

# Design and development of a scale measuring fear of complications in type 1 diabetes

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## Abstract

**Background** There are many determinants of glycaemic control in patients with type 1 diabetes. Patients with type 1 diabetes and poor glycaemic control have been reported as being more likely to have a greater fear of hypoglycaemia. The relationship between fear of diabetes-related complications and glycaemic control is unclear, and therefore a brief measure of fear of diabetes complications was developed.

**Methods** A questionnaire was designed, comprising items relating to general fears, specific fears (e.g. blindness, kidney problems, heart disease), lifestyle fears, fear of hypoglycaemia and weight gain. The questionnaire was piloted on 147 outpatients with type 1 diabetes, along with other measures such as the Hypoglycaemia Fear Survey, the Hospital Anxiety and Depression Scales, the Coping with Health, Injuries and Problems Scale and the Eysenck Personality Questionnaire.

**Results** Factor analysis was carried out on the 30 items and, after rotation, 15 emerged as loading heavily on the first factor. Factor analysis was rerun on these 15 items and the first factor accounted for 56% of the total variance. This factor remained invariant when the scale was split randomly and by age and gender. The reliability of the scale ( $\alpha$ ) was 0.94. The scale did not correlate with any demographic variables but did with measures of negative affectivity (HADS anxiety = 0.34,  $p < 0.001$ ; Depression = 0.24,  $p < 0.004$ ), the Hypoglycaemia fear survey worry Scale (0.44,  $p < 0.001$ ), presence of complications (0.17,  $p < 0.04$ ) and number of complications (0.28,  $p < 0.001$ ).

**Conclusions** These results indicate that the scale identifies a fear that is moderately related to the presence of complications and general negative affectivity but which is a uniquely diabetes-related emotion. Copyright © 2005 John Wiley & Sons, Ltd.

**Keywords** fear of complications; glycaemic control; type 1 diabetes

## Background

Patients with type 1 diabetes are faced with the conflict of maintaining good glycaemic control to avoid developing long-term complications such as retinopathy, neuropathy or macrovascular problems, whilst minimizing the risk of exposure to hypoglycaemia. Achieving optimal glycaemic control can be very difficult for many people. Research has shown that there is a relationship between fear of hypoglycaemia, mean daily blood glucose and blood glucose

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variability [1] and that fear of hypoglycaemia may also be more common in patients with poor glycaemic control [2]. The Hypoglycaemia Fear Survey [2] has been validated [3] as a screening tool establishing the relationship between this fear and poor glycaemic control.

There are many factors that may influence glycaemic control. It could be argued that the motivation to maintain good glycaemic control in some patients might in part be driven by a fear of long-term complications. Identifying a global fear that a patient may have about their condition means that clinicians can focus attention on specific concerns, reassuring the patient and possibly influencing long-term self-care behaviour. Ideally, complications-related fear should be identifiable through a brief, simple-to-administer measure.

As fear of hypoglycaemia has been successfully established as a factor influencing poor glycaemic control using the Hypoglycaemia Fear Survey (HFS), it was hypothesized that a scale measuring fear of complications might be similarly helpful in establishing the factors contributing to glycaemic control. Clarifying the complex relationships between psychological and emotional motivations and glycaemic control may be helpful in targeting more appropriate treatments for some patients. The aim of this study was to design and validate a Fear of Complications Questionnaire (FCQ).

## Methods

The research consisted of a cross-sectional design, the variables being the participants' responses on the measures of the Fear of Complications Questionnaire, and the other questionnaires, glycaemic control (glycosylated haemoglobin – HbA<sub>1c</sub>) and presence of diabetic complications.

### Development of a fear of complications questionnaire (FCQ)

The questionnaire originally comprised 30 candidate items, relating to general fears, specific fears (e.g. blindness, kidney problems, heart disease), lifestyle fears, fears of hypoglycaemia and weight gain. The 30 items had a 4-point response scale, scored 0 to 3, whereby 0 denoted low fear of complications and 3 denoted high fear. The layout and content were reviewed by clinicians at the Diabetes Clinic and an independent researcher and was subsequently piloted on 20 patients. The questionnaire was revised again following patients' comments and finally tested on 200 patients with type 1 diabetes. Complete data were obtained from 147 participants.

