Measurement of Health Status in Diabetic Patients

Diabetes Impact Measurement Scales

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OBJECTIVE — To develop an instrument to measure health status in adult insulin-dependent (type I) and non-insulin-dependent (type II) diabetic patients.

RESEARCH DESIGN AND METHODS — Correlative study to examine psychometric properties of the questionnaire. Test-retest reliability, item-scale correlations, principal-components analysis, correlations with global clinical ratings, and correlations with clinical data extracted from medical records were examined at the diabetes clinics at the University of California, Davis, Medical Center. Patients were volunteer clinic patients able to complete the questionnaire. One hundred thirty patients completed a first administration of the questionnaire, and 52 completed a second administration.

RESULTS — Test-retest reliability was satisfactory. Item-scale correlations showed that 40 of 44 questionnaire items were highly correlated with subscale and total scale scores. Principal-components analysis identified one major factor measured by the questionnaire. Cronbach's α, a measure of the scales' internal consistency, was of satisfactory magnitude. Global ratings of clinical status by patients and clinicians were highly correlated with scale scores. Correlations of scale scores with clinical data were generally of low magnitude but, where significant, were consistently in the direction hypothesized if the scale truly measures health status or disease impact.

CONCLUSIONS — The Diabetes Impact Management Scales (DIMS) is an easily administered questionnaire with internal consistency and test-retest reliability. Preliminary correlative analyses support the validity of the instrument as a measure of health status in adult type I and type II diabetic patients. Further work will be necessary to firmly establish the validity of the DIMS and its usefulness in clinical outcomes research.

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Over the past 20 yr, considerable effort has been devoted to the development of health-status measurement instruments to study outcomes in public-health and clinical research. These surveys provide valuable information complementing more traditional measures of clinical outcome such as morbidity and various physiological and pathological parameters (1,2). Some of these instruments have also been used effectively to study quality of life and disease impact in specific patient populations including cancer (3), arthritic (4–6), and hypertensive patients (7). An instrument used to measure health status in insulin-dependent (type I) diabetic patients in the Diabetes Control and Complications Trial has been described (8). This study describes another instrument developed to measure health status or disease impact in diabetic patients.

We aimed to develop a measure of clinical outcome in diabetes research that would complement traditional measures, e.g., blood glucose and glycosylated hemoglobin levels and presence and severity of diabetic complications. Our main purpose was to develop what has been termed an *evaluative index* (9), specifically designed to measure longitudinal change in diabetic patients to quantitate treatment benefit in clinical trials.

We drew heavily from previous research efforts to measure health status in general populations, most notably the health-status measures used in the Rand Health Insurance Study (2,10,11), the Sickness Impact Profile (12), and a scale designed to measure health status in arthritic patients, the Arthritis Impact Measurement Scales (4–6). The consensus of these and other groups has been that a health-status measure should reflect the presence of important symptoms, functional capacity or impairment, and general well being. These factors contribute to quality of life, yet are only indirectly, if at all, reflected in traditional measures of clinical outcome.

RESEARCH DESIGN AND METHODS— Questionnaire items were derived from discussions among a group of experienced clinicians including physicians, a diabetes nurse specialist, and a registered dietitian associated with the Diabetes Clinics at the University of California, Davis, Medical Center. We focused on common and significant symptoms of diabetes, patients' attitudes toward their disease and its management, patients' abilities to fulfill their social roles, and patients' general sense of well being. Some of the items relating to general well being were drawn directly from the Rand Study Scale (11).

Items were grouped into four subscales: *1*) symptoms, subdivided into symptoms relatively specific for diabetes and less specific for diabetes; 2) diabetes-related morale, pertaining to the patients' attitudes toward managing their disease; 3) social-role fulfillment; and 4) well being. Although it was recognized that there was considerable overlap between these categories, the subscales were constructed to explore the possibility that there may be identifiable independent factors contributing to health status in diabetic patients. Items were constructed to allow a graded response (i.e., Likert scales) for the purpose of providing high sensitivity to longitudinal change. Effort was made to use simple and unambiguous wording of items and response choices. The language of the items is estimated to require a sixth-grade reading ability. The items were designed for use with adult subjects but, with a few exceptions (e.g., items dealing with libido and sexual functioning), could be used with children and adolescents. The scale was designed to be applicable to both type I and non-insulin-dependent (type II) diabetic patients.

