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MILD HYPERTENSION

The known risks

The risks from untreated high blood pressure at even mildly elevated levels are well documented in quantitative terms. American insurance companies have since the inter-war years required a blood pressure reading from their prospective clients, and figures derived from their analysis of mortality rates according to initial blood pressure, based on a single reading, are shown in Table 1 (Society of Actuaries 1959).

These figures from the 'Build and Blood Pressure' study show that male mortality ratios (i.e. the ratio of actual mortality over the expected mortality for a healthy man) increase with each step upwards in both systolic and diastolic pressure. Table 1 (b) shows that for men an initial pressure of 162/100 Hg mm (which would not be considered seriously elevated by many clinicians) was associated with an expectation of death over the period of study about four times as high as that associated with an initial pressure of 120/80 Hg mm (i.e. a mortality ratio of 300 as opposed to 80).

Another perhaps clearer way of expressing hypertensives' excess risk of mortality is by analysis of life expectation. Figure 1 gives data from the experience of 26 American insurance companies over the years 1935-1954. (Metropolitan Life Insurance Company, 1961). It shows that both men, and to a lesser extent women (with their lower overall mortality rates), suffer a significantly diminished expectation of life. In this experience a man aged 45 with a blood pressure of 150/100 Hg mm could expect to live 11½ years less than a similar man with a pressure of 120/80 Hg mm or below. This is despite the probability that the vast majority of those in the study were symptomless at the time of measurement.

The excess mortality does not, of course, all come at the end of an otherwise 'normal life'. The marked reduction in average life expectancy is caused by a relatively small but significant number of early deaths, mainly from heart disease and to a lesser extent from stroke. Hence it cannot be argued that mildly elevated blood pressure merely reduces a person's expectation of prolonged retirement (which might not matter). What it does is to increase his chances of dying at a relatively early age. That is the reason why there has been recent concern about whether reducing a mildly elevated blood pressure also reduces the risk of early mortality. It is that question with which this *Briefing* is concerned.

Table 1 *Mortality according to variations in initial blood pressure 'Build and Blood Pressure' study. Society of Actuaries 1959. Standard and sub standard issues combined. Mortality Ratios.*

a) Men aged 15-39 at issue

Systolic BP mm Hg	*Diastolic BP mm Hg*				
	80	85	90	95	100
120	95	105	115	—	—
132	105	125	150	190	—
142	130	155	185	225	275
152	160	185	225	275	325

b) Men aged 40-69 at issue

Systolic BP mm Hg	*Diastolic BP mm Hg*				
	80	85	90	95	100
120	80	95	110	130	—
132	105	115	130	150	175
142	130	145	165	190	215
152	160	180	200	225	250
162	195	215	235	260	300

