Effects of Diet and Exercise Interventions on Control and Quality of Life in Non-insulin-dependent Diabetes Mellitus

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Evidence suggests that diet and exercise are associated with improved glucose tolerance for patients with non-insulin-dependent diabetes mellitus (NIDDM). Seventy-six volunteer adult patients with NIDDM were each assigned to one of four programs: 1) diet, 2) exercise, 3) diet plus exercise, or 4) education (control). Each program required ten weekly meetings. Detailed evaluations were completed prior to the program and after three, six, 12, and 18 months. Evaluations included various psychosocial measures, measures of the quality of life, and fasting blood glucose, glyco-sylated hemoglobin, and relative weight determinations. Of the 76 original participants, 70 completed the 18-month follow-up study. At 18 months, the combination diet-and-exercise group had achieved the greatest reductions in glycosylated hemoglobin measures. In addition, this group showed significant improvements on a general quality of life measure. These improvements were largely uncorrelated with changes in weight. The authors conclude that the combination of dietary change and physical conditioning benefits NIDDM patients, and that the benefits may be independent of substantial weight loss. Key words: diet; exercise; non-insulin-dependent diabetes mellitus. J GEN INTERN MED 1997;2:220–227.

Although there is considerable enthusiasm for diet and exercise in the management of non-insulin-dependent diabetes mellitus (NIDDM) there have been relatively few long-term clinical evaluations of the efficacies of non-pharmacologic interventions. Thirteen-year follow-up from the important, but controversial, University Group Diabetes Program showed no therapeutic benefit of insulin in either a standard or a varied dose in comparison with diet plus placebo.1 Weight loss does appear to improve glucose tolerance,2,3 but only Wing et al.4 have evaluated the benefits of a weight loss program in a systematic trial with more than one year of follow-up. Their study showed short-term but not long-term benefits of the intervention. Duration of follow-up is an important issue in evaluating weight loss programs. Virtually all dietary programs produce positive results in the short run. However, relatively few sustain benefits over the course of a year.5 Finally, it is important that evaluations consider the effects of the program on general measures of health status. These measures consider both benefits and side effects and express the outcome of a program in a general quality of life score.6

We report the results of a long-term randomized trial evaluating diet, exercise, diet plus exercise, and education (control) for the management of NIDDM in a cohort of volunteer patients. Patients were evaluated over an 18-month period. Physiologic and general quality of life outcome measures were used to evaluate the program.

METHOD

Subjects

Volunteers in San Diego County were invited by public radio announcements, newspaper notices, and physicians to contact a central telephone number regarding participation. At orientation meetings, they were told to volunteer only if they were willing to be randomly assigned to one of four alternative treatments. The specific interventions were not described in detail. One of the four treatment interventions — diet, exercise, diet and exercise combined, or education (control) — was randomly chosen for each patient volunteering at a particular recruitment meeting.7

Those who agreed to participate signed an informed consent form. They also asked their physicians to complete a referral questionnaire which included confirmation of the diagnosis of Type II diabetes and information about heart problems or other diseases that might interfere with the patient’s full participation in the program.

Overview

Each patient was assigned to one of the four ten-week programs: 1) diet, 2) exercise, 3) diet plus exercise, or 4) education (control). Prior to the program, and after three, six, 12, and 18 months, patients were evaluated by a variety of physiologic and psychosocial measures. The physiologic mea-
Measures included fasting blood glucose, glycosylated hemoglobin, blood lipids, relative weight, and exercise tolerance. The psychosocial assessment concentrated on a general quality of life measure. In this paper we report the results of measures of glycosylated hemoglobin, weight, and quality of life taken at the 18-month follow-up study.

**Physiologic Assessment**

Subjects reported to an exercise physiology laboratory in the morning after a 12-hour fast. With the subject in a seated position, 30 ml of venous blood were drawn from the antecubital vein. A 10-ml volume was analyzed to determine plasma glucose concentration and other characteristics. Four milliliters of whole blood were used to determine glycosylated hemoglobin according to the Isolab Quik-Sep Kit QS-9100 method. Glycosylated hemoglobin (HbA\textsubscript{c}) is believed to be an indicator of average blood glucose control over the preceding 90 to 120 days. Three blood pressures were obtained and averaged. Each participant was also weighed on a standard scale and by submersion in water. Body fat was estimated using hydrostatic weighing with a correlation for lung volume.

