COMPLIANCE WITH CHRONIC DIETARY REGIMENS:

MEASUREMENT, PREDICTION, AND OUTCOME

By

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COMPLIANCE WITH CHRONIC DIETARY REGIMENS
You will be flogged for being right and flogged for being wrong, and it hurts both ways - but it doesn't hurt as much when you're right.

Hunter S. Thompson,

*Generation of swine*
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Abstract

Compliance has been defined as "... the extent to which a person's behavior coincides with medical or health advice" (Haynes, 1979, pp. 1-2) and is an important area of research in behavioral medicine. There are several key issues involved in compliance research. Specifically these are: 1) How do we define and measure compliance?; 2) how can we predict compliance?; and 3) does compliance lead to a better outcome than does noncompliance? This dissertation focuses on the question of what does psychology have to contribute to our understanding of these issues? The first study investigated the amount of agreement between the various definitions of dietary compliance in patients on hemodialysis. It demonstrated that one reason why there is so little agreement on the factors that predict compliance is that researchers in this area define compliance in very different ways. The second study explored the possibility of using outcome to provide an objective definition of compliance. It was found that dietary compliance is not related to outcome for hemodialysis patients. The third study focused on the use of self-efficacy to predict compliance in patients with Type 2 diabetes mellitus, a condition where dietary compliance may be easily measured. The results suggested that gender differences influenced the
predictive power of self-efficacy. The interaction between gender and self-efficacy was confirmed in a laboratory task as well. Much of the experimental research on dieting and weight regulation ignores the potential impact of gender differences. The results of these studies suggest other paths for future research and also demonstrate that psychology can make a valuable contribution to research on compliance with chronic dietary regimens.
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Chapter 1

Review of psychological research on dietary compliance

Attempts to maintain control of the quantity or quality of their diets are part of the lives of many North Americans. For most, it is a voluntary attempt to control weight (Jeffery et al., 1984; Polivy & Herman, 1987; Schachter, 1982). There are, however, a significant number of people for whom dieting is a much more demanding activity. Their dieting is not motivated by their moods, the demands of fashion, or the latest diet craze but rather by the need to control or treat a serious and chronic medical condition. For this group, dieting is not a short-term endeavor; in many cases they must diet for the rest of their lives. Furthermore, if they fail to diet it is believed that they may suffer adverse consequences including serious medical complications or death (e.g., Kidney Foundation of Canada, 1983).

This dissertation will examine compliance with chronic diets prescribed for medical reasons and will attempt to address several related issues. One of the key issues to be discussed is the measurement of dietary compliance. Before attempting to employ psychological
constructs to predict dietary compliance we must first have a reliable and valid method of measuring compliance. This first chapter provides an introduction to psychological research on dieting and dietary compliance. The first issue which will be examined is the problem of measuring the degree to which a patient follows the diet. A reliable and valid method of measurement is a pre-requisite to progress. It will be argued that lack of agreement on measurement methods has impeded research in dietary compliance in hemodialysis. A method of empirically defining dietary compliance, in terms of outcome, will be investigated. The ability to predict dietary compliance by diabetics using a personality measure will then be examined. The results obtained with diabetic patients in a clinical setting will be replicated using obese non-diabetics and a standard laboratory procedure. This research uses a variety of methods to examine several key issues; specifically measurement, prediction, and outcome in the area of compliance with chronic dietary regimens.

There are several, largely independent, lines of research in progress on dieting and dietary compliance. While one might hope that researchers investigating related problems would share their findings this does not
seem to have been the case. Those conducting one line of research often seem to have little awareness of what researchers in the other areas are doing - nor do they express much interest in other areas of research. This lack of communication across sub-disciplines is not a new development (e.g., Cronbach, 1954, 1958). The two areas which must be discussed here can be broadly divided into the personality psychology and the dietary compliance approaches. The next section will define each of these areas more precisely and provide a brief overview.

1.1 Overview of the lines of research

There are many experimental laboratory studies in the psychological literature as well as clinical studies on weight reduction. Many of the clinical studies are not primarily concerned with dieting or obesity, instead they often focus on the evaluation of techniques to help modify people's behavior (e.g., Wilson, 1978). By using obese people who wish to lose weight they gain a large supply of subjects and an easily measured outcome variable. Because the focus of this dissertation is on what the experimental personality psychology approach has to offer those who are interested in compliance this section will focus on the personality research.
1.1.1 Personality psychology approach

1.1.1.1 Externality theory

There are two psychological theories of obesity and dieting which have been the focus of a great deal of research. The first of these is externality theory which was developed by Schachter and Nisbett (Nisbett, 1968; Schachter, 1971; Schachter, Goldman, & Gordon, 1968). The second theory is restraint theory, developed by Herman and Polivy (Herman & Mack, 1975; Herman & Polivy, 1975; Herman, Polivy, Pliner, Threlkeld, & Munic, 1978), which presents an alternative interpretation of previous findings on the eating behavior of obese persons.

One problem in reading about weight loss dieting is that some studies have defined their subject population as "obese" rather than as "dieters." Although arriving at a definition of obesity may seem to be easy it is, in fact, very complicated to develop a definition of obesity which achieves general acceptance (see Foster & Burton, 1985; Kraemer, Berkowitz, & Hammer, 1990a; National Institutes of Health, 1985; Rookus, Burema,
Deurenberg, & Wiel-Wetzels, 1985). As will be seen later, restraint theory provides a way to eliminate this confusion: it suggests that most obese people are dieters. Support for this suggestion is provided by Ruderman and Christensen (1983) who had to screen approximately 500 people in order to find 11 obese subjects who were not dieting.

Stunkard and Koch (1984) found that there was a very weak relationship between stomach contractions, as measured with an inflatable balloon, and self-reports of hunger by obese persons in contrast to the non-obese. Stunkard later concluded that the perception of gastric motility has little relationship to hunger or food intake (Stunkard & Fox, 1971). His original paper prompted people to search for other possible hunger cues. If obese people's hunger is not related to internal cues such as stomach contractions then what causes an obese person to eat? Since the original paper by Stunkard and Koch (1984) many researchers have searched for other internal cues which might influence food consumption and body fat regulation (for reviews see Bray, 1989; Grossman, 1982; Keesey & Powley, 1986; Stallone & Stunkard, 1991). The original Stunkard
and Koch paper is important, however, because it prompted others to consider the importance of internal and external cues related to food consumption.

Schachter (1971) and his colleagues felt that obese people's eating behavior, rather than being completely controlled by internal cues, might be influenced by external cues. A long series of studies has demonstrated that the obese are more sensitive to external food cues than are the non-obese. For example, when food is highly visible (an external cue) the obese eat more than when food cues are less salient; normals are less affected by the manipulation of salience (Ross, 1974; Schachter, 1971; Schachter & Friedman, 1974). Furthermore, Schachter, Goldman, and Gordon (1968) found that fear (an internal state) had a much greater effect on the eating behavior of normals than on the obese. Thus external cues appear to be an important factor in the eating behavior of the obese (see also Herman, Olmsted, & Polivy, 1983).

The obese, however, are not just more sensitive to external cues when it comes to eating; they seem to be more sensitive to external cues in general.
Overweight subjects were more readily distracted by emotionally upsetting material which was presented while they were engaged in a proofreading task. When there were no distractions the obese actually outperformed the normals (Rodin, 1973).

Food taste is another external cue which has received some attention. Nisbett (1980) found that the eating behavior of obese subjects was more affected by taste than was the eating behavior of non-obese subjects. The obese tended to eat less poor-tasting food than the normals did but they ate more of the good-tasting food than normals (Schachter, 1971; see also Spiegel, Shrager, & Stellar, 1989).

Conger, Conger, Costanzo, Wright, and Matter (1980) examined the influence of a model on eating behavior. They found that the eating behavior of obese and non-obese people is affected by a model but their research did not support externality theory which states that the obese will be more responsive to external cues than the non-obese. They suggested that externality theory applies only to purely sensory cues, not to social cues (Conger et al., 1980, p. 268). In contrast, Herman, Olmsted, and
Polivy (1983) found that both sensory and social cues influenced the selection of desserts by obese subjects.

Externality theory has inspired a great deal of research, not all of which have been supportive of the theory. Rodin (1981) presented a concise summary of the criticisms which have been directed at the externality theory. She pointed out that not all obese people are strongly affected by external cues and not all normal people are completely under the control of internal cues. It also appears that the distinction between internal and external stimuli is not as straightforward as externality theory suggests. External signals, such as the sight and smell of food, may produce internal cues, such as salivation and insulin release. If eating subsequently occurs can it be considered a result of the external cues, the internal cues, or some combination of both? Rodin and Slochower (1976) have also found that the non-obese may also be sensitive to external cues. Herman, however, feels that the concept of externality is still important and has not yet been invalidated (Herman, 1987).
1.1.1.2 Restraint theory

Nisbett (1972) observed that obese individuals acted much like hungry individuals. These similarities included an increased responsiveness to pleasant tastes, increased emotionality, and decreased activity levels. Furthermore, according to Nisbett, both food deprived and obese humans show elevated free fatty acid levels in their blood, a physiological indicator of an energy deficit. (p. 440; see also Hibscher & Herman, 1977). This observation led Nisbett to propose that obese people are actually hungry people. Nisbett suggested that for many people their set point is above a weight which is considered to be socially or medically acceptable. The set point is a specific amount of adipose tissue which the body is biologically programmed to maintain. If these people attempt to reduce their weights to below their set points then their bodies will try to increase their reserves of body fat, perhaps by reducing energy expenditure (Keesey, 1986; Keesey & Powley, 1986; Steen, Oppliger, & Brownell, 1988) or by changing their sensitivity to food palatability (e.g., Rodin, Moskowitz, & Bray, 1976; Spiegel et al., 1989), in
order to return to set point. As a result, people who are below their set points, even though they may still be obese, will act as if they are hungry because their fat regulating mechanisms will be trying to restore the body to its set point. This suggests that obese people who are dieting in an attempt to lose weight may be below their set points even though they are, by societal standards, obese. Nisbett concluded that obese people may therefore be hungry people.

Our society places a high value on physical appearance. Slimness is considered to be highly desirable, especially for women (Garner, Garfinkel, Schwarz, & Thompson, 1980), and many young girls and women are dissatisfied with their weight and body shape (Moore, 1988; Rozin & Fallon, 1986; Wardle & Beales, 1988; Zellner, Harner, & Adler, 1989). This suggests that many obese people, especially women, will attempt to reduce their weight. This led Herman to propose the restraint theory (Herman & Mack, 1975; Herman & Polivy, 1975; Hibscher & Herman, 1977). Restraint theory is based on the premise that due to social pressure almost all obese people will try, with varying degrees of success, to reduce their
weight. If their weight goes below their set points then they will begin to show the eating patterns which Schachter found in the obese.

Schachter's externality theory states that externality in an environment rich in food cues leads to overeating which leads to obesity. In contrast, restraint theory states that a weight which is too high according to societal standards leads to attempts to reduce weight. If the dieter's body fat reserves go below set point this may lead to an increased sensitivity to food cues and the other behaviors which characterized Schachter's externally controlled eaters. Herman and Mack (1975), Herman and Polivy (1975), and Hilscher and Herman (1977) have demonstrated that some of the previously observed differences in eating behavior between obese and non-obese could be replicated using subjects of normal weight who were classified as dieters or non-dieters. For example, dieters were found to be externally more distractible or responsive than non-dieters (Herman, Polivy, Pliner, Threlkeld, & Munic, 1978; Polivy, Herman, & Warsh, 1978).

In order to evaluate how concerned people are with dieting Herman and Mack (1975) developed a
questionnaire called the Restraint Scale which measures how much people try to consciously restrain their eating behavior. The original 5 item scale was expanded to 11 items (Herman & Polivy, 1975). This scale was subsequently modified and the resulting 10 item scale (Herman, Polivy, Pliner, Threlkeld, & Munic, 1978) is the one currently in use. There have been some concerns expressed about the Restraint Scale. For example, although the scale is supposed to measure dietary restraint it may produce two factors when factor analyzed (Blanchard & Frost, 1983; Drewnowski, Riskey, & Desor, 1982a, 1982b) although Ruderman (1983) obtained two factors when the scale was used with normal-weight subjects and four factors when the scale was used with obese subjects. Furthermore, the scale's internal reliability varies depending upon whether it is used with obese or normal weight subjects, with reliability being lower when used with obese non-dieters (Johnson, Lake, & Mahan, 1983) or with the obese in general (Ruderman, 1983). Some concern has also been expressed about whether or not the Restraint Scale is suitable for use outside of the university community (Johnson et al., 1983).
Furthermore, Ruderman (1986) found that obese subjects did not show the disinhibited eating produced by a preload in normal weight dieters (see also Ruderman & Christensen, 1983).

There have been at least two questionnaires developed as possible replacements for the Restraint Scale. One of these is the Three-Factor Eating Questionnaire (TFEQ) developed by Stunkard and Messick (1985). This questionnaire has scales which measure cognitive restraint of eating, disinhibition, and hunger. These scales all have adequate internal reliability as measured by Cronbach's alpha (Stunkard & Messick, 1985).

The second potential replacement for the Restraint scale is the Dutch Eating Behavior Questionnaire (DEBQ) developed by van Strien, Frijters, Bergers, and Defares (1986). The DEBQ contains subscales to measure restrained eating, eating in response to diffuse emotions, eating in response to clearly labelled emotions, and eating in response to external cues. The items in these subscales show adequate corrected item-total correlations. Subsequent research on the restraint subscale of the DEBQ found that this subscale
correlated negatively with self-reported intake of fat as well as with self-reported intake of sugar. There was also a negative correlation between the restraint subscale and the difference between the subjects' caloric intake and their energy requirements. In other words, the more restrained the subjects were, the more they deprived themselves.

Laessle, Tuschl, Kotthaus, and Pirke (1989) have compared the construct validity of these three approaches to measuring dietary restraint. They used 60 women with a mean age of 23.8 years as subjects and had them complete the Restraint Scale (RS), the restraint subscale of the Three Factor Eating Questionnaire (TFEQ-R), the restraint subscale of the Dutch Eating Behavior Questionnaire (DEBQ-R). They also gave their subjects the Eating Disorder Inventory (EDI), evaluated their subjects' concern about their body shape by use of the Body Shape Questionnaire, and their tendency to engage in disinhibited eating by use of the disinhibition subscale from the Three Factor Eating Questionnaire (TFEQ-D). The subjects were asked to keep a food diary for a 7 day period thus providing an estimate of daily caloric intake. Finally, the subjects'
height and weight were measured and used to compute the Body Mass Index (BMI = weight/height²). Cronbach's alpha for the RS was .78, for the TFEQ-R it was .80, and for the DEBQ-R alpha was .89. These values of Cronbach's alpha are all considered to be acceptable. All of the restraint scales were significantly correlated. The correlation between the RS and TFEQ-R was \( r = .35 \) \( (p < .01) \); the correlation between the RS and the DEBQ-R was \( r = .59 \) \( (p < .0001) \); and the correlation between the DEBQ-R and the TFEQ-R was \( r = .66 \) \( (p < .0001) \). Laessle et al. also calculated the correlations between the restraint scales and mean daily caloric intake. Caloric intake did not correlate with the RS \( (r = -.04, p > .05, \text{ns}) \), although it did correlate with the TFEQ-R \( (r = -.48, p < .0001) \) and with the DEBQ-R \( (r = -.49, p < .0001) \). This last finding suggests that the TFEQ-R and the DEBQ-R are better measures of restraint than is the RS. Unfortunately, they did not test whether the two subscales of the RS (Weight Fluctuation and Concern with Dieting) predicted caloric intake.

Finally, Laessle et al. performed a factor analysis. If the different scales are measuring
different things they should form different factors. On the other hand, if the scales are measuring similar constructs then the scales should load on the same factors. They obtained three factors. The first factor contained the RS, scales which measured disinhibited eating (EDI-Bulimia and TFEQ-Disinhibition), and concerns about physical appearance (EDI-Body Dissatisfaction, EDI-Drive for Thinness, and BSQ). The second factor contained the RS and measures related to weight (present BMI, highest BMI, and difference between the lowest and highest BMI). When the analysis was repeated using the two subscales (Weight Fluctuation and Concern for Dieting) of the RS the Concern for Dieting subscale was related to the first factor and the Weight Fluctuation subscale was related to the second factor. The final factor contained the TFEQ-R, the DEBQ-R, and the mean daily caloric intake.

Laessle et al. proposed two alternate conclusions. The first was that the three restraint scales measure different constructs. The second was that the three restraint scales measure three different components of restraint. Although their study is interesting it could be improved. The
addition of the maximum BMI and the difference between the subjects' maximum and minimum BMI as well as the other questionnaires which are not directly related to restraint complicated the interpretation of their factor analysis. Furthermore, they should have reported the correlation between caloric intake and the two subscales of the RS in addition to reporting the correlation between the total RS score and caloric intake. Finally, they indicated that they used a German translation of the TFEQ and their source for that translation but they did not indicate what language the other questionnaires were in.

Given the difficulties involved in translation is possible that their results may not be replicable when the English language versions of the questionnaires are used.

According to Heatherton, Herman, Polivy, King, and McGree (1988), many of the reported problems with the Restraint Scale are the result of misinterpretations of the scale and its purpose. They noted that the scale is not a pure measure of restraint but rather a measure of dietary restraint and disinhibition of eating. They argued that most dieters do suffer lapses in their dieting and so the
Restraint Scale measures a common form of dieting. The purpose of the scale, they asserted, is not to measure only restraint but rather to identify dieters. Because dietary restraint and failure of dietary restraint are common patterns of behavior seen in dieters, the scale is therefore successful in detecting dieters.

Despite this defense, the Restraint Scale may not be the best measure of restraint because it measures both restraint and failure of restraint. Although this pattern of unsuccessful dieting may be a common one among dieters it is a misnomer to call the scale the Restraint Scale. Despite this problem there has been a great deal of research based on the Restraint Scale. The Dutch Eating Behavior Questionnaire may be useful once the original reliability studies are confirmed using an English translation. Currently the best method of measuring dietary restraint appears to be the restraint subscale of the Three Factor Eating Questionnaire. Both of these last two scales have the advantage that they measure dieting, rather than the combination of successful and unsuccessful dieting measured by the
Restraint Scale (Heatherton et al., 1988), and they also share the disadvantage that relatively little research has been done using them.

The last finding which will be discussed is one which has been examined in terms of both externality theory and restraint theory and is known as counter-regulation. In the typical experimental procedure used to investigate this effect, food-deprived subjects are either "preloaded" or not "preloaded." Preloading is accomplished by having the subject consume a specific amount of food (e.g., two milkshakes). The subject is then asked to taste some food and to rate the food on a series of scales. The ratings serve to provide a pretext for leaving the subject alone with the food. Normal subjects who have been preloaded eat less of the taste test food than do non-preloaded normals, but obese subjects or restrained eaters who have been preloaded do not reduce their consumption of the taste test food to compensate for the calories contained in the preload (e.g., Hibscher & Herman, 1977; Ruderman & Christensen, 1983). This failure to regulate caloric intake after a preload is called counter-regulatory eating. With large preloads dieters do eat less food
on an *ad lib* basis which demonstrates that in some circumstances they can regulate their caloric intake in response to satiety (Herman, Polivy, & Esses, 1987).

Externality theory would interpret counter-regulatory eating as evidence of the obese person's insensitivity to internal cues such as a full stomach (Schachter, 1971). Restraint theory would treat counter-regulatory eating as an example of the abstinence violation effect (also seen in alcoholism). This occurs when a slight deviation from the treatment is seen by the patient as indicative of total failure of the treatment (Brownell, Marlatt, Lichtenstein, & Wilson, 1986; Nathan, 1980, p. 253-254). Subsequently, the patient proceeds on to a binge. Restrained eaters who have consumed a preload may see themselves as no longer being successful dieters. They may then proceed to act in an unrestrained manner and fail to compensate for their prior food consumption.

Restraint theory has also received some criticism. Ruderman and Christensen (1983), for example, obtained results which were inconsistent with two predictions based on restraint theory.
Although they did find a restraint by preload interaction in their preload and taste test procedure they observed that restrained eaters did not eat more after a preload. Instead, restrained eaters simply did not eat less after a preload but unrestrained eaters did eat less after preloading. Ruderman and Christensen also re-analysed the original data from Hibscher and Herman (1977) and found that these authors had obtained the same results. The second prediction which was disconfirmed was that restrained eaters will act like obese eaters. Ruderman and Christensen reported that obese subjects demonstrated regulatory eating in response to a preload but restrained eaters exhibited counter-regulatory eating when preloaded. Ruderman (1988) subsequently suggested that restraint theory may not be useful in understanding obesity but it may be relevant to understanding counter-regulatory eating.

Rodin (1981) has also criticized restraint theory. She pointed out that restrained eating may be a result of external responsiveness and that restrained eaters may have decided to restrain their eating in response to external cues. Externality theory said that obese people are obese because their
eating is controlled by external cues and they live in an environment which is filled with food-related cues. Restraint theory said that obese people will try to diet (albeit usually unsuccessfully); dieting leads to hunger, and hunger will cause them to be more sensitive to external food cues. Rodin has gone one step farther; she suggested that obese people are more sensitive to external social cues and, given that our society values thinness, this will lead them to diet to reduce their weight. This will then result in hungry dieters who are more sensitive to external cues. One approach to clearing up this disagreement over which comes first, sensitivity to external cues or restraint, would be to do a longitudinal study to see which of these characteristics actually does develop first.

1.1.1.3 Dieting self-efficacy

Another psychological construct used to examine the behavior of dieters is self-efficacy (e.g., Bernier & Avard, 1986; Mitchell & Stuart, 1984; Stotland, Roy, & Zuroff, 1988; Stotland, Zuroff, & Roy, 1991). A part of Bandura’s comprehensive theory of personality called cognitive social learning theory (Bandura, 1988b), self-efficacy has been
defined as "... the conviction that one can successfully execute the behavior required to produce the outcomes" (Bandura, 1977, p. 193). Self-efficacy has been effective in predicting success in performing health-related behaviors such as exercising (Kaplan, Atkins, & Reinsch, 1984; McAuley, 1992; Sallis, Hovell, & Hofstetter, 1992; Sallis, Hovell, Hofstetter, & Barrington, 1992) and cessation of smoking (DiClemente, Prochaska, & Gilbertini, 1985; Godding & Glasgow, 1985; Haaga & Stewart, 1992). Self-efficacy has also been found to be a good predictor of other health related outcomes (Holden, 1991).

Some research has also been done on the relationship between self-efficacy and weight regulation. For example, Edell, Edington, Herd, O'Brien, and Witkin (1987) found that self-efficacy was correlated with weight loss in a group of obese dieters. Stotland et al. (Stotland, Roy, & Zuroff, 1988; Stotland, Zuroff, & Roy, 1991) reported that self-efficacy predicted the amount of food consumed by dieters in a taste-test procedure. Using their Situation Based Dieting Self-Efficacy Scale (SDS) they found that "... low dieting self-efficacy
subjects ate significantly more than subjects with high dieting self-efficacy." (Stotland et al., 1991, p. 87). Two studies also reported that self-efficacy was a good predictor of remaining in weight loss treatment groups (Bernier & Avar, 1986; Mitchell & Stuart, 1984). Subjects who had high self-efficacy were less likely to drop out of the treatment groups. Despite the fact that self-efficacy has been successfully used to predict outcomes of health-related behaviors, including weight loss, it has not received as much research attention as dietary restraint has. Chapters 5 and 6 of this dissertation will examine the relationship between self-efficacy and dietary compliance.

1.1.2 Compliance with chronic medical diets

In general, compliance has been defined as "the extent to which a person's behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice" (Haynes, Taylor, & Sackett, 1979, p. xv). Despite the inclusion of diets in a widely cited definition of compliance, there has been a great deal published about compliance with specific diets but few publications discussing compliance with medical diets in general.
For example, many books on behavioral medicine either do not discuss dietary compliance or refer to it only in the context of treatment of obesity (e.g., Burish & Bradley, 1983; DiMatteo & DiNicola, 1982; Prokop & Bradley, 1981; Stone, Cohen, & Adler, 1979).

Glanz (1980) was one of the few authors to review the general area of dietary compliance. She concluded that dietary noncompliance was at least as common as medication noncompliance and suggested that further research was needed on the measurement of dietary compliance. Glanz also stated that medical caregivers should pay greater attention to psychological correlates of compliance. Dunbar and Stunkard (1979) felt that problems in measurement hampered research in compliance and emphasized the need for the development of better measurement techniques. They also argued for the importance of social support in understanding compliance and for the advantages of behavior modification in enhancing compliance. Both Glanz (1980) and Dunbar and Stunkard (1979) agreed that the development of better methods for measuring compliance is an area where research is greatly needed.

It is not clear why there is such a paucity of literature on this important subject. One possible
explanation is that the diets used to treat medical conditions are so diverse that they share few features in common, aside from the reluctance of patients to follow them. The diet used to treat Type 2 diabetes mellitus which emphasizes a well balanced diet with low amounts of refined carbohydrate, sodium, and fat (e.g., Expert Committee of the Canadian Diabetes Advisory Board, 1992; Wong, Eno, Hollands, Jenkins, Kenshore, & Marks, 1982) is very different from the diet used with patients on hemodialysis who are required to restrict their consumption of fluids, protein, potassium, and phosphorous (Finn & Alcorn, 1986; Henry, 1983; Kluthe, 1983). Subsequent chapters in this dissertation will review the literature on specific medically prescribed diets and dietary compliance where it is most appropriate.

1.2 Comparing psychological and dietary compliance research

A careful examination of the psychological research on dieting and the medical compliance research areas suggests that there are many differences which may make direct application of the results of the psychological research in medical settings problematic. The first part of this discussion is summarized in Table
The column on the left describes a characteristic typical of laboratory-based personality research while the column on the right presents the contrasting characteristic seen in dietary compliance research.

For example, the first item in the table deals with the source of the decision to begin dieting. In psychological research the subjects have typically decided to diet on their own while in compliance research the subjects have been told to diet by a medical caregiver. Similarly, most psychological research has focused on weight loss diets. But medically prescribed diets may be aimed at reducing the consumption of water or sodium or may even be prescribed to help the patients gain weight, instead of losing weight.

