MEASURING AND PREDICTING DIABETIC PATIENTS' COMPLIANCE

by

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ABSTRACT

The validity of self-report of compliance with treatment was assessed in 227 diabetic outpatients (150 on insulin regimens, 42 on oral hypoglycemic agent regimens, and 35 on diet alone regimens) by analysing a multitrait-multimethod matrix and by examining the relationship of self-report to health outcome measures, background factors, response bias measures, objective compliance measures, and actual levels of compliance. Self-report provided a relatively valid measure of compliance. Levels of compliance were generally found to be higher when calculated on the basis of patients', rather than physicians',criteria. The intercorrelations among different compliance behaviours were very low. Ninety patients, equally divided among the three types of regimen, and a spouse control group were assessed prospectively concerning their dietary compliance. Marlatt and Gordon's relapse classification scheme was used to categorize the conditions under which dietary deviations occurred. Emotional and social factors were found to be less important than temptations and urges as reasons for noncompliance. The Health Belief Model, Bandura's Social Learning Model, and actual health consequences were all unsuccessful in accounting for the frequency of dietary deviations.

RESUME

Des questions relatives à la mesure, à la consistance et aux déterminants de la conformité des patients diabétiques ont été examinées dans deux études. Dans l'étude 1, la validité de l'auto-rapport en tant que mesure de la conformité a été démontrée relativement à quatre des exigences d'un régime: le contrôle du poids, l'analyse, l'expression de symptômes et la sécurité. Les degrés de conformité calculés en tenant compte de la compréhension qu'ont les patients des exigences du régime différèrent substantiellement de ceux obtenus à l'aide des critères utilisés par les médecins traitants. Les niveaux de conformité des patients étaient inconsistants de l'une à l'autre des quatres exigences de régime. L'étude 2 était focalisée sur l'examen prospectif de la non-conformité alimentaire. Les niveaux de non-conformité des patients n'étaient pas consistants dans le temps, les écarts se produisant surtout dans des situations de tous les jours sous l'effet de la tentation. Le Modèle de croyance quant à la santé (Health Belief Model), le Modèle d'attentes de Bandura, ainsi que les conséquences sur l'état de santé des patients n'ont pu rendre compte de la fréquence des déviations alimentaires.

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CHAPTER 1

Introduction

It is generally recognized that serious discrepancies often exist between the actions recommended to patients by their physicians and patients' actual behaviours with respect to those recommendations. This has come to be known as the 'noncompliance problem'. Although other terms with less authoritarian connotations (e.g. adherence, co-operation, concordance) have occasionally been employed, the terms 'compliance' and 'noncompliance' are still those most commonly used and will therefore also be used here.

Although noncompliance is a problem in the treatment of all types of disorder, it has particular importance in chronic diseases such as diabetes. In order to avoid both immediate and long-term health consequences, diabetic patients must acquire new habits and make permanent modifications in lifestyle. Little is known with certainty about the extent to which they are successful in doing this or the factors which promote or inhibit such changes. This absence of reliable information is due in part to a paucity of relevant studies, and in part to serious methodological inadequacies in many of the studies which have been performed.

The purpose of this introduction is to present an overview of compliance research, with special reference to the problem of noncompliance in the context of diabetes. Some of the issues presented here will be discussed in greater detail in subsequent chapters in relation to specific studies.

The first section is devoted to an examination of the difficulties in adequately measuring compliance. The second is concerned with examining unresolved conceptual issues in compliance measurement. The third section will discuss the approaches and models most frequently used to explain compliance. The diabetes context will be described in the fourth section. With this background, the fifth and final section will review the few studies which have actually examined how well diabetic patients follow their prescribed treatments.

Measuring Compliance

A variety of methods have been developed in the attempt to determine exactly how closely patients' behaviour conforms to that required by their regimen. None of the methods is entirely satisfactory: each represents an uneasy compromise among ethics, practicality and accuracy. In the following sections, the strengths and weaknesses of each approach will be outlined, and those studies which have attempted to validate each method using adult patient populations will be reviewed. First, attention will focus on so-called 'objective measures', such as treatment outcome and pill count. Then attention will shift to the more 'subjective methods', such as self-report and staff ratings.

Physiological Measures

These methods aim to assess patients' behaviour by determining if changes in the body predicted to result from that behaviour have in fact occurred. Two types of measures are used: detection methods and treatment outcome assessment.

Detection methods. In some instances it is possible to detect the presence of prescribed medication or its metabolites in patients' blood or urine, or to add a tracer to the patients' medication with the same results. Such analyses may permit determination of whether or not a particular medication was taken within a limited time period prior to the urine or blood test, although it will not necessarily accurately assess the amount taken (Moulding, Onstad & Sbarbaro, 1970). Gordis (1979) points out that these results may be affected by pharmacokinetic variation, or individual differences in how drugs are absorbed, distributed, metabolized and excreted. Further, bioavailability, or the amount of drug absorbed from a particular formulation relative to the amount from a standard reference formulation, may vary depending upon the preparation of the drug and how it is administered. In addition, conclusions about compliance drawn from such measures may be weakened if patients detect the tracer or know that urine and blood analyses will reveal their drug-taking. Such knowledge may lead subjects to change their habitual patterns of compliance.

The final disadvantages of this type of measure are practical ones. Few drugs can be accurately assayed by these techniques, and the introduction of a safe, sensitive, unobtrusive marker is often difficult and costly. Its

usefulness is limited to those physician recommendations concerning substance ingestion, and is of no value in assessing compliance of with other types of behaviour (such as dietary change). Diabetic patients' compliance has not been assessed using these methods.

Treatment outcome. The debatable assumption underlying this approach to measurement is that readily detectible physical changes will ensue if patients are completely faithful to the treatment prescribed. The treatment outcome relationship is seldom so straightforward. As with the detection methods discussed above, individual variability will significantly influence response to treatment. Factors unrelated to compliance, such as exposure to stress in diabetic patients, and the adequacy and appropriateness of the prescribed treatment may also affect outcome. A good response may even result from poor compliance. A number of studies of weight loss programs have, for example, found that participants, who were successful in weight reduction had not necessarily complied with the techniques prescribed (Brownell & Stunkard, 1978). Diabetic patients may be highly noncompliant with their regimen, leading to an increase in blood glucose level, an undesirable outcome, but also to weight loss, a valued outcome.

The outcome of treatment, then, is frequently mediated by individual differences, adequacy of prescribed dosage and treatment, and by concomitant medical and nonmedical treatments, as well as by compliance. Alogna (1980) used two such diabetic treatment outcomes -- weight loss and blood glucose levels-- as the sole bases for classifying patients in

her sample as compliant or noncompliant. More often these measures are used in studies of diabetic compliance as an adjunct to self-report (e.g. Christensen, Terry, Wyatt, Pichert & Lorenz, 1983).

Pill Count

In assessing medication compliance, it is possible to compare the number of pills remaining at any one time with the number that should be present according to the prescription. This method of measuring compliance assumes that missing pills have in fact been appropriately ingestd by the patient rather than thrown out or given to a relative or friend. It also relies on patients to remember to bring their pills with them to the clinic visit or requires unscheduled home visits, a time-consuming undertaking. A recent and less onerous variant on the pill count method is use of a medication monitor, which typically records the occasions on which medications are removed from the packet. Medications can still, however, be removed and not ingested.

Two studies have compared this type of monitoring with physiological measures. When empty medication bottles seen at home visits compared with a blood tracer in 160 ulcer patients, Roth, Caron and Hsi (1970) found that patients consistently had blood levels significantly lower than expected by bottle count, although the overall between-method correlation was .80. Fletcher, Pappius & Harper (1979) did not find any relationship between pill count and serum digoxin concentration in congestive heart failure patients.

These results suggest that the pill count method does not necessarily have good validity, and it provides little

information concerning the regularity or pattern of drug-taking. None of the studies of diabetic patients' compliance have used such a method.

Health Professionals' Ratings

Members of the health care team would appear to have available to them much of the information necessary to make an accurate estimate of their patient' compliance. They have access to physiological measures and to patients' reports. A number of studies have compared health professionals' judgments with presumably more objective indices, such as pill counts or physiological indices. The value of these studies is variable, as many have used a very small number of raters or relatively inexperienced ones (interns and residents). The overall conclusion, however, is that while there may be significant correlations between health professionals' ratings and other methods, the level of compliance as determined by the objective criteria is generally considerably lower than that assigned by the professionals. Table 1 summarizes the studies which have examined this phenomenon.

Only one study has assessed the validity of health professionals' ratings of diabetic patients' compliance. Hadden, Montgomery, Skelly, Trimble, Weaver, Wilson & Buchanan (1975) used a dietitian's ratings of patient adherence to identify the 'good' and 'poor' dieters among 57 diabetics subsequent to a six month program of intensive dietary management. This classification was confirmed by differences in amount of weight lost and in changes in plasma insulin triglyceride levels, although not in changes in plasma glucose levels. Unfortunately, no statistical analyses were reported.

Table 1

Validity of Staff Ratings of Patient Compliance

Authors	Sample Characteristics	Raters	Target Behavior	Task	Validity Checks[4,5]	Summary of Findings
Preston & Miller (1964)	25 Tuberculosis outpatients	1 Physician[1]	Medication-taking	Classify as[3] defectors or nondefectors	Urine metabolites	Physician classified 3/7 noncompliers as compliant and 1/18 compliers as noncompliant.
Caron & Roth (1968)	525 Inpatients prescribed antacid	27 Residents[2]	Medication-taking	Estimate % taken	Bottle count	Median correlation = -.01; 22/27 overestimated compliance.
Moulding et al. (1970)	122 Tuberculosis outpatients	Each patient's physician and nurse	Medication-taking	Classify into 3 levels by % taken	1. Medication monitor 2. Urine metabolites	Significant correlation between ratings and medication monitor but 50% of patients misclassified. Most ratings overestimated compliance.
Hadden et al. (1975)	57 Diabetic patients	Dietitians	Dietary compliance	Classify as[3] "good" or "poor"	1. Weight loss 2. Changes in triglycerides 3. Changes in plasma glucose levels	Classification confirmed re weight loss and triglycerides; not re glucose levels.
Blackburn (1977)	Chronic hemodialysis patients	15 Nurses, technicians & dietitians	Diet	Classify whether or not compliant 50%+ of the time	Blood chemistry	Ratings tended to be accurate.

Continued...

Table 1 - Validity of Staff Ratings of Patient Compliance (Continued)

Authors	Sample Characteristics	Raters	Target Behavior	Task	Validity Checks[4,5]	Summary of Findings
Mushlin & Appel (1977)	187 Patients discharged from hospital	39 Residents[2] and interns	Appointment-keeping Medication-taking	Whether appointment kept and % medication taken	Appointment kept. Pill count	79% of appointment predictions accurate; 40% of medication predictions were accurate within 10%; only 8% underestimated noncompliance.
Roth & Caron (1978)	116 Peptic ulcer patients	3 Physicians[1]	Medication-taking	% Estimates over 2 years	Bottle counts	Significant correlation but estimates of patient intake 50% higher than bottle counts. No change over time.
Norell (1981)	81 Glaucoma patients	Physician[1] and assistant	Medication-taking	Estimate frequency of missed doses over 40 days	Medication monitor	Assistant's, but not physician's estimates, significantly correlated with monitor recording.
Witenberg et al. (1983)	Hemodialysis patients	Dietitian social worker, and nurse	Diet	Staff ratings[3]	Laboratory data	Ratings significantly higher than laboratory values.

1. Small number of raters limits extent to which results can be generalized.
2. Relative inexperience of raters limits extent to which results can be generalized.
3. Criteria used in classification unclear.
4. As described in text, blood and urine assays have potential problems with pharmacokinetic variation.
5. As indicated in text, it cannot be assumed that pill counts accurately measure number of pills ingested.

Informants' Reports

People living with patients are theoretically in an ideal position to provide compliance information. Surprisingly few studies have sought information from spouses or other family members concerning patients' compliance. This apparent neglect may result from a reluctance to ask family members to 'spy' on each other or, more importantly, from a concern that these reports may also be contaminated by the social desirability biases that are thought to affect patients' report of their own compliance.

Several studies have examined parents' reports of the medication-taking of their children and found significant discrepancies between these reports and pill counts (Gordis, 1969) or physiological measures (Bergman, 1963). As the parents, not the children, were responsible for compliance, these results are perhaps better considered a variant of self-report.

Epidemiologists have compared the data obtained from 'substitute or surrogate respondents' - usually spouses - with those obtained from target respondents. Kolonel, Hirohita & Nomura (1977) interviewed 300 pairs of subjects - usually husbands and wives - concerning their smoking, drinking and dietary behaviours using a procedure structured to preclude collaboration concerning responses. The between-partner differences were minimal. For 25 of the 26 items, 75% of couples agreed on the frequency of consumption in the past week within 2 units. In another study focussing on dietary behaviours, Marshall, Priore, Haughey, Rzepka & Saxon (1980) had 158 women estimate their husbands' weekly consumption of

various foods and assign it to one of four frequency categories. Husbands were also interviewed and their responses categorised. Sixty percent of the subjects' responses agreed exactly, while 90% of the estimates were within one category of each other. These results exceeded those expected by chance for all but 3 of the 77 items. Moore, Moore, Beasley, Hankins & Judlin (1970) also report high levels of agreement between wives' recall of timing, quantity and quality of food intake and husbands' records. No data analyses, however, are presented to support this conclusion.

The weakness common to all of these studies is the absence of any objective criterion other than agreement with subject's self-report. The validity of both spouse report and self-report therefore implicitly depends upon accurate memory and honest responses.

Self-report

Assessment of compliance through self-report is both the most frequently used and the most frequently criticized method of measurement. Its obvious strength derives from the patients' unique access to information concerning their own behaviour. Its major weaknesses relate to the possibility of conscious or unconscious distortions of the data to present a more socially desirable image, and to the potential for simple forgetting.

A number of studies have attempted to assess the validity of patients' responses by comparing these data to the results obtained using the 'more objective' measures previously discussed. Most studies have examined either self-reported

medication-taking or self-reported dietary intake.

Self-reported medication-taking A variety of studies have compared self-reports of medication-taking, usually obtained through interviews, with pill counts and/or blood or urine assays. No study has focussed on medicaton-taking self-report among diabetic patients. As can be seen in the studies listed in Table 2, self-reported level of compliance generally exceeds that obtained from the more objective measures. Again, little critical attention has been paid to potential error in these criterion measures.

One study, however, attempted to control for some of the problems inherent in using physiological outcome as a criterion. Sheiner, Rosenberg, Marathe & Peck (1974) compared serum digoxin levels in 43 cardiology clinic outpatients and in 50 inpatients at serial weekly visits. Based on outpatients' reports of their medication-taking, their levels should not have differed from those of inpatients, whose intake was assured. The results indicated that among outpatients serum digoxin levels were consistently lower than the levels found in inpatients, and similarly lower than that expected from self-report. The inpatient group served as an effective control for individual differences in drug response.

Self-reported dietary compliance. Studies examining the validity of patients' reports of adherence to a prescribed diet are few and tend to be impressionistic. In contrast to the medication-taking studies, these have usually supported the validity of self-report.

Three studies have examined the validity of diabetic patients' reports of food intake. Watkins, Roberts, Williams,

Table 2

Validity of Self-Reported Medication Taking

Authors	Sample Characteristics	Target Behaviors	Validity Checks[1,2]	Findings
Chaves (1960)	2622 Tuberculosis outpatients	1. Frequency 2. Timing of dose	Urine assays	78% of those who reported taking drug regularly had positive assays. 74% of those who reported taking drug in last 12 hours had positive assays.
Preston & Miller (1964)	25 Tuberculosis outpatients	Time drug last taken	Urine metabolites	24/25 claimed to have taken at time prescribed; only 18 appeared to have done so.
Weintraub et al. (1973)	101 Cardiology patients	Frequency	Serum digoxin levels	Those who claimed 100% compliance had significantly higher concentrations than those who reported missing a dose.
Sheiner et al. (1974)	43 Cardiology outpatients: 50 Cardiology inpatients	Frequency	Serum digoxin levels	Digoxin levels indicated that outpatients took only 72% of medications they claimed to have taken.
Hecht (1974)	47 Tuberculosis outpatients	Frequency	1. Urine tests 2. Pill counts	10 Patients admitted missing doses. From urine tests and pill counts 22 had made serious errors.
Roth & Caron (1978)	116 Peptic ulcer patients	Frequency	Bottle counts	Significant correlation between bottle counts and self-report, but self-report 100% higher than bottle count.

Continued...

Table 2 - Validity of Self-Reported Medication Taking (Continued)

Authors	Sample Characteristics	Target Behaviors	Validity Checks[1,2]	Findings
Fletcher et al. (1979)	68 Congestive heart failure outpatients	Frequency	1. Pill count 2. Serum digoxin levels	Stated level of compliance significantly correlated with digoxin levels. By pill count only 1 patient 100% compliant although 52-81% rated themselves to be.
Norell (1981)	81 Glaucoma patients	Frequency of missed doses	Medication monitor	Low but significant rank order correlation. Only 3 patients reported missing 2+ doses; monitor revealed 24 did so.

1. As described in text, blood and urine assays have potential problems with pharmacokinetic variation. Only the study by Sheiner et al. (1974) controlled for this problem.

2. As stated in text, it cannot be assumed that pill counts accurately measure number of pills ingested.

Martin & Coyle (1967) examined the 24-hour diet recall of diabetic patients. After comparing these data to patients' weight, they concluded that the recall was not representative of patients' diets. The statistical bases for this judgment were not reported. More recent studies have used better designs and more sophisticated data analyses. Ney, Stubblefield & Fischer (1983) in a study of pregnant diabetics used a 7 day record of food exchanges, a 24 hour recall of foods consumed and a 7 day recall of meal timing and consumption of high sugar foods to categorize patients as good, acceptable and unacceptable compliers. Blood sugar levels were significantly lower in good than in poor compliers. The ten patients classified as good compliers all regularly kept their records for the entire study period (up to 30 weeks), while 3 of the 6 'acceptable' compliers and the sole unacceptable complier did not complete and return their checklists consistently. Christensen et al. (1983) used 24 hour recall of the timing and content of the previous day's consumption to obtain an index of diet deviation among 97 insulin-dependent diabetic patients. The diet deviation scores were then compared for patients classified by glycosolated hemoglobin level as one standard deviation above or below the group mean. Patients in poor control deviated significantly more often on 3 or 6 dietary requirements. Groups extreme in their adherence (good or poor) to 3 of the factors tended to differ in glycosolated hemoglobin levels but the differences were not significant.

The validity of self-reported adherence to other medically- prescribed diets has been addressed in several

studies. Leren (1966) classified the dietary adherence of male survivors of myocardial infarctions according to their questionnaire responses concerning avoidance of certain foods. Those placed in the most compliant category reportedly showed the greatest cholesterol reduction, while those in lower categories had correspondingly poorer cholesterol changes. No statistical analyses are reported. Fleischman (1967) in a study of 33 coronary males also found that free fatty acid levels confirmed interview data concerning adherence. Again the extent of this relationship is not presented and the actual procedures used are unclear. In feasibility trials for the National Diet-Heart Study (Brown, 1968; Mojonnier and Ball, 1968) male volunteers were assigned to various diets differing in their predicted effects on cholesterol levels. Adherence to the diet was measured by patient recall, 7-day food records and ratings of nutritionists blind to type of diet and blood cholesterol. The results were only presented descriptively and indicated generally good correspondence between methods and betweeen ratings and cholesterol levels.

Several recent studies have attempted to examine the relationship between reported adherence to a prescribed weight loss program and actual weight loss. Brownell, Heckerman, Westlake, Hayes & Monti (1978) had 29 subjects estimate and record their daily calorie intake. Although significant weight loss occurred, this was not correlated with self-reported calorie scores. However, Mahoney (1974) had subjects on a weight loss program monitor their actual food intake. He then rank ordered the subjects according to the degree of behaviour change indicated by these records. He

found significant correlations with weight loss. Stalonas, Johnson & Christ (1978) evaluated the adherence of 44 volunteers to behavioural weight loss program which included quantity and snack restrictions along with specific behavioural strategies. Subjects were requested to record and graph their use of program behaviours, and their adherence was evaluated at weekly structured interviews. Self- report of 'uncontrolled eating' was the only one of ten adherence measures significantly correlated with weight loss. As all subjects reported very high levels of adherence, this lack of variance is postulated as an explanation for the unexpectedly weak adherence-weight loss relationship.

Rand measures of diabetic patient self-care. The most carefully conceived self-report measure of compliance with more than one regimen demand is the questionnaire developed by the Rand Corporation (Marquis and Ware, 1979). Their objective was to develop reliable and valid measures of diabetic patient knowledge, attitudes and behaviour regarding self-care.

Initially a panel of diabetes experts was solicited and asked to judge which self-care behaviours were most important for diabetic control. Thirty behaviours falling into six categories were rated as important and formed the basis for a questionnaire composed of 26 subscales. Each subscale required respondents to recall the frequency with which they had performed a particular self-care behaviour in some previous time period. This measure and the measure of 'Compliance Response Bias' also developed by the authors were then administered to 496 diabetics in a variety of endocrine

treatment facilities. Of these 496 subjects, 80% completed a retest questionnaire and 346 provided 'informants', usually family members, who were interviewed concerning the patients' behaviours. The data thus obtained allowed the authors to assess reliability and internal consistency for each subscale. Assessment of validity was based on the correlations with the social desirability measure and with the informants' report.

Overall, the authors rated three subscales - carried emergency glucose, takes insulin at appropriate times and achieves and maintains ideal body weight (+/- 10%) - as having met all of their measurement requirements. Another twelve subscales had most of the requisite qualities, and the remainder had serious deficiencies. In their attempt to assess self-report of medication taking, the investigators found a significant correlation between subject and informant report concerning two items relating to insulin timing and to oral medication frequency. Self-report was not related to compliance response bias. However, when patients were asked medication questions worded 'doing what your doctor's office told you to do' a relationship with compliance response bias did emerge. A similar finding with respect to very general questions was found in the subscale dealing with eating prescribed meals and following a meal schedule. These items were associated with significant levels of response bias and were unrelated to informants' reports. They concluded that the more specific and value-free the questions the more likely that valid responses would be elicited.

Adequate assessment of patients' actual treatment

behaviours continues to be a significant problem in exploring compliance. No one method suffices to give a completely valid picture. Studies in which a wide range of the available techniques are used and the results compared have not yet been performed.

Conceptual Issues in Compliance and its Measurement

Two generally unexplored assumptions underlie most attempts to understand and measure compliance. The first assumption is that patients' understanding of what their regimen requires is entirely congruent with the recommendations put forward by their physicians. The second is that patients' compliance in one situation is related to their compliance in another.

Congruity between Physicians' and Patients' Understanding of the Prescribed Treatment Regimen

In most attempts to measure compliance, there is an underlying assumption that patients have the same understanding of the demands of their regimen as their physicians do. If the medical records or physicians' reports indicate that a treatment has been prescribed, it is taken for granted that patients received and understood that prescription. A body of evidence is currently accumulating which suggests that patients' perceptions of the requirements of their regimen do not in fact coincide with their physicians' prescriptions.

Ley (1980) reviewed a number of studies conducted by himself and others concerning patients' recall and

understanding of information presented by their doctors. He concluded that the mean level of recall of what the doctor had said ranged from 46 to 63 per cent. Recall decreased with the number of statements presented. Level of understanding of physician-presented information was also low, with 7% to 53 % of patients claiming not to have understood what they had been told, and 53% to 89%e revealing inadequate understanding when questioned. Studies examining readability of pamphlets prepared for the general public also revealed that most were beyond the comprehension of over half of the population.

Confirmation of these findings in the diabetic context is found in several recent studies. Page, Verstraete, Robb and Etzwiler (1981) examined the recall of specific treatment recommendations made to 24 young diabetic patients during regular appointments. After being seen by a dietitian, physician, and nurse, patients (and in 13 cases, their parents) were asked open-ended questions concerning what treatment recommendations had been made to them. Patients' and parents' responses were then compared to the health professionals' record of recommendations they had made. The results revealed that members of the health team made an average of seven recommendations per patient; patients recalled an average of two of them.

These studies demonstrate the need, when measuring patient treatment behaviours, to discriminate between those who do not conform to recommendations in the absence of requisite knowledge, and those who do not conform in the presence of the necessary information. Most studies appear to have routinely used physicians' criteria, rather than those of

patients. This may be a useful approach in certain contexts, such as drug trials, when the only concern is the amount of drug ingested. When the goal of research is to assess the potential influence of more patient-centered factors, exclusive use of physicians' criteria is likely to obscure important information.

Consistency of Compliance

No research currently appearing in the literature has addressed the issue of patient consistency, of the extent to which compliance with one regimen demand is related to compliance with another (Di Matteo and Di Nicola, 1982). There is some indirect and direct evidence of behavioural specificity, of differences in response to different regimen demands. Nonetheless, researchers continue to treat compliance as a unitary phenomenon and to use global terms in their descriptions of levels of compliance.

Several studies have presented evidence that patients' responses to one demand may be fairly independent of their responses to others. Davis and Eichorn (1963) examined the possibility of using compliance with one regimen to predict compliance with others. Among 23 subjects with cardiovascular impairments, they found that most complied with one or two of the three regimens prescribed, relating to work, diet and change in personal habits. Only nine percent complied with all three. The work regimen was complied with most often, and over 60% of those who complied with it also complied with other regimens, while only 21% who did not comply with it complied with other regimens. The criteria used to categorize patients as compliant or noncompliant are unclear; however the

data appear more supportive of response inconsistency than consistency.

Roth, Caron & Hsi (1971) followed 160 patients subsequent to an attack of peptic ulcer. They found no correspondence between missed appointments and percentage of prescribed antacid taken, as measured by bottle count and tracer among the 96 patients who completed the follow-up (r=.12). They did however find a significant correlation between percentage of antacid taken and whether or not the prescribed atropine had been taken, as determined by examining urine metabolites (r=.65, p<.01).

Other studies have mentioned similar findings of low associations or high variability between regimen demands. For example, Caron & Roth (1971) in a study of peptic ulcer patients noted that compliance with the prescribed diet was not correlated with medication compliance, even in an inpatient sample. Pragoff (1962) examined compliance with a variety of treatment recommendations made to 66 tuberculosis patients. One year post discharge, twenty-four patients were considered to have complied satisfactorily in all categories and five to have been consistently unsatisfactory in their compliance. The remainder were satisfactory in some categories but not others. Again the bases for classification were unclear; however more than half the patients were obviously inconsistent in their compliance.

The results of two studies dealing with the complex regimen of the diabetic suggest that similar inconsistencies may exist in this population. In a comprehensive study of a variety of diabetic behaviours, Williams, Martin, Hogan,

Watkins & Ellis (1967) found that compliance levels were highly variable across the demands of the regimen. Marquis and Ware (1979) found similar results in their attempt to develop a single measure of diabetic patient compliance. Although they do not provide data concerning the extent of the intercorrelations among the 26 behavioural subscales, they report that factor analysis was not useful in data reduction and that the perceived multidimensionality was such as to require retention of multiple subscales in order to provide a meaningful measure of patients' behaviour.

This issue of consistency in response to demands for health actions has been directly addressed in an area closely aligned to compliance: that of preventive health behaviour.

The interrelationship among preventive health behaviours has been the focus of several studies. Based upon a conception that there is a general health motivation, a health role in response to which people act to prevent illness, this research has examined the extent to which diverse behaviours important for maintaining health are intercorrelated. In general the intercorrelations are moderate at best, with few exceeding .40. Typically the number of significant correlations exceeded that expected by chance thus also suggesting that neither are these behaviours completely independent.

Mechanic (1979), for example, in a 16-year follow up involving 319 young adults examined the intercorrelations among 7 health behaviours and attitudes, such as wearing seat belts, smoking, drinking and risk-taking. He found none of the correlations exceeded .27, although half of the

correlations were significant at the .05 level.

Steele and McBroom (1972) attempted to identify a factor which leads people to engage in a variety of preventive health behaviours. They examined the intercorrelations among self-reported extent of use of different health services when subjects were asymptomatic (physical check-ups, dental visits, eye check-ups). They too found very low intercorrelations.

Two studies have examined this pattern in greater detail. Williams and Wechsler (1972) in two surveys of 22 preventive health behaviours found some behaviours to be statistically related while others were not. Using Principal Components Analysis to test the assumption of unidimensionality, no general factor which explained a sizeable amount of the variance emerged. Rather five factors were needed of which only 4 could be labelled.

Langlie (1979) examined 11 behaviours and found 37 of 55 correlations significant at the .05 level, although none exceeded .44. She reasoned that such a pattern of results could emerge because some people are consistent while others are inconsistent. She found that most people were somewhat inconsistent but a consistent group could be identified. In this group 'direct risk behaviours' were all significantly correlated as were most of the 'indirect risk behaviours'. The two types of behaviours were not, however, correlated. A similar but weaker pattern emerged in the inconsistent group, but they tended to show negative correlations between the two types of behaviour. She concludes that although neither the unidimensional nor the independent assumption is correct, it may be possible to find useful predictive patterns.

These studies combine to suggest that the issue of patients' response consistency needs further exploration. If patients are found to be inconsistent, future research strategies and compliance models must take this factor into account.

Models of Patient Compliance

Little research has been conducted concerning determinants of diabetic patients compliance and most of the research conducted concerning determinants of patient compliance in general has not occurred within an explicit model (Leventhal, Meyer & Gutmann,1980). Nevertheless certain assumptions about the nature of compliance can be extrapolated from the type of research performed. A large number of studies have examined the relationship of compliance to stable intrapersonal factors, suggesting a belief that noncompliance is exclusively a property of patients and one which determines their behaviour regardless of the situation. Another group of studies has removed the onus entirely from the patient and credited environmental factors with creating the variance in compliance. A third approach has allowed for an interaction between the person and the situation by invoking patients' cognitions about the treatment situation to explain compliance. It is only in this last category that explicit models have been created and hypothesis-testing performed.

Compliance as a Function of Characteristics of the Person

Reviewers of the voluminous research with respect to patient sociodemographic characteristics have all concluded that these are unrelated to compliance (Marston, 1970; Kasl, 1974; Becker, 1976; Haynes, 1976, 1979; Kirscht and Rosenstock 1979). In most studies no relationship has been found between compliance with treatment and age, sex, race, income, occupation, education, socioeconomic status, religion and marital status.

This consensus among reviewers extends to the absence of a defaulting, or noncompliant, personality type. The evidence concerning an association between specific personality traits or constructs, such as Locus of Control, is also somewhat equivocal.

Despite its intuitive appeal, knowledge does not appear to be a consistent predictor of compliance. The degree of influence of knowledge on compliance is related to its specificity. General medical knowledge is thought to be unrelated to compliance and the effects of education programs to be short-lived, whereas specific knowledge of what the regimen demands is a necessary but not sufficient condition for compliance.

Compliance as a Function of Situational Factors

Situational factors examined in conjunction with compliance have ranged from features of the disease to adequacy of patient education and social support. There is, nevertheless, little controversy about the limited effects of all of these factors.

