and TS. T1DM and T2DM-n.i reported better values of HRQoL and T2DM-n.i better TS.

PDB50

CONCEPTUAL DEVELOPMENT OF A PATIENT SELF-ASSESSMENT TOOL TO IMPROVE PATIENT-CLINICIAN COMMUNICATION ON THE DAILY MANAGEMENT OF TYPE 2 DIABETES

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OBJECTIVES: Patients play a major role in the management of type 2 diabetes since this depends not only on medication but also on behavioural modifications in areas such as nutrition, physical activities and weight loss. Therefore, patients' understanding of the disease and its management are particularly important to ensure high compliance and reduce risk of late complications. The aim of this project was to develop a tool for clinical practice to 1) renew patient-clinician communication on type 2 diabetes management; 2) reinforce patients' motivation by rectifying or perfecting their knowledge; and 3) agree achievable micro-objectives between patients and clinicians. **METHODS:** Face-to-face semi-structured interviews were conducted with 10 adult type 2 diabetes patients by a psychologist in parallel with interviews with 5 general practitioners, involved in the management of type 2 diabetic patients. All interviews were recorded and transcribed, in order to analyse the content and organise it by domains. Based on these findings and on feedback from experts, a first version of the tool was developed. This was tested using a cognitive interview method with 5 type 2 diabetics, to assess the clarity, comprehension, and relevance of each item as well as the overall acceptability of the tool. **RESULTS:** Five major domains were identified as playing a role in type 2 diabetes disease management: physical activities, treatment, nutrition, knowledge of the disease and knowledge of glycaemia issues. A specific module was developed around each of the 5 domains, drafting items using patients' verbatim expressions. The tool allows patients to describe their beliefs, attitudes and priorities. The tool was revised after the patient tests. **CONCLUSIONS:** This tool should enhance patient-clinician communication on diabetes management. By revealing patients' beliefs, identifying their goals, triggering positive changes, this tool could help clinicians with the therapeutic education of patients. It will be tested in a specific validation study.

PDB51

UNDERSTANDING AND ASSESSING THE IMPACT OF DIABETES TREATMENT ACROSS MEDICATION DELIVERY SYSTEMS

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OBJECTIVES: Diabetes is a common, debilitating chronic illness with multiple impacts on patients' lives. Critical to understanding these impacts is the effect of the treatment delivery system. In diabetes multiple systems are available; however, a patient reported outcomes (PRO) measure assessing impacts appropriate for all systems is not available. As a result, impacts can't be compared across treatments and clinical decisions targeting treatments to patient needs is hampered. A well developed PRO measure appropriate across delivery systems is critical for future research. The purpose of the study was to understand the full spectrum of PRO issues and develop a measure of these impacts across all delivery systems. **METHODS:** Qualitative data was collected from literature, experts and patients and transcripts thematically coded. Additionally, validation findings from four previously developed diabetes PRO measures (ITSQ, Diab-MedSat, Diabetes Productivity, Diabetes Symptom) were examined for relevance. Based on a synthesis of all information, a conceptual model of the impact of treatment applicable to all delivery systems was developed and a PRO measure generated. **RESULTS:** A total of 143 patients in three countries (US, UK, Australia) treated with the full range of treatment options (oral, syringe, pen, inhaled, pump) were interviewed regarding the impact of diabetes treatment on functioning, well-being and health. Regardless of delivery system, common impacts of diabetes treatment were identified: psychological health, daily life interference (home/work), treatment burden, device satisfaction, perceived efficacy and side effects. Key modifiers to this impact (i.e., treatment history, occupation, activity level) and consequences (i.e., compliance, poor productivity) were also identified. Based on the conceptual model, a PRO impact measure (TRIM-Diabetes) was generated with six discrete domains. **CONCLUSIONS:** The instrument development process, the full conceptual model, and discussion of clinical implications will be presented. This information should help clinicians identify key PRO issues for diabetes, facilitate targeted treatments and allow for meaningful measurement of treatment effect regardless of treatment delivery system.

PDB52

A SELF-MANAGEMENT PROFILE FOR PATIENTS WITH TYPE-2 DIABETES

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OBJECTIVES: To develop concepts, domains and items for a patient-reported outcome profile measure that addresses the behaviors, attitudes, and importance of self-managing diabetes in patients with type 2 diabetes. This self-management profile complements traditional clinical outcomes to evaluate how diabetes treatments improve self-management behaviors. **METHODS:** We developed a conceptual model and conceptual framework of patient self-management to support a patient-reported self-management profile. These models incorporate treatment attributes identified through qualitative interviews with patients and the review of the American Diabetes Association (ADA) *2008 Standards of Medical Care in Diabetes*. The profile consists of items measuring patient behaviors, feelings, and attitudes about the importance of managing their blood glucose, medication regimen, weight, eating, exercise, and diabetes-related distress. Qualitative interviews were conducted with patients with Type 2 diabetes managed with combinations of lifestyle, oral and injectable therapy. Subjects were asked to provide information on their most positive and problematic experiences with treatment for their diabetes and their efforts to manage their condition. Qualitative transcripts were coded by like concepts and used with the ADA Standards to generate items and develop the self management profile. Additional patients participated in cognitive interviews to address relevance and clarity of items. **RESULTS:** Patients were enrolled from clinics across the United States. Participants in the concept elicitation interviews (n = 82) were 30–85 years of age (mean = 57.5);

42.7% were female. A 16 item instrument was developed and refined using cognitive interviews (n = 26). The new instrument is currently being evaluated for validity and sensitivity. **CONCLUSIONS:** Patient self-management of type 2 diabetes is a crucial element of successful outcomes in both research studies and clinical practice settings. The Diabetes Self-Management Profile will be useful for measuring the impact of different treatment modalities on patients' ability to manage the multiple aspects of their Type 2 diabetes.

