Development and Validation of a New Measure to Evaluate Psychological Resistance to Insulin Treatment

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OBJECTIVE — To develop a psychometric questionnaire to measure psychological barriers to insulin treatment in patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS — Scale development was based on principal component analyses in two cross-sectional studies of insulin-naïve patients with type 2 diabetes. The structure of the questionnaire was developed in the first sample of 448 patients and subsequently cross-validated in an independent sample of 449 patients.

RESULTS — Analyses in the first sample yielded five components that accounted for 74.5% of the variance based on 14 items and led to the following subscales: fear of injection and self-testing, expectations regarding positive insulin-related outcomes, expected hardship from insulin treatment, stigmatization by insulin injections, and fear of hypoglycemia. In addition, an overall sum score of all values was calculated. The structure of the questionnaire was cross-validated in the second sample, with almost identical component loadings and an explained variance of 69.4%. An additional confirmatory factor analysis also indicated an acceptable to good model fit with root mean square error of approximation equal to 0.04 and comparative fit index equal to 0.97. Coefficients of reliability (Cronbach's α 0.62–0.85 and 0.78 for overall sum score) were acceptable, considering the very small number of items for each scale.

CONCLUSIONS — The Barriers to Insulin Treatment Questionnaire appears to be a reliable and valid measure of psychological insulin resistance in patients with type 2 diabetes. This short instrument is easy to administer and may be used by both clinicians and researchers to assess the psychological barriers to insulin treatment.

Diabetes Care 30:2199–2204, 2007

Despite the increasing body of knowledge regarding diabetes treatment (1), a majority of patients with type 2 diabetes are still in persistently poor glycemic control (2), a state that leads to higher risks of poor health outcomes (3). A variety of factors are responsible for poor glycemic control, including the inadequacy of therapeutic regimens (1) as well as various psychosocial aspects (4,5). In recent years, researchers also have focused on the reluctance of patients to take insulin and the resistance of health care providers to prescribe insulin (6). These negative attitudes toward insulin treatment contribute to unnecessarily long delays for initiating insulin treatment and, consequently, to extended periods of hyperglycemia (7,8). This so-called "psychological insulin resistance" (9) includes, among other factors, fear of injection and self-testing, hypoglycemia, and weight gain; a perceived loss of control over one's life; poor self-efficacy concerning insulin treatment; and perceived lack of positive outcomes related to insulin (9,10).

To overcome these psychological barriers to insulin treatment, first it is necessary to identify these barriers in specific patients in order to decide which interventions are appropriate. Thus, a well-validated diagnostic tool may be helpful to identify specific obstacles against the initiation of insulin treatment. There are some questionnaires that measure different aspects of satisfaction with treatment or diabetes-related burdens or stress (11–17), but presently, to our knowledge, no specific measurement of the psychological barriers to insulin treatment has been created, validated, and published.

This article describes the development and evaluation of the self-administered Barriers to Insulin Treatment (BIT) Questionnaire. The process is based on principal component analyses in two independent samples (n = 448 and 449, respectively). The aim of the BIT Questionnaire is to measure various aspects of psychological obstacles to insulin treatment in patients who have type 2 diabetes.

RESEARCH DESIGN AND METHODS

— The development of the BIT Questionnaire was based on data from two independent German studies of insulin-naïve patients with type 2 diabetes. The results of the first study (sample A) formed the basis of the questionnaire development, and the dataset of the second study (sample B) was used for cross-validation of scale structure and consistency. Both studies were approved by the responsible ethical review boards, and written informed consent was obtained from all patients in the studies.

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Received for publication 3 October 2006 and accepted in revised form 6 June 2007.

Published ahead of print at http://care.diabetesjournals.org on 15 June 2007. DOI: 10.2337/dc06-2042.

F.P. has received consulting fees from Pfizer Germany. T.F. and A.P. have received honoraria and grant/research support from Pfizer Germany.

Additional information for this article can be found in an online appendix at http://dx.doi.org/10.2337/dc06-2042.

Abbreviations: BIT, Barriers to Insulin Treatment; CFA, confirmatory factor analysis; CFI, comparative fit index; OAD, oral antidiabetes treatment; RMSEA, root mean square error of approximation.