There is a general consensus that most features of the

disease play a relatively small role in predicting compliance. Neither disease severity nor symptoms was found to be associated with compliance, although degree of disability and presence of a psychiatric diagnosis may have an influence (Haynes, 1979).

Certain features of the regimen, however, have been shown to be related to compliance. The duration of treatment, the complexity of the regimen and the amount of behaviour change required are associated with decreased levels of compliance. Certain types of drugs and certain modes of drug administration are associated with better compliance. There is little evidence that side effects adversely affect compliance.

Characteristics of the treatment setting and care-giver relationship may also be related to compliance. Waiting time, whether for appointments or during appointments, has consistently been associated with poorer compliance. Higher levels of supervision and higher levels of patient satisfaction were found to be consistently associated with better compliance.

The broader social context of the patients also appears to play an important role in compliance. Haynes (1976) notes a consistent association between family instability and noncompliance, while support provided by significant others appeared to play an important positive role (Kasl, 1975; Caplan, Robinson, French, Caldwell & Shinn, 1976).

Compliance as a Function of Patients' Cognitions

The cognitive approaches to patient compliance were originally developed and tested in the context of preventive health behaviours, rather than of compliance per se. In their original forms, their pivotal construct was that patients' cognitions concerning health threats evoked avoidance responses in the form of positive health behaviours. Two lines of research and theory development evolved from this idea: the controlled investigations of the mechanisms of fear arousal and its effects on behaviour (e.g. Leventhal, Singer & Jones, 1965); and the Health Belief Model (HBM) which explored cognitions and health behaviours in more clinical settings.

The results of the resarch concerning fear arousal and its effects on preventive behaviours have recently been reviewed by Leventhal, Meyer and Nerenz(1980). Typically, the research involved manipulating level of fear through threat communications in combination with a variety of other variables, such as instructions on how to avoid the health threat. The effects on behaviour were somewhat inconsistent, and lead the authors to the conclusion that fear arousal might not in fact be essential, but that information about the health threat and the presence of a specific action plan were. Fear in fact is seen as interfering with coping. The authors have therefore proposed a self-regulatory model of compliance behaviour. People are thought to generate for themselves concrete models of their disease and then to use these potentially erroneous models to guide their coping responses. This interesting theory has not to date been adequately tested.

The HBM was originally developed in the early 1950's in an attempt to understand why people failed to take advantage of preventive programs and health screenings which were available to them at little or no cost (Rosenstock 1974). Its authors sought an explanation within the theories of Kurt Lewin, and in particular in Lewin's hypotheses that behaviour is a function of the value placed by an individual on a particular outcome and of the individual's perception of the probability that a particular behaviour will result in that outcome (Maiman and Becker 1974).

In applying these concepts to preventive health behaviours, four essential components emerged: perceived severity of the disease if it occurred; perceived personal susceptibility to the disease; perceived benefits of a specified action in reducing the risk; and perceived barriers to taking the action. Preventive health behaviours would occur only if the disease was perceived as one that had serious consequences and to which one was vulnerable, and if the benefits of the behaviours were evaluated as exceeding their costs. It was also hypothesized that a 'cue to action', a stimulus which triggered the threat cognitions, was required..

In a later reformulation, Maiman and Becker (1974) included a general health motivation, a stable internal disposition towards health concerns and practices that is postulated to operate in the same fashion across situations. Until the 1970's the model was primarily used in relation to preventive health behaviours. Rosenstock (1974) reviewed twenty years of this research, including several prospective

studies, and found support for all the components of the Health Belief Model. In the context of actual compliance with treatment, only a limited number of studies have been conducted and their results are somewhat ambiguous. These will be reviewed in connection with Study 2. It is, however, the only explanatory model which has generated any significant body of research to date.

It is apparent that the mechanisms underlying noncompliance with medical treatment remain largely unknown. Until recently, most investigations did not place noncompliance within a psychological as well as a medical context, and consequently did not make use of models of analogous non-health behaviours. The Health Belief Model and the proposed self-regulatory model do have such connections and further empirical investigations are required to assess their utility.

Diabetes Mellitus

In order to understand patients' compliance, it is helpful to understand the disease context in which such behaviour occurs.

Diabetes mellitus is a chronic metabolic disorder which can lead to impaired functioning and early death. Although the precise causes and mechanisms of the disease are not yet completely known, the clinical manifestations of the disease appear to result from a relative or absolute insulin

deficiency. Insulin is a hormone secreted by the beta cells of the Islets of Langerhans within the pancreas. Its purpose is to allow the tissues to remove glucose, amino acids and lipids from the bloodstream and store them. These are necessary for growth, energy and tissue repair. When insufficient insulin is available, this storage process is impaired and the liver produces glucose and ketone bodies which enter the urine and the bloodstream and give rise to symptoms such as polyuria, polydipsia, polyphagia, weight loss, fatigue and blurred vision (Genuth 1982).

Although genetic factors are generally acknowledged to play a major role in the etiology of diabetes, a number of other factors have also been implicated. This heterogeneity is also reflected in the classification of diabetes. Three major groupings are used- idiopathic, secondary and gestational (Genuth 1982). Idiopathic diabetes is the most frequent form and is itself divided into two types. Type I, or insulin-dependent diabetes, is characterized by an absolute requirement for exogenous insulin and a tendency towards ketosis if insulin is withdrawn. Ketosis refers to an excess production of ketone bodies, which can accumulate and create severe biochemical imbalances (ketoacidosis). Generally onset is below age forty and is accompanied by urinary excretion of carbohydrates (glycosuria). Its prevalence in the population is estimated at .5% (Felig 1981).

Type II or non-insulin dependent diabetes is generally associated with later onset, usually after age 40, and, in 70-80% of patients, with a history of obesity. Patients are not ketosis-prone and often insulin is not required. Insulin

synthesis and storage in the beta cells may still be present, but the amount may be inadequate or the body may have developed a resistance to it. Weight loss, caloric restriction, and treatment with certain drugs have all been shown to decrease insulin resistance or increase its secretion (Genuth 1982). Type II diabetes is considerably more prevalent than Type I (2 to 4%) (Felig 1981).

Secondary diabetes refers to hyperglycemia secondary to another disease and may resemble Type I or Type II diabetes. Gestational diabetes refers to hyperglycemia present only during pregnancy, again very similar to Type II diabetes (Genuth 1982).

The acute effect of a severe insulin deficiency is ketoacidosis, which if untreated, may progress through symptoms such as nausea, vomiting, and increasing drowsiness to coma and death. Crises also arise when there is an excess of insulin relative to the amount of glucose in the bloodstream. A hypoglycemic reaction is characterized by some of the same symptoms as hyperglycemia including nausea, and drowsiness, and may also lead to coma, but is typically of sudden onset. A major goal of treatment is therefore to avoid hypoglycemic and hyperglycemic crises.

The longer term complications of diabetes are vascular. Microangiopathy, or small blood vessel disease, causes retinopathy, nephropathy and neuropathy. Macroangiopathy or atherosclerosis appears to develop earlier and proceed more rapidly in diabetic patients. They are also more susceptible to infections, particulary of the skin, vagina and gums. These sequelae place diabetic patients at increased risk of

blindness, kidney failure, angina, myocardial infarction, cerebro-vascular accidents and limb amputations due to gangrene. The second major goal of treatment is therefore to prevent or delay these complications.

An estimated 500,000 Canadians suffer from diabetes (Hunt, 1980). According to self-report data collected in the Canada Health Survey (1981), 98% of diabetics are over fifteen, while 63% are between the ages of 15 and 64. About 61% of those reporting themselves to be diabetic were female and 39% male. Similar numbers of diabetic patients were found at each income level, although the frequency was marginally higher in the lowest income group.

Treatment of Diabetes

Treatment of diabetes depends on the severity of the disorder. Type II patients with mild diabetes can often be adequately managed by diet alone. Moderate diabetes may require medication such as oral hypoglycemic agents to stimulate insulin production in addition to the diet. All Type I patients and Type II patients with severe diabetes are treated with insulin, as well as with a controlled diet.

Treatment with diet alone. The major therapeutic objectives of diet therapy common to all types of diabetes and all types of regimen include:

1. ensuring overall health through optimal nutrition;
2. the attainment or maintenence of ideal body weight;
3. achieving normoglycemia in the hope of preventing or delaying microangiopathic complications;
4. the achievement and maintenance of normal lipid levels by reducing dietary fats, in the hope of preventing or

delaying atherosclerosis; and

5. creation of an individualized diet to suit the health needs and lifestyle of each patient (Hunt 1980).

The diets designed to meet these needs are typically varied and well-balanced. Restrictions are generally placed on the intake of simple sugars and saturated fats. For overweight patients, caloric intake is also restricted. To facilitate meal planning, patients are generally taught an exchange system which provides lists of foods which are equivalent in nutritional and caloric content.

For many patients adequate metabolic control can be acieved solely through proper diet and weight control. Their regimens may also require them to monitor their glucose levels and possible changes in control through regular home urine or blood testing. When urine testing is prescribed, a small quantity of urine is collected and either a tablet added to it or a paper stick dipped into it. The resulting colour is compared to a reference chart to ascertain glucose concentrations. The value of these results may however be reduced by their failure to accurately reflect current blood glucose levels. Home blood glucose monitoring avoids this problem. Patients prick their finger to obtain a blood sample, the glucose concentration of which is then assessed by the colour change of a chemical strip or by a digital meter. For many patients urine testing provides an adequate index. Increasing numbers of patients are, however, monitoring their fluctuations in control by blood glucose testing.

When significant or persistent changes in control or symptoms occur, patients are expected to seek medical

attention.

Treatment with oral hypoglycemic agents. Oral medications are currently available for treatment of patients with residual beta cell functioning. The sulphonylureas act by stimulating the beta cells to produce more insulin. As these create the same risk of hypoglycemia as insulin injection, a regimen in which medication, diet and activity are balanced and consistent from day to day is required. This means a regular schedule of feedings must be developed and appropriate compensation made for any deviations from the pattern.

Patients are also expected to plan ahead for possible hypoglycemic reactions by carrying a glucose source with them, wearing diabetic identification and informing co-workers, friends and family of its symptoms and treatment.

More frequent home monitoring of blood or urine glucose levels is also integral to the regimen, and changes in control or symptoms are considered grounds for seeking medical attention.

Treatment with insulin All Type I patients and some Type II patients require regular injections of insulin. In an attempt to simulate the body's normal patterns of insulin release, and achieve optimal control insulins come in forms varying in their duration of action and the prescribed frequency of injection may vary from once to four times daily. Food intake and exercise must be carefully balanced and scheduled in relation to insulin administration in order to avoid hyperglycemia and hypoglycemia.

Like patients on oral hypoglycemic agents, patients taking insulin must test for glucose regularly, ensure their

safety in case of hypoglycemia and report symptoms and changes in control to their physicians.

Levels of Compliance with Diabetic Treatment Regimens

The treatment regimens prescribed for diabetic patients are generally demanding and complex, often requiring significant changes in routines and habits. A small number of studies of patients' problems in making these adjustments indicate that they fail to comply adequately with many aspects of their regimens. Tables 3 and 4 present the studies conducted to date which have attempted to measure adult diabetic patient compliance. The studies have been divided into those concerned with several aspects of the patients' regimen and those that dealt only with patients' weight control and dietary compliance.

It is difficult to determine the precise extent of the problem as the criteria for classifying patients as compliant or noncompliant and the exact methods of measurement are not usually reported and appear to vary from study to study. In some studies, inadequate knowledge or skills are treated as noncompliance, while in others, a distinction is made between noncompliance and error. In several studies, data concerning several distinct behaviours are combined into a compliance score or used as a basis for classification, thus obscuring potential variations in compliance with different aspects of the regimen.

In general it appears that most diabetic patients are fairly compliant with some aspects of their regimen, in

Table 3

Studies of Diabetic Patients' Compliance with Regimen

Authors	Sample Characteristics	Type of Measure	Target Behaviors	Findings	Comments
Stone (1961)	160 Outpatients on insulin	Overall compliance ratings before and after education program	1. Urine testing 2. Insulin administration 3. Avoidance of acidosis and hypoglycemia 4. Frequency of dietary compliance	At Time 1: 21% in good control 17% in fair control 62% in poor control At Time 2: (2 years later) 53% in good control 11% in fair control 36% in poor control	Global assessment obscures differences between behaviors. Self-report only.
Watkins et al. (1967a)	60 Patients on insulin from varied referal sources	In-home observation and interview	1. Insulin administration 2. Insulin dosage 3. Urine testing 4. Eating proper foods 5. Eating regularly	Rates of unacceptable performance: Insulin administration 80% Insulin dosage 58% Testing 77% Diet 75% Meal regularity 75%	Confounds knowledge and skills with compliance. Self-report only.
Watkins et al. (1967b)	115 Patients on insulin 47 Patients on oral agents	In-home observation and interview	Medication dosage and frequency	Rates of unacceptable performance: Incorrect dosage: Insulin patients 58% Oral agent patients 25% Missed: 4% of insulin patients missed 1 injection/month. 12% of oral agent patients missed 1/week.	Clarifies knowledge - compliance - distinction. Self-report only.

Continued...

Table 3 - Studies of Diabetic Patients' Compliance with Regimen (Continued)

Authors	Sample Characteristics	Type of Measure	Target Behaviors	Findings	Comments
Hulka et al (1975a)	234 Patients on insulin and oral agents	Interview	1. Omission of prescribed drugs. 2. Taking medications not prescribed. 3. Dose and frequency errors based on misconceptions. 4. Dose and frequency noncompliance	40% consumed only exact drugs prescribed. 19% omitted prescribed drugs 19% took drugs not prescribed 17% misconceived dose and frequency 3% were noncompliant with dose and frequency	Self-report only.
Hulka et al (1975b)	242 Patients on insulin and oral agents	Interview	1. Testing 2. Carrying diabetic identification 3. Knows name of medication	66% of patients reported to have been instructed in testing recalled it, 99% of these tested properly. 52% of patients reported to have been told to carry identification recalled this. 87% of these did do. 65% of patients know their insulin type. Of these only 7% took the wrong type. Of patients who did not know, 68% took the wrong type. 61% knew their oral agent type. Of these 2% took the wrong type. Of patients who did not know, 19% took the wrong type.	Self-report only.

Continued...

Table 3 - Studies of Diabetic Patient's Compliance with Regimen (Continued)

Authors	Sample Characteristics	Type of Measure	Target Behaviors	Findings	Comments
Cerkoney & Hart (1980)	30 Insulin-dependent patients, 47% taking insulin < 1 year	Interview and direct observation	1. Insulin administration 2. Testing 3. Foot care 4. Care of hypoglycemia 5. Diet	Average levels of compliance: Insulin administration 81% Testing 57% Foot Care 77% Care of hypoglycemia 70% Diet 65%	In scoring, arbitrarily compensated for presumed self-report bias by doubling value of observational data. Unrepresentative sample. Knowledge and compliance confounded
University Group Diabetes Project (1982)	Varying numbers of patients involved in 12-14-year follow-up of clinical trials	Weight and prescription records; physicians' ratings	1. Medication taking (N = 619) 2. Weight Change (N = 301)	34-50% of patients consistently rated totally compliant over the years. Most patients' weight returned to baseline after initial drop.	Had clear criteria for compliance rating but no patient input.
Ruff (1983)	28 Diabetic patients on hemodialysis	15-item questionnaire including some knowledge items	1. Diet 2. Exercise 3. Eye care 4. Foot care 5. Oral care	More than half scored below minimum necessary for adequate compliance.	Knowledge - compliance confounded and criteria for adequate compliance not given

Table 4

Diabetic Patients' Dietary Compliance and Weight Control

Authors	Sample Characteristics	Type of Measure[1,2]	Target Behaviors	Findings	Comments
Seaton & Rose (1965)	98 Diabetic patients referred to weight loss program	Records	Treatment drop-out	6% withdrew after first visit. Significantly lower than non-diabetic rate.	-
Williams et al. (1967)	Study 1 60 Insulin-taking patients	24-hour diet recall	1. Adequacy of intake 2. Meal spacing	12% had no deficiencies in intake; one-third were less than 50% compliant. 75% noncompliant with spacing.	Self-report only.
	Study 2 17 Insulin-taking patients	7-day food record with daily reminder visits	1. Adequacy of intake 2. Meal spacing	75% were less than 50% compliant. 75% noncompliant with meal spacing.	Visits may increase reactivity.
Holland (1968)	2000 Diabetic participants in National Health Survey	Interview and questionnaire	Following prescribed diet	25% of whose who had been prescribed a diet did not follow it.	Used single, very general question.
Tunbridge & Wetherill (1973)	68 Patients from an outpatient clinic	7-day food record	Calorie intake	30% were within 10% of prescribed intake. 38% deviated 11-20% from prescribed intake. 32% deviated 20% +.	-

Continued...

Table 4 - Diabetic Patients' Dietary Compliance and Weight Control (Continued)

Authors	Characteristics	Type of Measure[1,2]	Target Behaviors	Findings	Comments
Goodner & Ogilvie (1974)	172 Patients from all regimens	5-year weight record	Weight change	Most patients changed less than 5% in 5 years	-
Borsey et al. (1979)	136 Newly diagnosed overweight patients	4-year weight records	Weight change	In oral agent group, gradual continuing weight loss. In diet alone group, weight loss in first year only. 64% dropped out of treatment.	Bias due to high drop-out.
Streja et al. (1981)	82 Noninsulin dependent diabetic patients	Weight records for 30 months	Weight change	Nutritional counselling lead to significant weight loss, which was only maintained in diet alone group.	-
McCulloch et al. (1983)	178 Insulin-dependent patients	Interviews + 7-day food records	1. Measurement of carbohydrate intake 2. Meal scheduling	36% neither estimated nor measured. 27% did not follow any meal schedule.	Self-report only.
Christensen et al. (1983)	97 Insulin-dependent patients, most under age 20	24-hour recall and blood glucose measures	1. Number of exchanges added-deleted. 2. Meal scheduling	Out of 100 exchanges, average number added 11, deleted 17. 10% of subjects adhered to the exchanges 90% of the time. Out of 100 meals, 11 scheduling deviations occurred. 67% of patients adhered to schedule 90% of the time.	

Continued...

Table 4 - Diabetic Patients' Dietary Compliance and Weight Control (Continued)

Authors	Sample Characteristics	Type of Measure[1,2]	Target Behaviors	Findings	Comments
Ney at al. (1983)	17 Pregnant women	Daily record, 24-hour recall and blood glucose levels	1. % of exchanges eaten 2. Meal timing 3. Intake of simple sugars	10/17 rated as good and had significantly better glucose levels. 6/17 rated as acceptable (3 did not record regularly). 1/17 unacceptable (did not record regularly).	Small, unrepresentative sample. Noncompliance confounded with failure to keep records.

1. The 24-hour recall method has potential problems with time-sampling bias. Food intake in previous 24 hours may be unrepresentative of usual eating habits.

2. The 7-day food record method has potential problems with reactivity, or the tendency for behavior to change in the desirable direction when it is being monitored.

particular with taking their medication as often as prescribed (e.g.Watkins et al.1967b.,Hulka et al.1975a.). Generally patients are much less successful in modifying other aspects, such as eating in conformity with the required diet and attaining their ideal body weight (e.g. Williams et al. 1967, Christenson et al. 1983) Other behaviours such as testing and foot care have been more often examined in relation to patients' skill or knowledge, rather than the extent to which they conformed to the prescribed frequency. It is apparent nonetheless that diabetic patients' treatment behaviours are not always optimal for the avoidance of immediate and long term health consequences.

Conclusions and Research Objectives

Current understanding of patients' compliance with medical regimens, and especially of diabetic patients' compliance, is very limited. This may in part be attributable to the difficulties inherent in measuring compliance and to an absence of knowledge about the underlying nature of compliance. The goal of the current research was to conduct a systematic investigation into some of these methodological and conceptual aspects of compliance. Resolution of these concerns appeared to be a prerequisite to exploring potential influences on compliance. Thus Study 1 was devoted to examining certain assumptions concerning compliance and its measurement. In Study 2 the results of Study 1 were able to be applied to further description of the nature of compliance and to testing a series of hypotheses about diabetic patients'

responses to their regimens' demands.

CHAPTER 2: STUDY 1

Introduction

The purpose of study one was to explore within the diabetic context several issues relevant to compliance research in general: the validity of self-report of compliance; the effects of calculating compliance based on criteria obtained from different sources; and the extent of patients' consistency in levels of compliance across the various demands of the diabetic regimen.

Previous studies have generally compared self-reported compliance with other measures of compliance (e.g.physiological) with the assumption that self-report is unreliable. The potential inadequacies of these criterion methods have generally been ignored, thus leaving considerable uncertainty about the actual scope of the compliance problem. Another approach is possible. Instead of focussing exclusively on the discrepancies between methods, such as between self-report and treatment outcome, the extent of agreement between the methods can be assessed and used as an index of validity.

This concept has been formalized and expanded into a system of convergent and discriminant validation by Campbell and Fiske(1959). In using this approach the target behaviour or construct is examined in terms of its relationships to other measures in hopes of finding positive correlations with measures of the same or similar constructs and an absence of correlations with measures of constructs from which the new

one is intended to differ. Campbell and Fiske devised a systematic way of assessing the extent to which such criteria are met. These are embodied in multitrait-multimethod analysis. The multitrait-multimethod analysis requires that two or more constructs be measured simultaneously by two or more methods,then combined into a matrix. Within that matrix, certain criteria must be met. First the correlations among different measures of the same thing (monotrait-heteromethod) must be significantly greater than zero and should be sufficiently large to justify further exploration and in order to claim convergent validity. To establish discriminant validity, these correlations must exceed both the correlations among different constructs measured by different methods (heterotrait-heteromethod) and the correlations among different constructs measured by the same method (heterotrait-monomethod). Finally, a similar pattern of results must be found across sources.

This procedure is more often used to validate the measure of a construct, rather than the construct itself. Evidence of the convergence of a measure of a construct or behaviour with different measures of the same behaviour and evidence that reports of each behaviour are independent and not an artifact of the measurement process provide support for the measure's validity.

In the current context, multitrait-multimethod analysis can therefore be used to assess the convergent and discriminant validity of self-report. Investigation of discriminant validity was possible as each treatment behaviour was hypothesized to be relatively independent of performance of the others, thus meeting the essential preconditions for this form of analysis.

Investigation of the convergent validity of the self-reports of these behaviours was possible through examination of their relationships with the reports of members of the patient's family and the ratings of health professionals. Further scope for convergent validation was present through examining the correlations between self-report and health and physiological measures, and between self-report and sociodemographic characteristics shown in previous studies to relate to health behaviours. The multitrait-multimethod validation approach provided a system by which multiple measures of the various behaviours of interest could be summarized and tentative conclusions drawn concerning the self-report measures' validity. Further scope for validation was present through examining the correlations between self-report and health and physiological measures, and between self-report and sociodemographic characteristics shown in previous studies to relate to health behaviours.

The second issue addressed related to the congruence between patients' understanding of what their treatment requires of them and their physicians' understanding of that same treatment. If these differ, the selection of the criterion against which patients' behaviours are judged acquires important implications. The criteria used may result in significantly different rates of compliance. If only physicians' criteria are used, it is not possible to know whether the observed discrepancy between behaviour and prescription is a function of inadequate knowledge, adequate knowledge but inadequate motivation, or both. If behaviour is measured against what patients think they should be doing,the

component relating to inadequate knowledge can at least be assessed and differentiated from motivational inadequacies.

On the basis of previous research (Ley, 1977, 1980, 1982; Hulka et al., 1975a, 1975b, 1976) it was predicted that a discrepancy would indeed exist between levels of compliance based on patients' criteria (patient-determined compliance) and levels of compliance based on physicians' criteria (physician-determined compliance), and that patient-determined levels of compliance would likely exceed physician-determined levels. The discrepancy was predicted to be greatest among patients who were more poorly educated and who had begun treatment more recently. A relationship with physiological and health outcome was also hypothesized. Patients whose perception of what was required was further from what was prescribed were predicted to be in poorer health.

The final area explored in this study related to the extent of patients' consistency in the adequacy of their compliance with different regimen demands. Previous research has suggested that patients' responses to equivalent health care requirements may be quite variable, that a patient who is highly compliant with respect to one aspect of a regimen may show poor compliance with another. Diabetic patients, whose regimen is highly complex and demanding, were predicted to show at best moderate consistency across regimen demands, even when these requirements were of approximately equal importance. It was nevertheless predicted that it would be possible to identify a significant group of patients whose behaviours were consistent.

Methods

Data were collected in three phases over a period of two years. The instruments used to collect the data and most of the procedures were identical across phases.

Subjects

All patients who met the following criteria were eligible for inclusion:

1. They had previously been diagnosed as having diabetes and identified themselves as diabetic.
2. They were currently being treated for their diabetes.
3. They were responsible for their own care (i.e. not institutionalized nor dependent on home nursing).
4. They had sufficient competence in spoken English to understand the interviewer's questions.
5. They had sufficient visual acuity to mark their responses to orally administered questions.

Eligible patients were approached either in the order in which they arrived at the clinic or in the order in which their names appeared on the appointment list.

Slight variations in subject selection procedures occurred across phases. As can be seen in the summary presented in Table 5, the differences in the criteria and procedures for subject selection generally were not associated with differences in scores on the dependent variables.

Overall, 227 patients met the criteria and agreed to

Table 5

Procedural Differences and Effects on Dependent Variables by Phase(a)

	1	2	3
Subject selection			
Subjects solicited from:(b)			
Royal Victoria Hospital	yes	yes	yes
Montreal General Hospital	yes	no	no
Regimen types solicited:(c)			
Insulin	yes	yes	yes
Oral agents	no	no	yes
Diet Alone	no	no	yes
Sample composition based on consecutive appointments(d)	yes	yes	no
Subjects must be able to answer questionnaires alone	no	yes	no(e)
Measures			
Compliance measure,K Scale,CRBS	yes	yes	yes
Additional measures(f)	no	yes	yes

(a) No significant differences in scores on the dependent variables were found between the phases.
(b) No significant differences in scores on the dependent variables were found between the two hospitals.
(c) The differences in regimen in Phase 3 were associated with a significant difference only in relation to one dependent variable, weight status ($F(2,118)=4.66, p<.05$).
(d) The Phase 3 procedure required equal numbers of males and females, and of normal weight and overweight (>10%) subjects. These restrictions did not result in a sample composition significantly different from that of Phases 1 and 2.
(e) In Phase 3, patients were permitted to chose whether to complete the questionnaire alone or with the interviewer. The 128 subjects who completed it with the interviewer in Phase 3 reported poorer weight control than those who completed the questionnaire with the interviewer in Phase 1 ($z(50,113)=2.39, p<.05$).
(f) No significant differences in scores on the dependent variables were found between subjects who completed only the compliance measures and those who completed additional measures.

participate: 50 in Phase 1, 36 in Phase 2, and 141 in Phase 3. Their characteristics are presented in Tables 6 and 7. Thirty-two patients who were approached and who apparently met the inclusion criteria refused to participate. Reasons given for their refusals included fatigue, worry or involvement in some other activity, not feeling well, and dislike of questionnaires. It was possible to compare across phases the sex distribution in the group who participated and the group who refused, and in Phase 3, to compare the regimen and weight status of subjects and refusals. Chi-squared analysis revealed no significant differences.

Materials

Measurement of Compliance

Self-report. Self-report data were collected concerning five self-care behaviours:

1. weight control
2. testing of urine and/or blood
3. medication-taking
4. symptom-reporting
5. safety

The measure used to assess these behaviours was adapted from the diabetic compliance questionnnaire designed by researchers at the Rand Corporation to provide a reliable and valid assessment of six categories of diabetic self-care (Marquis and Ware, 1979). Of the 26 subscales in the original version six subscales were initially chosen for use in the

Table 6

Demographic Characteristics of the Entire Sample

	Mean	Standard Deviation	Range
Age	51.9	16.5	17 to 80
Years of education	11.4	3.9	0 to 24
Income	20-25K	15K	<5K to 50K+
Occupational status(a)	48.6	16.7	21 to 75

	Number	Percentage
Sex		
Males	116	51
Females	111	49
Marital Status		
Married	144	63
Single	38	17
Widowed	25	11
Divorced	19	8
Living arrangements		
With others	192	85
Alone	35	15
First language		
English	145	65
French	41	19
Other	36	16
Country of origin		
Canada	149	67
Other	72	33

(a) Blishen and McRoberts(1976)

Table 7

Health Characteristics of the Sample

	Mean	Standard Deviation	Range
Years since diagnosis	11.1	16.5	<1 to 43
Rated Health (a)			
Diabetic Control	3.7	1.5	0 to 6
General Health	4.2	1.2	1 to 6
Kidneys	5.0	1.3	0 to 6
Retinae	5.1	1.1	1 to 6
Neuropathies (b)	5.0	1.2	0 to 6
Blood Glucose Measures			
Fasting (c)			
Day of interview	172.6	69.1	48 to 362
Annual mean	171.5	53.5	68 to 358
Glycosolated Hemoglobin(d)			
Day of interview	10.4	2.7	4.8 to 18.6
Annual mean	10.7	2.6	4.6 to 19.2

	Number	Percentage
Type of Diabetes		
Type I	55	30
Type II	129	70
Regimen Type		
Insulin	150	66
Oral agents	42	19
Diet Alone	35	15

(a) 0=very poor;6=very good. (b) 0=extremely extensive; 6=completely absent. (c) normal range=80 to 120. (d) normal range=3.5 to 8.5

current study. Selection was based on the following guidelines:

1. each of the categories of self-care behaviour identified by the diabetes experts (safety, medication, nutrition, urine/blood testing, obtaining medical care and hygiene) should be represented.
2. preference should be given to the behaviour within each category rated as most important by the experts.
3. the psychometric qualities of these subscales be described by the authors as acceptable or acceptable with modification.

The resulting scale was then circulated for comment among the physicians, nurses and dietitians at the participating hospitals. This resulted in the deletion of the hygiene item as being inappropriate for all but a small subgroup of patients; the addition of two items to the symptom-reporting subscale; and the inclusion of an item inadvertently omitted in the Rand study: 'taking medication as often as prescribed.'

The final questionnaire consisted of five subscales measuring the behaviours listed above (Appendix C). The home testing, medication-taking and symptom reporting subscales consisted of more than one scored item. The home testing and medication taking items asked about the frequency and the timing of the behaviour. The symptom-reporting subscale consisted of items relating to the frequency of care seeking in response to 6 types of symptoms. The safety, testing and medication subscales asked about behaviour both 'yesterday' and 'in the past week'. The frequency in the past week constituted the patient's score: frequency yesterday was only

used as a reliability check.

Because level of compliance constitutes a comparison between what is done and what should be done and as certain components of diabetic treatment are individualized, it was necessary to establish the specific prescription for each patient, both from the perspective of the health professionals and of the patients.

Information concerning optimal performance from the health professionals' perspective was obtained from a variety of sources. Ideal Body Weight (IBW) was obtained from patients' charts, or, where these data were missing, from the patients' dietitians. The patients' physicians were routinely asked to report the frequency and timing of medication taking and of home testing they had prescribed. When the data were not available in patients' charts, the information was taken from these physicians' reports. If the physicians had asked the nurse educator to instruct patients on testing, these data were obtained from her. The medical experts consulted by Marquis & Ware (1979) stated that all insulin patients should always have glucose with them and that the occurrence of certain symptoms always required medical attention. When the pilot compliance questionnaire was circulated to local physicians, none disagreed with these criteria.

