

costs (\$14,380 vs. \$9,800 respectively, $p < 0.05$). **CONCLUSIONS:** Diabetes patients with consistently high medication adherence to oral medications or having a history of an HbA1c test over a five-year period had lower medical costs and lower inpatient and emergency room costs than their counterparts.

PDB93

CLINICAL CHARACTERISTICS, QUALITY MEASURE ATTAINMENT, AND DIABETES-RELATED HEALTH CARE COSTS IN ELDERLY VERSUS OVERALL PEOPLE LIVING WITH TYPE-2 DIABETES MELLITUS (T2DM) RECEIVING METFORMIN (MET) AND SULFONYLUREA (SU)

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OBJECTIVES: This study examined the demographics, comorbidities, clinical characteristics, and treatments of people with T2DM and an elderly subgroup. Additionally, attainment of quality goals and its correlation with diabetes-related costs were assessed. **METHODS:** Health insurance claims and electronic medical records from 14,532 adults with T2DM (2007-2011) were used to identify a sample receiving MET+SU. The index date was defined as the first dispensing of MET+SU after 6 months of eligibility. Clinical characteristics were assessed during baseline and quality measure attainment, defined as no values above specific thresholds (HbA1c <8%, body mass index [BMI] <30 kg/m², blood pressure [BP] <140/90 mmHg, low-density lipoprotein cholesterol [LDL-C] <100 mg/dL), was evaluated during a 12-month landmark period after the index date. Association between quality measure attainment and diabetes-related costs, calculated after the landmark period, was evaluated using non-parametric bootstrap methods adjusting for imbalance in baseline characteristics between cohorts. **RESULTS:** 2,044 patients (mean age: 67 years; female: 46%), including 1,283 (62.8%) patients ≥65 years, were identified. Baseline comorbidities included cardiovascular disease (all patients: 25.5%; ≥65 years: 33.4%), congestive heart failure (5.9%; 8.1%), hypertension (66.5%; 74.2%), hyperlipidemia (73.9%; 78.1%), and neuropathy (16.0%; 20.2%). Statins and loop and non-loop diuretics were taken by 60.5%, 10.5%, and 21.1% of all patients, and 66.9%, 13.8%, and 24.5% of patients ≥65 years, respectively. The proportions meeting various quality goals were: 82.9% (≥65 years: 88.2%) for HbA1c, 34.4% (42.1%) for BMI, 31.6% (27.7%) for BP, and 68.2% (73.3%) for LDL-C. Quality measure attainment was associated with significantly lower diabetes-related costs per-patient per-year (adjusted mean cost differences: -\$1,445 for HbA1c; -\$1,218 for BMI; -\$2,029 for HbA1c and BMI; -\$2,073 for HbA1c, BMI, and BP; all $P < 0.05$) compared to non-attainment. **CONCLUSIONS:** This study highlights the high incidence of comorbidities and potential financial benefits of attaining T2DM quality outcomes at the population level.

