SAMPLE SELECTION BIAS IN INVESTIGATIONS OF MEDICAL TREATMENT NONCOMPLIANCE

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Janice Ramsay

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Abstract

In many investigations on noncompliance for medical recommendations, patients have the option to participate in the study. The question can therefore be raised about whether tendency to volunteer for medical research is consistent with tendency to comply with other medical requests related to treatment. In short, are volunteers or participants generally compliant relative to nonparticipants? This study examined past compliance for recommended follow-up appointments in patients who were requested to participate in a blood pressure screening program and in a subsequent study on compliance for hypertension regimens.

Patients were grouped on the basis of their responses to requests to participate and on hypertension status. The groups were: (1) unknown-nonparticipants; patients who would not attend blood pressure screening and, therefore, their hypertension status was unknown, (2) hypertensive-nonparticipants; patients who attended screening where they were found to require treatment for hypertension, but who refused follow-up, (3) normotensive-participants; patients who agreed to be screened, were found to be normotensive, and therefore did not require follow-up, (4) hypertensive-participants; patients who attended screening, were found to be hypertensive, agreed to attend follow-up and then did attend, and (5) hypertensive-nonattenders; patients who attended screening, were found to be hypertensive, agreed to attend follow-up but then did not attend. The follow-up program was offered in a subsequent hypertension compliance study.

Hospital records of the patients in the five groups were reviewed for the two year period of time which preceded the requests to participate. It was hypothesized that compliance for medical requests for follow-up visits (attendance compliance) would differ for participants and nonparticipants. A gradient of noncompliance for attendance was predicted across the groups in the following order, highest to lowest: unknown-nonparticipants, hypertensive-nonattenders, hypertensive-nonparticipants, hypertensive-participants, and normotensive-participants.

Analysis of variance demonstrated significant group differences in attendance compliance. A gradient effect was found when group means for attendance compliance were compared. Normotensive patients who agreed to participate in screening and hypertensives who agreed to participate in both screening and the subsequent hypertension compliance study had higher past attendance compliance rates than did nonparticipant groups. An exception in the predicted attendance compliance rates was found in a subgroup of hypertensive-nonparticipants; those who were screened but refused follow-up indicating that they would attend

their own physicians. This subgroup of nonparticipants had the highest past mean attendance compliance rate.

The data of the present study indicate that participants in a hypertension compliance study have higher past attendance rates and nonparticipants generally have lower rates. Thus, participants are compliant compared with nonparticipants.

The finding that participants are select for compliance, causes doubt to be cast on the outcomes of past research in which samples have consisted of volunteers. The implications of the results of this study upon future research were discussed and suggestions offered on avoiding or reducing sample selection bias.

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Sample Selection Bias in Investigations of Medical Treatment Noncompliance

Janice Ramsay

University of Manitoba

Medical treatment noncompliance refers to situations where individuals fail to adhere to medical recommendations. Although reported rates vary, noncompliance appears to be a frequent outcome of the patient care process. As a consequence, it is often suggested that noncompliance contributes to inefficiency within the health care system (Clinite & Kabat, 1976; Christensen, 1978; Nelson, Stason, Neutra, Solomon & McArdle, 1978). Concern about the effects of noncompliance has resulted in a recent increase in research on the topic (Haynes, Taylor, Snow, Sackett, Tugwell, Walsh, Hackett & Mukherjee, Note 1; Sackett & Haynes, 1976). A general review of noncompliance and related literature is attached (Appendix A).

The literature on noncompliance indicates that noncompliance is neither consistently related to sociodemographic factors nor to specific psychological profiles of patients (for example; Diamond, Weiss & Grynbaum, 1968; Krasnoff, 1977). Although results are not conclusive, some situational events seem to influence compliance. For example, the interpersonal climate of the clinical setting may contribute to noncompliance (Diamond et al., 1968). The literature also suggests that there are two major methodological problems that are inherent in noncompliance

investigations. The first is related to measurement of noncompliant behaviour and the second, the topic of this dissertation, is concerned with sample selection bias..

There are several typical sources from which samples are obtained in compliance investigations. The most common seems to be selection of patients from among those who are currently under care in defined clinical settings (for example, a private practice or outpatient department). Presumably, those who attend that particular private practice or outpatient department have some characteristics which distinguish them from those who would attend elsewhere. Further, patients in any practice or facility are different from those who, although symptomatic, do not consult health professionals and therefore remain unknown. A third group of patients, those who have failed to return for care as requested, are not under current care and therefore will not be selected for the sample.

While the three groups of patients described may differ along any number of dimensions, it is possible that one dimension is the degree of compliance: patients currently under care may be most compliant and patients never under health care may be least compliant. Thus, a sample of patients chosen for a typical study may be compliant relative to other patients.

The sample selection problem becomes more complex when patients chosen from the clinical setting have the option to participate or not participate in the study. Similarly, when

patients are actively recruited from the community they may or may not choose to volunteer. However, patients who volunteer to participate may do so because they are motivated toward the treatment under investigation.

When the central question of the study concerns noncompliance, the problem of sample selection bias is most critical. If such a sample consists of compliant individuals, investigation of matters related to noncompliance may be problematic. Once a study is in progress, patient attrition causes the sample to become more select. In short, the sample starts out being select and becomes more select as the investigation proceeds. This has special significance for noncompliance investigations since a tendency to be in or remain in the study may be correlated with measures on compliant behaviour.

Few studies have directly addressed questions related to sample selection bias. Usually, participants and nonparticipants are compared for sociodemographic factors or health status rather than for compliance. For example, in writing about the success of a blood pressure screening program, participants and nonparticipants were described in terms of age and earnings (Tilson, 1976). In another study, psychiatric patients who called for appointments but did not subsequently attend were identified as those who had nonspecific complaints, blamed others for their problems, were in crisis situations,

and/or wanted medications (Gould, Paulson & Daniels-Epps, 1970).

In a more direct test of differences between participants and nonparticipants, the outcomes of counseling appointments given to callers on a crisis line were assessed (Slaikeu, Tulkin & Speer, 1975). Those who attended appointments were given a questionnaire when they arrived at the clinic while those who did not attend and those who cancelled appointments were questioned later over the phone. Response rates varied. All attenders responded to the questionnaire; 93% of those who cancelled were contacted and 93% of them responded; only 68% of no-show callers were contacted and of them only 70% responded.

In response to questions about perceived helpfulness of crisis line volunteers, no-show callers thought the volunteers were not helpful whereas attenders thought the opposite. Ratings on helpfulness by those who cancelled appointments fell between the other two groups. Differences in questionnaire response rates may account in part for different evaluations of staff helpfulness and the potential reactivity of the questionnaire situation for attenders should not be overlooked. However, some support for the idea that attendance depends on patient perceptions of helpers comes from findings suggesting that the more positive the therapist's affective responses to a patient the more likely the patient will continue treatment (Shapiro, 1974).

Adami and Vegelius (1978) attempted to estimate the bias

introduced into investigations by nonvolunteers. The investigators had access to sociodemographic and some health data on groups of women with and without breast cancer. Comparisons could be made among those who agreed forthright, those who only agreed after several requests, and those who refused to respond to questions about breast cancer risk factors. Since nonparticipants and reluctant participants were not different for marital status and age but both were different from willing participants, it was concluded that the effects of nonparticipants on determination of risk factors could be estimated by data from reluctant participants. However, there were no differences between willing participants and reluctant participants for socioeconomic status and health history, suggesting that there might be as much or more similarity between these two groups than between reluctant- and nonparticipants. In fact, no matter how reluctant, they did agree to volunteer, whereas the others steadfastly refused to participate. Hence, reluctant participants may be more like willing volunteers than like nonparticipants.

Health history or health status rather than age or marital status seem to be relevant for comparing participants and nonparticipants since other studies have demonstrated primary differences between the two groups (Horwitz & Wilbek, 1971; Wilhelmsen, Ljunberg, Wedel & Werko, 1976; Criqui, Austin & Barrett-Connor, 1979). Two studies found higher mortality rates

among nonparticipants (Horwitz & Wilbek, 1971; Wilhelmsen et al., 1976). Causes of death were not specifically related to failure by nonparticipants to avail themselves of treatment offered (Wilhelmsen et al., 1976); however, those who refused to participate in Horwitz and Wilbek's (1971) tuberculosis vaccination program had higher mortality rates from tuberculosis than did participants. They had higher rates of death from other causes as well.

Findings of different rates of disease among nonparticipants and participants has recently been confirmed (Criqui et al., 1979). In that study, it was determined that those with risk factors present but no cardiovascular disease (the "worried well") were among the participants. However, among the nonparticipants were those without risk factors but who actually had cardiovascular disease.

Wilhelmsen et al. (1976) sent questionnaires related to coronary heart disease to men born in a specific 10-year time frame in a European city. Those who returned the questionnaire were asked to attend a screening program for coronary heart disease. Nonparticipants were those who did not respond to the questionnaire or to the request for screening. Comparisons on mortality, morbidity, and alcoholism were made between participant and nonparticipant groups. As mentioned above, mortality rates were significantly higher for nonparticipants. Furthermore, incidence of coronary death was higher for

nonparticipants although post mortem findings demonstrated no differences in degree of coronary atherosclerosis. The other finding was that there was a higher prevalence of chronic disease, including nonfatal myocardial infarction and alcoholism among nonparticipants.

For Wilhelmsen et al. (1976) the results were important on two points: (1) participants are not representative of the total population and, (2) there is no satisfactory explanation for differences in health status among participants and nonparticipants.

In summary, it appears that participants and nonparticipants are quite dissimilar in terms of some demographic factors and, importantly, in terms of health status. Nonparticipants tend to be older, have a higher socioeconomic status, greater incidence of chronic diseases, and higher mortality rates.

The question addressed by this dissertation concerns whether participants and nonparticipants are also different in their tendency to comply with medical recommendations. One study investigated differential compliance rates for participants and nonparticipants but the question was never satisfactorily resolved (Carr & Whittenbaugh, 1968). In that study, psychiatric outpatients were contacted and asked to participate in a "psychotherapy outcome study" done at a regularly scheduled appointment and taking several hours. The outcome measure was

volunteer status which was compared with MMPI, occupation, income, education, and psychiatric diagnosis, all of which had been obtained at earlier visits. The authors noted that there were fewer schizophrenics among the volunteers and therefore concluded that degree of psychopathology influences volunteering. Furthermore, they believed that the participants were more motivated about their treatment. Patient records obtained at some undisclosed time after the study were examined and they demonstrated that 57% of those who had volunteered had also continued therapy or been referred elsewhere. On the other hand, 69% of nonvolunteers had terminated early from the program.

The study is important since it suggests that nonparticipants are also noncompliant. Thus, participants may form a select sample with respect to compliance. However, it is possible that the contact with investigators and the consequences of a request to volunteer in this situation may have differentially affected later attendance in the clinic and, therefore, participants in general may not necessarily be more compliant. Conversely and equally important, prior experiences of patients in the clinic may have influenced tendency to volunteer.

It appears then, that it is still not known whether sample selection methods result in the creation of a compliant sample. Therefore, the present study was designed to examine prior compliance of participants and nonparticipants in a blood

pressure screening and treatment program. The assumption was that if there are no differences in prior compliance rates between participants and nonparticipants, then patients have not been selected on the basis of compliance. In this study, it was hypothesized that past compliance for attendance at appointments would predict later participation in a blood pressure screening program.

Method

Sample

Patients investigated in the present study were from among those who attended the Health Sciences Centre, Winnipeg, Canada. The Health Sciences Centre is a tertiary care hospital located in the inner city near the downtown core area as defined by the Social Planning Council of Winnipeg (Note 2). The hospital serves the entire city population but the ambulatory care departments (Primary Health Care, Outpatient Department, and the Emergency Department) are primarily utilized by the population from nearby areas. Therefore, patients attending the ambulatory care departments often come from an area marked by high incidences of unemployment, child neglect, and crime. In addition, the core area is the part of the city which is most heavily populated with Canadian Natives.

Patients who attended any of the ambulatory care departments during the period of March, 1978 to April, 1979 and who had a diastolic blood pressure of $\geq$ 100 mmHg recorded by

hospital staff, were requested to attend further blood pressure screening (a more detailed report of the screening protocol can be found in Appendix B). Participant status was determined on the basis of responses to the requests for screening and on hypertension status as determined by basal screening blood pressures. Five groups of participants and nonparticipants were formed:

1. Patients who would not attend blood pressure screening and therefore their health status and need for treatment were unknown (unknown-nonparticipant).

2. Patients who attended blood pressure screening, were found to require treatment for hypertension, but refused follow-up (hypertensive-nonparticipant).

3. Patients who agreed to participate in blood pressure screening, but were found to be normotensive after screening and therefore did not require follow-up (normotensive-participant).

4. Patients who attended blood pressure screening, were found to require treatment for hypertension, agreed to participate in follow-up and then did attend (hypertensive-participant).

5. Patients who attended blood pressure screening, were found to require treatment, agreed to participate in a follow-up program, but then did not attend (hypertensive-nonattender).

The patients in the five groups are different in terms of: (1) their health status or need for treatment and, (2) compliance

to various requests to participate in health programs. The primary difference between groups 3 and 4 is health status; and between groups 2, 4, and 5 is participant status: group 2 are nonparticipants, group 4 are participants, and group 5 are reluctant participants.

The size of the available study population was dependent on the screening program and varied by group (unknown-nonparticipant N=259, hypertensive-nonparticipant N=80, normotensive-participant N=268, hypertensive-participant N=115, and hypertensive-nonattender N=19).

Procedure

The type of compliant behaviour chosen to be investigated was attendance at recommended follow-up appointments, for two reasons. One was that attendance is the only common compliance measure which can be obtained for most patients. Since compliance for a patient varies across different treatment recommendations (Donabedian & Rosenfeld, 1964; Nelson, Stason, Neutra, Solomon & McArdle, 1978), it is essential to compare compliance along the same dimension. Thus, compliance for drug related recommendations cannot be compared with attendance compliance or with dietary compliance.

Attendance and volunteering to participate seem to be from the same behavioural domain. Both require the patient to present him/herself to the hospital by request of a health practitioner. Thus, attendance and volunteering, two behaviours the present

investigation expects to show are related, seem to be similar.

The second reason for studying attendance compliance was that attendance is routinely recorded for patients who have appointments. On the other hand, compliance for other recommendations may or may not be included in records and the method for measuring compliance varies across practitioners. For example, some practitioners may look for clinical signs of drug compliance and others may ask patients if they are drug compliant.

Attendance was investigated for the time prior to the screening request in order to control for the possibility that the request influenced later attendance for appointments. Hospital records of the patient's visits to the following departments were reviewed for a two year period preceding the screening request: Primary Health Care, Outpatient Department, and/or Emergency Department. These are the hospital departments from which recommendations for follow-up visits are made.

Not all patients in the five groups had previously attended a hospital department where they had been requested to make return appointments. In other words, in some cases there was no information on the critical measure, attendance compliance to earlier requests. It was decided that a minimum of three instances of physician-recommended return visits would be necessary for determining attendance compliance. To ensure uniformity, recommendations for follow-up visits were considered

for a two-year period prior to the date of screening contact. Thus, an ineligible patient would be one having fewer than three physician recommendations for follow-up in the two years prior to screening. A pilot review of charts had suggested that as many as 30% of the records would not have the required follow-up visits. The decision was made to randomly order and review charts sequentially from each of the groups until 40 cases per group were found. The exception was the hypertensive-nonattender group, with only 19 members, all of whom were included.

Each day 11 to 15 hospital records were reviewed on patients who had been randomly selected. Each medical visit was documented beginning with the visit nearest to two years preceding the date of screening and proceeding chronologically until the date of screening. The following information was noted: date of visit, patient's entrance complaint or reason for visit, blood pressure if available, any comment about hypertension or high blood pressure, diagnosis if given, occurrence of recommendation for follow-up, interval until the date of the follow-up visit, compliance for follow-up recommendation, and any pertinent written comments were taken verbatim. In addition, the following general information was obtained from the record: address, employment status, and casual blood pressure (recorded at the visit which precipitated referral to the screening program); date of birth; gender; and ethnic group (native or non-native). This information was

obtained for all patients whether or not they met the criterion of three follow-up visits. Data on patients not meeting the attendance criterion (noncases) were later analyzed to determine selection factors within this study.

For the purpose of this study, recommendations for follow-up visits consisted only of recommendations for visits with medical practitioners. Restricting the type of visit investigated assured uniformity in the study: most patients had recommended medical visits but few had visits recommended with other health professionals. In addition, attendance compliance may vary across health professionals in the same way that compliance varies across treatments, possibly because the categories of staff provide different treatments. Therefore, visits for laboratory or clinical investigations and visits with nurses, dieticians, dentists, and physiotherapists were excluded.

Some other data require explanation. Address provided the only consistent measure of socioeconomic status found in the chart and this was coded using specific geographic borders defining: (1) the core area of the city, (2) regions adjacent to the core area, and (3) all other regions. The core area, as defined in the present study[1] corresponded with the boundaries

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[1]The core area boundaries of the present study were: west on Portage Avenue to Maryland; north on Maryland and McPhillips to Mountain; and east on Mountain to the Red River. The downtown core area defined by the Social Planning Council was: west on York Street to Sherbrook; north on Sherbrook and Arlington to Burrows; and east on Burrows to the Red River. The fringe areas

used by the Social Planning Council of Winnipeg (Note 2). However, their boundaries were about five streets narrower in the north, one to five blocks narrower in the west, and three blocks wider in the south. In addition, the present study defined areas of urban decay (fringe area), most of which were in the inner city. The fringe areas corresponded to areas of social unrest that have been mapped by the Social Planning Council.

Employment status is routinely noted by the Health Sciences Centre on admission records of nonscheduled outpatient visits, including the Emergency Department. The employment status of the patient was obtained from the record for the date of the screening contact. Ethnic status is not always identified by those making entries in health records but patients who are North American Indian are often labelled. The records of the patients were searched for any reference to ethnic status. If none was found the patient was categorized as non-native.

Attendance compliance was expressed as a ratio: total appointments kept to total appointments recommended over the two year review period.

The general hypothesis stated earlier predicted that past compliance behaviour would be significantly related to current

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in the present study included: areas adjacent to the north, west, and south boundaries of the core area; the Ferry Road area; the east and west Wolseley district; the Stradbrook-Osborne area; the west Fort Rouge area at Pembina; and the areas near both the Redwood and Provencher bridges.

compliance. This hypothesis can now be stated in more specific terms for the five groups of participants and nonparticipants.

Hypotheses

1. Unknown-nonparticipants and hypertensive-nonattenders will have lower rates of compliance behaviour compared with normotensive-participants and hypertensive-participants.
2. The hypertensive-nonparticipant group is composed of those who would obtain follow-up care elsewhere and those who would not obtain any follow-up care. Therefore, rates of compliance behaviour will be higher than unknown-nonparticipants and lower than hypertensive-participants.

The two hypotheses imply a hierarchy or gradient of compliance across groups. Several additional hypotheses about health status differences among participants and nonparticipants, based on the larger literature (Appendix A) and on the literature related to participation and health status, were also tested.

3. Consistent with earlier studies, tendency to participate in screening will be greater among those with fewer chronic diseases.
4. Recommended visits will be better attended by patients making visits for serious diseases than for patients with less serious diseases.

Results

Cases Reviewed

In total, 393 patient charts were reviewed. The required 40 patients per group who met the three visit criterion were selected in the following groups: unknown-nonparticipant, normotensive-participant, and hypertensive-participant. All patient charts for hypertensive-nonparticipants and hypertensive-nonattenders were reviewed but only 34 and 13, respectively, met the selection criteria.