The test items are listed in the APPENDIX. A copy of the complete questionnaire including instructions, responses, and scoring key is available from the authors on request. The questionnaire was self-administered and took an average of 15–20 min to complete. Individual items were scored according to the response selected. Higher values were assigned for less-severe or less-frequent symptoms, greater diabetes-related morale, greater social-role fulfillment, and greater well being. Some items were reverse keyed on the administered questionnaire to avoid response bias. Subscale and total-scale scores were computed by adding individual item scores. The handling of missing values is discussed below.

The experimental protocol was approved by the University Human Subjects Review Committee. Subjects were selected from patients visiting the Diabetes Clinic at the University of California, Davis, Medical Center. Selection criteria were as follows: *1*) diagnosis of diabetes mellitus by conventional criteria (>2 fasting blood glucose levels >7.7 mM [>140 mg/dl] and/or random blood glucose levels >11.11 mM [>200 mg/dl]); 2) English-language reading ability sufficient to read and complete the questionnaire; and 3) willingness to participate in the study.

The questionnaire was completed during a clinic visit usually before the patient was seen by a clinician. Rating scales (see below) were also completed by clinicians (endocrinology faculty or fellows) at the time of the clinic visit.

A second administration of the questionnaire was performed at a subsequent visit for as many subjects as could be accomplished. The minimum time between first and second administrations was 1 mo.

Validation studies

Each questionnaire packet included two global rating scales consisting of a 99-mm line. The first scale was preceded by the instruction "show by marking an X on the line below how well your diabetes has been controlled during the past month (in terms of blood sugar, symptoms, and complications)." The second scale was preceded by the instruction "show by marking an X on the line below how good your general health (physical, mental, and emotional) has been during the past month." Beneath the leftward end of each scale was the label "could not have been worse;" beneath the center of the scale was the label "in between;" and beneath the rightward end of the scale was the label "could not have been better." The scale was scored by measuring the number of millimeters away from the leftward end X was marked.

Analogous scales for each participating subject were presented to clinicians for completion.

Patients' charts were abstracted for clinical data including sex, age, type of diabetes (I or II, according to chart notes), age of onset, and duration of diabetes. The presence of diabetic complications was tabulated for retinopathy (0, no retinopathy; 1, background retinopathy; 2, proliferative retinopathy), nephropathy (persistent proteinuria on urinalysis >75 mg protein in 24-h urine sample), neuropathy, gastropathy, and foot ulcer. Other medical diagnoses were coded as present or absent: hypertension, obesity, coronary artery disease, cerebrovascular disease, peripheral vascular disease, congestive heart failure, hypercholesterolemia (>5.2 mM [>200 mg/dl] total cholesterol), hypertriglyceridemia (>16.6 mM [>300 mg/dl]), renal insufficiency, rheumatologic disease or arthritis, other endocrinologic disease, pancreatic insufficiency, chronic obstructive pulmonary disease (COPD), and other miscellaneous medical diagnosis. The presence of these conditions was determined from problem lists or notes from other clinics found in the patients' medical record.

Clinical parameters included weight, blood pressure, pulse rate, HbA_{1c} (by high-performance liquid chromatography; 13), serum potassium, serum creatinine, blood urea nitrogen, creatinine clearance, protein on urinalysis, 24-h urinary protein excretion, serum cholesterol, and serum triglycerides. Laboratory values closest in time to the first administration of the questionnaire were used. If available, HbA_{1c} was recorded for the time of both the first ad-

ministration and the second administration of the questionnaire. Blood for serum lipid levels was usually collected from nonfasted patients. Because HbA_{1c} and self-monitored blood glucose results were customarily used in these clinics to evaluate glycemic control, few fasting laboratory blood glucose levels were available for analyses.

