initiation/intensification in patients uncontrolled on their current therapy. RESULTS: The median time to intensification of insulin regimen for T1 patients uncontrolled on premix regimens, was 4.0 years (95% CI 3.2 to 5.4). The median time to initiation of insulin for T2 patients, prescribed two or more oral agents, with evidence of poor glycaemic control was 7.0 years (95% CI 6.5 to 7.7). Finally, the median time to intensification of the insulin regimen was 4.2 years (95% CI 3.5 to 6.1) for T2 patients uncontrolled on a basal regimen and >8 years for those uncontrolled on a premix regimen. CONCLUSION: In spite of poor glycaemic control, insulin-naive and insulin-treated patients fail to initiate/intensify insulin therapy for many years. Earlier initiation/intensification of insulin therapy is likely to lead to better control and a reduction in the complications associated with diabetes. Barriers to insulin use must be overcome if patients are to achieve appropriate control.

PDB35

COST-EFFECTIVENESS OF INHALED INSULIN IN PATIENTS WITH DIABETES UNCONTROLLED ON THEIR CURRENT THERAPY: THE UK BASE CASE SUBMITTED TO THE NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE)

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OBJECTIVES: As part of the submission to NICE, we evaluated the cost-effectiveness of inhaled insulin (INH) in patients with type 1 diabetes uncontrolled on a premix regimen (T1), and patients with type 2 diabetes uncontrolled on oral anti-diabetic drugs (T2).

METHODS: Using the perspective of the National Health Service (NHS), a validated Markov model (EAGLE) was used to estimate the incremental costs and QALYs gained of: 1) a basal bolus regimen involving INH versus an injected basal bolus regimen in T1; and 2) a bolus of INH versus i) an injected basal regimen and ii) an injected premix regimen in T2. The model simulates the progression of diabetes in 1000 patients over a time frame of 20 years. A large UK dataset was used to document the patients' clinical characteristics. NHS reference costs were used as a source for medical costs. Utility/disutility data were collected in published studies and clinical trial data were used to document the efficacy of therapies. An annual 3.5% discount rate was used for both costs and outcomes. Probabilistic sensitivity analysis was performed. RESULTS: In T1 the total incremental costs (IC) were £202,746 and the total QALYs gained (IE) were 24, leading to a mean incremental cost-effectiveness ratio (ICER) of £8510/QALY. In T2, the mean ICER versus basal was £24,285/QALY with IC of £497,749 and IE of 21. The mean ICER versus premix was £24,555/QALY with IC of £503,185 and IE of 21. The probabilistic sensitivity analysis showed that for a willingness to pay of £30,000 per QALY gained, INH was cost-effective in 100% of the T1 simulations and in 92 to 95% of T2 simulations. CONCLUSION: INH was cost-effective therapy for T1 and T2 patients uncontrolled on their current therapy in the UK setting.

PDB36

THE TRANSLATION AND LINGUISTIC VALIDATION OF THE SATISFACTION WITH ORAL ANTI-DIABETIC AGENTS (SOADA) QUESTIONNAIRE

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OBJECTIVES: The objective of the study was to translate and linguistically validate the Satisfaction with Oral Anti-Diabetic Agents (SOADA) questionnaire for use in 11 countries. The questionnaire was developed in the United States in 2005 in order to assess satisfaction with oral anti-diabetic medication in patients with type 2 diabetes. METHODS: The accepted standard methodology was used: 2 forward translations, reconciliation, 2 back translations, back translation review, developer review, harmonisation meeting, linguistic validation interviews with 5 or 6 patients with type 2 diabetes and 2 proof readings. A universal approach was used for French and Spanish with the aim of developing a single Spanish and a single French version. RESULTS: While the majority of wording was easily agreed upon, certain words and phrases were more troublesome. Issues and solutions included: The first French suggestion, “médication,” did not take into account the possibility of more than one medication. The final agreement was on “médicament(s).” “Extremely [satisfied]” cannot be translated literally in Mexico as it is too formal. “Muy satisfecho” was selected as the best alternative for Mexico and Spain. “How quickly” was misunderstood in pilot testing in Korea so this was changed to a more idiomatic “the ‘fastness’.” “Tolerabilidad,” the original Spanish translation, was found to be problematic during cognitive debriefing interviews and a simpler alternative was found. The universal approach produced a single final version for French and Canadian French and very similar final translations for Spanish (for Spain) and Mexican Spanish. CONCLUSIONS: The SOADA has been translated and linguistically validated and is now available for use in 11 countries. The universal approach used for Spanish and French was successful. A number of cultural and linguistic issues became apparent and were resolved. The measure is now appropriate for use in multinational trials.

PDB37

SCORING AND PSYCHOMETRIC VALIDATION OF A SCALE FOR DIABETIC PATIENT PROFILING BASED ON PATIENT ATTITUDE TOWARDS INSULIN

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OBJECTIVES: Two patient self-report questionnaires were developed for use by physicians. They were intended to assess why diabetic patients were reluctant to switch their treatment from oral hypoglycaemic agents to insulin or to step up their insulin dosage when already treated with insulin. This study presents scores and psychometric validation for both questionnaires. METHODS: Patients treated with oral hypoglycaemic agents (n = 1382) and patients already treated with insulin (n = 1296) completed the questionnaire at baseline, Month 3 and Month 6. Psychometric properties were assessed: 1) structural analysis by Principal Component Analysis (PCA) with varimax rotation; 2) internal consistency reliability determination (Cronbach’s alpha); and 3) concurrent validation (Spearman correlation coefficients with the Fear of Self-Injecting (FSI) score of the Diabetes Fear of Injecting and Self-testing Questionnaire [D-FISQ]). The ability of scores to predict the switch to an insulin treatment and increased numbers of injections at the end of baseline visit was established by calculating the Area Under the ROC Curve (AUC). RESULTS: PCA analysis confirmed the final questionnaire structure of 14 items grouped into 3 dimensions (Acceptance/Motivation [AM], Insulin treatment: fear and constraints [FC], and Reluctance to be injected [RI]). Internal consistency reliability (Cronbach’s alpha ranging from 0.74 to 0.82) and concurrent validity (FIS...