A second session was used to perform a graded exercise test (GXT), which was used to measure maximal oxygen uptake, to evaluate heart function, and to develop an exercise prescription that was safe with respect to mode, frequency, duration, and intensity. A standard resting 12-lead electrocardiograph preceded the GXT.

**Quality of Life Measure**

To measure the general quality of life, we used a previously tested quality of well-being scale. Briefly, the index conceptualizes health as involving two components: current state of health and prognosis. Levels of well-being are the social preferences that society associates with observable levels of functioning. Three scales, mobility, physical activity, and social activity, represent associated, but distinct, aspects of function. Physical activity is divided into four graded levels, while mobility and social activity are each divided into five levels (Table 1). It is important to appreciate that Table 1 is not the scale. Instead, it describes summary levels from the scale.

In addition to evaluation of function, patients are classified as having any of 36 symptoms or problems that might inhibit function. For any particular examination, the observed level of function combined with the symptom/problem complex is weighted by preferences or utilities obtained from judgment studies involving random samples from the general population. Using these preferences, each combination of observable state of health and reported symptoms/problems is placed on a continuum ranging from 0 for dead to 1.0 for optimum function. Notice that symptoms as well as functional limitations affect the overall well-being score. A person in the top level of functioning for all scales in Table 1 would not get a score of 1.0 unless he or she were symptom-free. Even a minor symptom, such as itchy eyes, would bring the score below 1.0. The quality of well-being scale considers durations of stay in health states as well as current status. The system is designed to facilitate trade-offs between times in different states and numbers of cases. For example, two years in a state rated 0.5 are considered equivalent to one year in a state weighted 1.0. A treatment that improves quality of well-being scores from 0.5 to 0.6 for five people (5 people × 0.1 units = 0.5 units) is considered equivalent to a treatment that boosts quality of well-being from 0.35 to 0.85 (=0.5 units) for one person for an equal period. The Appendix provides more information about the system.

**Group Interventions**

Participants in all four groups were given the exchange diet (approximately 1,200 calories per day) recommended by the American Diabetes Association, and each received an exercise prescription based on the results of the graded exercise test. All were asked to attend two-hour meetings for ten consecutive weeks. A deposit of $40 was requested, some of which was returned contingent upon attendance according to a predetermined schedule in amounts ranging from $1 to $10. All participants except those in the education (control) group were weighed at the beginning of each meeting. (All subjects in all groups were weighed at every follow-up visit.)

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**TABLE 1**

| Dimensions and Steps for Function Levels in the Quality of Well-being Scale |
|-----------------|-----------------|-----------------|
| **Mobility**    | **Physical Activity** | **Social Activity** |
| Drove car and used bus or train without help (5) | Walked without physical problems (4) | Did work, school, or housework and other activities (5) |
| Did not drive, or had help to use bus or train (4) | Walked with physical limitations (3) | Did work, school, or housework but other activities limited (4) |
| In hospital (2) | In bed or chair (1) | Limited in amount or kind of work, school, or housework (3) |
| In special care unit (1) | | Performed self-care but not work, school or housework (3) |
|                |                  | Had help with self-care (1) |

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The treatment interventions were developed by incorporating behavior modification and strategies to increase compliance with the diet and/or exercise plan. The education group, designed to be a control condition, received information but did not experience the behavioral strategies. The focuses of the interventions in the four groups were diet, exercise, diet plus exercise, and education, respectively.

**Diet.** Subjects in the diet group identified goals for the ten-week intervention and participated in behavioral exercises. The behavior modification treatment used principles of modern learning theory. Participants in this group monitored eating behavior through the use of a diary and learned to identify external cues that lead to overeating or inappropriate eating patterns. They were introduced to specific methods for obtaining positive reinforcement and for altering their environment to make it possible to control food consumption. Diaries were reviewed weekly and individual feedback was given to each subject. The role of cognitions in altering habits was described. Subjects recorded their own positive and negative self-statements, which were then shared during group discussions. All participated in making changes in cognitions. A registered dietician explained the diet of 50 per cent complex carbohydrate, 20 per cent protein, and 30 per cent fat and how to make use of the exchange system. Brief relaxation exercises were also included as an alternative way of coping with stress. A detailed discussion of the diet program is available.

