PDB75

EFFECTS OF STATIN THERAPY ON HOSPITALIZATION AND MORTALITY IN PATIENTS WITH DIABETES: A RETROSPECTIVE COHORT STUDY

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OBJECTIVES: Clinical practice guidelines suggest that to achieve greater reductions in cardiovascular risk, statin therapy should be prescribed for diabetic patients at earlier stages. The objective of this study was to assess the influence of statin therapy on diabetes-specific hospitalization and all-cause mortality in diabetic patients enrolled in a state Medicaid program. **METHODS:** This is a retrospective cohort study of patients with diabetes using Medicaid pharmacy and medical claims data. Patients aged 40 years or older with a diagnosis of diabetes, who had continuous coverage in a state Medicaid program from January 2002 to December 2004, and who had a diagnosis of diabetes in 2002 were included in the study and were followed up until December 2004. Statin therapy was measured in using pharmacy claims data of 2003 and statin use was defined as at least two filled prescriptions for statin medications in 2003. The primary outcomes of interest were diabetes-specific hospitalization and all-cause mortality in 2004. Multivariate regression analyses were performed to assess the impact of statin therapy on outcome measures. **RESULTS:** A total of 21,110 patients met our inclusion criteria. Among them, 76.6% were females and the mean age was 62.9 (± 12.3) years. Less than 30% (28.7%) were prescribed statin medications in 2003. After controlling for baseline patient characteristics including age, gender, race, prior hospitalization, comorbidities (measured using Charlson comorbidity index), and use of insulin, oral hypoglycemic agents, and antihypertensive medications, in comparison to non-users, statin users were 29.1% less likely to have diabetes-specific hospitalizations (OR: 0.719; 95%CI: 0.628–0.824). The odds for all-cause mortality were also lower in statin users as compared to non-users (OR: 0.480; 95%CI: 0.327–0.705). **CONCLUSIONS:** The results of this study show that statin use rate is low among adults enrolled in a Medicaid program. Statin therapy in adult diabetic patients reduces diabetes-specific hospitalizations and all-cause mortality.

DIABETES/ENDOCRINE DISORDERS – Conceptual Papers & Research on Methods

PDB76

AN OPEN-SOURCE, INTERACTIVE MODEL TO ASSESS THE OUTCOMES AND ECONOMICS OF DIABETES INTERVENTIONS IN CANADA

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OBJECTIVES: Several decision-theoretic models exist to assess the long-term outcomes and economics of diabetic interventions. Since the models are proprietary, users are limited in their ability to critically review program code and modify inputs for their specific setting. The main objective was to develop a diabetes model with open-source code that is unlocked, transparent, and modifiable by users, which are important considerations for pharmaceutical decision makers, particularly in Canada. METHODS: The analytical framework is similar to the United Kingdom Prospective Diabetes Study (UKPDS)-based model (Clarke et al., Diabetologia 2004), and is created in Microsoft Excel, using visual basic. It is adaptable to both individual- and cohort-level data. Relationships between outcomes (e.g., myocardial infarction) and exogenous variables (e.g., HbA1c) were based on the equations as reported by Clark et al. The model was further modified to include (1) costs and disutilities associated with hypoglycemia and (2) options for emerging treatment intensification regimens as the patient's diabetes progresses. The model uses Canadian resource use data as defaults. The model was validated against the findings of the Ontario Diabetes Economic Model (ODEM, http://www.path-hta.ca/diabetes.pdf, 2006). RESULTS: The quality-adjusted life-year gain of 8.23 for the control arm in published results of ODEM fell within the 95% confidence interval of (8.20, 8.29) generated by the model. The corresponding results for life-years gained are also concordant. Unlike previous diabetes models, our model fulfills Canadian drug submission requirements, specifically the strict guidelines of the Common Drug Review (CDR) agency. CONCLUSIONS: An open-source, interactive diabetes model will greatly facilitate users' – specifically clinicians and other decision makers – ability to modify inputs specific to their setting and rigorously assess the validity of findings.