More generally, there is evidence that attempting to generalize from a psychology laboratory experiment to human behavior outside of the laboratory may be difficult. For example, Schachter (1959) claimed that people under stress prefer to affiliate with other people who are also under stress. This conclusion has been presented as if it were a fact in some introductory psychology textbooks (e.g., Bernstein, Roy, Srull, &
Wickens, 1991, pp. 453-454). But when Kulik and Mahler (1987, 1989, 1990) investigated the roommate preferences of patients who were about to undergo coronary-bypass surgery they found that preoperative patients preferred postoperative roommates rather than preoperative roommates. Other authors have also suggested that relying on university students or other selected groups and laboratory tasks may limit the generalizability of psychological research (Carlson, 1971; Sears, 1986; for a debate on this issue in reference to research on eating by humans see Booth, 1992; Kissileff, 1992; Heiselman, 1992a, 1992b; Mela, Rogers, Shepherd, & MacFie, 1992; Pliner, 1992; Rolls & Shide, 1992; Stellar, 1992; Tuorila & Lahteenmaki, 1992).
Table 1-1
Differences between diets studied by experimental and clinical scientists

<table>
<thead>
<tr>
<th>Personality research on dieters</th>
<th>Research on medical diets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-imposed</td>
<td>Imposed by others</td>
</tr>
<tr>
<td>Seldom medically indicated</td>
<td>Medically indicated</td>
</tr>
<tr>
<td>Minimal or no obesity</td>
<td>May be severe obesity</td>
</tr>
<tr>
<td>Young subjects</td>
<td>Middle-aged &amp; elderly</td>
</tr>
<tr>
<td>Hypocaloric diets</td>
<td>Not always hypocaloric</td>
</tr>
<tr>
<td>Subjects healthy</td>
<td>Subjects ill</td>
</tr>
<tr>
<td>Highly intelligent</td>
<td>Average intelligence</td>
</tr>
<tr>
<td>Females (generally)</td>
<td>Males and females</td>
</tr>
<tr>
<td>Laboratory setting</td>
<td>Real world</td>
</tr>
<tr>
<td>Duration of study &lt; 1 hour</td>
<td>Diet for rest of life</td>
</tr>
</tbody>
</table>

1.3 Compliance with chronic dietary regimens:
Measurement, prediction, and outcome

Based on this overview of the literature there appear to be several areas where research is needed. First of all, there is a need to take research methods and ideas which have been used in experimental
personality research and apply them to medical diets in order to learn how generalizable the results of the experimental work are. The findings will be of interest to both experimental psychologists and medical caregivers. Second, although it has not been discussed in great detail in this introduction, it can be argued that measurement is an important issue. If we cannot measure compliance then it will be difficult to study compliance and it has been previously noted that difficulties in measuring compliance are hindering research (Dunbar & Stunkard, 1979; Glanz, 1980). Measurement is an area of great concern and has been the focus of a great deal of research in psychology and this may be another place where psychology can make a valuable contribution. If we are to test the personality theories relating to dieting and obesity in a medical setting we must have reliable and valid methods of measuring compliance.

This dissertation employs a broadly based approach in the examination of several important areas of dietary compliance. It will use a combination of both laboratory and field studies in the course of this examination. Specifically, we will examine measurement, prediction, and the outcome of dietary compliance.
Measurement will be explored in two studies which look at dietary compliance in hemodialysis patients. The first of these (Chapter 3) demonstrates that the failure to agree on a method of measuring dietary compliance may be impeding research progress in this area. The second of these studies will also look at the outcome of compliance, do patients who follow diets lead longer and healthier lives (Chapter 4)? Finally, the ability of personality measures to predict dietary compliance will be tested in a longitudinal field study which involves diabetes mellitus (Chapter 5) and a laboratory investigation which looks at otherwise healthy, obese dieters (Chapter 8). By trying to extend some of the psychological research on dieting to medical compliance we may provide medical researchers with new theories to test and, at the same time, evaluate the generalizability of the psychological research on dieting.
Chapter 2

Review of diseases

The purpose of this chapter is to present a basic description of the two medical conditions, diabetes and end-stage renal disease, which were chosen for this research on dietary compliance. It is intended to provide the reader with a brief introduction to these two conditions, and the importance of dietary compliance in their treatment.

2.1 End-stage renal disease

2.1.1 Epidemiology

In 1987 there were 9,310 patients suffering from chronic renal failure in Canada, which yields a prevalence of 363.3 chronic renal failure cases per million population (Arbus, Fenton, Jeffery, & Tsui, 1989; see also Silins et al., 1989). Of this group 3,094 were on hemodialysis, 1,667 were on some form of peritoneal dialysis, and 4,549 had a functioning transplanted kidney. There were 1,828 new cases of chronic renal failure reported in Canada in 1987, or 71.3 cases per million population.
2.1.2 Causes of end-stage renal disease

Patients suffering from end-stage renal disease are those whose kidneys have lost all or part of their capacity to function properly. The kidneys play an important and complicated role in the homeostatic functioning of the circulatory system. They help to regulate levels of sodium (Na), potassium (K), phosphate, and other chemicals. They are also important in controlling the pH of the blood. Various metabolic by-products are removed from the blood by the kidneys and they also play a critical role in the control of fluid balance in the body. By filtering solutes from the circulatory system and extracting excess water the kidneys help to control the body's blood chemistry and fluid volume. For a more detailed discussion of fluid and electrolyte regulation see Sullivan and Grantham (1982) or Smith (1980).

There are many factors which can cause chronic kidney failure (Kidney Foundation of Canada, 1983). Diabetes mellitus can cause diabetic nephropathy (Chase et al., 1989; Herman & Teutsch, 1985; Levine, 1987; Maher, 1992). Kidney stones (renal calculi) and hypertension can also cause kidney failure (Kidney Foundation of Canada, 1983). Drugs, especially
analgesics, may affect kidney functioning (Berkow & Fletcher, 1987, pp. 1604-1610; Girdwood, 1984; National Institutes of Health, 1984). Finally, there are some conditions, such as glomerulonephritis, which may have a variety of causes (Berkow & Fletcher, 1987, pp. 1591-1595).

When the kidneys cease to function properly body physiology is seriously altered. Sodium, potassium and urea levels rise and acidosis, an decrease in the pH of the blood, develops (Epstein & Harill, 1977). Death will result if the condition is untreated. Once renal failure has occurred patients are placed on dialysis. When their condition is under control they may receive a kidney transplant but many remain on dialysis for long periods of time.

There are several methods used to perform dialysis. This chapter will focus on extracorporeal hemodialysis because that treatment modality is the focus of several subsequent chapters (Chapters 3 and 4; see Cogan & Garovoy, 1985; Nissenson, Fine, & Gentile, 1990).
2.1.3 Treatment

2.1.3.1 Peritoneal dialysis and transplant

There are several other methods of treating chronic kidney failure besides hemodialysis. One is to use the patients' peritoneal membranes for dialysis instead of a synthetic membrane (Kidney Foundation of Canada, 1983). A widely-used version of this approach is known as Continuous Ambulatory Peritoneal Dialysis (CAPD). In CAPD the patients instill a dialysate solution into their abdominal cavities via a catheter implanted in the abdominal wall. Osmotic pressure forces metabolites from their bodies into the dialysate through their peritoneal membranes. After a period of time the patients drain the dialysate from their abdomens and repeat the process with fresh dialysate solution. One medical drawback of CAPD is the high risk of peritoneal infection (e.g., Frascino, 1985; Nolph, 1984; Renal Network Coordinating Council of the Upper Midwest, 1981).

Kidney transplantation is another method of treating chronic renal failure. With the development of effective immunosuppressants, kidney transplantation has become a routine procedure with
good long-term outcomes. Currently, one of the major obstacles to kidney transplantation is the lack of suitable donor organs (Kleinman & Lowy, 1989; Levenson & Olbrisch, 1987; see also Shanteau & Harris, 1990). In 1984 there were 1,022 patients on dialysis in Canada who were waiting for a transplant (Jeffery, Hutchinson, Arbus, & Posen, 1986) and by 1987 the number had risen to 1,150 (Arbus et al., 1989, p. 98).

2.1.3.2 Performing extracorporeal hemodialysis

In hemodialysis, the patient’s blood circulates through the hemodialysis machine. The first practical method for obtaining access to the patient’s circulatory system was the Scribner shunt which used plastic tubing to connect an artery and a vein. The shunt was led through the surface of the skin and the exposed part was made of two separate tubes which were joined using locking couplers that could be connected to a dialysis machine.

One advantage of the Scribner shunt was that self-care patients did not have to insert needles into their blood vessels which was thought to be difficult for them to do. Many of the patients in
the St. Joseph's Hospital morbidity/mortality study, described in Chapter 4, were fitted with Scribner shunts for this reason.

Unfortunately, this method of angioaccess has numerous problems associated with it. Because the tubes of the shunt project through the skin they provide an easy entry path for bacteria resulting in frequent infections. Blood clots frequently form in the shunt and must be removed or the shunt will have to be replaced. Finally, damage to the shunt, whether accidental or deliberate, can lead to serious loss of blood.

The currently preferred method of angioaccess is the arteriovenous fistula. To construct the fistula an artery is connected to a vein. The higher pressure of the arterial blood expands the vein to produce a large blood vessel which lies near the surface of the skin. Access to the circulatory system is obtained by inserting one or more large needles. Because the fistula lies completely under the surface of the skin it is less prone to develop infections or suffer physical damage than the external shunts (Hirschman, Wolfson, Mosimann, Dante, & Wineman, 1981).
At the start of the dialysis procedure a needle is inserted into the fistula to supply blood to the dialysis machine and another needle is inserted into the fistula to return the blood to the patient. In order to prevent blood from clotting in the dialyzer an anticoagulant is added to the blood as it comes from the patient.

The blood flows from the patient to a blood pump and from there into the dialysis cartridge where the process of dialysis actually takes place. Inside the cartridge the blood flows through hollow tubes made of a semi-permeable material and surrounded by the dialysate solution which is continuously pumped through the cartridge. The dialysate contains chemicals in the appropriate concentrations to create osmotic pressure which will remove excess water and metabolites from the patient’s blood. The pressures in the blood and dialysate compartments can be altered to create a pressure differential. This is known as ultrafiltration and is used when it is necessary to help remove large quantities of water from the patient’s blood. Blood is returned to the patient through a second needle which is also inserted into the fistula.
Although the procedure may sound complicated, many patients can be trained to perform hemodialysis themselves either at home or in a satellite dialysis center (e.g., Gross, Keane, & McDonald, 1973; Kidney Foundation of Canada, 1983; Phillips, 1987). Those who cannot perform the procedure themselves receive dialysis in a hospital unit staffed by physicians and nurses who administer the treatment.

2.1.4 Compliance issues in hemodialysis

Physiological measures are the most commonly used method of assessing compliance. Because these patients excrete very little fluid any liquids which they consume are retained and this retained fluid adds weight to the patient. The amount of fluid consumed can be assessed by comparing the patient's weight after one dialysis treatment with the patient's weight before the next dialysis to compute the interdialytic weight gain. An alternative method is to weigh the patient immediately before and after dialysis. These measures are termed the "wet" and "dry" weights respectively and yield a measure of how much fluid was removed during dialysis. Weight is not a perfect measure of fluid
intake, as it is also affected by sodium intake (Lamping, 1981; Wenerowicz, Riskind, & Jenkins, 1978) as well as by food intake, excretion and exercise.

Blood urea nitrogen (BUN) is another commonly used measure of dietary compliance. BUN is affected by protein intake (Lamping, 1981; Wenerowicz et al., 1978). Although very high BUN levels are undesirable, low BUN levels are not necessarily good because they may indicate poor dietary therapy or non-compliance (Blackburn, 1977; Lamping, 1981).

Phosphorous (P) levels in the patients' blood is another commonly used measure of compliance. Depending on the patient's diet P can indicate two things. For those patients who are prescribed P binding antacids, elevated levels of P can result if the patient fails to take the prescribed amounts of antacid. For those patients who are on P restricted diets high P levels indicate a failure to adhere to the diet (Blackburn, 1977; Lamping, 1981; Wenerowicz et al., 1978).

Other measures are less commonly used. The levels of potassium (K) in the blood can be used to measure the patient's degree of compliance with dietary restrictions on fruits, vegetables, and certain other foods (Blackburn, 1977; Lamping, 1981). Some studies
(e.g., Kobrin, Kimmel, Simmens, & Reiss, 1991; Lamping, 1981) have also used behavioral measures such as the number of treatments missed and the number of treatments which the patient terminated early.

These measures all share some shortcomings as indicators of dietary compliance; they are all indirect and non-specific. In all cases we are not actually measuring what the patient eats or drinks, rather we are measuring a physiological variable which may reflect what the patient has consumed. Furthermore, many of these measures are affected by things other than the patients’ food consumption. In the case of weight, for example, we know that it will be affected by fluid intake but it will also be affected by exercise and excretion. Similarly, if patients have a high potassium level it could be that the patients have consumed large amounts of citrus fruit. But it is also possible that the patients failed to take potassium binding medication appropriately or they may have lost whatever residual renal capacity they had left or they may have missed a dialysis treatment.

2.1.4.1 Diet in ESRD

In order to decrease the frequency of the treatments, as well as to reduce the risk and
severity of complications, the patients are placed on a diet. The diet is intended to minimize the buildup of undesirable products in the body and provide adequate nutrition (Burton & Hirschman, 1983; Compher, Mullen, & Barker, 1991; Kopple, 1984). Although it is of great importance to the success of the treatment, many patients tend to have great difficulty in adherence to the diet (Finn & Alcorn, 1986).

The diets recommended for dialysis patients are very restrictive. Because phosphorous and potassium cannot be eliminated from these patients' bodies except by dialysis they are restricted. High levels of phosphorous can lead secondary hyperparathyroidism and subsequent bone disorders (Brautbar, 1984; Burton & Hirschman, 1983; Kidney Foundation of Canada, 1983, p. 1-3; Massry & Kaptein, 1984; Oberley & Oberley, 1979, pp. 49-50). In order to reduce the amount of phosphorous absorbed by their digestive systems the patients may be required to take antacids which bind with the phosphorous and prevent its absorption (Brautbar, 1984; Henry, 1983). Phosphorous is found in dairy products (Oberley & Oberley, 1979, p. 55; Phillips, 1987, p. 206). High levels of potassium
can cause changes in the electrical activity of the heart and death (Burton & Hirschman, 1983; Katz & DeFronzo, 1984; Kidney Foundation of Canada, 1983, p. 4-3). High levels of potassium are present in fruits and vegetables, coffee, chocolate, nuts, and dairy products (Kidney Foundation of Canada, 1983, p. 1-4; Oberley & Oberley, 1979, p. 54; Phillips, 1987, pp. 206-207).

Protein intake is also restricted to control the level of BUN (Berlyne, 1978; Burton & Hirschman, 1983; Hitch, 1981). This means that consumption of meat, fish, poultry, and cheese is limited (Phillips, 1987, p. 204). High levels of BUN can lead to nausea, vomiting, and diarrhea (Kidney Foundation of Canada, 1983, p. 1-3).

In addition to the food restrictions there are also restrictions on the quantity of fluid which the patients are allowed to consume. Because they excrete very little fluid most of the water which is taken in must be eliminated by dialysis. The quantity of fluid which is permitted varies from patient to patient. Patients are typically advised to gain no more than 1 to 2 kilograms of fluid weight between dialyses (Henry, 1983). This works out to
approximately one liter of fluid per day (Blackburn, 1977). Overconsumption of fluids can lead to edema, hypertension, and heart failure (Oberley & Oberley, 1979, p. 53).

Although the restrictions may be both difficult and unpleasant the consequences of non-compliance can be severe. Slight non-compliance may produce discomfort while extreme non-compliance can be fatal. Patients occasionally indulge in binge eating of prohibited foods with drastic results (Glassman & Siegel, 1970). Suicide, perhaps because of the severe and constant stress experienced by these patients, is 100 times more likely than in the normal population (Abram, Moore, & Westervelt, 1971). If one classifies death as the result of non-compliance to be suicide than this group of patients has a suicide rate 400 times that of the normal population (Abram et al., 1971). Similarly, in a study of 8, 432 over a 5 year period Silins et al. (1989) noted that 10% of the women and 9% of the men committed suicide. When patients adhere closely to the treatment requirements they can lead a productive life for many years (e.g., Scribner, 1978).
2.1.4.2 Medications used by hemodialysis patients

Although the research presented in this dissertation will focus on dietary compliance in hemodialysis patients it is important to realize that these patients are also on numerous medications. Noncompliance with the medication regimen may have a detrimental impact on the patients' health.

In order to help reduce the amount of phosphorous and potassium which the patients absorb, they may be required to take medications which bind with the phosphorous or potassium and prevent them from being absorbed. Because the process of hemodialysis removes water-soluble vitamins from the blood, the patients are given vitamin supplements. Calcium supplements are often given in order to prevent or control bone disorders. Hypertension can cause kidney failure and, conversely, kidney failure can also cause hypertension. Therefore, many of these patients are also on anti-hypertensive medication (Kidney Foundation of Canada, 1983, p. 6-1). Steroids may also be used to help rebuild body mass (Kidney Foundation of Canada, 1983, p. 6-1). Patients who have an external shunt are infection-prone and are frequently on antibiotics to
help treat any current infection. Finally, diabetes mellitus is an important cause of kidney failure and consequently many dialysis patients also have to use medication to control their diabetes.

2.1.5 Morbidity/mortality

There exists a certain amount of debate concerning the optimal mode of therapy for patients with end-stage renal disease (ESRD). Although it is not clear from the research literature whether dialysis or transplant is superior from the point of view of health, transplant probably provides a better quality of life for the patients (Devins et al., 1990; Evans et al., 1985). It should be noted, however, that transplant does not provide a complete return to health. Patients continue to suffer complications after transplant (e.g., Divakar, Bailey, Lynn, & Robson, 1991; Julian et al., 1991; Washer, Schroter, Starzl, & Weil, 1983). Transplant is also more cost-effective than dialysis. It costs a mean of $40,000 per year to provide dialysis to each patient in Ontario (1984 dollars; Robinette & Stiller, 1985, p. 4) and it has been estimated that each kidney transplant saves the province as much as $500,000 (Jeffery et al., 1986, p. 772). Unfortunately, the shortage of donor
kidneys (Kleinman & Lowy, 1989; Levenson & Olbrisch, 1987; Shanteau & Harris, 1990b, pp. 1-2) plus the unsuitability of some patients for transplantation will necessitate the continued use of hemodialysis in the future. For this reason, further research on dietary compliance in hemodialysis is needed.

2.2 Diabetes mellitus

2.2.1 Type 1 vs 2 diabetes mellitus

Diabetes mellitus is a very common metabolic disorder which involves elevated blood glucose levels caused by a relative or absolute lack of serum insulin (Pohl, Gonder-Frederick, & Cox, 1984; Steinke & Soeldner, 1977, p. 584). This disorder affects 1.5% of the Canadian population (Canada Health Survey, 1981, p. 110) and 2.4% of the American Population (Harris, 1985, p. VI-3). Currently diabetes mellitus is divided into three main types; Type 1, Type 2, and Gestational Diabetes (Rodger, 1982). The study which is described in this dissertation focuses on Type 2 diabetes mellitus which differs significantly from Type 1 diabetes. However, both types of diabetes will be defined because the two conditions are commonly confused.
2.2.2 Type 1 diabetes mellitus

When the "average" person hears the term diabetes he or she is likely to think of Type 1 diabetes. Part of the reason for the attention which this disorder has attracted, and the subsequent general familiarity with it, may be the relatively recent and dramatic advances which have been made in controlling what was, at one time, an inevitably fatal condition. For a description of the effects of Type 1 diabetes in the days before the clinical use of insulin, as well as an account of the discovery of insulin see Bliss (1982).

Type 1 diabetes, previously known as "insulin-dependent diabetes mellitus" or "juvenile-onset diabetes mellitus," is characterized by elevated levels of blood sugar (hyperglycemia) which is caused by the deficient production of insulin by the pancreatic beta cells (Dupre, Ehrlich, Hunt, Molnar, & Ross, 1982; Rodger, 1982). For a brief summary of the differences between Type 1 and Type 2 see Table 2-1. Symptoms which are associated with this disorder are the consumption of large quantities of liquids (polydipsia), the production of large quantities of urine (polyurea), excessive food consumption (polyphagia), and loss of weight which most often
occurs in childhood (Rodger, 1982; Steinke & Soeldner, 1977, p. 57). These patients are prone to the development of a condition known as ketoacidosis, formerly called diabetic coma, if they receive inadequate quantities of insulin (Berkow & Fletcher, 1987, p. 1042; Dupre et al., 1982). Treatment of Type 1 diabetes consists of insulin injections and a controlled diet in combination with frequent blood glucose testing (Berkow & Fletcher, 1987, pp. 1069-1086; Dupre et al., 1982; Expert Committee of the Canadian Diabetes Advisory Board, 1992; Jovanovic, Peterson, & Choppin, 1985; Menendez & Stoecker, 1985; Steinke & Soeldner, 1977; Wong et al., 1982).

2.2.3 Type 2 diabetes mellitus

In contrast to Type 1 diabetes, Type 2 diabetes has received relatively little attention and it appears that there are several possible reasons for this. One reason is that Type 1, with its need for frequent blood tests and insulin injections, may be seen as more difficult or challenging to manage. A second possibility is that Type 1 presents a more immediate danger to the health of the patients and a third reason may be that Type 2 is seen primarily in the middle-aged
and the elderly who might be perceived as being less interesting groups to work with than the younger Type 1 patients.

Table 2 - 1

Type 1 vs. Type 2 diabetes mellitus

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Type 1</th>
<th>Type 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at onset</td>
<td>Under 20</td>
<td>Over 40</td>
</tr>
<tr>
<td>Blood glucose level</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Serum insulin level</td>
<td>Low</td>
<td>Normal or high</td>
</tr>
<tr>
<td>Weight</td>
<td>May be underweight</td>
<td>Usually obese</td>
</tr>
<tr>
<td>Prone to ketoacidosis</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Genetic component</td>
<td>Weak</td>
<td>Moderate</td>
</tr>
<tr>
<td>Treatment</td>
<td>Insulin and diet</td>
<td>Diet only or, diet and oral hypoglycemics, or diet and insulin</td>
</tr>
</tbody>
</table>

2.2.4 Epidemiology

Diabetes is a common disease in Canada. The Canada Health Survey, using self-report measures, obtained a prevalence estimate of 1.5% in their sample of 23,023 Canadians (Canada Health Survey, 1981, p. 110). Unfortunately, the Canada Health Survey did
not differentiate between Type 1 and Type 2 diabetes and, as a result of relying on self-report, may have underestimated the actual prevalence because it would have missed any undiagnosed cases. One study found that the number of undiagnosed diabetics was equal to the number of previously diagnosed diabetics thus suggesting that there are many people who are unaware of the fact that they have diabetes (Harris, Hadden, Knowler, & Bennett, 1987). If this finding is applied to the Canada Health Survey it suggests that 3% of the Canadian population is diabetic. Type 1 diabetes has been reported to have a prevalence ranging from 4 to 38 per 100,000 depending upon the group studied (Zimmet & King, 1985, p. 8). Type 2 is much more common; it has been claimed that Type 2 is 20 times more common than Type 1 (Pohl et al., 1984, p. 3) while others have stated that it is 7 to 10 times more common (e.g., Turk & Speers, 1983, p. 193).

2.2.5 Causes of Type 2 diabetes

The exact cause of Type 2 diabetes mellitus is not known. It is believed that the tissues' lack of sensitivity to insulin is the primary defect. To compensate for this the patients' bodies produce large amounts of insulin but eventually their insulin
production declines. This leads to high glucose and high insulin levels (DeFronzo, Bonadonna, & Ferrannini, 1992). For comprehensive reviews of the risk factors and possible causes of Type 2 diabetes see DeFronzo et al. (1992), Fishman, Hoffman, Klausner, Rockson, and Thaler (1981), Harris and Hamman (1985), Nelson, Everhart, Knowler, and Bennett (1988) and Pohl et al. (1984).

Persons with Type 2 diabetes often present with the same symptoms as those with Type 1. They may complain of polyurea, polydipsia, and fatigue (Berkow & Fletcher, 1987, pp. 1069-1072) or they may come to medical attention as a result of a visual disturbance or neuropathy (Steinke & Soeldner, 1977, p. 571). These patients are typically over 40 years of age and 60 to 90 percent of them are overweight (Berkow & Fletcher, 1987, p. 1071; Pohl et al., 1984; Rodger, 1982, 1991). Type 2 diabetics also have elevated blood glucose levels but, unlike Type 1 patients, they are not affected by ketoacidosis (Berkow & Fletcher, 1987, p. 1071; Rodger, 1982). Another important difference between the two types of diabetes is that Type 2 diabetics have varying levels of serum insulin and are not always insulinopenic as are Type 1 diabetics.

2.2.6 Treatment

The treatment of Type 2 is aimed at restoring normoglycemia and focuses on weight reduction via dieting (Expert Committee of the Canadian Diabetes Advisory Board, 1992; Freeman, 1988; Morley & Perry, 1991; Wong et al., 1982; see also National Institutes of Health, 1988). Both the research and clinical literature have suggested that weight reduction by dieting can be an effective method of controlling blood glucose in Type 2 diabetics (Doar, Thompson, Wilde, & Sewell, 1975; Dupre et al., 1982; Fishman et al., 1981, p. 222; Hadden et al., 1975).

Unfortunately, it appears that it may be more difficult for Type 2 diabetics to lose weight than it is for non-diabetics. Wing, Marcus, Epstein, and Jalata (1987) paired six diabetic males and six diabetic females with their overweight nondiabetic spouses. The diabetic and nondiabetic subjects were comparable in terms of age, weight, and degree of obesity. All of the couples then entered a behavioral weight loss program. At the end of the treatment program the nondiabetic subjects had lost significantly more weight than had the diabetic subjects.
The diets used to treat Type 2 diabetes are individually tailored to suit the patients' dietary preferences and activity levels. In general, the goal of the diet is to produce a weight loss of approximately .5 kilograms per week until the ideal weight is attained and thereafter the diet is modified to maintain the patient at the ideal weight. The diabetic diet is a well balanced one which permits a wide variety of foods with a few restrictions. The patients are encouraged to avoid refined carbohydrates, such as sugar, and to reduce their intake of fats and salt. Because diabetics are at greater risk for the development of cardiovascular disease, reducing fat and sodium consumption may be a prudent practice (Crapo, 1983; Steinke & Soeldner, 1977; Wong et al., 1982). The diet is very flexible which makes it easier to follow than a rigid preplanned diet. In the diabetic diet the patients are prescribed a certain number of "choices" for each meal. A choice is simply a portion of one of the basic food groups (protein foods, starchy foods, milk, fruits and vegetables, fat and oils, extra vegetables, and an unrestricted category called "extras"; Angel et al., 1982). For example, one starchy choice could consist of one slice of bread or
125 ml of cereal or 125 ml of cooked macaroni or one half of a potato. One choice of protein food could consist of one slice of packaged, sliced cheese or 15 ml of peanut butter or one half of a wiener (Canadian Diabetes Association, 1980). Thus, instead of having to follow a rigid preplanned diet the patients are given a great deal of latitude in selecting their meals. If a patient is supposed to have two protein choices and two starchy choices for lunch this could be achieved by having one of the following: a peanut butter sandwich, a cheese sandwich, a hot dog, macaroni and cheese, or a baked potato with cheese. This may make it easier to comply with the diet if the patients are dining in a cafeteria or restaurant.