Data concerning patients' criteria were only collected in Phase 3. Patients were asked to complete a questionnaire asking what they thought their doctor wanted them to do concerning each of the five self-care behaviours. They were asked what their doctor would say was their ideal weight, how often and when he or she wanted them to test, how often and

when he or she wanted them to take medication, whether their doctor would want them to seek help if various symptoms arose, and whether they should always carry a sugar source (insulin patients only).

Two compliance scores for each subscale were determined by using both physicians' and patients' criteria. Subsequently, the terms 'compliance' or 'physician-determined compliance' will be used to refer to scores based on physicians' criteria. When scores based on patients' perceptions of physicians' criteria are being referred to, the term 'patient-determined compliance' will be used.

Scores were computed by calculating the self-reported frequency of a behaviour or weight as a percentage of the criterion frequency or weight. Where appropriate, absolute values were used. The higher the percentage score the higher the level of compliance.

Weight Control

$$=100 - \text{abs}\left(\frac{\text{reported wt. - criterion wt.}}{\text{criterion wt.}}\right) \text{ X } 100$$

Testing

$$=100 - \text{abs}\left(\frac{\text{reported testing - criterion testing}}{\text{criterion testing}}\right) \text{ X } 100$$

Medication-taking

$$=100 - \text{abs}\left(\frac{\text{reported medication-taking - criterion}}{\text{criterion}}\right) \text{ X } 100$$

Symptom Reporting

$$=100 - \left(\frac{\text{reported symptom-report. - reported symp.freq.}}{\text{reported symptom frequency}}\right) \text{X} 100$$

Safety = reported frequency as a percentage

Informant report. Replicating the procedure used in the Rand study, informants responded to the identical questionnaire items as did the patients, with the wording modified from 'you' to 'the patient'. Compliance scores were computed in relation to physicians' criteria.

Health professionals' compliance ratings. Physicians, nurses and dietitians were asked to rate each subject's compliance performance (Appendix D). The rating form first asked them to estimate the percentage by which patients' current weight deviated from their ideal body weight. The subsequent items asked them to estimate patients' frequency of compliance with the two criteria making up the testing subscale, with the two making up the medication subscale, with optimal symptom-reporting and safety precautions. Their ratings were made on an unbroken line anchored by 'never' and 'always'. Percentage scores were calculated from the placement of the marks on the lines.

Validation Measures

Background factors. Data were collected concerning patients' age, sex, marital status, education, first language, place of birth, income, occupation, years since diagnosis and living arrangements (Appendix B). Occupational status was calculated using a scale designed for Canadian populations by Blishen and McRoberts (1976). Education and income were also treated as socioeconomic status indicators.

Objective compliance measures. Objective assessment of patients' compliance was availabe for two subscales. Self-report of current weight was able to be compared to data obtained from medical records. Self-report of always carrying an emergency source of sugar--the safety measure--was able to be verified by asking patients to show the interviewer the glucose-containing substance they were carrying.

Health outcome measures. Data concerning blood glucose levels and patients' health status were sought as an indirect assessment of patients' behaviour. Stronger associations were expected with the more closely related behaviours (weight control, medication-taking, testing), and at best weak associations with the others (safety, symptom-reporting).

Fasting blood glucose levels were routinely assessed during clinic visits. These served as an index of the adequacy of the patients' current utilization of glucose, of their level of diabetic control. For each patient, this day of interview level was ascertained from the medical records. A mean fasting blood glucose level over the past year was also calculated from medical record data.

For some patients, a blood test to determine glycosolated hemoglobin level (HgAlc) was also ordered by their physician. This test is thought to permit an analysis of glucose utilization in approximately the last two months (Rabin & McKenna 1982). As with fasting blood glucose levels, the day of interview HgAic levels were obtained from the medical records, and the mean level over the past year calculated.

Patients' health status was assessed by having their physicians rate them on a 0 to 6 point scale (Appendix D). The

health areas rated were:

1. general health
2. level of diabetic control
3. status of kidneys
4. status of retinae
5. extent of neuropathies

Response Bias Measures

K Scale. To assess patients' tendency to present themselves in the most favourable light, the K Scale of the MMPI was administered (Appendix E). The K Scale was empirically developed to measure defensiveness in test-taking attitudes and high scores indicate a facade of absence of personal defects (Dahlstrom & Welsh, 1960). 24 of its 30 items are highly correlated with Edwards' social desirablity factor (Newmark, 1979).

Compliance Response Bias Scale (CRBS). This scale was designed as part of the Rand compliance measure validation study (Marquis & Ware 1979) to assess the tendency to give distorted responses concerning performance of health behaviours that are highly desirable but seldom achieved. The original form of the CRBS had adequate retest reliability and alpha levels, although the actual inter-item correlations were low. CRBS scores also showed the expected correlations with demographic characteristics, with certain types of compliance questions, and with two items designed to test the tendency to lie. As recommended by Marquis & Ware (1979) a shorter version of the scale with greater homogeneity was used (Appendix E).

Procedure

Standardized interview assessment and questionnaire administration techniques were used in data collection. Minor variations in procedure occurred between phases. Generally these were not associated with any differences in the dependent measures. Table 5 summarizes these variations and their effects.

Patient Assessment

After patients' eligibility for inclusion had been established, they were given a verbal and written description of the study and asked to sign a consent form (Appendix A). The interviewer then questioned patients concerning sociodemographic variables, using these responses to establish a more relaxed atmosphere and build rapport. The compliance questionnaire, the K scale, and the CRBS were then administered either as part of a battery of measures, or on their own. The questionnaires were either given to the patients to complete or read out to the patients, depending upon the phase and the patients' preference.

Informant Data

In Phases 1 and 2, after completing the consent form subjects were asked to name an 'informant': someone who knew about the patient's self-care and whom we could contact for an interview. Within the next 48 hours these people were contacted by telephone and asked to participate. Confidentiality and the right to withdraw at any time were guaranteed. Twenty-four informants agreed to participate in Phase 1, 26 in Phase 2. When they had given their consent, they were immediately interviewed over the telephone.

Health Professionals' Ratings

On the same day that each subject was interviewed, compliance rating forms were distributed to the patients' own physician and dietitian, and to the nurse who felt most familiar with each patient. Physicians received a second form concerning what they had prescribed for each patient with respect to medication and test timing and frequency. They were also asked to rate each patient's health status.

Overall, rating forms were completed by three nurses for 143 patients, by five dietitians for 103 patients and by twenty-two physicians for 110 patients. Since not all requested data were obtained, the number of subjects differs from analysis to analysis.

Interviewer

All patients were interviewed by the author.

Results

The data analyses were conducted in three stages. Stage I entailed a thorough examination of the validity of self-reported compliance. Stage II involved an investigation of the degree of congruity in the results when compliance is assessed using different criteria - physicians' and patients'. In Stage III, the degree of consistency manifested across the different demands of the regimen was examined.

Stage I: Validity of Self-Reported Compliance

Assessment of the validity of the responses to the compliance questionnaire was carried out in a series of steps. Having established that methodological differences between and within phases did not present any obstacles, the data from all three phases were merged and their frequency distributions examined. The reliability of each measure was then assessed. Lastly, the validity of the self-report variables was examined using a variety of techniques.

Psychometric Properties of the Merged Compliance Measures

The distribution of scores for all the dependent variables deviated to some extent from normality. Table 8 indicates the type and degree of these deviations. The absence of variance noted on the medication-taking, symptom-reporting and safety variables is particularly problematic. Since 77% of the subjects claimed perfect compliance with medication-taking, no further analyses using these measure could be conducted. Nonparametric procedures were used for all other analyses to compensate for the number of ties on the symptom-reporting and safety variables, and for the generally non-normal distributions.

The internal consistency of the dependent measures composed of more than one item was also evaluated. The alpha level of the testing measure (2 items) was .73 and that of the symptom-reporting measure (6 items) was .82.

Validation of Self-Report of Compliance

The validity of the self-report measure of compliance was assessed by evaluating: (a) whether the relationship between self-reported compliance and specific background variables conformed to the relationships usually reported in the literature; (b)the relationship between self-report and health and physiological measures; (c) the relationship of self-report to measures of response bias; (d) the multitrait-multimethod matrix of self-report and others' reports and ratings; (e) the conformity between self-report and actual compliance where possible; and (f) the relationship of reported levels to the levels expected. Support was found for the validity of all four self-care measures. All tests,

Table 8

Departures from Normality of the Distribution of Merged Compliance Scores

	Measures of Deviation from Normality			
Compliance Measure	Skewness(a)	Kurtosis(b)	Inadequate Variance(c)	K-S Test(d)
Weight control	-	+		2.98**
Testing		-		1.61*
Medication-taking	-	+	X	5.48**
Symptom-reporting			X	3.31**
Safety		-	X	3.98**

(a) Skewness: + skew > 1.00
- skew < -1.00

(b) Kurtosis: + kurtosis > 1.00
- kurtosis < -1.00

(c) Inadequate variance: X more than 40% of scores took the same value.

(d) K-S tests: Kolmogorv-Smirnov one-sample tests of the goodness of fit to the normal distribution.

* p<.05. ** p<.001.

unless otherwise stated, were one-tailed.

Relationship of self-report to background variables. While it has generally been concluded that sociodemographic factors are poor predictors of compliance (Haynes, 1976), certain background characteristics have repeatedly been found to relate to certain health behaviours. Lower socioeconomic status and greater age are associated with poorer weight control, while longer duration of treatment is associated with poorer overall compliance. As shown in Table 9, the current data confirmed the relationship between age and weight control ($tau(204)=-.10$, $p<.05$); between education and weight control ($tau(200)=.10$, $p<.05$) and between income and weight control ($tau(165)=.11$, $p<.05$). The association between treatment duration and compliance was not confirmed.

Females generally have greater problems with weight control than males, and this relationship was confirmed in the current data ($z(204)=3.01$, $p<.05$). The tendency of females to seek medical care more readily than males emerged in the current data only as a trend ($z(153)=1.48$, $p=.07$). No differences were found in levels of compliance between patients who might be considered more or less socially isolated based on their living arrangements and marital status. The predicted relationship of decreased compliance with longer duration of treatment did not emerge.

Table 9

Correlations of Self-reported Compliance with Background Variables

	Self-Report			
Background Measures	Weight Control	Testing	Symptom Reporting	Safety
Age	-.10* (204)	-.11	-.04	.04
Education	.10* (200)	.01	.00	-.08
Income	.11* (165)	.05	-.02	-.05
Occupation	.11	.01	-.01	.04
Duration of treatment	.04	.03	.11	.10

Note. All asterisked values are Kendall's tau and bracketed values are the number of subjects.

* $p<.05$.

Relationship of self-report to health variables.

Self-reported compliance was expected to show weak positive relationships with measures of physiological status and health outcome. As indicated in Table 10, this was confirmed for weight control, which was significantly correlated with day of interview fasting blood glucose levels (tau(198)=-.15, p<.01), with mean blood glucose levels (tau(178)=-.16, p<.01), with physicians' ratings of diabetic control (tau(133)=.22, p<.01), and of the status of patients' kidneys (tau(79)=.20, p<.05) and of the extent of their neuropathies (tau(79)=.15, p<.05). Self-reported testing also showed some small but significant correlations in the expected directions with fasting blood glucose levels on the interview day (tau(115)=-.12, p<.05) and with physicians' ratings of control (tau(114)=.16, p<.05). None of the other correlations reached significance.

Relationship of self-report to response bias measures.

Kendall correlations were examined between each measure of compliance and patients' scores on the K Scale and the CRBS to ascertain whether the self-reports were associated with response bias.

No significant correlations were found between the K scale scores and any of the compliance measures. Scores on the CRBS were weakly correlated with self-reported weight control (tau(184)=.11, p<.05) and with the safety measure (tau(134)=.16, p<.05), both in the positive direction, as expected.

Table 10

Correlations of Self-reported Compliance with Measures of Health Status

Health Measures	Self-Report			
	Weight Control	Testing	Symptom Reporting	Safety
General Health	.11	.04	.04	.03
Diabetic Control	.22** (133)	.16* (114)	.00	.00
Fasting blood glucose				
Day of interview	-.15** (198)	-.12* (115)	.00	-.09
Annual mean	-.16** (178)	.01	.01	-.01
Glycosolated Hemoglobin				
Day of interview	.03	-.10	.02	-.02
Annual mean	-.02	-.09	-.07	.06
Status of				
Kidneys	.20* (79)	-.09	.04	.00
Retinae	.07	-.03	-.04	.05
Neuropathies	15* (79)	.03	.00	.09

Note. Asterisked values are Kendall's tau. Bracketed values are the number of subjects.

*p<.05. **p<.01.

Multitrait-Multimethod Analysis. Multitrait-multimethod analysis was used to simultaneously assess the convergent and discriminant validity of the self-report measures. Certain criteria were established for the analysis. The number of cases in each correlation had to equal or exceed 25. Since the goal was to assess self-report, the focus was on correlations of other measurement methods with self-report rather than on all the inter-correlations among methods. Finally, as the scores on the compliance questionnaire were not normally distributed, the correlation matrix was created using nonparametric, rank order correlations. The frequency of tied ranks in the data indicated that Kendall's tau was the most appropriate statistic for this purpose.

Campbell and Fiske (1959) did not establish numerical cut-offs for their convergent and discriminant criteria. For the purposes of this investigation, correlation coefficients in the validity diagonal of .40 and over were deemed evidence of convergent validity and worthy of further investigation. If three quarters of these coefficients exceeded the heterotrait-heteromethod values and the heterotrait-monomethod values, the measure was considered to have acceptable discriminant validity.

The correlation matrix used for the analyses is presented in Table 11 and the extent to which three of the Campbell and Fiske criteria were met is shown in Table 12. The results differed among the variables.

Table 11

Multitrait-Multimethod Matrix of Behaviours and Sources

	Self-Report				Informant Report				Nurses' Ratings				Dieticians' Ratings				Physicians, Ratings			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Self-Report																				
1. Weight Control																				
2. Testing	11																			
3. Symptom-Reporting																				
4. Safety	05	11	07																	
Informant Report																				
1. Weight Control	59*	-07	-11	09																
2. Testing	08	39*		-12	00															
3. Symptom-Reporting	09	13	18	10	-18	17														
4. Safety	05	06	-19	44*	-02	05	16													
Nurses' Ratings																				
1. Weight Control	35*	22*	13	06	18	10	06	01												
2. Testing	18	27*	05	04	-15	16	09	-06	22*											
3. Symptom-Reporting	06	19*	05	14	-13		15	13	-06	36*										
4. Safety	00	16	-03	02	-21			-02	15	37*	22*									
Dietitians' Ratings																				
1. Weight Control	63*	08	06	09	59*			09	49*	10	-15	-04								
2. Testing	13	36*	06	22					12	21*	26*	15	15*							
3. Symptom-Reporting																				
4. Safety	06	09	11	24*					-04	-05	23	-18	-07	32*						
Physicians' Rating																				
1. Weight Control	60*	12	-02	10	31*	-13	03	00	42*	28*	04	11	62*	24*						
2. Testing	12	40*	09	13					12	27*	25*	16	06	38*		16	15*			
3. Symptom-Reporting	06	19	-10	04					-02	15*	32*	03	06	14		-01	13	20*		
4. Safety	19	18	-07	20*					01	18	24*	00	25	04			17	39*	44*	

Note: All values are Kendall correlation coefficients. Unenclosed values on the diagonal are the validity coefficients. All heterotrait-heteromethod triangles are enclosed by solid lines. Heterotrait-monomethod triangles are enclosed by broken lines.

* < .05

Table 12

Summary of Multitrait-Multimethod Validation - Self-Report

	Convergent		Discriminant	
	>.40	p<.05	Heterotrait-Heteromethod	Heterotrait-Heteromethod
Weight control	3/4	4/4	23/23	19/21
Testing	1/4	4/4	22/22	18/21
Symptom-reporting	0/3	0/3	6/17	7/18
Safety	1/4	3/4	19/23	12/21

Weight control. Three of the four Kendall correlations between self-report and other sources used to establish convergence exceeded the criterion of .40 and all were significant. All of these correlations also met the criteria for discriminant validity by exceeding all of the heterotrait-heteromethod correlations and 19 of the 21 heterotrait-monomethod correlations.

Testing. All four correlation between self-report and other sources were significant but only one exceeded .40. Nevertheless, they exceeded all of the heterotrait-heteromethod correlations and 18 of the 21 heterotrait-monoimethod correlations.

Symptom-reporting. All of the correlations between self-report and other sources were very low and nonsignificant. They failed to exceed half of the heterotrait-heteromethod and heterotrait-monomethod correlations.

Safety. Three of the four correlations relating to convergence were significant, but only one exceeded .40. These correlations did exceed 19 of 23 heterotrait-heteromethod correlations and 12 out of 21 heterotrait-monomethod correlations.

Health professionals tended to view the various behaviours as more highly intercorrelated than did patients or informants and these monomethod intercorrelations were generally the highest with respect to those measures with the lowest convergent and discriminant validity (symptom-reporting and safety).

Campbell and Fiske's final requirement, that the pattern

of results across sources be similar, generally appeared to have been met. For all sources, the highest levels of convergent validity were found with respect to weight control, with testing showing the next highest levels. The heterotrait-heteromethod triangles all had a similar pattern of very low intercorrelations, usually below .20. Finally in the heterotrait-monomethod triangles, the highest correlations were found among the same variables for virtually all of the sources. The actual assessment of the convergent and discriminant validity of other sources' reports and ratings is presented in Appendix F.

Overall, the multitrait-multimethod analyses indicated acceptable levels of validity for the weight control and testing self-report measures, marginally acceptable levels for the safety measure, and failed to provide any support for the symptom-reporting measure.

Comparison with actual compliance. For two measures it was possible to compare some of the self-report data with objective measures. Self-reported weight compliance correlated very highly with the weight recorded in patients' medical records ($\underline{tau}(207)=.86$, $\underline{p}<.01$). When patients who claimed to carry glucose 100% of the time were asked to produce it, 86% were able to show it to the investigator.

Self-reported levels of compliance. It is generally accepted that the major threat to the validity of self-report compliance data is patients' tendency to overestimate their compliance. If patients report very low levels of compliance, there may be a greater presumption of accuracy than if the levels they report are very high.

Examination of mean levels of compliance (Table 13) indicated that patients reported themselves to comply less than half of the time on the testingmeasure and less than one third of the time on the symptom-reporting measure. The health professionals rated patients' compliance with these regimen demands as much higher.

Table 14 summarizes the results of all of the validation procedures.

Stage II: Patient-Determined versus Physician-Determined Levels of Compliance

The second objective of study 1 was to ascertain whether patients' level of compliance differed when the criterion against which their behaviour was assessed was based on patients' understanding and recall of their doctors' recommendations, rather than on the recommendations themselves, as recorded in patients' charts or reported to the investigator. The normality of the distribution of patient-determined compliance scores was first examined. Paired t-tests were then used to determine whether a significant discrepancy in the results arose when patient-determined level

Table 13

Self-Reported Levels of Compliance

Compliance	Source				
	Self-Report	Informant Ratings	Nurses Ratings	Dietitian Ratings	Physician Ratings
Weight control					
M	80.3	91.4	78.7	78.0	80.0
n	211	41	143	94	111
SD	22.5	9.4	23.4	28.1	24.3
Testing					
M	40.5	37.5	57.2	64.4	63.5
n	118	43	123	98	74
SD	34.9	36.4	22.2	25.4	34.4
Symptom-reporting					
M	30.1	28.4	71.8	78.2	82.6
n	153	38	108	26	89
SD	36.2	40.4	19.0	27.1	22.4
Safety					
M	70.4	67.9	69.3	80.6	76.6
n	141	46	80	65	56
SD	43.0	41.7	24.0	20.4	33.7
Medication					
M	90.3	94.2	85.8	85.2	93.9
n	162	43	123	99	90
SD	23.8	15.6	13.0	16.6	12.4

Note. All values represent levels of compliance in percentages.

Table 14

Summary of Support for the Validity of Self-Reported Compliance

	Self-Report Compliance Measures			
	Weight Control	Testing	Symptom-Reporting	Safety
Multitrait-Multimethod Matrix	(*)	(*)	( )	(*)
Background Variables	(*)	-	(*)	-
Health Measures	(*)	(*)	( )	( )
Social Desirability	( )	(*)	(*)	(*)
Actual Measures	(*)	-	-	(*)
Reported Compliance Levels	-	(*)	(*)	(*)

Note. Dashes indicate support from this source was not predicted.

(*) indicates support from this source was both predicted and obtained.

( ) indicates support from this source was predicted but not obtained.

of compliance was compared with physician-determined level of compliance. The size of the discrepancy resulting from the different methods of calculation was then examined in relation to various factors thought likely to be associated with poorer knowledge.

Examination of Raw Data and Their Distribution

The frequency distributions of patient-determined scores on each dependent measure were assessed with respect to their normality. Patterns similar to those of the physician-determined score distributions were revealed. The measures of weight and medication taking were negatively skewed. Again this was very extreme with the medication variables. Patient-determined compliance levels of 100% were reported by 85% of the patients. The somewhat U-shaped distribution on the measures of testing, symptom-reporting and safety found using physicians' criteria persisted when patients' criteria were employed. Kolmogorov-Smirnov goodness of fit tests indicated the distributions of all five variables deviated significantly from normality.

The conclusions drawn from the distributions of these patient-determined scores were similar to those drawn with respect to physician-determined scores. No further analyses were possible with the medication variables and all other analyses required nonparametric approaches.

Levels of Compliance

Patient-determined levels of compliance exceeded physician-determined levels of compliance for all variables except safety (Table 15). Two of these differences reached significance using Wilcoxon's matched-pairs signed ranks test. Patient-determined weight control exceeded physician-determined weight compliance ($z(86)=5.27$, $p<.001$) and patient-determined symptom reporting compliance exceeded physician-determined ($z(64)=2.93$, $p<.01$).

Relationship of the discrepancy to other variables

It had been predicted that a larger discrepancy between patient-determined and physician-determined compliance would be associated with fewer years of education, shorter duration of treatment and poorer health and physiological status.

Level of education was found to be significantly correlated with the gap concerning weight compliance ($tau(88)=-.19$, $p<.05$) in the expected direction. Duration of treatment was associated with the symptom- reporting gap ($tau(52)=.18$, $p<.05$),but in the direction opposite to that predicted. The discrepancy relating to weight control was, as expected, significantly negatively correlated with physicians' ratings of diabetic control ($tau(45)=-.19$, $p<.05$) and with ratings of each of the complications. None of the other discrepancies was associated with health or physiological outcome.

Table 15

Comparison of Physician-Determined and Patient-Determined Levels of Compliance(a)

	Levels of Compliance	
	Physician-Determined	Patient-Determined
Weight Control(b)		
M	79.9	88.0
n	88	92
SD	19.3	11.1
Testing		
M	38.5	66.5
n	35	73
SD	36.0	37.2
Symptom-Reporting(c)		
M	31.6	44.0
n	67	53
SD	39.6	43.1
Safety		
M	69.8	63.5
n	43	40
SD	43.0	43.9
Medication-taking		
M	84.6	96.0
n	52	17
SD	30.9	14.0

Note. Values represent levels of compliance as percentages.
(a) Patients were included who had scores on both types of measure concerning at least one behaviour.
(b) The difference between means is significant ($z(86)=5.26, p<.001$).
(c) The difference between means is significant ($z(53)=2.93, p<.01$).

Stage III: Intraindividual Consistency in Compliance

Examination of the extent to which patients were consistent in their compliance across the demands of the regimen employed two approaches. The first assessed the intercorrelation matrices of patient-determined and physician-determined levels of compliance. The second attempted to identify high consistency subgroups within the sample.

Intercorrelations Among Levels of Compliance

The intercorrelations of the four dependent variables were assessed using Kendall correlation coefficients to compensate for the non-normal frequency distributions. Table 16 presents the resulting matrices. (The matrices which result from using Pearson correlations are presented in Appendix G).

In the physician-determined compliance matrix, all of the intercorrelations were below .15, and three of the four were below .10. None of the correlations among variables was significant.

The matrix based on patient-determined levels of compliance revealed that all of the correlations were below .30, with three of the six below .15. Two correlations were significant.

Table 16

Intercorrelations of Compliance Measures

	2	3	4
	Physician-determined		
1. Weight Control	.11	.02	.05
2. Testing		.09	.11
3. Symptom-reporting			.07
4. Safety			
	Patient-determined		
1. Weight Control	-.04	.00	.24*
2. Testing		.25*	.13
3. Symptom-reporting			.03
4. Safety			

Note. All values are Kendall's tau.

*$p < .05$.

Identification of Consistent Subgroups

Although the intercorrelations in general were very low, it remained possible that a subgroup of consistent patients existed. By defining degree of consistency as the amount of variation around their own average scores, subjects whose standard deviations from their mean level of compliance across regimen demands were small would constitute a consistent subgroup. High consistency was considered to have been demonstrated when the standard deviation was 15 or less. This criterion allows patients to deviate from their own mean on one occasion in seven, or on one day a week for behaviours requiring daily performance. Subjects whose standard deviations were large would constitute the low consistency subgroup.

Prior to performing these calculations, it was decided to include the medication variable previously excluded due to its skewed distribution. It was felt that if a consistent subgroup existed, it should be consistent across all regimen demands, including medication taking. Since not all subjects had scores on every dependent variable, certain criteria for inclusion of subjects in the analysis were established. For patients taking insulin, data had to be available for four of the five dependent measures; for patients on oral agents, data were required for three of the four measures; and for patients on diet alone, data were needed for two of the three measures. These criteria resulted in a sample size of 149 for the physician-determined compliance sample, and of 65 for the patient-determined compliance sample.

In the physican-determined compliance group, the mean

standard deviation was 38.3, with its own standard deviation of 12.2. Only seven subjects, or less than five percent, had standard deviations of fifteen or less. Of these, four had compliance levels which were consistently above the group mean, and three had compliance levels consistently below. Twenty-four subjects (16%) had standard deviations greater than fifty.

Analyses were then performed to determine if size of the standard deviations related to any of the background variables. No significant Pearson correlations were found with age, duration of regimen, education, income or occupation, K Scale scores, CRBS scores, nor with any of the physiological or health measures. Oneway analyses of variance revealed no regimen differences, and t-tests showed no differences based on marital status, diabetes type or living arrangements. A highly significant sex difference was found ($\underline{t}(150)=3.18$, $\underline{p}<.01$). Women on the average had smaller standard deviations than men (women=35.2, men=41.1). Separate intercorrelation matrices for males and females were then constructed. Among women, three of six correlations were significant, and three exceeded .15. Among men, none were significant and none exceeded .15.

In the patient-determined compliance group, the mean standard deviation was 31.4, with a standard deviation of 19.5. Here nineteen subjects (28%) had standard deviations of less than fifteen, and of these, nine had standard deviations less than five. Five of the nineteen had consistently poor compliance, and fourteen had consistently high levels. The standard deviations of twelve subjects (17%) exceeded fifty.

The relationship of the size of the standard deviation to background variables in the patient-determined compliance sample was examined in the same manner as in the physician-determined sample. Three significant relationships were found. There was a negative correlation between K scale scores and the size of the standard deviation ($\underline{tau}(61)=-.20$, $\underline{p}<.05$), the females were significantly more consistent than males ($\underline{z}(65)=2.57$, $\underline{p}<.001$) and married people were more consistent than single people ($\underline{z}(65)=2.87$, $\underline{p}<.01$).

Finally, Wilcoxon's matched-pairs signed ranks test was used to assess the difference between physician-determined levels of compliance standard deviations and patient-determined levels of compliance standard deviations. Patient-determined levels of compliance were associated with a significantly smaller standard deviation than were physician-determined levels of compliance ($\underline{z}(41)=2.51$, $\underline{p}<.05$).

Discussion

Three major issues were addressed in this study: the validity of self-reported compliance; the congruence in levels of compliance when calculated by patients' or physicians' criteria; and the extent of intraindividual consistency of compliance. These questions were studied in relation to the problems diabetic patients have adhering to their complex and demanding regimen.

The sample obtained appears to be relatively representative of the Canadian diabetic population when compared to the results of the Canada Health Survey (1981).

Certain of the constraints imposed in the current study, such as requiring equal numbers of males and females and excluding patients who were institutionalized or unable to care for themselves may have lead to some differences in relation to the sex and age distributions. The distribution of incomes paralleled that in the Canada Health Survey, with all income levels represented.

Validity of Self-Report of Compliance

Overall, the results provided some support for the validity of self-report of treatment behaviours. The full exploration of this issue was somewhat constrained, however, by the finding that most of the variables were not normally distributed and the medication-taking measure had so little variance as to require its exclusion from further analyses. To examine the remaining four measures, recourse was taken to more conservative nonparametric techniques. A further limitation arose from the quantities of missing data, particularly among other sources' ratings of patients' behaviour and concerning those behaviours which required the physicians to report their prescription in order to calculate compliance.

Within these constraints, most of the convergent and discriminant validation procedures yielded the expected results. The multitrait-multimethod analysis confirmed that for three of the four behaviours, self-report showed adequate validity in relation to informants' reports and health professionals' ratings. The fourth behaviour,

symptom-reporting, was apparently rendered less valid by the very low levels of compliance reported by patients in comparison to the relatively high levels assumed by the health professionals. The best support for the validity of self-report in the nultitrait-multimethod analysis appears to derive from its consistently strong relationship to informants' reports. Previous studies concerning dietary and other consummatory behaviours have shown good correspondence between subjects' reports and spouses' reports of the same behaviour. It is nevertheless possible that in the current study informants were only reporting the inaccurate information obtained by them from their spouses or that the informants were also attempting to present a socially desirable image to the interviewer. The absence of correlation between the tendency to want to present a socially acceptable image and the levels of self-reported compliance does not support such an explanation.

Health professionals' ratings of patients' responses to the various regimen demands also showed good convergence with self-report but tended to be more highly intercorrelated than did patients' or informants'. This may have served to reduce the discriminant validity of the self-report measures. It also suggested that, compared to patients, health professionals may perceive compliance more as a function of stable intrapersonal dispositions. This tendency to attribute others' behaviour to factors in the person rather than to factors in the situation is well documented in the psychological literature pertaining to actor-observer differences (Jones & Nisbett,1971). When observers are asked

to estimate others' behaviour in diverse situations, this tendency is likely to be activated and the ratings rendered less accurate. As previous research has also indicated problems with the validity of health professionals' ratings, it was important that convergence be established with other variables in addition.

Two of the measures, symptom-reporting and weight control, did converge as expected with an assortment of background variables. As expected, weight control and testing were correlated with the physiological and health measures. The symptom-reporting and safety measures did not show even the weak relationship with these indices that had been predicted.

