Hypertension in Cape Town clothing industry clinics.

Does treatment match risk?

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Contents

Abstract

Background:

The management of hypertension according to the patient's absolute risk of cardiovascular disease, rather than their blood pressure in isolation from other risk factors, is now widely advocated because it targets treatment at those with most to gain. In South Africa blood pressure is traditionally managed according to the patient's level of blood pressure.

Main Objective:

To identify the proportion of traditionally treated hypertensive patients who may benefit from cessation or intensification of treatment as judged by a risk-based approach to their management.

Design:

A cross sectional descriptive survey of patients and their medical records with assessment of absolute risk of cardiovascular disease using Framingham risk equations.

Setting:

Eight Clothing Industry Health Benefit Fund clinics in Cape Town, South Africa.

Participants:

382 women and men, predominantly coloured, attending for the treatment of hypertension

Main outcome measure:

The proportions of patients in whom the predicted risk of a cardiovascular event within 5 years is less than 10% and those in whom the risk within five years is greater than 20%.

Results:

65% of participants (CI 60 - 70%) were at less than 10% risk of a cardiovascular event in the next 5 years and 19% (CI 15-23%) were at more than 20% risk of a cardiovascular event despite current treatment.

5% (CI 3.2-7.9%) were at greater than 20% risk of a cardiovascular event in the next 5 years having no previous history of a cardiovascular event.

14% (CI 10-17%) were at greater than 20% risk of a cardiovascular event in the next 5 years because of a previous history of a cardiovascular event.

1.3% (CI 0.4-3%) were at less than 10% risk of a cardiovascular event within the next 5 years, despite having a systolic blood pressure over 170mmHg.

Conclusion:

Assessment of the cardiovascular risk of patients treated for hypertension identifies those patients at most and least risk. Resources could therefore be targeted at those with the most to gain from treatment and the unwanted side effects of antihypertensive medication avoided in those at low risk. Almost two thirds of patients currently being treated for hypertension were at less than 10% risk of developing a cardiovascular event within the next 5 years. A trial of medication reduction or cessation in this group is justified and the resources could be redirected at those 5% whose risk remains very high despite current levels of treatment.

Introduction

Cardiovascular disease has been recognized as a major cause of death in industrialized countries and is becoming more important in developing countries. In South Africa it has long been a common cause of death in some populations and is expected to become increasingly important in all groups. Risk factors for cardiovascular disease are well known (1) (2) (3). Reducing the level of these risk factors has been shown to be effective in reducing the probability of a future cardiovascular event such as a cardiovascular death, myocardial infarction or stroke. (4) (5) (6) (7)

The treatment of one important risk factor, hypertension, has traditionally been initiated if the blood pressure is above a certain level. Recent recommendations are that the patient's risk of a cardiovascular event should be considered rather than simply the level of blood pressure. (1) (8) (8) (9). The risk of a cardiovascular event is not well assessed by clinicians (10). It can be estimated using prediction equations developed from large cohorts that have been followed up for long periods of time (3) (11). The challenge is then to facilitate the use of the predicted risks in everyday clinical situations. Practice guidelines have been developed for use by primary care clinicians to present the risk in an accessible way (12) (13) (14). These guidelines include the use of "numbers needed to treat" which help the clinician and patients to consider the balance of advantages and disadvantages to the patient of initiating treatment (15) (16) (17). Using the risk predictors, patients who are at low risk can be identified. These patients can be considered for a step down or cessation of their treatment. Stepping down of treatment has possible financial advantages as well as reducing iatrogenic effects of medication. This study identifies patients in whom a change in treatment is potentially beneficial. This includes those in whom the risk of a cardiovascular event remains high despite their current treatment and patients in whom the risk is low and who may benefit from a reduction in treatment.

The study was set in the clothing workers benefit fund clinics. The majority of patients are coloured women of low income working in factories in occupations such as machinists. The fund is part of the

private sector and provides managed primary care. It is paid for by contributions from the workers and their employers.

The medical directors of the fund wanted to establish whether the resources spent on the management of hypertension could be used more efficiently. At the same time the South African Medical Research Council (MRC) was conducting a trial of national guidelines for the care of hypertension and diabetes within the clothing industry. The questionnaires and data sheets developed for the base-line data collection for the MRC study were modified to include data required for this study. Data were collected between April1998 and April1999.

The Importance of cardiovascular disease

Cardiovascular disease is the main cause of death in virtually all industrialized countries and there are indications that a similar epidemic can be expected in developing countries if current trends continue. (18)

In South Africa, the elements for a potential epidemic of atherosclerotic cardiovascular disease are present. (19) Mortality data in South Africa are incomplete but it is estimated that in 1988 28.5% of reported mortality in the 35 to 65 year age group was due to hypertension, atherosclerosis and diabetes. (20). The major causes of death contributing to these figures were cerebrovascular diseases (7.2% of all deaths and 7.9% of deaths of persons aged 35-64 years) and ischaemic heart disease (8.7% of all deaths and 9.6% of deaths of persons aged 35-64 years). Estimates from the reported prevalence rates were calculated for the major risk factors, based on the size of the South African population recorded in the 1985 census figures. Overall 4.88 million South Africans smoked, the largest group of smokers being black males (2.6 million). 5.5 million South Africans were hypertensive as defined as having a blood pressure above 140/90 mmHg; again the largest groups were blacks (3.0 million). 4.8 million South Africans had an increased risk of ischaemic heart disease due to raised cholesterol and 3.1 million due to raised low-density lipoprotein, blacks having the lowest levels (21) (20). As South African populations continue to make the demographic and epidemiological transition seen in other developing countries, these figures are expected to rise. (22)

The mortality rates for cardiovascular disease are particularly high among the coloured population of South Africa. Ischaemic heart disease in prosperous Western populations rose markedly in the 1940s, peaked between 1970 and 1975 and continues to fall. In South Africa, in all population groups other than blacks, ischaemic heart disease rates rose similarly, with Asians and whites attaining very high rates. From 1978 to 1989, rates fell by approximately 50% in the US and Australia. In South Africa,

the annual total death rate among white males (per 100,000 world population) fell from 1,002 to 631 (a 37% reduction), and the ischaemic heart disease mortality rate fell from 312 to 139 (a 56% reduction). Rates for coloureds and Asians fell much less. The total death rate in coloureds fell from 1,691 to 1,392 (an 18% reduction) and the ischaemic heart disease mortality rate from 171 to 110 (a 36% reduction). In Asians the total death rate fell from 1306 to 1130(a 14% reduction) and the ischaemic heart disease mortality rate from 355 to226 (a 36% reduction). In blacks, the total mortality remained unchanged; ischaemic heart disease rates were low, but these data are unreliable. (23)

Within the coloured female population the death rate from cardiovascular disease is already higher than that in the US. The age standardized mortality rates per 100 000 population per annum for cardiovascular disease among the coloured female population of South Africa is 227.9 (1984-6) (20) That of the total US population is 156.4. (1997) (24)

Recognition by the South African Department of Health of the need to tackle the Chronic Diseases of Lifestyle is evident in the creation of a National Program for Chronic Diseases. (25)

A risk-based approach to the prevention of cardiovascular disease

Trials have shown that antihypertensive treatment tends to have the same relative effect on risk of cardiovascular disease, regardless of the risk without treatment. (4) (1) (26) This means that the absolute effect increases as absolute risk without treatment increases.

Hypertension is one of the many risk factors that together determine the risk of cardiovascular disease. Blood pressure reduction does not eliminate the risk of cardiovascular disease but reduces it. The decision to prescribe hypotensive therapy should therefore be determined by the individual patient's risk of a stroke or heart attack and the associated opportunity for their prevention and not by a particular blood pressure level alone. (1) (8) (27) (9). Treatment should be targeted at those who are most likely to have a stroke or a heart attack because of their combination of risk factors or evidence of pre-existing vascular disease.

Redirection of clinical resources may spare many hypertensive persons whose absolute risk for a cardiovascular event is small from having life long treatment with concomitant side effects. At the same time, other persons currently classified as normotensive, will become candidates for blood pressure reduction because their cardiovascular risk is high. (28)

Current guidelines for the management of hypertension in South Africa are based, not on an individual patient's risk of cardiovascular disease, but on specified blood pressure levels. (29) (30) Lowering the thresholds for treatment in patients with other risk factors is mentioned in the rationale for hypertension guidelines for primary care in South Africa. (31). However, clinician's estimation of cardiovascular risk in hypertensive patients has been shown to be inaccurate. (10)

If South Africans are being treated according to the level of their blood pressure and not according to the overall risk of cardiovascular disease, some, with a raised blood pressure but a low overall risk, must be receiving unnecessary treatment. Others, who are at high risk of cardiovascular disease but with lower blood pressures, should receive more aggressive treatment but are not doing so.

This change from using a single measure as a basis for treatment to a broader approach has begun in New Zealand and in the UK.

Modelling using different thresholds of risk for treatment of hypertension in New Zealand has demonstrated that using treatment thresholds based on absolute risk could significantly improve the efficiency of drug treatment to lower blood pressure. (32)

Furthermore, the recently published Joint British Recommendations on the prevention of Coronary Heart Disease in Clinical Practice recommend that priority for treatment should be given to patients at high absolute risk of coronary disease, defined as the probability of developing coronary heart disease over a specific period, rather than "undue emphasis being placed on an individual risk factor." (13)

Risk reduction and numbers needed to treat

Reductions in risk associated with treatment can be expressed either as absolute risk reductions or as relative risk reduction.

The relative risk reduction (RRR) is calculated thus:

RRR = (risk without treatment – risk with treatment)/risk without treatment

The relative risk reduction takes no account of the measure of risk in untreated patients. If the adverse event were very rare in untreated patients, a 50% relative risk reduction may be of minor interest. If, however the adverse event were common in untreated patients the same 50% relative risk reduction would be highly significant.

The absolute risk reduction (ARR), or risk difference, is calculated thus:

ARR = risk without treatment – risk with treatment.

In order to measure the benefits of the treatment for individuals treated for hypertension we therefore need to know their baseline level of risk of cardiovascular disease. This can be calculated using information from epidemiological studies, as discussed below.

A measure of the input required to prevent an adverse outcome (in this case an episode of cardiovascular disease) is the number needed to treat (NNT). (17) The number needed to treat is the number of patients (at the same level of risk), who would have to be treated in order to prevent one adverse event.

NNT is calculated thus;

NNT = 1/(ARR)

The main advantage of the NNT is that it is easy for clinicians and patients to understand. It conveys both numerical and clinical significance to the clinician (33). Clinicians' views of the effectiveness of treatments are influenced by the way in which the information on the reduction in risk is presented to them. (15) and this difference in the perceived benefits of therapy alters the clinician's decision to

prescribe. (34) The number needed to treat formulation is becoming widely used as a tool for therapeutic decision making (35) and bedside teaching (36). The application of number needed to treat is one of the most important evidence-based medicine skills because decisions regarding therapy are so common in clinical practice. (16). Consequently, numbers needed to treat are used in the New Zealand guidelines on the management of raised blood pressure.

However, the use of numbers needed to treat has limitations, particularly in certain circumstances. Numbers needed to treat will vary with changes in the baseline risk within the population. Factors, which influence the baseline risk, include the outcomes considered, the characteristics of the patient (such as the levels of other risk factors), changes in the incidence of the outcome over time and the clinical setting. Numbers needed to treat derived from meta-analysis can be particularly misleading in this respect. (37) (38)

In the New Zealand Guidelines the numbers needed to treat are calculated from a single very large trial (not a meta-analysis) and are calculated for different combinations of baseline risk factors. The clear outcomes used and the justification for using these baseline risks in a coloured population in South Africa are discussed below. In order to reduce errors in the calculation of numbers needed to treat due to secular trends in the incidence of cardiovascular disease, the risk in untreated patients will have to be updated from time to time.

The effectiveness of available treatments

An overview of 17 completed randomised trials of antihypertensive treatment demonstrates that a 5-6 mm Hg reduction in diastolic blood pressure reduced stroke risk by 38% and coronary heart disease risk by 16% (26). These results indicate that a few years' treatment with diuretic or beta-blocker based therapy produces most or all of the long-term stroke avoidance and much of the long-term coronary heart disease avoidance that would be predicted from observational epidemiological studies of untreated subjects, given the blood pressure reductions that were achieved in the trials (1). The relative

risk reductions were similar in trials of older and younger patients, although the absolute reduction in events was more than twice as great in the trials in older patients. From these results it can be estimated that in fully compliant patients at similar risk of vascular disease to those included in the trials, antihypertensive treatment for 5 years would prevent one major vascular event among every 20 older patients treated and one major vascular event among every 60 younger patients treated. If patients are at higher risk than those included in the previous trials then treatment offers commensurately larger gains in the absolute risk reduction. The greatest benefits are likely to be achieved in those with a history of vascular disease, particularly cerebrovascular disease since their risk of future events is particularly high and the reduction in risk with treatment is large. (4). Among such patients it is possible that blood pressure reduction will confer worthwhile benefits in those whose blood pressure would not traditionally be labelled hypertensive. It is also possible that the benefits of treatment will be determined by the size of the blood pressure reduction and by the choice of the anti-hypertensive agent. However, each of these possibilities requires confirmation in large scale randomised controlled trials. (26)

Predicting the risk of cardiovascular disease: The Framingham Risk Prediction Equations

The development and use of equations to calculate an individual's risk of cardiovascular disease.

The Framingham study and equations.