Exercise has also been recommended as an aid in the reduction of obesity in diabetics (Reitman, Vasquez, Klimes, & Nagulesparan, 1984; Schneider & Ruderman, 1982; Wing, Epstein, Paternostro-Bayles, Kriska, Nowalk, & Gooding, 1988) although some concerns have been voiced about the long term effectiveness of exercise (Zinman, 1984). Compliance with exercise among Type 2 diabetics has received very little attention and may prove to be an interesting topic for future research. When weight reduction is either
ineffective in reducing glucose levels or is unattainable then other treatment approaches must be utilized. These include oral hypoglycemic medications and insulin injections (Fishman et al., 1981; Steinke & Soeldner, 1977, pp. 574-575).

The oral hypoglycemics most commonly used by the subjects in the following research studies are the sulfonylureas, and include Glyburide (glibenolamide) and Diabinese (chlorpropanide). These medications stimulate the release of insulin from the pancreas, decrease hepatic glucogenesis, and increase the efficiency of insulin utilization by the muscle tissue (Gerich, 1989; Groop, 1992; Johnson, 1988, p. 133; Toft, Campbell, & Sawers, 1984). These medications also present some risks. They may cause hypoglycemia, rashes, nausea, hyponatremia, gastrointestinal disturbances, jaundice, cardiovascular death, blood dyscrasias, disulfiram-like reactions to alcohol, liver dysfunction and other complications (Gerich, 1989; Johnson, 1988, p. 134; Nabarro, 1992; Rodger, 1991; Toft et al., 1984).

If diet and oral hypoglycemics fail to control blood glucose levels then insulin injections are used. Insulin injections present more difficulties than do
the oral medications because the patients must learn to administer insulin to themselves. Insulin injections also present their own associated risks including hypoglycemia, allergic reactions, insulin resistance, lipodystrophy, and weight gain (Johnson, 1988, pp. 130-132; Toft et al., 1984). Furthermore, insulin injections carry the risks of infection or complications due to poor technique associated with all injections.

2.2.7 Compliance issues

While weight reduction may be an effective method of metabolic control for Type 2 diabetes (Hadden et al., 1975) its effectiveness is strongly influenced by the patient’s degree of compliance with the diet. Noncompliance is a serious problem with long-term dietary regimens (Glanz, 1980) and the treatment of diabetes and obesity is no exception to this rule (e.g., Wing, Epstein, & Nowalk, 1984). Attrition rates from weight-loss programs for obese non-diabetics are high, in some cases attrition rates as high as 70% after 12 weeks have been observed (Volkmar, Stunkard, Woolston, & Bailey, 1981), and individuals who initially lose weight often regain their lost weight over time (Currey, Malcolm, Riddle, & Schachte, 1977;
Wooley, Wooley, Orland, & Dyrenforth, 1979). Research (discussed previously) also suggests that it is harder for diabetics to lose weight than it is for non-diabetics (Wing et al., 1987).

2.2.8 Morbidity/mortality

Diabetes is a serious health threat and has been described as the third leading cause of all deaths in the U.S. (Surwit, Feinglos, & Soovern, 1983, p. 255) but other authors have described it as the tenth largest cause of all deaths in the U.S. (Turk & Speers, 1983, p. 181). One possible explanation for the difference between these two estimates is that the ranking by Surwit et al. included deaths which were directly attributed to diabetes as well as those resulting from the complications of diabetes while the estimate by Turk and Speers may have included only those deaths which were directly attributed to diabetes. Because the focus of this dissertation is on psychological factors related to compliance it does not include a detailed discussion of the impact of diabetes. It will suffice to say that diabetes can lead to serious complications. Diabetes is a leading cause of all new cases of blindness in North America (Fishman et al., 1981, p. 232; Klein & Klein, 1985;

2.3 Similarities and differences between the two diseases

Diabetes mellitus and chronic kidney failure share some similarities. Treatment of both conditions requires the patients to follow a medically prescribed diet for long periods of time. Both conditions can significantly increase the risk of morbidity and mortality, although chronic kidney failure presents a more serious risk than does Type 2 diabetes. Additionally, diabetes and kidney failure, and their associated complications, can reduce the patients’ quality of life.
There are, of course, important differences between the two conditions as well as similarities. Type 2 diabetes mellitus can, in some cases, be treated by means of diet alone while end-stage renal disease inevitably involves the use of medication plus either dialysis or transplantation. Finally, it is much easier to measure dietary compliance in Type 2 diabetes than in kidney failure and the relationship between diet and outcome is more firmly established for diabetics than for patients on hemodialysis.
3 Chapter 3

Measuring and predicting compliance in hemodialysis patients¹

This chapter reviews previous efforts at finding psychological measures which predict compliance with the dietary requirements of hemodialysis. Prediction of who will comply with the requirements of a medical treatment regimen is, in general, a difficult problem and compliance with hemodialysis is no exception. It will briefly discuss the findings of previous studies and then explore several reasons why there has been little success in finding a reliable predictor of compliance. It will be demonstrated that there is little agreement on exactly how to define and measure compliance with this treatment regimen. Before attempting to use psychological constructs to predict compliance we must first deal with the difficult issue of measuring compliance and develop a reliable and valid method of measurement.

¹ Portions of this chapter have been published in the Journal of Compliance in Health Care (Lamping & Campbell, 1989) and in Seminars in Dialysis (Lamping & Campbell, 1990a, 1990b);
3.1 Compliance rates across studies

An average of 44% of hemodialysis patients are noncompliant with some aspect of the dietary regimen (Agashua et al., 1981; Blackburn, 1977; Borkman, 1976; Cummings, Becker, Kirsch, & Levin, 1982; Hartman & Becker, 1978; Kaplan de-Nour & Czaczkes, 1972, 1974; Poll & Kaplan de-Nour, 1980; Procci, 1978; Winokur, Czaczkes, & Kaplan de-Nour, 1973). This estimate corresponds closely with the 50% noncompliance rate reported for patients on long-term medical regimens (Sackett & Snow, 1979). Failure to comply with treatment requirements, including attendance at frequent and time-consuming dialysis sessions and strict adherence to dietary and fluid restrictions and prescribed medications, may have severe consequences necessitating emergency medical treatment or hospitalization. Extreme noncompliance may be fatal. Table 3-1 presents the noncompliance rates obtained from several studies.
Table 3-1

Percentage noncompliance rates across studies using different definitions of compliance

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Composite Index</th>
<th>Wgt</th>
<th>P</th>
<th>K</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agashua et al., 1981</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Criterion 1</td>
<td>70</td>
<td></td>
<td>64</td>
<td></td>
<td></td>
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<tr>
<td>Criterion 2</td>
<td>70</td>
<td></td>
<td>33</td>
<td></td>
<td></td>
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<tr>
<td>Blackburn, 1977</td>
<td>53</td>
<td>37</td>
<td>51</td>
<td>38</td>
<td>21</td>
</tr>
<tr>
<td>Borkman, 1976</td>
<td>681</td>
<td>30</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cummings et al., 1981</td>
<td>116</td>
<td></td>
<td>41</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Cummings et al., 1982</td>
<td>116</td>
<td></td>
<td>41</td>
<td>70</td>
<td>14</td>
</tr>
<tr>
<td>Hartman &amp; Becker, 1978</td>
<td>50</td>
<td>36</td>
<td>22</td>
<td>61</td>
<td>26</td>
</tr>
<tr>
<td>Kaplan de-Nour &amp; Czaczkes, 1972</td>
<td>43</td>
<td></td>
<td>45</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kaplan de-Nour &amp; Czaczkes, 1974</td>
<td>83</td>
<td></td>
<td>40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kaplan de-Nour &amp; Czaczkes, 1976</td>
<td>100</td>
<td></td>
<td>39</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poll &amp; Kaplan de-Nour, 1980</td>
<td>40</td>
<td></td>
<td>48</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procci, 1978</td>
<td>31</td>
<td></td>
<td>61</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wenerowicz et al., 1978</td>
<td>19</td>
<td></td>
<td>47</td>
<td>68</td>
<td>26</td>
</tr>
<tr>
<td>Winokur et al., 1973</td>
<td>38</td>
<td></td>
<td>59</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note. Only 2 studies measured BUN compliance rates separately and therefore a separate column was not added to record the results. These studies were Wenerowicz et al., 1978 (47% noncompliant) and Kaplan de-Nour and Czaczkes, 1976 (39%). The term "Composite index" will be discussed in a subsequent section. "P" and "K"
refers to the percentage of the patients in the study who were noncompliant with respect to phosphorous and potassium respectively. Although it was not explicitly stated in the article, Cummings et al. (1982) is likely based on the same group of subjects as Cummings et al. (1981).

As can be seen there is considerable variation in the noncompliance rates reported in each study. Estimates vary from a low of 30% in a questionnaire survey of dialysis centers which used subjective ratings of compliance (Borkman, 1978) to a high of 81% in a smaller sample which employed objectively defined compliance criteria (Procci, 1978).

3.2 Psychological prediction of compliance

In the hemodialysis compliance literature a great deal of effort has been devoted toward identifying predictors of compliance. In fact, the majority of the hemodialysis compliance literature has evolved from studies designed to predict compliance. These studies, which are generally correlational in nature, examine the relationship between compliance and hypothetical predictors, such as demographic or personality factors, or compare compliant and noncompliant patients on these predictive factors. The rationale for such studies is
that the ability to identify and predict which patients will be noncompliant is the first step in developing compliance-improving interventions.

The following section reviews studies which have investigated predictors of compliance with the dietary regimen used in hemodialysis. Included are studies of the relationship between compliance and demographic characteristics, cognitive functioning, personality factors, health beliefs, social support, and treatment-related characteristics. These studies are then evaluated in terms of the goal of identifying the predictors of compliance.

3.2.1 Cognitive functioning

Several studies have investigated the relationship between compliance and factors which may be related to patients' cognitive abilities including intelligence, understanding of the treatment regimen, and organic brain damage. In general, compliance and intelligence are unrelated. Three studies which assessed intelligence on the basis of the Wechsler Adult Intelligence Scale found no relationship between dietary compliance and intelligence (Schlebusch & Levin, 1982a, 1982b; Winokur et al., 1973). In a study which used staff ratings of intelligence it was found
that low intelligence was predictive of poorer compliance with shunt care and salt restrictions, but was unrelated to protein intake and fluid restrictions (Borkman, 1978). Because Borkman's (1978) study used staff ratings of both intelligence and compliance this finding may have been due to a halo effect. In fact, the objective of the study was to evaluate the relationships between staff members' perceptions and, as a result, may be used to support the argument that staff members' ratings are prone to bias.

Although intelligence appears to be unrelated to compliance, the patient's level of understanding or knowledge about the treatment regimen may be an important factor in determining some aspects of compliance (Borkman, 1978; Cummings et al., 1982). The relationship between intelligence and compliance may, therefore, be an indirect one which is mediated by the patient's level of understanding about dietary restrictions (Borkman, 1978). Moreover, it is reasonable to assume that a minimum level of intelligence and cognitive functioning is a prerequisite for compliance.
3.2.2 Demographic characteristics

Findings from studies investigating the relationship between demographic characteristics and compliance are fairly consistent for five of the seven factors that have been investigated. Work status demonstrates a consistently positive relationship to compliance. Patients who are employed or doing housework either full-time or part-time are better compliers than those who are not working (Procci, 1978; Winokur et al., 1973). It has also been fairly consistently shown that neither race (Blackburn, 1977; Borkman, 1976; O'Brien, 1980; Procci, 1978) nor income (Cummings et al., 1982; Hartman & Becker, 1978; Procci, 1978) are related to compliance.

Similarly, there is consistency among studies in the finding that marital status is unrelated to compliance (Blackburn, 1977; Borkman, 1976; Brown & Fitzpatrick, 1988; Procci, 1978). Although one study reported better weight compliance among married patients, no relationship was found between marital status and phosphorous or potassium compliance in the same study (Hartman & Becker, 1978). Another study found an inconsistent relationship between marital status and compliance (O'Brien, 1980).
Finally, most studies have consistently failed to demonstrate an association between compliance and education (Cummings et al., 1982; O’Brien, 1980; Poll & Kaplan de-Nour, 1980; Procci, 1978). One study did find that patients with higher education gained more interdialytic weight, but did not find a relationship between education and phosphorous or potassium (Blackburn, 1977). In another study higher educational levels were associated with poorer protein compliance but not with compliance with shunt care, water, or salt restrictions (Borkman, 1978). Contrary to the findings from the two previously mentioned studies, Kaplan de-Nour and Czaczkes (1974) reported that better educated patients were rated by nephrologists as being more compliant. It should also be noted that health care workers are, in general, not good at subjectively assessing patients’ compliance (e.g., DiMatteo & DiNicola, 1982, pp. 10-11; Gordis, 1979, pp. 39-40).

Findings regarding the relationship between compliance and age and gender are inconsistent. Age was uncorrelated with compliance in several studies (Blackburn, 1977; Borkman, 1976; Oldenberg, MacDonald, & Perkins, 1988; Poll & Kaplan de-Nour, 1980; Procci, 1978). Other studies, however, suggest that there may
be a relationship between age and compliance. In one study, older subjects were more compliant with phosphorous and weight restrictions although no relationship was found between age and potassium compliance (Cummings et al., 1982). In another study, older patients were more compliant with potassium and phosphorous restrictions but not with weight gain restrictions (Hartman & Becker, 1978). In a study which assessed compliance on the basis of self-report, older patients were more likely to report compliance with dietary restrictions (Brown & Fitzpatrick, 1988). One of the few studies done on dialysis compliance in children found a positive correlation between compliance, as measured by blood pressure, and age (Cohen, Kagan, Richter, Topor, & Saveedra, 1991). These researchers considered blood pressures which were less than or equal to the 95 percentile of normal blood pressures for a child of a given age to be a sign of good compliance. Other researchers have not used blood pressure as an indication of fluid compliance preferring to use inter-dialytic weight gain instead.

The findings related to compliance and gender are also inconsistent. Some studies found no relationship between compliance and gender (Borkman, 1976; Brown &
Fitzpatrick, 1983; Kaplan de-Nour & Czaczkies, 1974; O'Brien, 1980; Poll & Kaplan de-Nour, 1980; Procacci, 1978). Other studies suggested that gender may be related to compliance but differ as to whether men or women are better compliers. Two studies suggested that women are more compliant with some aspects of the treatment regimen. In one study women were found to be more compliant with potassium restrictions, but no relationship was found between gender and phosphorous or weight compliance (Blackburn, 1977). In another study women were more compliant with weight, whereas no relationship was found between gender and potassium or phosphorous (Cummings et al., 1982). Two other studies, however, suggested that men are more compliant. In one study males were found to be more compliant with phosphorous restrictions, but no relationship was found between gender and potassium or weight compliance (Hartman & Becker, 1978). In the other study males were more compliant with a global index of disease control based on objective compliance measures (Oldenberg et al., 1988).

3.2.3 Personality factors

Given that some demographic factors are related to compliance, this implies that some person factors
are involved thus suggesting that personality factors may play a role. However, personality factors have so far proven to be poor predictors of compliance. Studies investigating the relationship between locus of control and compliance produce conflicting results. Of seven studies, one reported a positive relationship indicating better compliance among internals (Poll & Kaplan de-Nour, 1978) and another found that internals were more compliant with phosphorous and as well as on a global compliance index but there was no relationship between locus and potassium, weight, or BUN compliance (Wenerowicz et al., 1978). Schneider, Friend, Whitaker, and Wadhwa (1991) also found a positive relationship between locus of control and fluid compliance. Three studies failed to find a relationship (Blackburn, 1977; Brown & Fitzpatrick, 1988; Foster, Cohn, & McKegney, 1973) and one produced results which were inconsistent across questionnaire items and the different compliance indicators (Hartman & Becker, 1978). Assessment of locus of control using a domain-specific scale such as the Multidimensional Health Locus of Control Scale (Wallston, Wallston, & Devellis, 1978), which has been found to be a more reliable predictor of behavior in health settings than
generalized measures such as Rotter's scale (Rotter, 1966), may help to resolve the inconsistencies regarding the relationship between locus of control and compliance.

Other personality factors which have been investigated as predictors of compliance include frustration tolerance and sick role behavior (Hartman & Becker, 1978; Kaplan de-Nour & Czaczkes, 1972), acceptance of disability (Brown & Fitzpatrick, 1988), depression (Kaplan de-Nour & Czaczkes, 1972, 1974, 1976; Schneider et al., 1991), self-control (Rosenbaum & Smira, 1988), denial (Yanagida, Streltzer, & Siemsen, 1961), anxiety and anger (Schneider et al., 1991), and general personality traits (Schlebusch & Levin, 1982a, 1982b). However, given that there has not been a sufficient number of studies investigating these factors, it is difficult to draw any firm conclusions about their predictive utility.

3.2.4 Health Beliefs

The Health Belief Model (Becker & Naiman, 1975; Rosenstock, 1974) has produced mixed results in the prediction of hemodialysis compliance. Although some studies reported an association between health beliefs and compliance (Cummings et al., 1981, 1982; Hartman &
Becker, 1978), results are inconsistent across specific health beliefs and different measures of compliance. For example, in two studies conducted by the same investigators a different pattern of relationships was obtained between four specific health beliefs and four different compliance measures (Cummings et al., 1981, 1982). Furthermore, only five out of 20 correlations between health beliefs and compliance that were presented in these studies were significant. Similarly, the positive associations between health beliefs and compliance reported in another study were highly specific to both individual items in the health belief questionnaire and to different measures of compliance (Hartman & Becker, 1978).

3.2.5 Social support

Several studies have investigated the relationship between social support and compliance. In general, the evidence suggests a stronger compliance-enhancing effect of support provided by family and friends than from staff members. With respect to staff support, one study found no relationship between staff support and compliance (Cummings et al., 1982). In another study, although noncompliance was found to be significantly related to
emotionally positive and negative responses by nurses, the relationship was extremely weak (Cummings et al., 1982). Findings from one study suggest that the influence of staff support may vary across time (O'Brien, 1980). Although support from caregivers did not influence compliance in the early stages of hemodialysis, staff support was more strongly associated with compliance behavior over time.

Although the impact of staff support on compliance increased over time, family support had a decreasing influence on compliance over time (O'Brien, 1980). In other studies, the impact of social support from family and friends has been demonstrated primarily in terms of better compliance as measured by weight (Brown & Fitzpatrick, 1988; Hartman & Becker, 1978; Reiss, Gonzalez, & Kramer, 1986) or a composite index (Procci, 1976) although compliance with phosphorous and potassium restrictions, as measured by the concentrations of these chemicals in the blood, appear to be less strongly related to support from family and friends (Hartman & Becker, 1978).

3.2.6 Treatment related characteristics

One factor which has been extensively investigated in relation to compliance is the number of
years of hemodialysis treatment. Despite the interest in this factor as a predictor of compliance the results have been strikingly inconsistent. Some studies have failed to find a relationship (Manley & Sweeney, 1986; Oldenberg et al., 1988; Poll & Kaplan de-Nour, 1980; Procci, 1978) whereas other studies reported an association between the two variables (Blackburn, 1977; Brown & Fitzpatrick, 1988; Cummings et al., 1982; Hartman & Becker, 1978; O'Brien, 1980). Of the studies which demonstrate a relationship between compliance and number of years on hemodialysis three indicate poorer compliance with increasing number of years on hemodialysis (Blackburn 1977; Brown & Fitzpatrick, 1988; Cummings et al., 1982) which could be interpreted in terms of "familiarity breeds contempt." Another explanation for the finding that the longer the patients are on hemodialysis the less compliant they are is that the patients who are compliant may be more likely to receive a kidney transplant and the patients who are noncompliant will be left on hemodialysis. Two studies suggest better compliance for more experienced patients (Hartman & Becker, 1978; O'Brien, 1980). This latter finding could be interpreted as being due to patients learning to be more compliant over the course
of time or, alternatively, a kind of natural selection process in which poor compliers die prematurely leaving behind only good compliers.

Other treatment related characteristics which have been investigated in relation to compliance include complexity of the treatment regimen (Cummings et al., 1982), location or type of dialysis (Oldenberg et al., 1988; Witenberg, Blanchard, McCoy, Suls, & McGoldrick, 1983), and expectations about receiving a transplant or previous transplant experience (Cummings et al., 1982). These factors have not been investigated thoroughly enough to be able to reach any conclusions about their predictive power.

3.2.7 Evaluation of predictive studies

In general, few factors have been found that are clearly and consistently related to compliance. Although findings from some studies suggest that certain factors may be useful in predicting compliance, by far the majority of studies have produced negative or inconsistent results. With the exception of work status, demographic factors appear to be unrelated to compliance. Although intelligence does not predict compliance, the evidence suggests that a minimal level of cognitive capacity and understanding of the
treatment regimen is essential to achieve compliance. As has been demonstrated in the general compliance literature, personality factors are also poor predictors of hemodialysis compliance. There is some evidence, however, to suggest the utility of both health beliefs and social support in predicting compliance behavior.

There are at least five possible explanations as to why predictive studies have not been particularly informative. The first involves differences in the designs used in various studies. Some studies evaluated short-term predictions and others used long-term predictions. It seems likely that long-term predictions of compliance will be less accurate than short-term predictions because in long-term studies the values of the predictor variables may change over time and additional factors may also come into play.

The second, and related, explanation concerns the implicit assumption that compliance behavior is a stable and relatively enduring characteristic of the person. Consequently, the measures used to predict compliance are based on dispositional models of behavior which emphasize stable traits as the major determinants of behavior. However, compliance may be a
highly situation-specific behavior which is determined to a large extent by environmental contingencies which vary over time and across different situations. The question of the stability and consistency of compliance will be explored in a subsequent chapter.

A third explanation is that the discrepancies between different studies regarding predictors of compliance may reflect variability between different patient samples. Whether these discrepancies are due to differences between patient samples or to artifactual differences between the studies is difficult to determine because compliance studies vary in sample size, sample composition, and geographical location. What is needed are studies based on large, representative samples of patients.

A fourth possibility is that some differences between studies result from differences in the choice of psychological measures used. Some studies, for example, used standardized tests to measure intelligence while others had staff members rate the patients' intelligence levels. Virtually all of the studies which employed staff ratings of psychological constructs or which used other measurement instruments which were developed by the authors failed to report
estimates of reliability and validity. Other potential psychometric problems are evident. For example, Kaplan de-Nour and her colleagues conducted their research in Israel and it is not clear whether they used psychological tests which were in English or which had been translated into Hebrew. If any of the measures had been translated or adapted for use in a different language, then the reliability of the modified version of the test should have been verified.

A fifth, and final, possibility is that there are inadequacies in current approaches to the measurement of compliance. Specifically, the methods and criteria used to determine compliance lack standardization across studies, with various investigators defining compliance in different ways. The particular definition of compliance is an area of great importance and the definition used in a given study may have a significant effect on the results of that study.

3.3 Definition of compliance

A great number of methods for assessing compliance have been developed (see Table 3 - 2). Some researchers have asked hospital staff members to rate patients' compliance without defining objective or explicit criteria. For example, Kaplan de-Nour and Czaczkes
(1974) asked nephrologists to rate compliance based on the patients' medical records and a physical examination. There were no objective definitions given of compliance and no measures of inter-rater reliability. This makes replication difficult, if not impossible.

Staff members' ratings of compliance can, for example, be affected by their treatment philosophies. Witenberg et al., (1983) asked nephrologists, dietitians, and social workers to rate their patients' compliance on a set of seven point scales. There were no criteria given to staff to use in their decisions. Two nephrologists who were blind to the identity of the patients rated their compliance based on the patients' charts and used more explicit criteria. The results indicated that the subjective ratings tended to produce higher estimates of compliance than did the objective ratings. These authors also reported that physicians were more likely to overestimate the compliance of home dialysis patients as opposed to hospital dialysis patients. There are two possible reasons for this. One is that the staff members were more familiar with the problems experienced by the hospital patients who they saw frequently. Alternatively, the staff members felt
that home dialysis was superior to hospital dialysis and this may have biased their ratings in favor of the home patients. In general, medical caregivers are poor at estimating compliance (Gordis, 1979).

Physiological measures are the most commonly used objective method of assessing compliance. There appear to be two ways to describe the various physiological rating methods: 1) the combined versus separate distinction; and 2) the continuous versus categorical distinction. (See Table 3 - 2.) Studies which used the combined approach use a number of conditions in combination to assess the degree of compliance. For example, they may require that the patient have BUN, K, and weight gain within certain ranges in order to be considered compliant (e.g., Kaplan de-Nour & Czaczkies, 1972). Studies which use a separate approach determine whether a patient is compliant with respect to each individual criterion. Thus in Blackburn’s (1977) study a patient who was K compliant would not necessarily be P compliant.

