

Development and Factor Analysis of a Questionnaire to Measure Patient Satisfaction With Injected and Inhaled Insulin for Type 1 Diabetes

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OBJECTIVE — To develop a self-administered questionnaire to address alternative delivery routes of insulin and to investigate aspects of patient satisfaction that may be useful for subsequent assessment and comparison of an inhaled insulin regimen and a subcutaneous insulin regimen.

RESEARCH DESIGN AND METHODS — Attributes of patient treatment satisfaction with both inhaled and injected insulin therapy were derived from five qualitative research studies to arrive at a 15-item questionnaire. Each item was analyzed on a five-point Likert scale so that higher item scores indicated a more favorable attitude. There were 69 subjects with type 1 diabetes previously taking injected insulin therapy who were enrolled in a phase II clinical trial. Their baseline responses on the questionnaire were evaluated and subjected to an exploratory factor analysis. Meaningful factors were retained and interpreted based on their psychometric properties.

RESULTS — Exploratory factor analysis suggested a two-factor solution accounting for 66 and 20% of the variance, respectively. The first factor contained 10 reliable items (Cronbach's $\alpha = 0.89$) relating to convenience and ease of use, and the second contained 5 reliable items (Cronbach's $\alpha = 0.82$) relating to social comfort.

CONCLUSIONS — Among patients with type 1 diabetes, this analysis highlighted and quantified two key factors contributing to patient satisfaction: convenience/ease of use and social comfort. The questionnaire underwent rigorous development, had reliable properties, and an interpretable and rich factor structure. This report is intended to help advance, in subsequent investigations, the understanding and measurement of treatment satisfaction with novel and existing forms of insulin delivery.

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The Diabetes Control and Complications Trial (1) and the Stockholm Diabetes Intervention Study (2) have demonstrated the benefits and impact of good glycemic control in type 1 diabetes. However, despite the results of these studies, intensive insulin therapy has been slow to gain acceptance in clinical practice settings.

One limitation may be the inconvenience and poor patient acceptability of a program of multiple daily insulin injections.

The search for a practical alternative to injections for therapeutic administration of insulin is nearly as old as the discovery of insulin itself. Recently, a novel dry powder insulin formulation and aerosol delivery

system that permits noninvasive delivery of rapid-acting insulin was developed (Inhale Therapeutics Systems, San Carlos, CA) that offers an effective and well-tolerated alternative to preprandial insulin injections in type 1 diabetes (3). Inhaled insulin, intended for use in a preprandial therapeutic regimen, is the first practical alternative to injections for therapeutic administration of insulin. However, measures of treatment satisfaction in diabetes have not directly examined delivery routes for insulin other than by injection (e.g., syringe, pen, or pump) and were developed at a time when only injectable forms of insulin were readily available in clinical practice (4–7). Therefore, patient satisfaction with inhalation delivery of insulin needs to be investigated.

This article reports the development of a self-administered questionnaire whose items are tailored to novel as well as existing forms of insulin delivery. As a first step to explore and identify attributes of patient satisfaction in this context, we undertook a factor analysis on baseline responses of the questionnaire. Such an analysis can serve as a conduit for subsequent research in the assessment and comparison of patient satisfaction with, for example, inhaled insulin therapy and subcutaneous insulin therapy.

RESEARCH DESIGN AND METHODS

Patient satisfaction questionnaire

Attributes of patient satisfaction with treatment for both injectable and inhaled insulin therapy were derived from five qualitative research studies that consisted of one-on-one interviews conducted in the U.S. Two studies ($n = 100$ and $n = 41$) included people with type 1 and type 2 (insulin-using) diabetes; one study ($n = 44$) included people with type 1 and type 2 (insulin-using and non-insulin using) diabetes; one study included 10 subjects (1 subject with type 1 diabetes and 9 subjects without diabetes) who used the inhaler system four times a day (placebo, no med-

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Abbreviations: PSIT, Patient Satisfaction with Insulin Therapy.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Table 1—Baseline clinical characteristics of the study population

n	69
Sex (M/F)	37/32
Age (years)	37.4 ± 9.0 (18.0–56.0)
Duration of diabetes (years)	14.6 ± 9.3 (1.2–35.0)
Race/ethnic group	
White	55 (80)
Black	2 (3)
Hispanic, other	12 (17)
Weight (kg)	
Men	81.3 ± 10.8 (56.3–103.6)
Women	64.1 ± 7.5 (50.2–76.7)
BMI (kg/m ²)	
Men	25.5 ± 2.7 (21.0–31.0)
Women	24.4 ± 2.8 (19.0–31.0)
HbA _{1c} (%)	8.5 ± 1.1 (6.4–11.2)

