocol

The three UK devices and one US device were supplied by Hawksley & Sons Ltd and were filled with mercury and calibrated by a representative of the company in the blood pressure measurement laboratory before the study began.

3 nurses were trained with an educational video film[14] until they satisfied the requirements of the BHS protocol.[13]

Interdevice variability assessment. The assessment done was modified from that recommended in the BHS protocol.[10] Interdevice variability was assessed before and after use for the UK model but not for the US model, on the assumption that if significant interdevice variability was absent for one model it was unlikely to be present for the others. 2 observers assessed three devices in 6 subjects with a representative range of blood pressure; the 2 observers were blinded from each other and measured blood pressure simultaneously, with the test device and a mercury sphygmomanometer connected to each other by a Y connector. For

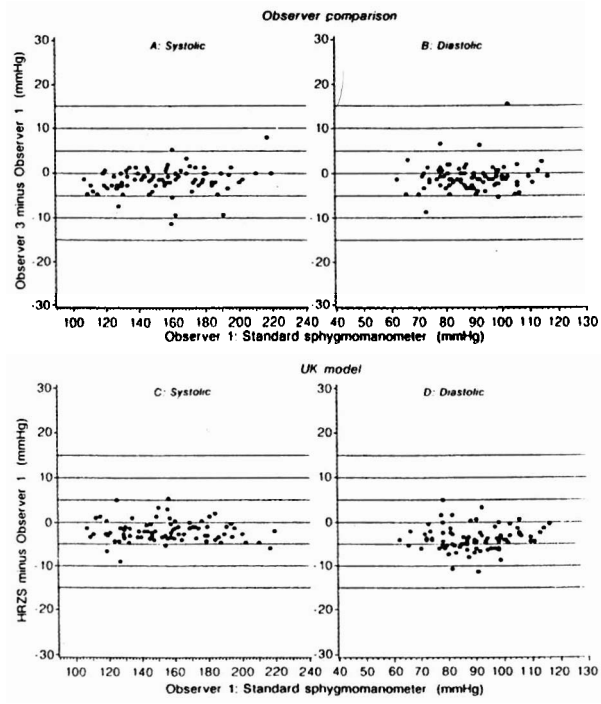

Fig 1—Differences between observers in blood pressure readings for standard sphygmomanometers (A and B), and when standard sphygmomanometer is compared with the Hawksley random zero sphygmomanometer (C and D). (AAMI Study.)

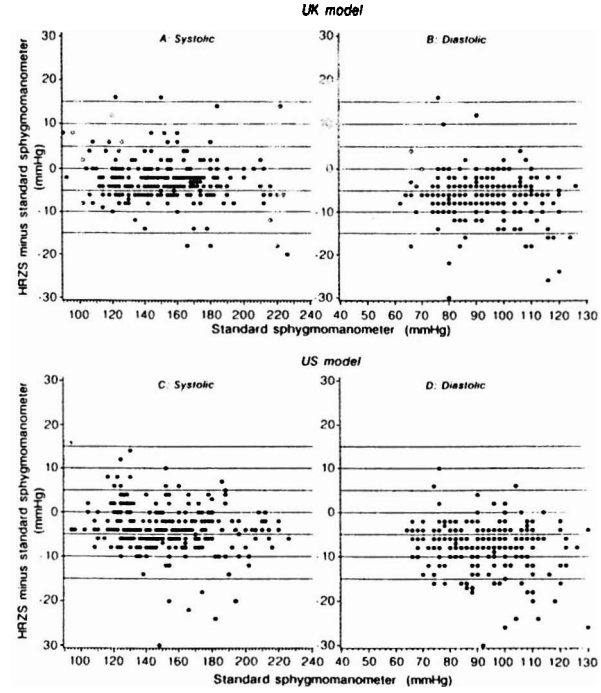

Fig 2—Differences between readings made on Hawksley random zero sphygmomanometer and those on standard sphygmomanometer. (A and B, UK model; C and D, US model.) (BHS Study.)

