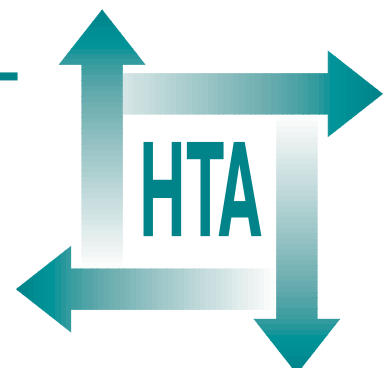


Detection, adherence and control of hypertension for the prevention of stroke: a systematic review

S Ebrahim



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Detection, adherence and control of hypertension for the prevention of stroke: a systematic review

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This report is one of a series covering acute care, diagnostics and imaging, methodology, pharmaceuticals, population screening, and primary and community care. It was identified as a priority by the Population Screening Panel and funded as project number 93/05/02.

The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for the recommendations for policy contained herein. In particular, policy options in the area of screening will, in England, be considered by the National Screening Committee. This Committee, chaired by the Chief Medical Officer, will take into account the views expressed here, further available evidence and other relevant considerations.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

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List of abbreviations

CI	confidence interval*
CINDI	Countrywide Integrated Non-communicable Diseases Programme
DBP	diastolic blood pressure
OHP	occupational health nurse
QALY	quality-adjusted life-year
RCT	randomised controlled trial*
SBP	systolic blood pressure
SE	standard error*

* Used only in tables and figures



Executive summary

Objectives

The objectives were to find out the most effective methods of:

- detecting hypertension
- improving patient adherence with treatment
- improving control of blood pressure
- improving professional compliance with standards of good practice.

Methods

The evidence was reviewed using systematic review methods of material published between 1966 and July 1996. The quality was assessed using a comprehensive assessment schedule. All articles abstracted were assessed by two readers independently. In studies where blood pressures were used as outcomes, net blood pressure changes were calculated.

Results

Detection

Population screening when compared with usual care or case finding does not appear to increase coverage of the population assessed for hypertension or detection of people with hypertension. Screening programmes in shopping centres or housing blocks do not reach the disadvantaged groups often intended. Case finding appears to be particularly effective when linked with professional training, protocols and reminders to record blood pressure given to both patients and doctors. Labelling of hypertensive patients does not appear to have any long-term effects on sickness absence or psychological well-being provided patients are managed by high-quality, comprehensive services. Ambulatory monitoring does not have any role in the detection of hypertension in the population.

Patient adherence

No single approach to improving adherence can be recommended based on the evidence reviewed. Complex interventions involving education, easier access to care, and use of protocols may improve adherence and control in some patients.

Educational interventions are unlikely to be effective on their own. While simpler drug regimens are likely to improve adherence, simple reminder packaging does not improve adherence or control.

Blood pressure control

A comprehensive 'stepped-care' approach (i.e. education, free care, specialist clinics, and protocols) achieves the greatest improvements in control. Self-monitoring of blood pressure at home appears to have a small but significant effect on blood pressure control and may be cost-saving. Patient education alone is unlikely to improve blood pressure control. Professional education may make a small contribution to blood pressure control, but is probably due to increased use of drug therapy.

Professional standards of care

The issuing and use of guidelines does not result in improvements in care. Locally, rather than expert, produced guidelines that are integrated into clinical practice improve both practice and clinical outcomes. The evidence to support nurse-led clinics is surprisingly sparse, and the only British trial found worse control in the nurse-led clinic.

Conclusions

Implications for health care

Policy and practice on high blood pressure might best be considered in conjunction with a review of all cardiovascular disease prevention advice to health authorities and general practitioners, as focusing on individual risk factors in isolation is unlikely to produce coherent proposals.

Detection

Standardisation of methods of blood pressure measurement is essential. Use of Korotkov V (disappearance of sounds) should be widely promoted in primary health care. Facilities for the routine maintenance of sphygmomanometers should be available in all health districts.

The British Hypertension Society guidelines on thresholds for starting treatment require review following publication of the New Zealand guidelines and the wider recognition of the importance

of absolute disease risk in formulating preventive health care policy.

Evidence to support detection and treatment of high blood pressure in older people is very strong. This evidence should be widely disseminated, and professional barriers to treating older people recognised as unacceptable and not consistent with best practice.

Ambulatory monitoring methods increase the cost and complexity of blood pressure detection without providing any tangible benefits, and should not be promoted in primary health care.

Blood pressure is only one of a number of powerful risk factors which predict the chances of suffering a stroke or ischaemic heart disease. Greater emphasis should be placed on examining risk factor scores (or profiles).

Adherence

Improving professional adherence to best practice in the management of high blood pressure through a range of mechanisms is required. More direct methods such as financial incentives and penalties require investigation as they may prove more effective than educational or clinical guideline approaches.

Evidence is lacking to support any specific approaches to improving patient adherence with antihypertensive drugs or lifestyle changes. Standardisation of methods of measuring and reporting on patient adherence is required. Further research on patient adherence should be linked with the associated question of improving blood pressure control.

Control

The British Hypertension Society's recommended target blood pressures which should be achieved on drug treatment need to be reviewed. Criteria should take into account co-morbidity, age and level of hypertension.

A stepped-care approach to management is supported by American randomised controlled trial evidence, but this is not directly applicable to British practice.

Evidence to support nurse-led compared with doctor-led care as a better option in achieving blood pressure control is very sparse.

Research recommendations

Little attention has been given to hypertension detection, adherence and control among the poor and ethnic minorities. Trials of specific interventions tailored to their special needs might be conducted.

Recommended research areas (in order of relative priority) are:

- A multicentre primary care randomised controlled trial comparing nurse-led management with general practitioner-led management in hypertension, including economic evaluation. Important outcomes include hypertension detection rates, professional adherence to best practice, patient adherence to treatment, and blood pressure control achieved.
- Large-scale randomised controlled trials including economic appraisal, of interventions that aim to improve patient adherence to treatments. Possible interventions that should be compared in factorial designs with usual care include educational/motivational approaches, follow-up, feedback, simplification of medication regimens. Outcomes should also include blood pressure control achieved.
- Randomised controlled trials to test the value of risk factor scores (or profiles) in giving general practitioners and nurses the information they need to reduce cardiovascular disease risk. Comparisons might include computer-aided prompts, and visual and interactive methods involving patients. Outcomes might also include actions taken and their effectiveness in reducing risk factors.
- Controlled comparisons of the effects of organisational and managerial initiatives on improving professional adherence to best practice in the management of high blood pressure compared with professional education and clinical guidelines.

Chapter I

Benefits to the NHS

- **Meeting Health of the Nation targets.** Achievement of Health of the Nation targets in stroke is a general health service priority. The contribution that might be made by improvements in the application of current knowledge of the efficacy to detecting and treating high blood pressure is of great importance in determining the amount and type of resources used.
- **Improving primary prevention.** Strategies such as health promotion clinics and routine recording of risk factors (banding) have been applied in general practice as a means of improving primary prevention of cardiovascular disease. It is clear that a systematic review of the evidence supporting different approaches to the detection and management of hypertension is required to achieve a more evidence-based approach to prevention.
- **Reduced costs of secondary care.** Since stroke is one of the most expensive diseases treated in secondary care, even a small proportionate reduction in incidence would yield substantial absolute cost savings. As continued pressure will be placed on hospitals to achieve greater efficiency, stroke prevention is a means of reducing disease burdens.
- **Application of evidence.** Rigorous randomised controlled trials and observational epidemiological studies conducted over the last four decades have provided a considerable body of evidence to support the effectiveness of blood pressure lowering to reduce risks of cardiovascular disease. The quality and strength of this evidence is as good and probably better than in any other area of non-communicable diseases prevention. Consequently, the major tasks are the ability of the health service and academic community to learn how to apply evidence to achieve health gain. Lessons learned in this area will have application in other diseases.

Chapter 2

Background

The pharmacological treatment of high blood pressure reduces the risk of stroke, and this has been confirmed in a large number of randomised controlled trials^{1,2} (*Figure 1*). The application of this knowledge in primary health care is prone to problems:

- inaccurate detection of the people most likely to benefit
- limited coverage of target populations
- poor adherence to treatment by patients
- poor adherence to established management guidelines by professionals.

These problems severely limit the efficacy reported from randomised controlled trials and may be sufficiently large to lead to complete loss of any potential health gains. For example, antihypertensive drug treatment reduces stroke risk by 42% as indicated in *Figure 1*. If only half the hypertensive population are detected, and only half are on treatment, and only half are well controlled, it is possible

that this efficacy of 42% will be reduced as follows:

$$\begin{aligned}
 &42\% \times 50\% \text{ detection} \\
 &\quad \times 50\% \text{ treated} \\
 &\quad \times 50\% \text{ controlled} = 5\% \text{ community} \\
 &\quad \quad \quad \quad \quad \quad \quad \quad \text{effectiveness}
 \end{aligned}$$

This drop in health gain is of major importance, and improving detection, treatment and control deserve to be major aims of primary care services.

Enthusiasm for blood pressure screening is limited by the small absolute benefits of treatment shown by the Medical Research Council Mild Hypertension Trial,³ the mistaken perception that side-effects of treatments used in the major trials were considerable^{4,5} and the small number of strokes occurring in a typical general practice. This has led to a 'received wisdom' that the risks outweigh the benefits of screening.

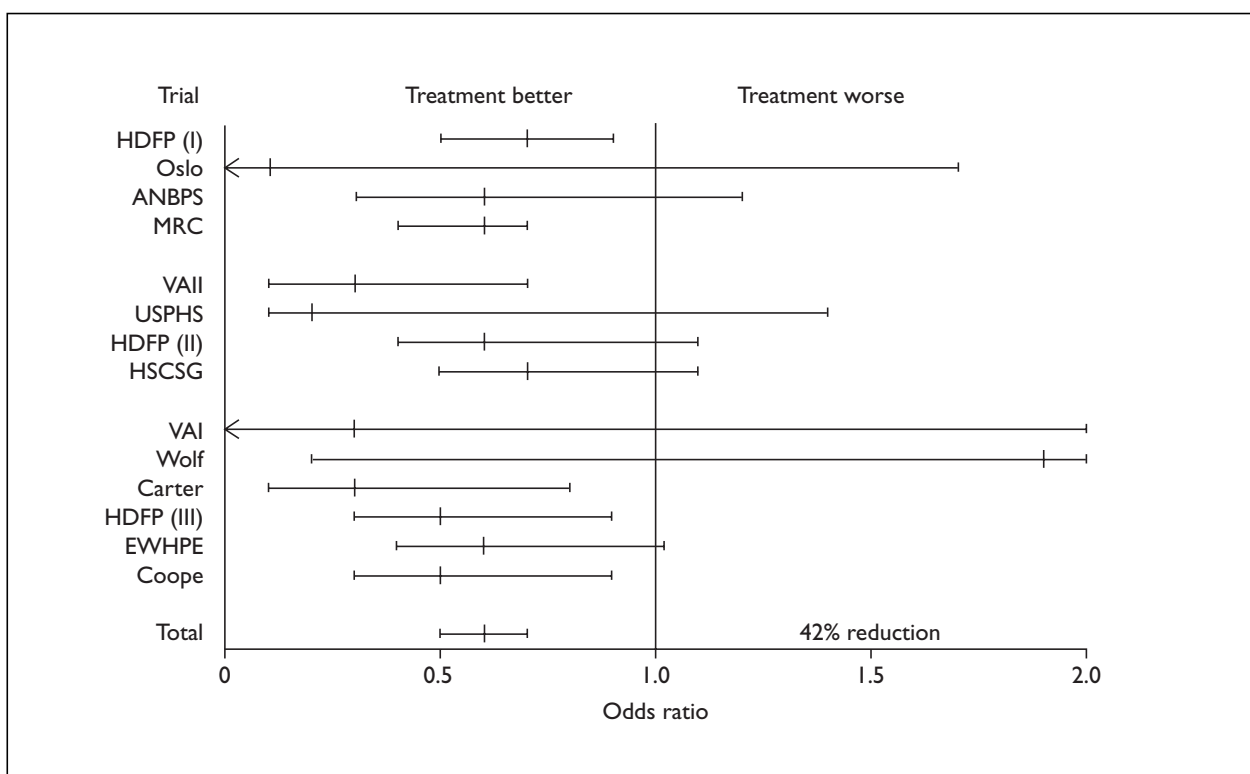


FIGURE 1 The effect of antihypertensive drugs on stroke events¹

Furthermore, economic appraisals of the cost-effectiveness of detection and treatment of high blood pressure have provided wide-ranging estimates (from £900 to £100,000 per quality-

adjusted life-year (QALY)), depending on the age, sex, level of blood pressure, co-morbidity, drugs used and discounting assumptions made.^{6,7}

Chapter 3

Evaluation

Assessing the effectiveness of community screening programmes is often complex because of the many steps involved in identifying early pre-symptomatic disease, maintaining treatment and reducing adverse outcomes. Ideally, evidence from randomised controlled trials that compare disease outcomes in those receiving a screening service would be compared with those receiving usual care. Such evidence is not often available, and alternative approaches have to be used. It is possible to break the steps down into smaller components and examine evidence that interventions to improve each step are effective. In blood pressure screening, the relevant steps are identification of hypertensive people, control of raised blood pressure, and reduction in risk of stroke.⁸

Figure 2 shows several alternative pathways from asymptomatic individuals to stroke prevention that may be studied to evaluate hypertension management. Pathway 1, the most direct route from asymptomatic people to stroke prevention is not often studied because such studies require considerable resources and time. One of the major trials, the Hypertension Detection & Follow-up Program,⁹ does cover pathway 1 by dealing with the detection, control and outcomes in a single trial comparing 'stepped' care with usual care. The 10,940 participants were all hypertensive patients (diastolic blood pressure (DBP) 90+ mmHg) detected through population screening in 14 sites in the USA of

159,000 people aged between 30 and 69 years of age. Approximately half were black and were relatively poor. The intervention was 'stepped care', which was a systematic protocol for control of blood pressure and modification of other cardiovascular disease risk factors, smoking, diet and weight reduction through caloric restriction and increased activity. Stepped care was received free of charge, and free transportation to clinics was provided. Control group participants were referred to their own physician. The Hypertension Detection & Follow-up Program 'stepped-care' group achieved a 4.9% net reduction in DBP. The stepped-care group experienced a 16.9% reduction in total mortality and reductions in cardiovascular disease, stroke and coronary heart disease mortality compared with the referred care group at 5 years of follow-up,¹⁰ and this persisted over longer follow-up.¹¹

Smaller steps indicated in *Figure 2* may give partial, but important, answers to the best approach to detect hypertensive individuals (pathway 2), the best means of improving control (pathway 3), and the likely clinical benefits (pathways 4 and 5). If each of the pathways is studied separately, it may be feasible to put together information from each step and build up a composite picture of the optimal services to be applied in clinical practice. Such an approach makes an important assumption that each of the steps is independent of each other.

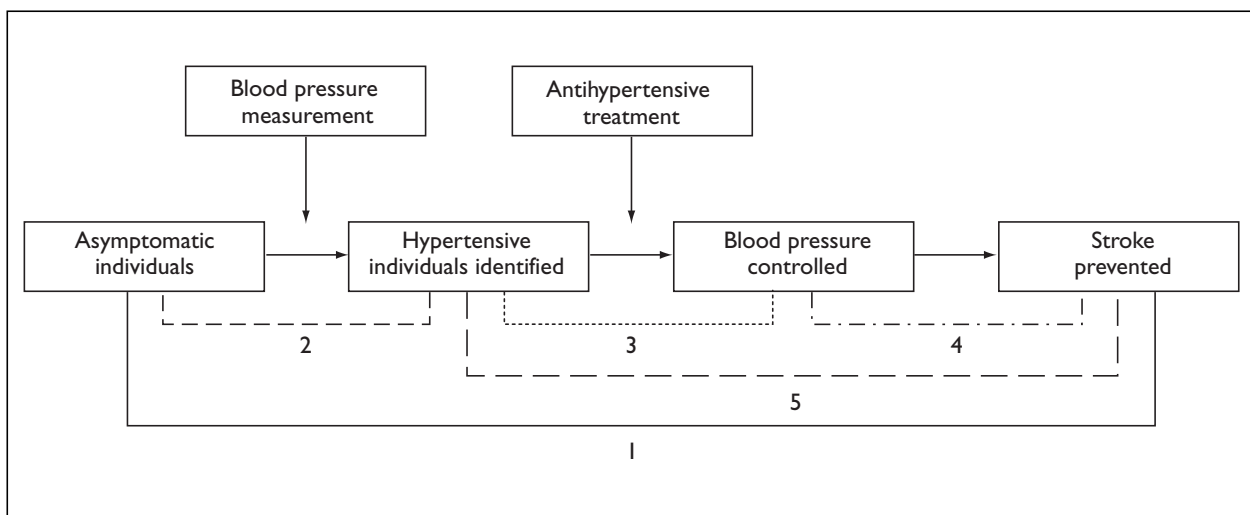


FIGURE 2 Causal pathways for blood pressure screening. (Redrawn from Woolff et al.⁸)

The Hypertension Detection & Follow-up Program was unique to the USA and the 1970s. While it is often considered to be a trial of the effects of drug treatment,^{1,2} as should be clear from the description above, it compared a free, comprehensive and organised system of care with an alternative, less well-organised system. The applicability of this evidence to current practice in a state-funded health care system is likely to be rather limited. Since there is no British equivalent of the Hypertension Detection & Follow-up Program, it is necessary to examine the efficacy of interventions targeted at the component steps in the prevention pathway.

Questions

In carrying out this review a set of questions were posed which form the structure for the following sections of the report:

- Which method of detection of hypertensive people is most effective in a British context?
- Which methods of improving professional compliance with standards of good practice are most effective?
- Which methods of improving patient adherence with treatment are most effective?
- Which methods of improving control of blood pressure are most effective?

Chapter 4

Study methods

The major aim of the study was to find all the relevant randomised controlled trials concerned with the means of improving detection, control and compliance. Systematic literature searches were made using MEDLINE from 1966 to July 1996, with comprehensive searching of the reference lists in the articles found. A standard OVID filter for randomised controlled trials was used, followed by the search terms 'hypertension' and 'high blood pressure', and the secondary terms 'detection', 'compliance' and 'control'. A further, but more limited, search of the Cochrane Library was conducted using the terms 'hypertension' (all fields) and 'detection', 'compliance' and 'control' (title fields). This search found many more trials but did not result in any further trials relevant to the questions posed for this review (see appendix 1).

The quality of trials was assessed using a comprehensive assessment schedule (see appendix 2) and where appropriate, findings were compared among trials of differing quality. All articles abstracted were assessed by two readers independently, and any inconsistencies were resolved by discussion. References were archived using Reference Manager[®] software.

Inclusion criteria

The major aim was to collect randomised controlled trials that would permit

unbiased assessments of the effectiveness of different strategies of improving detection, blood pressure control and compliance. Consequently, random allocation was the primary requirement. No duration for study requirements was set.

Exclusion criteria

The scope of the work was not concerned with the primary evidence of the effectiveness of blood pressure lowering. Drug and non-pharmacological interventions aimed at blood pressure lowering have been reviewed recently,¹² and, where relevant, reference will be made to this work. Details of excluded trials are given in appendix 4.

Statistical methods

In studies where blood pressures were used as outcomes, net blood pressure changes were calculated (i.e. intervention group blood pressure change minus control group blood pressure change) and presented in the relevant tables. When pooling blood pressures, account was taken of trial sample size and variances of blood pressure measurements and a standardised normal deviate approach used as recommended by Fleiss.¹³

Chapter 5

Detection of hypertension

Definitions

Epidemiological studies of the relationship between risk of stroke and ischaemic heart disease and blood pressure show that there is no 'threshold' above which hypertension exists and below which a person can be considered to have 'normal' blood pressure (see chapter 7, *Figure 5*). In general, the higher the blood pressure, the higher the risk of cardiovascular disease.^{2,14,15}

However, in clinical management it is necessary to use specific thresholds to define high blood pressure requiring monitoring or treatment. Evidence to support thresholds may be derived from two major sources, expert committee opinions and trials of the efficacy of the treatment of blood pressure of different levels.

Table 1 shows the criteria that have been set by different expert committees identified in a recent review,¹⁶ and also includes the Swedish recommendations.¹⁵ The diastolic phase for all these recommendations is phase V (disappearance of Korotkov sounds), although many clinicians still favour use of phase IV (muffling of sounds^{17,18}). Use of phase IV or V also has a large effect on the

TABLE 1 Recommendations for thresholds for starting pharmacological treatment for high blood pressure

Place	Blood pressure threshold (mmHg)	Observation period (months)
Australia ²¹	160+/100+	1
Britain ²²	< 60 years: 160+/100+ > 60 years: /90+	3–6
Canada ^{23,24}	/100+	–
New Zealand ²⁵	170+/100+	6
Sweden ¹⁵	< 70 years: /100+* > 70 years: 180+/100+*	3–6
USA ^{24,26}	140+/90+	3–6
WHO–ISH ²⁷	140+/90+	3–6

* Swedish recommendations specify lower levels for people with other risk factors.

proportion of people classified as hypertensive, as phase IV DBPs tend to be about 5 mmHg higher than phase V pressures.^{19,20}

The implications of applying these different guidelines are profound in terms of the proportion of the population that would be deemed in need of treatment. For example, in the *Health Survey for England* large differences in the prevalence of hypertension would result, with values as high as 41% or as low as 5% for men, simply depending on the criteria used (*Table 2*).

The *Health Survey for England* measured blood pressure three times on a single occasion, discarding the initial measurement and using the average of the second and third readings. Consequently, the prevalence figures will be higher than those obtained in routine practice where measurements will be repeated over several weeks or months leading to greater likelihood of measurement habituation and regression to the mean.