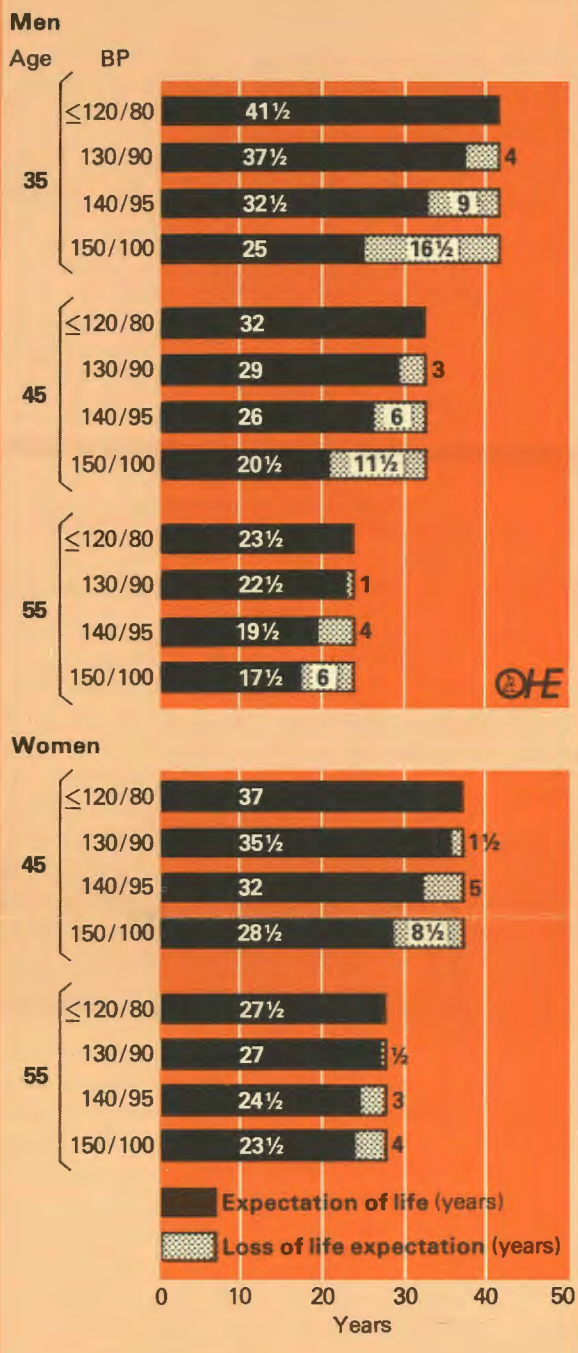
Note For all practical purposes, the population represented by insurance company data was an untreated one. This is because people with a pressure over 160/100 were excluded from life insurance altogether and probably no one with pressures below that level would have been given effective treatment over the years to which the figures relate.

The history of diagnosis and treatment

The diagnosis and treatment of hypertension can be traced back to the 1820s when Richard Bright noted, on autopsy, abnormalities in the hearts of some patients who had died with chronic renal disease[1]. He suggested, as one of the possible explanations, that there was an increased resistance to flow in the blood vessels. However, no instrument capable of measuring blood pressure in man was developed until the middle of the 19th century when Karl Vierordt introduced the principle of measuring the amount of counter pressure necessary to obliterate the pulsations in a peripheral artery in the arm. A number of

1 In fact Huang Ti (The Yellow Emperor) made the same observation about 2500 BC.

Figure 1 *Expectation of life associated with various initial blood pressure levels.*



Source: Blood Pressure: Insurance experience and its implications, 1961. New York. Metropolitan Life Insurance Company.

devices using this principle were developed and in 1896 in Italy, Riva-Rocci described an instrument which was in all its essentials the same as a modern sphygmomanometer. The main difference was the size of cuff. Riva-Rocci's cuff was only 4.5 cm wide but since this was found to give readings on the high side, 12 cm was eventually accepted as the standard width.

Up to this time only the systolic pressure (the pressure of the pulse of blood) was commonly recorded, but in 1905 a Russian named Korotkoff suggested a method of measuring the different phases of blood pressure which quickly gained acceptance and is now generally recognised as standard. The cuff is wrapped around the patient's arm and inflated to a pressure well over that necessary to obliterate the pulsations of the peripheral artery. As the cuff is deflated and the column of mercury drops, the first characteristic tapping sound is heard. This begins at the systolic blood pressure level and is due to the return of the pulse wave to the artery hitherto collapsed by the pressure of the cuff. A murmur develops at phase two but disappears at phase three when the initial pulse sound becomes louder. At the fourth phase the sound muffles. In Britain, this is still often taken as the diastolic level, the level of pressure where blood flow can take place through the artery throughout the entire cardiac cycle. The sound then disappears altogether. This is the fifth phase in which there is no obstruction at all to the blood flow in the artery. It is this point which is now taken in most studies to represent the diastolic pressure[2]. Thus the measurement of blood pressure has been a practical possibility throughout the 20th century, and in addition the main features of diseases associated with large changes in pressure levels were described and defined as early as the beginning of the 20th century.

