

OBJECTIVES: A telecommunications company, a founding member of the Leapfrog Group, undertook this study to evaluate its costs for retirees with Type-2 diabetes and the quality of care received. **METHODS:** Health care costs were evaluated for those with 6 months continuous enrollment prior to, and 12 months after, an initial Type 2 diabetes medical service noted in a claims database. Vascular complications (cardio-, cerebro-, micro- and peripheral) were grouped into a cohort hierarchy for analysis. Cost differences were estimated among groups adjusting for age, gender and severity of concurrent conditions. **RESULTS:** The mean age of the population (N = 9959) was 74.4 years; 50% were female. Adjusted annual costs for those without hospitalizations ranged from \$4877 with no complications to \$12,271 with four complications. For those with hospitalizations, adjusted annual costs ranged from \$18,839 with one complication to \$41,011 with 4 complications. Each group was significantly different ($p < 0.001$) from the no complication group. Average annual costs per beneficiary with/without hospitalizations were cardiovascular (excluding hypertension), \$11,128/\$22,952; hypertension, \$7656/\$17,927; stroke, \$15,349/\$25,333. No antidiabetic drug was present in 4360 (44%) beneficiaries in the 12-month period after the initial diabetes medical service. Of the 5599 prescribed an antidiabetic drug, 2072 (37%) received a sulfonylurea only; 913 (16%) received a sulfonylurea and metformin; 698 (12%) received metformin only; 566 (10%) received insulin only; and, 573 (10%) received a thiazolidinedione alone or in combination. **CONCLUSIONS:** Type-2 diabetes produces significant health care expenditures by an employer, its retirees and Medicare. Despite a generous prescription benefit, drug treatment patterns suggest misuse of agents with known adverse effects and underuse of agents with evidence-based therapeutic benefits. These results will support a targeted, evidenced-based, employer-sponsored intervention to improve quality-of-care and patient safety by focusing on drug treatment appropriate for the individual's circumstances.

PDB18

INCREASED HEALTH EXPENDITURES AMONG DIABETES PATIENTS ON INSULIN WITH HYPOGLYCEMIA

Orsini LS¹, Rhoads G², Wang S¹, Zhang Q³, Crown WH¹

¹The Medstat Group, Inc, Cambridge, MA, USA; ²University of Medicine and Dentistry of New Jersey, Piscataway, NJ, USA; ³Aventis Pharmaceuticals, Bridgewater, NJ, USA

OBJECTIVE: To quantify the effect of diabetes-related hypoglycemia on direct health care costs and utilization. **METHODS:** The sample consisted of 9162 privately insured employees that had at least 12 months of continuous enrollment between January 1, 1999 and December 31, 2001, and two or more prescriptions for diabetes-related medications within the same therapeutic class (insulin, sulfonylurea, or other oral diabetes-related medication) from Medstar's Health Productivity and Management database. Patients were grouped into two cohorts: hypoglycemia or non-hypoglycemia depending on whether they incurred a diagnosis of hypoglycemia (ICD-9-CM 250.8, 251.1, 251.2). The sample was further sub-set to those with claims for insulin (N = 2664)—64% of the original sample. Data were gathered starting from the first evidence of a diabetes-related medication. **RESULTS:** The incidence of hypoglycemia did not vary significantly by age, insurance type, or region of the country. However, the hypoglycemia group had evidence of significantly increased comorbidity including renal disease (14% vs. 6%, $p < 0.01$), ophthalmic findings (42% vs. 30%, $p < 0.01$), and neuropathy (30% vs. 15%, $p < 0.01$), as well as a higher mean Charlson Comorbidity Index (1.20 vs. 0.75, $p < 0.01$).

Hypoglycemia patients incurred on average twice as many hospitalizations (1.0 vs. 0.5, $p < 0.01$) and emergency room visits (0.8 vs. 0.4, $p < 0.01$) annually compared to insulin-users without hypoglycemia. Forty percent (40%) of the excess hospitalizations and 53% of the excess emergency room visits were associated with a hypoglycemia diagnosis. Hypoglycemia patients on insulin incurred twice the amount of overall health care expenditures (\$28,049 vs. \$14,019, $p < 0.01$) and three times the amount of diabetes-related health care expenditures (\$14,590 vs. \$5236, $p < 0.01$) compared to non-hypoglycemia insulin users. **CONCLUSION:** Hypoglycemia contributed significantly to medical care utilization and health care expenditures among patients using insulin. Analysis of the indirect costs among this population as well as investigation into hypoglycemia among diabetes patients on oral agents warrants further investigation.