The therapeutic regimen was also coded. Use of insulin and the number of injections per day were recorded as was the use of oral hypoglycemic agents. Also recorded was use of diuretics, β-blockers, central α-blockers, angiotensin converting enzyme (ACE) inhibitors, calcium-channel blockers, tricyclic antidepressants, phenytoin, and metoclopramide. Also, the total number of prescribed medications and the presence or absence of reported hypoglycemic episodes and of polydipsia/polyuria were recorded.

Statistical analyses

Descriptive statistics were performed on all variables. Most of the remaining statistical tests were correlative. Computed variables included a diabetes complications index (sum of scores for retinopathy, nephropathy, neuropathy, gastropathy, and foot ulcers) and a medical-diagnoses index (sum of all coded diagnoses).

Standard item analyses were performed, including interitem correlations and item-scale correlations for the total scale and the subscales. The item score was not included in the computation of scale scores for item-scale correlations. Cronbach's α, a measure of internal consistency or homogeneity of the scale and subscales, was also performed. A principal-components analysis and a canonical analysis between principal components and the subscales were performed.

Missing values were handled in several ways. When responses were omitted, the scale scores were adjusted to reflect the proportion of the total possible score when that item was omitted. This essentially assigns the average item score on a particular scale when an item is omitted. As discussed below, there was not a great number of missing responses to test items, but responses to some test items were more likely to be omitted than others. In all correlational analyses, pairwise deletions were made for missing values.

RESULTS

Sample characteristics

One hundred thirty patients completed a first administration of the questionnaire, and 52 completed a second administration. Fifty-five male (42% of sample) and 75 female (58% of sample) patients were included. Age range was 18–78 yr of age, with a mean ± SD age of 45 ± 15 yr. Fifty-one patients (39%) were diagnosed as type I and 77 patients (59%) as type II (2 patients could not be classified as type I or II). The age of onset of diabetes ranged from 1 to 74 yr with a mean of 34 yr. The number of years of duration of diabetes ranged from 0 (<1 yr) to 34 yr with a mean of 11 yr.

Seventy-eight (60%) patients were not documented to have retinopathy, whereas 30 (23%) were described as having background diabetic retinopathy and 21 (16%) as having proliferative retinopathy. Thirty-six (28%) patients were documented as having nephropathy, i.e., abnormal proteinuria. Thirty-nine patients (30%) had documented evidence of neuropathy (sensory loss or unequivocal loss of deep tendon reflexes), and 90 patients (70%) had none. Only 4 patients (3%) were documented as having gastropathy, whereas 125 (97%) showed no documented evidence of this diabetic complication. Five patients (4%) were documented as having foot ulcers, and 124 patients (96%) were not. Data regarding complications were not available for 1 patient. Frequencies of other medical diagnoses are shown in Table 1.

Among our sample, HbA_{1c} values ranged from 4.3 to 14.1% (mean ± SD 7.59 ± 1.8%; normal range 4–6%) at or near the time of the first administration of the questionnaire.

One hundred patients (77%) were taking insulin and 29 (22%) were not, with data missing for 1 patient. Of the 100 patients taking insulin, 4 took one injection per day, 25 took two injections, 23 took three injections, and 46 took four injections per day. Twenty-nine patients (22%) took an oral hypoglycemic agent and 101 (78%) did not.

Item analyses

Each item elicited responses throughout the possible range. Though some items were more frequently left unanswered than others, it appeared that the items were easily answered by most patients. No effort was made to insist that subjects answer every item. Ninety of 130 subjects responded to every item in a scorable fashion. Some omissions appeared to be due to simple oversight, which seemed particularly apparent when a page of the questionnaire was left blank (the printing format resulted in 4 items being presented on each page). There were occasional unscorable idiosyncratic responses (write in responses). One item (no. 15) was not applicable to 4 subjects because they were not taking hypoglycemic medications at the time of the questionnaire administration. Item 30 (5 missing values) was considered not applicable by several patients who stated that they had no family. Item 40 (3 missing values) may have been considered not applicable by patients who were not doing self-monitoring of blood glucose.