In continuous approaches the actual numerical value of the indicator is used. Binik et al. (1982), for example, used the levels of the various compliance indicators to predict the occurrence of pain. In
categorical approaches the patients are categorized according to where their measures fall in relation to specified cutting points. Cummings et al. (1981) classified patients as K compliant if their mean serum K was less than 5.5 and fluid compliance was defined as a mean interdialytic weight gain of less than 3.0 kg. It can be seen that those studies which used separate criteria may use continuous or categorical classifications while studies which used the combined approach were almost always categorical.
### Table 3-2

**Classification methodologies**

<table>
<thead>
<tr>
<th>Study</th>
<th>Separate vs Combined</th>
<th>Continuous vs Categorical</th>
<th>Objective vs Rating</th>
<th>Inter-rater reliability</th>
</tr>
</thead>
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<tr>
<td>Agashua et al., 1981</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Criterion 1</td>
<td>S</td>
<td>CA</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>Criterion 2</td>
<td>S</td>
<td>CA</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>Armstrong &amp; Woods, 1983</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>R</td>
<td>Yes</td>
</tr>
<tr>
<td>Rating 2</td>
<td>C</td>
<td>CO</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>Binik et al., 1982</td>
<td>S</td>
<td>CO</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>Blackburn, 1977</td>
<td>S</td>
<td>CA</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>Borkman, 1976</td>
<td>S</td>
<td>CA</td>
<td>R</td>
<td>No</td>
</tr>
<tr>
<td>Cummings et al., 1981</td>
<td>S</td>
<td>CA, CO</td>
<td>0</td>
<td>No</td>
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<td>S</td>
<td>CA, CO</td>
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</tr>
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<td>C</td>
<td>CA*</td>
<td>0</td>
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</tr>
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<tr>
<td>Study</td>
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<td>CA</td>
<td>R</td>
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<td>No</td>
</tr>
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<td>CA</td>
<td>O</td>
<td>No</td>
</tr>
<tr>
<td>O'Brien, 1980</td>
<td>C</td>
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<td>R</td>
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<td>O</td>
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<td>Procci, 1978</td>
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<td>O</td>
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<td>R</td>
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<td>CA</td>
<td>R</td>
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</tr>
<tr>
<td>Wenerowicz et al., 1978</td>
<td>C, S</td>
<td>CA</td>
<td>O</td>
<td>No</td>
</tr>
<tr>
<td>Winokur et al., 1973</td>
<td>C</td>
<td>CA*</td>
<td>O</td>
<td>No</td>
</tr>
<tr>
<td>Wirth &amp; Folstein, 1982</td>
<td>S</td>
<td>CO</td>
<td>O</td>
<td>No</td>
</tr>
<tr>
<td>Witenberg et al., 1983</td>
<td>C, S</td>
<td>CA</td>
<td>O</td>
<td>Yes</td>
</tr>
<tr>
<td>Rating 1</td>
<td>C</td>
<td>CA</td>
<td>R</td>
<td>Yes</td>
</tr>
<tr>
<td>Rating 2</td>
<td>C, S</td>
<td>CA</td>
<td>O</td>
<td>Yes</td>
</tr>
<tr>
<td>Wolcott et al., 1986</td>
<td>S</td>
<td>CA</td>
<td>O</td>
<td>NA</td>
</tr>
<tr>
<td>---------------------</td>
<td>---</td>
<td>----</td>
<td>---</td>
<td>----</td>
</tr>
<tr>
<td>Yanagida et al., 1981</td>
<td>S</td>
<td>CA</td>
<td>O</td>
<td>No</td>
</tr>
</tbody>
</table>

Note: * indicates poorly defined or unclear classification scheme.

Although the use of physiological measures to assess compliance may appear to be objective this is, in fact, not the case. Kaplan de-Nour and Czaczkes (1972) used definitions such as "...potassium levels are usually 6 mEq/liter or less, occasionally going up to 6.5 mEq/liter", "Weight gain...rarely going up to 2000 g.", and "...potassium levels are most of the time near 7.0 mEq/liter" (p. 335). Terms such as "occasionally", "rarely", and "most of the time" are difficult to define objectively (Bryant & Norman, 1980) and, because no inter-rater reliability is reported, it is impossible to be certain what degree of reliability these classifications possess.

Another problem with the categorical approach is the selection of cutting points to use with the various measurements. Criteria are usually determined by clinical judgment and consensus rather than by empirical evidence. If a researcher decides to use a 2 kg weight
gain as a cutting point this is because the researcher feels that a gain of more than 2 kg is undesirable. It does not mean that a patient who gains 1.9 kg is significantly more likely to lead a longer, healthier life than a patient who gains 2.1 kg. (The issue of developing compliance criteria based on empirical data on morbidity and mortality is dealt with in Chapter 4.)

Studies which utilize the combined approach face another problem because some patients do not adhere to all of the treatment requirements. These patients have been called "crazy quilt" compliers (Armstrong & Woods, 1983) because their measures of compliance are divergent. Using a combined approach such as Kaplan de-Nour's (e.g., Kaplan de-Nour & Czaczkes, 1972) a patient whose weight gain and BUN measurements were excellent but whose K measures were high would not be rated excellent or two-thirds compliant. In this particular system, a patient with weight gains of less than .5 kg and a stable BUN, but who has K levels of 6.6, does not neatly fit into any of the categories. Studies which categorize using a large number of measures may classify as noncompliant a patient who is, for the most part, compliant. Furthermore, some studies may completely fail to classify patients who do not fit
into one of their categories although, in many studies, their vague definitions usually make it possible to assign a patient to a category. As will be seen in Chapter 4, correlations between the different compliance indicators are generally low (see also Kobrin, Simmens, & Reiss, 1981). This means that patients who are compliant with one aspect of the treatment regimen are not always compliant with the remaining aspects.

The use of subjective and highly divergent definitions of compliance make it very difficult to determine which psychological factors are good predictors of compliance. Thus, if a psychological variable is related to compliance in one study but not in another there are at least two equally tenable hypotheses which may account for this. One is that the variable in question is not a good predictor of compliance and the other hypothesis is that the studies define compliance very differently and, as a result, may be trying to predict different things.

This leads to the question of whether or not the differences between the different definitions of compliance actually do have an effect on the outcome of a study. Would the patients who were classified as compliant using one study's definition also be
considered compliant using a second study's definition? In order to answer this question one could apply the definitions of compliance which have been discussed previously to a sample of hemodialysis patients and compare the noncompliance rates which result from the use of each definition. This would result in an estimate of the degree of agreement between the various definitions. If the definitions agree on who is or is not compliant then that would suggest that the failure to find a good predictor of compliance is not due to difference between the various definitions of compliance which have been employed. The following sections present the results of this analysis.

3.4 Method

3.4.1 Description of National Cooperative Dialysis Study (NCDS)

The purpose of the National Cooperative Dialysis Study (NCDS) was to develop techniques by which dialysis could be prescribed on an individualized and quantitative basis while keeping patients free from dialysis-responsive complications of uremia (Lowrie, 1983; Sargent, 1983; Wineman, 1983). Four experimental therapies were employed in a 2 X 2 design based on two parameters which could be controlled: the duration of
dialysis treatment time (long or short) and blood urea nitrogen concentration (high or low). The study was divided into four phases: 1) initiation; 2) induction; 3) control; and 4) experimental.

Data employed in the analyses reported in this chapter were obtained exclusively from the control phase. This was a 12-20 week period, prior to randomization to one of the four treatment groups, in which dialysis treatment parameters were adjusted on the basis of urea kinetic modelling to achieve control of the target time and BUN values.

3.4.2 Description of NCDS sample

The 262 subjects who entered the study were between 18 and 70 years of age, had been on center dialysis for at least 4 months, and had creatinine clearances of \( \leq 3 \text{ ml/min} \). They were also free of significant systemic diseases, such as diabetes mellitus and cardiovascular disease, and met minimum compliance criteria (Lowrie, Laird, & Henry, 1983). The compliance criteria required for inclusion in the NCDS included: no more than 1 dialysis missed per month in the past 3 months, mean interdialytic weight
gain < 3.5 kg for the past 3 months, and mean predialysis serum phosphorous < 8.0 in the past 3 months.

The NCDS study population was similar to the U.S. dialysis population except that the study excluded diabetic patients (Harter, 1983). A comparison of the demographic characteristics of the NCDS patients with similar data describing the U.S. dialysis population (Parker, Reed, & Lowrie, 1983) showed that the NCDS patients were somewhat younger than the national average (49.0 vs. 53.3 years) and had been on dialysis approximately 1 year longer (4.2 vs. 3.3 years). The gender distributions were comparable, with 5% more males in the NCDS than in the U.S. dialysis population (59.6% vs. 54.7% males), but the proportion of blacks was substantially greater in the NCDS (53% vs. 30% blacks). Diagnoses of patients in the NCDS sample were not different from those in the U.S. population if diabetic patients are excluded, and the laboratory values of study patients were similar to those obtained in a large national survey (Parker, Reed, & Lowrie, 1983).
3.4.3 Description of NCDS data set

The analyses reported in this chapter are based on the sample of patients who entered the control phase of the NCDS. Of the 282 patients who were initiated into the study, 224 (85.5%) entered the control phase. The 38 patients who withdrew from the study prior to the control phase did so primarily for personal reasons, e.g., the increased dialysis time interfered with their work schedule, the change in blood flow rate was disagreeable, the testing was too time consuming or caused too much discomfort, family problems or a change of mind, or the psychological tests were objectionable (Parker, Reed, & Lowrie, 1983).

Of the 224 patients who entered the control phase, 165 (73.7%) were eventually randomized into one of the four study groups. Of the 59 patients who dropped out of the study during the control phase, 38 did so for reasons that were unrelated to the protocol (e.g., patient preference, miscellaneous general reasons, and transplantation), while 21 could not be randomized because of failure to meet the criteria for entering the experimental phase (Parker, Reed, & Lowrie, 1983). Therefore, 74% of the patients who entered the control phase, or 64% of those who entered
the NCDS, advanced to the experimental phase. There were no important clinical differences in age, duration of dialysis, gender, or race between the randomized groups and the larger group of patients who entered the study (Parker, Reed, & Lowrie, 1983; Parker, Laird, & Lowrie, 1983). This suggests that the initial sample of patients who entered the study and the subset of patients who entered both the control and experimental phases of the NCDS did not differ greatly.

Of the 224 patients who entered the control phase, seven dropped out of the study prior to the first data collection point of the control phase and were, therefore, excluded from our analyses. Thus, the analyses reported in this chapter are based on a sample of 217 subjects for whom at least partial control phase data were available. These subjects (128 males, 89 females) ranged in age from 18-70 years ($\bar{x} = 47.62$, $sd = 13.29$) and had been on dialysis a mean of 4.3 years.

3.4.4 Variables utilized

The variables utilized to assess compliance included mean interdialytic weight gain, and pre-dialytic BUN, phosphorous, and potassium. All compliance indicators, except interdialytic weight
gain, were obtained from medical reports which were completed on a monthly basis during the control phase. The accuracy of the biochemical tests was monitored throughout the course of the NCDS (Frankel, Engel, Olivier, & Halpern, 1983). Interdialytic weight gain was calculated on the basis of a mean of the individual values obtained during the last 10 weeks of the control phase.

3.4.5 Compliance criteria utilized in this analysis

The compliance criteria used in this analysis were selected on the basis of a literature search of studies investigating the relationship between psychological variables and hemodialysis compliance (Lamping, 1984; Lamping & Campbell, 1990a, 1990b). Only those studies which employed objective, quantitative definitions of compliance based on physiological measures were included. Studies which employed subjective definitions based on staff estimates of compliance were excluded from this analysis because it has been shown that there is poor agreement between staff ratings and objective measures of compliance (Armstrong & Woods, 1983; Kaplan de-Nour & Czaczkes, 1974; Witenberg et al., 1983). In general, health care-givers tend to be poor judges of compliance
(Gordis, 1979). Furthermore, because the subjective definitions of compliance used in previous studies are usually stated in verbal terms such as "good complier" or "poor complier", these cannot be operationally defined in quantitative terms.

The compliance criteria used in our analysis are presented in Table 3-3. The majority of these were clearly defined and were employed as specified in the original studies. Some definitions which seemed vague or unclear were modified by setting explicit cutting points. For example, the compliance definition used by Winokur et al. (1973) is "...potassium levels are most of the time 8 mEq/l or less, occasionally going up to 8.5 mEq/l...Weight gain between dialyses is most of the time 1500-2000 g, occasionally going up to 2500 or even 3000 g." There may be disagreement on the meaning terms such as "most of the time" or "occasionally" (Bryant & Norman, 1960). Therefore, we selected an intermediate value to serve as the cutting point. That is, the definition used by Winokur et al. (1973) for "fair compliance" which was "weight gain between dialyses is most of the time 1000-1500 g, rarely going up to 2000 g" (p. 30) and "some abuse" as "weight gain
between dialyses is most of the time 1500-2000 g" (p. 30), we used a value of 1500 gm or 1.5 kg to divide the sample into compliers and noncompliers.

If, for example, the average interdialytic weight gain for an NCDS patient over the 10 week assessment period was less than 1.5 kg, then that patient would be classified as compliant in our analyses which corresponds to "fair compliance" according to the definition used by Winokur et al. An NCDS patient whose weight gain was greater than 1.5 kg would be classified as noncompliant in our analyses which corresponds to the "some abuse" designation of Winokur et al. In cases where investigators used multiple categories such as "excellent", "good", "fair", "some abuse", and "great abuse" we collapsed their definitions into dichotomous categories. Patients in the first three groups (i.e., "excellent", "good", "fair") were classified as compliers, while those in the last two groups (i.e., "some abuse", "great abuse") were classified as noncompliers. The difficulties encountered in programming a computer to use these definitions emphasized how poorly specified and subjective some of them were.
Table 3 - 3
Compliance criteria

<table>
<thead>
<tr>
<th>Study</th>
<th>Weight Gain (kg)</th>
<th>BUN (mg/dl)</th>
<th>P (mg/dl)</th>
<th>K (mEq/l)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agashua et al., 1981</td>
<td>&gt;=1.00</td>
<td></td>
<td>&lt;3.5</td>
<td>&lt;3.5</td>
</tr>
<tr>
<td>Criterion 1</td>
<td></td>
<td>&gt;=1.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Criterion 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blackburn, 1977</td>
<td>&gt;=1.80</td>
<td>&gt;5.0 or &lt;3.5</td>
<td>&gt;5.0 or &lt;3.5</td>
<td></td>
</tr>
<tr>
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<td>&gt;=3.00</td>
<td></td>
<td></td>
<td>&gt;=5.5</td>
</tr>
<tr>
<td>Cummings et al., 1982</td>
<td>&gt;=3.00</td>
<td>&gt;=5.5</td>
<td>&gt;=5.5</td>
<td></td>
</tr>
<tr>
<td>Kaplan de-Nour &amp; Czaczkes, 1972 a</td>
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<td></td>
<td></td>
<td>&gt;6.8</td>
</tr>
<tr>
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<td>1.75</td>
<td>&gt;90</td>
<td></td>
<td>&gt;6.8</td>
</tr>
<tr>
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<td>&gt;100</td>
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<td>&gt;6.0</td>
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<tr>
<td>Proci, 1978</td>
<td>.90</td>
<td></td>
<td></td>
<td>&gt;5.5</td>
</tr>
<tr>
<td>Wenerowicz et al., 1978</td>
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<td>&gt;100</td>
<td>&gt;4.5</td>
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<td></td>
<td>&gt;6.8</td>
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<td>.30</td>
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</tr>
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<td>Witenberg et al., 1983</td>
<td>.90</td>
<td>&gt;4.5 or &lt;2.5</td>
<td>&gt;5.2 or &lt;3.5</td>
<td></td>
</tr>
<tr>
<td>Wolcott et al., 1986 d</td>
<td>&gt;=3.0</td>
<td>&gt;=5.5</td>
<td></td>
<td>&gt;6.0</td>
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<tr>
<td>Yanagida et al., 1981 a</td>
<td>2.25</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Notes. a - modified definitions as discussed in the text
b - Original paper stated that 50% or more of the values out of range indicated noncompliance. Our subjects had from 1 to 3 measurements of these variables and so we used a simple majority vote to determine noncompliance (i.e., 1/1, 1/2, 2/3, or more out of range indicated noncompliance).
c - Original paper stated that 50% or more of the values out of range indicated noncompliance. We only had the mean value for the period immediately before transfer from control to experimental phase, therefore we classed patients as noncompliant if their mean value was outside the range.
d - Wolcott et al. (1986) proposed this definition of compliance, they did not actually utilize it to classify any patients
e - Yanagida et al. (1981) defined compliance as gaining ≤ 2 kg 75% of the time and noncompliance as gaining ≥ 2.5 kg on 50% of the time. We used a mean of ≤ 2.25 kg.

3.4.6 Procedure

During the control phase, compliance data were obtained on the basis of monthly medical reports.
Because the minimum duration of the control phase was 12 weeks, three medical reports were available for the majority of the patients. However, in cases where a patient failed to meet the requirements for transfer to the experimental phase and remained in the control phase for as long as 20 weeks, up to five monthly medical reports were available. In such cases, only the first three monthly medical reports were used. For patients for whom all three monthly reports were available, mean values for BUN, phosphorous, and potassium were calculated on the basis of the three monthly values and these mean values were employed in subsequent analyses. For patients for whom fewer than three reports were available because of a missed data collection point, means were calculated on the basis of the available data. The 217 patients in the NCDS control phase sample were then categorized as compliant or noncompliant on the basis of each of the compliance criteria in Table 3 - 3.

3.5 Results

The noncompliance rates in the NCDS sample, calculated on the basis of compliance criteria used in previous studies, are presented in Figures 3 - 1 through 3 - 4. Of the total NCDS sample, 99% were able to be
classified using BUN, phosphorous, and potassium criteria, and 76% were classified in terms of interdialytic weight gain criteria. Weight gain data were not available for 53 (24%) of the subjects who dropped out of the study during the control phase. The reason weight gain data were unavailable for these subjects was because dropout occurred prior to the point in the control phase during which interdialytic weight gain data were obtained, i.e., before the last 10 weeks of the control phase. As indicated previously, there were no important clinical differences between dropouts and the initial sample of patients who entered the study (Parker, Reed, & Lowrie, 1983; Parker, Laird, & Lowrie, 1983), suggesting that direct comparisons between the 93% and 76% classifiable sample may be valid.
Figure 3-1. Noncompliance rates for interdialytic weight gain

Notes: 1 - Agashua et al., 1981 - Criterion 1
2 - Agashua et al., 1981 - Criterion 2
3 - Blackburn, 1977
4 - Cummings et al., 1981
5 - Cummings et al., 1982
6 - Kaplan de-Nour & Czaczkies, 1972
7 - Kaplan de-Nour & Czaczkies, 1976
8 - Magrab & Papadopoulou, 1977
9 - Procci, 1978
10 - Wenerowicz et al., 1978
11 - Winokur et al., 1973
12 - Wirth & Folstein, 1982
13 - Wittenberg et al., 1983
14 - Wolcott et al., 1986
15 - Yanagida et al., 1981

The same numbering system applies to Figures 3 - 1 through 3 - 4.

Figure 3 - 2. Noncompliance rates for BUN
Figure 3 - 3. Noncompliance rates for phosphorous
As is evident from these results, there is a notable lack of agreement among the noncompliance rates in the NCDS sample when they are calculated on the basis of compliance criteria used in previous studies. For example, when NCDS data are analyzed in terms of previously reported criteria for weight gain compliance, noncompliance rates for interdialytic weight gain in the NCDS sample range from a low of 6% when the definition employed by Cummings et al. (1981, 1982) and Wolcott et al. (1986) is used, to a high of 75% when the criterion...
used by Wirth and Folstein (1982) is applied. The mean noncompliance rate for interdialytic weight gain in the NCDS sample when criteria from previous studies are applied is 39.9% (sd = 24.8). Fifteen subjects could not be classified due to missing data; 38 subjects (17.5%) who dropped out of the control phase and for whom weight data were unavailable were also excluded from the classification.

Similarly, potassium noncompliance rates vary widely when the compliance criteria used in previous studies are applied to the NCDS sample. The most stringent criterion is Blackburn’s (1977) which classifies 49% of the NCDS sample as being noncompliant, while the least stringent criterion (Kaplan de-Nour & Czaczkes, 1972, 1976; Winokur et al., 1973) assigns only 2% of the NCDS sample to the noncompliant category. The mean potassium compliance rate in the NCDS sample when criteria from 11 previous studies are applied is 21.7% (sd = 16.9). Two subjects (0.9%) were unclassified due to missing potassium data.

Rates for phosphorous noncompliance in the NCDS sample are less divergent than those for potassium. Phosphorous noncompliance rates in the NCDS sample range from 34% when the definition used by Cummings et al.
(1982) and Wolcott et al. (1988) is employed to 81% when the definition used by Witenberg et al. (1983) is employed. The mean phosphorus noncompliance rate in the NCDS when criteria from previous studies are applied is 49.0% ($s = 13.8$). Only one subject (0.5%) was excluded from classification due to missing data.

There is less divergence among the criteria used to define BUN compliance. This could be due to that the fact that elevated BUN levels are seen as less dangerous than the other compliance indicators and so researchers tend to be more liberal in defining BUN noncompliance. Noncompliance rates for BUN in the NCDS sample range from 11% when the definition of Wenerowicz et al. (1978) is used to 26% when the criterion used by Kaplan de-Nour and Czaczkes is applied. The mean BUN noncompliance rate in the NCDS sample when criteria from previous studies are applied is 19.0% ($s = 8.5$). Only one subject (0.5%) was excluded due to missing BUN data.

3.6 Discussion and implications

One of the difficulties involved in comparing studies which examine the psychological correlates of compliance is that many of the studies which have been reported in the literature used subjective estimates of psychological variables or used measurements of unknown
reliability and validity. For example, some studies used standardized intelligence tests (e.g., Winokur et al., 1973) but others simply had hospital staff members rate the patients' intelligence (e.g., Borkman, 1976). This makes comparison of the predictors used in different studies difficult.

The preceding analysis further suggests that there may be methodological problems in the definitions of compliance used in many studies. Not only are there wide discrepancies in the specified ranges of acceptable values for defining compliance with different aspects of the treatment regimen, but several compliance definitions lack objective criteria (i.e., the subjective ratings) and are of unknown reliability. The consequences of the lack of standardization among compliance criteria are evident in the wide discrepancies in noncompliance rates estimated in a single sample on the basis of different definitions. When different compliance criteria from previous studies are applied to a single sample, the noncompliance estimates show a great deal of variability, demonstrating poor agreement between previously used definitions of compliance. The largest discrepancies were found among the various criteria used with weight
gain and potassium, and smaller inconsistencies were demonstrated for phosphorous and BUN compliance. Although there may be some variation in noncompliance rates among different patient samples, results from this study suggest that the inconsistencies in the literature concerning the extent of noncompliance among hemodialysis patients are primarily due to problems with the definition and measurement of compliance.

These findings have several implications. First, without a reliable method of defining and measuring compliance, it is not possible to predict reliably who will be noncompliant. That is, because different compliance criteria for assessing outcome are employed across studies, factors which predict compliance in one patient sample may not reliably predict compliance in another sample. In studies which compare compliant and noncompliant patients on sociodemographic, psychological, and treatment related factors, few factors have been found that are clearly and consistently related to compliance.

Second, given the lack of standardized hemodialysis criteria, the development of interventions for improving compliance will be seriously limited. That is, compliance-enhancing strategies with
demonstrated effectiveness in one treatment setting may not be successful in other settings where compliance is defined on the basis of different criteria. This may explain in part why efforts to improve compliance have met with limited success.

Third, because many different definitions of compliance are employed in the literature, comparisons across studies are difficult to make and, consequently, there are numerous discrepancies in the conclusions reached by various investigators concerning compliance in hemodialysis. It is not surprising, therefore, that investigators who report a high noncompliance rate present an unfavorable view of adjustment to dialysis (Kaplan de-Nour & Czaczkes, 1972), which is in contrast to the more positive impression one gains from other reports which emphasize the adaptive capacities of these patients (Binik, 1983).

Finally, many definitions combine the commonly used physiological indicators of compliance in an idiosyncratic fashion. Their assumption that patients tend to be compliant or noncompliant with respect to all of the measures used may be incorrect (Armstrong & Woods, 1983). Furthermore, such definitions may leave many patients unable to fit into any of their
categories.

These findings seem relevant to the management of hemodialysis patients. Until standardized definitions of compliance are developed and widely used, there is likely to be disagreement among nephrologists concerning what the acceptable levels are for the various compliance indicators. In addition, the question of the compliance definitions needs to be addressed (Gordis, 1979). Among the various definitions of compliance, there is no method of determining the optimal one because a generally accepted standard for compliance measurement does not exist (Rudd, 1979). Furthermore, few compliance criteria have been examined with respect to outcome. Although it is generally assumed that failure to comply with diet, fluid, medication, and treatment requirements is directly and adversely related to outcome, few studies in the literature have examined the relationship between compliance and morbidity or mortality. Do compliant patients in fact live longer and have fewer complications than noncompliant patients? This issue will be explored in a subsequent chapter.

The findings from this re-analysis of the NCDS data are also relevant to researchers who wish to find psychological predictors of compliance. The large
differences observed when different definitions of compliance are applied to the same sample makes it evident that comparisons across studies which attempted to predict compliance may be futile. Any differences between the results of the studies may be due to the approaches they used to define and measure compliance. For example, Borkman (1978) found that intelligence was positively related to some aspects of compliance but Winokur et al. (1981) found that intelligence was not related to compliance. This disagreement may be due to the differences between the techniques used to measure intelligence in the two studies or the differences between the definitions of compliance they used.

Similarly, Blackburn (1977) reported that locus of control was unrelated to compliance but Poll and Kaplan de-Nour (1980) found that patients with an internal locus of control were more compliant. In this last example, both studies used the Rotter Locus of Control Scale and so the differences between their findings cannot be attributed to differences between the personality measurement techniques they employed.

Although the analyses reported in this chapter are based on only a subset of patients who entered the NCDS this sample was comparable to the overall sample of
study patients in terms of age, duration of dialysis, gender, and race. Furthermore, the NCDS study population was representative of nondiabetic dialysis patients in the U.S. although it was slightly younger and contained a greater proportion of blacks. Therefore, the findings from the analyses conducted on a sample of NCDS patients may be generalizable to other nondiabetic, adult dialysis patients in other U.S. dialysis centers.

An important issue concerns the stability of the compliance measures used in this study. The compliance data were drawn from a short 12-20 week period which may not generalize to long term compliance. However, there is evidence that compliance measures show stability over time, from a 12 week baseline period to 6, 12, and 18 months follow-up (Lamping, Campbell, & Churchill, 1988a; see also Chapter 4 in this dissertation). Therefore, the compliance estimates obtained in this subset of NCDS patients may be stable and generalizable to long term compliance.

One limitation of the current study is that the estimates of the prevalence of noncompliance may be conservative due to the exclusion criteria used in the NCDS. Because minimum compliance criteria were required
for inclusion in the NCDS sample, severely noncompliant patients were excluded. Therefore, noncompliance rates in the NCDS sample may underestimate the actual noncompliance rates in an unselected sample. However, because the focus of the present study was on investigating the problems related to the definition of compliance, rather than on examining the problem of compliance as such, this limitation is unlikely to affect the conclusions drawn from this study.