The assumption that patients bias their responses to compliance questions because of a tendency to want to present an image of the ideal patient was not supported by the current results. When the extent of such a tendency was assessed simultaneously with collection of self-report data, no correlations between the response bias measures and three of the four treatment behaviours were found. Only self-report of weight control was correlated significantly with scores on the K Scale: K Scale scores were also correlated with actual weight control, suggesting that a tendency to present oneself in a socially desirable light may influence weight control as well as sometimes influencing questionnaire responses. If inaccuracies in self-report are thought to persist, these response bias results would suggest that the cause be sought in failure of recall or even failure to register the noncompliance when it occurred.

Comparison of self-report with actual measures and examination of levels of compliance based on self-report also tended to support the validity of patients' statements. Reported weight control corresponded highly to actual weight control and reports of always carrying glucose were for the most part confirmed by patients' demonstrations. Perhaps most revealing, however, was the generally low level of compliance reported by patients for all aspects of the regimen except medication-taking. Although it is not possible to make a direct comparison with other studies because of the different measures used, these findings are in line with the relatively low levels of compliance reported by other diabetes researchers.

Self-report may be concluded to give a relatively valid assessment of patients' behaviour, at least when the questions asked are highly specific, cover only a short time period, and are asked in a nonjudgmental fashion.

Congruence of Patient-Determined and Physician-Determined Compliance

When levels of compliance based on physicians' report were compared with levels of compliance based on patients' understanding of the prescribed treatment in a subset of patients, quite different results were obtained. Significant discrepancies were observed in level of compliance with weight control and in level of compliance with symptom-reporting. As patients' standards were more lenient, patient-determined levels of compliance were generally higher than

physician-determined levels. Nonsignificant differences in the same direction were evident for testing and medication-taking. Only with respect to the safety measure did physician-determined compliance levels exceed patient-determined levels.

These results were based on a fairly small sample. They are nevertheless substantially in agreement with the findings of other diabetes researchers who have examined this phenomenon (Hulka et al, 1975a, 1975b, 1976). The transfer of regimen information from physicians to patients is apparently often inadequate and results in patients and physicians having quite different perspectives on the adequacy of patients' behaviours. Some of what health professionals may label as noncompliance and ascribe to motivational difficulties on the part of patients may more appropriately be viewed as a consequence of patients lacking the specific information necessary to comply.

Consistency of Compliance

The results pertaining to patients' response consistency provided strong support for the hypothesis that a weak relationship would exist among levels of performance of different regimen demands. When the intercorrelations of physician-determined levels of compliance were examined, none of the relationships even approached significance. When patient-determined compliance intercorrelations were considered, two of the six were significant but in neither case did level of performance of one behaviour explain even

10% of the variance in level of compliance with the other. No sizeable consistent subgroup emerged when individual variations in compliance were assessed. Exploratory examination revealed some differences in consistency based on certain demographic and disease characteristics. Even these did not yield better than moderate intercorrelations.

These differences in level of compliance occurred despite similarity of the importance ratings assigned to them by a panel of diabetes experts (Marquis and Ware 1979). These findings parallel the findings concerning the independence of preventive health behaviours previously reviewed.

Conclusions and Implications for Future Research

These results have brought into question certain basic implicit and explicit assumptions of most approaches to measuring and understanding compliance. Self-report appears to have the potential to be a relatively valid indicator of patients' treatment behaviours and does not appear to be tainted by a tendency to present a socially desirable image. Patients' and physicians' understanding and recall of regimen demands proved to be quite different, and consequently the extent of the compliance problem may be seen to vary dramatically depending upon the criteria used. Patients' responses to treatment demands were shown to be inconsistent, thus rendering prediction of compliance in one situation from compliance in another unreliable.

These results have important implications for the assessment of compliance and for the selection of models to

CHAPTER 3: STUDY 2

Introduction

The major objectives of Study 2 were first, to learn more about the conditions under which noncompliance occurs; and second, to assess the utility of selected models in explaining compliance. The results of Study 1 concerning the absence of consistency in compliance across regimen demands strongly influenced the form and direction of both aspects of this inquiry. It was first considered desirable to replicate these findings with two new behaviours and to assess consistency in level of response over time. Then attention was shifted to a description of the actual circumstances surrounding the noncompliance episodes, and an attempt was made to uncover patterns in the reasons given for their occurence, using a classification scheme developed and refined in a similar context. A more molar approach to understanding compliance was also taken. Two cognitive models, the Health Belief Model and Bandura's social learning model, were tested with respect to their ability to explain current and future levels of compliance. Finally, the relationship of background factors and of actual health consequences to compliance was explored.

Two specific dietary demands of the diabetic regimen were selected for investigation. Following the prescribed diet and maintaining a regular schedule of food intake were identified in the Rand study as important components of diabetic treatment. Diabetic diets are constructed so as to enable patients to attain and maintain ideal body weight, to

facilitate normoglycemia, and to reduce the risks of long-term complications. Failure to follow the prescribed diet therefore has many potentially negative health consequences. For patients on insulin regimens, and to a lesser extent, for those on oral agents, these consequences may be relatively immediate: insufficient food intake to balance insulin levels will result in hypoglycemic reactions. For patients on diet alone, the failure to follow their diet and to bring body weight under control may lead to a further reduction in the body's own insulin production or increased insulin resistance. This in turn may result in patients being prescribed a more restrictive regimen, such as that required by oral agents or insulin. For patients on all regimens dietary noncompliance may mean an increased risk of diabetic complications.

Following a regular meal schedule is particularly important for patients on insulin or oral agents. In an attempt to approximate the glucose metabolism of non-diabetics, the prescribed treatment involves a careful balancing of type of insulin or oral agent, timing of its administration, type and timing of activity and type and timing of food intake. A change in any of these factors may result in hypoglycemia or hyperglycemia. To avoid these consequences, patients are instructed to eat their prescribed meals and snacks at the same time every day.

Considerable evidence has already been presented that most patients do not follow their prescribed diets. Data on diabetic patients' weight change and self-report of their food intake reveal that under most circumstances people do not change their eating habits to conform to the diabetic diet and

that many patients do not adequately follow a meal schedule (e.g. Williams et al., 1967; Christensen et al. 1983; McCulloch et al. 1983).

Descriptive and Conceptual Issues in Dietary Compliance

Behavioural Consistency

The results of Study 1 which revealed patients' relative inconsistency in their levels of response to treatment demands challenged an important assumption about the nature of health behaviours. A second, equally important assumption is that patients' level of compliance does not vary much on a day-to-day or week-to-week basis. Both of these issues need further examination. Comparison of levels of compliance with these two ostensibly related regimen demands and comparison of levels of compliance at consecutive clinic visits were seen as providing important additional understanding of the nature of the compliance problem.

In Study 1, certain background characteristics, particularly sex, were found to be somewhat related to degree of consistency. Certain other factors were seen as bearing a relationship to dietary compliance. Overweight subjects were seen as more likely to be inconsistent, fluctuating between attempts at compliance and their usual maladaptive eating habits. Such generally unsuccessful efforts to regulate food intake characterize restrained eaters. Dietary restraint is a concept developed by Herman and Mack (1975) to describe an eating and attitudinal pattern involving high levels of vigilance and restriction concerning food intake which has

been observed in subjects who are seen as attempting to maintain a weight which is presumed to be below some biological setpoint. Diabetic patients of adult onset are typically asked to reduce their weight below their customary level, and consequently to develop this more restrained approach to eating. Patients who develop this pattern will not necessarily, however, be more successful in weight loss as the strain of restraint may make them more susceptible to counter-regulatory behaviour, i.e. binge eating. Conversely, their weight loss attempts may also have a desperate air - skipping meals, severe calorie restriction. Patients with high levels of restraint were therefore predicted to be less consistent across dietary demands and over time.

Relapse Episode Classification

In Study 1, adequacy of compliance was seen to vary across the demands of the regimen. Adequacy of compliance may also be related to situational factors. Marlatt and Gordon (1980),for example, found considerable similarity in the types of situation in which relapses occurred subsequent to abstinence-oriented treatment of a variety of substance abuse problems. They have developed a classification scheme for examining this phenomenon.

This scheme was developed from responses to interview questions concerning why relapses from abstinence had occurred when they did. One hundred thirty-seven subjects who had been involved in treatment programs for alcoholism, heroin addiction or smoking were asked to describe the circumstances under which their first relapse episode took place. These responses were then categorized into two major classes --

intrapersonal/environmental determinants and interpersonal determinants -- and eight subcategories. More than three-quarters of the relapse episodes were found to fall into only three of these categories: coping with negative emotional states, social pressure; and coping with interpersonal conflict. For the most part, the three types of subject (smokers, alchoholics and heroin addicts) were remarkably consistent in the frequencies with which relapses were assigned to each category.

Marlatt & Gordon (1980) predicted that a similar pattern would emerge in studies of other appetitive disorders and Rosenthal and Marx (1981) applied the model to university women who had recently completed a behavioural weight loss program. Interviewers questioned 71 subjects in two studies concerning the first time they had violated the rules they had been using for weight control. Using a smaller number of categories than Marlatt and Gordon (1980), they found a not dissimilar pattern in the categorization of relapse episodes. The 'negative emotional states when alone' category was the most frequently used, and 'positive emotional states with other people present'category was used next most frequently.

Kirkley (1982) adapted this procedure for use with Type I and Type II diabetic patients. She found that the categories used previously were insufficient to account for all of the first relapse episodes reported in her interviews with 84 subjects. An additional category,'busy/no choice', was used to classify 27% of the episodes and was the most frequently used category . Situations where the person was tempted were the next most common (21.3%), then social pressure (16.9%),

negative emotions (13.5%), positive emotions (12.4%). This represented a substantial deviation from the pattern results obtained by Rosenthal and Marx (1981) and by Marlatt and Gordon (1980). Table 17 summarizes these findings.

Kirkley suggested that these differences might be accounted for by a greater willingness of diabetic patients to accept personal responsibility for their relapses. The willingness was viewed as the consequence of a greater acceptance of an occasional deviation in the context of the requirement that they follow a diet for the rest of their lives.

The concept of a 'first relapse episode' does not have the same meaning for diabetic patients following a diet on an ongoing basis as it does for patients in an abstinence oriented or short-term treatment program. From the data concerning diabetic patients' weight control, it appears likely that they 'relapse' on a regular basis. The degree to which these relapses consistently occur in the same types of situation was of particular interest in the current study.

Models of Compliance

The study of the causes of compliance and noncompliance has been hampered in the past by some erroneous conceptions of the nature of the problem. It has tended to be viewed either as an exclusively medical problem, or as a psychological problem originating in some personality defect of the patient. In both instances, patients' compliance was considered to be consistent over all demands of the regimen. The results of

Table 17

Relapse Episode Classification

	Marlatt & Gordon(1980)	Rosenthal & Marx(1981)	Kirkley (1982)
Negative Emotional States			
Intrapersonal	58%	45%	14%
Interpersonal	15%	4%	7%
Positive Emotional States			
Intrapersonal	6%	6%	12%
Interpersonal	3%	26%	
Social Pressure	24%	14%	17%
Negative Physiological State	4%	5%	2%
Testing Personal Control	4%	-	21%
Urges and Temptations	7%	-	
Busy/No choice/Inconvenience	-	-	27%

Note. Dashes indicate category not used.

Study 1 have challenged the last assumption, and new approaches derived from the general psychological literature are increasingly and successfully being used to examine a variety of health behaviours (Surwit, Feinglos & Scovern 1983).

The problem of noncompliance has strong parallels outside the medical context. In order to follow a prescribed treatment regimen, patients must usually modify or eliminate many old patterns of behaviour and acquire various new ones. Not infrequently, the very behaviours which must be changed are ones, like weight control in diabetic patients, which have received considerable attention in psychological research. It would appear likely that the models which account for these behaviours and habit change in general in the non-medical context would also be applicable when patients are facing a more immediate health threat.

Many of the behaviours required by treatment regimens do not, in fact, have immediate health effects, but are prescribed in order to forestall long-term negative consequences. This is particularly true of many of the requirements of the diabetic treatment regimen. How people bridge the gap between current behaviour and future outcomes is the province of various psychological theories of self-regulation. Indeed, Leventhal et al(1980) have pointed out the appropriateness and need for exploration of these models in the compliance context.

The results of Study 1 have also provided insight into the nature of compliance and, by extension, into the types of models which will best account for it. The intraindividual

and interindividual variability in levels of compliance suggests that models which allow each person's unique interpretation of a situation or demand to influence his or her behaviour may prove especially enlightening in explaining this behaviour.

Ideally, a model of diabetic patient compliance would have both self-regulatory and habit change components, and would be able to explain any inconsistencies in patients' behaviour. In addition, it would be desirable if the models had already been used successfully in a compliance or analogous context.

No single model was available which met all of these requirements. It was,however, possible to find two models which between them fulfilled all of the criteria. In addition, the models were highly complementary with one another, thus providing a basis for a possible later integration. Nevertheless, they each also made a unique contribution whose relative merits in explaining compliance might be compared. A full examination of the concepts and predictions of each model was also viewed as likely to assist in comprehending several other issues raised by Study 1, such as the situational context and consistency of behaviour.

The Health Belief Model

The Health Belief Model (HBM) is the most frequently cited model of patient compliance, yet it has been infrequently tested in adult populations. Its apparent prevalence is not in itself sufficient justification for testing it in the current context, particularly in light of the equivocal nature of the findings in previous studies. The

HBM is, however, rooted in a well-established approach to motivation, generically termed expectancy-value models.

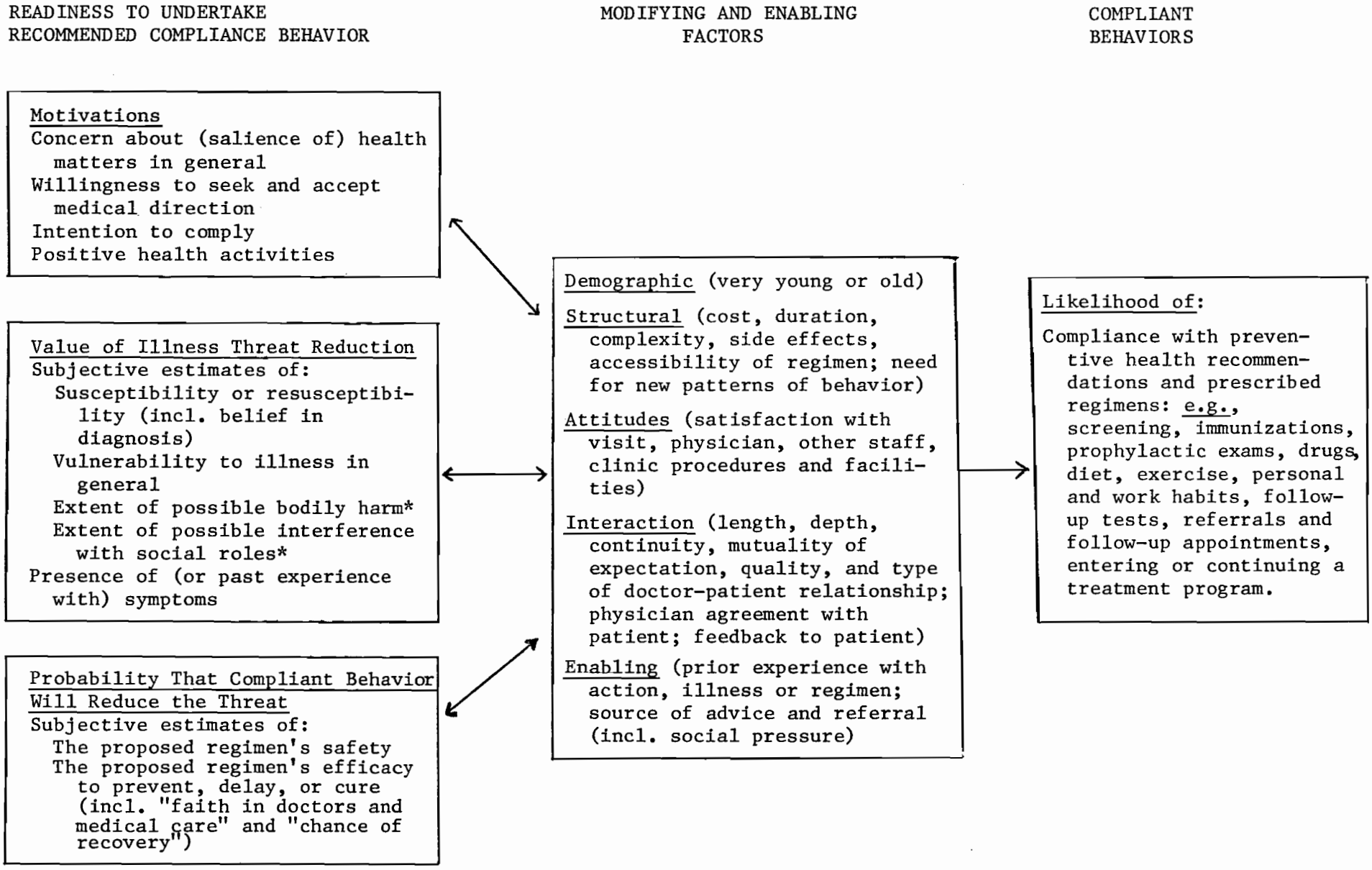
These formulations meet some of the criteria for the selection of a model to explain to diabetic patients' compliance. Such models have cognitions as their central component. They postulate that behaviour is determined by what people thing about their situation and, more particularly, by their subjective perceptions of the likelihood and value of the consequences attached to their actions. Different people may perceive the same situation differently, or may perceive apparently related situations as quite distinct. These differences in perceptions may then be manifested in differences in behavioural responses.

In the HBM these concepts have been elaborated and other factors added (Figure 1). Nevertheless, its basic components are still expectancy-value judgments. As such, it is capable of explaining inconsistencies of compliance behaviours. For example, if patients are less compliant with diet than with medications, it might be hypothesized that the health consequences of dietary noncompliance are perceived as less severe than those of medication noncompliance. Implicitly, the HBM is also a model of habit change. It predicts that if the appropriate cognitions are present, patients will bring their behaviour into conformity with their regimens' demands. As the HBM has been tested in a number of studies, it also fulfills the final requirement for selection of a model of diabetic patient compliance.

Table 18 summarizes this research. Only one study has attempted to assess the predictive efficacy of the Health

FIGURE I

The Health Belief Model



* At motivating, but not inhibiting, levels.

(After Becker and Maiman, 1977)

Table 18

Relationship of Health Beliefs to Compliance

Authors	Characteristics	Health Beliefs Assessed	Target Behaviours	Findings
Kirscht & Rosenstock (1977)	132 Hypertension patients	1. Belief in diagnosis 2. Perceived vulnerability 3. Perceived severity 4. Perceived treatment efficacy 5. Perceived benefits exceed perceived costs 6. Perceived difficulty in adhering	1. Self-reported medication taking 2. Self-reported dietary compliance 3. Refill prescription records	Medication-taking significantly associated with higher vulnerability, higher perceived benefits and higher perceived difficulty in adhering. Dietary compliance significantly associate with higher perceived difficulty in adhering. Prescription records unrelated to health beliefs
Taylor et al. (1978)	Study 1			
	144 Steelworkers prior to and after diagnosis of hypertension	1. General health motivation 2. Perceived severity 3. Perceived vulnerability 4. Perceived costs of the disease	Medication-taking	Pre-diagnosis belief in cost of disease significantly associated with compliance at 6 and 12 months. 6-month post-diagnosis belief in severity and costs of disease significantly associated with compliance at 12 months
	Study 2			
	136 Hypertension patients	Composite scale including: 1. Perceived severity 2. Perceived health benefits 3. Perceived treatment efficacy	1. Self-reported medication-taking 2. Pill counts	Scale score significantly associated with both compliance measures 6 months later

Continued...

Table 18- Relationship of Health Beliefs to Compliance (Continued)

Authors	Characteristics	Health Beliefs Assessed	Target Behaviours	Findings
Nelson et al. (1978)	142 Hypertension patients	1. General health motivation 2. Perceived vulnerability 3. Perceived severity 4. Perceived treatment efficacy 5. Barriers and benefits 6. Cues to action	1. Blood pressure control 2. Self-reported medication-taking 3. Appointment-keeping	Blood pressure control was significantly associated with perceived efficacy, perceived barriers and cues to action. Medication-taking was significantly associated with perceived severity and cues to action. Appointment-keeping was unrelated to health beliefs.
Nelson et al. (1980)	Hypertension patients	1. General health motivation 2. Perceived severity 3. Perceived vulnerability 4. Perceived treatment efficacy 5. Perceived barriers	1. Remaining in treatment 2. Medication-taking	Only perceived barriers made a significant independent contribution.
Hersey et al. (1980)	132 Hypertension patients	1. General health motivation 2. Perceived severity 3. Perceived vulnerability 4. Perceived benefits 5. Perceived control over illness	Self-reported medication-taking	Of health beliefs only perceived control and barriers were related to compliance
Derkoney & Hart (1980)	30 Insulin-treated diabetic patients	Standardized compliance questionnaire used to assess: 1. Perceived severity 2. Perceived susceptibility 3. Perceived benefits 4. Perceived barriers 5. Cues to action	Scale composed of self-reported and observed: 1. Insulin-taking 2. Treatment of hypoglycemia 3. Foot care 4. Diet 5. Urine testing	Total compliance score significantly associated with total health belief score. Insulin compliance related to total health beliefs and to cues. Hypoglycemia care related to perceived susceptibility Foot care related to perceived severity. Diet and urine testing unrelated to health beliefs.

Table 18 - Relationship of Health Beliefs to Compliance (Continued)

Authors	Characteristics	Health Beliefs Assessed	Target Behaviours	Findings
Alogna (1980)	50 Obese non-insulin dependent diabetics	1. Perceived control over illness 2. Perceived severity (from Stnadardized Compliance Questionnaire[a])	Classification based on: 1. Weight loss 2. Blood glucose levels.	Compliant patients perceived disease as more severe.
Bollin & Hart (1982)	30 Hemodialysis patients	Standardized Compliance Questionnaire[a] was used to assess: 1. General health motivation 2. Perceived severity 3. Perceived susceptibility 4. Perceived treatment efficacy	Compliance composite scale concerning: 1. Fluid intake 2. Potassium levels 3. Knowledge of own diet	Composite compliance scores unrelated to health beliefs. Fluid intake associated with cues to action. Potassium levels significantly associated with perceived severity. Dietary knowledge associated with health motivation, treatment efficacy, severity, and total health belief score.

[a]No longer recommended for use by its author (D.L. Sackett, personal communication, June 21, 1981).

Belief Model in the compliance context. Taylor, Sackett, Haynes, Johnson, Gibson & Roberts (1978) conducted a prospective study of health beliefs with two samples. In the first, the health beliefs of 144 steelworkers were assessed prior to diagnosis of hypertension and again six and twelve months later. Health beliefs related to general health motivation, perceived severity and perceived vulnerability at entry were unrelated to later medication-taking, with the exception of one of the perceived 'costs' of treatment - dependency on others. Compliance at 12 months was significantly related to three variables assessed at 6 months - perceived severity, negative attitudes towards drug taking, and a belief that illness leads to dependency. In the second sample a composite health belief measure including perceived severity, perceived benefits and perceived treatment efficacy was constructed. In 136 hypertension patients, changes in this scale over a 6 month period correlated with changes in compliance as measured by both pill count and self-report. In neither sample, however, did these correlations exceed .35.

Two studies have examined health beliefs and compliance in diabetic populations. Their results are consistent with the results found in other samples: relationships between some health beliefs and some behaviours do appear.

Cerkoney and Hart (1980) assessed the health beliefs and compliance of thirty insulin-treated diabetic patients six to twelve months after an education program. To assess five of the Health Belief components they used the Standardized Compliance Questionnaire, a scale no longer recommended for use by its author (D.L. Sackett, personal communication, June

21, 1981). They nevertheless found the measure to have good test- retest reliability. Compliance was measured by self-report and direct observation: the direct observation score was doubled to compensate for the presumed bias in the self-report. Items related to patient knowledge of correct procedure as well as to level of performance were included. The total compliance score was significantly correlated with the total health belief score and with scores on the perceived severity and cues subscales. Insulin compliance scores were also related to total health belief score and to cues. Compliance on the hypoglycemia and insulin reaction items was related to perceived susceptibility and scores on the foot care items were associated with perceived severity. Perceived benefits and barriers were unrelated to compliance with any of the regimen demands and no health beliefs were related to compliance with diet or urine testing. The small sample size and the way in which both compliance and health beliefs were measured limit confidence in these findings.

In a study of 50 obese, non-insulin dependent diabetic patients attending an outpatient clinic, Alogna (1980) assessed health locus of control, according to the HLC scale, and perceived severity of disease, according to the previously mentioned standardized compliance questionnaire. Subjects were classified as compliant or noncompliant on the basis of weight loss and plasma glucose levels. She found that compliant patients were significantly older and had higher perceived severity of disease scores. She also reported a trend for internals to be more compliant than externals. Forty-six of Alogna's 50 subjects were black and 40 were

female. As this is not representative of the diabetic population as a whole and as the measures used are of uncertain validity, these results must be treated with caution.

The inconsistency of the results observed in these studies and in the ones summarized in Table 18 may reflect differences in the samples, the operational definitions, the methods of measurement and the data analytic strategies used by the different researchers. Most studies have merely examined the simple relationship between each health belief and some measure of compliance whose validity has not been established. The few studies employing multivariate approaches have yielded the weakest results. Further, virtually every study has developed its own measure to assess compliance, again typically without any attempt at validation.

Several recent studies, however, have attempted to assess the validity of the hypothesized health belief constructs, their dimensionality, and the reliability of measures of the model. Maiman, Becker, Kirscht, Haefner & Drachman (1977) examined mothers' health beliefs in relation to the prescribed weight loss of their children. Analysis of the twelve scales constructed to measure the health beliefs revealed three relatively independent belief dimensions: threat, benefits and barriers; and one general health concern factor. In general, the items correlated significantly with weight loss and the items comprising each belief index showed acceptable levels of internal consistency (alpha=.80)

Cummings, Jette & Rosenstock (1978) used multitrait-multimethod analysis to assess the construct

validity of the Health Belief Model. Interest in health matters, health locus of control, perceived susceptibility, perceived severity, perceived benefits and perceived barriers were each measured using items with Likert scales for responses, multiple choice questions and vignettes in a sample of 85 graduate students. Interpretation of the multitrait-multimethod matrix in terms of the Campbell and Fiske criteria showed acceptable convergence for five of the six health beliefs; their independence,however,was less clearly established. The matrix was also examined using structural equation analysis and similar conclusions were reached.

Jette, Cummings, Brock, Phelps & Naessens (1981) have also attempted to elucidate the underlying structure and reliability of health beliefs. A 31-item questionnaire was administered by telephone interviews with 589 subjects in two community samples. Factor analysis yielded 8 interpretable factors accounting for 37% of the variance, with a general health threat factor relating to both severity and susceptibility accounting for the largest part of the variance. Measures relating to general health were distinct from condition-specific measures. The intercorrelations among items ranged from .39 to .77, higher reliabilities being associated with condition-specific measures. The results varied between samples, suggesting at best moderate reliability of the health belief measures.

Recently, (subsequent to the commencement of the current investigation) an explicit attempt to develop a psychometrically sound health belief measure for an adult

clinical population has been reported. Given, Given, Gallin & Condon (1983) have developed a measure of six diabetic patient health belief factors. After considerable pilot work, the resulting scale show good internal consistency and acceptable levels of independence among the factors.

The results of these studies suggest that the components of the Health Belief Model are at least capable of being reliably measured. The relationships among the health beliefs, the extent of their independence and their stability over time are not yet clearly defined.

The utility of the HBM as a framework for studying compliance is as yet unclear. Its status may be clarified through a methodologically sound investigation which draws on its potential as an expectancy-value model.

Within such an investigation, it is also possible to test one of the HBM's implicit assumptions: that health consequences -- or at least perceived health consequences-- are the primary motivator of health behaviours. The assumption of the superiority of health over other consequences has never been tested (DiMatteo and DiNicola, 1982) and the model itself through its juxtaposition of health consequences and other factors contains the means to do so.

Bandura's Social Learning Model

Bandura (1977a, 1977b) has presented a model of behaviour whose attributes are highly consonant with the criteria for a successful model established by Study 1. It places its emphasis on the processes underlying change in human behaviour, it concerns itself with the mechanisms of self-regulation, it promotes a microanalytic approach to deal

with the issue of behavioural specificity, and it has been used to examine the modification of habits such as smoking, which are in many ways similar to the problem of noncompliance. Like the Health Belief Model, it gives particular credence to the role of cognitions in explaining behaviour.

Bandura postulates that people's attempts to change their behaviour in accordance with some internal or external demand depend upon how people perceive the situation and themselves within the situation. Two types of cognition play a role. People are predicted to initiate and persist in a behaviour change attempt to the extent that they view the outcome of that behaviour as likely and as valuable (outcome expectancy) and to the extent that they perceive themselves as able to successfully perform the behaviour necessary to achieve that outcome (self-efficacy expectancy). These expectancies develop from various sources of information, primarily past experience, direct or indirect, of similar circumstances. A continuous reciprocal interaction of these components is hypothesized: behaviour modifies experience which modifies cognitions which modify subsequent behaviour. These processes are not only ongoing, but also highly specific. Bandura has proposed a microanalytic research strategy in order to assess them. Such an approach examines specific cognitions about a task or behaviour immediately prior, and immediately subsequent to its performance. Bandura's formulations concerning self-efficacy are largely derived from such an approach. In a number of studies of snake phobics (Bandura 1977, 1978) patients' perceived ability to perform a

hierarchically arranged series of approach tasks was highly correlated with their actual performance and performing the task had a marked effect on subjects' perceived ability to perform the next task. Bandura believes that it is this change in self-efficacy which in fact underlies all successful behaviour change, and research in a variety of areas has provided some support for this claim (Bandura 1982).

Of particular interest in the dietary compliance context are studies pertaining to habit change. Subjects' likelihood of success in changing habits would be considered a function of their perceived capacity to change that behaviour (the self-efficacy expectancy) and of the probability that some desired outcome would result from such behaviour change (the outcome expectancy).

The greatest amount of interest has been evinced concerning the relationship of self-efficacy expectancies to smoking reduction and cessation. Higher self-efficacy appeared to be related to reduction in number of cigarettes smoked in a week (Chambliss & Murray, 1979), whether or not subjects relapsed (Prochaska, Crimi, Lapsanki, Martel & Reed, 1982) and how long they maintained nonsmoking status (McIntyre, Lichtenstein & Mermelstein, 1983). Condiotte and Lichtenstein (1981) also found an association between the situation in which the relapse occurred and self-efficacy for abstinence in that type of situation.

One study has applied self-efficacy concepts to degree of success in weight loss attempts (Chambliss & Murray, 1979b). They found that, among 68 subjects in a weight loss program whose locus of control was internal, a manipulation designed

to increase self-efficacy resulted in a greater weight loss than for either internal subjects who did not receive the manipulation or for external subjects who did receive it.

The results of the Condiotte and Lichtenstein study (1981) in particular suggest that a highly situational appreach to self-efficacy in the dietary context might be useful. Self-efficacy concerning dietary relapse in high-risk situations such as those defined by the Marlatt and Gordon (1980) classification scheme is likely to prove an excellent predictor of whether or not relapse actually occurs in those situations.