The Framingham Heart Study is an epidemiological study of a North American cohort of people aged between 30 and 74 and who were free of cancer (apart from basal cell carcinoma) or cardiovascular disease at the onset. The population has been extensively studied for over 40 years. The study has identified various risk factors for cardiovascular disease.

Mathematical equations have been developed from the Framingham study to predict the probabilities of cardiovascular outcomes. These prediction equations predict the risk of a variety of endpoints including:

- Myocardial infarction
- Cardiovascular disease
- Death from ischaemic heart disease
- Cerebrovascular disease
- Ischaemic heart disease
- Death from cardiovascular disease

(3) (11)

The equations are based on the measurement of several known risk factors. The risk factors used are;

- Blood pressure
- Total cholesterol
- High density lipoprotein cholesterol
- Smoking
- Glucose intolerance
- Left ventricular hypertrophy
- Age
- Gender

One such risk equation uses a model, which allows prediction of risk over different lengths of time. These risk equations have subsequently been incorporated into guidelines such as The New Zealand Guidelines and the Joint British Recommendations on Prevention of Coronary Heart Disease in Clinical practice. Both these guidelines are for use in patients who have not already experienced a cardiovascular event. The New Zealand guidelines recommend that patients with a systolic blood

pressure consistently above 170 mmHg are treated irrespective of cardiovascular risk, whereas the Joint British guidelines recommend treatment irrespective of cardiovascular risk if the systolic blood pressure is above 160 mmHg. Patients with a previous history of a cardiovascular event are at high risk of death from cardiovascular disease and have the highest priority for coronary prevention. (Their risk of a further cardiovascular event within 5 years is greater than 20%). The quality of the evidence that their lives can be extended and their morbidity decreased is among the best available for any aspect of medical practice. In such patients it is not necessary to measure absolute coronary risk before deciding on intervention.

The New Zealand guidelines use the predicted risk over five years of a cardiovascular event including:

- Myocardial infarction
- Death from coronary heart disease
- Angina
- Coronary insufficiency
- Stroke, including transient ischaemic attacks
- Congestive heart failure
- Peripheral vascular disease

The Joint British recommendations use the risk of coronary heart disease over 10 years, which includes:

- Myocardial infarction
- Death from Coronary heart disease.

Both the New Zealand Guidelines and the Joint British Recommendations are for use in primary prevention of cardiovascular events. Patients who have a previous history of a cardiovascular event are at high risk of another event regardless of the levels of their individual risk factors.

Clinically, the most important difference between the two is that the New Zealand guidelines include cerebrovascular events, angina and peripheral vascular disease and the British recommendations are exclusively for heart disease.

The use of Framingham equations in different populations:

The Framingham equations were derived from a North American population. Their use has not been studied in a South African population. Other cohorts have been used to generate risk equations and could be considered for use in South African populations. All these cohorts are of white patients in the developed world. However, the advantages of the Framingham study are that both men and women over a wide range of ages were included and follow up was long and relatively complete. Other risk scores, derived from different populations, such as the Dundee risk score gives a relative risk rather than an absolute risk. It is preferable to use absolute risk for making management decisions (39).

Although the use of the Framingham equation has not been studied in a South African population, it has been studied in several populations other than the original one.

To assess the generalisability of the Framingham equations they have been evaluated in different cohorts. The external (or criterion) validity of an equation is measured by comparing the incidence of events predicted by the equation with the observed incidence of events in a cohort of people whose risk factors are known. The external validity of the Framingham equations has been measured and found to accurately predict absolute coronary heart disease risk in the following populations:

- Several North American populations (40) (41) (42) (43).
- A population of men in the West of Scotland, the West of Scotland coronary prevention study (WOSCOPS) (44).
- A population of men in the United Kingdom heart disease prevention project, (the Dundee risk score), (39)

- A population of German men in the prospective cardiovascular Munster (PROCAM) cohort (45) (39)

In populations with a low incidence of cardiovascular disease the Framingham equation overestimates the absolute risk of cardiovascular disease. It has however remained accurate in predicting the relative risks of treatment to no treatment. In a Swedish cohort, the Framingham equation overestimated the coronary heart disease death rate but over estimation was less in people at high risk. (46)

- A risk function derived from an Italian population produced lower rates than the Framingham equation. (47)
- In France, the Framingham model estimated coronary heart disease risk 2% higher than a model derived from a French cohort. (48)
- In the seven countries study, the risk of cardiovascular disease was over estimated using another American model in Southern European and Japanese populations where the incidence of cardiovascular disease is low. (49)

The multivariate coefficients of major coronary risk factors were however found to be similar between the populations even with different levels of cardiovascular disease.

The use of the Framingham equations in female coloured South Africans.

As the Framingham equation has been found to be valid in populations with a similar incidence of cardiovascular disease, it is necessary to compare the cardiovascular death rates in American populations from whom the Framingham equations were developed with those in the female coloured population of South Africa.

Age standardized mortality rates in South Africa have been published for males and females in blacks, whites, coloureds and Asians. The employees of the clothing industry in Cape Town are mainly coloured and female (83% in this study). The most recent age standardized mortality rates per 100 000

population per annum in South Africa are for 1984-6(20). The rates used for the US population are from the US National Vital Statistics Report for the population in 1997. (50)

Coloured South Africans have high mortality for cerebrovascular and heart disease. The rates for cerebrovascular diseases are higher than those in US and the rates for coronary vascular disease are approaching those in the US. (Table 1)

(The US mortality rates are standardized for the US standard population, defined by the US 1990 census. The South African rates are standardized for the world standard population. The rates are therefore not directly comparable. The US population is older than the world standard population and so the US figures will be biased upwards compared to the South African figures. Certification bias is a particular problem in South Africa. This could bias the figures either way.)

Table 1 Age standardized mortality rates per 100 000 population per annum for coronary vascular and cerebrovascular disease in the United States population (1997) (24) and in selected South Africans (1984-6) (20)

Cause of Death	United States	Coloured Urban South African Female	Coloured Urban South African	Black Urban South African
Coronary vascular Disease	**130.5**	**90.2**	**118.7**	**13.1**
Cerebrovascular Disease	**25.9**	**137.7**	**139.7**	**96.4**
Total cardiovascular disease	**156.4**	**227.9**	**258.4**	**109.5**

The categories used in the South African and the US rates are from The International Classification of Diseases (9th revision.)

Until sufficient data is available to enable the external validity of the Framingham risk equations to be tested in South Africa, a reasoned judgment must be made. The incidence of cardiovascular disease is comparable for coloured, but not for black, South Africans. Therefore the Framingham equations may overestimate the risks of cardiovascular disease in black South Africans but remains valid for coloureds. Even in the black population, the relative risk of cardiovascular disease, among treated relative to untreated patients would probably be valid because all the trials suggest that the relative risk remains the same even as the absolute risk varies. As the death rates from cardiovascular disease associated with the epidemiological transition in South Africa increase, the equations may become more accurate at predicting absolute risk even in the black population. The Framingham equations include equations for cardiovascular risk, including cerebrovascular risk (as used in the New Zealand guidelines) and for coronary vascular risk alone (as used in the Joint British Recommendations). It is more appropriate to use the former in the South African coloured population in view of the high risk of cerebrovascular disease.

The use of the Framingham equations in coloured South Africans can therefore be recommended because;

- There are no equations derived from South African populations
- The relative risks, with treatment relative to no treatment, remain similar in all populations so individuals with the most to gain from treatment can be targeted
- The importance of the major risk factors has been shown to be similar in different populations

- The incidence of cardiovascular disease is similar among coloured South Africans and the population from whom the equations were derived

There have been no previous studies in South Africa evaluating a risk-based approach to the management of hypertension. However, in a Cape Town community health centre (a public sector service), 51% of patients treated for hypertension had a mean blood pressure over a period of a year above 160/90. This was the level defined as unacceptable. (51) In a study in a mobile diabetic clinic in community health centres in Cape Town, only 38.5 % had acceptable blood pressure control. (52)

Facilitating the use of these research findings in clinical practice: Implementing practice guidelines.

In order for treatment to be effectively targeted on those South Africans who have the most to gain, the risk equations need to be straightforward for clinicians to use in everyday practice. This requires a change in clinician behaviour, which is known to be difficult. One of the strategies, which would help to change the current situation, would be to introduce practice guidelines, which promote the measurement of risk factors and management based on the calculated risk. These are not effective on their own and other effective change strategies including reminders, patient mediated interventions, outreach visits, opinion leaders and academic detailing are necessary. (53)

Practice guidelines are 'systematically developed statements to assist practitioner decisions about appropriate health care for specific clinical circumstances'. (54)

The aim of evidence-based practice is to integrate current best evidence from research with clinical policy and practice. Practitioners have difficulty finding, assessing, interpreting, and applying current best evidence. (55) Guidelines are one of the tools to ensure that research information is transferred to the point of decision making. (56)

Guidelines can change clinical practice and affect patient outcome. (57) Additionally, guidelines appear to have the potential to make a positive contribution to health care rationing through the better

direction of resources and by limiting inappropriate variation in clinical practice. (58) Guidelines are more likely to be effective if they take into account local circumstances, are developed with end user involvement, disseminated by an active educational intervention and implemented by patient specific reminders relating directly to professional activity. (54). Guidelines are more likely to be valid if they are developed using systematic reviews, national or regional guideline development groups (including representatives of key disciplines) and explicit links between recommendations and scientific evidence.(59) Evidence and guidelines must be understood by practitioners if they are to be applied well. (55) Any management plan suggested by evidence-based guidelines has to be modified to take into account individual patient's clinical circumstances, preferences, values and rights.

Assessment of risk and reduction of risk are well-accepted responsibilities of the clinician. The process involves the measurement of risk factors, the estimation of risk and the appropriate intervention to reduce risk. Although the process is apparently straightforward, failures can occur at each stage. Studies have shown that there is a failure to measure risk factors in the course of usual medical care (60) despite the availability of cardiovascular risk profiles and risk instruments for decades. (61)

Guidelines have been developed in New Zealand for the management of hypertension based on the absolute 5-year risk of a cardiovascular event and not simply on blood pressure levels (12). They have been evaluated in the United Kingdom, (62) (63) but not in South Africa.

In a randomised controlled trial of the management of hypertension in primary care in UK, use of the New Zealand risk chart was associated with a significant reduction in systolic blood pressure and increased prescribing of cardiovascular drugs. A computer based decision support system did not however confer any benefit in absolute risk reduction or blood pressure control and the authors suggested further development and evaluation before use in clinical care could be recommended. (63)

In the UK, the British Cardiac Society, the British Hyperlipidaemia Society, the British Hypertension Society and the British Diabetic Association have developed the Joint British recommendations on prevention of coronary heart disease in clinical practice.

The risk strata in the New Zealand Guidelines and the British recommendations are derived from Framingham equations.

Step-down of treatment

Step-down of treatment is the reduction or cessation of established treatment. The New Zealand guidelines recommend consideration of step-down treatment in patients whose risk of a cardiovascular event is less than 10% in 5 years, provided that their blood pressure is below 170/90. Below this level of risk, 40 or more people need to be treated for five years in order to prevent one cardiovascular event, assuming a reduction in systolic blood pressure of 10-15mmHg. (64)

A systematic review published in 1997, including 765 patients from 12 trials, found that the cessation of antihypertensive medication was successful in 40.3% of patients a year after stopping medication and 27.7% two years after stopping medication. (65) The trials included in the study had heterogeneous entry criteria, lengths of follow up and definitions of success. The authors concluded that further research was needed. A longitudinal study of 196 patients from 18 general practices in the UK found that 22% of patients with controlled hypertension in whom medication was stopped remained successfully off treatment after 3 years. A local protocol combining blood pressure and other risk factors was used to decide whether or not medication should be restarted. (66)

The Trial of Nonpharmacologic Interventions in the Elderly (TONE) was a clinical trial of the efficacy of weight loss and/or sodium reduction in controlling blood pressure after cessation of drug therapy in patients with a blood pressure below 145/85 mm Hg on antihypertensive medication. The study, in elderly hypertensives in the US, found that the success rates for remaining off antihypertensive medication were increased by 45% by adherence to lifestyle advice involving weight loss and sodium

reduction, and that up to 80% of recently diagnosed hypertensives who followed the lifestyle interventions remained successfully off treatment after a year. (67)

The possibility that discontinuation of drug therapy could precipitate clinical cardiovascular events has been studied. The same group (TONE) looked at cardiovascular event rates before during and after antihypertensive medication cessation in controlled elderly hypertensives. The event rates remained the same before, during and after the cessation of medication. The researchers concluded that antihypertensive medication could be safely withdrawn in older persons without clinical evidence of cardiovascular disease who have a blood pressure of below 150/90 mm Hg at cessation, providing that good blood pressure control can be maintained with nonpharmacologic therapy. (68)

In a Swedish study 333 elderly patients had their antihypertensive medication stopped and were followed up for 5 years; 20% remained off treatment for at least 5 years. During the state of no treatment the patients had a lower total mortality than that of the general Swedish population, matched for age and sex. They also had a lower number of cardiovascular events than those in the treated states (69).

All the above trials define success in terms of blood pressure measurements. Studies, which use the cardiovascular risk as the measure of outcome, are needed.

Stepping down treatment will represent a considerable saving in health service resources and opportunity costs as well as in the morbidity related to taking antihypertensive medication.

Patients whose risk of cardiovascular events remains high despite treatment should be assessed for adherence to treatment regimes. If compliance is judged to be good then medication should be stepped up.

Adverse effects associated with antihypertensive medication

As well as the possible financial savings associated with stepping down antihypertensive medication, patients can benefit from a reduction in adverse effects of antihypertensive medication.