It was predicted that 30% of the records would not have the required number of recommended follow-up visits. The actual rates were as follows: unknown-nonparticipants 68.5%, normotensive-participants 53.5%, hypertensive-participants 51.8%, hypertensive-nonparticipants 56.4%, and hypertensive-nonattenders 31.6%.

The hypertensive-nonparticipants were patients who had been screened but for some reason did not agree to accept treatment. It appeared that this group had essentially two types of patients in it: one said that they would return to their private physicians for care (n=9) and the other often failed to complete screening or declined treatment without mentioning that they would consult a private physician (n=25).

Some descriptive statistics suggested that there might be substantial differences between the two subgroups of the hypertensive-nonparticipants. Rates of alcoholism, blood

pressure, and age were not alike. The hypertensive-nonparticipant noncompleters had a 32% rate of alcoholism, mean age of 41.8 years (standard deviation 14.2), and mean prescreening diastolic blood pressure of 107.6 mmHg (standard deviation 6.9). On the other hand, the hypertensive-nonparticipant completers had an 11% rate of alcoholism, mean age of 52.7 years (standard deviation 8.9), and mean prescreening diastolic pressure of 104.4 mmHg (standard deviation 5.1). Therefore, it was decided to subdivide the group. The hypertensive-nonparticipants were partitioned into completers of screening (n=9) and noncompleters (n=25).

Since early analysis had given evidence of noncomparability of the two subgroups of hypertensive-nonparticipants, it became apparent that all data analysis for hypothesis testing would have to be accomplished with six groups of markedly unequal sizes. Both parametric and nonparametric analyses were employed.

Comparison of the Six Groups

Attendance compliance. The attendance compliance ratio was determined by dividing the total attended recommended follow-up visits over the two year review period by total recommendations for follow-up. Total recommended visits ranged from three to 69 (mean 7.7 visits, standard deviation 7.5). A gradient of noncompliance for attendance was predicted across the groups in the following order, highest to lowest: unknown-

nonparticipants, hypertensive-nonattenders, hypertensive-nonparticipants, hypertensive-participants, and normotensive-participants. Since the Cochran and Bartlett-Box tests demonstrated homogeneity of variances among the unequal sized groups, analysis of variance was used to determine if there were group differences for attendance compliance (F=2.33; df=5, 161; p<0.05). A post-hoc comparison appropriate for groups of unequal sizes was the Least Significant Difference procedure (Kirk, 1968) and this procedure was used in all post-hoc comparisons. It was determined with post-hoc comparisons that hypertensive-nonparticipant completers and hypertensive-participants were significantly different from hypertensive-nonparticipant noncompleters and unknown-nonparticipants (p<0.05). Table 1 shows the summary table for the analysis of variance and below it group means and standard deviations for attendance compliance ratios.

Occurrence of chronic disease. It was hypothesized that those patients who participated in screening would have fewer chronic diseases. Of the six groups, there were two that had no screening or only part screening. If the hypothesis is confirmed it could be expected that unknown-nonparticipants and hypertensive-nonparticipant noncompleters would have higher frequencies of chronic diseases.

For the two-year review period, all diagnoses indicating chronic disease were tallied. Each chronic disease was counted

Table 1

Analysis of Variance

Summary Table

Attendance Compliance by Group

Source	df	Sum of Squares	Mean Squares	F	Probability
between groups	5	0.8163	0.1633	2.33	<0.05
within groups	161	11.2988	0.0702		
total	166	12.1151			

Group	n	Mean Attendance Compliance	Standard Deviation
hypertensive-nonparticipant noncompleters	25	0.5578	0.3019
unknown-nonparticipant	40	0.6116	0.2523
hypertensive-nonattender	13	0.6410	0.2819
hypertensive-participant	40	0.6750	0.2805
normotensive-participant	40	0.7546	0.2253
hypertensive-nonparticipant completers	9	0.7611	0.2804

once although the patient may have made a number of visits for the problem. Examples of chronic disease were long-term psychiatric problems (such as chronic depression or schizophrenia), alcoholism, chronic obstructive lung disease, arthritis, hypertension, and pernicious anemia. Appendix C provides the chronic diseases in each category.

The Cochran and Bartlett-Box tests failed to find homogeneity of variances. Therefore, nonparametric procedures were employed. Table 2 contains a comparison of the occurrence of chronic disease among six groups. The analysis indicates a significant difference in the occurrence of chronic disease by groups (X^2=21.87 $\underline{df}$=5, $\underline{p}$<0.005). Based on the contribution of each cell to the total chi-square, hypertensive-nonparticipants who did not complete screening were less likely to have chronic diseases noted as were normotensive-participants. The unscreened group, the unknown-nonparticipants, had the expected high number of chronic diseases but hypertensive-nonattenders had more chronic diseases than expected. The major departures from expected frequencies were in the normotensive group and the hypertensive-participant group. As predicted, the normotensive group had fewer chronic diseases while the hypertensive-participant group had a higher frequency of chronic disease.

Five patients of the 167 reviewed were known to have died prior to this investigation. Group by group, the mortality rate per 1000 was as follows: unknown-nonparticipants 0,

Table 2

Comparison of Groups for Chronic Disease

Rate of Chronic Disease \ Groups	unknown nonparticipant	hypertensive-nonparticipant (noncompleter)	hypertensive-nonparticipant (completer)	normotensive participant	hypertensive participant	hypertensive nonattender	Total of Actual Frequency
none	17* 15.5680** 0.1317***	14 9.7300 1.8739	3 3.5028 0.0722	23 15.5680 3.5480	6 15.5680 5.8804	2 5.0596 1.8502	65
one or more	23 24.432 0.0840	11 15.27 1.1940	6 5.4972 0.0460	17 24.432 2.2607	34 24.432 3.7470	11 7.9404 1.1789	102
Total of Actual Frequency	40	25	9	40	40	13	167

chi-square = 21.87, df = 5, p <0.005

* actual frequency
** predicted frequency
*** contribution to total chi-square

hypertensive-nonparticipant noncompleters 0, hypertensive-nonparticipant completers 111, normotensive-participants 25, and hypertensive-participants 25, hypertensive-nonattenders 154. Therefore, mortality rates were highest among hypertensive-nonattenders and hypertensive-nonparticipant completers.

Disease severity. For uniformity of comparison, three of the total patient visits in the study time frame, each containing a follow-up recommendation, were randomly selected for all patients. The diagnoses given by the physicians were then coded on a crude 4-point scale for severity. The scale was crude because there is often not enough information in the health record to make fine discriminations within disease categories. Therefore, severity was classified on the basis of disease type alone assuming different degrees of life-threat for different diseases. Cardiovascular disease received the highest rating and minor trauma (the most common reason for visits) received the lowest rating. At a moderately low level of severity were diagnoses such as pneumonia, arthritis, and behavioural problems like depression. Moderately serious diseases included diabetes, alcoholism, and asthma. Appendix D contains diseases categorized on the 4-point scale.

The three severity ratings were summed to give an overall rating of occurrence of serious disease. The groups exhibited homogeneity of variance (Cochran and Bartlett-Box tests) and therefore analysis of variance was appropriate and indicated

overall group differences (F=3.02; df=5, 161; p<0.05). Table 3 summarizes the results of the analysis. Post-hoc comparisons (Least Significant Difference procedure, p=0.05) determined that hypertensive-participants had more serious diseases than hypertensive-nonattenders, hypertensive-nonparticipant completers, and normotensive-participants.

Kendall correlation coefficients were determined across groups for each of the three severity ratings with attendance at the recommended visit. The coefficients were as follows: 0.01, 0.27, and 0.01.

Additional Findings

Psychosocial problems. Various psychosocial and environmental problems were noted in physicians' records. It was acknowledged that there are deficiencies in using data from recorded social problems because not all problems are noted by physicians and those that are recorded may represent errors in documentation or biases of the physician. However, the decision was made to use the information that was recorded while keeping in mind the potential bias when interpreting the data. The recorded social problems were categorized as: alcoholism, problems related to family, violence or involvement with the law, financial, multiple problems, and no problems noted.

The six groups were compared for frequency of social problems. Because of small cell frequencies the number of categories were reduced to: alcoholism, no social problems

Table 3

Analysis of Variance

Summary Table

Disease Severity by Group

Source	df	Sum of Squares	Mean Squares	F	Probability
between groups	5	71.0234	14.2047	3.02	<0.05
within groups	161	756.6050	4.6994		
total	166	827.6282			

Group	n	Mean Disease Severity	Standard Deviation
hypertensive-nonattender	13	4.5385	1.6641
hypertensive-nonparticipant completers	9	4.6667	1.3229
normotensive-participant	40	4.8000	2.1268
hypertensive-nonparticipant noncompleters	25	5.6000	2.3629
unknown-nonparticipant	40	5.6250	2.4878
hypertensive-participant	40	6.4000	2.0102

noted, and other social problems. Chi-square analysis failed to detect significant group differences. However, visual inspection of the data suggested that incidence of alcoholism did differ across groups. When patients were categorized as alcoholic or nonalcoholic, group comparisons indicated significant differences in the rates of alcoholism (X^2=12.80, df=5, $p<0.05$, Table 4). Using cell contribution to the total chi-squares, it appears that occurrence of alcoholism is more frequent than expected in hypertensive-participants and hypertensive-nonattenders. At the same time, alcoholism occurs less frequently in normotensive-participants and hypertensive-nonparticipant completers.

Patients were broken into quartiles on attendance noncompliance: (1) noncompliant, 0 to 0.474, (2) moderately noncompliant, >0.474 to 0.667, (3) moderately compliant, >0.667 to 0.900, (4) compliant, >0.900 to 1.00. When attendance compliance categories were compared for all patients categorized as alcoholic or nonalcoholic, the chi-square test was significant (X^2=11.06, df=3, $p<0.05$). Nonalcoholics have a higher frequency of compliant behaviour than expected and alcoholics are less compliant than expected (Table 5). However, the Kendall correlation coefficient indicates a weak relationship (0.20) between alcoholism and the attendance compliance ratio. The coefficient was significant at $p<0.01$.

Age. There were group differences in ages of patients (F=3.22; df=5, 161; $p<0.01$; Table 6). Post-hoc comparisons

Table 4

Rates of Alcoholism by Group

	Groups						Total of Actual Frequency
	unknown nonparticipant	hypertensive-nonparticipant (noncompleter)	hypertensive-nonparticipant (completer)	normotensive participant	hypertensive participant	hypertensive nonattender	
Alcoholic	15* 15.3280** 0.0070***	8 9.5800 0.2606	1 3.4488 1.7388	11 15.3280 1.2221	20 15.3280 1.4240	9 4.9816 3.2414	64
Nonalcoholic	25 24.6720 0.0044	17 15.4200 0.1619	8 5.5512 1.0802	29 24.6720 0.7592	20 24.6720 0.8847	4 8.0184 2.0138	103
Total of Actual Frequency	40	25	9	40	40	13	167

chi-square = 12.80, df = 5, $p<0.05$

* actual frequency
** predicted frequency
*** contribution to total chi-square

Table 5

Comparison of Alcoholics and Nonalcoholics on Attendance Compliance

Past Attendance Compliance	Alcoholics	Nonalcoholics	Total of Actual Frequency
0 to 0.474 (noncompliant)	20* 15.328** 1.4240***	20 24.6685 0.8835	40
>0.474 to 0.667 (moderately noncompliant)	21 18.0096 0.4965	26 28.9842 0.3073	47
>0.667 to 0.900 (moderately compliant)	16 14.9440 0.0746	23 24.0505 0.0459	39
>0.900 to 1.000 (compliant)	7 15.7120 4.8306	34 25.2865 3.0026	41
Total of Actual Frequency	64	103	167

chi-square = 11.06, df = 3, $p<0.05$

* actual frequency
** predicted frequency
*** contribution to total chi-square

Table 6

Analysis of Variance

Summary Table

Age by Group

Source	df	Sum of Squares	Mean Squares	F	Probability
between groups	5	3086.5939	617.3186	3.22	<0.01
within groups	161	30862.6697	191.6936		
total	166	33949.2617			

Group	n	Mean Age	Standard Deviation
normotensive-participant	40	40.8250	13.3106
hypertensive-nonparticipant noncompleters	25	41.8400	14.1677
unknown-nonparticipant	40	43.9000	15.0891
hypertensive-nonattender	13	46.3846	13.7328
hypertensive-participant	40	51.2250	13.7309
hypertensive-nonparticipant completers	9	52.6667	8.9443

(Least Significant Differences, $p=0.05$) found that hypertensive-participants and hypertensive-nonparticipant completers were significantly older than normotensive-participants.

Blood pressure. A criterion blood pressure of 100 mmHg had been recorded on the referral date in one of the ambulatory departments and was used to alert staff for the need to have further blood pressure screening. The maximum recorded prescreening blood pressure was 140 mmHg. Since the group variances for prescreening diastolic blood pressures were found to be heterogeneous, nonparametric analysis was appropriate for comparing groups. The grand median diastolic blood pressure was determined to be 102 mmHg and frequency of blood pressure equal to or above the median and frequency below the median were determined across groups. Forty-eight percent of patients had blood pressures at the criterion of 100 mmHg. Chi-square analysis indicated no significant differences in prescreening blood pressures among groups.

However, group means (Table 7) suggested that there were blood pressure differences among groups that a median split chi-square analysis was failing to detect. The use of three or more blood pressure categories was precluded by a high rate of expected cell frequencies with values less than five. Group means and standard deviations indicated a more compact and lower dispersion of blood pressures among unknown-nonparticipants, hypertensive-nonparticipant completers, and normotensives. There

Table 7

Means and Standard Deviations

of Group Blood Pressures

Group	n	Mean Blood Pressure (mmHg)	Standard Deviation
unknown nonparticipant	40	103.67	5.11
hypertensive-nonparticipant noncompleters	25	107.56	6.92
hypertensive-nonparticipant completers	9	104.44	5.08
normotensive-participant	40	103.15	5.00
hypertensive-participant	40	107.17	9.07
hypertensive-nonattender	13	109.23	9.26

were fewer patients with seriously high blood pressures in the three groups with lower mean blood pressures.

Medical visits. Frequency of admission to hospital over the two-year time frame ranged from zero to a maximum of five (mean 0.7 visits and standard deviation 1.2). Nonparametric analysis was performed when heterogeneity of variances was found. Chi-square analysis failed to detect any significant differences between groups for hospitalization dichotomized into: (1) no admissions or (2) one or more admissions.

Visits per patient to ambulatory departments over two years ranged from three to 107 visits (mean 13.6 visits, standard deviation 12.3). Two classes of total visits were developed: above or equal to the median of 10 visits and below the median. Chi-square analysis did not detect any differences among groups for total ambulatory medical visits.

Total recommendations for follow-up visits per patient ranged from three to 69 (mean 7.7 visits, standard deviation 7.5). Because of heterogeneity of variances, nonparametric analysis was appropriate. Follow-up visits were again split on the basis of the median (5 visits). Analysis indicated no group differences in numbers of recommended follow-up visits.

Indicators of compliance. Several patient attributes (collapsed across groups) were examined to determine if they were related to the 4-point compliance scale. Neither gender nor past history of hypertension were related to compliance as determined

by chi-square analysis. However, cell contributions to the total chi-square suggested that native patients were more frequently noncompliant or moderately noncompliant while non-native patients were moderately compliant or compliant (Table 8, $X^2=20.99$, $df=3$, $p<0.001$). The Kendall correlation coefficient between ethnic status and the attendance compliance ratio was moderately weak (0.28) and was significant at $p<0.01$.

Employment status was also related to compliance behaviour. Two status categories were formed: (1) all people who were unemployed, on welfare, or receiving old age or disability pensions and (2) all people employed. From the cell contributions to the total chi-square, it appeared that the unemployed had a higher frequency of noncompliant behaviour (and lower frequency of compliance) and the employed had a higher frequency of compliant behaviour (and a lower frequency of noncompliance). Table 9 summarizes the data ($X^2=12.42$, $df=3$, $p<0.005$).

First order correlations were determined for the attendance compliance ratio and the following: age ($r=0.24$), blood pressure ($r=-0.14$), frequency of chronic disease ($r=-0.02$), frequency of hospitalization ($r=-0.10$), serious disease ($r=0.02$), total follow-up recommendations ($r=0.09$), and total ambulatory visits ($r=0.06$). Kendall correlation coefficients were obtained for three random follow-up visit intervals (time between the recommendation for follow-up visit and the date of the follow-up

Table 8

Ethnic Groups Compared for Attendance Noncompliance

Past Attendance Compliance	Native	Non-native	Total of Actual Frequency
0 to 0.474 (noncompliant)	25* 16.7680** 4.0414***	15 23.232 2.9169	40
>0.474 to 0.667 (moderately noncompliant)	25 19.7024 1.4244	22 27.2976 1.0281	47
>0.667 to 0.900 (moderately compliant)	13 16.3488 0.6860	26 22.6512 0.4951	39
>0.900 to 1.000 (compliant)	7 17.1872 6.0382	34 23.8128 4.3581	41
Total of Actual Frequency	70	97	167

chi-square = 20.99, df = 3, $p < 0.001$

* actual frequency
** predicted frequency
*** contribution to total chi-square

Table 9

Employment Status by Attendance Compliance

Past Attendance Compliance	Unemployed Welfare Pension	Employed	Total of Actual Frequency
0 to 0.474 (noncompliant)	31* 22.7560** 2.9866***	9 17.2440 3.9413	40
>0.474 to 0.667 (moderately noncompliant)	27 26.7383 0.0026	20 20.2617 0.0034	47
>0.667 to 0.900 (moderately compliant)	21 22.1871 0.0635	18 16.8129 0.0838	39
>0.900 to 1.000 (compliant)	16 23.3249 2.3003	25 17.6751 3.0356	41
Total of Actual Frequency	95	72	167

chi-square = 12.42, df = 3, $p<0.01$

* actual frequency
** predicted frequency
*** contribution to total chi-square

visit) and whether the patient attended or not. These were near zero (0.01, 0.04, 0.05) and none reached statistical significance ($p>0.05$).

Noncases

Of the 393 charts reviewed, 226 did not meet the criterion for three recommended follow-up visits. However, demographic and health related data were acquired on all noncases and analyses were done to determine the nature of selection bias in this investigation.

Since a criterion of three recommended follow-up visits was employed, the noncases differed from those investigated in terms of total ambulatory visits and total recommended follow-up visits. Ninety-six percent of noncases had six or fewer ambulatory visits (28% of reviewed cases had this number of visits). Of the 226 noncases, 138 had no recommended follow-up visits, 67 had one recommended visit, and 21 had two recommended visits. Three visits were considered a necessary minimum for calculating an attendance compliance ratio which would provide an estimate of overall attendance compliance. The 226 noncases were, therefore, considered to have inadequate information on attendance compliance and were not used in those analyses.

Besides medical visits, there were many other ways in which the cases and noncases differed. The noncases and the reviewed cases were separately collapsed across groups and comparisons made for blood pressure, past history of

hypertension, social problems, employment, ethnic group, gender, and place of residence.

Place of residence was significantly different for reviewed cases and noncases (X^2=27.08, df=2, p<0.005). Table 10 summarizes this data and indicates, by cell contribution to the total chi-square, that among cases reviewed, patients more frequently live in the core area whereas noncase patients more frequently reside in areas well outside of the core area.

Table 11 shows the comparison of cases and noncases for social problems using the following categories: no problems noted, alcoholism, and other problems. Noncase patients are more likely to have fewer social problems noted in their charts. The opposite is true for reviewed cases (X^2=31.40, df=2, p<0.005).