PDB94

BURDEN OF HEALTH RESOURCE UTILIZATION (HRU) AMONG INSULIN PEN USERS WITH TYPE 2 DIABETES MELLITUS

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OBJECTIVES: To characterize type 2 diabetes mellitus (T2DM) patients' newly initiating insulin therapy with an insulin pen and quantify their health resource utilization (HRU). **METHODS:** Adult patients with at least one new claim for an insulin pen between January 2006 and September 2010 were selected from the Truven Health MarketScan Research Databases. Patients required continuous enrollment for 12 months after the index insulin pen claim, with a diagnosis of T2DM and one prescription for an oral antidiabetic drug. Frequency and cost of health care encounters were highlighted. HRU includes inpatient admissions, emergency department and outpatient office visits, outpatient laboratory and radiology services, other outpatient services and outpatient prescriptions. HRU was calculated separately for all-cause and diabetes-related expenditures. **RESULTS:** Nine thousand two hundred and eighty five patients met the study criteria with average age of 58.5 (SD=12.4); 52.9% were male. The Deyo-Charlson comorbidity score for this sample was 2.3 (SD=1.8). Most frequently observed baseline microvascular and macrovascular complications included diabetic neuropathy (14.7%), renal disease (16.2%), and ischemic heart disease (22.9%). Other common comorbidities included hypertension (47.3%) and dyslipidemia (31.5%). Patients frequently continued to fill oral anti-diabetic prescriptions after initiating an insulin pen, most commonly biguanides (46.3%) or sulfonylureas (31.8%). Concomitant medication use was high: most patients (83.9%) used a hypertensive, dyslipidemia (72.7%), anti-depressant (28.7%), or anti-emetic/nausea (9.6%) medication in the year after insulin pen initiation. In the year after insulin pen initiation, all-cause expenditures averaged \$26,193 (SD=\$47,670), of which 15.8% were diabetes-related. Inpatient admissions accounted for 27.3% of total costs. Medication costs were substantial, accounting for 27.6% of total costs; 39.8% of medication costs were diabetes-related. **CONCLUSIONS:** Health expenditures associated specifically with T2DM patients initiating an insulin pen are substantial. Further research is required to explore the relationship of T2DM medication management on overall health resource utilization.

PDB95

EVALUATION OF POLYPHARMACY IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AND ITS ASSOCIATION WITH MEDICATION ADHERENCE AND HEALTH CARE COSTS

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OBJECTIVES: To assess level of polypharmacy in patients with type 2 diabetes mellitus (T2DM) and its association with adherence to oral anti-diabetic drugs (OAD) and health care costs. **METHODS:** The Thomson MarketScan Commercial

and Laboratory Databases 2005-2012 were used to select T2DM patients aged 18-64 with continuous enrollment ≥2 years (the first year as baseline) who used OADs. Prescriptions at baseline year with at least 90 days of cumulative days-of-supply were counted to determine level of polypharmacy according to active ingredient. Patients were categorized into four cohorts: no polypharmacy (≤2 drugs), minor (3-5 drugs), moderate (6-8 drugs), and major (≥9 drugs). Adherence to OADs was evaluated during 12-months follow-up using mean proportion of days covered (PDC). Adjusted association between polypharmacy and adherence (PDC ≥0.8) to OAD and total health care costs were examined using logistic regressions and generalized linear regression models, respectively. **RESULTS:** Of the total sample population (N=13,365), 22.4% had non-polypharmacy, 39.3% had minor, 25.3% had moderate, and 13.0% had major polypharmacy. The polypharmacy cohorts had significantly higher all-cause health care costs (non-polypharmacy: \$7,482; minor: \$9,144; moderate: \$14,465; major: \$25,072; all $p < 0.05$) and adherence to OADs (non-polypharmacy: 42.0%; minor: 63.1%; moderate: 73.9%; major: 78.3%; all $p < 0.05$) during the post-index period compared to non-polypharmacy. Annual incremental costs associated with polypharmacy were \$1,602 (minor), \$5,808 (moderate), and \$13,447 (major) when compared with non-polypharmacy cohort. A higher level of polypharmacy was associated with a higher likelihood of adherence than the non-polypharmacy cohort (minor: OR=2.18, 95% CI=1.99-2.40; moderate: OR=3.58, 95% CI=3.20-3.99; major: OR=4.70, 95% CI=4.07-5.43). **CONCLUSIONS:** Polypharmacy was common and associated with high economic burden among patients with T2DM. The positive association between polypharmacy and adherence to OAD warrants further investigation of the behavioral mechanism.

