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Development and Validation of a Questionnaire to Evaluate Patient Satisfaction With Diabetes Disease Management

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OBJECTIVE — To develop a reliable and valid questionnaire to measure patient satisfaction with diabetes disease management programs.

RESEARCH DESIGN AND METHODS — Questions related to structure, process, and outcomes were categorized into 14 domains defining the essential elements of diabetes disease management. Health professionals confirmed the content validity. Face validity was established by a patient focus group. The questionnaire was mailed to 711 patients with diabetes who participated in a disease management program.

To reduce the number of questionnaire items, a principal components analysis was performed using a varimax rotation. The Scree test was used to select significant components. To further assess reliability and validity, Cronbach's α and product-moment correlations were calculated for components having ≥ 3 items with loadings >0.50.

RESULTS — The validated 73-item mailed satisfaction survey had a 34.1% response rate. Principal components analysis yielded 13 components with eigenvalues >1.0. The Scree test proposed a 6-component solution (39 items), which explained 59% of the total variation. Internal consistency reliabilities computed for the first 6 components ($\alpha = 0.79-0.95$) were acceptable.

CONCLUSIONS — The final questionnaire, the Diabetes Management Evaluation Tool (DMET), was designed to assess patient satisfaction with diabetes disease management programs. Although more extensive testing of the questionnaire is appropriate, preliminary reliability and validity of the DMET has been demonstrated.

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E nhancing patient satisfaction with a diabetes disease management program (DDMP) raises the quality of care (1), controls costs, enhances outcomes (2,3), and thereby reduces patient attrition (4). Currently, there is no existing comprehensive tool that will capture patient satisfaction with the essential components of a DDMP. The purpose of this article is to describe the development of a tool designed to assess patient satisfaction with a DDMP that can be used for any diabetes population.

The use of DDMPs to control the complications of diabetes and the ensuing costs (estimated to exceed \$100 billion annually in the U.S. [5]) that accrue when diabetes is undiagnosed, untreated, or uncontrolled is becoming more frequent (6,7). However, despite the >10 million cases diagnosed in the U.S. (8) and the high associated costs, DDMPs are still evolving.

The American Diabetes Association (ADA) annually publishes their standards of medical care for patients with diabetes (9), and these standards serve as the basis for many DDMPs. However, these are standards for care and not standards for DDMPs. For these reasons, an operational definition is difficult to create. For this study, a definition of DDMPs was adopted from the literature and operationalized as "a systematic, population-based approach to identify persons at risk, intervene with specific programs of care, and measure clinical and other outcomes" (10).

In addition, the patient population and the curriculum directly shape the definition of DDMPs. Trends seen in local DDMPs suggest that most enrollees are newly diagnosed or are in the early stages of the disease. Because there are common aspects of care across types of diabetes, all diabetes types were considered for questionnaire design.

The cornerstone of current DDMPs is patient education based on the ADA's recommended standards (9). Education is also a key element leading to behavioral change through patient empowerment supported by the social learning theory (11). In addition, the Diabetes Control and Complications Trial (DCCT) established that education is critical to maintaining normal blood glucose ranges in patients with type 1 diabetes, which delays the onset of complications due to diabetes (12). Although no similar trial has been completed in people with type 2 diabetes, other studies have provided enough evidence to conclude that the results of the DCCT can reasonably apply to people with type 2 diabetes (8,13,14).

A review of the literature was conducted to investigate additional tools to measure satisfaction with diabetes care (Table 1). Although available instruments have unique

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Table 1—*Published studies between 1987 and 1997 based on questionnaires used to assess different aspects of diabetes*