The Irwin-Fisher Exact Test for large samples was used to compare cases and noncases on employment status. Noncase patients are more likely to be employed in contrast with case patients who have no difference in employment and unemployment rates (Table 12: Z=3.96, p<0.05). As for ethnic group, noncase patients are more likely to be non-native (Table 13: Z=7.27, p<0.05). Gender also is significantly different for cases and noncases (Table 14: Z=-6.58, p<0.05) there being more male patients among noncases but approximately equal numbers of males and females among cases.

Considering several health matters, there is no difference between cases and noncases for probability of blood pressures

Table 10

Place of Residence by Review Status

	core area	fringe area	other	Total of Actual Frequency
cases	83* 65.0097** 4.9785***	55 50.1382 0.4714	29 51.8378 10.0615	167
noncases	70 87.9903 3.6783	63 67.8618 0.3483	93 70.1622 7.4337	226
Total of Actual Frequency	153	118	122	393

chi-square = 27.08, df = 2, p <0.005

* actual frequency
** predicted frequency
*** contribution to total chi-square

Table 11

Social Problems by Review Status

	no problems	alcoholism	other	Total of Actual Frequency
cases	66* 93.0531** 7.8651***	64 48.4386 4.9993	37 25.4940 5.1929	167
noncases	153 125.9469 5.8109	50 65.5614 3.6936	23 34.5060 3.8367	226
Total of Actual Frequency	219	114	60	393

chi-square = 31.40, df = 2, p <0.005

* actual frequency
** predicted frequency
*** contribution to total chi-square

Table 12

Employment Status by Review Status

	Cases	Noncases	
Not Employed	95	83	178
Employed	72	143	215
	167	226	393

$Z = 3.96$
$p<0.05$

Table 13

Ethnic Group by Review Status

	Cases	Noncases	
Native	70	23	93
Non-native	97	203	300
	167	226	393

$Z = 7.27$
$p<0.05$

Table 14

Gender by Review Status

	Cases	Noncases	
Male	89	144	233
Female	78	82	160
	167	226	393

$Z = -6.58$
$p<0.05$

Table 15

Past History of Hypertension by Review Status

	Cases	Noncases	
No	112	194	306
Yes	55	32	87
	167	226	393

$Z = -4.41$
$p<0.05$

falling above or below the grand median of 102 mmHg (Z=-0.80). However, there is a significant difference in rates of documentation of past history of hypertension. Noncase patients are less likely to have a past history of hypertension noted in their hospital records than are case patients (Table 15: Z=-4.41, p<0.05).

Chi-square analyses done separately on cases and noncases for participant-nonparticipant groups by ethnic status, place of residence, employment status, and social problems, demonstrated no significant group differences for cases or for noncases. In addition, there were no participant-nonparticipant group differences for noncases on documented past history of hypertension. This was not so, however, for cases reviewed (Table 16). Cell contributions to the total chi-square indicated that normotensive-participants have lower frequencies of previously documented hypertension and hypertensive-participants have higher frequencies than expected (X^2=13.58, df=5, p<0.05).

A two-way analysis of variance for both review status and group by age indicated that there were no significant differences between cases and noncases for age. Neither was there a significant review status x group interaction. The significant group effect was discussed in an earlier section.

Table 16

Previous Documentation of Hypertension by Groups (Cases Reviewed)

Documented Past Hypertension	Groups: unknown nonparticipant	hypertensive-nonparticipant (noncompleter)	hypertensive-nonparticipant (completer)	normotensive participant	hypertensive participant	hypertensive nonattender	Total of Actual Frequency
Absent	29* 26.828** 0. 1758***	16 16.7675 0.0351	6 6.0363 0.0002	34 26.828 1.9173	19 26.828 2.2841	8 8.7191 0.0593	112
Present	11 13.172 0.3582	9 8.2325 0.0716	3 2.9637 0.0004	6 13.172 3.9051	21 13.172 4.6521	5 4.2809 0.1208	55
Total of Actual Frequency	40	25	9	40	40	13	167

chi-square = 13.58, df = 5, p <0.05

* actual frequency
** predicted frequency
*** contribution to total chi-square

Discussion

Sample Selection Bias

In this study it was proposed that a gradient of prior attendance compliance would be found across groups of participants and nonparticipants. The data indicate that different rates of past attendance compliance exist for participants and nonparticipants. Participants in compliance investigations have past attendance compliance in the middle of the range of attendance compliance. Most nonparticipants have past attendance compliance rates in the lower range.

Thus, past research outcomes based on samples of participants may not generalize to nonparticipants; to people who are more or less compliant than those who were studied. Various strategies or techniques that have been investigated to modify noncompliance may not have the same effect on those not represented in the sample. Reported correlates of noncompliance obtained by studying participants may also not apply to nonparticipants. In addition, reported correlation coefficients are frequently weak. This may be a consequence of a statistical effect arising from the unintentional selection of a restricted range of compliant individuals, as found among participants.

In short, the findings of earlier studies must be viewed with caution. Until proven otherwise, the results of previous studies should be generalized only to those who would participate in a compliance study. The results may or may not be found to

generalize to nonparticipants.

Several points should be made about this study. One is that the past compliance behaviour of patients who did not clinically qualify for a study is irrelevant to questions about selection bias. Regardless of any tendencies to attend, those who did not need treatment would not be selected. Thus, in this study, normotensive-participants should not come under consideration in a selection bias issue. In addition, the unknown-nonparticipants consist in part of individuals who, had they attended screening, would have been found normotensive and therefore would not be considered for a hypertension compliance investigation. The other, and important, part of the group in terms of defining sample selection problems are those who would be found to be hypertensive through screening. Since normotensives and hypertensives in the group cannot be distinguished without screening, differences in patterns of compliance cannot be identified.

The hypertensive-nonparticipant completers were compliant for the screening program but declined treatment in the Hypertension Clinic and indicated that they would seek treatment from another source. However, information was not available about whether or not they actually sought treatment for hypertension. Their nonacceptance of treatment in the Hypertension Clinic may reflect a preference for an alternate treatment facility rather than nonparticipant behaviour per se.

The group's high mean past attendance rate favours such an interpretation.

The groups which provide information for determining whether studies about compliance use compliant samples include the following: (1) hypertensive-nonparticipant completers, (2) hypertensive-participants, (3) hypertensive-nonattenders, (4) hypertensive-nonparticipant noncompleters and, with the above reservations, (5) unknown-nonparticipants.

An investigation on compliance using the hypertensive-participants was undertaken following the screening program. According to the present study, the hypertensive-participants had past attendance compliance rates in the middle of the range found for the six groups represented in the screening program. Thus, the subsequent investigation of compliance behaviour on hypertensive-participants employed a sample which was select for past attendance compliance. Through selection processes, the most and least compliant patients were under-represented in the sample. The results of that study on compliance among hypertensive-participants will have to be qualified in view of the evidence on selection bias.

It should be recognized that the present study has its own problems with sample selection bias. There were several problems present in this study which are also common to other investigations. First, the population chosen for the study on compliance was narrow; it included individuals in one region,

using hospital ambulatory facilities. Then, the study was select for disease; only hypertension was investigated.

In addition, in order to find sufficient data on past attendance compliance in the present study, some patient records were excluded. The reviewed cases seemed to represent patients who came from a lower socioeconomic group and who had made greater use of health services. However, the health status differences may result from socioeconomic differences. The Health Sciences Centre is located near the core area of the city and for that reason many health concerns of the noncases with their higher socioeconomic status may be treated at suburban hospitals or in private physicians' offices. With fewer visits to the Health Sciences Centre, the records would probably contain less information about past medical history and social history, indicating fewer health and social problems than actually exist.

Regardless of the existence of differences in health status, the reviewed cases and the noncases differ on socioeconomic status, which may or may not be a factor in compliance behaviour. Thus, any interpretation of findings in this study related to hypotheses about general indicators of compliance should consider that our sample is socioeconomically select. For example, when it is noted that age is related to compliance behaviour, it should be understood that this relationship may not be found in a sample with a higher socioeconomic status.

The critical question concerns the effect of the case versus noncase selection on the interpretation of data related to the major hypotheses. The cases reviewed in this study are biased toward a lower socioeconomic group. However, other compliance investigations are conducted with samples chosen from similar populations. Thus, generalization of the results of this study is not affected when the primary concern is the relationship between participation and compliance. On the other hand, generalization is affected if the primary concern is not selection bias because the results of this study apply to lower socioeconomic people.

Chronic and Serious Disease

This investigation found significant group differences in rates of chronic disease. However, it was predicted that higher rates of chronic disease would be found in nonparticipant groups as determined in previous studies. The hypothesis was not entirely supported. In fact, it appears that chronic disease is related primarily to health status. Although hypertensive-nonattenders do have a high rate of chronic disease, the group also has a greater proportion of alcoholics than any other group and this in part determines the rate of chronic disease. Similarly, there is a relationship between being normotensive and having fewer chronic diseases.

Rates of chronic disease in the predicted direction were found for two groups: the normotensive-participants and the

hypertensive-nonattenders. Evidently, health status determined those rates. Thus, in the screening and blood pressure investigation program upon which this study is based, tendency to participate is not related to rate of chronic disease but instead rate of chronic disease is related to health status. Findings of previous studies (for example, Wilhelmsen et al., 1976) were not supported.

There does not appear to be a relationship between severity of disease and tendency to attend a recommended follow-up visit. Of the three randomly selected visits, one showed a weak positive relationship and the other two showed no relationship. Thus, disease severity does not seem to be related to attendance compliance across groups of participants and nonparticipants.

There is some suggestion that, besides health status, severity of disease may be related to participant status: those with diagnosed diseases that are less severe may be unwilling to participate. However, as the data do not permit a clear overview of the relationship, other investigations should be undertaken to examine the matter.

Indicators of Group Composition or Compliance

Three additional factors were related to tendency to participate or not. Alcoholism and high prescreening blood pressures were found among hypertensive-nonattenders and generally lower prescreening blood pressures were found among the

normotensive-participants. These findings are consistent with the hypertension literature.

Finally, for this sample, the attendance compliance ratio tends to be lower for North American natives, the unemployed, and younger patients.

Conclusions

The purpose of this investigation was to determine if a sample chosen for a study about compliance behaviour consisted of volunteers or participants who had a proclivity to comply. Past compliance for recommended medical visits varied across groups of participants. Those who ultimately participated in the compliance study had past attendance compliance rates falling in the middle of the range.

The findings of this study suggested that previous studies on compliance used samples that were similarly biased. Generalizations based on those studies may be more limited than previously thought.

Implications for Future Research

The present study suggests directions for future research. The first, and possibly most important, is that care must be taken in the interpretation of past research. Studies that have relied on samples of volunteers do not provide general data on compliance behaviour. For example, when investigations of techniques to alter noncompliance employ volunteers in their samples, they tell us little about strategies for altering

noncompliance of nonparticipants.

On the other hand, some studies have not had to rely on volunteers (for example, the present study was able to examine past attendance without requiring patients to volunteer). Other studies ask for volunteers but are also able to assess participants and nonparticipants on relevant matters (for example, Carr & Whittenbaugh, 1968; Tilson, 1976).

Studies that investigate the inception cohort, as the last two types of studies have done, will not have select samples for compliance. Therefore, reviews of past compliance research should examine, study by study, sample selection methods and selectively exclude knowledge accquired by studies using poor sampling methods.

The next step is to compile the knowledge that we do have about compliance (once information from biased studies is eliminated) and to re-investigate matters previously studied with select samples.

Samples selected for studies re-examining compliance should be drawn from broader based populations; broader in terms of several characteristics. First, in terms of compliance behaviour, every effort should be made to encourage participation. The design of the study should contain a method for examining past and present behaviour on relevant variables for those who cannot be persuaded to participate. Some nonparticipants may even be willing to provide this information

though not willing to volunteer for the study. In addition, sociodemographic characteristics of participants and nonparticipants should be reported.

Second, samples should come from broader based populations in terms of general characteristics. Samples should be chosen from a wider range of socioeconomic levels (the exception, of course, is when specific socioeconomic levels or other factors are related to the matter under investigation). This means that research which has previously been conducted under the protective umbrella of outpatient or free clinics should move outward to include a broader range of settings and patients, for example, from private practices, industrial and business settings, and educational institutions.

If the above recommendations are followed, we may obtain information that will help to answer some of the questions that have been, and are yet to be, posed about compliance.

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APPENDIX A

NONCOMPLIANCE FOR THERAPEUTIC RECOMMENDATIONS

Janice Ramsay

University of Manitoba

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Noncompliance for Therapeutic Recommendations

Janice Ramsay

University of Manitoba

There exists a substantial body of literature on the subject of noncompliance or nonadherence to medical recommendations and the literature related to noncompliance is increasing in areas such as dentistry and psychology.

To medical professionals, noncompliance represents a major problem in health care since diseases that could be cured or arrested are not being treated adequately. Thus, it is often suggested that noncompliance contributes to inefficiency within the health care system (Clinite & Kabat, 1976; Christensen, 1978; Nelson, Stason, Neutra, Solomon & McArdle, 1978). Since noncompliance is viewed as a major health problem, an explicit definition of noncompliance should exist. However, this is not the case because noncompliance is defined in general terms; noncompliance is the extent to which therapeutic recommendations are not followed (Davidson, 1976).

A more extensive discussion of definitions of noncompliance is presented in a measurement section of this review. Other topics discussed in this review include: (1) historical perspectives on changes in attitudes toward noncompliance; (2) a general review of findings of noncompliance studies; (3) methodological problems confronting

researchers in this area; (4) techniques that have been developed as attempts to overcome noncompliance: and (5) the core theoretical model and revisions or extension of it. Throughout the review, an emphasis has been placed on the attitudes of patients and health care practitioners toward noncompliance.

HISTORICAL PERSPECTIVES

In the early period of medicine, noncompliance for medical procedures did not seem to be much of a problem. Of course, it is possible that the problem of noncompliance was more widespread but was not documented or, since access to health care was more limited than now, that only those with a proclivity to comply consulted physicians. Whatever the reason, there was little comment in the literature about noncompliance. However, it is a wonder that noncompliance was not an issue in view of some of the popular medical treatments reported.[1] However, none of the reports mentioned noncompliance as a problem.

Lack of noncompliance can be attributed to a number of factors. One is that, because the field of medicine was not as technical as now, care was often provided directly by the physician. Secondly, it was basically a nondrug era. Thus, responsibility for effecting treatment recommendations was not assumed by the sick and, therefore, opportunities for noncompliance were reduced. However, the advent of the drug era and advances in medical technology resulted in a shift in responsibility to the patient for effecting treatment

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[1] Venesection (bleeding) and emetics were preferred treatments for epilepsy and pneumonia (Reyburn, 1903; Brockbank, 1934; Collier, 1934), and epilepsy was also treated by infecting the patient with malaria. However, Colledge's (1934) description of various early tonsillectomy procedures done on awake (and apparently consenting) patients and Power's (1934) description of pre-Victorian treatment methods for gonorrhea reinforce an opinion that noncompliance should have been widely observed.

recommendations.

Attitudes Toward Compliance

Within the last 30 years, increasing numbers of reports have been written on the subject of noncompliance suggesting that either the prevalence is on the rise or that health professionals have become aware of the problem. Reported rates for noncompliance vary: from 25% to 59% (McKercher & Rucker, 1977), 19% to 72% (Hayes-Bautista, 1976), and 15% to 93% (Davis, 1968b). Whatever the incidence cited, noncompliance is a common occurrence.

One point in the literature is clear; attitudes of practitioners and patients have changed from what they were in the last century, and have changed especially in the past few decades. The current literature suggests that practitioners have several views on noncompliance behaviour. On the one hand, noncompliant patients have been considered deviant or incompetent in health matters. In one recent study, those who failed to stop smoking were considered not "entirely rational" because they were aware of adverse effects of the behaviour and yet continued to smoke (Burt, Thornley, Illingworth, White, Shaw & Turner, 1974).

In another study, the investigators thought that patients were often "incapable of accurately reporting" problems with drug taking (Preston & Miller, 1964). Furthermore, noncompliant patients apparently "defied" efforts designed to teach them to be compliant (Stone, D. B., 1961), or were considered "unrealistic"

when there was a discrepancy between their goals and the goals of the staff (Baretz & Stephenson, 1976). On the other hand, it has recently been recommended that we "view the patient-physician interaction, and with it compliance, as a negotiation between two active and equal participants." (Benarde & Mayerson, 1978), a view shared by Hayes-Bautista (1976).

Different sick role norms may be evident for different people for, according to Sobel and Ingalls (1964), psychiatric patients believed that a dependent role was appropriate for them while psychiatrists thought that the reverse was more likely to be associated with therapeutic success. Others have suggested, however, that an "independent attitude" in the poorly educated may be associated with resistance to medical treatment (Brand, Smith & Brand, 1977). Patient passivity and dependence may even be encouraged since a more effective work environment exists for staff (Lorber, 1975). This brings to mind a comment in Davidson's review (1976) which suggested that patient compliance may be therapeutic for health professionals.

Recent discussions about the use of the word "compliance" also suggest evolving attitudes about patient-practitioner roles. It is not clear when the term noncompliance first became popular for it was not used in one of the early studies on noncompliance (Cobb, Clark, Mcguire & Howe, 1954). However, it was used sporadically in the mid-1960's (Davis, 1966). By 1974, use of the word was still uncommon enough that participants at a

symposium on noncompliance (McMaster University, May 1974) were able to discuss the advisability of adopting another term (Sackett, 1976a). The major problem was that there were negative connotations associated with the word compliance, a word which "evokes images of a passive, subservient, and unfeeling patient" (Friedman & DiMatteo, 1979).

Nonetheless, participants at the symposium could come up with no better an alternative; adherence and therapeutic alliance being rejected as plausible alternatives (Sackett, 1976a). By now, the term compliance has the indisputable position of supremacy in the literature and seems likely to hold that position even though its use continues to trouble some researchers (Stimson, 1974; Komaroff, 1976; Friedman & DiMatteo, 1979). While alternatives, such as concordance-discordance, are openly being advocated (Hulka, Cassell, Kupper & Burdette, 1976; Komaroff, 1976), rejection of the word compliance is also occurring in a more subtle fashion since a trend in the literature is to use other terms such as (appointment) keepers and breakers (Jonas, 1971), dropouts (Morrow, Del Gaudio & Carpenter 1977), elopers (Pam, Bryskin, Rachlin & Rosenblatt, 1973), defaulters (Porter, 1969), shows-no-shows (Walfish, Tapp, Tulkin, Slaikeu & Russell, 1975), and "splitees" (Aron & Daily, 1976). Thus, lack of acceptance of the term "compliance" suggests that many practitioners are uncomfortable with the connotations of the word; this reflects an overall change in

attitude among health professionals.

Why Should Patients Comply?

According to Stimson (1974), no one asks the critical question "why should patients comply?". In fact, it seems unheard of that patients should not want to comply. Apparently, health professionals perceive themselves as the experts in medical matters and, therefore, noncompliance is "by implication irrational, in light of medical rationality" (Stimson, 1974).

Clearly, history has shown that unquestioning compliance to treatment recommendations is undesirable from any perspective. In fact, there are some occasions, in retrospect, when total noncompliance would have been preferable. For example, high concentrations of oxygen administered to some premature infants in the 1940's is thought to have been responsible for retrolental fibroplasia, causing blindness (Hoeck, 1954; James, 1976). In addition there was the use of head and neck irradiation in treating acne, tonsillitis, and thymic enlargement (a nondisease). This treatment resulted in the risk of thyroid cancer (Editoral: Thyroid Cancer, 1976; Greenspan, 1977). More recently, it has been found that administration of diethylstilbestrol (DES) to pregnant women has created a risk in female offspring for vaginal and cervical cancer (Mattingly & Stafl, 1976; Noller, Decker, Fish & Gaffey, 1976) and structural and functional abnormalities of reproductive organs for male offspring (Gill, Gebhard, Schumacher & Bibbo, 1976).