In a recent randomised, double blind, multicentre comparison of hydrochlorothiazide, atenolol, nitrendipine, and enalapril in antihypertensive treatment (the HANE study), 111 (12.8%) of 868 patients, stopped their antihypertensive medication. Sixty (54%) of these stopped because of side effects. (70)

Discontinuation of medication can reduce symptoms, as shown in a report of 11710 hypertensive patients in whom hypertensive medication was stopped for two weeks. After cessation of medication, except headache, which increased in frequency, there were major reductions in coldness of extremities, weakness, impotence, wheezing, flushing, chest pain and cough. (71)

It is likely that some hypertensive patients in South Africa are under treated while others are overtreated. This study was undertaken to clarify the effects of applying a risk-based approach to the management of hypertension in a South African population.

Method

Study Design.

A cross sectional descriptive sample survey comprising a record review, questionnaire, examination and blood sampling of patients attending primary care clinics for the treatment of hypertension.

Population and sampling.

The study population was employees of the clothing industry in Cape Town and their dependents who attended the clothing industry health benefit fund clinics for the treatment of hypertension.

Each of the eight clothing industry clinics already maintained a register of patients being treated for hypertension and their medical records were tagged. All patients on the hypertension register attending the clinics were selected for the study until the required sample size was obtained. During the study all the clinics were visited on every day of the week except Sunday and throughout the range of opening times. Patients who attended more than once during the study period were included on the first occasion only.

Those recruited into the study were therefore clinic attendees. Patients who were known to be hypertensive but who did not attend were not included in the study. Patients who were hypertensive but not diagnosed were also not included. All patients gave their fully informed consent. Ethics committee approval was obtained from the South African Medical Research Council.

Data collection.

A questionnaire (see Appendix) was administered to patients by a trained field worker. Data extracted included the patient's gender, age in years and a self reported history of treatment for stroke, heart attack, angina or diabetes.

Patients were asked about their current smoking status and previous smoking history. Patients who were current non-smokers and had not smoked for at least the previous year were defined as non-smokers. Current smokers and those who had given up for less than a year were defined as smokers. Cotinine validation of smoking status was considered but was too expensive.

Systolic and diastolic blood pressure in mm of mercury were measured using a mercury sphygmomanometer and blood was taken for a total cholesterol/HDL ratio, by clinic clinicians who had been trained according to guidelines (see Appendix 1). Blood samples were analysed at Groote Schuur hospital, in Cape Town.

The medical records of participants were hand searched for any record of cardiovascular disease (including stroke, angina, myocardial infarction, congestive heart failure, transient ischaemic attack and peripheral vascular disease) or electrocardiograph (ECG) diagnosed left ventricular hypertrophy (LVH) or diabetes.

Data were entered at the MRC of South Africa. Single data entry was used and was validated using frequency distributions and looking for anomalies and outliers.

Statistical analysis.

Prior sample size calculation

The total population of hypertensive patients being managed within the fund was estimated by the Medical Director to be approximately 1500 in 1997. It was estimated that 20% of those patients would have a risk of cardiovascular disease below 10% (the level below which treatment should be initiated or step-down of treatment considered). In order to estimate the proportion of patients in a risk category containing an estimated 20% of the patients, a sample size of 211 was required to detect this within

15-25% with a 95% confidence level.

Risk calculations.

The aims of the statistical analysis were to describe the distribution of cardiovascular risk among patients currently being treated for hypertension, and to estimate the proportion that would be eligible for reduction or cessation of treatment.

Each patient's risk of a cardiovascular event within the following five years (as used in the New Zealand guidelines) was calculated using Framingham equations (3). Patients with a previous history of cardiovascular disease were excluded from the risk calculations, which are applicable only in patients who have no previous history of cardiovascular disease. Those patients with a previous history of a cardiovascular event are at high risk of a further event irrespective of the levels of other risk factors and were categorised separately.

Risk calculations were performed for all patients without a history of cardiovascular disease irrespective of their blood pressure. This therefore included those patients who warranted treatment by virtue of the severity of their hypertension. The rationale for this was to identify patients in whom use of the risk calculation alone would have led to a misclassification of their need for treatment.

For 19 patients for whom data was incomplete, the sample mean was inputted into the risk equations. Re-analyses were performed to justify the use of sample means for the missing data. (See Appendix 2)

The equations used are given in the figures below

Figure 1. The Framingham equation to predict the risk of a cardiovascular event within the following five years (3).

First mu was calculated,

mu = 18.8144 – 1.2146 *female – 1.8443 log (age) + 0.3668 log (age) * female – 1.4032 log (systolic blood pressure) – 0.3899 * smoker – 0.5390 log (total cholesterol/HDL cholesterol) – 0.3036 * diabetes – 0.1697 *diabetes * female – 0.3362 * ECG LVH.

Log (sigma) was then calculated,

Log (sigma) = 0.6536 – 0.2402* mu

The antilog was then taken to calculate sigma.

For a five year risk, U = [log (5)- mu]/sigma

Five year risk = 1-exp[-exp(U)]

Each patient's ten-year risk of coronary heart disease (as used in the Joint British recommendations) was also calculated using the equation given in figure 2.

Figure 2. The Framingham equation to predict the risk of coronary heart disease within the following ten years (3).

mu was again calculated first,

mu = 15.5305 + 28.4441 – 1.3792 log(age) – 14.4588 log (age) * female + 1.8515 – 0.9119 log(systolic blood pressure) – 0.2767 * smoker – 0.7181 log(Total cholesterol/ HDL cholesterol) – 0.1759 * diabetes – 0.1999 * diabetes * female – 0.5865 * ECG LVH.

Log (sigma) was then calculated.

Log (sigma) = 0.9145 – 0.2784 * mu

The antilog was then taken to calculate sigma.

For a ten year risk, U = [log (10)- mu]/sigma

Ten year risk = 1-exp [-exp(U)]

STATA statistical soft ware was used to perform the calculations.

Patients were divided into the risk categories used in the New Zealand guidelines and the joint British recommendations.

The results were analysed twice, once by the standards of the New Zealand guidelines and once using the standards from the joint British recommendations.

Patients were categorised into those in whom it would be appropriate to attempt cessation of their antihypertensive medication and those in whom it would not. The patients in whom cessation of antihypertensive medication was appropriate were defined firstly according to the New Zealand guidelines, which suggest a reduction in medication in those patients who had no previous history of

cardiovascular disease, a systolic blood pressure of below 170mm Hg and a risk of a cardiovascular event of less than 10% in the following five years. The patients were then categorised according to the Joint British recommendations on prevention of coronary heart disease in clinical practice, which suggests initiating treatment if patients are at more than a 15%, risk of coronary heart disease in the following ten years or have a systolic blood pressure of over 160mm Hg. For reduction of treatment, the same level at which treatment initiation is recommended was used, as no level for reduction was specified in these recommendations.

Results

Characteristics of risk factors

◊ **Gender**

315 of 382 (82.7%) of the sample were female.

◊ **Age, blood pressures, and cholesterol.**

The distributions of ages (years), systolic and diastolic blood pressures (mm of mercury) serum total cholesterol (mmol/l) and serum HDL cholesterol (mmol/l) are given in Table 2.

Table 2. The distributions of age (years) systolic and diastolic blood pressures (mm of mercury) serum total cholesterol (mmol/l) and serum HDL cholesterol (mmol/l)

Variable	Obs	Mean	Std. Dev.	Min	Max	IQR
Age	**382**	**46.0**	**8.41**	**21**	**81**	**41 -52**
Systolic BP	**382**	**142.1**	**18.91**	**90**	**240**	**130-150**
Diastolic BP	**382**	**91.7**	**10.53**	**60**	**160**	**85-100**
Total cholesterol	**382**	**5.55**	**1.27**	**2.6**	**10.5**	**4.6-6.2**
HDL cholesterol	**382**	**1.08**	**0.312**	**0.3**	**2.7**	**0.9-1.2**

