Relationship between patient practice-oriented knowledge and metabolic control in intensively treated Type 1 diabetic patients: Results of the validation of the Knowledge and Practices Diabetes Questionnaire

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ABSTRACT. Aims: **To validate a newly developed questionnaire for the measurement of patients' knowledge and practices, with particular attention to its ability in predicting HbA_{1c} levels.** *Research design and methods:* **The Knowledge and Practices Diabetes Questionnaire (KPDQ) is a questionnaire composed of two scales, investigating patient knowledge and practices. Twenty-two questions, 12 dealing with patients' knowledge and 10 relative to patients' practices, were initially identified. Factor analysis and reliability analysis were used to validate the questionnaire. The ability of the two scales in predicting metabolic control was then evaluated. The questionnaire was administered to a population of Type 1 diabetic subjects intensively treated and regularly attending the diabetes outpatient clinic of Pescara General Hospital. The mean of all HbA_{1c} measurements performed after patients were taken in charge by the clinic was used as an indicator of metabolic control.** *Results:* **Out of 133 Type 1 patients identified, 77 (58%) filled in the questionnaire. Respondents had a mean age (±SD) of 37±13 years and a mean diabetes duration of 13±9 years. The application of factor and reliability analyses led to the definition of two final scales composed of 10 (Knowledge Score, KS) and 5 items (Practice Score, PS), respectively. Item-scale correlation was ≥0.40 for all the items investigated. Cronbach's α coefficient exceeded the value of 0.70 for both scales. The mean number of HbA_{1c} determinations during a median period of observation of 4 years was of 11±5. The mean HbA_{1c} value for the whole population was of 7.0%±1.4, while the proportion of patients with values ≤7.0% was of 57%. After adjusting for clinical and patient-related characteristics, the KS was the only independent predictor of metabolic control. Patients in the lowest quartile of the KS showed a more than 20-fold increased risk of having mean HbA_{1c} values ≥7.0% as opposed to those in the highest quartile (odds ratio, OR=23.3; p=0.009). No association emerged between metabolic control and PS.** *Conclusions:* **The KPDQ presents excellent psychometric properties. The KS also shows a very impressive association with the mean HbA_{1c} values over a period of 4 years. These findings are particularly remarkable in that many studies have failed in documenting such a relationship. The KS can thus be considered as a quick and efficient screening tool to be used in an ambulatory setting to monitor the level of practice-oriented knowledge of patients with Type 1 diabetes as well as to identify those subjects who need individualized educational interventions.**

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INTRODUCTION

Results of the Diabetes Control and Complications Trial (DCCT) have clearly shown that, despite intensive metabolic control, less than 5% of the patients had values of HbA_{1c} constantly in the normal range, while 56% of them never reached normal values during a period of observation of 6.5 years (1). Patients' education and their active involvement in disease management are considered fundamen-

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Key words: Type 1 diabetes mellitus, metabolic control, patient knowledge, questionnaire development, questionnaire validation.

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tal tools to achieve the desired therapeutic goals (2).

Several studies have been undertaken to measure patients' knowledge and to evaluate its relationship with metabolic control (3). Nevertheless, results have often been inconsistent and many methodological flaws have been reported (4).

Aim of this study was to validate a newly developed questionnaire to measure in a standardized and reproducible way patients' knowledge and practices, with particular attention to its ability in predicting satisfactory HbA_{1c} levels.

The properties of the questionnaire were evaluated in a population of Type 1 diabetic subjects regularly attending the diabetes outpatient clinic of Pescara General Hospital and receiving homogeneous levels of care.

SUBJECTS AND METHODS

Study population

The diabetes outpatient clinic of Pescara General Hospital was established in 1993. It represents the reference structure for a population of over 250,000 inhabitants, of which about 3.5% are expected to be affected by diabetes.

Among all the patients attending the clinic, those affected by Type 1 diabetes were identified by selecting subjects with an age at diagnosis of less than 30 years and treated with insulin from the onset. All patients regularly attending the clinic (*ie* ≥3 visits/year) were considered eligible, irrespective of their age and diabetes duration.

The study was carried out between October 1997 and April 1998.

Instruments

A questionnaire was developed to investigate patients' knowledge and practices relative to different aspects of diabetes care (Knowledge and Practices Diabetes Questionnaire - KPDQ).