While the different guidelines are apparently based on the same evidence derived from clinical trials demonstrating treatment benefits, it is surprising that such widely divergent views on the best thresholds have arisen. There are many practical problems (e.g. workload, costs, dangers of labelling and risks of drug treatments) with low thresholds which define so many of the population as hypertensive and potentially in need of treatment.

All the guidelines, with the exception of those from New Zealand, have used criteria based on relative effects of treatment, which assumes that treatment effects are always worthwhile even in low-risk populations. The New Zealand approach has defined those requiring treatment as having an absolute risk of cardiovascular disease above 2% per year.²⁵ Such an approach has the advantage of ensuring that treatment benefits are likely to outweigh any hazards and that the number needed to be treated will be reasonable.

Thresholds for treatment

The importance of absolute risk is increasingly recognised and emphasised by the findings of the

TABLE 2 Percentage distribution of different blood pressure thresholds by age and sex in those not taking drugs that might affect blood pressure

Blood pressure threshold (mmHg)	Age group (years)							Total
	16–24	25–34	35–44	45–54	55–64	65–74	75+	
Systolic blood pressure (SBP)								
Men								
140+	29	25	26	39	62	74	79	41
160+	1	2	2	8	21	35	50	12
170+	0	0	0	2	13	23	35	7
Women								
140+	7	8	16	34	59	72	88	32
160+	0	1	3	7	22	40	60	13
170+	0	1	0	5	12	30	50	9
Diastolic blood pressure (DBP)								
Men								
90+	2	4	12	23	30	32	27	15
95+	1	0	5	12	19	21	24	9
100+	1	0	1	5	13	17	17	5
Women								
90+	1	3	8	11	20	20	39	9
95+	0	1	1	6	14	14	30	5
100+	0	1	0	4	8	9	20	3

Source: Health Survey for England, 1991.²⁸

Medical Research Council Mild Hypertension Trial, which showed that although the **relative** reduction in risk was substantial in people with mild hypertension – and similar to that found in more severe hypertension, the absolute reduction in risk was small, resulting in about 1000 people needing to be treated for 1 year to avoid one clinical event.³ Using the thresholds for treatment applied in clinical trials does not take account of the levels of absolute risk experienced by different people. For example, elderly people are at markedly greater absolute increased risk of stroke and ischaemic heart disease, as these diseases show an almost exponential increase in risk with increasing age.

A recent systematic review of the benefits of treatment in older people²⁹ has emphasised the importance of absolute levels of risk (*Table 3*). Despite this evidence of benefit, it seems unlikely that the promotion of guidelines using absolute risks³⁰ will overturn this trend of treating those younger people at lower risk in preference to older people, which is probably due to an innate prejudice against using potentially toxic drugs in elderly people.

Despite evidence of similar relative treatment efficacy and greater absolute treatment benefits in older people, it appears that British general practi-

TABLE 3 Number needed to treat for five years to avoid a death due to specific causes

	Younger people	Elderly people
Cardiovascular mortality	205	58
Cerebrovascular mortality	365	193
Coronary heart disease mortality	–	88

tioners are resolutely unwilling to incorporate these findings into their routine clinical practice. *Table 4* shows data from a national survey³¹ and two local surveys^{32,33} of British general practitioners who were asked for the pressure at which they would consider starting drug treatment for high blood pressure at different ages. This evidence suggests that general practitioners are reluctant to consider treatment at levels stated in national guidelines, particularly the lower levels for elderly people.

Similar data concerning thresholds in middle-aged men collected in Finland in the 1970s showed that only 33% of general practitioners would start treatment below a blood pressure of 100 mmHg and 41% would not treat until a threshold of

TABLE 4 Median blood pressure treatment thresholds and proportion of general practitioners treating hypertension in different patient age groups in three recent studies

Age (years)	Median (% treating)		
	National (1993)	Northamptonshire (1993)	Leicestershire (1991)
SBP			
< 60	160 (92)	—	—
60–69	160 (92)	—	—
65–69	—	166 (98)	175 (98)
70–79	170 (92)	170 (98)	180 (96)
80–89	180 (82)	180 (85)	190 (62)
DBP			
< 60	95 (98)	—	—
60–69	100 (98)	—	—
65–69	—	100 (98)	100 (98)
70–79	100 (97)	100 (98)	106 (96)
80–89	100 (86)	100 (72)	110 (62)
No. of participants	583	92	360

110 mmHg,³⁴ which suggests that thresholds for treatment have declined since the publication of the newer trials demonstrating effectiveness of treatment of mild hypertension.

The importance of age and other risk factors for cardiovascular disease, while recognised in the New Zealand recommendations and by the British guidelines which suggest a lower threshold (90 mmHg) for treatment in people aged 60+ years, are not considered in other national guidelines (see above) and, in particular, are not acted upon by clinicians.³⁵

Economic appraisal of detection thresholds

It has been claimed that guidelines based on evidence of efficacy are insufficient and that costs must also be considered.³⁰ In Sweden, a review of cost-effectiveness of using different thresholds for treatment of high blood pressure has been conducted, and demonstrated that **cost savings** result at a DBP threshold of 100 mmHg at ages above 45 years but that among people aged less than 45 years, thresholds from 90 to 105+ mmHg were associated with costs in the region of £28–180 per life-year gained.³⁶ This novel approach provides a means of defining thresholds logically and could be refined by including other risk factors which would identify higher-risk groups in whom treatment would have even greater cost-effectiveness and efficiency.

Rule of halves

The rule of halves summarises the detection, treatment and control of high blood pressure and suggests that half of all hypertensive patients are undetected, half of those detected are untreated, and half of those treated are uncontrolled (*Figure 3*).^{37,38}

The 1991 *Health Survey for England* provides data on the ratio of treated to untreated hypertensive patients (i.e. 160+/95+ mmHg). The untreated patients may represent undetected hypertensive patients, hypertensive patients treated with non-pharmacological interventions (e.g. weight reduction, salt restriction or alcohol reduction), or failures of adherence to treatment. Treated normotensive patients probably reflect those individuals with adequate control of their high

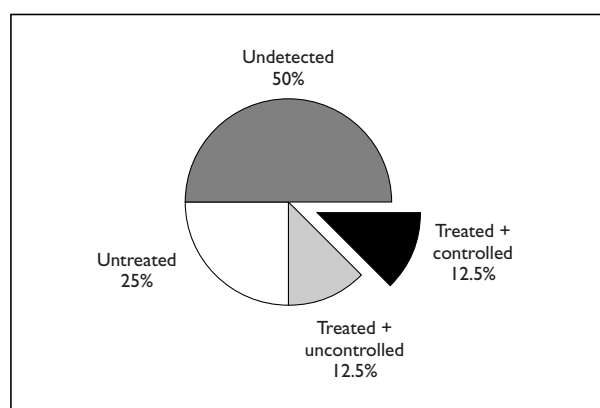


FIGURE 3 Hypertension detection and management: the rules of halves

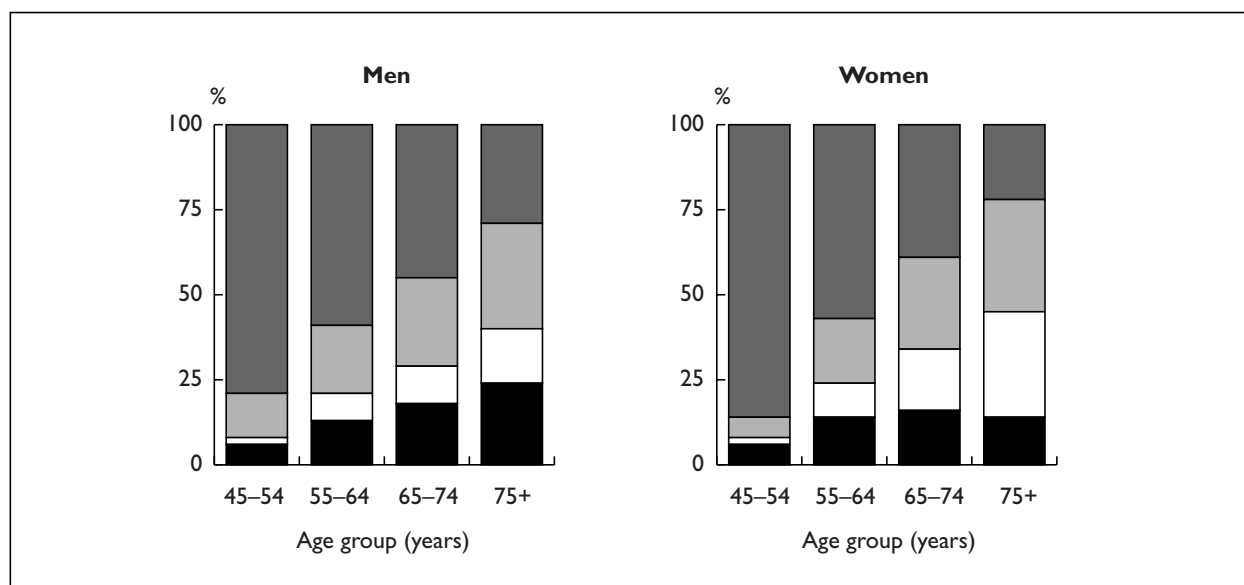


FIGURE 4 Blood pressure detection and treatment for men and women at different ages (Health Survey for England, 1991²⁸) (blood pressure (mmHg): ■, < 160/95 untreated; □, 160/95+ untreated; □, 160/95+ treated; ■, < 160/95 treated)

blood pressure. At every age, the proportion of untreated hypertensive patients compared with treated hypertensive patients (both controlled and uncontrolled) was slightly lower, suggesting persisting problems with detection and initiation of treatment (Figure 4).

Time trends in the *Health Survey for England* from 1991²⁸ to 1995³⁹ show that the proportion of untreated hypertensive patients has fallen and the treated normotensive patients (i.e. those who are controlled) has increased over this period, suggesting that detection and treatment of hypertension has improved. This is welcome, as the health gain associated with improvements in detection and treatment are likely to be greater than those associated with improving quality of care in those already identified and treated (see chapter 6, Table 8).

Causes of variation in blood pressure

Physiological experiments have shown the importance of several factors (Table 5) in blood pressure measurement, and it is routine practice to standardise conditions of measurement as much as possible to reduce these causes of variation.⁴⁰

It is usual to measure blood pressure several times to provide evidence of **sustained** hypertension and to avoid classifying as hypertensive those people who have a marked pressor response to measurement (i.e. ‘white coat’ hypertension – see the

TABLE 5 Causes of variation in blood pressure

Ambient temperature
Posture
Diurnal changes
Food intake
Cuff size
Level of noise
Acute anxiety

following section). However, evidence from epidemiological studies has consistently shown that casual single measurements (or repeated measurements) on one occasion have important prognostic significance. By contrast, randomised controlled trials of pharmacological treatments have followed clinical practice and made repeated measurements on several occasions.

One published study⁴¹ has examined the effects of estimating prevalence of hypertension using measurements made on a single occasion compared with up to three visits spread over three consecutive weeks among 2737 people aged 18+ years. At the first visit, 14.9% were defined as hypertensive (DBP 90+ mmHg), but at the second and third visits, 12.2 and 11.5%, respectively, were hypertensive, an over-diagnosis of 30% if estimates were based on only one visit. Over-diagnosis particularly affected the unknown and untreated categories of hypertension, suggesting that surveys (e.g. *Health Survey for England*) will tend to over-estimate the extent of problems of poor detection and treatment.

Ambulatory versus clinic measurement

It is well known that some people have a higher blood pressure in the clinic than when measurement is carried out at home – so-called ‘white coat’ hypertension.⁴² The explanation for this phenomenon is not clear, but there is growing evidence that such people may be at increased risk of pathological cardiac damage⁴³ and clinical events.⁴⁴ However, large-scale epidemiological studies of outcomes and clinical trials of the effects of treatment in people with ‘white coat’ hypertension have not yet been reported.⁴⁵

The ability to measure blood pressure non-invasively over 24 hours has led to a considerable amount of research activity, but the role of ambulatory monitoring in primary care is not clear.⁴⁶ Ambulatory blood pressures tend to be lower than clinic pressures, but without prognostic or treatment efficacy information it is not possible to provide clinical guidance about the implications or actions appropriate for particular levels or profiles of ambulatory monitoring.

The use of normative approaches (e.g. +2 standard deviations from an age–sex mean^{42,47}) is not very helpful as this will always define 2.5% of the population as ‘abnormal’ – a much smaller proportion than yielded by application of the recommended thresholds for treatment (see *Tables 1* and *2*). Information from conventional clinic measurement shows that considerably more people than this are at risk from raised blood pressure and require intervention.

Comparisons of clinic blood pressure diagnosis of hypertension with ambulatory blood pressure values shows that over a third of hypertensive patients have ambulatory values below the 95th percentile but the implications of this are not clear.⁴⁸

Ambulatory devices are increasingly used, but their value is unproven. Indeed, they appear to have no value in increasing the power of clinical trials,⁴⁹ nor do they predict left ventricular dysfunction any better than well-conducted clinic blood pressures.⁵⁰ At present, ambulatory monitoring does not provide a better means of detecting hypertension than conventional sphygmomanometry and repeat measurements over a period of time.

Alternative screening instruments

While the focus of this review is on the detection and treatment of raised blood pressure in stroke

prevention, alternative methods may be used to ‘screen for stroke’. An obvious approach is to examine stroke risk factors and their interactions to determine which groups of risk factors have the greatest accuracy in predicting stroke risk. Data from the British Regional Heart Study⁵¹ highlighted the combined role of smoking and blood pressure, which gave a relative stroke risk of 12-fold. A stroke risk score derived from the British Regional Heart Study data has been produced which identifies 82% of men who will suffer a stroke among those falling in the top fifth of the score distribution (SBP).⁵²

$$\begin{aligned} \text{risk score} = & 9 \times \text{age (years)} \\ & + 2.85 \times \text{SBP} \\ & + 70 \text{ if angina present} \\ & + 90 \text{ if smokes 1–20 cigarettes/day} \\ \text{or} & + 130 \text{ if smokes 21+ cigarettes/day} \end{aligned}$$

The stroke risk score performs better than use of detection of hypertension (i.e. SBP 160+ mmHg) alone, which identifies two-thirds of the strokes occurring in one fifth of the population, or the combination of smoking and hypertension, which yields 44% of the strokes among 9% of the population.

In primary care, it is unlikely that screening for high risk of stroke would be carried out independently of screening for high risk of myocardial infarction as both diseases share similar risk factors and methods of intervention. Further refinements of the British Regional Heart Study Score⁵³ using a combined myocardial infarction and stroke outcome has been derived from British Regional Heart Study data which have been modified so that scores correspond to absolute levels of risk, and thresholds for action can be defined by clinicians.

A major advantage of composite stroke risk scoring is that it focuses attention on the importance of other risk factors and highlights the need for specific management of smoking and angina. However, the scores do not include physical inactivity or heavy alcohol consumption, which are both powerful stroke risk factors and might merit intervention.^{51,54}

Improving methods of detection

The techniques that might be employed to increase detection include self-recording of blood pressure, opportunistic blood pressure detection in routine primary care clinic contacts, systematic screening programmes in the general population or in the

workplace, case finding in opticians shops and dental surgeries, or 'health fairs' held in shopping centres. A further interest is detection of high blood pressure in so-called 'hard to reach' groups such as ethnic minorities, the poor and homeless. Both experimental and observational study designs can be used to examine different methods of detection. Cross-sectional surveys can be used to examine the number of people with known and unknown high blood pressure and thereby give estimates of the efficacy of routine case-finding procedures. However, given variation in thresholds used to define 'hypertension', making comparisons between observational studies is difficult, and the proportion of known to unknown hypertensive patients is more likely to be determined by the thresholds adopted than by any particular method used.

Comparisons between hypertensive patients detected by routine clinical services and by more intensive screening programmes may be unreliable if the screened population is only assessed on one occasion, as this will tend to overestimate the number of hypertensive patients and will make routine services appear worse than they really are (see the rule of halves described earlier).

Evidence from randomised controlled trials comparing different approaches to detection is needed to choose between different policy options for improving detection. A systematic review of such trials has been carried out for this report.

Controlled comparisons

Randomised controlled trials of methods of detection are scarce, and where randomisation has been carried out, general practices or geographic areas were the unit of randomisation with the exception of the D'Souza trial, which was part of the influential South London Screening Study which examined the effects of multiphasic screening.⁵⁵

The quasi-experimental designs reported have either used a contemporary control group, which in most cases was not randomly allocated to control status, or a before-and-after comparison. The interventions tested have been mainly some form of intensive screening compared with either less intensive screening or routine health services (see *Table 6* and appendix 3).

The main outcomes considered were the coverage of the population achieved and the detection rates of new and known hypertensive patients. The latter will be dependent on the thresholds of blood

pressure used, and making comparisons between studies is difficult. In none of the studies were outcomes measured blind of group allocation.

The trials conducted in areas where coverage was likely to be inadequate, for example poor, black people in American housing blocks, were more likely to demonstrate increased coverage by more intensive methods of screening (e.g. door-to-door). The methodologically less rigorous studies using before-and-after designs were also more likely to demonstrate increased coverage with more intensive screening. The better trials and those conducted in populations with reasonable access to health care suggested that screening interventions did not greatly increase the coverage of the population.

Trials that examined the yield of unknown hypertensive patients obtained by screening compared with routine case finding showed that there were seldom any differences in the detection rates of hypertension. In these trials of different methods of improving detection, there is such heterogeneity of intervention and outcome (proportion detected) that formal meta-analysis would not be advisable and has not been carried out.

In Britain, a well-organised system of primary health care exists and access is not restricted by patient charges, levels of contact with primary care teams are high and opportunistic surveillance of hypertension is fairly common and encouraged. These circumstances appear to provide sufficient coverage of the population for the detection of the majority of people with mild to moderate levels of hypertension.

Uncontrolled studies of blood pressure detection

Information on the effects of detection programmes can be obtained from observational studies which lack a comparison group. However, the major assumption that must be made is that detection would be unlikely to vary in a systematic way in the absence of the programme. It is well-known that Hawthorne effects can be important as non-specific motivators of improved performance. Secular trends of declining hypertension prevalence over relatively short periods may underestimate the impact of screening programmes. Finally, external factors (e.g. contractual changes for health care) may have an impact independently of any detection programme.

Uncontrolled studies have provided interesting findings, some of which are reported here. No attempt has been made to be systematic in coverage

TABLE 6 RCTs and quasi-experimental trials of screening interventions in the detection of high blood pressure

Trial	Population and design	Intervention	Blood pressure threshold (mmHg)	Coverage	Detection rate
D'Souza (1976) ⁸¹	Primary care n = 7299, 40–64 years RCT	Nurse screening, two phases, versus usual care	105+	1st: 73% 2nd: 66%	New hypertensive patients: 1st: 50 (2%) 2nd: 9 (0.5%) No difference in prevalence of hypertension at the final screening
Stahl (1977) ⁸²	Population n = 2612, 16–70 years Contemporary control group	(A) Home blood pressure (B) Clinic (C) Clinic + gift (D) Home blood pressure appointment (E) Control	95+	(A) 17% (B) 1.7% (C) 2.3% (D) 20.7% (E) 0.7%	New hypertensive patients: Any home blood pressure: 11 (2.5%) Any clinic: 12 (2.7%) All hypertensive patients: Any home blood pressure: 28 (6.3%) Any clinic: 50 (11.2%)
Krishan (1979) ⁸³	Population, door to door n = 6902, 30–69 years Contemporary control group	Housewife screening and community hypertension clinic versus personal doctor	160+ 95+	–	New hypertensive patients, initial screening: Community clinic: 18.5% Control areas: 11.1% Rescreening compliance: Community clinic: 98% Personal doctor: 90%
Cooke (1983) ^{84,85}	Tenants n = 1237 RCT	Door-to-door volunteer screening versus central site screening	95+	Door to door: 43% Central site: 8%	Not reported by the intervention group. A total of 22 uncontrolled hypertensive patients were found
Nissinen (1983) ⁸⁶	Population n = 10,940, 25–59 years Contemporary control group	North Karelia multiple methods versus Koupio region	175+ or 100+ or treated	Both areas: 90%	All hypertensive patients: North Karelia: males 25.4%, females 29.3% Koupio: males 27.1%, females 25.3% New hypertensive patients: North Karelia: males 12%, females 8% Koupio: males 13.5%, females 7% Blood pressure decline over 5 years greater in North Karelia
Bass (1986) ⁸⁷	Primary care n = 32,124, 20–65 years RCT	Nurse-led case finding + protocol care versus usual care	90+	Nurse: 91% Usual: 80%	Not reported Mean blood pressure lower in experimental group
McDowell (1989) ⁸⁸	Primary care n = 5744, 18+ years RCT	(A) Computer doctor prompt (B) Letter reminders (C) Phone reminders (D) Usual care (E) Extra control	90+ and age cut-offs for SBP	(A) 30.7% (B) 35.7% (C) 24.1% (D) 21.1% (E) 18.6%	DBP 90+ mmHg: (A) 5.3% (B) 4.7% (C) 2.8% (D) 1.7% (E) 2.5%
Adorian (1990) ^{89,90}	Primary care n = 62,857, 18+ years Contemporary control group	(A) Audit, feedback, group discussion (B) Usual care	160+ 95+	–	Hypertensive patients detected and treated: (A) 9.2% (B) 5.0%
Holmen (1991) ⁹¹	Primary care n = 74,977, 20+ years Before–after comparison	Case finding versus screening	By age + sex	Screen: 88.1%	All hypertensive patients: Screen: 1413 (12.1%) Case finding: 10,248 (87.9%)
<i>RCT, randomised controlled trial.</i>					
<i>continued</i>					

TABLE 6 contd RCTs and quasi-experimental trials of screening interventions in the detection of high blood pressure

Trial	Population and design	Intervention	Blood pressure threshold (mmHg)	Coverage	Detection rate
McMenamin (1992) ⁹²	Primary care n = 754, 30–69 years Before–after comparison	Case finding versus screening (multiple preventive care interventions)	Not stated	Case-finding: 48% Screen: 85%	Not reported
Aubin (1994) ⁹³	Hospital care n = 817, adults all ages Contemporary control group	(A) Physician education, protocol and clinical aids versus (B) usual care	Not stated	Baseline: (A) 59.8% (B) 71.9% 1 year: (A) 78.7% (B) 59.1%	Not reported

RCT, randomised controlled trial.

as a very large literature of uncontrolled comparisons exists, and owing to the likelihood of biased assessment of effects, there is little point in including them all. The studies cited provide the only information on innovative methods that might be considered useful in improving detection but have not yet been evaluated in randomised controlled trials.