PDB96

PREVALENCE AND RISK FACTORS OF DIABETIC PERIPHERAL NEUROPATHY IN TYPE 2 DIABETES MELLITUS OUT-PATIENTS

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OBJECTIVES: The primary objective was to assess the prevalence of DPN using Vibration Perception Threshold (VPT) using biothesiometer considered as the gold standard for the diagnosis of DPN. The secondary objectives of the study were to compare the prevalence between Known Diabetics (KD) and Newly Detected Diabetics (NDD), assess the neuropathy prevalence pattern and identify any modifiable risk factors associated with occurrence of DPN among diabetics. **METHODS:** The study was cross-sectional, observational study. Subjects were recruited from Endocrinology clinic of a public tertiary care hospital. Subjects with duration of diabetes (≤6 months) were considered to be NDD. VPT measurements were done to assess neuropathy (cut off ≥20V). Severity of neuropathy was graded into three groups based on VPT score as mild (20-24.99 V), moderate (25-39 V), and severe (>39 V). 791 subjects were included on a random sampling basis which includes 638 KD and 153 NDD. Multivariate analysis was performed for assessing independent risk factors associated. **RESULTS:** The median duration of diabetes was found to be 6 (2 - 12) years. 300 subjects were found to have DPN accounting for 37.9% (95%CI: 34.5-41.4) prevalence. Higher prevalence was observed in KD compared to ND (43.7% Vs 13.7%, $p < 0.001$). The prevalence of mild neuropathy was 10.4%, moderate neuropathy was 18.9%, and severe neuropathy was 8.6%. Regression analysis has shown age ($p = 0.007$), female gender ($p = 0.001$), duration of diabetes ($p = 0.001$), dyslipidemia ($p = 0.008$) and presence of other microvascular complication ($p < 0.001$) to be associated with DPN occurrence among diabetics. **CONCLUSIONS:** This cross-sectional study shows the prevalence of DPN to be 37.9%. Severe neuropathy prevalence was found to be 8.6% who were at the risk of foot ulceration or lower limb amputation. DPN was associated significantly with increasing age, early onset of diabetes, female gender and dyslipidemia.

PDB97

HEALTH CARE COSTS AND CLINICAL OUTCOMES ASSOCIATED WITH RATES OF SULFONYLUREA USE BY PHYSICIANS

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OBJECTIVES: To study the association between rates of sulfonylurea (SU) use at a physician's practice and average health care costs and complication rates among the physician's patients with type 2 diabetes mellitus (T2DM). **METHODS:** We performed a retrospective group-level analysis on a sample of 7,905 patients (214,230 patient-months) insured by Humana, aged 18-64 with an incident T2DM diagnosis between 2007 and 2011. We regressed physician-level monthly complication rates (cardiovascular, lower extremity, ophthalmic, renal, neuropathy, and hypoglycemia) and average health care costs on 3-month-lagged rates of SU use controlling for use of 10 other T2DM therapy classes in each physician's practice, and patient and practice characteristics. Costs were estimated using a generalized linear model with log link to account for common zero costs. **RESULTS:** SU use was associated with increased rates of lower extremity, ophthalmic, and renal complications relative to no drug use ($p < 0.05$). For each complication class, we identified the best performing therapy and estimated the effect of a hypothetical switch in prescribing patterns from 100% use of this class to 100% use of SU, as percentages of the respective average complication rates. Our estimates were: 93% increase in cardiovascular when switching from meglitinides, 133% increase in lower extremity when switching from alpha glucosidase inhibitors (AGI), 433% increase in ophthalmic when switching from amylinomimetics, 47% increase in renal when switching from biguanides, 147% increase in neuropathy when switching from AGIs and 252% increase in hypoglycemic complications when switching from amylinomimetics. Despite SU's association with higher complication rates, the

association between average costs and rate of SU use was not significant. Other therapy classes were associated with increased costs with the exception of premixed insulin, meglitinides and amylinomimetics (no significant association) and biguanides and alpha glucosidase inhibitors (negative association). **CONCLUSIONS:** Use of SU could potentially increase complications in type 2 diabetes.