**Exercise.** A fourth of the patients participated in a program focusing on exercise. Goal setting, planning for exercise, and self-monitoring strategies were introduced at the first meeting, and participants were asked to complete a diary for the next week to obtain baseline activity. Foot care instructions were also given.

The second meeting was devoted to explaining the results of the graded exercise test, answering individual questions and concerns, and engaging in the stretching exercises to be used before walking—the recommended mode of activity for all but one of the subjects. Target heart rates were used to guide the intensity of exercise. The target heart rate was 60–70 per cent of each subject’s maximal work capacity.

During exercise sessions, several exercise leaders walked with the participants to provide modeling, positive feedback, and suggestions for managing problems arising from exercise. The format of 20 minutes of stretching, 45–60 minutes of walking, 5–10 minutes more of stretching, and 30 minutes of group discussion was followed from the third through the tenth sessions. Each participant was asked to perform the recommended exercise at least two other times each week. Subjects were encouraged to attend other adult fitness program sessions during the week. At the beginning of each session exercise diaries were collected. The results were graphed so that participants could see the progress they were making.

Specific issues addressed during the 30 minutes allotted to behavioral modification included planning, use of reinforcers and contingencies, overcoming barriers to exercise, negative and positive self-talk, use of distractors to make exercise more enjoyable, choosing routes, and scheduling exercise during holidays and vacations. Behavioral contracts were completed in the last session to promote maintenance of the exercise plan.

**Diet and Exercise.** This group received a modification of the dietary intervention for the first five weeks. The sixth meeting focused on the exercise prescription, self-monitoring, foot care, and stretching. The remaining four meetings followed the 20 minutes of stretching, 45–60 minutes of walking/jogging, and 30 minutes of behavior modification format.

**Education/Control Group.** The final group was exposed to health care specialists, including an endocrinologist, a podiatrist, an ophthalmologist, a psychologist, a registered dietician, an official of the American Diabetes Association, a representative from a company that manufactures home glucose monitoring equipment, and an exercise physiologist. Each of these experts offered a two-hour presentation over a ten-week period. Although the lectures provided information about diabetes care, they did not offer specific instructions for making behavioral changes. Previous research suggests that knowledge of the facts about diabetes is unrelated to control of diabetes. Since the education program did not provide specific guided practice in self-care behaviors, we did not expect significant changes in these patients. However, the weekly lectures did enhance interest and allowed for control in the amount of time spent with the patients.

**Statistical Methods**

For each follow-up period, change scores for each measure were created by subtracting values obtained at the follow-up visit from pretreatment values. One-way analysis of variance was used to compare the groups for the change scores. The between-groups effect for one-way analysis of variance of change scores is identical to the time by treatment interaction in the repeated measures analysis of variance. Comparisons between each treatment group and the education control group were accomplished using the method of planned comparison. One degree of freedom was used for the three orthogonal contrasts that compared each treatment with the control.
RESULTS

At orientation, 87 subjects were recruited. Eighty-nine per cent of those attending the orientation meetings volunteered to participate, and this percentage did not differ significantly across conditions. Nine individuals withdrew because of job conflicts, insufficient potassium concentrations to participate in the graded exercise testing, diagnostic misclassification, or too great a distance between home and the meeting site. One participant died in an accident a few days after the initial assessment. A second participant withdrew after five weeks of the intervention when she was diagnosed as having terminal cancer. Seventy-six subjects (32 men and 44 women) with a physician-confirmed diagnosis of non-insulin-dependent diabetes mellitus and a fasting (12-hour) plasma glucose greater than concentration 3.62 mmol/l participated.

Table 2 shows the group means and standard deviations and the F values for comparisons between groups on the measures taken prior to the interventions. The groups did not differ significantly prior to the interventions. Average attendance at group meetings exceeded 80 per cent for all groups. Differences between groups for participation in sessions and for attendance at follow-up examinations were non-significant.