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

Sample A

A total of 4,000 physicians were randomly selected from a countrywide database (pan-address, Planegg, Germany), which contained details of 31,155 general practitioners and 18,860 internists, to generate a representative cross-section of doctors in Germany. Physicians were approached between 2001 and 2003 by letter and were asked to recruit the next eligible patient during a routine appointment. Eligibility was based on the following inclusion criteria: clinical manifestation of type 2 diabetes, psychological and physical competence to participate in the study, and the patient's informed consent. Physicians provided data on the age, sex, height, and weight of the patient as well as the confirmation of type 2 diabetes diagnosis, duration of diabetes, and A1C levels. For the purpose of development of the BIT Questionnaire, only data from insulin-naïve outpatients (n = 448) were included.

Sample B

This study was performed in 20 practices of general practitioners and internists all over Germany in 2005. A total of 449 type 2 diabetic outpatients were included who had an A1C suggesting more intensive therapeutic interventions were necessary including insulin treatment as defined by current treatment guidelines (18). Inclusion criteria were type 2 diabetes treated only with diet or oral antidiabetes treatments (OADs), age between 18 and 70 years, and insufficient oral antidiabetes treatment defined as A1C >8.5% (treated with diet alone), A1C >8.0% (one OAD), or A1C ≥7.5% (two or more OADs). The different cutoffs were chosen based on preexisting therapies and the current standards for the initiation of insulin treatment in Germany and other countries. Participants discussed treatment optimization options with a physician who recommended insulin treatment because of the failing OAD treatment. Subsequently, the patients were asked to make a theoretical choice about future diabetes treatment. The options were to continue with OADs or to move on to subcutaneous insulin. A set of medical data were measured that included the same variables as those in sample A (Table 1) (19).

Table 1—*Sample characteristics in samples A and B*

	Sample A	Sample B
n	448	449
Age (years)	62.4 ± 10.2	56.7 ± 8.7
Female sex	47.2% (209/443)	32.3% (145/449)
BMI (kg/m^2)	28.7 (26.5–32.0)	31.2 (27.7–31.2)
A1C (%)	7.1 (6.5–7.8)	8.1 (7.4–9.3)
Diabetes duration (years)	5.0 (3.0–10.0)	5.0 (2.0–10.0)

Data are means ± SD or median (interquartile range) unless otherwise indicated.

Psychological measures

Psychological barriers to insulin treatment assessed in sample A. A pool of items, 35 regarding different attitudes toward insulin treatment, was created by an expert panel of health care professionals who were experienced in diabetes treatment based on patient interviews and current literature (9,10). The following attitudes toward insulin treatment were identified: positive feelings about the benefits of the treatment, fear of the consequences of diabetes, fear of injections, social barriers to the use of insulin, aversion to dependence on the drug, fear of insulin-related side effects, and negative feelings about one's competence to manage the insulin treatment. Each of the 35 items was presented as a statement, which the patient was asked to score using a 10-point Likert-type scale with the extreme scores labeled "completely disagree" (1) and "completely agree" (10).

Psychological barriers to insulin treatment assessed in sample B. The psychological barriers to insulin treatment were assessed using the BIT Questionnaire developed in sample A (see RESULTS). The BIT Questionnaire includes 14 items, a total sum score, and the following five subscales: fear of injection and self-testing, expectations regarding positive insulin-related outcomes, expected hardship from insulin treatment, stigmatization by insulin injection, and fear of hypoglycemia.

To obtain a validated English version of the BIT Questionnaire, a linguistic validation (from German to English [U.S.]) was performed and certified by the MAPI Research Institute. This validation process included two forward translations; reconciliation; a backward translation, with review and discussion and retranslation as needed; clinician review and further changes as needed; cognitive debriefing with patients; and finalization and proofreading (20). An English and German version of the BIT Questionnaire can be found in an online appendix at http://dx.doi.org/10.2337/dc06-2042.

