RELIABILITY AND VALIDITY OF THE GENERAL DIABETES KNOWLEDGE TEST

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OBJECTIVES: Public health education is a cornerstone in primary prevention of diabetes mellitus (DM). However, valid and reliable tools to evaluate outcomes of DM education among the general public are lacking. We aim to evaluate the reliability and validity of the General Diabetes Knowledge Test (GDKT) for use among subjects with and without DM. METHODS: The GDKT is a 36-item questionnaire (range 0-100) constructed based on existing public DM education materials and covers six content areas: overview, risk factors, symptoms, complications, management and monitoring (for both Type-1 and 2 DM). To achieve wide representation, English-speaking subjects (aged > 21) were recruited by convenience sampling at a public health promotion event. The GDKT was first administered to 54 DM and 42 non-DM subjects. Eighteen subjects voluntarily participated in retest (all were DM). Internal consistency of GDKT was assessed using Kuder-Richardson Formula 20 (KRF20). Item difficulty was assessed by calculating the ratio of number of correct answers to number of respondents, range 0.00 (most difficult) to 1.00 (least difficult) and compared between DM and non-DM subjects using Students’ t-test. Test-retest reliability was assessed using intraclass correlation coefficient (ICC). Construct validity was assessed using a known-group approach where DM subjects were expected to have higher GDKT scores than non-DM subjects. RESULTS: Internal consistency of GDKT was high (KRF20 = 0.9289). Item difficulty ranged from 0.59-0.97 and was significantly different (p < 0.05) between subjects with and without DM for 8 items. Test-retest reliability was moderate (ICC = 0.54, median = 94.4, range = 72.2-100.0, 95% CI: 0.77). Mean scores at first (91.8 ± 9.83) and second (93.3 ± 1.24) administrations were not significantly different (p = 0.38). As expected, DM subjects reported better mean ± SD) GDKT scores (90.8 ± 11.35) compared to non-DM subjects (85.7 ± 20.80) although the difference was not statistically significant (p = 0.13). CONCLUSION: The internal consistency and construct validity of the GDKT was demonstrated in this study.

HEALTH ECONOMIC COMPARISON OF INSULIN ASPART, A FAST-ACTING INSULIN ANALOG, VERSUS HUMAN INSULIN AS MEALTIME INSULIN IN THE TREATMENT OF TYPE-I DIABETES IN AUSTRIAN, DANISH, DUTCH, FINNISH, GERMAN, NORWEGIAN, SPANISH AND SWEDISH SETTINGS

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OBJECTIVES: The aim of this study was evaluate the long-term costs and clinical outcomes of using either insulin aspart or human insulin (HI) at mealtimes in patients with type-1 diabetes, based on the clinical findings of a multicentre, randomized, open-label comparative trial in 882 patients, which showed that mean (±SEM) HbA1c was lower after 12 months with insulin aspart than with HI (7.78 ± 0.03 versus 7.93 ± 0.05, P = 0.005). METHODS: Long-term clinical and cost outcomes were estimated using the CORE Diabetes Model, a peer-reviewed, validated model that employs standard Markov/Monte Carlo simulation techniques to describe the incidence and progression of diabetes-related complications. Transition probabilities were derived from major clinical studies. Published country-specific costs, health care resource utilization, clinical data and recommended discount rates were used. A lifetime horizon and third party payer perspective was taken (direct costs only). Extensive sensitivity analyses were performed. RESULTS: Discounted quality-adjusted life expectancy (QALE) was improved by 0.08 to 0.22 years with insulin aspart versus HI in the nine countries investigated. Lifetime cost savings were observed with insulin aspart in the Austrian, Dutch, French, and Norwegian settings. Overall costs were increased with insulin aspart versus HI in Denmark, Finland, Germany, Spain and Sweden, with incremental cost-effectiveness ratios of DKK20,814, €4434, €9553, €20,916 and SEK32,541 per QALY gained respectively. CONCLUSIONS: Improvements in glyemic control associated with insulin aspart led to improved QALE due to reduced incidence of complications versus HI. Insulin aspart was projected to be either cost-saving or cost-effective compared to HI over patient lifetimes according to accepted international thresholds.

MEASURING THE EFFECT OF THE VARIABILITY OF INSULIN USE ON HEALTH CARE COSTS IN DIABETES

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OBJECTIVES: Using claims data, develop a measure of variability in insulin use that could be used as a proxy measure of non-adherence to insulin. Measure the effect of variability of insulin use on total and diabetes-attributable health care costs in a managed care population. METHODS: Using a large managed care administrative claims database, all patients with a prescription for long- or intermediate-acting insulin from January, 2000 through June, 2001 were selected (n = 12,336) from among continuously eligible patients age 18 years and older. Total insulin units dispensed with each prescription were computed by multiplying quantity (ml) from the claims data and strength (units/ml) from NDC reference data. Units-per-day were computed for each prescription pair by dividing units dispensed by the number of days until the next prescription. A time series of units-per-day was created for each patient during a one year follow-up period.
The standard deviation of units-per-day over the year was used as the proxy measure of non-adherence. Total and diabetes-attributable costs were computed including insurance payments and patients’ co-payments. Multivariate log-linear regressions were estimated for costs using variability in long/intermediate-acting insulin, diabetes severity, overall comorbidity burden, hospitalization in prior six-months, insulin pump use, comorbid use of short-acting insulin, oral anti-diabetic medications, patient initiating anti-diabetic therapy, insurance plan, and demographic variables. RESULTS: A total of 11,125 patients had at least three prescriptions for long-acting or intermediate-acting insulin and were used in the models. The standard deviation of units-per-day ranged from zero to 210, with a median of 11 and 20th and 80th percentiles of five and 23, respectively. Total costs increased 0.39% and diabetes-attributable costs increased 0.31% for each unit increase in the standard deviation of insulin units-per-day. CONCLUSIONS: Increased variability of insulin use increases total and diabetes-attributable annual costs.

