A STRATEGY FOR THE PERIODIC ASSESSMENT OF THE DEGREE OF

HYPERTENSION CONTROL IN THE COMMUNITY
A STRATEGY FOR THE PERIODIC ASSESSMENT OF THE DEGREE OF

HYPERTENSION CONTROL IN THE COMMUNITY

By

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A Thesis

Submitted to the School of Graduate Studies

in Partial Fulfilment of the Requirements

for the Degree

Master of Science

McMaster University
MASTER OF SCIENCE (1978)  McMaster University
(Medical Sciences)  Hamilton, Ontario.

TITLE: A Strategy for the Periodic Assessment of the Degree of Hypertension Control in the Community

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NUMBER OF PAGES: xiv, 275
Hypertension is a chronic affliction which has a significant economic and health impact on Canadian society. Efforts to control hypertension are likely to produce significant returns, if the programs are effective in treating the hypertensive population. Before research efforts can be profitably directed at determining the most efficient method of achieving hypertension control, the state of, and deficiencies in, the present health care system must be identified. The best approach to obtaining the information needed to evaluate the present system, is through a special-purpose, population-based survey.

The proper methodologic design of a population survey requires the use of probability sampling procedures. In addition, the blood pressure should be measured at several visits, using a standardized procedure. Examination of the literature reveals that no study satisfies all of the basic standards.

It is possible to identify six steps that must be followed if hypertension control is to be achieved. These steps form a conceptual model that can provide the basis of a general measurement strategy that can be used to assess the degree of hypertension control in a specific community.

This measurement strategy is used to develop a survey design to measure the degree of hypertension control in the Province of Ontario.
A specially-created interview team will examine 3,850 individuals, located in selected geographic areas across the Province. Blood pressure will be measured using a Hawksley Random-zero Sphygmomanometer, at a maximum of three separate visits. Questionnaires will be developed to obtain valid information about health knowledge, attitudes and beliefs. The survey design will permit regional comparisons.
I want to thank the large number of people without whose help and guidance this thesis would never have reached its final form. My special thanks to Dr. D.L. Sackett for directing my attention to the need for evaluating hypertension control and for then helping me to struggle through the development of this idea. In addition, I want to express my deep appreciation for the two years of stimulation and counselling that I have received from him. Dr. G.D. Anderson provided a much needed source of encouragement and direction for resolving the statistical complexities which have been a major part of this thesis. Dr. A.L. Johnson provided many stimulating comments for improving the final presentation. These members of my thesis committee have shown the ability to assimilate a large volume in a short time in order to help meet my deadlines.

I thank Dr. P. Tugwell for being available when I needed to talk. Wayne Taylor has helped to shape the investigation of the psychosocial aspects of this problem. The staff of the Health Sciences Library has been very helpful - I hope your Xerox machine has survived! To my office mates, thank you, and you now have your desks back again. Special appreciation is directed to the three typists who helped to get my late copy ready in time. Mrs. Jane Wright and Mrs. Ruby Mitchell provided a much needed boost at the end. My most special appreciation goes to Mrs. Jane Sicurella whose ceaseless hours of typing and preparation and many thoughtful
comments have eased the preparation of this rather large document.

My last, but far from least, thanks are for my dear wife, Sharon. The last weeks of preparing this thesis have prevented me from participating fully in our new adventure. Now that this document is finally completed, may we share many years of happiness together in our new home.
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1. INTRODUCTION

Hypertension refers to a chronic, usually non-remitting, elevation of blood pressure. Although hypertension should not be regarded as a disease, it will be seen (Chapter 2) that hypertension is a risk factor for the development of cardiovascular disease, cerebrovascular disease and certain types of renal disease. It will also be seen that efficacious treatment is available which will reduce the risk of developing these complications. The present chapter will examine the impact that hypertension, and its complications, have on the health of society.

In Canada, vital statistics data indicate that in 1971, ischaemic heart disease was responsible for 31.1% of all deaths in Canada and 9.3% of all days in hospital (107). Cerebrovascular disease accounted for an additional 10.2% of deaths and 5.4% of hospital days (107). These two disease classes are exceeded only by accidents as a cause of loss of potential years of life, accounting in 1971 for a loss of nearly 240,000 potential years of life (107). Many of these lost years represent the most productive years of life. It is obvious that the economic impact of these diseases is large. Estimates of the actual extent of this impact vary. Kristen (91), calculated that hypertension cost the United States populace $15.9 billion in 1975, a figure which represented 1.1% of the Gross National Product for that year. In Ontario, the Ontario Council of Health (161) estimated that, in 1971, cardiovascular, cerebrovascular and hypertensive disease cost a combined
direct and indirect amount of $400 million, a figure which represents 16% of the total cost of ill health. Hypertension and cerebrovascular disease alone represented a cost of about $100 million. Smith (152) estimated the cost of preventable ischaemic heart disease in Canada, using 1971 data, to be $550 million. An estimate of the cost attributable to hypertension was $184 million.

Despite the variation, it can be seen that the economic impact of hypertension, and its complications, is large. However, it is doubtful if secondary prevention could achieve the full savings which might be thought possible based on the above figures. This doubt is based on three factors:

(1) the cost of therapy;

(2) the problems of patient compliance with long-term therapy;

(3) the observed fact that therapy does not result in complete removal of excess risk, especially for complications such as ischaemic heart disease (126).

Kristen (91) provides a relatively optimistic estimate that a secondary prevention program could save the United States nearly $4 to $6 billion per year. Weinstein and Stason (183) performed a cost-effectiveness analysis of hypertension and reached the conclusion that the therapy is cost-effective only for certain types of patients. They also estimated that a completely effective secondary prevention program would produce an increase in life-expectancy of between 10 and 15%, depending upon age.
The above discussion reveals the impact of hypertension and its complications at a particular point in time. It is also important to assess the manner in which this impact varies over time. Figure 1.1 reveals the mortality rate from four selected forms of cardiovascular disease in Canada from 1958-1968 (160). It is seen that while mortality from arteriosclerotic heart disease has remained constant, mortality from hypertension and its complications has been declining. Figure 1.2 shows evidence that this trend has been occurring since at least 1950 (165). Since this was before effective antihypertensive therapy became generally available, this trend is probably not due, solely, to the use of antihypertensive therapy. Variation in the interpretation of ICDA reporting categories represents one possible explanation. Such variation is difficult to document.

Despite the apparent decline in mortality for hypertension-related diseases, the societal impact is still large. There is also definite promise that secondary prevention of hypertension represents one of the few community health programs which are demonstrably beneficial and cost-effective (165). Evidence will be presented in Chapter 4 to indicate that the present health care system is not realizing the full potential that such a secondary prevention program could achieve. Efforts are presently underway to develop alternative, and more effective methods, of implementing a prevention program (1, 19, 25, 32, 68, 88, 89, 126, 139, 171, 172, 195). However, as Chapter 4 will discuss, before implementing research activities aimed at improving the present health system, it is necessary to have an accurate diagnosis of what actual deficiencies are present. The purpose of
Figure 1.1: TREND IN MORTALITY FROM HEART DISEASE IN CANADA, 1958-1968

Arteriosclerotic and Degenerative Heart Disease

All Hypertension

Hypertension With Heart Disease

Hypertension Without Heart Disease
Figure 1.2: HYPERTENSIVE DISEASE MORTALITY RATES (PER 100 000 POPULATION) 
BY SEX AND AGE FOR SELECTED COUNTRIES, 1950-71

AGE-GROUP - GROUPE D'ÂGE 45-54

AGE-GROUP - GROUPE D'ÂGE 55-64

AGE-GROUP - GROUPE D'ÂGE 65-74

AGE-GROUP - GROUPE D'ÂGE 75-84

AGE-GROUP - GROUPE D'ÂGE 85+

AUSTRALIA - AUSTRALIE
Males - Hommes
Females - Femmes

CANADA
Males - Hommes
Females - Femmes
this thesis is to develop a strategy which can be employed in a variety of situations to evaluate the extent of hypertension control. The strategy will also provide evidence about possible gross determinants of this measured control.
2. THE NATURE OF HYPERTENSION

2.1 Introduction

The definition of hypertension is: "abnormally high blood pressure" (33). This tautological definition conceals many subtleties which must be explored in order to obtain an understanding of the nature of hypertension. Such understanding provides the background which is necessary to appreciate the possibility and importance of control of hypertension. The meaning of, and biologic variation in, blood pressure, per se, begins the documentation of the nature of hypertension, as presented in this chapter.

Consideration is then given to methods which can be used to measure blood pressure. Next, attention is directed towards examining why it is bad to have high blood pressure and to an examination of a rational approach to develop criteria which can be used to label a person as hypertensive. Lastly, evidence is summarized that demonstrates that antihypertensive therapy is efficacious.

The literature related to hypertension is very extensive. A comprehensive search revealed that between 1920 and 1950 a total of 16,460 articles had been published which related to hypertension (23). It can easily be appreciated that no single review will ever be able to examine all the published literature. This chapter will concentrate on major articles in selected areas of interest.
2.2 The Biology of Blood Pressure

One of the most basic truths of biology is that all living cells require a constant supply of new nutrients (e.g., oxygen and glucose) and produce a constant supply of potentially toxic by-products (e.g., carbon dioxide, lactic acid). In unicellular animals, this flux of materials can be maintained by passive diffusion. However, as the complexity of living organisms increases, it rapidly became impossible to rely on a passive mechanism. Instead, an active system evolved whereby the cellular components of the organisms were bathed in a nutrient solution which was constantly replenished. Specialized organs also evolved to enable the efficient purification of this nutrient solution by delivering the toxic by-products to the outside environment and replenishing the supply of nutrients from this environment. In man, the nutrient solution is extracellular fluid. This is replenished by diffusion with blood which in turn circulates throughout the body in the cardiovascular system. Exchange with the environment occurs primarily in the lungs, kidney and gastrointestinal tract. Since the blood must be circulating throughout the body, it is necessary that a source of power be included in the cardiovascular system. This is provided by the heart, which functions like a pump by increasing the pressure head at one end of the cardiovascular system. It is this pressure head which is referred to as blood pressure.

Employing this conceptually simple model, one can quickly identify the two prime physiologic determinants of blood pressure. First, if the rate of circulation of the blood increases (increased
blood flow or cardiac output) and all other conditions are unchanged, then the pressure head also must be increased. Secondly, if there is increased resistance to flow through the cardiovascular system (peripheral resistance), then the pressure head must again increase. These relationships can be written:

\[ \text{Pressure} = \text{Cardiac Output} \times \text{Peripheral Resistance} \]

This relationship forms the basis of most physiologic investigations into hypertension.

The biological sciences rarely admit a model which is simple. This model is no exception. There are a number of complications which must be imposed upon this basic model before an accurate reflection of human physiology is achieved. It is beyond the scope of this thesis to discuss these complications in detail. The interested reader is referred to the discussions by Rushmer (134), Guyton (54), Milnor (105), and McDonald (101).

A short discussion of one of these complications is enlightening. The heart does not produce a constant blood pressure. Rather, the pressure fluctuates in a cyclical pattern corresponding to the contractile state of the left ventricle of the heart (Figure 2.1). This fluctuation is complex. Accurate measurement of instantaneous blood pressure of ambulant people is difficult. It is customary to compress the information of Figure 2.1 into two representative pressures:

1. The systolic pressure, or the highest pressure measured.
2. The diastolic pressure, or the lowest pressure measured.

The selection of these two pressures is entirely arbitrary and based
primarily on grounds of convenience. Although most research on blood pressure is based upon measurement of these values, there is no reason to restrict attention to only these characteristics of the blood pressure curve. Wheat et al. (186), suggest that the prognosis of dissecting aortic aneurysms is related to the rate at which the blood pressure increases during systole, rather than to the absolute blood pressure levels. Further research into similar relationships would be interesting.

The above discussion relates to the physiologic determinants of blood pressure. The maintenance of adequate blood flow to vital organs is crucial to survival. Since blood flow is dependent upon blood pressure, sophisticated control systems have evolved to provide for homeostatic control of blood pressure. The basic control system has three components:

(1) the sympathetic nervous system (29, 54);

(2) the renin-angiotension system (117);

(3) the control of salt and water load by the kidney.

A more detailed discussion of these components is beyond the scope of this thesis.

It is important to recognize that the control system does not exert tight control. Various external and internal stimuli can drastically change the blood pressure level (Table 2.1). The magnitude of such biologic variation has been documented by using automatic sphygmomanometers to measure 24-hour blood pressure on volunteers (11, 61, 75, 98, 140, 141, 185). Bevan et al. (11) recorded direct arterial pressure and obtained the representative tracing illustrated in
Table 2.1: SOME FACTORS WHICH HAVE SHORT-TERM EFFECTS ON SYSTEMIC ARTERIAL BLOOD PRESSURE*

(1) Diurnal Variation

(2) Environmental Factors
   - Defence Reflex
   - Emotion
   - Pain
   - Urinary Bladder Distention
   - Posture
   - Exercise
   - Valsalva Manoeuvre
   - Coitus

(3) Sleep

*Adapted from Pickering (119).

Figure 2.1: NORMAL PRESSURE PULSE CONTOUR
Figure 2.2a. Figure 2.2b summarizes the range of diastolic and systolic pressure recorded by this group. The tremendous variation is apparent. It is worth noting that several volunteers exhibited diastolic pressures in excess of 95 mm Hg at some time during the day.

From among the many stimuli inducing biologic variation, two related stimuli can be selected for further consideration because they have significant impact upon the clinical interpretation of blood pressure measurements. The defense (or orienting) reflex refers to the physiologic adjustments which accompany the focusing of attention of a new, strange or frightening object. It serves to prepare for a "fight or flight" response. One of the consequences of this reflex is an acute rise in blood pressure. The physician and clinic often constitute an intense stimulus to the patient, and thus provoke this type of response. Blood pressure is usually found to be higher at the clinic than at home (75) and is often found to reduce as the patient acclimatizes to the clinic and the physician (7, 116, 118, 125). A cardiovascular response, similar to that produced by the defense response, can be produced by fear or anger.

In view of this considerable biological variation, it is not surprising that attempts have been made to standardize the environmental circumstances under which blood pressure is measured. Pickering (119) discusses basal blood pressure, a procedure which minimizes environmental stress by using an overnight hospital admission combined with phenobarbitone administration. But, as Pickering concludes, "I have never had the physical or human resources
*Figure 2.2a: BILOGIC VARIATION IN BLOOD PRESSURE*

Arterial pressure, plotted at 5 min intervals, of subject A. The period of sleep is shown by the horizontal bar. The high pressures shown at 16 00 and 24 00 hours are due to a punitful stimulus and culus respectively.

*Figure 2.2b: DAILY RANGE OF ARTERIAL BLOOD PRESSURE*

Range of arterial pressure. The top bar of each range represents the average pressure during the highest recorded hour. The bottom bar represents the average during the lowest hour.
to measure such pressures on more than an occasional patient" (119). A more feasible compromise is to obtain a quasi-basal blood pressure. In this procedure, the patient is allowed to rest undisturbed for 5-10 minutes in a sitting position after first emptying his/her bladder. Then three consecutive blood pressure values are obtained and the results averaged. Even using this approach, the blood pressure will decrease over repeat visits (116) thus confirming that the defense reflex is still active.

2.3 Procedures for Measuring Blood Pressure

Thus far, the discussion has considered some of the biological barriers to accurate assessment of blood pressure and its impact. It is now time to consider how blood pressure can be measured clinically. There are two basic approaches in present use. The first involves inserting a pressure transducer directly into a convenient artery (e.g., the brachial artery). This method is the present reference standard for blood pressure measurement and is called the direct blood pressure. It is the only technique which can obtain a complete tracing of the instantaneous blood pressure. Its use is usually confined to specialized hospital units, although some groups have used this procedure in research projects to analyze ambulant patients (11, 98, 185). However, direct arterial pressure measurement does not yet have a role in the routine assessment of ambulant patients.

The second technique is called indirect measurement because it is non-invasive. There are many different procedures in use, but they all depend upon the same basic principle. This is illustrated
in Figure 2.3. First, a flexible cuff is wrapped around the patient's arm. This cuff contains an inflatable bag which is attached to an inflation bulb and a manometer. The cuff is then inflated until the artery is compressed between the bag and the deeper tissues, and no blood is flowing. As the cuff is slowly deflated, blood begins to flow through the artery, during the systolic part of the cardiac cycle. The turbulence of this intermittent flow produces sounds (called the Korotkoff sounds) which can be heard by listening over the brachial artery with a stethoscope. Finally, when the pressure is lowered to the extent that blood flow is continuous, the Korotkoff sounds cease. During the period of pressure fall, a total of five distinct phases can be detected (79). There is general concensus that the direct systolic pressure is best estimated by phase I but that this phase tends to under-estimate the direct blood pressure by about 10 mm Hg. Significant argument still rages over whether the phase IV (muffling) or phase V (disappearance) reading is the best value to use to represent the direct diastolic blood pressure (62,99,146,169). In one of the latest reviews of this problem, Short (146) recommends the use of phase V value. He suggests that, when compared to phase IV readings, the phase V pressure represents a slight but less significant overestimate of the direct diastolic pressure, and is subject to less observer variation. In fact, as implied by Short, the actual relationship between the direct and indirect pressure levels is not of overwhelming concern. Since all epidemiologic and therapeutic trials are based upon the use of indirect sphygmomamometry, mostly
**Figure 2.3:** INDIRECT SPHYGMOMANOMETRY

When the pressure within the sphygmomanometer cuff is increased above arterial blood pressure, the arteries under the cuff are occluded and no pulse can be palpated at the wrist. As the cuff pressure is gradually released, the systolic peaks of pressure finally exceed cuff pressure and blood spurs into the arteries below the cuff, producing palpable pulses at the wrist. The sudden acceleration of blood below the cuff produces vibrations which are audible through a stethoscope. The pressure in the mercury manometer at the time the pulse is heard or felt indicates systolic pressure. As cuff pressure is further diminished, the sounds increase in intensity and then rather suddenly become muffled at the level of diastolic pressure where the arteries remain open throughout the entire pulse wave. At still lower pressures, the sounds disappear completely when laminar flow is re-established.

*Reference (134).*
using the phase V values, it is more important to select a measurement that has the greatest possible reliability.

There are four sources of variability in blood pressure measurement:

1. biologic variation;
2. instrument maladjustment;
3. artifactual hypertension;
4. observer variation.

Biologic variation has been considered in section 2.2. The effect of this source of variation can be considerable. Quasi-basal blood pressure measurement will reduce, but not eliminate, this problem. The standard clinical solution requires that the blood pressure be repeated on several different occasions. The presence of an elevated blood pressure at each of these occasions is used to diagnose sustained (or clinical) hypertension. It will be seen later, that the clinical trials which demonstrated therapeutic usefulness of antihypertensive therapy used this type of criterion to demarcate the experimental population.

Instrument maladjustment should not occur if proper instrument and maintenance procedures are used (28). Aneroid sphygmomanometers, which employ a spring mechanism as the manometer, are especially liable to instrument maladjustment (108). The important source of potential bias, which falls into this category, involves the use of an inappropriate size of sphygmomanometer cuff. Park et al (115) report that using a small cuff (bladder width: arm circumference < 0.35 cm) resulted in a 13% over-estimate of blood pressure.
produced a 6% under-estimate of blood pressure. Similar results were obtained by Geddes and Tricy (43) who developed a table of recommended bladder sizes for specific ranges of arm circumference (Table 5.12).

Artificial, or pseudo, hypertension is a rare form of bias. It refers to circumstances where even an accurate indirect blood pressure measurement produces biased results due to mechanical effects such as aortic valve replacement (45), stiff brachial artery (162), or muscular activity (150).

Observer variation is an important source of bias which will be dealt with in some detail. The prime origin of this form of variation is that indirect sphygmomanometry uses human judgment about changes in sound quality to determine the blood pressure measurements. This use introduces many possible sources of variation, at both the subconscious and conscious levels (Table 2.2). Jane Wilcox (189) performed one of the first systematic studies of inter-observer variation in blood pressure measurement. Two different experimental models were used to study graduate nurses: a double stethoscope comparison and a specially designed sound motion picture. Similar results were obtained in both experiments and revealed the following standard deviations:

systolic blood pressure: 3 mm Hg
phase IV blood pressure: 13 mm Hg
phase V blood pressure: 7 mm Hg

These values suggest that inter-observer variation is a significant problem and that phase V blood pressure is subject to less variation.
Table 2.2: SOME COMPONENTS OF THE CONCEPT OF OBSERVER-VARIATION

(1) Incorrect application of the cuff.

(2) Eye not level with mercury meniscus.

(3) Blood pressure release too slow or too fast.

(4) Stethoscope pressure too light or too heavy.

(5) Auditory acuity.

(6) Timing of measurement with Korotkoff sounds.

(7) Preconceived idea of patient's blood pressure.

(8) End-digit preference.
More detailed analysis of these data indicates that a significant proportion of this variation can be attributed to a few aberrant recorders. Rose et al. (129) repeated part of this study with a group of physicians and found similar results. This study suggested that clinical training was associated with more variability in measurement.

End-digit bias refers to a tendency for an observer to record an excess of blood pressure values which end with particular digits (usually 0 or an uneven digit). Oldham et al. (112) report, that in one large-scale epidemiological study, over 70% of the blood pressure readings ended with zero. Similar results were found by Rose et al. (129) and Nielsen et al. (110). The effect of end-digit bias is to effectively render the blood pressure scale less sensitive than it need be. Thus, in the above study, a diastolic pressure of 90 mm Hg could represent 85 or 95 mm Hg. This reduces the usefulness of the measurement.

Expectation bias is a subtle bias which is produced when an observer knows what cut-off level will be used to delineate the hypertensive population. This knowledge can result in a scarcity of values recorded at the cut-off point together with a relative increase in the number of values which are recorded near to the cut-off. This bias can be compounded by a measurement bias (130), such that the observer tends to produce values that are higher or lower than those of other observers. These forms of bias are difficult to quantitate. However, their importance is clearly
demonstrated by Oldham et al. (112) who examine apparent bimodality in blood distribution curves, and ascribe this visual impression to an expectation-type bias.

Now that the significance of observer variation has been established the question arises as to what can be done to improve the situation. Several strategies can be developed to reduce the magnitude of observer variation (Table 2.3). As discussed earlier, there is some evidence that the use of naive observers will lead to improved precision in data collection (129). However, the usefulness of of strategies #1, 2, 4, 5, and 6, as listed on Table 2.3, has not yet been demonstrated. Rose (130) discusses a training program whereby special series of blood pressure recordings are used as training tools. This protocol has the advantage of providing an objective assessment of the mean bias that a particular observer exhibits. This estimate can be reported with research to provide an estimate of the potential bias in the results (see, for example, Hart (58)).

Most attempts to minimize observer variation have proceeded by providing improvements in the measuring instruments. An ideal solution would involve the development of an indirect technique for sphygmomanometry which did not involve human judgment. In recent years, several automatic blood pressure measuring devices have been produced. One class of automatic sphygmomanometers uses microphones to amplify the Korotkoff sounds. These are then recorded in some permanent media for subsequent interpretation. This system tends to be bothered by artifactual noise which can render accurate inter-
Table 2.3: STRATEGIES TO REDUCE THE MAGNITUDE OF OBSERVER VARIATION

(1) Improve the precision of the definition of the phenomena being described.
(2) Collect observations not interpretations.
(3) Use "naive" observers.
(4) Collect quantitative data in preference to qualitative data.
(5) Train and pre-test the observers.
(6) Randomly assign observers to the subjects.
(7) Modify the measuring device and "blind" the observer.
pretation difficult. A second class of automatic sphygmomanometer utilizes Doppler ultrasound to detect the resumption of blood flow.

Since no amplification is involved, this system does not suffer from the same lack of reliability as does the previous class of instruments.

Labarthe et al. (92, 93) report a well designed study which compared five standard automatic sphygmomanometers. Two devices utilized the Doppler ultrasound principle, while three were based upon amplification of the Korotkoff sounds. The instruments were evaluated against several criteria including: reliability, accuracy, sturdiness, portability and cost. This study found that all of the automatic devices were subject to significant bias when compared to results obtained using a standard mercury sphygmomanometer.

These findings have been questioned by Webber et al. (182) who studied similar devices in a pediatric population. Further clarification is needed before the usefulness of these automatic sphygmomanometers can be properly assessed.

Automatic sphygmomanometers which provide continuous or semi-continuous recording (75, 98, 140, 141, 185), have already been described. Schneider et al. (141) demonstrate excellent agreement between the blood pressure recorded by their device and casual blood pressure measured simultaneously in the other arm. This type of apparatus warrants further study to determine the potential usefulness in a clinical situation.

Two instruments, which have been shown to decrease observer variation and bias, are available for use in epidemiologic studies.
While these instruments do employ human judgment in obtaining the blood pressure measurements, the instrument itself is modified in such a way that the observer is "blinded" from the actual measurement. The first of these instruments is the London School of Hygiene and Tropical Medicine Sphygmomanometer (129). This machine is designed to provide automatic cuff inflation and constant-flow cuff deflation. The mercury manometer columns are hidden from view. The observer has available three switches which he/she can use to fix the mercury level in each of three manometers. Thus, phases I, IV and V can be recorded in a "blind" manner. Later, the manometer levels can be read at leisure. Rose et al. (129) performed a series of experiments which showed that use of this device eliminated end-digit preference, and observer prejudice. Its use also resulted in improved agreement among three observers. This instrument is thus seen to have many desirable properties. However, it is very large and bulky. This is a major handicap, since many epidemiologic studies require considerable travel. It is also too expensive to enjoy widespread use.

An alternative to the London School of Hygiene Sphygmomanometer was developed by Garrow (42) and modified by Wright (196). The basic instrument is a regular mercury sphygmomanometer which has been adapted so that the zero pressure level can be varied. A special device, or zero-muddler, is attached so that the zero level can be randomized before each measurement. Standard protocol is followed to perform the measurement (Wright's device has provision for automatic inflation and constant deflation). Then, the zero-offset
is subtracted to provide the actual blood pressure reading. Evans et al. (35) show that, while this device will obscure end-digit preference and expectation bias, it is not as successful as the London School of Hygiene Sphygmomanometer. However, the random-zero sphygmomanometer has the distinct advantages of portability, ruggedness and lower cost. The random-zero sphygmomanometer also performed well in the evaluation by Labarthe et al. (92).

The actual measurement procedure which will be employed in a study must be determined by the nature of the study. Labarthe (71) suggests that, under controlled conditions, the reference measurement technique should be a trained observer using a standard mercury sphygmomanometer. Under less ideal conditions, some modification of the measurement technique is indicated in order to improve the quality of the data being collected. The London School of Hygiene Sphygmomanometer has been demonstrated to be most effective in this regard but is awkward to use. The random-zero sphygmomanometer can provide an effective compromise which should be employed in most epidemiologic research.

2.4 The Clinical Significance of High Blood Pressure

2.4.1 Clinical Complications

It has been recognized since around the end of the 19th Century, that elevated blood pressure is associated with diminished longevity. In 1914, Volhard and Fahr (179) differentiate between the malignant and benign forms of hypertension. The former follows a rapidly progressive course with over 80% dying within one year of diagnosis (44). Life insurance companies were among the
first groups to apply the knowledge that raised blood pressure had a detrimental effect on longevity and health. By 1907, extra premiums were being assessed against clients demonstrating elevated blood pressure (123). The risk of mortality was examined by determining the amount to which systolic blood pressure exceeded the mean for age. This measurement was applied to premiums issued between 1907 and 1927. Excess mortality was found to be directly related to the degree of excess blood pressure, rising from 63% to 235% above the expected level (Table 2.4). However, at the first major Symposium on the Epidemiology of Hypertension, presented in Chicago in 1951, there was still a dissenting opinion that the level of blood pressure was not related to subsequent disease (44). Since that symposium, a large volume of literature has been accumulated to firmly establish a causal link between raised blood pressure and subsequent disease.

In 1959, the Society of Actuaries published an extensive review of life insurance policies issued in the preceding years (154). They found strong evidence that mortality risk increased in a consistent manner as blood pressure rose. There was evidence that this increased risk occurred even at levels regarded as "normotensive". Long-term cohort studies in Framingham (72, 76-78), Evan's County (168), Chicago (145) and San Francisco (155) firmly established the excess risks involved with elevations in blood pressure.

The major causes of death in patients with untreated hypertension are (155):
Table 2.4: DEATHS ACCORDING TO DIASTOLIC PRESSURE*

<table>
<thead>
<tr>
<th>Diastolic Blood Pressure</th>
<th>Actual Deaths</th>
<th>Expected Deaths</th>
<th>Ratio of Actual to Expected</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;100 mm Hg</td>
<td>104</td>
<td>63.88</td>
<td>163% ± 11</td>
</tr>
<tr>
<td>100-105 mm Hg</td>
<td>43</td>
<td>20.35</td>
<td>211% ± 21</td>
</tr>
<tr>
<td>&gt;106 mm Hg</td>
<td>33</td>
<td>9.86</td>
<td>335% ± 39</td>
</tr>
</tbody>
</table>

*Reference (23).
(1) myocardial infarction (22%)
(2) apoplexy or stroke (34%)
(3) uraemia (20%)
(4) heart failure (14%).

The major complications of hypertension are produced by four distinct processes (119):

(1) nodular arteriosclerosis
(2) Charcot-Bouchard aneurysms
(3) fibrinoid necrosis
(4) increased work requirement for the heart.

Arteriosclerosis is a chronic disease process which produces a progressive narrowing of the small and large arteries. This can lead to myocardial insufficiency and infarction, cerebral infarction and peripheral vascular insufficiency. The cause of this process is unknown, but epidemiologic studies have demonstrated an association with blood pressure, smoking, serum cholesterol and age.

Charcot-Bouchard aneurysms are microaneurysmal dilations of the small perforating arteries in the brain. Under the influence of prolonged hypertension, the media of these aneurysms can rupture producing a cerebral hemorrhage. Only age and blood pressure are known to be associated with the pathogenesis of Charcot-Bouchard aneurysms.

Fibrinoid necrosis refers to a peculiar lesion associated with breakdown of the walls of small arteries and arterioles. This lesion is the anatomical basis of malignant hypertension. All organs can be affected, but those predominantly involved are: kidney, pancreas,
adrenals, G.I. tract, brain and eye.

Myocardial oxygen consumption is related to many factors. Among the more important are: systemic blood pressure, heart rate, systolic left ventricular volume and the contractile state of the myocardial muscle. In hypertension, the systemic blood pressure is high. In addition, the myocardial muscle will hypertrophy and, often, dilate. There is frequently associated coronary arteriosclerosis. All these factors compromise the myocardial oxygen supply and can contribute to the premature development of angina pectoris and myocardial failure (144). A reduction in systemic blood pressure will often produce a pronounced clinical improvement.

The above discussion indicates that hypertension can produce a wide-range of clinical consequences. In clinical practice, assessment of the severity of hypertensive complications is usually made by assessing the degree of damage in five target organs: brain, heart, kidney, eyes and the major arteries.

There is an anomaly concerning the complications of hypertension - although widespread deterioration can be present, there are usually no symptoms associated with this disorder until a catastrophic event occurs (114, 184). This observation is of tremendous importance when discussing programs to control hypertensive disease. The only way to know that one has hypertension is by having a blood pressure measurement.
2.4.2 Criteria to Diagnose Hypertension

No mention has yet been made of the blood pressure level at which hypertension should be diagnosed. This question caused considerable controversy, which reached a peak around 1960. There were two opposing schools. One, championed by Sir Robert Platt (120) contended that hypertension was a qualitative disease. By this, he meant that it was possible to identify a clearly defined group of patients who were fundamentally different from the rest of the population. This group could be diagnosed as hypertensive. This view represents the traditional view of disease, which arose through experience with infectious disease. Thus, a patient with pneumonia is different from the general populace because he/she is infected with a bacteria. An opposing view, supported by Sir George Pickering (112), suggested that hypertension represented a new type of disease, namely a quantitative disease. This concept implies that there is no qualitative difference between normotensive and hypertensive individuals. Rather, the risk of increase morbidity and mortality increases directly as the blood pressure also increases. The weight of evidence discussed earlier, presents strong support for the view that hypertension is a quantitative disease.
Once it is recognized that the risk from hypertension is directly related to the measured blood pressure level, it makes no sense to specify an upper-limit for normal blood pressure. While this concept provides an interesting insight into the nature of hypertension, it does not seem to be of much direct benefit to the clinician who must make practical decisions for individual patients. Closer inspection of the implications of this above conclusion, reveals that it can actually lead to an increased freedom of choice for the clinician. Thus, he/she need no longer devote attention to diagnosing a disease but can consider the far more basic and important question - which patients should be treated? The next section will review the evidence that therapeutic intervention is beneficial. This evidence can be used to develop guidelines for clinicians to use in assessing the need for therapeutic intervention in individual patients.