TABLE II—HAWKSLEY RANDOM ZERO SPHYGMOMANOMETER VALIDATION RESULTS

	UK model				US model			
	Systolic		Diastolic		Systolic		Diastolic	
	Sarndard	HRZS	Standard	HRZS	Standard	HRZS	Standard	HRZS
Mean (SD) BP (mm Hg)	152·9 (28·1)	149·1 (22·7)	92·0 (13·7)	84·4 (14·0)	152·6 (28·2)	149·4 (27·7)	92·5 (13·8)	86·3 (14·0)
Mean (SD) differences*	..	−3·8 (3·5)	..	−7·5 (3·8)	..	−2·6 (3·4)	..	−6·2 (3·7)
% of 258 readings differing by (mm Hg):								
<5	..	58·1	..	27·1	..	68·6	..	36·4
10	..	95·0	..	82·2	..	94·2	..	87·6
15	..	97·7	..	91·5	..	97·7	..	94·2
BHS gradet		C		D		B		D

*Differences from standard mercury sphygmomanometer.
†Grade A when cumulative % readings differing by < 5, < 10, and < 15 mm Hg are 80, 90, 95, respectively; B when 65, 85, 95; C when 45, 75, 90, and D when worse than C.[14]

the before-use assessment two blood pressure measurements were made with each device in each of the subjects in a randomised sequence, to give twelve pairs of measurements per device and thirty-six overall. The UK devices were next subjected to clinical use for a month, during which each model was used at least 50 times. After a month of clinic use the three devices were retested for interdevice variability as before, to determine whether interdevice agreement had changed with clinic use.

Device validation. Since interdevice variability did not change after a month of use, one device was selected at random from the three UK devices for the main validation test, to which the US device was also subjected. 86 subjects aged 15–80 years were selected to provide blood pressures in the range recommended by the BHS protocol.[13] Same-arm blood pressure was measured simultaneously with test device and a standard mercury sphygmomanometer by connecting them together with a Y connector. Observer 1, who read the mercury sphygmomanometer, was completely blinded from observer 2, who read the Hawksley instrument. The observers exchanged places after the first 43 subjects. For each subject there were three pairs of blood pressure readings, giving 258 pairs of readings.

Results

Evaluation of the UK model by the AAMI protocol

Device validation. The mean difference between the two standard measures was 1·5 (SD 2·8) for systolic blood pressure and 0·9 (3·0) mm Hg for diastolic blood pressure. Compared with the standards the Hawksley random zero sphygmomanometer underestimated systolic pressure by 2·0 (SD 2·4) and 0·5 (SD 3·6) mm Hg and diastolic pressure by 3·7 (2·7) and 2·8 (2·9) mm Hg (table I). For diastolic blood pressure, agreement between standard measures was better than between the standard and Hawksley random zero sphygmomanometer (fig 1).

Evaluation of the UK and US models by the BHS protocol

Interdevice variability assessment. There was no significant interdevice variability in the assessment before or after use.

Device validation. On average diastolic blood pressure was underestimated by 7·5 (3·8) mm Hg with the UK device and by 6·2 (3·7) mm Hg with the US device, and the resulting grade was D (table II). The corresponding values for systolic blood pressure were: UK model 3·8 (3·5), grade C; and US model 2·6 (3·4) mm Hg, grades C and B (fig 2).

Discussion

In 1964, Rose and his colleagues classified observer error into three categories: systematic error, terminal digit preference, and observer prejudice.[15]

Two devices have been designed specifically to overcome these sources of error in research. Their limitations must be balanced against those that occur when the standard technique is used by carefully trained observers. The first such device to be introduced, the London School of Hygiene sphygmomanometer,[15] was surprisingly accepted as the gold standard for blood pressure measurement without having been subjected to validation. The calibration error identified in 1982[16] has, as far as we know, not been rectified, and that sphygmomanometer is not now much used.

The Hawksley random-zero sphygmomanometer is larger than a conventional sphygmomanometer and some ten times more expensive. The manometer function is similar to the mercury sphygmomanometer, but a wheel is spun before each measurement to adjust the zero to an unknown level, and the resevoir for mercury differs from that in the conventional sphygmomanometer. Once the blood pressure has been measured the level of zero may be determined and the pressure reading corrected. This device is generally accepted as the instrument of choice for epidemiological and clinical studies because in hypertension it reduces observer bias and obscures digit preference,[15] though the opportunity for reducing terminal digit preference that it offers has been questioned.[17–19] Because the random-zero sphygmomanometer is basically a mercury sphygmomanometer, its accuracy has been accepted uncritically and it has replaced the London School of Hygiene sphygmomanometer as the gold standard against which other devices are assessed;[20,21] it has also been used extensively in clinical and epidemiological studies.[22–26] Hunyor and his colleagues found the random-zero device to be reasonably accurate[27] but recent studies suggest that it systematically gives lower readings than the standard mercury sphygmomanometer.[4–11]