**PDB39**

**DEVELOPMENT OF AN INTEGRATED DIABETES DATABASE ACROSS COMMUNITY CLINICS AND HOSPITALS**

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Electronic medical records (EMR) have been incorporated into many health care settings to assist physicians in sharing patient information effectively across health care providers. Most EMRs were designed to optimize sharing of clinical information and not to accommodate the needs of health services researchers. Building a comprehensive database that includes information from multiple databases and EMR sources can be challenging. OBJECTIVE: To develop a comprehensive diabetes dataset of clinical resource utilization information and costs using a community clinics and hospital-based EMR and charge data. This allows a direct comparison of resource utilization and economics associated with various anti-diabetic treatments. METHODS: Prescription order data for patients on anti-diabetic medications or with a diagnosis of diabetes in 2001–2003 were obtained from the community clinics EMR system. Other health care information was collected from the hospital outpatient clinics and hospital EMR systems. Pertinent health care information included site of care, procedures performed, laboratory tests results, and diagnosis. Missing information was retrieved manually from the EMR chart from physician notes which are not transferred to the EMR database or imputed from retrieved data sources. Resource use information was matched to financial data based on patient visit numbers. Professional charges were matched to each visit based on patient identifier and approximate visitation date, with Institutional Review Board approval. RESULTS: The final dataset includes pertinent clinical, costs resource utilization information for patients suffering from diabetes across 810 patients receiving insulin. This dataset was used to determine the differences in resources and cost differences between different insulin regimens. CONCLUSION: Integrated data systems across outpatient and inpatient settings can be very useful in outcomes research however pulling together information from various datasets can be challenging.

**PDB40**

**THE USE OF DIABETES PREVENTION PROGRAM RESULTS TO MODEL COST-EFFECTIVENESS OF THE INTERVENTION IN A MORE GENERALIZED HYPOTHETICAL POPULATION**

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OBJECTIVES: The Diabetes Prevention Program (DPP) excluded subjects at baseline due to multiple disease states. The objectives of this study were to 1) design a long-term cost-effectiveness model to evaluate the use of intensive lifestyle intervention to prevent type-2 diabetes (T2DM) based on the DPP study design; and 2) attempt to project these findings onto a more generalized hypothetical population than that studied by the DPP. METHODS: Markov models were developed based on the DPP results incorporating the states of normal glucose tolerance, impaired glucose tolerance, T2DM and death. Transition probabilities were derived from DPP and current literature. A three-year intervention was assumed with outcomes of 1) a three-year duration of effect; and 2) a lifetime duration of effect. A second set of models, based on a hypothetical, more generalized population included higher direct medical control cost of illness, and US Life Table mortality figures. RESULTS: Lifestyle dominated placebo in both models, with the following results derived for incremental cost-effectiveness ratios: 1) DPP model—three-year duration = −$6,319/LY; 2) DPP model—lifetime duration = −$11,804/LY; 3) generalized model—three-year duration = −$16,064/LY; and 4) generalized model—lifetime duration = −$19,496/LY. A maximal acceptable cost of intervention per year for the three-year duration of effect that could be used to maintain lifestyle domination was also established. These values were: 1) DPP model—three-year duration = $1820/year; 2) DPP model—lifetime duration = $6500/year; 3) generalized model—three-year duration = $2910, and 4) generalized model—lifetime duration = $9750. CONCLUSION: In this model that examined an intervention that had little apparent effect on life expectancy, increasing control cost of illness increased incremental costs and incremental cost-effectiveness ratios, and ultimately increased the apparent cost-effectiveness of this preventive treatment.

**PDB41**

**VALIDATION OF THE GERMAN TRANSLATION OF THE NORFOLK QOL-DN, NERVE FIBER SPECIFIC QUESTIONNAIRE IN A NATIONAL, MULTICENTER COST OF ILLNESS STUDY (DIMICO) FOR DIABETIC MICROVASCULAR COMPLICATIONS IN GERMANY**


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OBJECTIVE: The objective was to validate the construct of the German-translated version of the Norfolk QOL-DN by factor analysis in a German population with five stages of neuropathy and correlate the resulting factors with degrees of neuropathy. METHODS: Conducted in 97 sites in Germany, 186 patients (type-1 n = 33; type-2 n = 153) with diabetic neuropathy were assessed and categorized: asymptomatic DN (n = 40); symptomatic DN (n = 46); DN with history of foot ulcers (n = 32); DN with amputations (n = 22); and DN with history of amputations (n = 46). Data was assessed from completion of two self-administered HQOL questionnaires: Short Form-12 (SF-12) and Norfolk QOL-DN, a 47 item nerve fiber specific tool, back and forward translated from English into German. Factor analysis by Varimax rotation was performed; relationship of the factors to stages of complications was conducted using two METHODS: least squares regression and PLUM. Complication stage was entered as the dependent variable, with all five factors as predictors. RESULTS: Five factors resulted from analysis of this German neuropathy population (multi-staged), matching factors from a European study population (mild neuropathy). The first factor (Functional Status/Large Fiber) and third factor Activities...