However, despite the recognition of the implications of high blood pressure there was little that could be offered as a safe and effective means of lowering pressure even in severe cases. The only drugs available at the time of the first war were the nitrites but their transitory action was of no value for long term medication. In the inter-war years, the thiocyanates were widely used as antihypertensives but they were not very effective, the side effects were severe, and they soon lost favour with doctors. During these years when medical intervention was ineffective, surgical procedures were sometimes successful in lowering blood pressure. One such procedure was the removal of a diseased kidney which was responsible for the raised blood pressure. But the risks were high, the success rate only about a quarter according to one review of published cases, and the procedure was only relevant to a very small minority of very severely hypertensive patients. Great controversy arose over another surgical procedure intended to reduce pressure levels, surgical sympathectomy. This procedure developed to the stage where the whole of the thoraco-lumbar sympathetic chain was excised, but results were generally disappointing.

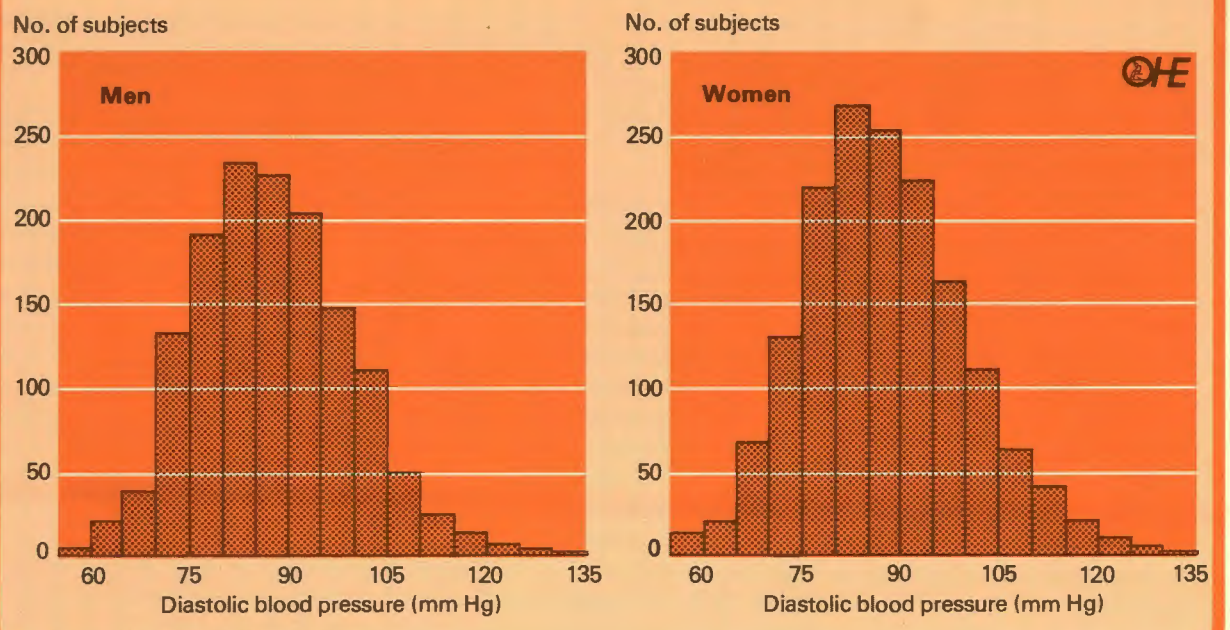
Attempts were also made to manage hypertension through restriction of salt intake. This did have some effect in lowering blood pressure, occasionally by significant amounts. The popularity of this form of treatment reached its peak in the 1940s but few seemed able to tolerate the virtually saltless dietary regime over a long period of time. Nevertheless in 1980 moderate restriction of dietary salt intake is once again being considered seriously as a possible means of treating mild hypertension. (Lancet Editorial 1980, b). However, no systematic trials have been undertaken to demonstrate its effectiveness.

In 1949 the ganglion blocking drugs were first introduced and effective treatment of severe hypertension became possible. Special clinics for treatment of hypertensives were founded in various parts of the world and reports from these indicated that the prognosis of malignant hypertension was much improved with ganglion blocking drugs. However, the severity of side effects and the need for strict control over their use meant that they were only a practicable form of treatment when complications had already set in and when life was immediately threatened. They could not be conceived as a preventive regime for the vast majority of people whose hypertension was as yet asymptomatic.