Four items (6, 21, 22, and 32) had relatively high rates of missing values (16, 13, 15, and 10 answers missing, respectively). Some patients appeared to be inhibited in responding to the items (21 and 32) pertaining to sexual functioning and libido. This phenomenon has been noted previously (4). A few patients wrote in that they were sexually inactive. The items concerning the occurrence of hypoglycemia with exercise were perhaps difficult to understand or perhaps felt to be not applicable in cases of extreme limitation of exercise. These four items were retained for analysis be-

Table 1—*Frequency of other medical diagnoses and diabetes and related morbidity in study sample*

	PRESENT	ABSENT	DATA MISSING
HYPERTENSION	33 (26)	96 (74)	1
OBESITY	49 (38)	80 (62)	1*
CORONARY ARTERY DISEASE	14 (11)	115 (89)	1
CEREBROVASCULAR DISEASE	4 (3)	125 (97)	1
PERIPHERAL VASCULAR DISEASE	2 (2)	127 (98)	1
CONGESTIVE HEART FAILURE	4 (3)	125 (97)	1
HYPERCHOLESTEROLEMIA	54 (43)	71 (57)	5
HYPERTRIGLYCERIDEMIA	24 (19)	100 (81)	6
RENAL INSUFFICIENCY	17 (13)	112 (87)	1
ARTHRITIS/RHEUMATOLOGIC DISEASE	10 (8)	119 (92)	1
OTHER ENDOCRINE DISEASE	13 (10)	116 (90)	1
PANCREATIC INSUFFICIENCY	4 (3)	125 (97)	1
COPD	9 (7)	120 (93)	1
OTHER DIAGNOSIS†	27 (21)	103 (79)	0
RETINOPATHY		78 (60)	1
BACKGROUND	30 (23)		
PROLIFERATIVE	21 (16)		
NEPHROPATHY	36 (28)	93 (72)	1‡
NEUROPATHY	39 (30)	90 (70)	1
GASTROPATHY	4 (3)	125 (96)	1
FOOT ULCER	5 (4)	124 (96)	1

Values in parentheses are percentages. COPD, chronic obstructive pulmonary disease.
*Not listed as medical problem or diagnosis.
†Miscellaneous, e.g., psychiatric disorders, gout, migraine.
‡Abnormal proteinuria not documented.

cause they were felt to be potentially significant in assessment of disease impact of diabetes and because they were satisfactorily answered by most respondents.

The strategy of assigning a value for missing responses equal to the average of all other responses on the scale (or subscale) was felt to be justified for several reasons. First, if all questionnaires with a missing value were disqualified from analysis, a significant proportion of the sample (40 of 130) would have been lost, which could have introduced a bias in the patient sampling. Second, the items with the highest rate of nonresponse deal with potentially important clinical information. Again, even the items with the highest rate of nonresponse were satisfactorily answered by most subjects. Finally, with one exception (item 22), these items correlated highly with scale scores, which minimized the likelihood of introducing a significant bias by retaining them.

Item-scale (and interitem) correlations are available from the authors on request. Four items (16, 22, 39, and 42) performed poorly, not correlating significantly with the total-scale score ($P > 0.01$). All other items showed significant ($P < 0.01$) correlations with their respective subscale totals and the total-scale score. Because of their poor performances, items 16, 22, 39, and 42 will be deleted from the scoring of the Diabetes Impact Measurement Scales (DIMS) in its future applications.

Distributions of subscale and total-scale scores

Distribution characteristics of each subscale and the total scale are presented in Table 2. Scores are presented as T scores. The T scores represent the scale score as the proportion of the total possible score on the scale, multiplied by 10, yielding a range of possible values from 0 to 10. Each scale yielded a reasonably wide range of scores. The scales are all negatively skewed, reflecting the generally observed characteristic of quality-of-life measures to concentrate scores closer to the upper end of the scale (11). Note that the total-scale score here is derived from a simple sum of responses to all items. This gives disproportionate weight to the subscales with the greater number of items. It can be argued that the subscales (symptoms, well being, diabetes-related morale, and social role fulfillment) should be weighted equally in determining the total-scale score. This would be easily accomplished by simply taking the average of the subscale scores as the total-scale score. In future applications of the DIMS, we will explore both methods of obtaining total-scale scores.