### Patient selection

Two hundred patients were approached whilst attending a routine diabetes clinic appointment. Four refused to

participate, and 149 returned questionnaires, of which one was late and the other was spoiled, leaving 147 for analysis. The 47 people who did not return questionnaires did not differ as a group from those who did in terms of age (mean = 38 ± 10.8 years). Males were over-represented amongst the non-returners (37 males, 10 females). The distribution of glycaemic control across the non-returners was not significantly different from that of the returners.

Participants were between 18 and 60 years of age and were excluded if there was a history of alcohol excess, a psychotic illness, or if they were blind, pregnant, planning to become so, or had given birth in the last six months. All patients had been diagnosed as having type 1 diabetes at least five years previously to avoid the effect of the 'honeymoon period' on glycaemic control. Patients who fulfilled the inclusion criteria were selected on a random basis from clinic lists and approached during their routine clinic appointment.

Clinical data including the presence of significant diabetes-related complications were recorded from case notes. A significant diabetes-related complication included severe retinopathy (including proliferative, pre-proliferative retinopathy and previous laser treatment), proteinuria (defined as dipstick positive proteinuria), or established cardiovascular disease. Neuropathy was not included because of incomplete data. The decision to include only significant serious complications in statistical analyses was based on the long duration of diabetes experienced by the sample, resulting in only 26.5% of the sample having no evidence of complications at all. Experience of severe hypoglycaemia was self-recorded by the patients. They were asked how many episodes of hypoglycaemia they had experienced in the last year and over their lifetime. An episode of severe hypoglycaemia was counted if it had required the intervention of another person.

Ethical approval was received and written consent was acquired in all cases.

### Procedure

Participants were approached during their appointment at the clinic and asked to complete eight questionnaires. The Hospital Anxiety and Depression Scales (HADS) [4] is a well-validated measure of negative affectivity (regarded as a construct underlying anxiety and depression [5,6]) designed for use with physically ill populations. The Hypoglycaemia Fear Survey [2] (HFS) has two sub-scales measuring worry and behaviour related to fear of hypoglycaemia. The Eysenck Personality Questionnaire [7] (EPQ-R) is a well-established measure of personality variables (psychoticism, neuroticism, extraversion and introversion). Coping with Health, Injuries and Problems [8] (CHIP) is used to measure coping style in illness and injury. Its sub-scales comprise negative emotion, palliative, instrumental and distraction coping styles. The researchers developed the eighth questionnaire: a Fear of Complications Questionnaire (FCQ). Participants also

completed the National Adult Reading Test (NART) [9] to provide a brief measure of pre-morbid intelligence.

Participants were given the questionnaire pack and a stamped addressed envelope and asked to return the completed questionnaire pack as soon as possible. The researcher reminded participants with a telephone call after one month if questionnaires had not been returned. The statistical analysis was conducted using SPSS For Windows 9.0. Factor analysis was used as a means of reducing the number of questionnaire items to produce a unitary short scale of complications. Validity of the scale was then tested against other variables such as other validated questionnaires and clinical data.

## Results

Demographic, social and clinical data were collected using patients' records and questionnaires. The age and social characteristics were similar to the diabetes clinic population (see Table 1). The mean age was  $37.0 \pm 10.0$  years. The mean age at diagnosis was  $18.0 \pm 9.8$  years and the mean duration of diabetes was  $19.0 \pm 9.5$  years. The frequency of hypoglycaemic episodes and complications is shown in Table 2.