Statistical analysis

In a first step, a principal component analysis (with oblique rotation) that included all 35 items was conducted in an exploratory approach in sample A. The Kaiser-Guttman criterion (eigenvalue >1) was used to decide on the number of components to be retained (21,22). Subsequent principal component analyses were conducted to eliminate items or components until a result became available that had good test statistical values and was interpretable concerning its contents. The criteria for the item-respective component elimination were the following: items with ambiguous loadings on rotated component (in first-step items with a ≤0.40 factor loading and in subsequent-step items with a <0.60 factor loading were eliminated), items with multiple loadings on other components (>0.25), and items with an item selectivity ≤0.35. Components that contained fewer than two items with sufficient loadings were eliminated together with all their items. In some components, items that missed the criteria, but appeared necessary due to textual and test-related theoretical considerations, were retained after careful consideration.

Principal component analyses were conducted successively with the items remaining from the previous analysis until all objectives were met. The resulting components represent the subscales of the BIT Questionnaire, whose scale stability was verified in sample B. Finally, a second-order component analysis with oblique rotation was performed including the obtained components that represent the subscales of the BIT Questionnaire in order to analyze if the creation of a BIT Questionnaire sum score will be appropriate.

Using sample B data, a principal component analysis with the final BIT Questionnaire items of sample A was performed. This approach allowed for a demonstrative comparison of component loadings in both independent samples before the aggregated model was tested by a confirmatory factor analysis (CFA). Following current recommendations for a CFA, we report the comparative fit index

Table 2—*Component matrix of component loadings in principal component analyses after oblique rotation in samples A and B*

	Components									
	1		2		3		4		5	
Items (abbreviations)	A	*B*	A	*B*	A	*B*	A	*B*	A	*B*
1) I am afraid of the pain when injecting insulin.	0.93	0.89	0.01	0.01	0.02	0.03	−0.00	0.08	0.01	0.03
2) Besides the pain, I am just afraid of injections.	0.92	0.91	0.00	0.02	−0.04	−0.05	0.05	0.06	0.02	0.01
3) I am afraid of the pain during regular blood glucose checks.	0.82	0.80	0.01	−0.02	0.06	0.05	0.01	−0.06	0.06	−0.02
4) Insulin works better than pills.	0.15	0.07	0.85	0.80	0.05	−0.01	−0.02	−0.11	−0.08	−0.08
5) People who get insulin feel better.	−0.03	0.04	0.84	0.77	0.07	−0.05	−0.01	−0.12	−0.09	−0.05
6) Insulin can reliably prevent long-term complications.	−0.18	−0.10	0.65	0.74	−0.20	0.05	−0.03	0.17	0.15	0.09
7) I don't have enough time for regular doses of insulin.	0.06	0.01	−0.03	−0.06	0.85	0.81	−0.06	−0.02	−0.06	−0.10
8) I can't pay attention to my diet as insulin treatment requires.	0.03	0.01	0.05	0.01	0.83	0.89	0.04	−0.09	0.09	0.01
9) I can't organize my day as carefully as insulin treatment requires.	−0.06	0.01	−0.01	0.05	0.83	0.84	0.10	0.13	0.06	0.07
10) Injections in public are embarrassing to me.	0.02	0.04	0.05	0.01	−0.04	0.01	0.84	0.71	0.05	−0.06
11) Insulin treatment causes feelings of dependence.	−0.09	0.02	0.00	−0.01	0.11	−0.03	0.83	0.76	−0.03	−0.02
12) When people inject insulin, it makes them feel like they are drugged.	0.15	0.02	−0.09	−0.04	−0.05	0.05	0.73	0.73	0.00	−0.01
13) Hypoglycemia: concerns about damage to my health.	0.07	−0.01	0.02	0.04	−0.04	0.02	0.03	0.01	0.88	0.89
14) Hypoglycemia: afraid of accompanying symptoms.	0.01	−0.01	−0.09	−0.02	0.14	0.00	−0.00	0.07	0.82	0.89

(CFI) and the root mean square error of approximation (RMSEA) (23). Indicators of a well-fitting model would be evidenced by a CFI ≥0.93 and an RMSEA <0.05 (24,25).

To replicate the test of whether the creation of a BIT Questionnaire sum score will be appropriate, we performed a second-order CFA with the components representing the subscales of the BIT Questionnaire. Pearson's correlations of all subscales were calculated to evaluate interrelations among the subscales, and Cronbach's α was computed for the subscales and the total sum score to measure internal consistency reliability.