2.5 Evidence that Antihypertensive Therapy is Beneficial

The discussion of the previous section has established that hypertension is quantitatively associated with a wide range of clinical effects. Thus, hypertension can be defined as a risk factor for these effects. However, it does not follow that reducing blood pressure will necessarily reduce the risk of developing complications. Similarly, it is not necessarily true that agents which produce the same decrement in blood pressure will produce the same risk reduction. This latter point has been largely ignored in the published literature.
The one year mortality rate for malignant hypertension approaches 100% (33). Therefore, any study which demonstrates an increased survival among malignant hypertensives provides evidence about the benefits of treatment. Such an increase in survival was clearly demonstrated shortly after active antihypertensive medication became available (33, 97).

When considering the treatment of benign hypertension, the mortality rate is much less. As a consequence, the methodologic design of a therapeutic trial must be closely examined when interpreting the conclusions. In particular, therapeutic trials should utilize the methodology of a randomized control trial. The Ontario Council of Health Task Force on Hypertension identified five studies which meet this criteria (65, 153, 177, 178, 194).

The Veterans Administration trials demonstrated a risk reduction of 92% for patients with diastolic blood pressure between 115 and 129 mm Hg (177) and a reduction of 70% for patients with blood pressure between 90 and 114 mm Hg (178). This last group had an unexpectedly high prevalence of target organ damage prior to the initiation of the trial. The Public Health Services trial examined uncomplicated patients with diastolic blood pressures between 90 and 114 mm Hg and found a risk reduction of 37% (153). All of these trials found that the risk of hypertensive complications (e.g., heart failure, stroke, and accelerated hypertension) was significantly reduced while there was not effect on the risk of arteriosclerotic complications
(e.g., myocardial infarction). However, the Veterans Administration trial was suggestive was that antihypertensive therapy decreased the case-fatality rate from myocardial infarction. Long-term trials of patients with relatively mild hypertension are continuing at the present in an effort to further investigate this discrepancy in therapeutic effect (64).

The trials referenced above have clearly documented the benefits of treating to at least one sub-group of hypertensive patients suffering from benign hypertension. What conclusions can be drawn as to the characteristics of patients who should receive treatment? Firstly, all of the referenced studies pre-selected a group of patients who were likely to comply with a long-term medication regimen. However, in a general population, the degree of compliance with a long-term medication regimen is known to be poor (137). Further, evidence is now developing, that the event of being labelled hypertensive, can provide negative psycho-social effects (138). The blood pressure measurement techniques used to select the experimental groups were complicated, requiring several repeat visits and a possible hospital admission. Thus, the conclusions as to treatment benefit apply only to the treatment of sustained hypertension. Also, the absolute blood pressure levels may differ from those which would have been obtained in a family doctor's office. The evidence is not as strong that treatment is effective for women.

Faced with these difficulties, the Ontario Council of Health Task Force on Hypertension arrived at the following recommendations for initiating treatment (126):
(1) Initiate appropriate therapy in all adults whose fifth phase diastolic blood pressures are consistently at or above 105 mm Hg.

(2) Initiate appropriate therapy in adults with diastolic blood pressures between 90 mm Hg and 104 mm Hg, when evidence of target organ damage is present.

These recommendations will probably require modification as additional data is collected.

2.6 Summary

This chapter has reviewed many of the problems associated with blood pressure measurement. The recommended procedure involves using a bias-reducing sphygmomanometer and an adequate training program for the observers. The evidence demonstrating the relation of hypertension to clinical complications was reviewed next, and the question of defining hypertension was considered. Guidelines for therapeutic intervention were presented.
3. A PRIMER IN SAMPLE SURVEY METHODOLOGY

3.1 Introduction

A survey is a method of collecting information about a human population, in which direct contact is made with the units of the study through such systematic means as questionnaires and interview schedules (181). A sample survey is a survey, in which information obtained from a scientifically selected portion of the population under study, is used to represent the whole (181).

The concepts contained in the above definition of a survey should be familiar. The advantages of using survey techniques to obtain information in the medical and/or social sphere are many. Much information can only be obtained by direct measurement of a study group. Thus, data such as weight, smoking habits, political views and social attitudes can be obtained only by measuring these attributes in members of a population. One approach to this measurement would be to use routinely collected, aggregate data, as, for example, election results, tobacco sales or clothing manufacturing statistics. These data have an increased accuracy in certain situations (e.g., global abortion utilization statistics versus data collected from individuals). The major disadvantage is that aggregate data do not identify individuals. Thus any real attempt to explain the observed data is precluded.
Other routinely collected data would be available from sources such as vital statistics registries, death certificates, doctors' billing records or income tax returns. While these data do identify individuals, they suffer from a marked and indeterminate variability of the quality of the data (3, 22). Confidentiality requirements would create difficulties in any attempt to utilize these data to identify individuals. Finally, much data that would have research interest is not routinely collected (e.g., hemoglobin levels, drug usage).

An alternative to using routinely collected data is the design of a special purpose study. For this purpose, two contrasting approaches can be used; surveys or participant observation. The second of these two techniques involves direct observation of the behaviour of the population under study. This observational technique has advantages when the data of interest are variables such as social interaction, and group or family function. In such cases, the subjects would often neither be aware of, nor able to report on, many of the variables of interest. The major disadvantage of the observational approach is that the technique is costly and time-consuming, thus limiting the number of population members who can be examined.

Survey techniques involve direct questioning and/or examination of the population. This technique can provide most information which is needed for medical research purposes.
When compared to participant observation, surveys usually have a lower cost per interview. In social research, an additional advantage of survey-style research relates to an improved ability to quantify the data which have been collected. This improvement is a direct result of obtaining the information by asking a series of questions rather than by observing and recording behaviour patterns. However, Warwick and Linninger express a concern that direct questioning will not provide a valid assessment of behaviour or attitudes (181). Greenberg et al. also consider the possible nonvalidity of information collected in "sensitive" areas (e.g., contraception methods, sexual behaviour, prejudices) (49).

The most important advantage of survey research is the opportunity to generalize the results obtained by examining part of a population. In most research projects, it is possible to identify a group of people about whom one wishes to obtain information. This group can be called the target population. One obvious approach to obtaining the desired information would be to examine the entire target population. This would be called a census. Superficially, this might seem to be the only valid method. However, it is of tremendous import that such information need be collected on only a small portion of this population (i.e., on a sample). In fact, the quality and utility of information obtained by sampling is often superior to the quality and utility of information obtained by performing a complete census. There are five basic advantages of sampling rather than performing a complete census. In the first
place, the sample survey is less costly. Secondly, the data can be collected with more speed. In fact, both the American and Canadian governments use sampling techniques to provide preliminary but rapid results from census data (24). Thirdly, largely because of the cost reduction, the quality of the interviewers' training and equipment, the depth of examination and the quality of field supervision can be higher in the sample survey. Collectively, these aspects should lead to more reliable data. Fourthly, there is greater flexibility in the topics which can be explored in a survey. This increased flexibility is a result of the more highly trained staff and the smaller survey size. Lastly, the sample survey is less visible and hence provokes less ill-will and political controversy. This controversy often centres around a feeling that researchers are invading the privacy of the study subjects. However, it can also touch areas such as racial prejudice and international politics (181).

There is one major requirement before the advantages of sampling can be realized - the relationship between the sample and the target population must be known. The examination of "convenience" samples or samples of volunteers does not permit a valid extrapolation to the target population. This occurs because these types of samples will tend to be atypical of the target population (144, 188). A similar problem can occur if a large proportion of a well-selected sample refuses to participate (104, 191).
The theoretical study of techniques which can be used to select representative samples is called, logically, sampling theory. The basic concept behind this theory is the use of probability methods to select the sample of subjects to be examined. The use of probability methods requires that each subject have a known (or at least calculable) probability of being selected into the sample. The most direct method of meeting this requirement involves obtaining a list of the entire target population and then directly assigning the probability of selection to each member of this list. Since such a procedure is rarely feasible, more sophisticated methods have been developed which avoid the need to obtain a complete list of the target population.

The procedure used to select the sample is the starting point for most research in sampling theory. The primary concern is with developing formulae which can be used to estimate various population parameters, but which are based solely upon the measurements obtained from the examined sample. When probability techniques are used, it is also possible to estimate the precision of these estimates. This ability to estimate precision represents the single most important reason for using probability techniques for sample selection.

The discussion above can be summarized to provide a general
framework to be followed when designing a sample survey (Table 3.1): By following this outline, and using probability sampling methods, the data obtained from the survey will have maximum generalizability and utility. These criteria have been expanded into a checklist of methodologic criteria for sample survey research (see Appendix 1).

The rest of this chapter reviews the techniques of sample selection and estimation. This area has an extensive literature and it will not be possible to discuss all aspects of sample selection in detail. The discussion will follow Cochran (24) and Kish (80) to which the reader is referred for further details. Supplemental information can be found in two additional references (55, 197).
### Table 3.1: The Principle Steps in a Sample Survey

1. Define the objective(s) in a clear manner.
2. Decide what data to collect and how to collect it.
3. Define the target population.
4. Decide how to select the sample from this population.
5. Determine the size of the sample, based on the desired precision of the population estimates.
6. Pretest the data collection and sample selection methods.
7. Collect and analyze the data.
3.2 Simple Random Sampling

The most elementary of the probability sampling procedures involves obtaining a detailed list of all members of the population and then selecting a sample in such a manner that all units in the sample have the same probability of selection. This technique is called simple random sampling. The population size will be denoted as \( N \) and the sample size by \( n \). The sampling fraction is \( f = \frac{n}{N} \). Associated with each unit in the sample will be one or more observations (denoted by \( x_i, y_i, z_i \), etc.). These values could be actual numbers (e.g., height, age, hemoglobin concentration) or "dummy" variables \( y_i = 1 \) if the unit has a certain qualitative attribute and \( y_i = 0 \) otherwise). Dummy variables are used when it is desired to estimate the proportion of the population belonging to a certain class (e.g., the proportion of the population who will vote Liberal in the next election).

There are two types of population variables which are frequently estimated by surveys: (1) the population mean (or proportion) \( \bar{Y} = \sum_{i=1}^{N} \frac{y_i}{N} \) and (2) the population total (or the number in the class) \( Y = \sum_{i=1}^{N} y_i \). Since \( Y = N \bar{Y} \), the problems of estimation of these two variables are similar and one need only consider the case of estimating the population mean. The standard estimator of the population mean is:

\[
\bar{y} = \frac{1}{n} \sum_{i=1}^{n} y_i
\]
It is straightforward to demonstrate that this estimator is unbiased, i.e.:

\[ E(\bar{y}) = \bar{Y} \text{ where } E(\ ) \text{ denotes the expectation taken over all possible samples. The variance of the sample estimate is given by:} \]

\[ V(\bar{y}) = \frac{(1-f)}{n} \frac{\sum_{i=1}^{N} (y_i - \bar{Y})^2}{N-1} \]

\[ \text{(2)} \]

Since this formulae depends upon a knowledge of the observed values for all members of the population, it cannot be used to calculate the precision of the sample estimate from the sample data alone. A formula must be developed which can be used for this purpose.

Such a formula is:

\[ V(\bar{y}) = \frac{(1-f)}{n} \frac{\sum_{i=1}^{n} (y_i - \bar{y})^2}{n-1} = \frac{(1-f)}{n} s^2 \]

\[ \text{(3)} \]

One can easily show that:

\[ E(\bar{V}(\bar{y})) = V(\bar{y}) \]

and hence the estimator is unbiased. The further assumption that the distribution of \( \bar{y} \) is Gaussian enables one to calculate confidence limits for the sample estimate:

\[ y \pm t_{\alpha/2, (n-1)} \left( \frac{s \sqrt{1-f}}{\sqrt{n}} \right) \]

\[ \text{(4)} \]

where \( t_{\alpha/2, (n-1)} \) is the abscissa of the student t-distribution having \( (n-1) \) degrees of freedom that cuts off a one-tail area equal to \( \frac{\alpha}{2} \).
In the case where the sample is estimating the proportion of the population which belongs to class C, formulae (3) and (4) can be somewhat simplified. Let, \( p \) = proportion of sample elements in the class C and let \( q = 1-p \). Then, the variance estimator is given by:

\[
\sigma^2 = \frac{(1-f)}{n-1} pq
\]

and the confidence limits are given by:

\[
\hat{y} \pm t_{a/2, (n-1)} \left( \frac{\sqrt{(1-f) pq}}{(n-1)} \right)
\]

If either \( p \) or \( q \) is close to zero, then the normality assumption used in deriving the confidence limits is not justified. Alternative approaches utilizing the binomial and hypergeometric distributions have been developed (137).

One further simplification is frequently possible in formulae (2), (3), and (4). Since most samples examine only a very small fraction of the total population, then \( n \ll N \). This implies that \( (1-f) = 1 \). Thus, one can remove this factor from formulae (2), (3), and (4) without introducing any significant bias.

The above theory can be used to estimate the size of sample which should be examined in order to obtain a desired degree of precision in the sample estimate. This procedure is based upon one assumption and the specification of 3 "parameters":
(1) The sample estimate is assumed to be distributed according to the Gaussian distribution.

(2) The confidence limit corresponding to the desired precision has an associated probability of (1-\(\alpha\)).

(3) The confidence limit has length "\(d\)".

(4) The population standard deviation can be "guestimated".

The formula to calculate the sample size is:

\[
n = \frac{(tS/d)^2}{1 + \frac{1}{N}(tS/d)^2}
\]

where \(S\) = estimate of the standard deviation \(t\) = abscissa of the Gaussian curve that cuts off an area "\(a\)" at the tails.

When estimating the proportion, formula (5) becomes:

\[
n = \frac{t^2PQ}{d^2} \cdot \frac{1}{1 + \frac{1}{N}\left(\frac{t^2PQ}{d^2} - 1\right)}
\]

While confidence limits are used to measure precision, an alternate and standard measure of precision is the coefficient of variation. This is defined as: \(c = \frac{\text{standard error}}{\text{proportion}}\).

Using the above model, we have:

\[
\text{variance} = \upsilon = \frac{d^2}{t^2}
\]

\[
\text{proportion} = P = \sqrt{\frac{d^2}{t^2}}
\]

Therefore, \(c = \sqrt{\frac{t^2}{P}} = \frac{d}{tP}\)

\[
\text{or,} \quad \frac{t^2}{d^2} = \frac{1}{Pc^2}
\]
Substituting into formula 6, one obtains:
\[
    n = \frac{Q}{P} \frac{\frac{1}{c}}{1 + \frac{1}{N} (\frac{Q}{P} \frac{1}{c} - 1)}
\]

A further simplification can be obtained by noting that \(\frac{1}{N} = 0\). Thus, a good approximation to the required sample size is:

for means: \( n = \frac{s^2}{v} \) 5A

for proportions: \( n = \frac{Q}{P} \frac{1}{c^2} \) 6B

3.3 Stratified Sampling

The major advantage of simple random sampling is relative conceptual simplicity. In practice, more complex procedures are used. These have two major advantages:

1. improved precision of the sample estimates
2. more feasible sample selection which avoids the necessity for a complete population census.

One important method of increasing the precision of the sample estimates is through the use of stratification. The data in Table 3.2a will be used to illustrate this advantage. The target population consists of six people (3 male and 3 female). The observed values are seen to be higher in males than in females. Suppose it is desired to estimate the population mean, by examining a sample of two subjects. All possible simple random samples and their means are listed in Table 3.2b. The expected sample mean is 23.67 and the variance of the sample estimate is 12.76.
An alternative approach would involve the recognition that males and females have different mean values. Such a decision could be reached "a priori" or be based on the results of a preliminary survey. If such a decision is made, one could then select the sample in such a way that the one member was male and one was female. The samples which satisfy this constraint, and their mean values, are listed in Table 3.2c. The expected sample mean remains unchanged (23.67) but the variance is now much reduced (3.4 compared to 12.76). Thus, this new procedure has produced a significant increase in precision with no increase in sample size.

The technique illustrated above can be used in general sampling procedure. The first stage involves dividing the target population into a number of groups or strata based upon some readily available data (e.g., geographic location). Then, within each stratum, a sample is selected using probability sampling strategies. Finally, the estimates from within strata are combined to provide an overall population estimate. There are two new problems which must be solved before using this stratification procedure:

1. How are the individual estimates to be combined and what are the properties of this combined estimator?
2. How many of the total number of examinations will be collected from each stratum?
**Table 3.2a: EFFECT OF STRATIFICATION**

<table>
<thead>
<tr>
<th>MALE</th>
<th>OBSERVED VALUE</th>
<th>FEMALE</th>
<th>OBSERVED VALUE</th>
</tr>
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<tbody>
<tr>
<td>1</td>
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<td>4</td>
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<td>2</td>
<td>25</td>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td>3</td>
<td>31</td>
<td>6</td>
<td>21</td>
</tr>
</tbody>
</table>

TOTAL MEAN: 28.67

TOTAL MEAN: 18.67

COMBINED TOTAL: 142

COMBINED MEAN: 23.67
<table>
<thead>
<tr>
<th>Sample Elements</th>
<th>Probability of Selection</th>
<th>Sample Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, 2</td>
<td>1/15</td>
<td>27.5</td>
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<tr>
<td>1, 4</td>
<td>1/15</td>
<td>25.0</td>
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<tr>
<td>1, 5</td>
<td>1/15</td>
<td>22.5</td>
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<td>20.5</td>
</tr>
<tr>
<td>5, 6</td>
<td>1/15</td>
<td>18.0</td>
</tr>
</tbody>
</table>

Expected Sample Mean: 23.67
Variance of Sample Mean: 12.76
<table>
<thead>
<tr>
<th>SAMPLE ELEMENTS</th>
<th>PROBABILITY OF SELECTION</th>
<th>SAMPLE MEAN</th>
</tr>
</thead>
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<tr>
<td>1, 4</td>
<td>1/9</td>
<td>25.0</td>
</tr>
<tr>
<td>1, 5</td>
<td>1/9</td>
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<td>1, 6</td>
<td>1/9</td>
<td>25.5</td>
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<tr>
<td>2, 4</td>
<td>1/9</td>
<td>22.5</td>
</tr>
<tr>
<td>2, 5</td>
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<td>1/9</td>
<td>23.0</td>
</tr>
<tr>
<td>3, 6</td>
<td>1/9</td>
<td>26.0</td>
</tr>
</tbody>
</table>

EXPECTED SAMPLE MEAN: 23.67

VARIANCE OF SAMPLE MEAN: 3.44
It is necessary to introduce some additional notation in order to examine further the properties of stratified sampling. Let "L" be the total number of strata and let the subscript "h" refer to values in the \(h^{th}\) strata (e.g., \(y_{hi}\) are the observed values in the \(h^{th}\) strata; \(N_h\) is the size of the \(h^{th}\) strata, etc.). Then, the population mean is given by:

\[
\bar{Y} = \frac{\sum_{h=1}^{L} N_h \bar{Y}_h}{N}
\]

where \(N = \sum_{h=1}^{L} N_h\)

and the sample estimate of the population mean is:

\[
\bar{y}_{st} = \frac{\sum_{h=1}^{L} N_h \bar{y}_h}{N}
\]

In general, this is not the same as the actual sample mean. Frequently it will be necessary to estimate \(N_h\) in order to calculate \(\bar{y}_{st}\). The sampling strategy used within the strata can be as complex as desired. Provided that the sample means within each strata (\(\bar{y}_h\)) are unbiased, then the overall estimator \(\bar{y}_{st}\) will also be an unbiased estimate of the population mean.

The variance of \(\bar{y}_{st}\) can be calculated as below:

\[
V(\bar{y}_{st}) = \frac{\sum_{h=1}^{L} N_h^2 V(\bar{y}_h)}{N^2}
\]

where \(V(\bar{y}_h)\) is the variance of the sample mean within the \(h^{th}\) stratum. When a simple random sample is drawn from within each stratum, the value \(V(\bar{y}_h)\) is given by formula (2) as:
\[ V(\bar{y}_h) = \frac{S_h^2}{n_h} \cdot (1-f_h) \]. Substituting into \(7\), the variance of the sample mean is seen to be:

\[ V(\bar{y}_{st}) = \frac{1}{N} \sum_{h=1}^{L} \frac{N_h}{n_h} \frac{S_h^2}{n_h} \]

(7A)

An unbiased sample estimate of this variance can be obtained by replacing each \( S_h^2 \) by its unbiased estimator \( s_h^2 = \frac{1}{n_h-1} \sum_{i=1}^{n_h} (y_{hi} - \bar{y}_h)^2 \) to obtain:

\[ V(\bar{y}_{st}) = \frac{1}{N^2} \sum_{h=1}^{L} \frac{N_h}{n_h} \frac{s_h^2}{n_h} \]

(7B)

The above formulae will all be seen to have a basic underlying structure. First, unbiased estimates are obtained from within each stratum. The form of these estimators is determined by the particular sampling technique used within the stratum. Then, these individual stratum estimates are combined by using a weighting scheme based on the size of the stratum. It can be readily seen that a significant increase in precision will occur when the strata are more homogenous than the entire population.

The second new problem to which attention was drawn, namely the partition of the sample amongst the various strata, is not easily amenable to analysis. In general, precision is increased if all strata are well represented in the sample. However, an unbalanced distribution can sometimes produce a more precise estimate. Various authors (24, 55, 80) have attempted to use estimates of the cost of obtaining measurements from subjects in each of the strata to determine the least costly but most precise estimate possible. However, the applicability of these techniques seems limited at present.
3.4 Clustering

Stratification can be used to improve the precision of the sample estimates. However, within each stratum, one must still decide on the most efficient procedure to select the actual sample to be examined. Simple random sampling requires the construction of a detailed sampling frame based on a complete population census. This is a costly and time-consuming procedure. In an attempt to obviate the necessity for a complete census, various complex sampling schemes have been developed. These schemes are based upon the concept of clustering, which will be considered in this section.

Suppose one wishes to determine the shopping habits of the population of Hamilton. A simple random sample would require a listing of all citizens of the city. As an alternative approach, one could use the routinely updated directory of city blocks to select a simple random sample of blocks. Then all people living in these blocks would form the sample and would be examined. The unit of sampling (i.e., city blocks) and the unit of examination (i.e., citizens) are different, with the former representing a group or cluster of the latter units. Such a sampling scheme is referred to as single-stage cluster sampling. It will be seen later that the effect of clustering on the precision of the variance estimates depends on the correlation among the units within the cluster,
It is again necessary to modify the notation that has been
in use thus far. It is now assumed that the population is
divided into "N" clusters of sizes \( M_i \), \( i = 1 \ldots N \). Let \( M_0 = \sum_{i=1}^{N} M_i \).
The sample selection involves drawing a sample of "n" clusters.
One of the most general methods of cluster selection is
selection with arbitrary probabilities (also called: selection
with probability proportional to an estimate of size). To use this
method, the selection of the cluster is done with replacement, which
implies that the same cluster could be selected more than once.
Associated with each cluster is a probability \( \pi_i \) that it will be
selected into the sample each time a new cluster is selected.

The observation associated with the \( j \)th element of the \( i \)th
cluster will be given by \( y_{ij} \). Further, let \( \bar{y}_i = \frac{1}{z_i} \sum_{j=1}^{M_i} y_{ij} \). Then, a
sample estimate of the population mean per element will be given by:

\[
\bar{Y}_{\text{pnes}} = \frac{1}{nM_0} \sum_{i=1}^{n} \frac{y_i}{z_i}
\]

This estimate is unbiased and has variance:

\[
\text{V}(\bar{Y}_{\text{pnes}}) = \frac{1}{nM_0^2} \sum_{i=1}^{N} \left( \frac{y_i}{z_i} - \bar{Y} \right)^2
\]

where \( \bar{Y} = \) population total.

An unbiased estimate of this variance is given by:

\[
\text{V}(\bar{Y}_{\text{pnes}}) = \frac{1}{n(n-1)M_0^2} \sum_{i=1}^{n} \left[ \frac{y_i}{z_i} - M_0 \bar{Y}_{\text{pnes}} \right]^2
\]

Examining the form of the variance estimate, it is seen that it
depends upon variability amongst cluster totals rather than upon
direct variation within the clusters. Thus, precision could be
increased if the cluster totals are nearly equal.

The effect of clustering is more clearly seen if the sample selection procedure is slightly simplified. Assume that all clusters have the same size, M, and that the clusters in the sample are selected by simple random sampling. Then, the variance of the sample estimate for the population mean per element is approximately:

\[
V = \frac{(1-f)}{nM} \cdot \frac{S^2}{(1+(M-1)\rho)} \sum_{N}^{M} \frac{\sum_{j=1}^{M} (y_{ij} - \bar{Y})^2}{NM-1}
\]

where \( S^2 = \frac{\sum_{i=1}^{N} \sum_{j=1}^{M} (y_{ij} - \bar{Y})}{NM-1} \)

\( \bar{Y} \) = population mean

\[
\bar{Y} = \frac{\sum_{N}^{M} \sum_{i=1}^{M} \sum_{j=1}^{M} (y_{ij} - \bar{Y}) (y_{ik} - \bar{Y})}{(M-1)(NM-1)S^2}
\]

and \( \rho = \frac{\sum_{i=1}^{N} \sum_{j=1}^{M} \sum_{k=1}^{M} (y_{ij} - \bar{Y})(y_{ik} - \bar{Y})}{(M-1)(NM-1)S^2} \) is the expected intracluster correlation coefficient.

The variance which would be obtained without clustering is:

\[
\frac{1-f}{nM} S^2.
\]

Thus, the factor \((1+(M-1)\rho)\) indicates the change in variance due to the use of clusters. Clearly, if \( \rho > 0 \) (i.e., within clusters, elements tend to be similar) then the variance will be larger when clustering is employed. However, if \( \rho < 0 \), the variance will actually be smaller.
3.5 **Multistage Sampling**

The example given at the start of section 3.4 utilized the city directory to select a sample of blocks. Then, each block was exhaustively examined to provide the final sample elements. Since the amount of work involved with exhaustive examination of these blocks is still quite large, it would be of benefit if the number of examinations could be reduced. This would have the added advantage, that more blocks could be included in the sample without increasing the overall sample size. This would produce a more representative sample. A direct approach to this problem is to recognize that, within each block, it should be possible to select a sample of individuals to estimate the results that would be obtained from a census within the block. Since this compound procedure requires taking two samples, it is referred to as two-stage cluster sampling. This procedure could be continued indefinitely, to produce multi-stage cluster sampling.

The general procedure of two-stage cluster sampling can be outlined as follows. Let the target population consist of $M_0$ units divided into $N$ clusters (primary units) having sizes $M_1$. The first stage selection procedure chooses "n" clusters. Within each cluster, the second stage procedure selects $m_1$ units for examination. Each unit will have an associated measurement, $y_{ij}$. Each cluster will have an associated measure of size, $z_i$.

There are two basic estimation techniques used in two-stage sampling. The first technique is analogous to that discussed in section 3.4. An estimate, $y_i$, is obtained within each cluster.
These are then added to provide the overall sample estimate:
\[ y' = \frac{\sum_{i=1}^{n} y_i'}{n} \]  \hspace{1cm} (12)

It is easily shown that \( y' \) is an unbiased estimate, provided that each cluster estimate, \( y_i' \), is unbiased. Variance formulae can be calculated (24) but rapidly become complex and will not be reproduced here. The primary sampling units can be selected by two major methods. The simplest, uses selection without replacement and with the same probability of selection, namely \( \frac{1}{N} \). In this case when estimating a population mean per element, (12) becomes:

\[ \hat{Y}_U = \frac{N}{nM_0} \sum_{i=1}^{n} M_i \overline{y}_i \]  \hspace{1cm} (12A)

and the estimate of the variance of \( \hat{Y}_U \) is given by:

\[ v(\hat{Y}_U) = \frac{(1-f_1)}{nM^2} \sum_{i=1}^{n} (M_i \overline{y}_i - \hat{Y}_U)^2 + \frac{f_1}{nM^2} \sum_{i=1}^{n} \frac{M_i^2}{m_i} (1-f_{2i}) s_{2i}^2 \]  \hspace{1cm} (13)

where
\[ f_1 = \frac{n}{N} \]
\[ f_{2i} = \frac{m_i}{M_i} \]
\[ M = \frac{M_0}{N} \]
\[ m = f_2 \overline{M} \]
\[ \overline{Y}_U = \frac{1}{n} \sum_{i=1}^{n} M_i \overline{y}_i \]

and if \( f_1 = 0 \), this variance can be approximated by:

\[ v(\hat{Y}_U) = \frac{n}{n(n-1)M^2} \sum_{i=1}^{n} (M_i \overline{y}_i - \hat{Y}_U)^2 \]  \hspace{1cm} (13A)

which depends only on the variation amongst the cluster totals.
An alternate approach to selecting the primary units, uses sampling with replacement and with the probability of selection proportional to estimated size (section 3.4). The sample estimator now becomes:

\[ \hat{Y}_{\text{pes}} = \frac{1}{n^0} \sum_{i=1}^{n} \frac{M_i}{z_i} \hat{y}_i \]  

(12B)

An estimate of the variance of this estimator is given by:

\[ \nu \left( \hat{Y}_{\text{pes}} \right) = \frac{1}{n(n-1)M_0^2} \sum_{i=1}^{n} \left( \frac{M_i}{z_i} \hat{y}_i - \bar{y}_i \right)^2 \]  

(13B)

where \( \bar{y}_i = \frac{1}{n} \sum_{i=1}^{n} \frac{M_i}{z_i} \hat{y}_i \).

There is a second category of estimators which must now be considered. These are called ratio estimates and are of the general form: \( \frac{\Sigma y_i}{\Sigma x_i} \). These types of estimators are often used when estimating proportions over subpopulations. They are also employed when socio-demographic characteristics of the samples are used to "adjust" the estimates (9). The major difficulty encountered when using this class of estimator, is to obtain useful sample estimates of the variance of the ratio estimator. Detailed discussion of this problem will be deferred until the next section.

Ratio estimates of a population mean can be obtained using either sampling procedure discussed above:

\[ \frac{\Sigma}{\bar{y}} = \frac{1}{n} \sum_{i=1}^{n} \frac{M_i}{z_i} \hat{y}_i \]  

(12C)
Probability proportional to estimated size:  

\[ \sum_{i=1}^{n} \frac{M_i y_i / z_i}{\sum_{i=1}^{n} M_i / z_i} \]

These estimators are biased but this bias is small if "n" is large. Approximate variance formulae can be computed (137) but will not be reproduced here.

Thus far in the discussion the choice of the "m_i" and "z_i" has been essentially arbitrary. It is often useful to select m_i and z_i in such a way that all elements in the population have an equal chance of being selected. This is referred to as a self-weighting sample and leads to simplification in the calculation of the sample estimates. It is shown in Appendix 2, that a necessary and sufficient condition that a sample be self-weighting is:

\[ \frac{z_i m_i}{M_i} = \frac{f_0}{n} \]

where \( f_0 \) is the expected overall sampling fraction. In the case of sampling proportional to size, this becomes:

\[ m_i = \frac{f_0}{n} M_i \]

That is, a constant number of elements must be selected in each cluster. Formulae (13) and (13A) can be used to estimate the values of z_i and m_i necessary to obtain a pre-specified overall sampling estimate. These arguments are easily expandable to multi-stage sampling procedures.
3.6 Variance Estimation

Published reports of survey research usually present only the population estimates. However, the accurate interpretation of these estimates is difficult without some indication of the precision of the estimate. This requires that the variance of the population estimate be estimated from the sample.

Variance estimates are necessary building blocks for any inferential or analytic strategies. These strategies can provide much insight into the structure of data (40, 41, 85). Variance estimates also permit comparison of sub-populations within the target population and are necessary if a study attempts to examine changes over time in a population parameter. Thus, the value of variance estimates can be seen to be great. Despite this value, there is no single approach to variance estimation which has received universal acceptance.

The preceding sections have presented some formulae which can be used for variance estimation. However, as the sampling strategies and/or the population estimators become more complex, it becomes extremely difficult to obtain theoretically correct variance estimators. Various approaches have been developed in an attempt to overcome this difficulty. This section will briefly summarize these approaches.

Kish (80) suggests a general conceptual framework whereby the effect of a complex sampling strategy can be illustrated. In this approach, the variance obtained under the complex sampling scheme is expressed as a fraction of the variance estimate which
would be obtained if a simple random sample of the same size were analyzed. This ratio is called the Design Effect Factor and is represented by DEFF. If the DEFF is less than 1, then the sampling procedure employed, gives more precise estimates than simple random sampling. This is usually the case when using stratification. However, the use of clustering will tend to inflate the DEFF so that it becomes greater than 1. Simulation studies (9, 81, 83) suggest that the DEFF is around 3.0 when estimating population means or proportions with a cluster design. With more complex statistics it tends to be somewhat lower (= 1.5 to 2.0) (83).

The use of the DEFF provides an estimate of the impact of using a particular sample design. It does not, however, provide any direct assistance with variance estimation. There are three basic approaches to obtaining approximate variance estimates.

The first method involves the obvious strategy of selecting several independent samples which will then provide several independent estimates of the population parameter of interest. These values can then be directly used to estimate the variance of the sample estimator. This procedure is usually implemented by selecting what are called interpenetrating samples (80). The major difficulty is the extra cost needed to obtain sufficient independent values to provide reasonable variance estimates.