Most of the investigations of Bandura's model have dealt exclusively with this self-efficacy component. Bandura's hypotheses concerning self-regulation, however, have most often been discussed in relation to the outcome expectancy component of his model. He has postulated that when the direct consequences of a behaviour are absent or are far removed in time, the required behaviour may be maintained by cognitions concerning future outcomes, by social reinforcement,and by self-reinforcement. These formulations do not appear to have been explicitly tested within an adult population.

The outcome expectancy is virtually indistinguishable from other forms of expectancy-value approach, including that of the Health Belief Model. The crucial factor distinguishing the two approaches relates to the relative importance they assign to direct and indirect consequences of behaviours. The Health Belief Model considers health behaviours to be primarily a function of direct health consequences, whereas in

Bandura's social learning model, health behaviours might result from the perception of a diverse array of perceived outcomes which might or might not relate to health.

The two models would in fact appear highly complementary. While there is considerable conceptual overlap, the Health Belief Model has been refined to suit the context of health behaviours. In the self-efficacy expectancy, Bandura's model contributes a new and apparently powerful construct relating to patients' perceptions of their own abilities to comply. Together these models may be capable of explaining and predicting considerably more of the variance in dietary compliance than either model alone.

Other Determinants and Influences

Health Consequences and Compliance

In Study 1, all the behaviours were rated by experts as being comparable in importance for patients' health. The high intraindividual variability observed in levels of performance of these behaviours suggested that equivalent health consequences may not necessarily result in equivalent levels of compliance. Previous research (not involving diabetic patients) has failed to establish a relationship between disease severity or the presence of symptoms and compliance (Haynes 1979). These results suggest, again indirectly, that actual health consequences do not strongly influence compliance. It remains possible, however, that consequences which are not only more severe but also more immediate and whose potential occurrence is cued more frequently will indeed

affect performance of required behaviours.

The nature of diabetes and its treatment permitted a quasi-experimental investigation of the importance of health consequences in determining behaviour. Depending on the patients' regimen the health consequences of not following the prescribed diet may be more serious, more immediate and more salient. Patients on insulin regimens may experience hypoglycemia if they do not eat the foods prescribed and at the scheduled times. As blood and/or urine testing is performed more frequently, they are also likely to receive more frequent feedback about their dietary inadequacies. Finally, the very process of following an insulin regimen regularly cues patients that they have a disease, and a disease with both short- and long-term consequences. Patients whose diabetes is being managed by diet alone are unlikely to experience any immediate effects of noncompliance and are likely to be receiving less evidence of the health impact of their dietary deviations because they are testing their urine or blood at much less frequent intervals. The consequences are well removed in time from the action and the non-dietary demands of the regimen are less intrusive, thus rendering the fact of the illness and its consequences far less salient than for the insulin group. For patients on an oral agent regimen, the salience, immediacy and seriousness of the health consequences are intermediate between those of the insulin and diet alone regimens. There is some risk of hypoglycemia, more frequent feedback concerning levels of control, and the regimen's intrusiveness is such as to present regular reminders of health status.

These three levels of 'regimen seriousness' should, if health consequences are a critical motivator, be associated with different levels of compliance. Diabetic patients should also be better at following their diets than a non-diabetic group would be in adhering to a healthy diet, as the non-diabetics are not susceptible to any immediate,salient or serious health risk as a function of their noncompliance.

Background Factors

A number of other factors were also perceived as making potentially important contributions to understanding compliance, As a group these variables were labelled 'background factors'. They were selected primarily on the basis of previously demonstrated relationships with compliance or weight control.

Weight control has frequently been found to be associated with age, sex, and socioeconomic status, and an association has been demonstrated with a measure of Weight Locus of Control (Saltzer, 1978) and of dietary restraint (Herman and Polivy 1980). It was predicted that a measure of patients' tendency to self-reinforce would also show such a relationship

Other factors have been found to be associated with compliance with regimen demands and were thought likely to demonstrate the same relationship to dietary compliance. Social isolation, duration of treatment and Health Locus of Control were predicted to show negative correlations with compliance. The evidence concerning the relationship of compliance to a variety of other disease and treatment factors, including knowledge, was seen as less clear and requiring further investigation.

Objectives and Hypotheses

Two objectives were pursued in Study 2. The first related to improving our understanding of the nature of compliance through detailed descriptions of the situations in which dietary noncompliance occurred, and to attempt to identify any patterns or consistencies in diabetic patients' dietary behaviours.

The second goal was to test a series of hypotheses concerning the determinants of compliance in a prospective design. The major hypotheses tested were as follows:

1. Patients with stronger health beliefs would have higher current levels of compliance and would become more compliant in the future.
2. Patients with stronger self-efficacy and outcome expectancies would have higher current levels of compliance and would become more compliant in the future.
3. Patients with both stronger health beliefs and stronger self-efficacy would have higher current levels of compliance and would become more compliant in the future.
4. Patients for whom health consequences are more immediate severe and salient would have higher current levels of compliance and would become more compliant in the future.

Methods

Subjects

Diabetic Patients

All diabetic subjects were recruited from the Metabolic Day Centre at the Royal Victoria Hospital. The basic criteria for participation were identical to those in Study One. In addition, however, the study's design required equal numbers of patients who were more than 10% over their ideal body weight and within 10% of their ideal weight and who were following each of the three types of treatment regimens. Fifteen subjects (approximately evenly divided between males and females) were needed for each cell. All patients meeting the criteria were approached until the quota for each cell was filled. Since, after four months of daily patient solicitation, there were only 14 subjects in the 'normal weight-diet alone' cell, this cell was never filled. This difficulty reflects the fact that Type II diabetic patients who achieve normal weight also often achieve normoglycemia, require much less medical attention, and therefore are seen infrequently at the MDC. One additional subject was included in the 'normal weight-insulin regimen' cell due to an error in calculating weight status. The total sample size was therefore 90. The characteristics of the sample are presented in Tables 19 and 20.

Non-diabetic subjects

The non-diabetic spouses of diabetic subjects constituted

Table 19

Demographic Characteristics of the Diabetic Subjects

	Mean	Standard Deviation	Range
Age	53.0	14.9	21 to 79
Years of education	12.0	3.9	4 to 24
Income	20-25K	15K	<5K to 50K+
Occupational status(a)	52.3	20.0	21.9 to 74.2

	Number	Percentage
Sex		
Males	42	47
Females	48	53
Marital Status		
Married	58	64
Not married	32	36
Living arrangements		
With others	75	83
Alone	15	17
First language		
English	53	59
French	24	27
Other	13	14
Country of origin		
Canada	61	68
Other	29	32

(a) Blishen and McRoberts(1976)

Table 20

Health Characteristics of the Sample

	Mean	Standard Deviation	Range
Years since diagnosis	9.4	8.4	<1 to 33
Rated Health (a)			
Diabetic Control	4.2	1.5	0 to 6
General Health	4.6	1.0	2 to 6
Kidneys	5.4	.8	3 to 6
Retinae	5.4	.9	1 to 6
Neuropathies (b)	5.3	1.1	0 to 6
Blood Glucose Measures			
Fasting (c)			
Day of interview	164.8	64.0	63 to 362
Annual mean	162.9	55.9	85 to 358
Glycosolated Hemoglobin(d)			
Day of interview	9.8	2.7	4.8 to 15.9
Annual mean	9.6	2.4	4.6 to 15.0

	Number	Percentage
Type of Diabetes		
Type I	11	12
Type II	67	74
Unclassified	12	13

(a) 0=very poor;6=very good. (b) 0=extremely extensive; 6=completely absent. (c) normal range=80 to 120. (d) normal range=3.5 to 5.9

the non-diabetic control group. All spouses were eligible for inclusion if their diabetic spouses confirmed that they were in good health and were not following a special diet for medical reasons. All married diabetic subjects (57) were asked if they would permit the investigator to contact their spouses concerning participation in an interview identical to the one they had experienced. Nineteen diabetic patients asserted that their spouses met the criteria and volunteered their spouses' names; eighteen spouses agreed to participate. Table 21 presents the background characteristics of these nondiabetic volunteers.

Measurement of Dependent Variables

Dietary Compliance-Diabetic Patients

The Rand Compliance Questionnaire contained two subscales relating to diet. The first subscale 'eats prescribed meals', questioned patients concerning their adherence to restrictions on food type and quantity and the second, 'eats at prescribed times', examined the adherence to prescribed timing of meals and snacks. The authors found that although both subscales had adequate alpha levels and stability, both also contained moderate amounts of compliance reporting bias and required further development.

One immediately apparent problem with items in the 'eats prescribed meals' subscale was the absence of specificity of the response options. Subjects were not asked to recall discrete episodes or situations but rather to make general assessments of their week's intake. The same response option

Table 21

Demographic Characteristics of the Nondiabetic Subjects

	Mean	Standard Deviation	Range
Age	48.5	14.0	21 to 74
Years of education	12.6	4.3	5 to 22
Income	20-25K	10K	<5K to >50K
Occupational status(a)	51.1	10.3	23.2 to 68.7

	Number	Percentage
Sex		
Males	7	39
Females	11	61
First language		
English	10	56
French	6	33
Other	2	11
Country of origin		
Canada	14	78
Other	4	22

(a) Blishen and McRoberts(1976)

format was used for the items concerning meal timing in the past week.

The items were therefore redesigned for this study to require the patients to recall the exact frequency of occurence of each of these events in the past week,if necessary using a day-by-day recall, starting with the day before the clinic visit.

Circulation of the revised items to clinic staff resulted in the suggestion of an additional item concerning meal balancing. Patients were asked how often in the past week they had eaten a meal which was not properly balanced, and the item added to the 'eats prescribed meals' subscale. As this title appeared only to describe food intake at meals, the measure was renamed 'eating prescribed diet' and failures to comply were termed 'dietary deviations'. Scores greater than 0 on 'eats at prescribed times' subscales were considered 'scheduling deviations'.

Scores were not normally distributed on either subscale. The distribution of scores on the 'eats prescribed diet' subscale was leptokurtic and somewhat positively skewed as a function of the absence of dietary deviations reported by fifteen subjects. The Kolmogorov-Smirnov one-sample test of the goodness of fit to the normal distribution revealed a significant depature from normality (K-S $z(90)=1.74$, $p<.01$). The degree and type of deviation were less extreme than for the variables in Study One and did not appear to require abandonment of parametric analyses. Instead, a more conservative alpha level was selected for further analysis.

The distribution of scores on the 'eats at prescribed

times' subscale indicated that 51% of the respondents reported perfect compliance. This absence of variance precluded further consideration of the measure and prevented its use in validating the eating prescribed foods measure via mltuitrait multimethod analysis.

Other evidence for the validity of self-reported dietary compliance was weak. Correlations with dietitians' and physicians' ratings were in the correct direction but did not achieve significance. Likewise, no significant relationships were found with the health measures. The scores, however, were also unrelated to the two measures of response bias- the K Scale and the CRBS.

Dietary Compliance-Spouses

Dietary compliance for non-diabetics was defined as 'following an ideal diet' and 'eating regular meals'. To parallel the Rand subscale items, following an ideal diet was further defined as avoiding unhealthy or non-nutritious foods and beverages, eating only the quantities needed to attain and maintain ideal weight and eating well-balanced meals. Positive responses to these items represented 'dietary deviations' and the total frequency across the three items constituted the dietary deviation score.

Dietary Deviation Espisode Assessment-Diabetics and Spouses

The situations in which the three most recent dietary deviations occurred were assessed by interview. Patients were asked to describe the nature of the deviation, when and where it occurred, and who was present. They were also asked about the psychological context of the episode: whether or not their stress levels and mood were different from usual, and whether or not they experienced guilt subsequently. These questions were adapted from the dietary deviation interviews conducted by Kirkley (1982), the abstinence violation interviews reported by Marlatt and Gordon (1980) and the smoking relapse interviews used by Shiffman (1982).

The most important reason for the relapse was assessed by asking patients to select from a list of seventeen alternatives, rather than by interview as done in previous studies. It was hypothesized that patients would make fewer 'psychological' attributions for their deviations because they had not undergone a psychological treatment program, but that if such psychological alternatives were available, they would endorse such reasons as often as the non-medical, psychologically treated populations in previous studies. Fourteen of the choices were direct adaptations of Marlatt and Gordon's proposed relapse categories and one derived from Kirkley's finding of a high frequency of classification of episodes as 'busy/no choice'. These items were initially pretested in a sample of twenty diabetic patients. They were asked to comment upon the utility and understandability of each alternative and to suggest any factors they felt were not covered. This lead to the addition of two new choices: going

off the diet when they wanted to reward themselves for something, and when they found the prescribed foods unappetizing. Four items relating to different types of negative emotions and two to positive emotions in both the interpersonal and intrapersonal context were seen as highly redundant. These comments suggested a need to modify slightly the relapse categories presented by Marlatt and Gordon (Table 17). Although the items pertaining to these categories were retained, the intrapersonal versus interpersonal origins of positive and negative emotional states were not distinguished by this patient sample. Kirkley (1982) reports a similar finding in her sample. Thus six relapse categories were examined: negative emotions, positive emotions, social influence, negative physiological states, temptations, and inconvenience.

A further pretest of the seventeen items with 19 patients revealed no additional difficulties in comprehensibility.

Measurement of Independent Variables

Health Belief Measurement

No standardized measure of health beliefs for use in all compliance situations is currently available. Previous studies concerning health beliefs have developed their own measures, generally without reference to any psychometric standards and often apparently lacking in even face validity.

It was therefore decided to develop a new scale for this study based on the expectancy-value approach from which the Health Belief Model derived. Thus each component of the

Health Belief Model to be examined was operationally defined in expectancy-value terms:

1. Perceived severity of the health threat:
   the subjective value attached to current and future health and avoidance of the potential consequences of the illness.
2. Perceived vulnerability to the health threat:
   the subjective probablility that the patient will suffer these consequences.
3. Perceived treatment efficacy:
   the subjective probability that the negative health consequences could be avoided by following the prescribed regimen.
4. Perceived benefits
   the subjective value attached to potential non-health benefits of the treatment multiplied by the subjective probability that compliance will lead to those benefits.
5. Perceived costs
   the subjective value attached to potential costs of the treatment multiplied by the subjective probability that compliance will lead to these costs.

(Appendix J)

Since the essence of the Health Belief Model is that patients' perceptions, rather than objective reality, motivate behaviour, it was decided to solicit health beliefs concerning health outcomes, costs and benefits through interviews with diabetic patients. Sixty patients volunteered to participate; twenty dieting and non-dieting nondiabetic subjects were

solicited to ensure adequate coverage of weight concerns unrelated to health. In a semi-structured interview, subjects were asked to report all of the potential advantages and disadvantages of following a prescribed diet, and the advantages and disadvantages of different weight levels--current weight, ideal weight, ten percent over ideal weight, and more than 10% above their ideal weight.

From these responses, one hundred five relatively unique outcomes of dieting and weight loss were recorded. Each response was then assessed with respect to frequency of endorsement and its order of mention during the interview. The forty-two conceptually distinct responses endorsed by all diabetics and endorsed most often and earliest in the interview formed the basis for item construction. Three health items specific to insulin regimens and 2 each for the oral agent and diet alone regimens were also included.

Following the format used by Mausner and Platt (1971) in a study of smoking cessation, two questions were asked about each item, one referring to its strength and valence, the other to its probability of occurring if the patient was compliant.

The items were initially tested with a group of twenty diabetic volunteers. They were asked to comment on each item and explain why they answered as they did to ensure that the questions were being properly understood and were tapping the desired dimensions. As a result, revisions were made in the wording of some items and in the response format.

A new sample of diabetic patients was solicited and this revised expectacy-value questionnaire administered along with

other measures. Analyses conducted after twenty subjects revealed an absence of variance in the responses to a number of items. Patients tended to make extreme responses. They also complained of the length of the battery and what they perceived as item redundancy. The number of items was therefore reduced to 25, retaining all items which were considered important and conceptually unique, and the regimen-specific items. The response format was again modified and the instructions changed to emphasize the importance of gradations of response and to include an example of how this might be done.

Analysis of data obtained from nineteen additional diabetic subjects indicated that patients were no longer treating the questions as dichotomous and were using all of the response line, not merely the poles. Individual differences in response were also apparent. Appendix H presents the final questionnaires.

The identical items were used to assess spouses' perceived severity, vulnerability, costs and benefits. The wording of the treatment efficacy items was changed from 'follow your diet' to 'follow an ideal diet'. This modified questionnaire is presented in Appendix I.

Self-Efficacy and Outcome Expectancies

Self-efficacy was assessed with respect to several behaviours. Patients' perceived ability to follow their diet and to follow the meal schedule constituted the primary dietary self- efficacy measures. Self-efficacy with respect to more specific behaviours (e.g. ability to avoid proscribed foods) and more general behaviours (e.g. ability to maintain

an ideal weight) was also assessed. Situational self-efficacy was explored through questioning patients about the likelihood that they would be able to follow their diet under certain high risk circumstances. These corresponded to the relapse categories previously defined. Six situational self-efficacy subscales were therefore created. Levels of self-efficacy were assessed for negative emotional situations, positive emotional situations, social influence situations, temptation and urge situations, negative physiological states and inconvenient situations. The composition of each of these categories is presented in Appendix J.

Outcome expectancy was operationally defined as the sum of the expected consequences, positive and negative, health and non-health, of following the prescribed diet. The perceived value and probability of each possible outcome of compliance was combined multiplicatively, then an additive total for all possible outcomes computed. This involved rescoring the expectancy-value questionnaire by ignoring the health belief subscales and computing a global score for the entire measure.

To assess the self-efficacy of the nondiabetic subjects, wherever the diabetic questionnaire referred to 'following your diet' or 'following your prescribed diet', the spouse version referred to 'following an ideal diet'. No other changes were made.

Measurement of Background Factors

Sociodemographic variables.

Data concerning subjects' age, sex, marital status, living arrangements,education,income and occupation were collected by the interviewer.

Stable intrapersonal characteristics.

Revised Restraint Scale (Herman and Polivy, 1980). This 10-item scale was developed to assess the extent to which respondents were restrained eaters. It has been successful in predicting counter-regulation (eating beyond acceptable limits) under a variety of conditions. Its psychometric properties are unknown--an earlier version showed good test-retest reliability over four weeks (.93) and a low correlation with the Edwards Social Desirability Scale (r=.11) (Kickham and Gayton, 1977).

Health Locus of Control Scale (Wallston, Wallston, Kaplan and Maides, 1976) This measure was developed to assess the extent to which people believed their health was determined by thir own behaviour (internal health locus of control) or by factors outside their own control (external locus of control). Initial research by the authors established that the scale had adequate reliability and validity (Wallston et al 1976).

Weight Locus of Control Scale (Saltzer 1978). This four item scale was designed to assess the extent to which people believe they have the power to control their own weight, rather than their weight being determined by external forces. The scale correlated significantly with the Internal-External Locus of Control Scale and with the Health Locus of Control Scale and has been shown to have the expected predictive validity with respect to weight loss intentions (Saltzer 1982).

Frequency of Self-Reinforcement Scale (Heiby 1983). This scale was recently designed to assess the tendency to adminster appropriate self-reward and to avoid excessive self-blame. Its predictive validity was assessed with respect to depression: depression is thought to be associated with low levels of self-reward (Heiby 1983).

K Scale of the MMPI. This scale, as described in Study 1, was designed and used to assess defensiveness.

Compliance Response Bias Scale. This scale was also used and described more fully in Study 1. Its purpose was to assess the tendency to give socially desirable or dishonest responses to questions about compliance.

Disease and Treatment Factors.

Regimen type. These data were obtained from hospital records and confirmed by questioning the patients.

Weight status. Patients' weight on the day of interview as recorded in the hospital records was compared with the ideal weight also recorded there. If patients' weight was ten per cent or more above ideal, they were classified as overweight. If they were less than 10% above ideal weight

they were classified as normal weight.

Diabetes Type. Patients' classification as Type I or Type II was ascertained from the medical records, or where necessary in consultation with the patient's physician.

Level of Diabetic Control on Day of Interview. Patients' fasting blood glucose as recorded in their charts for the day of the interview served as an index of current control.

Duration of treatment. Patients were asked to recall the date they began treatment.

Knowledge (Appendix H). Patients' knowledge about the diabetic diet was assessed by questionnaire and by demonstration. The questionnaire was specifically developed for the current study, as none of the available measures was totally suited to the Canadian context and their psychometric qualities were largely unknown. The initial step in composing the questionnaire was nonetheless to select suitable items from some previously published measures(Etzwiler, 1967; Simon and Stewart, 1976; Windsor et al., 1982). To these were added questions supplied by the clinic dietitians. This pool of items was then administered to ten diabetic patients identified by the dietitians as having good dietary knowledge, and to ten identified as having poor knowledge. Their responses were then used to eliminate items which all patients in both groups answered correctly or incorrectly and which they found difficult to understand. Items were retained on which the patients with good knowledge scored highly and the patients with poor knowledge failed.

A number of demonstration items were also prepared.

These covered three skills essential for adequate dietary adherence: understanding food labels; knowing the classifications of common foods according to the exchange system; and accurately visually estimating food quantities, since pretesting had revealed that nineteen of twenty patients no longer measured their quantities. Subjects were first presented with a label from a food product and asked to state which ingredient was present in the largest quantity and which ingredient in the smallest amount, according to the label. Responses indicated whether patients knew the rule governing the order in which ingredients are listed. They were then asked to identify three types of sugar (sugar,glucose,honey) present in the product. A list of fifteen common foods was then presented, and subjects requested to select two foods found on a meat exchange list,two found on a fruit exchange list, and two found on a bread exchange list. Subjects were also asked to examine three piles of peanuts of varying sizes (1/3 cup, 1/2 cup,2/3 cup) and to point to the pile containing one-half cup. Finally they were asked to fill a drinking glass with one half cup of water. Any amount between 3.5 and 4.5 ounces was treated as a correct response. Total possible score for all the demonstration items was twelve.

The revised eight item questionnaire and the demonstration items were administered to a randomly selected group of ten diabetic patients and to eleven members of the psychology department who had had no previous experience with diabetes. Scores on the combined

measure differed significantly and in the expected direction between the two groups ($t(19)= 3.97, p<.01$).

Procedure

Diabetic Patients

Patients who met the subject selection criteria were approached in the patient lounge and the general purposes of the study and the requirements of participation explained. If they agreed to participate they were given an information sheet/consent form to read and sign.

The interviews were conducted with each subject individually in a separate office within the Metabolic Day Centre. Initially questions were asked about background variables such as age and education. Then the interviewer reiterated statements from the information sheet concerning the pervasiveness of difficulty in complying and asked the patients to recall the situations in which they had problems following their diet in the past week. The items from the modified version of the Rand subscales 'eats prescribed diet' and 'eats at prescribed times' were then administered orally. Patients were asked to recall in more detail the three most recent dietary deviations and to answer the questions required for dietary deviation episode assessment. A brief weight history was then obtained and the dietary knowledge test administered. When this was complete patients were given a choice as to whether they wished to complete the remaining questionnaires on their own or with the interviewer. The subjects who selected the former option were given verbal

instructions concerning each questionnaire. They were then free to complete the packet when and where they chose in the MDC. When they finished, they were seen again by the interviewer to ensure that all items had been completed and any misunderstandings clarified.

Subjects who worked with the interviewer were given verbal instructions for each questionnaire. Where required by visual or English language deficits, the interviewer read the items aloud, although patients were always required to indicate their own responses. Certain medical terms repeatedly presented problems for bilingual Francophone subjects: standard translations were offered.

The nine questionnaires were arranged randomly within the packet--the two Locus of Control Scales were, however, administered as one questionnaire, as were the K Scale and the Compliance Response Bias Scale. The compliance questionnaire was routinely administered last.

When all questionnaires were complete, married subjects were asked if they thought their spouses would be willing to answer the same questions at a time and place of their convenience. They were also asked if they themselves would be willing to be re-interviewed at some indefinite time in the future.

An attempt was then made to re-interview all subjects at least two months and no more than six months after the initial interview. Patients who did not return to the MDC during this time period were contacted whenever possible, and asked to participate in the second interview at a time and place of their choosing.

Subjects were seen for the second time during scheduled MDC appointments or by special arrangement. The procedure followed was then identical to that at Time 1, except that some measures were not re-administered. The background and weight history data, the knowledge test, the WLC and HLC scales, the Revised Restraint Scale, the Frequency of Self-Reinforcement Scale, the K Scale, the CRBS and the compliance questionnaire were omitted at Time 2 as they were not essential to the hypotheses and this procedure reduced the time burden on the patients.

Spouses

Spouses whose names had been volunteered by the diabetic patients were contacted by telephone, the study explained and their participation requested. An appointment was fixed for a time and place suitable to the spouses. They were given an information sheet explaining the rationale for their inclusion in the study and asked to sign a consent. The procedure followed was then identical to that employed with the diabetic patients at Time 1. Only the Compliance Questionnaire was omitted.

Results

The initial stage in the data analysis was devoted to investigation of the descriptive issues: the frequency of dietary deviations, the consistency of dietary behaviours, and the situational contexts of dietary relapse episodes. The second stage was concerned with testing the hypotheses related to prediction of compliance. The efficacy of the Health

Belief Model, of Bandura's social learning model, and of actual health consequences in explaining and predicting dietary compliance were assessed.

Stage I

Levels of Dietary Compliance

The mean frequency of dietary deviations in the previous week was 6.02 (SD=6.67) at Time 1 and 6.47 (SD=7.75) at Time 2. The average number of weeks between Time 1 and Time 2 was 15.2. Stepwise regression analysis in which Time 1 compliance was entered first, and number of weeks second, established that the length of this interval did not contribute significantly to the change in dietary deviations from Time 1 to Time 2 ($F(1,75)=.003$, $p>.01$). Only 15 of 90 subjects claimed not to have deviated at all in the previous week at Time 1. At Time 2 17 of 79 subjects reported perfect compliance.

Consistency of dietary behaviours

The consistency of patients' level of compliance across different regimen demands could not be assessed as a result of the absence of variance in responses to the meal scheduling variable (more than half the subjects claimed perfect compliance). The extent to which patients' scores on the 'eating prescribed foods' measure was consistent across time was able to be assessed in the seventy-nine subjects who were interviewed twice within a 6 month period.

Patients' reported frequency of dietary deviations at Time 1 was not significantly correlated with reported

frequency at Time 2 ($r(79)=.14$, $p>.01$) (Table 22). Thirty-seven percent of patients reported fewer deviations at Time 2, 44% reported more, and 19% reported the same number at both times. A similar pattern of change was demonstrated in relation to meal scheduling. Thirty-five per cent of patients were less compliant at Time 2 than at Time 1, 27.5% were more compliant and 37.5% stayed the same.

As seen in Table 22, certain groups showed lower levels of test-retest stability than others. Males were less consistent than females, overweight patients were less consistent than normal weight patients, and patients whose restraint scores were above the median were less consistent than those whose scores were below.

Level of weight control at the two interviews was highly correlated ($r(70)=.98$, $p<.001$). The average weight change was very small ($M=-.14$ kg)

Dietary Relapse Episodes

Descriptions of 160 relapse episodes were obtained at Time 1 and another 160 at Time 2. For the purposes of describing the contexts in which these episodes occurred and examining their classification, the data from time 1 and time 2 were combined.

Type and context of reported relapses. Forty percent of the deviations reported related to type of food, 40% to amount and 20% to meal balancing (Table 23). Most dietary deviations occurred at meals (63%), although after supper was the second most frequent single time period (20%). The home was the most frequent site of dietary deviations (64%) and other people were usually present (70%). Those present were most often

Table 22

Correlation Between Frequency of Dietary Deviations at Times 1 and 2

Groups	Correlation between Times 1 and 2
All	.14
Sex	
Males	.03
Females	.37**
Weight Status	
Overweight	-.03
Normal Weight	.25
Restraint	
High Restraint	.07
Low Restraint	.32*

* $p<.05$; ** $p<.01$

Table 23

Situational Contexts of Dietary Deviations

Time of Day			
At breakfast	3%	Between lunch and supper	14%
Between breakfast and lunch	3%	At supper	42%
At lunch	18%	After supper	20%
Location			
At home	64%	At other's home	13%
At work	4%	Other	8%
At restaurant	12%		
Social Context			
With others	70%	Alone	30%
Family	65%		
Friends	23%		
Colleagues	7%		
Other	4%		
Others eating?			
Yes	85%		
No	15%		
Stress Levels			
Higher than usual	22%	Lower than usual	3%
Mood			
Better than usual	22%	Worse than usual	18%
Guilt afterwards			
Yes	28%	No	71%

family (65%) with friends as the next most frequent group(23%). Patients reported more stress than usual in 22% of their deviations and less stress than usual in 3%. Better than usual mood was reported in relation to 21% of the episodes, while worse mood than usual was reported in 18%. Only 28% reported feeling guilt subsequent to the dietary deviation.

Relapse categories. The category to which the most relapse episodes were assigned was temptations and urges (Table 24). Of the 320 relapse episodes 26% were attributed to giving in to temptation. Eighteen percent of the episodes were attributed to negative physiological states, 17% to positive emotional states, 15% to social pressure, 14% to inconvenience, and finally, 10% to negative emotional states.

Intra-category Consistency in Reports of Relapse

The frequency with which patients assigned their deviations to a single category was examined within each interview and across both interview sessions.

Within sessions. At Time 1, 47 subjects reported and categorized more than one dietary deviation. Of these, 11 (23%) reported that all deviations took place in the same relapse category and 22 (47%) reported that two-thirds of their deviations occurred in the same category. The remaining 14 subjects (30%) gave different categories for each deviation.

At Time 2, 53 subjects reported and categorized more than one dietary deviation. Seventeen patients (32%) placed all deviations in the same category and 25 (47%) placed two-thirds of their deviations in a single category. Eleven subjects

Table 24

Dietary Deviation Episode Classification

1. negative emotional states	10%
2. positive emotional states	17%
3. negative physiological states	18%
4. direct and indirect social pressure	15%
5. temptations and urges	26%
6. inconvenience	14%

Table 25

Within-Session Consistency in Use of Relapse Categories

	Number of Relapse Categories Used		
	1	2	3
Time 1	23%	47%	30%
Time 2	32%	47%	21%

Note. Values are percentages of sample.

(21%) reported different categories for each deviation. Table 25 summarizes these results.

Across time. Forty-nine patients reported and categorized dietary deviations at both Time 1 and Time 2. Only two subjects (4%) were totally uniform in their category selection across time. Thirteen additional subjects (27%) reported that two-thirds or more of their deviations were in the same category at Time 1 and Time 2, and another eight (16%) placed half or more of their deviations in the same category at the two times. The remaining subjects used the same category less than half the time.

