

given the increase in medicines, especially injectables, coming to market in the future.

PDB71

ASSOCIATION OF BLOOD GLUCOSE CONTROL WITH HEALTH-RELATED QUALITY-OF-LIFE UTILITY FOR TYPE-1 DIABETES PHARMACOECONOMIC MODELS

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OBJECTIVES: Pharmacoeconomic models in diabetes link blood glucose control as measured by hemoglobin A1c to diabetes-related complications. Despite advances in diabetes modeling, there is limited research on the relationship between A1c and health-related quality of life (HRQoL) that is independent of diabetes-related complications. Our objective was to quantify the cross-sectional relationship between A1c and HRQoL utility scores in adult type-1 diabetes (T1D) patients, after adjusting for diabetes-related complications. **METHODS:** The EuroQoL-5 dimensions (EQ-5D) questionnaire was administered to adult T1D patients during one clinic visit at the University of Colorado Barbara Davis Center for Diabetes (BDC) from November 2011 – July 2012. We combined individual-level data from the EQ-5D questionnaire with A1c data from the BDC medical record. Utility scores were derived using the US time-tradeoff valuation of the EQ-5D. Unadjusted mean utility scores were estimated for the overall population and stratified by A1c. We used ordinary least squares regression with robust standard errors to estimate the cross-sectional relationship between A1c and utility, adjusting for demographic variables and diabetes-related complications. **RESULTS:** Mean (SD) age in years for the population (N = 176) was 38 (12.2); duration of diabetes in years was 22 (12.1); and number of chronic conditions other than diabetes was 2.7 (2.0). Unadjusted mean (SD) utility was 0.94 (0.09) for those with A1c levels < 7% (n = 54); 0.89 (0.15) for those with A1c ≥ 7% (n = 122); and 0.91 (0.14) for all patients. On average, a 1% absolute increase in A1c was associated with a significant disutility of -0.03 (95% CI: -0.06, -0.006), after adjustment. **CONCLUSIONS:** Findings suggest that after adjusting for diabetes-related complications, poor blood glucose control is associated with decrements in utility not currently captured in existing diabetes pharmacoeconomic models. Longitudinal research is needed to strengthen this cross-sectional evidence on the relationship between A1c and HRQoL utility.

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ASSESSING HEALTH RELATED QUALITY OF LIFE IN PERSONS WITH DIABETES: VARIATIONS AMONG SIX GENERIC INDEXES

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OBJECTIVES: Generic health measures are routinely used to assess HRQoL in population studies of persons with diabetes and other chronic illness. It is not known whether these measures provide consistent results in assessing HRQoL in patients with diabetes or whether these measures are able to discriminate between the HRQoL of persons with and without diabetes and across levels of diabetes severity. To compare HRQoL differences across levels of diabetes severity using six generic indexes and to examine the generic indexes ability to discriminate between the HRQoL levels across diabetes severity. **METHODS:** The National Health Measurement Study is a population-based, cross-sectional survey of 3844 non-institutionalized adults in the United States. Participants completed six generic measures of HRQoL—EQ-5D, HUI2, HUI3, QWB-SA, SF-36v2 (yielding PCS, MCS, and SF-6D), and HALex. Diabetes severity was classified as non-diabetic, diabetes without medication, diabetes with medication, and diabetes with insulin. Weighted mean difference scores between each diabetes category adjusted for age, sex, and gender were calculated for each index. Effect sizes were calculated for each index between each diabetes group by standardizing to the population standard deviation among those without diabetes. **RESULTS:** A total of 726 (19%, unweighted) individuals self-reported diabetes. Across all indexes persons with diabetes demonstrated statistically significantly lower unadjusted and adjusted HRQoL scores than those without diabetes (p < 0.001). The HALex had the highest effect sizes for all comparisons between diabetes categories (ranging from 0.16 through 1.30), followed by the SF-36v2 PCS (ranging from 0.24 through 0.98), and the SF-36v2 MCS (ranging from 0.06 through 0.57). **CONCLUSIONS:** Results demonstrate the ability for generic HRQoL indexes to differentiate between persons with and without self-reported diabetes. The HALex was consistently better at differentiating among diabetes severity as. This study indicates that generic indexes are useful for evaluating HRQoL even in a diabetes-specific context.

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THE EXPECTED VALUE OF BIO-ARTIFICIAL PANCREAS DEVELOPMENT IN VIEW OF ENDOCRINOLOGISTS' AND PATIENTS' PREFERENCES

