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EMPIRIC PSYCHOLOGICAL TYPING OF PATIENTS WITH TYPE 2 DIABETES MELLITUS TREATED ORALLY, AND CORRESPONDING GLYCAEMIC CONTROL/RESULTS FROM THE SETT2D SURVEY

Stridde E, Leverkus F

Pfizer Pharma GmbH, Karlsruhe, Germany

OBJECTIVES: People with T2D insufficiently controlled on oral antidiabetic drugs often delay the start of sc insulin (SCI) treatment for different reasons. This cross-sectional prospective survey (EC approved) aimed at investigating whether these patients have different levels of acceptance regarding SCI. **METHODS:** Basic data (age, gender, duration of DM, BMI; HbA1c, HOMA index), social status were recorded. Aversions to SCI were investigated by using the Barriers to Insulin Questionnaire (BIT) which covers 5 dimensions using 14 questions. The first 3 principal components of the 5 BIT domains were analyzed with Ward's Minimum Variance Clustering Algorithm. The number of clusters were determined with Pseudo T Statistic, CC Criteria and judgment. The BIT domains were Z standardized and tabulated against the cluster. T-values between -2 and 2 are reported as 0; low or high t-values between -5 and -2 or 2 and 5 as '-' and '+', respectively; very low or very high t-values below -5 or greater than 5 are reported as '+ +' and '- -'. The association between the clusters and certain medical and sociodemographic variables was analyzed exploratively with the Chi sq test for nominal/ordinal variables and Kruskal-Wallis test for continuous variables. **RESULTS:** 532 patients were eligible for analysis (male 354/age 56.5 ± 8.8/duration of diabetes 6.7 ± 6.1/BMI 32.5 ± 6.6/HbA1c 8.3 ± 1.5); 5 clusters were found. In cluster 1 we find patients having positive expectations regarding SCI but fear of burden with insulin treatment and hypoglycemia. Cluster 2 patients had no barriers. Cluster 3 patients are similar to cluster 2, but have some fear of hypoglycemia. Type 4 patients have strong barriers concerning insulin injection, fear of stigmatization and hypoglycemia. Negative expectations are characteristic for the patients in cluster 5. **CONCLUSION:** The BIT results have a major impact on the definition of the clusters; educational level has an impact as well. The patients did not differ in their glycaemic control.

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PSYCHOMETRIC EVALUATION OF THE DIABETES SYMPTOM CHECKLIST- REVISED (DSC-R): FACE, CONTENT AND CONSTRUCT VALIDITY

Humphrey L¹, Vardeva K², Arbuckle R¹, Viala M³, Scott J⁴, Snoek FJ⁵

¹Mapi Values Ltd, Bollington, Cheshire, UK, ²Global Health Outcomes, Greenford, Middlesex, UK, ³Mapi Values France, Lyon, France, ⁴Mapi Values Ltd, Boston, MA, USA, ⁵VU University Medical Centre, Amsterdam, The Netherlands

OBJECTIVES: To test face, content and psychometric validity of the DSC-R, a widely-used patient reported outcome (PRO) measure of diabetes symptom distress, in line with FDA Guidance. **METHODS:** Face and content validity of the DSC-R was evaluated according to draft FDA guidance. Interviews with 20 US patients with Type-2 Diabetes Mellitus were conducted to assess the comprehensibility and acceptability of the English language DSC-R version. Patients were asked open-ended questions about their diabetes symptoms and symptom-bother before cognitive debriefing. Psychometric validity of the DSC-R was assessed using blinded data from 2 large scale trials of approximately 4000 patients each. **RESULTS:** All symptoms spontaneously reported by patients are included in the DSC-R. Upon probing, patients reported experiencing symptoms of itchy skin, increased hunger, sweats and gender-specific sexual symptoms

not directly included in the DSC-R. Patients found all DSC-R questions easy to understand and answer, with the exception of "dull head" and "frequent voiding". Both items had been inaccurately reworded when translated from Dutch to English. These have been corrected through subsequent linguistic validation. Patients generally understood the instructions and response options. Patients used various recall periods to answer the DSC-R other than the 4 weeks specified. Confirmatory factor analysis and multi-trait analysis indicated that the scoring of the DSC-R has strong construct validity and reliability. DSC-R domains discriminated among patients who differed according to body mass index ($p < 0.0001$) and C-reactive protein levels ($p < 0.0001$). **CONCLUSION:** The DSC-R items are regarded relevant and easily understood by patients. Revision of the recall period may be considered, in view of FDA Guidance. DSC-R demonstrated excellent psychometric properties when tested in two large-scale diabetes clinical trials.

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EFFECTS OF AN INTENSIFIED THERAPY WITH INSULIN GLARGINE AND INSULINE GLULISINE ON PATIENT REPORTED OUTCOMES IN DIABETES MELLITUS

Daikeler R¹, Hoegy B²

¹Specialist in Internal Medicine, Diabetologist, Sinsheim, Germany,

²Sanofi-Aventis Germany GmbH, Bad Soden, Germany

OBJECTIVES: Intensive conventional insulin therapy (ICT) is to be considered as the gold standard for treatment of type 1 and type 2 diabetes mellitus. However, conventional insulin preparations do not always result in a sufficient outcome. An observational study was conducted to assess efficacy, tolerability, quality of life and treatment satisfaction of patients with type-1 and type-2 diabetes over a period of 6 month. **METHODS:** A total of 1447 type-1 and 5695 type-2 diabetes patients with different prior insulin treatments were switched to a combination of insulin analogues insulin glargine and insulin glulisine. Clinical efficacy and safety was evaluated by blood glucose and HbA1c values and by incidence of adverse events. Patient reported outcomes (PRO) were measured with a visual analogue scale (VAS) and the diabetes treatment satisfaction questionnaire (DTSQs). Six categories of quality of life were evaluated from physician's perspective by means of 5-stepped Likert-Scale. **RESULTS:** Mean blood sugar values and HbA1C value significantly decrease during the observational period in both patient groups. Total scores for quality of life were improved about 30% in mean for diabetes type 1 and about 32% in mean for diabetes type 2, respectively. VAS-scores (0 to 100) improved from 41.9 ± 22.0 to 19.6 ± 14.1 for diabetes type 1 and from 49.6 ± 20.9 to 22.8 ± 16.0 for diabetes type 2, respectively. DTSQs total scores increased from 20.7 ± 6.7 to 29.3 ± 5.1 and from 19.1 ± 6.6 to 28.4 ± 5.2, respectively ($p < 0.0001$ for all differences). **CONCLUSION:** Basal-bolus therapy with a combination of insulin glargine and insulinglulisine improved treatment satisfaction and quality of life in accordance with clinical efficacy in patients with type 1 and type 2 diabetes pretreated with ICT. The analysis was funded by Sanofi aventis Germany.

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THE TRANSLATION AND LINGUISTIC VALIDATION OF THE INSULIN TREATMENT SATISFACTION QUESTIONNAIRE (ITSQ) FOR USE IN EASTERN EUROPE

Ellis G¹, Wild D¹, Christensen T²

¹Oxford Outcomes Ltd, Oxford, UK, ²Novo Nordisk A/S, Bagsvaerd, Denmark

OBJECTIVES: The objective of the study was to translate and linguistically validate the Insulin Treatment Satisfaction Ques-