Health professionals do not seem to appreciate that patients should not always comply. As a consequence, many researchers treat noncompliance as deviancy and attempt to isolate causative factors or to develop techniques to solve the "problem". Consistent with the view of noncompliance as deviancy, most techniques developed to overcome noncompliance have not required responsible participation by the patient (Stimson, 1974). Recently, alcoholics were given the "choice" between a jail term or administration of disulfiram (antabuse) by a probation officer (Haynes, S. N., 1973). Furthermore, since clinicians have not been able to rely on compliance with oral doses of disulfiram, techniques have been developed to implant the drug for long-term control of alcohol abuse (Kline & Kingstone, 1977; Mann & Vogel-Sprott, 1977). Other techniques, for example some behavioural control techniques (McMorrow, Cullinan & Epstein, 1978), have not required responsible participation by the patient either.

Summary

Noncompliance behaviour occurred infrequently in the early periods of medical history even though many treatment regimens, in retrospect, seem to demand noncompliance. Lack of noncompliant behaviour in early times can be attributed to lack of patient responsibility in effecting the treatment.

Patient-practitioner attitudes toward medical treatments have changed in the last century and especially in the recent

past. However, it is clear that there are presently two conflicting views: one which defines the patient role as dependent and passive and the other which defines the role as active and responsible. That researchers have predominantly held the first view accounts for failure to pose the question "why should patients comply?".

GENERAL FINDINGS OF COMPLIANCE STUDIES

Sackett and Haynes (1976) compiled a bibliographic listing of articles about noncompliance for the period up to 1974, which contained approximately 300 references. In a 1978 revision of this bibliography there were about three times as many publications as in the original listing, providing testimony for the increased interest in this area of research (Haynes, Taylor, Snow, Sackett, Tugwell, Walsh, Hackett & Muckherjee, Note 1). Nonetheless, the results of these studies have failed to dispel many of the mysteries associated with issues of noncompliance.

Areas of noncompliance that have been investigated are related to either (1) attendance-participation or (2) treatment regimens. Table 1 summarizes findings of attendance-participation studies and Table 2 summarizes findings of studies on treatment regimen adherence.

Attendance-Participation

From the literature, researchers seem to view noncompliance either as a stable psychological attribute or as precipitated by environmental or situational factors; that is, a trait versus a state. The belief that noncompliance is a trait is evidenced by the many studies which have sought to find a relationship between various sociodemographic variables and attendance noncompliance behaviour (Table 1). However, no conclusive findings have been published which support relationships between attendance noncompliance and ethnicity,

religion, age, gender, education, socioeconomic status, marital status, and employment status or occupation. For example, noncompliance was found to have no association with age (Macdonald, Hagberg & Grossman, 1963; Glick, 1965; Davis, 1968; Diamond, Weiss & Grynbaum, 1968; O'Leary, Rohsenow & Donovan, 1976), and yet was found to be associated with those who were younger (Abernethy, 1976; Jellinek, 1978; Nelson et al., 1978) and with those who were older (Tilson, 1976; Adami & Vegelius, 1978). Thus, age has not been shown to be related to compliance.

Studies examining noncompliance behaviour and situational factors have been a little more productive. Although results are not conclusive, there is a suggestion that situational events influence compliance behaviour. Prognosis seems to have some mixed effects on compliance (Diamond et al., 1968; Oldridge, Wicks, Hanley, Sutton & Jones, 1978). Apparently severity or intensity of the health problem is associated with nonattendance. For example, more expensive drugs, greater numbers of prescriptions per patient (Brand et al., 1977), and more serious health problems (Heinemann, Moore & Gurel, 1976) were found in nonattenders. Furthermore, patients who rated themselves as anxious were less likely to participate (Diamond et al., 1968).

The effect of the referral process upon compliance is mixed. The type of primary treatment facility from which a patient has been referred does not influence compliance (Glick, 1965; Jellinek, 1978). The length of wait until the scheduled

appointment may or may not be associated with nonattendance (Gould, Paulson & Daniels-Epps, 1970; Levy & Claravall, 1977) and the same is true for appointment reminders (Kidd & Euphrat, 1971; Levy & Claravall, 1977).

On the other hand, the influence of interpersonal relationships upon noncompliance seems to be a promising area of study (Charney, 1972). Several investigations have determined that poor family relationships interfere with attendance compliance (Macdonald et al., 1963; Diamond et al., 1968; Heinzelmann & Bagley, 1970). Furthermore, relationships between patients and health care practitioners and/or hospital staff seem to exert an influence on noncompliance. For example, when patients believed they had poor relationships with their practitioners and were disgruntled about time spent waiting for attention or about seeing different physicians on each visit, attendance for appointments declined (Diamond et al., 1968; Finnerty, Mattie & Finnerty, 1973).

In addition, when patients perceived that their needs were either totally met or totally unmet by health care workers, their attendance rates dropped (Horenstein & Houston, 1976) and patients who did not feel encouraged to be independent by hospital staff were also known to have poor attendance (Pratt, Linn, Carmichael & Webb, 1977). Bowen and Twemlow (1978b) noted that noncompliance increased with increases in staff absenteeism, suggesting that the relationship between patient and worker

suffered when continuity of care broke down. Furthermore, when patients had a low readiness for counseling, they were less likely to attend (Slaikeu, Tulkin & Speer, 1975; Heilbrun, 1978) as they were when the staff were perceived to be less helpful (Slaikeu et al., 1975), to have low status (Levine, Moss, Ramsey & Fleishman, 1978), or if they were of the same gender as the patient (Vail, 1978).

Treatment Regimens

Unlike studies on attendance noncompliance, investigations on treatment noncompliance suggest that gender may be related to noncompliance for specific treatment regimens (men maintain longer abstinence from cigarettes) (Kanzler, Jaffe & Zeidenberg, 1976). Otherwise age, education, socioeconomic status, and marital status appear to have no effect (Table 2). Again there is no relationship between noncompliance and MMPI scores (Lie Scale) (Roth, Caron & Hsi, 1970) nor is there a relationship between authoritarianism or anomie and treatment noncompliance (Davis, 1968a).

Research investigating noncompliance for treatment regimens has suggested that the nature of the illness and aspects of the treatment regimen have mixed effects on noncompliance. Specifically, complex treatment recommendations have been found to be associated with noncompliance (Davis, 1966; Hulka et al., 1976; Brand et al., 1977) although Mucklow and Dollery (1978) did not find support for this view. Similarly both positive and

negative findings have been reported for severity of the illness, for knowledge of the treatment regimen, and for cost of the treatment (Table 2). However, perceived value of the treatment seems to be related to compliance for, if the treatment was not perceived to be valuable (Hammel & Williams, 1964) or if attitudes toward the treatment were negative (Best, 1975), noncompliance was more likely to occur.

Consistent with reports on factors related to attendance noncompliance, interpersonal relationships seem to be factors in treatment noncompliance. Observation of family relationships in children with renal transplants suggested that those children with difficult family relationships were more likely to be noncompliant for immunosuppressant therapy (Korsch, Fine & Negrete, 1978). Poor relationships between patient and practitioner or hospital staff were also likely to be related to noncompliance for treatment regimen (Davis, 1968b) and to drug errors by patients (Hulka et al., 1976). Along the same vein, failure of practitioners to be specific and detailed in making treatment recommendations (Levanthal, Singer & Jones, 1965) and attempts to arouse fears in patients (Raw, 1976) were likely to be associated with noncompliance. As for attendance noncompliance, when the health practitioner is perceived to have low status, treatment noncompliance may occur (Raw, 1976). Table 2 summarizes the results of studies on treatment noncompliance.

RESEARCH METHODOLOGY

There seem to be two major methodological problems which are inherent in noncompliance investigations. The first is related to measurement of noncompliance behaviour and the second is concerned with sample selection. In this section, both methodological problems will be discussed.

Measurement of Noncompliance

In an earlier section of this review, the point was raised that there did not seem to be a comprehensive definition of noncompliance in the literature even in view of the large number of studies. Further discussion has been delayed until now.

In an annotated bibliography, Sackett and Haynes (1976) rated 185 studies on the adequacy of the definition of noncompliance. They considered that approximately half had vague definitions of noncompliance or none at all. Among noncompliance definitions that Sackett and Haynes considered replicable were: "swallowing a pill" (Azrin & Powell, 1969); return of a protective glove by sugar cane cutters before the completion of the study (Suchman, 1966); "administering the prescribed medication and keeping the followup appointment" (Becker, Drachman & Kirscht, 1972a); and termination of the "detoxification process against medical advice before the treatment had been completed" (Cuskey, Chambers & Wieland, 1971).

More general definitions have been proposed. There is for example, Sackett's (1976a) definition: compliance is the "extent

to which the patient's behavior (in terms of taking medications following diets or executing other life-style changes) coincides with the clinical prescription". This definition, which seems to express the views of most researchers, suggests that there are degrees of compliance.

However, it is often implicit in the reports that total compliance with recommendations must occur before the patient is judged to be compliant. By contrast, missing one appointment or one dose of a drug is sufficient to be judged noncompliant. For example, noncompliance was defined as a negative blood assay or negative patient report (Becker, Rosenstock, Drachman, Schuberth & Teets, 1978). Thus, one instance of a negative blood assay was cause to label a patient noncompliant. Another study also required adherence to all recommendations all of the time in order for a rating of compliance to be made (Brand et al., 1977). The operational definitions of compliance that were rated by Sackett and Haynes (1976) and cited above also imply that compliance means total acceptance of the regimen.

By contrast, in some clinical situations there appear to be degrees of compliance that are acceptable. Gordis (1976) suggested that compliance could be viewed as the minimal amount of adherence to a treatment that would still produce a therapeutic effect. Thus, consuming 60% of a prescribed drug, for example, could be adequate therapeutically, and the patient considered compliant.

However, Gordis also noted that the use of biologically based criterion scores would not be feasible in all situations. In those cases, use of some criterion score other than 100% compliance seems preferable but has been used on infrequent occasions (for example, Macdonald et al., 1963; Davis, 1968a, 1968b). Difficulties in establishing realistic criteria for rating noncompliance may be a problem in research but not in clinical situations. If this is so, researchers may be well advised to turn to clinicians for a solution to rating problems.

Lack of a comprehensive definition has contributed to another measurement problem. Implicit in the theoretical models is the concept of compliance as a decision making process. In other words, the individual weighs all relevant evidence and makes a choice to comply or not comply. However, in some research, patients have been labelled noncompliant without having had a choice. For example, there are the elderly who are unable to open safety capped medication containers (68% were unable to open the containers; Atkinson, Gibson & Andrews, 1978). There are also those who are given badly phrased instructions (Bradshaw, Ley, Kincey & Bradshaw, 1975) and those judged noncompliant for program completion when in fact they have been discharged from the program (Morrow et al., 1977). Kellaway and McCrae (1975) found that about 29% of patients in their study who were labelled noncompliant actually had incorrectly written prescriptions and this precipitated their noncompliance.

Definitional problems in the area of noncompliance, therefore, create several problems. For one, the absence of a concise definition contributes to the fallacy that only 100% adherence constitutes compliant behaviour. Second, what is called compliance by one investigator may be called noncompliance by another. The lack of precision contributes to difficulties in comparing results across studies.

Therefore, Sackett's (1976a) definition of compliance could be improved by the addition of two statements: that compliance may occur with less than 100% adherence to the clinical prescription and that noncompliance involves simple forgetting or involves a decision to take a specific course of action but does not include those situations where the choice is removed or never given.

Related to a discussion about definitions is the matter of using ratings from composite scores of several different measures of compliance (Macdonald et al., 1963; Davis, 1968a; 1968b; Brand et al., 1977). Thus, an individual may be rated low on compliance because of nonadherence to one recommendation out of several (Davis, 1967). However, theoretical models suggest that a decision to comply is made for each individual recommendation. The decision is based on multiple factors, including some specifically related to the treatment. Furthermore, to combine scores invites loss of specificity of information about what recommendations are not supported by the patient.

A comparison of various methods of measurement of noncompliance follows for attendance, drug regimens, and other treatment regimens.

Comparison of Drug Noncompliance Measures

The extent to which the patient follows the drug prescription can be measured in several ways: the patient can be asked to report his drug compliance; the practitioner can assess whether the patient is taking the drugs; pill counts can be made to compare amount of drugs remaining with what should be left; or biochemical analysis can be done to determine if there are drug traces in the body.

It is clear that there is a lack of correspondence among results of the four measurement methods. First, patients misrepresent the extent to which they actually follow the treatment (Preston & Miller, 1964; Park & Lipman, 1964; Gordis, Markowitz & Lilienfeld, 1969; Roth & Caron, 1978) and it is difficult to assess how inaccurate their reports are since alternate methods also have inadequacies. Based on a comparison with a drug count, Roth and Caron (1978) found that only half of the patients who said they were taking their antacid had actually the correct amount of drug remaining. However, in another study, a comparison of patient reports and urine assay showed that 25% of patients claiming to be compliant for tuberculosis therapy did not have positive biochemical assays (Preston, & Miller, 1964). Even hospitalized patients given medications by hospital staff

(which would seem to increase compliance) had a 25% noncompliance rate by urine assay (Hare & Willcox, 1967).

Porter (1969) recommended what he believed to be a better method of patient reports for drug compliance. He suggested that patients be asked if they needed their prescriptions refilled. The timing of the request for more drugs could be compared with the time the request should have been made based on dosage and quantity of drug prescribed at the previous visit. However, Porter's procedure estimates noncompliance and fails to provide information on drug scheduling (whether the patient has followed the prescribed schedule), which is a critical matter with many drugs.

A more recent study (Roth, Caron, Hsi, 1971), found only 20% of patients requested new prescriptions at the rate prescribed and urine assay suggested that 36% of them were actually taking the drug. The discrepancy in findings suggests, again, a lack of correspondence in methods.

Physician assessments of patient drug noncompliance have also been found to be inaccurate (Preston & Miller, 1964; Mushlin & Appel, 1977; Roth & Caron, 1978) and therefore cannot provide a check on patient reports. In fact, both physician and patient reports are considered to provide only an estimate of true noncompliance (Roth et al., 1971).

Measurement of drug noncompliance by pill counts also has problems: pills that have been removed from the container are

not necessarily consumed by the patient (Eshelman & Fitzloff, 1976). In one study, bottles of antacids (containing a tracer substance) were supplied to patients and a drug count done on empty bottles and remaining drugs (Roth et al., 1971). The study noted that there were low correlations between bottle counts and urine assay when patients did not retain the empty bottles for purposes of the count and yet reported that they had consumed the drugs in the missing bottles.

Finally, biochemical assay as a measurement method would appear to be an accurate, direct measure of drug noncompliance. However, the method also has difficulties. The most critical problem is that a random assay used to search for a trace of a specific chemical usually only detects whether the drug was present in the body for a specific, brief period of time prior to the test: 24 hours for some psychiatric medications (Hare & Willcox, 1967), 24-48 hours for urine assay of some antihypertensives (Lowenthal, Briggs, Mutterperl, Adelman & Creditor, 1976), less than 12 hours for a urine colouring substance (Epstein & Masek, 1978), and one week for a saliva test for anticonvulsants (Mucklow & Dollery, 1978). Therefore, if the drug has been consumed in the sensitive period of the assay but not prior to that period, the patient is falsely labelled compliant. Furthermore, drug assays do not provide information on drug scheduling. Finally, the cost of biochemical assay in clinical practice is prohibitive.

Several recent studies have undertaken to compare methods of drug compliance measurement. Perhaps the most illuminating of these studies is the one by Eshelman and Fitzloff (1976). They were attempting to determine the effectiveness of different methods of pill packaging on compliance rates. Those results are not of as much interest at this point as the fact that they chose to obtain three separate but concurrent measures of compliance: urine assay for the drug chlorthalidone, pill counts, and patient self-reports of compliance.

First of all, two methods of drug dispensing were tested: traditional bottle or dial pack. Eshelman and Fitzloff determined that there was no difference in compliance rates for the two dispensing methods based on a pill count. The noncompliance rate was about 40%. However, urine assay showed substantial and significant differences in noncompliance rates on the same patients for the two dispensing methods. Those with the traditional bottle had a noncompliance rate of about 30% while those with the dial pack had a rate of less than 10%. In other words, the urine assay suggested that most patients in the dial-pack-group had taken the drugs while the pill count contradicted those findings.

There are at least two explanations. One is that some patients consumed drugs on the day of the urine assay but not regularly before thus giving false positive compliance rates for urine assay. The other possibility is that some patients were

taking the drugs as prescribed but used old stocks kept at home or possibly were sharing drugs with another family member (neither are uncommon events). These situations would produce false negative compliance rates with a drug count.

The question of whether or not the prescribed medications were being taken was also posed to patients. Concordance and discordance rates were then determined for the three measurement methods giving some interesting results. Not only were there a number of patients who said they took their drugs but for whom drug counts and urine assay agreements not obtained but there were a substantial number of patients who said they forgot to take their drugs even though urine assay and drug counts labelled them compliant.

In addition to explanations that patients are taking another's drugs or have taken pills on the day of the appointment, there is another explanation for incorrect compliance ratings. Patients may interpret the question "Do you forget to take your medications?" in a way other than what the investigators intended. Perhaps patients cited instances where one dose of a medication was missed but made up later in the day (scheduling delay). While these explanations may account for some cases that were incorrectly labelled noncompliant or compliant, it seems clear that in most cases the shortcomings of the drug measurement methods accounted for the errors.

A nonclinical study on drug taking behaviour of university

students assessed different approaches for solving noncompliance (Epstein & Masek, 1978). In this case, urine assay was not performed. Instead, some Vitamin C tablets used in the study had a urinary analgesic tracer agent chemically tied to them, having the effect of colouring the urine orange. Students were given several bottles of tablets (some with and some without the tracer substance) and also schedules for taking the different tablets. Then urine analysis was "performed" based on subject reports of time of urine discolouration compared with time the effect was expected if drugs were taken as recommended. In addition, students were given a variable number of extra tablets in their "prescription" (0 to 4 per week) and drug counts were based upon how many of the extra tablets were returned each week.

Clearly, their procedures were unusual. They developed a method of urine assay that was less costly than the one usually undertaken and they believed that the urine colour test was nonreactive since there was such a high baseline noncompliance rate. Additionally, the use of healthy university students who were taking a drug they knew to be harmless, for a short duration, and for nondisease was an unusual procedure. Nonetheless, the correlations between pill count and urine report ranged from .65 to .79 depending on the type of monitoring and experimental contingencies being evaluated. Correspondence between measurement methods in this study was better than that found in some clinical studies.

One other study (Davis, 1968a), examined incongruence in outcomes across different compliance methods. Forty percent of patients who reported compliant attitudes, were judged to be noncompliant and 52% of patients who reported noncompliant attitudes were actually judged to be compliant. Although the study does support findings that different measurement methods produce different results, it is important to note that patients were judged to be compliant or noncompliant based on an index developed from physicians' reports, patients reports, and chart audits.

Roth et al. (1971) confirmed findings that there is little correspondence among different drug measurement methods. They found no correlation between attendance at appointments, drug counts, patient requests for repeat prescriptions, and urine assay. The one exception was that patients were likely to take both drugs prescribed in the treatment program or none at all. In short, if they took the antacid, they would also take the atropine tablet.