Principal components factor analysis with varimax rotation was carried out on the subject items, and 15 items emerged as strongly loading on a first factor accounting for 34% of the total variance. No other factor accounted for more than 7.5% of the variance. Consequently, factor analysis was rerun with these 15 items alone. The unrotated factor structure is presented in Table 3. It can be seen that all items load highly on the first unrotated principal component; this component accounted for 54.6% of the variance among items. The second factor is a contrast factor; it tells us that items that share the same sign share variance that is not shared with the variables of opposite sign. However, the loadings on this factor were for the most part modest and it accounted for only 9.1% of the variance. These 15 items were accepted as a complete questionnaire, and all further analysis incorporating the FCQ used this reduced version. (see Appendix I for sample).

**Table 1. Demographics of sample**

Age bands	<i>n</i>	% of total	
17–29	34	23	
30–44	73	50	
45–59	40	27	
T	147	100	
Males	68	46	
Females	79	54	
T	147	100	
	<i>n</i>	Mean	SD
Age (years)	147	37.0	10.0
Education (years)	146	13.1	2.7
NART-estimated IQ	139	93.4	10.8

**Table 2. Experience of hypoglycaemia<sup>a</sup> and complications<sup>b</sup> in sample**

	Number	Number of subjects	Percent
Severe hypoglycaemic episodes across the lifetime	0	36	24.6
	1–3	29	19.9
	4–5	27	18.5
	6+	54	37.0
	Total	146	100
Presence of complications	0	114	77.6
	1	26	17.7
	2	7	4.7
	Total	147	100

<sup>a</sup>Total number of hypoglycaemic episodes 'requiring the assistance of someone else' over the lifespan.

<sup>b</sup>'Complications' refers to significant long-term diabetic complications including severe retinopathy, proteinuria and all cardiovascular conditions.

The subject sample was randomly split and factor analysis rerun. The same items emerged on the first factor. The coefficient of congruence [10] between the factor loadings of the random split sample and those of the total sample was 0.998. The sample was then split according to gender and age, and factor analysis was carried out again on the 15 items. The coefficient of congruence between genders was 0.994, and between the age groups 18 to 29 years and 30 to 44 years the coefficient was 0.991, between the age groups 30 to 44 years and 45 to 59 years it was 0.999.

The reduced FCQ was correlated with various demographic data, namely, age, gender, years of education and intelligence and none of these correlations achieved significance. The absence of any effect of demographic variable, especially intelligence or education, simplifies the potential clinical use of the FCQ.

## Reliability

The reliability (internal consistency) of the FCQ was measured using Cronbach's alpha and was found to be 0.94 (95% CI = 0.923 to 0.952). The results indicate that the scale has very high reliability and that the estimate of reliability is highly accurate (shown by the narrowness of the confidence interval).

## Validity

Diabetes specialists and patients made critical contributions to the questionnaire's design, making recommendations as to whether questions were relevant, appropriate and comprehensible. It was agreed that the questionnaire had good face validity and that its content was relevant and was clearly aimed at measuring fear of diabetic complications.

The FCQ was compared against the other scales completed by the subjects to further establish construct validity. Pearson's correlations showed that the FCQ

Table 3. Factor structure of FCQ

		Factor 1	Factor 2
Eigen value		8.2	1.4
Percentage of total variance		54.6	9.1
Item			
14	I am afraid I will develop kidney problems one day	0.82	0.24
15	How often do you think about long-term complications of diabetes	0.80	-0.18
20	Do you ever worry about your future health?	0.79	-0.30
10	I am afraid I will need a kidney transplant one day	0.78	0.21
13	I am afraid I may need kidney dialysis one day	0.78	0.41
11	I am afraid of developing long-term complications as a result of frequent high blood sugars	0.74	-0.26
1	I feel afraid of long-term complications of diabetes	0.74	-0.28
6	I worry about losing my eyesight because of diabetes	0.74	0.37
8	I worry that having diabetes increases my chances of heart disease	0.73	0.38
25	I am scared of having a heart attack in the future	0.72	0.32
22	Do you worry about future problems when your blood sugars are erratic?	0.72	-0.35
24	I am scared that diabetes could affect my feet	0.71	-0.15
21	I worry that the diabetes specialist will find something wrong with my eyes	0.69	-0.31
27	I worry about developing problems with circulation	0.66	0.03
18	I worry that I might be at higher risk for having a stroke	0.64	0.51