The items were identified in focus groups with insulin-treated patients and health professionals. Two main areas were defined, the first investigating patients' practices (blood glucose self-monitoring, modality and time of insulin injections, time and characteristics of meals), the second focusing on patients' knowledge (adjustment of insulin doses, glycemic content of meals, risk of major diabetic complications).

The questionnaire was designed to cover those aspects of knowledge specifically related to disease management. For this reason, we included only a few questions dealing with diabetic complications. Far from being exhaustive, these items were simply considered as a marker of one patient's broader knowledge of diabetes consequences.

Twenty-two questions, 12 dealing with patients' knowledge and 10 relative to patients' practices, were initially identified.

The questionnaire was reviewed by two independent experts to evaluate the extent to which the domains of interest were comprehensively sampled by the items chosen (content validity).

Questions included in the first version of the KPDQ are reported in Appendix 1. All answers were coded as 1 (correct answer) or 0 (wrong answer) and linearly combined to obtain two separate scores, the Knowledge Score (KS) and the Practices Score (PS).

The questionnaire was filled in by the patients during a routine follow-up visit.

Clinical data

All clinical information was obtained by the computerized registry of the clinic and included: age, sex, years of education, diabetes duration, number of insulin injections, U/kg/day of insulin, body mass index (BMI), presence of major diabetic complications. Metabolic control was evaluated as the mean of all HbA_{1c} determinations from the first time patients were taken in charge by the clinic until September 1997. The adoption of such an indicator has two main reasons: first of all, the consideration of all HbA_{1c} values represents a more robust indicator of metabolic control in our patients as opposed to a single measurement. As a second point, all patients received regular educational information (at least once a year) on an individual basis; we thus considered more appropriate to rely upon a summary measure reflecting metabolic control across the whole period patients were in the charge of the clinic.

Nevertheless, since the length of observation was not uniform, we also carried out an additional analysis based on the mean HbA_{1c} values in the last year (median number of HbA_{1c} measurements per patient: 4, range 1-6; 75% of the patients had ≥3 measurements).

Glycated hemoglobin was determined by high

performance liquid chromatography (Menarini 8141). The interassay coefficient of variation was 0.98% at levels of 6-9%. Normal values of our laboratory were 3.5-5.5%. The same method was used in all patients along the whole follow-up period.

Questionnaire validation

1. *Factor analysis:* Since two underlying dimensions were postulated, a forced two-factor Principal Axis Factoring (PAF) procedure with varimax orthogonal rotation was carried out on the 22 items (5). All items with factor loading <0.30 were excluded.
2. *Reliability:* The reliability of the KPDQ was evaluated by estimating the item-scale correlation coefficients corrected for overlapping and the Cronbach's α coefficient. Item-scale correlation coefficients ≥ 0.40 and values of Cronbach's α coefficient ≥ 0.70 are widely accepted as satisfactory (6).
3. *Discriminant validity:* The discriminant validity of the KPDQ scales, *ie* their ability to distinguish between groups of individuals on the basis of pre-specified assumptions, was measured with respect to metabolic control. In particular we predicted that patients with poor metabolic control would score significantly lower than those in good metabolic control on the KS and PS scales.

Statistical methods

Glycated hemoglobin was utilized as both continuous and dichotomous dependent variable. In the latter case, the cut-off value of 7.0% was chosen to investigate risk factors related to unsatisfactory metabolic control.

Analysis was initially carried out based on a series of univariate comparisons. In order to simultaneously control for the possible confounding effect of the different variables, multiple linear regression and multiple logistic regression analyses with stepwise variable selection were utilized (7). The association between exposures and outcome is thus expressed in terms of β parameters for linear regression and odds ratios (ORs) together with their 95% confidence intervals (95% CI) for logistic regression. ORs greater than 1 suggest an increased risk, while those less than 1 indicate a protective effect. When the 95% CI include the null value of 1.0, no statistically significant difference (at the 5% level) is present.

In both linear and logistic regressions the following covariates were evaluated: age (continuous variable), years of education (≤ 5 *vs* >5 years), diabetes duration (continuous variable), U/kg/day of insulin (continuous variable), BMI (continuous variable), presence of complications (yes *vs* no), PC and KS (entered as continuous variables in the multiple regression analysis). For the logistic regression analysis KS was categorized in quartiles (≤ 6, 6.1-8, 8.1-9, >9) and PC in tertiles (≤ 3, 3.1-4, >4), the higher quartile and tertile being considered as reference categories.