Study investigator(s) (reference)	Survey name	Description
Anderson et al. (39)	Diabetes Attitude Scale	A 50-item diabetes-related questionnaire that measures the patients' attitudes toward the need for special training, patient compliance, seriousness of type 2 diabetes, glucose control and complications, impact of diabetes on patients' lives, patient autonomy and team care.
Bradley (15)	Diabetes Treatment Satisfaction Questionnaire (DTSQ)	The 8-item questionnaire captures satisfaction with treatment and understanding of diabetes. It also measures frequency of acceptable blood sugars, convenience, and flexibility.
Bradley and Lewis (40)	Treatment Satisfaction and Psychological Well-being	The treatment satisfaction segment of the instrument consisted of 11 questions that assess a patient's satisfaction with their recent treatment.
Day et al. (41)	The Ipswich Diabetes Self-Management Questionnaire	The 41-item questionnaire relates to the patients' attitudes toward and influence on actual self-management behavior, blood testing routine, and estimates of diabetic control.
Davis et al. (42)	Diabetes Educational Profile (DEP)	The 110-item survey examined the relationship of patients' psychosocial adjustment to disease type, treatment mode, and indexes of control.
Fitzgerald et al. (43)	Diabetes Care Profile	The 234-item instrument measures social and psychological factors related to diabetes and its treatment.
Diabetes Control and Complications Trial (DCCT) Research Group (12)	Diabetes Quality of Life (DQOL)	The questionnaire was designed to assess diabetes treatment regimens on the appearance and progression of early vascular complications. However, the DQOL may also be useful in evaluating the quality of life in other groups of patients with type 1 diabetes.
American Hospital Association and the Picker Institute (20)	Picker Patient Satisfaction Survey	The survey elicits specific reports from patients about the aspects of care they perceived as important.

strengths, no instrument includes a broad array of items measuring satisfaction with DDMPs. The Diabetes Treatment Satisfaction Questionnaire (DTSQ) (15) has been used most often to measure satisfaction with diabetes care. Even though this brief 8-item questionnaire provides important information about selected aspects of traditional diabetes treatment, it was not designed to cover the breadth of DDMPs that were nascent when the DTSQ was developed. Most importantly, the DTSQ does not assess the patients' satisfaction with their ability to control their diabetes, and it doesn't include the self-care components of diabetes control, such as nutrition and physical activity (9).

A new tool that elicits satisfaction with a DDMP would be beneficial to health professionals as DDMPs have become the standard for improving diabetes outcomes. Furthermore, a tool modeling the theoretical framework of Donabedian (16), which emphasizes structure, process, and outcome, will best capture the dynamics of DDMPs that are essential for measuring patient satisfaction.

Questionnaire development
Stage 1: Item generation. To prepare a comprehensive set of items measuring the most important aspects of DDMPs, an expert panel of health care professionals identified the 14 following domains of patient satisfaction that are important for successful DDMPs: physical activity, nutrition, glucose monitoring, program amenities, staff, meetings, information taught, acute complications, severe complications, time commitment, convenience, general program, follow-up, and treatment. As directed by the expert panel and reinforced by the current literature on the management of diabetes, 3 of these 14 domains of disease management (nutrition, physical activity, and glucose monitoring) were evaluated in depth. These 3 components are the foundation for managing all types of diabetes (17–19) and are essential to managing patients with type 2 diabetes who may not rely on insulin to control glucose (18,19).

Given the emerging emphasis on patient-centered experiences advocated by the Agency for Healthcare Research and Quality and the Picker Institute (20), items were added to elicit satisfaction with the patients' understanding of their condition, their personal influence over their treatment plans, and the likelihood of behavior modification.

Each domain was populated with items by using the overlying themes of structure, process, and outcomes, as described by Donabedian (21,22). This theoretical framework was used to capture how the structure of a DDMP affects patient satisfaction, how patients perceive their experiences navigating through the delivery of care, and how the process affects the patient's health.

Stage 2: Validation. To assess content validity, diabetes care professionals from the Jefferson Health System (Philadelphia, PA) reviewed the questionnaire to ensure relevance and clarity of the items. Two expert panels totaling 25 individuals that included certified diabetes educators, nurses, pharmacists, and physicians were formed. Feedback from the expert panels clarified appropriate use of terminology, such as "physical activity" instead of "exercise." Suggested additions included questions about weight management, counseling, medicinal effects, and the effect nutrition and physical activity have on glucose levels. The expert panels confirmed that all of the areas pertinent to the management of diabetes were sampled.