was significantly positively correlated with the EPQ Neuroticism sub-scale, the HADS Anxiety and Depression sub-scales, the HFS behaviour and worry sub-scales and the CHIP Distraction and Negative Emotion sub-scales (Table 4), although none of the correlations exceeded 0.5. This indicates that the FCQ relates to general negative affectivity. In addition, partial correlations (Table 4) controlling for negative affectivity demonstrated a correlation between fear of hypoglycaemia and fear of complications.

There was a statistically significant difference in scores between participants with and without serious diabetic complications ( $t = 3.935$ ,  $df = 144$ ,  $p < 0.001$ ).

Table 4. Pearson's correlations between FCQ and other scales of emotion

	FCQ	
	Correlation	Significance
EPQ neuroticism	0.338	0.001
HADS anxiety	0.341	0.001
HADS depression	0.241	0.004
CHIP negative emotion	0.480	0.001
HFS behaviour	0.343	0.001
HFS behaviour controlling for EPQ neuroticism	0.110	0.250
HFS behaviour controlling for HADS anxiety	0.187	0.038
HFS behaviour controlling for HADS depression	0.206	0.021
HFS behaviour controlling for CHIP negative emotion	0.098	0.284
HFS behaviour controlling for negative affectivity i.e. EPQ, HADS, CHIP	0.041	0.683
HFS-worry	0.439	0.001
HFS-worry controlling for EPQ neuroticism	0.275	0.003
HFS-worry controlling for HADS anxiety	0.316	0.001
HFS-worry controlling for HADS depression	0.338	0.001
HFS-worry controlling for CHIP negative emotion	0.279	0.002
HFS-worry controlling for negative affectivity i.e. EPQ, HADS, CHIP	0.229	0.019

However, the effect size (i.e. the proportion of variance in FCQ scores that could be attributed to group differences) was small ( $r^2 = 0.07$ ), which indicates that the presence of complications alone was not a major factor in dictating the respondent's fear levels. This demonstrated that the FCQ did not simply identify the presence of complications.

To further examine the possibility that fear of hypoglycaemia and fear of complications simply reflected a common underlying general worry concerning diabetes, a joint factor analysis of the FCQ and the worry items of the Hypoglycaemic Fear scale was conducted (using principal components analysis with *a priori* specification of two factors and varimax rotation). The results are presented in Table 5. It can be seen that, in general, the items from the two questionnaires load on two separate factors. The exception is item 15 of Hypoglycaemia worry scale, which reflects fear of long-term complications of hypoglycaemia.

## Conclusions

The FCQ would appear to be a reliable, brief and easily administered instrument for identifying fear of complications in type 1 diabetes. Although the sample size is not large, the Cronbach's alpha was very high and the scale showed a high level of congruence when the sample was split randomly and by age and gender. The FCQ is positively correlated with measures of negative affectivity, which lends credence to its validity, especially as it is moderately correlated with CHIP Negative Emotion (0.48), which supposedly measures negative emotion towards illness. The positive correlation with the HFS-worry scale is an interesting finding and suggests that patients with fear of hypoglycaemia may also have a fear of complications. The revised FCQ did not include any questions about hypoglycaemia and was clearly aimed at

factors relating to long-term complications only, so the correlation cannot be explained by convergent questions. However, the correlation was moderate, so the overlap between fear of complications and fear of hypoglycaemia is not complete. In addition, this correlation persisted when controlling for negative affectivity, suggesting that the FCQ is not just a measure of negative affectivity but also appears to measure some diabetes-specific fear as well as a unique fear of complications. The second factor analysis of all the FCQ and HFS-worry items displayed in Table 5 confirms that these two scales are not measuring the same fears.