Continuous variables are reported as mean±SD.

Mean HbA_{1c} levels in the different KS and PS categories were compared by using one-way analysis of variance, while for the comparison of proportions of patients with mean HbA_{1c} levels $\leq 7\%$ the Mantel-Haenszel chi-square for linear association was applied.

Missing values in the questionnaire were replaced by the mean value of all non-missing items of the same scale. When more than 50% of the items of a scale were missing, the observation was discarded.

RESULTS

Out of 199 Type 1 patients seen in the clinic over a period of 4 years, 133 regularly attended the structure (≥ 3 visits/year) and were asked to participate; 77 patients (58%) filled in the questionnaire and thus represent the denominator of our study.

Non-respondents did not differ from respondents for any of the variables investigated (50% males; age 38±11 years; mean diabetes duration 13±9 years; retinopathy 36%; nephropathy 18%; BMI males 25.3±2.7; BMI females 25.0±4.1; U/kg insulin 0.62±0.21).

The general characteristics of the study population are reported in Table 1.

Almost all patients were treated with 4 insulin injections; 9 subjects received continuous subcutaneous insulin infusion. The mean number of HbA_{1c} determinations during a median period of observation of 4 years was 11±5. The mean HbA_{1c} value for the whole population was 7.0±1.4%, while the proportion of patients with values $\leq 7.0\%$ was 57%.

Table 1 - *General characteristics of the study population (n=77).*

Gender	
Males	52%
Females	48%
Age (years, mean±SD)	37±13
Years of education	
≤5	16%
6-8	20%
>8	35%
Students	20%
Unknown	10%
Diabetes duration (years, mean±SD)	13±9
Diabetes complications	
Retinopathy	35%
Nefropathy	15%
Body mass index	
Males	25.5±2.6
Females	25.2±4.5
Number of insulin injections (mean±SD)	4.0±0.2
U/kg insulin (mean±SD)	0.64±0.22

Factor analysis

Factor analysis confirmed the theorized structure of the questionnaire, clearly distinguishing two orthogonal factors, explaining 36% of the total variance. Among the items which were hypothesized to compose the KS, one (KS9) had a higher factor loading for the practice factor, while 3 additional items (KS4, KS8, KS10) showed a low factor loading on both factors and were thus discarded. Similarly, 2 items of the PS (PS7 and PS9) had a higher factor loading on the knowledge factor and 2 had loadings below 0.30 and were thus removed (PS8 and PS10) (Table 2).

The remaining 17 items were again subjected to a forced two-factor PAF analysis with varimax rotation. In this case the two factors accounted for 45% of the total variance.

The further validation step, *ie* reliability analysis, was therefore applied to a KS including 10 items (KS1, KS2, KS3, KS5, KS6, KS7, KS11, KS12, PS7, PS9) and a PS composed of 7 items (PS1 to PS6, KS9).

Reliability

Reliability analysis (Table 3) showed that for 2 items of the PS (PS6 and KS9) the item-scale correlation coefficient was lower than 0.40 and that, after removing them, the Cronbach's α coefficient improved from 0.62 to 0.77. For this reason, and for the lack of any clear relationship between the content of item KS9 and the other questions pertaining to the PS scale, the two items were removed. The final PS was thus composed of 5 items (PS1, PS2, PS3, PS4, PS5) with a score ranging from 0 to 5. All items of the KS but one (PS7) showed an item-scale correlation coefficient >0.40. Since the deletion of this item did not modify the Cronbach's α coefficient (0.85 with and 0.86 with-

Table 2 - *Results of the factor analysis after varimax orthogonal rotation (factor loadings <0.30 are not reported).*

Items	Factor 1	Factor 2
KS1	0.58	-
KS2	0.78	-
KS3	0.53	-
KS4	-	-
KS5	0.88	-
KS6	0.88	-
KS7	0.88	-
KS8	-	-
KS9	-	-0.38
KS10	-	-
KS11	0.62	-
KS12	0.52	-
PS1	-	0.66
PS2	-	0.70
PS3	-	0.72
PS4	-	0.82
PS5	-	0.55
PS6	-	0.41
PS7	0.39	-
PS8	-	-
PS9	0.55	-
PS10	-	-

Table 3 - *Results of the reliability analysis.*

Items	Item-scale correlation* KS	Item-scale correlation* PS
KS1	0.48	
KS2	0.70	-
KS3	0.46	-
KS5	0.77	-
KS6	0.78	-
KS7	0.75	-
KS11	0.46	-
KS12	0.41	-
PS7	0.32	-
PS8	0.46	-
PS1	-	0.43
PS2	-	0.55
PS3	-	0.47
PS4	-	0.61
PS5	-	0.43
PS6	-	0.25
KS9	-	-0.23

*corrected for overlapping.