Several pharmacological developments in the late fifties and early sixties had the effect of extending the limit of effective and practical treatment to include asymptomatic hypertensives for the first time. First, in the early 1960s guanethidine and methyldopa were introduced. They were followed by others such as bethanidine, guanoxan and debrisoquine. By their selective action they avoid many of the unpleasant side effects associated with the ganglion blocking drugs. The regime is such that lifelong treatment can be contemplated with reasonable equanimity by a hypertensive whose alternative is a markedly more risky, if asymptomatic, existence. However, some important side

2 There is approximately 4-6 mm Hg difference in pressure between phases IV and V. This must be taken into account in interpreting clinical results.

Figure 2 *Distribution of diastolic blood pressure at primary screening of a population aged 45-64 in Scotland, 1972.*



Source: Hawthorne, Greaves and Beevers.

Table 2 *Proportion of Subjects aged 45-64 above Three Different Levels of Diastolic Blood Pressure at Primary Screening in 1972.*

	Number Examined	*Diastolic Blood Pressure (mm Hg)*		
		>90	>95	>100
Men	1,409	567 (40.2%)	367 (26.0%)	220 (15.6%)
Women	1,592	628 (39.5%)	407 (25.6%)	248 (15.6%)
Total	3,001	1,195 (39.8%)	774 (25.8%)	468 (15.6%)

Source: Hawthorne, Greaves and Beevers.

Table 3 *Prevalence of hypertension among adults at different ages*

Sex	*Age*	*Percentage with diastolic pressure of 115 or more*	*Percentage with diastolic pressure of 95 or more*
Male	35-	.5	5.3
	45-	1.2	12.7
	55-	7.1	33.0
	65-74	6.8	30.2
Female	35-	1.7	12.4
	45-	4.9	20.8
	55-	7.7	36.4
	65-74	9.7	66.0

Source: Derived from data from Hamilton, Pickering, Roberts and Sowry (1954).

effects still remain, particularly the tendency to orthostatic hypotension – for example, a sudden drop in pressure on standing up. This manifests itself as a feeling of faintness or weakness. This drop in pressure also occurs after exertion.

A second pharmacological development has been even more important in expanding the limits of effective, practicable treatment of asymptomatic hypertension. This was the introduction of the first potent oral diuretic, chlorothiazide, in 1957. Modern diuretics have fewer side effects, at least in the short term, and they have the great advantage that they do not lead to excessive falls in blood pressure on standing up. Over the past twenty years a wide range of diuretics has been developed, recently including frusemide and ethacrynic acid. Although they are not sufficiently effective on their own in the treatment of severe hypertension, they have become the treatment of choice in the control of mild asymptomatic hypertension.

Most recently, the beta blockers, as they are called, have been introduced originally for the treatment of heart disease. This new group of medicines have also proved valuable in the control of hypertension, and are increasingly being used as first line treatment instead of diuretics. However, most controlled clinical trials in the treatment of mild hypertension have used a diuretic as the standard treatment in the first instance[3].