The great differences between the definitions of compliance examined in this chapter present a serious problem for the researcher. Specifically, how does one select the best definition? One method would be to evaluate the various definitions in terms of criterion validity. That is, the best definition of compliance would be one that predicts patient survival. Given the poorly defined and subjective nature of many of these predictions, however, a better approach would be to develop an objective definition of compliance based on patient outcome. The next chapter deals with an attempt to develop an objective and valid method of measuring compliance.
4 Chapter 4

Dietary compliance and outcome in hemodialysis

One key issue in compliance research is the question "Is compliance in the patient's benefit?" In other words, do those patients who follow medical advice lead longer or healthier lives than those who do not? Despite the considerable amount of research on dietary compliance in hemodialysis patients, and the efforts made to improve their compliance, there have been few attempts made to relate dietary compliance to morbidity or mortality. It is especially surprising that none of the proposed definitions of compliance have been validated against outcome because that would appear to be an optimal method of establishing a definition of compliance. Furthermore, it would appear that a definition of compliance that had criterion validity could be useful in further research. In order to develop a definition of this nature we would have to determine the relationship between various aspects of the treatment program and outcome. Using this information we could then select only the aspects of the

2 Parts of this study have appeared in Lamping, Campbell, and Churchill, 1988a, 1988b.
treatment program which are related to outcome and use this information to develop a definition of compliance that had criterion validity.

There are two other issues which may also be of importance but which have not yet been addressed in the research literature. The first of these is the degree of temporal stability seen in the dietary compliance of hemodialysis patients. Do patients tend to show the same degree of compliance over time? The second is the degree to which the patients show consistency across compliance measures. Do patients who comply with one aspect of the diet tend to comply with other aspects of the diet too?

The present study followed a group of hemodialysis patients for a period of 2 years. During that time the standard physiological indicators of dietary compliance were recorded as well as the reasons for each hospitalization. The aim of this study was to examine the relationship between compliance and outcome which could be used to develop an outcome-based definition of compliance. Because of this we avoided use of any of the previously published categorical definitions of compliance. Instead the actual value of each compliance indicator was used in the analyses. It should be noted that the design of this study is retrospective because data collection for the
study started in 1985.

4.1 Method

4.1.1 Subjects

Names of patients who were in the end-stage renal disease program at St. Joseph's Hospital were recorded in an annual directory prepared by hospital personnel. All of the patients who were listed in 1980 and 1981 were considered to be potential subjects. In order to qualify for inclusion in the sample the patient had to have been on hemodialysis for 3 or more consecutive months. Those who had been on hemodialysis for 3 or more months as of January 1, 1980 were entered into the study on the date of their first hemodialysis treatment in 1980. Other subjects were added to the sample as soon as they met the criterion. New subjects were added until December 31, 1981. All subjects were followed for a period of 2 years from the date on which they became eligible for the study. Patients who had a failed transplant or who had been on another form of dialysis were eligible after they had switched to hemodialysis and had been on it for 3 consecutive months.
Study patients who received a kidney transplant during the study period were not followed after the transplant procedure. For example, a patient who entered the study in January of 1980 and was transplanted several months later would not be followed post-transplant even if the patient been on hemodialysis for more than 3 months after failure of the transplant. Similarly, patients who switched from hemodialysis to another form of treatment such as CAPD were not followed after they switched.

The sample consisted of 99 patients, 86 men and 33 women. They ranged in age from 11.8 to 77.3 years (mean = 47.6, sd = 15.8) and had been on hemodialysis for .25 to 12.8 years (mean = 3.09, sd = 3.28). The sample include 14 subjects who had one unsuccessful transplant and two subjects who had two failed transplants. The most common primary diagnoses for the cause of chronic renal failure were glomerulonephritis with unspecified pathological lesion in the kidney (n = 26) and nephritis and nephropathy (n = 12) all of which are nonspecific diagnoses. In addition there were subjects with cystic kidney disease (n = 11), and diabetes with renal manifestations (n = 8). Diabetes mellitus had been diagnosed in 13 of the patients. Two
subjects who did not have any notation in their charts concerning the presence or absence of diabetes and who were not receiving insulin or oral hypoglycemics were classified as non-diabetic on the grounds that if a serious condition such as diabetes existed it would have been recorded on the chart.

4.1.2 Procedure

4.1.2.1 Compliance indicators

At entry into the study the patients entered a 3 month baseline compliance assessment period. During the baseline assessment period all of the compliance indicators were recorded. All of the interdialytic weight gains in this period were recorded and their mean was computed in order to obtain a reliable measure of interdialytic weight gain. BUN and K values were recorded for the first treatment of each month. P was also measured monthly and recorded. The mean values of BUN, K, and P were calculated and used in subsequent analyses.

Following the baseline compliance assessment period the compliance indicators were recorded for each of the patients at 6, 12, and 18 months after they entered the study. In these subsequent assessment periods the first measurement of BUN, K,
and P which was entered on the patients' charts for the time period was recorded. Interdialytic weight gains for the month were recorded and the mean values were calculated and used in subsequent analyses.

4.1.2.2 Morbidity and mortality

Reasons for hospitalizations were recorded on hospital discharge records which were kept in each patient's chart. In order to analyze the results it was necessary to collapse the various diseases into several categories. These categories were based on the International Classification of Disease (ICD-9; United States Department of Health and Human Services, 1980) and clinical experience. All of the hospital discharge records contained the ICD-9 codes of the diseases for which the patient was hospitalized. Furthermore, ICD-9 codes were also recorded on death certificates so that the same categories could be used in classifying cause of death.

The seven disease categories were;

1) Infectious illness - respiratory
2) Infectious illness - non-respiratory

3 Thanks to D.N. Churchill
3) Access related complications  
4) Cardiovascular disorders  
5) Cancer  
6) Chronic renal failure related conditions  
7) Other (e.g., psychiatric)  

4.1.2.3 Two year follow-up  

For the 2 year follow-up hospitalization records, which were part of the patients' charts, and dialysis treatment records were used as the sources of information on compliance and hospitalizations. This represents a total of 129 patient-years. Due to the small number of deaths in the 2 year period it was not possible to examine cause of death although the relationship between compliance and survival was investigated.  

4.2 Results  

4.2.1 Descriptive statistics on compliance indicators  

Descriptive statistics on the baseline compliance indicators are presented in Table 4 - 1. There was only one outlier for these variables. Subject 92 had a mean potassium value of 9.8 which is 8 std units above the mean calculated with this subject excluded. Therefore, this subject was excluded from the
regression analyses which included potassium as a predictor. Because multiple regression uses a least-squares criterion, it can be strongly influenced by extreme outliers leading to seriously distorted results.

Outliers were also found on potassium at the 12 month and eighteen month assessment periods. At 12 months subject 63 had a measurement of 10.4 which was 5.9 sd above the mean of 5.2 (sd = .88) computed without subject 83. Similarly, at 18 months subject 13 had a potassium level of 9.6 which was 5.2 sd above the mean of 5.1 (sd = .88) computed without this subject. Subject 63 was excluded from all analyses which used the 12 month potassium values and subject 13 was excluded from those analyses which used the 18 month potassium value.

Table 4 - 1
Baseline compliance indicators

<table>
<thead>
<tr>
<th>Compliance indicator</th>
<th>Units</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUN</td>
<td>mg/dL</td>
<td>94</td>
<td>71.42</td>
<td>18.77</td>
</tr>
<tr>
<td>K</td>
<td>mEq/L</td>
<td>92</td>
<td>4.97</td>
<td>.79</td>
</tr>
<tr>
<td>P</td>
<td>mg/dL</td>
<td>92</td>
<td>5.37</td>
<td>1.37</td>
</tr>
<tr>
<td>Weight gain</td>
<td>kg</td>
<td>92</td>
<td>1.54</td>
<td>.85</td>
</tr>
</tbody>
</table>
4.2.2 Stability over time

The stability correlations are presented in Table 4-2. They were calculated by correlating the compliance measurements taken at baseline with the same measurements taken at each of the follow-up points. It can be seen that the patients were, on average, stable in their degree of compliance. All of the compliance indicators showed significant correlations over the 18 month period.4 There are minor changes in the magnitude of the correlations from one time period to another however, given that for an r of .50 the 95% confidence interval is plus or minus .29, it is unlikely that these differences are statistically significant.

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4 All of the analyses reported in this dissertation used an alpha level of .05 to determine statistical significance. In a few analyses where a large number of tests were performed a lower value of alpha was used to control the Type I error rate. When a value of alpha other than .05 was used, it is specifically stated.
Table 4 - 2

Temporal stability of compliance indicators

<table>
<thead>
<tr>
<th>Compliance indicator</th>
<th>6 month</th>
<th>12 month</th>
<th>18 month</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUN</td>
<td>.63***</td>
<td>.59***</td>
<td>.43**</td>
</tr>
<tr>
<td></td>
<td>(62)</td>
<td>(53)</td>
<td>(42)</td>
</tr>
<tr>
<td>K</td>
<td>.61***</td>
<td>.42***</td>
<td>.59***</td>
</tr>
<tr>
<td></td>
<td>(61)</td>
<td>(52)</td>
<td>(42)</td>
</tr>
<tr>
<td>P</td>
<td>.62***</td>
<td>.42**</td>
<td>.43**</td>
</tr>
<tr>
<td></td>
<td>(64)</td>
<td>(51)</td>
<td>(42)</td>
</tr>
<tr>
<td>Weight gain</td>
<td>.78***</td>
<td>.49***</td>
<td>.73***</td>
</tr>
<tr>
<td></td>
<td>(70)</td>
<td>(58)</td>
<td>(48)</td>
</tr>
</tbody>
</table>

NOTE. All tests are one-tailed, * indicates \( p < .05 \), ** indicates \( p < .01 \), *** indicates \( p < .001 \). The number in brackets indicates the number of subjects that the correlation was based on.

4.2.3 Consistency across indicators

The baseline compliance measures showed little consistency across the various indices. The results of these correlations are presented in Table 4 - 3. BUN was weakly but significantly related to K and P. This may be due to the fact that foods which would produce high BUN values, such as meat or cheese, tend to be high in K and P as well (Pennington & Church, 1980).
Table 4 - 3
Consistency of baseline compliance

<table>
<thead>
<tr>
<th></th>
<th>K</th>
<th>P</th>
<th>Weight gain</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUN</td>
<td>.37**</td>
<td>.38***</td>
<td>.13</td>
</tr>
<tr>
<td></td>
<td>(92)</td>
<td>(89)</td>
<td>(90)</td>
</tr>
<tr>
<td>K</td>
<td></td>
<td>.22*</td>
<td>.10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(87)</td>
<td>(88)</td>
</tr>
<tr>
<td>P</td>
<td></td>
<td></td>
<td>.18</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(87)</td>
</tr>
</tbody>
</table>

NOTE. All tests are two-tailed, * indicates \( p < .05 \), ** indicates \( p < .01 \), and *** indicates \( p < .001 \).
The number in brackets indicates the number of subjects which the correlation coefficient is based on.

4.2.4 Morbidity, mortality, and compliance

Upon examination of the hospitalization information it was noted that eight subjects (subject numbers = 18, 24, 50, 84, 85, 88, 95, and 98) had spent an excessive number of days in the hospital. All eight of these subjects, who were from 3.8 to 35.0 standard deviations above the mean, were excluded from the analyses which involved the number of days in hospital, however they were included in the analyses which were based on whether or not the patient had been hospitalized.
The average patient (excluding outliers) spent a mean of 14.8 (sd = 17.7) days in hospital in the 2 year study period. The most common reason for hospitalization was complications associated with chronic renal failure which was a cause of hospitalization for 44% of the patients. Twenty-one percent of the patients had been hospitalized for cardiovascular disorders, and 18% had been hospitalized for other diseases. Only 17 of the patients died during the 2 year period. The analyses presented here are based on whether or not the patient was hospitalized for each type of disease in the 2 year study period. Because whether or not the patients had been hospitalized for a particular disorder was effect-coded, it was not necessary to exclude any of the outliers on the hospitalization variables. In effect-coding a value of -1 was used to represent the absence of the condition while a value of +1 was used to represent the presence of the condition (see Pedhazur, 1982, pp. 289-290). The analyses have also been repeated based on the number of times each patient was hospitalized for each disease, with outliers excluded. There were no differences between the results in terms of statistical significance and so the
second set of analyses is not reported here. Because each set of analyses (i.e., one for compliance and one for other predictors) required a total of nine regression equations a \( p \) value of .005 was used as the criterion for determining statistical significance for these specific analyses. This would produce an overall error rate of .045 for each set of analyses.

The first relationship examined was that between the baseline compliance indicators and the number of days each patient spent in the hospital during the study period. Eight outliers on the total number of days in hospital and one outlier on the baseline potassium measures were excluded. The relationship was not statistically significant (multiple \( R = .23, F(4, 73) = 1.02, p = .405, ns \)). The second relationship examined was that between compliance and whether or not the patient survived to the end of the study period. Once again, this relationship was not statistically significant (multiple \( R = .233, F(4, 79) = 1.132, p = .347, ns \)). One subject who was an outlier on baseline K was excluded from this analysis.

There was no statistically significant relationship between compliance and hospitalization for
cardiovascular disorders (multiple $R = .16$, $F(4, 79) = .502$, $p = .735$, ns; one outlier on baseline K was excluded). Baseline compliance did not predict hospitalization for respiratory infections (multiple $R = .14$, $F(4, 79) = .423$, $p = .791$, ns; one outlier on baseline K was excluded) nor did it predict hospitalizations for non-respiratory infections (multiple $R = .32$, $F(4, 79) = 2.231$, $p = .073$, ns; one outlier on baseline K was excluded). Compliance was also unrelated to hospitalization for cancer (multiple $R = .20$, $F(4, 79) = .804$, $p = .528$, ns; one outlier on baseline K was excluded). Compliance also did not predict access related complications (multiple $R = .32$, $F(4, 79) = 2.241$, $p = .072$, ns; one outlier on baseline K was excluded). Hospitalization for other disorders was also not related to compliance (multiple $R = .09$, $F(4, 79) = .166$, $p = .955$, ns; one outlier on baseline K was excluded). Finally, hospitalization for complications associated with chronic renal failure was not related to compliance (multiple $R = .20$, $F(4, 79) = .812$, $p = .521$, ns; one outlier on baseline K was excluded).

In summary it appears that the compliance indicators are not good predictors of death,
hospitalization, or the development of disease. All of the regression analyses predicted 10% or less of the variance observed and none reached statistical significance.

4.2.5 What does predict outcome?

Given the poor performance of compliance in predicting outcome one is then led to wonder if outcome can be predicted at all. It has been suggested that age, diabetes mellitus, and the number of years on hemodialysis may be good predictors of outcome (D.N. Churchill, personal communication; Hutchinson, Thomas, & MacGibbon, 1982). Therefore the relationship between these measures and morbidity and mortality was examined.

This second set of predictors did not predict the total number of days the subjects spent in the hospital (multiple R = .198, F(3, 78) = 1.064, p = .369, ns; eight subjects who were outliers on the number of days in hospital were excluded). The second set of predictors did predict mortality (multiple R = .581, F(3, 85) = 13.005, p < .00005; see Table 4-4). Age and diabetes both made significant contributions to the prediction (p < .00005 and p < .008, respectively). Older patients and patients with diabetes were more
likely to die than were younger patients and those without diabetes. Hospitalization for cardiovascular disorders was not related to age, diabetes, or the number of years on dialysis (multiple $R = .255$, $F(3, 85) = 1.977$, $p = .124$, ns). Neither was hospitalization for respiratory infections (multiple $R = .17$, $F(3, 85) = .846$, $p = .473$, ns) and hospitalization for non-respiratory infections (multiple $R = .29$, $F(3, 85) = 2.550$, $p = .081$, ns). The second set of predictors did not predict hospitalization for cancer (multiple $R = .24$, $F(3, 85) = 1.683$, $p = .181$, ns) nor did they predict hospitalization for access related complications (multiple $R = .09$, $F(3, 85) = .244$, $p = .866$, ns). Hospitalization for other disorders was unrelated to the second set of predictors (multiple $R = .09$, $F(3, 85) = .248$, $p = .862$, ns) as was hospitalization for complications associated with chronic renal failure (multiple $R = .17$, $F(3, 85) = .803$, $p = .498$, ns).
Table 4 - 4

Relationship between other predictors and mortality

<table>
<thead>
<tr>
<th>Predictor</th>
<th>B</th>
<th>β</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>.020</td>
<td>.433</td>
<td>4.611</td>
<td>&lt;.00005</td>
</tr>
<tr>
<td>Diabetes</td>
<td>.564</td>
<td>.257</td>
<td>2.715</td>
<td>.008</td>
</tr>
<tr>
<td>Years of dialysis</td>
<td>-.001</td>
<td>-.040</td>
<td>.438</td>
<td>.863, ns</td>
</tr>
<tr>
<td>Constant</td>
<td>-1.675</td>
<td></td>
<td>7.676</td>
<td>&lt;.00005</td>
</tr>
</tbody>
</table>

Again it would appear that outcome in hemodialysis patients is difficult to predict. The only statistically significant prediction which was observed was for death. Age and diabetes both made significant contributions to this relationship with older patients and diabetics more likely to die.

4.3 Discussion

In summary it appears that dietary compliance, assessed using conventional methods, has little influence on morbidity or mortality in hemodialysis patients. This is in contrast to the frequently repeated claims that dietary compliance is of crucial importance in the treatment of these patients (e.g., Finn & Alcorn, 1986; Stretzer & Hassell, 1988). It was
found that age and the presence of diabetes were good predictors of survival which is in agreement with similar studies.

Several studies have been done which examined the relationship between survival and various predictors other than dietary compliance. Hellerstedt (Hellerstedt, Johnson et al., 1984; Hellerstedt, Shapiro, & Anderson, 1984) reported results that are consistent with the findings of this study. They reported that diabetics and older patients had shorter survival times. Held et al., (1987), in their 5 year study of 4,881 patients, also found that older patients were more likely to die than were younger patients. Devins et al. (1990) also looked at predictors of survival in hemodialysis patients. They followed 100 patients for 46 months and found that the best physical and demographic predictors of survival were age and the number of comorbid conditions. Patients who were younger and had fewer medical problems were likely to survive longer. Hutchinson et al., (1982) obtained comparable findings in their study of 220 patients. They found that age, the duration of diabetes, and left-sided heart failure were strongly related to the 5 year survival rate. Older patients, patients who had
diabetes for longer periods of time, and those who had left-sided heart failure were more likely to die. Neff et al. (1983) followed 37 hemodialysis patients for 10 years and found that older patients were more likely to die but they did not find a relationship between diabetes and death. Similarly, Silins et al. (1989) followed 8,432 patients with end-stage renal disease who were receiving dialysis or had received a transplant and found that older patients were much more likely to die than were younger patients.

Ruggiero, Brantley, and Bruce (1988) followed 110 hemodialysis patients for 4 years. Using measurements of BUN, K, and weight gain, but not P, to evaluate compliance they found that dietary compliance was not a significant predictor of the number of months that the patients survived. They did find that age at onset of dialysis and age at the time of the study were good predictors of survival. Manley and Sweeney (1986) followed 34 patients for 1 year. They found that there were no significant differences in the levels of BUN, K, or interdialytic weight gain between the patients who were hospitalized with complications and those who were not. Manley and Sweeney did not measure their patients' levels of P. One study did find that low levels of BUN
were associated with longer survival. Foster et al., (1973) followed 21 patients for approximately two years and found that the patients who died had higher BUN levels than did those who survived.

It should be noted that the conventional methods of measuring dietary compliance, as used in this study and in others, do have some problems. Specifically, they are indirect and non-specific. When measuring compliance using these physiological indicators we are not measuring compliance directly. We assume, for example, that if a patient's potassium has gone up then the patient's consumption of potassium has been high although we do not, in fact, directly measure the patient's potassium consumption. This leads to the second problem; the measures used are non-specific. Once again, we assume that if a patient's potassium level is high that means that the patient has consumed a large amount of potassium but there are actually several possible explanations for elevated potassium levels. It could be that the patient did consume a large amount of potassium. Another explanation is that the patient did not take potassium binding medication or did not take the medication appropriately. Yet another explanation is that the patient missed the previous dialysis
treatment or terminated the previous treatment prematurely. Therefore, an elevated potassium level may reflect something other than cheating on the diet.

The failure of this study and others to find a relationship between dietary compliance and outcome makes it ethically permissible to do a true experiment to determine if there really is no relationship. The ideal approach would be to recruit new patients when they are just beginning hemodialysis and to randomly assign half of them to a strict diet and half to a more liberal diet prescription and then follow the patients for a period of at least 2 years. If diet actually does have no effect on outcome then the two groups would not differ in terms of morbidity and mortality. Previously it would have been unethical to conduct this type of study because it was felt by many that a liberal diet would have serious negative effects on the patients' health. The current research suggests, however, that this may not be the case and raises the possibility that many patients are on diets which are too restrictive and which may adversely affect the patients' quality of life and likelihood of compliance. However, before proceeding with such a study it would be prudent to replicate the current study at another dialysis center.
to confirm these results. Such a replication would be considerably easier than the current study because some dialysis units are switching to computerized databases to record information about their patients and this could significantly reduce the time and effort involved. A final area of research which should also be explored is the exact relationship between food consumption and the commonly used indicators of compliance. It is not known, for example, how strong the relationship is between the number of grams of protein consumed and BUN levels.

The preceding two chapters indicate that there is little agreement on how to measure dietary compliance in hemodialysis. Given the lack of a relationship between compliance assessed using physiological measurements and outcome, it may be impossible to develop a definition of compliance that has criterion validity. This difficulty in developing an objective and valid approach to the measurement of compliance in dialysis presents a serious obstacle for research on predictors of compliance. For this reason, the focus of the research in this dissertation changed from dietary compliance in hemodialysis patients to dietary compliance in Type 2 diabetics where there is agreement on how to measure
compliance and the strong likelihood that there is a relationship between compliance and outcome in diabetes. This condition might be a more appropriate choice for an effort to examine the relationship between personality factors and compliance than hemodialysis would be.
5 Chapter 55

Prediction of compliance in Type 2 diabetes mellitus

This study examined the ability of two psychological theories to predict weight reduction in obese Type 2 diabetics for whom weight loss was medically indicated. The theories which were examined were self-efficacy, which is a part of cognitive social learning theory (Bandura, 1986a, 1986b), and the Health Belief Model. Physiological factors, such as insulin levels, which could influence weight loss were also examined.

5.1 Method

5.1.1 Procedure

The study took place at the Diabetic Day Care Clinic (DDCC) of the McMaster University Health Sciences Center which provides a referral service for the Hamilton and Niagara Peninsula regions. A standardized clinical service is provided by eight staff physicians, three full-time clinical nurse specialists, and one full-time and one part-time dietitian.

5 Portions of this chapter have been presented in Campbell, Haynes, Lamping, & Owens (1988) and Campbell, Owens, Lamping, & Haynes (1988).
Every morning the experimenter reviewed the charts of all of the patients who had appointments to see one of the dietitians. If any of the patients qualified for inclusion a marker was placed on the dietitian's timetable beside the patient's name. The dietitian then explained the study to the subject, obtained informed consent, and administered the questionnaire to the subject. Weight, blood glucose, serum insulin, and hemoglobin A1c were measured at this time. (Hemoglobin A1c is an indication of the highest glucose levels the patient experienced during the past month and is useful in assessing long-term glycemic control; Boden, Master, Gordon, Shuman, & Owen, 1980; Bunn, 1981; Nathan, Singer, Hurxthal, & Goodson, 1984; Service, O'Brien, & Rizza, 1987). When patients completed their first visit an appointment was made for them to return in 6 months.

Shortly before their 6 month follow-up visit the patients were mailed a reminder letter and another copy of the questionnaire to complete at home prior to their clinic visit. When they returned to the clinic the dietitian collected their completed questionnaires and repeated the physiological measurements. Any physiological measurements which were made at an
intermediate point in time, i.e. approximately 3 months after the first visit, were also recorded. When patients missed their 6 month follow-up visit they were contacted by phone in order to book another appointment.

5.1.2 Questionnaire

The 75 item questionnaire (Appendix A) was developed on the basis of previous pilot-testing. Most of the items were selected from a pilot version of the questionnaire which was composed of questions formulated on the basis of a review of research on obesity. Other questions were included which addressed specific concerns of clinic staff members. The questionnaire was self-administered although someone was available to assist the subjects with any difficulties which they may have had with it.

Three formats were used for the questions. The least common format required the patients to write an answer, such as weight loss goal, in a blank space. The majority of the questions were either multiple choice, where the subject was instructed to select the most appropriate answer or answers, or a seven point rating scale. Seven point rating scales were used because although the reliability of a rating scale
increases with the number of points only small increases in reliability occur with more than seven points (Nunnally, 1967, p. 521).

The actual items used in the questionnaire were derived from several sources. The items in the self-efficacy scale were generated based on Bandura's (1977, 1982, 1986a, 1988b) definition of self-efficacy and an examination of self-efficacy scales developed in other areas. Health Belief Model questions were based on examples given by Becker (Becker & Naiman, 1975; Becker et al., 1979). Reliability and validity of these measures are discussed below.

At the start of the present research there were only two studies which had examined the relationship between self-efficacy and weight loss or food consumption. In a conference presentation, Glynn and Ruderman (1984) reported a relationship between self-efficacy and weight loss and food consumption. Examination of the contents of their "Eating Self-Efficacy Scale (ESES)" suggests, however, that the scale does not measure self-efficacy. The questions include items such as "How difficult is it to control your... [ellipsis in original] 1) Overeating after work or school ... 5) Overeating when tense..." (Glynn &
Ruderman, 1988, p. 408). These questions ask about current difficulties in controlling overeating. Self-efficacy is a future-oriented theory and is based on the subjects’ expectations about their future behaviors. Although using current behavior to predict future behavior, which is what the ESES does, is a valid strategy it does not measure self-efficacy. This failure of the questionnaire to measure self-efficacy may explain why it has not been used in any further published research.

The second study to examine the relationship between eating and dieting self-efficacy was presented by Stotland, Roy, and Zuroff (1988). Their conference abstract did not contain the items used in their questionnaire and they failed to respond to a request for a copy of the questionnaire and further information about their study. A subsequent publication (Stotland, Zuroff, & Roy, 1991) did contain the items used in their questionnaire but it was too late to be included in this study.