The results of these studies suggest that compliance measurement for drug regimes has real limitations because of differences in precision among different methods. Fortunately, the same problems are not present to the same extent for other treatment regimens.

Measurement of Attendance Noncompliance

Attendance noncompliance measurement has relatively few problems compared with measurement of drug noncompliance since, in general, attendance can be accurately measured. However, there are few problems. For example, the patient who is not informed of a scheduled appointment may be labelled noncompliant when he fails to appear. Further, a patient may withdraw from a program by mutual agreement of patient and practitioner. Although failure to complete the program, in this case, is not a matter of noncompliance, the distinction has not always been made (Morrow et al., 1977). In addition, some investigators select an arbitrary number of clinic appointments as the criterion for deciding if the patient is still in the program (Horenstein, 1975) (some patients return at a later stage of the program after a period of absence).

One study that had measurement problems involved compliance to attend referral appointments among psychiatric patients (Jellinek, 1978). Compliance to attend was assessed by phoning the patients and asking if they had kept the arranged appointments. In other words, the patients reported on their attendance. There was no verification with the referral agency.

Measurement of Other Noncompliance

Other investigations of noncompliance have centered upon treatment regimens involving nondrug-nonattendance behaviour such as smoking (Mann & Janis, 1968; Barrett & Sachs, 1974; Burt et

al., 1974; Karoly & Doyle, 1975; Kanzler et al., 1976), exercise programs (Heinzelmann & Bagley, 1970; Oldridge et al., 1978), dietary regimens (Glennon, 1966; Magrab & Papadopoulou, 1977), and dental care (Evans, Rozelle, Lasater, Dembroski & Allen, 1970; Barnes, Gunther, Jordan & Gray, 1971).

There are two major difficulties with studies of compliance for recommendations to cease smoking. First, as Kanzler et al., (1976) noted in their review of smoking studies, most studies have short-term or no follow-up of success rates. For example, in two experimental studies of smoking behaviour there were varying but brief study periods: a 5-week experimental session (Karoly & Doyle, 1975); and a 1-month follow-up (Barrett & Sachs, 1974). One exception is a study by Mann and Janis (1968) which employed 8- and 18-month follow-ups.

The second difficulty is that researchers generally rely upon subject reports to assess effectiveness of the program (Mann & Janis, 1968; Barrett & Sachs, 1974; Burt et al., 1974; Karoly & Doyle, 1975). The results may only be estimates of true compliance rates.

Barrett and Sachs (1974) reported a 55% dropout rate in their test of aversive techniques to aid in ceasing smoking. For those who remained, there was no difference in effectiveness of one procedure from the other and, incidentally, there were no differences across treatments in attrition rates. As in the Karoly and Doyle study (1975), measures of smoking were dependent

on subject reports.

Several studies in the area of dental care were able to obtain more objective measures of noncompliance rates. In an investigation of effects of fear arousal messages on dental health care, children gave reports of improved dental care a short time after the communication but reported baseline levels of care at a 6-week follow-up. Examination of amount of plaque present showed a treatment effect at five days after the communication and no effect at a 6-week follow-up, confirming the verbal reports (Evans et al., 1970).

Similarly, another dental hygiene study had an objective measure of noncompliance where obtaining dental care was the outcome measure of a fear arousal study (Barnes et al., 1971). Apparently, the study was undertaken in a community where the investigators were able to obtain all dental records in order to assess the effects of a school dental health program.

Another area of compliance research concerns dietary regimens. One study with a 1-year follow-up for weight loss found that only 12% of the patients maintained their 20-pound weight loss (Glennon, 1966). In this case the measure of compliance was objective; pounds lost. Weight level, as well as serum BUN and potassium levels, were the measures of compliance for children who needed to maintain a special diet while undergoing hemodialysis (Magrab & Papadopoulou, 1977). The data were obtained daily on children hospitalized in a dialysis unit

and were considered sensitive measures of compliance to dietary restrictions.

One other area for compliance reasearch involves physical activity programs. However, the measure of compliance in these programs concerned attendance rather than physical outcomes (Heinzelmann & Bagley, 1970; Oldridge et al., 1978).

In conclusion, there are a number of methods for measuring noncompliance, specific to the noncompliance problem investigated. Most measurement methods are adequate. The exception, however, is with drug noncompliance measurement where there is poor correspondence among different measurement methods. The difficulties in drug noncompliance measurement may account for a greater tendency of researchers to investigate attendance or other forms of noncompliance.

Sample Selection

The procedure by which samples are obtained present a handicap to generalizability. In the first place, samples tend to be selected from narrow parts of the population; those who attend outpatient facilities (Mucklow & Dollery, 1978) or free clinics (Finnerty et al., 1973), occasionally some select patients from physicians' private practices (Stone, D. B., 1961), and workers in specific industrial settings (Tilson, 1976; Sackett, 1975). Second, those who have symptoms but do not consult health professionals are not included in the sample. In short, the sample starts out being select and, unfortunately,

becomes more select as the investigation proceeds. The process of selection bias is not unique to compliance studies but it does have special significance.

For example, patients may be self-referred or are referred to the study setting (usually a clinic or outpatient facility) from another clinic, emergency service, or other health service agency. However, some patients do not comply with the referral recommendation and, therefore, are not entered onto the patient roll. At this point, those who are on the patient roll and who have complied with the referral recommendation, might be considered to be more compliant than those who did not accept the recommendation for referral. Thus, any sample selected from the patient roll may also be compliant relative to those not on the roll. If patients have the option to participate or not participate in the study, then the sample consists of those who would comply with a referral recommendation and those who would comply with a request to participate in a health study. Ultimately, some patients stay for the duration of the study and some drop out before giving completed data. Therefore, results from investigations on noncompliance may be determined with a sample that is basically more compliant than a nonparticipant sample.

Of course there are statistical consequences of working with a restricted range of the sample but there are also more pragmatic concerns. Any technique developed to deal with

noncompliance behaviour may not generalize to the population. The same holds true for factors found to identify noncompliance behaviour.

There are a number of studies that contribute to this discussion since they have problems with respect to selection bias and illustrate the points in the discussion. For example, some studies begin with samples that are select because of the way they are chosen (initial selection bias). In one study, the patients were among those who showed up for appointments on a particular day, had no transportation problems, were taking two or more drugs (but only those that could be measured by serum assay), and consented to be in the study (Spector, McGrath, Uretsky, Newman & Cohen, 1978). Then, the patients were randomly assigned to two groups: the control group and the intervention group which received general information about causes of noncompliance. There were no differences in chemical assay results for the two groups, possibly because the intervention was ineffective but it is also possible that both groups were so select for compliance behaviour that the intervention was pointless. Incidentally, only 39% of patients completed the study, thus adding to the selectivity of the sample.

In other cases, patients volunteer for or are referred into a special program and then are investigated on a matter of compliance (Carnahan & Nugent, 1975; Kanzler et al., 1976). Jellinek (1978) asked psychiatric emergency patients for consent

to do a follow-up study. Fifteen percent refused and another 14% did not respond when contacted. Another group of patients were asked about their perceptions of an alcohol treatment program and of staff-patient relationships (Pratt et al., 1977). However, the patients who discussed their perceptions about staff and the program were selected only from among those who completed the program.

At the opposite extreme, only those who dropped out of a program were interviewed in order to determine what factors in the program were sources of trouble (Finnerty et al., 1973; Abernethy, 1976). Finding that early terminators of the program were dissatisfied with staff-patient interpersonal relationships (Finnerty et al., 1973) or had family or work problems (Abernethy, 1976) may not be unique to noncompliers, since there was no parallel information obtained from patients who continued to attend. Another initial selection problem was noted in one study where those who gave "unreliable information" (13% of the patients) were not included in a study of compliance for diabetic regimens (Stone, D. B., 1961).

Clearly, many of the selection problems noted in the preceding discussion are self-imposed. They are methodological problems that could be eliminated with careful planning. However, there is another class of selection problems that are difficult or impossible to eliminate. This concerns the group of patients who fail to complete the study (terminal selection bias)

and by virtue of the fact that they have not completed the program, they may be more noncompliant. Conclusions of the study may be based upon results given by those who remain in the study and who possibly are more compliant. The problem is extensive: dropout rates range from as low as 0-3% to 91% (Table 3).

Kanzler et al. (1976) attempted to contact by phone and by mail, a group of patients who have been involved in a commercial smoking termination program. Apart from the measurement problems of asking respondents for self-reports of smoking behaviour, there was the additional problem that those who responded may have been those who were more likely to have successfully quit smoking.

While the incidence of selection bias (either initial or terminal) is high, there has been relatively little concern expressed in the literature. Researchers have been cautioned to consider the entire sample or inception cohort in investigations of compliance (Sackett, 1976b), and some have, but very few.

In some cases, when the entire sample is accessible and there is some supporting descriptive data available, the task of considering the inception cohort is made easier. Tilson (1976) offered a blood pressure screening program to members of his trade union. Participants and nonparticipants could be described with a limited amount of information known (age and earnings). Similarly, addicts who entered a vocational training program were given the MMPI and Edwards Personal Preference Inventory (Lester,

Narkunski, Burkman, & Gandica, 1975). Later, the measures were used to attempt to discriminate those who completed vocational training from those who did not. There were no differences between participants and nonparticipants on these measures.

In another case, psychiatric patients were interviewed by social workers when they called an outpatient department for an appointment. Later, attendance at the scheduled appointment was compared with the complaint made over the phone. Those who did not attend the appointment were found to have nonspecific complaints, blame others for their problems, be in a crisis situation, and/or want medication (Gould et al., 1970).

In a study on smoking cessation, Barrett and Sachs (1974) were able to compare some dropouts with those who continued at the second of three aversion sessions. One problem was that students who dropped out at the third session were treated as nondropouts at session two producing some measurement error. It again raises the matter of the use of an arbitrary number of appointments as the cutoff for determining dropout status (Horenstein, 1975). The composition of dropout and nondropout groups at session three was different by session four and, therefore, Barrett and Sachs' (1974) conclusion that there was no difference in smoking behaviour for dropouts and nondropouts at session three might not be the same for session four. One conclusion which was not session-dependent was that it is not very effective planning to run a smoking termination study for

students just a few weeks before final exams (dropout rate was 55%).

It has also been suggested that certain clinical styles in therapists are correlated with rates of attrition of psychiatric patients (Fiester & Rudestam, 1975). However, in the study there were two different therapy centers (a state general hospital and a state psychiatric clinic) which had different personnel and presumably different referral processes. Since there were no differences among types of patients in the two centers and no differences in dropout rates, but there were differences in qualifications and experiences of staff of the two sites and reasons for dropping out, it was concluded that the reasons for terminating were influenced by styles of the staff. Patients who dropped out from the hospital group reported greater satisfaction with the therapist after one session and also felt capable of handling their own problems. On the other hand, dropouts from the state clinic expressed dissatisfaction with the treatment they had received. Ironically, state clinic staff were more experienced therapists. The confounding of site with staff, referral process, and patients makes it difficult to evaluate the results of the study. Furthermore, those who did not attend the first appointment were not included in this study.

However, those who drop out may evaluate counselors differently (Slaikeu et al., 1975). All callers on a crisis line over a 1-month period who were given appointments for counseling

were followed to determine the outcome of the appointments. Callers were divided by outcome into appointment keepers, no-shows, and cancels. Those who attended appointments were given a questionnaire when they arrived at the clinic while those who did not attend and those who cancelled appointments were questioned over the phone. Response rates varied. All attenders responded to the questionnaire; 93% of those who cancelled were contacted and 93% of them responded; only 68% of no-show callers were contacted and of them, only 70% responded.

In response to questions about perceived helpfulness of crisis line volunteers, no-show callers considered volunteers to be not helpful; attenders believed the volunteers were helpful. Ratings on helpfulness by those who cancelled fell between attenders and no-show callers. Differences in questionnaire response rates may account in part for different evaluations on staff helpfulness. However, the potential reactivity of the questionnaire situation for attenders should not be overlooked.

Several studies have concentrated upon certain aspects of volunteering behaviour as related to compliance investigations. In fact, one attempted to estimate the bias introduced into investigations by nonvolunteers (Adami & Vegelius, 1978). The investigators had access to sociodemographic and some health data on groups of women with and without breast cancer. Comparisons could be made among those who agreed to participate, those who agreed only after several requests, and those who refused to

participate in a study on risk factors associated with breast cancer. Since nonparticipants and reluctant participants were not different for marital status and age but both were different from willing participants, it was concluded that the effects on epidemiological data of nonparticipants could be estimated by reluctant participants. However, there were no differences between willing participants and reluctant participants for socioeconomic status and health history suggesting that there might be as much or more similarity between these two groups than between reluctant- and non-participants. In fact, no matter how reluctant, they did agree to volunteer, whereas the others steadfastly refused to participate. Hence, reluctant participants may be more like willing volunteers than like nonparticipants.

Another study called for psychiatric outpatients to be contacted and asked to participate in a "psychotherapy outcome study" done at a regularly scheduled appointment and taking several hours (Carr & Whittenbaugh, 1968). The outcome measure was volunteer status which was compared with MMPI, occupation, income, education, and psychiatric diagnosis, all of which had been obtained at earlier visits. The authors believed that there were fewer schizophrenics among volunteers and therefore concluded that degree of psychopathology influences volunteering. Furthermore, they believed that volunteers were more motivated about their treatment.

Patient records, obtained at some undisclosed time after the study, were examined and they demonstrated that 57% of those who had volunteered had also continued therapy or been referred elsewhere. On the other hand, 69% of nonvolunteers had terminated early from the program.

The study is important since it suggests that nonvolunteers are also more noncompliant. Thus, volunteers may form a select sample with respect to compliance. An important point to be made, however, is that it is possible that the contact with investigators and consequences of requests to volunteers may have differentially affected later attendance in the clinic and, therefore, volunteers may not necessarily have been more compliant. Conversely, but equally important, prior experiences of patients in the clinic may have influenced tendency to volunteer and later decision to terminate care.

The report of Roberts and Wurtele (1980) is disquieting. The investigators wanted to utilize various behavioural techniques to help diabetic patients who had been identified as noncompliant. However, the study was aborted because 82% of patients who were noncompliant for the diabetic regimen were also nonvolunteers for the program. Roberts and Wurtele raised the question about the existence of a noncompliance trait. However, long-standing conditions causing noncompliance on both occasions would be an alternate explanation.

Summary

Measurement and sampling problems seem to present major obstacles for researchers in the area of noncompliance research. Problems such as lack of precision with drug measurement methods and terminal selection bias seem unavoidable. Until new drug measurement methods are developed or old ones refined, researchers will have to take into account the lack of measurement precision in the interpretation of their findings. However, selection bias is a critical issue. Initial selection bias can be reduced by more rigorous experimental control. Studies should be evaluated for terminal selection bias in order to define differences between those who drop out and those who remain. In particular, it is critical to determine the extent to which noncompliance behaviour in general and tendency to drop out are correlated.

TECHNIQUES TO ALTER NONCOMPLIANCE

Since investigations to determine factors associated with noncompliance have not been illuminating, emphasis has shifted to the search for techniques to change noncompliance behaviour. Work in this area has developed in a number of directions.

Fear Messages

First, earlier studies used fear arousing communications, assuming that fear would increase perceived susceptibility to a disease and motivate the individual to comply with the recommendation (Levanthal et al., 1965). The studies are of two types: those that do not have an objective measure and those that do (Levanthal et al., 1965; Evans et al., 1970; Becker, Maiman, Kirscht,Haefner & Drachman, 1977).

The results of the studies are not compelling. Levanthal et al. (1965) believed that high or low fear had positive effects on compliance to preventive health recommendations provided that the fear message is delivered along with specific instructions. The results of that study (Levanthal et al., 1965) are in contrast with those of Evans et al. (1970) where the largest change in behaviour occurred for those receiving elaborate instructions rather than those receiving fear messages. However, the results in the Levanthal study are supported in part by Becker et al. (1977) who found that both high and low fear messages are effective. Others reported a combination of high and low fear to be more effective than either one alone (Barnes

et al., 1971).

Regarding duration of the reported effect, Evans et al. (1970) mentioned that dental care improved five days after the communication but had returned to baseline after six weeks. Thus, neither the effects of fear nor elaborated instructions were lasting. However, in another study, subjects reported reductions in smoking behaviour at 8- and 18-month follow-up (Mann & Janis, 1968).

Discrepancies have been reported in effects on attitudes and behaviours following fear messages (Levanthal et al., 1965; Evans et al., 1970). For example, fear about tetanus and intentions to seek tetanus immunization were reported to be high in the high fear groups (Levanthal et al., 1965) although only those who received either high or low fear along with specific instructions actually sought immunization. Incidentally, it should be noted that conclusions were based on responses of nine out of 59 students because only nine students complied with the recommendation whereas for 50 students, neither fear nor specificity of recommendations made any difference in their noncompliance.

By contrast, Kirscht, Haefner, and Eveland (1975) observed that neither fear arousal nor neutral messages had a differential effect on response rates for preventive health screening. They believed that a "positive appeal" resulted in a higher rate of screening. An examination of their "postive" message, however,

suggests that the appeal might be congruent with what others have labelled a low fear arousing message.

Contingency Management

A popular method to research compliance requires the subject to make a deposit of money that is refundable, contingent upon successful completion of a program or part of program. In several cases, the outcome of contingency management has been compared with other types of management. Lando (1976) determined that a deposit of money, the return of which was contingent upon cessation of smoking, was initially more effective than an aversive conditioning program. However, the effect was not sustained and by six months there were no differences in smoking behaviour for the groups.

Hagan, Foreyt and Durham (1976) examined the size of the deposit in relation to attrition and weight in a weight control program. They found that attrition rate was lowest for largest deposits ($20.00) but weight loss was highest for the no-deposit group and lowest for the high deposit group. The results suggested that contingency management affects attrition rates and treatment compliance differentially.

Other studies have used deposits in conjunction with particular treatments under investigation. One of these involved the treatment of alcoholics for whom a portion of their deposit was forfeited if they failed to pick up their drugs (Bigelow, Strickler, Liebson & Griffiths, 1976). Best (1975) also asked

subjects for a deposit which was returned if all data forms were completed and apparently this was quite successful. A similar procedure was used to encourage attendance at a weight loss program (Bellack, 1976).

Self-Monitoring

Carnahan and Nugent (1975) provided blood pressure measurement devices to patients with hypertension. Contrary to predictions, patients monitoring their blood pressure did not achieve better control than patients receiving traditional treatment. On the other hand, patients using a daily drug reminder chart improved compliance to drug taking (Gabriel, Gagnon & Bryan, 1977).

Instruction Methods

Various procedures to enhance learning of health information have been tested. Among these are programmed instruction methods. Clark and Bayley (1972) used traditional written programmed instructions to help patients improve knowledge about their drugs. However, compliance was not assessed. Computer programmed instructions were also used by patients to improve compliance for correct techniques in collecting specimens (Fisher, Johnson, Porter, Bleich & Slack, 1977). The researchers noted that computer instructions were effective with poorly educated people who, it would seem, lacked experience using the computer. Apparently, the computer instructions were superior to written and spoken instruction.

Similarly, programmed instructions were used with young diabetics to enhance acquisition of knowledge about diabetes. Although improved knowledge was found, there was no change in the ability of diabetics to manage their health (Etzwiler & Robb, 1972). Consistent with these results, it has been found that increased education about the specific disease does not result in improved compliance (Sackett, Gibson, Taylor, Haynes, Hackett, Roberts, & Johnson, 1975).