The differences in magnitude of error between the random sphygmomanometer and standard mercury measurements in our two studies and other studies merit comment. The mean differences and standard deviations for systolic pressure between the first (AANI) and second (BHS) studies are reasonably constant for systolic blood pressure and compare with other studies.[4–7] However, in the AAMI study differences in diastolic pressure and standard deviations between the Hawskley and the standard sphygmomanometer were similar to other studies,[4–7] but in the second (BHS) study the differences were larger (mean difference 3·2 *vs* 7·5 for the UK model and 6·2 mm Hg for the US model). To further confirm the inaccuracy of the Hawksley sphygmomanometer we did a supplementary experiment. Two observers were isolated from each other in

booths, one with a mercury sphygmomanometer and the other with a Hawksley sphygmomanometer. The sphygmomanometers were joined by a T-tube to each other and then to a mercury sphygmomanometer, complete with inflating bulb and cuff, which was in a third booth, where the controller of the experiment measured blood pressure five times on each of 10 patients with a representative range of blood pressure. When systolic and diastolic blood pressure were auscultated the controller gave auditory cues to the Hawksley and mercury observers, who wrote down the mercury levels of their respective sphygmomanometers. The following results were obtained:

	Hawksley	*Mercury*	*Difference*
Systolic BP	122·6 (SD 12·9)	127·7 (13·4)	−5·1 (3·5)
Diastolic BP	77·5 (10·6)	81·4 (10·6)	−3·9 (3·0)

These findings have practical implications for the use of the Hawksley random zero sphygmomanometer in research. With mean differences of diastolic pressure ranging from 1·8 mm Hg[6] to 7·5 mm Hg reported here, clearly quite large errors will result in studies using the Hawksley sphygmomanometer. This device has been used in many epidemiology and intervention studies over the past two decades. Clearly the blood pressure data in such studies need reassessment. In epidemiology, where small differences in pressure may be considered important, it seems wise not to use this device. There are also implications for intervention studies, since levels of blood pressure for inclusion or exclusion will be underestimated.

We believe that, for the present, the closest we are to an acceptable gold standard for blood pressure measurement is that taken by an accurate observer with a standard mercury sphygmomanometer and stethoscope, and that the accuracy demanded for research work justifies a stringent programme of training for observers. For clinical practice, though, such effort would not be practical.