DB2/PDB19

THE ECONOMIC BURDEN OF TYPE 2 DIABETES MANAGEMENT BY ETHNIC GROUP IN THE TEXAS MEDICAID POPULATION

Lee WC¹, Stephens JM¹, Tran KT¹, Wang Q¹, Dirani RG², Pashos CL³

¹Abt Associates Inc, Bethesda, MD, USA; ²Glaxo Smith Kline, Philadelphia, PA, USA; ³Abt Associates Inc, Cambridge, MA, USA

OBJECTIVES: Diabetes disproportionately affects the poor and medically underserved minorities, populations typically served by State Medicaid programs. This study sought to assess the patterns of diabetes-related health care costs incurred by the Texas Medicaid program for Hispanics, African-Americans, and Caucasians with type-2 diabetes. **METHODS:** Treatment-naïve adult patients in 2000 were identified. Total costs were assessed in the 12-months following the initiation of therapy, defined as the first filling of a prescription following 6 months of no such prescription. Patient demographic and disease severity measures as well as county level variables were evaluated. To assess factors associated with treatment cost, bivariate and multivariate linear regression analyses were performed, where log transformed cost was used as a dependent variable. **RESULTS:** Resource utilization patterns and treatment costs of patients with type-2 diabetes differ among the race and ethnic groups studied. In the first year of diabetes management, total treatment costs for Hispanics (\$7189) and (\$6715) were substantially lower than for white patients (\$8549). Although the difference in health care costs between Caucasians and African-Americans was mostly accounted for by demographic, clinical, and county level variability, the cost difference between Hispanics and Caucasians still persisted with regard to these factors. **CONCLUSIONS:** The immediate cost to care for patients with type-2 diabetes is substantial in this Medicaid population, regardless of race or ethnicity. Moreover, the differences in costs between the groups are substantial, suggesting that race- or ethnicity-related factors associated with persistence need to be addressed in optimizing early therapy.

PDB20

COST-EFFECTIVENESS OF DULOXETINE VERSUS ROUTINE TREATMENT FOR PAINFUL DIABETIC NEUROPATHY IN A RANDOMIZED TRIAL FROM A SOCIETAL PROSPECTIVE

Wu EQ¹, Birnbaum HG¹, Mareva MN¹, Le TK², Rosen A², Robinson R², Corey-Lisle P²

¹Analysis Group Inc, Boston, MA, USA; ²Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: Painful neuropathy is a common complication of diabetic patients. The purpose of this study is to compare the cost-effectiveness of duloxetine to routine treatment in the

management of pain associated with diabetic neuropathy from a societal perspective. **METHODS:** The study sample includes patients enrolled in the 52-week, randomized, multi-center, open-label extended phase of a duloxetine versus routine treatment trial in the management of pain associated with diabetic neuropathy. The first patient was enrolled in the study on June 14, 2001 and the last patient completed the extended phase study on April 28, 2003. A sub-population of 233 U.S. patients with diabetic neuropathic pain was randomized to either duloxetine 60mg BID or routine pain treatment. The primary efficacy measure was the Medical Outcomes Study Short Form 36 (SF-36) bodily pain domain (BP). Total costs (direct medical and indirect productivity loss cost), adjusted to 2002 dollars using Consumer Price Index, were analyzed from a societal perspective. Bootstrap method was applied to calculate statistical inference of incremental cost-effectiveness ratio (ICER). **RESULTS:** Duloxetine treatment was associated with a significant improvement in SF-36 BP score compared with routine treatment (p -value = 0.05). From societal perspective, duloxetine is both a more cost-effective (ICER = $-\$429/1$ BP, p = 0.04) and dominant (p = 0.06) therapy compared to routine treatment in the management of pain associated with diabetic neuropathy. **CONCLUSIONS:** This study shows that duloxetine is more cost-effective and dominant treatment for painful diabetic neuropathy compared to routine care.