PDB53

VALIDATION OF THE HUMAN GROWTH HORMONE PREFERENCE AND SATISFACTION QUESTIONNAIRE (HGH-PSQ)

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OBJECTIVES: To validate the Human Growth Hormone Preference and Satisfaction Questionnaire (HGH-PSQ), a new instrument for assessing preference for and satisfaction with HGH treatment modalities. **METHODS:** Following IRB approval, the initial instrument was pilot tested at 4 clinical sites specializing in pediatric endocrinology. Clinicians, patients, and parents participated in assessing the properties, overall functionality, and comprehension of the instrument. Eligible patients completing the instrument were children and adolescents 10–18 years old, and were either new or established users of HGH. Face validity, statistical validity, internal reliability, domain intercorrelations, and test-retest reliability were assessed for each domain, as well as for the entire instrument. **RESULTS:** Forty-nine patients and their parents were administered the instrument, with 48 completing the retest. Following structured feedback and statistical analysis, the final instrument was reduced to 27 items in the patient version and 30 items in the parent version, covering 5 domains of affect, non-interference, ease of administration/preparation, pain, and overall satisfaction. Structured development of the instrument with input from clinicians, psychometricians, patients and their families ensured maximum face validity. Variability and distribution in scores supported statistical validity of the instrument. Strong internal reliability was indicated, with Cronbach's alpha of 0.85 and 0.89 for the patient and parent versions, respectively. Intercorrelation coefficients for each domain with the overall instrument score demonstrated convergent and discriminant validity. The instrument also had good overall test-retest reliability, with correlations of 0.80 for patients and 0.73 for parents, with moderate to good coefficients for the individual domains. **CONCLUSIONS:** The HGH-PSQ shows good psychometric properties and appears to be a valid and reliable instrument to evaluate overall treatment satisfaction with and patient preference for HGH delivery devices. Future studies using larger samples of new users with HGH are warranted to examine the sensitivity of the instrument to detect differences among treatments.

PDB54

PSYCHOLOGICAL INSULIN RESISTANCE (PIR): PATIENT AND PHYSICIAN BELIEFS IMPACTING DIABETES MANAGEMENT

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OBJECTIVES: Insulin is a potent drug available to manage diabetes and avoid serious complications and disease progression. Unfortunately, psychological insulin resistance (PIR) is not uncommon and negatively influences both initiation and compliance with insulin treatment. Thus, understanding etiologies of PIR is critical to ensure optimal diabetes management. **METHODS:** Systematic literature review of peer reviewed journals using MEDLINE database including all articles (English) from 1985–2007. The keywords and phrases used for the search included psychological insulin resistance, type 1/2 diabetes, resistance to insulin therapy, insulin side effects/complications, reluctance to treat, treatment refusal, barriers to compliance, switching, racial/ethnic/cultural/gender issues/barriers initiating insulin, patient reluctance, psychological adjustment, needle/injection anxiety/phobia/fear, psycho-social aspects, patient perceptions, acceptance/adherence and patient preference. A total of 106 articles were reviewed. **RESULTS:** Multiple etiologies of PIR were identified including patients' beliefs and knowledge about diabetes/insulin, negative self perceptions and attitudinal barriers, fear of side effects, complications from insulin use, social stigma and lifestyle adaptations required by insulin use. Gender, socio-economics and culture may modify this impact. Additionally, individual or physician beliefs that one cannot comply with treatment or cope with repeated blood tests, fear of hypoglycemia or weight gain and physicians' previous experience with insulin may also contribute to PIR. These etiological influences, both independently and in combination, constitute patients' PIR and may results in compromised glucose control. **CONCLUSIONS:** PIR is complex and multifaceted and plays an important, often ignored role in diabetes management. This presentation will review the full scope of PIR etiologies and discuss treatment implications. Assisting health care professionals to better understanding PIR and tailor insulin treatment modalities accordingly (e.g., with modern insulin analogues associated with less weight gain and less hypoglycemia and/or insulin pen devices), may greatly reduce patients' PIR associated with using human-insulin in vial and syringe.

PDB55

PSYCHOMETRIC STRENGTH OF CURRENT TREATMENT SATISFACTION QUESTIONNAIRES IN NON-INSULIN TREATED TYPE 2 DIABETES

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OBJECTIVES: Approximately 90% of the diabetes population has type 2 diabetes, which has been predicted to become the epidemic of the 21st century. Treatment satisfaction is not only an important patient-reported outcome (PRO) but also a significant predictor of medication adherence, with implications for the prevention of long-term complications, e.g. retinopathy, neuropathy, nephropathy. The FDA has made recommendations regarding the development and use of PRO measures. Our aim was to identify treatment satisfaction questionnaires for use in non-insulin-treated type 2 diabetes and scrutinize their development history and psychometric properties. **METHODS:** We used a PICO (population, intervention, competitor and outcome) strategy to search Scopus from 2000 to present for relevant articles. Key search terms included "type 2 diabet*" and "satisfact*". Following screening, specific searches for instrument names and citation searches were then conducted. **RESULTS:** A total of 2154 abstracts were screened. Four treatment satisfaction instruments were identified as designed for use in non-insulin-treated type 2 diabetes: the Diabetes Treatment Satisfaction Questionnaire (DTSQ), the Diabetes Medication Satisfaction (Diab-MedSat) questionnaire, the Diabetes Tablet Treatment Questionnaire (DTTQ) and the Satisfaction with Oral Anti-Diabetic Agent Scale