The predictive validity of the BIT Questionnaire scales was verified by comparision of subgroups of study B in the theoretical treatment choice scenario (described above). Using *t* tests, we compared the scores of patients who accepted to move on to subcutaneous insulin to those patients who have been offered insulin and decided to continue with the OAD treatment. Effect sizes for the differences between both groups were calculated using Cohen's *d* with pooled SD (26). Statistical analyses were performed with SPSS 12.0.1 (Chicago, IL), Amos 5.0 (Chicago, IL), and ClinTools (Brain Sciences Institute, Swinburne University, Swinburne, Australia).

RESULTS

Table 1 provides descriptive statistics for socioeconomic, medical, and psychological variables for samples A and B.

Scale development in study A. As a result of the first principal component analysis with 35 items, seven components with an eigenvalue >1 could be extracted. We eliminated items with ambiguous component loadings and identified a component structure that explained 74.5% of the variance; this component structure included 14 items and five components for which no ambiguous component loadings had been observed (Table 2). The results of the second-order principal component analysis showed only one component with an eigenvalue >1 and an explained variance of 49.3%, indicating that it is appropriate to create a sum score of the total barriers to insulin treatment.

Replication of component structure in study B. The principal component analysis in the sample used for cross-validation resulted in a clear replication of the questionnaire's structure. With an explained variance of 69.4%, five components with almost identical component loadings were identified (see Table 2). Results of the CFA also confirmed the structure of the BIT Questionnaire with an acceptable to good model fit with RMSEA = 0.04 (90% CI 0.03–0.05) and CFI = 0.97. The second-order CFA confirmed a good model fit with RMSEA = 0.04 (0.02–0.04) and CFI = 0.97, showing again that it is appropriate to create a total score.

The BIT Questionnaire scales were based on the items with the highest component loading in sample B and labeled according to the wording of the items as follows: fear of injection and self-testing, expectations regarding positive insulin-related outcomes, expected hardship from insulin treatment, stigmatization by insulin injections, and fear of hypoglycemia. Mean values were computed for each

Table 3—*Wording and statistical measures of the BIT Questionnaire items and scales in sample B*

Item number and wording	Means ± SD	Item selectivity	Cronbach's α without item
Scale 1: "Fear of injections and self-testing" (α = 0.85)	3.19 ± 2.78		
1. I am afraid of the pain when injecting insulin.	3.62 ± 3.33	0.80	0.70
2. Besides the pain, I am just afraid of injections.	3.58 ± 3.50	0.79	0.72
3. I am afraid of the pain during regular blood-sugar checks.	2.37 ± 2.64	0.60	0.89
Scale 2: "Expectations regarding positive insulin-related outcomes" (α = 0.66)	7.36 ± 1.87		
4. Insulin works better than pills.	8.19 ± 2.41	0.39	0.68
5. People who get insulin feel better.	7.42 ± 2.46	0.53	0.49
6. Insulin can reliably prevent long-term complications due to diabetes.	6.46 ± 2.38	0.51	0.52
Scale 3: "Expected hardship from insulin therapy" (α = 0.81)	4.20 ± 2.74		
7. I just don't have enough time for regular doses of insulin.	3.30 ± 3.04	0.62	0.78
8. I can't pay as close attention to my diet as insulin treatment requires.	4.73 ± 3.25	0.67	0.73
9. I can't organize my day as carefully as insulin treatment requires.	4.58 ± 3.38	0.70	0.70
Scale 4: "Stigmatization by insulin injections" (α = 0.62)	4.30 ± 2.52		
10. Injections in public are embarrassing to me. Pills are more discreet.	5.45 ± 3.78	0.42	0.55
11. Regular insulin treatment causes feelings of dependence.	5.06 ± 3.46	0.42	0.53
12. When people inject insulin, it makes them feel like drug addicts.	2.38 ± 2.70	0.48	0.49
Scale 5: "Fear of hypoglycemia" (α = 0.78)	6.21 ± 2.73		
13. An insulin overdose can lead to extremely low blood glucose levels (hypoglycemia). I am afraid of the unpleasant accompanying symptoms.	6.61 ± 2.92	0.64	*
14. An insulin overdose can lead to extremely low blood glucose levels (hypoglycemia). I have concerns about possible permanent damage to my health.	5.81 ± 3.11	0.64	*
BIT Questionnaire sum score (α = 0.78)	4.17 ± 1.55		

n = 448–449. Item selectivity = part-whole corrected item selectivity. Cronbach's α without item = Cronbach's α if item deleted. *Not applicable because scale contains only two items.

scale with a value range 1–10 for each scale (Table 3).