Subscale analyses

Information regarding the relationships between the subscale scores and the total-scale scores is listed in Table 3, a correlation matrix of these scores. All subscale scores were highly correlated ($P < 0.001$) with all other subscales, but the correlations are far enough from unity to suggest that the subscales are not redundant. (An exception is the high correlation of the two subdivisions of the symptoms subscale—specific and nonspecific symptoms of diabetes, with the combined-symptoms subscale.)

Cronbach's α, a test of the internal consistency of the subscales and total DIMS scale, was performed (Table 4). The obtained values are within the range generally considered desirable by psychometric standards.

Principal-components analysis

A principal-components analysis was done to explore statistically the factor structure of the questionnaire. A major principal-component accounting for 32% of the variance was identified. Beyond this, nine components accounting for ≤7.5% of the variance each were

Table 2—*Distribution of subscale and total-scale scores on the 1st questionnaire administration*

SCALE		SKEWNESS
IA	7.70 ± 1.21 (3–9.7)	−0.77
IB	7.30 ± 1.29 (3.8–10.0)	−0.23
I	7.40 ± 1.17 (4.5–9.4)	−0.37
II	6.70 ± 1.71 (2.6–10.0)	−0.25
III	7.70 ± 1.08 (4.2–9.6)	−0.45
IV	7.10 ± 2.08 (2.2–10.0)	−0.36
TOTAL	7.40 ± 1.15 (3.8–9.5)	−0.31

Values are means ± SD of proportion of total possible score on the scale × 10. Ranges given in parentheses. IA, diabetes-specific symptoms; IB, nonspecific symptoms; I, combined symptoms; II, well being; III, diabetes-related morale; IV, social role fulfillment; Total, total diabetes impact measurement scales score.

identified, bringing the cumulative variance explained to 69%.

All subscale scores were highly correlated with the first principal component (r = 0.75–0.95) and variably correlated with the remaining components.

A canonical correlational analysis was performed to examine relationships between the principal components and subscales. Aside from again showing the strong positive correlation between all the subscales and the first principal component, a contrast between scale I (symptoms) and scale III (diabetes-related morale) in relation to the second principal component was suggested (scale I correlated negatively and scale III correlated positively with the second principal component).

The principal-components analysis suggests that there is a major factor being measured by all subscales and the total-DIMS score and several minor factors. Although we did not see statistical support for unique significance of the subscales, we will continue to study the relationship of subscale scores to clinical variables to determine whether the subscales provide information beyond that of the total-DIMS score. The subscales are expected to perform differently when nondiabetic patient populations are studied and compared with diabetic patients.

Validation studies

A traditional test of test-retest reliability was not possible within the design of this study because the interval between repeated administrations of the scale varied from subject to subject. However, scale scores on the first and second administrations (Table 4) were all highly significantly correlated.

Construct validation of the DIMS was sought by exploring correlations of the DIMS scores with the global rating scales and the clinical variables (Table 5). For the most part, the DIMS subscale and total-scale scores were highly correlated with both patients' and clinicians' global ratings of overall diabetic control and health status.

We hypothesize that higher DIMS scores would generally be negatively correlated with clinical variables indicating presence of disease. Correlations between DIMS scores and the numerous clinical variables recorded were of variable but generally low magnitude. Clinical variables showing no significant correlation with DIMS scores included diabetes type, duration of disease, presence of retinopathy, nephropathy, gastropathy, foot ulcer, diagnosis of hypertension, coronary artery disease, peripheral vascular disease, congestive heart failure, renal insufficiency, hypercholesterolemia, hypertriglyceridemia, systolic and diastolic blood pressures, presence of insulin reactions, use of insulin, number of daily insulin injections, use of oral hypoglycemic agents, and most other medications recorded (diuretics, β-blockers, central α-blockers, ACE inhibitors, and calcium-channel blockers). The diabetes-complications index (sum of all coded complications) was not significantly correlated with DIMS scores. For some of these variables, the frequency distribution within the sample was not conducive to generating a correlation, e.g., less-common diabetic complications (gastropathy and foot ulcers). Other variables would not have been expected to relate to the scale scores (e.g., blood pressure, which was generally reasonably well controlled and is typically asymptomatic). Other variables might be expected to be differently related to diabetes impact in different situations, e.g.,