A patient focus group was conducted to establish the face validity of the questionnaire. A DDMP run by the family practice group at Thomas Jefferson University Hospital was used to obtain participants for the focus group. At the completion of this 6-week program, a list of patients who attended at least 2 meetings was used to make random phone calls for recruitment. Acquiring patients in this manner was

important in gaining a sample representative of all levels of satisfaction, by including patients that may have dropped out of the program.

Feedback from the focus groups consisted of patients identifying ambiguous items and suggesting additional items. Items were reworded to eliminate ambiguous phrasing. For instance, the word "diet" was replaced with "what you can eat"; "glucose" was replaced with "blood sugar"; "counseling" was replaced with "the help you received"; and "referrals" was replaced with "getting help in scheduling appointments." New items included references to advertising the program, program supplies, prejudice against people with diabetes, wound healing, and the effects of depression, weight gain, stress, sexual function, and blood pressure on glucose levels. Issues that were addressed more extensively were fear of diabetes, availability of support groups, and maintaining a diet plan. This step established face validity by having a sample of respondents verify that all areas intended to be measured by the questionnaire really were (23). Combined with the content validity of the provider focus group, the face validity of the patient focus group addressed all the variants of patient satisfaction that are relevant to disease management.

Stage 3: Questionnaire finalization. The final questionnaire consisted of 87 items organized in 3 sections. The first section (73 items) referred to the patients' satisfaction with services provided by the DDMP, satisfaction with their understanding of diabetes, and their ability to use the information they learned. Satisfaction was measured using 71 randomly ordered items with Likert scale responses (1 = very dissatisfied, 2 = slightly dissatisfied, 3 = neither satisfied nor dissatisfied, 4 = slightly satisfied, and 5 = very satisfied). This Likert scale was chosen because it has been used commonly in patient satisfaction questionnaires (3,24) and is therefore familiar to patients. Two additional items in this section required yes-or-no responses. The second section (8 items) captured behavioral change as a result of the DDMP using the following Likert scale responses: 1 = very unlikely, 2 = slightly unlikely, 3 = neither likely nor unlikely, 4 = slightly likely, and 5 = very likely. The final section (6 items) measured global satisfaction as a comparison for statistical analyses and also used a Likert scale with responses ranging from "very dissatisfied" to "very satisfied." For

the Likert-scaled items, each response scale was preceded with the sixth option of "does not apply."

RESEARCH DESIGN AND METHODS — The study sample included 711 patients who either completed a diabetes program at the Jefferson Family Medicine Diabetes Program, Frankford Hospital between 1993 and 1998 or other Jefferson Health System (JHS) patients identified with diabetes. Subjects received a demographics survey, the satisfaction questionnaire, a short-form 36 quality-of-life questionnaire (25), a description of the incentive (glucose monitor), and a definition of DDMPs. Nonrespondents were contacted to encourage a response.

Data analysis
Respondents were included in the analysis if all 3 surveys were completed, severe complications were not reported, and at least 90% of the questions on the satisfaction questionnaire were completed. This action was taken because if >10% of the questions did not apply, it was assumed that the subject had not participated in a program that met criteria for a DDMP (7,10). Questions were deleted from the analysis when the option "does not apply" was chosen by >15% of all of the respondents. For all of the remaining items, a response of "does not apply" was recoded as "neither satisfied nor dissatisfied."

To determine if there were empirically derivable subscales and to reduce the number of questionnaire items, a principal components analysis was performed. Prior communality estimates of one were used to verify that each variable was given one full unit of variance to be factored in the original correlation matrix. The criterion of Kaiser (26) was used to retain the individual items (23) with eigenvalues >1.0.

The retained component structure was rotated using varimax rotation methods. Component loadings of ≥0.50 were considered significant and were retained for the final questionnaire. These components were subjected to the Scree test (23,27), which determined which of the components would be most meaningful for measuring patient satisfaction with a DDMP.