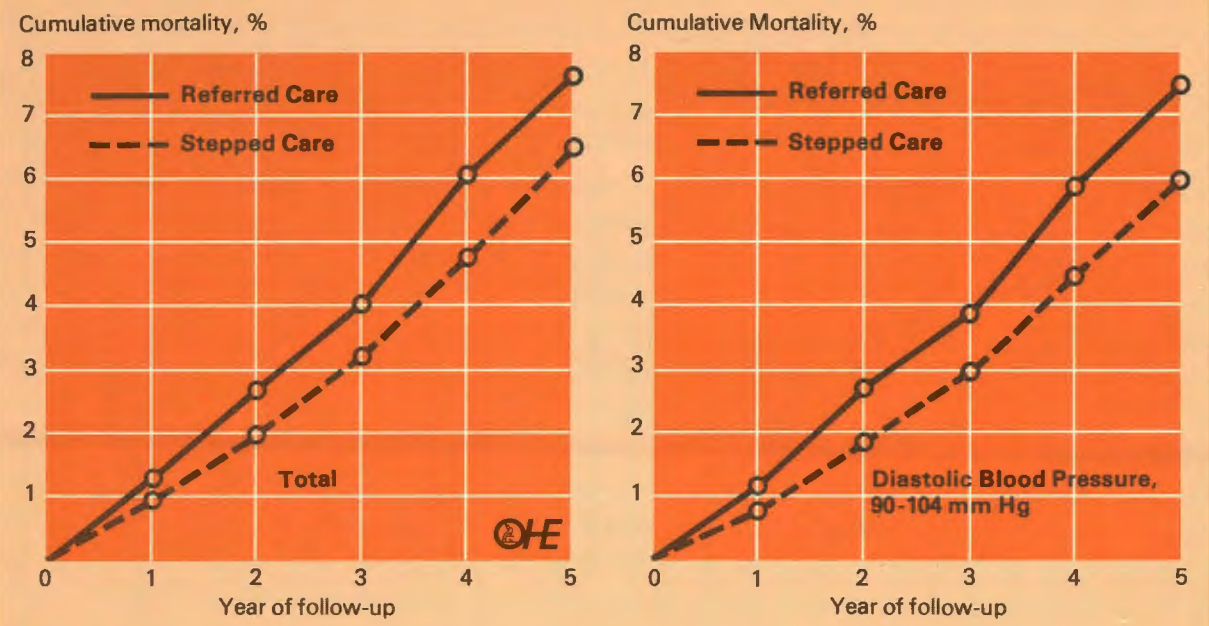
3 The Australian trial, quoted later, used chlorothiazide supplemented if necessary by methyldopa, propanolol and pindalol. The HPFP trial used chlorthalidone, again supplemented as necessary.

The prevalence of mild hypertension

Statements about the prevalence of mild hypertension depend on an arbitrary definition. It can be said that it is a symptomless medical condition which is only significantly present if treatment for it can be shown to be effective. The problem is that at present it has still not been established precisely when treatment is effective. Hence the prevalence can be stated only as the proportion of the population with different levels of blood pressure. Exactly how many of them should be regarded as in need of treatment remains an open question.

Figure 2 shows the distribution of blood pressure measurements which was found in a general health screening survey in a population of 3,000 adults between the ages of 45 and 64 in Renfrew in Scotland in 1972. (Hawthorne V.M. et al 1974). It can be seen that there is a statistically continuous distribution with no clearcut break between a 'healthy' and a 'diseased' population. Table 2 shows the prevalence of various levels of hypertension in this population. These findings are more or less consistent with the much earlier results obtained in Greater London in 1952. (Hamilton M. et al 1954). Table 3 shows the 1952 findings, which indicate clearly the increase in blood pressure with age. It can be concluded from these two studies that about one quarter of the 'middle-aged'

Figure 3 *Hypertension detection and follow-up program cumulative life table all-causes death rates, total and stratum 1 (diastolic blood pressure, 90 to 104 mm Hg).*



Source: HDFP Trial.

population (over the age of 45) have a diastolic blood pressure over 95 mm Hg at any one time.

An important point, however, is that blood pressure fluctuates considerably for the same individual not only due to stress and exertion, but also at rest over a period of time. Thus in the Medical Research Trial to be referred to later almost one third of people originally found to have a blood pressure in excess of 90 mm Hg were subsequently found to have pressures below this level after a mean of four blood pressure readings.

In the Australian trial, again referred to later, 12.8 per cent of subjects found by two separate screenings to have pressures in excess of 95 mm Hg never again reached these levels during four years of follow-up, despite receiving no treatment. Thus, apart from the argument of what level of blood pressure justifies treatment, there is also the argument of whether a limited set of readings (say two or three on one or two occasions) should be taken as an appropriate measure, or whether the readings must be repeated on more than two different occasions in order to get a meaningful measure. Methods of measurement, the age, sex and ethnic composition of the population and the end point taken to define the diastolic blood pressure markedly influence the reported prevalence of mild hypertension. The findings in this *Briefing* are all based on the Phase V diastolic pressure.