In addition, a sum score was created that summed up the values of the items of the BIT Questionnaire (items of the scale "Expectations regarding positive insulin-related outcomes" were inverted first). No ceiling effect could be observed, which was demonstrated by the percentages of patients with maximum values between 0% for the sum score and 3.8–18% for the different BIT Questionnaire scales.

Reliability measure. Acceptable coefficients of reliability were observed for scales 1, 3, and 5, with Cronbach's α ranging from 0.78 to 0.85 and the total sum score with α = 0.78. Scales 2 and 4 showed only moderate values (α = 0.62 and 0.66, respectively). However, taking into consideration that each of these scales contains only three items, the results can be viewed as adequate.

Wording and statistical measures of the BIT Questionnaire items. The analysis of the changes in reliability coefficients for the respective scales that would result if the single item were eliminated showed that only item three would result in a significant increase in reliability if it were eliminated (Table 3). Since the scale already demonstrated good reliability, we decided to keep the item in order to consider also the fear of blood glucose measures together with the fear of injection. This was done because all items measure aspects of "blood and injection phobia," and we think that patients expect that insulin treatment requires more frequent testing of blood glucose. Item four was kept as well, since its elimination would yield only a marginal advantage (α = 0.68 instead of 0.66).

Intercorrelation of BIT Questionnaire scales. The concept of the BIT Questionnaire assumes intercorrelated subscales, since each is intended to measure a different aspect of the same construct (barriers to insulin treatment). The intercorrelation of subscales was very low to moderate, with Pearson's *r* between −0.05 and 0.36.

Validity analysis. The results of the *t* tests indicated a clear predictive validity of all BIT Questionnaire scales. Patients who opted for OADs consistently reported significantly higher barriers to insulin treatment than the patients who were willing to move onto subcutaneous insulin. The magnitude of these differences between both groups was medium for the subscales and strong for the BIT Questionnaire sum score according to Cohen's criteria (see Table 4) (27). No substantial increase in the predictive power of the BIT Questionnaire was obtained in a stepwise logistic regression analysis when including items that were excluded from the final BIT Questionnaire (data not shown).

CONCLUSIONS

— Our report describes the development and evaluation of a questionnaire that measures barriers to the acceptance of insulin treatment in orally treated patients with type 2 diabetes. The BIT Questionnaire was developed first in a sample of 448 patients; the development was based on principal component analyses. Our results yielded an easily interpretable five-component solution based on only 14 items. These components were used to define the following subscales: fear of injection and self-testing, expectations regarding positive insulin-related outcomes, expected

Table 4—*Predictive validity of the BIT Questionnaire scales in sample B*

BIT Questionnaire scales and treatment choice	Means ± SD	*t*	d.f.	*P*	Cohen's *d* (95% CI)
Scale 1: "Fear of injections and self-testing"					
Continue OADs	3.39 ± 2.85	3.29	447	<0.01	0.44 (0.20–0.69)
Change to subcutaneous insulin	2.26 ± 2.18				
Scale 2: "Expectations regarding positive insulin-related outcomes"					
Continue OADs	7.15 ± 1.84	−5.20	447	<0.001	−0.66 (−0.91 to −0.42)*
Change to subcutaneous insulin	8.33 ± 1.71				
Scale 3: "Expected hardship from insulin therapy"					
Continue OADs	4.36 ± 2.75	2.70	447	<0.01	0.35 (0.1–0.6)
Change to subcutaneous insulin	3.44 ± 2.58				
Scale 4: "Stigmatization by insulin injections"					
Continue OADs	4.48 ± 2.53	3.41	446	<0.01	0.45 (0.20–0.69)
Change to subcutaneous insulin	3.41 ± 2.26				
Scale 5: "Fear of hypoglycemia"					
Continue OADs	6.42 ± 2.65	3.66	447	<0.001	0.44 (0.20–0.69)
Change to subcutaneous insulin	5.20 ± 2.90				
BIT Questionnaire sum score					
Continue OADs	4.36 ± 1.53	5.87	447	<0.001	0.76 (0.51–1.01)
Change to subcutaneous insulin	3.27 ± 1.34				