Weight

Although there were modest changes in weight early in the study, the lost weight had been regained by the time of the 18-month follow-up examination. At the three-month follow-up examination there were significant differences between the diet and control groups (average loss 2.52 kg vs. gain of 1.37 kg, F\(_{1/60} = 5.29, p < 0.03\)). By six months, there was approximately a 4.5-kg differential in weight loss between the diet group (loss = 3.49 kg) and the control group (gain = 1 kg). These differences were statistically significant (F\(_{1/54} = 6.50, p < 0.02\)). The exercise group had achieved less weight loss (1.42 kg), while the diet-plus-exercise group had remained approximately the same (loss = 0.24 kg). However, after six months the diet group had regained weight. By the time of the 18-month follow-up examination, this group had regained an average of 1.81 kg. Of interest was the finding that there was very poor maintenance of weight loss in the exercise group, and weight was essentially constant across the experiment for the diet-plus-exercise group.

Changes in Glycosylated Hemoglobin

There were borderline significant differences between groups for changes in \(\text{HbA}_1\text{C}\) over the 18-month period (F\(_{3/61} = 2.26, p < 0.10\)). The diet-plus-exercise group reduced their mean \(\text{HbA}_1\text{C}\) from 9.18 per cent to 7.70 per cent (decrease of 1.48 per cent), while the control group increased 0.36 per cent from 8.21 per cent to 8.57 per cent. The difference in these changes was significant by planned comparison and by the Duncan Multiple Range Test (p < 0.05). In the diet-only group \(\text{HbA}_1\text{C}\) decreased by 0.46 per cent, while in the exercise-only group it increased by 1.30 per cent. These changes were not significantly different from that in the control group (Fig. 1).

![FIGURE 1. Changes in glycosylated hemoglobin at the 18-month follow-up study.](image-url)
Changes in Quality of Life

Over the 18 months of follow-up, the combination diet-plus-exercise group generally showed steady improvement in quality of life measures, while the education control group showed modest declines throughout (Fig. 2). The exercise group showed relatively few gains or losses in quality of life. The diet group also improved in general quality of life after the first year. By the 18-month assessment, the combination group had received 0.06 units of improvement in well-being, as compared with 0.03 for the diet group, 0.0 for the exercise group, and −0.04 for the control group. The difference between the combination group and the control group was equal to 0.092 units of well-being. These differences at 18 months were significant ($F_{3/61} = 2.95, p < 0.05$).

Planned comparisons demonstrated that the combined-treatment group ($F_{1/61} = 7.29, p < 0.01$) and the diet group ($F_{1/61} = 4.00, p < 0.05$) each differed from the control, while the difference between the exercise and control groups was non-significant.

Cost/Utility Analysis (Tables 3 and 4)

One of the reasons we measured quality of well-being is that it can be used for policy analysis. Using a set of conservative assumptions, we used the index to calculate the expected effects on health of the diet-plus-exercise program as 0.092 years of well-being for each participant. In other words, the average patient in the combined-treatment group received 0.092 units of benefit in comparison with the control group. This figure represents the measured difference between treatment and control groups at each point weighted by duration of stay and adjusted to provide a one-year rate. The calculation is shown in Table 4. We believe the objectives of health care include the extension of life and improvement of the quality of life. For each 100 participants in such a program, 4.7 well years (or 100 patients × 0.047 well years) would be produced. If the program cost $1,000 per patient, the cost to produce a well year would be $10,870. Costs of the program were estimated using 1986 clinical charges in the San Diego community. They include charges for history and physical, laboratory work, sessions, and medical consultations. The charges are summarized in Table 3. Discounting was not performed because costs and benefits were evaluated in the near term. Indirect costs were not considered in this analysis. There were no known costs associated with side effects. As shown in Table 3, the approximate clinical costs would be $1,000. This is somewhat more expensive than other health care programs but comparable to many widely advocated alternatives. If the effects were long-lasting and complications of diabetes were averted, the cost-utility ratio would be even more favorable.

Medication Effects

At entry to the study, 29 patients were using oral hypoglycemic medications, 19 were using insulin, and 28 were being managed without medications. Although patients were not randomly assigned to these medication conditions, we compared the changes in outcome as a function of treatment strategy and evaluated interactions between medica-

![Table 3](image)

<table>
<thead>
<tr>
<th>Service</th>
<th>Charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>History and physical</td>
<td>125</td>
</tr>
<tr>
<td>Screening laboratory tests (panel, HbA1c, lipids)</td>
<td>100</td>
</tr>
<tr>
<td>ECG, resting and exercise</td>
<td>200</td>
</tr>
<tr>
<td>Intervention, ten sessions ×$40/session</td>
<td>400</td>
</tr>
<tr>
<td>Follow-up laboratory tests</td>
<td>100</td>
</tr>
<tr>
<td>Medical consultation/supervision</td>
<td>75</td>
</tr>
<tr>
<td></td>
<td>$1,000</td>
</tr>
</tbody>
</table>