Hospital physician and 'day sheets' in primary care

Time trends in hypertension detection in a single practice have been reported and show marked increases in response to, first, a cluster of sudden deaths in young hypertensive patients and, secondly, the introduction of a hospital clinician together with the use of a 'blood pressure day sheet' for recording measurements.⁵⁶ Neither effect was sustained.

Public health screening 'fairs'

The use of health fairs in shopping malls or housing blocks has been promoted as a means of targeting 'difficult to reach' groups. An assessment of two programmes, one in a shopping mall and the other in a housing block conducted in 1975–1976 showed that contrary to expectations, both approaches failed to attract blacks, younger people and men. Of those screened, half were known hypertensive patients, and of those found to have a DBP of over 95+ mmHg, 94% were already known to have hypertension.⁵⁷

In New Brunswick, Canada, screening in shopping malls and work sites resulted in very low participation rates (11.6%), and further efforts to screen using a door-to-door campaign, while doing

somewhat better (47% participation), failed to achieve adequate coverage of the population.⁵⁸

Use of an automated device (Vita-Stat®) was evaluated in a range of settings (car parks, a railway station, a shopping centre and hospitals) over 6 weeks in south-east England in 1982.⁵⁹ Age-related thresholds were used and any hypertensive patients detected were referred to their own general practitioners. Of 6259 screened, 619 were already known to be hypertensive or were outside the age range, a further 106 were found to be known hypertensive patients and a total of 688 were referred to their general practitioners. Of these only 150 (2.4% of all screened individuals) were confirmed as new hypertensive patients.

In Copenhagen, Denmark, medical students measured the blood pressures of 24,377 people over five consecutive afternoons in supermarkets.⁶⁰ A total of 5653 (23%) individuals were referred to their general practitioners as their blood pressures exceeded age-defined systolic values or a DBP of 100+ mmHg. About 5% of all those screened had values thought to require treatment, and the screening procedure increased general practice visits for measurement of blood pressure by about 2–3 times that observed in a control week prior to the screening programme. However, the level of general practitioner measurement fell back to pre-screening values 6 months after the programme. The investigators felt that such programmes had value in educating the public and promoting general practitioners to measure patients' blood pressures but that the campaigns would have to be repeated regularly.

Tagging of general practice records

The use of simple tagging of patient medical records without measurements, when studied in an uncontrolled study in Wales among patients aged 20–64 years, was reported to result in almost complete recording (97%) whereas 3 years previously only 69% had had a blood pressure record in the previous four years.⁶¹ It is not possible to determine whether the tagging was responsible or whether greater awareness of a policy of routine blood pressure recording would have achieved similar results.

Primary care screening

Unlike the randomised controlled trials assessing screening compared with usual care or case finding, uncontrolled evaluations have tended to show positive results. In a Welsh mining community, Hart showed that a screening programme could be adopted in general practice and that without this up to half of all hypertensive individuals would not be routinely detected.⁶² In Renfrew, Scotland, comparisons were made between population screening of blood pressures and general practice records prior to the screen in 3001 men and women aged 45–64 years in 1972.⁶³ Of these, only 1045 (37.9%) had a blood pressure record, of which almost half (48%) were carried out for presenting symptoms (e.g. dizziness, nosebleeds or depression). The investigators concluded that, unlike the Canadian experience, screening detected people who had not been assessed previously by their general practitioners. Similar findings have been reported from a study conducted at the same time.⁶⁴

In contrast, a more recent study of screening found only very small yields, probably reflecting the increased emphasis on preventive health care in British general practice, and concluded that such screening was not necessary.⁶⁵

Work-site screening

The greater ease of access to occupational health screening resulted in a number of early uncontrolled assessments of its value, which showed very variable rates of coverage (from 35 to 69%) and even more variable rates of successful referral to a primary care physician (14–88%).⁶⁶ The investigators called for careful and rigorous controlled studies of the costs and benefits of work-site blood pressure control programmes, which are still lacking.

Potential adverse effects of detection

With any screening or case finding, it is possible that there will be adverse consequences related

to the psychological sequelae of either finding out about previously unrecognised disease (e.g. adoption of a sick role or labelling), or inability to accept a clean bill of health – the so-called ‘worried well’.

Labelling

Being diagnosed as suffering from hypertension, a life-long, potentially life-shortening condition might be expected to cause some adverse consequences, despite the proven benefits of detection and treatment of hypertension.⁶⁷ Attention was drawn to the effects of so-called ‘labelling’ in a widely quoted study which examined sickness absence from work among steel factory workers classified according to their awareness of hypertension before the introduction of a screening programme.⁶⁸ The findings are shown in *Table 7*.

TABLE 7 Work absenteeism in the year before and after labelling

	Days absent per year, mean (SE)		
	All participants, n = 208	Unaware participants, n = 138	Aware participants, n = 70
Year prior to screening	3.6 (0.6)	2.7 (0.6)	5.4 (1.4)
Year after screening	7.6 (1.2)	8.4 (1.6)	6.1 (1.9)
Increase	4.1 (1.2)	5.8 (1.5)	0.7 (2.1)
<i>Source: Haynes et al.⁶⁸</i>			

It is clear that following the workplace screening programme, sickness absence rose dramatically and far more than the 9% rise seen in the general unscreened workforce. Interestingly, the report uses one-tailed tests in the analysis, which tends to make more of the fairly small differences between the groups. Further subgroup analyses show that sickness absence was greatest in those treated men who were not compliant with their medication. Other indicators studied – total days absent or number of illness episodes – did not show these findings, but the number of days per episode of illness was longer in those who were previously unaware of their hypertension.

Findings from a US life insurance company confirmed the increase in sickness absence among those people who were unaware of their hypertension but also showed that this was a short-term effect which attenuated during a second year of

follow-up. In a normotensive control group they showed that sickness absence increased by 27% over 2 years compared with 16% in the hypertensive group. The study concluded that the adverse effects of labelling can be mitigated by a systematic and long-term intervention programme.⁶⁹ Attenuation of the labelling effect with time has also been shown in Finland,⁷⁰ but a longer follow-up of Canadian steel millworkers showed persisting increases in sickness absence.⁷¹

The Hypertension Detection & Follow-up Program compared sickness absence in those people who were unaware prior to screening of their hypertension and were managed either with stepped care (free, comprehensive care) or referred to usual care. Those people receiving stepped care did not suffer any increase in sickness absence whereas those receiving usual care did, suggesting that sickness absence is not an inevitable consequence of labelling.⁷²

Adjustment for potentially confounding factors such as age and co-morbidity which may be related both to hypertension and to sickness absence, has been carried out and shows that once these factors are taken into account the contribution of labelling to sickness absence is only small.⁷³

Psychological well-being and the 'worried well'

More-recent literature on the effects of blood pressure screening has focused on the psychological effects as measured by standardised questionnaires. In the Hypertension Detection & Follow-up Program, 10,070 people were asked about their health perceptions and worries at the baseline and again after 1 year.⁷⁴ In those people who were previously unaware of hypertension but remained untreated during the course of the year – labelled only – there was no change in their perceived health status. Among those people who were labelled and treated, perceived health declined. However, those allocated to stepped care (a free and comprehensive approach) had a significant improvement in their perceived health status and spent less time worrying about their health. By contrast, those allocated to usual care showed no changes in these variables. Similar psychological benefits of being involved in a clinical trial were reported from the British Medical Research Council Mild Hypertension Trial,⁷⁵ and a Swedish hypertension trial.⁷⁶

Some studies have examined the psychological health of 'false-positives', those people who are initially told they have hypertension, but subse-

quently turn out to have normal blood pressure. Equivocal findings have been reported, in part due to methodological problems of using self-reports of a diagnosis of hypertension and failure to use a concurrent comparison group of correctly labelled hypertensive patients.⁷⁷ In a large Norwegian study, comparisons of psychological health were made between previously unaware hypertensive patients, previously treated hypertensive patients, and a random sample of normotensive people.⁷⁸ Changes in psychological well-being were not related to labelling or blood pressure status but other life events or stresses were associated with a deterioration in well-being.

Is labelling a problem?

The growing consensus^{77,79,80} from these varied findings is that methodological issues play a major part in explaining differences between studies. Small sample sizes, cross-sectional and retrospective study designs, failure to control for confounding variables, reliance on unvalidated reports of awareness of diagnoses and use of unstandardised psychological instruments were among the problems noted in many of the studies. Overall, it is likely that there are short-term effects on sickness absence of labelling people as hypertensive, but that longer-term sequelae are mitigated, and indeed health status may improve, if people receive high-quality health care.

Conclusions

The controlled trial evidence of screening versus usual care or case finding does not provide support for screening either in terms of its ability to increase coverage of the population or in terms of the detection of hypertension. Specific screening programmes in shopping centres or housing blocks do not appear to reach disadvantaged groups. Case finding appears to be particularly effective when linked with training and protocols but the published studies may not be generalisable to more typical primary care services. Reminders to record blood pressure given to both patients and doctors may be helpful in improving coverage and detection of hypertension. Ambulatory monitoring does not have any role in the detection of hypertension in the population, and its clinical value remains to be established.

Labelling and associated sickness absence is not as great a problem as initially suspected. A short-term effect on sickness absence is likely, but this, and psychological ill-health, may be reversed by well-organised, high-quality health care.

Remarkably, few randomised controlled trials have been carried out on optimal methods of increasing population hypertension detection rates. Most of the work has been carried out in Britain and Canada which both have well-organised primary care services, and the findings may well be inapplicable to the USA and many European countries. Very little attention has been given to hypertension detection among the poor, ethnic minorities and homeless people.

Evaluation of cardiovascular disease risk-scoring systems in comparison with blood pressure measurement alone would be valuable. Specific issues of importance are factors that determine the use of scores (e.g. nurse-led versus doctor-led care; computer-aided prompts versus paper systems), and the development of protocols to guide intervention in those defined as high risk.

Chapter 6

Adherence with treatment for hypertension

The focus on most adherence research has been on the patient rather than on the doctor or nurse. However, the rule of halves³⁷ would suggest that greater health gain would be obtained by improving professional standards of detection of hypertension (see chapter 5) and the proportion of patients with hypertension receiving treatment. Indeed, the relationship between patient adherence with tablet taking and control of blood pressure is not linear (see *Table 12*), and efforts in this area may be of less value than might be expected. The health gain that might be achieved from the treatment of high blood pressure is a 30% reduction in cardiovascular disease incidence.¹ Improving professional and patient adherence should have an impact on the rule of halves. The potential health gain in terms of the proportion of treatment effect achieved by improving aspects of compliance assuming that the rule of halves applies in practice is shown in *Table 8*. It can be seen that focusing on the patient would not necessarily produce the greatest health gain but that improving professional standards of detection and treatment would achieve more.

TABLE 8 The potential health gain in terms of the proportion of treatment effect achieved by improving aspects of adherence assuming the rule of halves applies in practice

Strategy	Health gain (%)
Do nothing (i.e. accept rule of halves)	12.5
Improve professional standards of detection and treatment from 50 to 100%	50
Improve patient adherence from 50 to 100%	25

Professional standards of care

Definition

In the management of hypertension, it has often been assumed that doctors will do the right things when confronted with a patient with raised blood pressure. Professional adherence with adequate standards of care may therefore be defined as the activities required to ensure that a patient's blood pressure is controlled using a range of techniques which may include both drug treatment and non-pharmacological interventions.

Improved professional adherence and its impact on outcomes is best demonstrated by the findings of the Hypertension Detection & Follow-up Program.^{9,94,95} This large-scale trial found that stepped care, that is, care provided according to protocol guidelines, was far superior in terms of clinical outcomes to usual care for a wide range of patients.

Barriers to professional adherence

The reasons for poor professional adherence have not been studied systematically, but probably include the following: lack of knowledge; insufficient time; failure to remember; lack of incentives; and no feedback on performance.

In addition, the relatively small absolute benefits of treatment among younger patients with mild hypertension result in very large numbers needing to be treated to avoid clinical events. Given the costs and side-effects of treatment it is likely that some professionals consider the health gains too small to merit the costs involved. Interestingly, there is evidence to suggest that doctors are more likely to treat younger patients than older patients despite the more favourable numbers that need to be treated at older ages²⁹ (see page 9).

A wide range of interventions might be used to improve professional compliance (*Table 9*) but clinical guidelines have been subjected to randomised controlled trial interventions more often than other interventions.⁹⁶

Educational interventions, while capable of increasing knowledge,⁹⁷ are unlikely to have a major impact on clinical practice, but do tend to form the mainstay of interventions aimed

TABLE 9 Improving professional compliance

Continuing medical education
Re-accreditation
Financial incentives
Financial punishments
Legal pressures
Prescribing monitoring
Audit
Guidelines

at improving preventive health care. A single randomised controlled trial of the effects of continuing medical education on hypertension has been published, and demonstrated that mailed information did not have any impact on knowledge, clinical performance, or blood pressure levels.⁹⁸

Continuing medical education may have effects on both practice and disease outcomes, but the methods must involve the engagement of physicians in the learning process,⁹⁹ and more labour-intensive approaches, such as outreach visits, are more likely to result in professional behaviour change.^{100,101} However, it does not appear that any single approach can be prescribed with certainty,¹⁰² and multiple interventions, reinforced by mandatory continuing professional education, need to be tested for their effectiveness. Continuing medical education and clinical audit, while requirements, are not sufficiently focused to achieve specific improvements in preventive care.

Clinical guidelines

The use of clinical guidelines derived from scientific evidence has gained greater prominence in the 1990s through the advance of the evidence-based medicine movement. Consequently, much of the evidence on improving professional compliance is in this area, and has recently been summarised.⁹⁶ Five randomised controlled trials of the use of guidelines for hypertension have been published, and the findings are summarised in *Table 10*.

As can be seen from *Table 10*, none of the studies were conducted in Britain which limits the generalisability of their findings. Effects on either process or care were limited suggesting that further research in Britain should not simply repeat this work but build on those elements that appear to be important in improving care. It also important that British research does not focus solely on guidelines as the most important means of improving professional standards of care. Evaluation of many of the areas listed in *Table 9* is both feasible and needed.

Conclusions

Improving professional compliance with strategies aimed at improving the detection, treatment and monitoring of management of hypertensive patients is a major priority. The bulk of the research in this area is of low quality and of small scale, and many areas which might be effective are not researched.

The issuing and use of guidelines does not result in automatic improvements in care. It appears that locally, rather than expert, produced guidelines that are integrated into clinical practice (e.g. through computer prompts) are prerequisites for improving both practice and clinical outcomes.

Patient adherence to regimens

Definitions: adherence or compliance?

No single definition of adherence or compliance has been agreed between investigators or in clinical

TABLE 10 Guidelines in hypertension: RCTs

Setting	End-user involvement	Intervention to promote use of guidelines	Design	Effect on process	Effect on outcome
US ambulatory care	No	National guidelines modified locally: patient-specific feedback without consultation	RCT	+	0
Canadian general practice	No	Provincial guidelines sent by mail, computer-generated patient-specific feedback	RCT	0	++
Canadian general practice	Yes	Guidelines developed with end-users	RCT	-	0
US ambulatory care	Yes	Guidelines implemented by computer-generated reminders	RCT	-	0
US ambulatory care	No	Local guidelines implemented by computer-generated patient-specific reminders	RCT	++++	++

Source: Grimshaw et al.⁹⁶

practice. In general, arbitrary definitions, based on tablet counts (e.g. more than 80% of tablets taken), or on frequency of clinic attendance have been used (*Table 11*). The indicator used will have an impact on the level of adherence obtained from different interventions, thus comparability between trials is compromised.

TABLE 11 Indicators of adherence

Percentage of pills taken in time period
Percentage of patients taking 80%+ pills
Improvement in number of pills taken
Drop-outs from treatment and follow-up
Missed appointments
Change in blood pressure
Achievement of target blood pressure

Dictionary definitions of compliance suggest concepts of yielding, submission and consent, which are currently unattractive concepts in the management of hypertension where a partnership between doctor and patient is considered a more appropriate model. The term adherence has been promoted as a better alternative as its connotations of sticking to, or remaining firmly attached to treatment are less value loaded. However, little attention has been given to the effects of different models of the doctor-patient relationship and their effects on compliance and control of hypertension.

Validation

Validation of adherence measurement is difficult in this area as tablet counts may well be affected by patients' prior awareness of checks, and a desire to 'please' doctors may result in falsification of information based on tablet counts. 'Unobtrusive' counting has been carried out^{103,104} but it is hard to see that such practice is consistent with current views on improving the quality of management of chronic diseases in primary care.¹⁰⁵

Alternative means of validation could be conducted by comparing indicators based on reports or tablet counts of adherence with levels of blood pressure achieved. *Table 12* shows data obtained in such a comparison. The sensitivity and specificity of adherence measured in terms of tablet counts is low. Interestingly, validation of methods of measuring adherence in terms of outcomes (blood pressure levels) has not been widely used, perhaps because achieving adherence has become an end in itself with little concern about the relationship between adherence and achievement of blood pressure targets.

TABLE 12 Relationship between adherence and achievement of target blood pressures

Adherence	Target blood pressure (%)		
	Achieved	Not achieved	Total
High	23	34	57
Low	12	31	43
Total	35	65	100

Source: Sackett (1978).¹⁰⁶

It is possible to compare pill counts with detection of thiazides in urine or with biochemical changes in serum potassium and/or urate levels, or with changes in blood pressure; one such comparison showed that self-reports of adherence with tablet taking were more accurate than blood biochemistry or drug assays when compared with pill counts.¹⁰⁷

Difficulties in studying adherence

In addition to the problems of definition and criteria, interventions aimed at improving adherence may also result in improved detection of hypertensive patients, and, also, increased intensity of treatment. These factors may confound the relationship between improved adherence and achievement of target blood pressures. For example, improved detection may lead to inclusion of patients who are more unwilling to take medication and thus lead to lower levels of control. Alternatively, changes in treatment (e.g. using more effective drugs, or those with fewer side-effects) may result in better control, independently of any specific effect of improving adherence.

Barriers to adherence

Sackett highlighted specific reasons why hypertensive patients failed to take their medication¹⁰⁸ the duration of disease is life-long; the pills may have side-effects; the regimen is often complicated; hypertension is usually symptomless; and health beliefs may contravene pill taking. These together with other reasons should be considered, and are shown in *Table 13*. For each reason, it is possible to define a strategy to improve adherence. It would be sensible to attempt to define the cause of poor adherence for individual patients and then implement a specific strategy. No trials of such patient-centred approaches have been conducted.

Trials of improvement of patient adherence

Much of the literature is concerned with improving adherence with taking medication. However, one

TABLE 13 Barriers to patient adherence and potential strategies to overcome them

Barrier to adherence	Strategy
Lack of knowledge	Health education
Denial, health beliefs	Counselling, rewards
Risk perception	Education and counselling, self-monitoring
Complex regimens	Simplification, memory aids, tailoring to routines, better drug labelling
Poor memory	Memory aids, rewards, tailoring to routines
Inconvenient care provision	Work-site or home care
Side-effects of medication	Medical review of prescribing
Costs of medication and care	Free care
Long duration of disease	Health education, counselling, rewards

review¹⁰⁹ has focused on attendance at medical clinics, and reported that simple methods such as postal and telephone reminders can reduce default rates by two-fold, and more complex methods such as contracting with patients do not do any better.

A recently published systematic review has examined the randomised controlled trials that have studied means of assisting patients to follow prescribed medications. This review assumed that the context within which these interventions were used was independent of their efficacy, and consequently combined interventions used in treatment of hypertensive patients, schizophrenia, asthma, epilepsy and acute infections.¹¹⁰

It seems implausible that interventions will have similar efficacy under different clinical conditions. While some of the factors listed in *Table 13* may apply in other diseases, several of them are specific to hypertension and suggest that evidence on adherence from other disease areas should not be used to support clinical practice in management of hypertension.

The evidence

Improving adherence might be seen as only having relevance if it is associated with improved blood pressure control **and** disease outcomes. In practice, very few trials have been mounted that

are sufficiently large to examine the effects of adherence in this way. The majority identified by the review have examined adherence effects on both pill taking and on blood pressure control (see later). The very large trials (e.g. the Hypertension Detection & Follow-up Program, the Medical Research Council Mild Hypertension Trial and the Medical Research Council Elderly Trial) that have both control and disease outcome effects are of much less relevance for examining the effects of improving adherence as they have relatively little data on adherence (apart from drop-outs), and the selection bias involved in participating in a trial of improving blood pressure control and outcomes makes them less generalisable for practice and policy purposes. In the trials of different methods of improving patient adherence there is such heterogeneity of intervention and outcome (criteria for improved adherence) that formal meta-analysis would not be advisable and has not been carried out.

Trials with only adherence or only blood pressure outcomes

Four randomised controlled trials were found with only adherence outcomes and one with only blood pressure outcomes, and these are summarised in *Table 14* and appendix 3. The trials were of rather poor-quality, having many deficiencies. Interestingly, all reported benefits of intervention ranging from pill bottle aids to family support. This is in stark contrast to the review of high-quality studies of adherence aids, where no method stood out as particularly helpful in hypertension. It is tempting to assume that the positive findings are a reflection of biased ascertainment of outcomes due to lack of blinding, poor measurements of adherence, and selection bias due to drop-outs.