Stage II

Background Variables and Dietary Compliance

The relationships of Time 1 and Time 2 dietary deviations to sociodemographic variables, to stable intrapersonal characteristics, and to disease/treatment factors were assessed (Table 26). As the dependent variable is number of dietary deviations, or frequency of noncompliance all correlations are reversed. None of the simple correlations with Time 1 dietary deviations was significant. At Time 2, only the correlation between scores on the Revised Restraint Scale and frequency of dietary deviations was significant ($r(72)=.37, p<.01$). All of the background variables were entered into multiple regression equations to predict dietary compliance at Time 1 and Time 2. At Time 1, the entire set of background variables accounted for 20.7% of the variance ($F(19,67)=.92, p>.01$) and at Time 2, 19.4%

Table 26

Correlations of Background Factors with Dietary Compliance

	Time 1	Time 2
Sociodemographic Factors		
Age	.08	.06
Sex	.14	.01
Marital Status	-.06	.17
Years of Education	-.01	-.10
Living Arrangements	-.17	.05
Income	.01	.03
Occupation	-.17	-.02
Stable Intrapersonal Characteristics		
K Scale	.05	-.13
CRBS	-.24	-.21
Weight Locus of Control	-.02	.05
Health Locus of Contol	.01	.10
Restraint	.05	.37*
Frequency of self-reinforcement	-.14	.00
Disease/Treatment Factors		
Regimen seriousness	-.15	.08
Weight status	-.19	-.10
Diabetic control	.10	-.11
Diabetes type	.11	.19
Treatment duration	-.05	.11
Dietary knowledge	-.15	-.03

* $p<.01$.

($F(19,47)=.61, p>.01$).

Health Beliefs and Compliance

After examining the psychometric properties of the measures of health beliefs and assessing the extent to which the data met certain of the Model's assumptions, the hypotheses concerning the relationship between health beliefs and dietary compliance were examined.

Psychometric properties of the Health Belief measures. The final version of the expectancy-value measure of Health Beliefs displayed adequate variance for all items. Scores on the items related to specific regimens (e.g."How much do you care about avoiding insulin reactions?") all showed extremely negatively skewed distributions and were therefore eliminated from further analysis. Some negative skewness was observed in the distributions of responses concerning long term health consequences. These items were, however, retained and combined with related items to form the perceived severity scale. The items comprising the five Health Belief scales are presented in Appendix J. Scores on all scales conformed relatively well to the normal distribution as determined by visual inspection, by levels of kurtosis and skewness, and by the results of Kolmogorov-Smirnov tests of goodness of fit.

As seen in Table 27, all scales had adequate internal consistency and were surprisingly stable over time. Three of the scales showed some relationship to measures of response bias--all, however, were in the direction opposite to that expected.

The Health Belief Model has generally assumed that its component beliefs were independent of each other. This

Table 27

Validity of Health Belief Measures

Health Belief Measures	Internal Consistency	K Scale	CRBS	Test-Retest
Perceived severity	.75	-.24*	.07	.30**
Perceived treatment efficacy	.82	-.17	.07	.35**
Perceived vulnerability	.86	-.17	-.13	.52**
Perceived benefits	.88	-.24*	.11	.64**
Perceived costs	.64	-.08	-.20*	.27**

* $p<.05$. **$p<.01$.

assumption was assessed through examination of their intercorrelations (Table 28). At Time 1, perceived severity was significantly correlated with perceived treatment efficacy ($r(90)=.37$, $p<.01$), with perceived vulnerability ($r(88)=.19$, $p<.05$) and with perceived benefits ($r(89)=.52$, $p<.01$); and perceived treatment efficacy was significantly correlated with perceived benefits ($r(89)=.64$, $p<.001$). At Time 2, the pattern was similar. Perceived severity was significantly correlated with perceived treatment efficacy ($r(78)=.25$, $p<.05$), and with perceived benefits ($r(74)=.41$, $p<.01$) Perceived treatment efficacy was again associated with perceived benefits ($r(74)=.63$, $p<.001$)

Relationship to frequency of dietary deviations. The analyses conducted to assess the hypothesized relationship between health beliefs and compliance involved the construction of three equations to examine the two concurrent relationships (Time 1 with Time 1; Time 2 with Time 2) and the predictive relationship (Time 1 with Time 2). In the predictive equation, the initial level of compliance and the time between interviews were treated as covariates and their effects removed before the other variables were entered. Likewise the Health Belief Model's prediction that the relationship between compliance and both perceived severity and perceived vulnerability was curvilinear was tested by inclusion of the squared value of each of these beliefs in the regression equations. The total contribution of health beliefs to explaining and predicting diabetic dietary compliance was examined through multiple regressions. As none of the background factors was found to be consistently and

Table 28

Intercorrelations of Health Beliefs

	2	3	4	5
Time 1				
1. Perceived severity	.37**	.19*	.52**	-.13
2. Perceived treatment efficacy		.03	.64**	-.01
3. Perceived vulnerability			.01	-.09
4. Perceived benefits				-.02
5. Perceived costs				
Time 2				
1. Perceived severity	.25*	.18	.41**	-.01
2. Perceived treatment efficacy		.11	.63**	-.14
3. Perceived vulnerability			.19	-.03
4. Perceived benefits				.11
5. Perceived costs				

* p<.05 . **p<.01.

significantly correlated with compliance, these variables were not analysed further.

Table 29 presents the results of the regression analyses. The multiple regression at Time 1 revealed that health beliefs were able to account for 10.3% of the variance in frequency of dietary deviations ($F(7,79)=1.30$, $p>.01$). Only one belief, perceived costs, made a significant contribution to this outcome ($F(1,79)=3.92$, $p<.01$). Its relationship to compliance, however, was in the direction opposite to that predicted by the model ($r(90)=-.23$, $p>.01$). In predicting Time 2 compliance, the Time 1 measures of health beliefs accounted for 12.7% of the variance ($F(7,66)=1.40$, $p>.01$). No belief made a significant independent contribution. Time 2 measures of health beliefs resulted in 15.7% of the variance in Time 2 dietary deviations being accounted for ($F(7,64)=1.71$, $p>.01$). The power of these tests was, however, quite low (.32,.19 and .47 respectively for the Time 1, Time1-Time 2, and Time 2 analyses).

Table 30 presents the simple correlations between health beliefs and frequency of dietary deviations.

Perceived Health and Non-Health Outcomes and Compliance

The relative effects on compliance of perceptions of health consequences and of perceptions of other, non-health consequences (e.g.social approval, improved appearance) were compared. Initially, a new variable was computed which was comparable to the perceived benefits component of the Health Belief Model (which assessed only non-health benefits). The value assigned to each health outcome was multiplied by the perceived efficacy of treatment in bringing about those

Table 29

Variance in Dietary Deviations Accounted for by Compliance Models

Models	Time 1	Time 1-Time 2	Time 2
Health Beliefs	.103 (F(7,79)=1.30, p>.01)	.127 (F(7,66)=1.40, p>.01)	.157 (F(7,64)=1.71, p>.01)
Outcome & Efficacy Expectancies	.087 (F(2,84)=4.02, p>.01)	.030 (F(2,71)=2.32, p>.01)	.033 (F(2,76)=1.29, p>.01)
Health Beliefs & Efficacy Expectancies	.156 (F(8,78)=1.81, p>.01)	.147 (F(8,65)=1.43, p>.01)	.157 (F(8,63)=1.47, p>.01)

Note. Unbracketted values are the squared values of the multiple correlation.

Table 30

Correlations between Health Beliefs and Compliance

Health Beliefs	Time 1	Time 1-Time 2	Time 2
Perceived severity	.03	.26	-.09
Perceived treatment efficacy	.01	.25	.13
Perceived vulnerability	.18	.00	.29
Perceived benefits	.10	.22	.15
Perceived costs	-.23	-.16	.06

outcomes. The simple correlations of this new perceived health benefits measure and of the perceived benefits measure with frequency of dietary deviations were then examined and compared. The results are summarized in Table 31. At Time 1, neither measure correlated significantly with compliance and the difference between the two types of belief was nonsignificant. In predicting Time 2 compliance from Time 1, the correlation of health benefits with dietary compliance was significant ($r(79)=.31, p<.01$), and the difference between the two correlations was significant ($t(76)=2.36, p<.05$). At Time 2, the results were reversed: the correlation with perceived benefits was higher ($r(72)=.19, p<.05$) than with perceived health benefits ($r(75)=.08, p>.05$). This difference too was significant ($t(69)=2.57, p<.01$).

Bandura's Social Learning Model and Compliance

After examining the validity of the expectancy measures and the extent to which fundamental assumptions of Bandura's model were met by the current data, multiple regression equations were used to assess the relationship between expectancies and frequency of dietary deviations. The relationship of situation-specific self-efficacy expectancies to the occurrence of relapse in those situations was assessed using point biserial correlations.

Validity of self-efficacy and outcome expectancy measures.

The validity of the dietary self-efficacy item was assessed by examining its convergence with the self-efficacy associated with both more general and more specific dietary tasks. Its relationship to measures of response bias was also assessed. The dietary self-efficacy item showed consistently good

Table 31

Relationship of Health and Non-Health Benefits to Compliance

	Dietary Deviations		
Beliefs	Time 1	Time1-Time2(a)	Time 2(b)
Perceived benefits	.13	.22	.19
Perceived non-health benefits	.08	.31*	.08

(a) The difference between the two correlations was significant ($t(76)=2.36, p<.05$).

(b) The difference between the two correlations was significant ($t(69)=2.57, p<.01$)

* $p<.01$

correlations with these other self-efficacy measures (Table 32). It was not found to correlate with the K Scale, but was correlated with the CRBS ($r(75)=.34$, $p<.01$).

The six situational self-efficacy subscales' validity was confirmed through examination of their relationships with the response bias measures, their internal consistencies and their stability between Times 1 and 2. Table 33 summarizes these findings.

The validity of the outcome expectancy was assessed in the same way. It was found to have adequate internal consistency (alpha(88)=.84) and good stability from Time 1 to Time 2 ($r(73)=.57$, $p<.001$). Outcome expectancy scores were, however, related to scores on the K Scale ($r(75)=-.26$, $p<.05$).This relationship was in the direction opposite to that expected.

Independence of the expectancies. Bandura's model, like the Health Belief Model, assumes the independence of efficacy and outcome expectancies. The correlations between the two expectancies were low, but approached significance at Time 1 ($r(90)=-.16$, $p=.07$) and at Time 2 ($r(73)=.18$, $p=.07$).

Relationships of Bandura's Expectancies to Compliance

Multiple regressions. (Table 29). The multiple regression at Time 1 revealed that the two expectancies together accounted for 8.7% of the variance in dietary deviations ($F(2,84)=4.02$, $p>.01$). Only the self-efficacy expectancy contributed significantly ($F(1,84)=7.99$, $p<.01$). Use of Time 1 expectancies to predict Time 2 compliance lead to 3.0% of the variance being accounted for after the effects of Time 1 compliance and weeks between interviews were removed

Table 32

Correlations of Dietary Self-Efficacy and Other Self-Efficacy Measures

Related Self-efficacy Judgments	Dietary Self-Efficacy Judgments
Efficacy for attaining ideal weight	.49*
Efficacy for maintaining ideal weight	.46*
Efficacy for avoiding overeating	.56*
Efficacy for avoiding proscribed foods	.55*
Efficacy for eating balanced meals	.71*

* $p<.001$

Table 33

Validity of Situational Self-Efficacy Scales

Self-Efficacy Scales	Internal Consistency	K Scale	CRBS	Test-Retest
Negative Emotional States	.94	.19*	.37**	.66**
Positive Emotional States	.75	.02	.22*	.61**
Negative Physiological States	.63	-.05	.22*	.42**
Social Pressure	.81	.08	.18	.55**
Temptations and urges	.77	.06	.15	.51**
Inconvenience	n/a	-.03	.35**	.24*

* $p<.05$. ** $p<.01$.

($F(2,71)=2.32$, $p>.01$). At Time 2, the two expectancies together accounted for 3.3% of the variance ($F(2,76)=1.29$, $p>.01$). Neither expectancy made a significant contribution. Again, power analyses revealed that the power of these test was low (.49,.10 and .11 for the Time 1, Time 1-Time 2, and Time 2 analyses respectively).

Table 34 presents the simple correlations of outcome expectancies and self-efficacy expectancies with compliance.

Effects on self-efficacy of changes in dietary compliance. Bandura's model predicts that behaviour change should be reflected in changed self-efficacy. Thus, the extent of change in self-efficacy from Time 1 to Time 2 should be related to the extent of change in compliance from Time 1 to Time 2. A stepwise regression analysis was performed, with Time 1 self-efficacy and compliance entered first, then Time 2 compliance. Time 2 compliance did not account for a significant amount of the variance in Time 2 self-efficacy ($F(1,67)=.05$, $p>.05$).

Situational self-efficacy and reported relapse situations. The extent of the relationship between perceived self-efficacy with respect to specific situations and the occurence of relapse in those situations was examined through point biserial correlations. As revealed in Table 35, level of perceived self-efficacy with respect to specific types of situations was not highly successful in distinguishing between patients who did or did not relapse in those situations.

Relationship of Health Beliefs and Self-Efficacy to Frequency of Dietary Deviations

The value of combining Bandura's social learning model

Table 34

Correlations of Expectancies with Compliance

Expectancies	Time 1	Time 1-Time 2	Time 2
Outcome expectancy	-.04	.18	.13
Self-efficacy expectancy	-.29	-.18	-.29

Table 35

Correlations between Self-Efficacy and Relapse in High-Risk Situations

	Time		
Relapse Categories	Time 1	Time 1-Time 2	Time 2
Negative emotional states	-.25*	(a)	(a)
Positive emotional states	-.03	-.18*	-.10
Negative physiological states	-.17	.07	-.13
Social pressure	-.05	-.06	-.25*
Temptations and urges	-.09	.01	.01
Inconvenience	-.22*	-.13	-.19*

Note. The values represent one-tailed point biserial correlations.

(a) Insufficient subjects assigned relapses to the negative emotion category to perform the Time 2 analyses.

* $p<.05$

and the Health Belief Model was assessed by establishing the change in the variance accounted for when beliefs and the efficacy expectancy were entered into the equation together (Table 29).

At Time 1, the multiple regression revealed that the models together accounted for 15.6% of the variance ($F(8,78)=1.81$, $p>.01$). Only the self-efficacy expectancy made a significant independent contribution ($F(1,78)=4.94$, $p<.01$) and entered the equation in the expected direction ($r(87)=-.23$, $p>.01$). At Time 2, after controlling for level of compliance at Time 1 and time between interviews, the Time 1 measures accounted for 14.7% of the variance ($F(8,65)=1.43$, $p>.01$). None of the variables made a significant independent contribution. The multiple regression composed of the measures obtained at Time 2 resulted in 15.7% of the variance being accounted for ($F(8,63)=1.47$, $p>.01$) and again no single variable's contribution was significant. The power of these test was somewhat greater than in the previous analyses but was still quite low (.57, .41 and .54 respectively for the Time 1, Time 1-Time 2, and Time 2 analyses).

Comparison of Diabetic and Nondiabetic Spouses

Discriminant analysis was used to compare diabetic and nondiabetic subjects with respect to their frequency of dietary deviations, health beliefs, and efficacy expectancies (Table 36).

The overall number of dietary deviations did not differ significantly in the two groups ($F(1,98)=.36$, $p>.01$). As in the diabetic sample, a sizeable proportion of the subjects reported no dietary deviations with respect to type of foods

Table 36

Levels of Dietary Deviations, Health Beliefs, and Self-Efficacy in Diabetic Patients and Nondiabetic Spouses

	Diabetic Patients	Nondiabetic Spouses
Dietary Deviations	6.0	5.8
Health Beliefs		
Perceived severity	6.8	6.4
Perceived treatment efficacy	13.9	13.4
Perceived vulnerability	8.8	7.7
Perceived benefits	51.2	52.7
Perceived costs	-19.5	- 5.8
Dietary self-efficacy	11.2	11.2
Situational self-efficacy		
Negative emotional states°	11.2	12.4
Positive emotional states	13.2	13.4
Negative physiological states	11.4	11.4
Social Pressure	14.3	13.4
Temptations and urges	13.8	12.9
Inconvenience	12.4	13.1

eaten (33%), quantities eaten (61%), and meal balancing (44%). On the meal timing subscale, 39% of the nondiabetic subjects reported following a schedule perfectly.

Nondiabetics subjects' health beliefs did not differ significantly from diabetics'. They did not view themselves as significantly less vulnerable to the potential consequences of diabetes and obesity ($F(1,98)=1.00$, $p>.05$), and perceived the efficacy of following a healthy diet as just as great ($F(1,98)=.13$, $p>.05$). They did not differ from diabetics in their perception of the severity of the consequences of the disease ($F(1,98)=.48$, $p>.05$) or of the non-health benefits ($F(1,98)=.04$, $p>.05$). Although the difference did not reach significance, patients did perceive the costs of following a diet to be greater than did nondiabetics ($F(1,98)=2.50$, $p=.10$).

Perceived self-efficacy was not significantly different in the two groups ($F(1,98)=.01$, $p>.05$) and none of the situation specific self-efficacy ratings differed. Nondiabetic spouses' level of knowledge about the diabetic diet was equivalent to that of diabetics ($F(1,98)=.11$, $p>.05$).

Chi-squared tests were performed to ascertain whether the two groups differed in the relapse categories of their dietary deviations or in the situational contexts in which such breakdowns occurred. No significant differences emerged.

Discussion

The results of this study provided additional information about the nature of compliance, but they did not support the

utility of the models tested in explaining and predicting the frequency of diabetic patients' dietary deviations. It had been planned to explore these issues in relation to two aspects of dietary compliance. This was not possible due to the absence of variance in scores on one variable--eats at prescribed times.

Consistency of Compliance

Although the results did not supply any further evidence concerning the consistency of compliance in response to different regimen demands, they did reveal a striking lack of consistency across time. Overall, subjects' level of compliance at Time 2 was virtually totally unrelated to their level of compliance at Time 1, especially among men, more restrained eaters, and overweight patients. Most patients' dietary behaviour appears to vary from week to week despite highly stable weight.

There is no apparent evidence that this is variability is solely an artifact of the measurement procedure. A time-sampling bias is unlikely as data were collected over a period of 8 months, all patients knew well in advance of the first interview that they would be attending the clinic, and at least a week in advance that they would be re-interviewed by the investigator or seen again in the clinic.

Inconsistency in calorie intake from day to day has frequently been noted in studies of nonclinical poplations. Edholm, Fletcher, Widdowson and McCance(1955) for example, observed the food intake and energy expenditure of a group of

cadets at a military camp over 14 days. They found considerable intraindividual variability in food intake, and noted that this variability was unrelated to energy output. This absence of balance between intake and output on the basis of daily, weekly, or even fortnightly periods has been accepted as commonplace, as has the relatively low correlation between daily calorie balance and daily weight change (Edholm, 1961). Tunbridge and Wetherill (1970) have noted this same intraindividual variability in their diabetic patients. They examined the 7-day food records of 63 patients and found considerable differences from day to day, even among those who were generally adhering well to the diet. No attempt was made to quantify the extent of this variability.

These data are consistent with the existence of a powerful regulatory system through which, over some indeterminate period, a balance is struck in order to maintain a particular weight. Within that period, however, the system would appear to allow considerable variability as long as overall weight is unaffected. Whether this self-regulation is physiologically based, as in a biological setpoint, or represents a conscious effort to achieve a balance and a desired body weight is not certain. The evidence that overweight and restrained eaters are less consistent, although no different in actual frequency of dietary deviations, provides some support for restraint theory's conceptualization of the chronic dieter as constantly struggling against physiology to achieve a weight below some biological setpoint, and usually losing. Eating habits would be expected to be less regular in this group, except for a pattern of

fluctuation between tight control and counter-regulatory episodes. It remains to be seen, however, to what extent inconsistency can find its basis in biology and to what extent it represents an allowable fluctuation within limits consciously set.

Relapse Situations

In Marlatt and Gordon's original investigations of initial relapse episodes among ex-smokers, ex-alchoholics and ex-heroin addicts(1980), most initial relapses occurred in relation to negative emotional states, social pressure or interpersonal conflict. Rosenthal and Marx (1981) found a similar pattern concerning the importance of emotional states among dieters. In the current study most relapses were related to non-emotional causes-- inconvenience and temptation. These findings are similar to those of Kirkley (1982) who examined the most recent dietary relapse among diabetic patients. It had been hypothesized that actually providing subjects with a list of all the categories would increase the frequency with which "psychological" reasons were endorsed, thus making the categorization more similar to that found in studies of nondiabetics. This prediction was not supported. The results of this procedure in fact paralleled those of Kirkley (1982), who used an interview and patient-generated reasons to categorize their dietary relapses.

Other studies have focussed on the initial relapse episode following a period of complete adherence. In neither

the current study nor the Kirkley study was an attempt made to identify such an abstinent period or some initial breakdown. Diabetic patients are under an ongoing pressure from both internal and external sources to adhere. The mean frequency of dietary deviations, however, suggests that most patients are successfully adherent only for short periods, if at all. Thus in the context of the diabetic diet, it is not an "initial relapse episode" that is being described, and initial relapses as measured by Marlatt and Gordon (1980) and Rosenthal and Marx (1981) may well be governed by different factors than those affecting subsequent dietary deviations.

Kirkley (1982) attributes these differences in results to the lifelong nature of the diabetic diet, which is presumed to generate an attitude of acceptance of occasional episodes of noncompliance and a willingness to accept responsibility for the episodes. Such an attitude might also foster the development of a set of personal dietary standards within which a certain frequency of deviations is permitted. This perspective is not generally what is required in an abstinence-oriented treatment or a weight loss program, where typically no deviations are permitted. It may, however, be more typical of how those not being treated for an appetitive disorder in fact manage their intake. The resemblance between diabetics and the spouses of some of these patients in the situations in which relapses were reported to occur tends to support this notion, although the spouses' eating behaviour is undoubtedly influenced by the sharing of meals with the diabetic partner.

The possibility that some people are consistent in the

types of situation in which they relapse received some support. A substantial number of patients assigned most of their relapses to the same category at each time and across times. The sample size was insufficient to delineate clearly relapse types--for example, "negative emotion eaters", "temptation eaters", and to attempt to identify factors which distinguished between them.

Background Factors

The variables selected as potentially important influences on compliance did not singly or as a group contribute significantly to understanding dietary deviations. The absence of a relationship between sociodemographic, personality-like and disease/treatment factors and compliance is in conformity with most of the other findings in the compliance literature (Haynes, 1979).

Health Belief Model

The independent and joint contributions of the various elements of the Health Belief Model were not found to be useful in explaining current and future dietary compliance.

In none of the three regression equations did the joint contribution of all health beliefs account for a significant amount of the variance. Two beliefs- perceived costs and perceived efficacy of compliance with treatment--did make significant independent contributions to the variance accounted for in one or more of those equations. In both

cases, their relationship to compliance was directly opposite to that predicted. Higher frequencies of dietary deviations were associated with perception of lower costs and of greater vulnerability to negative health outcomes. A check was conducted to assess whether the vulnerability- compliance relationship was curvilinear. There was no evidence to support this contention.

An examination of the simple correlations between each belief and compliance revealed that the correlations were very low (under .30) and almost all were in the direction opposite to that predicted.

To establish the causes of this failure of the Health Belief Model to explain and predict frequency of dietary deviations, the potential inadequacies in measurement and in the model itself must be considered.

The extent to which the measures designed to measure health beliefs in fact measured patients' cognitions about these aspects of their health and treatment can only be inferred, as no objective verification of such internal cognitive processes is possible. Support for the measure's validity can be obtained from the procedures used in constructing the measure, its absence of relationship to measures of response bias, and its internal consistency and test-retest reliability.

In constructing the questionnaire the content of most items was empirically derived from the responses of patients themselves. The format of the items was based on expectancy-value questionnaires used successfully in studies of other appetitive problems. The congruence between how

patients understood the items and what the items were intended to assess was checked by having patients think aloud as they read and answered the items in two pilot studies. These precautions enhanced the likelihood that the measures were valid.

It was expected that if the validity of the health belief measures was threatened by a response bias, patients who were trying to present a socially desirable facade would have stronger beliefs. Instead, scores on the K Scale were negatively associated with perceived severity and perceived benefits: Patients who were more defensive perceived avoidance of negative health consequences as less valuable and had weaker expectancy-values concerning potentially desirable non-health outcomes. This form of defensive responding should not automatically be treated as evidence of the invalidity of the measures of health beliefs.

Scores on the Compliance Response Bias Scale were correlated in the expected direction with only one health belief --perceived costs. Patients who scored high on the CRBS perceived there to be fewer costs associated with compliance. The assumption underlying the CRBS is that few, if any, people would be so consistent in following recommended health actions as to score highly on the test without being somewhat dishonest. This assumption may not be correct. In Study 1, a group of patients did present themselves as being consistently compliant with all of the demands of their regimens. Since the validity of the CRBS may itself be questionable, a low correlation between it and another measure should not be sufficient grounds alone to invalidate that

measure.

Reliability is a necessary condition for validity. Acceptable levels of internal consistency were found for perceived severity, vulnerability and treatment efficacy. The levels were lower for perceived benefits and costs. These measures were not designed to be unidimensional but to assess a wide variety of unique outcomes. Although no hypotheses were formulated about the stability of health beliefs, they might have been expected to change with changes in compliance. Responses given at Time 2 were all significantly correlated with responses given at Time 1.

It is also possible that the measurement of dietary deviations was not valid. It did not show significant convergence with health professionals' ratings or with physiological measures, although trends in the appropriate direction emerged. These findings are in fact consistent with the variability in dietary behaviour previously discussed. The convergent validation measures are less reflective of day-to-day fluctuation than they are of stable patterns emerging over a longer period. Nevertheless a major threat to the validity of the dietary deviation measure would arise if a strong relationship was found with the measures of response bias. This did not occur.

In sum, these data do not provide strong support for the possibility that the weak relationship between health beliefs and compliance was strictly a function of invalid measures.

In the compliance context, the relative failure of health beliefs to contribute significantly to explanation and prediction is not totally unexpected. In most of the studies

concerned with adult self-care previously reviewed, no more than one of the beliefs tested has typically been related to compliance. The strength of the relationships found in these studies cannot be compared directly to the associations found in the current study, due to differences in measurement and data analytic strategies. However, the findings in the prospective study by Taylor et al (1978) that most of their significant simple correlations between health beliefs and behaviour were between .20 and .30 are not atypical, and are not that dissimilar from the results presented here.

Low correlations between attitudes and behaviour are well documented in the psychological literature. The argument usually made, however, is that these poor results are the result of a lack of specificity in the attitudes and behaviours measured (Ajzen & Fishbein, 1977). In the current instance, a substantial effort was made to ensure situational specificity. The items used were derived from diabetic patients and each referred to a specific behaviour or a specific outcome. Where specificity was lacking, perhaps, was in the assumption that the importance of health beliefs in influencing behaviour, as opposed to the power of other factors, remained constant regardless of the situation. The Health Belief Model views human behaviour as a function of rational choices based on considerations of long-term well-being. It fails to acknowledge that the desire for more immediate gratification can interrupt or interfere with such motivations.

The failure of these data to provide support for the Health Belief Model does not appear to have resulted

exclusively from measurement error. The sample size was comparable to that in other studies, and, unlike most studies the design was prospective. The results of the power analysis do not, however, rule out the possibility that these results occurred by chance. Thus further investigations are required before the relationship between health beliefs and compliance can be conclusively established.

Bandura's Social Learning Model

Bandura's model of outcome and efficacy expectancies was not highly successful in explaining and predicting the frequency of dietary noncompliance. It was unable to account for even 10% of the variance in dietary deviations. Generally the self-efficacy expectancy was related to frequency of dietary deviations in the direction expected and contributed more to the variance accounted for than the outcome expectancy; however, the two expectancies were not independent.

Contrary to prediction, self-efficacy did not change concomitantly with changes in frequency of dietary deviations. Again issues of measurement and model appropriateness must therefore be examined.

The same principles and procedures used to ensure the greatest possible validity in constructing the health belief measures were also applicable to the outcome expectancy measure. The diversity of possible outcomes was extensive. A fairly encouraging level of test-retest reliability was found, nevertheless. As in the measurement of health beliefs, a

significant association was found between the K scale and the outcome expectancy measure, and again it was in the opposite direction to that expected if the responses were given to present a socially desirable image.

In measuring self-efficacy, Bandura's approach is to ask highly specific questions and to ignore issues of contruct, trait, convergent and discriminant validation as irrelevant (Bandura, 1978). As self-efficacy is seen as constantly changing in response to behaviour, issues of test-retest reliability would also be meaningless.

The single item used to assess self-efficacy was therefore made as specific as possible and the task to which it referred clearly defined. Its validity was supported by substantial and significant correlations with measures of self-efficacy in relation to other more and less specifically-defined tasks. Level of self-efficacy was, however, positively correlated with scores on the Compliance Response Bias Scale, although not with those on the K scale. If responses to the CRBS items in fact reflect actual behaviour, congruence with levels of self-efficacy would be expected. The measurement of the expectancies appears to have been largely in accordance with Bandura's guidelines.

Bandura's self-efficacy model was proposed as a way to explain how behaviour change occurs and how it is maintained in the face of successes and failures. Bandura (1978) states that such efficacy cognitions will no longer occur when behaviours have become habitual. Self-efficacy mechanisms are only activated under conditions of behaviour change. In the current context, it was assumed that since patients'

compliance was not perfect, the patients were responding to external and/or internal demands for better dietary compliance. This assumption may have been incorrect. Patients may indeed have been satisfied with their current dietary behaviour and have rejected any external pressure to change.

The current study also failed to take a truly microanalytic approach in which, before and after every dietary deviation, self-efficacy was assessed. Rather patients were asked to judge their efficacy over some indeterminate future time period. While this approach has not attenuated results in other studies (e.g. McIntyre et al., 1983), performance of the target behaviours in these studies may have been associated with less variability and therefore been more predictable.

Situation Specific Self-Efficacy and Relapse Categories

The hypothesis that level of self-efficacy with respect to a specific high-risk situation should relate to whether or not a relapse is assigned to that category was only partially supported. Patients who relapsed in a particular type of situation did not necessarily have lower self-efficacy concerning that type of situation than those who did not.

Situational self-efficacy was assessed by questionnaire items relating to efficacy in six types of high risk situations. Varying numbers of items made up each situational self-efficacy scale but all had adequate levels of internal consistency. Situational self-efficacy scores were associated with CRBS scores but not generally with scores on the K scale. The correlations between Time 1 and Time 2 scores were all significant. These data suggest that the measurement of

situational self-efficacy was relatively adequate.

The form of analysis used, however, provided a very conservative test of the hypothesis. Since only a brief time period and a small number of relapse episodes were sampled per person, patients having low self-efficacy with respect to a particular type of situation may not have been able to report relapses in that situation due to these procedural constraints.

As discussed above, Bandura's model is based on a microanalytic approach, which was not used in the present study. Nonetheless, Condiotte and Lichtenstein (1981) found that their ex-smokers' situational self-efficacy was related to the subsequent relapse situation occurring up to 4 months later. From a practical perspective, however, the model's utility in fact depends upon its capacity to predict events somewhat removed in time and not absolutely identical to the situation presented.

Perceived and Actual Health Consequences

The presumed superiority of perceived health over perceived non-health consequences in predicting and explaining compliance was not supported; however neither type of consequence was shown to have a significant relationship with dietary deviations.