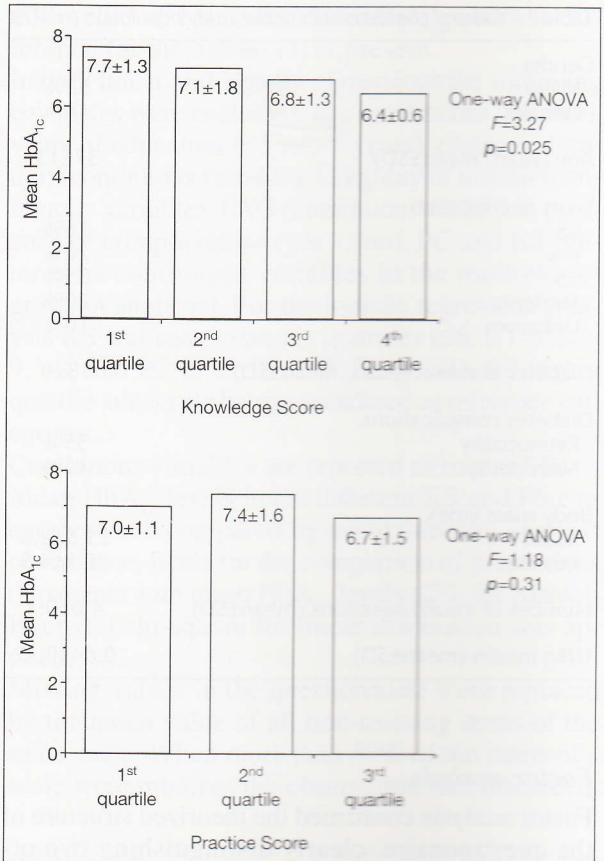

Fig. 1 - *Mean HbA_{1c} levels (±SD) according to Knowledge and Practice Scores categories.*

out the item), we decided not to remove it. The final KS was therefore composed of 10 items (KS1, KS2, KS3, KS5, KS6, KS7, KS11, KS12, PS7, PS9), with a score ranging from 0 to 10.

Discriminant validity

The study population had a median KS of 8 (range 0-10) and a median PS of 4 (range 0-5). For 2 patients (KS) and 3 patients (PS) scores were computed by replacing missing values in the questionnaire with the mean value of all non-missing items of the same scale. Due to missing values in more than 50% of the items, the PS could not be computed in 3 additional patients.

The distribution of mean HbA_{1c} values according to PS tertiles and KS quartiles is reported in Figure 1, showing a statistically significant difference among KS but not among PS categories. Figure 2 reports the proportion of patients with mean HbA_{1c} levels ≤7% according to KS and PS categories. Again, a statistically significant trend is present for KS quartiles but not for PS tertiles.

The analysis restricted to the last year of observation confirms these results, mean HbA_{1c} values being 7.7±1.3, 7.2±1.1, 6.9±1.0 and 6.6±0.6 for the 4 KS quartiles (p=0.01) and 7.3±1.0, 7.4±1.2 and 6.7±1.1 for PS tertiles (p=0.06).

These findings are further supported by multivariate analyses. In fact, the multiple regression model shows that the only independent predictor of metabolic control is represented by the KS (β=0.17; p=0.0004). Similarly, the application of the logistic regression model shows that the risk of having HbA_{1c} values exceeding 7% is strongly related to the KS (Fig. 3). In particular, subjects in the lowest quartile of the KS had a more than 20-fold increased risk of