Trials with both adherence and control outcomes

Many randomised controlled trials aimed at improving pill taking and also examining effects on outcomes (i.e. blood pressure control) have been found than were included in the recent review by Haynes and colleagues.¹¹⁰ The findings are summarised in *Table 15* and appendix 3.

Conclusions

The trials examined showed a very wide range of quality with scores as low as 5 out of 34 and as high as 29 out of 34 possible points. There was no significant difference in the mean quality score of those trials detecting improved patient adherence compared with those that did not (mean (standard deviation) quality scores 15.9 (5.5) points versus

TABLE 14 Trials of interventions to improve adherence with only adherence outcomes

Trial and quality score	Intervention	Effect on adherence	Comments
Kirscht (1977) ¹¹¹ 13	4 × 4 factorial design: educational material, nurse phone calls, self-recording of blood pressure, social support sequentially applied for 4 months each. Approximately 100 in each group. Follow-up to 1 year	Yes	Only small changes in self-reported adherence scores for nurse phone call and social support groups. High probability of selection bias
Strogatz (1983) ¹¹² 11	Parallel group randomisation to usual care (n = 54), usual care + periodic home visits, usual care + periodic home visits (n = 54) + family measurement of blood pressure (n = 110) carried out for 2 years	Yes	Uncontrolled hypertensive patients, but no data on control group reported. Overall drop-out rate of 21%, but was much higher in the control group. High likelihood of bias
Eshelman (1976) ¹¹³ 5	Parallel group randomisation to medicine container (n = 50) or usual bottle (n = 50). Duration not stated	Yes	Consecutive patients prescribed once-daily chlorthalidone. Adherence assessed by urinary assay and by pill counts. Drop-outs at least 33%. Improvements in assays but not pill counts. Conclusion: probably unreliable
Sclar (1991) ¹¹⁴ 17	Parallel group randomisation of old and new atenolol patients to prescription refill pack including drugs and educational material (n = 163, 50) versus supply of drugs (n = 181, 59). Duration 180 days	Yes	Adherence assessed by medication received and not by pill counts or those actually taken. No drop-outs mentioned despite uneven numbers randomised. However, drugs received were far higher in both old (82 versus 48%) and new (93 versus 52%) patients than in controls
Binstock (1988) ¹¹⁵ 16	Parallel group randomisation of hypertensive patients to: group 1 (n = 32), education only – control; group 2 (n = 23), self-monitored blood pressure; group 3 (n = 15), behavioural contracting and rewards; group 4 (n = 30), calendar pill packs; group 5, all interventions. Intervention for 1 year	Yes	Adherence assessed by changes in blood pressure. Significant effects when groups 2–5 were pooled: –17/–11 mmHg versus –3/–1 mmHg for the control group. Outcomes were not assessed blind, and it is likely that large drop-outs occurred as the group sizes are uneven

18.7 (5.5) points in positive and negative trials, respectively; Mann–Whitney *U* test, $Z = -1.14$, $t = 0.26$).

The majority of studies were too small to have adequate statistical power to detect clinically important differences. For common problems, even small effect sizes may have an important impact at the population level. In future, suitable sample sizes should be recruited to examine specific interventions. In general, to detect moderate effect sizes (e.g. 15% improvement) in adherence would require 300 participants in both the intervention and control groups.

Several of the trials examined complex interventions, including the effects of clinical guidelines/protocols. Since the relative costs and effects of component parts of an intervention may be very different, factorial study designs that permit the disentangling of the major components of interventions are required.

No single approach to improving adherence can be recommended on the basis of the evidence reviewed. Complex interventions may improve

adherence and control in difficult patients. Work-site, nurse-led, protocol-guided care may have advantages over usual care in younger men. Unfortunately, the wide variation in the types of intervention used and the outcomes measured make statistical meta-analysis methods inappropriate.

Educational interventions are unlikely to be effective on their own. Changes in the location of care (e.g. work-site to home care) without use of guidelines to improve professional adherence are also unlikely to yield benefits. While simpler drug regimens are likely to improve adherence, simple reminder packaging does not improve adherence or control.

Given the importance of improving drug adherence (and other non-pharmacological interventions), the paucity of experimental randomised controlled trial data is remarkable. The majority of trials were conducted one to two decades ago with little work conducted in the UK.

Only two of the interventions were subjected to an economic appraisal, both of which demonstrated that any benefits were exceeded by the extra costs

TABLE 15 RCTs of different methods of improving patient adherence in hypertension

Trial and quality score	Intervention	Effect on adherence	Effect on control group	Comments
Sackett (1975) ¹¹⁶ 18	2 × 2 factorial design comparing doctor-led work-site care; 'mastery' learning; both work site and learning versus neither (n = 230)	No	No	Steel workers detected following screening. Knowledge was increased by learning
Haynes (1976) ¹⁰⁴ 24	Self-measurement of blood pressure and pill taking; 2-weekly review, tailoring and rewards (n = 20) versus usual care (n = 19)	Yes	No	Steel workers, who following 6/12 treatment were non-compliant and uncontrolled. Study lacked statistical power
Johnson (1978) ¹¹⁷ 22	Self-monitoring of blood pressure (n = 34), monthly home visits (n = 33), both (35) and neither (n = 34)	No	No	Adherence increased by 10% in self-recording groups, but the study lacked statistical power
Logan (1979) ¹¹⁸ 27	Nurse-led work-site care, self-monitoring of blood pressure + pill counts, target blood pressure set, protocol used (n = 232) versus usual care (n = 225)	Yes	Yes	Volunteers from businesses in Toronto detected by screening and with DBP 95+ mmHg or SBP 140+ mmHg
Logan (1983) ^{119,120} 29	Occupational health nurse monitoring care, specific help with adherence if needed (n = 97) versus usual care (n = 97)	No	No	Screen detected work-site participants. Cost-effectiveness analysis showed much higher occupational nurse costs for minimal benefit
Baird (1984) ¹²¹ 20	Once (n = 196) versus twice (n = 193) daily metoprolol	Yes	No	Only stringent adherence criterion showed a significant effect. Patients already well controlled
Becker (1986) ¹⁰³ 15	Reminder packaging (n = 86) versus usual packaging (n = 85)	No	No	Participants mostly middle-aged black women with poor control of blood pressure
Nessman (1980) ¹²² 18	Nurse and psychologist teaching self-determination (n = 26) versus nurse + protocol run clinic (n = 26). Weekly visits for 8 weeks for both groups	Yes	Yes	Patients attending a hospital outpatient department; all were non-compliant and uncontrolled. Complete follow-up. Greater effect may be due to patients opting for more potent drug therapy
Webb (1980) ¹²³ 15	Three sessions of education (n = 37), three sessions of counselling (n = 31) versus family physician (n = 55). Intervention for 3 months and follow-up for 3 months	No	No	Post-randomisation pre-intervention drop-outs of the original 150 patients led to unequal groups. Small advantages in blood pressure control not significant, and adherence was generally high
Takala (1979) ¹²⁴ 19	Improved primary care service: written instructions, blood pressure record card, invitations for checks (n = 100). Six visits over 1 year versus usual care (n = 102)	Yes	No	All newly diagnosed hypertensive patients found by community screening. Substantial drop-outs in both groups (10 versus 18%) used as the adherence criterion. Net changes in blood pressure not significant but the study gives percentage controlled and uses inappropriate denominator and claims significant benefits
Gonzalez-Fernandez (1990) ¹²⁵ 18	In-hospital education: knowledge of blood pressure, exercise, diet and adherence (n = 30) versus usual care (n = 29)	Yes	Yes	Individuals were all hypertensive patients on treatment but admitted for other conditions. Large improvements in blood pressure control may be because of lack of access to drugs following discharge in the control group. No data on pill counts reported, with reliance on self-reports of adherence

continued

TABLE 15 contd RCTs of different methods of improving patient adherence in hypertension

Trial and quality score	Intervention	Effect on adherence	Effect on control group	Comments
Kerr (1985) ¹²⁶ 21	Four groups: control (n = 29); education and self-monitoring of blood pressure (n = 26); self-monitoring of blood pressure (n = 30); education only (n = 31). Intervention for 1 day and 3 month follow-up	No	No	Work-site volunteers; all hypertensive patients on regular treatment. Very large drop-outs – 50% in all groups. Self-reports of adherence showed improvements in all intervention groups, and blood pressure control improved in all groups. Inconsistencies between denominators in tables and drop-outs appear to vary for adherence and blood pressure outcomes
Powers (1979) ¹²⁷ 11	Factorial design with 16 groups. Main interventions were: directiveness of nurse; self-responsibility + measurement of blood pressure; emphasis on negative consequences; number of meetings. Interventions over 2 weeks and 3 month follow-up	Yes	No	Participants were drawn from a wide range of health care facilities. Adherence assessed as goal attainment for medication and it appeared that self-responsibility + measurement and increased meetings improved adherence. All groups showed an improvement in blood pressure
Asplund (1984) ¹²⁸ 19	Crossover study of one combination (β blocker + thiazide) tablet (n = 80) versus two tablets (n = 80). 4 months on each treatment	No	No	Participants were all hospital outpatient department attenders, already taking β blockers and thiazide and well controlled. Adherence was assessed as 100% by self-reports and by tablet counts. blood pressure showed a large improvement in both groups during the first phase of the trial
Rehder (1986) ¹²⁹ 11	Randomised to four groups: control (n = 25); disease and medication counselling (n = 25); date/dose medication container (n = 25); counselling + medication container (n = 25). Intervention monthly for 3 months and outcomes assessed at 3 months	No	No	Participants were all hypertension clinic attenders who were taking at least two medications. Adherence was assessed by pill counts, attendance, and returns of drug containers. High levels of adherence were achieved by all groups (85%) and tended to be highest in those given a medication container. DBP was highest at the baseline in the group receiving both counselling and containers, and this group had a significant fall in blood pressure but this may be a regression to the mean effect. There may have been bias in group allocation to the nurse or pharmacist recording blood pressure. Conclusion: any special attention helps
Saunders (1991) ¹³⁰ 17	New and infrequent attenders randomised in strata to written reminders, patient-held records, home visits (n = 110) versus usual care (n = 104). All patients advised to attend every 4 weeks. Intervention for 6 months	Yes	Yes	Patients were outpatient department attenders in Soweto, South Africa. Adherence was defined as the receipt of medication and pill adherence 80%+. Substantial numbers were not assessed for pill counts. Drop-outs were lower in the intervention groups but much higher in new than infrequent attenders. DBP was significantly lower in the new patient intervention group
McKenney (1992) ¹³¹ 16	Comparison of an electronic medication aid cap fitted to the drug bottle (n = 36) versus usual drug bottle (n = 34) over 12 weeks	Yes	Yes	Patients were drawn from the retirement community and primary care (mean age 73 years). Adherence assessed pill counts of 80%+ and as doses consumed/doses prescribed. Adherence rates were high in both groups but significantly greater in the intervention group. Large net falls in blood pressure in the intervention group, but not measured blind of trial status. Supports use of the electronic bottle cap

continued

TABLE 15 contd RCTs of different methods of improving patient adherence in hypertension

Trial and quality score	Intervention	Effect on adherence	Effect on control group	Comments
McKenney (1992) ¹³¹ 10	Comparison of usual bottle (n = 17), electronic bottle cap (n = 18), electronic cap + patient-held blood pressure record (n = 18), electronic cap + record + self-measured blood pressure (n = 17) over 12 weeks	Yes	Yes	Patients were the same as in the previous trial who were re-randomised to the four groups, thus some had had previous exposure to at least part of the intervention. Adherence only presented as pills taken/pills received but very high adherence achieved with any intervention. Very large falls in intervention groups following the intensity of intervention. blood pressure in control group went up. No drop-outs, and outcomes were not assessed blind. Supports use of electronic bottle caps
Morisky (1985) ¹³² 12	Factorial design randomising to eight groups with combinations of exit interview, family support, and small groups. Four groups had family support (n = 200) and four did not (n = 200). Intervention for 3 years and follow-up for 5 years	Yes	Yes	Predominantly black hypertensive patients attending Johns Hopkins outpatient department. Outcomes were assessed at 5 years. Adherence was assessed by self-reports graded 0–4 (low–high) and by attendance. blood pressure control was assessed by achieving control in prespecified age-related categories. Family support resulted in lower self-reported adherence, but higher attendance and better blood pressure control than no family support. Drop-outs were similar in the two groups (27–28%)

associated with a more intensive work-site intervention. Since any intervention to improve adherence will have cost implications, it is essential that economic appraisal should form part

of any further research. Since adherence with medication must be maintained over several years, interventions should be tested over periods of at least 6 months.

Chapter 7

Improving control

Achieving control of blood pressure usually requires some sort of intervention. In some cases it may be feasible to control blood pressure with non-pharmacological approaches such as weight reduction or salt and alcohol restriction. In a majority of patients, antihypertensive drugs will be needed in addition to lifestyle modifications. The choice of drug will depend on several factors: evidence of efficacy in reducing clinical events, cost, side-effects, interactions with other medication, and dosing schedule. The issues of lifestyle modification have been covered in a recent review and are summarised here. Questions of choice of drug are beyond the scope of the current review.

Blood pressure control

The concept of control assumes that a target blood pressure has been specified when starting treatment for high blood pressure, and that patients achieving this target blood pressure are considered to be controlled. The relationship between blood pressure and risk of stroke follows a linear, positive and graded response (*Figure 5*) which suggests that the lower the blood pressure the lower the risk of disease. Therefore, a threshold

for determining 'control' is as arbitrary as a threshold for defining hypertension (see chapter 5).

The J-shaped curve

A decade ago, it was suggested that it might be dangerous to lower blood pressure too much, particularly in people with coexisting coronary artery disease and stroke. Observations among 902 patients treated with atenolol (a β blocker), of whom 91 died during 10 years of follow-up, showed a J-shaped relationship between mortality and on-treatment blood pressure, with the lowest mortality rate at a DBP of 85–90 mmHg.¹³³ These observations were confirmed in several studies^{134–137} and led to caution over how far to lower DBP.

Recently, more data have shown that the J-shaped curve may be the result of selection bias in the studies included,¹³⁸ that the relationship is not found in stroke^{137,139} and that use of antihypertensives may not be a causal factor in increasing mortality but that the lower blood pressures may simply reflect more severe disease.¹⁴⁰ An analysis of the Multiple Risk Factor Intervention Trial cohort of 5362 men with coronary heart

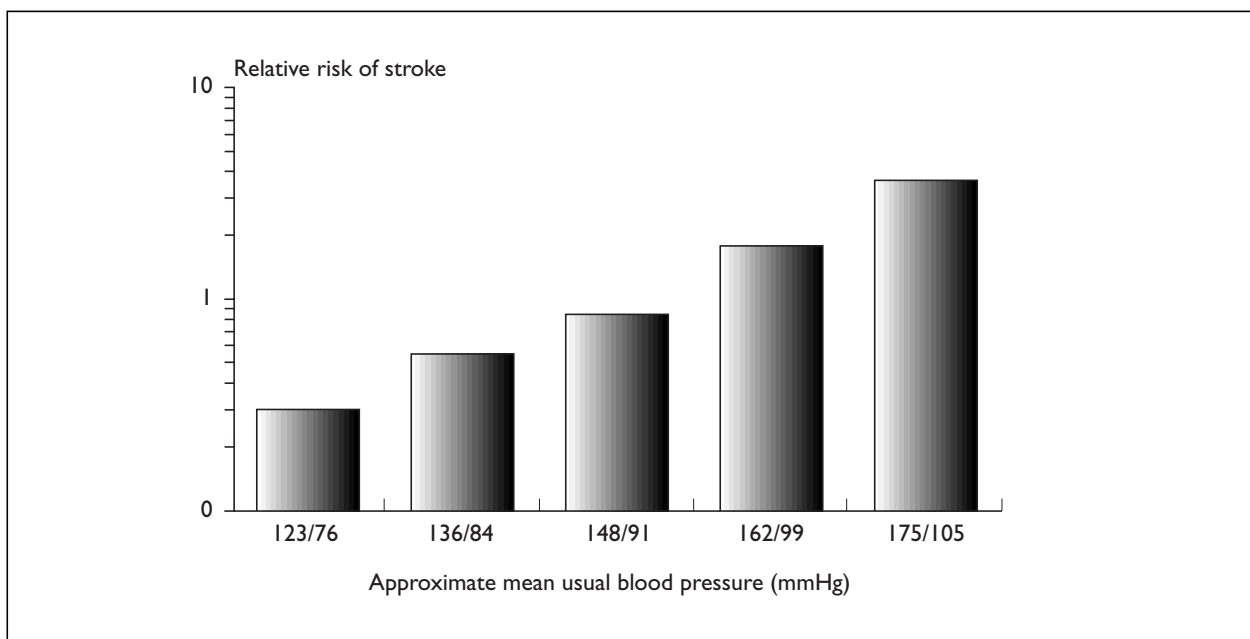


FIGURE 5 Stroke risk and usual blood pressure in seven prospective cohort studies. (Data from Collins and MacMahon²)

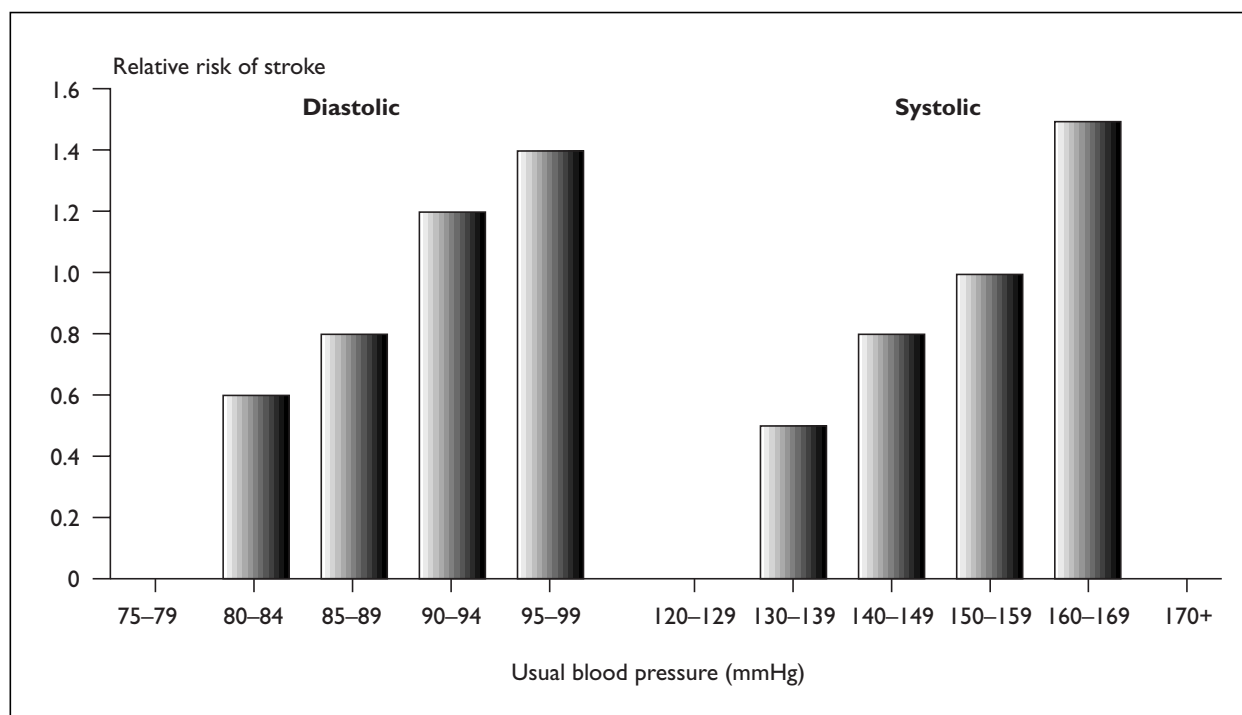


FIGURE 6 Stroke risk at different levels of blood pressure in people following a transient ischaemic attack or stroke. (Data from Rogers et al.¹⁴⁴)

disease showed that a J-shaped relationship was only found during the first 2 years follow-up among older men. After 2 years, relationships between coronary heart disease mortality and total mortality showed positive and graded relationships.¹⁴¹ Among older people drawn from the general population, similar confounding by ill-health appears to explain J-shaped relationships.^{142,143}

Among stroke survivors involved in the UK-TIA aspirin trial, no evidence of a J-shaped relationship between blood pressure and stroke risk was found,¹⁴⁴ as shown in *Figure 6*. These new findings suggest that there is no threshold below which lowering blood pressure may be harmful even in the presence of cardiovascular disease. However, randomised controlled trials of the effects of anti-hypertensive treatment after stroke will provide more data to confirm this hypothesis.¹⁴⁵

Guidelines for control

The guidelines shown in *Table 16* have used two approaches in recommending criteria for control. First, they have used the same criterion as that for defining hypertension requiring drug treatment, and, secondly, the reductions achieved in randomised controlled trials of drug therapy have been used. While the epidemiological evidence would suggest that the lower the blood pressure the better, this has

TABLE 16 Recommendations for achieving control in pharmacological treatment of high blood pressure

Place	Threshold for diagnosis (mmHg)	Goal of therapy (mmHg)
Australia ²¹	160+/100+	< 160/100
Britain ²²	< 60 years: 160+/100+ > 60 years: /90+	< 160/90, caution below /80
Canada ^{23,24}	/100+	< /100
New Zealand ³⁰	170+/100+	Without coronary heart disease: 120-140/70-80 With coronary heart disease: not below /70-80
Sweden ¹⁵	< 70 years: /100+* > 70 years: 180+/100+*	< 70 years: < /90 > 70 years: < 160/90
USA ^{24,26}	140+/90+	< 140/90
WHO-ISH ²⁷	140+/90+	< 65 years: < 120-130/80 > 65 years: < 140/90

* Swedish recommendations specify lower levels for people with other risk factors.

not yet been confirmed in clinical trials. Experience of symptoms of postural hypotension tends to limit clinical enthusiasm for aggressive blood pressure lowering, particularly in elderly people where such side-effects are much more common.