Data are n, means ± SD (range), or n (%). A total of 73 men and women with type 1 diabetes were enrolled. One subject was discontinued before randomization, and complete data were not available. Of the remaining 72 subjects, there were no discernible differences between the 3 subjects excluded and the 69 subjects included (3).

ication of any kind was given) for 14 days and maintained a daily diary; and one study (n = 10) included health care professionals (2 primary care physicians, 2 internists, 2 endocrinologists, 2 pharmacists, and 2 certified diabetes educators).

Based on these studies, items and content relating to patient satisfaction with insulin treatment were identified. The initial item pool was further reduced to contain only items that were clear and not redundant. Emphasis was placed on using simple and unambiguous wording of items and responses. The resulting questionnaire—the Patient Satisfaction with Insulin Therapy (PSIT) Questionnaire—consisted of 15 items, and responses to each item were based on a five-point Likert scale ranging from strongly agree to strongly disagree.

Responses to each item on the questionnaire were analyzed so that a higher item score indicated a more favorable attitude. Each of the 15 items received equal weight when summed to arrive at a global (total) score. The global satisfaction score can therefore be from as low as 15 (least satisfaction) to as high as 75 (most satisfaction).

Study population

The questionnaire was self-administered at baseline and at week 12 by subjects with

type 1 diabetes recruited into a 12-week parallel study of an inhaled insulin regimen versus a conventional subcutaneously injected insulin regimen conducted at 10 centers in the U.S. Subjects completed the baseline questionnaire in ~5–10 min. The design and clinical results of this study have been reported elsewhere (3).

Subjects were aged 18–56 years and on a stable insulin administration schedule (for at least 2 months) involving two to three prescribed insulin injections daily. Both screening and prerandomization HbA_{1c} values were between 7.0 and 11.9%, with fasting plasma C-peptide ≤0.2 pmol/ml. All had body weight of 80–130% of ideal (Metropolitan Life Insurance Tables). Subjects were non-smokers (for at least 6 months) and had a normal chest X-ray, normal pulmonary function test results, and an electrocardiogram with normal sinus rhythm at a rate of 50–100 beats/min. All subjects performed home blood glucose monitoring four times daily. Baseline responses from a total of 69 subjects were considered in the factor analysis.

Factor analysis

To further understand and identify attributes of patient satisfaction, we conducted an exploratory factor analysis of the baseline questionnaire responses. Factor analysis is a statistical technique that reduces a large number of interrelated questions to a smaller number of underlying common factors or domains that are primarily responsible for covariation in the data (8).

We followed a standard approach to conducting an exploratory factor analysis (8,9). Three major sequential steps were undertaken. Step 1 involved identifying the number of meaningful factors to retain based on the scree test (10) and the percentage of (common) variance accounted for by a given factor. Using the scree test, we plotted the eigenvalue (i.e., the amount of variance that is accounted for by a given factor) associated with each factor and looked for a break between the factors with relatively large eigenvalues and those with smaller eigenvalues. Factors that appeared before the break were assumed to be meaningful and were retained for rotation (9–11). Factors appearing on the horizontal line after the break were taken to account only for a trivial amount of variance and were therefore not retained. In addition, we prespecified and required that at least 10% of the variance be explained by a retained factor and that at least 75% of the cumulative variance be explained by the set of retained factors.

Step 2 involved a promax (oblique) rotation on the retained factors to help with interpretation. An oblique rotation was applied because it was hypothesized (and later confirmed) that the factors would be correlated with one another. Step 3 involved interpreting the rotated solution by identifying which items load on each retained factor, the conceptual meaning of items that load on the same factor, and conceptual differences in items that load on different factors. Pattern loadings near 0.40 or greater (in absolute value) were used to interpret the results (9,11).

Internal consistency and stability

Cronbach's α reliability coefficient (12) was computed for each factor (domain) and total scale to measure internal consistency. An item-total correlation between an individual item and the sum of the remaining items on a factor or total scale was calculated to further assess reliability.