A second approach attempts to approximate the sample estimator with a more tractable estimator, usually a linear function. This is most frequently implemented using a Taylor series
expansion of the complex estimator. A direct variance estimate is then obtained using the modified estimator (164).

The last approach resembles the selection of interpenetrating samples, in that it also attempts to provide a series of estimates of the population mean which can then be used to estimate the variance for the sample estimator. The procedures to be considered now are different, however, in that the series of estimates is obtained from one sample by selecting various sub-samples for independent analysis. The estimates so created are not independent but empirical evidence shows that the variance estimates obtained by these techniques are highly successful.

There are two similar techniques which are of this type. The first, based on a method of Quenouille and, later, Tukey (48, 109), utilizes the jackknife statistic. In this technique, each sample element is removed from the sample in turn. The value of the complex estimator is then calculated for each required sample. These data are then combined, using a jackknife statistic, to produce the variance estimate. The data in Table 3.3 will be used to illustrate the jackknife technique. Data has been collected on the size of seven cities in 1920 \((x_i)\) and 1930 \((y_i)\). The statistic of interest is the ratio of the 1930 population to the 1920 population. The first step in the jackknife procedure is to calculate the ratio estimate when each of the seven cities is in turn excluded from the data set. The calculations are shown on the first three lines of Table 3.3b. Then the jackknife statistic \(\left(\frac{(n)r_{all} - (n-1)r\{i\}}{n} \right)\) is calculated for each sub-sample. Lastly,
Table 3.3a: JACKKNIFE VARIANCE ESTIMATION

<table>
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<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
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<td>115</td>
<td>57</td>
<td>58</td>
<td>52</td>
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<td>120</td>
<td>60</td>
<td>44</td>
<td>38</td>
<td>71</td>
<td>36</td>
<td>445</td>
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</tbody>
</table>

(Population size in thousands).

Table 3.3b: JACKKNIFE DETAILS

<table>
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<tr>
<th></th>
<th>Exclude all</th>
<th>Exclude 1</th>
<th>Exclude 2</th>
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</tr>
</thead>
<tbody>
<tr>
<td>y_i</td>
<td>487</td>
<td>407</td>
<td>372</td>
<td>430</td>
<td>429</td>
<td>435</td>
<td>408</td>
<td>441</td>
</tr>
<tr>
<td>x_i</td>
<td>445</td>
<td>369</td>
<td>325</td>
<td>385</td>
<td>401</td>
<td>407</td>
<td>374</td>
<td>409</td>
</tr>
<tr>
<td>r(i) = \frac{y_i}{x_i}</td>
<td>1.094</td>
<td>1.103</td>
<td>1.145</td>
<td>1.117</td>
<td>1.070</td>
<td>1.069</td>
<td>1.091</td>
<td>1.078</td>
</tr>
<tr>
<td>7r_{all} - 6r(i)</td>
<td>-0.040</td>
<td>0.788</td>
<td>0.956</td>
<td>1.238</td>
<td>1.244</td>
<td>1.112</td>
<td>1.190</td>
<td></td>
</tr>
</tbody>
</table>

standard ratio estimate = \frac{487}{445} = 1.094

jackknife ratio estimate = 1.081

standard error of jackknife ratio estimate = 0.0631

95% confidence limits of jackknife ratio estimate = (0.927 to 1.235)
these jackknife statistics are used to provide estimates for the mean and variance of the population ratio. The estimated mean is seen to differ slightly from the standard ratio estimate. Although this example has jackknifed out only one data item at a time, in practice any size unit could actually be jackknifed.

Balanced repeated replications is a technique which is quite similar to the jackknife technique (9, 81, 83, 151).

The new technique proceeds by examining one-half of the sample at a time, until all possible half samples have been examined. Then this series of estimates is used for variance estimation. Frequently, it is not necessary to examine all possible half-samples. One could select a random sub-set of half-samples.

Alternatively, McCarthy (100) has developed a method of identifying an orthogonal sub-set of half-samples which can be used to completely represent the results that would be obtained from using the entire set of half-samples. The Survey Research Institute at the University of Michigan has developed a computer package to assist with calculating variance estimates using the above-mentioned techniques (83).
The properties of the variance estimators described above have been examined by using simulation techniques. Bean (9) used data from the Health Interview Survey to study the ability of linearization and balanced repeated replications to estimate the variance of ratio estimates. She found that both techniques were highly satisfactory. The relative bias was approximately 3 to 5 per cent. The distribution of the variance estimators approximated Student's t-distribution with the number of degrees of freedom being given by the number of strata. Kish and Frankel (83) found similar results when the three techniques described above were examined.

The simulation studies described above provide reassurance that these techniques are useful for variance estimation. Further studies are needed, however, before the relative merits and properties of each of these techniques will be completely understood. Such techniques have a particularly important role in providing convenient and tractable variance estimates of complex estimators when multi-stage cluster sampling strategies are employed.

3.7 Sampling to Assess Change

The type of survey that is performed on a routine bases, will provide estimates of the prevalence of a characteristic in the population. While this information is useful, it is frequently more useful to have some indication of the incidence or of how this prevalence is changing with time. For example, political parties would like to know, not only how popular they are at present, but also, if this popularity is increasing or decreasing. An overall impression
of change could be obtained by simply repeating the study at a later time. This would provide an estimate of the net change, but would omit much useful information about gross change (i.e., why did the net change occur?). For example, the proportion of people in favour of civil rights for Negroes might change from 30% to 40% during the time that an educational programme is in effect. What this data do not reveal, is whether the shift occurred because 10% of the people were newly convinced and 30% remained convinced or whether the 40% comes entirely from the non-believers who were converted while the 30% who believed at the time of the first survey, have now been alienated. The importance of this distinction should be clear. Information on the gross changes behind a net change, can only be obtained by examining the same individuals on two or more occasions. These types of surveys are called panel studies.

The major decision which must be reached when designing a panel study is how the successive samples will relate (i.e., how much overlap will there be?). Many possible overlap schemes can be developed, depending upon the particular application (80). However, all panel studies suffer from one major problem - the initial examination of the panel may change the response of panel members and render it non-representative of the general population. This could occur by modifying behaviour, stimulating recall of forgotten events, an increasing confidence in the interviewers, etc. The impact of panel deterioration must always be assessed before deciding upon the type of panel design to be employed.
3.8 Summary

This chapter has presented a brief overview of survey methodology. It has concentrated upon the strategies involved with using probability sampling methods and illustrated some of the advantages of this procedure. Finally, it briefly examined the methods which could be used when a study wishes to determine changes in a population parameter.
4. A METHODOLOGY TO ASSESS THE QUALITY OF
HYPERTENSION CONTROL IN A COMMUNITY

4.1 Introduction

The discussion in Chapter 2 has presented the background necessary to develop a methodology to assess the adequacy of community control of hypertension. From that discussion, it is clear that one can define a group of patients for whom the efficacy of antihypertensive treatment has been demonstrated. Furthermore, Weinstein and Stason demonstrate that such treatment can provide a net benefit even when some patients are non-compliant (183). These conclusions lead directly to two questions:

(1) How effective are present efforts to provide antihypertensive therapy to those who need it?
(2) What can be done to improve the delivery of such antihypertensive therapy?

Before deciding how the present health care delivery system should be improved, it is logical to assume that high quality information would need to be available describing where and why the present system fails to provide adequate antihypertensive control. The actual expenditure of effort is quite different. Much attention has been directed to areas such as population screening, (8, 34, 58, 149, 156, 188) the role of physician extenders (1, 88, 89), relocation of the treatment centre as, for example, to the workplace (1, 19, 136), compliance improving strategies (137) and attempts.
to modify physician behaviour, both by continuing education (68) and behaviour modification (25). Later in this chapter, it will be seen that, in comparison to the wide spectrum of activity listed above, little systematic attention has been directed to "diagnosing" the problem. This is especially true in Canada, where no population-based sample survey has been undertaken.

The basic question under consideration is that of assessing the quality of care provided at a community level. Much attention has been directed at the analogous problem of assessing the quality of care given to individual patients by individual physicians. The methodology developed in this area can be extended to provide a theoretical approach to the problem of assessing the quality of care provided by a community to a group of citizens.

This chapter will begin by briefly reviewing the methods which are presently used to evaluate quality of care. These methods will be extended to develop a method of measuring quality of care at a community level. This methodology will then be used to produce a specific model which can be employed to measure the quality of hypertension control. Section 4.6 will examine the published literature and provide an estimate of the magnitude of the problem of hypertension control. The chapter will then conclude by examining alternative evaluation strategies.

4.2 The Methodology of Assessing the Quality of Patient-Physician Encounters

Assessment of the quality of health care provided by medical
both the lay and medical press. This interest has two main motivating forces. One is the altruistic desire to provide the best possible medical service to patients. The second is an economic incentive to limit expenditure on health care and to obtain the most efficient use of those monies allocated to provide health services. It is regrettable, but perhaps inevitable, that this second force seems to be predominant in motivating a review of quality of care. Thus, the U.S. government has introduced Professional Service Review Organizations (PSRO) (47) and the Ontario Ministry of Health uses Hospital Medical Records Institute (HMRI) data to attempt cost-containment in hospital usage. The Ontario Hospital Insurance Plan (OHIP) utilizes an indicator of physician service volume to identify potential abuse and poor patient care (47). Many private organizations, such as Blue Cross (31), and the San Joaquin Foundation for Medical Care (16) have instituted quality of care assessment for the purpose of cost-containment. There is now some evidence that improving quality of care can lead to cost-savings (14, 95). Most studies demonstrating cost-savings have concentrated on "errors of commissions" or over-utilization of health care services.

The use of quality of care evaluation in an attempt to improve patient care is usually effected by peer-review procedures. These procedures are largely concerned with ensuring that patients receive appropriate and sufficient medical services.

Such an orientation naturally involves consideration of "errors of
 omission" (i.e., under-utilization of services) as well as errors of commission (14, 15, 50, 51, 52, 132). Such an evaluation will tend to increase utilization and, hence, costs. In order to justify such increased costs, recommendations for improving quality of care by increasing utilization must be combined with evidence as to the effectiveness and efficacy of treatment.

The methodology of quality of care assessment has been extensively reviewed (13, 15, 31). The following paragraphs will briefly summarize these considerations. Further details can be found in the original references.

There are three major approaches to evaluation of quality of care. These are referred to as the evaluation of the structure, process and outcome of medical care. Structure refers to factors such as: the physical aspects of the facilities, equipment and staff, the qualifications of the personnel and the administration organization of the health care system. Examples of structural factors are physician:population ratios, hospital bed:population ratios, referral systems, liscensure and accreditation.

Process refers to the activities of health care personnel in the management of patients. Thus, the management of a patient with chest pain could involve taking an EKG, chest X-ray, history and physical; monitoring in the C.C.U.; follow-up EKG's and subsequent counselling. All these steps are items in the process of care. The quality of care could be evaluated by determining if any process items were omitted or if any unnecessary items were
Outcome measurement involves the examination of the results of care. Patient survival, mobility, the rate of disease recurrence and patient's psycho-social function are examples of outcomes which might be examined. The distribution of observed outcomes would be compared to a norm and provide a measure of quality of care.

Each of the three approaches outlined above has advantages and disadvantages. Structural variables are relatively straightforward to measure and to modify. However, the validity of using this approach rests on two basic assumptions:

(1) Good care is provided by well trained staff in new buildings, with sound administrative management, etc.

(2) One can identify those attributes of organization which are "good".

Structural assessment has been widely used by administrative bodies, and especially by governmental departments. However, the indirect relationship between structural change and improved care presents a major problem in using this technique to quantitate quality of care.

Process measurement has become a popular approach in many recent quality of care studies. The methodology of this technique involves identifying a series of events which might occur during the delivery of care. Standards are then developed to indicate the way in which these events should occur if good care is being provided. Lastly, data are collected to ascertain the way these events occur in actual practice.
A variety of different techniques have been developed to concretize these concepts. The selection of the events to be studied is usually performed by a committee. The techniques used to establish standards vary. Criteria can be based on local norms, provincial or national norms, "ideal norms", minimally acceptable norms, or many other possible types of norms (31). The techniques used to combine individual criteria into an overall assessment of quality, also vary. Approaches include: algorithms (132), maps (13), statistical weighting (31) and threshold logic (27). The presence of such a variety of procedures attests to the lack of one technique which is clearly superior. A detailed discussion of the relative merits can be found in Donabedian (31).

Once a decision has been reached as to what data will be collected and how it will be assessed, it is necessary to examine the procedure which will be employed to collect these data. Here again, a variety of procedures is in use. Analysis of patient records and charts is used extensively but suffers from an unknown bias due to faulty recording (37). Direct observation is costly and time-consuming. Patient and physician logs can provide useful information but have a potential to modify the process normally employed by the practitioner (147). Again, no one technique is superior.

The major disadvantage of using the analysis of process as a measure of quality of care is that of establishing the validity of the process criteria. Attempts to correlate process measurement with subsequent patient outcomes have often failed to reveal any
significant relationships (111, 167). Until the validity of process
criteria can be demonstrated, the role of process measurement as
the sole determinant of quality of care will remain clouded.

The use of outcome measurement would seem to provide an
ideal approach. In this technique, attention is directed to the
possible results of illness. Under the assumption of good quality
of care, one could then determine the prevalence and/or incidence
of each outcome which would be acceptable. The actual quality of
care could then be assessed against these criteria. Codman used this
methodology in 1913 during one of the pioneer attempts at
measuring quality of care (30). It still finds extensive use,
as for example in the Quality Assurance Monitor (QAM) system
(27) and at hospital morbidity and mortality rounds. A detailed
discussion and advocacy of the use of outcome measures was recently
written by Brook et al. (15).

Despite the apparent advantages of an evaluation based
on outcome measurement, the procedure often will not reflect the
actual "quality" of health care. As an extreme example, consider
a situation where mortality or morbidity outcomes are to be used
to evaluate the quality of care provided to patients suffering
from minor upper respiratory infections (URI). The mortality and
morbidity from a minor URI is nearly zero even if no care is
provided. It is, thus, probable that a physician who "over-cares"
for patients with URI's (e.g., by doing spirometry and chest X-ray,
antibiotic treatment, and possible hospitalization) would be found
to be delivering an acceptable quality of care when evaluated
using the above technique. Clearly, such an assessment is inappropriate.

The reasons for the inappropriate conclusion reached in the above example are two:

(1) The outcome measure is too insensitive to reflect even wide variations in health care delivery.

(2) The outcome measure is not influenced by the variation in process (i.e., a lack of correlation between process and outcome).

These two reasons are actually related. If the outcome measure is insensitive, then one would probably not be able to demonstrate a process outcome correlation. Similarly, if there is no process outcome correlation, then the outcome measure is an insensitive indicator of variation in health care delivery. As indicated earlier, studies often fail to demonstrate a correlation between process and outcome. Thus, good outcomes could be obtained despite excessive under- or over-utilization of services. At present, it is doubtful if any system based solely on outcome measures provides an accurate evaluation of quality of care.

Summarizing the above discussion, it seems doubtful at this time that an evaluation of quality of care based solely on structure, process or outcome could provide an adequate assessment. A more useful approach would be to combine these factors into a composite index. If subsequent evidence could be obtained to correlate process and outcome, then the use of process criteria would become much more attractive.
4.3 Methodology to Assess the Quality of Care at the Community Level

The type of protocol which should be used for evaluating a community health project is different from that which is used for evaluating the physician-patient interaction. The physician is often faced with the problem of making decisions based on incomplete information or in emergency situations. An evaluation of the quality of care should recognize the nature of the decision-making process under investigation. In contrast to the above, community health programs are organized at a relatively leisurely pace and should be based on well-collected data demonstrating that the program is worth while. A decision to implement a community-wide program should not be reached when the supporting documentation is incomplete. This view reflects two important facts:

(1) Community programs usually involve a substantial financial outlay, both starting capital and for operating expenses.

(2) If a program is implemented before the evidence of benefit is available, and it is later necessary to withdraw the program (either because it is ineffective or even detrimental), then public confidence will be severely damaged. Subsequent programs, even those with a proven benefit, will be harder to implement.

Traditionally, the eva
as possible. No attention was directed towards demonstrating that
the program was actually of benefit to the community (180). With
such an evaluation technique, physicians in the 18th Century would
have been justified to conclude that blood-letting was a good
community project (135). Such an uncritical evaluation strategy
can not be tolerated, especially not in times of fiscal restraint.

Sackett (135) in a paper presented to the Community Health
Centre Project, recommended a scientific, four-stage approach to
evaluating community programs:

(1) Is the program efficacious? That is, does it do
more benefit than harm in those who will adhere
to the program?

(2) Is the program effective? That is, does it do more
benefit than harm in those to whom the program
is offered?

(3) Is the program available? That is, is the program
accessible to all members of the community who can
benefit from it? This concept involves not only the
care-delivering facilities but also programs informing
the public about the need for this care.

(4) Is the program efficient? That is, is the
program made available in a manner which optimizes
the use of resources?

Evaluation at any stage should be performed only after evaluation at
all previous stages has been completed.
As the evaluation scheme progresses through the four stages listed above, there is a change in the actual program being evaluated. Consider, for example, the evaluation of a hypertension control program. The efficacy step of evaluation requires a demonstration that antihypertensive therapy, if taken, will reduce complications. When effectiveness is considered, the program no longer involves just the drug under consideration. It now involves also the strategy being used to maximize compliance. There are many different programs which make use of the same therapeutic action but which use different compliance enhancement strategies. Each of these programs should receive a separate evaluation. Similarly, the program being evaluated at the availability level involves not only the therapeutic agent and the compliance enhancement strategy, but also an attempt to ensure that the public will use the program. Again, evaluation of the overall program may vary depending upon how the availability of the program is broadcast. While these distinctions may seem obvious, it is important that they be recognized. Researchers should be aware of the entire program which is being evaluated. Also, it may now be recognized that one cannot evaluate the availability of antihypertensive therapeutic manoeuvre in isolation from the delivery vehicle. Generally, efficacy will be demonstrated before consideration is given to implementing a manoeuvre as a community project. There will often be some demonstration of effectiveness. Thus, the rest of this section will concentrate on strategies to evaluate availability.
In a manner analogous to the evaluation of the individual physician-patient interaction, the availability of a community program can be evaluated by three approaches - structure, process, and outcome. Structure still refers to the availability of adequate facilities and staff, the qualifications of the staff, and the administrative support. There is clearly a minimum standard of structure required before a viable community program can be implemented. However, beyond this minimum level, the relationship between structural factors and the quality of care is tenuous.

Turning to an evaluation based on outcome, one finds that the outcome variables of interest are different from those considered in the previous section. Since the primary unit receiving care is now a group of patients, one need not be concerned with the response of individual patients. Instead one can examine fatality rates, recurrence rates, incidence and prevalence of various end-points of interest, life-expectancy curves and similar data. Most of these data could be obtained from vital statistics tables. The major difficulty with this procedure is that the outcome measures are likely to be influenced by many factors outside the health care procedure under evaluation. For example, the mortality rate from stomach cancer in the U.S.A. has declined from 30 to 8/100,000 (165), a substantial decrease which superficially suggests a remarkably successful health care system. In fact, there is no evidence to link this decline to health care.
The use of process evaluation is promising. These process variables do not refer solely to the individual components of the patient-physician interaction. They relate now to the question of how groups of patients interact with the health care system (e.g., how are patients with stomach cancer detected, do they receive appropriate follow-up?). In section 4.2, a major impediment to utilizing an evaluation based on the process of care was the difficulty of establishing a link between process and outcome. The present situation is quite different, since studies of efficacy and effectiveness should be completed before beginning to evaluate the availability of care. These studies provide a link between process and outcome and make process-based evaluation much more attractive.

In summary, this section has reviewed the methodology of evaluating community health care projects. It has been shown that process-based evaluation is an appropriate procedure to be used when evaluating the availability of care.

4.4 Application of the Methodology to Hypertension

The concepts derived in the preceding section can be applied to the specific situation of evaluating the quality of present community efforts to control hypertension. The general evaluation strategy is applicable to this area. In particular, the efficacy of antihypertensive therapy has been well demonstrated, at least in certain patient sub-groups. There is some evidence showing that antihypertensive therapy can be effective despite the many problems with compliance, etc. (183). These facts suggest
the construction of an evaluation procedure based on the process of care.

The Ontario Council of Health Task Force on Hypertension presents a six-step model of the process involved in the community control of hypertension (126). This model is illustrated in Figure 4.1. Consideration will now be given to each of these steps and to possible methods of measuring them.

Detection refers to the identification and labelling of those individuals who have hypertension. Since hypertension is usually asymptomatic, this procedure involves the routine measuring of blood pressure in "normal" people. Settings where this could take place include, among others: general practitioners' offices during routine visits, emergency rooms, optometrists' offices, places of employment and supermarkets. Evaluation of performance in this process component would involve determining the proportion of the hypertensive population who remain undetected. This could be recorded either as the proportion of prevalence cases not yet found, or as the proportion of incidence cases not found. The former ratio relates to the system's ability to locate any backlog of untreated cases, while the latter ratio would reflect an ability to cope with the influx of new cases. Incidence data would require the follow-up of an inception cohort and hence would require more time to obtain usable data. One obvious data collection method would involve direct patient questioning. A group of hypertensive people would be identified and then questioned to determine the number who were unaware of their hypertension. This data could be
Figure 4.1: PROCESS MODEL FOR COMMUNITY CONTROL OF HYPERTENSION

- DETECTION

- LINKAGE TO A SOURCE OF CARE

- EVALUATION:
  - SECONDARY BP
  - TARGET ORGAN DAMAGE

- INITIATION OF THERAPY

- COMPLIANCE WITH THERAPY

- LONG-TERM FOLLOW-UP:
  - MEDICATION MODIFICATION

- RESULT:
  - CONTROL
complemented by information from physicians and/or medical insurance plans. However, there are so many places where the diagnosis of hypertension can be made that one could not hope to canvass all possible sources. In view of these difficulties, the most reasonable approach would involve only direct patient questioning. This questioning could produce some misclassification, either because the subject did not provide the correct information or because the subject had not been told by his/her physician that he/she had hypertension.

Any hypertensives who are detected by an agency other than their own physician will need to be linked to a source of care. While this can present a major problem (126), the extent of linkage required is very dependent on the detection program being used. Some indication of the quality of linkage to care could be obtained by determining where the hypertensives were detected. Further questioning could determine if they actually visited a physician to have the hypertension evaluated and/or treated. However, the data obtained in this manner would be subject to bias in patient recall. Better quality data could be obtained by prospective observation of an inception cohort. More specific information on problems in this area would require special purpose program-based evaluation.

Once a patient has been seen by a physician, an evaluation of the extent of the problem must take place. This evaluation has two components. Firstly, one must establish the extent of target organ damage. This information provides an estimate of the severity and longevity of the hypertension. It is also useful in deciding
which patients require treatment (126). The second component involves determining whether the patient has a form of secondary hypertension. The return from this avenue of investigation is very low, when applied to an unselected hypertensive population (126). Evaluation of quality in these areas cannot be done in a patient-based survey, since consideration of patient-physician interaction is involved. Evaluation of this component of quality of care will not be pursued further in this thesis.

The last three process items listed in Figure 4.1 all relate to the therapeutic manoeuvre. The control of hypertension depends upon the adequate use of the therapeutic armatorium. The decision to commence treatment will be dictated both by the results of the evaluation and by the physician's knowledge and beliefs about hypertension. These will also modify the initial choice of therapeutic agent. Hypertension is a chronic disease and once therapy has been initiated, follow-up must take place in order to ensure that adequate control is obtained and maintained. This may require adjustment of medication and further investigation of refractory cases. Control may also be difficult because of poor patient compliance with the therapeutic regimen.

The details of therapeutic techniques are not particularly relevant to assessing community control of hypertension. It is more important to reduce the blood pressure by whatever means are available. Information as to the therapeutic regimens used could provide some interesting ancillary information but will not be included in the basic model for evaluating the quality of hypertension
Information relating to initiation of therapy would be made available by direct questioning of patients. Details could be collected about all forms of therapy including dietary, chemical, psychiatric and relaxation modes. The adequacy of follow-up could be assessed with a three-pronged technique. Firstly, the overall degree of control could be determined. Secondly, information could be collected about those who are no longer under therapy. This would also provide some data relevant to evaluating the problem of non-compliance. Lastly, patients could be asked directly about the follow-up arrangements with their physicians.

The issue of patient compliance is difficult to handle. There are no "sure fire" techniques to evaluate compliance (137). Even sophisticated biochemical testing has many problems (137). Most strategies which are available at present are more useful in the prospective follow-up of patients in drug trials (137). One of the simplest ways to investigate compliance is by directly asking patients if they have problems remembering to take their pills. This procedure has been shown to have a sensitivity = 53% and a specificity = 96% when used to identify patients with compliance difficulties (163). This procedure can be used to identify a sub-group of poor compliers who could be examined to estimate the impact of compliance as a determinant of patient control.
4.5 Outline of the Protocol Which Will Be Used to Assess the Quality of Hypertension Control

The discussion of the previous chapter can be formulated into a cohesive plan which can be used to evaluate the quality of hypertension control in a community. This is summarized in Table 4.1. As indicated in section 4.4, the measurements can be taken on either an inception cohort or on a cross-sectional sample. The choice between these alternatives must be based on the availability of funds and time. Since the measurement techniques involved are quite similar, the rest of this thesis will concentrate on developing an implementation of the prevalence model. A further reference to the use of incidence data can be found in section 5.12.

Item 1 of Table 4.1 relates to the selection of a group of subjects for further study. An adequate definition of the population under study is necessary to allow consistent interpretation of the results. Techniques for the selection of the study population should be based on valid sampling theory as expounded in Chapter 3. Convenience samples or volunteer groups are often used as study populations. This use severely interferes with the confidence with which results can be generalized to a larger population group. The need to provide an adequate definition of those who should receive treatment is obvious but is frequently neglected in published studies. Most criteria are based on one or more blood pressure measurements. Cut-off points for treatment can be based on diastolic and/or systolic values. There is substantial variation in the actual levels selected (e.g., from 90–115 mm Hg diastolic),
Table 4.1: Protocol for Evaluating the Quality of Hypertension Control in a Community

<table>
<thead>
<tr>
<th>PROCESS ITEM</th>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Identify the hypertensive population to be studied.</td>
<td>(a) State the criteria which will be used to determine if an individual has clinically significant hypertension.</td>
</tr>
<tr>
<td></td>
<td>(b) Obtain a representative population sample for study.</td>
</tr>
<tr>
<td>(2) Detection.</td>
<td>(a) Determine what proportion of the identified hypertensive population is unaware of being hypertensive.</td>
</tr>
<tr>
<td>(2a) Detection and linkage.</td>
<td>(a) For those who know about their hypertension, determine how they found out about it!</td>
</tr>
<tr>
<td>(3) Linkage.</td>
<td>(a) For those who know about their hypertension, determine how many have seen a physician, specifically because of this problem.</td>
</tr>
<tr>
<td></td>
<td>(b) For those who have seen a physician, determine how long it took to see this physician, after they learned about having hypertension.</td>
</tr>
<tr>
<td>PROCESS ITEM</td>
<td>ACTION</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>(4) Evaluation (indirect assessment)</td>
<td>(a) For those who have seen a physician because of hypertension, obtain a list of those procedures used by this physician before deciding if treatment were necessary.</td>
</tr>
<tr>
<td>(5) Initiation of treatment.</td>
<td>(a) For those who have seen a physician because of hypertension, determine how many were started on treatment.</td>
</tr>
<tr>
<td>(6) Compliance</td>
<td>(a) For those who are presently on a treatment regimen, determine what proportion of the prescribed medication is being taken.</td>
</tr>
<tr>
<td>(7) Follow-up.</td>
<td>(a) For those who were started on treatment, determine how many are still taking some form of treatment.</td>
</tr>
</tbody>
</table>
|                        | (b) For those still on treatment, determine how long it has been since they last saw a
<table>
<thead>
<tr>
<th>PROCESS ITEM</th>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>(3) Control.</td>
<td>(c) For those still on treatment, determine the type of follow-up arrangement their physician uses. (a) Determine what proportion of the hypertensive population is under acceptable clinical control?</td>
</tr>
</tbody>
</table>
Based on a review of the published randomized controlled trials of antihypertensive treatment, the Ontario Council of Health Task Force on Hypertension recommends complementing blood pressure determination with a consideration of target organ damage (126). By this procedure, all patients with sustained diastolic blood pressure ≥105 mm Hg would require treatment. Patients with a sustained diastolic blood pressure between 90 and 105 mm Hg would receive treatment only if target organ damage was found. While this compound criterion is well-founded, no published report has utilized this approach.

The remaining steps of Table 4.1 relate to information which will be collected during the survey. The rationale supporting each data item can be found in section 4.4. Examination of this table shows that all elements of the process model are probed directly except that of patient evaluation. This later element is assessed indirectly by means of a stimulated recall procedure. Unfortunately, such a procedure is subject to many sources of bias and the quality of data so obtained can be questioned.
4.6 Review of the Published Literature Evaluating the Quality of Hypertension Control in the Community

4.6.1 Methodologic Considerations

The evaluation of the degree of hypertension control is an area of topical concern. In the last twenty years, many studies have been published which have attempted to determine how well the present health care system is achieving the goal of hypertension control to identify areas in need of improvement (2,4,5,8,10,17,34,38,39,56,58,59,64,66,87,90,102, 121,127,128,142,144,149,156,170,176,187,188). Unfortunately, the methodology employed in these studies was frequently less than ideal. Examination of these papers reveals one major reason for the use of inappropriate research methods — many of these studies were primarily intended as demonstration or service projects. The information used to evaluate the state of hypertension control was often available free by analyzing data collected for other purposes. Thus, several observers (8,10,34,39,144,149,156,188) have used data collected during the performance of "screening" manoeuvres. Since the population screened consisted of volunteers who were likely to differ in health status from non-volunteers (104,188,191), the results obtained cannot be generalized to any larger population of interest.

Utilizing the work presented in Chapter 3 and earlier in this chapter, it is possible to identify standards to which research in this area should adhere (Table 4.2). First, the study should identify a target population of interest. This population should be the actual population of interest, not a convenient substitute. Then, the study subjects should be selected by probability sampling techniques. If appropriate, a complete census could be used. Following careful selection of
Table 4.2: Methodologic Standards for Studies of the Quality of Hypertension Control in the Community

(1) Identify "true" target population.

(2) Select a sample using probability sampling techniques.

(3) Examine the sample using standardized procedures.

(4) The basic definition of hypertension should refer to sustained hypertension.

(5) Measure the racial, social and sexual mix of the sample.
the sample, equal care should be taken in the examination. Blood pressure measurement should utilize standardized techniques. Repeat visits should be made, with several measurements obtained at each visit. This requirement reflects the realities of clinical life. Present evidence of the efficacy of antihypertensive therapy is based upon the concept of sustained hypertension. Since blood pressure is a labile clinical measure, it is not surprising to find that many individuals whose initial blood pressure measurement is hypertensive, are subsequently found to be normotensive (7,116,118,125). In fact, this is one of the annoying complications which must be overcome when attempting to demonstrate the efficacy of antihypertensive treatment. The failure to obtain blood pressure measurements at repeat visits, results in a substantial over-diagnosis of clinical hypertension. This misclassification produces a bias which is both extensive and subtle. First, the prevalence of hypertension will be inflated. In addition, since these new "hypertensives" are in reality normotensive, they will, of course, be unaware of their "hypertension". Hence, the measure of hypertension control will be diminished. Accurate diagnosis of clinical hypertension is necessary in order that an accurate evaluation be obtained. The last methodologic standard requires the measurement of the facial, social and sexual mixture of the sample. This will be of assistance in interpreting the results since the prevalence and severity of hypertension are related to these attributes.
4.6.2 Detailed Consideration of the Published Literature

Twenty-nine studies can be identified for consideration.

A summary of the methodology of each study can be found in Table 4.3. The first part of this table, Table 4.3a, summarizes the socio-demographic information associated with each study. The next part, Table 4.3b, considers the sampling methods. Table 4.3c reports the blood pressure measurement procedures employed. Finally, in Table 4.3d, the observed results are presented. The studies are arranged in temporal sequence, beginning with the earliest. The rest of this section will discuss, in more detail, the data presented in Table 4.3. The studies will be discussed in logical groupings, rather than in strict temporal order.

The first group consists of the studies of Komachi (87), Richard (128), and Borhani (66). The first two studies were discussed in papers related to the evaluation of hypertension control but the study was not the main focus of the paper. In preparation for an intervention program, Komachi investigated the degree of hypertension control in two Japanese towns. Richard reported on a group of workers in a French factory. As presented, neither study was accompanied by a sufficiently detailed discussion of the methodology employed to permit proper interpretation of the results. Borhani studied the population of Alameda County, California. This study represents one of the earliest attempts to evaluate the degree of hypertension control in a defined community. However, the methods employed in the design of this study are not now available for
examination. Since the results of this study are compatible with other similar studies performed at the same time, this study will not be pursued further. These three projects are mentioned only for completeness.