Other studies have tried to improve the quality of instructions. For example, specific instructions that are highly readable enhance recall of medical advice (Bradshaw et al., 1975). Furthermore special and specific instructions provided by a pharmacist resulted in improved compliance for drug taking (Clinite & Kabat, 1976; MacDonald, MacDonald & Phoenix, 1977).

In person requests seem to be more effective than mail contact. Face to face contact with the family pediatrician requesting installation of automobile seat belts was most effective in a safety appeal campaign (Bass & Wilson, 1964). Direct contact by a technician in a blood pressure screening program was also effective in achieving blood pressure follow-up (Stahl, Lawrie, Neill & Kelley, 1977). Neither letters nor offers of gifts resulted in as many blood pressures being taken as when the technician offered to go into the patient's home to take the blood pressures (rather than having the patient go to a clinic). Other researchers found improved attendance rates in a

clinic because of telephone reminders to patients about appointments (Levy & Claravall, 1977).

Other Behaviour Methods

The Premack Principle has been used to increase ward activities in noncompliant psychiatric patients (McMorrow et al., 1978). In another study, a token economy system was developed for use with noncompliant children requiring strict adherence to diet because of kidney failure (Magrab & Papadopoulou, 1977). To earn points, the children had to have daily weights and blood test results within specific ranges. This could only be done by adherence to the recommended diet. The researchers reported dramatic improvements for noncompliers and also reported that compliers had reductions in weight under the same program.

For clinicians wanting to utilize behaviour modification principles in their practices, a step by step guideline has been developed (Tapp, Krull, Tapp & Seller, 1978).

Summary

Overall, the methods developed to help overcome noncompliance have not proved to be very effective. Use of fear communications does not seem to be particularly beneficial although specific and detailed instructions (even when given by a computer) seem to be helpful. Increasingly, recommendations are being made that applied analysis of behaviour techniques be used to change noncompliance behaviour (Meyer & Henderson, 1974; Zifferblatt, 1975; Haynes, Gibson, Hackett, Sackett, Taylor,

Roberts & Johnson, 1977; Steckel & Swain, 1977; Sackett, Haynes, Gibson, Taylor, Roberts & Johnson, 1977). At the same time, social psychological theories about attraction and social influence are being emphasized for clinical style (Stone, G. C., 1979a; 1979b; Janis & Rodin, 1979; Rodin & Janis, 1979).

MODELS OF HEALTH AND ILLNESS BEHAVIOUR

Core Model

Preventive Health Model

One of the earliest papers to integrate findings of noncompliance studies into a theoretical model was published by Rosenstock, Derryberry, and Carriger (1959). It was an important paper and has formed the underpinnings of more recent models of noncompliance behaviour. The theory postulated that factors associated with noncompliance toward preventive health measures could be grouped into two categories: personal readiness factors and social-situational factors.

Personal readiness factors. According to Rosenstock et al. (1959), three health beliefs determine personal readiness to take a specific health action. These beliefs are related to: (1) susceptibility to the disease; (2) seriousness of the disease and, (3) safety and efficacy of the treatment. Rosenstock et al. emphasized that it is the individual's perceptions of susceptibility, severity, safety and efficacy rather than medical perceptions that are critical in determining personal readiness. In addition, it was emphasized that the interaction of these three beliefs determined personal readiness. For example, perceptions of susceptibility and seriousness would not be expected to result in compliant behaviour if the treatment were considered to be unsafe and/or ineffective.

Social-situational factors. Factors in the social situational category were split into two components.

(1) For the social-pressure factor, it was suggested that pressure to comply with some health action is introduced by salient, high-status people. Further, Rosenstock et al. noted that those who are compliant are more likely to have discussed the idea of the preventive measure with others.

(2) The "convenience factors" included barriers associated with cost and ease of attainment. The fewer the barriers, the more likely compliance would occur, especially if personal readiness factors were strong.

Rosenstock et al. speculated on the relationship between personal readiness factors and social-situational factors suggesting that in most cases they interact to produce an effect upon behaviour. However, Rosenstock et al. also believed that one set of factors, when strong, could influence compliance if the other set were inactive. This would be the case for the individual who considers it unlikely that he would ever have tuberculosis and has no strong beliefs about treatment efficacy. In other words, he would not seem to be motivated to take any preventive action. However, if his job requires and provides for annual chest x-ray, he would likely exhibit the preventive behaviour.

Suchman's Epidemiological Model. Suchman (1967) adapted the Preventive Health Model for use in applied epidemiological problems. Briefly, he proposed that preventive health behaviour be viewed in terms of epidemiological models (Suchman, 1967). Factors influencing health behaviour were divided into host, environmental and agent factors. Host factors are those related to the individual such as demographic variables, attitudes, experiences, and values. Environmental factors are the influences of experiences such as exposure to the news media and social groups. Agent factors include efficacious, safe treatments that are easily acquired. In short, host, environmental and agent factors are similar to readiness, social-control and convenience factors conceptualized by Rosenstock et al. (1959) and their interaction determines preventive health behaviour.

The Original Health Belief Model

In 1966, Rosenstock made some revisions to the preventive health model he had developed with others (Rosenstock et al., 1959). The readiness component, including factors of perceived susceptibility and seriousness, were basically unchanged. However, the concept of perceived benefits of action replaced the component detailing social-situational factors. Determinants of overall benefits of the action included perceived efficacy and safety of the treatment which were previously part of the readiness component. Other determinants of benefits of the

action included physical, psychological, and economic costs and the convenience of the action.

A major addition to the theory was the concept of a "cue to action" in which some event was thought to be an essential prelude to preventive health action. In Rosenstock's terms, the state of readiness was the source of "energy" for the action, the perceived benefits determined the "path of action", and the cue to action was the charge to initiate the process. Typically, cues were thought to be derived from internal physical events, social pressures, news media, or hearing of illnesses of acquaintances. It was predicted that stronger cues are necessary to initiate health behaviour when levels of readiness are low.

It was clear that Rosenstock was convinced that the health beliefs (perceived susceptibility, seriousness, and benefits) were influenced by many factors such as social norms, situational events, and demographic factors (Rosenstock, 1966; 1975). However, none were explicitly incorporated into the model.

Contemporary Models

There are two major contemporary models of health-sickness behaviour, both of which are derived from the preventive health behaviour model of Rosenstock et al. (1959). These are the Health, Illness, and Sick Role Model of Kasl and Cobb (1966a, 1966b) and the Health Belief Model of Becker et al. (Becker Drachman & Kirscht, 1972a, 1972b, 1974; Maiman & Becker, 1974;

Becker & Maiman, 1975).

Health, Illness, and Sick Role Behaviour

Kasl and Cobb (1966a, 1966b) have contributed important knowledge about health behaviour by adapting the theory of Rosenstock et al. (1959) into a general three-stage model of health, illness and sick role behaviour in which each of the three behaviours is influenced or determined by a number of factors. Definitions of the three stages of health-sickness behaviour precede a discussion of the factors influencing the behaviours.

According to Kasl and Cobb (1966a) the three aspects of behaviour are defined in the following terms and include associated biological states and psychosocial behaviours (health identity and role related behaviours):

(1) Health behaviour is directed toward prevention of disease or toward detection of asymptomatic disease and is consistent with feeling healthy, being able or willing to maintain usual social roles, and with being illness-free or with having asymptomatic disease.

(2) On the other hand, illness behaviour is the stage in which the individual who now perceives himself to be sick searches for confirmation that he is sick and for treatment suggestions. This stage is associated with feeling sick, with having reduced ability to function in normal roles or with making preparations to assume the sick role, and with

having asymptomatic or symptomatic disease. Furthermore, diagnosis of the disease may have been determined in this stage.

(3) Behaviour directed toward the restoration of health is sick role behaviour and, according to Kasl and Cobb, involves an adjustment in usual roles. In the sick role stage, the individual does indeed know he is sick, functions in the capacity of or prepares to leave the sick role and has been diagnosed and is undergoing treatment.

Relationship of three-stage model to compliance. Each of the three stages has specific and corresponding psychosocial behaviours and biological states. It appears that unless conditions are right and appropriate stages, behaviours, and states are properly aligned, compliance with recommendations may not occur. For example, the individual who, in spite of being sick, perceives himself to be healthy and maintains his usual roles is unlikely to respond positively to treatment recommendations. Therefore, failure to adopt the sick role completely accounts for some noncompliance behaviour.

However, another aspect of noncompliance behaviour involves the person who has assumed a sick role but opts for some other treatment than that recommended. In this case, there is alignment of the components of the sick role stage but other factors or conditions account for noncompliance.

Factors influencing health, illness, sick-role behaviour. There are a number of factors which are believed to influence health, illness, and sick role behaviour. Since Kasl and Cobb conceptualized health-sickness behaviour to exist on a continuum, many of the factors which impinge upon one of the three stages do so on the other two stages.

Factors influencing health behaviour. There seem to be two central components to this stage. These are perceived threat of the disease and perceived value of the health action. Both are influenced by many other variables, some shared, and both have direct influence on health behaviour. Shared variables include age, sex, race, ethnic origin, socio-economic factors, and knowledge about the disease. However, in addition, perceived threat of the disease is influenced by perceived susceptibility, perceived seriousness, and the value the individual places on health. Similarly, factors which contribute to perceived value of the action include the costs incurred by the action, the perceived efficacy of the action, and prior experience with health services. Figure 1 demonstrates the relationship between the factors associated with health behaviour.

Clearly, there are similarities between this stage of Kasl and Cobb's model and the preventive health model (Rosenstock et al., 1959) or the Health Belief Model (Rosenstock, 1966). The two components, perceived threat of the disease and perceived value of the action, compare favourably with components of the

Figure 1

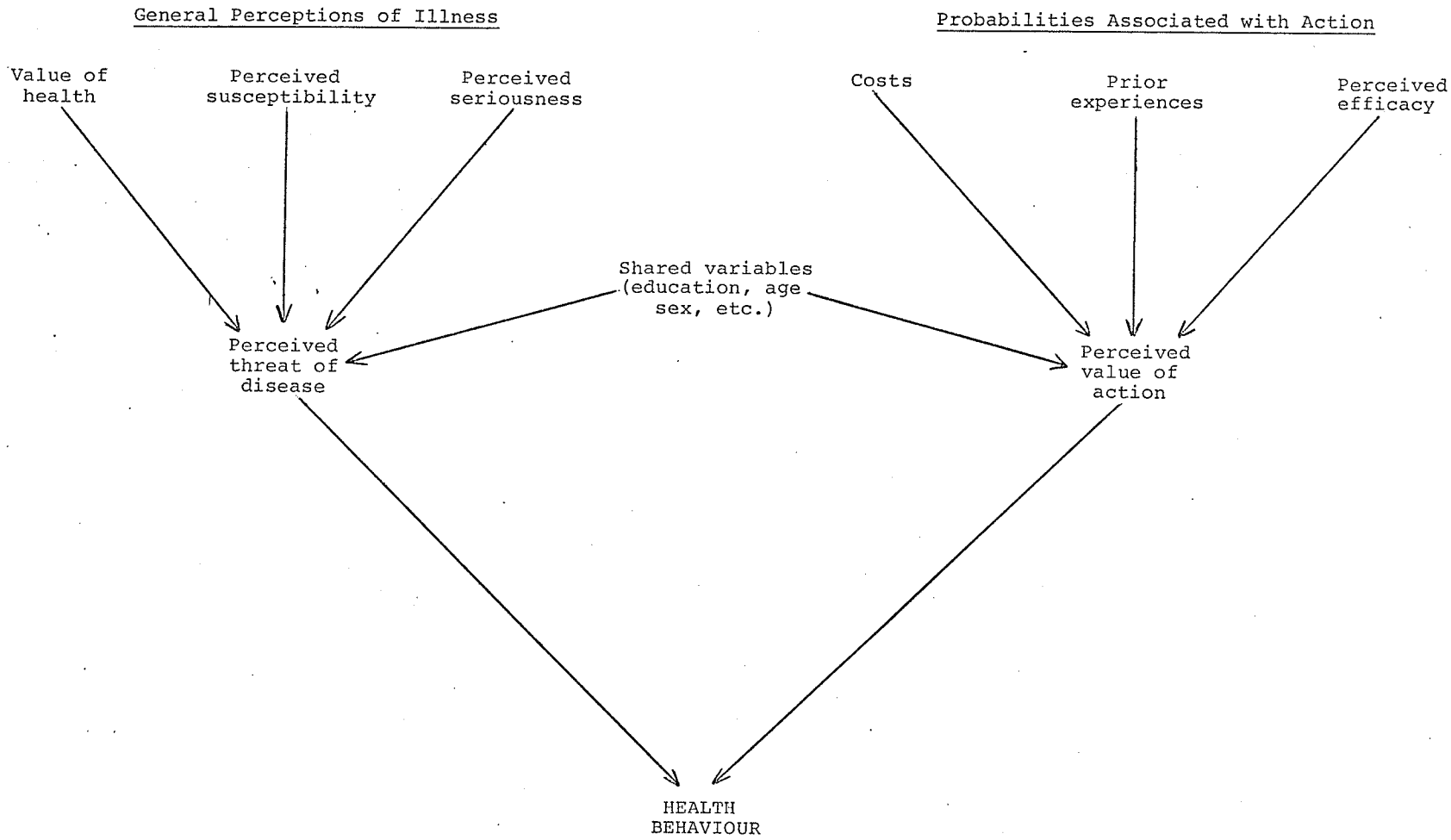

Figure 1: Interrelationship of factors which influence health behaviour according to Kasl and Cobb (1966a)

earlier models. In addition, Kasl and Cobb (1966a) have been more explicit about factors influencing the components. However, compared with the model of Rosenstock (1959), the health behaviour stage conceptualized by Kasl and Cobb (1966a) lacks provision for interpersonal or social influence factors considered to be important in determining the nature of the health action.

Factors influencing illness behaviour. Several new components were added to this stage of the model. One was a feedback loop between psychological distress and pain or discomfort associated with the disease. In this component, psychological distress should intensify discomfort and in turn, the intensified discomfort should magnify the psychological distress. Furthermore, psychological distress is hypothesized to influence perceived threat of the disease and, ultimately, illness behaviour. The model makes no allowance for the reverse effect of perceived threat of the disease on psychological distress but it seems that the model should be modified to predict two-way interactions between perceived threat and psychological distress.

Another modification by Kasl and Cobb to the second stage was an expansion of factors which commonly affect perceived value of action and perceived threat of disease. These factors, also influencing psychological distress, were identified as self-acceptance, mechanisms for coping with anxiety, site where

symptoms are experienced, and thresholds for discomfort and disability. Although not included in the model, a stimulus or cue to action was considered necessary to initiate behaviour. Kasl and Cobb cited the same cues for health behaviour as did Rosenstock (1966) but suggested that symptoms acted as cues in illness behaviour. The relationships among factors and illness behaviour are illustrated in Figure 2.

Factors influencing sick role behaviour. The most complex of the health-sickness behaviours seems to be sick role behaviour (Kasl & Cobb, 1966b). In this stage, a variety of sick role norms influence not only sick role behaviour but also the course of the disease and perceived threat of the disease. Sick role norms, conveyed by family, friends, physicians, and co-workers, may be acted upon by: conformity behaviour; extent to which the norms are congruent with self-concept and other roles; and "mutuality of doctor-patient expectations" (Kasl & Cobb, 1966b).

Furthermore, the disease process is also determined by motivation to regain health, the strength of which is defined by personal needs and "environmental and interpersonal incentives and barriers to recovery" (Kasl & Cobb, 1966b). Therefore, in this stage, in addition to effects on sick role behaviour from perceived threat of disease, perceived value of action, and psychological distress, there are two additional determinants of sick role behaviour: sick role norms and motivation to regain health (figure 3).

Figure 2

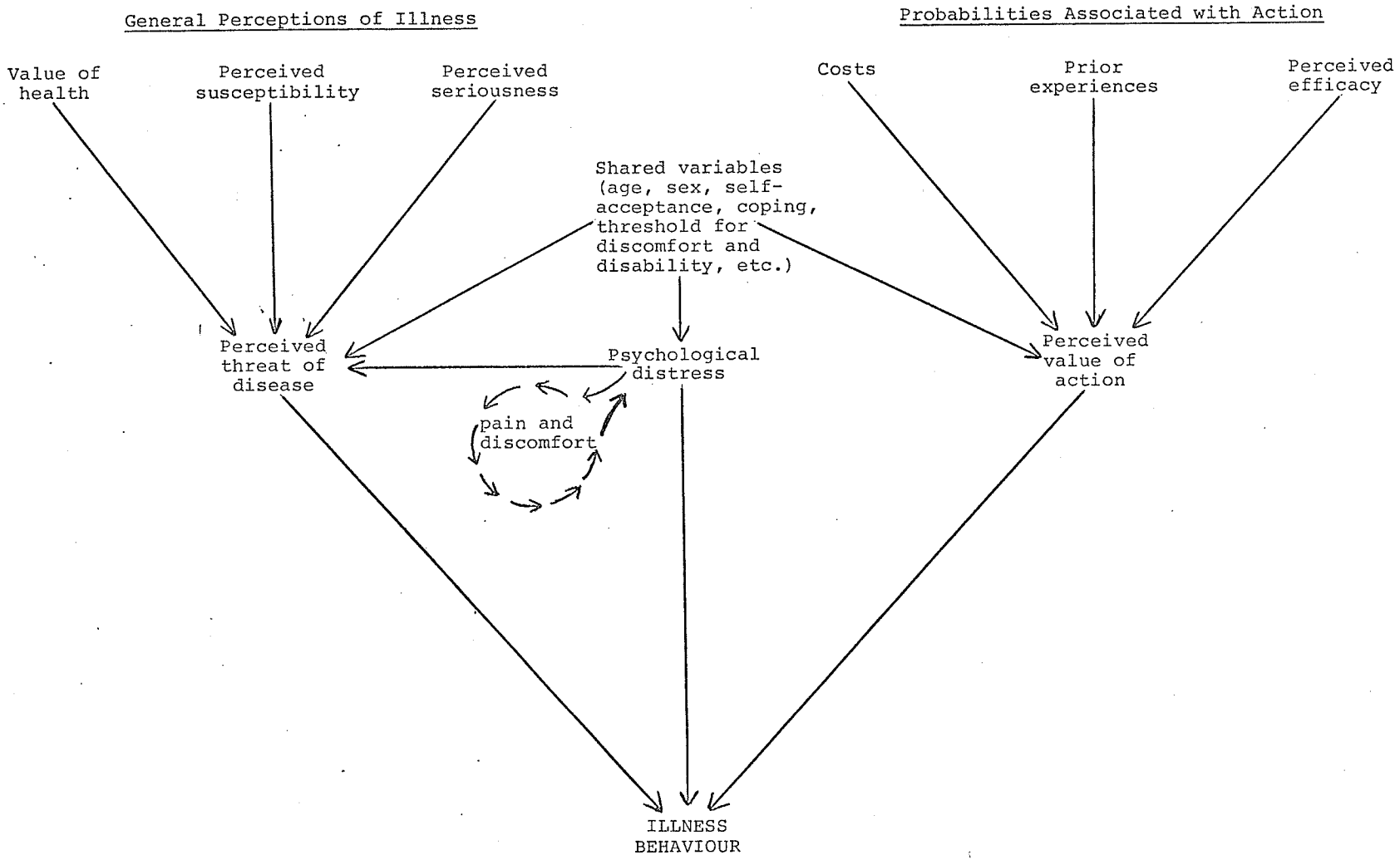

Figure 2: Factors determining illness behaviour according to Kasl and Cobb (1966a)

