

tionnaire (ITSQ) for use in 18 countries in 22 languages, including Czech, Greek, Hungarian, Romanian, Russian, Serbian, Slovenian and Turkish. The questionnaire was developed in 2003 and was designed to assess the satisfaction with insulin treatment by patients with diabetes. **METHODS:** The methodology employed was: 2 forward translations and their reconciliation, 2 back translations, back translation review, client affiliate review, linguistic validation interviews with 5 patients with diabetes and 2 proof readings. **RESULTS:** While the majority of wording was easily agreed upon, certain words and phrases were more troublesome. Issues and solutions included: “How much bother” was difficult to render in some languages. In Bulgarian, for example, this was translated as “How difficult”, with the context implying “being annoying and causing frustration”. In Romanian, “burdensome” was rendered as “troublesome”, and “fatigue” was rendered as “extreme tiredness”, as there is no direct translation of these English terms. Russian patients could not understand the direct translation of “avoid” (as in “avoid symptoms of hyperglycaemia”)—this was revised to read “will not have”. Slovenian patients could not understand the translation of “stability” (as in “stability of blood sugar levels”)—this was revised to a word meaning “permanency” or “invariability”. **CONCLUSION:** The ITSQ has been translated and linguistically validated and is now available for use in 18 countries (including 8 Eastern European nations) and in 22 languages. This project has also highlighted the importance of linguistic validation interviews.

PDB76

**TREATMENT SATISFACTION IS POSITIVELY ASSOCIATED WITH GLYCEMIC CONTROL AND NEGATIVELY ASSOCIATED WITH PATIENT REPORTED EXPERIENCE OF HYPOGLYCEMIC SYMPTOMS AMONG PATIENTS WITH TYPE-2 DIABETES MELLITUS (T2DM) ON ORAL ANTI-HYPERGLYCEMIC AGENTS (OHA) IN EUROPE**

Alvarez-Guisasaola F<sup>1</sup>, Tinahones FJ<sup>2</sup>, Pfeiffer A<sup>3</sup>, Krishnarajah G<sup>4</sup>, Yin D<sup>5</sup>, Lyu R<sup>5</sup>, Mavros P<sup>5</sup>

<sup>1</sup>Centro de Salud La Calzada II, Gijón, Spain, <sup>2</sup>H.C.U. Virgen de la Victoria, Malaga, Malaga, Spain, <sup>3</sup>Charite University Medical School Berlin, Berlin, Germany, <sup>4</sup>Merck & Co, Whitehouse Station, NJ, USA, <sup>5</sup>Merck & Co., Inc, Whitehouse Station, NJ, USA

**OBJECTIVES:** To assess whether treatment satisfaction is associated with effectiveness of OHA and with the experience of hypoglycemic symptoms among patients with T2DM who added sulfonylureas (SU) or glitazone (PPAR) to metformin (MF). **METHODS:** A retrospective clinical chart review and patient survey (June 2006–February 2007) was conducted in 7 countries (Finland, France, Germany, Norway, Poland, Spain, UK). Patients recruited (aged 30 years at T2DM diagnosis) added SU or PPAR $\alpha$ -agonist to previous MF. Patients with gestational diabetes and those using insulin were excluded. The Treatment Satisfaction Questionnaire for Medication (TSQM), a 14-item grouped in 4 domains validated instrument, was used to measure patients’ treatment satisfaction with current OHA. Adequate glycemic control was defined according to the IDF-2005 recommendations as A1C < 6.5%. Unadjusted differences in treatment satisfaction by experience of hypoglycemia and glycemic control was assessed using the chi-square test. **RESULTS:** 1709 patients were included. Average age was 63 (SD = 11) years and 45% were female. The mean A1C level was 7.1% (SD = 1.1), while 28% (477 patients) had adequate glycemic control. 652 (38%) reported hypoglycemic symptoms of varying severity and frequency. Relative to those reporting experience of hypoglycemic symptoms, patients not experiencing hypoglycemic symptoms report higher scores on all domains of TSQM: effectiveness (71.5

vs. 67.8), side effect (91.9 vs. 81.4), convenience (77.0 vs. 73.4), and global satisfaction (76.3 vs. 71.6) (all  $p < 0.0001$ ). Treatment satisfaction with therapy was higher for patients with adequate glycemic control than for those without, for all TSQM domains: effectiveness (71.3 vs. 69.6;  $p = 0.08$ ), side effect (89.5 vs. 87.1;  $p = 0.0339$ ), and convenience (76.9 vs. 75.0;  $p = 0.14$ ) and global satisfaction ((75.8 vs. 74.0;  $p = 0.0436$ ). **CONCLUSION:** Twenty-eight percent of patients had A1C < 6.5% while 38% experienced hypoglycemic symptoms. Patient-reported experience of hypoglycemia is associated with statistically significant lower treatment satisfaction. Global satisfaction with treatment is statistically significantly higher among patients with adequate treatment control.

PDB77

**BARRIERS TO INSULIN THERAPY QUESTIONNAIRE: HOW TO USE THE “BIT” IN DAILY PRACTICE AND SCIENCE?**

Stridde E, Leverkus F

Pfizer Pharma GmbH, Karlsruhe, Germany

**OBJECTIVES:** Patients with Type 2 Diabetes (T2D) not well controlled with oral antidiabetic drugs (OAD) often postpone the start of insulin therapy (IT). The reasons of this so called “psychological insulin resistance” are multifaceted. We have developed and validated a simple tool to identify “barriers to insulin” the “BIT” questionnaire. **METHODS:** Scale development was based on principle component analysis in two cross-sectional studies in insulin naïve patients with T2D (first sample  $n = 448$ ; cross-validated in an independent sample of 449 patients). **RESULTS:** Analysis in the first sample yielded 5 components that accounts 74.7% of the variance based on 14 items and 69.4% in the second sample. Confirmatory factor analysis indicated a good model fit with RMSEA = 0.04 and CFI = 0.97. The 5 components are: Expectation regarding insulin-related outcome; fear of injection and blood glucose self testing; expected hardship from IT; stigmatization by IT; fear of hypoglycaemia. In daily practice conditions the questionnaire can be used to identify BIT in general by focusing on the “sum score. In addition physicians and diabetes educators can go more in detail when analysing the results of the 5 components, separately. So objections against IT can be discussed in total or physicians/educators can focus on “specific barriers”. The “BIT” can also be used to investigate scientific questions regarding “psychological insulin resistance”. **Scientific view:** We investigated patients with T2D on IT. The result of the BIT differs extremely between patients having good/worse glycemic control. **CONCLUSION:** The “BIT” is the first valid and reliable instrument to measure “psychological insulin resistance” in patients with T2D. Patients with T2D need 2–3 minutes to fill the BIT. The results should be discussed with the patients. Established barriers could be broken down systematically. This could reduce the individual workload. In addition the BIT is a valid tool to use in research.

PDB78

**COMPARISONS BETWEEN ITEQ AND DTSQ IN A SAMPLE OF TYPE 2 DIABETES MELLITUS PATIENTS**

Moock J, Kubiak T, Dingler D, Kohlmann T

University of Greifswald, Greifswald, Germany

**OBJECTIVES:** Treatment satisfaction (TS) is a key outcome criterion of diabetes therapy. Existing instruments mainly address general aspects of TS. In contrast the new Insulin Treatment Experience Questionnaire (ITEQ) was developed in German language to assess subtle but relevant effects of TS in a wide range of insulin therapy regimens (e.g. BOT, intensified insulin therapy with or without insulin analogues) focusing on T2DM patients.