Thirteen studies (studies #6, 7, 11, 12, 17, 18, 21, 22, 23, 25, 27, 28, 29), did not make any attempt to employ probability sampling techniques. As a consequence of this deficient design, it is not possible to generalize the observed results to any larger population without risk of introducing significant bias. The measurement procedures used in twelve of these thirteen studies also do not fulfill the standards presented earlier in this section. In view of the above deficiencies, these twelve studies need not be examined further.

The remaining study of this group was performed by Alderman et al. (2) who examined 69% of three unions located in New York City. They felt that the composition of these unions adequately reflected that of the working population of New York City. The response rate was high for this type of sample (e.g., compare 25% for Eckenfels (34) and 26% for Wilber (188)) although all respondents were volunteers. This sample will probably be more representative of the target population than most studies obtained using non-probability methods. In addition, this study was one of only two studies which obtained repeat blood pressure measurements before diagnosing hypertension. In summary, the overall methodology in this study, while less than

(text continues on Page 102)
<table>
<thead>
<tr>
<th>Study Number</th>
<th>Principal Author</th>
<th>Time Period</th>
<th>Location</th>
<th>Target Population</th>
<th>% Non-White</th>
<th>Rural/Urban</th>
<th>Socioeconomic Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>National Health Survey (66,170 )</td>
<td>1960-62</td>
<td>U.S. in its entirety</td>
<td>non-institutionalized adults ≥18 yrs.</td>
<td>≥10</td>
<td>Mixed</td>
<td>Mixed</td>
</tr>
<tr>
<td>2</td>
<td>Wilber, J.A. (187)</td>
<td>1962</td>
<td>Baldwin County, Georgia</td>
<td>non-institutionalized adults ≥15 yrs.</td>
<td>40</td>
<td>Mainly Rural</td>
<td>Poor</td>
</tr>
<tr>
<td>3</td>
<td>Komachi, Y. (87)</td>
<td>1964-71</td>
<td>Japan</td>
<td></td>
<td>-</td>
<td>Rural</td>
<td>Poor</td>
</tr>
<tr>
<td>4</td>
<td>Borhani, N.O. (66)</td>
<td>1966</td>
<td>Alameda County, California</td>
<td></td>
<td>-</td>
<td>Urban</td>
<td>Middle Class</td>
</tr>
<tr>
<td>5</td>
<td>Fodor, J.G. (38)</td>
<td>1967</td>
<td>Newfoundland, 4 communities</td>
<td>non-institutionalized adults ≥19 yrs.</td>
<td>0</td>
<td>Rural</td>
<td>Poor</td>
</tr>
<tr>
<td>6</td>
<td>Schoenberger, J.A. (142 )</td>
<td>1967-71</td>
<td>Chicago</td>
<td>volunteers working in Chicago industry</td>
<td>10</td>
<td>Urban</td>
<td>Middle Class</td>
</tr>
<tr>
<td>7</td>
<td>Richard, J. (128)</td>
<td>1967-70</td>
<td>Paris</td>
<td></td>
<td>-</td>
<td>Urban</td>
<td>Poor</td>
</tr>
<tr>
<td>8</td>
<td>Hart, J.T. (58)</td>
<td>1968-69</td>
<td>Glyncor, Wales</td>
<td>all adults ≥20 yrs. living in district</td>
<td>0</td>
<td>Urban</td>
<td>Poor</td>
</tr>
<tr>
<td>9</td>
<td>Harburg, E. (38, 56)</td>
<td>1968-69</td>
<td>Detroit</td>
<td>married, adults between 25-60 yrs. living in 4 defined areas</td>
<td>51</td>
<td>Urban</td>
<td>Poor</td>
</tr>
<tr>
<td>10</td>
<td>Berglund, G. (10)</td>
<td>1970</td>
<td>Göteborg, Sweden</td>
<td>men aged 47-54 yrs., ambulatory</td>
<td>0</td>
<td>Urban</td>
<td>Middle Class</td>
</tr>
<tr>
<td>11</td>
<td>Wilber, J.A. (188)</td>
<td>1970-71</td>
<td>Atlanta</td>
<td>adults ≥15 yrs. in defined areas</td>
<td>≥100</td>
<td>Urban</td>
<td>Poor</td>
</tr>
<tr>
<td>12</td>
<td>McMahon, F.G. (102)</td>
<td>1971</td>
<td>New Orleans</td>
<td>adults in low-rent areas</td>
<td>95</td>
<td>Urban</td>
<td>Poor</td>
</tr>
<tr>
<td>13</td>
<td>Apostolides, A.Y. (4 )</td>
<td>1971</td>
<td>Baltimore</td>
<td>non-institutionalized Negroes aged 30-69 yrs.</td>
<td>100</td>
<td>Urban</td>
<td>Poor</td>
</tr>
<tr>
<td>Study Number</td>
<td>Principal Author</td>
<td>Time Period</td>
<td>Location</td>
<td>Target Population</td>
<td>Non-White</td>
<td>Rural/Urban</td>
<td>Socioeconomic Status</td>
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<tr>
<td>--------------</td>
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<td>-------------------</td>
<td>-----------</td>
<td>-------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>14</td>
<td>Prineas, R.J. (121)</td>
<td>1971</td>
<td>Albury, Australia</td>
<td>adults 50-59 yrs. in inner city area</td>
<td>0</td>
<td>Urban</td>
<td>Middle Class</td>
</tr>
<tr>
<td>15</td>
<td>Hawthorne, V.M. (59)</td>
<td>1971-72</td>
<td>Burgh. of Renfrew, Scot.</td>
<td>all adults 45-64 yrs.</td>
<td>0</td>
<td>Urban</td>
<td>Mixed</td>
</tr>
<tr>
<td>16</td>
<td>Apostolides, A.Y. (5)</td>
<td>1971</td>
<td>Baltimore</td>
<td>adults 30-69 yrs.</td>
<td>100</td>
<td>Urban</td>
<td>Poor</td>
</tr>
<tr>
<td>17</td>
<td>Eckenfels, E.J. (34)</td>
<td>1972</td>
<td>Holmes County Mississippi</td>
<td>people ≥5 yrs.</td>
<td>100</td>
<td>Rural</td>
<td>Poor</td>
</tr>
<tr>
<td>18</td>
<td>Silverberg, D.S. (149)</td>
<td>1973</td>
<td>Edmonton</td>
<td>&quot;adults&quot;</td>
<td>0</td>
<td>Urban</td>
<td>Mixed</td>
</tr>
<tr>
<td>19</td>
<td>Apostolides, A.Y. (5)</td>
<td>1973</td>
<td>Baltimore</td>
<td>adults 30-69 yrs.</td>
<td>100</td>
<td>Urban</td>
<td>Poor</td>
</tr>
<tr>
<td>20</td>
<td>Hypertension Detection and Follow-Up Program (64)</td>
<td>1973</td>
<td>Various U.S. locales</td>
<td>adults 30-69 yrs.</td>
<td>26</td>
<td>Mixed</td>
<td>Mixed</td>
</tr>
<tr>
<td>21</td>
<td>Verdesca, A.S. (176)</td>
<td>1973</td>
<td>New York City</td>
<td>volunteers in industry</td>
<td>-</td>
<td>Urban</td>
<td>Middle Class</td>
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<tr>
<td>22</td>
<td>Stamler, J. (156)</td>
<td>1973-75</td>
<td>Various locales</td>
<td>&quot;volunteers&quot; who were screened</td>
<td>11</td>
<td>Mixed</td>
<td>Mixed</td>
</tr>
<tr>
<td>3</td>
<td>Alderman, M.H. (2)</td>
<td>1973-75</td>
<td>New York City</td>
<td>employees belonging to several union locales</td>
<td>30</td>
<td>Urban</td>
<td>Middle Class</td>
</tr>
<tr>
<td>4</td>
<td>Kotchen, J.M. (90)</td>
<td>1974</td>
<td>Kentucky</td>
<td>adults ≥16 yrs. living in a specific commun.</td>
<td>0</td>
<td>Rural</td>
<td>Poor</td>
</tr>
<tr>
<td>5</td>
<td>Foote, A. (39)</td>
<td>1974</td>
<td>Detroit</td>
<td>various mixed populat.</td>
<td>-</td>
<td>Urban</td>
<td>Mixed</td>
</tr>
<tr>
<td>6</td>
<td>Carey, R.M. (17)</td>
<td>1974</td>
<td>Charlottesville Virginia</td>
<td>adults ≥15 yrs.</td>
<td>15</td>
<td>Urban</td>
<td>Middle Class</td>
</tr>
<tr>
<td>Study Number</td>
<td>Principal Author</td>
<td>Time Period</td>
<td>Location</td>
<td>Target Population</td>
<td>% Non-White</td>
<td>Rural/Urban</td>
<td>Socioeconomic Status</td>
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<tr>
<td>--------------</td>
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<td>-------------</td>
<td>----------------</td>
<td>-------------------</td>
<td>-------------</td>
<td>-------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Shapiro, M. (144)</td>
<td>1975</td>
<td>Montreal</td>
<td>&quot;adults&quot;</td>
<td>0</td>
<td>Urban</td>
<td>Mixed</td>
<td></td>
</tr>
<tr>
<td>Merck-Sharpe &amp; Dohme (127)</td>
<td>1975-76</td>
<td>Canada</td>
<td>adults ≥21 yrs.</td>
<td>0</td>
<td>Mixed</td>
<td>Mixed</td>
<td></td>
</tr>
<tr>
<td>Baitz, T. (8)</td>
<td>1975</td>
<td>Hamilton, Ontario</td>
<td>adults ≥15 yrs.</td>
<td>= 0</td>
<td>Urban</td>
<td>Mixed</td>
<td></td>
</tr>
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</table>

Notes: Information was not reported.
Table 4.3b: SUMMARY OF STUDIES EXAMINING THE QUALITY OF COMMUNITY CONTROLS OF HYPERTENSION: SAMPLING DESIGN

<table>
<thead>
<tr>
<th>Study Number</th>
<th>Sampling Procedure</th>
<th>Probability Sample</th>
<th>Size of Examined Sample</th>
<th>Response Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>highly stratified, multi-stage probability sample</td>
<td>Yes</td>
<td>6672</td>
<td>86 %</td>
</tr>
<tr>
<td>2</td>
<td>geographically determined random sample</td>
<td>Yes</td>
<td>3084</td>
<td>96.8%</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>census of two towns selected haphazardly</td>
<td>Yes/No</td>
<td>1499</td>
<td>70 %</td>
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<tr>
<td>6</td>
<td>volunteers for a screening program</td>
<td>No</td>
<td>22929</td>
<td>≈50 %</td>
</tr>
<tr>
<td>7</td>
<td>volunteers for a screening program</td>
<td>No</td>
<td>6788</td>
<td></td>
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<tr>
<td>8</td>
<td>entire G.P.'s practice (census)</td>
<td>Yes/No</td>
<td>910</td>
<td>99.8%</td>
</tr>
<tr>
<td>9</td>
<td>4 strata based on &quot;stress&quot; level, then random sample</td>
<td>Yes</td>
<td>1000</td>
<td>84%</td>
</tr>
<tr>
<td>10</td>
<td>one-third sample of target population</td>
<td>Yes</td>
<td>7455</td>
<td>75%</td>
</tr>
<tr>
<td>11</td>
<td>mixture of methods including door-to-door canvassing and blood pressure centres</td>
<td>No</td>
<td>6012</td>
<td>26% (of total community)</td>
</tr>
<tr>
<td>12</td>
<td>unclear, probably door-to-door</td>
<td>No</td>
<td>11309</td>
<td>85%</td>
</tr>
<tr>
<td>13</td>
<td>random sample from 27 convenient census tracts</td>
<td>Yes</td>
<td>1785</td>
<td>78%</td>
</tr>
<tr>
<td>14</td>
<td>census of target population in convenient city</td>
<td>Yes/No</td>
<td>1515</td>
<td>78%</td>
</tr>
<tr>
<td>15</td>
<td>census of target population</td>
<td>Yes/No</td>
<td></td>
<td>82%</td>
</tr>
<tr>
<td>Study Number</td>
<td>Sampling Procedure</td>
<td>Probability Sample</td>
<td>Size of Examined Sample</td>
<td>Response Rate</td>
</tr>
<tr>
<td>--------------</td>
<td>------------------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>-------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>16</td>
<td>random sample of households from 13 convenient census tracts</td>
<td>Yes</td>
<td>846</td>
<td>90+ %</td>
</tr>
<tr>
<td>17</td>
<td>haphazard door-to-door sample</td>
<td>No</td>
<td>4235</td>
<td>=25 %</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(of target population)</td>
</tr>
<tr>
<td>18</td>
<td>haphazard sample at shopping centre</td>
<td>No</td>
<td>9591</td>
<td>-</td>
</tr>
<tr>
<td>19</td>
<td>random sample of households from 13 convenient census tracts</td>
<td>Yes</td>
<td>5306</td>
<td>90+ %</td>
</tr>
<tr>
<td>20</td>
<td>varied among each of 14 communities</td>
<td>Yes/No</td>
<td>158906</td>
<td>-</td>
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<tr>
<td>21</td>
<td>volunteers at one industrial plant</td>
<td>No</td>
<td>1544</td>
<td>35 %</td>
</tr>
<tr>
<td>22</td>
<td>volunteers at shopping centres, etc.</td>
<td>No</td>
<td>1049225</td>
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<tr>
<td>23</td>
<td>volunteers at work</td>
<td>No</td>
<td>8579</td>
<td>69 %</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(of target population)</td>
</tr>
<tr>
<td>24</td>
<td>census of convenient town</td>
<td>Yes/No</td>
<td>1092</td>
<td>-</td>
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<tr>
<td>25</td>
<td>several convenience samples</td>
<td>No</td>
<td>7671</td>
<td>-</td>
</tr>
<tr>
<td>26</td>
<td>census of convenient city</td>
<td>Yes/No</td>
<td>12371</td>
<td>42 %</td>
</tr>
<tr>
<td>27A</td>
<td>volunteers at convenient locations</td>
<td>No</td>
<td>11331</td>
<td>-</td>
</tr>
<tr>
<td>27B</td>
<td>random sample from 4 census tracts</td>
<td>Yes</td>
<td>724</td>
<td>68 %</td>
</tr>
<tr>
<td>28</td>
<td>invited sample of physicians reporting on a convenient group of patients</td>
<td>No</td>
<td>45122</td>
<td>-</td>
</tr>
<tr>
<td>29</td>
<td>shopping plaza screening</td>
<td>No</td>
<td>18380</td>
<td>-</td>
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</tbody>
</table>

(- Denotes information not reported.)
<table>
<thead>
<tr>
<th>Study Number</th>
<th>Instrument Used</th>
<th>Number of Visits</th>
<th>Number of Measurements per Visit</th>
<th>Diastolic Phase</th>
<th>Home/Clinic</th>
<th>Cut-Off Level</th>
<th>Attempt at Standardization</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Hg.</td>
<td>1</td>
<td>3 (average)</td>
<td>V</td>
<td>Clinic</td>
<td>160/95</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>-</td>
<td>1</td>
<td>3 (average)</td>
<td>-</td>
<td>Home</td>
<td>160/95</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>4</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>160/95</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>London School of Hygiene Device</td>
<td>1</td>
<td>1</td>
<td>V</td>
<td>Home</td>
<td>DBP &gt;100</td>
<td>Yes</td>
</tr>
<tr>
<td>6</td>
<td>Hg.</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>Clinic (work)</td>
<td>160/95</td>
<td>No</td>
</tr>
<tr>
<td>7</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>160/95</td>
<td>-</td>
</tr>
<tr>
<td>8</td>
<td>Hg.</td>
<td>3</td>
<td>1</td>
<td>IV</td>
<td>Clinic</td>
<td>DBP &gt; cut-off on each of 3 occasions</td>
<td>Yes</td>
</tr>
<tr>
<td>9</td>
<td>Hg.</td>
<td>1</td>
<td>3 (average)</td>
<td>V</td>
<td>Home</td>
<td>160/95</td>
<td>Yes</td>
</tr>
<tr>
<td>10</td>
<td>Hg.</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>Clinic</td>
<td>175/115</td>
<td>Yes</td>
</tr>
</tbody>
</table>

(- Denotes information not reported; DBP = Diastolic Blood Pressure  Hg = Mercury sphygmomanometer)
<table>
<thead>
<tr>
<th>Study Number</th>
<th>Instrument Used</th>
<th>Number of Visits</th>
<th>Number of Measurements per Visit</th>
<th>Diastolic Phase</th>
<th>Home/Clinic</th>
<th>Cut-Off Level</th>
<th>Attempt at Standardization</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Aneroid</td>
<td>1</td>
<td>5</td>
<td>-</td>
<td>Home and/or Clinic</td>
<td>160/95 or age-adjusted</td>
<td>Yes</td>
</tr>
<tr>
<td>12</td>
<td>Aneroid</td>
<td>1</td>
<td>1</td>
<td>V</td>
<td>Home</td>
<td>150/90</td>
<td>No</td>
</tr>
<tr>
<td>13</td>
<td>Hg.</td>
<td>1</td>
<td>3 (3rd value used)</td>
<td>V</td>
<td>Home</td>
<td>DBP &gt;95</td>
<td>Yes</td>
</tr>
<tr>
<td>14</td>
<td>London School of Hygiene Device or Hg. Manometer</td>
<td>1</td>
<td>2 (2nd value used)</td>
<td>V</td>
<td>Clinic</td>
<td>DBP &gt;110</td>
<td>Yes</td>
</tr>
<tr>
<td>15</td>
<td>London School of Hygiene Device</td>
<td>1</td>
<td>1</td>
<td>V</td>
<td>Clinic</td>
<td>DBP &gt;100</td>
<td>Yes</td>
</tr>
<tr>
<td>16</td>
<td>Hg.</td>
<td>1</td>
<td>3 (3rd value used)</td>
<td>-</td>
<td>Home</td>
<td>DBP &gt;95</td>
<td>Yes</td>
</tr>
<tr>
<td>17</td>
<td></td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>Home</td>
<td>160/95</td>
<td>No</td>
</tr>
<tr>
<td>18</td>
<td>Hg.</td>
<td>1</td>
<td>2 (lower value used)</td>
<td>V</td>
<td>Clinic (plaza)</td>
<td>Age</td>
<td>Yes/No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt;40 155/95</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>40-64 160/95</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;65 165/100</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Hg.</td>
<td>1</td>
<td>3 (3rd value used)</td>
<td>-</td>
<td>Home</td>
<td>DBP &gt;95</td>
<td>Yes</td>
</tr>
<tr>
<td>Study Number</td>
<td>Instrument Used</td>
<td>Number of Visits</td>
<td>Number of Measurements per Visit</td>
<td>Diastolic Phase</td>
<td>Home/Clinic</td>
<td>Cut-off Level</td>
<td>Attempt at Standardization</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
<td>------------------</td>
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<td>-----------------</td>
<td>-------------</td>
<td>---------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>20</td>
<td>Hg.</td>
<td>1</td>
<td>3 (average)</td>
<td>V</td>
<td>Home</td>
<td>DBP &gt; 95</td>
<td>Yes</td>
</tr>
<tr>
<td>21</td>
<td></td>
<td>1</td>
<td>1</td>
<td>V</td>
<td>Clinic</td>
<td>160/95</td>
<td>No</td>
</tr>
<tr>
<td>22</td>
<td>Varied</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>Clinic (plaza)</td>
<td>DBP &gt; 95</td>
<td>No</td>
</tr>
<tr>
<td>23</td>
<td></td>
<td>3 (each visit BP must be high)</td>
<td>2 (average)</td>
<td>-</td>
<td>Clinic (work)</td>
<td>160/95</td>
<td>No</td>
</tr>
<tr>
<td>24</td>
<td>Hg.</td>
<td>1</td>
<td>Continued until 2 readings within 2 mm Hg.</td>
<td>V</td>
<td>Home</td>
<td>140/90 or 160/100</td>
<td>No</td>
</tr>
<tr>
<td>25</td>
<td></td>
<td>1</td>
<td>3 (need, 2/3 high before diag)</td>
<td>-</td>
<td>Clinic (plaza)</td>
<td>2/3 &gt; 160/95</td>
<td>No</td>
</tr>
<tr>
<td>26</td>
<td>Aneroid</td>
<td>1</td>
<td>1</td>
<td>V</td>
<td>Home</td>
<td>Age &lt; 55 DBP &gt; 90</td>
<td>Yes/No</td>
</tr>
<tr>
<td>27</td>
<td></td>
<td>1</td>
<td>2 (average)</td>
<td>IV</td>
<td>Clinic</td>
<td>160/95</td>
<td>No</td>
</tr>
<tr>
<td>28</td>
<td>Varied</td>
<td>Varied</td>
<td>Varied</td>
<td>Varied</td>
<td>Clinic</td>
<td>DBP &lt; 90, 91-99, 100-109, &gt;100</td>
<td>No</td>
</tr>
<tr>
<td>29</td>
<td>Hg.</td>
<td>1</td>
<td>3</td>
<td>V</td>
<td>Clinic (plaza)</td>
<td>Age 40-64 160/95</td>
<td>No</td>
</tr>
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</table>
Table 4.3d: SUMMARY OF STUDIES EXAMINING THE QUALITY OF CONTROL OF HYPERTENSION: THE SPECTRUM OF HYPERTENSION CONTROL IN COMMUNITIES

<table>
<thead>
<tr>
<th>Study</th>
<th>Hypertension Criteria</th>
<th>Sample Size</th>
<th>Prevalence</th>
<th>Number of Hypertensives</th>
<th>% Unaware</th>
<th>% Aware/Untreated</th>
<th>% Aware/Treated Uncontrolled</th>
<th>% Aware/Treated Controlled</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>(mean of 3 values) ≥160/95</td>
<td>6672</td>
<td>18.2%</td>
<td>1214</td>
<td>42.8</td>
<td>21.5</td>
<td>19.4</td>
<td>16.3</td>
</tr>
<tr>
<td>(b)</td>
<td>history of treatment for high blood pressure</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>(a)</td>
<td>(mean of 3 values) ≥160/95</td>
<td>3084</td>
<td>20.4%</td>
<td>630</td>
<td>41.0</td>
<td>29.3</td>
<td>15.7</td>
<td>14.0</td>
</tr>
<tr>
<td>(b)</td>
<td>history of treatment for high blood pressure</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Osaka</td>
<td>23.5%</td>
<td>-</td>
<td>-</td>
<td>49.5</td>
<td>37.7</td>
<td>12.8</td>
<td>0*</td>
</tr>
<tr>
<td></td>
<td>Akita</td>
<td>42.0%</td>
<td>-</td>
<td>-</td>
<td>42.1</td>
<td>43.0</td>
<td>14.9</td>
<td>0*</td>
</tr>
<tr>
<td>(a)</td>
<td>≥165/95</td>
<td>2495</td>
<td>16.8%</td>
<td>420</td>
<td>-</td>
<td>64.3</td>
<td>13.1</td>
<td>22.6</td>
</tr>
<tr>
<td>(b)</td>
<td>history of treatment for high blood pressure</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>(a)</td>
<td>DBP ≥100</td>
<td>644</td>
<td>8.5%</td>
<td>55</td>
<td>-</td>
<td>72.7</td>
<td>-</td>
<td>27.3</td>
</tr>
<tr>
<td>(a)</td>
<td>≥160/95</td>
<td>22929</td>
<td>20.2%</td>
<td>4625</td>
<td>58.9</td>
<td>16.5</td>
<td>13.4</td>
<td>11.2</td>
</tr>
<tr>
<td>(b)</td>
<td>history of treatment for high blood pressure</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>(a)</td>
<td>≥160/95</td>
<td>6788</td>
<td>16.5%</td>
<td>1120</td>
<td>-</td>
<td>89.5</td>
<td>6.0</td>
<td>4.5</td>
</tr>
<tr>
<td>(b)</td>
<td>history of treatment for high blood pressure</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>(a)</td>
<td>DBP ≥ cut-off on each of 3 occasions</td>
<td>912</td>
<td>4.2%</td>
<td>38</td>
<td>55</td>
<td>5.3</td>
<td>59.7</td>
<td>0*</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Age</th>
<th>M</th>
<th>F</th>
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<tbody>
<tr>
<td>&lt;40</td>
<td>100</td>
<td>110</td>
</tr>
<tr>
<td>≥40</td>
<td>105</td>
<td>115</td>
</tr>
<tr>
<td>Y Number</td>
<td>Hypertension Criteria</td>
<td>Sample Size</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>(a)</td>
<td>(mean of 3 values)</td>
<td>1000</td>
</tr>
<tr>
<td>(b)</td>
<td>history of treatment</td>
<td></td>
</tr>
<tr>
<td>for high blood pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a)</td>
<td>≥175/115</td>
<td>7455</td>
</tr>
<tr>
<td>(b)</td>
<td>history of treatment</td>
<td></td>
</tr>
<tr>
<td>for high blood pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a)</td>
<td>≥160/95</td>
<td>6012</td>
</tr>
<tr>
<td>(b)</td>
<td>history of treatment</td>
<td></td>
</tr>
<tr>
<td>for high blood pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a)</td>
<td>age ≥39 ≥160/95</td>
<td>6012</td>
</tr>
<tr>
<td>age ≥40 ≥170/100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a)</td>
<td>≥150/90</td>
<td>11309</td>
</tr>
<tr>
<td>(b)</td>
<td>history of treatment</td>
<td></td>
</tr>
<tr>
<td>for high blood pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a)</td>
<td>third DBP ≥95</td>
<td>1738</td>
</tr>
<tr>
<td>(b)</td>
<td>history of treatment</td>
<td></td>
</tr>
<tr>
<td>for high blood pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a)</td>
<td>second DBP ≥110</td>
<td>1515</td>
</tr>
<tr>
<td>(b)</td>
<td>history of treatment</td>
<td></td>
</tr>
<tr>
<td>for high blood pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a)</td>
<td>third DBP ≥100</td>
<td>3001</td>
</tr>
<tr>
<td>(b)</td>
<td>history of treatment</td>
<td></td>
</tr>
<tr>
<td>for high blood pressure (by M.D.'s records)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample Size</td>
<td>Hypertensive Prevalence</td>
<td>Hypertensives</td>
</tr>
<tr>
<td>-------------</td>
<td>-------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>846</td>
<td>49.6%</td>
<td>420</td>
</tr>
<tr>
<td>4235</td>
<td>34.0%</td>
<td>1441</td>
</tr>
<tr>
<td>9591</td>
<td>12.0%</td>
<td>1158</td>
</tr>
<tr>
<td>5286</td>
<td>37.0%</td>
<td>1985</td>
</tr>
<tr>
<td>158906</td>
<td>23.0%</td>
<td>36478</td>
</tr>
<tr>
<td>1544</td>
<td>9.7%</td>
<td>149</td>
</tr>
<tr>
<td>1049225</td>
<td>21.0%</td>
<td>220217</td>
</tr>
<tr>
<td>Per Hypertension Criteria</td>
<td>Sample Size</td>
<td>Prevalence</td>
</tr>
<tr>
<td>---------------------------</td>
<td>-------------</td>
<td>------------</td>
</tr>
<tr>
<td>(a) ≥160/95 mean BP at each of 3 visits</td>
<td>1092</td>
<td>31.9%</td>
</tr>
<tr>
<td>(b) History of treatment for hypertension</td>
<td>1092</td>
<td>13.5%</td>
</tr>
<tr>
<td>(a) ≥140/90</td>
<td>7671</td>
<td>27.1%</td>
</tr>
<tr>
<td>(b) History of treatment for high blood pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Age ≤54 DBP ≥90</td>
<td>12371</td>
<td>21.0%</td>
</tr>
<tr>
<td>(b) Age ≥55 DBP ≥100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) History of treatment for high blood pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Mean of 2 values ≥160/95</td>
<td>(A) 11331</td>
<td>18.8%</td>
</tr>
<tr>
<td>(b) History of treatment for high blood pressure</td>
<td>(B) 724</td>
<td>30.1%</td>
</tr>
<tr>
<td>(a) DBP ≥90</td>
<td>6197</td>
<td>41.5%</td>
</tr>
<tr>
<td>(b) History of treatment for high blood pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) DBP ≥95</td>
<td>18380</td>
<td>16.9%</td>
</tr>
<tr>
<td>(b) History of treatment for high blood pressure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Notes: Information not available. *Denotes that data does not conform well to the categories used and may be misleading.
perfect, is likely to produce some useful information.

The next group consists of seven studies which have utilized some concepts from probability sampling (studies 85, 8, 14, 15, 20, 24, 26). These studies are identified in Table 4.3b by the designation "Yes/No" in the column labelled "Probability Sampling". Six of these studies represent censuses on conveniently selected geographic areas. While the results obtained may be valid within that area, one cannot generalize outside that area with any reliability. Lastly, one study represents a composite sample drawn using different techniques in different geographic areas.

Fodor et al. (38) examined two Newfoundland towns, one located on the coast and the other in the interior. Response rates average 70%. Blood pressure measurement was well standardized, utilizing the London School of Hygiene Sphygmomanometer (31). However, hypertension was diagnosed by one casual blood pressure value. Since this study was primarily directed at a comparison of the prevalence of hypertension in individuals living on the coast compared with those living in the interior, the over-estimate of the prevalence of hypertension did not present a serious problem. This over-estimate does produce difficulties when trying to extrapolate these observations to other areas. In addition, insufficient data were collected to accurately determine the awareness about and control of hypertension in these communities.
Hart (58) reports an interesting study demonstrating that it is feasible for a general practitioner to perform a comprehensive examination of his practice and thereby to improve the degree of hypertension control in a community. Since 99.8% of the identified population were examined, the data are an excellent representation of the target population. The criteria used to determine the hypertension sub-population include consideration of sustained hypertension. An attempt is made to quantitate the bias in blood pressure measurement. The actual blood pressure levels used to demarcate this group are rather high (Table 4.3b). This is reflected by a low prevalence rate for hypertension of 4.2%. Regretably, this interesting study is tarnished by a somewhat confusing presentation of the data which does not allow one to easily identify the relative prevalence of the components of the evaluation model.

Prineas et al. (121) report a census of the population in Albury, Australia who were aged 50-59 years old. The response rate was acceptable at 78%. Blood pressure measurement used a combination of the London School of Hygiene Sphygmomanometer (129) and a regular mercury sphygmomanometer. The individuals measured with each device cannot be distinguished. Only one casual blood pressure was used to detect the hypertensive individuals. The cut-off value for hypertension was high (diastolic blood pressure > 110 mm Hg.). This hypertensive group was supplemented with those individuals who were receiving antihypertensive treatment and had a diastolic blood pressure reading less than 110 mm Hg. It is likely that many hypertensive individuals in this "treated" group had less severe
hypertension than indicated by the diastolic "cut-off" value, thus making the interpretation of these data difficult.

Hawthorne et al. (59) studied the population aged 45 to 64 in a Scottish town. Over 80% of the total population was examined, using the London School of Hygiene Sphygmomanometer (129). A single casual blood pressure reading was used to distinguish the hypertensive population. The information obtained during the survey was supplemented by "linking" each patient to his doctor. This linkage was successful in 85% of the subjects and provided information on treatment, and previously detected hypertension. A total of 394 normotensive subjects (17%) could not be linked. The information used to determine the extent of controlled hypertension was obtained only from this linkage. The analysis used in this paper assumes that all subjects who were not linked to records, were normotensive. However, even if only a small proportion of this non-linked group were controlled hypertensives, the degree of control would be significantly increased (e.g., ten additional controlled hypertensives would increase the measure of control by 20%). Thus caution must be used when interpreting these data.

The Hypertension Detection and Follow-up Program (HDFP) (63, 64) is a multicentre randomized trial designed to investigate the efficacy of antihypertensive therapy in a population based group. In order to identify sufficient hypertensive individuals for inclusion in the study, large scale screening activities were initiated in fourteen communities. The results of the screening activity have been reported separately (64) and form the basis of the
present discussion. Within each centre, the sampling strategy varied. Some centres selected random samples (e.g., Birmingham) while others attempted door-to-door screening. The variability in sample selection makes generalization difficult. Blood pressure measurement was a two-stage procedure. While, entrance into the HDFP trial was based upon demonstrating sustained hypertension measured using a Random Zero sphygmomanometer (196), the prevalence data utilize only the results from the first-stage screen which utilized a single measurement made with a mercury sphygmomanometer. As a result, this study should over-estimate the prevalence of hypertension and of uncontrolled hypertension.

Kotchen et al. (90) report the results of an enumeration of a rural Kentucky community. Blood pressure was measured until two readings agreed to within 2 mm Hg. This procedure is open to bias, since no attempt was made to "blind" or standardize the observer. No return visits were made. Two different cut-off values were used to analyze the data. While this study provides information about how the degree of control varies depending upon the severity of the hypertension, it does not provide generalizable information about the absolute degree of control.

The Charlottesville Blood Pressure Survey is reported by Carey et al. (17). It began as an attempt to survey the entire community of Charlottesville but only 42% of the populace was actually examined. Blood pressure was measured using an aneroid
sphygmomanometer. Measurements were obtained at two visits - the first at home and the second in a clinic. Nearly 30% of those found to be hypertensive at visit #1 did not return for a repeat visit. The measurement procedure employed is reasonable but significant problems exist when an attempt is made to generalize the results.