![Table 4](image)

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>Mean Difference of Diet-plus-exercise vs. Control</th>
<th>Duration (Years)</th>
<th>Well Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-month</td>
<td>0.044</td>
<td>0.25</td>
<td>0.011</td>
</tr>
<tr>
<td>6-month</td>
<td>0.052</td>
<td>0.25</td>
<td>0.013</td>
</tr>
<tr>
<td>12-month</td>
<td>0.043</td>
<td>0.50</td>
<td>0.022</td>
</tr>
<tr>
<td>18-month</td>
<td>0.092</td>
<td>0.50</td>
<td>0.046</td>
</tr>
</tbody>
</table>

Cost/utility (see also Table 3) = $1,000/0.092 = $10,870/well year.
tions and behavioral regimen. Those managed on insulin entered the study in poorer control of their diabetes. Therefore, fasting blood glucose was used as a covariate in all analyses. The data were analyzed using a behavioral group assignment by medication factorial analysis of variance. In addition, all analyses considered changes in parameters, statistically controlling for initial values.

There were no statistically reliable effects \((p<0.05)\) attributable to medication or to the interaction between medication and behavioral intervention.

**Within-group Comparisons**

Pearson Product Moment Correlations were used to evaluate associations between physiologic and quality of life outcomes, independent of group assignment. There were significant correlations between improvements in quality of well-being and decreases in glycosylated hemoglobin \((r = -0.22, p < 0.05)\). Patients who reduced their fasting blood glucose reported significantly fewer symptoms \((r = 0.35, p < 0.01)\). In addition, patients who lost weight also experienced significant improvements in quality of life (QWB) \((r = -0.24, p < 0.05)\).

**DISCUSSION**

Behavioral programs to restrict diet and increase exercise appear to have significant benefits for NIDDM patients. We observed that patients assigned to a diet-plus-exercise program had better psychosocial (quality of life) and physiologic (HbA1c) outcomes than did their peers assigned to an education-only program. These benefits appeared to be independent of group differences in weight loss. We previously reported that the behavioral diet program produced significant increases in HDL cholesterol in comparison with education-only control groups.\(^{13}\) The cost/utility analysis demonstrated that the diet-plus-exercise program produced a well-year of life at a cost comparable to those of many widely advocated health care programs.

Two important questions are relevant to the non-pharmacologic management of Type II diabetes. The first concerns the value of diet and exercise in the management of this condition. Some evidence suggests that both diet\(^{14}\) and exercise\(^{15}\) play significant roles in the management of NIDDM. Under controlled conditions, patients who are exercised or forced to make controlled dietary changes appear to benefit.

A second, and perhaps neglected, problem in the non-pharmacologic management of NIDDM concerns compliance with these interventions. Despite recommendations by the American Diabetes Association\(^{10}\) for the management of NIDDM with diet and exercise, we know relatively little about the likelihood that patients assigned to these treatments will benefit. West\(^{16}\) argued that a substantial proportion of those assigned to dietary change will neglect the physician’s advice. Our investigation considered the impact of assignment to diet, exercise, or diet and exercise. The evidence suggests that a diet-plus-exercise program combined with behavior modification can produce significant health status benefits over an 18-month period.

We must be cautious in our interpretation of these data for several reasons. First, the patient participants were volunteers and may not be representative of NIDDM patients in general. Although their obesity levels and blood glucose levels were in the expected range, their mean total cholesterol value of 5.13 mmol/l was lower than expected. In an epidemiologic study of the general population in the San Diego community, using the same lipid lab, the mean total cholesterol level was 5.64 mmol/l (averaged across genders) for diabetic adults.\(^{17}\) The mean total cholesterol for men of the same age in the National Lipid Research Clinic’s sample was 5.51 mmol/l with a standard deviation of 0.96 mmol/l.\(^{18}\)

Thus, there is some reason to suspect that the sample was not representative of diabetics in general. However, the values were not toward the extreme of the distribution (Lipid Research Clinic 10th percentile = 4.32 mol/l), and the groups did not differ prior to the intervention. Pretreatment equivalence is important because the major inferences in this study are based upon differential changes among patients assigned to the different treatments.