Cronbach's α (23,28) estimated the internal consistency reliability of components with eigenvalues >1.0 that also included ≥3 items with weights >0.50 in the rotated component-loading matrix.

Table 2—*Demographics of patients responding to the mailout questionnaire* (n = 202)

Age (years)	
Mean	55.7
Range	3–98
>65 (n [%])	58 (28.9)
Total responses	201
Sex (n [%])	
M	79 (39.7)
F	120 (60.3)
Diabetes type (n [%])	
Type 1	24 (12.1)
Type 2	172 (86.9)
Gestational	2 (1.0)
Diabetes duration (years)	
Mean ± SD	8.8 ± 13.6
<6 months (n [%])	60 (31.9)
Total responses	188
Insured (n [%])	199 (97.4)
Enroller of patient (n [%])	
Doctor	115 (67.7)
Health insurer	7 (4.1)
Other	48 (28.2)
Short-form 36 scores (averages)	
Physical function	69
Role physical	56
Pain	62
General health	56
Vitality	51
Social function	72
Role emotion	64
Mental health	69

Data are n, unless otherwise indicated.

Product-moment correlations were computed between component satisfaction scores and the 6 items measuring global satisfaction to assess construct validity.

RESULTS

Patient demographics
A total of 242 of 711 patients returned the questionnaires. Of these, 23 were not analyzed because >10% of the items were checked as "does not apply" and an additional 17 did not meet the inclusion criteria. Table 2 reports demographics for the 202 analyzed questionnaires.

Of the 3 questionnaire sections (patient satisfaction, behavioral change, and global satisfaction), the behavioral change questions consistently demonstrated low correlations and were excluded from the final analysis. These patterns suggest that behavior change is not positively associated with patient satisfaction. The 6 global satisfac-

Table 3—*The 6-component solution and the component loadings for the items defining each component*

	Component loadings					
Component and item labels	I	II	III	IV	V	VI
Factor I: meetings*						
Q11: Helpful staff	.53	.09	.21	.08	.05	.11
Q22: Ease of scheduling a time	.60	.08	.19	.16	.21	.02
Q13: Discuss your type of diabetes	.61	.20	.13	.17	.18	.13
Q30: Ease of reaching schedule person	.61	.06	.04	.06	.17	.38
Q15: Availability of refreshments	.65	.20	.06	.01	.23	.04
Q16: Convenience of location	.66	.07	.02	.19	.05	.01
Q25: Safety	.66	.01	.02	.09	.03	.28
Q39: Staff treats you with respect	.67	.04	.19	.20	.07	.14
Q21: Useful information	.68	.08	.26	.04	.00	.11
Q19: Interesting discussion topics	.68	.17	.19	.01	.13	.29
Q29: Pleasantness of schedule person	.71	.04	.20	.09	.04	.13
Q05: Information program gave you	.72	.15	.18	.15	.14	.09
Q41: Ease of finding	.75	.12	.02	.10	.04	.13
Q51: Cleanliness	.76	.11	.01	.14	.08	.04
Q03: Begin on time	.77	.01	.20	.04	.11	.05
Q04: Topics are always different	.78	.22	.07	.00	.05	.04
Q54: Speakers are interesting	.79	.19	.11	.02	.00	.18
Q14: Last the right amount of time	.80	.07	.09	.16	.24	.04
Factor II: understanding general complications†						
Q52: Sexual organs	.08	.50	.32	.30	.21	.08
Q64: Things you can and can't do	.22	.55	.10	.23	.16	.12
Q68: Depression	.20	.72	.24	.01	.26	.14
Q58: Blood pressure	.14	.74	.05	.34	.01	.05
Q59: Stress	.15	.79	.18	.22	.09	.12
Q60: Weight gain	.09	.81	.15	.07	.07	.16
Factor III: personal nutrition‡						
Q31: When to check blood sugar levels	.22	.28	.50	.12	.13	.18
Q57: How to deal with diabetes	.20	.38	.51	.16	.20	.18
Q56: What to eat for control	.18	.15	.53	.43	.31	.12
Q61: Food labels	.06	.32	.66	.24	.18	.15
Q23: What you can and can't eat	.20	.28	.68	.23	.23	.15
Factor IV: personal physical activity§						
Q06: Physical activity for diabetes control	.27	.19	.40	.55	.22	.13
Q53: Help for planning physical activity	.08	.37	.24	.65	.24	.03
Q43: Amount of physical activity needed	.15	.23	.23	.68	.10	.38
Q50: Types of physical activity	.11	.30	.12	.78	.16	.11
Factor V: personal time commitment‖						
Q33: Flexibility of food plan	.10	.23	.33	.04	.64	.09
Q07: Amount of time spent watching what you eat for control	.08	.11	.19	.25	.73	.01
Q08: Amount of time spent getting checkups	.06	.15	.08	.11	.79	.28
Factor VI: understanding severe complications¶						
Q32: Unexpected problems	.15	.29	.27	.05	.15	.54
Q09: Diabetes emergency	.26	.13	.15	.12	.26	.67
Q42: Eye care	.23	.22	.14	.33	.05	.68