The remaining eight studies (studies #1, 2, 9, 10, 13, 16, 19, 27) all examined probability samples of a pre-defined target population. Six of these studies (studies #9, 10, 13, 16, 19, 27) were actually interested in extrapolating the observed results to an even larger population than the identified target population. They proceeded by selecting a convenient sub-population of this larger group to serve as a "target" population. Then a probability sample was selected from this "target" population. While this method will provide data which can be generalized to the "target" population, further generalization to the larger population is not possible. The only studies which do not follow the above described format are studies #1 and #2. The first study examines a multi-stage probability sample of the entire American population. The second study is the prelude to a randomized trial into strategies to improve the control of hypertension. Even with this latter study, there was a strong inclination to use the observed data in a more general manner.

Apostolides has presented data obtained from three surveys utilizing similar methodology (4, 5). In 1971, a random sample was selected from within 27 census tracts in Baltimore. These tracts
were chosen because they were near to one of two hospitals and had a nearly 100% Negro population. Two subsequent studies (5), in 1971 and 1973, studied independent random samples from within 13 census tracts in West Baltimore. The response rate in these latter two studies was in excess of 90%. Blood pressure measurement utilized the third of three readings obtained at one visit in the home, using a standard mercury sphygmomanometer. The interviewers are reported to be trained and tested on the measurement of phase V blood pressure. The methodology used in these studies could be improved. However, since all three studies have utilized the same methodology, there is the possibility for comparison without the confounding effect of differing criteria and/or sampling techniques. Caution must still be exercised about extrapolating any observed changes to different populations.

In an early study, Wilber (66) examined a 25% random sample of the population of Baldwin County, Georgia. The response rate was excellent (96.8%). The blood pressure measurement involved averaging three readings taken at one visit. The population is mainly rural with a larger component of non-whites than in the overall 1960 U.S. census. No specific attempt was made to randomly select a town representative of the rural U.S. population but Wilber feels that such representation was actually achieved. This "belief", alone, is not sufficient to allow reliable generalization of the observed results.

Harburg et al (56) divided the census tracts in Detroit into four strata – high/low stress, Black/White. They then selected one representative census tract from each strata and examined a random sample of the populace within each selected census tract.
Blood pressure was measured as the mean of three values. The intent of the original study was to investigate the effect of chronic stress on hypertension. Foote et al. (39) report a secondary analysis of these data, not included in the original paper. In this secondary analysis, the prevalence of various categories of hypertension control was obtained. In view of the selected composition of the sample, it is doubtful that these data will represent the true state of hypertension control, either in Detroit or any other "target" population of interest.

Berglund et al. (10) studied a one-third sample of Swedish men aged 47 to 54 years and living in the City of Goteborg, Sweden. This target population was selected for convenience as it was the investigators' home city and would facilitate the continuation of this project as a multiple risk factor intervention program. The response rate of 75% was low but acceptable. Blood pressure was measured once at one clinic visit in the afternoon. No repeat measurements or visits were performed. While this mode of measurement presents many problems, once unexplained finding is the high prevalence of severe hypertension found in this population (16% of the community either had blood pressure >175/115 mm Hg or were on treatment). Berglund et al. attempt to explain this finding by suggesting that blood pressure measured in the afternoon is significantly higher than that measured in the morning. This suggestion is based primarily on a comparison of the afternoon blood pressure with a re-measured blood pressure taken in the morning, two weeks after the initial measurement (190). The mean blood pressure
for the group dropped by 15/14 mm Hg. However, since it is well known that repeat blood pressure measurements tend to be lower than the initial values (7, 116, 118, 125), it is inappropriate to attribute the observed drop simply to having measured the blood pressure in the morning rather than the afternoon. This opinion is supported further by the results of Thulin et al. (77) who found no evidence for a significant rise in afternoon blood pressure. A more likely hypothesis is that the community physicians in Goteborg are treating hypertension of less severity than chosen by this study. This would then inflate the size of the group used to calculate the prevalence of hypertension. Hence, the prevalence figure obtained need not relate in any predictable manner to the actual prevalence of severe hypertension. For the above reasons, the data presented by this study have questionable usefulness.

Shapiro et al. (144) examined a sample composed partly of volunteers and partly of a random sample of dwellings selected from four Montreal census tracts. The data is presented in such a way that each sub-sample can be analyzed separately. The response rate in the random sample was low (68%). The final blood pressure measurement was determined as the mean of two values obtained at one visit. Diastolic blood pressure was recorded as phase IV. No specific attempt was made to ensure standardization of the measurement techniques. Despite the problems with measurement, this study is the most methodologically sound of the five Canadian-based studies.

The last study to be examined was actually the first of the studies to be executed. It formed a part of the 1960-62 National Health Survey conducted by the U.S. Department of Health, Education and Welfare (66, 170). The sample selection was complex but well-designed
with a good response rate (86%). Unfortunately, the blood pressure measurement techniques did not satisfy the standards advanced earlier in this section. The mean of three values obtained at one visit was used to diagnose clinical hypertension. There were no specific quality control measures. Despite these problems, this study represents the only example to date, of a study which has used proper sampling techniques to obtain a representative assessment of hypertensive control in a diffuse area. It is also the only study to present estimates of the precision of the prevalences obtained from the sample.

4.6.3 Summary of the Most Useful Published Data

It can be seen that none of the published studies satisfy all of the methodologic standards presented at the start of this section. In fact, only two studies (#8 and #23) measured blood pressure at more than one visit. Both of these studies suffer from other problems which impair interpretation of the observed results. Despite this generally negative assessment, several studies demonstrated sufficiently "sound" methodology that the results are likely to provide an indication of the degree of hypertension control. These data are summarized in Table 4.4.

The prevalence of hypertension varied from 14.6% to 49.6%. The lowest value was obtained by Alderman. This finding was to be expected since the population under study in his sample was healthy enough to work at a regular job. The high prevalences found by Apostolides are interesting and require further comment. His population was 100% Negro and of ages 30-69 years living in the inner city of Baltimore. The area was generally of poor social class but was more...
### Table 4.4: SUMMARY OF METHODOLOGICALLY ACCEPTABLE STUDIES

<table>
<thead>
<tr>
<th>Study Number</th>
<th>Principal Author</th>
<th>Time Period</th>
<th>Cut-Off</th>
<th>Prevalence of Hypertension</th>
<th>% Unaware</th>
<th>% Aware/Untreated</th>
<th>% Aware/Treated/Uncontrolled</th>
<th>% Aware/Treated/Controlled</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>National Health Survey</td>
<td>1960-2</td>
<td>160/95</td>
<td>18.2%</td>
<td>42.8</td>
<td>21.5</td>
<td>19.4</td>
<td>16.3</td>
</tr>
<tr>
<td></td>
<td>Wilber</td>
<td>1962</td>
<td>160/95</td>
<td>20.4%</td>
<td>41.0</td>
<td>29.3</td>
<td>15.7</td>
<td>14.0</td>
</tr>
<tr>
<td></td>
<td>Apostolides</td>
<td>1971</td>
<td>DBP&gt;95</td>
<td>36.8%</td>
<td>32.1</td>
<td>25.0</td>
<td>25.3</td>
<td>17.6</td>
</tr>
<tr>
<td></td>
<td>Apostolides</td>
<td>1971</td>
<td>DBP&gt;95</td>
<td>49.6%</td>
<td>29.8</td>
<td>31.2</td>
<td>26.2</td>
<td>12.9</td>
</tr>
<tr>
<td></td>
<td>Apostolides</td>
<td>1973</td>
<td>DBP&gt;95</td>
<td>37.6%</td>
<td>22.4</td>
<td>20.6</td>
<td>18.7</td>
<td>38.7</td>
</tr>
<tr>
<td></td>
<td>Alderman</td>
<td>1973-5</td>
<td>160/95</td>
<td>16.8%</td>
<td>14.6</td>
<td>19.1</td>
<td>33.8</td>
<td>32.4</td>
</tr>
<tr>
<td></td>
<td>Shapiro</td>
<td>1975</td>
<td>160/95</td>
<td>30.1%</td>
<td>41.3</td>
<td>39.0</td>
<td></td>
<td>19.7</td>
</tr>
</tbody>
</table>
social level. It is known that Negros have a higher rate of hypertension and hypertensive heart disease (66). In addition, Apostolides et al. (4) suggest that the area in question has suffered from a selective migration whereby the most able, healthy and young subjects have moved away, leaving a less healthy populace. This migration would tend to further inflate the prevalence of hypertension.

The four studies performed before 1971 reveal a remarkably similar pattern. About one-third of the populace was unaware that they were hypertensive and an alarmingly high 85 per cent were not being effectively treated. The remaining studies suggest that the situation has improved somewhat since 1971, although there is still more than 60 per cent of the population that is not receiving effective treatment. The one Canadian study included in Table 4.4 (Shapiro) suggests that community hypertension control may be less effective in Canada than in the United States. This conclusion must be tempered by a realization of the potential for bias in this study. Of additional importance when considering the relevance of these data to Canada, is the observation that the studies of Wilber and Apostolides were made on predominantly Negro populations.

One can obtain a better assessment of the change in the degree of community hypertension control by restricting attention to the three studies of Apostolides. These studies utilized the same design and the last two, even utilized the same sampling frame. From these studies, there is evidence of definite improvement in the control of hypertension. It would appear that most of this change
has resulted from more effective treatment of identified hypertensives. It would be tempting to ascribe this change to physician or patient education programs (e.g., the U.S. Department of Health, Education and Welfare, National Blood Pressure Education Program [171, 172]), but such an attribution is not warranted by present evidence.

More detailed analysis of the data from many studies suggest that the following groups are less likely to be aware that they have hypertension and are less likely to be under control: males (2, 5, 64, 90, 142, 156); the young (5, 156). There is no evidence that Negros are more or less likely to be under adequate treatment (2, 64, 142, 156). Similarly, social or economic class do not seem to be of major significance (34).

In conclusion, a methodologic review of twenty-nine published studies reveals the need for a well-designed survey to adequately document the degree of community hypertension control. This need is especially true in Canada where no completely acceptable evidence is available. The best available information suggests that the degree of control has recently been improving but that over 60 per cent of the hypertensive population is still receiving inadequate treatment.

4.7 Alternate Strategies

The preceding sections of this chapter have concentrated on providing the framework which could be used to support a special purpose survey to assess the degree of hypertension control in a community. However, special purpose surveys are relatively expensive and time-consuming. It is relevant to examine whether
the necessary information could be collected via an alternative method.

The Laboratory Centre for Disease Control in Ottawa recently conducted a conference to discuss and review programs related to cardiovascular disease in Canada. A workshop at this conference considered strategies which could be used to evaluate the degree of hypertension control (195). This discussion will form the basis of the present section.

The workshop identified four strategies which could be used to estimate the degree of community control of hypertension:

1. Data collected by the Canada Health Survey.
2. Routinely collected statistics.
3. Special studies of individual care practices.
4. Special purpose surveys.

Each of these strategies was then evaluated against the process model described in section 4.3. The results of this evaluation are summarized in Table 4.5.

The Canada Health Survey is a large-scale project designed to assess the social, physical and mental health of Canadians. It is similar in design and concept to the U.S. National Health Survey and will use complex probability sampling to select a nationally representative sample of 40,000 people (70). This data will be used to provide national and provincial-wide estimates, but estimates for smaller divisions will not be possible (71). Blood pressure will be measured by obtaining one measurement. Other data will be obtained by physical examination and questionnaires. This survey could provide estimates of:
Table 4.5: EVALUATION OF PROPOSED STRATEGIES TO EVALUATE THE DEGREE OF COMMUNITY CONTROL OF HYPERTENSION

<table>
<thead>
<tr>
<th>STAGES OF PROCESS MODEL</th>
<th>(1) CANADA HEALTH SURVEY</th>
<th>(2) ROUTINE STATISTICS</th>
<th>(3) STUDIES OF INDIVIDUAL PRACTICES</th>
<th>(4) REPEATED POPULATION SAMPLE SURVEY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detection</td>
<td>Partially</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Linkage</td>
<td>Partially</td>
<td></td>
<td></td>
<td>Partially</td>
</tr>
<tr>
<td>Clinical Evaluation</td>
<td></td>
<td>Partially</td>
<td>Yes</td>
<td>Partially</td>
</tr>
<tr>
<td>Treatment</td>
<td>Partially</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Compliance</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Life Long Follow-up</td>
<td>Partially</td>
<td>Partially</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Decrease in Mortality/ Morbidity</td>
<td>Partially</td>
<td>Yes</td>
<td>Partially</td>
<td></td>
</tr>
<tr>
<td>Changes in Health and Social Costs</td>
<td>Partially</td>
<td>Partially</td>
<td>Partially</td>
<td></td>
</tr>
</tbody>
</table>
(1) The distribution of blood pressure. This could be used to provide an overestimate of the prevalence of clinically significant hypertension.

(2) The prevalence of "labelled" hypertension. Question 49 of the Family Interview Questionnaire (122) asks: "Does anyone in your family presently have high blood pressure?" The use of the restriction "presently" should result in some misclassification. Of more importance, is the fact that surrogate-reporting will be allowed.

(3) The prevalence of treated hypertension. Question 19C of the Family Interview Questionnaire (122) asks: "Yesterday, or the day before, did you or anyone in the family take or use medicine for the heart or blood pressure?" Again, surrogate reporting is allowed. The time restriction attached to this question should produce some misclassification. Lastly, it will be difficult to distinguish drugs used for hypertension from those used for heart disease. Some attempt to clarify this will be made in subsequent questions (#20 through #22 of the same questionnaire). Success in achieving this distinction remains to be shown.

(4) The frequency with which recent medical contacts included a blood pressure measurement (see questions #65-76 of the Family Health Interview Questionnaire (122)).
(5) A general indication of the health status of the hypertensive population.

The above summaries reveal that the measurement procedures are not sufficient to provide a comprehensive and methodologically acceptable summary of the process model. Some of the difficulties could be resolved by introducing special-purpose questions into the survey. Other difficulties, such as the need to obtain re-visit blood pressure measurements, would require redesign of the study and could not be easily implemented. In summary, the Canada Health Survey will provide some useful evaluative data but will not provide the data needed for an exhaustive and unbiased evaluation of hypertension control in the community.

Routinely collected statistics could include: Medicare data, hospital separation data, prescription use, and mortality data. The former three categories are of variable quality and only available on persons who have already entered the health care system. Mortality data can provide a useful overall indicator of the effectiveness of hypertension control. However, the lag between effective control and decreased mortality, the present temporal trend towards decreased mortality (4, 94) and variation in interpreting ICD codes, all decrease the utility of this approach.

It would be possible to select a number of physician practices which could then be studied in depth. This type of study could provide much useful information relating to the individual physician-patient relationship. However, the observations would be practice-specific and could not be easily generalized. In addition, information
would be available only for individuals who were already in the health care system.

The above discussions demonstrate that only population-based surveys can collect methodologically sound data which can be used to evaluate the quality of hypertension control in the community. Alternate forms of data collection, as presented above, can act as useful supplements to such surveys. The remainder of this thesis will present a "portable" survey design which can be used to measure the concepts presented in this chapter.

4.8 Summary

This chapter has presented a discussion of techniques which could be used to evaluate the quality of hypertension control in the community. A process-based model is described and a possible strategy to measure the data needed for this model is developed. The chapter concludes with a discussion of past and future attempts to evaluate hypertension control. This discussion justifies the need for a special-purpose population-based survey.
5. IMPLEMENTATION OF THE GENERAL PROTOCOL FOR EVALUATION OF THE QUALITY OF HYPERTENSION CONTROL IN THE PROVINCE OF ONTARIO

5.1 Introduction

The discussion of the Chapter 4, led to the formation of a general protocol which can be used to evaluate the quality of hypertension control within a community. Subsequent examination of this protocol, identified two major methodological issues of importance to any practical implementation of this protocol. These two issues – the selection of a representative sample and an appropriate method of identifying the hypertensive population – have already been discussed in Chapters 3 and 2, respectively. The present chapter will synthesize the above mentioned discussions to provide a specific research design which can evaluate the quality of hypertension control within the Province of Ontario.

The chapter is structured into three major divisions. It begins with a consideration of the sampling component of the evaluation procedure. In particular, the target population is defined and a sampling strategy is developed. The second division describes the measurement techniques which will be employed. Measuring and controlling observer variation will receive special attention. The third division discusses the various miscellaneous aspects of the design. First, the problems involved with assessing change in the quality of hypertension control are discussed. This is followed by a discussion of the
changes that would be necessary in order to implement recommendations of the Ontario Council of Health Task Force on Hypertension (126).

The chapter concludes with a consideration of various techniques which would be used in the analysis of the data collected by this survey.

5.2 Overview of the Design

The quality of hypertension control in the community is assessed using a descriptive survey. The target population is the non-institutionalized adult population of Ontario, excluding the remote North. A sample selection procedure is developed which utilizes a complex multi-stage selection procedure. This permits statistically valid estimates of population parameters and the associated variances to be calculated. The Province of Ontario is stratified into eight regions. Within each strata, a random process is used to select from one to four primary units. Using data from the 1976 census, a random sample of enumeration areas is selected from within each primary sampling unit. Finally within each enumeration area, ten households are selected for detailed examination.

Measurement data will be collected during one to three visits at weekly intervals, the number determined by the measured blood pressure values. Information to be collected will relate to the blood pressure level, to treatment status, to socio-demographic parameters and to attitudes towards and knowledge about high blood pressure and health care. These data will be obtained by a combination of questionnaires and physical examination. The interviews will be performed by specially-trained nurses.
The primary analysis will be performed in two ways. Firstly, standard formulae will be used to estimate the proportion of individuals who are in various categories of diagnosis, treatment and control. Secondly, more sophisticated techniques will be used to correct these estimates for socio-demographic co-variates. Secondary analysis will be performed to search for possible determinants of the quality of care provided by the community for the control of hypertension.

An essential component of this study will be the assessment of any change in the quality of hypertension control. For this purpose, it is intended to repeat the study on a regular basis by selecting independent samples from within the enumeration areas selected for the initial survey.

5.3 Research Questions

The primary thrust of the present investigation is to determine the quality of health care being provided for hypertension. Repetition of this evaluation will permit assessment of any overall change in the quality of health care delivery, occurring either as a result of interventions programs, or as an independent shift over a period of time.

In Chapter 4, a protocol was developed which provides a framework which can be used to evaluate the quality of hypertension control in a community. The protocol is based on a model involving several aspects of the process of care delivery to a group of patients with hypertension (Figure 4.1). The protocol implements this
theoretical model by relating several measurable variables to the stages in the process model (Table 4.1). These variables involve determination of the awareness and treatment status for each hypertensive individual in a representative sample from the community of interest.

Based on the preceding theory, the basic research question can now be formulated as: **Within the Province of Ontario, what is the overall quality of care provided by the health care system for the control of hypertension?** This question will be answered by obtaining the information shown in Table 4.1.

In addition to this primary research question, four secondary questions are of interest:

(1) Is the quality of hypertension control improving or worsening?

(2) Is there evidence of regional differences in the quality of hypertension control?

(3) If such regional differences are detected, can any attributes be found which help explain the observed variation?

(4) Does the concept of "health locus of control" (180) have any predictive value for the likelihood that an individual will be receiving successful anti-hypertensive therapy?
5.4 **Target Population**

The target population will consist of non-institutionalized adults over the age of 18 who reside within the provincial boundaries of Ontario but excluding those persons living in the rural areas of the extreme north of the Province. Specifically, all residents of the counties of Kenora, Thunder Bay and Cochrane will be excluded except those living in the following towns: Kenora, Thunder Bay, Timmins, and Kapuskasing. Data from the 1976 census (159) indicates that approximately 1.5% of the total population of Ontario lives in the rural North. Practical difficulties in selecting and surveying such a scattered population make it necessary to exclude them from the survey. Data used by the Canada Health Survey (20) permit one to estimate that a further 1.5% of the population of Ontario is institutionalized. The Canada Health Survey excluded old age homes but this study will not do so. Thus, it can be estimated that approximately 3% of the population will be excluded by the above criteria. The remaining population of approximately 8,016,531 will form the target population (Table 5.1).

**Table 5.1: STUDY POPULATION WITH EXCLUSIONS**

<table>
<thead>
<tr>
<th>Description</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survey Population Base</td>
<td>8,016,531</td>
</tr>
<tr>
<td>Institutionalized Population (est.)</td>
<td>123,967</td>
</tr>
<tr>
<td>Northern Exclusions (based on 1976 census)</td>
<td>123,967</td>
</tr>
<tr>
<td>Ontario Population (based on 1976 census)</td>
<td>8,264,465</td>
</tr>
</tbody>
</table>

Source: (ref. 159).
5.5 Sampling Procedures

5.5.1 General Discussion

Once the target population has been identified, it is necessary to describe the procedure by which a representative sample will be selected for examination. It would be desirable to obtain a sample which is distributed diffusely across the Province. Such a sample would enable subsequent analysis to combine various sub-groups in the sample, thus enhancing the possibility of regional analysis. A diffuse sample would, however, be very expensive to examine. There would be a substantial amount of travel involved and there would be problems in developing a revisit procedure for non-responding households.

An alternative procedure would be to stratify the Province into a number of geographic units. These would be selected in such a manner that areas within one strata were relatively homogeneous with respect to health care delivery. Since there is no readily available description of the pattern of health care delivery across the Province of Ontario, homogeneity cannot be directly ensured. An alternative approach would involve the identification of factors which determine the manner in which health services are utilized. These variables could be used to provide a stratification scheme which would yield relatively homogeneous strata. These variables would need to be readily available from published statistics.

After a stratification scheme has been decided on, consideration must be given to the method of selection for the group of subjects to be visited. The techniques in Chapter 3 will be utilized to develop
a three-stage cluster sampling procedure. The units employed by this sampling procedure will be derived from the 1976 census. The census partitions each province into a variety of geographical units. The largest partition consists of units called census divisions. This is a general term applying to counties, regional districts, regional municipalities, etc. (158). The census divisions are further partitioned into a variable number of census sub-divisions which correspond to municipalities, Indian Reserves, unorganized territories and other similar sub-divisions (158). The smallest divisions, which form the basic building block for all larger divisions, are the Enumeration Areas (also abbreviated, E.A.). The formal definition of an enumeration area is: "The spatial unit canvassed by one census representative. It is defined according to the following criteria:

(1) Population - An enumeration area may include as many as 375 households, depending on its location.

(2) Number of Farms - An enumeration area always includes fewer than 100 farms.

(3) Limits - An enumeration area, being the building-block of all geostatistical areas, never cuts across any area recognized by the census. Moreover, enumeration area boundaries are such that the census representatives will be able to locate them without difficulty as, for example, streets, roads, railways, rivers and lakes." (158)

The census department has available for distribution, information necessary to locate all E.A.'s. This can be provided as
maps, printed information or a computer tape. This last medium provides sufficient information to locate the E.A.'s and to combine them into city, town and county units. It also supplies some basic socio-demographic information (157). For the 1976 census, Canada was divided into approximately 35,000 E.A.'s which yields a mean population density of 625 people per E.A. Approximately 13,000 E.A.'s were located within the provincial boundaries of Ontario (157). These are combined to produce 53 census divisions (Map I).

5.5.2 Stratification Procedures

Examination of the distribution of health care facilities and personnel (i.e., structural variables) reveals a highly heterogeneous distribution. In order to ensure adequate representation from the various regions of the Province, a geographic stratification procedure will be employed. This will also lead to a decrease in the variance of provincial estimates. The stratification further makes it possible to examine regional differences in the quality of hypertension control.

A secondary benefit of geographic stratification is that it optimizes the use of the interviewers. An interviewer can be assigned to work within one geographic locale thus facilitating re-visits to non-respondents. It will also be possible to develop an interview schedule in which the return visits to one group overlap with the initial visits to a second group.
The variables, which will form the basis for the stratification, should be selected because they have been shown to be related to health care delivery. However, the determinants of health usage are not well established. A large scale international study was recently coordinated by the World Health Organization (86). It found that the major determinant of health utilization was a patient's assessment of disease severity. Correlations with structural variables were generally weak. The rate of physician usage was positively correlated with population size, the general practitioner:specialist ratio, and the patient:specialist ratio. Use of prescription drugs was positively correlated with the patient:total physician ratio and with the patient:specialist ratio and negatively correlated with the general practitioner:specialist ratio. Vayda et al. (74, 175) also support the relationship between the patient:physician ratio and the pattern of health care.

The basis for stratification will be provided by a composite index formed from three geo-social variables. These are:

(1) northern location versus southern location
(2) urban area versus rural area
(3) proximity to a health sciences centre.

The allocation of areas to particular strata will be arbitrary but rational. The relevance of the above listed criteria is suggested by an examination of physician distribution in the areas corresponding to each of the dichotomies created from these variables (Table 5.2). There is substantial variation in the four ratios which recorded viz:
Table 5.2: PHYSICIAN: PATIENT RATIOS IN REGIONS OF ONTARIO

<table>
<thead>
<tr>
<th>AREA</th>
<th>GENERAL PRACTITIONERS</th>
<th>SPECIALISTS</th>
<th>TOTAL</th>
<th># OF GENERAL PRACTITIONERS # OF SPECIALISTS</th>
<th>POPULATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>N. Ontario</td>
<td>582 (1:1404)</td>
<td>299 (1:2733)</td>
<td>881 (1:928)</td>
<td>1.95</td>
<td>817,141</td>
</tr>
<tr>
<td>S. Ontario</td>
<td>7377 (1:986)</td>
<td>5577 (1:1317)</td>
<td>12954 (1:567)</td>
<td>1.32</td>
<td>7,347,324</td>
</tr>
<tr>
<td>Rural</td>
<td>1411 (1:1319)</td>
<td>502 (1:3706)</td>
<td>1913 (1:973)</td>
<td>2.81</td>
<td>1,860,477</td>
</tr>
<tr>
<td>Urban</td>
<td>6548 (1:963)</td>
<td>5374 (1:1173)</td>
<td>11922 (1:529)</td>
<td>1.22</td>
<td>6,303,988</td>
</tr>
<tr>
<td>No Health Science Ctr.</td>
<td>2759 (1:1341)</td>
<td>1432 (1:2583)</td>
<td>4291 (1:862)</td>
<td>1.93</td>
<td>3,699,549</td>
</tr>
<tr>
<td>Health Science Centre</td>
<td>5200 (1:859)</td>
<td>4444 (1:1005)</td>
<td>9644 (1:463)</td>
<td>1.17</td>
<td>4,464,916</td>
</tr>
</tbody>
</table>

North: Algoma, Cochrane, Kenora, Manitoulin, Nippising, Parry Sound, Rainy River, Sudbury (Reg. Mun.), Sudbury (Terr. Dist.), Thunder Bay, Timiskaming


Health Science Centre: Brant, Elgin, Fronenac, Halton, Hamilton-Wentworth, Middlesex, Ottawa-Carleton, Oxford, Toronto (Metro.), Waterloo, Wellington, York

1 Based on Ontario Statistics 1976, Volume 1, Social Series, p. 148. (113)
general practitioner:patient; specialist:patient; physician:patient; general practitioner:specialist. Material presented earlier suggests that variation in these ratios will be associated with differences in health care delivery. Hence these three variables can be considered a reasonable basis for the stratification procedure.

These variables will be combined into a composite index which will produce eight distinct strata. For the purpose of stratification, each census division will be divided into three parts:

1. those parts of census sub-divisions which are municipalities with a population greater than 100,000
2. those parts of census sub-divisions which are municipalities with a population between 10,000 and 100,000
3. the remainder of the census division.

This remainder will be classified as rural or urban based on the character of the urban population centres within the census division. Table 5.3 lists all census divisions and sub-divisions which will be employed in the stratification. The detailed stratification can be found in Table 5.4.
<table>
<thead>
<tr>
<th>DISTRICT</th>
<th>CITY (&gt;100,000)</th>
<th>CITY (10,000-100,000)</th>
<th>TYPE</th>
<th>POPULATION</th>
<th>% POPULATION</th>
<th>CLASSIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algoma</td>
<td>Sault Ste. Marie</td>
<td>81,048</td>
<td>III</td>
<td>122,883</td>
<td>66</td>
<td>R</td>
</tr>
<tr>
<td>Brant</td>
<td>Brantford</td>
<td>66,950</td>
<td>I</td>
<td>99,099</td>
<td>68</td>
<td>U</td>
</tr>
<tr>
<td>Bruce</td>
<td></td>
<td></td>
<td>II</td>
<td>57,472</td>
<td>0</td>
<td>R</td>
</tr>
<tr>
<td>Cochrane</td>
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Table 5.3: Census Divisions and Sub-Divisions of the Province of Ontario Based on 1976 Census (159)
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Classification Codes:

1 Near Health Science Centre and Southern Ontario
2 Not Near Health Science Centre and Southern Ontario
3 Not Near Health Science Centre and Northern Ontario
R Rural
U Urban
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<th>STRATUM CHARACTER</th>
<th>MEMBERSHIP</th>
<th>POPULATION</th>
<th>TOTAL STRATA POPULATION</th>
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<td>196,526</td>
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5.5.3 Sampling Frame and Selection Procedure

The term, sampling frame, refers to the lists of units from which a sample is to be selected. Often, it is neither possible nor necessary to provide an actual printed list. Instead, as was discussed in Chapter 3, a staged sample could be selected. Using this approach, the sample would be selected in two or more stages. The early stages would use geographical or similar data to select clusters of individuals. Only these smaller clusters would then need to be enumerated. In view of the variety of possible sampling strategies, several different procedures were considered for this survey. These procedures are summarized in Table 5.5.

The first decision which must be made is to specify the final sampling unit. In the present survey, there are two choices — individual persons or households. In the latter case, all adult members of the household would be examined. The major difficulty with using individuals as the final sampling unit involves obtaining an appropriate sampling frame. The simplest sampling procedure would work from a complete census of each strata and select a simple random sample from this list. While the 1976 government census might represent a listing of all such individuals, consideration of confidentiality renders it unavailable for the purpose of sample selection. This list would also become rapidly outdated. Since there are no updated and exhaustive lists of individuals in the Province available for routine use, it would be necessary to generate such a list in the course of the sampling procedure. It is clearly be too expensive to enumerate the entire Province.

The only alternative would involve using a multi-stage sampling
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<th>PROCEDURE</th>
<th>ADVANTAGES</th>
<th>DISADVANTAGES</th>
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<td>Individual</td>
<td>obtain a list of all people in Ontario and then select a simple random sample</td>
<td>statistical manipulations are easier and better understood</td>
<td>no such list exists and would be too expensive to create (cannot use official census data due to confidentiality)</td>
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<tr>
<td>Individual</td>
<td>multistage sample (1) area sample to obtain a cluster of individuals (2) enumerate the cluster and then select people to be surveyed from this enumeration</td>
<td>avoids needing to consider inter-family correlations of blood pressure</td>
<td>costly in time and money to get required census</td>
</tr>
<tr>
<td>Individual</td>
<td>with any of the following strategies, only one member of the selected household need be examined</td>
<td>avoids needing to consider inter-family correlations of blood pressure</td>
<td>problems of acceptance in family when not all members are examined</td>
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<tr>
<td>Household</td>
<td>obtain a list of all households in Ontario, sample this list and examine all adults in these households</td>
<td>statistics are easier than for cluster sampling</td>
<td>list of households hard to obtain and standard lists are likely to be dated</td>
</tr>
<tr>
<td>Household</td>
<td>select random longitude and latitude measurements and examine the household at this location</td>
<td>easy to implement</td>
<td>hard to locate houses</td>
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<td></td>
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<td>many locations will not be houses</td>
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### Table 5.5: Continued....

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<th>PROCEDURE</th>
<th>ADVANTAGES</th>
<th>DISADVANTAGES</th>
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</thead>
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<td>- multistage sample</td>
<td>- readily adaptable to other areas</td>
<td>- quality of postal code assignments unknown</td>
</tr>
<tr>
<td></td>
<td>(1) using the postal code directory, select a sample of random locations</td>
<td>- postal code directory easily available and frequently updated</td>
<td>- cannot determine which codes correspond to non-residential areas</td>
</tr>
<tr>
<td></td>
<td>(2) enumerate each location for dwellings and use this list to select the households to be examined</td>
<td></td>
<td>- unable to correlate socio-demographic information with postal code</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- area corresponding to separate codes is too small</td>
</tr>
<tr>
<td></td>
<td>- multistage sample</td>
<td>- there is a possibility that city directories could be used to avoid the enumeration of the selected blocks</td>
<td>- requires extensive cooperation from government</td>
</tr>
<tr>
<td></td>
<td>(1) select geographic areas to represent the Province</td>
<td></td>
<td>- maps may not be updated at regular intervals</td>
</tr>
<tr>
<td></td>
<td>(2) use local governments to obtain detail maps and then select blocks for enumeration</td>
<td></td>
<td>- quality of data in rural areas is unknown</td>
</tr>
<tr>
<td></td>
<td>(3) use these enumeration lists to obtain households for examination</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- multistage sample</td>
<td>- computer tapes of E.A.'s readily available</td>
<td>- multi-stage sampling &quot;inflates&quot; the variance of population estimates</td>
</tr>
<tr>
<td></td>
<td>(1) select a small number (1-6) of census subdivisions to represent each strata (primary sampling units (PSU))</td>
<td>- sociodemographic information readily available</td>
<td>- there is some disagreement about the optimal statistical analysis of multi-stage samples (129)</td>
</tr>
<tr>
<td></td>
<td>(2) within each PSU select a number of E.A.'s as the next stage</td>
<td>- E.A.'s are of reasonable size to enumerate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(3) enumerate each E.A. for households</td>
<td>- E.A.'s preserve existing political boundaries</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(4) use this to select a sample of households</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
procedure. The first stage would select geographically limited areas which would then be enumerated. These enumeration lists would then be used to select those individuals to be included in the study. Although far less costly than obtaining a provincial census, the cost to enumerate an area for individuals, both in time and money, would be significant. For this reason, the above approach does not appear useful.