DIABETES (including Parathyroid Disease)

DIABETES (including Parathyroid Disease)—Quality Of Life/Patient Preference Studies

PDB21

THE IMPACT OF COMMON DIABETIC COMPLICATIONS ON QUALITY OF LIFE

Holmes JW¹, Hemmett L¹, New JP², Vaughan N³, Sharplin P⁴, Marchant NJ⁵

¹Beaufort International, London, United Kingdom; ²Hope Hospital, Salford, United Kingdom; ³Royal Sussex County Hospital, Brighton, United Kingdom; ⁴Aventis Pharma UK, West Malling, Kent, United Kingdom; ⁵Pfizer Ltd, Sandwich, Kent, United Kingdom

OBJECTIVE: The microvascular and macrovascular complications of diabetes are generally associated with poorer health related quality of life, but few studies have assessed utility values associated with specific individual or multiple complications. This study estimated utilities for the most common complications, to establish whether patients have a poorer quality of life than those without complications. **METHODS:** EQ-5D index data were generated through cross-sectional postal surveys of patients on two regional registers in the UK, stratified according to the 17 most prevalent individual or multiple complications (including “none”). Amputation and blindness did not appear in this list. Subgroup analysis was undertaken on patients without chronic co-morbidities. **RESULTS:** Response rates were 62% in Brighton (n = 589) and 65% in Salford (n = 491). Nine of the most prevalent complication groups in Brighton and seven in Salford represented multiple complications. In Brighton, the lowest mean score was for patients with previous ischaemic heart disease plus peripheral vascular disease or claudication. Symptomatic neuropathy appeared in five out of the eight complication groups, which had significantly lower mean scores (p < 0.05) than the group without complications. Normalising for co-morbidities did not fundamentally change the findings, although mean scores were generally higher in the subgroups without co-morbidities. Stroke appeared in two, and angina in three, of the seven complication groups, which had significantly, lower

mean scores (p < 0.05) than the group without complications. **CONCLUSIONS:** Patients with the most common diabetic complications have a poorer quality of life than those without complications. Understanding the interaction of different complications on patients’ quality of life will be increasingly important as new strategies are explored to reduce the risk of such complications.

PDB22

THE VALUE TO HIGH-RISK PATIENTS OF PREVENTING A CASE OF DIABETES

Johnson FR, Manjunath R, Hoerger TJ

Research Triangle Institute, Research Triangle Park, NC, USA

OBJECTIVES: The objective of this study was to improve the design of diabetes risk-reduction interventions by quantifying high-risk patients’ value of diabetes risks relative to the discomfort, inconvenience, and costs of diet, exercise, and weight-loss features of hypothetical diabetes-prevention programs. **METHODS:** A web-based, stated-choice survey instrument presented respondents with a sequence of choices among pairs of diabetes prevention program features and a “Neither” alternative. The instrument was pretested with a convenience sample of 16 subjects. The survey was administered to 400 subjects identified as high risk (obese, over age 45, 25% minorities) and to 200 subjects identified as lower risk (not obese, over age 45, 25% minorities). Each subject evaluated 9 choice tasks describing programs with varying levels of 7 features: diet, exercise, counseling, medication, weight loss, cost, and risk reduction. **RESULTS:** Discrete-choice patterns reveal the implicit relative importance of program features. More than half of the subjects evaluated diet, exercise, or counseling as more important than cost, medication, and weight-loss goal. However, cost proved to be important in actual stated choices among programs for over 85% of subjects. Over half of the subjects indicated they were willing to incur significant discomfort to reduce risks if the baseline diabetes risks were greater than 30%, which they are for high-risk individuals. Obese subjects were more likely to prefer interventions that included medication. **CONCLUSIONS:** There are significant cost-reduction benefits in avoiding the cost of glucose control and subsequent serious complications of diabetes patients. However, patient’s adherence to a risk-reduction intervention depends on patients’ perceived value of risk reduction relative to the of risk-reducing behavior. Patients are more likely to be adherent to risk-reduction programs with features that include effective diet and counseling features. Discrepancies between observed behavior and stated preferences for risk reduction may indicated poor perceptions of baseline risks and risk-reduction benefits.

PDB23

IS PSYCHOLOGICAL GENERAL WELL-BEING AN IMPORTANT PATIENT-REPORTED OUTCOME FOR THE EVALUATION OF DIABETES DRUG THERAPY?

Hayes RP, Bowman L

Eli Lilly & Company, Indianapolis, IN, USA

OBJECTIVE: Psychological general well-being is an important aspect of the quality of life of individuals with type-2 diabetes. The objective of this study was to determine the value of assessing psychological general well-being in diabetes drug therapy evaluations. **METHODS:** We administered the Psychological General Well-Being Schedule (PGWB) to 111 patients with type 2 diabetes (mean age = 55.8 years, 62% male, baseline A1c mean = 8.2%) participating in a Phase II randomized placebo-controlled trial of oral anti-diabetes treatment. The PGWB consists of 22 items divided into 6 subscales—anxiety, depressed