*α Reliability = 0.95, variance explained = 38.2%, and eigenvalue = 22.9; †α reliability = 0.88, variance explained = 9.1%, and eigenvalue = 5.5; ‡α reliability = 0.87, variance explained = 3.4%, and eigenvalue = 2.0; §α reliability = 0.87, variance explained = 3.0%, and eigenvalue = 1.8; ‖α reliability = 0.79, variance explained = 2.6%, and eigenvalue = 1.5; ¶α reliability = 0.78, variance explained = 2.4%, and eigenvalue = 1.5.

tion scores were used in the analysis as comparison items.

Of the 73 patient satisfaction items, 13 were dropped from the multivariate analysis because 15% of patients checked the "does not apply" option. These questions targeted parking, equipment, handicap accessibility, availability of meetings, public transportation, support groups, sexual activity, prejudices, advertising, and program length. Sixty satisfaction items were used in the final analyses.

Although most of the remaining 60 patient satisfaction items showed mean satisfaction scores above 4.5, there was enough variation to justify their inclusion in the multivariate analysis. Frequency distributions were analyzed to ensure that floor-ceiling effects did not cause the mean satisfaction score to be abnormally high. Acquiescence (24) and social desirability (29) did not appear to have an effect. The logical components produced would not otherwise be seen if response-set bias was an issue.

Principal components analysis

Kaiser's criterion (eigenvalue = 1.0) (26) was used to enter the 60 items into the analysis, and 13 components were extracted. A varimax rotation was performed to distribute the total variance explained by the 13 components more evenly.

An examination of the Scree plot (27) of the eigenvalues of the 13 components demonstrated a curve that had several plausible breaks where a meaningful solution could be retained. A 6-component solution suggested by the Scree plot adequately represented the data in a meaningful way. The 6-component solution was accepted because it didn't eliminate too many items in this preliminary analysis and because it ensured that several different dimensions of DDMPs were still captured.

The 6 components explain 59% of the variation in satisfaction, and each include ≥3 items (Table 3). The components that were eliminated included availability of information, travel time, meeting topics, frequency of abnormal glucose levels, counseling, staff's helpfulness and knowledge, understanding of blood sugar monitors, recipes, fear, confidence, and check-ups.

Table 3 contains items defining each component along with their varimax component loadings for the component on which the item loads most highly. The final set of items included several aspects of the essential areas of DDMP (nutrition, physical activity, and glucose monitoring) as defined by the provider focus groups. Four questions address physical activity by asking about the patient's understanding with the types and amount of physical activity necessary to control diabetes, general satisfaction with the types of physical activity taught, and satisfaction with the support received to

plan types of physical activity. Nutrition was encompassed by 5 questions asking satisfaction with: the amount of time spent and flexibility of watching what you eat to control diabetes, understanding what to eat to control diabetes, the help received to make a food plan, and how to follow food labels to control diabetes. Glucose monitoring was assessed by 4 questions that asked satisfaction with understanding of when to check blood sugar levels and understanding of how blood pressure, stress, and depression affects blood sugar levels.