PDB77

IDENTIFYING THE UNDERLYING FACTORS FOR DIABETES CARE AND ATTITUDES

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OBJECTIVES: This paper used data from an ongoing Merck sponsored study evaluating the effectiveness of diabetes self management education (DSME): *Journey for Control of Diabetes: the IDEA Study*. During enrollment visits, patients with suboptimally controlled Type 2 diabetes (A1c < 7%) completed surveys with 19 attitudinal and behavioral scales; clinical measures were also obtained. Although the primary outcome for DSME evaluation was A1c, we included the attitudinal/ behavioral survey to identify intervening variables. Our goal was to identify a set of underlying factors to efficiently explain attitudes and clinical outcomes. METHODS: A total of 623 patients were enrolled from 2 sites, Minnesota and New Mexico. The baseline survey included the following instruments: general health (SF-12); depression (PHQ-9); Diabetes Empowerment (DES-SF); diabetes attitudes (DCP, 5 scales); personality (TIPI); Problem Areas in Diabetes (PAID); diet (RFS); physical activity (BRFSS); Readiness to Change; and hypoglycemia and hyperglycemia events (self-report). Several clinical measurements were also obtained (BMI, waist circumference, and A1c level). Data from the above sample were used to conduct a factor analysis. RESULTS: Factor analysis was performed using varimax orthogonal rotation using the survey and clinical variables. Five factors were identified for the sample of 588 patients with measures on all variables. The first factor related to "agreeable" personality characteristics from the TIPI; the second and fourth factors both related to poor physical health with the second factor including those items relating to empowerment and low A1c while the fourth factor included extroversion, low activity levels, and increased glycemic events. Factor three was high weight and waist circumference as well as low activity levels, and factor five was primarily readiness to change. Communality scores ranged from .317 to .829. CONCLUSIONS: Factor analysis can help explain underlying factors affecting patients with diabetes. Future analyses will use these factor scores to predict the effectiveness of DSME.

PDB78

RANDOMIZED CLINICAL TRIAL (RCT) DESIGN AND ANALYTIC ISSUES IMPACTING ASSUMED CLINICAL EFFECTS AND RESULTS OF COST-EFFECTIVENESS ANALYSES: ILLUSTRATION FROM A RECENT CANADIAN REPORT ON THE COST-EFFECTIVENESS OF BLOOD GLUCOSE TEST STRIPS FOR TYPE 2 DIABETES

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Most cost-effectiveness analyses of interventions in type 2 diabetes mellitus (T2DM) are based on clinical effects from randomized clinical trials (RCTs). While RCTs are conducted to minimize certain types of bias, protocol design and analytic approach can minimize the magnitude of treatment effect and thus, degree of projected long-term cost-effectiveness. The goal of this review was to provide a methodological critique of trials used in a recent report by The Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) on the cost-effectiveness of blood glucose test strips for T2DM patients, and to discuss specific factors impacting input assumptions and model results. Seven RCTs were included in the COMPUS meta-analysis of non-insulin treated T2DM patients (n = 2,270). Assuming 1.29 strips/day and a weighted mean HbA1c effect of –0.25%, the base case incremental cost-utility ratio was $CAN 113,643/QALY. Source trials varied widely in terms of patients' ability to act upon monitoring results, and required and actual monitoring frequency. Several characteristics of the trial most-heavily weighted in the COMPUS analysis illustrate how potential effects of monitoring may be obscured. The standardized protocol did not allow patients to obtain monitoring feedback and discuss it with health care providers in a timely fashion. Although assessed through intent-to-treat analyses, approximately half of HbA1c endpoint data attributed to the "intensive" monitoring group was provided by patients who had not been monitoring for an extended period. In contrast, strip costs used as model inputs were "maximized" by assuming 100% protocol adherence. Cost-effectiveness analyses of T2DM interventions can benefit from a careful review of RCT design and analytic issues that may serve to underestimate clinical effects. Studies assessing the clinical value of monitoring should include protocols that optimize patients' ability to act upon results, as well as analyses that link assumed clinical effects to actual monitoring frequency.

GASTROINTESTINAL DISORDERS – Clinical Outcomes Studies

PGI1

ASSOCIATION OF WARFARIN, NSAIDS, AND GASTROINTESTINAL BLEED

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OBJECTIVES: To determine the association of gastrointestinal (GI) bleed over one year in a cohort of Medicare/Medicaid dual eligibles (Duals) taking warfarin alone or warfarin & non-steroidal anti-inflammatory drugs (NSAIDS) and determine the annual health care costs for patients with GI bleed versus no GI Bleed. **METHODS:** Data were obtained from Arizona State Medicaid Agency from January 1, 2005 through December 31, 2005. Inclusion criteria consisted of Duals ³65 and <90 years of age with at least two claims for warfarin. Duals were grouped as taking warfarin alone or warfarin plus NSAID. Factors examines included age, sex, race/ethnicity membership, rural or urban residence, with adjustment for total number of prescription claims and comorbidities. Analysis was performed utilizing a logistic regression model to determine odds of GI bleed when taking warfarin compared to warfarin plus NSAID. **RESULTS:** A total of 2916 patients met inclusion/exclusion criteria: 2538 taking warfarin alone and 378 taking warfarin plus NSAID. Males comprised 771 (30.4%) of warfarin and 88 (23.3%) of warfarin plus NSAID groups. Mean age (SD) was 76.6 (6.8) and 74.0 (6.1) in the warfarin and warfarin plus NSAID groups respectively. There were 126 (5.0%) GI bleed events in the warfarin and 29 (7.7%) events in the warfarin plus NSAID groups (p = 0.02). The odds ratio for GI bleed was 1.51 (0.98–2.33). Mean total annual health care costs (SD) were $13,232 (15,476) in