A modification to the above procedure could lead to a cost-reduction. In the modified procedure, the enumerators would enumerate households rather than individuals. A number of households would then be selected for inclusion in the sample. Within each household, one member would then be randomly selected for detailed examination. There are two major problems with this technique. The least significant is that by restricting the examination to only one member of a family, resentment might be provoked in the other members. More significantly, the non-examination of the other household members would increase the travel necessary to obtain the complete sample. From these considerations, it can be seen that the best final sampling unit would be households.

The most direct sampling procedure using the household unit would again utilize simple random sampling. The difficulties in obtaining a useful provincial enumeration of households are significant. It is doubtful that this approach would be feasible. An alternative, but still conceptually simple approach, would make use of the latitude-longitude grid. Random locations would be selected within the Ontario boundaries by generating a series of
latitude and longitude measurements. This technique has the advantages of simple random sampling but obviates the need for a complete enumeration. Although attractive, this approach presents two major problems. Firstly, many locations selected at random would be located in lakes, forest, or similar non-residential areas. Even more importantly, it would be extremely difficult and costly to locate the households specified by the random measurements.

A multi-stage sampling procedure could be based on any of several possible population partitions. Here, attention is concentrated on three specific partitions. All of the procedures employ a common first stage; namely, the selection of between 1 and 6 of the sub-divisions within each strata. These become the primary sampling units (hereafter: PSU). One possible second stage sampling procedure would be based on the postal code directory. Postal codes are assigned to all geographic areas in Canada. Within urban areas, the codes are allocated to contiguous and small segments of housing (e.g., part of one side of a block, or an apartment building) while in rural areas, one code is assigned to each forward sortation area (106). The major advantages of the postal codes are the easy availability of the information and the adaptability of the procedure to areas other than the entire Province of Ontario. It is also not affected by migration. However, there are some major problems. The size of area corresponding to one postal code is determined by the volume of mail delivered rather than by population density. There is also no method to distinguish residential from industrial areas. Similarly, no socio-demographic information is correlated
with postal codes. There is no reverse index of codes and, finally, the unit size is quite small. Statistics Canada is investigating the feasibility of improving the applicability of the code to sampling (106) but at the present it should not be used for this purpose.

A second approach uses city and township directories as a basis to select the blocks which would be enumerated. Then a sub-sample of households would be selected from each block. There are two major problems with the procedure. Firstly, it requires significant cooperation with many governmental agencies in distinct political areas. This could be difficult to arrange. Secondly, the quality of data contained in the directories is largely unknown, especially in rural areas.

The last approach which is listed in Table 5.5 is that which will be adopted in this survey. Within each PSU, a number of enumeration areas or clusters are selected. Each cluster will be enumerated to provide a list of households. Then a simple random sample of households will be selected from this list. This procedure is very similar to that employed by the Canada Health Survey (20, 21). For this survey, a standard procedure was developed to enumerate a cluster (see Appendix 3). This procedure will be adapted by the present study. A similar enumeration procedure was developed by CDC-Atlanta to assist Public Health Departments to evaluate the state of immunization (143). In application, it was found that a nurse could enumerate and interview approximately
35 households in a single day. Further, the Canada Labor Force Survey, using a similar sampling procedure, estimates that a single observer can completely enumerate between 40 and 50 homes in less than two hours (103). It is unlikely that the present enumeration will impose an unreasonable workload on the interviewers.

The selection of the PSU's and the E.A.'s will employ sampling with replacement and with probability proportional to size. As was developed in Chapter 3, this technique will simplify the estimation procedure by making it self-weighting. Each PSU and E.A. has available a population derived from the 1976 census. This will be expressed as a proportion of the total population of the strata and the PSU respectively. These proportions will be used as the probability of selection into the sample. A computer program will be developed to select the sample members based on these probabilities.

The number of PSU's which will be selected from within each strata has been arbitrarily selected (Table 5.6). An attempt was made to ensure maximum geographic closeness of the sample clusters within a PSU without obtaining too large a proportion of the sample from one or two small E.A.'s. Consideration of the details involved with subsequent stages of selection will be deferred to section 5.6.
5.5.4 Summary

The Province is stratified into eight strata. Within each strata, a variable number of primary sampling units are selected with probability proportional to size. Using data provided by Statistics Canada, enumeration areas will be selected with probability proportional to size to provide secondary sampling units. Finally, a detailed census of each enumeration area will be used to select the households which will enter the sample. The last stage selection will be a simple random sample of households in the census of the E.A.

Table 5.6: NUMBER OF PRIMARY SAMPLING UNITS (PSU) TO BE SELECTED FOR EACH STRATUM

<table>
<thead>
<tr>
<th>STRATUM</th>
<th>NUMBER OF PSU's</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>8</td>
<td>3</td>
</tr>
</tbody>
</table>
5.6 Sample Size Considerations

5.6.1 General

The preceding section identified the major structural aspects of the sampling procedure. It still remains to determine the sample size which will be employed. In a complex sampling procedure such as this, there are three aspects of sample size to be considered. A decision must be made about the number of examinations that will be required to ensure adequate precision of the estimates. Then the number of households to be selected from each enumeration area must be decided. Using this information, it is then possible to calculate the total number of enumeration areas which must be selected to ensure an adequate sample. The last task will be to decide how many enumeration areas will be selected from each of the eight strata.

5.6.2 Number of Households

Although regional estimates will be of great interest when analyzing this study, the overall provincial estimate will form the basis for deciding on sample size. Since regional estimates are calculated from sub-samples of the original sample, the precision of these regional estimates will be less than that of the overall estimate.

The theory developed in Chapter 3 can be used to provide relatively simple estimates of sample size where the sampling procedure involves simple random sampling or stratified random sampling. The use of multi-stage sampling procedures introduces complications to this procedure. The major effect of such a complex sampling strategy will be to change the variance of the sample estimate.
Effective stratification will tend to decrease this variance. The effect of clustering is less predictable and depends upon the degree of inter-cluster correlation. The tendency will be to inflate the variance. Such uncertainty makes accurate sample size estimation difficult.

One standard solution, as advanced by Kish (80) is to obtain an initial sample size estimate under the assumption of simple random sampling and then to inflate this estimate using a design effect factor (DEFF). This study will be estimating the proportion of a hypertensive population who fall into various treatment categories. In this case, empirical evidence suggests the design effect factor will be about 3.0 (82).

Data from Chapter 4 reveals that the proportions being estimated; here, range from about 3-20%. It seems reasonable to determine the sample size necessary to estimate a proportion, \( P = 3\% \), with a precision that has yet to be specified. Using formula from Chapter 3, the sample size required is given, approximately, by:

\[
    n = \frac{Q}{P} \cdot \frac{1}{C^2}
\]

where \( P \) = proportion being estimated
\( Q = 1 - P \)
\( C \) = coefficient of variation for \( P \)

A graphical depiction of the relationship between "n" and "C" is diagrammed in Figure 5.1. Figure 5.2 illustrates the amount by which the coefficient of variation would decrease; for a unit increase in sample size. Table 5.7 lists several possible sample sizes and indicates the coefficient of variation and 95% confidence
limits which would be obtained when estimating a proportion, \( P = 0.03 \).

Examination of Figures 5.1 and 5.2 reveals that when the sample size is small (i.e., <1500), then significant improvements in precision can be obtained by a comparatively minor increase in sample size. The data presented in Table 5.7 further suggests that a sample size of 2000 would be regarded as an "optimal" compromise between a desired increased precision and the rapidly increasing cost which must be spent to achieve this increased precision.

Assuming that the design has a \( DEFF = 3.0 \) and a response rate of 90\%, the estimated sample size becomes:

\[
\frac{2,000 \times \sqrt{3.0}}{0.9} = 3,850 \text{ subjects}
\]

Using data from Ontario Statistics 1976 Social Series (113), the mean number of adults in a household is found to be 1.7. Thus one would expect to need to visit \( \frac{3,850}{1.7} \approx 2,260 \) households to obtain the required number of examinations.

5.6.3 Number of Households to be Examined in Each Enumeration Area

The sampling procedure used to select the enumeration areas is based on sampling proportional to size. It is shown in Appendix 2 that with this technique, a constant number of final sample units (i.e., households) should be selected in order to ensure that all finaly sampling units have the same probability of being included in the sample. What would be the effect of varying the number of subjects examined within each cluster while maintaining a fixed sample size? It is clear that, as the cluster size increases, then the number of clusters that can be examined must decrease, if the
Figure 5.1: RELATIONSHIP BETWEEN SAMPLE SIZE AND THE COEFFICIENT OF VARIATION

COEFFICIENT OF VARIATION (%)

SAMPLE SIZE (IN THOUSANDS)

p = 0.03

p = 0.20
Figure 5.2: RELATIONSHIP BETWEEN SAMPLE SIZE AND THE RATE OF CHANGE OF THE COEFFICIENT OF VARIATION
Table 5.7: SAMPLE SIZE RELATED TO THE PRECISION OF ESTIMATION

<table>
<thead>
<tr>
<th>SAMPLE SIZE</th>
<th>COEFFICIENT OF VARIATION</th>
<th>95% CONFIDENCE LIMITS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>LOWER LIMIT</td>
</tr>
<tr>
<td>500</td>
<td>25.4%</td>
<td>1.5%</td>
</tr>
<tr>
<td>1,000</td>
<td>18.0%</td>
<td>1.9%</td>
</tr>
<tr>
<td>1,500</td>
<td>14.7%</td>
<td>2.1%</td>
</tr>
<tr>
<td>2,000</td>
<td>12.7%</td>
<td>2.3%</td>
</tr>
<tr>
<td>2,500</td>
<td>11.4%</td>
<td>2.3%</td>
</tr>
<tr>
<td>3,000</td>
<td>10.4%</td>
<td>2.4%</td>
</tr>
<tr>
<td>4,000</td>
<td>9.0%</td>
<td>2.5%</td>
</tr>
<tr>
<td>10,000</td>
<td>5.7%</td>
<td>2.7%</td>
</tr>
</tbody>
</table>
sample size is to remain unchanged.

Let:  \( n = \) number of clusters selected

\( m = \) number of elements selected within each strata

and \( s = \) total sample size

Then, \( s = mn \) \( \square \)

Now, the sampling strategy being considered is a two-stage cluster sample where the first stage units are selected with replacement and with probability proportional to size. An unbiased variance estimate of the population mean can be obtained from Cochran (24):

\[
v = \frac{1}{n(n-1)m^2} \sum_{i=1}^{n} (y_i - \bar{y})^2
\]

where \( y_i = \) total of the observations obtained on the elements in the \( i \)th cluster

and \( \bar{y} = \frac{\sum_{i=1}^{n} y_i}{n} \)

Now, substitute relation 1 into this formula to get:

\[
v = \left( \frac{1}{s(s-m)} \right) \left( \frac{n}{\sum_{i=1}^{n} (y_i - \bar{y})^2} \right) \phantom{\square}\]

\[
\square \phantom{=} 2
\]

Now, as \( m \to s \), \( \frac{1}{s(s-m)} \to \infty \) and thus \( v \) will become large. But now, let \( m \) be small (i.e. \( s-m=s \)). Then 2 becomes:

\[
v \approx \frac{1}{s^2} \left( \sum_{i=1}^{n} (y_i - \bar{y})^2 \right)
\]

It is easily seen that, in expectation, the expression \( \left[ n \sum_{i=1}^{n} (y_i - \bar{y})^2 \right] \) is a monotonically increasing function of \( n \). Thus, as \( m \) gets
smaller, the expected variance will also rise. This relation is sketched in Figure 5.3. The above discussion implies the existence of a cluster size which will result in a minimal variance. The location of this minimum is difficult to ascertain. In the Canada Health Survey (21), the actual cluster size was determined on logistical, not statistical, grounds. Similar considerations apply here, but it should be possible to monitor the variance and inter-cluster correlations during the course of the study. If it becomes apparent that modifying cluster size could lead to a significant decrease in variance, consideration will be given to implementing this change in subsequent surveys.

There are two logistical considerations in deciding upon a cluster size. Firstly, it will be necessary to have a sufficient number of clusters to allocate to each strata in order to obtain a sufficient geographic coverage. This concept is difficult to quantitate but at least 12 to 14 clusters would probably be needed within each strata. A second consideration is the efficient use of the interviewer's time. A preliminary estimate is that each interviewer could interview an average of between 6 and 7 new households per week (148). It is planned that the interviewers be able to complete the initial interviews on a particular cluster in one week.

All the above considerations suggest that a cluster size of ten households would be appropriate. This corresponds to a sampling fraction of about 2% within each E.A.
Figure 5.3: SCHEMATIC REPRESENTATION OF THE RELATIONSHIP BETWEEN CLUSTER SIZE AND VARIANCE
5.6.4. Allocation of the Clusters to the Strata

The preceding sections have established that 2,260 households (final sampling units) will be selected and then ten households will be selected within each E.A. (cluster). Thus, a total of $\frac{2,260}{10} = 226$ clusters must be selected. It must now be decided how many of these clusters will be selected from each strata. Many possible procedures may be used here, all of which have some justification. The ultimate allocation should obtain the most precise regional estimates possible while still maintaining sufficient clusters in each strata to obtain good provincial estimates. The precision of regional estimates will depend upon the number of subjects examined within the region. As will be seen from Figure 5.1, the same absolute increase in sample size produces a significantly greater increase in precision when the sample size is low.

The simplest allocation protocol would allocate an equal number of clusters to each strata (Table 5.8, column 1). As an alternative, Cochran (24) shows that, under certain assumptions, the variance of an estimate of a population proportion is minimum if Neyman allocation is followed; that is, $n_h = \frac{n \sum N_h S_h}{\sum N_h S_h}$

where $n_h =$ number of clusters allocated to stratum $h$

$n =$ total number of clusters to be allocated

$N_h =$ size of cluster $h$

$S_h =$ standard deviation of the estimate in cluster $h$

If it is further assumed that $S_h$ is constant across all strata, the allocation becomes allocation proportional to size i.e.,
\[ n_h = n \frac{N_h}{\sum N_h} \] (Table 5.8, column 2). This procedure tends to underrepresent the smaller strata and so produce some regional estimates with inflated variance. In an attempt to improve the regional estimates without producing a significant loss of precision in the provincial estimate, the Canada Health Survey (71) utilized allocation proportional to the square root of size, i.e.:

\[ n_h = n \frac{\sqrt{N_h}}{\sum \sqrt{N_h}} \] (Table 5.8, column 3). This procedure will be selected for the present study.

5.6.5 Summary

This section has been concerned with the specification of sample size, cluster size and the allocation of clusters to the various strata. It is estimated that it will be necessary to include approximately 2,260 households in the sample. This corresponds to approximately 3,850 individuals. A total of ten households will be examined within each enumeration area. It will be necessary to select 226 enumeration areas. The E.A.'s will be allocated to eight strata by a method proportional to the square root of the strata size.
Table 5.8: POSSIBLE SCHEMES FOR THE ALLOCATION OF CLUSTERS TO STRATA

<table>
<thead>
<tr>
<th>STRATA</th>
<th>POPULATION</th>
<th>EQUAL ALLOCATION</th>
<th>ALLOCATION PROPORTIONAL TO POPULATION</th>
<th>ALLOCATION PROPORTIONAL TO \sqrt{POPULATION}</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2,124,291</td>
<td>28</td>
<td>59</td>
<td>42</td>
</tr>
<tr>
<td>2</td>
<td>1,017,203</td>
<td>28</td>
<td>28</td>
<td>29</td>
</tr>
<tr>
<td>3</td>
<td>1,070,345</td>
<td>28</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>4</td>
<td>468,579</td>
<td>28</td>
<td>13</td>
<td>20</td>
</tr>
<tr>
<td>5</td>
<td>371,082</td>
<td>28</td>
<td>11</td>
<td>18</td>
</tr>
<tr>
<td>6</td>
<td>1,062,343</td>
<td>29</td>
<td>29</td>
<td>29</td>
</tr>
<tr>
<td>7</td>
<td>1,208,329</td>
<td>29</td>
<td>33</td>
<td>32</td>
</tr>
<tr>
<td>8</td>
<td>816,485</td>
<td>29</td>
<td>23</td>
<td>26</td>
</tr>
<tr>
<td>TOTAL</td>
<td>8,138,657</td>
<td>226</td>
<td>226</td>
<td>226</td>
</tr>
</tbody>
</table>
5.7 Data Collection Procedures

5.7.1 General

Data will be collected by a nurse interviewer directly from every eligible adult. A summary of the interview format can be found in Table 5.9. Each household member will be interviewed in private.

The data to be collected can be classified into four main areas relating to:

(1) socio-demographics
(2) information to be used in the process model
(3) attitudes to and knowledge about hypertension
(4) general health behaviour and attitudes.

The following sections will discuss each of these areas in detail, describing the measurements which will be obtained.

5.7.2 Socio-demographic Data

The data collected here will provide various identifying information about the subjects. These data will be used to adjust the population estimates for deviations in the sample from the characteristics of the target population. Potentially useful information includes: age, sex, education, occupation, socio-economic status, and race. In addition to the analytic uses, these data will be used to establish initial contact between the interviewer and the subjects and also to "pace" the interview and provide a slight break between some of the more serious and thought-provoking questions asked in the later sections. In light of these requirements, the questions will be interspersed throughout the interview. In view of the above discussion, the specific questions which will be
Table 5.9: CONTENT OF THE INTERVIEW

1) Introduce and explain the nature of the project and the interview:
   - obtain consent of subject(s)
   - schedule appointment to examine eligible subjects not at home

2) Collect background socio-demographics.

3) Administer questionnaires regarding past history and blood pressure status.

4) Administer questionnaire regarding attitudes to, and knowledge about, hypertension.

5) Measure arm circumference and blood pressure three times.

6) Schedule follow-up visits based upon blood pressure values.
asked are not presented. However, Table 5.10 summarizes the more important variables which will be ascertained in this area. The occupation of the husband will be coded using the Blishen Scale of socio-demographic status (12) to provide a numerical score for subsequent use. Proxy answers will be accepted to avoid unnecessary repetition during the interview.

5.7.3 Information Related to the Process Model

5.7.3.1 Introduction

In Chapter 4, a model was developed to facilitate the evaluation of the quality of hypertension control using a procedure based on process assessment. This section will discuss the measurement techniques which will provide the information needed by this model. The required data is summarized in Table 5.11. This table also indicates the type of measurement technique which will be used to obtain each datum of information.

5.7.3.2 Blood Pressure Measurement

A detailed discussion of the problems associated with blood pressure measurement can be found in Chapter 2. That discussion concluded that the variability inherent in sphygmomanometry, as routinely practised during clinical work, is of a larger magnitude than could be accepted in a research study. The London School of Hygiene Sphygmomanometer (129) or the Hawksley Random-Zero Sphygmomanometer (196) should be used to reduce this variability and bias. Further, all persons who engage in blood pressure measurement should be trained in the proper technique necessary to reduce variability and bias. Finally, these people should be evaluated to quantitate the
Table 5.10: SUMMARY OF SOCIO-DEMOGRAPHIC DATA ITEMS

- Name
- Sex
- Age; Date and Place of Birth; Marital Status
- Race
- Present Occupation - type
  - shift work (yes/no)
  - number of years
  - if unemployed, previous job
- Highest Education Level Obtained
- Present Address and How Long There
- Hobbies
Table 5.11: DATA TO BE COLLECTED WHICH RELATES TO THE PROCESS MODEL

<table>
<thead>
<tr>
<th>DATA</th>
<th>SOURCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Have you ever been told that your blood pressure is too high?</td>
<td>History</td>
</tr>
<tr>
<td>- Who told you that your blood pressure was too high?</td>
<td>History</td>
</tr>
<tr>
<td>- When did they tell you your blood pressure was too high?</td>
<td>History</td>
</tr>
<tr>
<td>- Have you seen a doctor about your high blood pressure?</td>
<td>History</td>
</tr>
<tr>
<td>- When was this?</td>
<td>History</td>
</tr>
<tr>
<td>- Were you given any treatment?</td>
<td>History</td>
</tr>
<tr>
<td>- Are you still taking treatment?</td>
<td>History</td>
</tr>
<tr>
<td>- What is your treatment?</td>
<td>History</td>
</tr>
<tr>
<td>- Do you still see your doctor about high blood pressure?</td>
<td>History</td>
</tr>
<tr>
<td>- How often do you see the doctor?</td>
<td>History</td>
</tr>
<tr>
<td>- When was the last appointment?</td>
<td>History</td>
</tr>
<tr>
<td>- When is the next appointment?</td>
<td>History</td>
</tr>
<tr>
<td>- Do you book your return visit before you leave your doctor's</td>
<td>History</td>
</tr>
<tr>
<td>office or does he call you later with the new date?</td>
<td>History</td>
</tr>
<tr>
<td>- Do you have trouble remembering to follow your treatment plan?</td>
<td>History</td>
</tr>
<tr>
<td>- What is the circumference of the right arm?</td>
<td>Physical Exam</td>
</tr>
<tr>
<td>- What is the blood pressure?</td>
<td>Physical Exam</td>
</tr>
</tbody>
</table>
presence of any residual bias.

The above suggestions will be followed in this study. The London School of Hygiene Sphygmomanometer is too heavy and bulky to be a suitable instrument for use when a study design requires a significant amount of travel. However, the Hawksley Random-Zero Sphygmomanometer is easily portable. This device will be used to measure blood pressure in the present study.

Cuff size will be determined by arm circumference measured immediately prior to cuff application. A blank tape (2 cm x 25 cm) will be placed to encircle the arm, midway between the elbow and shoulder. The circumference will be indicated by drawing a line at the appropriate position. This procedure will be repeated three times. The three lengths will then be measured using a standard metric tape measure. The mean value will be used to determine cuff size (Table 5.12).

Table 5.12: CUFF SIZE AND ARM CIRCUMFERENCE

<table>
<thead>
<tr>
<th>ARM CIRCUMFERENCE</th>
<th>CUFF SIZE</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;25.0 cm</td>
<td>9 x 18 cm</td>
</tr>
<tr>
<td>25.0 - 36.0 cm</td>
<td>12 x 22 cm</td>
</tr>
<tr>
<td>&gt;36.0 cm</td>
<td>18 x 35 cm</td>
</tr>
</tbody>
</table>
The following paragraph summarizes the procedure by which the blood pressure will be measured. The blood pressure measurement will be obtained at the end of the interview. The patient will first be asked to urinate if he/she wishes, and then to bare the upper right arm. A notation will be made if circumstances require the left arm to be used. The size of blood pressure cuff will be determined by measuring arm circumference. The cuff will be applied to the selected arm and the subject will then sit quietly for five minutes while answering a series of non-threatening questions. Prior to each measurement, the zero offset will be re-randomized. Phase I (systolic) and phase V (diastolic) blood pressures will be recorded. If no phase V value can be found, then a phase IV reading will be used to provide the diastolic measurement and a special notation will be made. The measurements will be repeated at intervals of two minutes until a total of three readings have been obtained.

A second visit will be made to all subjects who revealed a diastolic blood pressure $\geq$85 mm Hg. This visit will occur one week after the initial interview. At this time, the blood pressure measurement procedure will be repeated. An additional visit will be made one week later to those subjects who revealed a mean diastolic blood pressure $\geq$90 mm Hg at both the initial and first follow-up visits.
5.7.3.3 Historical Information

Many research efforts have been directed towards obtaining information about the historical data outlined in Table 5.11 (Chapter 4). However, no questionnaires designed for measuring this area, have received an adequate and published validation. An independent questionnaire will be developed for this study Appendix 4). It is intended to validate this instrument so that it can be used in subsequent investigations. Proposed validation procedures will include: test/re-test reliability, use in programmed patients, and correlation with free-form interviewing by qualified physicians.

5.7.4 Health Behaviour, Attitudes and Knowledge
5.7.4.1 General

The basic measurements described in the previous section will be sufficient to provide an assessment of the process of community control of hypertension as developed in Chapter 4. Further information will be collected to provide an additional delineation of the present situation. Specifically, data will be collected which can be used to assess general health behaviour and attitudes, and to assess specific knowledge about and attitudes towards hypertension. These data can be used to investigate determinants of the observed process status (e.g., what factors are associated with an increased detection, treatment, etc.). These data will be used to investigate regional differences and to provide suggestions for programs which aim to
firm base upon which prospective studies could be built. Such studies could include special purpose re-visits to the initially identified cohort and also repeat surveys of analogous samples, as described in Section 5.12.

5.7.4.2 Attitudes Towards, and Knowledge About, Hypertension

This information will be obtained from all subjects via a questionnaire administered by the interviewer. This questionnaire will be adapted from several sources. The questions relating to knowledge of hypertension are primarily derived from a questionnaire used to assess the impact of a mastery learning program which was used in a study of compliance at the Hamilton Foundries and Steel, Limited (136). Those questions, which relate to attitudes towards hypertension, are modified from a questionnaire used by Harris and associates in a U.S. survey in 1973 (57). The questionnaires can be found in Appendix 5.

5.7.4.3 General Health Behaviour and Attitudes

Specific information related to health service utilization and attitudes will be obtained by a self-administered questionnaire given during the course of the initial interview. This questionnaire can be found in Appendices 6 and 7.

At the conclusion of the interview, each subject who is not scheduled for a re-visit will be left a self-administered version of a health locus of control questionnaire (180). They will be asked to complete this questionnaire and to return it by mail in an addressed pre-stamped envelope. Three weeks will be allowed for the questionnaire to be received at the Study Centre. At the end of this
period a reminder will be mailed to each non-responding subject. After a further two weeks, a telephone call or personal visit will be made to ensure completion of the questionnaire. Those individuals whose initial blood pressure values require return visits will have the questionnaire administered during the second visit. This questionnaire can be found in Appendix 8.

5.8 Training of the Interviewers

5.8.1 Introduction

The data presented in Section 5.6.2 suggests eight interviewers will be needed to complete one pass of the survey in one year. They will be registered nurses, licensed to practice in Ontario. It is expected that they will have a definite, but variable, knowledge about hypertension and research methodology. A three-week training program will be developed to acquaint the interviewers with the project. This training will serve three main purposes:

1. to provide knowledge about hypertension and its consequences;
2. to provide a general introduction to the methodology of epidemiologic research, with emphasis on the need for standardized measurement procedures;
3. to provide training in the techniques to be used in the execution of this study.

In addition, this period will be used to measure the reliability of each procedure.

A detailed training schedule cannot be presented at this time. The logistics for this period will be very dependent upon the av.
of resources at the time that the study is implemented. The purpose of the following sections is to present general guidelines which will be used in constructing the final schedule.

There is clearly a need to provide a period of training in the use of the standardized measurement procedures which will be employed in this study. Less obvious is the justification of the decision to provide a general knowledge base in the area of hypertension and research methodology. The primary reason for inclusion of this aspect of the training is to ensure that the interviewers can respond to inquiries from study subjects in an accurate and helpful manner. One concern of survey research studies similar to this design, is that the subjects feel "used" (181). It is hoped that much of this problem will be avoided by encouraging an open, friendly and responsive attitude on the part of the interviewers. This attitude will be promoted by educating the interviewers about the program. In addition, the interviewers will leave hypertension education packages at the conclusion of the interview. It is hoped that such an approach will improve the response to follow-up studies.

An additional concern involves the standardization of the interviewers. Each interviewer will have prior experience with blood pressure measurement and patient interviewing. It is possible that during prolonged field work, the standardized measurement techniques will drift back toward prior bad habits. It is hoped that the emphasis on the importance of maintaining the protocols will retard this drift.
5.8.2 Knowledge About Hypertension

Instruction conveying factual information about hypertension will be presented early in the training period. It will consist of a short series of lectures, demonstrations, and audio-visual material. The purpose will be to convey a general overview of the present state of knowledge in the field of hypertension. Attention will be directed to the following areas:

(1) the effects of hypertension (1 lecture);

(2) evidence that treatment of hypertension is beneficial (1 lecture);

(3) problems in measuring blood pressure and defining hypertension (2 lectures, 1 laboratory);

(4) barriers to the effective community control of hypertension (1 lecture).

The discussion of blood pressure measurement will be preceded by a practical demonstration of observer variability.

5.8.3 Epidemiologic Methodology

Information will be presented on epidemiologic methodology. Emphasis will be placed on the following areas:

(1) general design of survey research (1 lecture);

(2) problems with measurement techniques and possible solutions with emphasis on the necessity for "standardized" measurement procedures (2 lectures);

(3) techniques of sample selection (1 lecture).
5.8.4 Project Techniques

The major portion of the training period will be devoted
to acquiring familiarity with the various procedures to be used
during the course of this study. These will include:

(1) sample selection;
(2) measurement procedures;
(3) conduct of the interview.

The interviewers will be trained in the use of a standard
procedure to list households within the selected enumeration area
(Appendix 3), and in the use of a random number table to
select the households to be interviewed. A work schedule, for
use in the field, will be developed, whereby the enumeration of
each cluster and the selection of households for interview will
be integrated to provide for the most efficient use of the
interviewer's time.

A summary of the measurement procedures, which will need
to be learned, can be found in Table 5.13. It will be expected
that prior training will have acquainted the interviewers with
the inter-personal communication skills required to interview
the subjects. Further training in the collection of historical
information will emphasize familiarity with the questionnaires.
This will be acquired primarily through repeat application of the
questionnaires in a series of real and simulated situations.

Training in the measurement of blood pressure determination
will commence with a practical demonstration of inter- and intra-
observer variation utilizing a standard blood pressure film (189).
Table 5.13: MEASUREMENT TECHNIQUES TO BE LEARNED BY INTERVIEWERS

(I) HISTORICAL:

- Socio-demographic
- History of Hypertension Questionnaire
- Knowledge of Hypertension Questionnaire
- Attitudes of Hypertension Questionnaire
- General Health Behaviour Questionnaire

(II) PHYSICAL EXAMINATION:

- Blood Pressure
- Arm Circumference
The interviewers will next acquire a familiarity with the Hawksley Random-Zero Sphygmomanometer and learn the necessary basic maintenance procedures. They will then be trained in the procedure to be followed when measuring the blood pressure. Throughout the training, pre-developed tapes will be used to enhance appreciation of the problems in blood pressure measurements (130). The training will conclude with the repeat assessment of observer variation. Training in the measurement of arm circumference will involve repeated determinations on volunteers.

5.8.5 Evaluation of Observer Variations

An integral component of the training program will be an evaluation of the magnitude of observer variation associated with each of the measurement procedures. This information will also provide data which can be used to estimate the reliability and validity of the questionnaire instruments. In general, three types of testing will be used:

1. correlation and agreement testing based both on standard "test packages", and on "real life" situations;
2. the use of "programmed" patients to act as experimental subjects;
3. performance of interviews under the direct observation of the training staff.

The following criteria would be considered as the minimally acceptable standards:
(1) correlation coefficients ≥0.8

(2) agreement ≥80%

(3) obtaining 90% of the available information from programmed patients.

Additional evaluation strategies will be developed which relate specifically to the individual measurement components. As an example, for each interviewer, an estimate will be made of the magnitude of bias in measuring blood pressure (130). There will also be a form of "quality control" during the actual survey period. The instructor of the interviewers will periodically "sit in" on a randomly selected interview, to ensure that standard protocol is being followed.
5.9 Administrative Details

5.9.1 Publicity

Sponsorship will be solicited from organizations which have a high national and provincial profile (e.g., Canadian and Ontario Heart Foundations). Letters will be mailed to physicians and hospitals in the area and also to the local police and city hall. These letters will explain the purpose of the study and identify the areas where the interviewers are working. These arrangements will permit subjects to confirm the identity of the interviewer.

5.9.2 Contact with the Subjects

A letter of introduction will be left at all households selected to participate in the study. This letter will describe the purpose of the study and its importance. It will mention the supporting agencies and suggest that the subjects contact the local police or city hall if they have any doubts as to the validity of the project. Finally, it will specify a time at which the interviewer will return to speak with the household.