Evidence of benefits of treatment

At present a major Medical Research Council clinical trial is under way to attempt to measure specifically the benefits of treatment at different levels of diastolic blood pressure between 90 and 109 mm Hg. (Miall W.E. 1980). Above the latter level it is now generally agreed that serious disease is present even if it is asymptomatic, and it is accepted medical teaching that patients with a blood pressure of 110 or over should be receiving therapy – although this is by no means universal practice. The question mark in relation to treatment has recently lain in the area covered by the MRC trial.

However, in advance of the results of the MRC trial, which will cover 18,000 'patients' and whose results will not be available until 1985, there is already important evidence of benefits from treatment for older men particularly at the higher end of the 'area of uncertainty'. The two principal studies concerned are the Hypertension Detection and Follow-Up Programme (HDFP) trial in the United States published in 1979, (HDFP Co-operative Group 1979) and the Australian Therapeutic Trial in Mild Hypertension published in 1980. (Management Committee 1980). A previous trial by the US Public Health Service published in 1978 reached no positive conclusions about the benefit of therapy, but emphasised the limitations of its

Table 4 *Mortality from all causes for Stepped Care (SC) and Referred Care (RC). Participants during five-year follow-up by Diastolic Blood Pressure (DBP) at entry*

DBP, mm Hg, at Entry	*Sample size* SC	RC	*Deaths* SC	RC	*Life table death rates per 100 (SE)** SC	RC	*95% Confidence Limits for Difference in RC and SC Rates*	*Percent reduction in mortality for SC group†*
Total	5,485	5,455	349	419	6.4 (0.3)	7.7 (0.4)‡	0.37-2.29	16.9
90-104	3,903	3,922	231	291	5.9 (0.4)	7.4 (0.4)‡	0.40-2.62	20.3
105-114	1,048	1,004	70	77	6.7 (0.8)	7.7 (0.8)	—1.25-3.21	13.0
115+	534	529	48	51	9.0 (1.2)	9.7 (1.3)	—2.84-4.18	7.2

*For the year-by-year mortality data, used for the life table analyses, see Table 6. SE indicates standard error.
†(RC rate – SC rate)/(RC rate) × 100.
‡$P<.01$.

Source: HDFP Trial; JAMA 242: 23: 2562 (1979).

Table 5 *Number of deaths by cause, Stepped Care (SC) and Referred Care (RC). Participants, total and stratum 1**

Cause of Death (ICDA Codes)†	Total		Stratum 1 (DBP, 90-104 mm Hg)	
	SC	RC	SC	RC
Total	349	419	231	291
All cardiovascular diseases	195	240	122	165
Cerebrovascular diseases (430-438)	29	52	17	31
Myocardial infarction (410)	51	69	30	56
Other ischemic heart disease (411-413)	80	79	56	51
Hypertensive heart disease (402)	5	7	5	5
Other hypertensive disease (400-401, 403-404)	4	7	2	3
Other cardiovascular diseases (390-458 exclusive of above)	26	26	12	19
All noncardiovascular diseases	154	179	109	126
Renal diseases (580-599)	15	10	7	5
Diabetes mellitus (250)	5	10	4	8
Neoplastic diseases (140-239)	61	74	45	57
Breast cancer (174)	(2)	(5)	(2)	(4)
Gastrointestinal diseases (530-537)	11	20	9	15
Respiratory diseases (460-519)	13	17	9	10
Infectious diseases (000-136)	6	3	4	2
Accidents, suicides and homicides (800-999)	26	25	20	17
Other diseases	17	20	11	12

*DBP indicates diastolic blood pressure.

†From death certificates. ICDA Codes indicates International Classification of Diseases Adapted Codes.

Source: HDFP Trial.

own methodology. (McFate Smith W. 1978).