Comparision of patients who accepted versus refused insulin treatment in a theoretical treatment choice scenario. Patients who wanted to continue with OADs: n = 371 vs. patients who were willing to change to subcutaneous insulin: n = 77–78. P value = two-tailed significance. *d is negative due to the inversion of the items of this scale.

hardship from insulin treatment, stigmatization by insulin injections, and fear of hypoglycemia. In addition, an overall sum score of all values was calculated in order to summarize the 14 items of the BIT Questionnaire in a single score. The subscales of the BIT Questionnaire address a wide range of the most important psychological barriers to insulin treatment, as those barriers are described in the current literature (9,10).

In a next step, a cross-validation of the structure of the BIT Questionnaire was performed based on data from an independent sample of 449 insulin-naïve patients with type 2 diabetes. This cross-validation used the 14-item BIT Questionnaire developed in the first sample. The results of both the exploratory principal component analyses and the confirmatory factor analysis confirmed the structure of the BIT Questionnaire. The scales demonstrated adequate reliability and validity. The frequency distribution of the scores revealed a fairly normal distribution, with no ceiling effect; this distribution is especially important when assessing changes in retest measures (12).

We successfully performed a linguistic validation of the German BIT Questionnaire into the English version presented here in order to makes it possible to pool and/or compare the results obtained in Germany across English-speaking countries. This certifies that the language versions obtained are conceptually equivalent, culturally relevant, and acceptable to the target populations.

A possible limitation of our approach is that some of the topics that were excluded from scale construction may be highly relevant for some patients. On the other hand, we chose to keep in the BIT Questionnaire only those items that demonstrated a clear and unambiguous component loading. Another limitation at this stage of development of the BIT Questionnaire is that the test-retest reliability and sensitivity to change of this new instrument still need to be determined.

In summary, the 14-item BIT Questionnaire has gone through rigorous empirical development and offers reliable psychometric properties as well as an interpretable and relevant component structure. Our findings suggest that clinicians and researchers now can use this instrument in a valid and reliable way to assess and address psychological barriers to insulin treatment in insulin-naïve patients with type 2 diabetes.

Acknowledgments— This study was supported by Pfizer.

Parts of this study were presented in abstract form at the 66th Scientific Sessions of the American Diabetes Association, 2006; at the 41th Annual Session of the German Diabetes Association, 2006; and at the 42nd European Association for the Study of Diabetes Annual Meeting, 2006.

References

1. DeWitt DE, Hirsch IB: Outpatient insulin therapy in type 1 and type 2 diabetes mellitus: scientific review. *JAMA* 289:2254–2264, 2003
2. Koro CE, Bowlin SJ, Bourgeois N, Fedder DO: Glycemic control from 1988 to 2000 among U.S. adults diagnosed with type 2 diabetes: a preliminary report. *Diabetes Care* 27:17–20, 2004
3. U.K. Prospective Diabetes Study (UKPDS) Group: Intensive blood-glucose control with sulfonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 352:837–853, 1998
4. Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE: Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) study. *Diabet Med* 22: 1379–1385, 2005
5. Petrak F, Herpertz S, Albus C, Hirsch A, Kulzer B, Kruse J: Psychosocial factors and diabetes mellitus: evidence-based treatment guidelines. *Curr Diab Rev* 1:255–270, 2005
6. Peyrot M, Rubin RR, Lauritzen T, Skovlund SE, Snoek FJ, Matthews DR, Landgraf R, Kleinebreil L, the International DAWN Advisory Panel: Resistance to insulin therapy among patients and provid-