Reliability

Internal consistency reliabilities were computed for the 6 components. Table 3 displays the α values (scale reliability coefficients) ranging from 0.79 to 0.95. As expected for scores computed from scale items grouped by principal components criteria, the observed reliabilities are acceptable (23) at this stage in research and even highly significant for the 6 components.

Validity

The product-moment correlations between the component satisfaction scores and the 6 global items dealing with overall patient satisfaction suggest strong relationships, confirming construct validity. Overall program satisfaction was most highly correlated (0.71) with meetings (component I), as expected from the literature (30,31). The patients' satisfaction with their understanding of nutrition (component III) had a moderately positive correlation ($r = 0.41$–0.54), reflecting an increased satisfaction with all aspects of the program as satisfaction with their understanding of nutrition increased. The correlation score between component V (time commitment) and overall program demonstrated a weak positive correlation (0.28), which indicated that as satisfaction with time commitment decreased, satisfaction with the overall program decreased as well.

CONCLUSIONS — This brief questionnaire, the Diabetes Measurement and Evaluation Tool (DMET), was developed to assess patient satisfaction with the structure, process, and outcomes of comprehensive DDMPs.

The most important and distinctive feature of the DMET is that it assesses the patients' satisfaction with a DDMP. Whereas other patient satisfaction surveys measure selected aspects of diabetes care, no other survey includes an array of items that cov-

ers all of the components encompassed by a DDMP. In addition to their satisfaction with their understanding of diabetes-related complications, the DMET assesses patients' satisfaction with the structure and process of meetings, personal time commitment, the level of physical activity, and their personal nutrition requirements needed to maintain their health.

A second strength is that it addresses patient satisfaction with outcomes in addition to the traditional evaluation of the structure and process of health care delivery (1). There is increasing recognition of the need to use patient satisfaction in outcome surveys. This need has been shown in a study undertaken by the Picker Institute and the American Hospital Association, which found that the patient satisfaction reported on questionnaires was consistently higher than the level of satisfaction reported by patients in focus groups and patient interviews (20). Therefore, the DMET was designed to assess time, costs, and traits, as suggested by Ross et al. (32); the structure, process, and outcomes according to Donabedian (16,33); and comprehensive care across the continuum, as defined by Press (34).

This initial study of the instrument has several limitations. The response rate of 33% is comparable with other mailed patient satisfaction questionnaires (35), and it is adequate for this study. Although the sample size of 202 patients would be inadequate for a definitive principal components analysis (23), it is noteworthy that in this exploratory stage, the component structure condensed the 14 domains into 6 representative valid components. Nevertheless, the respondents' experiences and motivations for participation possibly differ from those of the nonresponder. Additionally, this sample was limited to one health system and may therefore represent a limited sample of the population of patients with diabetes. Further testing of the DMET in a variety of diabetes populations, especially type 1 diabetic populations, will confirm the validity and reliability of the questionnaire.

It is worth noting that two-thirds of the respondents were registered for a DDMP by their physician, whereas <5% were referred by their health insurer. As Jonsson (36) noted: "The costs for control of diabetes constitute less than 25% of the total costs of diabetes. Improvements in the control of diabetes have the potential to reduce direct costs for treatment of complications as well as indirect costs. Improvements in the treatment of complications can reduce

the indirect costs." This conclusion was reiterated in more recent articles (37). The advancements made by organizations such as the Pennsylvania Health Care Containment Council (38), which includes diabetes control benchmarks in quality improvement activities, could be enhanced if insurers would encourage the use of DDMPs for all of their patients to control diabetes-related costs.

In conclusion, the DMET was found to be reliable and valid for the assessment of patient satisfaction with DDMPs. As with all questionnaires, continuous testing and refinement is necessary.

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