The HDFP trial covered 10,940 persons and compared the effect on five-year mortality of a systematic antihypertensive programme (Stepped Care) with ordinary referral to their normal medical advisers (Referred Care)[4]. Participants for the trial were recruited by population-based screening of 158,906 people aged 30 to 69 in 14 communities throughout the United States. Those included in the trial were randomly allocated to Stepped Care or Referred Care within blood pressure groups in the 90-104 mm Hg; 105 to 114 mm Hg and over 115 mm Hg ranges. Control of blood pressure was consistently better in the Stepped Care group than in the Referred Care group and five year mortality was 17 per cent lower in the former. For the lower blood pressure group, 90-104 mm Hg, mortality was 20 per cent lower in the Stepped Care than in the Referred Care group. That is, the five year mortality was 5.9 per 100 as opposed to 7.4 per 100. Table 4 and Figure 3 show these results.

However, Table 5 indicates that in the HDFP trial the reduction in mortality for the Stepped Care group did not come exclusively from cardiovascular disease. To some extent, therefore, it suggests that the reduced mortality was due to overall better medical care in this group. A more detailed analysis of the HDFP findings concluded that the benefits could be specifically demonstrated only for all men aged over 49 years on entry to the trial and for black women, (Table 6). Younger men and white women had in any case comparatively low death rates and therefore could not be expected to show clearcut benefit in the trial. Nevertheless the report of the trial concluded that 'the systematic effective management of hypertension has a great potential for reducing mortality for the large numbers of people with high blood pressure in the population including those with 'mild' hypertension'.

The Australian National Blood Pressure Study was a controlled therapeutic trial of antihypertensive treatment in 3,427 men and women aged 30 to 69 years, with mild hypertension, started in 1973. The group was randomly divided and given either active or placebo tablets for an average of four years. The results showed a significant reduction in mortality, mainly due to a reduction of two-thirds in deaths from cardiovascular disease. Indeed in 1979 the Management Committee of the trial reported evidence of clinical benefits from treatment above the threshold of 100 mm Hg which was sufficiently clearcut to discontinue the trial because it no longer appeared ethical to give placebos to patients above this level of blood pressure. However, as in the HDFP trial, no benefit was found from the treatment of those under 50 years of age or in women. *The Lancet* has commented that more research needs to be carried out on subgroups of the hypertensive population. (Lancet Editorial; 1980; a).

Conclusions and economics

It has been recognised for the past decade or more that mild hypertension can be a life threatening condition, and there has been evidence since the early study by Hamilton and others in 1964 (Hamilton M. et al 1964) that treatment to reduce a person's asymptomatic blood pressure would also reduce the subsequent risk of complications. New evidence since then has indicated benefits at lower levels of blood pressure than those currently accepted as requiring treatment. A long-term Medical Research Council clinical trial has been started in Britain following the publication of the results of a successful pilot programme in 1977. (Medical Research Council Working Party. 1977). The

4 The Stepped Care group were offered antihypertensive therapy in special centres. Therapy was increased stepwise to achieve and maintain reduction of blood pressure to or below set goals.

Table 6 *Mortality from all causes for Stepped Care (SC) and Referred Care (RC). Participants during five-year follow-up by race, sex or age at entry*

Race, Sex or Age, yr	Sample size		Deaths		Life table death rates per 100 (SE)*		Percent reduction in mortality for SC group
	SC	RC	SC	RC	SC	RC	
Black men	1,064	1,084	112	140	10.6 (0.9)	13.0 (1.0)	18.5
Black women	1,344	1,354	70	98	5.2 (0.6)	7.2 (0.7)	27.8
White men	1,892	1,861	109	126	5.8 (0.5)	6.8 (0.6)	14.7
White women	1,185	1,156	58	55	4.9 (0.6)	4.8 (0.6)	—2.1
30-49	2,429	2,374	81	82	3.3 (0.4)	3.5 (0.4)	5.7
50-59	1,852	1,909	115	159	6.2 (0.7)	8.3 (0.6)	25.3
60-69	1,204	1,172	153	178	12.7 (1.0)	15.2 (1.0)	16.4

*SE indicates standard error.