The hypothesized relationship between the severity, immediacy and salience of health consequences and compliance was also not supported. Diabetic patients were not distinguishable in their compliance on the basis of regimen,

and as a group diabetics were not distinguishable from their spouses. The cognitions of the two groups were also unexpectedly similar: patients did not even feel significantly more vulnerable to health consequences than the spouses.

Diabetic patients' spouses were selected as a health control group because of their similarity to patients on sociodemographic variables and because they were expected to have some knowledge of a healthy diet through their contact with the patient. This systematic exposure to diabetes and its treatment differentiates this group from a randomly selected community sample and reduces the extent to which these results can be generalized. Nonetheless the inability to distinguish between diabetic patients and their spouses on the basis of health attitudes and behaviours which was demonstrated in this study provides further evidence that disease factors which apparently increase health threat do not influence compliance (Haynes, 1979).

Conclusions

The descriptive analysis of diabetic patients' dietary compliance provided some unexpected information about the nature of compliance problems. The results indicated that patients' dietary behaviours were inconsistent over time. They also revealed that episodes of noncompliance do not typically occur under special environmental or psychological circumstance, but more often happen under everyday conditions: at home, with family, at meals.

In attempting to explain and predict current and future

compliance, none of the variables or models tested made a significant contribution. The failure of background factors and level of health threat to show any consistent relationship to dietary behaviours has many precedents in the compliance literature. Neither is the absence of evidence for a relationship between compliance and health beliefs entirely unexpected, as previous, less rigorous investigations have usually found only weak and inconsistent associations. Bandura's social learning model had not previously been used in the compliance context. Its inability to account for dietary deviations may in part be due to a possible failure to meet some of the model's assumptions. Further investigations of these models using more powerful analyses are required.

CHAPTER 4

Implications and Conclusions

Two studies were conducted to investigate the problem of noncompliance with medical treatment among diabetic patients. Failure to adhere to the prescribed regimen is likely to have immediate and long-term adverse effects on patients' health. Previous research has established that patients' treatment behaviours often do not coincide perfectly with the behaviours prescribed. The extent to which this problem exists and the best approaches to understanding it have not been resolved due to controversies over measurement techniques and failure by researchers to clarify assumptions concerning the nature of compliance. Both studies addressed these issues. In addition, the results of Study 1 provided guidelines for selecting appropriate explanatory models of compliance and two of these were tested in Study 2. Neither model was successful in explaining or predicting dietary compliance. The contribution of these two studies, then, is methodological and descriptive, rather than explanatory.

The most important finding from both a conceptual and methodological viewpoint is the absence of consistency in compliance across regimen demands and, with dietary compliance, over time. Most patients appear to be highly compliant with some regimen demands, and highly noncompliant with others. They may also be very compliant one week, and less so the next. Such patterns must be taken into account in posing research questions, planning research strategies and in

generalizing from research results.

If the research goal is to uncover factors which explain and predict episodes of noncompliance, two possible approaches present themselves. The first is typified by Bandura's microanalytic strategy: the principles which guide behaviour in a specific situation are extracted from observations of that situation, and are used only to predict behaviour in similar situations. The results of this type of procedure, however, lack practical utility, unless they can eventually be applied to less similar and less specific sets of circumstances. A second, and potentially complementary approach, is the use or creation of a model which assumes, and attempts to account for, such variability in behaviour. Explanatory frameworks, such as the Health Belief Model, which are derived from decision- making or attitude conceptualizations tend to assume stability of cognitions and consistency of behaviours and are thus doomed to inadequacy in the compliance context. Models which attempt to predict whose behaviour will change, how it will change, and under what circumstances it will change, have greater potential for success. Restraint Theory (Herman and Mack, 1975) is an example of such an approach.

The specificity of treatment behaviours also has implications for the measurement of compliance. Global measures which encompass or reflect more than one behaviour (e.g. staff ratings of overall compliance, physiological outcomes) will not in fact be able to provide accurate information concerning patients' performance of any one behaviour. Measurements at a single point in time may also be

inadequate. Repeated measurement in an attempt to uncover predictable patterns of compliance and noncompliance are likely to be more fruitful.

The need for specificity constrains generalization from one compliance context to another and the occurence of significant individual differences in compliance with some demands may hinder extrapolation to new samples.

A second major finding with relevance to future research relates to the lack of evidence that health consequences, actual or perceived, play a major role in health behaviours. While reviewers have repeatedly noted the lack of association between compliance and disease factors such as diagnosis and severity, the implications of such findings appear to have been largely ignored. One conclusion that may be drawn is that distinctive theories do not have to be created to explain behaviour in a health context. Rather, models pertaining to behaviour and habit change in non-health situations should be considered equally appropriate for application to problems such as compliance.

The evidence of substantial disparities in rate of compliance depending upon the criteria used suggests that any conclusions about the nature and causes of noncompliance must consider the potential contribution of some form of knowledge factor. These results also draw attention to the whole domain of personal standards. In the studies reported here, only patients' knowledge concerning their physicians' recommendations, their physicians' criteria of adequate performance, was queried. What was not assessed were patients' own standards, the level of behaviour which they

personally felt was acceptable. The finding in Study 2 that most patients did not experience guilt subsequent to their noncompliance suggests that noncompliance, as usually defined, may occur without patients perceiving a breach of personal standards.

Finally, the nature of compliance data as obtained in the current investigation must be considered in subsequent research. Self-report did not appear to be influenced by any response bias, suggesting that inaccuracies might be better attributed to memory failures. It is therefore important to consider this factor in selecting a time period for study. A very short time period, however, is likely to increase the problems with lack of variance as occurred in the current investigations. These variance and recall issues require furhter empirical investigation.

The clinical implications of these results parallel the research implications. The finding of high levels of specificity means that each patient's unique problem areas need to be carefully assessed, and the tendency to make generalizations about patients' overall compliance from small behaviour samples needs to be curtailed. The conceptualization of compliance as a flexible response to particular situations indicates that problems with compliance may be highly amenable to remediation through behavioural approaches such as those reviewed by Surwit, Scovern and Feinglos (1982).

The absence of evidence that health consequences are the major determinants of compliance indicates that intervention strategies based on fear and health threat may be

unproductive. Most diabetic patients appear to believe that they are at risk and that avoiding these consequences is valuable, yet on a moment-to-moment basis, these motivations apparently lose their ascendancy and patients fail to comply. The critical point for intervention may not, then,be at the general motivational level, but at the level of specific situational factors.

The disparity between patients' understanding and physicians' recommendations suggests that greater educational efforts and improvements in communication are needed. The diabetic regimen is highly complex and patients may receive a wide variety of treatment recommendations from various health professionals. To the extent that these can be presented clearly, in simple language, reiterated and perhaps written down, patients' comprehension of what has been prescribed should improve.

Patients' self-report of compliance appears fairly accurate when obtained through highly specific questions in a nonjudgemental atmosphere. When the clinician obtains such information and finds it highly discrepant from other sources, a response bias tendency should not be assumed. Rather it may well reflect how patients perceive their own compliance and may require investigation of their comprehension, memory function, and own personal model of their diabetes and its treatment.

Overall, the results of the current investigation suggest that interventions to improve compliance must be highly tailored to individual patients, based on their needs for both improved knowledge and specific strategies to maintain

compliance under diverse circumstances.

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APPENDIX A

Patient Information Sheet

The adequate treatment of diabetes involves the patients taking a great deal of responsibility for their own care. The treatment demands that certain things be done on a regular basis, regardless of circumstance. From time to time, most diabetics have problems doing all the things they are required to do. This causes concern both among patients and medical staff.

The present study hopes to investigate the causes of these problems and to find ways of improving the situation. In order to do this, we require your co-operation. We need to know how you actually do take care of yourself. We need accurate information about the times when you do things perfectly, and the times when you make mistakes or forget to do things you are required to do.

If you feel that you can make an honest contribution to this project and agree to participate in our interview, we guarantee that your answers will be kept completely confidential, that they will not be discussed with your doctor or the clinic staff, and that they will not become part of your medical record. At any time in the interview, you will be free to withdraw from participation.

We would also like your permission to talk to your husband or wife, or someone who knows about how you take care of yourself.

If you would like to participate in this study, please sign your name below and give the name and telephone number of the person we can contact. If no such person is available, we still invite you to participate.

_____

Patient's signature

_____

Contact person

APPENDIX B

BACKGROUND INFORMATION

NAME: ADDRESS:

TELEPHONE:

AGE: MARITAL STATUS:

SEX: OCCUPATION:

EDUCATION: INCOME:

PRIMARY LANGUAGE: COUNTRY OF ORIGIN:

LIVING ARRANGEMENTS:

TREATMENT HISTORY

DATE OF DIAGNOSIS:

CURRENT TREATMENT: DURATION:

PREVIOUS TREATMENTS:

APPENDIX C

PATIENTS' COMPLIANCE QUESTIONNAIRE

NAME:.....

The next questions are about how you take care of your diabetes. In order for this information to be helpful to us, it must be as hones and accurate as possible. Remember that all of your answers are confidential and will not be discussed with clinic staff or your docto

Answer the questions either by circling the appropriate response or by writing in your answer.

1. About how much do you weigh right now?_____
2. About how much did you weigh 6 months ago?_____
3. About how much did you weigh one year ago?_____
4. According to your doctor, do you weigh:
    1. too much?
    2. too little?
    3. about right?
    4. don't know.
5. Yesterday, or on the last day you were not sick, how many times did you test your urine or blood for sugar? _____

6. Yesterday, at which of these times did you test your urine/blood?

    1. just before breakfast
    2. just after breakfast
    3. just before lunch
    4. just after lunch
    5. just before supper
    6. just after supper
    7. at bedtime
    8. at any other time?

7. During the past 7 days, or on the last 7 days that you were not sick on how many days did you test your urine/blood for sugar?

_____

8. On those days in the past week when you did test your urine/blood, what was the average number of times per day you tested it?

_____

9. In the past 7 days, on how many days did you test:

1. just before breakfast	0	1	2	3	4	5	6	7
2. just after breakfast	0	1	2	3	4	5	6	7
3. just before lunch	0	1	2	3	4	5	6	7
4. just after lunch	0	1	2	3	4	5	6	7
5. just before supper	0	1	2	3	4	5	6	7
6. just after supper	0	1	2	3	4	5	6	7
7. at bedtime	0	1	2	3	4	5	6	7
8. at any other times?	0	1	2	3	4	5	6	7

10. Yesterday, or on the last day you were not sick, how many times did you inject your insulin/take your oral agents?_____

11. Yesterday, at which of these times did you inject your insulin/take your oral agents?

    1. just before breakfast
    2. just after breakfast
    3. just before lunch
    4. just after lunch
    5. just before supper
    6. just after supper
    7. at bedtime
    8. at any other time

12. During the past 7 days, on how many days did you inject your insulin/take your oral agents? _____

13. During the past 7 days, how many times did you miss taking your insulin/oral agents at the scheduled time? _____

14. How many times did you inject your insulin/take your oral agents

1. just before breakfast	0	1	2	3	4	5	6	7
2. just after breakfast	0	1	2	3	4	5	6	7
3. just before lunch	0	1	2	3	4	5	6	7
4. just after lunch	0	1	2	3	4	5	6	7
5. just before supper	0	1	2	3	4	5	6	7
6. just after supper	0	1	2	3	4	5	6	7
7. at bedtime	0	1	2	3	4	5	6	7
8. at any other times?	0	1	2	3	4	5	6	7

C-155 OMITTED

SINCE YOU STARTED TAKING INSULIN/ORAL AGENTS

15. The last time you lost consciousness from low blood sugar reaction did you contact your doctor's office or clinic about it?

    0 I have never lost consciousness from low blood sugar reaction

    1 Yes

    2 No

    3 Other (explain)

    If yes, how long afterwards?

    1 same day

    2 within 2-3 days

    3 within a week

    4 more than a week

16. The last time you had repeated low blood sugar reactions with symptoms such as shaking, sweating or headache, did you contact your doctor's office or clinic about it?

    0 I have never experienced this

    1 Yes

    2 No

    3 Other (explain)

    If yes, how long afterwards?

    1 same day

    2 within 2-3 days

    3 within a week

    4 more than a week

17. Since your medication dosage was stabilized, the last time you had a period where you experienced increased thirst, increased urination, rapid weight loss and/or elevated glucose levels, did you contact your doctor's office or clinic about it?

    0 I have never experienced this

    1 Yes

    2 No

    3 Other (explain)

    If yes, how long afterwards?

    1 same day

    2 within 2-3 days

    3 within a week

    4 more than a week

18. The last time you had several urine/blood tests in a row with high sugar readings when doing your testing at home, did you contact your doctor's office or clinic about it?

    0 I have never experienced this

    1 Yes

    2 No

    If yes, how long afterwards?

    1 same day

    2 within 2-3 days

    3 within a week

    4 more than a week

19. The last time you had a 3+ or higher sugar reading when doing your testing at home, did you contact your doctor's office or clinic about it?

    0 I have never experienced this

    1 Yes

    2 No

    If yes, how long afterwards?

    1 same day

    2 within 2-3 days

    3 within a week

    4 more than a week

20. The last time you had a foot injury or infection, did you contact your doctor's office or clinic about it?

    0 I have never experienced this

    1 Yes

    2 No

    If yes, how long afterwards?

    1 same day

    2 within 2-3 days

    3 within a week

    4 more than a week

21. Yesterday, or on the last day you left your house, did you take something with you with sugar in it for emergencies?

    1 Yes

    2 No

22. During the last 7 days, or the last 7 days that you left the house, about what percentage of the time did you have something with you with sugar in it? _____

ACCORDING TO YOUR DOCTOR:

1. What is your ideal weight?
2. How often should you test your blood and/or urine?
3. At what times of the day in relation to meals should you test your blood and/or urine?
4. How often should you take your insulin/oral agents?
5. At what times of the day in relation to meals should you take your insulin/oral agents?

6. How often should you carry sugar with you?

CIRCLE THOSE TIMES WHEN YOUR DOCTOR OR THE CLINIC STAFF WOULD SAY YOU SHOULD CALL THE CLINIC

1. when you lose consciousness from low blood sugar?
2. when you have repeated low blood sugar reactions?
3. when you have a period of increased thirst, urination and rapid weight loss with elevated glucose levels?
4. when you have several urine/blood tests in a row with high sugar readings when doing your testing at home?
5. when you have a 3+ or higher sugar reading?
6. when you have a foot injury or infection?

INFORMANTS' COMPLIANCE QUESTIONNAIRE

NAME:.....

I would like to ask you some questions about how _____ takes care of his/her diabetes. In order for this information to be helpful to us, it must be as honest and accurate as possible. All of your answers are confidential and will not be discussed with the patient or the clinic staff.

1. About how much does he/she weight right now? _____
2. About how much did he/she weigh 6 months ago?_____
3. About how much did he/she weigh one year ago?_____
4. According to his/her doctor, does he/she weigh:
    1. too much?
    2. too little?
    3. about right?
    4. don't know.
5. Yesterday, or on the last day he/she was not sick, how many times did he/she test his/her urine or blood for sugars? _____

6. Yesterday, at which of these times did he/she test his/her urine or blood?

    1. just before breakfast
    2. just after breakfast
    3. just before lunch
    4. just after lunch
    5. just before supper
    6. just after supper
    7. at bedtime
    8. at any other time?

7. During the past 7 days, or on the last 7 days that he/she was not sick on how many days did he/she test his/her urine or blood for sugar?

    _____

8. On those days in the past week when he/she did test his/her urine o blood what was the average number of times per day he/she tested it

    _____

9. In the past 7 days, on how many days did he/she test:

1. just before breakfast	0	1	2	3	4	5	6	7
2. just after breakfast	0	1	2	3	4	5	6	7
3. just before lunch	0	1	2	3	4	5	6	7
4. just after lunch	0	1	2	3	4	5	6	7
5. just before supper	0	1	2	3	4	5	6	7
6. just after supper	0	1	2	3	4	5	6	7
7. at bedtime	0	1	2	3	4	5	6	7
8. at any other times?	0	1	2	3	4	5	6	7

10. Yesterday, or on the last day he/she was not sick, how many times did he/she inject his/her insulin or take his/her oral agents?

_____

11. Yesterday, at which of these times did he/she inject his/her insuli or take his/her oral agents?

    1. just before breakfast
    2. just after breakfast
    3. just before lunch
    4. just after lunch
    5. just before supper
    6. just after supper
    7. at bedtime
    8. at any other time

12. During the past 7 days, on how many days did he/she inject his/her insulin or take his/her oral agents? _____

13. During the past 7 days, how many times did he/she miss taking his/her insulin/oral agents at the scheduled time? _____

14. How many times did he/she inject his/her insulin or take his/her oral agents:

1. just before breakfast	0	1	2	3	4	5	6	7
2. just after breakfast	0	1	2	3	4	5	6	7
3. just before lunch	0	1	2	3	4	5	6	7
4. just after lunch	0	1	2	3	4	5	6	7
5. just before supper	0	1	2	3	4	5	6	7
6. just after supper	0	1	2	3	4	5	6	7
7. at bedtime	0	1	2	3	4	5	6	7
8. at any other times?	0	1	2	3	4	5	6	7

SINCE HE/SHE STARTED TAKING INSULIN/ORAL AGENTS

15. The last time he/she lost consciousness from low blood sugar reaction did he/she contact his/her doctor's office or clinic about it?

    0 has never lost consciousness from low blood sugar reaction

    1 Yes

    2 No

    3 Other (explain)

    If yes, how long afterwards?

    1 same day

    2 within 2-3 days

    3 within a week

    4 more than a week

16. The last time he/she had repeated low blood sugar reactions with symptoms such as shaking, sweating or headache, did he/she contact his/her doctor's office or clinic about it?

    0 has never experienced this

    1 Yes

    2 No

    3 Other (explain)

    If yes, how long afterwards?

    1 same day

    2 within 2-3 days

    3 within a week

    4 more than a week

17. Since his/her medication dosage was stabilized, the last time he/she had a period where he/she experienced increased thirst, increased urination, rapid weight loss and/or elevated glucose levels, did he/she contact his/ her doctor's office or clinic abou it?

    0 has never experienced this

    1 Yes

    2 No

    3 Other (explain)

    If yes, how long afterwards?

    1 same day

    2 within 2-3 days

    3 within a week

    4 more than a week

18. The last time he/she had several urine/blood tests in a row with high sugar readings when doing his/her testing at home, did he/she contact his/her doctor's office or clinic about it?

    0 has never experienced this

    1 Yes

    2 No

    If yes, how long afterwards?

    1 same day

    2 within 2-3 days

    3 within a week

    4 more than a week

19. The last time he/she had a 3+ or higher sugar reading when doing his/her testing at home, did he/she contact his/her doctor's offic or clinic about it?

    0 has never experienced this

    1 Yes

    2 No

    If yes, how long afterwards?

    1 same day

    2 within 2-3 days

    3 within a week

    4 more than a week

20. The last time he/she had a foot injury or infection did he/she contact his/her doctor's office or clinic about it?

    0 has never experienced this

    1 Yes

    2 No

    If yes, how long afterwards?

    1 same day

    2 within 2-3 days

    3 within a week

    4 more than a week

21. Yesterday, or on the last day he/she left his/her house, did he/sh take something along with sugar in it for emergencies?

    1 Yes

    2 No

22. During the last 7 days, or the last 7 days that he/she left the house, about what percentage of the time did he/she have something along with sugar in it? _____

APPENDIX D

Health Professionals' Ratings of Patient Compliance

PATIENT: RATER:

1. WEIGHT
   Ideal weight:
   Currently overweight: Yes No By what percentage?
   Currently underweight: Yes No By what percentage?

2. HOME URINE/BLOOD GLUCOSE TESTING
   How often does the patient actually test as often as he/she should? Don't know_____

   never _____ always

   How often does the patient test at the correct times in relation to meals? Don't know_____

   never _____ always

3. INSULIN or ORAL AGENTS
   How often does the patient actually take his/her insulin or oral agents as often as prescribed? Don't know_____

   never _____ always

   How often does the patient actually take his/her insulin or oral agents at the prescribed times? Don't know_____

   never _____ always

4. EMERGENCY SUGAR SUPPLY
   How often does the patient carry an emergency source of glucose when he/she leaves the house? Don't know_____

   never _____ always

5. OBTAINING MEDICAL CARE
   How often does the patient seek medical care when serious problems arise (such as repeated high tests, repeated hypoglycemic episodes, foot problems)? Don't know_____

   never _____ always

6. DIET(Study 2 only)
How often does the patient eat or drink more than his/her diet allows? Don't know_____

never _____ always

How often does the patient consume foods or beverages that his/her diet does not allow? Don't know_____

never _____ always

How often does the patient fail to eat a meal or snack at the proper time? Don't know_____

never _____ always

How often does the patient fail to eat meals which are properly balanced? Don't know_____

never _____ always

KNOWLEDGE(Dietitians only)
How good is the patient's knowledge of the diabetic diet?

very poor _____ very good

PHYSICIANS' PRESCRIPTION AND HEALTH STATUS RATINGS

PATIENT: PHYSICIAN:

Type: I II

1. IDEAL WEIGHT:

   Is the patient currently taking any medication which would cause weight gain or loss? Yes No If Yes, please give details:

2. HOME URINE/BLOOD GLUCOSE TESTING
   What is the frequency and timing of urine/blood testing that you have recommended?

3. INSULIN/ORAL AGENTS
   What is the frequency and timing of insulin injections or oral medications that you have recommended?

4. EMERGENCY SUGAR SUPPLY
   Should this patient carry an emergency source of glucose when he/she leave the house? Yes No

HEALTH STATUS

1. Level of Diabetic Control

0	1	2	3	4	5	6
extremely poor						extremely good

2. Diabetes related health

   Kidneys

0	1	2	3	4	5	6
extremely poor						extremely good

   Retinae

0	1	2	3	4	5	6
extremely poor						extremely good

   Neuropathies

0	1	2	3	4	5	6
extremely extensive						completely absent

3. General Health

0	1	2	3	4	5	6
extremely poor						extremely good

APPENDIX E

K Scale

		TRUE	FALSE
1.	At times my mind seems to work more slowly than usual.	T	F
2.	I have sometimes felt that difficulties were piling up so high that I could not overcome them.	T	F
3.	I have often met people who were supposed to be experts who were no better than I.	T	F
4.	I find it hard to set aside a task that I have undertaken, even for a short time.	T	F
5.	I like to let people know where I stand on things.	T	F
6.	At times I feel like swearing.	T	F
7.	At times I am full of energy.	T	F
8.	At times I feel like smashing things.	T	F
9.	I have never felt better in my life than I do now.	T	F
10.	It takes a lot of arguments to convince most people of the truth.	T	F
11.	I have periods in which I feel unusually cheerful without any special reason.	T	F
12.	I certainly feel useless at times.	T	F
13.	Criticism or scolding hurts me terribly.	T	F
14.	I think a great many people exaggerate their misfortunes in order to gain the sympathy and help of others.	T	F
15.	Often I can't understand why I have been so cross and grouchy.	T	F
16.	I get mad easily and then get over it soon.	T	F
17.	What others think of me does not bother me.	T	F
18.	I have very few quarrels with members of my family.		

K SCALE (Cont'd)

	TRUE	FALSE
19. I am against giving money to beggars.	T	F
20. At times my thoughts have raced ahead faster than I could speak them.	T	F
21. I frequently find myself worrying about something.	T	F
22. I worry over money and business.	T	F
23. It makes me impatient to have people ask my advice or otherwise interrupt me when I am working on something important.	T	F
24. People often disappoint me.	T	F
25. I often think, "I wish I were a child again".	T	F
26. I find it hard to make talk when I meet new people.	T	F
27. When in a group of people I have trouble thinking of the right things to talk about.	T	F
28. Most people will use somewhat unfair means to gain profit or an advantage rather than lose it.	T	F
29. It makes me uncomfortable to put on a stunt at a party even when others are doing the same sort of things.	T	F
30. I think nearly anyone would tell a lie to keep out of trouble.	T	F

Compliance Response Bias Scale

		TRUE	FALSE
1.	I always get the right amount of exercise every day.	T	F
2.	I always do what my doctor's office or clinic tells me to.	T	F
3.	I have made mistakes before in taking care of my health.	T	F
4.	There have been times when I have not washed my hands before eating.	T	F
5.	I inspect my gums for problems every day.	T	F
6.	Some days I do not eat the minimum daily required number of vitamins and minerals.	T	F
7.	I have never missed taking medicine when I should.	T	F
8.	At times I have eaten food that is not good for me.	T	F

APPENDIX F

Table F-1

Summary of Multitrait-Multimethod Validation - Informants' Report

	Convergent		Discriminant	
	>.40	p<.05	Heterotrait-Heteromethod	Heterotrait-Heteromethod
Weight control	2/4	3/4	16/16	15/21
Testing	0/2	1/2	10/10	8/12
Symptom-reporting	0/2	0/2	9/9	7/12
Safety	1/2	1/2	8/10	7/12

Table F-2

Summary of Multitrait-Multimethod Validation - Nurses' Ratings

	Convergent		Discriminant	
	>.40	p<.05	Heterotrait-Heteromethod	Heterotrait-Heteromethod
Weight control	2/4	3/4	22/23	20/21
Testing	0/4	3/4	19/21	17/21
Symptom-reporting	0/3	1/3	11/16	9/18
Safety	0/4	0/4	3/22	1/18

Table F-3

Summary of Multitrait-Multimethod Validation - Dietitians' Ratings

	Convergent		Discriminant	
	>.40	p<.05	Heterotrait-Heteromethod	Heterotrait-Heteromethod
Weight control	4/4	4/4	15/15	21/21
Testing	0/3	3/3	13/14	12/15
Symptom-reporting				
Safety	0/2	1/2	5/10	6/9

Table F-4

Summary of Multitrait-Multimethod Validation - Physicians' Ratings

	Convergent		Discriminant	
	>.40	p<.05	Heterotrait-Heteromethod	Heterotrait-Hetermethod
Weight control	3/4	4/4	19/19	21/21
Testing	1/3	3/3	16/17	13/15
Symptom-reporting	0/3	1/3	6/12	4/10
Safety	0/2	1/2	6/12	7/12

APPENDIX G

Intercorrelations of Compliance Measures - Pearson Correlations

	2	3	4
Physician-Determined			
1. Weight control	.10	.03	.05
2. Testing		.05	.16
3. Symptom-reporting			.10
4. Safety			
Patient-Determined			
1. Weight control	-.11	-.08	.22
2. Testing		.32*	.14
3. Symptom-reporting			.03
4. Safety			

*p<.05.

APPENDIX H

Patients' Dietary Compliance

Most people have trouble from time to time following their diets exactly. Sometimes they eat more than they should, sometimes they eat or drink things they are not allowed, sometimes they eat meals which are not balanced the way they should be, and sometimes they miss meals or are late for them.

I would like you to think back over the past seven days to last _____ and try to remember any times when you went off your diet.

1. In the past week did you ever eat or drink anything your diet does not allow?

   How many times?

2. In the past week did you eat or drink more of something than your diet allows?

   How often?

3. In the past week did you eat any meals that you thought were unbalanced?

   How often?

4. In the past week did you skip any meals?

   How many?

5. Did you eat any of your meals more than an hour later than your usual time?

   How many?

ABSTINENCE VIOLATION

1. What was it that you did that interfered with your diet? (type of food vs quantity vs lack of balance)

2. What food did you eat and how much?

3. Now describe the situation as clearly as possible, paying special attention to those factors you think may have lead you to go off your diet.

4. What time of day was it?

5. What were you doing?

6. Were other people present? Who? Were they eating? What?

7. Were you under any more stress than usual? Any special circumstances or events?

8. What was your mood like?

9. What thoughts went through your mind just before you went off your diet?

10. What thoughts or feelings did you have afterwards? Did you feel guilty?

11. How often did this exact situation happen in the past week?

12. What would you say is the main reason you went off your diet?

Here is a list of reasons other people have given for going off their diets. Circle the number beside the most important reason for going of your diet in this particular situation.

1. other people offering you something to eat or drink that your diet does not allow.
2. other people pressuring you to go off your diet
3. just being around other people who are eating or drinking things that your diet does not allow.
4. feeling hungry.
5. feeling tired, ill or in pain.
6. wanting to test your willpower or to find out what would happen.
7. giving in to temptation after seeing something that your diet does not allow.
8. giving in to temptation after thinking about something that your die does not allow.
9. trying to cope with feelings of frustration, anger or guilt arising from conflict with another person or persons.
10. trying to cope with other negative feelings arising from conflict with others (such as anxiety, fear, tension, worry, or concern)
11. trying to cope with feelings of frustration, anger or guilt arising from more purely personal problems or misfortunes.
12. trying to cope with other negative feelings arising from more personal sources (such as anxiety,fear, tension, worry, sadness, loneliness, boredom, depression, grief or loss).
13. finding it too inconvenient to obtain the proper food in the proper quantity.
14. being in a good mood and wanting to increase those good feelings by going off your diet.
15. having a good time at a party or celebration and wanting to increase those good feelings by going off your diet.
16. wanting to reward yourself for something you've done
17. finding the food you should eat unappetizing

KNOWLEDGE QUESTIONNAIRE

Circle the letter beside the answer you think is best.

1. A diabetic diet is:

   a. A guide for planning only the carbohydrate or sugar content of a meal.
   b. A well-balanced diet that the whole family can use.
   c. A carefully planned system of special dietetic foods.
   d. I don't know.

2. As a diabetic you can eat as much as you want of which ONE of the following foods:

   a. peas
   b. bananas
   c. carrots
   d. clear broth
   e. dietetic jelly
   f. I don't know

3. Fruits contain mainly carbohydrate, and one orange may be exchanged for:

   a. one banana
   b. one cup of orange juice
   c. one small apple
   d. I don't know

4. A diabetic should:

   a. eat the same foods at the same time each day.
   b. eat at the same time each day but vary the diet by substituting different foods correctly from the diet exchange list.
   c. eat only when hungry.
   d. I don't know.

5. One egg can be exchanged for:

   a. 3 ounces of meat
   b. 1 slice of chees (1 oz.)
   c. 4 tablespoons of peanut butter
   d. I don't know

6. A diabetic should never eat which of the following foods: (choose only one)

   a. rice
   b. vanilla ice cream
   c. potatoes
   d. bread
   e. marmalade
   f. I don't know

7. If your diet allows you only one teaspoon of margarine, you can:

   a. use one teaspoon of margarine in cooking.
   b. use one teaspoon of margarine on bread.
   c. do both of the above.
   d. do either one or the other but not both.
   e. none of the above.
   f. I don't know.

8. A diabetic who is nauseated or vomitting should:

   a. go to bed and not eat anything.
   b. take some fluids.

KNOWLEDGE DEMONSTRATION ITEMS

Ability to Read Labels

1. Looking at this label, can you tell me which ingredient there is most of and which ingredient least?

   Most:

   Least:

2. Can you tell me what the three types of sugar in this product are?

   1.

   2.

   3.

Ability To Select Foods According To Exchanges

1. Looking at this list of foods, tell me two that would be considered meat exchanges or that would be found on a meat exchange list.