Figure 3. Age Distribution

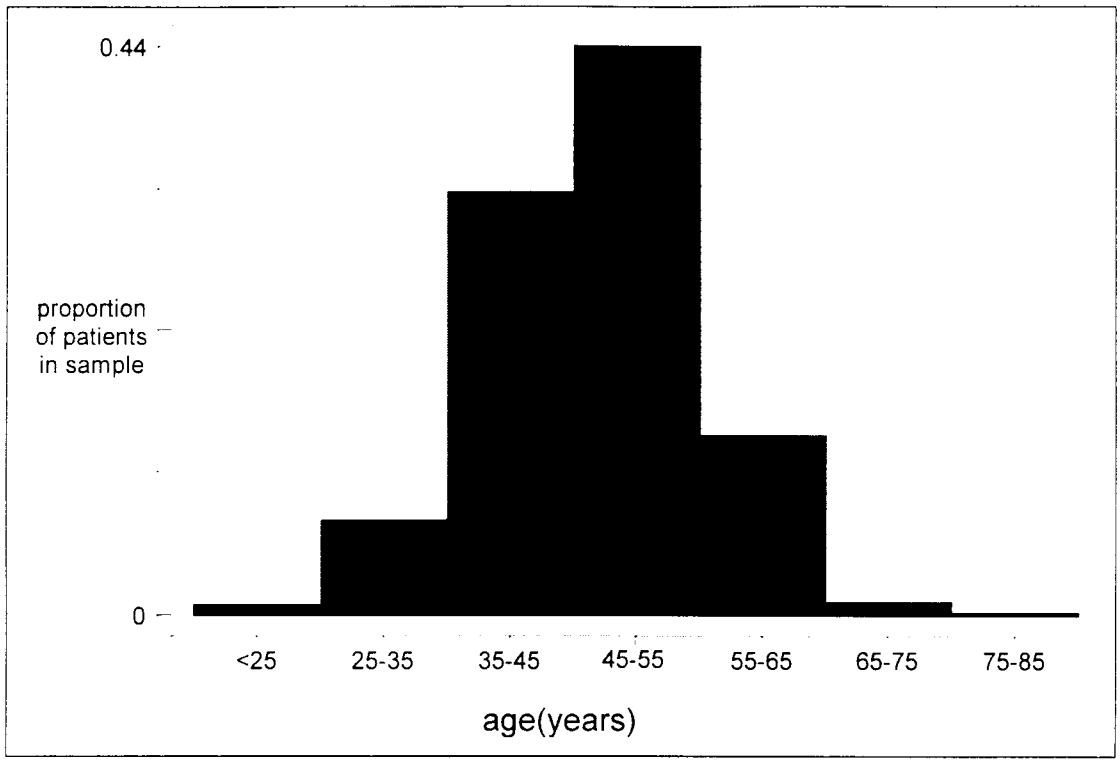


Figure 4. Systolic blood pressure distribution

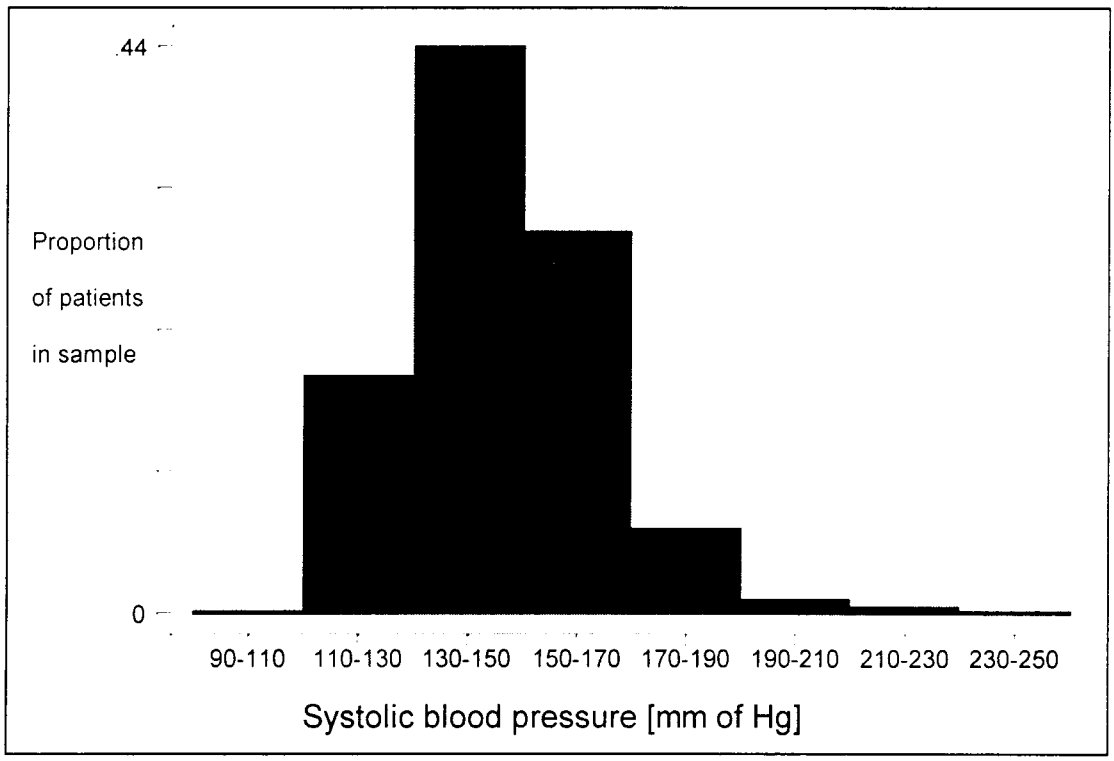


Figure 5. Diastolic blood pressure distribution

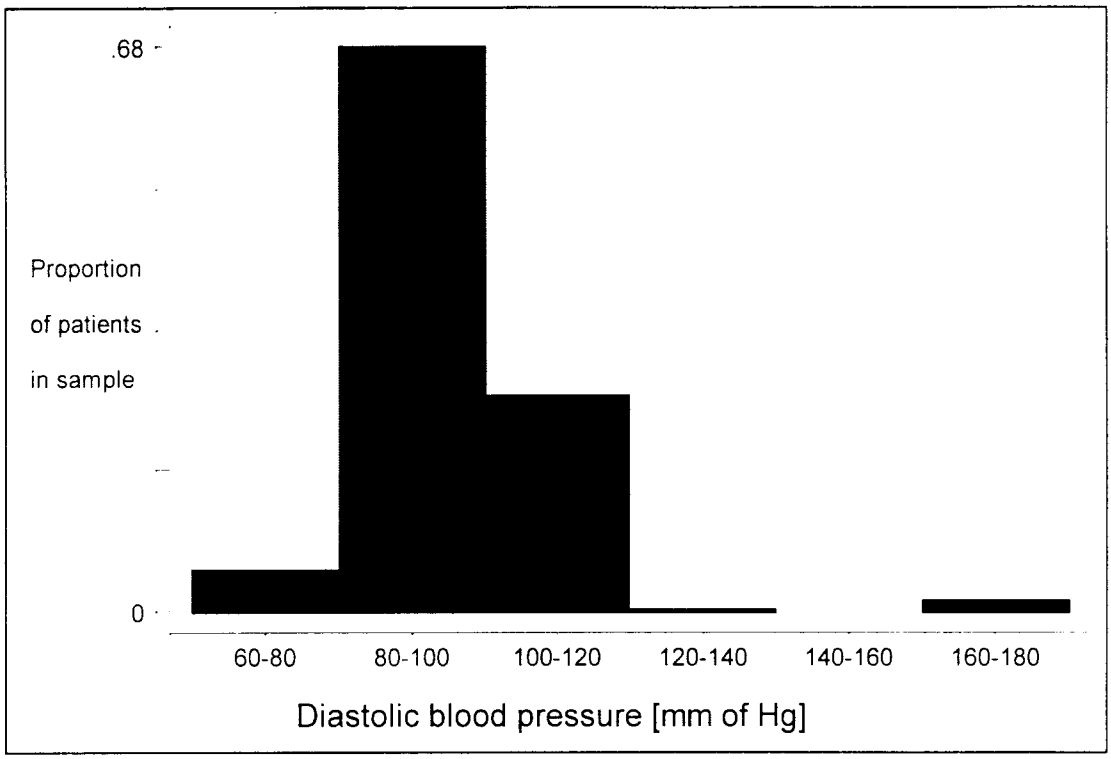


Figure 6. Total cholesterol distribution

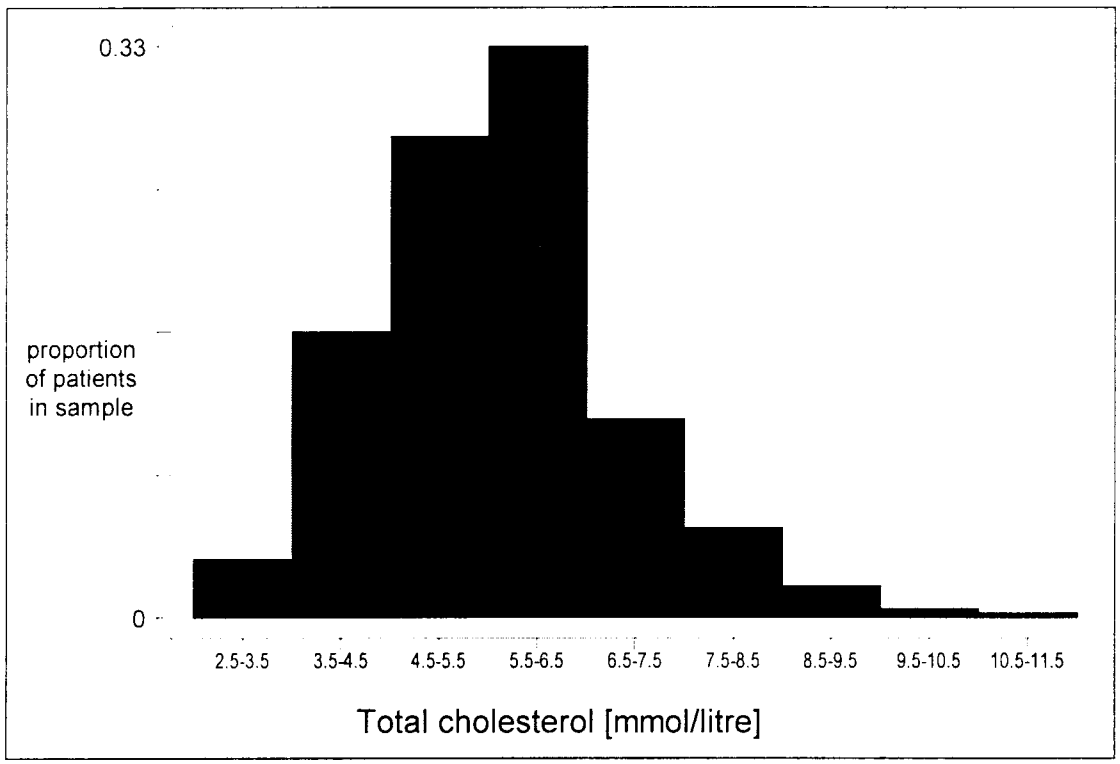
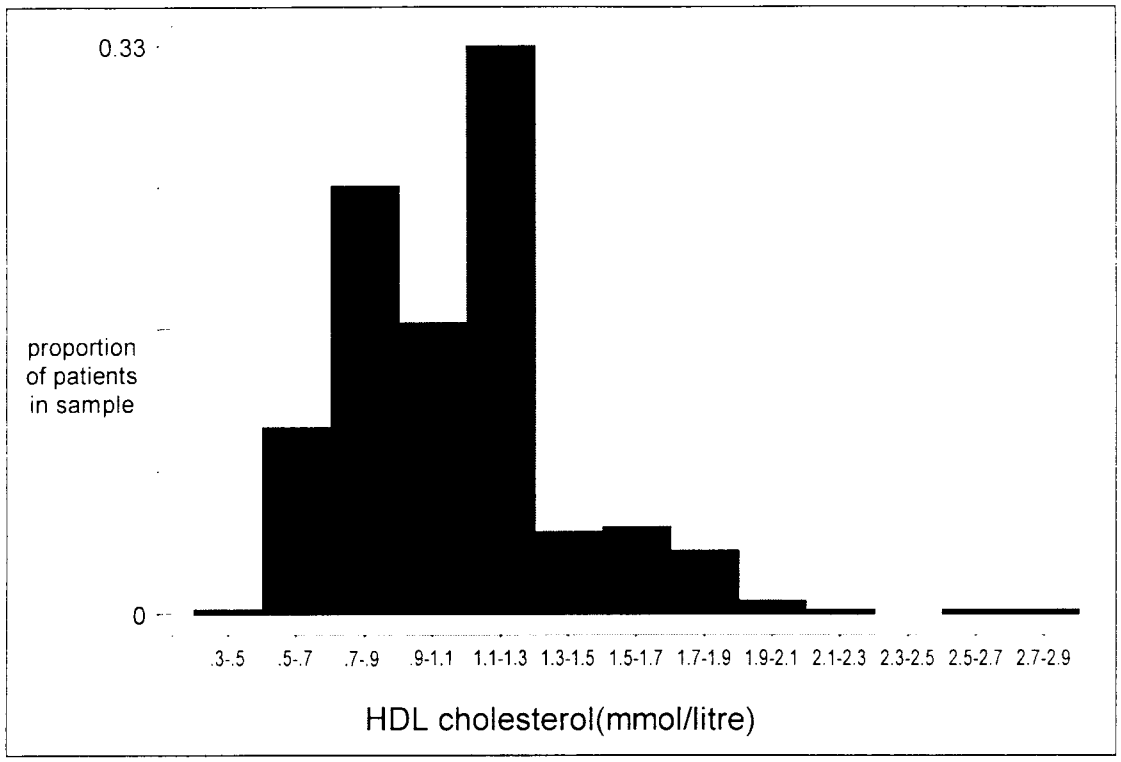


Figure 7. HDL cholesterol distribution



◊ **Smoking**

141 patients (36.9% [CI: 32.0- 42.0]) were current smokers or had smoked within the previous year

◊ **Diabetes**

91 patients (23% [CI 19.6 - 28.5]) were diabetic

◊ **Previous cardiovascular disease**

52 patients (13.6% [CI 10.3 - 17.5]) had previous cardiovascular disease

Risk categories

Complete data for every risk category was available for 363 patients.

Table 3. The distribution of risk of a cardiovascular event over the next five years. (New Zealand guidelines)

CVD 5 year risk	Freq.	Percent	Cum.
<2.5%	**91**	**23.8**	**23.8**
2.5-5%	**80**	**20.9**	**44.8**
5-10%	**77**	**20.2**	**64.9**
10-15%	**42**	**11.0**	**75.9**
15-20%	**20**	**5.2**	**81.2**
>20%	**20**	**5.2**	**86.4**
Previous CVD	**52**	**13.6**	**100.0**
Total	**382**	**100.0**	

Figure 8. The distribution of risk of a cardiovascular event in the following five years. (New Zealand guidelines)

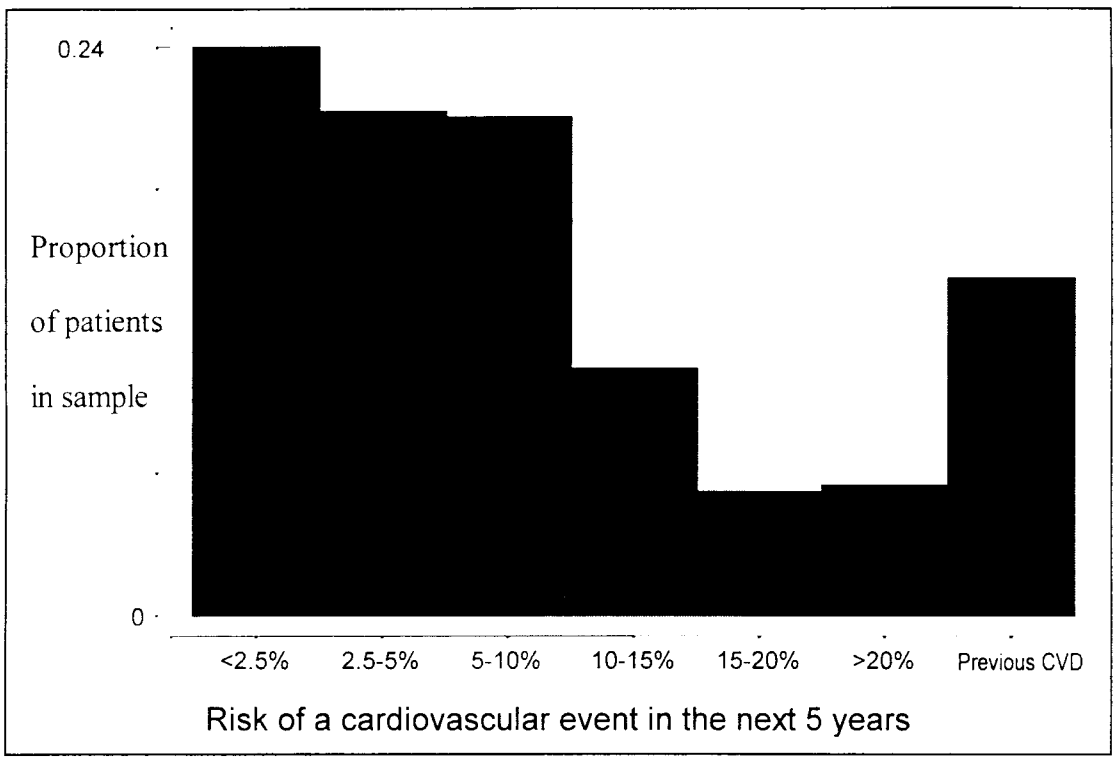
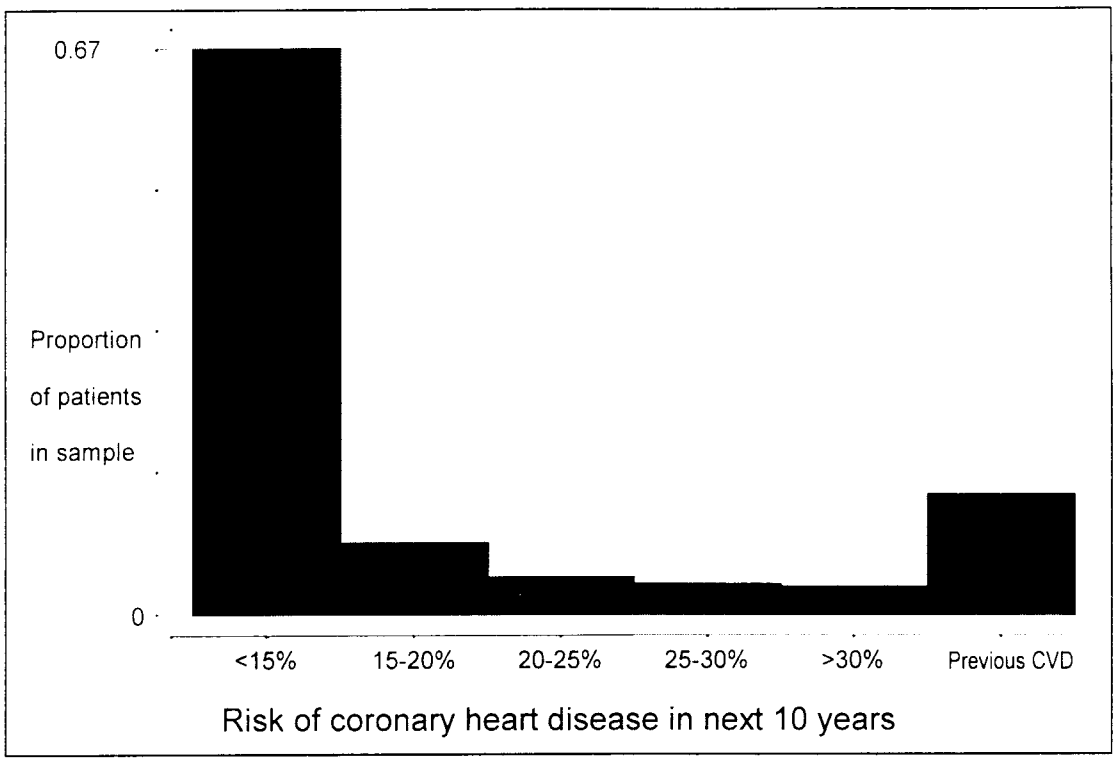