It has been noted that the wide variation in criteria for control results in widely differing 'success' rates when applied to hypertensive patients, ranging from 18 to 85% controlled simply depending on the criterion used.¹⁶

Control in clinical trials

In those drug trials where target blood pressures were explicitly set, it is apparent that typically a third of patients in treatment groups were 'uncontrolled'.¹⁵ Even patients in the control groups of many trials had blood pressures which were in the controlled range by the end of the trial. For example, in the Medical Research Council trial of mild hypertension in younger people, 75% of those

on active treatment were controlled compared with 46% of those in the placebo group.³

As shown in *Table 17*, marked differences in blood pressure reduction were apparent in these trials conducted among older hypertensive people. Despite variation in entry blood pressure levels, final blood pressures and degree of control achieved, a remarkable consistency in reducing risk of disease is apparent. The mean blood pressure reduction achieved was -16/-6 mmHg with entry blood pressures in the range 195-160/77-100, suggesting a control range of 180-145/70-95.

Control achieved in practice

The WHO has produced a useful monograph on hypertension control.¹⁴⁶ Even in the WHO's Countrywide Integrated Non-communicable Diseases Intervention Programme (CINDI) on hypertension, participating countries have used different criteria for defining control.¹⁴⁷ The

TABLE 17 Findings from trials of drug treatment of high blood pressure at older ages. Figures for group size and deaths are intervention/control groups from Ebrahim and Davey Smith¹²

	Group size	Odds ratio			Net change in blood pressure (mmHg)	
		Total mortality	Coronary heart disease mortality	Stroke mortality	Systolic	Diastolic
Kuramoto (1981)	38/41	1.10 (0.34-3.48)	1.09 (0.21-5.74)	2.22 (0.19-25.6)	-5	-2
Sprackling (1981)	60/60	1.00 (0.3-3.3)	-	-	-18	-12.4
EWHP (1985)	416/424	0.89 (0.67-1.18)	0.61* (0.37-0.97)	0.67 (0.38-1.19)	-20	-4
Coope (1986)	419/465	0.96 (0.7-1.4)	0.99 (0.6-1.7)	0.29* (0.1-0.88)	-16	-10
SHEP (1991)	2365/2371	0.87 (0.7-1.06)	0.81 (0.6-1.14)	0.72 (0.3-1.6)	-12	-4
STOP-H (1991)	812/815	0.55* (0.4-0.84)	0.49* (0.25-0.97)	0.26* (0.09-0.80)	-22	-10
MRC (1992)	2183/2213	0.96 (0.8-1.14)	0.77 (0.6-1.03)	0.89 (0.6-1.39)	-17	-5
Pooled results of treatment (blood pressures weighted by sample sizes)		0.89* (0.80-0.99)	0.75** (0.62-0.90)	0.66** (0.49-0.88)	-15.8	-5.6
* p < 0.05; ** p < 0.01.						

CINDI projects in a range of countries have also demonstrated the difficulties of controlling blood pressure even when clinical audit is applied, suggesting the level of control in routine clinical practice is much worse.¹⁴⁷ **Table 18** shows the proportions of men and women aged 25–64 years with controlled blood pressures in countries using blood pressures below 140/90 and 160/95 mmHg as the criteria for control.

TABLE 18 Variation in blood pressure control between countries

Country	Blood pressure (mmHg)	Percentage controlled	
		Men	Women
Canada	< 140/90	28	60
Czechoslovakia		14	8
Lithuania		2	10
Portugal		15 (men and women)	
Russian Federation		6	23
Estonia	< 160/95	3	14
Finland		7	5
Poland		19	24
Spain		14	26

Data: WHO.¹⁴⁷

Women appear to have consistently better control rates than men. Possible explanations for this finding are their better adherence to medical advice, greater pharmacological effect of drugs, lower consumption of alcohol and generally better lifestyle factors, which may make antihypertensive medication less effective.

Since the randomised controlled drug trials achieved levels of control among groups of patients of around 75%, it would seem that this is a suitable target to set in clinical audits of the quality of management of hypertensive patients. Levels of control of 40–50% were achieved in the placebo groups, suggesting that non-specific effects of regression to the mean, measurement habituation, and lifestyle changes play a considerable part in reducing blood pressures in those people found to have high blood pressures at screening or case finding.

Methods of improving control

Methods of improving control operate through different mechanisms which may not be independent of each other. For example, if an intervention improves adherence with tablet taking, control may be improved (see chapter 6). However, nurse-led care or self-monitoring may

work through more careful application of guidelines and tailoring of drug therapy to response. Non-pharmacological advice (e.g. reduction in alcohol consumption or weight reduction) may directly affect blood pressure and make control easier to achieve. Some of the methods that might be used to improve control are listed below:

- more effective drugs
- altering the drug regimen
- non-pharmacological interventions
- self-monitoring of blood pressure
- education of staff and patients
- guidelines/protocols
- nurse-led clinics
- specialist clinics
- free health care
- computerised decision support.

It is commonplace to modify treatment regimens, usually by adding a second active drug to a first-line treatment, but little evidence is available to support the use of two or more drugs in improving blood pressure control. Studies have not been conducted that attempt to disentangle the effects of extra medication from improvements in compliance which may be achieved through greater attention to patient care. Additional non-pharmacological advice has been tested in several trials which have examined the additional benefit of dietary and other forms of advice.¹² While these are beyond the scope of this review, **Table 19** gives a summary of these trials. The randomised controlled trial evidence reviewed here has focused primarily on the effects of self- or home monitoring and educational interventions.

TABLE 19 Blood pressure reductions achieved by different types of non-pharmacological intervention¹²

	Mean (SE) reduction in blood pressure (mmHg)	
	SBP	DBP
Weight reduction	–5.5 (1.5)	–4.3 (0.7)
Salt restriction	–2.5 (1.4)	–3.6 (2.0)
Exercise	–2.6 (1.4)	–
Alcohol restriction	–2.0 (1.3)	–
Stress reduction	–2.8 (1.8)	–1.3 (1.3)
Multiple risk factor intervention	–3.7 (0.25)	–2.9 (0.10)
Drug therapy	–15.8 (0.4)	–5.6 (0.2)

The evidence

The majority of trials did not report results in terms of the proportion of participants achieving control or the duration of time for which they were controlled. Even where such outcomes were reported, different criteria for blood pressure control were applied which made pooling data impossible. Comparable data on net changes in blood pressure could be obtained from the majority of trials and were used in obtaining pooled estimates of the degree of blood pressure control achieved by different interventions. The detailed findings of individual trials are summarised in *Tables 21–24*. *Table 20* shows a summary of the pooled findings. There was no relationship between the quality of trials as assessed using standard criteria (see appendix 2) and the level of blood pressure control achieved.

TABLE 20 Summary of effects on blood pressure of different methods of improving control

Method	Net reduction in blood pressure (95% CI) (mmHg)	
	SBP	DBP
Home monitoring	–	–0.5 (–0.7 to +1.7)
Self-monitoring	–	–1.5 (–0.3 to –2.7)
Patient education	–7.6 (–6.7 to –8.5)	–4.2 (–3.8 to –4.6)
Without Hypertension Detection & Follow-up Program	–0.7 (–2.8 to +1.4)	–0.6 (–1.6 to +0.4)
Professional education	–	–1.9 (–0.5 to –3.3)

CI, confidence interval

Self-monitoring of blood pressure

Self-monitoring of blood pressure at home appears to have a small but significant effect on blood pressure control. However, the pooled estimates for home monitoring included family monitoring, which was associated with a net rise in blood pressure in one study, and thereby an insignificant reduction of blood pressure. In the one study that examined costs, the effects of self-monitoring were cost-saving. These studies were all conducted prior to the widespread use of ambulatory monitoring but suggest that simpler techniques of self-monitoring may be effective. The evidence base to support self-monitoring of blood pressure is small.

Patient education

Patient education stands out as producing the largest reductions in blood pressure but this is explained by the Hypertension Detection & Follow-up Program, which achieved major reductions in blood pressure due to a comprehensive stepped-care approach involving several elements (i.e. education, free care, specialist clinics, and protocols). Consequently, it is likely that the small and statistically insignificant effects of patient education found in the remaining trials is more typical of what might be achieved without attention to other aspects of hypertensive patient care.

Professional education

Professional education achieved a small but statistically significant pooled effect in lowering blood pressure. These beneficial findings were probably due to the increased use of drug therapy in intervention groups rather than to the greater use of other non-pharmacological approaches to blood pressure control or better adherence to treatment.

Miscellaneous methods

Of these, the evidence to support nurse-led clinics is most surprising. Only one trial directly compared nurse-led with doctor-led care and found substantially worse blood pressure control, although as the sample size was so small, this difference may have been due to the play of chance. A Canadian trial¹¹⁸ included in the professional education group might also be considered as a comparison of nurse-led versus doctor-led care, and this provided stronger evidence to support nurse-led clinics. This area stands out as requiring more robust evidence to support current practice.

The evidence to support free preventive health care comes only from the Rand Health Insurance Trial and its relevance to current practice in the UK is limited. However, the finding that methods of financing of health care, particularly for poorer people and those with risk factors that require a preventive approach, have an impact on control is relevant should the NHS consider moving towards user charges in primary care.

Conclusions

The quality of trials of methods of improving blood pressure control was very variable with overall scores ranging from 6 to 29 out of a total of 34 possible points. The major problems were the small size of studies, failure to make blind (i.e. observer) assessments of blood pressure control, losses to follow-up, and poor presentation of findings.

Methods of improving blood pressure control have been not been studied in a rigorous way and have tended to focus on home monitoring, and patient and professional education. The evidence from

randomised controlled trials in this area is very limited, and a priority should be made for more primary research, particularly on organisational aspects of hypertensive management in primary care.

TABLE 21 RCTs of home monitoring of blood pressure on the control achieved

Trial and quality score	Characteristics	Intervention	Net change in blood pressure, SBP/DBP (mmHg)	Comments
Carnahan (1975) ¹⁴⁸ 20	VA Hypertension Clinic, USA, n = 100 (98 men), age 54–57 years	Instructed in the use of sphygmomanometer and measured their own blood pressure twice daily at home. Readings recorded and delivered to the clinic when visiting. Duration 6 months	-7/0	Goal DBP <90 mmHg. Only 3% drop-out rate
Haynes (1976) ¹⁰⁴ 24	Employees of steel mill, Canada, n = 39 (all men). Poorly compliant	Loaned a sphygmomanometer and instructed in its use. DBP measured each day. Fortnightly follow-up and rewards (credits towards ownership of blood pressure cuff and stethoscope). Duration 6 months	/-3.5	Goal blood pressure < 90 mmHg. Only one drop-out. Men had been involved in a previous trial and had poor compliance
Johnson (1978) ¹¹⁷ 20	Screenees from a shopping centre, n = 140 (82 men), age 35–65 years. On drug treatment for > 1 year and DBP > 95 mmHg	(A) Blood pressure measured daily and charts taken to physician appointments (B) Home visits: participants had blood pressure measured in home monthly, with results reported to physician and participant. Duration 6 months	Monitor: /-1.3 Visits: /-0.9 Both: /-0.5	Factorial design comparing self-monitoring and home visits. blood pressure goal undefined. Only four drop-outs
Soghikian (1992) ¹⁴⁹ 23	Physician referrals, USA, n = 430 (50% men), mean age 54 years	Electronic blood pressure device used with twice weekly blood pressure measurement. Record of readings, medication, and side-effects mailed every 4 weeks to the project office. Duration 1 year	-3/-2	Blood pressure goal undefined. Costs 29% lower in home care group. 40 (9%) drop-outs
Stahl (1984) ¹⁵⁰ 14	Community screening + outpatient department/emergency room, USA, n = 406, age 16–70 years. Uncomplicated hypertension, predominantly low income and black	Self- and family monitoring groups, plus nurse education. Patients seen every 2–4 weeks until blood pressure was controlled, then every 2–4 months. Duration 36 months	Family: /+4.8 Self: /-1.5	Not true random allocation. Goal DBP < 95 mmHg. Higher percentage controlled in both family and self-monitored groups. 125 (31%) drop-outs

TABLE 22 RCTs of patient education interventions aimed at improving blood pressure control

Trial and quality score	Characteristics	Intervention	Net blood pressure change, SBP/DBP (mmHg)	Comments
Billault (1995) ¹⁵¹ 21	Outpatient department clinic, France, n = 200 (63% men), mean age 51–55 years	Personal standardised medical record including blood pressure and lifestyle data held by patient and mailed to outpatient department regularly. Duration 1 year	–0.2/–0.3	Only half used the record as instructed. Blood pressure goal undefined. 33 (16%) drop-outs
Fielding (1994) ¹⁵² 22	Work-site hypertensive volunteers, USA, n = 159	Monthly 10 min individual education sessions at work site with a trained counsellor and monthly mailing of personalised letter and information. Duration 1 year	–7.6/–2.4	More of the intervention group patients were started on drug treatment, which may explain the better control achieved. Goal blood pressure undefined. 14 (9%) drop-outs
Hypertension Detection & Follow-up Program (1979) ^{9,10,153,154} 29	Community centres, USA, n = 10,940 (39% men), mean age 51 years	Stepped-care intervention providing high levels of patient education, free antihypertensive treatment and protocols for care. Referred care provided by the patients' usual physician was used as the control. Randomised in strata of blood pressure (mmHg): 90–104 = I, 105–114 = II and 115+ = III. Duration 5 years, but blood pressure data for 1 year follow-up	I: –8.2/–4.2 II: –11.7/–6.5 III: –10.7/–7.5	Trial showed major reductions in cardiovascular disease mortality at 5 years. Goal DBP < 90 mmHg or if baseline 90–99 mmHg, –10 mmHg reduction. 39% with no 1 year blood pressure measurements overall but only 20% in stepped-care group
Martínez-Amenós (1990) ¹⁵⁵ 13	Primary care centres, Spain, n = 722 (41% men), mean age 61 years	Individual education group, team education (conducted by doctors and nurses) group and control group receiving usual care. Duration 2 months.	No data	Individual and team education resulted in 6 and 7.5% net increases in blood pressure control. Blood pressure control < 160/95 mmHg. No drop-outs reported
Moriskey and Levine (1979) ^{156–160} 12	Outpatient department clinic, USA, n = 400 (25% men), mean age 54 years	Complex 2 × 2 × 2 factorial design examining three different health education interventions (individual, family and small group) which were grouped as a single 'education' group and compared with a no-education control group. Duration 5 years	No data	Trial showed a reduction in mortality at 5 years. Goals defined by age. Blood pressure control achieved in 66% of the intervention group and 50% of the control group. 110 (28%) drop-outs at 5 years
Mühlhauser (1993) ^{161,162} 21	10 general practices, Germany, 20 hypertensive patients randomly selected from each practice (45% men), age 30–60 years	Intervention group received hypertension treatment and teaching program (HTTP) involving self-monitoring of blood pressure, 4-weekly group teaching sessions by trained paramedics on nutrition, weight and alcohol consumption. Duration 18 months	–5/–4	Intervention group patients were on less medication at the end of the study. Body weight fell more in the intervention group. Goal blood pressure undefined. 40 (20%) patients lost to follow-up

continued

TABLE 22 contd RCTs of patient education interventions aimed at improving blood pressure control

Trial and quality score	Characteristics	Intervention	Net blood pressure change, SBP/DBP (mmHg)	Comments
Roca-Cusachs (1991) ¹⁶³ 25	Outpatient department hypertension clinic, Spain, n = 287(49% men), mean age 52 years	Intervention group received two talks 1 week apart and one personal tutorial. Follow-up at 6 months.	+2/+1	Both groups showed falls in blood pressure, but was greater in the control group. Knowledge improved in the intervention group. Goal blood pressure undefined. 92 (32%) drop-outs, with more in the intervention group
Sackett (1975) ¹¹⁶ 18	Steel Mill employees, Canada, n = 230 (all men)	2 × 2 factorial design examining (A) work-site clinic and (B) education on hypertension, benefits of treatment and importance of compliance. Duration 6 months	No data	Goal blood pressure < 90 mmHg. At 6 months, 24% controlled in education groups versus 19% in control groups – not significant
Takala (1983) ¹⁶⁴ 22	Community participants, n = 147 (49% men), mean age 54 years	Intervention group received written information explaining hypertension and stressing the importance of seeking treatment and continuing it. Duration 2 years	40–49 years: –3/0 > 50 years: –1/–1	44 and 35% blood pressure controlled in intervention and control groups, respectively. Blood pressure control defined by age (< 160/95 + < 170/105 mmHg). Seven (5%) drop-outs
Tanner (1981) ¹⁶⁵ 18	Family practice, USA, n = 30 (37% men), age 22–65 years	A <i>Guide to Essential Hypertension</i> given to participants, and information in it discussed at fortnightly visits to the practice. Control group also visited practice fortnightly but for usual care. Duration 4 months	/+0.2	Intervention group had increased knowledge. Blood pressure control < 90 mmHg. No drop-outs reported
Watkins (1987) ¹⁶⁶ 23	General practice, UK, n = 414 (41% men), age 35–64 years	An information and medical record booklet was mailed to patients with a letter from general practitioner. Duration 1 year	+1/+1	Intervention group had better knowledge. Blood pressure goal undefined. Care generally good in both groups. Drop-outs not reported
Weiner (1980) ¹⁶⁷ 6	Industrial settings, USA, n = 20	Patient education by a nurse, including reinforcement to take medication, observation for side-effects, side instruction, blood pressure and weight checks, education and counselling aimed towards understanding and acceptance of hypertension. Duration 3 months	No data	Mean SBP lower in intervention group. Weight also lower. Blood pressure goal undefined. Drop-outs not reported
Zismer (1982) ¹⁶⁸ 19	Private family practice, USA, n = 39 (51% men), age 21–76 years	Intervention groups had education program pill taking, regular follow-up visits and dietary sodium reduction with or without involvement of a family member. The control group received usual care, stressing pill taking and follow-up visits but without educational component. Duration 6 months	–15.7/–8.7	Control group was not well-matched: 10 years older and diagnosed for longer. Blood pressure goal undefined. Drop-outs not reported

TABLE 23 RCTs of professional education interventions aimed at improving blood pressure control

Trial and quality score	Characteristics	Intervention	Net blood pressure change, SBP/DBP (mmHg)	Comments
Logan (1979) ¹¹⁸ 26	Volunteers from business settings, Canada, n = 457 (80% men), mean age 47 years	Work-site care provided by experienced nurses using a protocol with clear aims to achieve blood pressure control. Control group received usual care from their own physicians. Duration 6 months	-3.8	Protocol specified more frequent visits until control was achieved. Nurses tended to use more drug therapy than the usual care control group. Goal blood pressure < 140/90 mmHg. 47 (10%) drop-outs
Evans (1986) ¹⁶⁹ 23	Community screening, Canada, n = 209, age 30–69 years. Patients' physicians (n = 76) randomised	Intervention group physicians received 14 weekly instalments of practice-oriented information designed to be read in 3–5 min each, on diagnosis, work-up, therapy and follow-up of hypertensive patients. Duration 1 year	+1/+1	Blood pressures of all participants declined over the study. Goal blood pressure < 90 mmHg. 15 (8%) drop-outs
Gullion (1987) ¹⁷⁰ 13	Physicians, San Francisco Bay Area, USA, n = 111 (95% men). Hypertensive patients of physicians assessed, n = 2583, age 20–80 years	Physicians randomised to four groups: medical education (n = 27), behavioural education (n = 28), both (n = 30) or neither intervention (n = 27). Duration 1 year	All groups: /0	Overall, 68% of patients were in control at end of the study. Goal blood pressure undefined. Physician drop-outs not reported, but 539 (21%) of patients not included in the final analysis
McAlister (1986) ¹⁷¹ 19	Primary care physicians, Canada, n = 60. Patients n = 2231 (47% men)	All physicians completed and returned a data collection form on their hypertensive patients. Intervention group received computer feedback including comments on treatment prescribed, based on the stepped-care protocol. Duration 16 months	-0.8	Proportion of patients controlled in each group was similar (89 versus 88%). Goal blood pressure < 90 mmHg. More patients with moderate hypertension in the intervention group received drug treatment. 10 (17%) physicians dropped out

TABLE 24 Trials of miscellaneous methods used to improve blood pressure control

Trial and quality score	Characteristics	Intervention	Net blood pressure change, SBP/DBP (mmHg)	Comments
Brook (1983) ^{172,173} 11	Families living in one of six sites in USA, n = 3958 belonging to 2005 families (47% men, 18% non-white females), age 14–61 years, mean age 33 years	Participants randomised to various health insurance plans, which were subsequently grouped into four categories: free care or 25, 50 or 95% of cost sharing of health bills. Duration 5 years	All: -0.7/-0.9 Hypertensive patients: -1.8/-1.9	Poorer people with high blood pressure had -3 mmHg lower DBP on free care. Free care led to increased physician contacts, and better lifestyle changes. Goal blood pressure < 160/95 mmHg. 463 (12%) drop-outs
Cummings (1985) ¹⁷⁴ 23	Family practice, USA, hypertensive patients, n = 973, mean age 60 years. Predominantly black, low-income population	Appointment reminder programme: reminder card sent to the patient 1 week before scheduled appointment. Card included brief message about the importance of continuing treatment and seeing the doctor. Missed appointments followed up by telephone and/or letter. Control group received usual care. Follow-up 5–8 months	-2/-1	Goal blood pressure < 140/90 mmHg. 51% intervention versus 39% control group had blood pressure controlled. Drop-outs higher in control group (25 versus 14%)
Earp (1982) ¹⁷⁵ 13	Outpatient department hypertension clinic patients, n = 218 (41% men, 77% black), mean age 48	Family and home visits by a nurse or pharmacist versus home visits versus usual care as control group 3. Family/home visit group 1 also had daily blood pressure monitoring. Home visit group 2 received a mean of 6 home visits. Duration 2 years	No data	By year 2, proportions with blood pressure uncontrolled were: group 1, 25%; group 2 21%; and control group 3, 42%. Goal blood pressure < 95 mmHg. 127 (58%) drop-outs
Jewell (1988) ¹⁷⁶ 14	Primary care, UK hypertensive patients, n = 36, age 30–64 years	Nurse-led hypertension clinic versus usual care. Duration 1 year	Nurse: +20/+5	Patients attending the nurse-led clinic had lower blood pressures than those attending the doctor. Levels of blood pressure control were similar (67 versus 63%). Goal blood pressure < 90 mmHg. Only two drop-outs in the nursing group
Robson (1989) ¹⁷⁷ 17	Primary care, UK, n = 3206, age 30–64 years	Nurse-led preventive care with computer-assisted follow-up. Duration 2 years	No data	Intervention group patients were more likely to have had a blood pressure recording in the past 5 years (93 versus 73%) with similar findings among hypertensive patients (97 versus 69%). Control not considered

Chapter 8

Recommendations

General

- In general and of relevance to most recommendations, implementation of policy and practice should follow evidence-based principles: local rather than central development of guidelines; end-user involvement in the process; and integration of guidelines into routine practice
- Where cost-effectiveness information is needed, recommendations for further randomised controlled trials should include an economic appraisal.
- Policy and practice on high blood pressure might best be considered in conjunction with a review of all cardiovascular disease prevention advice to health authorities and general practitioners as a modification of individual risk factors in isolation is unlikely to produce coherent proposals.
- Audit in primary care should review the levels of detection, treatment, adherence and control of high blood pressure. Evidence of the impact of audit and effects of specific interventions found to improve the 'rule of halves' might be collated by Medical Audit Advisory Groups, published and disseminated widely.