Table 3—*Correlations of subscale and total-scale scores*

	IA	IB	I	II	III	IV	TOTAL
IA	1.000	0.700	0.859	0.552	0.485	0.459	0.735
IB	0.700	1.000	0.967	0.704	0.556	0.634	0.875
I	0.859	0.967	1.000	0.703	0.571	0.617	0.890
II	0.551	0.704	0.703	1.000	0.622	0.759	0.890
III	0.485	0.556	0.571	0.622	1.000	0.518	0.797
IV	0.459	0.634	0.617	0.759	0.518	1.000	0.811
TOTAL	0.735	0.875	0.890	0.890	0.797	0.811	1.000

IA, diabetes-specific symptoms; IB, nonspecific symptoms; I, combined symptoms; II, well being; III, diabetes-related morale; IV, social role fulfillment; Total, total diabetes impact measurement scales score. $P < 0.001$ for all comparisons.

Table 4—*Cronbach's α scores for subscales and total Diabetes Impact Measurement Scales (DIMS) scale and test-retest correlations*

Scale	α	*n*	Test-retest correlation (N = 52)
Specific symptoms	0.6045	109	0.750
Nonspecific symptoms	0.7861	112	0.689
Combined symptoms	0.8532	94	0.724
Well-Being	0.8522	118	0.609
Diabetes-Related Morale	0.7666	111	0.778
Social Role Fulfillment	0.8545	123	0.651
Total DIMS	0.9394	87	0.770

n varies because casewise deletion was used for missing values to calculate Cronbach's α.
$P < 0.001$ for all comparisons.

use of insulin, which is generally required in more-severe diabetes, but which clearly produces therapeutic benefits, or presence of hypoglycemic episodes, which can be seen in both poorly controlled, "brittle", diabetes and tightly controlled diabetes.

Diagnosis of other endocrine disease (primarily thyroid disease) was negatively correlated with the symptoms subscales ($P = 0.005$, 0.01, and 0.005, respectively, for specific symptoms, nonspecific symptoms, and combined-symptoms subscales) and the total-DIMS score ($P = 0.03$). Presence of COPD was negatively correlated with the symptoms subscales ($P < 0.001$ for specific, nonspecific, and combined-symptoms subscales), well being ($P = 0.01$), social-role fulfillment ($P = 0.02$), and the total-DIMS score ($P = 0.001$). Presence of miscellaneous diagnoses was negatively correlated with the nonspecific-sumptoms subscale ($P = 0.03$) and combined-symptoms subscale ($P = 0.03$), well-being subscale ($P = .001$), social-role–fulfillment subscale ($P = .008$) and total-DIMS score ($P = 0.005$). The medical-diagnoses index (sum of medical diagnoses) was significantly negatively correlated with the nonspecific-symptoms ($P = 0.001$) and combined-symptoms subscales ($P = 0.003$), the social role–fulfillment subscale ($P = 0.03$), and the total-DIMS score ($P = 0.03$).

Presence of neuropathy was negatively correlated with the nonspecific symptoms subscale ($P = 0.009$) and the combined-symptoms subscale ($P = 0.02$), although not with the specific-symptoms subscale ($P = 0.14$), despite that the latter includes an item pertaining to uncomfortable paresthesias. Presence of obesity was negatively correlated with the specific-symptoms subscale ($P = 0.03$). Pulse rate was negatively correlated with the specific-symptoms subscale ($P = 0.03$), the nonspecific-symptoms subscale ($P = 0.02$), and the total-DIMS score ($P = 0.03$).