Table 4. The distribution of risk of coronary heart disease over the following 10 years. (Joint British guidelines)

CHD 10 year Risk	Freq.	Percent	Cum.
<15%	**255**	**66.8**	**66.8**
15-20%	**33**	**8.6**	**75.4**
20-25%	**17**	**4.5**	**79.8**
25-30%	**13**	**3.4**	**83.3**
>30%	**12**	**3.2**	**86.4**
Previous CVD	**52**	**13.6**	**100.00**
Total	**382**		**100.00**

Figure 9. The distribution of risk of coronary heart disease over the following 10 years. (Joint British guidelines)



Reanalysis of the data excluding the 19 patients in whom data were incomplete gave very similar results (see Appendix 2) Details of the missing data are given in Appendix 3.

◊ **Those patients above the cut off point for initiating treatment**

Using the New Zealand guidelines;

134 patients (35% [CI 30-40]) were at more than 10% risk of a cardiovascular event over the next 5 years. This is the cut off point for the initiation of treatment or the level at which reduction in medication is suggested in those on treatment.

Using the joint British recommendations;

127 patients (33%[CI 28-38]) were at more than 15% risk of coronary disease in the next 10 years.

◊ **Those patients below the cut off point for initiating treatment**

Using the New Zealand guidelines;

248 patients (65% [CI 60-70]) were at less than 10% risk of a cardiovascular event in the next 5 years (248 patients). Of these, five had a systolic blood pressure > 170 mmHg for whom the New Zealand guidelines recommends treatment regardless of the cardiovascular risk.

Using the joint British recommendations;

255 patients (67% [CI 61 – 71]) were at less than 15% risk of coronary heart disease in the next 10 years. Of these, 21 of these had a systolic blood pressure over 160 mm Hg for whom the joint British guidelines recommend treatment regardless of the level of risk.

Table 7. Patients above and below the levels at which treatment should be initiated according to the New Zealand guidelines and the Joint British recommendations.

	Patients with favourable* risk calculation, without severe hypertension**	Patients with favourable risk calculation, but with severe hypertension	Patients with unfavourable risk calculation	Total
According to New Zealand guidelines	243 (64% [CI 59-68])	5 (1.3% [CI 0.4-3.0])	134 (35% [CI 30-40])	382
According to Joint British recommendations	234 (61%) [CI 56-66%]	21 (5.5% [CI 3.1-8.2])	148 (39% [CI 34 –44])	382

*A favourable risk calculation is defined as less than a 10% risk of cardiovascular disease within five years (New Zealand guidelines) or less than 15% risk of coronary heart disease within the following ten years (Joint British recommendations). An unfavourable risk calculation is above these levels of risk.

**Severe hypertension is defined as systolic blood pressure above 170mmHg (New Zealand guidelines) or above 160 mmHg (Joint British recommendations).

◊ **Those who remain at very high risk despite treatment.**

Using the New Zealand guidelines;

72 patients (19% [CI 15 - 23 %]) are at > 20% risk of a cardiovascular event in the next 5 years.

20 of these patients, 5% of the total, [CI 3.2-7.9%] have not had a previous cardiovascular event and

52 of them, 14% of the total [CI 10-17%] are at high risk because of a previous cardiovascular event.

Using the joint British recommendations;

64 patients (17% [CI 13-20%]) are at > 30% risk of coronary heart disease in the next 10 years.

12 of these patients, 3.3% of the total [CI 1.6 -5 %] have not had a previous cardiovascular event and

52 of them, 14% of the total [CI 10 –17] are at high risk because of a previous cardiovascular event.

Discussion

In this study of hypertensive patients 61-64% were at low risk of cardiovascular disease and therefore should be considered for cessation of treatment. This approach also identifies 17- 19% who remain at high risk despite current treatment and may benefit from more intensive treatment.

The management of mild to moderate hypertension by assessment of cardiovascular risk is preferable to using only the level of blood pressure. (1) (8) (27) (9). This study illustrates that there is scope to retarget the limited resources available to those at highest risk and who have the most to gain from treatment.

Strengths and weaknesses of the study

The study benefits from the inclusion of detailed information on the relevant risk factors on almost all patients. Reanalyses explored assumptions about missing data and confirmed that the assumptions were justified. The study population of mainly female, working class coloured South Africans attending a private sector clinic, has rarely been included in other studies.

Appropriateness of the Framingham equations

The use of the Framingham equations has been justified because the Framingham study included women, had relatively complete and long follow up and has been validated in other populations. The incidence of cardiovascular disease is comparable between the US and coloured South Africans, and in other populations with similar incidences of cardiovascular disease, the Framingham equations have reliably predicted the risk of cardiovascular disease. However, all the populations in whom the equations have been validated are white high-income populations. Although the overall incidence of cardiovascular disease is similar in both populations, there is a much higher incidence of cerebrovascular disease and a lower incidence of ischaemic heart disease in coloured women than in

the US population. The potential biases of these factors are unknown. The Framingham equations remain the best available until similar studies are done in South Africa.

Possible Biases

Selection bias

Data was collected on just over a quarter of patients eligible for the study. Patients were selected if they attended the clinic while a fieldworker was recruiting. Included patients were therefore attendees and more likely to be complying with their management than the group not recruited. Patients with severe cardiovascular disease may have been too ill to attend the clinic. Both these factors would tend to bias the calculated risks downwards. Patients with unrecognised hypertension were excluded from the study. This could bias the risk levels in either direction.

Information bias

Data about previous cardiovascular disease and diabetes were extracted from patients' records and from self-reporting by the patients. There would be inaccuracies from both, probably more under reporting, which would bias the results towards falsely lower levels of risk. Patients with diabetes are more likely to have been attendees than non-diabetic patients. This would bias the risk categories upwards. However, the prevalence of diabetes in this sample was 23%. A study of randomly selected non-institutionalised coloured South Africans over the age of 64 found the prevalence of diabetes using glucose tolerance testing to be 30.3% in women. (72) This figure would be commensurate with the figure of 23% in this sample with a mean age of 46 years.

Patients' replies to questions about their smoking history are susceptible to reporting bias. This is also likely to bias the risk categories downwards. Studies in South Africa, New Zealand and UK have demonstrated under reporting of smoking history by about a quarter when self reporting was compared with cotinine validated smoking levels. (73) (74)

Precision

The sample size was more than adequate to ensure satisfactory precision. (Minimum sample size calculated was 211 and the study included 382 patients.)

Reliability

Despite careful training of the clinicians involved in the study, manual sphygmomanometer blood pressure readings are subject to operator related variation. However, two studies in Germany evaluating manual sphygmomanometers and externally validated automatic devices concluded that manual sphygmomanometers should not be replaced by automatic devices in epidemiological studies. (75). Measurement of cholesterol levels is subject to random variation due both to biological variation and variation in the laboratory analysis.

Limitations of the study design

The study was a cross sectional study and the patients were currently on treatment. Treatment will have affected their blood pressure. The study was unable to evaluate the pre-treatment risks and so the appropriateness or otherwise of the initial decision to start treatment. It is likely that a proportion of the patients, in whom this study suggests that cessation of treatment is appropriate, would not have been started on treatment if that initial decision had been risk-based. Conversely, some patients with a high risk of cardiovascular disease but mildly raised blood pressure will have been missed from the study because they were not being treated. The risk may have remained high despite treatment in some patients because of poor adherence to treatment or the failure of the treatment regime used; this was not examined.

The outcome of most interest, cardiovascular events, could not be studied in a small cross sectional study. A longitudinal study with a follow up long enough for sufficient cardiovascular events to occur would be required.

The management of cardiovascular risk requires evaluation and management of all the risk factors such as smoking, high cholesterol and the control of diabetes. This study demonstrates the use of risk categories, which can be used to identify those who will benefit most from interventions in any of the risk factors to reduce cardiovascular risk. However, only the treatment of blood pressure is discussed. The principle of managing blood pressure according to cardiovascular risk may be generalised to other settings; however because the incidence of cardiovascular disease varies in different populations the absolute risk categories derived from Framingham data may not be generalisable.

It is not logical to assess whether there was an independent effect of age or gender on the adequacy of treatment, expressed as risk, as these factors are themselves risk factors for cardiovascular disease.

Potential cost savings:

The drug costs saved by step-down of treatment have been estimated. They have been estimated assuming that treatment would be withdrawn only from patients whose risk is currently below the level recommended for initiation of treatment. This is the level at which step-down of treatment is recommended in the New Zealand guidelines. Of patients in whom treatment would be withdrawn, it was assumed that 27.7% would remain below the level of risk at which treatment is recommended after 2 years. (65). Only the savings made from withdrawing treatment on patients who would successfully remain at low risk off treatment for at least 2 years were included.

Estimated cost saving from step-down of treatment in patients treated in the public sector.

Two estimates of drug costs have been used to predict the savings, which would be made by stepping down treatment, one for the public sector and one for the private sector.

Firstly, the mean monthly drug cost of 8.24 South African rands, per patient treated for hypertension, measured at a community health centre in the Cape Flats area of Cape Town in 1992 was used. This figure examined costs in the public sector. (76)

The savings per currently treated hypertensive patient over two years by attempting step-down on suitable low risk patients were calculated as follows:

(proportion who are suitable low risk patients) * (proportion of those who could be expected to remain off treatment) * (monthly drug cost) * 24 months

= (243/382) * 0.277 * 8.25 * 24 = R35

This represents a potential saving over two years of R35 per patient or 18% of the total cost of treating hypertension.

Estimated cost savings from step-down of treatment in the clothing workers clinics.

The actual monthly costs to the clothing industry workers' fund for hypertensive medication per patient were calculated by the medical director of the fund in October 2000 to be R19.20. (77). The difference in the two cost estimates can be explained partly by the effects of inflation in the intervening 8 years but also because drug costs to the public sector are discounted and a larger number of more expensive drugs such as angiotensin converting enzyme inhibitors are used in the private sector.

The savings over two years by attempting step-down on suitable patients were calculated:

(proportion who are suitable low risk patients) * (Proportion who could be expected to remain off treatment) * (monthly drug cost) * 24 months

= (243/382) *0.277 * 19.20* 24 = R81.20

This represents a potential saving over two years of R 81.20 per patient or 18% of the total cost of hypertensive treatment.

If there were 1500 hypertensive patients in the fund then the annual cost savings for the fund would be R60900.

In addition to saving the costs of the medication, the iatrogenic effects of unnecessary anithypertensive medication would be avoided. Although those patients in whom medication has been withdrawn would still need to be followed up, there may be a reduction in the number of consultations necessary and in investigations necessary only for those on medication.

There are additional costs involved with using a risk-based approach. Measuring and recording the risk factors takes a few minutes within the consultation and blood must be taken and analysed for cholesterol measurements. The costs for total and HDL cholesterol measurement in the private sector in South Africa are set by the Medical Scheme Benefit tariff. In 2000 the costs were R17.90 and R25.60 respectively. These would be one off costs for each patient at the time of diagnosis of hypertension. Using the sample mean for total and HDL cholesterol would be a cheaper alternative but would produce changes in the risk categories, which are clinically unacceptable. (See appendix 4)

Appropriate cautions when using a risk-based approach to the management of hypertension.

Tables of risks derived from risk equations can be used to inform the management of hypertension. The risk tables estimate the risk of a cardiovascular event. They do not include any judgement by the patient or the clinician about the importance to the individuals of these risks or the disadvantages and side effects of being on antihypertensive treatment. A study in elderly patients with atrial fibrillation in the UK examined the impact of patients' preferences, on treatment choices. Patients' preferences, were expressed using decision analysis and were compared with evidence-based recommendations based on absolute risk of stroke. The authors concluded that patients' preferences could have an important impact on treatment choice in elderly patients, with nearly 40% of patients with atrial

fibrillation in the study preferring not to receive anticoagulation. Furthermore, when compared with guidelines based on absolute risk of stroke, there was marked disagreement. Guidelines ignoring patients' preferences would recommend treatment for a higher proportion of patients. (78)

The risk calculations are applicable only to patients with mild to moderate hypertension. The application of the risk calculations to patients with severe hypertension, in this study, would have resulted in the inappropriate cessation of treatment in 5 (1.3% [CI 0.4-3.0]) patients (New Zealand guidelines) who had a low risk but severe hypertension. (21 patients (5.5%[CI 3.1-8.2]) according to the joint British recommendations). The risk calculations are also invalid for patients with a history of cardiovascular disease. Clinicians using risk calculations must be aware of their limitations.