Detection of high blood pressure

- Standardisation of methods of blood pressure measurement is essential. Use of Korotkov V (disappearance of sounds) should be widely promoted in primary health care. Facilities for the routine maintenance of sphygmomanometers should be available in all health districts.
- The British Hypertension Society guidelines on thresholds for starting treatment now require review following publication of the New Zealand guidelines and the wider recognition of the importance of absolute disease risk in formulating preventive health care policy.
- Evidence to support detection and treatment of high blood pressure in older people (i.e. aged 65–79 years) is now very strong. This evidence should be widely disseminated, and professional barriers to treating older people recognised as unacceptable and not consistent with best practice.

- Ambulatory monitoring methods increase the cost and complexity of blood pressure detection without providing any tangible benefits. Their use should not be promoted in primary health care.
- Blood pressure is only one of a number of powerful risk factors which predict the chances of suffering a stroke or ischaemic heart disease. Greater emphasis should be placed on examining risk factor scores (or profiles).

Adherence

- Improving professional adherence to best practice in the management of high blood pressure through a range of organisational and management mechanisms is required. More direct methods such as financial incentives and penalties require investigation, as they may prove more effective than educational or clinical guideline approaches.
- Standardisation of methods of measuring and reporting on patient adherence is required. Empirical data should be examined to determine the implications of the wide range of criteria for adherence currently used. Validation of report measures by plasma or urine drug assay would also be valuable in determining the most accurate methods.
- Evidence is lacking to support any specific approaches to improving patient adherence with antihypertensive drugs or lifestyle changes. Further research on patient adherence should be linked with the associated question of improving blood pressure control (see below).

Control

- The British Hypertension Society-recommended target blood pressures to be achieved on drug treatment require review, and criteria proposed should take into account co-morbidity, age and level of hypertension.
- A stepped-care approach (i.e. education, specialist clinics, free care (including drugs), and use of protocols) to management is supported by American randomised controlled trial evidence which is not directly applicable to British practice.

- Evidence to support nurse-led care compared with doctor-led care as a better option in achieving blood pressure control is very sparse.

Trajectory of the knowledge base

Evidence of efficacy

More evidence on the effects of blood pressure lowering at older ages (i.e. over 80 years) and following the onset of cardiovascular diseases will accrue from trials already underway and will be published between 2002 and 2005. In addition, trials on cholesterol lowering in old age will also be published in the same period. It is likely that recommendations for detection and management will require review in the light of this new evidence.

Decision support

Considerable effort is currently going into methods of aiding primary care decision support in a wide range of areas, including hypertension. These aids include telemedicine, computer prompts and patient-held records. Review of this area of work would be worthwhile in the next 2 years so that the scope of the work and its relevance to cardiovascular disease prevention may be assessed.

Risk scoring

A European Union concerted action on cardiovascular risk scoring has been established by Professor Ian Graham, Royal College of Surgeons, Dublin, Ireland. This work should be included in a review of the different methods of assessing risk.

New primary research

The primary research is now out of date and little new work appears to be occurring from spontaneous curiosity-driven enquiry. The NHS research and development cardiovascular diseases and stroke initiative (1993–1995) has produced data of direct relevance to this area of work. Much of this work is due to be completed in 1998, and is likely to be published by 2000.

Little attention has been given to hypertension detection, adherence and control among the poor and ethnic minorities. Trials of specific interventions tailored to their special needs might be conducted in the areas suggested below. The specific primary research areas recommended are listed in order of relative priority.

- A multicentre primary care randomised controlled trial comparing nurse-led management with general practitioner-led management in hypertension is urgently required. This trial would require an economic evaluation. The focus of this trial would be on the overall management of hypertension in adults, and outcomes of importance would be hypertension detection rates, professional adherence to best practice, patient adherence to treatment (both pharmacological and non-pharmacological) and blood pressure control achieved.
- Large-scale, randomised controlled trials, including economic appraisal, of interventions that aim to improve patient adherence with treatments are urgently required. Possible interventions that should be compared in factorial designs with usual care include educational/motivational approaches, follow-up, feedback and simplification of medication regimens. Outcomes considered should include not only patient adherence with treatment but also blood pressure control achieved. If large enough, such trials would be able to measure clinical event outcomes and provide British replication of the American Hypertension Detection & Follow-up Program of stepped care versus usual care.
- Randomised controlled trials to test the value of risk factor scores (or profiles) in giving general practitioners and nurses the information they need to reduce cardiovascular disease risk. Comparisons might include computer-aided prompts, and visual and interactive methods involving patients. Outcomes might include not just greater awareness and recording of risk levels but actions taken and their effectiveness in reducing risk factors.
- Controlled comparisons of the effects of organisational and managerial initiatives (e.g. financial incentives and penalties) on improving professional adherence to best practice in the management of high blood pressure compared with professional education and clinical guidelines.

Updating of this review

An update of this review would be appropriate following publication of the primary research commissioned by the NHS Executive. Preliminary enquiries should be made of investigators to determine likely completion dates and to gain access to information that might be included in the review but might not be published. Given present information, a review carried out in 2001 would be timely.



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Appendix I

Search strategy used to identify trials

Basic search strategy for meta-analyses

(meta-analysis or review literature).sh.
 meta-anal\$.tw.
 metaanal\$.tw.
 (systematic\$ adj4 (overview\$ or review\$)).tw.
 meta-analysis.pt.
 case report.sh.
 letter.pt.
 historical article.pt.
 review of reported cases.pt.
 review, multicase.pt.
 6 or 7 or 8 or 9 or 10
 1 or 2 or 3 or 4 or 5
 12 not 11
 limit 13 to human

Basic search strategy for trials

randomised controlled trial.pt.
 randomised controlled trials/
 random-allocation.sh.
 double-blind-method.sh.
 single-blind-method.sh.
 1 or 2 or 3 or 4 or 5
 clinical trials.pt.
 clinical trials.sh.
 clin\$ near trial\$.ti.
 clin\$ near trial\$.ab.
 placebo.sh.
 placebo.tw.

random.tw.
 7 or 8 or 9 or 10 or 11 or 12 or 13
 limit 14 to human

Blood pressure detection (adherence and control terms)

exp hypertension.sh
 exp blood pressure.sh
 blood pressure determination.sh
 blood pressure monitoring.sh
 mass screening/
 patient care/
 exp decision making, computer assisted/
 physicians, family
 physicians practice patterns.sh
 physicians role.sh
 control.tw
 compliance.tw
 adherence.tw
 detection.tw

Cochrane Library search

Advanced search method used:
 hypertension (all fields)

Title field only:
 control
 compliance
 adherence
 detection

Appendix 2

Quality of randomised controlled trials of blood pressure

Design features	Score	Design features	Score
1.1. Randomisation procedures:		Assessed by independent observer	1
Adequate	2	Self-assessed	1
Not known	1	Assessed by unblinded observer	0
Inadequate (possibility of biased allocation)	0	Not assessed	0
1.2. Comparability of groups		3.1. Interventions	
Comparable and demonstrated	2	Clearly described and replicable	2
Probably comparable	1	Described	1
Not comparable (size, baseline variations)	1	Not described	0
Not possible to say	0	3.2. Duration of intervention	
1.3. Design		Defined	1
Double-blind, at least one outcome	2	Not defined	0
Single-blind, at least one outcome	1	4.1. Follow-up duration	
Unblinded	0	Defined, 25+ weeks	2
1.4. Sample size		Defined, less than 24 weeks	1
Moderate effects assessable (n = 50+)	2	Not defined	0
Sample size estimates, power mentioned	1	4.2. Losses postrandomisation	
Moderate effects not assessable (n < 50)	0	Defined	1
1.5. Participants		Not defined	0
Generalisable, primary care	2	4.3. Losses greater than 80% sample	
Selected, hospital outpatient department	1	No	2
Not clear	0	Yes	0
1.6. Participants		Don't know	1
Age, sex, duration hypertensive	2	5.1. Analyses	
Age, sex given	1	Intention to treat	2
Age, sex not given	0	Explanatory only	1
1.7. Numbers randomised to each group		Not clear	0
Given	2	5.2. Presentation of data	
Not given	0	Confidence intervals, or standard errors given	2
2.1. Compliance outcomes		Standard deviations given, standard errors calculable	1
Assessed by independent, blind observer	2	No standard deviations, standard errors, or <i>p</i> values only	0
Assessed by independent observer	1	5.3. Changes in outcomes	
Self-assessed	1	Net changes used	2
Assessed by unblinded observer	0	End of trial outcomes only	1
2.2. Compliance outcomes		No relevant data given	0
Validated and relevant	2		
Unvalidated and relevant	1		
Unvalidated and ?relevant	0		
2.3. Blood pressure outcomes			
Assessed by independent, blind observer	2		
		Maximum total quality score (= best)	34

Appendix 3

Details of included trials

Details of trials of methods of improving detection (see *Table 6*)

D'Souza (1976)⁸¹

The lists of patients of two general practices (Kent and Greater London, UK) were searched, and all patients aged 40–64 years identified. Spouses of these patients whose ages were outside the limits were also included in the study, giving a total of 7229 participants. Participants were randomly allocated by family into two groups, 'screening' and 'control'. The screening group was invited to two screenings, 1967–1968 and 1969–1970, and all participants were invited for a comparison survey in 1972. In the screening group, 3297 participants were invited to the first screening, 73% of whom attended, and 2677 participants to the second screening, 66% of whom attended. In each case the remainder refused the invitation. Five years after the initial screening, the prevalence of DBP 105+ mmHg was similar in the screening (3.1%) and control (3.2%) groups. Using a lower threshold of 95+ mmHg, similar prevalence rates were observed (10.8 versus 10.9%). Screening identified new cases of hypertension and led to a modest amount of intervention. There were quite substantial losses over the study period, due to participants moving or dying (these factors are not separated), administrative difficulties and refusals of screening. It is suggested that since over 93% of all the patients on the lists in the 40–64 year old age group had seen their general practitioner for some other reason within the last 5 years, case finding may be a more cost-effective method of identifying hypertensive patients.

Stahl (1997)⁸²

This study allocated four geographic areas of predominantly black people in inner-city Indianapolis, USA, to two types of intervention: local door-to-door measurement of blood pressure (active) and letter invitations to attend a central clinic for blood pressure measurement (passive). The added effects of providing a gift with the letter, follow-up visits for non-responders and the use of appointment times for home visits were also assessed. A fifth area was used as a control. The outcome assessed was the number of blood pressure measurements made per 100 of the at-risk population from census data (corrected for business addresses and vacant houses). A letter invitation (with or without a gift)

produced a very low blood pressure measurement rate, whereas any of the home visit strategies produced much higher rates, but only about a quarter of possible people were measured. The active methods were more likely to detect new, rather than known, hypertensive patients.

Krishan (1979)⁸³

The Mayo Three-Community Hypertension Control Program was set up in three rural communities. All communities received community screening and public education, but in one area a cost-subsidised nurse-run community hypertension clinic was also provided, in addition to physician education. Local housewives were trained to measure blood pressure, and carried out the community screening. Repeat measurement of screening blood pressures was more often carried out in those referred specifically to the community hypertension clinic but it is uncertain whether the subsidised service explained this finding. In all three communities blood pressures fell and the proportions on treatment increased. Drop-outs at 1 year were lower in the community hypertension clinic. The investigators do not comment on the higher prevalence of hypertension detected or the higher adherence with advice to seek re-measurement in the community with the community hypertension clinic.

Cooke (1983)^{84,85}

Three apartment complexes (Virginia, USA) similar in rent fees and distance from the 'downtown' area were selected and randomly assigned to three experimental conditions; door-to-door screening by volunteer residents, central site screening by volunteers from a resident health committee, or central site screening by research assistants. All initial screening was performed in the same 3 week period and central sites manned for approximately the same number of hours necessary for door-to-door screening. For door-to-door, resident central site and research central site screening, respectively 49, 14.5 and 11.6% of occupied apartments were screened, corresponding to 43, 8 and 8% of residents. Of a total of 265 residents screened, 22 hypertensive individuals were detected. Hypertensive patients were randomly allocated to a contact or control group. The contact group members were mailed a week after referral and telephoned after another 2 weeks to encourage

the seeking of treatment. Contact and control group patients were both telephoned 1 month after referral to ascertain status, and visited after 3 months for remeasurement. At the 3 month follow-up, one hypertensive patient from each group had moved away. The remaining 10 members of the contact group and five of the control group had visited a physician. Door-to-door screening was significantly more effective than either central screening methods, and contacting identified hypertensive patients appeared to have a beneficial effect on their seeking treatment.

Nissinen (1983)⁸⁶

As part of the North Karelia project in Finland, a specific hypertension detection project was initiated. The design was quasi-experimental, with an intervention group (North Karelia) and a comparison group (Koupio). The North Karelia intervention involved public health education, staff training, reorganisation of primary care services and new information services. In Koupio no efforts were made to set up or change services. The screening in both areas was carried out in similar ways so, not surprisingly the levels of hypertension detected were similar. Changes in blood pressure among hypertensive patients identified at screening over the following 5 years were greater in North Karelia than in Koupio, although a decline was also found in untreated patients in both areas, suggesting that regression to the mean explains some of the observed decline. It was concluded that the high coverage brought most hypertensive patients to attention and under control, although no data on control is presented in this study.

Bass (1986)⁸⁷

Thirty-four general practices in south-western Ontario, Canada, were randomly allocated to an experimental or control group. The control group continued with usual care. In the experimental group a specially trained nurse reviewed the charts of all patients tagging them as either no recorded DBP in the previous 2 years or a previous blood pressure of over 90 mmHg. A 5 year case-finding programme was implemented (1978–82) in which blood pressure was measured in patients attending the office for any reason. In addition, an 'outreach' programme was performed in 1980, for patients not attending the office. Of those patients contacted, 31% visited for blood pressure measurement. Effort was made to ensure that all patients with elevated readings attended for a second measurement. At the end of the study, 91% of the experimental group patients had at least one blood pressure reading, and 70% had at least two readings. The corresponding rates for the control

group were 80 and 57%, respectively. No data on prevalence of hypertension detected are presented. Information on adherence is given (in the experimental group, 75% reported missing no more than one pill per week, compared with 67% in the control group) and mean blood pressures were lower in the intervention group (137.2/81.9 versus 140.1/83.0 mmHg). Finally, cardiovascular disease mortality rates were higher in the experimental group (1.96 versus 1.52% over 5 years).

McDowell (1989)⁸⁸

This randomised controlled trial involved six practices in Ottawa, Canada, from March 1985 to February 1986, and compared 'active' and 'passive' methods of advising patients to have their blood pressure checked. Two practices were designated control practices (2554 individuals) and the other four, study practices (5744 individuals). Patients of the study practices were randomly allocated by **family** to a control group (n = 1371) or one of three experimental groups: physician computer-generated reminder (n = 1432); letter reminder (n = 1508); or nurse telephone reminder (n = 1433). The analysis concerned only those participants (74% of those randomised overall) who had not had a blood pressure measurement within the last year. After the 1 year intervention period, blood pressure had been checked most often in the letter reminder patients, and the highest detection of hypertension was in the physician computer reminder group. However, when the analysis was repeated, removing those people who did not visit the practice (physician and control groups) and those who did not receive a telephone or letter reminder, the physician computer reminder scheme most often resulted in measurement of blood pressure, and the telephone reminders appeared to be worse than either control group. The cost-effectiveness of each intervention was assessed in terms of costs per blood pressure measurement made. The physician computer reminder was the most cost-effective by far, at US \$1.7 per blood pressure reading, the letter reminder was US \$14.37 per blood pressure reading, and the telephone reminder was US \$31.27 per blood pressure reading. Although physician reminders were found to be the most cost-effective, they depend on patients visiting the doctor and are thus not strictly comparable with interventions seeking to increase contact between doctors and patients.

Adorian (1990)^{89,90}

An interesting Israeli study used a system of regular medical record review, feedback, group discussion and comparison with expected numbers of

hypertensive patients and with other local general practitioners. The audit programme demonstrated dramatic increases in the prevalence of detected and treated hypertension over a 7 year period (4.0–9.2%) and also showed that the detection/treatment rates were higher in the intervention area than in other geographic control areas. Among hypertensive patients, the control achieved was also better in the audit practices.

Holmen (1991)⁹¹

Case finding by general practitioners was compared with a screening programme in the county of Nord-Trøndelag, central Norway, using a before and after design. Intensive training of general practitioners, protocols and feedback were instituted from 1980. In 1982–1983 an intensive case-finding exercise was carried out for 12 months during which general practitioners were asked to measure blood pressure in all visiting patients (before phase). The screening was conducted from January 1984 to February 1986, when all 85,100 residents of the county aged 20 years or older were invited to a health screening, 88% of whom attended. At the screening, 2399 participants were identified with blood pressures above the threshold values used, and referred to general practitioners. A total of 11,661 people required either drug treatment or monitoring of blood pressure. Of these, the earlier case finding had found 87.9% and the screening programme only detected a further 12.1%.

Participation rates were lower among those who were unmarried or separated and those who were living in the largest municipalities. The overall high participation rate and low detection rate of new hypertensive patients by screening suggest that the case-finding method (which included training, protocols and feedback) detected the majority of those needing monitoring or treatment.

McMenamin (1992)⁹²

In a single New Zealand general practice, 754 patients aged 30–69 years were invited by the doctor to make an appointment for a preventive health check which comprised several measurements, including blood pressure. During the 3 years prior to this scheme information was collected on blood pressure recording to make a comparison with blood pressure recording during the health check years. Overall preventive health care activities, including blood pressure recording, increased during the screening phase compared with the earlier period. The coverage of Maori men (78%) was lower than whites (85%) (but not statistically significantly different). No data were reported on new and old cases of hypertension

detected. The investigators concluded that the doctor invitation to a screening health check was more effective than their earlier case-finding approach.

Aubin (1994)⁹³

This study was based in a hospital family medicine centre and compared rates of blood pressure measurement before and after a physician training programme together with clinical aids to recording and follow-up. A control family practice that had not received any special training was also studied. Retrospective case note review was used to collect information. Blood pressure recording was improved in the intervention practice; however, in the control practices, levels of recording showed marked variation between measurement periods. The study provided no information on hypertension detection rates.

Details of trials examining adherence with only adherence or blood pressure outcomes

(see *Table 14*)

Kirscht (1977)¹¹¹

In this complex factorial design, 417 hypertensive patients treated by eight private community physicians were randomly allocated to 36 different treatment groups. The interventions comprised sequential use of printed educational materials, nurse telephone calls, self-monitoring of blood pressure, and social support, each administered for 4 months, and a further 12 months of follow-up. Outcomes were assessed as adherence to recommended diets, weight control, and self-reported adherence, backed up by pharmacy records of pills received. Outcomes were not presented as numbers or proportions but were assessed as scores ranging from good to bad. Baseline characteristics of the comparison groups varied but were used as covariates in the analysis which presented adjusted mean scores for the main effects of each intervention. In interpreting these scores, it has to be assumed that the order in which an intervention is received does not affect the outcomes. Only small differences in means scores were found for drug adherence outcomes where the nurse phone calls and the social support interventions were associated with better scores, but the printed information and self-monitoring did not appear to have any effects. Drop-outs were relatively small at 16% of the total sample but intervention specific drop-outs were not reported. The denominators for many of the comparisons varied by large amounts, suggesting that missing data may have led to

biased comparisons, and would tend to over-estimate effects if only those participants who had good adherence responded to self-reports.