ers: results of the cross-national Diabetes Attitudes, Wishes, and Needs (DAWN) study. *Diabetes Care* 28:2673–2679, 2005
7. Korytkowski M: When oral agents fail: practical barriers to starting insulin. *Int J Obes* 26 (Suppl. 3):S18–S24, 2002
8. U.K. Prospective Diabetes Study (UKPDS) Group: United Kingdom Prospective Diabetes Study (UKPDS) 13: relative efficacy of randomly allocated diet, sulphonylurea, insulin, or metformin in patients with newly diagnosed non-insulin dependent diabetes followed for three years. *BMJ* 310:83–88, 1995
9. Polonsky WH, Fisher L, Guzman S, Villa-Caballero L, Edelman SV: Psychological insulin resistance in patients with type 2 diabetes: the scope of the problem. *Diabetes Care* 28:2543–2545, 2005
10. Meece J: Dispelling myths and removing barriers about insulin in type 2 diabetes. *Diabetes Educ* 32 (Suppl. 1):9S–18S, 2006
11. Herschbach P, Duran G, Waadt S, Zettler A, Amm C, Marten-Mittag B: Psychometric properties of the Questionnaire on Stress in Patients with Diabetes–Revised (QSD-R). *Health Psychol* 16:171–174, 1997
12. Bradley C: Diabetes treatment satisfaction questionnaire: change version for use alongside status version provides appropriate solution where ceiling effects occur. *Diabetes Care* 22:530–532, 1999
13. Cappelleri J, Gerber R, Kourides I, Gelfand R: Development and factor analysis of a questionnaire to measure patient satisfaction with injected and inhaled insulin for type 1 diabetes. *Diabetes Care* 23: 1799–1803, 2000
14. Mollema ED, Snoek FJ, Pouwer F, Heine RJ, van der Ploeg HM: Diabetes Fear of Injecting and Self-Testing Questionnaire: a psychometric evaluation. *Diabetes Care* 23:765–769, 2000
15. Paddock LE, Veloski J, Chatterton ML, Gevirtz FO, Nash DB: Development and validation of a questionnaire to evaluate patient satisfaction with diabetes disease management. *Diabetes Care* 23:951–956, 2000
16. Welch GW, Jacobson AM, Polonsky WH: The Problem Areas in Diabetes Scale: an evaluation of its clinical utility. *Diabetes Care* 20:760–766, 1997
17. Polonsky WH, Fisher L, Earles J, Dudl RJ, Lees J, Mullan J, Jackson RA: Assessing psychosocial distress in diabetes: development of the Diabetes Distress Scale. *Diabetes Care* 28:626–631, 2005
18. American Diabetes Association: Standards of medical care in diabetes—2007 (Position Statement). *Diabetes Care* 30 (Suppl. 1):S4–S41, 2007
19. Pfützner A, Pfützner AH, Stridde E, Huppertz E, Reimer T, Derwahl M, Forst T, Petrak F: Insulin resistance and β-cell dysfunction in insufficiently controlled patients with type 2 diabetes. *Diabetes, Stoffwechsel und Herz* 2:91–96, 2007
20. Acquadro C, Conway K, Giroudet C, Mear I: *Linguistic Validation Manual for Patient-Reported Outcomes (PRO) Instruments*. Lyon, France, MAPI Research Trust, 2004
21. Floyd F, Widaman K: Factor analysis in the development and refinement of clinical assessment instruments. *Psychol Assess* 7:286–299, 1995
22. Gorsuch R: *Factor Analysis*. Hillsdale, NJ, Lawrence Erlbaum Associates, 1983
23. Hu L, Bentler P: Fit indices in covariance structure modeling: sensitivity to underparameterized model misspecification. *Psychol Methods* 3:424–453
24. Hu L, Bentler P: Cutoff criteria for fit indexes in covariance structure analysis: conventional criteria versus new alternatives. *Struct Equat Model* 6:1–55
25. Schermelleh-Engel K, Moosbrugger H, Müller H: Evaluating the fit of structural equation models: tests of significance and descriptive goodness-of-fit measures. *Meth Psychol Res On* 8:23–74, 2003
26. Rosnow RL, Rosenthal R: Computing contrasts, effect sizes, and counternulls on other people's published data: general procedures for research consumers. *Pyschol Meth* 1:331–340, 1996
27. Cohen J: *Statistical Power Aanalysis for the Behavioral Sciences*. 2nd ed. Hillsdale, NJ, Lawrence Earlbaum Associates, 1988