Recommendations to the Clothing Industry Benefit Fund

On the basis of this study, clinicians working in the clothing workers benefit clinics should be encouraged to evaluate hypertensive patients according to their absolute risk of cardiovascular disease rather than their blood pressure in isolation from other risk factors. Patients already on treatment for their blood pressure whose risk is below the recommended levels for the initiation of treatment should be considered for reduction or cessation of treatment. The cardiovascular risk of newly diagnosed hypertensive patients should be assessed, and management directed at reducing the risk by considering all the risk factors including blood pressure. Current clinical practice needs to be changed in the clinics.

Although this study was a cross sectional study, able only to study patients already on treatment, the findings can be extrapolated to new hypertensive patients, suggesting that this approach to the initiation as well as maintenance of treatment should be adopted.

Guidelines, which use an absolute risk approach, should be developed locally. The guidelines need to be sensitive to local epidemiology and cost-benefit considerations. They are more likely to be successfully implemented if local professionals are involved in their development and promotion. (54)

As cerebrovascular disease is particularly common in this population, guidelines, which include cerebrovascular disease as an end-point are more appropriate than those which use only coronary heart disease. For this reason guidelines similar to the New Zealand guidelines are recommended rather than the joint British recommendations.

Risk charts have been developed, from Framingham equations, to make estimation of patients' risks easier for clinicians (79). Similar charts are incorporated into both the New Zealand and joint British guidelines. These risk charts are also available on the internet and could be incorporated into local guidelines. Computer decision support systems have also been developed to calculate individual patient's risk (80) (81). A study in general practice in UK using an early computer decision support system did not show any improvement in absolute cardiovascular risk compared to normal care. Using risk charts a non-significant reduction in absolute risk and a significant reduction in mean systolic blood pressure (4.6 mmHg) was demonstrated when compared to normal care (63). Currently risk charts rather than computer support systems are recommended. Later, if the computer systems improve and the clothing fund medical records are computerised, this recommendation can be reassessed.

Recommendations to health services in South Africa and other middle-income countries.

The use of risk categories developed from the Framingham equations are justifiable in the coloured population of South Africa because the population has a similar incidence of cardiovascular disease to

that in the US where the Framingham study was conducted. Considerable caution would have to be exercised if these risk categories were used in other populations in South Africa, particularly the black population who have a much lower incidence of cardiovascular disease. (20) Even in the black population, in whom the predicted absolute risk would probably be over estimated, the relative risk, in treated compared with untreated patients, should be accurately predicted and could help to target the resources at those who would most benefit from treatment (39). In other middle- income countries the use of the risk categories would depend on the baseline incidence of cardiovascular disease.

Priorities for future research

Further studies are needed to evaluate the risks of cardiovascular disease in South African patients at the time of diagnosis of hypertension before treatment is initiated.

A study is recommended to determine the number of patients in whom treatment is stopped and who can remain off treatment, using absolute risk rather than only the level of blood pressure as a threshold for stopping treatment and measuring success.

Risk equations developed from South African populations would be preferable to using the Framingham risk equations but would require a large cohort to be studied for a long period with good follow up which would be difficult and expensive. Such a study could evaluate the effect on cardiovascular morbidity and mortality of clinical guidelines, which promote a risk-based approach to the management of hypertension.

A full economic analysis of using a risk-based approach could be included.

Conclusion

This study demonstrates that managing patients with mild to moderately raised blood pressure, who have no previous history of cardiovascular events, according to their absolute risk of cardiovascular disease would result in a different group of patients being treated. The treatment should be targeted at

those with most to gain from treatment. Treatment and its costs and side effects could be avoided in patients who are at low risk of cardiovascular disease. Clinicians need to be encouraged to take a risk-based approach to the management of hypertension in their everyday clinical practice. This study shows that such an approach could have a dramatic effect on the targeting and effectiveness of hypertension treatment.

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Appendices

Appendix 1

Instructions for clinicians

Measuring mid upper arm circumference

- Remove clothing
- Locate mid arm;

  Bend fore-arm

  Measure between bony shoulder and elbow parts

  Calculate centre and mark arm with pen
- Allow arm to relax
- Wrap tape measure around mid-arm at mark
- Hold firmly but not tight
- Take reading to nearest 0.1 cm
- Record measurement

Measuring blood pressure

- Seat respondent at least 5 minutes and explain procedure. *
- Make sure respondents legs are not crossed
- Place right arm on table at arm level
- Remove tight clothing
- Apply correct cuff to bare arm
- Rubber inflatable part should cover inner arm and artery
- Leave 2.5 cm space above cubital fossa

- Feel radial pulse
- Inflate cuff to locate **estimated systolic pressure** watch the mercury on inflation when pulse disappears and/or on deflation when pulse is felt
- Release air rapidly
- Wait one minute before measuring with stethoscope....
- Place stethoscope bell over brachial artery at ant cubital fossa
- Press firmly and keep airtight
- Inflate cuff to **30 mmHg** above **estimated systolic pressure**
- Deflate immediately at a pace of 2-3mm per second
- Listen for 2 consecutive beats
- Read diastolic pressure when sound disappears
- Deflate cuff
- Record reading exactly where sounds are heard i.e. **do not round off to the nearest mark on the mercury column**
- Repeat measurement twice after waiting one minute in between

* Explain you will be taking a few measurements to get the correct reading.

Appendix 2

Reanalysis of the data without the 19 subjects for whom data were incomplete:

Table A. The risk of a cardiovascular event over the following five years (without imputing data)

CVD Risk Category	Frequency	Percentage	Cum.
<2.5	86	23.7	23.7
2.5-5%	75	20.7	44.4
5-10%	74	20.4	64.7
10-15%	38	10.5	75.2
15-20%	19	5.2	80.4
>20%	19	5.2	85.7
Previous CVD	52	14.3	100.00
Total	363	100.00	

Table B. The risk of coronary heart disease over the next 10 years. (without imputing data)

CHD Risk Category	Frequency	Percentage	Cum.
<15%	240	66.1	66.1
15-20%	31	8.5	74.7
20-25%	15	4.1	78.8
25-30%	13	3.6	82.4
>30%	12	3.3	85.7
Previous CVD	52	14.3	100
Total	363	100	

Appendix 3

Details of the missing data.

The following items of data were missing in the 19 patients for whom data were incomplete;

Item of missing data	Number missing
Gender	1
Self reported history of diabetes	4
Self reported history of heart disease	5
Self reported history of stroke	4
Smoking history	5
History of angina in medical records	3
History of stroke in medical records	2

Appendix 4

Reanalysis of the data using mean values for total cholesterol and HDL cholesterol

Table A. The risk of a cardiovascular event over the next five years using mean total cholesterol and HDL cholesterol values.

CVD 5 year risk	Freq.	Percent	Cum
< 2.5%	**88**	**23.0**	**23.0**
2.5-5%	**74**	**19.4**	**42.4**
5-10%	**105**	**27.5**	**69.9**
10-15%	**35**	**9.2**	**79.1**
15-20%	**13**	**3.4**	**82.5**
>20%	**15**	**3.9**	**86.4**
Previous CVD	**52**	**13.6**	**100**

Table B. The risk of coronary heart disease over the next 10 years using mean total cholesterol and HDL cholesterol values.

CHD risk category	Frequency	Percentage	Cum.
<15%	**278**	**72.8**	**72.8**
15-20%	**29**	**7.6**	**80.4**
20-25%	**13**	**3.4**	**83.8**
25-30%	**6**	**1.6**	**85.3**
>30%	**4**	**1.0**	**86.4**
Previous CVD	**52**	**13.6**	**100**
Total	**382**	**100**	**100**

Appendix 5

Data sheet used for collecting the data from patient's medical records.

(File converted from Word Perfect)

Appendix 5

Data sheet used for collecting the data from patient's medical records.

(File converted from Word Perfect)

Appendix 5

Data sheet used for collecting the data from patient's medical records.

(File converted from Word Perfect)

CLOTHING INDUSTRY: HYPERTENSION DATA COLLECTION SHEET

13/02/98

Office Use

I.D. Nr 4

1.	Study Number: ______________________				
2.	Clothing Fund Number: ______________________				
3.	Doctor's code: ______________________				
4.	Factory: ______________________				17
5.	Name of patient: ______________________				
	Is patient principal member?	Yes = 1	No = 2		
6.	Gender:	Male = 1	Female = 2		
7.	Date of birth:	Day	Month	Year	25
8.	Address:	______________________			
		______________________			
		______________________			
		______________________			
9.	Name of Clinic:	Athlone	1		
		Mitchell's Plain	2		
		Delft	3		
		Charlesville	4		
		Grassy Park	5		
		Salt River	6		
		Elsies River	7		
		Atlantis	8		
10	Occupation: ______________________				27

	HYPERTENSION DATA																		
11	Date of diagnosis of hypertension? (9999 if not recorded)																		33
		Day			Month			Year											
12	Family history of hypertension recorded?	Yes = 1			No = 2														42
13	Family history of heart disease recorded?	Yes = 1			No = 2														42

Office Use

	RECORDED SYMPTOMS OF, OR PAST MEDICAL HISTORY OF				
14	Heart attack / angina?	Yes = 1	No = 2		
15	Stroke, transient ischaemic attack?	Yes = 1	No = 2		
16	Leg cramps at rest or after walking (claudication)?	Yes = 1	No = 2		47
17	Postural Hypotension?	Yes = 1	No = 2		
	RECORD OTHER DISEASES				
18	Asthma?	Yes = 1	No = 2		
19	Diabetes	Yes = 1	No = 2		
20	Hyperlipidaemia?	Yes = 1	No = 2		50
	RECORD OTHER RISK FACTORS				
21	Smoking? Not recorded = 0	Yes = 1	No = 2		
22	Alcohol? Not recorded = 0	Yes = 1	No = 2		52
	WERE THE FOLLOWING EXAMINATION FINDINGS RECORDED?				
23	Height?	Yes = 1	No = 2		
	IF YES, Results: _____				
24	Weight?	Yes = 1	No = 2		54
	IF YES, Results: Before Study: _____ _____				

		During Study: _____			
25	Waist circumference?	Yes = 1	No = 2		
	IF YES, Results:	Before Study: _____			
		During Study: _____			
26	Hip circumference?	Yes = 1	No = 2		
	IF YES, Results:	Before Study: _____			
		During Study: _____			

Office Use

27	Heart examined?	Yes = 1	No = 2		60
	IF YES, Results: _____				
28	Pulses examined?	Yes = 1	No = 2		
	IF YES, Results: _____				
29	Ophthalmoscopy?	Yes = 1	No = 2		
	IF YES, Results: _____				
30	Blood pressure?	Yes = 1	No = 2		
	IF YES, Results:	Before study: _____			
		During study: _____			
31	Total Cholesterol?	Yes = 1	No = 2		
	IF YES, Results:	Before study: _____			
		During study: _____			
32	Triglycerides?	Yes = 1	No = 2		67

	IF YES, Results:	Before study: _____________________ _____________________________	
		During study: ____________________ _____________________________	

33	Urine test? Yes = 1 No = 2 **IF YES,** Results: Glucose _ _ _ _ _ _ _ _ _ _ _ _ _ _ Protein _ _ _ _ _ _ _ _ _ _ _ _ _ _ Blood _ _ _ _ _ _ _ _ _ _ _ _ _ _				***Office Use***
34	Creatinine?	Yes = 1	No = 2		68

	IF YES, Results:	Before study: _____			
		During study: _____			
35	ECG?		Yes = 1	No = 2	
	IF YES, Results:	Normal		1	
		AF		2	
		LVH		3	
		Past MI		4	
		Ischaemic		5	
		Other: _____		6	
36	CXR?		Yes = 1	No = 2	71
	IF YES, Results:	Normal		1	
		LVH		2	
		Enlarged heart		3	
		Other: _____		4	
37	Management plan recorded?		Yes = 1	No = 2	
38	Education delivered?		Yes = 1	No = 2	74
				I. D. Nr	4
39	Blood pressure controlled?		Yes = 1	No = 2	16
	IF YES, _ according to guidelines?		Yes = 1	No = 2	
	IF NO, _ according to guidelines?		Yes = 1	No = 2	18
					Office Use
40	Treatment:	Monotherapy	Yes = 1	No = 2	19
		Diuretics only	Yes = 1	No = 2	
		Beta Blockade	Yes = 1	No = 2	

		Calcium antagonist	Yes = 1	No = 2		
		Reserpine	Yes = 1	No = 2		
		Alpha Blocker	Yes = 1	No = 2		
		ACE Inhibitor	Yes = 1	No = 2		
		Other agents (specify)	Yes = 1	No = 2		26
		_____				
	Combination therapy:	Including diuretic	Yes = 1	No = 2		
		List other drugs: _____				
		Excluding diuretic	Yes = 1	No = 2		
		List other drugs:_____				
	IF NO, was medication changed according to guidelines?		Yes = 1	No = 2		29
41	Referrals:	Day Hospital	Yes = 1	No = 2		
		Hypertension Clinic	Yes = 1	No = 2		
		Other hospital	Yes = 1	No = 2		
42	New complications during study?		Yes = 1	No = 2		36
	IF YES, Results: _____					
43	Time off work recorded?		Yes = 1	No = 2		
	IF YES, how many half -days?		_____			
44	Number of visits in previous 6 months?		_____			41
45	Family Planning	None	1			
		Contraceptive pill	2			

		Depo injection	3		
		Condoms/creams	4		
		Sterilization	5		
		Post menopausal	6		
46	Pap smear in the past year	Yes = 1	No = 2		43

Appendix 6

Questionnaire administered by field workers.