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OBJECTIVES: Islet transplantation is an accepted transplantation method in type 1 Diabetes Mellitus, yet islet survival is hampered due to an insufficient transplantation site and severe immunological and inflammatory responses. The development of a bio-artificial pancreas (BAP) may contribute to transplanted islet functionality and survival. The objective of this study is to identify the most important transplantation characteristics and to assess patients' and endocrinologists' preferences for three potential BAP scenarios in order to guide further development. **METHODS:** The current standard of care and characteristics that determine clinical decisions for a particular transplantation method were analysed based on a literature search, semi-structured interviews and focus groups. A decision tree was constructed covering the main attributes

effectiveness, patient safety, impact of the treatment for the patient and the required amount of donor material. The analytic hierarchy process was used to obtain the relative weights for each defined attribute in type 1 DM patients (n=21) and endocrinologists (n=12). Based on these weights, overall preferences for three potential BAP scenarios were calculated and compared to conventional pancreas and islets transplantation. **RESULTS:** The three most important treatment attributes are the effectiveness of the transplant for glucose control, patient safety and the surgical procedure. However, there were considerable differences between patients and endocrinologists in the importance of effectiveness of the transplant (weights were 0.471 and 0.257 respectively) and patient safety (0.331 and 0.423). While considering both endocrinologists' and patients' preferences, all three BAP scenarios assessed gained a higher overall preference in comparison to conventional islet transplantation. **CONCLUSIONS:** This study indicates the prospects of BAP development. Nevertheless, the study also highlights the discrepancies between endocrinologists' and type 1 diabetes patients' preferences. In the future, BAP developers can benefit from this multidisciplinary approach by critically reviewing their BAP design, in view of patient safety and clinical performance.

PDB74

PATIENT PREFERENCES FOR THE TREATMENT OF TYPE-2 DIABETES: A SCOPING REVIEW AND ASSESSMENT OF METHODS

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OBJECTIVES: Patient-centered outcomes research (PCOR) aims to incorporate patient preference into the evaluation of competing therapies. We sought to identify and categorize methods used to assess patient preferences in the literature, focusing on medication preference of adults with type-2 diabetes. **METHODS:** Studies of patient preferences for type-2 diabetes medications were identified from the PubMed, EMBASE, CINAHL and EconLit databases using a registered study protocol (CRD42012002285) and aided by the PRISMA guidelines. Studies were included if they presented data on the preferences of adults with type-2 diabetes and excluded if they had no primary data on preference, focused only on behavioral change or on treatments for complications or co-morbid conditions. Two investigators reviewed titles, abstracts, and articles sequentially to select studies based on the inclusion and exclusion criteria. Disagreements were resolved by consensus. Data were abstracted into standardized forms and summary statistics were calculated. **RESULTS:** In total, 1883 unique papers were identified, of which 57 published between 1985 and 2011 met the selection criteria. Of these, 40% could be categorized as being primarily focused on preferences, using systematic methods such as conjoint analysis (n=10), contingent valuation (n=1), qualitative research (n=1), revealed preference (n=5), standard gamble (n=2), and time trade-off (n=6). The remaining 35 papers had preference data as a secondary aim, asking patients about their preferences and/or willingness to continue using or recommend products studied in a clinical trial. **CONCLUSIONS:** While an extensive literature focused on medication preferences of patients with type-2 diabetes can be identified, evidence synthesis is hindered by the diverse range of methods, including a majority of papers that assess preferences in an unsystematic way. Further research is needed to compare results of different methods and to assess the quality of preference studies.

PDB75

PATIENT-REPORTED SEVERE HYPOGLYCEMIC EVENT RATE IN NATIONAL HEALTH AND WELLNESS SURVEY

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OBJECTIVES: Severe hypoglycemic events are serious yet underreported condition that may lead to morbidity and even mortality. These events are an important limiting factor to good glycemic control. The objective of this study was to determine self-reported severe hypoglycemic rate in T2DM, basal insulin users in the National Health and Wellness Survey (NHWS) US population. **METHODS:** NHWS is a large international self-reported, real-world, patient-level survey which collects information on metrics such as patients' demographics, behaviors and attitudes towards diseases in over 165 therapeutic conditions. We used an extract from the 2010 NHWS dataset composed of T2DM patients who were taking basal insulin monotherapy or in combination with oral anti-diabetic medications (OAD). The respondents (n=425) recalled number of severe hypoglycemic events they had in the last 4 weeks and 6 months prior to the survey. We analyzed event rates using multiple regression. **RESULTS:** Fifty-one percent of respondents were female and the mean age was 61.6 (SD=10.03). The overall severe hypoglycemia event rate for the 4 week and 6 month recall periods were 0.34 and 0.27 per patient-year, respectively. Among basal insulin only users (n=60), the event rates were 0.43 (6 month recall) and 0.37 (4 week recall) per patient-year. Among basal insulin plus OAD users (n=365), the rates were 0.32 (6 month recall) and 0.26 (4 week recall) per patient-year. The relationship between presence of severe hypoglycemia rates and insulin treatment categories after adjusting for the covariates were non-significant. **CONCLUSIONS:** Basal insulin only users reported higher rates of severe hypoglycemia than basal insulin plus OAD users, but the difference was not statistically significant likely due to small sample size. Recall bias could also contribute to differences between the rates. Overall, our rates were higher than what have been reported in the literature with claims data, suggesting that severe hypoglycemia may be underreported.

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PATIENT-REPORTED OUTCOMES (PROS) IN ANTIDIABETIC PRODUCT APPROVALS IN EUROPE AND IN THE USA