Strogatz (1983)¹¹²

Patients with uncontrolled hypertension were drawn from university outpatient department or community hospital clinics and were randomised to: group 1, routine care plus periodic home visits by nurse or pharmacist plus a family member was selected by the patient to be trained to monitor blood pressure several times a week; group 2, routine care plus periodic home visits; or group 3, routine care. A total of 218 patients were randomised in a 2:1:1 ratio (i.e. about 110:54:54 but this is not specified). Main outcomes were drop-outs and blood pressure control but no data are provided on the latter. The published drop-out rates favour groups 1 (11%, 8/75) and 2 (11%, 5/44) and were highest in the routine-care group (25%, 13/32). Unfortunately, 47/218 (21.6%) drop-outs occurred postrandomisation but were excluded from further consideration by the investigators. If these drop-outs are included and it is assumed that they were equally distributed between the three groups, a similar picture emerges: group 1, 28%; group 2, 31%; and group 3, 46%. Although the conclusion that either intervention is better than the control is still supported, the overall drop-out rates are extremely high and the conclusion is unsafe as it is quite possible that the drop-outs were not distributed equally between the groups.

Eshelman (1976)¹¹³

A consecutive series of hypertensive hospital outpatient department patients with a prescription for once-daily chlorthalidone were randomised to either a special medication dispenser or the traditional bottle. Details of the randomisation procedure were not given nor was the duration of the study and follow-up reported. No baseline data for the two groups were presented. Outcomes were assessed as pill counts, urinary chlorthalidone assay, and drop-outs. Not all the patients were assessed, and 33 were 'dropped' from analyses because of missed appointments, lack of follow-up or misunderstandings! Thus the denominators for comparisons appear to be 29 for the intervention group and 36 for the control group. Intervention patients were more compliant in providing a urine sample for assay (93 versus 69%, $p < 0.01$) but pill counts were similar in both groups (63 versus 61%) although the criterion for an acceptable pill count is not given and the denominators fall by a further seven individuals. The investigators conclude that the new medicine dispenser is effective in improving adherence as measured by urinary assay.

Sclar (1991)¹¹⁴

Hypertensive patients managed in a Health Maintenance Organisation and were with atenolol were randomly allocated to a prescription refill intervention comprising a 30 day drug supply, educational newsletter about hypertension, information on nutrition and lifestyle, and an explanation of the purpose of the kit. The control group were supplied with a 30 day supply of atenolol. The intervention and control were maintained for 180 days. A total of 453 patients were stratified by whether they were new to atenolol or had received it for between 3 months and 1 year and then randomised. Adherence was assessed as the medication possession ratio, that is, the number of days supply of medication obtained divided by the number of study days (180). Over the study, both old and new patients had higher medication possession ratios than the control groups (old, 0.82 versus 0.48; new, 0.93 versus 0.52; $p < 0.001$). However, no checks on what was actually taken and no drop-out rates are reported despite the rather uneven numbers in the various groups, suggesting losses did occur.

Binstock (1988)¹¹⁵

Hypertensive patients were randomised to one of five groups, all of which had an educational component. Group 1 ($n = 32$) acted as the control, group 2 ($n = 23$) self-monitored blood pressure, group 3 ($n = 15$) used behavioural contracting and rewards, group 4 ($n = 30$) used calendar pill packs and group 5 received all the interventions. A total of 112 patients were stated to have been randomised, although the aforementioned numbers total 111! In addition, although the group sizes are very variable, no losses to follow-up over the 1 year study were reported. No adherence indicators were measured although changes in blood pressure were used as a proxy indicator for adherence. The authors found that differences in blood pressure from baseline over 1 year ranged from $-3/-1$ mmHg in the control group to $-21/-11$ mmHg in group 2, and the combined group 2-5 changes were statistically significant ($-17/-10$ mmHg). It is not clear whether blood pressures were measured blind. The differences in blood pressure are very large and suggest that factors other than the intervention were operational.

Details of trials of interventions for improving adherence (see Table 15)

Sackett (1975)¹¹⁶

This trial used a factorial design to examine the effects of two interventions – doctor-led work-site care and 'mastery' learning – used singly and in

combination and compared with usual site of care and no learning. 'Mastery' learning simply meant information provision on the facts about hypertension and techniques on adherence, which were carried out by a high school graduate with no special training, value of treatment, and supply of an audio-tape slide pack. The work-site care was considered more convenient, but the costs of drugs were similar between work-site and usual site care. The findings are analysed by the main effects, which showed that in all groups, adherence was around 50–56%, and the combined outcome of compliant and achieving target blood pressures was only achieved for between 19 and 24% of patients. A borderline significant interaction was found between those getting both mastery learning and work-site care having the same adherence as those receiving neither intervention (both 48%), and those not receiving mastery learning and work-site care having the highest adherence (62%). Interestingly, the large increase in the proportions started on treatment (70–76 versus 49–56%) in the intervention groups are not commented upon. Figures provided by the author for the recent review¹¹⁰ bear no relationship to those published in the original paper.

Haynes (1976)¹⁰⁴

This trial examined the effects of a complex intervention among a group of 'difficult' hypertensive men detected during a screening exercise in a Canadian steelworks. The men had all failed to achieve target DBPs of below 90 mmHg V and pill counts of greater than 80% after 6 months of treatment. The intervention was very intensive, comprising self-monitoring of both blood pressure and pill counts, use of a high school graduate to visit the men every two weeks, tailoring of pill taking to suit individual routines, and even a reward of US \$4 credit note towards the purchase of a sphygmomanometer and stethoscope for achieving control and adherence targets. Both groups increased their adherence (80% versus 39%) at 6 months, and 6/20 and 2/19 achieved target blood pressures in the intervention and control groups, respectively. In addition to the intervention, patients in the experimental group also received more aggressive blood pressure treatment. No attempt was made to control for attention bias. While the trial lacked statistical power to detect differences in control, a significant impact on adherence was detected. Allocation to groups was not strictly random but conducted by a minimisation technique.

Johnson (1978)¹¹⁷

Participants in the trial had been volunteers in a shopping centre screening in Hamilton, Canada.

All had been treated for at least 1 year but had blood pressures 95+ mmHg. All four groups showed falls in blood pressure of about –8 mmHg. Adherence improved by 10% in both the groups receiving monthly home visits, but it was not stated who conducted these visits. The trial lacked statistical power to detect a difference of this size. A *post hoc* subgroup analysis showed that those patients admitting trouble remembering to take their medication had greater changes in DBP on either intervention. However, as neither intervention was focused on memory training, this finding is probably spurious.

Logan (1979)¹¹⁸

Participants were predominantly white-collar workers detected during screening of Toronto businesses. Of 851 eligible for the trial only 457 were willing to take part. By 6 months, more in the intervention group were on drug treatment (86 versus 53%), more had achieved the target blood pressure (48 versus 28%), DBP had fallen more in the intervention group (–10 mmHg versus –6 mmHg) and adherence was better (80%+ tablets taken, 68 versus 49%). Nurse-led care was much more drug orientated than usual general practitioner-led care, but General practitioners were more likely to omit drug treatment even in those with very high blood pressures. It is impossible to disentangle the specific effects of adherence-oriented intervention from the more general effects of protocol guideline care. The authors conclude that nurse-led work-site care is acceptable, although almost half of those eligible declined to take part in the trial, suggesting that acceptability may be low, although drop-outs due to dissatisfaction were low at 14/232.

Logan (1983)^{119,120}

This trial compared the use of occupational health nurses (OHNs) employed in monitoring the care of hypertensive patients using protocols, aids to adherence, and regular visits with regular care of work-site employees aged 30–69 years. Of 213 eligible employees, 194 agreed to take part and were randomly allocated to either intervention. At 1 year, outcomes were assessed by independent researchers, and showed that DBP had fallen in both groups: –10.5 (standard error 1.1) versus –7.7 (standard error 1.1) ($p = 0.07$) for OHN and regular care, respectively. Adherence was similar in both groups at 55%. The costs per patient for OHN and regular care were US \$404 versus US \$250, respectively, and the incremental cost-effectiveness of OHN was US \$54 per 1 mmHg DBP reduction per year, which was higher than the basic cost-effectiveness ratio of US \$33 per 1 mmHg for regular care. The authors conclude

that OHN monitoring is neither clinically effective nor cost-effective.

Baird (1984)²¹

Patients were drawn largely from family physicians in 10 centres throughout Canada. A total of 289 mild to moderate hypertensive patients already controlled on β blocker treatment were randomised to either once or twice daily doses of a β blocker. Patients were followed for 10 weeks, and tablet counts were used to assess adherence, and blood pressure was measured to assess efficacy. At 10 weeks, there were no differences in final SBPs (139 versus 141 mmHg in the once- and twice-daily groups, respectively) although both groups showed a decline in blood pressure over the follow-up period. Adherence, measured conventionally as the percentage taking at least 80% of the prescribed medication over the whole study, was 96 versus 90% in the once- and twice-daily groups, respectively ($p = 0.06$) but when the more stringent criterion of 90% of tablets taken was used, adherence was 92.8 versus 81.5% for the once and twice daily groups, respectively ($p = 0.01$). Interestingly, the distribution of urine metoprolol did not differ between the two groups.

Becker (1986)¹⁰³

Participants were predominantly middle-aged black women who were attending a community health practice but had poor diastolic control (i.e. 90+ mmHg V). Pills to be taken at the same time were all sealed into a single blister labelled with the day of the week and time of day to be taken. Twenty-eight consecutive doses were provided in a perforated strip. Control group medication was provided in conventional separate vials labelled with the drug name, dosage, instructions and the physician's name. Between pre-enrolment and baseline assessments, both the intervention and control groups had improved blood pressure levels, suggesting non-specific effects of expecting to take part in a trial. After 3 months, 72% had a DBP below 90 mmHg in the intervention group, compared with 55% in the control group; however, self-reported adherence was similar (56 versus 54%), and similar proportions were taking 80%+ of their pills (84 versus 75%).

Nessman (1980)¹²²

Of 675 routine hypertension outpatient clinic attenders, 52 non-compliant patients (only one woman) who also had poor blood pressure control were randomised to either a nurse-led clinic or a patient-led clinic (intervention). The patient-led clinic nurses and a psychologist encouraged patients to take responsibility for their

management, measure their own blood pressures, and select drugs and doses using a protocol which was also used in the nurse-led control clinic. Outcomes were measured at 8 weeks and 6 months. Net DBP change in the intervention group was greater than in the control group at 8 weeks (17.2 versus -9.3 mmHg). Pill counts were correct in 88 and 62% of intervention and control group patients at 8 weeks respectively. Attendance for weekly training sessions was also better, on the whole, for intervention patients. The authors conclude that patient-led care may offer substantial benefits over traditional nurse-led clinics.

Webb (1980)¹²³

Of 217 hypertensive patients attending a rural health clinic, 150 uncontrolled patients diagnosed for at least 1 year, on medication and aged between 20 and 80 years, were randomly allocated to one of three groups for 3 months: education, individualised counselling or standard care. Follow-up was carried out for 18 months but the majority of outcomes were assessed at 3 months, post-intervention. Unfortunately, there were substantial post-randomisation losses to some groups such that data are only presented on 37 education patients, 31 counselling patients, and 55 standard treatment patients. Although baseline measurement of variables was similar in these groups, substantial bias may have occurred. However, groups 1 and 2, with the biggest losses, had higher DBPs at the baseline. Adherence, measured by clinic attendance and by bringing medications to the clinic, did not differ between the groups, and was high. Pill counts were made but not reported. Net differences between the education group and the counselling group were -3.3 and -2.3 mmHg, respectively, at 3 months, and were not statistically significant. However, differences were reported to be greater at 15 months, and statistically significant, although net changes show very similar patterns: -3 and 10.7 mmHg for education and counselling, respectively. The big advantage for counselling was not apparent at 9 or 18 months, and suggests the effect is spurious and related to selection bias.

Takala (1979)¹²⁴

Of 1245 screenees attending a community health centre, a total of 202 were found to have formerly undiagnosed hypertension (159/94 < 50 years and 169/104 > 50 years) and were randomised to either an improved service requiring six visits in 1 year including written instructions, personal blood pressure follow-up card, and invitations for follow-up among defaulters or usual care. The findings are presented in a somewhat misleading way in the paper as substantial drop-outs occurred in both

groups (new service 10% versus usual care 18%, $p < 0.01$). Not all patients were put on treatment and not all finished the study. In the paper, the denominator used is those started on treatment which results in significant differences in those achieving a 10% reduction in blood pressure and improved control by 1 year. Recalculating these effects using those who finished the study at 1 year (i.e. those in whom the outcome can be assessed) shows no difference between groups. Mean reductions in blood pressure also show very little difference: $-3/-3$ mmHg for those under 50 years and $-3/-5$ mmHg for those over 50 years. The authors' conclusion that the new service improved adherence as evidenced by reduced drop-outs appears secure, but effects on control are not established.

Gonzalez-Fernandez (1990)¹²⁵

In this study, 59 hospital in-patients already on antihypertensive treatment but admitted for an unrelated condition were randomised to either an in-hospital education programme or a control group. The intervention focused on knowledge of blood pressure, effects of diet, exercise and adherence with medication, and was completed over 2 days in hospital. Outcomes were assessed at 8 weeks, but unfortunately 7 out of 29 and 5 out of 30 patients were lost from the control and intervention groups, respectively. Massive net reductions in blood pressure of $-24/-8$ mmHg were reported for the intervention group owing to a large 10 mmHg rise in the control group SBP. The authors suggest this occurred because of lack of access to medication and a low-salt diet in the control group following discharge from hospital. Adherence was reported to be better in the intervention group (96% versus 36% reported adherence to medication) but data on pill counts were not reported.

Kerr (1985)¹²⁶

Work-site intervention was based in large newspaper and telephone companies using occupational medical services. A total of 116 staff volunteered to take part who were all hypertensive patients on regular treatment. They were randomised to four groups: control ($n = 29$); education and self-monitoring of blood pressure ($n = 26$); self-monitoring of blood pressure ($n = 30$); and education only ($n = 31$). Interventions took place on a single day, and participants were asked to return each month, and the final follow-up was at 3 months. The baseline DBP was lowest in the control group but not significantly so. Adherence was based on self-reports of the proportions achieving 100%, > 90%, > 80% and < 80%, and was compared with tally sheets kept by participants.

Unfortunately, between a third and a half of all participants failed to provide adherence information at 3 months and were classified as drop-outs. Of those who did give information, all intervention groups involving self-monitoring showed a higher proportion reporting 100% adherence. Curiously, the drop-out rates for blood pressure outcomes were much lower, ranging from 17 to 21%, and the numbers measured at the baseline differ between tables in the paper. All groups showed a reduction in DBP, and this was greatest for the education-only group, but differences were not significant.

Powers (1979)¹²⁷

Participants were drawn from a wide range of health care facilities, but all were on antihypertensive treatment. Of these, 160 were randomised in a factorial design to four groups (directiveness of nurse; emphasis on self-responsibility plus self-measurement of blood pressure; emphasis of negative consequences; number of meetings) with a high and low option within each group. This resulted in 16 allocation groups, allowing for all feasible combinations. Adherence was assessed by goal attainment, which was graded by the nursing staff who provided the interventions, and blood pressure control was assessed by the same nurses. Patients allocated to self-responsibility plus blood pressure measurement and those having more meetings showed a significant increase in achieving medication goals. All patients tended to improve their blood pressure. Results are all presented as regression coefficients rather than actual values owing to the complex analysis carried out to identify the main and interaction effects.

Asplund (1984)¹²⁸

Hospital outpatient hypertensive patients already on treatment with a β blocker and a thiazide diuretic and well controlled were randomised to a single combination tablet ($n = 80$) or to two tablets ($n = 80$) in a crossover design, each phase lasting 4 months. It is necessary to assume that there were 15 drop-outs from each group although this is not clearly stated in the paper but seems likely. Self-reports of 100% adherence on one tablet for both groups were 51% ($((33 + 33)/(65 + 65))$), which was validated by pill counts and shown to be accurate for 42% overall. Adherence on two tablets is only reported for the group which received two tablets after the crossover. In this group, 52% ($34/65$) claimed 100% adherence, and compared with pill counts, this fell to 36% ($23/65$), which is not a significant difference. Blood pressures fell by $-4/-0.2$ and $-5.7/-3.7$ mmHg in the one-tablet and two-tablet groups, respectively, during the initial phase of the trial. Following the crossover, much

smaller differences were observed: $-1.4/-1.4$ versus $-0.3/-1.9$ mmHg in the one- and two-tablet groups, respectively. It would appear that taking part in the study resulted in both groups having a lower blood pressure but this effect was not altered by the subsequent change in the number of tablets following the crossover. Overall, it appears that adherence was no different either.

Rehder (1980)¹²⁹

Hospital clinic-treated hypertensive patients were randomised to four groups: control ($n = 25$); disease and medication counselling ($n = 25$); date/dose medication container ($n = 25$); and counselling plus medication container ($n = 25$). Intervention was monthly for 3 months, and outcomes were assessed at 3 months. There were considerable differences in blood pressure at the baseline between the groups. Adherence was assessed by doses taken/doses prescribed $\times 100$, by appointments kept and numbers returning containers. All groups achieved very high pill taking adherence (85%) with no significant differences between groups, but a trend was noted for those using the medication container to have higher adherence. Data on blood pressure are only provided in a figure, but appear to show that those receiving counselling and the medication container had significantly lower DBP at 3 months. However, this group had the highest baseline blood pressure, and the effect may be a regression to the mean phenomenon. It is not clear whether there was bias in blood pressures measured by clinic nurses or by pharmacists at the 3 month outcome.

Saunders (1991)¹³⁰

Hospital outpatient department attenders in Soweto, South Africa, were stratified into newly diagnosed hypertensive patients and infrequent outpatient department attenders, and randomly allocated to written reminders, patient-held records and field worker visits in necessary ($n = 110$) versus usual care ($n = 114$) over a 6 month period, with both groups advised to be seen at the outpatient department every 4 weeks. Outcomes were assessed at a home visit, but the assessor was not blind to the group allocation. Adherence was assessed by days of treatment received from the clinic and pill counts at the home visit. The percentages receiving more than 80% of their needed medication were significantly higher in the intervention groups than in the control groups for both new and infrequent attenders (59 versus 29% and 87 versus 42% for new and infrequent attenders, respectively). Pill count data are difficult to interpret because of drop-outs, and could only be done in those where the remaining tablets were available to be counted

and where tablets obtained from other sources were known. In the new patients, pill adherence of 80%+ of tablets was achieved by 31 versus 15% (p not significant) of the intervention and control groups, respectively. For infrequent attenders, the pill adherence proportions were 68% versus 37% ($p < 0.01$), respectively. DBPs did not show very marked differences although the proportion of new patients with a DBP below 80 mmHg was higher than in the control group. Drop-outs were also lower in the intervention groups than the control groups. The authors conclude that intervention was associated with better adherence in both groups and improved blood pressure control in new patients.

McKenny (1992)¹³¹

This paper reports two distinct trials but uses the same patients to test the interventions. Trial 1 compares drug bottles fitted with a electronic adherence aid cap ($n = 36$) versus normal drug bottles ($n = 34$) among an elderly retirement community and a primary care group of antihypertensive-treated patients (mean age 73 years). The effects of intervention were measured over 12 weeks, and adherence estimated by both consumption of 80%+ of pills and the pills taken/pills received percentage. Large improvements in adherence were seen: the mean adherence rate was 95 versus 78% in the intervention and control groups, respectively. Blood pressure also showed large net falls in the intervention group: $-4.8/-8.5$ mmHg. Trial 2 randomised the same patients to four groups: control ($n = 17$); electronic cap ($n = 18$); electronic cap plus patient-held record ($n = 18$); and electronic cap, record and self-measurement and recording of blood pressure ($n = 17$). The trial was again over 12 weeks. Medication adherence was only reported as mean adherence, but was much higher in all the intervention groups (79% versus 94, 99 and 100% in the control versus other groups). Blood pressures also showed large changes, and actually went up in the control group, which led to very large net falls: electronic cap, $-12.3/-19.3$ mmHg; cap plus record $-15.5/-13.8$ mmHg; and cap plus record plus self-monitoring, $-19.5/-12.7$ mmHg. No drop-outs were reported. It should be noted that because the same patients were used in the second trial, half of them had already been exposed to use of the cap, and a quarter of them ended up in the control group. Evidence strongly supports the use of the electronic cap.

Morisky (1985)¹³²

In this randomised factorial design trial, 400 predominantly black hypertensive

patients attending the Johns Hopkins outpatient department were allocated to one of seven groups, including one of more of the following interventions: exit interview, family support, small group meetings or control. Fifty patients were allocated to each of the eight groups. Intervention was for 3 years, and follow-up continued for a further 2 years, when outcomes were measured. This paper contrasts the main effects of family support ($n = 200$) with no family support ($n = 200$). Adherence was assessed by self-reports, by attendance and by drop-outs. Blood pressure control was assessed simply by reporting the percentages of patients achieving control, which was defined according to age. Drop-outs were considerable, and outcomes are presented on only 290 (72%) of those randomised: family support ($n = 144$) and no family support ($n = 146$). Self-reported pill taking on a scale of 0–4 (low–high) was lower in the family support group (mean 0.9 versus 1.9) but attendance was better, with 73 versus 33% turning up to more than 79% of appointments in the family support and control groups, respectively. Drop-outs at 5 years were similar in the two groups, at 28 and 27% for the family support and control groups, respectively. Blood pressure control was also better in the family support groups (77 versus 51%). The authors conclude that family support leads to better appointment keeping and better blood pressure control. It is curious that self-reported adherence with medication was so much worse in the family support group, but this is not commented upon and may be a reflection of the inaccuracy of self-reports of adherence.

Details of trials of self-monitoring as a means of improving blood pressure control (see Table 21)

Carnahan (1975)¹⁴⁸

Self-monitoring of blood pressure was investigated in a group of patients starting treatment for essential hypertension. Home blood pressure readings were recorded and brought to clinic visits but only measurements made at the clinic were used in analyses. There were no group differences in initial DBP or SBP. SBP was significantly lower ($p < 0.05$) in the intervention group for four of the 30 day time periods used in analysis. At the end of the study, SBP had declined in both the control and intervention groups. The net group difference of -7 mmHg was considered by the authors to be very modest. Possibilities given for the difference in blood pressure included self-monitoring having a positive effect on patient adherence with medication, the provision of

feedback enabling participants to lower their blood pressure (as in a biofeedback-type mechanism) or the habituation of patients to blood pressure measurement. The authors found self-monitoring of limited value although acknowledge its usefulness in managing particular patients.