QUESTIONNAIRE ON DIABETES AND HYPERTENSION - CLOTHING INDUSTRY

13/02/98

						Office Use
					I.D. Nr	4
A	**GENERAL AND DEMOGRAPHIC INFORMATION** ***Firstly, we would like to ask some questions about yourself.*** ***Everything you say will be strictly confidential.***					
1.	Interviewer's name _______________________________ ___					
2.	Name of Factory _______________________________ ___					
3.	Type of Factory	Large = 1	Small = 2	Intermediate = 3		9
4.	Clothing Fund Number ________________________ ___ ___					16
5.	Date	Day	Month	Year		22
6.	Name of Patient: _______________________________					

	_ _ _ _ _ _ _ _
7.	Address: _
	Telephone number: _
8.	Gender — Male = 1 — Female = 2
9.	Age at last birthday _
	Date of Birth — Day — Month — Year — 31
10.	Home Language: Afrikaans 1; English 2; Other (specify) _ 3

11.	Marital Status	Single	1		
		No partner	2		
		Married	3		
		Divorced	4		
		Widowed	5		
		Separated	6		
		Living with partner	7		33
12.	Religion	Muslim	1		
		Protestant	2		
		Catholic	3		
		Other_____________________________	4		34
13.	What is the highest standard you have passed in school?			***Office Use***	
		Less than standard 5	1		
		Standard 5	2		
		Standard 6	3		
		Standard 7	4		
		Standard 8	5		

		Standard 9	6		
		Matric	7		35
14.	Do you have further education or training?	Yes = 1	No = 2		
	IF YES:				
	What is your highest qualification? ________________________ ___				
	How did you obtain it?	College	1		
		Technicon	2		
		University	3		
		In-service Training	4		
		Other (specify) ________ ___ __________________ ___	5		37
B	**USE OF HEALTH SERVICES** *We would like to ask where you have been for your health care in the last 3 months*				
1.	Have you attended the Clothing Fund Clinic for medical care during the last 3 months?	Yes = 1	No = 2		
	IF YES,				

How many times? _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _			40

Some people say that the treatment they got at the clinic is good, some say it is alright, others say it is not good at all. What do you think?

	Good = 1	Satisfactory = 2	Poor = 3	

IF POOR, Why was it poor? ***DO NOT PROMPT THE OPTIONS***

Long Wait	1		
Short consultation	2		
Staff rude / unkind	3		
Didn't see the doctor	4		
Doctor did not examine	5		
Didn't get all the tablets you needed	6		
No reason given	7		
Other (specify) _	8		42

_ _

_ _

					Office Use
2.	Have you attended a Panel Doctor for medical care during the last 3 months?				
		Yes = 1	No = 2		43
	IF YES,				
	How many times? _____				
	Some people say that the treatment they got at the panel doctor is good, some say it is alright, others say it is not good at all. What do you think?				
	Good = 1	Satisfactory = 2	Poor = 3		
	IF POOR, Why was it poor? ***DO NOT PROMPT THE OPTIONS***				
	Long Wait			1	
	Short consultation			2	
	Staff rude / unkind			3	
	Doctor did not examine			4	
	Didn't get all the tablets you needed			5	
	No reason given			6	
	Other (specify) _____ _____			7	47

_____

_____

3. Have you attended a Day Hospital for medical care during the last 3 months?

Yes = 1	No = 2	

IF YES,

How many times? _____

Some people say that the treatment they got at the day hospital is good, some say it is alright, others say it is not good at all. What do you think?

Good = 1	Satisfactory = 2	Poor = 3	

IF POOR, Why was it poor? ***DO NOT PROMPT THE OPTIONS***

Long Wait	1
Short consultation	2
Staff rude / unkind	3
Didn't see the doctor	4
Doctor did not examine	5
Didn't get all the tablets you needed	6
No reason given	7

	Other (specify) _____ _____ _____ _____	8		52	
4.	Have you attended any of the following for your health during the last 3 months?				***Office Use***
	Private doctor (not panel doctor)	Yes = 1	No = 2		53
	Health services at factory	Yes = 1	No = 2		
	Chemist shop	Yes = 1	No = 2		
	Faith healer/ Traditional healer	Yes = 1	No = 2		
	Dentist / dental nurse	Yes = 1	No = 2		
	Other Clothing Fund clinic	Yes = 1	No = 2		
	Referral hospital (eg Tygerberg, Groote Schuur, etc.)	Yes = 1	No = 2		
	Private Hospital	Yes = 1	No = 2		
	Other (specify) _____ _____ _____ _____	Yes = 1	No = 2		61

5.	Do you have any suggestions to improve the medical care you receive within the clothing industry?	Yes = 1			
		No = 2			
		Don't know = 3			
	IF YES, (specify) _____ ___ _____ ___ _____ ___				
C	**FAMILY MEDICAL HISTORY**				
1.	Do you have a mother, sister or daughter who has had a heart attack, or angina (pain in the chest with exertion)?	Yes	1		
		No	2		
		Don't know	3		
	IF YES, at what age? _____				65
2.	Do you have a father, brother or son who has had a heart attack or angina (pain in the chest with exertion)?	Yes	1		
		No	2		
		Don't know	3		
	IF YES, at what age? _____				68

3.	Do you have a mother, sister or daughter who has had a stroke?	Yes	1	
		No	2	
		Don't know	3	
	IF YES, at what age? _ _ _ _ _ _ _ _ _ _ _ _ _ _ _			71
4.	Do you have a father, brother or son who has had a stroke?	Yes	1	
		No	2	
		Don't know	3	
	IF YES, at what age? _ _ _ _ _ _ _ _ _ _ _ _ _ _ _			74
5.	Do you have a close blood relative (father, mother, brother, sister or child) who has had diabetes or blood sugar trouble? *(suikersiekte)*	Yes	1	
		No	2	
		Don't know	3	
	IF YES, at what age? _ _ _ _ _ _ _ _ _ _ _ _ _ _ _			77
6.	Do you have a close blood relative (father, mother, brother, sister or child) who has had raised blood pressure? *(hoë bloeddruk)*	Yes	1	***Office Use***
		No	2	
		Don't know	3	78
	IF YES, at what age? _ _ _ _ _ _ _ _ _ _ _ _ _ _ _			80

	I.D. Nr							4
D	**PERSONAL MEDICAL HISTORY** ***Tell us about you and your condition.***							
1.	Do you have high blood pressure or tablets for high blood pressure (also called hypertension)?	Yes	1					
		No	2					
		Don't know	3				5	
	IF NO, go to next question (nr 2)							
	IF YES,							
1.1	Have you been told about high blood pressure (also called hypertension) by your doctor or nurse?	Yes	1					
		No	2					
		Don't know	3					
1.2	Would you, if you were feeling completely well,							
	Stop your blood pressure tablets?	Yes	1					
		No	2					
		Don't know	3					
	Continue with your blood pressure tablets?	Yes	1					
		No	2					
		Don't know	3				8	

1.3	What happens if blood pressure is not treated? ***DO NOT PROMPT THE OPTIONS***				
	Stroke	Mentioned = 1	Not mentioned = 2		
	Heart attack	Mentioned = 1	Not mentioned = 2		
	Kidney failure	Mentioned = 1	Not mentioned = 2		
	Heart failure	Mentioned = 1	Not mentioned = 2		
	Don't know	Mentioned = 1	Not mentioned = 2		
	Other: _____ __	Mentioned = 1	Not mentioned = 2		14
	_____ _____				
1.4	How do you know if your blood pressure is high? ***DO NOT PROMPT THE OPTIONS***				
	Measure it	Mentioned = 1	Not mentioned = 2		

Headache	Mentioned = 1	Not mentioned = 2		
Feel tired	Mentioned = 1	Not mentioned = 2		
Dizzy / nausea	Mentioned = 1	Not mentioned = 2		
Other: ____________ ______________________________________	Mentioned = 1	Not mentioned = 2		19

Office Use

1.5 If a person's blood pressure is high what can he/she do to bring it down?

DO NOT PROMPT THE OPTIONS

Control weight	Mentioned = 1	Not mentioned = 2		20
Limit salt intake	Mentioned = 1	Not mentioned = 2		
Limit alcohol intake	Mentioned = 1	Not mentioned = 2		
Take blood pressure tablets	Mentioned = 1	Not mentioned = 2		

		Other: ___________	Mentioned = 1	Not mentioned = 2
1.6	If someone does not take his/her blood pressure tablets regularly, what are the reasons? ***DO NOT PROMPT THE OPTIONS***			
		Forget	Mentioned = 1	Not mentioned = 2
		Costs	Mentioned = 1	Not mentioned = 2
		Run out of tablets	Mentioned = 1	Not mentioned = 2
		Feel healthy	Mentioned = 1	Not mentioned = 2
		Tablets make you feel bad	Mentioned = 1	Not mentioned = 2
		Other: ___________	Mentioned = 1	Not mentioned = 2
2.	Do you have diabetes (or high blood sugar)?		Yes	1

25

		No	2		
		Don't know	3		31
	IF NO, go to next question (nr 2.5)				
	IF YES,				
2.1	If diabetes is not well treated, what problems can occur in that person's body? ***DO NOT PROMPT THE OPTIONS***				
	Eye problems	Mentioned = 1	Not mentioned = 2		
	Kidney problems	Mentioned = 1	Not mentioned = 2		
	Foot problems	Mentioned = 1	Not mentioned = 2		
	Heart attacks	Mentioned = 1	Not mentioned = 2		
	Don't know	Mentioned = 1	Not mentioned = 2		
	Other: _____ _	Mentioned = 1	Not mentioned = 2		37

	_____	

Office Use

2.2	How do you know if your blood sugar is high? ***DO NOT PROMPT THE OPTIONS***				
	Pass more urine	Mentioned = 1	Not mentioned = 2		38
	Infections / thrush	Mentioned = 1	Not mentioned = 2		
	Tiredness	Mentioned = 1	Not mentioned = 2		
	Loss of weight	Mentioned = 1	Not mentioned = 2		
	Thirsty	Mentioned = 1	Not mentioned = 2		
	Don't know	Mentioned = 1	Not mentioned = 2		
	Other: _____	Mentioned = 1	Not mentioned = 2		
	_____				

2.3 If blood sugar is high, what can be done to bring it down?

DO NOT PROMPT THE OPTIONS

Increase treatment	Mentioned = 1	Not mentioned = 2		45
Stop eating sweet foods	Mentioned = 1	Not mentioned = 2		
Eat less	Mentioned = 1	Not mentioned = 2		
Exercise more often	Mentioned = 1	Not mentioned = 2		
Don't know	Mentioned = 1	Not mentioned = 2		
Other: _____ __	Mentioned = 1	Not mentioned = 2		

_____ _____

2.4 If someone does not take his/her diabetes (blood sugar) tablets regularly, what are the reasons? ***DO NOT PROMPT THE OPTIONS***

Forget	Mentioned = 1	Not mentioned = 2		51

	Costs	Mentioned = 1	Not mentioned = 2	
	Run out of tablets	Mentioned = 1	Not mentioned = 2	
	Feel healthy	Mentioned = 1	Not mentioned = 2	
	Tablets make them feel bad	Mentioned = 1	Not mentioned = 2	
	Other: _____	Mentioned = 1	Not mentioned = 2	

_____

2.5	Were you ever told about a low fat diet?	Yes	1		
		No	2		
		Don't know	3		57

Office Use

2.6	Tell us what do you do to reduce the fat in your diet. ***DO NOT PROMPT THE OPTIONS***				
	Eat less sausages, processed meat	Mentioned = 1	Not mentioned = 2		58

	Drink low fat milk	Mentioned = 1	Not mentioned = 2		59
	Avoid butter	Mentioned = 1	Not mentioned = 2		
	Don't use full-fat cheese	Mentioned = 1	Not mentioned = 2		
	Avoid ice cream, chocolates	Mentioned = 1	Not mentioned = 2		
	Trim fat off meat	Mentioned = 1	Not mentioned = 2		
	Fry food less often	Mentioned = 1	Not mentioned = 2		
	Vegetarian	Mentioned = 1	Not mentioned = 2		
	Other _____ _	Mentioned = 1	Not mentioned = 2		
	_____ _____				
2.7	Do you feel you can ask your doctor for advice about		Yes	1	

	diabetes or blood pressure?	No	2		
		Don't know	3		67
2.8	Do you feel you can ask your nurse for advice about diabetes or blood pressure?	Yes	1		
		No	2		
		Don't know	3		
2.9	Would you come to the clinic for talks about diabetes or blood pressure?	Yes	1		
		No	2		
		Don't know	3		
E.	**MEDICATION TREATMENT** ***We would like to know about your treatment***				
1.	Do you use any tablets or injections regularly that have been prescribed by a doctor or nurse?	Yes	1		
		No	2		
		Don't know	3		70
	IF YES,				
2.	How often?	Every day	1		
		Occasionally forget	2		
		More than 5 days a week	3		
		Less than 5 days a week	4		74