The unique nature of this scale also means that there is no 'gold standard' against which to validate it. By comparing the scale against measures of anxiety and depression, previously found to be related [1], fear of hypoglycaemia, personality and demographic variables, there is some reassurance that the scale is measuring a state variable (similar to anxiety, depression and fear of hypoglycaemia) and not a trait variable (such as personality). Nevertheless, the relatively modest correlations indicate that the FCQ is not just another measure of anxiety/depression or negative affectivity but that diabetes-related fear is associated with negative affectivity. Nor does the scale measure an effect of duration of diabetes, knowledge of diabetes or pre-morbid intelligence. It is also likely that current intelligence does

not exert a strong influence on the FCQ scores as although cognitive impairment can be a feature of diabetes, the effects are not typically severe [11]. This increases the potential clinical utility of the scale, as the clinician using it as a brief measure of fear need not be concerned by demographic variables influencing the patient's score.

Finally, it is worthwhile noting the relationship between the presence of complications and fear of complications. Whilst patients with complications showed significantly higher fear of complications, according to the FCQ, the presence of complications only accounts for 7% of the overall variance in scores. This may be an underestimate as a result of incomplete recording of complications such as neuropathy. However, this does suggest that the FCQ is measuring fear of complications rather than anything else and that it is a useful clinical and research tool because it identifies fear that is not necessarily dependent on the presence of complications, that is, the scale is not simply identifying patients with complications.

Fear of complications has not been studied before, and the development of this brief one-factor scale provides researchers and clinicians with a new tool for measuring psychological correlates in diabetes. The Hypoglycaemia Fear Survey [2] has facilitated study of the relationship between fear and self-management in diabetes. It is hoped that, with this new scale, the study of fear can become more exact and that a model for psychological distress in

**Table 5.** Joint factor analysis of FCQ and hypoglycaemia fear worry scale items using principal components analysis with *a priori* specification for two factors and varimax rotation

	Item	Factor 1	Factor 2
14	I am afraid I will develop kidney problems one day (FCQ)	0.83	0.09
15	How often do you think about long-term complications of diabetes (FCQ)	0.78	0.08
20	Do you ever worry about your future health? (FCQ)	0.75	0.29
10	I am afraid I will need a kidney transplant one day (FCQ)	0.79	0.11
13	I am afraid I may need kidney dialysis one day (FCQ)	0.80	0.07
11	I am afraid of developing long-term complications as a result of frequent high blood sugars (FCQ)	0.73	0.12
1	I feel afraid of long-term complications of diabetes (FCQ)	0.70	0.14
6	I worry about losing my eyesight because of diabetes (FCQ)	0.71	0.18
8	I worry that having diabetes increases my chances of heart disease (FCQ)	0.73	0.12
25	I am scared of having a heart attack in the future (FCQ)	0.71	0.16
22	Do you worry about future problems when your blood sugars are erratic? (FCQ)	0.66	0.25
24	I am scared that diabetes could affect my feet (FCQ)	0.69	0.21
21	I worry that the diabetes specialist will find something wrong with my eyes (FCQ)	0.69	0.14
27	I worry about developing problems with circulation (FCQ)	0.64	0.20
18	I worry that I might be at higher risk for having a stroke (FCQ)	0.63	0.10
1	Not recognizing I am having a reaction (HFS-worry)	0.13	0.66
2	Not having food, fruit or fruit juice with me (HFS-worry)	0.11	0.40
3	Feeling dizzy or passing urine in public (HFS-worry)	0.17	0.74
4	Having a reaction while asleep (HFS-worry)	0.27	0.63
5	Embarrassing myself or my friends in a social situation (HFS-worry)	0.12	0.76
6	Having a reaction while alone (HFS-worry)	0.11	0.67
7	Appearing drunk or stupid (HFS-worry)	0.05	0.82
8	Losing control (HFS-worry)	0.05	0.82
9	No one being around to help me during a reaction (HFS-worry)	0.09	0.75
10	Having a reaction while driving (HFS-worry)	0.18	0.52
11	Making a mistake or having an accident at work (HFS-worry)	0.13	0.76
12	Getting a bad evaluation at work because of something that happens at work when my sugar is low (HFS-worry)	0.09	0.76
13	Having seizures or convulsions (HFS-worry)	0.20	0.73
14	Difficulty thinking clearly when responsible for others (children, etc.) (HFS-worry)	0.23	0.64
15	Developing long-term complications from frequent low blood sugar (HFS-worry)	0.54	0.36
16	Feeling lightheaded or faint (HFS-worry)	0.20	0.69
17	Having an insulin reaction (HFS-worry)	0.30	0.53