Figure 3

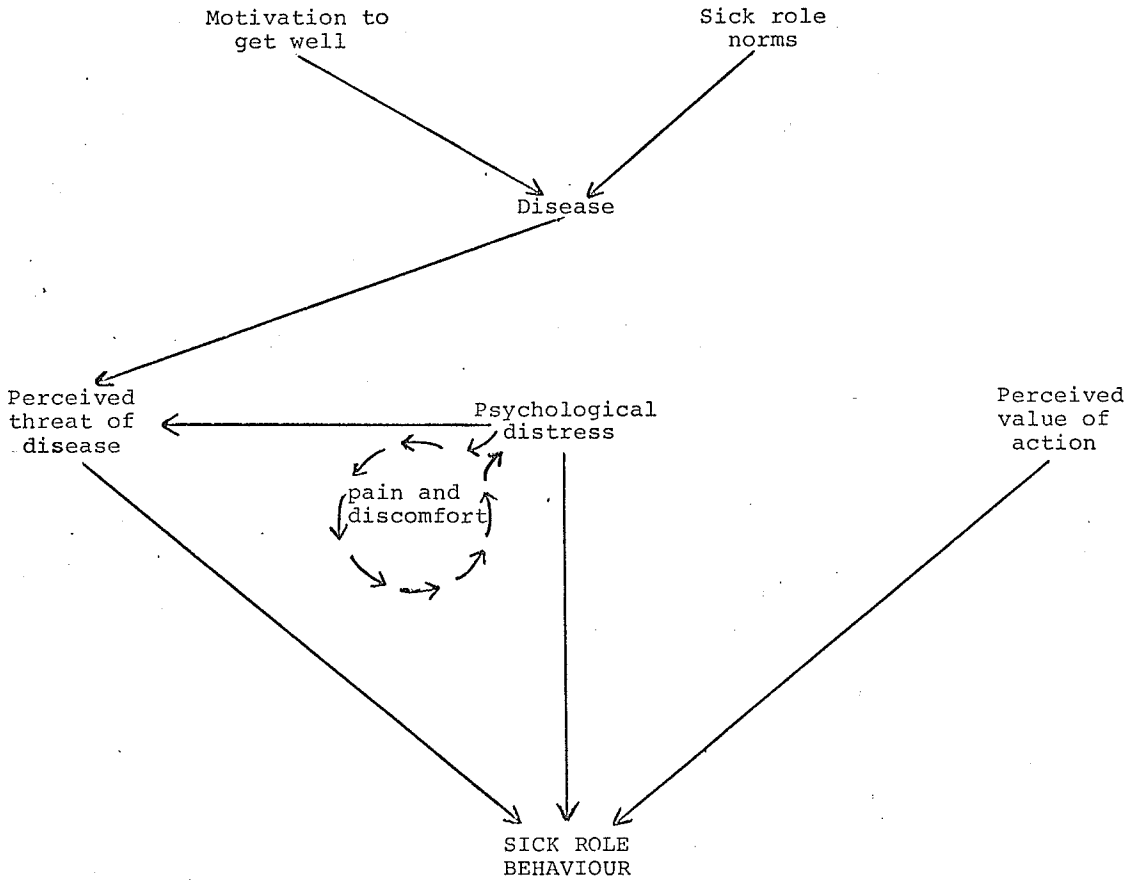

Figure 3: Determinants of sick role behaviour according to Kasl and Cobb (1966b)

Summary of the model. In the Kasl and Cobb model, there are three stages to health-sickness behaviour: (1) health, (2) illness and (3) sick role. The three behaviours are associated with specific biological and psychosocial states, all of which exist along interfacing continua. Furthermore, health, illness, and sick role behaviour are determined by complex interactions of variables and are expected to vary across individuals and across occurrences with any individual.

The model has evolved from the theory of Rosenstock et al. (1959) and has been more specific than other models in identifying the factors influencing health-sickness behaviour and in specifying the interrelationships between factors. However, the diagramatic models are probably incomplete since Kasl and Cobb (1966a) acknowledged the importance of some psychological and demographic variables upon factors but did not include the components in the model.

Health Belief Model

Development of the model. The model presented by Rosenstock et al. (1959) was the original Health Belief Model and this was later revised by Becker and his colleagues (Becker et al., 1972a; 1972b; 1974; Maiman & Becker;, 1974; Becker & Maiman, 1975). Factors were regrouped into the following three categories (Becker et al., 1972a):

(1) General health motivation influenced by perceived threat of the disease, need to control health matters, and general

concern for health.

(2) Motivation to reduce the threat as determined by: perceived severity, perceived susceptibility, and extent to which social roles were disrupted by the illness.

(3) Perceived value of the action determined by perception of the efficacy of the diagnosis, the treatment, and of medical care in general.

Essentially, perceptions of health and related matters were considered to motivate or fail to motivate the individual to take certain health actions. The model of Becker et al. is an illness model rather than a preventive model but Becker believed that the preventive model could be adapted to any stage of health-sickness behaviour.

In later papers Becker et al. added the influence of barriers and of social pressure to the representation of the model (Becker et al., 1974; Becker & Maiman, 1975). In addition, past health experience, patient-practitioner relationships, family relationships, and demographic factors ("modifying and enabling" factors) were included. All of these, as well as factors described earlier (Becker et al., 1972a) were thought to influence readiness to act which in turn determined whether the individual would pursue a specific health action (figure 4). The concept of a cue to action appears to have been discarded (Becker & Maiman, 1975).

In comparing the Health Belief Model of Becker and his

Figure 4

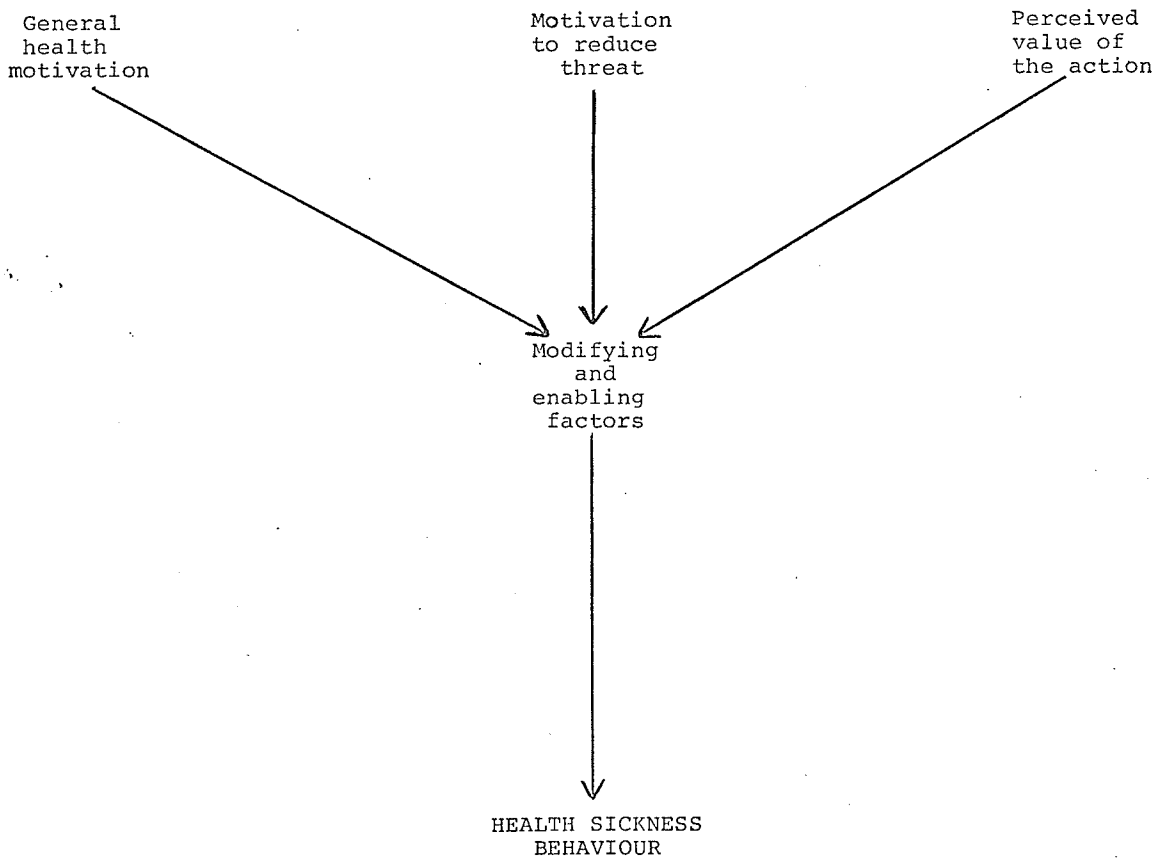

Figure 4: Interrelationship of factors influencing health sickness behaviour according to the Health Belief Model

associates with the model of Kasl and Cobb (1966a, 1966b), it is apparent that both are extensions of the Rosenstock model and that both have reorganized the original model and introduced additional factors thought to influence health-sickness behaviour. However, Kasl and Cobb (1966a, 1966b) thought that more factors influenced behaviour than what Becker et al. did. As well they have stressed the complex interactive nature of the factors in influencing health, illness, or sick role behaviour. They also believed that a core group of factors influenced all stages of behaviour but that certain factors were important for specific stages. Therefore, Kasl and Cobb stressed the importance of maintaining a three-stage model.

On the other hand, Becker et al. seemed to suggest that a single factor, perceived severity for example, is able to predict health-sickness behaviour as are combinations of factors. Furthermore, Becker et al. believed that the same factors influenced all health-sickness behaviour and that one model was therefore appropriate for any stage of health-sickness behaviour.

On the whole Kasl and Cobb (1966a, 1966b) have been more explicit in identifying different factors thought to influence health-sickness behaviour and have specified the direction of the inter-relationships among factors.

Compliance Behaviour Model. Christensen (1978) suggested that compliance behaviour to drug recommendations could be explained using a modified Health Belief Model which he called

the Compliance Behaviour Model. He proposed a dynamic model in which there are periodic adjustments to perceptions during the progression of disease. On the first visit to the practitioner, according to Christensen (1978), the patient has existing beliefs about the likelihood of an effective treatment as influenced by demographic factors, past experience, and peer group norms. The patient-practitioner interaction provides a knowledge-base for evaluating perceived threats of the disease and perceived benefits of action in order to determine the course of action. The greater the difference between the information imparted by the practitioner and the beliefs held by the patient, the less probable it is that the patient will comply.

Other adjustments are made as the disease progresses or as the treatment is followed, that is, as new information arrives, necessary adjustments are made. The dynamic nature of the model is an important concept which does not appear to be embodied in the Kasl and Cobb model nor the Health Belief Model. It seems important to acknowledge that the behavioural outcome for each episode of illness does not result from a static process because perceptions and experiences may undergo transformation during any particular illness. For example, costs and barriers related to a particular health problem may change during the course of an illness.

Other than the inclusion of the concept of dynamic processes, the model is a restatement of the contemporary Health

Belief Model. Furthermore, the Compliance Model is also specific to drug treatment regimens and, therefore, to sickness behaviour rather than preventive behaviour.

Tests of the Health Belief Model. Becker and his colleagues have completed several tests of the Health Belief Model (Becker et al., 1972a, 1974; Becker et al., 1977; Becker et al., 1978). The research procedure was similar in each of the studies; mothers or grandmothers of children were interviewed to measure dimensions of the Health Belief Model. The interview items were not available in the studies but some have been included in the Sackett-Haynes Compliance Questionnaire (Note 2).

Typically, the respondents were black, female, and of low socio-economic status. The children who were related to the respondents were under treatment in a hospital outpatient clinic for otitis media (Becker et al., 1972a, 1974), obesity (Becker et al., 1977), or asthma (Becker et al., 1978). Respondents were asked questions at the initial visit and data obtained on several compliance measures (appointment keeping, drug taking, weight, and/or reports from respondents).

Table 4 presents measures of association between some health beliefs and several measures of compliance from three studies by Becker et al. (Becker et al., 1972a; Becker et al., 1977; Becker et al., 1978). While it is not intended that the results be compared in depth across studies, there are several points that should be made. Variability exists among the

measures of association across different diseases and across measures of compliance. This suggests that health beliefs may vary for different diseases and different measures of compliance. In addition, because it was not apparent that the same questions were posed in each of the three studies, the variability in results may reflect different questions. Many of the correlations reported by Becker et al., although statistically significant, are not significant in their ability to aid in predicting noncompliance (for example, in the study on obese children the measure of association between perceived susceptibility to illness and attendance was 0.185, a statistically significant value that has little practical significance). However, Becker et al. have stated that health beliefs are "useful in the explanation and prediction of compliance behaviour" (Becker et al., 1974).

Another investigation of the Health Belief Model did not obtain correlations as high as Becker et al. and concluded that the model could not predict compliance to treatment regimens (Taylor, Note 3). This study involved foundry workers who were under drug treatment for hypertension. Scores on items (Sackett-Haynes Standardized Compliance Questionnaire, Note 2) were included if "homogeneous with respect to the belief being measured" and composite scores were developed for each belief. Measures of correlation included pill counts, review of medical and pharmacy records, and patient reports. Health beliefs were

measured before treatment onset and six months after. Simple correlations between health beliefs (susceptibility, severity, benefits, safety) and pill counts or patient reports ranged from 0.01 to 0.15. Correlations at six months were higher (0.02 to 0.32) but the largest proportion of variance explained for different measures of compliance and testing times was 15%.

Because the correlations were higher at the second testing session, Taylor concluded that health beliefs do not precede but instead develop during the disease or the treatment process. Furthermore, he suggested that the health beliefs were of little value in identifying noncompliant patients although he suggested that different study populations might offer different results.

In a study which corresponds in many ways to the Taylor study, higher correlations between compliance behaviour and health beliefs were found (Ramsay, Note 4). Patients were hypertensives who were screened in a manner similar to Taylor's study. Compliance measures included appointment attendance, blood pressure levels, and weights rather than drug taking.

Not all of the items on health beliefs were used from the Sackett-Haynes Standardized Compliance Questionnaire. Some items were not selected because they were inappropriate for an adult population or because they seemed to be poorly constructed. Multiple regression analysis was performed between individual items of health beliefs (not composite scores) and compliance measures. Health beliefs could explain 24% of the variance in

appointment attendance, 23% of the variance for dropout rates, and only 11 or 13% of the variance for two blood pressure recordings. The results at this point, were not markedly different from Taylor's results.

However, Ramsay added several revised items of the Health Belief Model and reported substantial increases in amount of variance that could be explained (49% in appointment nonattendance, 37% in dropout rates, and 36-37% for blood pressure levels). The conclusion was that health beliefs could aid in predicting compliance behaviour but that careful revision and testing of the items was essential.

There are several differences in the studies that should be mentioned. First, Taylor used composite scores for each health belief while Ramsay correlated individual test items with compliance measures. A second and critical difference was that the measures of compliance were not the same in the two studies. A third difference was that Taylor studied male industrial workers while Ramsay studied both males and females.

One other difference between the two studies was that Taylor suggested the Health Belief Model itself was responsible for the failure to predict. Ramsay, on the other hand, attributed the poor predictive ability to the lack of validity of the items used to test the model. It is probable that both are partial explanations for the failure of the model to predict compliance.

A recent study has examined the relationship between health beliefs and adoption of an aerobic exercise program (Lindsay-Reid & Osborn, 1980). A surprising outcome from that study was not that there was a strong correlation between perceived susceptibility to disease and successful maintenance of the exercise program but was that low perceived susceptibility to disease was common in those who adopted the regimen. This result surely causes traditional views of health beliefs to come under question. Lindsay-Reid and Osborn did not use the Health Belief Model test items which may, in part, explain differences in results between this and Taylor's and Ramsay's studies.

One other finding in the Lindsay-Reid and Osborn study that should be noted is that an interaction was found between perceived susceptibility and perceived ability to reduce the risk of the disease. This finding supports an earlier statement in the present review on the importance of factor interactions, a matter apparently overlooked in Becker's theories.

Summary. An overview of the theoretical models of health-sickness behaviour suggests a marked similarity among the models. All are derived from the model proposed by Rosenstock et al. (1959) and have maintained the central features of it (readiness or threat-value of the illness and value of the health action). In addition, all have acknowledged the multiplicity of factors and events contributing to health-sickness behaviour, although some models suggest that a larger number of factors are

implicated.

Clearly, none of the models has addressed issues related to quantification: how strong must beliefs be to produce a particular health action? Nor has the question been completely addressed on the direction of the interaction of factors which contribute to health-sickness behaviour.

In view of the difficulties associated with applications of the contemporary Health Belief Model, that is, whether the model is a good predictor or not, it may be necessary to re-evaluate recent studies to determine if a new interpretation of the data is in order.

NEW DIRECTIONS

This review of compliance literature has suggested that there are several research problems that are contributing to our failure to define noncompliance. Thus, new directions are now suggested for research.

Evaluation of noncompliance behaviour using recent social-psychological theories has recently become evident (Janis & Rodin, 1979; Rodin & Janis, 1979). Among these is the "attribution theory" and credit should go to Davidson as one of the first to adapt the concept to health-illness behaviour (Davidson, 1976). According to Janis and Rodin (1979), the causes to which the patient attributes his/her health-illness will influence health actions taken. They give the example of the elderly attributing depression-related symptoms (memory loss, fatigue, etc.) solely to the aging process rather than to loss of spouse or loss of other family and friends and to changes in economic conditions. Causal attributions like the latter would generate different expectations about health than the former.

Janis and Rodin (1979) also point out that knowledge about causal attributions has advanced to the point that it should be possible to manipulate attributions and, consequently, health actions. Other social-psychological theories are being adapted in health care settings to explain patient and practitioner behaviour. Included are theories related to social power and influence (Rodin & Janis, 1979) and decision making processes

(Rodin & Janis, 1979).

The trend toward use of contemporary social-psychology is an important step in compliance research. Too many past studies have concentrated efforts on finding correlates of noncompliance, few of which can be manipulated to affect noncompliance behaviour. The trend is also important because it will encourage development of more effective techniques for solving noncompliance. As Davidson (1976) pointed out, current techniques frequently stipulate external supervision of the patient in successful management of noncompliance. However, the responsibility for effecting lifestyle changes or adhering to other treatment regimens falls primarily on the patient, who spends most of his/her time in unsupervised settings. New techniques should aim to enhance motivation to comply and should provide the patient with strategies for managing his/her own behaviour.

Adaptation of social-psychological theories to the study of noncompliance does not require that older theories of noncompliance behaviour be discarded. In fact, the theories are compatible and should be integrated. In addition, development of an instrument to identify potential noncompliants should be undertaken. In view of the problems that have arisen with use of Becker's items for identifying a patient's health beliefs, it is recommended that the instrument undergo further evaluation.

The present literature review discussed compliance

research methodologies at length. Several major methodological problems impede progress in compliance research. One of these, problems associated with measurement of noncompliance, should have a high priority for consideration by researchers.

There is a need for a clear understanding of exactly what noncompliance is. Noncompliance is the discrepancy between the patient's action and either the practitioner's recommendation or a health behaviour initially generated by the patient. Furthermore, a patient may be compliant for one regimen but noncompliant for another. Finally, compliance is not a dichotomous variable but instead has a wide range of values.

A second methodological problem concerns sample selection biases in compliance research. There is some indication that samples investigated for noncompliance behavior may actually have a tendency to be compliant because of sample selection methods. If such a bias does exist, previous research outcomes may be suspect. Therefore, investigations to determine if selection bias occurs should be undertaken.