3.	Do you know what the tablets or injections are for?		Yes	1	
			No	2	
	If YES:		All of them	3	
			Some of them	4	76
4.	Which of the following health problems do you use the tablets or injections for:				***Office Use***
					I.D. Nr 4
	High Blood Pressure?	Yes = 1	No = 2	Don't know=3	5
	Diabetes / Sugar?	Yes = 1	No = 2	Don't know=3	
	High Blood Cholesterol?	Yes = 1	No = 2	Don't know=3	
	Angina / chest pain?	Yes = 1	No = 2	Don't know=3	
	Heart condition?	Yes = 1	No = 2	Don't know=3	
	Asthma, Emphysema or Bronchitis?	Yes = 1	No = 2	Don't know=3	

Tuberculosis	Yes = 1	No = 2	Don't know=3		
Stroke	Yes = 1	No = 2	Don't know=3		
Hormone Replacement Therapy	Yes = 1	No = 2	Don't know=3		
Family Planning (contraception)	Yes = 1	No = 2	Don't know=3		14

5.	**IF SO,** how many different type of tablets or injections for each condition listed in 4:				
	High Blood Pressure?	_ _ _ _ _ _ _ _			16
	Diabetes / Sugar?	_ _ _ _ _ _ _ _			
	High Blood Cholesterol?	_ _ _ _ _ _ _ _			20
	Angina / chest pain?	_ _ _ _ _ _ _ _			
	Heart condition?	_ _ _ _ _ _ _ _			

	Asthma, Emphysema or Bronchitis?		_____ __		26
	Tuberculosis?		_____ __		
	Stroke?		_____ __		
	Hormone Replacement Therapy?		_____ __		32
	Family Planning (contraception)?		_____ __		
	Don't know? (NA = 0)		3		35
6.	Do you have any side effects from the medication?	Yes	1		
		No	2		
		Don't know	3		
	IF YES, please specify. _____ _____ _____ _____ _____ _____				

7.	**IF YES,** Have you discussed the side-effects with your doctor / clinic nurse?	Yes	1	
		No	2	
F.	**HABITS AND LIFESTYLE** ***Now, we would like to know about your daily life***			
1.	How do you usually eat your food?	Very salty	1	
		Lightly salty	2	
		Not salted	3	
		Don't know	4	38

Office Use

2.	Do you eat salty snacks more often than three times per week (Such as chips, niknaks, salted peanuts, salty biscuits, biltong, dried sausage, dried fish, smoked fish)?	Yes	1	
		No	2	39
3.	Do you eat fried food often?	Yes	1	
		No	2	
4.	Do you personally think that you are:	Underweight	1	
		Normal weight	2	
		Overweight	3	

		Don't know	4		
5.	Have you ever smoked?	Yes	1		
		No	2		42
	IF NO, go to next question, nr 6 **IF YES,**				
5.1	Have you ever smoked at least 100 cigarettes or the equivalent amount of tobacco in you lifetime?	Yes	1		
		No	2		
5.2	Have you ever smoked daily, regularly or every day?	Yes	1		
		No	2		
5.3	Do you now smoke daily, occasionally, or not at all?	Daily	1		
		Occasionally	2		
		Not at all	3		45

5.4	On average, what number of the following items do/did you smoke per day? ***PROBE AND FILL IN NUMBER FOR EACH ITEM***	Manufactured cigarettes					47
		Hand-rolled cigarettes					
		Pipefuls of tobacco					51

		Cigars/cheroots/cigarillos					
5.5	How old were you when you started smoking daily?						
5.6	How many years have you smoked / did you smoke daily?						57
5.7	Have you ever tried to quit smoking?	Yes	1				
		No	2				58

IF YES, how long has it been since you last smoked daily?

Less than one month	1		
One month or longer but less than six months	2		
Six months or longer but less than one year	3		
One year or longer but less than five years	4		
Five years or longer but less than ten years	5		
10 Years or longer	6		59

Office Use

5.8	Some people think that smoking is harmful to one's health; Other people think that smoking is good for your health; Some people think it does not matter to one's health whether one smokes or not.

	What do you think?	Harmful to one's health	1		
		Good for one's health	2		
		Does not matter	3		60
5.9	Do you live in a house where other people smoke cigarettes regularly?	Yes	1		
		No	2		
5.10	Do you now work in a job where other people smoke cigarettes around you?	Yes	1		
		No	2		
6.	Do you drink alcohol?	Yes	1		
		Never	2		
		Used to	3		63
	IF NEVER, go to question 7. **IF YES**, go to question 6.1 **IF USED TO,** go to question 6.7				
	KEY: ONE DRINK *(for questions 10, 11)*				

	= 25 ml hard liquor (1 tot) - (rum, gin, whisky, etc.) = 60 ml sweet wine/sherry = 120 ml table wine = 340 ml beer ("dumpie") = 1l sorghum beer = "concoction"			
6.1	How much alcohol do you drink on average during the week?	No drinking during the week	1	
		1-2 Drinks per day	2	
		3-4 Drinks per day	3	
		5 or More drinks per day	4	
		Communal drinking	5	
6.2	How much alcohol do you drink on average on weekends?	No drinking during weekend	1	
		1-2 Drinks per day	2	
		3-4 Drinks per day	3	
		5 or More drinks per day	4	
		Communal drinking	5	65
6.3 .	Have you ever felt that you should cut down on your drinking?	Yes	1	
		No	2	
6.4	Have you ever felt bad or guilty about your drinking?	Yes	1	
		No	2	

6.5	Do you get annoyed if someone mentions your drinking?	Yes	1		
		No	2		
6.6	Do you sometimes feel like a drink first thing in the morning to steady you nerves or get rid of hang-over?	Yes	1		
		No	2		69

Office Use

6.7	When you used to drink, did you ever feel you should cut down on your drinking	Yes	1		
		Often	2		
		Sometimes	3		
		Never	4		70
6.8	When you used to drink, did you ever fell guilty about drinking?	Yes	1		
		No	2		
6.9	When you used to drink, did ever get annoyed if someone mentioned your drinking?	Yes	1		
		No	2		
6.10	When you used to drink, did ever feel like a drink first thing in the morning to steady your nerves or get rid of a hang-over?	Yes	1		
		No	2		73
			I.D. Nr		4
7.	We would now like to ask some questions about exercise over the last 7				

	days (By exercise we mean an action like walking, carrying, jogging, that can make you sweat or breath faster or make your heart beat faster.	
7.1	Please think about your typical work-day. Estimate all the activities performed during a typical work-day (including the lunch break) and the average duration with an accuracy of 15 minutes.	

Activities at work	Duration					
Sitting	________ h ________ min					8
Standing	________ h ________ min					
Walking on a level	________ h ________ min					
Climbing stairs	________ h ________ min					20
Lifting or carrying heavy things	________ h ________ min					
Walking to get to and from work	________ h ________ min					
Other (specify) _	________ h ________ min					32

7.2	How many days of the last 7 days did you work? _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ (days)	

7.3	On average, how many hours do you work each day? _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ (hours)		36
7.4	**Seven-Day Physical Activity Recall (PAR)** Interviewer-administered ***(Circle Workdays)***	*Office Use*	

PAR WORKSHEET

		Mon	Tues	Wed	Thursday	Friday	Saturday	Sunday
Sleep hours								
MORNING	Moderate							
	Hard							
	Very hard							
AFTERN	Moderate							
	Hard							
	Very							

O O N	hard												
E V E N I N G	Moderate												
	Hard												
	Very hard												
7.5	Total moderate activity:			Working days	_ _ _ _ _ _ _ _ _ _ (minutes)								40
				Non-working days	_ _ _ _ _ _ _ _ _ _ (minutes)								
7.6	Total hard activity:			Working days	_ _ _ _ _ _ _ _ _ _ (minutes)								48
				Non-working days	_ _ _ _ _ _ _ _ _ _ (minutes)								
7.7	Total very hard activity:			Working days	_ _ _ _ _ _ _ _ _ _ (minutes)								

		Non-working days	___________ (minutes)							60
7.8	Compared to your physical activity over the past 3 months, was last week's activity more, less or about the same?									
		More = 1	Less = 2	Same = 3						
	INTERVIEWER'S QUESTIONS:									
7.9	Were there any problems in administering the 7-day PAR?		Yes = 1	No = 2						
	IF YES, Please explain: ______________________________ ________ ____ ________									
7.10	Do you think this was a valid 7-day PAR interview?		Yes = 1	No = 2		63				
	IF YES, Please explain: ______________________________ ________ ____ ________									

Office Use

	I. D. Nr					4	

7.1	Were there any activities which you did not know how to classify?						
1		Yes = 1	No = 2				
	IF YES, Please list activity, and the intensity and duration which you allocated to it. Please explain.						
	Activity _____ _____				7		
	Intensity _____ _____						
	Duration (min) _____ _____						13
	Activity _____ _____						
	Intensity _____ _____				17		
	Duration (min) _____ _____						21
	Activity _____ _____						
	Intensity _____ _____				25		

		Duration (min) _____ _____					29
7.12	Other comments: _____ _____ _____ _____ _____ _____ _____ _____						31
7.13	Some people say that exercise can help for diabetes or hypertension or diabetes and hypertension, some say it makes no difference, others say it is bad. What do you think?	Good	1				
		No difference	2				
		Bad	3				
		Don't know	4				
7.14	In relation to other people of your age at your factory do you:	Exercise More?	1				
		About the same amount?	2				
		Probably less?	3				
		Don't know?	4				

7.15	In relation to your friends, relatives and neighbours of the same age, do you:		
	Exercise More?	1	
	About the same amount?	2	
	Probably less?	3	
	Don't know?	4	34

Office Use

7.16	Can you tell us why exercise is said to be good for you?			
	Makes you fit	Mentioned = 1	Not mentioned = 2	35
	Makes you feel good	Mentioned = 1	Not mentioned = 2	
	Helps for hypertension (lowers BP)	Mentioned = 1	Not mentioned = 2	
	Can help for diabetes (lowers blood glucose)	Mentioned = 1	Not mentioned = 2	38
	Helps for the heart	Mentioned = 1	Not mentioned = 2	

	Helps you lose weight	Mentioned = 1	Not mentioned = 2		
	Helps you relax	Mentioned = 1	Not mentioned = 2		
	Other (specify) _____ ___	Mentioned = 1	Not mentioned = 2		42
	_____ _____				

G	**FAMILY / DOMESTIC ARRANGEMENTS**					
1.	Do you have help with:	Usually	Occasionally	Never		
	Cooking?	1	2	3		
	House cleaning?	1	2	3		
	Child care?	1	2	3		
	Home budget?	1	2	3		
2.	How many children do you care for? _____ ___					48
3.	Is childcare a problem for you while you are at work?	Yes	1			
		No	2			

4.	How many people, including children, belong to your household? (not visitors) _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _				
5.	How many rooms (only bedrooms and living rooms) are there in the house / place where you live? _				53
6.	If married, or living with partner:				
6.1	Is your partner employed?	Yes	1		
		No	2		
6.2	Is your partner on medical aid?	Yes	1		
		No	2		
7.	Do you feel that you have someone to share your problems with?	Yes	1		
		No	2		
		Don't know	3		56
	IF YES, Who? _				
					Office Use
8.	Do you have any ways to relax?	Yes	1		
		No	2		
		Don't know	3		57

	IF YES, (Specify): _____ _____ _____ _____			
9.	Have you sought help for personal problems?	Yes	1	
		No	2	
	If yes, from whom? _____ _____ _____ _____ _____ _____			
10.	Would you trust your doctor with private information?	Yes	1	
		No	2	
		Don't know	3	
		Do not see a private doctor	4	
11.	Would you trust your nurse with private information?	Yes	1	
		No	2	
		Don't know	3	
		Do not see a nurse	4	60
12.	Would you trust your social worker with private	Yes	1	

	information?	No	2		
		Don't know	3		
		Do not see a social worker	4		
H	**WORK AND YOUR DISEASE** ***Can you now tell us something about your work?***				
1.	Are you able to leave work to keep appointments at the clinics / CHC?	Yes	1		
		No	2		
		Sometimes	3		
2.	Do you use your full allocated sick leave every year?	Yes	1		
		No	2		63
3.	How many days or ½days have you taken off for Blood pressure in the last 3 months? _ _ _ _ _ _ _ _ _ _ _ _ _ _ _				
4.	How many days or ½days have you taken off for Diabetes in the last 3 months? _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _				
5.	What job do you do at work?	Machinist	1		
		Cutter	2		
		Packer	3		

			4	
			5	68

Office Use

6.	Are you a shop steward?	Yes	1	
		No	2	69
7.	Do you work shift hours?	Yes	1	
		No	2	70

I PROBLEMS

Now we would like to ask about things that worry you

	I. D. Nr						4

1.	Are you exposed to any unpleasant factors at work?	Yes	1	
		No	2	

IF YES, Which of the following (can be more than one):

Too much heat	Yes = 1	No = 2		
Too much cold	Yes = 1	No = 2		
Too much noise	Yes = 1	No = 2		
Dust	Yes = 1	No = 2		
Exhaust gas, smoke, gas	Yes = 1	No = 2		10

Eyes overworked	Yes = 1	No = 2		
Too much travelling	Yes = 1	No = 2		
Shift hours	Yes = 1	No = 2		
Overtime work	Yes = 1	No = 2		
Uninteresting / boring work	Yes = 1	No = 2		
Bad relationship with supervisor	Yes = 1	No = 2		
Bad relationship with SACTWU representatives	Yes = 1	No = 2		17
Bad relationship with other colleagues	Yes = 1	No = 2		
Other (specify) ______ ___ _________________________ ____	Yes = 1	No = 2		19

2. In relation to other people your age, do you regard yourself as being?

Less Healthy	1		
More Healthy	2		
Same	3		22