5.1.3 Subjects

In order to qualify for participation in this study all of the subjects had to meet the diagnostic criteria for Type 2 diabetes mellitus established by
the Canadian Diabetes Association (Rodger, 1982). In addition, subjects had to weigh 10% more than the ideal weight for their height (Metropolitan Life Insurance Company, 1983), speak and read English fluently, and give informed consent. Table 5 - 1 presents the inclusion criteria.

Table 5 - 1
Inclusion criteria

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elevated glucose</td>
<td>Fasting glucose $\geq 7.8$ mmol/l repeated or Glucose $\geq 11.1$ mmol/l once prior to glucose tolerance test and $\geq 11.1$ at least twice during the test</td>
</tr>
<tr>
<td>Exogenous insulin administration</td>
<td>Cannot be receiving insulin injections</td>
</tr>
<tr>
<td>Not insulinopenic</td>
<td>Serum insulin $&gt; 100$ pmol/l on randomly collected basis</td>
</tr>
<tr>
<td>Obese</td>
<td>At least 10% above Metropolitan Life standards for height and gender (assume everyone is large framed)</td>
</tr>
<tr>
<td>Age</td>
<td>Between 21 and 75 years old</td>
</tr>
<tr>
<td>English</td>
<td>Reads and speaks English fluently</td>
</tr>
<tr>
<td>Consent</td>
<td>Must sign consent form (Appendix A)</td>
</tr>
</tbody>
</table>
5.1.4 Exclusions

During the entry phase of the study a total of 809 charts were reviewed. Of these, 734 failed to qualify for inclusion in the study. The reasons for exclusion are presented in Table 5-2.
Table 5-2

Reasons for rejection

<table>
<thead>
<tr>
<th>Reason</th>
<th>N</th>
<th>Percent of rejections</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose too low</td>
<td>80</td>
<td>11</td>
</tr>
<tr>
<td>Insulin injections</td>
<td>324</td>
<td>44</td>
</tr>
<tr>
<td>Insulinopenic</td>
<td>60</td>
<td>8</td>
</tr>
<tr>
<td>Not obese</td>
<td>147</td>
<td>20</td>
</tr>
<tr>
<td>Outside age limits</td>
<td>180</td>
<td>25</td>
</tr>
<tr>
<td>English fluency</td>
<td>16</td>
<td>2</td>
</tr>
<tr>
<td>Refused consent</td>
<td>2</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Not diabetic</td>
<td>86</td>
<td>12</td>
</tr>
<tr>
<td>Not a clinic patient</td>
<td>17</td>
<td>2</td>
</tr>
<tr>
<td>Pregnant</td>
<td>5</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Other disorder or medication which could affect weight or glucose</td>
<td>5</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Psychiatric disorder</td>
<td>2</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

Note. Some patients were rejected for more than one reason.

Total number of patients rejected = 734

Total number of reasons for rejection = 924
5.1.5 Subjects included in the study

Of the 75 subjects who entered the study 7 refused to return for their 8 month follow-up visit, 1 moved and could not be located, and 11 missed two appointments with the experimenter or dietitian. In cases where subjects refused to come for a follow-up visit their charts were reviewed and if they had been examined by a hospital staff member then the data on the charts were used. Because of this some subjects have only partial follow-up information. Follow-up weights were obtained for 65 of the 75 subjects who entered the study which gave a completion rate of 86.7%.

It is important to note that the number of subjects and degrees of freedom reported for the various statistics will change. This is due to several factors. Some data were unavailable for some subjects because the subject missed a question on the questionnaire or did not go to the lab for blood samples. Furthermore, when conducting t-tests, if there was a significant difference in the variances of the two measures a version of the t was used which does not pool the variances and involves calculating degrees of freedom using a non-standard approach (Nie, Hull,

This method inevitably results in fewer degrees of freedom than that obtained by use of the common method.

5.1.6 Time course of the study

Recruitment of subjects began in January 1986 and follow-up continued until June 1988. Because subjects were not entering the study at the expected rate the inclusion criteria were relaxed. We had originally planned to include only subjects who were making their first visit to the clinic but beginning on February 7, 1986 we accepted patients who had been seen previously in the clinic. On April 25, 1986 the minimum serum insulin requirement was lowered from > 150 to >= 100 pmol/l. This relaxation of the inclusion criteria was done in order to increase the sample size. Because the original inclusion criteria were extremely strict the revised criteria still met the Canadian Diabetes Association's diagnostic criteria for Type 2 diabetes (Rodger, 1982) and thus still permitted a test of our hypotheses.

The Family Practice Unit at the hospital agreed to refer diabetics to the DDCC for dietary counselling in order to help increase sample size. At the "Day In
Diabetes" seminars held on January 7, 1987 fliers were distributed to all attendees describing the study and asking them for patient referrals.

5.1.7 Dropouts andCompleters

To ensure that subjects who completed the study were representative of patients who were eligible for the study, dropouts and completers were compared on measures of the physiological and psychological variables made on their first visits. These comparisons were done using multiple regression. Dropout status was dummy coded with a value of zero for subjects who dropped out of the study and a value of one for subjects who completed the study. The regression equation was first computed using the psychological measures of interest and then the baseline physiological measures were added to determine if they added to the predictive power of the equation. The psychological measures are described more fully in a subsequent section.

The first variables entered were baseline self-efficacy and Factor 1 from the Health Belief Model. (The factor analyses are presented in a subsequent section.) This produced a multiple $R$ of .26
which accounted for 6.9% of the variance. The result was not statistically significant \( F(2, 68) = 2.52, p = .088, \text{ ns} \).

Because preliminary analyses and prior research (Forster & Jeffery, 1988) had suggested an interaction between gender and the psychological variables, gender (dummy coded zero for males and one for females) and gender interaction terms were entered next into the equation. The results (see Table 5-3) were a multiple \( R \) of .40 which accounted for 16% of the variance observed. The results were statistically significant \( F(5, 65) = 2.44, p = .043 \) although the first factor of the Health Belief Model Scale was the only one of the individual variables which reached significance.
Table 5 - 3
Prediction of dropout using psychological measures and gender

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>B</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-efficacy</td>
<td>.012</td>
<td>.04</td>
<td>.854</td>
<td>.396, ns</td>
</tr>
<tr>
<td>HBM - 1</td>
<td>.023</td>
<td>.36</td>
<td>2.083</td>
<td>.041</td>
</tr>
<tr>
<td>Gender</td>
<td>.858</td>
<td>1.14</td>
<td>1.517</td>
<td>.134, ns</td>
</tr>
<tr>
<td>Gender x SE</td>
<td>-.015</td>
<td>-.397</td>
<td>.893</td>
<td>.375, ns</td>
</tr>
<tr>
<td>Gender x HBM - 1</td>
<td>-.011</td>
<td>-.578</td>
<td>.702</td>
<td>.485, ns</td>
</tr>
<tr>
<td>(Constant)</td>
<td>-.327</td>
<td></td>
<td>.740</td>
<td>.462, ns</td>
</tr>
</tbody>
</table>

Note. HBM-1 represents the first factor of the Health Belief Model and SE represents self-efficacy.

In the final step physiological variables were entered into the equation. The result was a multiple $R$ of .51 which was significant ($F(9, 56) = 2.222$, $p = .034$) and explained 26% of the variance. The only individual variable that was significant was baseline weight; those with a higher initial weight were less likely to complete the study. (See Table 5 - 4).
Table 5 - 4

Combined psychological and physiological prediction of dropout

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>( \beta )</th>
<th>t</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-efficacy</td>
<td>.003</td>
<td>.051</td>
<td>.205</td>
<td>.838, ns</td>
</tr>
<tr>
<td>HBM - 1</td>
<td>.015</td>
<td>.225</td>
<td>1.182</td>
<td>.242, ns</td>
</tr>
<tr>
<td>Gender</td>
<td>.376</td>
<td>.510</td>
<td>.597</td>
<td>.553, ns</td>
</tr>
<tr>
<td>Gender x SE</td>
<td>-.005</td>
<td>-.131</td>
<td>.283</td>
<td>.778, ns</td>
</tr>
<tr>
<td>Gender x HBM - 1</td>
<td>-.005</td>
<td>-.249</td>
<td>.300</td>
<td>.766, ns</td>
</tr>
<tr>
<td>Glucose</td>
<td>.004</td>
<td>.052</td>
<td>.333</td>
<td>.740, ns</td>
</tr>
<tr>
<td>HAlc</td>
<td>.046</td>
<td>.278</td>
<td>1.857</td>
<td>.069, ns</td>
</tr>
<tr>
<td>Weight</td>
<td>-.005</td>
<td>-.324</td>
<td>2.187</td>
<td>.033</td>
</tr>
<tr>
<td>Weight goal</td>
<td>-.003</td>
<td>-.045</td>
<td>.308</td>
<td>.759, ns</td>
</tr>
<tr>
<td>(Constant)</td>
<td>.160</td>
<td>.243</td>
<td>.809</td>
<td>.686</td>
</tr>
</tbody>
</table>

Note. HBM-1 represents the first factor of the Health Belief Model and SE represents self-efficacy. HAlc represents hemoglobin A1c.

Using the final multiple regression formula to predict whether or not the subject will complete the study produced the following results. (See Table 5 - 5.) Because of missing information 66 subjects were included in the final regression equation. The predictions based on regression were correct 88% of the time but this result was not statistically significant.
(Fisher's exact test $p = .14$, ns). Therefore, subjects who completed the study are likely to be representative of those who entered the study.

Table 5 - 5
Predicting dropout

<table>
<thead>
<tr>
<th>Predicted</th>
<th>Dropout</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dropout</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Completed</td>
<td>0</td>
<td>57</td>
</tr>
</tbody>
</table>

Note. The total number of subjects is 66 because some were missing data and were consequently excluded from the regression equation.

5.2 Results from completed cases

The following analyses focus on three main issues: changes in the physiological measurements, the results of the psychological measurements, and the prediction of weight loss using both psychological and physiological variables.

It should be remembered that the primary focus of the study was the prediction of compliance with a weight loss prescription in this group. Other changes, such as a decrease in serum glucose, are incidental to the study.
but when physiological improvements do occur in combination with weight loss they help to confirm that weight loss was an appropriate treatment.

There are several methods of computing weight loss. The most common one is total weight loss which is calculated by subtracting the weight at the end of the time period from the weight at the start. This measure will be used to compare the results of the present study with previously published literature, however it is not the best measure of compliance. If total weight loss is used as the measurement of compliance then two patients who lost 10 kg will be seen as equally compliant even though one patient may have been told to lose 10 kg and another to lose 20 kg. The best way to avoid this problem is to use percentage of total weight loss goal actually achieved which is calculated using the following formula.

\[
\text{Percentage loss} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Weight loss goal}} \times 100\%
\]

Using the percentage loss approach the two patients in the previous example would be considered to be 100% and 50% compliant respectively. The two measures, total loss and percentage of total goal, are related and correlated .855 (p < .001, two-tailed) in the present study.
In order to interpret the regression coefficients it is important to bear in mind that a weight loss will produce a positive percentage loss. This approach was used because in the case of Type 2 diabetes a weight loss is generally considered to be an improvement in the patients' health.

For the present group, the mean of self-reported weight loss goals was 14.2 kg (range = 3.6 - 34.0, sd = 5.9), although one patient claimed not to have been given a weight loss goal. The mean reported weight loss goal did not differ significantly (t = .94, df = 73, p = .349, ns) from the dietitians' prescription for a 6 month weight loss goal which was 14.4 (range = 4.5 - 34.0, sd = 5.7).

5.2.1 Demographic variables

The total sample of subjects who entered the study consisted of 23 males and 52 females and had a mean age of 51.3 years (sd = 13.4). The majority of the sample was married (n = 55 or 73%). Eight (11%) had been predeceased by their spouse and a further eight were single. Two (3%) were divorced and two (3%) were living common-law.
5.2.2 Did the patients' condition improve?

One important issue, aside from the prediction of compliance, is the changes, if any, in the patients' condition. The question of interest is did the patients' condition improve according to the physiological measurements? The most important of these measurements, from the point of this study, was weight loss. If weight decreased then glucose would also be expected to decrease (Stanik & Marcus, 1980; Wales, 1982; Wing, Epstein, Nowalk, Koeske, & Hagg, 1985) because the purpose of prescribing weight loss for these patients was to reduce their glucose levels. Hemoglobin A1c, which is a long-term indicator of glycemic control, should also decrease if the patient lowers glucose levels for a period of time.

In order to compare weight, glucose, and hemoglobin A1c at baseline and at 6 month follow up a repeated measures MANOVA was used. The multivariate $F$ was significant ($F(3, 51) = 1087.92, p < .00005$). All of the measures showed a statistically significant decrease which means that the patients' condition improved. (See Table 5 - 6 for the results of the univariate statistics.)
Although the changes were statistically significant it is not clear if all of the changes would be considered clinically significant. Glucose changed from a mean of 13.7 mmol/l (sd = 4.9) to a mean of 11.7 (sd = 4.3) which is still above the cutoff point of 7.8 adopted by the Canadian Diabetes Association as the diagnostic criterion for diabetes (Rodger, 1982). Hemoglobin A1c decreased from a mean of 12.2% (sd = 2.1) to a mean of 10.7% (sd = 2.6) which is still above the normal range of 4.5 - 7.5.

Lastly, weight went from a mean of 96.4 kg (sd = 18.2) to a mean of 93.8 (sd = 19.2). This represents a mean decrease of 19.3% (sd = 33.8) of their prescribed weight loss goal. Fifteen subjects gained weight. Two subjects who were given very modest weight loss goals were outliers on this variable and achieved a weight loss of more than 3 standard deviations above the mean for the group with their scores excluded. In fact, the percentage of their weight loss goals which they achieved was more than 5.5 sd above the mean. These two women were excluded from all regression analyses which used the percentage of weight loss goal achieved. Aside from being extremely successful at losing weight, these outliers did not
appear to differ greatly from the other members of the sample. They were within 1.5 standard deviations of the mean age, body mass index, baseline self-efficacy, dietary prescription (in kilojoules), and were within two standard deviations of the mean for baseline glucose and hemoglobin A1c for the women in the sample (calculated with them excluded).

Table 5 - 6
Improvements in physiological measures

<table>
<thead>
<tr>
<th>Measurement</th>
<th>F</th>
<th>df</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>9.81</td>
<td>1, 53</td>
<td>.0028</td>
</tr>
<tr>
<td>Hemoglobin A1c</td>
<td>14.13</td>
<td>1, 53</td>
<td>.0004</td>
</tr>
<tr>
<td>Weight</td>
<td>18.16</td>
<td>1, 53</td>
<td>.0001</td>
</tr>
</tbody>
</table>

5.2.3 Results from the psychological measurements

The psychological measures of interest in this study are self-efficacy and the Health Belief Model. The scales used to measure these two constructs were developed specifically for use in this study. Self-efficacy is defined as one's capability to perform the behaviors required to reach a goal (Bandura, 1977, 1982, 1983, 1986a, 1986b). The Health Belief Model states that people's decisions about whether or not to
comply with medical caregivers' advice are based on an informal cost/benefit analysis by the patient which takes into account the patients' perceptions of severity of disease, susceptibility to complications, benefits of compliance, costs of compliance, and cues for compliance.

5.2.3.1 Self-efficacy

Dietary self-efficacy was measured using five questions, each answered on a seven point rating scale with higher numbers indicating higher levels of self-efficacy. (See Table 5 - 7). Cronbach's alpha for the baseline self-efficacy scale was .70 and for the follow-up self-efficacy scale was .77. Test-retest reliability was .54 ($n = 54, p < .001$) over the 6 month period. The mean baseline self-efficacy score was 18.7 ($sd = 5.9$).
Table 5 - 7
Self-efficacy scale items

<table>
<thead>
<tr>
<th>Question Number</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>29</td>
<td>How difficult do you feel it is to change someone's weight?</td>
</tr>
<tr>
<td>30</td>
<td>How confident are you that you will be able to reach your goal weight?</td>
</tr>
<tr>
<td>31</td>
<td>How easy would it be for you to lose 20 pounds in the next six months?</td>
</tr>
<tr>
<td>32</td>
<td>How easy do you feel it is to diet?</td>
</tr>
<tr>
<td>34</td>
<td>How easy is it to control your weight?</td>
</tr>
</tbody>
</table>

Because the self-efficacy questionnaire was a new measure developed specifically for this study, a more detailed examination of its characteristics was undertaken. A principal components factor analysis was done on the self-efficacy scale and, after varimax rotation (Kim & Mueller, 1978; Pedhazur, 1982; Tabachnick & Fidell, 1983) two factors emerged. (The factor loadings are presented in Table 5 - 8.) Questions 29 and 34 loaded heavily on Factor 2 while questions 30 through 32 loaded on Factor 1. Factor 1 accounted for 47% of the variance and Factor 2 for 21%. The follow-up self-efficacy scale was unifactorial (See Table 5 - 9). This suggests that the two factors obtained in the baseline
questionnaire may be the result of chance variation.

Table 5 - 8
Factor loadings - Baseline self-efficacy

<table>
<thead>
<tr>
<th>Question</th>
<th>Factor 1</th>
<th>Factor 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>29</td>
<td>-.092</td>
<td>.887</td>
</tr>
<tr>
<td>30</td>
<td>.843</td>
<td>.007</td>
</tr>
<tr>
<td>31</td>
<td>.678</td>
<td>.080</td>
</tr>
<tr>
<td>32</td>
<td>.671</td>
<td>.497</td>
</tr>
<tr>
<td>34</td>
<td>.440</td>
<td>.766</td>
</tr>
</tbody>
</table>

Table 5 - 9
Factor loadings - Follow-up self-efficacy

<table>
<thead>
<tr>
<th>Question</th>
<th>Factor 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>29</td>
<td>.774</td>
</tr>
<tr>
<td>30</td>
<td>.485</td>
</tr>
<tr>
<td>31</td>
<td>.721</td>
</tr>
<tr>
<td>32</td>
<td>.845</td>
</tr>
<tr>
<td>34</td>
<td>.808</td>
</tr>
</tbody>
</table>

5.2.3.2 Health belief model

The five subscales which comprise the Health Belief Model and the questions on which they are based are presented in Table 5 - 10. All of the questions were answered using a seven point scale.
where higher numbers indicate more of the attribute. Table 5 - 11 presents Cronbach's alpha for each of the subscales.
Table 5 - 10

Subscales and questions for the Health Belief Model

<table>
<thead>
<tr>
<th>Question</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Severity</td>
</tr>
<tr>
<td>25</td>
<td>How serious do you feel the effects of overweight are from a health point of view?</td>
</tr>
<tr>
<td>60</td>
<td>How serious do you feel your diabetes is?</td>
</tr>
<tr>
<td></td>
<td>Susceptibility to complications</td>
</tr>
<tr>
<td>24</td>
<td>How much of a health risk do you feel being overweight is for you?</td>
</tr>
<tr>
<td>59</td>
<td>How much of a risk to your health do you feel diabetes is?</td>
</tr>
<tr>
<td></td>
<td>Benefits of compliance</td>
</tr>
<tr>
<td>26</td>
<td>Do you feel that dieting is good for you?</td>
</tr>
<tr>
<td>40</td>
<td>How does dieting make you feel?</td>
</tr>
<tr>
<td></td>
<td>Costs of compliance</td>
</tr>
<tr>
<td>27</td>
<td>How many barriers or obstacles do you feel that there are which make it very hard to follow your diet?</td>
</tr>
<tr>
<td>35</td>
<td>How uncomfortable does dieting make you feel?</td>
</tr>
<tr>
<td>37</td>
<td>How many problems has dieting created in your family?</td>
</tr>
<tr>
<td>38</td>
<td>Does dieting make it difficult for you to get through the day?</td>
</tr>
<tr>
<td>39</td>
<td>Is it difficult to prepare or to get the food required by your diet?</td>
</tr>
<tr>
<td></td>
<td>Cues for compliance</td>
</tr>
<tr>
<td>43</td>
<td>Do your friends make it easier or harder to diet?</td>
</tr>
<tr>
<td>45</td>
<td>Does your family (e.g., spouse, parents) make it easier or harder to diet?</td>
</tr>
<tr>
<td>-----</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>61</td>
<td>How often do your family or friends remind you to follow your diet?</td>
</tr>
<tr>
<td>63</td>
<td>How often do your family or friends remind you to exercise daily?</td>
</tr>
</tbody>
</table>

The mean scores for the severity scale were 11.6 ($sd = 2.2$) and for the susceptibility scale the mean was 12.3 ($sd = 2.0$). The benefit scale produced a mean score of 11.2 ($sd = 2.4$) and the costs scale produced a mean score of 15.8 ($sd = 5.9$). Finally, the cues scale had a mean score of 14.7 ($sd = 4.5$).

Table 5 - 11
Cronbach's alpha for Health Belief Model Subscales

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Baseline alpha</th>
<th>Follow-up alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity</td>
<td>.622</td>
<td>.332</td>
</tr>
<tr>
<td>Susceptibility</td>
<td>.688</td>
<td>.682</td>
</tr>
<tr>
<td>Benefits</td>
<td>.486</td>
<td>.612</td>
</tr>
<tr>
<td>Costs</td>
<td>.710</td>
<td>.755</td>
</tr>
<tr>
<td>Cues</td>
<td>.399</td>
<td>.660</td>
</tr>
</tbody>
</table>

From the preceding table it can be seen that few of the subscales in the Health Belief Model have high levels of reliability. The only subscales which reached an acceptable level of reliability on both baseline and follow-up questionnaires were
Susceptibility and Costs. (It has been suggested that reliability coefficients in the range from .70 to .80 are satisfactory for use in research [Kaplan & Saccuzzo, 1982, p. 106].)

A principal components factor analysis with varimax rotation was done on the Health Belief Model subscales for two reasons. First, if some of the subscales were measuring the same attribute they could be combined to yield a more reliable measure of that attribute. Second, if two of the subscales were measuring the same attribute then they could be combined to reduce the number of variables in the analyses. The results are presented in Table 5-12 and Table 5-13.

Table 5-12
Factor loadings on baseline Health Belief Model subscales

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Factor 1</th>
<th>Factor 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity</td>
<td>.918</td>
<td>-.130</td>
</tr>
<tr>
<td>Susceptibility</td>
<td>.919</td>
<td>.055</td>
</tr>
<tr>
<td>Benefits</td>
<td>.611</td>
<td>.416</td>
</tr>
<tr>
<td>Costs</td>
<td>-.058</td>
<td>-.808</td>
</tr>
<tr>
<td>Cues</td>
<td>-.004</td>
<td>.758</td>
</tr>
</tbody>
</table>
Table 5 - 13

Factor loadings on follow-up Health Belief Model subscales

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Factor 1</th>
<th>Factor 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity</td>
<td>.895</td>
<td>.066</td>
</tr>
<tr>
<td>Susceptibility</td>
<td>.915</td>
<td>.037</td>
</tr>
<tr>
<td>Benefits</td>
<td>.443</td>
<td>.702</td>
</tr>
<tr>
<td>Costs</td>
<td>.005</td>
<td>-.832</td>
</tr>
<tr>
<td>Cues</td>
<td>-.023</td>
<td>.789</td>
</tr>
</tbody>
</table>

In the factor analysis of the baseline Health Belief Model subscales Severity, Susceptibility, and Benefits comprise the first factor while Costs and Cues comprise the second one. But in the analysis of the follow-up questionnaire the first factor is composed of Severity and Susceptibility while the second factor is composed of Benefits, Costs, and Cues. For the baseline questionnaire Factor 1 accounts for 43% of the variance and Factor 2 for 27%. On the follow-up questionnaire Factor 1 accounted for 44% of the variance and Factor 2 for 29%. Because the purpose of the factor analysis was to provide information which might help to reduce the number of items in the Health Belief Model and because the baseline questionnaires were the ones to
be used in predicting dropout and weight loss it was decided to use the results of the baseline factor analysis in aggregating subscales.

Therefore, the items were collapsed to form two scales with the first consisting of Severity, Susceptibility, and Benefits and the second of Costs and Cues. It should be noted that the questions that make up the first factor are largely health related and ask about health risks of obesity, diabetes and the health benefits of dieting. The items that make up the second factor focus more on social factors such as the effects of one’s diet on the family and external barriers to compliance. Factor 1 accounted for 43% of the variance and Factor 2 for 27%. In order to see if more reliable factors had been obtained using this approach Cronbach’s alpha was computed for the two factors. Because Costs loaded negatively on the second factor it was given a weighting of -1 when the new scales were calculated.

The resulting alphas were .759 for the first factor and .461 for the second factor. The first alpha is acceptable but the second alpha is unacceptably low. Because of the low level of internal consistency in the second factor of the
Health Belief Model scales it was dropped from further analyses. Factor 1 had a mean score of 34.9 ($sd = 5.4$).

5.2.4 Prediction of amount of weight loss goal achieved

To evaluate the power of the two psychological theories to predict compliance, hierarchical multiple regression was used with the percentage of the total weight loss goal achieved as the criterion variable. Because the focus of the study was on psychological predictors the psychological measures were entered first followed by physiological measures. All of the psychological measures used for predictive purposes were obtained from the patients' responses to the baseline questionnaire that they filled out when they entered the study.

In the first step of the analysis self-efficacy and Factor 1 of the Health Belief Model were entered first. The resulting multiple $R$ of .247 accounted for 8% of the variance in weight loss and was not statistically significant ($F(2, 58) = .189, p = .161, ns$, see Table 5 - 14).
Table 5 - 14

Psychological prediction of weight loss

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>B</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBM-Factor 1</td>
<td>.390</td>
<td>.054</td>
<td>.395</td>
<td>.695, ns</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>1.277</td>
<td>.221</td>
<td>1.605</td>
<td>.114, ns</td>
</tr>
<tr>
<td>(Constant)</td>
<td>-16.743</td>
<td></td>
<td>.512</td>
<td>.610, ns</td>
</tr>
</tbody>
</table>

Because preliminary analyses found gender differences in the predictive power of self-efficacy as had a previous study (Forster & Jeffery, 1986), gender and gender interaction terms were entered into the equation. It should be noted that gender was dummy coded and a value of 0 was assigned to the males and a value of 1 assigned to the females. The gender interaction terms were created by multiplying the value for gender by the value of self-efficacy and the Health Belief Model - Factor 1 from the baseline questionnaire. The resulting multiple R of .43 accounted for 19% of the variance in the criterion variable and was statistically significant ($F(5,55) = 2.504, p = .041$). The only individual predictors that reached significance were self-efficacy and the Gender × Self-efficacy interaction. The Gender
x HBM Factor 1 interaction was very close to the conventional level of statistical significance. (See Table 5 - 15.)