A second baseline measurement was not available for baseline test-retest reliability (stability). However, Pearson correlations between baseline ("test") and posttreatment ("retest") scores at 12 weeks were measured among patients who continued with, and were randomized to, traditionally administered subcutaneous insulin. Statistical significance was based on $P < 0.05$.

Relationship of satisfaction scores with demographic and medical variables

We examined the relationship of satisfaction scores with the demographic and medical variables found in Table 1. Pearson correlation (r) was used to measure the association of satisfaction scores with these variables except race, for which an analysis of variance model was applied. Statistical significance was based on $P < 0.05$.

RESULTS

Satisfaction items

Table 1 gives the baseline characteristics of the 69 subjects. Table 2 provides descriptive statistics at baseline for the 15 individual items and the global satisfaction score.

Exploratory factor analysis

Step 1: Determination of the number of retained factors. The scree plot in Fig. 1 depicts an abrupt break or discontinuity before factor 3, suggesting that only the first two factors were meaningful to be retained.

Table 2—Baseline descriptive statistics for individual satisfaction items*

Items	Mean \pm SD
1. I find it easy to take insulin the way I take it now.	3.58 \pm 1.28
2. I have no discomfort taking insulin the way I take it now.	3.07 \pm 1.38
3. I find it convenient to take insulin the way I take it now.	3.09 \pm 1.36
4. I am self-conscious about taking insulin away from home.	3.20 \pm 1.37
5. I find it easy to take all the doses of insulin my doctor recommends.	3.90 \pm 1.18
6. I find the time it takes for each dosing acceptable.	3.87 \pm 1.21
7. I find that my eating schedule can be flexible with few problems.	3.28 \pm 1.38
8. I prefer to stay home rather than take insulin away from home.	3.71 \pm 1.45
9. I do not mind measuring my blood glucose before each meal.	3.74 \pm 1.23
10. I feel good on my current insulin treatment schedule.	3.72 \pm 1.04
11. I find it difficult to take every dose of insulin my doctor recommends.	3.90 \pm 1.19
12. I find it difficult to take insulin away from home.	3.71 \pm 1.41
13. I would find it difficult to take insulin four times a day.	2.86 \pm 1.41
14. I find it easy to travel for a few days and take all my doses of insulin.	3.74 \pm 1.18
15. Overall, I am satisfied with my current way of taking insulin.	3.40 \pm 1.21
Global (total) score	52.77 \pm 12.05

Data are means \pm SD. $n = 69$. A higher item score (range 1–5) indicated a more favorable attitude. Items 1, 2, 3, 5, 6, 7, 9, 10, 14, and 15 were analyzed so that 1 = strongly disagree, 2 = slightly disagree, 3 = neither agree nor disagree, 4 = slightly agree, and 5 = strongly agree; and items 4, 8, 11, 12, and 13 were analyzed so that 1 = strongly agree, 2 = slightly agree, 3 = neither agree nor disagree, 4 = slightly disagree, and 5 = strongly disagree. *Copyright © 1996 Pfizer Inc. All rights reserved (Patient Satisfaction with Insulin Therapy Questionnaire).

A two-factor solution was supported by the percentage of variance accounted for by each factor. The first factor accounted for 66% of the variance, and the second factor accounted for an additional 20%. The third factor accounted only for an additional 7% of the variance, and subsequent factors independently accounted for progressively lower percentages of variance. Therefore, a two-factor solution was chosen based on the scree test and our requirements that at least 10% of the variance be explained by a retained factor and at least 75% of the cumulative variance be explained by the set of retained factors.

Step 2: Rotation of the chosen factors. In common factor analysis, the observed items are viewed as linear combinations of the factors, and the elements of the rotated factor pattern are regression coefficients (or regression weights) associated with each factor in the prediction of item score. When all of the items and factors are standardized to have a mean of 0 and SD of 1, the resulting standardized regression weights are analogous to the standardized regression coefficients in regression analysis.

The rotated factor pattern of pattern loadings from the promax rotation of two factors is given in Table 3. The pattern loadings in this matrix are essentially standardized regression coefficients comparable to those obtained in multiple regression.

Their absolute values reflect the unique contribution that each factor makes to the variance of the observed item. We used this matrix to determine which groups of items are measuring a given factor and for interpreting the meaning of each factor.