Finally, this review suggests that it is time to initiate a search for solutions to noncompliance problems, particularly noncompliance in patients who actually express the desire to comply with the regimen. Specifically, a special effort is required in the area of compliance for recommended lifestyle changes.

At the same time, consideration should be given to cost-

effectiveness of programs which deal with noncompliance, particularly programs for noncompliant patients who did not express a desire to comply. In the final analysis, some instances of continued noncompliance may be less costly to the health care system than the implementation of programs to change noncompliance.

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Table 1: Correlates of Attendance Noncompliance

Factor Associated with Being *More Noncompliant*	Source*
ETHNIC GROUP:	
1. negative	Macdonald, Hagberg & Grossman (1963); Diamond, Weiss & Grynbaum (1968).
2. blacks & hispanics	Jonas (1971).
3. whites	Lipman, Rickels, Uhlenhuth, Park & Fisher (1965).
EDUCATION:	
1. negative	Carr & Whittenbaugh (1968); Davis (1968b); Diamond, Weiss & Grynbaum (1968); Gould, Paulson & Daniels-Epps (1970); O'Leary, Rohsenow & Donovan (1976); Oldridge, Wicks, Hanley, Sutton & Jones (1978).
2. less education	Cuskey, Chambers, Wieland (1971); Brand, Smith & Brand (1977); Jellinek (1978).
3. higher education	Lipman, Rickels, Uhlenhuth, Park & Fisher (1965).
AGE:	
1. negative	Macdonald, Hagberg & Grossman (1963); Glick (1965); Davis (1968b); Diamond, Weiss & Grynbaum (1968); O'Leary, Rohsenow & Donovan (1976).
2. younger	Caldwell, Cobb, Dowling &de Jongh (1970); Abernethy (1976); Gates & Colborn (1976); Jellinek (1978); Nelson, Stason, Neutra, Solomon & McArdle (1978).
3. older	Tilson (1976); Adami & Vegelius (1978).

Table 1 - Continued

Factor Associated with Being *More Noncompliant*	Source
SOCIOECONOMIC STATUS:	
1. negative	Gould, Paulson & Daniels-Epps (1970); Finnerty, Mattie & Finnerty (1973).
2. lower earnings or lower status	Caldwell, Cobb, Dowling & de Jongh (1970); Fiester & Rudestam (1975); Elinson, Henshaw & Cohen (1976); Heinemann, Moore & Gurel (1976); Brand, Smith & Brand (1977); Shah, MacBride & Lamb (1977).
3. higher earnings	Tilson (1976).
GENDER:	
1. negative	Macdonald, Hagberg & Grossman (1963); Glick (1965); Diamond, Weiss & Grynbaum (1968).
2. females	Abernethy (1976).
RELIGION:	
1. negative	Glick (1965); Davis (1968b); Diamond, Weiss & Grynbaum (1968).
EMPLOYMENT STATUS:	
1. negative	Glick (1965); Carr & Whittenbaugh (1968); Davis (1968b); Diamond, Weiss & Grynbaum (1968); Gould, Paulson & Daniels-Epps (1970); Oldridge, Wicks, Hanley, Sutton & Jones (1978).
2. unemployed	Nelson, Stason, Neutra, Solomon & McArdle (1978).

Table 1 - Continued

Factor Associated with Being *More Noncompliant*	Source
MARITAL STATUS:	
1. negative	Davis (1968b); Diamond, Weiss & Grynbaum (1968).
2. married	Cuskey, Chambers & Wieland (1971); Adami & Vegelius (1978).
3. widowed & single	Brand, Smith & Brand (1977).
FAMILY SUPPORT:	
1. poor family relationships	Macdonald, Hagberg & Grossman (1963); Diamond, Weiss & Grynbaum (1968).
2. nonsupport of health program by wife	Heinzelmann & Bagley (1970).
DIAGNOSIS:	
1. negative	Diamond, Weiss & Grynbaum (1968); Oldridge, Wicks, Hanley, Sutton & Jones (1978).
2. negative in psychiatric sample	Glick (1965); Shapiro (1974).
3. more schizophrenics in psychiatric sample	Carr & Whittenbaugh (1968).
4. no difference between compliers and noncompliers for MMPI or Edwards Personal Preference Inventory	Lester, Narkunski, Burkman & Gandica (1975); Krasnoff (1977).
5. no difference in self-esteem	Heinemann, Moore & Gurel (1976).
6. no difference in locus of control for early dropouts but dropouts from alcoholic after-care program more likely to be Internals	O'Leary, Rohsenow & Donovan (1976).
7. no difference in dropout rate and locus of control	Bowen & Twemlow (1978). (a)
8. patients with nonspecific health complaints	Gould, Paulson & Daniels-Epps (1970); Walfish, Tapp, Tulkin, Slaikeu & Russell (1975).

Table 1 - Continued

Factor Associated with Being *More Noncompliant*	Source
PROGNOSIS:	
1. negative	Diamond, Weiss & Grynbaum (1968).
2. attrition when lifestyle demonstrates high risk for repeat myocardial infarction	Oldridge, Wicks, Hanley, Sutton & Jones (1978).
3. when psychological prognosis is poor	Shapiro (1974).
SEVERITY OR INTENSITY OF HEALTH PROBLEM:	
1. high anxiety	Diamond, Weiss & Grynbaum (1968).
2. more serious health complaints	Heinemann, Moore & Gurel (1976).
3. more expensive drugs and more prescriptions	Brand, Smith & Brand (1977).
REFERRAL PROCESS:	
1. negative for source of referral-from	Glick (1965).
2. negative for source of referral-to	Jellinek (1978).
3. negative for length of wait for scheduled appointment	Gould, Paulson, & Daniels-Epps (1970); Gates & Colborn (1976).
4. long wait for appointment and/or no reminder	Levy & Claravall (1977); Shah, MacBride & Lamb (1977).
5. telephone reminder did not improve appointment keeping	Kidd & Euphrat (1971).
6. telephone and mail reminders improved attendance	Schroeder (1973); Gates & Colborn (1976).
7. lack of in-person contact	Stahl, Lawrie, Neill & Kelley (1977).
8. attendance poor when patients given block appointments as opposed to individually scheduled appointment	Rockart & Hofmann (1969).

Table 1 - Continued

Factor Associated with Being *More Noncompliant*	Source
RELATIONSHIP WITH DOCTOR OR HOSPITAL STAFF:	
1. with same sex therapist	Vail (1978).
2. poor relationship or poor therapist skill level	Davis (1968b); Diamond, Weiss & Grynbaum (1968); Howard, Rickels, Mock, Lipman, Covi & Baumm (1970); Jellinek (1978).
3. with increase in staff absenteeism	Bowen & Twemlow (1978). (b)
4. dissatisfied with waiting times & seeing different doctor each visit	Finnerty, Mattie & Finnerty (1973).
5. perceived volunteer phone counselors to be less helpful	Slaikeu, Tulkin & Speer (1975).
6. low readiness for counseling	Slaikeu, Tulkin & Speer (1975); Heilbrun (1978).
7. perceived needs either totally met or totally unmet	Horenstein & Houston (1976).
8. patients perceived less emphasis on self-autonomy by hospital staff	Pratt, Linn, Carmichael & Webb (1977).
9. poorly given medical instructions	Brand, Smith & Brand (1977).
10. perceived that health professional was treating them as low status	Levine, Moss, Ramsey & Fleishman (1978).

Table 1 - Continued

Factor Associated with Being *More Noncompliant*	Source
MISCELLANEOUS:	
1. negative for weather conditions	Jonas (1973).
2. negative for patient's belief in the efficacy of the treatment	Heine & Trosman (1960).
3. poor knowledge of disease in conjunction with high degree of experience with illness	Tagliacozzo & Ima (1970).

* includes studies where one overall rating is given for compliance to attend and for adherence to medical regimes.

Table 2: Correlates of Medical Regimen Noncompliance

Factor Relationship with Regimen *Noncompliance*	Source
GENDER:	
1. negative	Hulka, Cassel, Kupper & Burdette (1976).
2. women less likely to effect long-term abstinence from smoking	Kanzler, Jaffe & Zeidenberg (1976).
EDUCATION:	
1. negative	Hulka, Cassel, Kupper & Burdette (1976); McKercher & Rucker (1977).
AGE:	
1. negative	Roth & Berger (1960); Hulka, Cassel, Kupper & Burdette (1976).
SOCIOECONOMIC STATUS:	
1. negative	Hulka, Cassel, Kupper & Burdette (1976).
MARITAL STATUS:	
1. negative	Hulka, Cassel, Kupper & Burdette (1976).
PSYCHOSOCIAL:	
1. negative for authoritarianism & anomie	Davis (1968a).
2. negative for MMPI Lie Scale	Roth, Caron & Hsi (1970).
3. low frustration tolerance, denial of sick role, acting out, or suicidal behaviour	Kaplan de-Nour & Czaczkes (1972).
4. negative for IQ	Winokur, Czaczkes, & Kaplan de-Nour (1973).

Table 2 - Continued

Factor Relationship with Regimen *Noncompliance*	Source
RELATIONSHIP WITH DOCTOR OR HOSPITAL STAFF:	
1. with "high-fear" communications	Raw (1976).
2. nonspecific medical recommendations	Levanthal, Singer & Jones (1965).
3. when patient labelled as demanding, overbearing, obstructive	Davis (1968a).
4. when health care worker is perceived to be of low status	Raw (1976).
5. more drug errors with some diseases when relationship with doctor is poor	Hulka, Cassel, Kupper & Burdette (1976).
6. poor interpersonal relationships	Francis, Korsch & Morris (1969); Korsch & Negrete (1972).
COMPLEXITY OF REGIMEN:	
1. negative	Mucklow & Dollery (1978).
2. more complex regimens	Brand, Smith & Brand (1977); Hulka, Cassel, Kupper & Burdette (1976).
3. when change in personal habit is required	Davis (1966).
4. depends on the treatment recommended	Donabedian & Rosenfeld (1964); Nelson, Stason, Neutra, Solomon & McArdle (1978).
5. when written instructions are complex or difficult	Ley, Jain & Skilbeck (1976).
FAMILY SUPPORT:	
1. poor family relationship	Korsch, Fine & Negrete (1978).

Table 2 - Continued

Factor Relationship with Regimen *Noncompliance*	Source
SEVERITY OF ILLNESS:	
1. negative	Hulka, Cassel, Kupper & Burdette (1976); Podell, Kent & Keller (1976).
2. more severe illnesses	Davis (1968a).
KNOWLEDGE OF TREATMENT REGIMEN:	
1. negative for drug name, instructions, or general medical knowledge	McKercher & Rucker (1977).
2. negative for knowledge of specific disease	Etzwiler & Robb (1972); Podell, Kent & Keller (1976).
3. increased drug errors (commission & scheduling misconceptions) when drug function not known	Hulka, Cassel, Kupper & Burdette (1976).
COST OF TREATMENT:	
1. negative	Hammel & Williams (1964).
2. more expensive	Brand, Smith & Brand (1977).
PERCEIVED VALUE OF TREATMENT:	
1. perceived that recommended treatment was not needed	Hammel & Williams (1964).
2. attempts to change attitudes occurred at time when attitude and expectation about treatment were negative	Best (1975).

Table 3: Attrition Rates in Compliance Studies

Source	Attrition/Refusal
Adami & Vegelius (1978).	11% nonvolunteer
Barnes, Gunther, Jordan & Gray (1971).	30% from study
Barrett & Sachs (1974).	45% from study
Bellack (1976).	11% from study
Brand, Smith & Brand (1977).	22% did not attend follow-up
Carnahan & Nugent (1975).	3% dropped out of program
Carr & Whittenbaugh (1968).	37% nonvolunteer
Eshelman & Fitzloff (1976).	33% did not attend follow-up
Finnerty, Mattie & Finnerty (1973).	42% from program
Fisher, Johnson, Porter, Bleich & Slack (1977).	12% did not attend
Glick (1965).	54% from program
Glogow (1970).	10% at first visit
Green, Levine & Deeds (1975).	33% did attend appointments
Hagan, Foreyt & Durham (1976).	38% from program
Heinemann, Moore & Gurel (1976).	14% from program
Horenstein & Houston (1976).	31% at third visit
Kanzler, Jaffe & Zeidenberg (1976).	56% nonvolunteer (attrition rate not given)
Lester, Narkunski, Burkman & Gandica (1975).	24% end of program

Table 3 - Continued

Source	Attrition/Refusal
Levanthal, Singer & Jones (1965).	0% (one session)
Levy & Claravall (1977).	35-55% did not attend follow-up
Mitchell & Robson (1977).	38% did not attend follow-up but most returned after telephone prompting
Morrow, Del Gaudio & Carpenter (1977).	48% from program
Mushlin & Appel (1977).	20% did not attend follow-up
Oldridge, Wicks, Hanley, Sutton & Jones (1978).	42% at 1 year
Pratt, Linn, Carmichael & Webb (1977).	91% attended fewer than 4 sessions 63% never came
Roth & Caron (1978).	17% at 6 months
Roth, Caron & Hsi (1970).	25% dropped out of program
Slaikeu, Tulkin & Speer (1975).	48% did not attend follow-up
Spector, McGrath, Uretsky, Newman & Cohen (1978).	61% at third visit
Tilson (1976).	23% did not participate
Vail (1978).	49% attended fewer than 3 sessions

Table 4: Relationship Between Health Beliefs and Compliance According to Becker

Health Beliefs	Taking Medications	Attending Appointments
Concern about child's health		
Otitis media	0.351*	0.430*
Obesity		0.140*
Asthma	0.190	
Susceptibility to illness		
Otitis media	0.300	0.276
Obesity		0.185*
Asthma	0.173	
Severity of the problem		
Otitis media	0.416*	0.340*
Obesity		0.066
Asthma	0.733*	
Efficacy of the drug		
Otitis media	0.332*	0.081
Asthma	0.529*	
Safety of diet		
Obesity		0.223*

*statistical significance was reported

APPENDIX B

Appendix B: Blood Pressure Screening Programs

Among the patient population served by the Health Sciences Centre, Winnipeg, Canada are many individuals who are unable or unwilling to utilize conventional medical facilities in private physicians' offices or in hospitals and clinics. Many of these patients sporadically utilize the emergency and walk-in services at the hospital for health care leaving little opportunity for successful continuity of care. Given this situation, clinical management of health problems for these individuals is usually difficult.

When the health problem is hypertension, patient behaviour of this type is particularly unsuited to successful clinical management. In attempting to identify an acceptable type of care for patients who shun conventional health care, a decision was made to develop a model clinic in which primary health care would be provided by nurses working under medical supervision. The central research concern was patient compliance for hypertension regimens recommended in the Nurse Hypertension Clinic.

In order to conduct a hypertension compliance study, the Nurse Hypertension Clinic had to be established: suitable hypertensives had to be identified and enrolled in the clinic and this was accomplished with a blood pressure screening program.

Initial screening involved a daily review of the Emergency and Primary Health Care Unit records to identify patients with casual diastolic readings of more than 100 mmHg and who also

appeared to meet the minimal clinical requirements. To these were added the names of patients that had been supplied by the various wards within the Health Sciences Centre.

Among the clinical requirements were: casual diastolic blood pressure greater than 100 mmHg, not currently under treatment for hypertension, and no serious health problems. In addition, the criteria included the provision that the patient not have had a myocardial infarction, stroke, or transient cerebral ischemia within the preceding six months; increasing angina within the preceding three months; or severe heart failure interfering with regular activities.

All patients who had diastolic blood pressures at or above 100 mmHg, who appeared to meet the clinical criteria; and who did not mention having attended a private physician were approached directly in order to schedule appointments for follow-up in a second stage screening clinic. In other cases, the private physician was contacted for permission to continue the screening and if necessary to take the patient into the treatment program.

Patients who attended second stage screening were left to rest for a minimum of 10 minutes before three lying blood pressures were obtained from the arm with the highest reading, followed by three standing blood pressures from the same arm at two-minute intervals. Later the patient was asked a series of questions relating to past hypertension history and general health history. Initial clinical investigation included

urinalysis, serum creatinine, BUN, and CBC. The patient was then asked to return approximately one week later for the second set of resting blood pressures.

On that occasion, the same blood pressure procedure was followed and where the resting diastolic blood pressure was greater than 95 mmHg and all other selection criteria were met, the patient was offered treatment in the Hypertension Clinic. If the patient agreed to attend the clinic, an informed consent was obtained and, with socioeconomic status and gender controlled, the patient was then randomly assigned to one of the six nurses. The first clinic appointment was booked by the screening personnel after which the patient's continuing care was managed by the clinic nurse.

Records were maintained on all patients who were found to have casual diastolic blood pressures at or above 100 mmHg. Outcomes of requests to participate in primary screening and/or secondary screening were noted. In addition, reasons for refusal to participate were recorded.

The primary screening and second stage screening programs commenced in March, 1978 and continued until the end of April, 1979.

APPENDIX C

Appendix C: Diseases Categorized as Chronic

hypertension
chronic obstructive lung disease
alcoholism
arthritis (rheumatoid, osteoarthritis)
diabetes
diabetic neuropathy
diabetic retinopathy
Hashimoto's thyroiditis
hypothyroidism
asthma
brochiectasis
chronic personality disorder
schizophrenia
chronic depression
long term drug abuse
hepatic cirrhosis
alcoholic cerebellar degeneration
Korsakoff psychoses
coronary artery disease
pernicious anemia
chronic stasis ulcer
chronic abdominal pain
chronic prostatism

APPENDIX D

Appendix D: Diseases Classified by Severity Scale

Least Serious - 1 -	2	3	Most Serious 4
strains	fracture of:	alcoholism	hypertension
sprains	ulna	diabetes	pulmonary
contusions	fibula	chronic	emboli
lacerations	iliac crest	obstructive	coronary
abrasions	nose	lung disease	artery
muscle spasm	humerus	stab wound from	disease
ganglion (ankle)	metatarsal head	criminal assault	congestive
cysts	radius	asthma	heart
cellulitis	patella	phlebitis	failure
mallet finger	malleolus	abnormal pap smear	claudication
soft tissue	zygoma	angio-neurotic	severe
foreign body	glenoid rim	edema	diabetes
bursitis	rib	skull fracture with	femoral
myalgia	pneumonia	concussion	artery
tenosynovitis	bronchitis		emboli
baker's cyst	tuberculosis		
low back pain	tympanoplasty		
venereal disease	septorhinoplasty		
upper respiratory	surgical follow-up		
tract infection	for: cholelithiasis		
sinusitis	hysterectomy		
furuncle	abdominal pain (not		
laryngitis	yet diagnosed)		
otitis media	flank pain		
impetago	pyelonephritis		
pharyngitis	urinary tract		
vaginitis	infection		
monilial infection	pelvic inflammatory		
conjunctivitis	disease		
gastritis	menorrhagia		
allergic dermatitis	epididymo-orchitis		
acne	duodenal ulcer		
dandruff	cataracts		
scabies	bilateral corneal		
pinworms	abrasions		
tympanic membrane	vitreous hemorrhage		
perforation			
anxiety	optic nerve		
physical exam	infarction		
iron deficiency	macular burn		
anemia	schizophrenia		
ingrown toe nail	acute psychoses		
dental caries	depression		
frost bite	Korsakoff psychoses		
corneal abrasion	suicide gesture		
epistaxis	herpes zoster		
minor burns	major frost bite		
	major burn		
	chronic stasis ulcer		
	dislocation shoulder		
	arthritis		
	prolapsed lumbar		
	disc		
	verrucous papilloma		
	hypothyroidism		
	amputation distal		
	phalanges		