Table 5 - 15 - Predicting weight loss - Psychological variables and gender

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>β</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBM-Factor 1</td>
<td>-2.672</td>
<td>-.372</td>
<td>1.415</td>
<td>.163, ns</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>4.510</td>
<td>.781</td>
<td>2.844</td>
<td>.006</td>
</tr>
<tr>
<td>Gender</td>
<td>-78.627</td>
<td>-1.016</td>
<td>.995</td>
<td>.324, ns</td>
</tr>
<tr>
<td>Gender x</td>
<td>4.317</td>
<td>2.027</td>
<td>1.974</td>
<td>.053, ns</td>
</tr>
<tr>
<td>HBM-F1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender x SE</td>
<td>-4.483</td>
<td>-1.176</td>
<td>2.467</td>
<td>.017</td>
</tr>
<tr>
<td>(Constant)</td>
<td>37.251</td>
<td></td>
<td>.528</td>
<td>.600, ns</td>
</tr>
</tbody>
</table>

The interaction between gender and self-efficacy found in the previous analysis (Table 5 - 15) was examined using the Johnson-Neyman technique (Pedhazur, 1982, pp. 468-472). If we plot two separate regression lines for self-efficacy, one for each gender, the Johnson-Neyman technique will give us a range of self-efficacy scores for which the two groups do not differ significantly in their weight loss. In other words, it will give us a range where the differences in the predictive power of self-efficacy are not significant. This will then enable us to calculate the ranges where the predictive power of self-efficacy does
differ significantly between the genders. Figure 5 - 1 shows the raw data for the group and Figures 5 - 2 and 5 - 3 show the separate regression line for each gender.

Figure 5 - 1. Self-efficacy x Percent of goal achieved
Figure 5-2. Raw data for men
Figure 5 - 3. Raw data for women

In the final step of the analysis the physiological variables (age and glucose) were included. (See Table 5 - 16.) Hemoglobin A1c was not included because it was expected to be correlated with glucose. Upon analysis it was found that glucose and hemoglobin A1c were significantly correlated \( r = .62, df = 68, p < .0005 \). Insulin levels were excluded from the following analyses because they are not used by health care providers when evaluating the degree of metabolic control achieved by a diabetic. Furthermore,
excluding insulin levels from the following analysis made it possible to obtain a subject:variable ratio of at least 10:1. The resulting multiple $R$ of .445 accounted for 20% of the variance in weight loss and was not statistically significant ($F(7, 53) = 1.770$, $p = .113$, ns, see Table 5 - 18). Thus the addition of the physiological variables to gender and self-efficacy increased the amount of variance explained by 1%.

Although the regression equation was not statistically significant overall it is interesting to note that the only predictor variables which did reach statistical significance were self-efficacy ($p = .006$) and the Gender x Self-efficacy interaction ($p = .017$).
Table 5-16

Predicting weight loss - Psychological and physiological variables and gender

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>β</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBM-Factor 1</td>
<td>-2.394</td>
<td>-.334</td>
<td>1.186</td>
<td>.237, ns</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>4.244</td>
<td>.735</td>
<td>2.504</td>
<td>.015</td>
</tr>
<tr>
<td>Gender</td>
<td>-71.008</td>
<td>-.928</td>
<td>.881</td>
<td>.382, ns</td>
</tr>
<tr>
<td>Gender x HBM-F1</td>
<td>3.949</td>
<td>1.854</td>
<td>1.690</td>
<td>.097, ns</td>
</tr>
<tr>
<td>Gender x SE</td>
<td>-4.094</td>
<td>-1.075</td>
<td>2.050</td>
<td>.045</td>
</tr>
<tr>
<td>Age</td>
<td>.154</td>
<td>.060</td>
<td>.427</td>
<td>.671, ns</td>
</tr>
<tr>
<td>Glucose</td>
<td>.271</td>
<td>.038</td>
<td>.294</td>
<td>.770, ns</td>
</tr>
<tr>
<td>(Constant)</td>
<td>20.128</td>
<td>.254</td>
<td>.801</td>
<td>.801, ns</td>
</tr>
</tbody>
</table>

Using the Johnson-Neyman technique with an α of .05 yielded a range of 8.4 to 23.4 for which there is no between-gender difference in the predictive power of self-efficacy. Therefore outside of this range there is a significant between-gender difference in the predictive power of self-efficacy. Figure 5-4 shows the regression line for each gender and the boundaries according to Johnson-Neyman.
5.3 Brief summary of results

The 65 patients who completed the study were representative of the type 2 patients who qualified for inclusion in the study and also appear to have been typical of Type 2 diabetics encountered elsewhere (see discussion section). Over the course of the study they lost small amounts of weight and generally failed to meet their weight loss goals. In addition to achieving
moderate weight losses they also showed an improvement in their conditions which was reflected in the statistically significant reductions in their glucose and hemoglobin A1c levels.

To summarize, it appears that weight loss can be predicted in obese Type 2 diabetic men but not women. The baseline Health Belief Model was a very poor predictor of weight loss for this group while self-efficacy was a good predictor once the interaction with gender was taken into account. The significant Sex \( \times \) SE interaction term demonstrated that the slopes of the regression lines for men and for women were significantly different from each other. For men the slope of the regression line was significantly different from 0 in the positive direction (\( B = 3.44, p = .035 \)) but for women, the slope of the regression line was not significantly different from 0 (\( B = .57, p = .475, \text{ns} \)). The gender differences were largely unanticipated although one previous study did report similar findings (Forster & Jeffery, 1988).
5.4 Discussion

5.4.1 Is the sample representative?

Table 5 - 17 - Comparison of samples across studies

<table>
<thead>
<tr>
<th>Criterion</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample size</td>
<td>75</td>
<td>46</td>
<td>184</td>
<td>53</td>
<td>12</td>
</tr>
<tr>
<td>Age - mean</td>
<td>51.3</td>
<td>52.9</td>
<td>57.9</td>
<td>55.1</td>
<td>51.3</td>
</tr>
<tr>
<td>Age - sd</td>
<td>13.4</td>
<td>12.1</td>
<td>10.2</td>
<td>7.3</td>
<td>9.0</td>
</tr>
<tr>
<td>Male/female ratio</td>
<td>23/52</td>
<td>22/24</td>
<td>61/123</td>
<td>20/33</td>
<td>6/6</td>
</tr>
<tr>
<td>Weight - mean (kg)</td>
<td>98.1</td>
<td>81.5</td>
<td>NA</td>
<td>98.4</td>
<td>88.9</td>
</tr>
<tr>
<td>Weight - sd</td>
<td>21.1</td>
<td>15.9</td>
<td>NA</td>
<td>18.7</td>
<td>19.4</td>
</tr>
<tr>
<td>Duration of study (months)</td>
<td>6</td>
<td>18</td>
<td>NA</td>
<td>16</td>
<td>5</td>
</tr>
<tr>
<td>Change in weight - mean</td>
<td>-3.0</td>
<td>NA</td>
<td>NA</td>
<td>-2.8</td>
<td>-7.5</td>
</tr>
<tr>
<td>Insulin - mean</td>
<td>279</td>
<td>NA</td>
<td>NA</td>
<td>138</td>
<td>NA</td>
</tr>
<tr>
<td>Insulin - sd</td>
<td>191</td>
<td>NA</td>
<td>NA</td>
<td>89</td>
<td>NA</td>
</tr>
<tr>
<td>Glucose - mean</td>
<td>13.3</td>
<td>NA</td>
<td>NA</td>
<td>9.9</td>
<td>NA</td>
</tr>
<tr>
<td>Glucose - sd</td>
<td>4.7</td>
<td>NA</td>
<td>NA</td>
<td>3.4</td>
<td>NA</td>
</tr>
<tr>
<td>Hemoglobin A1c - mean</td>
<td>11.7</td>
<td>10.7</td>
<td>10.0</td>
<td>9.3</td>
<td>9.7</td>
</tr>
<tr>
<td>Hemoglobin A1c - sd</td>
<td>2.1</td>
<td>NA</td>
<td>2.2</td>
<td>2.2</td>
<td>2.4</td>
</tr>
<tr>
<td>Completion rate (Percentage)</td>
<td>87</td>
<td>83</td>
<td>NA</td>
<td>94</td>
<td>100</td>
</tr>
</tbody>
</table>

Notes. Glucose, insulin, HAlc, and weight were all measured at the start of each study. NA means "Not Available."
Study 1 - present study
Study 2 - Heitzmann, Kaplan, Wilson, & Sandler, 1987
Study 3 - Wilson, Ary, Biglan, Glasgow, Toobert, & Campbell, 1986
Study 4 - Wing et al., 1985
Study 5 - Wing et al., 1987

In general the present study and sample of diabetics were comparable to those which had been reported in the past with only a few exceptions due primarily to differences in design of the studies. (See Table 5 - 17.) For example, study 3 (Wilson et al., 1986) was a one-shot study where the subjects made only one visit and could not, therefore, provide a measure of weight loss. Similarly, in study 5 (Wing et al., 1987) subjects were deliberately matched on the basis of gender and therefore had equal numbers of males and females.

Another important comparison is the percentage of variance explained by the measures in this study and the success of other, similar, studies in accounting for the observed variance in weight loss. The present study, using gender and baseline measures of self-efficacy and the Health Belief Model, accounted
for 19% of the variance in weight loss in the entire sample of Type 2 diabetics (outliers excluded). Bernier and Avard (1986) found that self-efficacy correlated .26 with weight loss in a group of normal obese women, and thus their measure accounted for 7% of the variance in weight loss. Edell et al. (1987) found that a combination of self-efficacy and motivation accounted for 32% of the variance in weight loss in their sample of 147 men and women. Forster and Jeffery (1986) reported only the significance levels of their results and did not provide the correlation or regression coefficients or an estimate of the percentage of the variance which they explained.

Table 5 - 18 provides a comparison of several studies in terms of the amount of variance accounted for. It is difficult to find comparable articles on weight loss in Type 2 diabetics. Much of the research on compliance with this group uses compliance measures other than weight loss such as glucose and glycosylated hemoglobin levels, a composite scale which includes a variety of self-care behaviors, or diet diaries.
Table 5 - 18

Comparison of studies in terms of variance accounted for

<table>
<thead>
<tr>
<th>Author</th>
<th>Sample</th>
<th>Predictor</th>
<th>Percent of variance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bernier &amp; Avard,</td>
<td>Obese</td>
<td>Self-efficacy</td>
<td>7</td>
</tr>
<tr>
<td>1986</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Currey et al.,</td>
<td>Obese</td>
<td>Demographic &amp; physiological</td>
<td>ns</td>
</tr>
<tr>
<td>1977</td>
<td></td>
<td>(actual values not given)</td>
<td></td>
</tr>
<tr>
<td>Edell et al.,</td>
<td>Obese</td>
<td>Self-efficacy &amp; motivation</td>
<td>32</td>
</tr>
<tr>
<td>1987</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kincey,</td>
<td>Obese</td>
<td>Intelligence</td>
<td>1</td>
</tr>
<tr>
<td>1983</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>present study</td>
<td>Type 2</td>
<td>Self-efficacy</td>
<td>19</td>
</tr>
</tbody>
</table>

5.4.2 Self-efficacy

The gender differences in the predictive power of self-efficacy were unanticipated. Edell et al. (1987), using a sample of approximately equal numbers of men and women, found that self-efficacy and motivation were both predictive of weight loss. They did not examine their data for gender differences. Bernier and Avard (1986) found that self-efficacy predicted weight loss

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8 They have not responded to a letter asking them about this.
and dropout from a weight control group for their sample of women. Similarly Stotland, Roy, and Zuroff (1988) found that self-efficacy predicted eating behavior of women in a lab setting. However, Forster and Jeffery (1986) found that men had higher self-efficacy ratings than did women and that self-efficacy was a better predictor of weight loss for men than for women. In the present study, there was not a significant difference between the mean levels of self-efficacy for the genders \((t(73) = 1.39, p = .17, ns)\) although the differential success of self-efficacy as a predictor for men reported by Forster and Jeffery was replicated. (Neither was there a gender difference in terms of percentage of weight loss goal achieved in the present study \([t(61) = .97, p = .334, ns]\).)

5.4.3 Health Belief Model

In the present study the Health Belief Model was not a significant predictor of weight loss although the combination of the Health Belief Model Factor 1 and gender nearly reached conventional significance levels \((p = .053)\). In contrast Brownlee-Duffeck et al.

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7 They did not respond to a request for a copy of their questionnaire. It was subsequently published in Stotland, Zuroff, and Roy (1991).
(1987), using a one-shot design, found that health beliefs accounted for a significant proportion of the variance in both self-reported adherence and glycosylated hemoglobin in a group of Type 1 diabetics. Similarly, Glasgow, McCaul, and Schafer (1986) found that barriers to adherence, part of the Health Belief Model, were significantly related to self-reported compliance for Type 1 diabetics. Bond, Aiken, and Somerville (1992) followed a group of Type 1 diabetics for a period of 4 to 6 weeks. They found that metabolic control, as measured by hemoglobin A1c, was poorest when both threats and cues to compliance were highest and that metabolic control was highest when both threats to compliance were low and cues to compliance were high. Polly (1992) found that perceived barriers to adherence were related to self-reported adherence and perceived severity of the disease was related to hemoglobin A1c. Finally, Wilson et al. (1986) found a relationship between health beliefs and self-reported self-care behaviors for Type 2 diabetics.

One significant difference between the present study and three of the previously mentioned studies of diabetics is that they (i.e., Bond et al., 1992;
Brownlee-Duffeck et al., 1987; Glasgow et al., 1986) looked at Type 1 diabetics while the present study looked at Type 2 diabetics. These studies were discussed here because, although the treatments of the two conditions are different, the diseases do share some common features and there is a lack of similar studies using Type 2 diabetics. Generalizations from studies based on Type 1 diabetes to Type 2 diabetics should be done extremely cautiously. Furthermore, other studies have not done a factor analysis of the Health Belief Model as was done in this study and different questionnaires were employed in all studies.

Another important difference between this chapter and the previously mentioned studies is that this chapter used a longitudinal design and followed the subjects for 6 months. Brownlee-Duffeck et al. (1987), Glasgow et al. (1988), Polly (1992), and Wilson et al. (1988) all used cross-sectional designs. Taylor (1979) reported that baseline health beliefs were not related to subsequent compliance with a hypertensive medication regimen 6 months later. Becker et al. (1979) also reached similar conclusions based on a review of the literature (p. 81). A final difficulty is that this chapter used weight changes to provide an objective
measure of compliance and Wilson et al. (1986) used self-report measures and both Bond et al. (1992) and Polly (1992) used self-report measures and hemoglobin A1c.

5.5 Conclusions

This study compared self-efficacy, a part of the cognitive social learning theory of personality, and the Health Belief Model, a commonly used theory in medical research, to predict compliance in Type 2 diabetics. In general, the Health Belief Model was not a good predictor of weight regulation for this group but self-efficacy was, once gender was taken into account. Self-efficacy was a good predictor of weight regulation for men, but not for women, over a 6 month period. The gender-differences in the predictive power of dieting self-efficacy were similar to those observed by Forster and Jeffery (1986). These gender-differences present a serious problem for studies done using only one gender. Most of the laboratory-based work on dieting has used females exclusively and thus would not be capable of finding gender differences. Similar concerns about the impact of gender differences have been expressed concerning research on cardiovascular disease which
focuses almost exclusively on men and may be limited in the generalizability of its findings (Eaker, 1989; Gurwitz, Col, & Avorn, 1992; Healy, 1991).

The interaction between gender and self-efficacy found in this study was largely unanticipated. In order to evaluate the robustness of this effect, a more controlled laboratory study was conducted. The results of this laboratory study are presented in the next chapter.
6 Chapter 6

Dieting self-efficacy and food consumption in a laboratory setting

Self-efficacy, assessed using a variety of scales, has been found to be a good predictor of people's performance on a wide variety of tasks, including dieting. Bernier and Avar (1986) found that self-efficacy correlated .26 (p < .05) with weight loss in a group of normal obese women. Forster and Jeffery (1986) observed that self-efficacy was a better predictor of weight loss for men than for women.

Edell et al. (1987) reported that a combination of self-efficacy and motivation accounted for 32% (p < .01) of the variance in weight loss in their sample of 147 men and women. Unfortunately, Edell et al. did not examine their data for gender differences. In all of these studies the subjects used were obese but otherwise healthy adults.

The first study in this dissertation (Chapter 5) which examined the ability of self-efficacy to predict compliance with a medically indicated weight loss diet

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8 Portions of this chapter have appeared in Campbell (1990).
used Type 2 diabetics. In this study self-efficacy was found to be a good predictor of compliance for men but not for women. Because gender differences in the predictive power of self-efficacy have also been observed by others (Forster & Jeffery, 1986) it seems likely that the differences observed in the diabetes study were not due to an experimental artifact. In order to confirm these findings, a laboratory study was conducted using standard experimental procedures. The goal of this study was to discover if these gender differences could be observed in the lab setting with the same self-efficacy questionnaire which was used in the Chapter 5 diabetes study. The prediction that was tested in the present study was that there will be an interaction between sex and self-efficacy. Specifically, that the slope of the regression line relating self-efficacy and food consumption for men will be significantly different from the slope of the regression line relating self-efficacy and food consumption for women. Furthermore, it is hypothesized that the slope of the regression line for the men will be more negative than the slope of the regression line for the women.

This study used the preload and taste test procedure (e.g., Herman, Polivy, & Esses, 1987) in which subjects
are forced to break their diet and are then given food to
taste and rate. Actually, the ratings are not the topic
of interest but rather the amount of food eaten is the
important variable. Previous research found that
self-efficacy predicted food intake in subjects who had
been preloaded but did not predict food intake in subjects
who were not preloaded (Stotland et al., 1988) therefore
all subjects in this study were preloaded. The hypothesis
being tested in this study is that when predicting food
consumption in the laboratory setting there will be an
interaction between dieting self-efficacy and gender. In
other words, there will be a significant difference
between the slopes of the regression line for the men and
the slope of the regression line for the women when using
self-efficacy to predict food consumption.

6.1 Method

6.1.1 Subjects

Subjects were recruited from several sources. The
majority were clients of the "Less On For Life"
weight loss program conducted by Nutrition Services of
Chedoke-McMaster Hospitals. This program is conducted
by registered professional dietitians and uses a
life-style modification approach to weight regulation.
These dietitians were also asked to refer any of their
private practice patients who met the criteria to the study. In addition, advertisements were placed on bulletin boards and in the McMaster Courier, a newspaper which is distributed to the university community. All of the subjects were offered either five dollars or reimbursement for their transportation expenses, whichever was greater.

Thirty-six subjects participated in the study, 12 men and 24 women. For reasons which will be given subsequently, two of the men were eliminated from the analyses which left a total of 10 men and 24 women. The following descriptive statistics were calculated after the two men were eliminated. The mean age for the group was 44 years ($sd = 10.8$). The mean height for the men was 175.6 cm ($sd = 6.1$) and their mean weight was 98.9 kg ($sd = 15.7$). The women's mean height was 160.4 cm ($sd = 5.6$) and their mean weight was 80.1 kg ($sd = 17.8$).

All of the subjects met the inclusion criteria presented in Table 6 - 1 except for two subjects who were 21 and 28 years old. Although they did not meet the requirement that they be middle-aged, they were included on the grounds that several of the diabetic subjects were in their twenties.
Table 6 - 1

Inclusion criteria

<table>
<thead>
<tr>
<th>Overweight</th>
<th>&gt;= 10% above ideal body weight for height (Metropolitan Life, 1983)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dieting</td>
<td>Following a diet to lose weight</td>
</tr>
<tr>
<td>Healthy</td>
<td>No diseases such as diabetes or kidney failure which would restrict their intake of sugar or fluids</td>
</tr>
<tr>
<td>Middle-aged</td>
<td>Between 30 and 60 years</td>
</tr>
<tr>
<td>Consenting</td>
<td>Sign informed consent form</td>
</tr>
</tbody>
</table>

6.1.2 Materials

6.1.2.1 Questionnaires

The questionnaires used were the previously used dieting self-efficacy scale, the Herman and Polivy Restraint Scale (Herman et al., 1978), and the Semantic Differential Scale (Osgood & Suci, 1969; Osgood, Suci, & Tannenbaum, 1969). The self-efficacy scale was used as one of the predictor variables in the regression analysis of the study. The Restraint Scale served to verify that the subjects were indeed dieting and the Semantic Differential Scale provided a rationale for leaving the subjects alone to taste
the cookies for 10 minutes. Both the Herman and Polivy Restraint Scale and the dieting self-efficacy scale appear in Appendix B.

6.1.2.2 Stimuli

The stimuli used consisted of commercially prepared milk shakes and cookies. Subjects were preloaded with 400 ml of a refrigerated chocolate milk shake (Sunfresh Ltd., Toronto, Ontario). Those who reported an allergy or a strong aversion to chocolate were given a vanilla milk shake preload. (Only one of the subjects refused the chocolate milk shake.) The cookies were of three different varieties: chocolate chip, oatmeal, and lemon (Sunfresh Ltd., Toronto, Ontario). Subjects were presented with approximately 120 gm of each type of cookie (approximately one dozen), pile up on three plates in order to make it hard to see how many cookies were on the plate.

6.1.3 Procedure

All subjects were tested 2 or more hours after a meal. They were allowed to drink water, diet pop, and coffee or tea (without milk or sugar) prior to the experiment. The plates of cookies were prepared and
weighed before the subject arrived. After arriving at the lab subjects were given a brief description of the procedures used and were asked to sign an informed consent form (included in Appendix B). They were then given the self-efficacy scale and the Herman and Polivy Restraint Scale. While they were completing these forms they were given the milk shake preload to drink.

After completion of the forms and preload they were presented with a tray containing three plates of cookies and three copies of the Semantic Differential Scale. The experimenter explained how to use the Semantic Differential and told the subjects to use one copy of the scale to rate each type of cookie (i.e., one copy was used to rate the chocolate chip cookies, the second to rate the oatmeal cookies, and the third to rate the lemon cookies). The experimenter then gave the subjects a glass of water, and left the room for 10 minutes. Upon returning the experimenter debriefed the subjects and measured their height, weight, and frame size. They were then paid and escorted from the lab and the plates of cookies were weighed.
6.2 Results

6.2.1 Debriefing

After the procedure all of the subjects were debriefed. As part of the debriefing they were told that they had not been told the measurement that the study focused on and were asked to guess what it might be. None of the subjects guessed that food consumption was a key variable in this study.

6.2.2 Psychological measures

The reliability of the two psychological measures was evaluated using Cronbach's alpha. The self-efficacy scale had an alpha of .66 which is comparable to that obtained in the diabetes study (Chapter 5) The restraint scale had an alpha of .56 which is comparable to some of the previously published values. For example, Ruderman (1983) obtained a Cronbach's alpha of .86 when the scale was used with non-obese but the alpha for obese subjects was .51. Subjects in the present study were directed to answer the questions on the Restraint Scale about weight using their normal weights and not to include times when they were pregnant or severely ill. The mean score on the
restraint scale was 18.7 ($sd = 4.0$) which suggests that subjects were making a conscious attempt to restrain their food consumption.

The men and women did not differ in their mean levels of self-efficacy ($\text{mean} = 18.6$, $sd = 3.2$ and $\text{mean} = 18.9$, $sd = 5.7$ respectively; $t = .87$, $df = 32$, $p = .390$, $ns$, outliers excluded).

8.2.3 Amount eaten

Initial inspection of the total amount eaten revealed that two male subjects ate more than 135 gm of cookies. When the mean and standard deviation (28.3 and 17.2, respectively) of the amount eaten were calculated without these subjects it was seen that the amounts which they ate were more than six standard deviations above the mean. Therefore, these two subjects were eliminated from the analyses because their high intakes would have a disproportionately large effect on the analyses (Cohen & Cohen, 1983, p. 128; Pedhazur, 1982, pp. 37-38; Tabachnick & Fidell, 1983, p. 74).

The two outliers did not appear to differ from the other men in the study. They were within one standard deviation of the mean self-efficacy and dietary restraint and within two standard deviations of
the mean age. They were also within three standard deviations of the mean body mass index for the men (all means computed with the outliers excluded).

The genders did differ in the amount of food they consumed. The men ate significantly more than did the women (mean = 43.0 sd = 16.2 and mean = 22.1, sd = 13.8 respectively; \( t = 3.83, df = 32, p = .001 \))

8.2.4 Prediction of amount eaten

Hierarchical multiple regression was used to predict the amount eaten. The terms entered into the equation were self-efficacy, gender, and a Gender X Self-efficacy interaction term. Gender was dummy-coded with a value of 0 for men and 1 for women. Because the focus of the study was on the interaction between gender and self-efficacy the interaction term was entered into the equation first followed by gender and self-efficacy. The Gender X Self-efficacy interaction term produced a multiple \( R \) of .47 which accounted for 22% of the variance and was statistically significant (\( F(1, 32) = 9.20, p = .0048 \)). Entering gender and self-efficacy increased the amount of variance explained to 33% and the multiple \( R \) of .58 was also statistically significant (\( F(3, 30) = 4.97, p = .0084 \)). The results of the final step in the analysis are
presented in Table 6 - 2. Figure 6 - 1 displays the raw data and the regression lines. The Johnson-Neyman range is not shown on Figure 6 - 1. The range of nonsignificance according to the Johnson-Neyman technique extends from Self-efficacy scores of 23 to scores of 54.

The t tests on the individual variables in the regression equation are not statistically significant because of the high intercorrelation between the variables. The interaction term was produced by multiplying Gender by Self-efficacy and therefore one would expect it to be highly correlated with the other two variables. In fact, the correlation between gender and the interaction term is .85 (df = 32, p < .001) and between self-efficacy and the interaction term it is .36 (df = 32, p < .05).

Table 6 - 2

Multiple regression analysis

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>β</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-efficacy</td>
<td>-1.44</td>
<td>-.42</td>
<td>.90</td>
<td>.37, ns</td>
</tr>
<tr>
<td>Gender</td>
<td>-47.62</td>
<td>-1.28</td>
<td>1.55</td>
<td>.13, ns</td>
</tr>
<tr>
<td>Gender X Self-efficacy</td>
<td>1.44</td>
<td>.77</td>
<td>.88</td>
<td>.39, ns</td>
</tr>
<tr>
<td>(Constant)</td>
<td>69.09</td>
<td></td>
<td>2.36</td>
<td>.03</td>
</tr>
</tbody>
</table>
6.3 Discussion

The significant Gender X Self-efficacy interaction obtained in this investigation confirmed that obtained in the diabetes study (Chapter 5). There was a significant interaction between gender and self-efficacy. As was also predicted, the slope of the regression line for the men was more negative than the slope of the regression line for the women ($B = -1.4, p = .44, ns$ and $B = .04, p = .94, ns$, respectively). In the diabetes study men
who were higher in self-efficacy were more successful at losing weight. In the present study men who were higher in self-efficacy ate less food and would therefore likely be more successful in losing weight.

