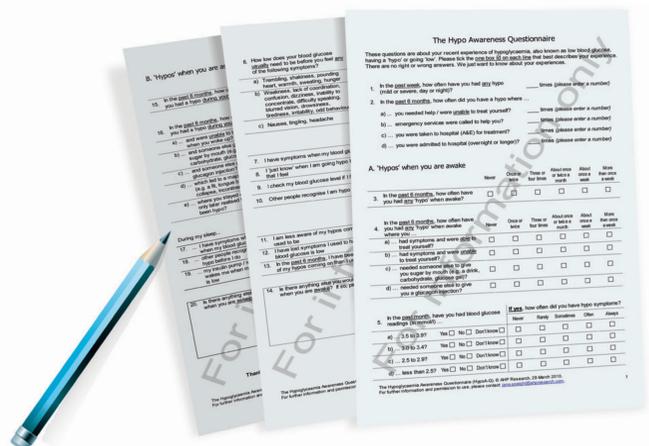


# Psychometric Validation of a Novel Measure of Impaired Awareness of Hypoglycemia: the Hypoglycemia Awareness Questionnaire (HypoA-Q)

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## Introduction

- Approximately 20-25% of adults with type 1 diabetes (T1DM) have some impaired awareness of hypoglycemia (IAH)<sup>1</sup>, which is associated with a six-fold increased risk of severe hypoglycaemia<sup>2</sup>.
- Current recommendations for identifying IAH involve use of the Gold score and Clarke Questionnaire, separately or in combination<sup>3</sup>.
- The single item Gold score<sup>2</sup> is brief, valid and responsive but does not enable detailed characterization of all features of IAH.
- The Clarke Questionnaire<sup>4</sup> provides a detailed assessment but has limitations: out-dated definitions; no consensus for glycemic thresholds; inconsistent recall periods; absence of relevant issues (e.g. nocturnal hypoglycemia).
- Consequently, the Clarke Questionnaire lacks face validity and both instruments lack some sensitivity to change.
- We previously reported the design of a novel detailed measure of awareness of hypoglycemia (the HypoA-Q), using a comprehensive, collaborative and iterative design<sup>5</sup>.
- The HypoA-Q includes 18 items (plus two free text responses) assessing recall of hypoglycemic events, blood glucose thresholds at which symptoms occur, awareness of symptoms, altered awareness, and frequency of checking blood glucose when 'feeling low'.
- Our aim was to conduct preliminary psychometric validation of the HypoA-Q.

## Methods

- A case-controlled study was conducted in 120 adult outpatient with T1DM – 60 on an existing clinical register of IAH and 60 who were not.
- The following questionnaires were completed at routine outpatient clinic appointments:
  - HypoA-Q<sup>5</sup>, Gold score<sup>2</sup>, Clarke Questionnaire<sup>4</sup>, assessing IAH
  - Problem Areas in Diabetes (PAID)<sup>6</sup>, assessing diabetes-related distress
- HbA1c was collected from clinic records.

## Results

- The sample included 120 adults (53 women) with T1DM with/without clinically diagnosed IAH:
  - mean age: 44.4 ± 15.8 years
  - duration of diabetes: 22 ± 13.4 years
  - HbA1c 8.2 ± 1.3%
- Acceptability was indicated by high completion rates (>95% for 12 items, >90% for 6 items).
- Principal components analysis revealed the HypoA-Q to include three scales reflecting 'impaired awareness' (5 items), 'symptom frequency' (4 items), and 'symptom level' (3 items; Table 1), plus individual items measuring recall of mild / severe hypoglycemic events, nocturnal hypoglycemia / awareness and healthcare resource use.

- Internal consistency reliability (Cronbach's alpha) was satisfactory for each of the 3-5 item scales (Table 1).
- Satisfactory convergent validity was demonstrated, e.g. between 'impaired awareness' and other measures of IAH (Table 2).
- Divergent validity was supported, e.g. with low correlations between 'impaired awareness' and HbA1c, age, duration of diabetes, and diabetes-related distress (Table 2).
- 'Impaired awareness' discriminated significantly between those on a clinical register of IAH (n=60) and those not on the register (n=60; U=640.00, p<0.001), correctly classifying 72% of participants.

**Table 1. HypoA-Q scale structure and internal consistency reliability**

Item no and label / 'actual wording'	HypoA-Q Scale (factor loadings) <sup>a</sup>		
	Impaired Awareness	Symptom Level	Symptom Frequency
5a Symptoms experienced at blood glucose readings '3.5-3.9 mmol/L'	–	–	0.80
5b Symptoms experienced at blood glucose readings '3.0-3.4 mmol/L'	–	–	0.92
5c Symptoms experienced at blood glucose readings '2.5-2.9 mmol/L'	–	–	0.92
5d Symptoms experienced at blood glucose readings 'Less than 2.5 mmol/L'	–	–	0.84
6a BGLs at which autonomic symptoms occur <sup>b</sup>	–	0.91	–
6b BGLs at which neuroglycopenic symptoms occur <sup>b</sup>	–	0.88	–
6c BGLs at which malaise symptoms occur <sup>b</sup>	–	0.88	–
7 'I have symptoms when my blood glucose is low' <sup>c</sup>	0.66	–	–
8 'I 'just know' when I'm going hypo by the way I feel' <sup>c</sup>	0.69	–	–
10 'Other people recognise I am hypo before I do'	0.64	–	–
11 'I am less aware of my hypos coming on than I used to be'	0.82	–	–
12 'I have lost symptoms I used to have when my blood glucose is low'	0.84	–	–
<b>Cronbach's Alpha</b>	<b>0.79</b>	<b>0.86</b>	<b>0.89</b>

<sup>a</sup> Principal components analysis: factor loadings <0.3 suppressed <sup>b</sup> Examples of symptoms used in actual questions <sup>c</sup> Item scoring reversed BGLs: blood glucose levels

**Table 2. HypoA-Q scale correlations with Gold score, Clarke Questionnaire, PAID scale and clinical characteristics**

	HypoA-Q: IA	HypoA-Q: SL	HypoA-Q: SF	Gold	Clarke	PAID	Age	Duration diabetes
HypoA-Q Impaired Awareness (IA)	–							
HypoA-Q Symptom Level (SL)	0.09	–						
HypoA-Q Symptom Frequency (SF)	-0.35*	-0.44**	–					
Gold score	0.75**	0.08	-0.37	–				
Clarke Questionnaire	0.76**	0.19*	-0.54**	0.70**	–			
Problem Areas in Diabetes (PAID)	0.25**	-0.31**	-0.12	0.10	0.25**	–		
Age (years)	0.16	0.21*	0.05	0.16	0.23*	0.00	–	
Duration of diabetes (years)	0.22*	-0.01	0.01	0.18*	0.19*	-0.13	0.60**	–
Glycated haemoglobin: HbA <sub>1c</sub>	-0.05	-0.12	0.24	-0.10	0.07	-0.26**	-0.07	0.00

Spearman's rho correlations significant at \* p<0.05, \*\* p<0.01

## Conclusions

These preliminary psychometric analyses demonstrate that the HypoA-Q has satisfactory structure, internal consistency reliability, and validity (convergent, divergent, and known groups). The HypoA-Q is likely to enable improved classification of the spectrum of hypoglycaemia awareness in clinical practice and evaluation of medical fitness for activities such as driving. Its responsiveness now needs to be examined in clinical trials.

## Enquiries

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