A related problem is that analyses were performed for four major outcome variables and the number of patients was small. The chances of a spurious treatment effect were also inflated because three planned comparisons were performed to compare the four groups on each outcome measure. In other words, 12 separate statistical tests were performed for the 18-month follow-up. Assuming that the tests are independent, the probability of obtaining at least one significant effect by chance alone is \(1 - (1 - 0.05)\)^{12} or about 0.45. On the other hand, the results in the present study were in the direction predicted by theory (i.e., the control group performed most poorly) and, even after adjustment for multiple comparisons, the number of significant effects exceeds what would be expected by chance.

A final concern was that some of the expected differences were weak or not statistically significant. Because of the small sample size, it is not clear whether significant differences would have emerged if more patients had been studied. Of particular interest is the marginal effect for glycosylated hemoglobin. In order to estimate how many patients would be required to detect a significant change in...
glycosylated hemoglobin, we performed a post hoc power analysis. Given the observed differences between the diet-plus-exercise and control groups, and an alpha level of 0.05, we estimated that 74 patients would be required for a 0.9 probability of detecting a difference and 55 patients per group would be needed for a 0.8 probability. Because of the larger differences observed for the quality of well-being scale, the post hoc power analysis suggested that 23 patients per group would be required to obtain 0.9 power and only 17 patients would be required for a 0.8 chance of detecting a difference. The differences between groups might have been statistically stronger had there been a larger sample size and less within-group variation. However, it is important to consider the clinical meaning of the observed group differences. A difference of 1.48 percent in HbA1C represents a meaningful clinical reduction. This effect is equivalent to the observed difference between "tight control" and standard care set in the power calculations for the Diabetes Control and Complications Trial (DCCT). This difference, if maintained over time, is expected to translate into significantly different rates of diabetic complications. As noted above, a difference of 0.092 units on the QWB scale means that the perceived equivalent of 9.2 years of well life is generated for each 100 patients who maintain this difference for a year. Thus, we believe the observed differences would be clinically meaningful if replicated on a larger scale.

Findings reflecting absence of differences between medical management strategies should be interpreted with caution. Patients were not randomly assigned to insulin, oral hypoglycemic medications, or diet alone. Indeed, it is likely that patients were systematically assigned to these treatments as a function of their diabetes control. In addition, the small sample sizes may not have provided enough statistical power to detect small effects. However, the diet and exercise interventions did produce significant effects with the same sample sizes. The findings may reflect the strength of the behavioral effects given that significant differences are difficult to detect among great variability.

All of the interventions in this study were considerably more involved than standard office practice. Our data confirm other reports suggesting that information alone has little impact on the control of diabetes. Behavioral programs that train patients to make changes in diet and exercise are more involved than simply providing advice. Effective programs provide specific instruction about how to make these lifestyle changes and provide reinforcement for the practice of the behaviors. Although these programs are time-intensive, they have few risks and they may produce significant health benefits.

In summary, we observed some benefits and few risks associated with diet and exercise programs for NIDDM patients. However, the programs were labor-intensive and some of the benefits were not well maintained over time. Further studies with larger samples may help clarify some of the benefits of non-pharmacologic interventions for NIDDM.

REFERENCES

The quality of well-being outcome measure is part of a general health policy model. The purpose of the system is to express benefits and side effects of the program in terms of equivalents of completely well years of life. The years-of-life figure is adjusted for diminished quality of life produced by disease or disability. Scores on the well-being scale are obtained by classifying people into one step in each of the scales described in Table 1. In addition, patients indicate the symptom or problem that bothered them most on a particular day. Each of these steps is associated with a weight derived from community surveys to reflect social preference or utility for the state on a scale ranging from 0 (dead) to 1.0 (for optimum functioning). A score of 0.64, for example, suggests that an individual is in an observable state for which the societal preference is 64 per cent of the distance between death and optimum functioning. The person remaining in this state for one year would have lost 0.36 (or 1.0 — 0.64) well years. Prognoses in the model are defined by transitions among observable states over time. These are represented in all calculations of well years. Using this system, it is possible to estimate the number of well-year equivalents a program produces. Dividing the cost of the program by the well-year production results in an estimate of the cost/utility of the program. The cost/utility ratio can be used to compare the relative values of different programs, thereby providing a common metric for comparison of programs with different specific objectives.