Approximately three days later, the interviewer will return to the household. She/he will identify herself/himself to the household head, explain briefly the purpose of the visit and ask for the family's cooperation. The next step will be to determine how many household members are eligible to be included in the examination. Where feasible, the interviews will be performed at this time. Appointments will be made to interview all eligible members not examined during the initial contact.
5.9.3 The Handling of Non-Respondents

Lack of response at the initial visit could occur for two reasons. Firstly, there could be no contact at all (i.e., not at home). Secondly, there could be refusal to participate.

In the event of non-contact because of absence from home, the interviewer will leave a card indicating that she had called but found no one at home. The card will include a time, at which the interviewer will return. There will also be a telephone number, at which the interviewer could be reached if the scheduled time is inconvenient. If the second visit is also non-productive, the interviewer will attempt to determine, if the household is away from the house for a prolonged period. In this event, a repeat contact will be attempted when the family returns, provided that the interviewer is still working in the same area. If such a repeat visit cannot be arranged, the household will be recorded as non-responders. Where contact has not been made after two interviews but the household is not on a prolonged trip, a third visit will be scheduled about ten days later. A failed contact on this visit will be classified as non-response.

It is possible that an empty dwelling could be selected for interviewing. When this is detected, a replacement household will be drawn at random after the empty household has been removed from the enumeration list.

Some households will refuse to be interviewed, even when contact is made. In this situation, the interviewer will attempt to obtain as much information as possible, by using a modified
interview. She/he will also attempt to determine the reason for refusal. These data will be used in the analysis of the data. Consideration will be given to "imputing" the expected values for non-responders (80).

5.9.4 Consent and Release of Information

A consent form will be obtained from each subject prior to beginning the interview. A specimen form can be found in Appendix 9. Subjects will be encouraged to permit the results of the examination to be mailed to their personal physician. A special consent form will be provided for this purpose (Appendix 10).

Each subject will receive a summary of the examination results. This summary will be compiled at the central office. Each report will be examined by the Project Director to determine if it should be recommended that the subject contact a physician for further evaluation and/or treatment. Where such a recommendation is considered necessary, a personalized letter from the Project Director will be included with the summary.

5.10 Pre-Testing

A series of pre-tests will be developed to allow for refinement of the interview and sampling techniques (Figure 5.4). The first pre-test will occur immediately after the training period and will involve administration of the questionnaires to a select group of volunteers. These encounters will occur in a supervised setting under direct observation. Consideration will be given to using video recording. The primary purpose of this pre-test will be to provide
**Figure 5.4: TIME COURSE OF THE SURVEY**

<table>
<thead>
<tr>
<th>TIME</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start</td>
<td>Recruitment, Acquisition of Equipment, Printing of Forms, Formulation of Training Program</td>
</tr>
<tr>
<td>4th Week</td>
<td>Training Interviewers</td>
</tr>
<tr>
<td>7th Week</td>
<td>Pre-Test I</td>
</tr>
<tr>
<td>9th Week</td>
<td>Pre-Test II</td>
</tr>
<tr>
<td>12th Week</td>
<td>Pre-Test III</td>
</tr>
<tr>
<td>16th Week</td>
<td>Final Evaluation of Pre-tests, Selection of Sampling Units</td>
</tr>
<tr>
<td>18th Week</td>
<td>Main Study</td>
</tr>
</tbody>
</table>
the interviewers with an opportunity to practice using the newly learned techniques. There will also be opportunity for extensive "debriefing" of the volunteers which will allow assessment of the acceptability of the procedures being used.

The second pre-test will also involve the use of volunteers. The interview will be performed in the volunteer's home in a manner identical to that which will be used in the final survey. The purpose of this stage will be to refine further the measurement tools, with special attention being paid to improving the questionnaire design. It will also provide an initial appraisal of difficulties which might be encountered with the diagnostic equipment which will be used.

The final stage of the pre-test period will involve a "dry-run" of all the survey procedures. This will occur in Hamilton-Wentworth and will involve selecting one enumeration area for each interviewer. The interviewer will select twenty households from within this area and apply the interview protocol to these households. This pre-test will allow evaluation of the techniques of sample selection. It will also be the first encounter between the general public and the survey. The information gained should provide a useful measure of acceptability and response rate.
5.11 Design to Assess Changes in the Quality of Care

5.11.1 General

One of the primary goals of this survey will be to assess the way in which the quality of care delivered to people with hypertension changes with the passage of time. These changes will have multifactorial causation and the survey will not directly attempt to elicit these causes. The methodologic issues involved with sampling strategies to assess change have been discussed earlier (section 3.7). The major factor which must be determined is the relationship between successive samples (i.e., the degree of overlap). A panel design makes it possible to examine the question of net change as opposed to gross change (e.g., why did the percentage under control increase?). Counter-balancing this useful feature of panel studies is the effect that observation can have on the behaviour pattern of the panel members (i.e., deterioration of the panel). This will render the panel unrepresentative of the general population and inhibit generalization to the larger group (80).

The problem of panel deterioration would be anticipated to be quite large in this survey. All members of the sample will receive a report of the results of their examination. In those people with definite hypertension, this report will be accompanied by a letter strongly recommending that they seek medical care. While it is unlikely that all such individuals will actually enter into care, the intervention will have an unpredictable, but probably significant, impact on the manner with which these individuals use the health care
system. It is also reasonable to hypothesize that a reassuring report will have an effect on the behaviour of the non-hypertensive segment of the sample. Thus, there are definite a priori reasons to suggest that panel deterioration would be significant.

5.11.2 Design

The survey will be repeated on a regular basis. It is estimated that one year will be required to complete a single pass of this survey. The design presented in this document involves the development of a special purpose interviewing team. In order to make the most efficient use of the interviewer training and skills, it is proposed to repeat this study at yearly intervals. Each new sample will be independent of the preceding samples. The selection for subsequent samples will be made from within the list of enumeration areas selected during the initial sample selection procedure but excluding those households selected for previous samples (80). It is expected that at least six repeat samples could be obtained without needing to select new enumeration areas. Where possible, interviewers will continue to work within the same set of enumeration areas on subsequent surveys.

5.11.3 Evaluation of Panel Deterioration

Discussion earlier in this section has indicated that there are a priori reasons to expect significant panel deterioration. It would be interesting to investigate this hypothesis further. Such an investigation could provide useful information about net change, incidence of hypertension and the impact of the survey on modifying health behaviour.
To answer these questions, a parallel project could be designed to re-visit a sub-sample of the primary sample one year after the initial interview. If this study revealed that the problem of panel deterioration was not as significant as anticipated, consideration could be given to revising the protocol for selecting subsequent samples.

5.12 Additional Components Which Could be Used to Complement the Basic Design

5.12.1 General

There are several additional measurements which could be obtained on the study population. These would allow a refinement of the basic measurements. The inclusion of these procedures would lead to a significant increase in complexity and expense. The assessment of target organ is important and should be included if at all feasible. An attempt to diagnose secondary hypertension in a community survey is, of necessity, cursory and of far less importance. Further evaluation of the effect of using the random-zero sphygmomanometer would be of interest but would not represent a high priority. Lastly, follow-up of an inception cohort would supply much interesting information on the type of changes occurring within the population and the possible reasons for these changes.
5.12.2 Assessment of Target Organ Damage

The decision to treat a patient for hypertension is usually based upon an assessment of the phase V diastolic blood pressure. However, as discussed by the Ontario Council of Health Task Force on Hypertension (126), when patients have a sustained diastolic blood pressure between 90 and 105 mm Hg but are without target organ damage, the evidence of therapeutic benefit is equivocal. An evaluation of the quality of community care should be based upon identifying the group of patients known to benefit from such treatment. Therefore, evaluation of the quality of hypertension control would be improved by an assessment of target organ damage in individuals with sustained diastolic blood pressure between 90 and 105 mm Hg. This assessment would provide a more precise indication of the group of patients requiring treatment. A summary of the suggested measurements can be found in Table 5.14. Additional risk factors which should be assessed are indicated in Table 5.15.

It can be seen that an adequate assessment of target organ damage involves collection of additional information on history, physical examination and laboratory testing. Standardized questionnaires are available to assess congestive heart failure, angina pectoris and smoking (131). Standardization of the laboratory procedures would also present no major problems. The use of the Minnesota code for EKG interpretation improves the quality of measurements based on this procedure (73, 131).
Table 5.14: TARGET ORGAN DAMAGE

<table>
<thead>
<tr>
<th>SITE</th>
<th>ABNORMALITY</th>
<th>TESTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye</td>
<td>-A:V ratio &lt;1:2</td>
<td>physical examination</td>
</tr>
<tr>
<td></td>
<td>-haemorrhages</td>
<td>physical examination</td>
</tr>
<tr>
<td></td>
<td>-exudates</td>
<td>physical examination</td>
</tr>
<tr>
<td></td>
<td>-papillopdauma</td>
<td>physical examination</td>
</tr>
<tr>
<td>Kidney</td>
<td>-urine specific gravity &lt;1.020 on three overnight</td>
<td>laboratory</td>
</tr>
<tr>
<td></td>
<td>specimens</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-proteinuria &gt;1+</td>
<td>laboratory</td>
</tr>
<tr>
<td></td>
<td>-azotemia</td>
<td>laboratory</td>
</tr>
<tr>
<td>Heart</td>
<td>-dyspnea of cardiac origin</td>
<td>history</td>
</tr>
<tr>
<td></td>
<td>-angina pectoris</td>
<td>history</td>
</tr>
<tr>
<td></td>
<td>-prior myocardial infarction</td>
<td>history + laboratory</td>
</tr>
<tr>
<td></td>
<td>-LVH on EKG</td>
<td>laboratory</td>
</tr>
<tr>
<td></td>
<td>-cardiac enlargement on chest x-ray</td>
<td>laboratory</td>
</tr>
<tr>
<td>Brain</td>
<td>-prior stroke or transient ischemic attack</td>
<td>history</td>
</tr>
</tbody>
</table>

Table 5.15: ADDITIONAL RISK FACTORS

<table>
<thead>
<tr>
<th>RISK FACTOR</th>
<th>TESTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking</td>
<td>history</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>laboratory</td>
</tr>
<tr>
<td>Glucose</td>
<td>laboratory</td>
</tr>
<tr>
<td>Uric Acid</td>
<td>laboratory</td>
</tr>
</tbody>
</table>
The technique of fundoscopy would require a significant improvement in reliability. Observer variation is large, for both hand-held ophthalmoscopy (74) and fundal photography (6, 74). The latter technique would present problems of patient acceptance and safety, because mydriatics must be used. Since the assessment of the fundal blood vessels plays a major role in determining target organ damage, improvement in this procedure would be needed before implementation of this section could be completed.

5.12.3 Secondary Hypertension

Secondary hypertension is rare, and potentially curable secondary hypertension even rarer (Table 5.16). It is not cost-effective to perform extensive investigations on all new hypertensives. A preferable approach consists of performing a small number of screening procedures which are expected to detect many cases of secondary hypertension (Table 5.17). Further investigations would be performed in two major settings:

(1) the young, severe hypertensive;

(2) individuals who fail to respond to appropriate medical therapy to which they are compliant.

This basic approach has been recommended by the Ontario Council of Health Task Force on Hypertension (126).

While this approach is appropriate in clinical practice, any attempt to utilize a similar approach in a research study would underestimate the prevalence of secondary hypertension. This approach would, however, provide useful information as to the projected results of implementing the recommendations of the Ontario Council of Health
Table 5.16: PREVALENCE OF SECONDARY HYPERTENSION

<table>
<thead>
<tr>
<th>CAUSE</th>
<th>(46) CLEVELAND CLINIC</th>
<th>(36) MICHIGAN STATE U. COMMUNITY-BASED REFERRAL CLINIC</th>
<th>(153) ONTARIO G.P.</th>
<th>(67) JAPANESE RAILWAY WORKERS (MEN)</th>
<th>(192) SWEDISH GENERAL POPULATION SAMPLE</th>
<th>CURABLE?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pheochromocytoma</td>
<td>0.2%</td>
<td>0</td>
<td>0</td>
<td>0.2%</td>
<td>0</td>
<td>Yes</td>
</tr>
<tr>
<td>Cushing's Syndrome</td>
<td>0.3%</td>
<td>0.4%</td>
<td>0.2%</td>
<td>0</td>
<td>0</td>
<td>Yes</td>
</tr>
<tr>
<td>Aldosteronism</td>
<td>0.5%</td>
<td>(0.4%)</td>
<td>0</td>
<td>(0.9%)</td>
<td>0.1%</td>
<td>Yes</td>
</tr>
<tr>
<td>Coarctation of Aorta</td>
<td>0.7%</td>
<td>0</td>
<td>0.2%</td>
<td>-</td>
<td>0.1%</td>
<td>Yes</td>
</tr>
<tr>
<td>Renovascular</td>
<td>5.0%</td>
<td>2.8%</td>
<td>0.2%</td>
<td>0</td>
<td>0.6%</td>
<td>=33%</td>
</tr>
<tr>
<td>Renal Parenchymal</td>
<td>5.9%</td>
<td>2.4%</td>
<td>4.7%</td>
<td>5.8%</td>
<td>4.6%</td>
<td>No</td>
</tr>
<tr>
<td>Oral Contraceptives</td>
<td>-</td>
<td>4.5%</td>
<td>0.2%</td>
<td>n/a</td>
<td>-</td>
<td>Yes</td>
</tr>
<tr>
<td>Post-Polioencephalitis</td>
<td>-</td>
<td>-</td>
<td>0.2%</td>
<td>-</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>Hyperparathyroidism</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.3%</td>
<td>Yes</td>
</tr>
<tr>
<td>Intial Hypertension</td>
<td>87.4%</td>
<td>89.5%</td>
<td>94.3%</td>
<td>93.1%</td>
<td>94.3%</td>
<td></td>
</tr>
<tr>
<td>Stable Hyper tension*</td>
<td>6.7%</td>
<td>8.1%</td>
<td>0.8%</td>
<td>1.1%</td>
<td>1.1%</td>
<td></td>
</tr>
<tr>
<td>Usually Curable**</td>
<td>3.1%</td>
<td>2.4%</td>
<td>0.6%</td>
<td>1.2%</td>
<td>1.1%</td>
<td></td>
</tr>
</tbody>
</table>

Pheochromocytoma, Cushing's, Aldosteronism, Coarctation of Aorta, Renovascular, Oral Contraceptives, Hyperparathyroidism.
Table 5.17: EVALUATION RELATING TO DIAGNOSING SECONDARY HYPERTENSION

<table>
<thead>
<tr>
<th>MANOEUVRE</th>
<th>REASON</th>
<th>TESTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Are you pregnant? Are you taking birth control pills or estrogen?</td>
<td>(1) ↑ estrogens ↓ blood pressure</td>
<td>History</td>
</tr>
<tr>
<td>(2) Have you ever had kidney surgery, pain and/or trauma to either flank?</td>
<td>(2) If positive, search for renovascular causes should be considered.</td>
<td>History</td>
</tr>
<tr>
<td>(3) Do you eat a lot of licorice?</td>
<td>(3) Licorice intoxication</td>
<td>History</td>
</tr>
<tr>
<td>(4) Do you have episodes of pounding headache and sweating and palpitation and anxiousness together?</td>
<td>(4) Suggests pheochromocytoma.</td>
<td>History</td>
</tr>
<tr>
<td>(5) Auscultate for subcostal bruits.</td>
<td>(5) A bruit increases likelihood of a renovascular cause.</td>
<td>Physical Examination</td>
</tr>
<tr>
<td>(6) Simultaneous radial and femoral pulses.</td>
<td>(6) Aortic coarctation.</td>
<td>Physical Examination</td>
</tr>
<tr>
<td>(7) Arm and leg blood pressure.</td>
<td>(7) Aortic coarctation.</td>
<td>Physical Examination</td>
</tr>
<tr>
<td>(8) Physical stigmata of Cushing's syndrome, myxoedema, acromegaly.</td>
<td>(8) Rare endocrine causes.</td>
<td>Physical Examination</td>
</tr>
<tr>
<td>(9) Urine for glucose and protein.</td>
<td>(9) Diabetes; parenchymal renal disease.</td>
<td>Laboratory</td>
</tr>
<tr>
<td>(10) Serum potassium.</td>
<td>(10) ± aldosteronism.</td>
<td>Laboratory</td>
</tr>
<tr>
<td>(11) Serum creatinine</td>
<td>(11) Renal function.</td>
<td>Laboratory</td>
</tr>
</tbody>
</table>
Task Force on Hypertension. A more detailed attempt to diagnose secondary hypertension would require extensive and expensive laboratory and radiologic testing. Such an attempt would best be organized as an auxiliary project.

5.12.4 Effect of Labelling

Recent investigations have suggested that the effect of being "labelled" hypertensive has a significant impact on psychosocial functioning (138). This study could provide an interesting forum to investigate further the phenomenon of "labelling". Firstly, psychosocial function could be assessed in the prevalence study. This would allow comparisons of the functioning of "hypertensive" and unaware group with both the "normal" population and the hypertensive and aware group. These comparisons might supply some useful information but would be subject to the potential of significant bias. Of more importance, the assessment of psychosocial function during the initial survey would provide baseline information on an inception cohort of newly labelled hypertensives. This group could then be followed to assess changes in psychosocial functioning.

5.12.5 Evaluation of the Random-Zero Sphygmomanometer

Evans and Prior provide evidence that use of the random-zero sphygmomanometer will diminish end-digit preference (35). It is likely that use of this instrument will also decrease expectation bias. However, there are no published data demonstrating that this bias is actually reduced (60). It would be possible to modify the blood pressure measurement procedure described in section 5.7, to
permit collection of data using both a Random-zero sphygmomanometer and a standard mercury sphygmomanometer. These data could then be used to examine the above-mentioned hypothesis.

5.12.6 Cohort Studies

After the first "pass" of this survey, a substantial amount of baseline information will be available both on a group of hypertensives and on a group of normotensives. It would be possible to design cohort studies to follow either, or both, of these populations. These studies could provide much useful information about:

(1) the incidence of hypertension

(2) the predictive value of the health attitudes and knowledge questionnaires

(3) the impact upon health beliefs, made by the diagnosis of a chronic disease

(4) the natural variability of health beliefs.
5.13 Analytic Strategies

The evaluation model developed in Chapter 4 is based, primarily upon the assessment of the proportion of a hypertensive population belonging to various treatment categories. The initial step in the analysis requires a definition of the criteria used to construct these classes. The overall outline of these definitions is illustrated in Figure 5.5. First, it is necessary to decide on the criteria which will delineate the hypertensive population. The diagnosis of hypertension will utilize a composite criterion dependent upon blood pressure measurement and historical information. The level of blood pressure chosen to demarcate the hypertensive population is largely arbitrary (119). Evidence that treating people with high blood pressure provides a net benefit is the standard used to define a cut-off value (119). The value used to identify the hypertensive population will be a diastolic blood pressure >95 mm Hg on each of three weekly visits. A sensitivity-type analysis will examine the impact of varying the cut-off value. This analysis will also provide information about treatment delivered to sub-groups at higher risk. In addition to the actual blood pressure measurement, the study will collect historical information related to diagnosis or treatment of hypertension. A positive response to any of the following questions would classify an individual as hypertensive:
Figure 5.5: Flow chart used to classify the population

(a) Diastolic BP > 95 mm Hg on each of 3 visits
or (b) A history of hypertension or of treatment for hypertension

- Normal BP
- No

Diagnosed; hypertension

- High BP but unaware
- No

Aware of hypertension?
- Yes

- High BP
- Aware
- Never Treated
- No

Given any treatment?
- Yes

- High BP
- Aware
- Treatment stopped
- No

Still being treated?
- Yes

- High BP
- Aware
- Treated
- Not controlled
- No

BP controlled?
- Yes

- High blood pressure
- Aware
- Treated
- Controlled
(1) Have you been told that you have high blood pressure?
(2) Have you ever taken treatment for high blood pressure?
(3) Have you ever visited a physician because of high blood pressure?

The definitions for the rest of the categories are straightforward. Awareness will represent a composite of those people indicating that they knew that they had high blood pressure combined with those who indicated that they were under treatment. Treatment will be assessed in terms of "ever-treated" and "still-being-treated". Any modality of treatment will represent a positive response (dietary, chemical, physical or psychological treatment). Adequate control will require the diastolic blood pressure to be <90 mm Hg on the initial visit.

There are two additional categories of interest which are not illustrated in Figure 5.5. The most important of these categories is compliance. As indicated earlier, the data collected in this area will identify only about 50% of the non-compliers (163). This information will enable the formation of supplemental categories to investigate whether the degree of control differs from the good and poor compliance groups. This will not represent a part of the primary analysis. An additional area of secondary concern is that some people belonging to the category - "high blood pressure, aware but treatment stopped" - will now have normal blood pressure. The magnitude of this problem will be examined in a secondary analysis.
Several different estimation procedures will be used. Since
the procedure will be identical for all treatment categories,
one description will be needed. Furthermore, it was
shown in Chapter 3 that sampling strategies employing stratification
can be analyzed by combining estimates obtained within the separate
strata. Accordingly, the estimation formulae presented in this
section will be those to be used within a particular stratum.

The sampling procedure employed in the present design is a
three-stage selection procedure:

Stage 1: census sub-divisions

Stage 2: enumeration areas (E.A.)

Stage 3: households

Finally, all members of a particular household are examined. The
notation presented in Chapter 3 must be expanded for present uses:

\[ y_{ijk} = 1, \text{ if } \text{ the } k^{th} \text{ member of the } j^{th} \text{ household of the } \]
\[ i^{th} \text{ E.A. of the } i^{th} \text{ census sub-division belongs } \]
\[ \text{to the category under consideration} \]

\[ = 0 \text{ otherwise} \]

\[ N = \text{ number of census sub-divisions in the strata} \]
\[ n = \text{ number of census sub-divisions selected} \]
\[ M_i = \text{ number of E.A.'s in the } i^{th} \text{ census sub-divisions} \]
\[ m_i = \text{ number of E.A.'s selected from } i^{th} \text{ census sub-divisions} \]
\[ z_i = \text{ probability that } i^{th} \text{ census sub-divisions will be selected} \]
\[ M_0 = \sum_{i=1}^{N} M_i \]
\[ C_{ij} = \text{number of households in the } i^{th} \text{ E.A. of the } i^{th} \text{ census sub-division} \]
\[ c_{ij} = \text{number of households to be selected from the } j^{th} \text{ E.A. of the } i^{th} \text{ census sub-division} \]
\[ p_{ij} = \text{probability that the } j^{th} \text{ E.A. of the } i^{th} \text{ census sub-division will be selected} \]
\[ C_{io} = \sum_{j=1}^{M} c_{ij} \]
\[ D_{ijk} = \text{number of individuals in the } k^{th} \text{ household of the } j^{th} \text{ E.A. of the } i^{th} \text{ census sub-division} \]
\[ C_{ij} \]
\[ D_{ijo} = \sum_{k=1}^{M} D_{ijk} \]
\[ D_{o} = \text{total number of individuals in the population} \]
\[ \sum_{j=1}^{M} y_{ijk} \]
\[ y_{ijk} = y_{ijk}^+ \]

Two different sample estimators will be used to estimate the proportion of the population belonging to a particular class.

Justification of the first formula presented, can be found in Appendix II.

(1) Base - Whole Population:

\[ \hat{p}_{1} = \frac{1}{D_{o} \left( \sum_{i=1}^{n} m_{i} \right)} \sum_{i=1}^{n} \frac{m_{i}}{\sum_{j=1}^{m_{i}} \frac{y_{ij}}{z_{ij} \cdot p_{ij}}} \]

and \[ y(p_{1}) = \frac{1}{D_{o} \left( \sum_{i=1}^{n} m_{i} \right)^2} \sum_{i=1}^{n} \frac{m_{i}}{\sum_{j=1}^{m_{i}} \left( \frac{y_{ij}}{z_{ij} \cdot p_{ij}} - p_{1} \right)^2} \]

where \[ y_{ij} = \frac{C_{ij}}{C_{ij} \sum_{k=1}^{M} y_{ijk}} \]
(2) Base - Hypertensive Population

Estimators using the hypertensive population as a denominator are of the form: \( \frac{\text{number of hypertensives who are in class } C}{\text{number of hypertensives}} \).

They are ratio estimators.

Let \( x_{ijkl} \) = 1 if the individual is hypertensive
\[ = 0 \text{ otherwise} \]

\( y_{ijkl} \) = 1 if the individual is hypertensive and has another characteristic of interest
\[ = 0 \text{ otherwise} \]

Then, from formula 1, estimates of the total population in classes \( y \) and \( x \) will be:

\[
N_y = \frac{1}{D_0 \left( \sum_{i=1}^{n} \sum_{m_1}^{m_i} \right)} \sum_{j=1}^{n} \sum_{k=1}^{m_i} y_{ij} \]

and

\[
N_x = \frac{1}{D_0 \left( \sum_{i=1}^{n} \sum_{m_1}^{m_i} \right)} \sum_{j=1}^{n} \sum_{k=1}^{m_i} x_{ij} \]

and the ratio estimate will be: \( \hat{p}_2 = \frac{N_y}{N_x} \) with an estimated variance which can be found from formula 2 but instead of using \( y_{ijkl} \), use \( y'_{ijkl} = y_{ijkl} - \hat{p}_2 x_{ijkl} \).

Both estimates given above are slightly biased. An alternative variance estimate will be obtained using the jackknife technique (section 3.6).

The above methods will form the primary analysis. Several forms of secondary analysis will be employed. These will include:
(1) The use of more complex ratio estimates to allow for data adjustment based upon the observed prevalence of relevant socio-demographic information. Variance estimates would be calculated using the jackknife technique.

(2) Comparisons within defined geosocial regions.

(3) Investigation of attitudinal information to identify possible determinants of the quality of hypertension control. Techniques which could be used here include:

(a) correlations
(b) comparison of sub-groups
(c) regression, utilizing weighted least squares

(40, 41, 85).
6. CONCLUSIONS AND SIGNIFICANCE

This thesis has examined the many difficulties which present themselves when evaluating the quality of hypertension control in a community. The implications of this thesis are best illustrated by a consideration of the conceptual framework which underlies the document. This framework is summarized in Table 6.1.

Initial attention must be directed at establishing the need for evaluating the degree of hypertension control. This demonstration consists of two separate steps. First, the impact of hypertension on society and individuals must be examined. Then the possibility of, and advantages to, treating persons with hypertension must be established.

Once it is seen that hypertension control is a desirable objective, one must develop a model which could be used to monitor the quality of control in a specific community. A six-stage model is presented, which represents the steps required before an individual with hypertension can be successfully treated (Figure 4.1). Appropriate standards can easily be established against which present community efforts could be compared.

This model could be used as a foundation for several different types of evaluation proposals, some of which are discussed in section 4.7. This section concludes that the most effective evaluation proposal is a special-purpose survey during which, the survey team
Table 6.1: CONCEPTUAL FRAMEWORK FOR THE THESIS

(1) Justify the importance of this problem.

(2) Develop a model which can serve as a base for evaluating the degree of hypertension control.

(3) Determine the best type of evaluation proposal using this model.

(4) Decide upon the specific types of sampling and measuring procedures which should be used.

(5) Implement this design to assess the degree of hypertension control in the Province of Ontario.
would collect information on the treatment status of blood pressure levels of the populace. The measurement techniques should use standardized procedures. This stage in the development of the model is used to develop methodologic standards (Figure 4.1) against which the published literature is compared. It is found that no single study satisfies all the criteria.

The next stage, in the development of the model into a useful evaluation strategy, requires consideration of the specific sampling and measurement procedures which will be used. The sampling procedure uses a complex, stratified multi-stage probability scheme with the household as the basic unit of sampling. The blood pressure measurement employs repeated measurements on a Hawksley Random-zero Sphygmomanometer. Validated questionnaires will also be developed to obtain historical information. This stage in the design will be discussed further in a subsequent paragraph.

The last step, in implementing the evaluation procedure, involves a specific description of a study which will be used to evaluate hypertension control in the Province of Ontario. Eight special-purpose interviewers will be selected to examine 3,850 people over a one-year period. This study will be repeated at yearly intervals to assess any change in the quality of hypertension control. Several possible extensions of the basic design are discussed in section 5.

One of the most useful aspects of the present thesis, is the design corresponding to Step 4 of Table 6.1 At this stage, the design has great potential to be a portable package which could be
to assess the quality of hypertension control in many diverse settings. Such applications would require specification of population-specific factors such as: the target population, the sample size and the interviewer characteristics. The integration of these concrete factors with the model under consideration would be relatively straightforward. Situations where this package might be used include:

(1) A special project by a District Health Council, to assess the quality of hypertension control within their area of jurisdiction.

(2) A project by a Public Health Department utilizing public health nurses as interviewers.

(3) A cooperative project involving several Public Health Departments.

The use of a similar basic methodology would also improve the comparability among studies which otherwise might utilize conflicting methods of evaluation.

The significance of this thesis is three-fold. Firstly, the examination of strategies for the evaluation of hypertension control provides a firm foundation for subsequent evaluation research in this area. Secondly, the design that was presented in Chapter 5, will provide good quality, surveillance-style information describing the state of hypertension control in Ontario. This information is not available at present, but is definitely needed. The information would also provide suggestions of profitable areas for research aimed at improving hypertension control. Thirdly, the methodology described
here can be used in widely different circumstances. The use of a standard protocol will lead to more comparability data and a better understanding of how it is possible to improve the quality of hypertension control and, thus, to improve the health of society.
Appendix 1: METHODOLOGIC STANDARDS FOR SAMPLE SURVEY RESEARCH

Study: ____________________________________________

Investigator(s): ____________________________________

Methodologic Standards:

(1) Statement of Purpose:
   (a) stated clearly?
   (b) formulated prior to data collection?
   (c) substitution game?
      - if yes, is it justified?
   (d) does present survey data dredge previously
collected data?
   (e) list sponsoring agency
   (f) evaluation study?
      - if yes, do the questions asked representa content valid analysis of the evaluation?

(2) Target Population:
   (a) clear description?
   (b) specify exclusions

(3) Sampling Procedures:
   (a) ability to duplicate sampling procedure with precision?
   (b) was probability sampling used?
      - if no, - justify the use of alternative procedures
      - discuss potential biases in using this procedure
Appendix 1: Continued.....

- volunteer bias
- convenience sample bias

(c) was stratification used?
- if yes, define the criteria used to construct the strata
- justify the strata used
- describe the procedure used to collect the data used in the stratification procedure

(d) report the time of the study
- year(s)
- season
- length
- racial composition

(e) was it a design to assess change?
if yes, report the degree of overlap between successive samples
- discuss panel deterioration
- drop-outs
- interviewer variation

(4) Sample Size:
(a) was a sample size calculated prior to the field work?
if yes, were sufficient subjects actually examined?
Appendix 1: Continued....

(b) exclude non-responders in an appropriate manner from the study

(c) report the non-response rate

(d) compare non-responders and responders using available data

(5) Outcome Measurement:

(a) report measurement instruments employed

(b) were non-standard techniques employed?
   - if yes, they should be:
     - adequately described
     - adequately referenced
     - validated
     - available for examination

(c) the techniques should be:
   - standardized
   - objective
   - validated

(6) Analysis:

(a) report the formulae used to produce the population estimates?

   if yes, were the estimation formulae appropriate?

(b) are variance estimates calculated?

   if yes, were appropriate methods used?
   - the methods should be described
Appendix 1 : Continued.....

(c) Identify missing data

(d) Report the actual data not only p-values

(7) Interpretation:

(a) Restrict conclusions to the appropriate populations

(b) Discuss the effect of non-response on generalizability

(c) Consider other potential biases

(d) Consider alternative explanations for the data

(e) Discuss the implications of any "substitution game"

(f) Discuss the total cost of the survey

(g) Identify a contact who could provide additional information

Code:

S+  = satisfied in full
S+  = satisfied in part
S-  = not satisfied
DNA = does not apply
DK  = insufficient information to assess this standard
Appendix 2: A USEFUL PROPERTY OF SAMPLE SELECTION WITH PROBABILITY PROPORTIONAL TO SIZE

Consider a two-stage sampling procedure. First, select "n" primary units from a total of "N", sampling with replacement. This procedure will involve the independent drawing of primary units. Using the notation defined in Chapter 3, the probability of selecting the \( i^{th} \) primary unit, at each drawing will be given by \( z_i = \frac{M_i}{M_0} \). The second stage of sampling will be independent of the first stage. A simple random sample of size "\( m_i \)" will be selected from within the \( i^{th} \) primary unit. Since the first stage selection involves replacement, it is possible that the \( i^{th} \) unit could be selected more than once, say "\( t_i \)" times. In the event that a unit is selected more than once, a completely independent second stage sample will be selected.