Haynes (1976)¹⁰⁴

The effect of an intensive programme was investigated in a group of steelworkers whose blood pressure had not come under control in an earlier trial of education and work-site care.¹¹⁶ DBP decreased in both groups, significantly so in the experimental group ($p < 0.001$). There were, however, no significant differences in blood pressure between groups at the beginning or end of the study ($p > 0.05$), and the net changes were not significant. The decrease in blood pressure achieved in the experimental group in this study was interpreted as showing that a very intensive regimen can salvage an important proportion of hypertensive patients who are neither at goal blood pressure nor compliant with therapy 6 months after starting treatment. However, the authors note that the intervention group patients received more attention than the control group patients, which could have itself contributed to adherence and control of blood pressure. Furthermore, although there was no contact between the programme coordinator and physicians, the physicians prescribed, on average, more vigorous therapy to the intervention group than to the control group. Finally, 39% of the patients in the control group increased their adherence, which might have been expected to lead to greater control.

Johnson (1978)¹¹⁷

The independent effects of two interventions, self-recording of blood pressure and monthly home visits, were investigated in a community group of hypertensive patients. After 6 months of intervention, blood pressure fell by similar amounts in all four groups. However, *post hoc* significant interactions were found between participants having trouble remembering to take medication at entry and each of the interventions ($p = 0.03$ for self-recording and $p = 0.004$ for home visits). The change in blood pressure was slight for those who were not having trouble remembering, but greater for those who said they had such a problem. Patients were treated by their physician independently of the study, and there was no standardised therapeutic regimen, but there were no significant differences in changes in therapeutic regimen between groups.

Soghikian (1992)¹⁴⁹

Ninety-four physicians in four medical centres were invited to refer patients with uncomplicated

hypertension for participation in a trial of home blood pressure monitoring. The baseline blood pressure was similar for the two groups. At follow-up at 1 year, SBP had decreased slightly in the intervention group and increased slightly in the control group. DBP had decreased slightly in both groups. SBP was significantly lower in the intervention group but DBP was similar. After adjusting for age, race, sex, baseline blood pressure and baseline use of antihypertensive medication, SBP at follow-up was significantly lower in the home group. Falls in SBP were more marked in men than in women. Cost analysis showed the home care to be US \$37.00 (i.e. 29% less) lower than usual care. The authors conclude that home care can reduce costs without compromising blood pressure control.

Stahl (1984)¹⁵⁰

The effects of two interventions, self- and family monitoring of blood pressure, were investigated in patients identified from a community screening programme and hospital out-patients and emergency rooms. Participants in the monitoring groups were instructed in blood pressure measurement, but no information is given about how often they measured blood pressure or whether any note was made of results. All patients were seen by a physician every 2–4 weeks until blood pressure was controlled, then every 2–4 months. Analyses were performed on 6-monthly after the start of treatment. After 36 months, there were no group differences in DBP, change in blood pressure or percentage of patients at goal blood pressure. However, at 6 months the self-monitoring group had a greater reduction in blood pressure than either the family monitoring or control group. The authors say that the drop-out rate from the control group and self monitoring group was significantly higher than from the family monitoring group, but the data are confused since numbers given in the tables do not match up. With such high levels of drop-outs, it is difficult to interpret the observed findings. Allocation to interventions was randomly determined for the first patient each week and thereafter was carried out sequentially for the remainder of the week.

Details of trials examining the effects of patient education in improving blood pressure control

(see *Table 22*)

Billault (1995)¹⁵¹

The effects on the health of a personal medical record was compared with routine care, to determine whether hypertensive patients could play a part in their own care and whether their

participation had a measurable effect on their risk factors for cardiovascular disease. At follow-up, the number of patients who attended, were smokers, exercised regularly or had adherence problems, and the fall in blood pressure, were comparable for both the intervention and control groups. Of the 82 intervention group participants who attended the follow-up, 44 had completed the personal record as planned. Within the intervention group, the proportion attending follow-up was greater among users of the record than non-users ($p < 0.01$). Users also visited their practitioner slightly more often ($p < 0.03$), had a slightly greater decrease in SBP and better adherence than non-users. Approximately half the patients who were given the personal record used it as planned, which the authors suggest may be an overestimate for the general population, since these patients sought care in a specialised clinic which might be a characteristic of better record use. However, it is also possible that patients' participation will be greatest at the initial diagnosis of disease, in which case the 50% demonstrated in this study could be an underestimate of the general population.

Fielding (1994)¹⁵²

This study investigated the effectiveness of a work-site blood pressure control programme. Participants in the intervention group received monthly 10 min individual work-site counselling from trained counsellors and regular mailings. Follow-up measurements were made after a year. At the end of the study, blood pressures had fallen to a greater extent in the intervention group than in the control group ($p < 0.05$). After adjustment for baseline differences in age, sex and initial blood pressure, the difference in SBP, but not DBP, remained statistically significant. The analyses did not consider the significantly greater use of drug treatment among those allocated to the intervention group. It was concluded that this programme, directed at high-risk individuals, could be beneficial when incorporated with the comprehensive health promotion programme also operated at the work sites.

Hypertension Detection & Follow-up Program (1979)^{9,10,153,154}

This very large trial was set up in 14 communities throughout the USA. An initial screening phase involved 158,906 people aged 30–69 years, of whom 22,650 had a DBP of 95+ mmHg and were invited for a second screening. Of these, 11,237 had a DBP 90+ mmHg, and 10,940 met criteria for randomisation to either stepped care or referred care. Randomisation was by strata of blood pressure. Stepped care was a comprehensive and free

hypertension service which involved patient education in addition to protocol-led care. Referred care was usual care provided by primary/family physicians, and was used as the control. The main outcomes were blood pressure control and mortality. The trial showed a substantial effect on mortality at 5 years. Blood pressure control was better in the stepped care than in the usual-care groups. Overall, 80.4% of stepped-care participants were actively engaged with the programme. This study cannot disentangle the effects of patient education from other aspects of comprehensive care, in particular use of protocols and free care.

Martínez-Amenós (1990)¹⁵⁵

This study was designed to assess the efficacy of individual and team education in hypertensive patients treated in local primary care centres. The proportion of patients with controlled blood pressure (< 160/95 mmHg) increased in motivated patients in both individual- and team-educated groups ($p < 0.05$). There was no significant change in the control group, and no significant change in either the individual-education or control group in non-motivated patients. Follow-up was only 2 months after the intervention, and it cannot be determined whether improvement would be sustainable in the long term.

Morisky and Levine (1979)¹⁵⁶⁻¹⁵⁹

The potential of allocating patients the most appropriate form of health education treatment was investigated by randomising participants to one of all possible combinations of three health education interventions. The participants were predominantly poor, black women. This study, because of randomisation of a relatively small number of patients to eight different groups, and the high levels of drop-outs (25%), is difficult to interpret. Overall, the seven groups allocated to some form of education tended to have better control and also experienced lower mortality rates. Many publications based on the same data set have been produced which further confuses the overall findings.

Mühlhauser (1993)^{161,162}

This study investigated the influence of a structured hypertension treatment and teaching programme in patients with essential hypertension. The programme comprised 4-weekly teaching sessions and self-monitoring of blood pressure. Follow-up measurements at 18 months showed blood pressure to have decreased slightly in both groups, and the decrease in SBP and DBP to be greater in the intervention than in the control group ($p = 0.07$ and 0.02 , respectively). At the time of follow-up, only 46 of the 86 patients in the intervention group

had participated in the programme within the time limits of the study protocol. The change in blood pressure values within the intervention group was most prominent in those patients who participated in hypertension treatment and teaching programme, but due to small patient numbers the differences between subgroups did not reach statistical significance. It was concluded that the introduction of a structured treatment and teaching programme into general practices led to better control of blood pressure, and that the programme was effective despite only half of the intervention group patients completing the programme. The lack of improvement in blood pressure in the control group demonstrated that increasing physician awareness was insufficient to be of benefit. The patients in this study may not be representative of all patients with hypertension but appeared to be an ideal target group for such a programme.

Roca-Cusachs (1991)¹⁶³

The value of a patient education programme was investigated in a group of hospital hypertensive patients. The intervention group received two talks and a personal tutorial. There were no differences between intervention and control group blood pressures at the beginning or end of the intervention phases. At 6 months follow-up, both intervention and control groups had large reductions in blood pressure (intervention, $-16/-8$ mmHg; control, $-18/-9$ mmHg). However, substantial drop-outs (over 30% occurred in both groups). The authors concluded that the education programme was not successful in improving hypertension control.

Sackett (1975)¹¹⁶

The influence of two interventions, the extra convenience of a work-site clinic during work hours and an educational programme designed to give facts about hypertension, on adherence and achievement of goal blood pressure were investigated. At the 6 month follow-up, 23% of participants with access to the work site clinic were 'compliant' and at goal blood pressure, compared with 19% of those without augmented convenience. Of those undergoing mastery learning, 24% were 'compliant' and at goal blood pressure, compared with 19% of those not learning. These differences were not significant.

Takala (1983)¹⁶⁴

This study investigated participants who were identified as hypertensive in a screening programme and whether sending written information concerning hypertension encouraged individuals to seek treatment more than only sending a letter advising that they do so. At the 2 year follow-up, the decrease in SBP was significant in both groups ($p < 0.05$)

although that in DBP was not. (Other outcomes: there was no significant difference in proportions seeking treatment in each group (55 of 71 in the intervention group, 56 of 69 in the control group); initiation of treatment was equally common among those seeking care from each group (85% of the intervention group, 84% of the control group), as was continuation of treatment (intervention group 89% and control group 79% of those who began treatment.) Among those who did not seek treatment, rates of high blood pressure were similar for both groups (79% of the total). Of those started on therapy, 49% of the intervention group and 38% of the control group were at goal blood pressure, a difference which was not significantly different. A similar proportion of the total number of participants at follow-up were normotensive, 44% of the intervention group and 35% of the control group. It seemed that written information explaining the nature of hypertension and stressing the importance of its treatment did not lead to a significant increase in seeking treatment over simply advising patients to seek treatment.

Tanner (1981)¹⁶⁵

The effect of a patient education programme was tested in patients identified from lists at a family practice. Results are not clearly described, and it is unclear which level of significance is applied. At entry to the study, DBP appears similar in the intervention and control groups, but no statistical test results are reported for this comparison. DBP is also similar between groups at the end of the study ($t = -0.48$, $df = 28$). The authors found a significant decrease in DBP in the intervention group ($t = 2.02$, $p = 0.05$) and also in the control group ($t = 1.83$, $0.05 < p < 0.1$). The results indicated that structured teaching about essential hypertension was not effective in assisting patients in the intervention group to significantly lower their mean DBP over those in the control group.

Watkins (1987)¹⁶⁶

The effect of an information and medical record booklet on patients' knowledge about hypertension and its management as indicated by their blood pressure was tested in six general practices. One year after the booklet was mailed to patients there was no significant difference in blood pressure between groups, either with or without adjustment for stratifying variables. Several possible reasons were suggested to explain this observation. In the 76% of patients measured prior to the study the overall control of blood pressure was satisfactory, leaving little room for improvement. Overall knowledge of hypertension was also satisfactory, but this was assessed at the end of the study, not the begin-

ning. Identifying patients through prescriptions may have identified those who attended for treatment more regularly and were more compliant with better control of blood pressure. However, comparison of hypertensive patients from the chronic disease registers rather than prescription records did not show different results.

Weiner (1990)¹⁶⁷

Patients who attended a nurse-managed hypertension clinic as part of a hypertension control programme were compared to patients receiving care from their physicians. After 3 months, the decrease in maximum and average SBP was found to be significantly greater in the intervention group than in the control group ($p = 0.02$). No significant difference in decrease in DBP was seen between the groups, which is suggested to be due to the fact that the mean pretreatment DBP was only 92.5 mmHg. No blood pressure data were presented in this short report.

Zismer (1982)¹⁶⁸

The efficacy of a patient education programme in reducing the blood pressure of hypertensive patients was tested. The programme focused on pill taking, appointment keeping and dietary sodium, while stressing taking responsibility for one's own care. At the baseline, SBPs and DBPs were similar in the intervention and control groups, but at the 6 month follow-up they were lower in the intervention group ($p < 0.05$). The change in blood pressure was significantly greater ($p < 0.01$) in the intervention group than in the control group. No group differences in numbers of follow-up visits were found. This study indicated that an educational-behavioural approach to the management of hypertension in a private medical practice can be effective. There is, however, no comment on age differences between groups (45 versus 56 years) or differences in average blood pressure at the first clinic therapy (undefined) is made. Changes in antihypertensive medication were made for some patients in both groups, but details are not given.

Details of trials examining the effect of professional education on improving blood pressure control

(see *Table 23*)

Logan (1979)¹¹⁸

This study examined the influence of work-site care, provided in company time as compared with usual physician care in a group of predominantly white collar workers. At the end of 6 months, blood pressure in both groups had decreased significantly,

the mean reduction in the work-site group being significantly greater than that of the usual care group. In addition, more patients in the work-site group reached goal blood pressure regardless of whether the physician-determined goal, or a goal of 90 mmHg or of 95 mmHg was applied in analyses. The proportion of patients deemed to require therapy was similar in both groups, but the method of treatment differed. After 6 months, more of the work-site group were on medication and had been prescribed medication at some point during the study. Non-drug therapy was not used in the work-site group but prescribed for 28.4% of patients in the usual care group, which included 25% of moderate hypertensive patients. It was concluded that provision of care at work significantly improved blood pressure control, probably because access to care was more convenient, and therapy more vigorously prescribed. However, even amongst patients on drug therapy, the reduction in blood pressure was greater in the work-site group. It is impossible to separate the effects of guidelines and goal setting from easy access of care, and this is not discussed.

Evans (1986)¹⁶⁹

The effect of a continuing-education programme mailed to primary care physicians on the control of hypertension was examined. There was no significant difference in SBP or DBP between intervention and control groups at the beginning or end of the study. However, over the study period, blood pressures decreased considerably, and the proportion of patients prescribed medications increased, by similar amounts, in both groups. The study showed no influence of a mailed continuing medical education programme on the practices of physicians or control of blood pressure in hypertensive patients. The authors suggest that this might be due to information being transmitted to physicians but forgotten before being implemented, that physicians in both groups were performing as well as permitted under current circumstances and there was little room for improvement, or that the manner of recruiting and referring patients overwhelmed the effect of the educational programme. The results are believed to be generalisable to similar Med Care settings since the patients were selected to be representative of their communities and all patients' physicians were included in the study.

Gullion (1987)¹⁷⁰

This study investigated the effect of physician medical education on the control of hypertension. Physicians were stratified according to the percentage of patients whose DBP was in control, and the physician's ethnic group and speciality, and randomised to one of four groups. Physicians

received medical education, behavioural education, both or neither, for a period of 1 year. At the end of the study there were no significant group differences in mean DBP for all patients, patients whose blood pressure had been out of control at the baseline, or in the percentage of patients whose blood pressure was in control for each physician. These results were adjusted for baseline blood pressure but the statistical analysis is not clearly described. The authors conclude that the educational intervention was insufficient to demonstrate an effect on blood pressure, which may have been due to an increase in physician knowledge and treatment of hypertension in recent times, or to the fact that the sample was composed of volunteers who may have been highly motivated.

McAlister (1986)¹⁷¹

Sixty family doctors were stratified and randomised to an intervention group, in which they were provided with computer-assisted management of hypertension, or to a control group. Ten doctors dropped out, and the analysis is based on the remaining 50. Although doctors were randomised, outcome variables were associated with patients. Rather than analysing results from individual patients, one 'score' was derived to represent all observations from each practice. For continuous variables the median observation was chosen as the practice score. The mean score (mean of practice medians) was used as the summary statistic for each of the intervention and control groups. Regardless of the number of patients, individual observations were reduced to 50 practice scores, which limits the power to detect differences and probably underestimates the significance of the observed differences. Drop-out patients, defined as those not seen for 3 months or more at the end of the trial included 38% of the intervention group and 42% of the control group. Using the 10% level of significance, hypertensive patients in the intervention group were followed up for longer than those in the control group, 199 versus 167 days ($p < 0.09$). Moderately hypertensive patients (DBP > 104 mmHg) in the intervention group showed a slightly greater change in blood pressure, -22 mmHg, than their control group counterparts, -17 mmHg ($p < 0.06$). Other differences did not reach significance.

Details of trials of miscellaneous interventions for improving blood pressure control (see *Table 24*)

Brook (1983)^{172,173}

This study examined the effect of various health insurance plans on blood pressure

control. The insurance plans were grouped into four categories, providing either free care or cost-sharing, in which the family paid 25, 50 or 95% of health bills. Seventy per cent of families participated for 3 years, and 30% for 5 years. Results are based on 3495 adults who completed the study and were screened at exit. Based on 60% of participants that were screened at entry, DBP was similar by plan ($t = -1.9$), as was the prevalence of hypertension ($t = 0.9$). Differences were larger in the low-income (lowest fifth) hypertensive patients; those on the free plan had DBPs an average of -3.5 mmHg lower than those on pay plans. The difference of 1.1 mmHg in the high-income group (top 40%) was not significant. The authors conclude that free care resulted in more contact with the health system (7% of patients on the cost-sharing plan did not visit their physician, compared with 2% of those on the free plan, $p < 0.01$) and thus better detection and treatment of currently untreated hypertensive patients. This study excluded severely disabled persons eligible for Medicare and all those over the age of 61 years. Data from drop-outs were analysed and reported elsewhere, showing that differences by plan should not be affected.

Cummings (1985)¹⁷⁴

The effect of an appointment reminder system on appointment keeping and blood pressure control was evaluated. Average individual appointment keeping rate was significantly higher in the intervention group (87%) than in the control group (79%) ($p < 0.01$), but appointment keeping rates would have been influenced by drop-outs, which is not accounted for. Since the drop-out rate was 46% lower in the intervention group, it was concluded that reminder cards and follow-up of missed appointments were an effective way to keep hypertensive patients in care. Blood pressure was similar at the beginning and end of the study in both groups, but the end-of-study blood pressure was not obtained in 8% of the intervention group, and 14% of the control group, and these patients had a higher than average baseline blood pressure. It appeared that the reminder system was most effective in **maintaining** blood pressure control; among patients whose blood pressure was controlled at the baseline, 51% in the reminder group and 39% in the control group remained under control at the end of the study (not significantly different, $p > 0.05$). Of patients who were uncontrolled at the baseline, 75% of the reminder and 65% of the control group were controlled at the end of the study ($p > 0.05$).

Earp (1982)¹⁷⁵

The effectiveness of two social support programs in lowering blood pressure was compared to each other, and to a control group. One programme involved home visits by health practitioners, and the other, home visits and involvement of a 'significant other' in the home visits and in home blood pressure monitoring. After 1 year, the proportion of patients with uncontrolled blood pressure (DBP ≥ 95 mmHg) had decreased in all three groups. At the end of 2 years, the control group had regressed somewhat, with the proportion of patients with uncontrolled blood pressure rising, whereas in the intervention groups, the proportion continued to decrease. There was no difference between the two intervention groups. Thus, patients with home visits were more likely to have controlled blood pressure than those without, but involvement of a 'significant other' did not appear to confer additional benefit. Several reasons are suggested for this finding, including possible bias in the follow-up sample and informal involvement of family in the home visits only group. The very high levels of drop-outs make it more likely that the findings are due to selective loss of those with poor blood pressure control, rather than a delayed effect of social support.

Jewell (1988)¹⁷⁶

This study compared management of hypertension by a nurse in a 'hypertension clinic' with usual care by a doctor in practice. Both the nurse and doctor followed an agreed protocol determining patient treatment and frequency of attendance. Both initial and final blood pressure measurements were performed by the doctor. At the end of the study, group differences in SBP and DBP were not significant ($p < 0.05$). Net changes were large but are not commented upon. The patients in the doctor group had substantially higher blood pressures at the baseline, suggesting that some of the fall in the doctor group may be simply due to regression to the mean. Patients in both groups demonstrated a similar frequency of attendance and knowledge of medication, and expressed high levels of satisfaction with care received. It was concluded that a nurse is as good as a doctor in managing hypertension although possible shortcomings in the study were noted. About half the previously diagnosed hypertensive patients invited for review declined and therefore the study population may have been more compliant. The sample size was very small, and thus the rather large blood pressure differences in favour of the doctor may simply be due to chance.

Robson (1989)¹⁷⁷

The recording and follow-up levels of blood pressure were compared in two groups, one

managed by both a health promotion nurse whose primary task was the preventive care of adults and a general practitioner, the other managed by general practitioners alone. After 2 years, 93% of the intervention group and 73% of the control group had had a blood pressure measurement, with a significant difference ($p < 0.001$). The proportion of patients with hypertension or who had had fewer than three

readings in the hypertensive range but had not had blood pressure recorded within the preceding year was 97% in the intervention group and 69% in the control ($p < 0.001$). The results suggest that high levels of recording and follow-up of risk factors in general practice can be achieved with computer facilities and attention to responsibilities and organisation of care, even in adverse inner-city conditions.

Appendix 4

Excluded studies

Articles selected from the search but not included in the review are listed below.

Professional standards and patient adherence

- No control group: references 52,178–187
- Intervention not relevant: references 188–191
- Non-random allocation: references 192–194
- Non-parallel group design: reference 195

- No outcome data: reference 196
- Reviews: references 197–200

Blood pressure control

- No control group: references 201–215
- Intervention not relevant: references 216–218
- Non-random allocation: references 67, 219–249
- No outcome data: references 97, 250–259
- Review: reference 260

Health Technology Assessment panel membership

This report was identified as a priority by the Population Screening Panel.

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