Step 3: Interpretation of the factors.

Table 3 indicates that factor 1 made a large and unique contribution to the variance of the following 10 items: easy to take, comfort, convenient, all doses, time, flexible, before meals, good, travel, and satisfied—items 1,

2, 3, 5, 6, 7, 9, 10, 14, and 15 in Table 3. Because these items relate to convenience and ease of use of insulin therapy, factor 1 was labeled “convenience/ease of use.” Factor 2 made a unique and noticeable contribution to the variance of the following five items: self-conscious, stay at home, difficult, away from home, and four injections—items 4, 8, 11, 12, and 13 in Table 3. Because these items relate to social stigma and use of insulin delivery away from home, factor 2 was labeled “social comfort.”

The interfactor correlation of 0.43 revealed a moderate positive correlation between the two factors. Higher levels of convenience and ease of use were associated with higher levels of social comfort.

Internal consistency and stability

Cronbach's α was satisfactory: 0.89 for factor 1 (convenience/ease of use), 0.82 for factor 2 (social comfort), and 0.89 on the global scale. With the exception of item 9, item-total correlations ranged from 0.50 to 0.80 for factor 1, from 0.47 to 0.76 for factor 2, and from 0.40 to 0.76 on the global scale. Even item 9, with modest (although not poor) correlations of 0.27 on the global scale and 0.32 on the first factor, justified retention. Item-total correlations were therefore generally reasonably strong in demonstrating reliability and supporting that items on the same factor (and the global scale) were measuring the same construct.

We correlated baseline (“test”) and posttreatment (“retest”) scores at 12 weeks among patients who continued with, and were randomized to, traditionally administered subcutaneous insulin, even though

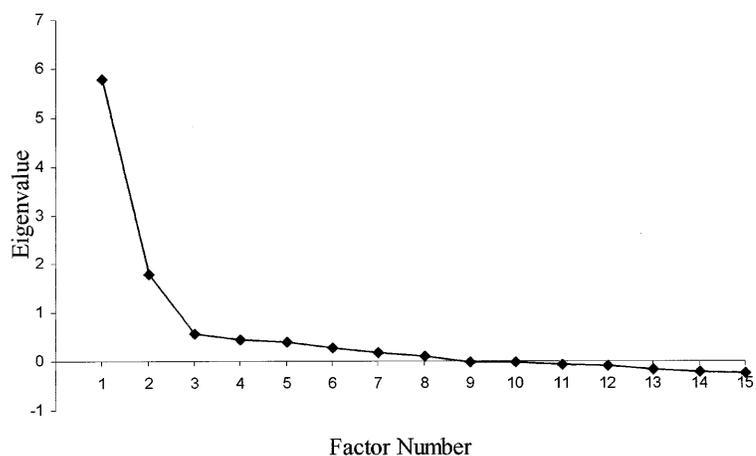


Figure 1—Scree plot showing the amount of variance accounted for by each factor. Because the cumulative percentage of variance exceeds 100% at some points in the analysis, it was necessary mathematically that some trivial factors have negative eigenvalues.

Table 3—Rotated factor pattern: standardized regression coefficients

Items*	Factor 1	Factor 2
1. I find it easy to take insulin the way I take it now.	82	9
2. I have no discomfort taking insulin the way I take it now.	83	-15
3. I find it convenient to take insulin the way I take it now.	87	-20
4. I am self-conscious about taking insulin away from home.	3	61
5. I find it easy to take all the doses of insulin my doctor recommends.	47	34
6. I find the time it takes for each dosing acceptable.	57	25
7. I find that my eating schedule can be flexible with few problems.	55	16
8. I prefer to stay home rather than take insulin away from home.	-19	84
9. I do not mind measuring my blood glucose before each meal.	37	-7
10. I feel good on my current insulin treatment schedule.	58	-4
11. I find it difficult to take every dose of insulin my doctor recommends.	-1	70
12. I find it difficult to take insulin away from home.	9	82
13. I would find it difficult to take insulin four times a day.	5	50
14. I find it easy to travel for a few days and take all my doses of insulin.	60	21
15. Overall, I am satisfied with my current way of taking insulin.	80	10

Standardized regression coefficients have been multiplied by 100 and rounded. Factor 1 consists of items 1, 2, 3, 5, 6, 7, 9, 10, 14, and 15; Factor 2 consists of items 4, 8, 11, 12, and 13. *Copyright © 1996 Pfizer Inc. All rights reserved (Patient Satisfaction with Insulin Therapy Questionnaire).

these patients manifested some significant improvements in patient satisfaction at 12 weeks (13), perhaps from being in a controlled clinical trial and reaping the subsequent benefits of monitoring and care.