Source: HDFP Trial.

results of the main study are not expected before 1985. It covers blood pressures in the range of 90 to 109 mm Hg.

In the meantime there is clear evidence from Australia that for males with a diastolic blood pressure of over 100 mm Hg treatment can significantly reduce mortality. Furthermore, the HDFP from the United States indicates a 20 per cent reduction in mortality for males (and black women) over the age of 50 with blood pressures in the range 90 to 104 mm Hg. A question mark remains over how this benefit is spread within this fairly broad band of pressures, and whether those, for example, in the range 90-94 mm Hg would benefit in addition to those in the 100-104 range.

The Lancet has also posed the question of whether relaxation techniques and control of salt in the diet could be as effective as pharmaceutical treatment with diuretics or beta-blockers in the control of mild hypertension and hence in the prevention of premature mortality. (Lancet Editorial; 1980; a). No trials seem at present to be contemplated in this connection, so that in the foreseeable future available evidence will continue to point to the use of medication.

On this evidence, there is an argument for general practitioners systematically to seek out male patients over the age of 50 with blood pressures which are consistently over 95 mm Hg, and to persuade them to accept antihypertensive therapy, as well as general advice on diet, smoking and stress, even if they are experiencing no symptoms. Between now and 1985, by the time the definitive results of the MRC trial are available, such a policy could, if successful, have perhaps avoided up to 12,000 deaths among men in Britain in the age group 50-64 years[5].

On the other hand the cost of therapy (mainly using diuretics) for the 800,000 males who would be diagnosed and treated as hypertensive under this policy would be of the order of £15 million a year. The cost of general practitioners' time in screening and diagnosis (assuming a slightly lower prevalence of hypertension but at 1976 prices) has been estimated at about £6 per case detected. (Bryers F. et al 1978). This gives another £5 million or so for the male population between 50 and 65 years of age. Thus there would be a total cost of the order of £6,700 per life saved.

However, in normal economic conditions taking the mean age of the life saved as 57 years and the average earnings at about £5,000 a year, there would be a 'pay-off' of £40,000 for the medical investment of £6,700. These are all order-of-magnitude figures. They assume that those saved would be at work rather than unemployed and do not discount the present value of future earnings. Nevertheless it is a simple demonstration of how an apparently formidable additional cost of perhaps £80 million between 1980 and 1985 for screening and treatment of mild hypertension could bring a substantial financial return for the families involved and for the economy. There is also of course the question of treatment given and lives saved during retirement, and the added cost to the economy implied by such non-productive survival. However, this merely brings home the fact that much of expenditure on medical care is a 'consumption' expenditure bringing wellbeing and avoidance of misery rather than being a productive investment.

This *Briefing* has set out a case to suggest that Britain – and other developed countries – should now accept the weight of the epidemiological evidence and hence the desirability of setting out positively to detect and treat cases of mild hypertension at least in men between the ages of 50 and 65. This must be primarily the responsibility of general practitioners in the British National Health Service.

Against the background of this conclusion, the continuing Medical Research Council clinical trial remains of very great importance, particularly in elucidating more precisely the lower limits and the demographic subgroups for which the detection and treatment of mild hypertension can be justified. It will also quantify more clearly the balance of benefits against possible adverse reactions to therapy.

5 This calculation is based on a male population of 4.7 million between the ages of 50 and 64 years. According to the Renfrew screening programme, 26 per cent would have a blood pressure over 95 mm Hg at initial screening. Based on the experience with the MRC trial, two-thirds of these would still have the same elevated blood pressure after rescreening., This gives a population at risk of approximately 0.8 million. Applying the difference in 5 year mortality between Stepped Care and Referred Care in the HDFP trial (1.5 per cent) to this figure gives the saving of 12,000 lives. The Australians made a proportionately higher estimate of 2,000 deaths a year being avoidable in their own smaller population. This would imply a potential saving of the order of 40,000 lives in Britain between 1980 and 1985.

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