The question to be addressed is: What values of "\( m_i \)" will ensure that each element of the population has an equal chance of being included in the sample? The answer is derived from the following lemmas:

**Lemma 1:**

Under the conditions listed above, the probability that element \( y_{ij} \) will be selected a total of "\( z \)" times into the sample is given by:

\[
P(y_{ij} \text{ selected } "z" \text{ times}) = \binom{n}{z} \left( \frac{z_i m_i}{M_i} \right)^z \left( 1 - \frac{z_i m_i}{M_i} \right)^{n-z}
\]
Proof:

If \( y_{ij} \) is in the sample "\( \ell \)" times, then the \( i^{th} \) cluster must have been selected at least "\( \ell \)" times. Using a theorem from elementary probability theory:

\[
P \left( y_{ij} \text{ selected } "\ell" \text{ times} \right) = \sum_{k=\ell}^{n} P \left( y_{ij} \text{ selected } "\ell" \text{ times} \mid i^{th} \text{ P.S.U. selected } "k" \text{ times} \right) \cdot P \left( i^{th} \text{ P.S.U. selected } "k" \text{ times} \right)
\]

Now, the distribution of the "\( t_i \)" is multinomial. It is easily shown that:

\[
P \left( i^{th} \text{ P.S.U. selected } "k" \text{ times} \right) = \binom{n}{k} z_i^k (1-z_i)^{n-k}
\]

Within the \( i^{th} \) cluster, the element \( y_{ij} \) has a probability \( \left( \frac{m_i}{M_i} \right) \) of being included in sample, each time the \( i^{th} \) cluster is drawn. Since the selection of second stage elements is done independently if the \( i^{th} \) cluster is selected more than once, it follows that

\[
P \left( y_{ij} \text{ selected } "\ell" \text{ times} \mid i^{th} \text{ P.S.U. selected } "k" \text{ times} \right) \text{ has a binomial distribution, namely:}
\]

\[
P \left( y_{ij} \text{ selected } "\ell" \text{ times} \mid i^{th} \text{ P.S.U. selected } "k" \text{ times} \right) = \binom{k}{\ell} \left( \frac{m_i}{M_i} \right)^\ell \left( 1 - \frac{m_i}{M_i} \right)^{k-\ell}
\]

Combining (2), (3), and (4), one gets:
Lemma 2:

Under the above conditions,

\[ P(\text{y}_{ij} \text{ selected at least once}) = 1 - \left[ 1 - \frac{z_i m_j}{M_i} \right]^n. \]

Proof:

\[ P(\text{y}_{ij} \text{ selected at least once}) = 1 - P(\text{y}_{ij} \text{ not selected}) \]

\[ = 1 - \binom{n}{0} \left( \frac{z_i m_j}{M_i} \right)^0 \left( 1 - \frac{z_i m_j}{M_i} \right)^{n-0} \]

by Lemma 1

\[ = 1 - \left[ 1 - \frac{z_i m_j}{M_i} \right]^n. \] QED.
Lemma 3:

Under the above conditions,

\[ E (\# \text{ times } y_{ij} \text{ selected}) = n \frac{z_i m_j}{M_1} \]

Proof:

The distribution of (\# of times \( y_{ij} \) selected) is binomial with

\[ P = \left( \frac{z_i m_j}{M_1} \right) \]

therefore, \( E (\# \text{ times } y_{ij} \text{ selected}) = n \frac{z_i m_j}{M_1} \) QED.

Now, the above three lemmas can be used to prove the following result.

Theorem:

Under the previously specified conditions, a necessary and sufficient condition that all elements of the population have an equal probability of selection into the sample is:

\[ \frac{z_i m_j}{M_1} = k \quad i=1...N. \]

In the case of sampling proportional to size, this simplifies to:

\[ m_i = k' = kM_0 \quad i=1...N. \]

Proof:

Necessary:

By Lemma 2, \( P (y_{ij} \text{ selected at least once}) = 1 - \left( \frac{z_i m_j}{M_1} \right)^n \).

Thus, to have equal probability of selection, we must have:

\[ 1 - \left( 1 - \frac{m_i z_j}{M_1} \right)^n = 1 - \left( 1 - \frac{m_j z_i}{M_j} \right)^n \quad i, j = 1...N. \]

or \[ \frac{m_i z_j}{M_1} = \frac{m_j z_i}{M_j} \quad i, j = 1...N \]

\[ \Rightarrow \frac{z_i m_j}{M_1} = k \quad i=1,...N. \] QED
Sufficient:

This follows immediately from Lemma 2.

In the case of sampling proportional to size, \( z_i = \frac{M_i}{M_0} \)

\[
\frac{m^*_i}{M_i} = \frac{m_i}{M_0} = k \quad i=1\ldots N.
\]

\[\Rightarrow m_i = kM_0 = k' \quad i=1\ldots N.\]

QED
Appendix 3: Procedure for Enumerating the Households in an Enumeration Area

E.A. = Enumeration area determined by census

Dwelling:

1. Is a set of living quarters in which a person or group of persons reside or could reside.

2. It is structurally separate from the living quarters of other dwellings.

3. Has a private entrance outside the building or a private entrance from a common hall or stairway inside the building. The entrance must be one which can be used without passing through the living quarters of another dwelling.

In the majority of cases, a dwelling is a house or an apartment. It may also be a motel unit, house trailer, etc. if used as living quarters.

Collective Dwelling:

Is a dwelling in which a large number of persons are likely to reside. Examples of collective dwellings are: hotels, motels, hospitals, institutions, guard-houses, work-camps, all jails and missions, or nursing homes, home of a religious order or a business establishment.

Introduction:

The main purpose of listing is to make sure every dwelling in the test area is covered so that it could be used for selecting a sample.
Appendix 3: Continued.....

How to Plan Your Route:

The boundary of your E.A. is outlined on your map in red and each block in blue.

Where a road or a street forms the boundary between two blocks only the dwelling on side of the road or street within the boundary of that block are to be listed under that block number. Plan your route in such a way that in built up (or urbanised) area 5:

1. Blocks are enumerated in ascending numerical order.
2. You always begin at one corner of the block and proceed around it in a clockwise direction.
3. Canvass one side of the street then the other.

Example:

In Typical Rural Areas:

1. Start your route at one corner of your E.A. and proceed if possible, in a clockwise direction.
2. Canvass both sides of each road, crossing back and forth as you come to each dwelling but remain within your E.A.

Example:
Appendix 3: Continued.....

You will be provided with the map of the selected E.A. and a form to enter the address or the description of the dwelling. Example of form:

<table>
<thead>
<tr>
<th>Listing No.</th>
<th>Description</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>001</td>
<td>2-story aluminum siding veranda E side</td>
<td>Con. II Lot 10</td>
</tr>
<tr>
<td>002</td>
<td>Tar paper bungalow surrounded by high hedge</td>
<td>Con. II Lot 16</td>
</tr>
<tr>
<td>003</td>
<td>Grey stucco attached to post office</td>
<td>Con. III Lot 2</td>
</tr>
<tr>
<td>004</td>
<td>Red brick bungalow south of 001</td>
<td>Con. III Lot 5</td>
</tr>
<tr>
<td>005</td>
<td>3 River Road</td>
<td></td>
</tr>
<tr>
<td>006</td>
<td>5 River Road</td>
<td></td>
</tr>
<tr>
<td>007</td>
<td>7 River Road</td>
<td></td>
</tr>
<tr>
<td>008</td>
<td>9 River Road</td>
<td></td>
</tr>
<tr>
<td>009</td>
<td>X General Hospital</td>
<td></td>
</tr>
</tbody>
</table>

**Importance of Your Map:**

You will be provided with the most up-to-date map available. However, some corrections might still be necessary. There might be a new road which is not shown on your map or a road or street that no longer exists, or the name of an existing street has changed. Whenever any change is discovered, correct the map, making your changes distinct. Your map will be your most important aid in getting a complete listing of the area. Make sure you are able to read and understand your map before you start.
Listing Procedures:

(1) Use your preplanned route to find and list every dwelling within your E.A. with a minimum amount of travelling. Indicate by arrowheads (>>>) the route you plan to follow. See examples above.

(2) Examine every structure from outside for signs of a dwelling or additional dwellings within (e.g. door bells, mail boxes, side entrance, stairs at the rear, etc.).

(3) Ask at stores, garages, restaurants, schools, churches, etc. to determine if there might be living quarters within above or behind.

(4) In rural areas, look for telephone wires, trails, mail boxes, etc. which may lead you to a dwelling not visible from the road.

Listing Order Within Buildings That Have More Than One Dwelling:

(1) List numbered apartments in numerical order and lettered apartments in alphabetical order.

(2) List unnumbered or unlettered apartments by outer description and in order of: from bottom to top; left side of floor before right; front before rear.

Do not canvass collective dwellings but mark them down on the map with an "X" so that we would be sure that a single dwelling has not been missed. See examples of collective dwellings above.
Appendix 3: Continued.....

Completing Your Listing Form:
The forms you are required to do a listing, will resemble the one described above. Enter the listing number, description and address according to the titles of the column. Your listing number and the number you enter on the map should agree.

Dwelling Within Commercial Buildings:
Many commercial buildings, churches, schools, etc., contain living quarters, therefore, enquiries must be made and living quarters, if they exist, must be listed.

Several Dwellings Within One Structure:
Where there is external evidence that a building contains more than one dwelling, make enquiries about all living quarters in the building. Assign each dwelling a separate listing number.
If there is any doubt about structural separateness, assign the building one listing number. Separateness will be determined at the time of interview.

Seasonal Dwellings:
In some areas, some dwellings are used only seasonally by persons with a usual place of residence elsewhere. If it can be positively established, that such dwellings are used seasonally only, do not list them. But if the seasonal dwellings are intermingled with permanent residence, assign individual listing numbers. Uniquely describe these on form provided (example above).
Appendix 4: PRELIMINARY DRAFT OF QUESTIONNAIRE TO OBTAIN HISTORICAL INFORMATION RELATED TO THE PROCESS MODEL

(1) Have you ever been told that you have high blood pressure or hypertension: ☐ Yes ☐ No ☐ Don't Know

If yes, (A1) Who told you that your blood pressure was too high?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Don't Know</th>
</tr>
</thead>
<tbody>
<tr>
<td>family doctor</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>emergency room</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>dentist</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>chiropractor</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>podiatrist</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>&quot;eye doctor&quot;</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>friend</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>other (specify)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Obtain name and address, if possible:

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

(A2) Why did you visit this person?

☐ routine visit
☐ worried about high blood pressure
☐ other (specify) __________________________

(A3) When were you first told about your high blood pressure?

____________________(date)
Appendix 4: Continued.....

(2) Have you ever visited a physician because of high blood pressure?

☐ Yes ☐ No ☐ Don't Know

If yes:

(B1) Can you tell me his/her name and specialty?

__________________________________________________________

__________________________________________________________

(B2) When did you first see this physician? _____________(date)

(3) Have you ever, at any time, had any treatment prescribed specifically for high blood pressure?

☐ Yes ☐ No ☐ Don't Know

If no:

Go to Question 5....

If yes:

(C1) Did you ever take this treatment?

☐ Yes ☐ No ☐ Don't Know

(C2) Are you now taking any treatment for high blood pressure?

☐ Yes ☐ No ☐ Don't Know

If no:

(C2.1) When did you last take any treatment? _____________

(C2.2) Why did you stop taking this treatment? _____________

(C2.3) Can you tell me what type of treatment this was?

__________________________________________________________

Go to Question (4)
Appendix 4: Continued....

If yes:

(C2.1) Does this treatment involve:

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Don't Know</th>
<th>Specify</th>
</tr>
</thead>
<tbody>
<tr>
<td>drugs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>diet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>counselling</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>relaxation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(yoga, transen-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>dental meditation)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>other</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(C2.2) Many people have problems remembering to follow a treatment plan. Would you say that you have any trouble remembering to take this treatment.

Never  Occasionally  Often  Always

(C2.3) If sometimes you have problems remembering your treatment, are there any specific things which make it harder? Like:

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Don't Know</th>
<th>Specify</th>
</tr>
</thead>
<tbody>
<tr>
<td>side effects</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cost</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>don't like the treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>embarrassment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>others</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(C2.4) Do you do anything special to remember your treatment?

□ Yes  □ No  □ Don't Know

If yes, specify ___________________________________________
(C2.5) In the last week, could you estimate the proportion of your pills you remembered to take? ____________

(4) Do you still see a physician about high blood pressure?

☐ Yes  ☐ No  ☐ Don't Know

If no:

(D.1) When did you last see a physician about high blood pressure?

_____________________________(date)

(D.2) Why did you stop seeing this physician?

__________________________________________________________

If yes:

(D.1) When did you last see your doctor about high blood pressure?

_____________________________(date)

(D.2) When is your next appointment scheduled?

_____________________________(date)  ☐ None scheduled

(D.3) How many times a year do you see your doctor about your high blood pressure?

☐ <1  ☐ 1  ☐ 2-5  ☐ 6+

(D.4) Let us suppose that you have just seen your doctor, about your high blood pressure. How would you make a return appointment?

☐ made before I leave the office

☐ the doctor's office will call me later

☐ I will call the office

☐ other (specify: ____________________________ )
Appendix 4: Continued....

(5) Now, I would like you to remember back to the time that you first discovered that you had high blood pressure. Can you tell me if you had any of the following tests:

- overnight hospital stay
- kidney x-rays (IVP)
- blood tests
- urine tests
- gallbladder x-ray
- chest x-ray
- electrocardiogram (EC)
- heart catheterization
- arterial x-rays
- exercise testing
- psychiatric examination

(6) Can you tell me if you are taking any of the following medications?

- antibiotics
- antacids
- tranquillizers
- water pills (diuretics)
- heart pills
- hormones
- birth control pills
Appendix 4: Continued.....

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Don't Know</th>
</tr>
</thead>
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<tr>
<td>estrogen</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>antidepressants</td>
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<td></td>
</tr>
<tr>
<td>anti-asthma medication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>steroids (cortisone)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If yes, can you supply the name of the medication?

_________________________  ___________________________
Appendix 5: PRELIMINARY DRAFT OF QUESTIONNAIRE ON KNOWLEDGE ABOUT HYPERTENSION

(1) People with high blood pressure often feel quite well even though they are not receiving treatment.
Circle the correct answer: True False

(2) For most people with high blood pressure it is possible to find a cause and cure the high blood pressure with surgery.
Circle the correct answer: True False

(3) In time, high blood pressure will go away on its own.
Circle the correct answer: True False

(4) About how many people taking pills for high blood pressure have "side-effects" which make them feel unwell?
Check (✓) the best answer:
(a) all
(b) most
(c) about half
(d) a few
(e) none
Appendix 5: continued

(5) High blood pressure itself often makes you feel sick,
Circle the correct answer: True False

(6) You can best help in bringing your blood pressure back to normal by,
Check (√) the best answer:
(a) resting and sleeping a lot,
(b) cutting down on exercise and quitting smoking,
(c) taking your blood pressure pills as prescribed,
(d) doing nothing because there is nothing you can do.

(7) Untreated high blood pressure may cause,
Check (√) the best answer:
(a) stroke
(b) diabetes mellitus ("sugar" diabetes)
(c) pneumonia
(d) insomnia (difficulty sleeping)
(e) none of these
Appendix 5:......continued

(8) Untreated high blood pressure may lead to,

Check (✓) the best answer:

(a) damage to the heart
(b) damage to the eyes
(c) damage to the kidneys
(d) all of these
(e) none of these

(9) About what proportion of all adults have high blood pressure,

Check (✓) the best answer:

(a) 8 of every 10 adults
(b) 6 of every 10 adults
(c) 2 of every 10 adults
(d) 2 of every 100 adults

(10) For those people whose high blood pressure is properly treated, the risk of damage from the high blood pressure is,

Check (✓) the best answer:

(a) ten times less
(b) seven times less
(c) three times less
(d) not changed
Appendix 5: continued

We would like to ask your opinion regarding the following questions.

(11) First, we'd like to know how serious a problem you think high blood pressure is IN GENERAL.

Would you say it is:

Not a problem? .................. ☐
A mild problem? .................. ☐
A serious problem? ............... ☐
A very serious problem? .......... ☐

(12) Below are the names of several medical conditions. For each one please check (✓) in the space provided whether you think it is usually less serious than high blood pressure, about the same seriousness as high blood pressure, or more serious than high blood pressure.

<table>
<thead>
<tr>
<th>Medical Condition</th>
<th>Less Serious</th>
<th>About the same</th>
<th>Less Serious</th>
<th>Don't Know</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Pneumonia</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>(b) Diabetes</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>(c) Flu</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>(d) Arthritis</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>(e) Asthma</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
Appendix 5: ......continued

(13) If a person has high blood pressure, how likely do you think it would be that any serious health problem would result from it?
Would you say:

- Not likely ........... [ ]
- Probably ........... [ ]
- Definitely ........... [ ]
- Don't know ........... [ ]

(14) If a person did have high blood pressure, how much do you think he or she would benefit from medical treatment?
Would you say:

- A little ........... [ ]
- Some ............... [ ]
- A lot ............... [ ]
- Don't know ........... [ ]

(15) Do you think a person with high blood pressure should see a doctor regularly?

- No ................. [ ]
- Yes ................. [ ]
- Don't know ........... [ ]
Appendix 5: continued

(16) What kinds of long range benefits, if any, do you think people with high blood pressure should expect from receiving medical treatment for high blood pressure?

<table>
<thead>
<tr>
<th></th>
<th>NO</th>
<th>YES</th>
<th>DON'T KNOW</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Fewer colds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(b) Better vision</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(c) Longer life</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(d) Less chance of getting cancer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(e) Less chance of getting heart disease</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 5: continued

(17) Do you agree or disagree with the following statements?

<table>
<thead>
<tr>
<th>(a) High blood pressure is considered alright after middle age</th>
<th>Agree</th>
<th>Disagree</th>
<th>Don't Know</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) If a person has high blood pressure, it won't hurt to keep busy and active</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(c) Strokes are commonly caused by high blood pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(d) When a person gets excited his blood pressure goes up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(e) High blood pressure runs in the family</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(f) A person with high blood pressure should see a doctor regularly</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(18) In comparison with other people your age, how likely do you think you are to develop high blood pressure?

Less likely ............ □
About the same ......... □
More likely ............ □
(19) Which of the following are likely causes of high blood pressure?

<table>
<thead>
<tr>
<th>Cause</th>
<th>Definite</th>
<th>Possible</th>
<th>Not A</th>
<th>Not Sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emotional pressure, worry</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overweight</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improper diet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatty foods - cholesterol</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over exertion</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Heredity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Too much salt</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hardening of the arteries</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pork</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of exercise</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Old age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(20) (a) What symptoms does high blood pressure produce?

[Blank lines for answers]
(20) (b) How likely are the following to be caused by high blood pressure?

<table>
<thead>
<tr>
<th>Condition</th>
<th>Very Likely</th>
<th>Likely</th>
<th>Unlikely</th>
<th>Very Unlikely</th>
<th>Not Sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart Attacks</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headaches</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nervousness, &amp; Irritability</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue, Tiredness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kidney Problems</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blurred Vision</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fainting</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Hardening of the Arteries</td>
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<tr>
<td>Nose Bleed</td>
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<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Anemia</td>
<td></td>
<td></td>
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<td></td>
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<td>Hepatitis</td>
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<td>Arthritis</td>
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<td></td>
</tr>
<tr>
<td>Asthma</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
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</tbody>
</table>
Appendix 6: PRELIMINARY DRAFT OF A QUESTIONNAIRE ABOUT HEALTH ATTITUDES

The purpose of this questionnaire is to provide some information about how you feel about medicine and medical treatment.

(1a) Compared with your parents' generation, are people today:

☑ healthier
☑ not as healthy
☑ not much different
☑ not sure

(1b) If you feel people are less healthier, can you tell us why?

(2a) People can find out about health and medicine from many sources.

For each of the following, can you indicate how important they are to you in providing such information.

<table>
<thead>
<tr>
<th>Source</th>
<th>a lot</th>
<th>some</th>
<th>not at all</th>
<th>never use</th>
<th>not sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>own doctor at clinic</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>public service messages</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>magazines</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>newspapers</td>
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<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>T.V. news stories</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>publications from Blue Cross, etc.</td>
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<td>☐</td>
<td>☐</td>
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<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>T.V. advertising</td>
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<td>☐</td>
<td>☐</td>
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Appendix 6: Continued....

<table>
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<th>not at all</th>
<th>never use</th>
<th>not sure</th>
</tr>
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<td>school</td>
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</tr>
<tr>
<td>pharmacist</td>
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</tr>
<tr>
<td>union</td>
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<td></td>
</tr>
<tr>
<td>employer</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>other</td>
<td></td>
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</tr>
</tbody>
</table>

(specify: __________________________)

(2b) How reliable do you think information from each of these sources would be?

<table>
<thead>
<tr>
<th>Source</th>
<th>very reliable</th>
<th>reliable</th>
<th>unreliable</th>
<th>very unreliable</th>
<th>not sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>own doctor at clinic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>public service messages</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>magazines</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>newspapers</td>
<td></td>
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Appendix 6: Continued...

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(specify: __________________________)  

In the next set of questions, we would like to know how you feel about illness in general. There are no "right" answers; we would just like to know exactly how you feel. Please indicate whether you agree or disagree with the statement by checking the box under "Agree" or "Disagree". If you have no opinion, please check the box under "Don't Know".

(3) In general, illness makes a person a burden on the other folk around him.  

(4) It is risky to take drugs, even when prescribed by a doctor.  

(5) It is usually not the patient's fault that he is sick.  

(6) When a doctor prescribes drugs for someone, it must be because he is sick.  

(7) Many people act sicker than they are just in order to get sympathy.  

(8) People who are healthy should not have to take drugs every day.
Appendix 6: Continued.....

<table>
<thead>
<tr>
<th>Number</th>
<th>Statement</th>
<th>Agree</th>
<th>Disagree</th>
<th>Don't Know</th>
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<tr>
<td>(9)</td>
<td>People who are sick have a right to expect that others will help them.</td>
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<tr>
<td>(10)</td>
<td>Medicines prescribed by a doctor usually are very helpful.</td>
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<td>(11)</td>
<td>One trouble with being sick is that you have to depend on other people.</td>
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<td>(12)</td>
<td>People should only take drugs when they are sick.</td>
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<tr>
<td>(13)</td>
<td>In general, people demand too much from a person who is ill.</td>
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<tr>
<td>(14)</td>
<td>Drugs, even when prescribed by a doctor, usually do more harm than good.</td>
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<tr>
<td>(15)</td>
<td>In general, people make allowances for the fact that a sick person is not able to carry out his normal responsibilities.</td>
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Appendix 7: PRELIMINARY DRAFT QUESTIONNAIRE ON HEALTH BEHAVIOUR

1) Do you have a regular family doctor?

Yes ☐ No ☐

If yes, could you record his name and address:


2) How long has it been since you visited a:

Physician

Dentist

Optometrist

Public Health Nurse

Chiropractor

Social Worker

Occupational Health Clinic

3) a. During the past month have you received any medical care for any reason from a doctor or at a hospital or clinic?

Yes ☐ No ☐ (if no, go to Q. 6b)
IF YES,

b. Where did you receive MOST of your medical care - was it:
   A hospital clinic? ................. □
   A neighbourhood health centre? ...... □
   An emergency room? ................. □
   A private physician? ................. □
   At your place of employment? ....... □
   Other, please specify: ______________________________

c. In total, about how many times have you seen or talked to a doctor during the past 2 weeks?
   [ ] times

d. During the past 6 months, have you been a patient overnight in a hospital?
   No ............ □
   Yes .......... □
   Don't know .. □

IF YES, □

e. 1. Taking the past 6 months in total, how many nights did you spend in a hospital?
   □□ nights

   2. How many different times were you a patient overnight in a hospital during the past 6 months?
      □□ times
Appendix 7: continued

3. Name of hospital(s) __________________________

4. In general, how satisfied have you been with the care you have received when seeking medical help?

   (INTERVIEWER: Read choices and check (✓) the one chosen).

   Very satisfied............................ □
   Somewhat satisfied..................... □
   Somewhat dissatisfied.................. □
   Very dissatisfied...................... □
   Not applicable (no medical care)...... □

5. People sometimes give the following reasons for not seeing a medical doctor. Have any of these reasons ever kept you from seeing a doctor? "I'll read the list and ask you to please say "yes" if the reason has kept you from seeing a doctor.

   (INTERVIEWER: Please check (✓) appropriate box for each reason)

   (a) You don't like to bother the doctor
       unless it's necessary .................... □ □ □

   (b) You were too busy, you didn't have
       time ...................................... □ □ □

   (c) You have difficulty finding transportation
       to his office or clinic ................... □ □ □
Appendix 7: ....continued

<table>
<thead>
<tr>
<th></th>
<th>NO</th>
<th>YES</th>
<th>DON'T KNOW</th>
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<tr>
<td>(d) You have to wait too long in the doctor's office or clinic</td>
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<tr>
<td>(e) You didn't think the doctor could help you any</td>
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<tr>
<td>(f) It might be painful, the doctor might hurt you</td>
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<td>(g) You don't like the doctor to examine you with your clothes off</td>
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<td>(h) The doctor might want to put you in the hospital</td>
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<td>(i) You didn't know any really good doctor</td>
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<td>(j) Doctor's offices or clinics are not open when you can go</td>
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<td>(k) Is there any other reason you have had for putting off seeing the doctor</td>
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(Please specify) __________________________________________

6. (a) During the last year, what is the longest period in which you took (have taken) any kind of medicine?

Length of time in months: __________________
Appendix 7: ....continued

(b) Now think about that one medication you have taken for the longest period of time.
How often did the doctor tell you to take the medicine each day?

______________ times a day

(c) During the time you took (have been taking) this medication how often during a typical week did you skip (miss, fail to take) the daily medication?
Number of times a week medication not taken __________

7. (a) Are (were) family members aware of your taking this medicine?

   No .............   □   → (Go to Question 8)

   Yes ............. □

   Don't know .... □

(b) If answered "yes" to question 7(a) does (did) one or more of these family members help remind you to take the medicine?

   No ............. □

   Yes ............. □

   Don't know .... □
Appendix 7: continued

8. Compared with people your own age, how would you rate your health?

   Poor ........... □
   Fair ........... □
   Good ........... □
   Excellent .... □

ANSWER QUESTION 9 ONLY IF YOU ARE MARRIED:

9. Compared with your wife, how would you rate your health?

   Poor ........... □
   Fair ........... □
   Good ........... □
   Excellent .... □

10. Compared with people with whom you live, how would you rate your health?

    Poor ........... □
    Fair ........... □
    Good ........... □
    Excellent .... □
    Live alone .... □
Appendix 7: continued

11. How much do you worry about your health?

   Never ............ □
   Rarely ............ □
   Occasionally ...... □
   Frequently ....... □

THE NEXT FEW QUESTIONS REFER TO THE TWO WEEKS ENDING THIS PAST SUNDAY.

12. (a) During those 2 weeks, did you stay in bed because of illness or injury?

   No ...... □
   Yes ...... □

   (b) During those 2 weeks, how many days did illness or injury keep you from work?

   _______ work days lost

   IF ONE OR MORE WORK DAYS LOST, on how many of these days lost from work did you stay in bed all or most of the day?

   _______ days
Appendix 7: .......continued

12 (c) NOT COUNTING the day(s) in bed or lost from work, were there any (other) days during those 2 weeks that you cut down on the things you usually do because of illness or injury?

No ....... [ ]

Yes ....... [ ]

IF YES, how many days? ________ days
Appendix 8: PRELIMINARY DRAFT OF THE HEALTH LOCUS OF CONTROL QUESTIONNAIRE

(1) If I get sick, it is my own behavior which determines how soon I get well again.

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<thead>
<tr>
<th>Strongly Disagree</th>
<th>Moderately Disagree</th>
<th>Slightly Disagree</th>
<th>Slightly Agree</th>
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(2) No matter what I do, if I am going to get sick, I will get sick.

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<thead>
<tr>
<th>Strongly Disagree</th>
<th>Moderately Disagree</th>
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(3) Having regular contact with my physician is the best way for me to avoid illness.

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Moderately Disagree</th>
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<th>Slightly Agree</th>
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(4) Most things that affect my health happen to me by accident.

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<th>Strongly Disagree</th>
<th>Moderately Disagree</th>
<th>Slightly Disagree</th>
<th>Slightly Agree</th>
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(5) Whenever I don't feel well, I should consult a medically trained professional.

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<th>Strongly Disagree</th>
<th>Moderately Disagree</th>
<th>Slightly Disagree</th>
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(6) I am in control of my health.

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<th>Strongly Disagree</th>
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<th>Slightly Agree</th>
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(7) My family has a lot to do with my becoming sick or staying healthy.

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<th>Strongly Disagree</th>
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Appendix 8: Continued......

(8) When I get sick I am to blame.

- Strongly Disagree
- Moderately Disagree
- Slightly Disagree
- Slightly Agree
- Moderately Agree
- Strongly Agree

(9) Luck plays a big part in determining how soon I will recover from an illness.

- Strongly Disagree
- Moderately Disagree
- Slightly Disagree
- Slightly Agree
- Moderately Agree
- Strongly Agree

(10) Health professionals control my health.

- Strongly Disagree
- Moderately Disagree
- Slightly Disagree
- Slightly Agree
- Moderately Agree
- Strongly Agree

(11) My good health is largely a matter of good fortune.

- Strongly Disagree
- Moderately Disagree
- Slightly Disagree
- Slightly Agree
- Moderately Agree
- Strongly Agree

(12) The main thing which affects my health is what I myself do.

- Strongly Disagree
- Moderately Disagree
- Slightly Disagree
- Slightly Agree
- Moderately Agree
- Strongly Agree

(13) If I take care of myself, I can avoid illness.

- Strongly Disagree
- Moderately Disagree
- Slightly Disagree
- Slightly Agree
- Moderately Agree
- Strongly Agree

(14) When I recover from an illness, it's usually because other people (for example, doctors, nurses, family, friends) have been taking good care of me.

- Strongly Disagree
- Moderately Disagree
- Slightly Disagree
- Slightly Agree
- Moderately Agree
- Strongly Agree
Appendix 8: Continued.....

(15) No matter what I do, I'm likely to get sick.

Strongly Disagree  Moderately Disagree  Slightly Disagree  Slightly Agree  Moderately Agree  Strongly Agree

(16) If it's meant to be, I will stay healthy.

Strongly Disagree  Moderately Disagree  Slightly Disagree  Slightly Agree  Moderately Agree  Strongly Agree

(17) If I take the right actions, I can stay healthy.

Strongly Disagree  Moderately Disagree  Slightly Disagree  Slightly Agree  Moderately Agree  Strongly Agree

(18) Regarding my health, I can only do what my doctor tells me to do.

Strongly Disagree  Moderately Disagree  Slightly Disagree  Slightly Agree  Moderately Agree  Strongly Agree
Appendix 9: CONSENT FORM

The Community Hypertension Detection Program has been explained to me and I understand that I have been selected to participate in this survey.

The purpose of the survey and the nature of the interview have been explained to me. I understand that in the course of the interview the following activities will occur:

(1) Measurement of the circumference of my arm.

(2) Measure of my blood pressure using a blood pressure cuff applied to my arm.

(3) The possibility of two return visits to measure subsequent blood pressure.

I understand that I may withdraw from this survey at any time.

The above points have been explained to me to my satisfaction and, understanding them fully, I hereby give my consent for the interviewer to proceed with the examination.

__________________________
Signature of Participant

__________________________
Printed Name of Participant

__________________________
Date

__________________________
Address of Participant

__________________________
Signature of Witness
Appendix 10: RELEASE OF INFORMATION FORM

I, __________________________________, hereby authorize the Community Hypertension Detection Program, to release all results of tests performed upon myself, to my personal physician,

Dr: __________________________________ of __________________________________

__________________________________________

Signature of Participant

__________________________
Date

__________________________
Printed Name of Participant

__________________________
Address of Participant

__________________________
Signature of Witness
Appendix 11: DERIVATION OF THE ESTIMATES PRESENTED IN CHAPTER 5

The sampling procedure is in three stages. The first two stages employ sampling with replacement. This will produce a series of independently selected Enumeration Areas. Further sampling within each E.A. will result in a series of independent estimates of the population total. This series can be used to obtain the estimators presented in Chapter 5. More specifically, the sampling technique employed involves obtaining a cluster sample from within the \(^{i}j^{th}\) E.A. From Cochran (24), an unbiased estimate of the population total within this E.A. is given by:

\[
y_{ij} = \frac{C_{ij}}{C_{ij}} \sum_{k=1}^{C_{ij}} y_{ijk}
\]

The probability of selecting this particular E.A. is: \(z_i \cdot p_{ij}\). Therefore, one unbiased estimate of the population total is: \(\frac{y_{ij}}{z_i p_{ij}}\).

Since each E.A. which is selected produces an independent estimate of the population total, these estimates can be used directly to provide the estimators of Chapter 5:

\[
p = \frac{1}{\sum_{i=1}^{n} m_i t_{i,j}} \sum_{i=1}^{n} m_i \frac{y_{ij}}{p_{ij} z_i}
\]

and \(v(p) = \frac{1}{\sum_{i=1}^{n} m_i} \left[ \sum_{i=1}^{n} \frac{m_i}{m_i - 1} \right]^{\frac{1}{2}} \sum_{i=1}^{n} m_i \frac{(\frac{y_{ij}}{p_{ij} z_i} - p)^2}{p_{ij} z_i} \)

The ratio estimators follow directly from these basic formulae as indicated in Chapter 5. The variance estimate of the ratio estimator follows directly from Page 313 of Cochran (24).
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