Nonetheless, the scales were as reliable or stable over 12 weeks as scales on fear of self-injecting and fear of self-testing that showed no statistical mean difference between test and retest (14). "Test" and "retest" scores were moderately and significantly associated with a correlation of 0.64 for global satisfaction and convenience/ease of use ($n = 33$, $P < 0.01$) and 0.50 for social comfort ($n = 34$, $P < 0.01$).

Relationship of satisfaction scores with demographic and medical variables

Higher global satisfaction scores were associated with decreasing age ($r = -0.26$, $P < 0.05$) and lower HbA_{1c} ($r = -0.24$, $P < 0.05$). Higher convenience/ease of use scores were associated with lower HbA_{1c} ($r = -0.25$, $P < 0.05$). Higher social comfort scores bore a relationship with decreasing age ($r = -0.32$, $P < 0.01$) and shorter duration of diabetes ($r = -0.25$, $P < 0.05$). No significant relationship between satisfaction scores and the other variables was observed.

CONCLUSIONS — In this exploratory factor analysis, each of four criteria to judge interpretability and overall results was met. First, at least three items loaded on each retained factor. Second, the items

that loaded on a given factor shared some conceptual meaning. Third, the items that loaded on different factors measured different underlying constructs. Finally, the rotated factor pattern demonstrated simple structure in that 1) most of the items had high (pattern) loadings (≥ 0.40) on one factor and low loadings on the other factor, and 2) each factor had high loadings for some items and low loadings for the others (Table 3).

Further support for a two-factor solution and its interpretation came from the simple structure of the semipartial correlations and from the simple bivariate correlations between an item and a factor (data not shown). The three-factor solution, on the other hand, gave a vague interpretation of how certain items related to particular factors. In addition, its semipartial correlations were more ambiguous and less compelling in demonstrating simple structure compared with the semipartial correlations from the two-factor solution.

Construct validity is an ongoing process. We began this process by having our expectations met that lower HbA_{1c} relates to at least some improved aspects of patient satisfaction, whereas race, sex, BMI, and weight may not. The relationship of improved patient satisfaction with a decrease in age and in duration of diabetes, though not inconsistent with expectations, merits further research.

A potential ceiling effect at baseline is important to consider in the validation of a

questionnaire (15,16). The maximum global satisfaction score of 75 was reached by 1 of 69 subjects (1.4%). The maximum satisfaction scores of 50 for convenience/ease of use and 25 for social comfort were reached by 2 (2.9%) and 4 (5.8%) subjects, respectively. These small percentages suggest that a ceiling effect is not likely to compromise the validity of the questionnaire. The average score \pm SD was 52.8 ± 12.0 on the global scale, 35.4 ± 8.9 on the convenience/ease of use domain, and 17.4 ± 5.2 on the social comfort domain.

This phase II trial is the first to explore the topic of satisfaction with alternative delivery routes of injected insulin and can serve as a stepping stone to foster more advanced work on patient satisfaction. We encourage more research to build on this questionnaire and its psychometric properties by further validating instruments in subsequent stages to further increase knowledge of patient satisfaction with novel and existing forms of insulin delivery. We are currently engaged in examining sensitivity to change and, with more rigor, construct validity of the questionnaire items with other measures in clinical trials.

In summary, the 15-item PSIT questionnaire provides a short and reliable way to help assess patient satisfaction with insulin among patients with type 1 diabetes. It has been through rigorous empirical development, offers reliable psychometric properties, and has an interpretable and rich factor structure. This preliminary investigation, based on completion of the questionnaire at entry to a phase II trial of inhaled insulin versus subcutaneous insulin therapy, is intended to actuate and advance the understanding of patient and treatment satisfaction with insulin delivery, including inhaled insulin. The study revealed that two broad aspects of patient satisfaction with insulin are 1) convenience and ease of use and 2) social comfort. Scores on these two domains, as well as on the global score, may provide a basis for future comparative assessments of treatment satisfaction with inhaled and injected insulin.

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