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REFERENCES

1. O'Brien I, O'Malley K. The ABC of blood pressure measurement: the observer. *Br Med J* 1979; ii: 775–76.
2. Garrow JS. Zero-muddler for unprejudiced sphygmomanometry. *Lancet* 1963; iv: 1205.
3. Wright BM, Dore CF. A random-zero sphygmomanometer. *Lancet* 1970; i: 337–38.
4. Evans JG, Prior IAM. Experience with the random-zero sphygmomanometer. *Br J Prev Soc Med* 1970; **24**: 10–15.
5. Labarthe DR, Hawkins CM, Remington RD. Evaluation of performance of selected devices for measuring blood pressure. *Am J Cardiol* 1973; **32**: 546–53.
6. De Gaudemaris R, Folsom AR, Prineas RJ, Luepker RV. The random-zero versus the standard mercury sphygmomanometer: a systematic blood pressure difference. *Am J Epidemiol* 1985; **121**: 282–90.
7. Parker D, Liu K, Dyer AR, Giumetti D, Liao Y, Stammler J. A comparison of the random-zero and standard sphygmomanometers. *Hypertension* 1988; **11**: 269–72.
8. Kronmal RA, Rutan GH, Borhani NO, Manolio TA, Furberg CD. Potential problems with the random zero sphygmomanometer. *Lancet* 1990; i: 360.
9. Poole PH, Parr GD. Potential problems with the random zero sphygmomanometer. *Lancet* 1990; ii: 254.
10. Hense HW. Potential problems with the random zero sphygmomanometer. *Lancet* 1990; ii: 254–55.
11. Kronmal RA, Rutan GH, Borhani NO, Manolio TA, Furberg CD. Potential problems with the random zero sphygmomanometer. *Lancet* 1990; ii: 255.
12. American National Standard for Electronic or Automated sphygmomanometers. Association for the Advancement of Medical Instrumentation. USA. 1987.
13. Jamieson M, Petrie J, O'Brien E, Padfield PL, Littler WA, de Swiet M. Blood pressure measurement: British Hypertension Society. London: British Medical Journal Publications, 1989.
14. O'Brien E, Petrie J, Littler WA, et al. British Hypertension Society protocol: evaluation of automated and semi-automated blood pressure measuring devices with special reference to ambulatory systems. *J Hypertens* 1990; **8**: 607–19.
15. Rose GA, Holland WW, Crowley EA. A sphygmomanometer for epidemiologists. *Lancet* 1964; i: 296–300.
16. Fitzgerald D, O'Malley K, O'Brien ET. Inaccuracy of London School of Hygiene sphygmomanometer. *Br Med J* 1982; **284**: 18–20.
17. Silman AJ. Failure of random zero sphygmomanometer in general practice. *Br Med J* 1985; **290**: 1781–82.
18. Hayler CR. "Failure" of the random-zero sphygmomanometer in general practice. *Br Med J* 1985; **291**: 137.
19. Hosie GAC, Hosie J. "Failure" of the random zero sphygmomanometer in general practice. *Br Med J* 1985; **291**: 137–38.
20. Sloan JM, Zezulka A, Davies P, Sangal A, Beevers M, Beevers DG. Standardized methods for comparison of sphygmomanometers. *J Hypertens* 1984; **2**: 547–51.
21. Steiner R, Luscher T, Boerlin H-J, Siegenthaler W, Vetter W. Clinical evaluation of semiautomatic blood pressure devices for self-recording. *J Hypertens* 1985; **3** (Suppl1): 23–25.
22. Prineas RJ, Gillum RF, Horibe H, Hannan PJ. The Minneapolis children's blood pressure study part 1: standards of measurement for children's blood pressure. *Hypertension* 1980; **2** (suppl): 118–24.
23. Report of the Medical Research Council Working party on mild to moderate hypertension. Randomised controlled trial of treatment for mild hypertension: design and pilot trial. *Br Med J* 1977; i: 1437–40.
24. Hypertension Detection and Follow-up Program cooperative group. Five year findings of the Hypertension Detection and Follow-up Program. 1. Reduction in mortality in persons with high blood pressure, including mild hypertension. *JAMA* 1979; **242**: 2562–71.
25. Management Committee. The Australian therapeutic trial in mild hypertension. *Lancet* 1980; i: 1261–67.
26. Wilhelmsen L, Berglund G, Elmfeldt D, et al. Beta-blockers versus diuretics in hypertensive men: main results from the HAPPY Trial. *J Hypertens* 1987; **5**: 561–72.
27. Hunyor SN, Flynn JM, Cochineas C. Comparison of performance of various sphygmomanometers with intra-arterial blood pressure readings. *Br Med J* 1978; ii: 159–62.

From The Lancet

Heraldry and medicine

Probably the first medical man in this country to receive a grant of arms was John Leche, surgeon to Edward III, in whose blazon appeared an arm erect proper grasping a leech or snake environed round the arm vert. Corporate medicine did not fall under the cognizance of the heralds until the year 1451, when arms were granted to the Guild of Surgeons, followed about a century later by a grant to the Royal College of Physicians of London. The surgical arms show three fleams argent, a fleam being the instrument used for cupping and bleeding purposes. The medical arms appropriately contain a hand proper feeling the pulse of an arm proper issuing from the sinister side of the shield, with a pomegranate to represent therapy. The Physicians of Ireland have a similar coat-of-arms without the fruit. In all the arms we have mentioned so far the field is sable, possibly allusive to the fact that a doctor is frequently brought into contact with the phenomena of death. The traditional bearings most frequently met with are two in number—namely, the staff of Aesculapius and the wand of Mercury. The former is a wooden staff, whose roughness is supposed to be typical of the doctor's life, entwined by the serpent who imbued the physician with wisdom. The staff of Aesculapius has been borne by many medical men, including Lord Lister, and appears in the arms of St George's Hospital and the badge of the Royal Army Medical Corps. The caduceus, or wand of Mercury, is a rod of white metal, probably quicksilver, entwined by two serpents. It appears for the first time in English medical heraldry in the crest of Sir William Butts, physician to Henry VIII, and since in that of many other medical celebrities, not, however, being confined to medicine, as it occurs in the borough arms of Rotherham.

(Nov 20, 1915)