To summarize this study, it was predicted that there would be a gender by self-efficacy interaction when self-efficacy was used to predict food consumption in a laboratory setting. The predicted interaction was statistically significant. This helps to demonstrate that the interaction found in the diabetes study is robust.
private practice patients who met the criteria to the study. In addition, advertisements were placed on bulletin boards and in the McMaster Courier, a newspaper which is distributed to the university community. All of the subjects were offered either five dollars or reimbursement for their transportation expenses, whichever was greater.

Thirty-six subjects participated in the study, 12 men and 24 women. For reasons which will be given subsequently, two of the men were eliminated from the analyses which left a total of 10 men and 24 women. The following descriptive statistics were calculated after the two men were eliminated. The mean age for the group was 44 years ($sd = 10.8$). The mean height for the men was 175.6 cm ($sd = 6.1$) and their mean weight was 93.9 kg ($sd = 15.7$). The women's mean height was 160.4 cm ($sd = 5.6$) and their mean weight was 60.1 kg ($sd = 17.8$).

All of the subjects met the inclusion criteria presented in Table 6 - 1 except for two subjects who were 21 and 28 years old. Although they did not meet the requirement that they be middle-aged, they were included on the grounds that several of the diabetic subjects were in their twenties.
compliance. Another reason for the lack of agreement concerning predictors of compliance, which was not explored in the analysis reported in this dissertation, is the diversity of approaches used to measure psychological constructs; and, in addition, some of the measures used as predictors were of unknown, and possibly low, reliability and validity.

One further benefit from the re-analysis is that the methodology used here can be employed in other areas where there is a lack of agreement concerning the best methods to measure or predict compliance. In order to compare a variety of definitions of compliance one can use the definitions to categorize a number of patients. By comparing the results from the use of each definition one can determine the impact which the differences between the definitions have on how the patients are classified. This method of comparing different definitions of compliance is actually a method of determining inter-definitional agreement and may be seen as analogous to inter-rater agreement.

7.1.2 St. Joseph's Morbidity/Mortality Study

Based on the results of the NCDS re-analysis study it appeared that there was a need for a standard definition of dietary compliance in hemodialysis
patients. What should be done to develop a definition of compliance is to evaluate the impact of different aspects of the treatment, such as fluid restriction, on outcome. Once we have determined which aspects of the treatment program are related to outcome, we can use this information to develop a method of measuring compliance based on outcome. In other words the measurement technique would have criterion validity. This measurement technique could then be employed to measure compliance in other samples.

In this study we examined the relationship between dietary compliance and morbidity and mortality in hemodialysis patients. Dietary compliance did not enable us to predict survival. The best predictors of outcome in our study were age and the presence of diabetes mellitus. This demonstrates that at least one belief commonly held by researchers in this area, that there is a causal relationship between dietary compliance and outcome, is not supported by the research evidence.

7.1.3 Predicting weight loss in Type 2 diabetes

The results from the St. Joseph's morbidity/mortality study suggested that more information about compliance could be obtained if one
examined a patient population where compliance was easier to measure and where compliance was known to be related to outcome. Type 2 diabetes mellitus appeared to meet these conditions. The preferred method of controlling Type 2 diabetes is a hypocaloric diet which produces weight loss and leads to lower blood glucose levels (e.g., Doar et al., 1975; Dupre et al., 1982; Fishman et al., 1981, p. 222; Hadden et al., 1975; Henry, Scheaffer, & Olefsky, 1985; Wales, 1982; Wing et al., 1984; Wing et al., 1985). In addition, lower glucose levels are related to a lower risk of developing diabetic complications (e.g., Bikowski & Smith, 1988; Chase et al., 1989; Herman & Teutsch, 1985; Klein & Klein, 1985; Reaven, Thompson, Nahum, & Haskins, 1990).

Because many of the problems of measuring compliance and relating it to outcome in Type 2 diabetes had been dealt with by others the third study dealt with finding a predictor of compliance. Because there were no good predictors of dietary compliance for this group, finding a predictor that explained even a moderate amount the weight loss could be useful. Self-efficacy had been shown to be successful in predicting other types of health-related behaviors and
so it was examined in diabetes patients. The Health Belief Model was also employed in this study because it had been employed in many other studies of compliance, although with limited success. The Health Belief Model, by contrast, was a poor predictor of weight loss in both genders. Other researchers have reported interactions between the gender of the subjects and self-efficacy (e.g., Forster & Jeffery, 1988). The results show that there are differences between the genders in terms of psychological predictors of compliance and the importance of including both genders in research studies.

Because most weight-loss dieters are female, most research on dieting involves females. This is acceptable if the factors influencing success in following a diet do not differ by gender. If gender does influence the relationship between predictors of dietary success and dietary success, this presents a problem for researchers or clinicians who want to extend the laboratory based-research to men or mixed gender groups. These researchers should be aware that gender may play an important role in predicting dietary success and should include it as a variable in their analyses. Similar concerns about the focus on only one
gender limiting the generalizability of research has also been expressed in the area of research on cardiovascular disease. Much of the research in this area has focused on men and the methods of predicting, diagnosing, and treating cardiovascular disease in men may not be as effective when used with women (Eaker, 1989; Gurwitz et al., 1992; Healy, 1991).

Although Type 2 diabetics offer advantages to the researcher in that the relationship between compliance and outcome is already known and their level of compliance is much easier to measure than with dialysis patients there are problems associated with this group. Type 2 diabetics are seldom referred to diabetes speciality clinics and are difficult to access in sufficient numbers. If sufficient Type 2 diabetics can be found, then diabetics would be a good group to use for further research.

7.1.4 Weight loss dieters and self-efficacy

Although the interaction between gender and self-efficacy in the diabetes study was not anticipated there was one study which provided a precedent for this outcome (Forster & Jeffery, 1986). We decided to investigate this gender interaction in a different way. In order to do so we used the same self-efficacy
questionnaire as previously but with a different population and procedure. The subjects used were obese adults attending a weight loss clinic and the procedure was the standard preload and taste-test laboratory method. In this procedure subjects are given a preload which consists of a high calorie food and following this they are asked to rate the taste of several food items. The dependent variable used is the amount of food eaten in the taste-test. The results obtained in this study agreed with the findings of the previous study: there was a significant gender by self-efficacy interaction. This provides further support for the recommendation that studies should either use both genders or, at the very least, avoid generalizing findings based on one gender to members of the opposite gender.

The results from the preload and taste-test study show that obese persons attending weight loss programs are a good group to use for research purposes. They are similar to Type 2 diabetics in several ways but they are much easier to locate. Unfortunately, many commercial weight loss organizations are unwilling to cooperate with researchers. The only other difficulty presented by this type of group is that men tend to be
under-represented which can make the examination of gender differences difficult. If researchers choose to form their own weight loss groups in order to obtain subjects they ought to consider aiming at the male population. For example, they could have groups only for men or groups led by men. They could also try placing advertisements where men are more likely to read them. This strategy would help to correct the relative shortage of men in these groups.

There is another positive suggestion which can be derived from the taste-test study. We observed a similar gender by self-efficacy interaction in the field study with diabetics and in the laboratory study with dieters. In the diabetes study there was an interaction between gender and dieting self-efficacy when the outcome variable was weight loss; in the taste-test study there was an interaction between gender and dieting self-efficacy when the outcome variable was food consumption. This suggests that the preload and taste-test procedure commonly used in experimental research may have some important similarities to dieting behavior in more naturalistic settings.
This issue can be explored very simply. One could administer the usual taste-test procedure, both with and without preloads, to a group of obese dieters. The subjects would then be followed for a period of at least 6 months and re-weighed at the termination of the study. The taste-test procedure could also be repeated at this point in order to get an estimate of its test-retest reliability. The main hypothesis tested would be that the amount of food consumed in the laboratory is predictive of subsequent weight loss. The effects of preloading on the predictive power of the laboratory procedure should also be examined as well as the effects of gender. If the taste-test procedure does prove to be a good predictor of weight loss then that would help to support the validity of the experimental research done using that procedure. It could also provide a method of predicting weight loss. Unfortunately, this study could not be done with the subjects used in the final study in this dissertation because they were promised that there would be no follow-up after the procedure.

7.2 Conclusions

A conclusion that can be drawn from work reported in this dissertation and previously published studies is
that there are substantial differences between the laboratory research on dieting and research on medically prescribed diets. Given that researchers in both areas are examining diets and dieting, one would expect some similarities as well as some differences. In fact, the differences greatly outweigh the similarities. If we want to take advantage of the well-controlled experimental research and apply it in medical settings then we have to make an effort to compare the two areas and see what differences exist that should be examined when attempting to generalize.

This dissertation has examined three aspects of compliance with chronic dietary regimens: measurement, prediction, and outcome. Measurement of compliance is a basic issue in this area of research and one which, in some cases, has not been thoroughly investigated. In order to conduct research on compliance with a particular diet there must be a method for measuring compliance which is both objective and reliable. Ideally, we would evaluate the impact of the different aspects of the treatment program in terms of their relationship to outcome. This information could then be used to develop a definition of compliance that would have criterion validity. It has also been demonstrated
that problems in the measurement of dietary compliance in hemodialysis may be responsible for the lack of agreement on psychological predictors of compliance.

Where the measurement of compliance is reasonably well defined, such as with Type 2 diabetics, there is a need for research which will take findings from laboratory studies and try to extend and validate them by applying them to patients. An alternative is the use of subjects who are more similar to the clinical population than subjects who are normally used in laboratory research. In these cases, a measure which predicts dietary compliance may be useful in deciding which patients should be given more frequent follow-up appointments or more intensive treatment. Furthermore, a good predictor of compliance may provide information about how to design a program to improve compliance.

This dissertation has focused the question "What does psychology have to contribute to our understanding of compliance with chronic dietary regimens?" In answer to that question it has been shown that there is a lack of agreement between definitions of compliance in hemodialysis patients and it has been argued that this lack of agreement is one reason why researchers in this area cannot agree on what does or does not predict
compliance (Chapter 3). It was subsequently shown that, contrary to the generally accepted beliefs, compliance does not enable prediction of survival in hemodialysis patients (Chapter 4). These two preceding issues can be dealt with in psychometric terms. The diabetes and self-efficacy study (Chapter 5) demonstrated that compliance can be predicted, to an extent, using psychological predictors in men, but not in women. This finding revealed what may be a serious obstacle for those who want to generalize the results of research on one gender to the opposite gender or to mixed gender groups. Further research should examine gender differences in dieting in more detail. Finally, it was demonstrated that the gender differences in the predictive power of dietary self-efficacy, which were originally observed in diabetics, can also be observed using standard laboratory procedures (Chapter 6). In general, the research reported here also emphasizes the importance of further research on measurement issues due to their extreme importance to both researchers and health-care providers. We need to develop better measurement techniques and research methodologies if we wish to develop better theories and to conduct better research.
The answers which have been provided to the opening question show that psychology has a great deal to contribute in the area of compliance with chronic dietary regimens. Psychology can add to our knowledge of the measurement, prediction, and outcome of compliance with long-term medical diets. Findings from psychological research may be useful in enhancing compliance by providing us with better methods of measuring and predicting compliance. Finally, psychological research on compliance with medically prescribed diets also provides insights which can be used to advance the development of psychological theories and research methods.
8 References


Rudd, P. (1979). In search of the gold standard for compliance measurement. *Archives of Internal Medicine, 139*, 627-628.


9 Appendix A

Questionnaire used in Chapter 5 (Diabetes study)

Because this questionnaire was developed specifically for use in the diabetes study reported in Chapter 5 and has not been published, a copy of it is included in this appendix. Information concerning the reliability and validity of this questionnaire appears in Chapter 5.
Consent form

Dieting and Weight Control in Diabetes

I, ________________________, consent to take part in a study of the effects of various factors on dieting and weight control.

The study, which is being conducted by Dr. R.B. Haynes, MD, PhD and Dr. D.L. Lamping, PhD, will involve filling out the same questionnaire two times, once during my first clinic visit and then 6 months later. The questionnaire contains questions about times and places when it is difficult or easy to follow a diet. It will also ask me about my feelings concerning dieting. The investigators will also need to copy information about my age, weight, and blood sugar from my medical chart.

I understand that there are no risks and no direct benefits to me from participating in this study.

I also understand that I may withdraw from the study at any time, even after signing this form, and that this will in no way affect the regular care that I will receive. All the information which is obtained during the study will be kept confidential. My name will not appear on any of the data collection forms used in the study. If any results from the study are published I will not be identified in any way.

Date__________________

Name (print)__________________Signature__________________

I have explained the nature of the study to the patient and believe the patient has understood it.

Name (print)__________________Signature__________________

For further details the researchers may be telephoned at 525-9140.

Dr. Haynes - ext. 2311
Dr. Lamping - ext. 3015.
This questionnaire takes about 20 minutes to complete. It asks a series of questions which will help us to find out what makes dieting easy for some people and difficult for others. We hope that the information we gain from these questions will help us develop a program which will make it easier for people who want to lose weight to follow a diet. If you have any questions about the questionnaire or this project please feel free to ask the person who gave you the questionnaire.

1) How many pounds were you asked to lose in the next six months? _______

Were you asked to lose a specific amount of weight in the next few weeks starting now?

[ ] no (please go to question 2)
[ ] yes - How many pounds? _______
    Over how many weeks? _______

2) What is the lowest weight you have had since you turned 20? _______ lb.

What is the highest weight you have had since you turned 20? _______ lb.

3) Marital status (check one)

[ ] common law
[ ] divorced
[ ] married
[ ] separated
[ ] single
[ ] widowed
[ ] other (specify) __________________________

4) Do you live ... (check one)

[ ] alone
[ ] with parents
[ ] with relative (other than parents or spouse)
[ ] with spouse (and children - if any)
[ ] with unrelated others (e.g., share an apartment or house)
[ ] other (specify) __________________________
5) Who prepares most of your meals? (check one)
   [ ] eat out (in restaurant)
   [ ] prepare own meals
   [ ] someone else at home prepares meals (e.g., parent or spouse)
   [ ] other (specify) ______________________

   When answering questions about dieting please think about the most recent time you dieted or tried to lose weight.

6) What is your most important goal when you diet? (check one)
   [ ] change eating habits
   [ ] lose a specific amount of weight
   [ ] lose an unspecified amount of weight
   [ ] reach a specific weight
   [ ] reduce number of calories eaten
   [ ] other goals (specify) ______________________
   [ ] no specific goals (please go to question 8)

7) If you have goals, how helpful are they? (please circle the most appropriate number)

   1  2  3  4  5  6  7

   Not at all  Extremely

8) Do you keep track of your diet by writing down any of the following information? (check all that apply)
   [ ] do not write down any information
   [ ] calories eaten
   [ ] weight lost
   [ ] current weight
   [ ] other (specify) ______________________

9) Do you use rewards to make it easier to follow your diet? Do you... (check one)
   [ ] reward yourself for reducing calories
   [ ] reward yourself for losing weight
   [ ] reward yourself for something else (specify)

   [ ] do not use rewards (please go to question 11)
10) What rewards do you use? (please give some examples)

11) Do you punish yourself when you fail to stick to your diet? Do you... (check one)

[ ] punish yourself for eating more than you should
[ ] punish yourself for not losing enough weight
[ ] punish yourself for something else (specify)

[ ] do not use punishment (please go to question 13)

12) What punishments do you use? (please give some examples)

13) Which sources of professional help have you used in trying to lose weight? (check ALL that apply)

[ ] did not use professional help (please go to question 16)
[ ] commercial weight loss program (e.g., TOPS, Weight Watchers)
[ ] dietitian
[ ] nurse
[ ] physician
[ ] psychologist/psychiatrist
[ ] other (specify) ______________________

14) Which source of professional help has been MOST important to you in trying to lose weight? (check most important one)

[ ] commercial weight loss program (e.g., TOPS, Weight Watchers)
[ ] dietitian
[ ] nurse
[ ] physician
[ ] psychologist/psychiatrist
[ ] other (specify) ______________________
15) How helpful was the most important source of professional help which you checked in question 14?

1  2  3  4  5  6  7

Not at all  Extremely

16) Did any of the people you live with diet at the same time as you did?

[ ] live alone (please go to question 18)
[ ] yes
[ ] no (please go to question 18)

17) How helpful did you find it that the people you live with were dieting too?

1  2  3  4  5  6  7

Not at all  Extremely

18) Did any of your close friends diet at the same time as you did?

[ ] no (please go to question 20)
[ ] yes

19) How helpful was it that your close friends were dieting too?

1  2  3  4  5  6  7

Not at all  Extremely

20) How many weeks did you diet for in the last 12 months?

21) Do you smoke?

[ ] yes
[ ] no (please go to question 23)

22) On the average, how many cigarettes a day? _______
On the average, how many cigars a day? _______
On the average, how many pipes a day? _______
23) Do you have any medical conditions other than diabetes which affect your dieting (e.g., high blood pressure or kidney disease)?
[ ] yes (specify) ______________________
[ ] no

24) How much of a health risk do you feel being overweight is for you?
   1  2  3  4  5  6  7
   Very low risk                      Very high risk

25) How serious do you feel the effects of overweight are from a health point of view?
   1  2  3  4  5  6  7
   Not at all serious                 Very serious

26) Do you feel that dieting is good for you?
   1  2  3  4  5  6  7
   Not at all good                   Very good

27) How many barriers or obstacles do you feel that there are which make it very hard to follow your diet?
   1  2  3  4  5  6  7
   No barriers                      Very many barriers

28) How safe do you feel dieting is from a health point of view?
   1  2  3  4  5  6  7
   Not at all safe                  Very safe

29) How difficult do you feel it is to change someone’s weight?
   1  2  3  4  5  6  7
   Not at all difficult             Very difficult
30) How confident are you that you will be able to reach your goal weight?

1 2 3 4 5 6 7
Not at all confident Very confident

31) How easy do you think it would be for you to lose 20 pounds in the next six months?

1 2 3 4 5 6 7
Not at all easy Very easy

32) How easy do you feel it is to diet?

1 2 3 4 5 6 7
Not at all easy Very easy

33) How worried or concerned are you about your weight?

1 2 3 4 5 6 7
Not at all worried Very worried

34) How easy is it to control your weight?

1 2 3 4 5 6 7
Not at all easy Very easy

35) How uncomfortable does dieting make you feel?

1 2 3 4 5 6 7
Not at all uncomfortable Very uncomfortable

36) How satisfied are you with dieting?

1 2 3 4 5 6 7
Not at all satisfied Very satisfied

37) How many problems has dieting created in your family?

1 2 3 4 5 6 7
No problems Very many problems
38) Does dieting make it difficult for you to get through the day?  
   1 2 3 4 5 6 7
   Not at all difficult Very difficult

39) Is it difficult to prepare or to get the food required by your diet?  
   1 2 3 4 5 6 7
   Not at all difficult Very difficult

40) How does dieting make you feel?  
   1 2 3 4 5 6 7
   Very bad Very good

41) What is the major influence on your dieting?  
   1 2 3 4 5 6 7
   Other people Myself

42) How much do you want to diet?  
   1 2 3 4 5 6 7
   Do not really want to Really want to

43) Do your friends make it  
   1 2 3 4 5 6 7
   Easier to diet Harder to diet

44) In what way do your friends make it easier or harder?  
   (please explain or give some examples)
   Easier

   Harder

   $\$
45) Does your family (e.g., spouse, parents) make it easier or harder to diet?

Harder or Easier

46) In what way does your family make it easier or harder? (please explain or give some examples)

Easier

Harder

47) How often do you eat something that was offered to you in order to avoid insulting or hurting the feelings of the person who offered it to you?

Never or Very often

48) How often do you eat as a result of seeing pictures of food or smelling food (e.g., after seeing a TV ad for food or after walking past a bakery)?

Never or Very often

49) How hard do you find it to follow your diet when eating at home?

Not at all difficult or Very difficult

50) How hard to you find it to follow your diet when eating out (e.g., in a restaurant or cafeteria)?

Not at all difficult or Very difficult
51) How hard do you find it to follow your diet when at a social event (e.g., a party or wedding reception)?

1 2 3 4 5 6 7
Not at all difficult Very difficult

52) How hard do you find it to follow your diet when at work?

1 2 3 4 5 6 7
Not at all difficult Very difficult

53) What things tempt you to "cheat" on your diet? (check ALL that apply)

[ ] high calorie foods
[ ] favorite foods
[ ] high calorie beverages
[ ] favorite beverages
[ ] feeling that other people expect you to eat something
[ ] feeling that other people expect you to drink something

54) Do you use any special diet products? (check ALL that apply)

[ ] do not use special diet products
[ ] artificial sweeteners
[ ] low calorie or special "dietetic" foods
[ ] meal substitutes (e.g., Metrecal or Herbal Life)
[ ] other (specify) ________________________________

55) How do you get your mind off food and eating? (check ALL that apply)

[ ] do not do anything
[ ] exercise
[ ] hobbies
[ ] reading
[ ] other (specify) ________________________________

56) How many times have you dieted or tried to lose weight before? _____
57) Did you ever eat because you were bored and had nothing better to do?
   1  2  3  4  5  6  7
   Never    Often
58) Did you ever eat to make yourself feel less "blue" or less tense?
   1  2  3  4  5  6  7
   Never    Often
59) How much of a risk to your health do you feel that diabetes is?
   1  2  3  4  5  6  7
   Not at all serious    Very serious
60) How serious do you feel your diabetes is?
   1  2  3  4  5  6  7
   Not at all serious    Very serious
61) How often do your family or friends remind you to follow your diet?
   1  2  3  4  5  6  7
   Never    Always
62) How often do your family or friends participate in daily exercise with you?
   1  2  3  4  5  6  7
   Never    Always
63) How often do your family or friends remind you to exercise daily?
   1  2  3  4  5  6  7
   Never    Always
64) Do your family or friends insist that you carry diabetic identification with you?

1 2 3 4 5 6 7

Never  Always

65) How often do you follow the number of food choices prescribed in your diet?

1 2 3 4 5 6 7

Never  Always

66) How often do you eat within one-half hour of the usual time for each meal?

1 2 3 4 5 6 7

Never  Always

67) How often do you eat food that you should avoid on your diet?

1 2 3 4 5 6 7

Never  Always

68) How often do you eat food from each of the food choice groups every day?

1 2 3 4 5 6 7

Never  Always

69) How often do you exercise daily in addition to the exercise you get at home or at work?

1 2 3 4 5 6 7

Never  Always

70) Do you wear or carry diabetic identification with you?

1 2 3 4 5 6 7

Never  Always
71) Do you obtain home blood glucose results as often as your doctor orders?

1 2 3 4 5 6 7

Never Always

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

1 2 3 4 5 6

Strongly agree Strongly disagree

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

1 2 3 4 5 6

Strongly agree Strongly disagree

74) 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 agree Strongly disagree

75) 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 agree Strongly disagree

We would like to thank you for your valuable assistance with this study. If you have any further questions please feel free to ask us.
10 Appendix B

Questionnaires used in Chapter 6 (Self-efficacy and food consumption)

This appendix contains the dieting self-efficacy questionnaire used in Chapters 5 and 6 and the Restraint Scale (Herman et al., 1978) used in Chapter 6 to verify that the subjects were dieting. Information about the reliability and validity of these questionnaires appears in Chapter 6.
Lab taste test

Subject ID __________
Age_______________
Sex_______________
Height___________
Frame size_______
1) How many times have you tried to lose weight in the past? 

2) How many times have you tried to lose weight in the past year? 

3) How long did your most recent weight loss effort last? weeks 

4) During your most recent weight loss effort how much did you lose? pounds/kilos (circle one) 

5) Are you currently a member of a weight loss program? Yes/No (circle one) 

6) If you answered "Yes" to question 5, which program are you in? (please fill in the blank) 

How long have you been in this program? weeks 

How much have you lost since starting the program? pounds/kilos
CDA SE

1) How difficult do you feel it is to change someone's weight?
   1  2  3  4  5  6  7
   Not at all difficult  Very difficult

2) How confident are you that you will be able to reach your weight goal?
   1  2  3  4  5  6  7
   Not at all confident  Very confident

3) How easy do you think it would be for you to lose 20 pounds in the next six months?
   1  2  3  4  5  6  7
   Not at all easy  Very easy

4) How easy do you feel it is to diet?
   1  2  3  4  5  6  7
   Not at all easy  Very easy

5) How easy is it to control your weight?
   1  2  3  4  5  6  7
   Not at all easy  Very easy
H & PRQ

1) How often are you dieting? (circle one)
   0) Never
   1) Rarely
   2) Sometimes
   3) Often
   4) Always

2) What is the maximum amount of weight (in pounds) that you have ever lost within 1 month? (circle one)
   0) 0 - 4
   1) 5 - 9
   2) 10 - 14
   3) 15 - 19
   4) 20 +

3) What is your maximum weight gain (in pounds) within a week? (circle one)
   0) 0 - 1
   1) 1.1 - 2
   2) 2.1 - 3
   3) 3.1 - 5
   4) 5.1 +

4) In a typical week, how much does your weight fluctuate (in pounds)? (circle one)
   0) 0 - 1
   1) 1.1 - 2
   2) 2.1 - 3
   3) 3.1 - 5
   4) 5.1 +
5) Would a weight fluctuation of 5 lbs. affect the way in which you live your life? (circle one)
   0) Not at all
   1) Slightly
   2) Moderately
   3) Very much

6) Do you eat sensibly in front of others and splurge alone? (circle one)
   0) Never
   1) Rarely
   2) Often
   3) Always

7) Do you give too much time and thought to food? (circle one)
   0) Never
   1) Rarely
   2) Often
   3) Always

8) Do you have feelings of guilt after overeating? (circle one)
   0) Never
   1) Rarely
   2) Often
   3) Always

9) How conscious are you of what you're eating? (circle one)
   0) Not at all
   1) Slightly
   2) Moderately
   3) Extremely
10) How many pounds over your desired weight were you at your maximum weight? (circle one)
   0) 0 - 1
   1) 1 - 5
   2) 6 - 10
   3) 11 - 20
   4) 21 +