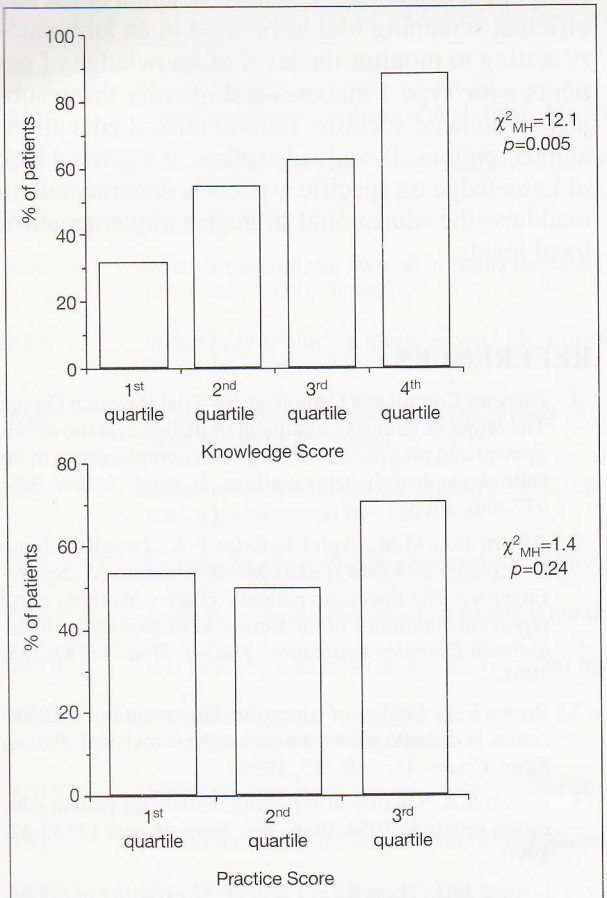

Fig. 2 - *Percentages of patients with mean HbA_{1c} levels ≤7%, according to Knowledge and Practice Scores categories.*

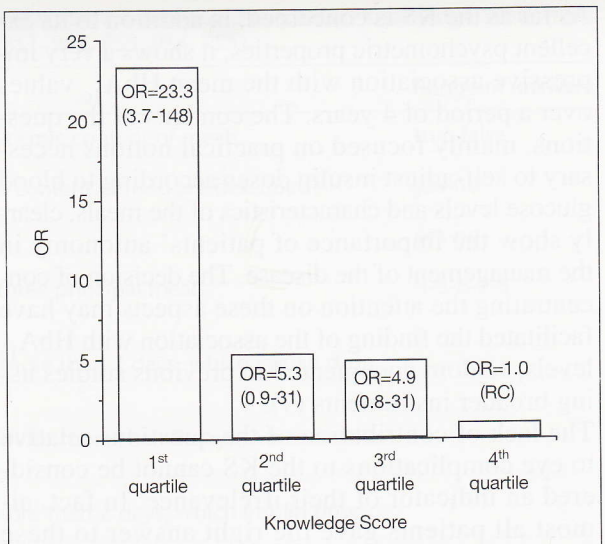

Fig. 3 - *Risk of having mean HbA_{1c} levels >7% according to Knowledge Score categories: results of the logistic regression. Results are expressed in terms of odds ratios (ORs) together with their 95% confidence intervals (CI). RC=reference category.*

having mean HbA_{1c} levels over 7% as opposed to those in the highest quartile (OR=23.3; p=0.009). The KS was the only independent predictor of metabolic control; in fact, none of the other variables investigated entered the logistic model. To this respect, it is worth mentioning that, although the PS did not represent an independent predictor of metabolic control, it was significantly related to the KS (r=0.31; p=0.006).

DISCUSSION

Despite general agreement that education leads to better patient knowledge and better metabolic control (3-8), conflicting results have been obtained when the relationship between patient knowledge and metabolic control has been investigated (9). The heterogeneity in the instruments used to assess knowledge, as well as the lack of documentation of their reliability and validity, can be at least partially responsible for these results (4).

The two scales of the KPDQ, a newly developed questionnaire, have been shown to be valid and reliable instruments to investigate patients' knowledge and practices. Nevertheless, while the KS was able to clearly distinguish patients according to their metabolic control, the PS showed poor discriminative properties.

These findings can be explained by the fact that some of the questions initially identified turned out to be poorly correlated with the underlying dimension, leaving only 5 valid items to investigate patients' practices. The narrow range of the resulting score can thus be responsible for its inability in predicting HbA_{1c} levels.

Furthermore, the only items left were all investigating blood glucose self-monitoring. It is thus not surprising that this practice is not, *per se*, an indicator of metabolic control.