The use of certain medications was negatively correlated to DIMS scores. Tricyclic antidepressant use was negatively correlated to the specific-symptoms subscale ($P = 0.004$), the nonspecific-symptoms subscale ($P = 0.001$), the combined-symptoms subscale ($P < 0.001$), and the social role–fulfillment subscale ($P = 0.01$) and the total-DIMS score ($P = 0.004$). Phenytoin use was negatively correlated with the specific-symptoms subscale ($P = 0.005$), nonspecific-symptoms subscale ($P < 0.001$), and the combined-symptoms subscale ($P < 0.001$), and the well-being subscale ($P = 0.01$), the diabetes-related–morale subscale ($P < 0.001$), social-role–fulfillment subscale ($P = 0.01$), and the total-DIMS score ($P < 0.001$). Use of metoclopramide was negatively correlated with the nonspecific-symptoms subscale ($P = 0.002$), the combined-symptoms subscale ($P = 0.007$), the well-being subscale ($P = 0.02$), the social role fulfillment subscale ($P = 0.04$), and the total-DIMS score ($P = 0.007$). Finally, the total number of prescribed medications was negatively correlated with the nonspecific-symptoms subscale ($P < 0.001$), the combined-symptoms subscale ($P = 0.003$), the well-being subscale ($P = 0.04$), and the total-DIMS score ($P = 0.02$).

The report of polydipsia and/or polyuria was negatively correlated with the specific-symptoms subscale ($P <$

Table 5—*Correlations of rating scales with subscale and total-scale scores*

	Diabetes Rating scale		Wellness scale	
	Patient	Clinician	Patient	Clinician
Scale				
IA	0.349	0.340	0.269*	0.368
IB	0.249*	0.294*	0.317	0.330
I	0.305	0.334	0.325	0.368
II	0.367	0.347	0.470	0.452
III	0.546	0.338	0.361	0.321*
IV	0.222†	0.243†	0.308	0.288*
Total	0.432	0.383	0.429	0.432

$P < 0.001$, unless noted.
*$P < 0.01$.
†$P > 0.01$.

0.001; this subscale contains an item specifically addressing this symptom), the nonspecific-symptoms subscale ($P < 0.001$), and the combined-symptoms subscale ($P < 0.001$), and the well-being subscale ($P = 0.008$), the social-role–fulfillment subscale ($P = 0.01$), and the total-DIMS score ($P = 0.001$). The HbA_{1c} levels were negatively correlated with the nonspecific-symptoms subscale ($P = 0.04$), the combined-symptoms subscale ($P = 0.04$), the well-being subscale ($P = 0.05$), the diabetes-related–morale subscale ($P = 0.01$), and the total-DIMS score ($P = 0.005$).

The hazards of relying on tests of statistical significance when multiple tests are conducted are well known. However, virtually all of the above-listed significant correlations are in the direction that would be expected if the DIMS is a valid measure of health status or disease impact. Of the 266 correlations examined above (7 subscale and total scores with 38 clinical variables), 57 (21%) had $P < 0.05$, well above the number that would be expected to occur randomly.

We also found some significant ($P < 0.05$) correlations between clinical variables and scale scores that were not predicted by our general hypothesis but are interesting. Age was positively correlated with the well-being subscale ($P = 0.026$) and the diabetes-related–morale subscale ($P = 0.003$). Sex was strongly correlated to the symptoms subscale, for specific symptoms of diabetes ($P < 0.001$), nonspecific symptoms ($P < 0.001$), and combined-symptoms subscales ($P < 0.001$) (female patients reported more symptoms). Sex was also similarly correlated with well-being scores ($P = 0.002$) and diabetes-related morale ($P = 0.002$), with female patients scoring lower. The relationship of sex to social-role fulfillment was in the same direction but not as strong ($P = 0.06$). There was a high negative correlation between sex and the total-DIMS score ($r = -0.332$, $P < 0.001$). The age of onset of diabetes was positively correlated with diabetes-related morale ($P = 0.01$).

CONCLUSIONS— In this article, we discuss the development, psychometric characteristics, and preliminary validation studies of a new instrument designed to measure health status in diabetic patients. The DIMS is designed for use in adult patients with either type I or type II diabetes mellitus. It was specifically designed as an evaluative index to measure longitudinal changes in health status or disease impact in clinical trials of therapeutic interventions in diabetes but may also serve for other purposes such as comparisons across groups of diabetic patients.

The questionnaire is simple and straightforward, consisting of easily understood items covering a broad range of content relevant to diabetes impact.