diabetes can be found. Ultimately, this greater knowledge can be used to develop appropriate interventions for patients who have difficulties managing their condition.

The scale does need further validation with different populations, including patients with shorter-duration type 1 diabetes and type 2 diabetes, and with other scales of emotion. The findings of this study suggest a reliable and valid instrument for measuring a factor that may influence diabetes management.

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## APPENDIX I – revised fear of complications questionnaire

This questionnaire is designed to help us understand how you feel about your Diabetes and how it affects you, particularly in the **long-term**. Please answer the following questions as honestly as possible. Your answers will be kept in strictest confidence.

Please answer each question by circling the response most appropriate to yourself:

1. I feel afraid of long-term complications of Diabetes  

<b>Very</b>	<b>Moderately</b>	<b>A little</b>	<b>Not at all</b>
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2. I worry about losing my eyesight because of Diabetes  

<b>All the time</b>	<b>Frequently</b>	<b>Occasionally</b>	<b>Never</b>
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3. I worry that having Diabetes increases my chances of heart disease  

<b>All the time</b>	<b>Frequently</b>	<b>Occasionally</b>	<b>Never</b>
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4. I am afraid I will need a kidney transplant one day  

<b>Very</b>	<b>Moderately</b>	<b>A little</b>	<b>Not at all</b>
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5. I am afraid of developing long-term complications as a result of frequent high blood sugars  

<b>All the time</b>	<b>Frequently</b>	<b>Occasionally</b>	<b>Never</b>
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6. I am afraid that I may need kidney dialysis one day  

<b>Never</b>	<b>Occasionally</b>	<b>Frequently</b>	<b>Constantly</b>
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7. I am afraid that I will develop kidney problems one day  

<b>All the time</b>	<b>Frequently</b>	<b>Occasionally</b>	<b>Never</b>
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8. How often do you think about long-term complications of Diabetes?  

<b>Hardly ever</b>	<b>Occasionally</b>	<b>Frequently</b>	<b>All the time</b>
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9. I worry that I might be at a higher risk for having a stroke  

<b>All the time</b>	<b>Frequently</b>	<b>Occasionally</b>	<b>Never</b>
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10. Do you ever worry about your future health?  

<b>Not at all</b>	<b>Occasionally</b>	<b>Frequently</b>	<b>All the time</b>
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11. I worry that the Diabetes Specialist will find something wrong with my eyes  

<b>Not at all</b>	<b>Occasionally</b>	<b>Frequently</b>	<b>Constantly</b>
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12. Do you worry about future problems when your blood sugars are erratic?  

<b>Not at all</b>	<b>Occasionally</b>	<b>Frequently</b>	<b>All the time</b>
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13. I am scared that Diabetes could affect my feet  

<b>Very</b>	<b>Moderately</b>	<b>A little</b>	<b>Not at all</b>
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14. I'm scared of having a heart attack in the future  

<b>Not at all</b>	<b>A little scared</b>	<b>Moderately scared</b>	<b>Very scared</b>
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15. I worry about developing problems with circulation  

<b>Never</b>	<b>Occasionally</b>	<b>Frequently</b>	<b>All the time</b>
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*Thank you for your cooperation.*