   1.

   2.

2. Tell me two that woulld be considered fruit exchanges.

   1.

   2.

3. Tell me two that would be considered bread exchanges.

   1.

   2.

Quantity Estimation

1. Can you tell me which of these three piles of peanuts is closest to half a cup?

   1/3 1/2 2/3

2. Here is a jug of water and an empty glass. Please pour 1/2 cup of water into the glass as accurately as you can.

   < 3 1/2 oz. 3 1/2 - 4 1/2 oz. > 4 1/2 oz

INSTRUCTIONS

On the following pages you will find several different questionnaires. These are designed to find out how YOU FEEL about different things, so there are no right or wrong answers. Read each question carefully, taking as much time as you need to make sure your answers reflect what you really mean. If you find something unclear, please ask the interviewer about it. Try to answer every question and not leave any questions out.

Remember that all your answers will be kept completely anonymous and confidential.

HBM

HOW LIKELY DO YOU THINK IT IS THAT YOU WILL

1. die younger than other people?

definitely will NOT happen _____ definitely will happen

2. suffer severe loss of vision?

definitely will NOT happen _____ definitely will happen

3. have kidney problems?

definitely will NOT happen _____ definitely will happen

4. have serious problems with your legs and feet?

definitely will NOT happen _____ definitely will happen

5. have a heart attack?

definitely will NOT happen _____ definitely will happen

6. have a stroke?

definitely will NOT happen _____ definitely will happen

7. have high blood pressure?

definitely will NOT happen _____ definitely will happen

8. have problems with your gall bladder?

definitely will NOT happen _____ definitely will happen

9. have problems with your joints?

definitely will NOT happen _____ definitely will happen

V SCALE

Make a mark on the line to show how strongly you feel about the following things happening.

HOW DO YOU FEEL ABOUT

1. having more energy than now

extremely undesirable _____ extremely desirable

neutral

2. your partner or potential partners responding more favourably to your appearance than now

extremely undesirable _____ extremely desirable

neutral

3. being more self-confident than now

extremely undesirable _____ extremely desirable

neutral

4. having to spend more money on food than now

extremely undesirable _____ extremely desirable

neutral

5. being more able to be physically active than now

extremely undesirable _____ extremely desirable

neutral

6. your general mood improving

extremely undesirable _____ extremely desirable

neutral

7. your body feeling healthier than now

extremely undesirable _____ extremely desirable

neutral

8. people close to you responding more favourably to how you manage your diet and weight than now

extremely undesirable _____ extremely desirable

neutral

HOW DO YOU FEEL ABOUT:

9. having to deny yourself your favourite foods more often than now

extremely undesirable _____ extremely desirable

neutral

10. your diet creating more inconvenience for others than now

extremely undesirable _____ extremely desirable

neutral

11. being more pleased with your appearance than now

extremely undesirable _____ extremely desirable

neutral

12. being more able than now to AVOID health problems related to being overweight (such as high blood pressure, stroke, heart disease, problems with gall bladder and joints)

extremely undesirable _____ extremely desirable

neutral

13. adding years to your life

extremely undesirable _____ extremely desirable

neutral

14. being more pleased with your eating habits than now

extremely undesirable _____ extremely desirable

neutral

15. people in general responding to your appearance more favourably than now

extremely undesirable _____ extremely desirable

neutral

16. feeling hungry more often than now

extremely undesirable _____ extremely desirable

neutral

17. your choices in what you can eat and drink being more restricted than now

extremely undesirable _____ extremely desirable

neutral

HOW DO YOU FEEL ABOUT:

18. being more able to have a good sex life than now

extremely undesirable _____ extremely desirable

neutral

19. being more able than now to AVOID health problems related to diabetes (such as kidney disease, eye problems, and loss of limbs)

extremely undesirable _____ extremely desirable

neutral

20. being more able to fulfill your responsibilities than now

extremely undesirable _____ extremely desirable

neutral

21. your doctor and the clinic staff responding more favourably to how you manage your diet and weight than now

extremely undesirable _____ extremely desirable

neutral

22. having to spend more money on clothes than now

extremely undesirable _____ extremely desirable

neutral

23. having to spend more time organizing and cooking meals than now

extremely undesirable _____ extremely desirable

neutral

24. your eating habits being more different from those of other people than they are now

extremely undesirable _____ extremely desirable

neutral

25. being closer to your ideal weight than now

extremely undesirable _____ extremely desirable

neutral

IF YOU TAKE INSULIN

HOW DO YOU FEEL ABOUT

1. being able to take less insulin than now

extremely undesirable _____ extremely desirable

neutral

2. having fewer insulin reactions than now

extremely undesirable _____ extremely desirable

neutral

3. being more able than now to go off insulin someday

extremely undesirable _____ extremely desirable

neutral

IF YOU TAKE PILLS FOR YOUR DIABETES

HOW DO YOU FEEL ABOUT

1. being more able than now to avoid having to take insulin someday

extremely undesirable _____ extremely desirable

neutral

2. being more able than now to avoid reactions

extremely undesirable _____ extremely desirable

neutral

IF YOUR DIABETES IS BEING MANAGED BY DIET ALONE

HOW DO YOU FEEL ABOUT:

1. being more able than now to avoid having to take insulin someday

extremely undesirable _____ extremely desirable

neutral

2. being more able than now to avoid having to take pills someday

extremely undesirable _____ extremely desirable

neutral

E SCALE

Make a mark on the line to show HOW LIKELY you think it is that these things would happen as a result of following your diet exactly.

IF YOU FOLLOWED YOUR DIET EXACTLY, HOW LIKELY IS IT THAT

1. you would have more energy than now

definitely would NOT happen _____ definitely would happen

2. your partner or potential partners would respond more favourably to your appearance than now

definitely would NOT happen _____ definitely would happen

3. you would be more self-confident than now

definitely would NOT happen _____ definitely would happen

4. you would have to spend more money on food than now

definitely would NOT happen _____ definitely would happen

5. you would be able to be more physically active than now

definitely would NOT happen _____ definitely would happen

6. your general mood would improve

definitely would NOT happen _____ definitely would happen

7. your body would feel healthier than now

definitely would NOT happen _____ definitely would happen

8. people close to you would respond more favourably to how you manage your diet and weight than now

definitely would NOT happen _____ definitely would happen

IF YOU FOLLOWED YOUR DIET EXACTLY, HOW LIKELY IS IT THAT:

9. you would have to deny yourself your favourite foods more often than now

definitely would NOT happen _____ definitely would happen

10. your diet would create more inconvenience for others than now

definitely would NOT happen _____ definitely would happen

11. you would be more pleased with your appearance than now

definitely would NOT happen _____ definitely would happen

12. you would be more able than now to avoid health problems related to being overweight (such as high blood pressure,stroke, heart disease, gall bladder and joint problems)

definitely would NOT happen _____ definitely would happen

13. you would add years to your life

definitely would NOT happen _____ definitely would happen

14. you would be more pleased with your eating habits than now

definitely would NOT happen _____ definitely would happen

15. people in general would respond to your appearance more favourably than now

definitely would NOT happen _____ definitely would happen

16. you would feel hungry more often than now

definitely would NOT happen _____ definitely would happen

IF YOU FOLLOWED YOUR DIET EXACTLY,HOW LIKELY IS IT THAT:

17. your choices in what you can eat and drink would be more restricted than now

definitely would NOT happen _____ definitely would happen

18. you would be more able to have a good sex life than now

definitely would NOT happen _____ definitely would happen

19. you would be more able to avoid health problems related to diabetes (such as kidney disease, eye problems and loss of limbs)than now

definitely would NOT happen _____ definitely would happen

20. you would be more able to fulfill your responsibilities than now

definitely would NOT happen _____ definitely would happen

21. your doctor and the clinic staff would respond more favourably than now to how you manage your diet and weight

definitely would NOT happen _____ definitely would happen

22. you would have to spend more money on clothes than now

definitely would NOT happen _____ definitely would happen

23. you would have to spend more time organizing and cooking meals than now

definitely would NOT happen _____ definitely would happen

24. your eating habits would be more different from those of other people than they are now

definitely would NOT happen _____ definitely would happen

25. you would be closer to your ideal weight than now

definitely would NOT happen _____ definitely would happen

IF YOU TAKE INSULIN

IF YOU FOLLOWED YOUR DIET EXACTLY, HOW LIKELY IS IT THAT:

1. you would be more able than now to take less insulin

definitely would NOT happen _____ definitely would happen

2. you would have fewer insulin reactions than now

definitely would NOT happen _____ definitely would happen

3. you would be more able than now to go off insulin completely

definitely would NOT happen _____ definitely would happen

IF YOU TAKE PILLS FOR YOUR DIABETES

IF YOU FOLLOWED YOUR DIET EXACTLY, HOW LIKELY IS IT THAT:

1. you would be more able than now to avoid having to take insulin someday

definitely would NOT happen _____ definitely would happen

2. you would be more able than now to avoid reactions

definitely would NOT happen _____ definitely would happen

IF YOUR DIABETES IS BEING MANAGED BY DIET ALONE

IF YOU FOLLOWED YOUR DIET EXACTLY, HOW LIKELY IS IT THAT:

1. you would be more able than now to avoid having to take insulin someday

definitely would NOT happen _____ definitely would happen

2. you would be more able than now to avoid having to take pills someday

definitely would NOT happen _____ definitely would happen

SEQ

In this questionnaire, we would like to find out how you feel about your own ABILITIES with respect to diet and weight control. Make a mark on the line to show HOW LIKELY it is you will be able to do these things

1. How likely is it that you will be able to achieve the ideal weight prescribed for you?

definitely will NOT happen _____ definitely will happen

2. How likely is it that you will be able to maintain that ideal weight?

definitely will NOT happen _____ definitely will happen

3. How likely is it that you will always be able to avoid eating and drinking more than your diet allows?

definitely will NOT happen _____ definitely will happen

4. How likely is it that you will always be able to avoid eating and drinking foods and beverages that your diet does not allows?

definitely will NOT happen _____ definitely will happen

5. How likely is it that you will always eat your meals and snacks at the right times?

definitely will NOT happen _____ definitely will happen

6. How likely is it that you will always eat properly balanced meals?

definitely will NOT happen _____ definitely will happen

7. How likely is it that you will always be able to follow your diet exactly?

definitely will NOT happen _____ definitely will happen

How likely is it that YOU WILL BE ABLE TO FOLLOW YOUR DIET EXACTLY when:

1. you are trying to cope with feelings of frustration, anger or guilt arising from conflict with another person or persons.

definitely would NOT be able to _____ definitely would be able to

2. you are trying to cope with other negative feelings arising from conflict with others (such as anxiety,fear,tension, worry or concern)

definitely would NOT be able to _____ definitely would be able to

3. you are trying to cope with feelings of frustration, anger or guilt arising from more purely personal problems or misfortunes.

definitely would NOT be able to _____ definitely would be able to

4. you are trying to cope with other negative feelings arising from more purely personal sources(such as anxiety,fear, tension, worry, depression, sadness, loneliness, boredom,grief or loss)

definitely would NOT be able to _____ definitely would be able to

5. other people are offering you something to eat or drink that your diet does not allow.

definitely would NOT be able to _____ definitely would be able to

6. other people are pressuring you to eat or drink something that your diet does not allow.

definitely would NOT be able to _____ definitely would be able to

7. you are having a good time at a party or celebration and want to increase those good feelings by eating or drinking something that your diet does not allow.

definitely would NOT be able to _____ definitely would be able to

8. you are in a good mood and want to increase those good feelings by eating or drinking something that your diet does not allow

definitely would NOT be able to _____ defintiely would be able to

How likely is it that YOU WILL BE ABLE TO FOLLOW YOUR DIET EXACTLY when:

9. you are with other people who are eating or drinking something that your diet does not allow.

definitely would NOT be able to _____ definitely would be able to

10. you are feeling hungry

definitely would NOT be able to _____ definitely would be able to

11. you are feeling tired, ill or in pain.

definitely would NOT be able to _____ definitely would be able to

12. you want to test your willpower or to find out what would happen.

definitely would NOT be able to _____ definitely would be able to

13. you are tempted by seeing some type of food or drink that your diet does not allow

definitely would NOT be able to _____ definitely would be able to

14. you are tempted just by thinking about something that your diet does not allow

definitely would NOT be able to _____ definitely would be able to

15. you find it too inconvenient to eat the proper foods in the proper quantity

definitely would NOT be able to _____ definitely would be able to

16. you want to reward yourself for something you've done

definitely would NOT be able to _____ definitely would be able to

17. you find the food you should eat unappetizing

definitely would NOT be able to _____ definitely would

Revised Restraint Scale

Circle the answer which is most true for you.

1. How often are you dieting?

   never rarely sometimes often always

2. What is the maximum amount of weight (in pounds) that you have ever lost within one month?

   0 - 4 5 - 9 10 - 14 15 - 19 20+

3. What is the maximum weight gain within a week?

   0 - 1 1.1 - 2 2.1 - 3 3.1 - 5 5.1+

4. In a typical week, how much does your weight fluctuate?

   0 - 1 1.1 - 2 2.1 - 3 3.1 - 5 5.1+

5. Would a weight fluctuation of 5 pounds affect the way you live your life?

   not at all slightly moderately very much

6. Do you eat sensibly in front of others and splurge alone?

   never rarely often always

7. Do you give too much time and thought to food?

   never rarely often always

8. Do you have feelings of guilt after overeating?

   never rarely often always

9. How conscious are you of what you are eating?

   not at all slightly moderately extremely

10. How many pounds over your desired weight were you at your maximum weight?

    0 - 1 1 - 5 6 - 10 11 - 20 21+

Weight Locus of Control Scale

Circle a number between 1 and 6 showing how much you agree or disagree with the following statements.

1. Whether I gain, lose, or maintain my weight is entirely up to me.

1	2	3	4	5	6
strongly disagree					strongly agree

2. Being the right weight is largely a matter of good fortune.

1	2	3	4	5	6
strongly disagree					strongly agree

3. No matter what I intend to do, if I gain or lose weight, or stay the same in the near future, it is just going to happen.

1	2	3	4	5	6
strongly disagree					strongly agree

4. If I eat properly and get enough exercise and rest, I can control my weight in the way I desire.

1	2	3	4	5	6
strongly disagree					strongly agree

Health Locus of Control Scale

1. If I take care of myself, I can avoid illness.

1	2	3	4	5	6
strongly disagree					strongly agree

2. Whenever I get sick it is because of something I've done or not done.

1	2	3	4	5	6
strongly disagree					strongly agree

3. Good health is largely a matter of good fortune.

1	2	3	4	5	6
strongly disagree					strongly agree

4. No matter what I do, if I am going to get sick, I will get sick.

1	2	3	4	5	6
strongly disagree					strongly agree

5. Most people do not realize the extent to which their illnesses are controlled by accidental happenings.

1	2	3	4	5	6
strongly disagree					strongly agree

6. I can only do what my doctor tells me to do.

1	2	3	4	5	6
strongly disagree					strongly agree

7. There are so many strange diseases around that you can never know how or when you might pick one up.

1	2	3	4	5	6
strongly disagree					strongly agree

8. When I feel ill, I know it is because I have not been getting the proper exercise or eating right.

1	2	3	4	5	6
strongly disagree					strongly agree

9. People who never get sick are just plain lucky.

1	2	3	4	5	6
strongly disagree					strongly agree

10. People's ill health results from their own carelessness.

1	2	3	4	5	6
strongly disagree					strongly agree

11. I am directly responsible for my health.

1	2	3	4	5	6
strongly disagree					strongly agree

Frequency of Self-Reinforcement Scale

Below are a number of statements concerning beliefs or attitudes people have. Indicate whether the statements are characteristic and descriptive of you by circling T if the statement is somwhat or very true for yourself. Circle F if the statement is somewhat or very false for yourself. Please be as honest as possible.

		TRUE	FALSE
1.	When I fail at something, generally I am still able to feel good about myself.	T	F
2.	I can stick to a tiresome task that I need to complete for a long time without someone encouraging me.	T	F
3.	I don't often think positive thoughts about myself.	T	F
4.	When I do something right, I take time to enjoy the feeling.	T	F
5.	I have such high standards for what I demand of myself that I rarely meet those standards.	T	F
6.	I seem to blame myself when things go wrong and am very critical of myself.	T	F
7.	There are pleasureable activities which I enjoy doing alone at my leisure.	T	F
8.	I usually get upset when I make mistakes because I rarely learn from them.	T	F
9.	My feelings of self-confidence and self-esteem fluctuate a great deal.	T	F
10.	When I succeed at small things I become encouraged to go on.	T	F
11.	Unless I do something absolutely perfectly, it gives me little pleasure.	T	F
12.	I get myself through hard things mostly by planning to enjoy myself afterwards.	T	F
13.	When I make mistakes, I take time to criticize myself.	T	F
14.	I encourage myself to improve by feeling good about myself or giving myself something special whenever I make some progress.	T	F

15. If I didn't criticize myself frequently, I would continue to do things poorly forever. T F

16. I think talking about what you've done right is being too boastful. T F

17. I find I feel better and do better when I silently praise myself for even small achievements. T F

18. I can keep trying at something when I stop to think of what I've accomplished. T F

19. The way I keep up my confidence is by acknowleding any success I have. T F

20. The way I achieve my goals is by rewarding myself every step along the way. T F

21. Praising yourself is being selfish and egotistical. T F

22. When someone criticizes me, my self-confidence is shattered. T F

23. I criticize myself more frequently than others criticize me. T F

24. I have a lot of worthwhile qualities. T F

25. I silently praise myself even when others do not praise me. T F

26. Any activity can provide some pleasure regardless of how it comes out. T F

27. If I don't do the best possible job, I think less of myself. T F

28. I should be upset if I make a mistake. T F

29. My happiness depends more on myself than it does on other people. T F

30. People who talk about their own better points are just bragging. T F

APPENDIX I
DIABETES SELF-CARE STUDY

Non-Patient Information Sheet

The treatment of diabetes mellitus requires that patients carefully follow a diet and achieve and maintain an optimal body weight. To help us better understand the problems diabetics have in controlling their diet and weight we also wish to discuss these isssues with people who are non-diabetic. We are interested in knowing how you actually manage your diet and weight. We need accurate information about the times when you eat well and the times when you have problems with your eating habits.

If you participate in our interview, we guarantee that your answers will be kept completely confidential and anonymous. At any time in the interview you will be free to withdraw from participation.

Your co-operation in this project will in the future benefit both diabetics and non-diabetics in helping them learn better ways to control their diet and weight. Please sign your name below if you are willing to participate.

_____

Subject's signature

DIETARY COMPLIANCE

It is generally accepted that the best way for people to manage their diet and weight is to follow a well-balanced diet, to eat regular meals, to watch the amount they eat, and to avoid foods and beverages which are high in fats and refined sugars. We are interested in finding out the extent to which you follow such an ideal diet and your attitude and feelings about doing so.

Most people have trouble from time to time following their diets exactly. Sometimes they eat more than they should, sometimes they eat or drink things they are not allowed, sometimes they eat meals which are not balanced the way they should be, and sometimes they miss meals or are late for them.

I would like you to think back over the past seven days to last _____ and try to remember any times when you went off your diet.

1. In the past week did you ever eat or drink anything your diet does not allow?

   How many times?

2. In the past week did you eat or drink more of something than your diet allows?

   How often?

3. In the past week did you eat any meals that you thought were unbalanced?

   How often?

4. In the past week did you skip any meals?

   How many?

5. Did you eat any of your meals more than an hour later than your usual time?

   How many?

SEQ

In this questionnaire, we would like to find out how you feel about your own ABILITIES with respect to diet and weight control. Make a mark on the line to show HOW LIKELY it is you will be able to do these things

1. How likely is it that you will be able to achieve your medically ideal weight?

definitely will NOT happen _____ definitely will happen

2. How likely is it that you will be able to maintain that ideal weight?

definitely will NOT happen _____ definitely will happen

3. How likely is it that you will always be able to avoid eating and drinking more than an ideal diet would allow?

definitely will NOT happen _____ definitely will happen

4. How likely is it that you will always be able to avoid eating and drinking foods and beverages that an ideal diet does not allow?

definitely will NOT happen _____ definitely will happen

5. How likely is it that you will always eat your meals regularly?

definitely will NOT happen _____ definitely will happen

6. How likely is it that you will always eat well balanced meals?

definitely will NOT happen _____ definitely will happen

7. How likely is it that you will always be able to follow an ideal diet exactly?

definitely will NOT happen _____ definitely will happen

How likely is it that YOU WILL BE ABLE TO FOLLOW AN IDEAL DIET EXACTLY when:

1. you are trying to cope with feelings of frustration, anger or guilt arising from conflict with another person or persons.

definitely would NOT be able to _____ definitely would be able to

2. you are trying to cope with other negative feelings arising from conflict with others (such as anxiety,fear,tension, worry or concern)

definitely would NOT be able to _____ definitely would be able to

3. you are trying to cope with feelings of frustration, anger or guilt arising from more purely personal problems or misfortunes.

definitely would NOT be able to _____ definitely would be able to

4. you are trying to cope with other negative feelings arising from more purely personal sources(such as anxiety,fear, tension, worry, depression, sadness, loneliness, boredom,grief or loss)

definitely would NOT be able to _____ definitely would be able to

5. other people are offering you something to eat or drink that your diet does not allow.

definitely would NOT be able to _____ definitely would be able to

6. other people are pressuring you to eat or drink something that your diet does not allow.

definitely would NOT be able to _____ definitely would be able to

7. you are having a good time at a party or celebration and want to increase those good feelings by eating or drinking something that your diet does not allow.

definitely would NOT be able to _____ definitely would be able to

8. you are in a good mood and want to increase those good feelings by eating or drinking something that your diet does not allow

definitely would NOT be able to _____ defintiely would be able to

How likely is it that YOU WILL BE ABLE TO FOLLOW AN IDEAL DIET EXACTLY when:

9. you are with other people who are eating or drinking something that your diet does not allow.

definitely would NOT be able to _____ definitely would be able to

10. you are feeling hungry

definitely would NOT be able to _____ definitely would be able to

11. you are feeling tired, ill or in pain.

definitely would NOT be able to _____ definitely would be able to

12. you want to test your willpower or to find out what would happen.

definitely would NOT be able to _____ definitely would be able to

13. you are tempted by seeing some type of food or drink that your diet does not allow

definitely would NOT be able to _____ definitely would be able to

14. you are tempted just by thinking about something that your diet does not allow

definitely would NOT be able to _____ definitely would be able to

15. you find it too inconvenient to eat the proper foods in the proper quantity

definitely would NOT be able to _____ definitely would be able to

16. you want to reward yourself for something you've done

definitely would NOT be able to _____ definitely would be able to

17. you find the food you should eat unappetizing

definitely would NOT be able to _____ definitely would

E SCALE

Make a mark on the line to show HOW LIKELY you think it is that these things would happen as a result of following an ideal diet exactly.

IF YOU FOLLOWED AN IDEAL DIET EXACTLY, HOW LIKELY IS IT THAT:

1. you would have more energy than now

definitely would NOT happen _____ definitely would happen

2. your partner or potential partners would respond more favourably to your appearance than now

definitely would NOT happen _____ definitely would happen

3. you would be more self-confident than now

definitely would NOT happen _____ definitely would happen

4. you would have to spend more money on food than now

definitely would NOT happen _____ definitely would happen

5. you would be able to be more physically active than now

definitely would NOT happen _____ definitely would happen

6. your general mood would improve

definitely would NOT happen _____ definitely would happen

7. your body would feel healthier than now

definitely would NOT happen _____ definitely would happen

8. people close to you would respond more favourably to how you manage your diet and weight than now

definitely would NOT happen _____ definitely would happen

IF YOU FOLLOWED AN IDEAL DIET EXACTLY HOW LIKELY IS IT THAT:

9. you would have to deny yourself your favourite foods more often than now

definitely would NOT happen _____ definitely would happen

10. your diet would create more inconvenience for others than now

definitely would NOT happen _____ definitely would happen

11. you would be more pleased with your appearance than now

definitely would NOT happen _____ definitely would happen

12. you would be more able than now to AVOID health problems related to being overweight (such as high blood pressure,stroke, heart disease, gall bladder and joint problems)

definitely would NOT happen _____ definitely would happen

13. you would add years to your life

definitely would NOT happen _____ definitely would happen

14. you would be more pleased with your eating habits than now

definitely would NOT happen _____ definitely would happen

15. people in general would respond to your appearance more favourably than now

definitely would NOT happen _____ definitely would happen

16. you would feel hungry more often than now

definitely would NOT happen _____ definitely would happen

IF YOU FOLLOWED AN IDEAL DIET EXACTLY HOW LIKELY IS IT THAT:

26. you would be more able to AVOID developing diabetes

definitely would NOT happen _____ definitely would happen

18. you would be more able to have a good sex life than now

definitely would NOT happen _____ definitely would happen

19. you would be more able to AVOID health problems related to diabetes (such as kidney disease, eye problems and loss of limbs)than now

definitely would NOT happen _____ definitely would happen

20. you would be more able to fulfill your responsibilities than now

definitely would NOT happen _____ definitely would happen

21. your doctor and the clinic staff would respond more favourably than now to how you manage your diet and weight

definitely would NOT happen _____ definitely would happen

22. you would have to spend more money on clothes than now

definitely would NOT happen _____ definitely would happen

23. you would have to spend more time organizing and cooking meals than now

definitely would NOT happen _____ definitely would happen

24. your eating habits would be more different from those of other people than they are now

definitely would NOT happen _____ definitely would happen

25. you would be closer to your ideal weight than now

definitely would NOT _____ definitely

APPENDIX J

Construction of Health Belief Scales

Perceived severity

Scores on the perceived severity scale represented the mean value assigned to the following health outcome items:

7. being more able than now to AVOID health problems related to being overweight (such as high blood pressure, stroke, heart disease, problems with gall bladder and joints)
12. adding years to your life
13. your body feeling healthier than now
19. being more able than now to AVOID health problems related to diabetes (such as kidney disease, eye problems, and loss of limbs)

Perceived treatment efficacy

Scores on the perceived treatment efficacy scale represented the mean likelihood that the following outcomes would occur if the diet was followed exactly:

7. your body would feel healthier than now
12. you would be more able than now to AVOID health problems related to being overweight (such as high blood pressure,stroke, heart disease gall bladder and joint problems)
13. you would add years to your life
19. you would be more able to AVOID health problems related to diabetes (such as kidney disease, eye problems and loss of limbs)than now

Perceived vulnerability

Scores on the perceived vulnerability scale represented the mean likelihood that the following health outcomes would ensue without reference to treatment behaviour:

How likely do you think it is that you will

1. die younger than other people?
2. suffer severe loss of vision?
3. have kidney problems?
4. have serious problems with your legs and feet?
5. have a heart attack?
6. have a stroke?
7. have high blood pressure?
8. have problems with your gall baldder
9. have problems with your joints?

Perceived benefits

The value assigned to each of the following outcomes was multiplied by the probability that it would occur if the diet was followed exactly. Scores on the perceived benefits scale represented the mean of these expectancy-values.

1. having more energy than now.
2. your partner or potential partners responding more favourably to you appearance than now
3. being more self-confident than now
5. being more able to be physically active than now
6. your general mood improving
8. people close to you responding more favourably to how you manage you diet and weight than now

14. being more pleased with your eating habits than now
15. people in general responding to your appearance more favourably than now
18. being more able to have a good sex life than now
20. being more able to fulfill your responsibilities than now
21. your doctor and the clinic staff responding more favourably to how you manage your diet and weight than now

Perceived costs

The value assigned to each of the following outcomes was multiplied by the probability that it would occur if the diet was followed exactly. Scores on the perceived benefits scale represented the mean of these expectancy-values.

4. having to spend more money on food than now

having to deny yourself your favourite foods more often than now

10. your diet creating more inconvenience for others than now
16. feeling hungry more often than now
17. your choices in what you can eat and drink being more restricted than now
22. having to spend more money on clothes than now
23. having to spend more time organizing and cooking meals than now
24. your eating habits being more different from those of other people than they are now

Relapse and situational self-efficacy category items

Negative emotional states

9. trying to cope with feelings of frustration, anger or guilt arising from conflict with another person or persons.

10. trying to cope with other negative feelings arising from conflict with others (such as anxiety, fear, tension, worry, or concern)

11. trying to cope with feelings of frustration, anger or guilt arising from more purely personal problems or misfortunes.

12. trying to cope with other negative feelings arising from more personal sources (such as anxiety,fear, tension, worry, sadness, loneliness, boredom, depression, grief or loss).

Positive emotional states

14. being in a good mood and wanting to increase those good feelings by going off your diet.

15. having a good time at a party or celebration and wanting to increase those good feelings by going off your diet.

16. wanting to reward yourself for something you've done

Negative physiological states

4. feeling hungry.

5. feeling tired, ill or in pain.

Social pressure

1. other people offering you something to eat or drink that your diet does not allow.

2. other people pressuring you to go off your diet

3. just being around other people who are eating or drinking things that your diet does not allow.

Temptations and urges

6. wanting to test your willpower or to find out what would happen.

7. giving in to temptation after seeing something that your diet does not allow.

8. giving in to temptation after thinking about something that your die does not allow.

17. finding the food you should eat unappetizing

Inconvenience

13. finding it too inconvenient to obtain the proper food in the proper quantity.

APPENDIX K

QUESTIONNAIRE ITEMS BY SOURCE - STUDY 1

WEIGHT CONTROL ITEMS

Self-Report: About how much do you weigh right now?

Informants' Report: About how much does _____weigh right now?

Health Professionals Ratings: Patient's Ideal Weight:
Currently overweight? Yes No By what percentage
Currently underweight? Yes No By what percentage

TESTING ITEMS

Self-Report: How many times in the past week did you test your urine/blood?
At what times in the past week did you test your urine/blood?

Informants' Report: How many times in the past week did _____ test his/her urine/blood?
At what times in the past week did _____ test his/her urine/blood?

Health Professionals Ratings: How often does the patient actually test as often as he/she should? never_____always
How often does the patient test at the correct times in relation to meals? never_____always

SYMPTOM-REPORTING ITEMS

Self-Report: Did you contact your doctor's office or clinic about (losing consciousness from low blood sugar reactions) (repeated low blood sugar reactions)(symptoms of high blood sugar)(high sugar readings)(3+ sugar reading) (foot injuries or infections)?

Informants' Report: Did _____contact the doctor's office or clinic about (losing consciousness from low blood sugar reactions (repeated low blood sugar reactions)(symptoms of high blood sugar)(high sugar readings) (3+ sugar reading) (foot injuries or infections)?

Health Professionals Ratings: How often does the patient seek medical care when serious problems arise (such as repeated high tests, repeated hypoglycemic episodes, foot problems)? never_____always

SAFETY ITEMS

Self-Report: During the last 7 days, or the last 7 days that you left the house, about what percentage of the time did you have something with you with sugar in it?

Informants' Report: During the last 7 days, or the last 7 days that _____left the house, about what percentage of the time did _____have something with him/her with sugar in it?

Health Professionals Ratings: How often does the patient carry an emergency source of glucose when he/she leaves the house?
never_____always