The psychometric properties of the DIMS reflected in our analyses appear satisfactory. Four items that did not perform well in terms of item-scale correlations (items 16, 22, 39, and 42) will not be scored. The additional information provided by the subscales of the DIMS is of uncertain value, but it is expected that unique properties of the subscales may appear when diabetic and nondiabetic patient populations are compared with the DIMS. Future studies with the DIMS will examine the potential usefulness of the subscales. For now, we suggest that each subscale of the DIMS be considered a separate indicator of clinical outcome and that the average score of the major subscales (symptoms, well being, diabetes-related morale, and social-role fulfillment) be used as an overall index of diabetes impact. Further refinements of the scoring may evolve with future use of the DIMS. In future studies, we will compare responses to the DIMS in diabetic and nondiabetic patients and study the change of DIMS scores in response to therapeutic interventions.

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APPENDIX

IA	1.	How often were you bothered by excessive thirst and urination during the past month?
II	2.	During the past month, have you been anxious or worried?
III	3.	During the past month, have you felt optimistic about your diabetes?
IB	4.	How good has your muscular strength and endurance been during the past month?
IB	5.	Over the past month, have you been bothered by blurring of vision?
IA	6.	Over the past month, how much exercise could you do without developing low blood sugar?
II	7.	During the past month, have you felt that you were good at doing the most important things you do (for example, your work, school, homemaking, parenting, handling personal affairs)?
III	8.	Over the past month, how much have you felt personally in charge of managing your diabetes?
IB	9.	Over the past month, how much energy have you had?
IB	10.	During the past month how well have you slept?
III	11.	During the past month, how worried have you been about having an insulin reaction or a dangerously low blood sugar?

IV 12. Have you met the obligations and responsibilities you feel toward your family during the past month?

IB 13. During the past month, have you been bothered by constipation?

II 14. Have you felt depressed during the past month?

II 15. During the past month, was it an inconvenience or bother to you to take your diabetes medicine (pills or insulin)?

III 16. During the past month, have you eaten too much?

IA 17. During the past month, were you bothered by burning, tingling, pain, or numbness in your feet or hands?

II 18. During the past month, how worried or fearful have you been about your future?

II 19. Have you eaten what you wanted to during the past month?

III 20. During the past month, have you felt it was worth the effort to take care of your diabetes?

IB 21. During the past month, how often were you able to function sexually as well as you wanted to?

IA 22. Over the past month did you develop low blood sugar with exercise?

IV 23. Have you functioned well, not limited by your health, in your usual occupation (homemaking, school, work, etc.) during the past month?

IA 24. How often did you vomit after eating during the past month?

III 25. During the past month, my whole schedule of activities was restricted by my diabetes.

IB 26. Over the past month, have you been bothered by feeling faint or dizzy on sitting up or standing up?

II 27. How much of the time, during the past month, has your daily life been full of things that were interesting to you?

III 28. Overall, during the past month, how do you think your diabetes has been doing?

IB 29. Has your appetite been good during the last month?

IV 30. During the past month, have you participated in and enjoyed family life?

IV 31. During the past month, how often have you been able to function wellinyourusualoccupation(homemaking, school, work, etc.)?

II 32. How high has your interest in sex been over the past month?

IA 33. How often did you have abdominal discomfort after eating during the past month?

III 34. How often during the past month have you been uncertain about how much to eat and/or how much insulin to take?

IV 35. Have you enjoyed social and recreational activities during the past month?

II 36. During the past month, have you felt useful?

IB 37. During the past month, how much of the time were you lacking enough energy?

IB 38. How often did you have diarrhea during the past month?

III 39. During the past month, have you been able to follow medical recommendations concerning your diabetes?

III 40. During the past month, was your diabetes monitoring an inconvenience or bother to you?

II 41. During the past month, how much of the time did you feel that things were going well for you?

II 42. Have you eaten when you wanted to during the past month?

IB 43. During the past month how often did you feel nauseated after eating?

III 44. Over the past month, how well do you feel you have understood your diabetes?

IA, diabetes-specific symptoms subscale; IB, nonspecific symptoms subscale; II, well-being subscale; III, diabetes-related morale subscale; IV, social role fulfillment subscale.

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