To calculate well-being values, data are obtained at defined time points. In this study, those points were at the initial interview, and three, six, 12, and 18 months later. Previous studies have shown that quality-of-well-being values over four days are more reliable than the value obtained on any one day. Therefore, quality of well-being data were obtained for the four days preceding each visit, and the mean value across the four days was used for all calculations.

A "quality of well-being" score can be expressed mathematically to yield the average well-being score for a group of persons at a given time. The quality of well-being scale is expressed as:

\[ W = \frac{\sum W_i N_i}{N} \]

where:
- \( W \) is the symptom-standardized time-specific index of well-being
- \( I \) indexes the function levels \( I = 1, \ldots, I \)
- \( W_i \) is the level of well-being (weight, utility, relative desirability, social preference) for each function level, standardized (adjusted) for all possible symptom/problem complexes
- \( N_i \) is the number of persons in each function level
- \( N \) is the total number of persons in the group, cohort, or population

A weighted or well-life expectancy can be derived using the repeated well-being measurements to provide an estimate of prognosis or probability of transition among levels of function over time. This aspect of the system considers stochastic process and often is represented by Markov chains. The equation for the well-life expectancy \( (E) \) is:

\[ E = \sum W_i Y_i \]

where:
- \( E \) is the symptom-standardized well-being expectancy in equivalents of completely well years
- \( Y \) is the expected duration of stay in each function level or case type estimated with an appropriate statistical (preferably stochastic) model

The weighted or well-life expectancy formula contains a function, \( Y \), that reflects the expected transition from one level of function to another over time. When transition is used in this way, consideration of a particular disease state is no longer required. The fact that a person has diabetes would not be of concern unless current function was affected or the probability of function loss at some future time was affected.

One feature of this system is that it provides a very general description of health status, independent of a particular disease. Some physicians argue that blood glucose levels are the most important outcome measures in diabetes research. We suggest that blood sugar is an intermediate outcome. The ultimate goal is to improve current functioning, future functioning, and/or life expectancy. Blood sugar is important because it may predict poor outcomes, including diabetic complications. The quality of life measures are a more direct measurement of current functioning. It is important that outcome measures be sufficiently sensitive to detect minor variations in health status.

The quality of well-being scale is quite sensitive to slight changes in function.

The sensitivity of the measure is best illustrated by example. Suppose that an NIDDM patient were evaluated at two points in time. At the first visit, the patient was best described by the following scale steps:

- Drove car and used bus or train without help (mobility 5)
- Walked without physical problems (physical activity 4)
- Limited in amount or kind of work, school, or housework (social activity 3)
- Headache, dizziness, or ringing in the ears (symptom 16)

The weight the community associates with this level of functioning is 0.668, with an adjustment of 0.013 for the symptom/problem. So, the preference weight is 0.681.

Now consider the same patient at time 2. This time he is classified as follows:

- Drove car and used bus or train without help (mobility 5)
- Walked without physical problems (physical activity 4)
Did work, school, or housework but other activities limited (social activity 4)
Taking medication or staying on prescribed diet for health reasons (symptom 34)

The preference associated with this state of functioning is 0.686. The adjustment for symptom/problem 34 is 0.156. So, the preference weight is 0.842.

The difference between the two states described here is 0.161 units of well-being. If this difference is maintained for a year, 0.161 well years will have been gained. If this benefit accrued to 100 people, the benefit would be 16.1 well years. Or if it affected one person for ten years, the benefit would be 1.61 well years. Another way to think of this benefit is that it is a perceived 16 per cent improvement in the quality of life. The only difference between the two described states was that in the second situation the patient performed work duties but was limited in other activities, while in the first the patient was limited in work activities. The major limiting symptom switched from headache and dizziness to taking a prescribed diet. This example and a variety of current studies have demonstrated that minor differences in function are reflected in statistically significant differences in quality of well-being. Other studies have demonstrated substantial correlations between this measure and those used in other major studies. However, as demonstrated by this example, this particular index picks up aspects of dysfunction that are missed by similar systems.

Use of the system requires a standardized questionnaire, which has been validated in several studies.