From this point of view, this section needs to be reconsidered after a careful evaluation of possible additional relevant items to be included, in order to improve its discriminative properties.

As far as the KS is concerned, in addition to its excellent psychometric properties, it shows a very impressive association with the mean HbA_{1c} values over a period of 4 years. The contents of the questions, mainly focused on practical notions necessary to self-adjust insulin doses according to blood glucose levels and characteristics of the meals, clearly show the importance of patients' autonomy in the management of the disease. The decision of concentrating the attention on these aspects may have facilitated the finding of the association with HbA_{1c} levels, seldom documented in previous studies using broader instruments (9).

The lack of contribution of the questions relative to eye complications to the KS cannot be considered an indicator of their irrelevance. In fact, almost all patients gave the right answer to these questions, showing that eye complications are one of the topics they are more sensitive to. The lack of association with the KS is thus just a reflection of the low variance in the answers given. On the other hand, the awareness of the association between glycemic control and renal complications seems to be less generalized, as shown by the important contribution given to the KS by the two questions on this topic.

Our data show that, in a population of Type 1 diabetic patients intensively treated and receiving homogeneous standards of care, the administration of a 10-item questionnaire is able to discriminate different levels of patient knowledge, which are in turn strictly related to HbA_{1c} levels.

These findings can be particularly remarkable in that many studies have failed in documenting such a relationship (9-12); furthermore, the results have been obtained in a population characterized by generally good metabolic control and with low variability in glycated hemoglobin values. On the other hand, we cannot exclude that the strong correlation between KS and HbA_{1c} levels could be at least partially related to some unknown confounding factors not considered in the multivariate models. The KPDQ will be used in the Pescara General Hospital diabetes outpatient clinic as a routine instrument in all Type 1 patients. It will thus be possible to verify our findings in a larger patient sample and evaluate the ability of the questionnaire to detect longitudinal changes in the level of knowledge.

If its properties will be confirmed, the knowledge component of the KPDQ will represent a quick and efficient screening tool to be used in an ambulatory setting to monitor the level of knowledge of patients with Type 1 diabetes and identify those subjects who need specific, individualized educational interventions. It could also allow, if a general lack of knowledge on specific aspects is documented, to readdress the educational strategies implemented at local level.

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PPENDIX 1 - Initial structure of the KPDQ questionnaire. The final scales are composed as follows: Knowledge Score (KS1, S2, KS3, KS5, KS6, KS7, KS11, KS12, PS7, PS9); Practice Score (PS1, PS2, PS3, PS4, PS5).

em	Content	Range of answers
S1	The dose of short-acting insulin is related to the glycemic content of meals.	true-false
S2	Do you have a booklet where nutrients and calories content of food are described?	yes-no
S3	If yes, do you use it?	yes-no
S4	What is the optimal interval in hours between the three principal meals (breakfast, lunch, dinner)?	4-5-6-7-8
S5	When fasting glucose levels exceed 150 mg/dl for more than 2 days, which insulin dose has to be increased by 1-2 U?	
S6	When glucose levels before lunch exceed 150 mg/dl for more than 2 days, which insulin dose has to be increased by 1-2 U?	
S7	When levels before dinner exceed 150 mg/dl for more than 2 days, which insulin dose has to be increased by 1-2 U?	
S8	Long-lasting poor metabolic control can be responsible of eye complications.	true-false
S9	Diabetic retinopathy is the first cause of blindness.	true-false
S10	It is important to have an eye examination by a specialist at least once a year.	true-false
S11	Long-lasting poor metabolic control can be responsible for renal complications that may require dialysis.	true-false
S12	Microalbuminuria is the only early marker of renal impairment.	true-false
PS1	How often do you measure your blood glucose during one month?	
PS2	How often do you measure your blood glucose before breakfast?	always to never
PS3	How often do you measure your blood glucose before lunch?	always to never
PS4	How often do you measure your blood glucose before dinner?	always to never
PS5	How often do you measure your blood glucose at bed-time?	always to never
PS6	When you feel symptoms which can be related to hypoglicemia, do you measure your blood glucose before taking glucose?	always to never
PS7	How many minutes before meals do you take your short-acting insulin?	
PS8	What time of the night do you take your long-acting insulin?	
PS9	Do you know the amount of glucose you take with meals?	yes-no
PS10	Do you have your meals at the same time every day?	yes-no