the choice and consumption of brand name and generic OHAs for each outpatient visit in the Defined Daily Dose. RESULTS: The regression results suggested a positive relationship between the reimbursement price and probability of prescribing brand name OHAs (odds ratio: 1.37, 95% CI: 1.36–1.37). The lower reimbursement price likely results in the lower consumption of both brand name (1.23; p < 0.01) and generic (0.93; p < 0.01) OHAs. The price elasticity of brand name OHAs is greater than that of generics OHAs. Large scale and private hospitals tend to prescribe generic OHAs, and those with higher accreditation level are inclined to prescribe brand name OHAs. CONCLUSION: The NHI price regulation generates the profit margin between reimbursement price and acquisition cost. Reducing the reimbursement price may squeeze the profit margin from brand name drugs, likely resulting in decreasing the probability of prescribing brand name drugs. The consumption of brand name drugs tends to be more sensitive to price adjustment than that of generic counterparts.

PDB32
AMPUTATIONS IN DIABETIC FOOT ULCER PATIENTS USING NPWT
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OBJECTIVES: This study aims to investigate the relative risk reduction (RRR) and number-needed-to-treat (NNT) estimates related to lower limb amputation events among patients with diabetic foot ulcer wounds using Negative Pressure Wound Therapy (V.A.C.® Therapy) compared to a similar patient population receiving other wound care treatments. METHODS: RRR and NNT estimates with NPWT in relation to an amputation event were evaluated using three distinct data sources. Two retrospective administrative databases of diabetic ulcer patients, including a commercial and a Medicare (CMS) population, as well as RCT data for diabetic foot wound patients were evaluated. RRR and NNT for lower limb amputation events were calculated and compared between groups in each of the three populations. RESULTS: The commercial data yielded over 3500 patients, the Medicare data included over 12,700 patients, and the RCT included 162 patients. The RRR in amputation occurrence with NPWT vs. the control group was 34% for the commercial patient group and 35% for the Medicare patient group. The RRR was found to be even greater in the RCT group where NPWT was associated with over a 70% reduction in the risk of an amputation event. The NNT to prevent one amputation event with NPWT therapy was 14 for the commercial patient group, 18 for the Medicare patient group and 13 for the RCT group. Target NNTs in the range of 12–35 have been reported for preventing a subsequent adverse event. CONCLUSIONS: Using three different sources, this study is the first to evaluate the effectiveness of NPWT therapy by reporting calculated RRR and NNT related to lower limb amputations. The NNT to prevent an amputation event with NPWT therapy was consistent and low, ranging from 13 to 18. This data suggests that NPWT therapy is an effective intervention in reducing risk of amputation events in diabetic ulcer patients.

PDB33
THE EFFICACY OF INSULIN GLARGINE COMPARED TO OTHER INJECTABLE THERAPIES—A META-ANALYSIS OF CLINICAL OUTCOMES IN INSULIN NAIVE TYPE 2 DIABETES PATIENTS
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OBJECTIVES: Achieving therapeutic goals in Type 2 diabetes often becomes more difficult as the disease progresses; many patients eventually require treatment beyond oral hypoglycaemic agents (OHA). The objective of this meta-analysis was to investigate which injectable therapies were either superior/inferior to bedtime-administered insulin glargine, (glargine) for key clinical outcomes. METHODS: A systematic review of all published glargine clinical trials (prior to October 2005) was conducted. Based on pre-defined inclusion criteria, the review encompassed all randomised controlled trials of at least eight-weeks duration that compared combination therapies (injectable therapy and OHA(s)), in insulin naive patients. A random effects model was employed to incorporate the variability in between-study conditions. RESULTS: Seven trials met the specified criteria, with glargine chosen as the reference regimen. Although biphasic insulin aspart (BIA) and insulin lispro 75/25 were more efficacious than glargine at reducing HbA1c in (unadjusted (adjusted) analyses further reductions of −0.46 % (−0.41) and −0.39 % (−0.40) respectively were observed), this increase in efficacy was also associated with relative increases in the risk of experiencing hypoglycaemic events for both insulins and increased weight gain for BIA. Compared to glargine, exenatide and NPH were equally as efficacious at reducing HbA1c, although patients taking exenatide also benefited from weight reduction and a reduced risk of experiencing a nocturnal hypoglycaemic event. With respect to fasting blood glucose, exenatide, insulin lispro 75/25 and NPH were less efficacious than glargine. CONCLUSIONS: This meta-analysis found a slight increase in efficacy observed with the two twice-daily insulin regimens compared to glargine; however this result must be carefully balanced against the observed increase in adverse events, especially for patients where weight gain or hypoglycaemic events may be an issue. When glargine was compared to exenatide, similar HbA1c reduction was found but exenatide treated patients had fewer nocturnal hypoglycaemic events and experienced weight loss.

PDB34
A POPULATION-BASED STUDY OF THE TIME TO INSULIN INITIATION/INTENSIFICATION AFTER FAILURE ON CURRENT THERAPY IN PATIENTS WITH TYPE 1 AND TYPE 2 DIABETES IN THE UK
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OBJECTIVE: To determine the time that patients with type 1 and type 2 diabetes remain on their existing therapy whilst uncontrolled, before starting insulin or intensifying their insulin regimen. METHODS: A retrospective cohort study was conducted among subjects with type 1 and type 2 diabetes. A total of 154 clinical practices with continuous data over a 10-year period from 1st May 1995 until 30th April 2005 were included in this analysis. The study identified 9979 individuals with type 1 diabetes (T1) and 62,533 individuals with type 2 diabetes (T2). Four patient groups were analysed: T1 on premix regimens; T2 prescribed ≥2 orals; T2 on basal regimen and T2 on premix regimens. The main study outcome was the median time to insulin
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-naïve 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: i) 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 is a 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, “medication,” did not take into account the possibility of more than one medication. The final agreement was on “medicament(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.