PDB98

A LONGITUDINAL EVALUATION OF DIABETES MANAGEMENT IN COMMERCIALY INSURED PATIENTS IN THE UNITED STATES

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OBJECTIVES: Many patients on antidiabetics do not reach the ADA-recommended A1c level (<7%). This cross-sectional epidemiologic study evaluated A1c levels and diabetes-related complications among commercially insured US patients receiving antidiabetics. **METHODS:** Patients aged ≥18 years, diagnosed with T2DM, with ≥1 oral antidiabetic or insulin fill and continuous pharmacy and medical health plan enrollment for 2008, 2009, 2010, or 2011 were selected from the HealthCore Integrated Research DatabaseSM, an integrated claims dataset representing a large national health insurer. Characteristics and outcomes were assessed descriptively. **RESULTS:** We identified 265,411 patients for 2008, 266,104 for 2009, 264,220 for 2010 and 229,079 for 2011. Electronic A1c lab results were available for 22.2% of patients. In 2008 48.2% of patients had an A1c <7%; the percentage of patients achieving this target decreased through 2011 with only 44.5% achieving an A1c <7%. The percentage of patients with an A1c ≥9% increased from 15.3% in 2008 to 17.7% in 2011. Mean A1c was 7.47, 7.55, 7.50, and 7.62 for the years 2008, 2009, 2010, and 2011, respectively. An analysis of the 2011 population revealed that patients with an A1c <7% were less likely to have neuropathy (7.1% vs.10.5%), retinopathy (8.0% vs. 12.3%), or amputations/ulcerations (1.6% vs. 2.7%), compared to patients with an A1c ≥7% (P<0.001 for each). The 2011 average A1c for patients with versus without neuropathy was 7.97 versus 7.59; for retinopathy, 7.89 versus 7.59; and for amputation/ulceration, 8.13 versus 7.61. **CONCLUSIONS:** These results suggest that diabetes management in the US over the past four years has worsened in this sample of commercially insured patients, with potentially adverse cost consequences. Diabetes-related complications were more common in patients with worse diabetes control. As more than half of patients had A1c levels above the ADA recommendation, the study highlights the unmet need for improved glycemic control.

PDB99

PERSPECTIVES ON COMPLEMENTARY DATA SOURCES IN DIABETES HEALTH TECHNOLOGY ASSESSMENT: AN ENROLLING PRACTICE-BASED RESEARCH NETWORK AND A LARGE COMMERCIAL HEALTH PLAN

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OBJECTIVES: Diabetes FORWARD (DF) is a practice-based research network (PBRN) focused on Type-2 Diabetes (T2DM) health technology assessment (HTA) and health services research (HSR) in North America, based in primary care practices with electronic medical records (EMR) and enriched with supplementary patient- and provider-reported information. Recruitment is currently 9% of goal, with interest in early evaluations of how the DF source population might relate to other T2DM populations. **METHODS:** Eligible patients are adults with T2DM receiving pharmacotherapy, and other criteria previously reported. We examined the T2DM cohort of the DF-EMR, the DF population enrolled between March and September 2012 (DF), and members with continuous enrollment through 2011 in a large commercial health plan (LHP). We reviewed preliminary descriptive information to inform future analyses of patient subgroups and outcomes among populations in these data sources. **RESULTS:** DF-EMR source population (n=187,991) and DF patients (n=935) varied from LHP (n=719,041) in ways to be expected from sources created for different purposes. DF-EMR and DF had slightly greater proportions of males versus LHP, respectively (48.1 and 43.6 vs. 54.2%), and a US geographic distribution skewed toward the South (62.6 and 68.4 vs 42.0%). Insurance types reflected the nature of the data sources: Commercial, 51.1 and 47.4 versus 87.2%; Medicare, 41.9 and 39.8 versus 6.1%; and Medicaid, 1.5 and 7.7 versus 0.3%. The DF population had slightly greater prevalence of insulin (18.6 vs. 17.3%) and oral antidiabetic drug (OAD) use versus LHP, reflecting the DF pharmacotherapy criterion: No OAD, 7.4 versus 45.7%; 1 OAD, 43.1 versus 27.6%; 2 OAD, 37.4 versus 18.2%; 3 or more OAD, 12.1 versus 8.2%. **CONCLUSIONS:** HTA and HSR require complementary data sources to translate findings into improved outcomes across patients and settings. This descriptive assessment begins to investigate the potential applicability of findings across populations from such important complementary data sources.

PDB100

A FOCUS ON REAL LIFE DATA CONCERNING ANTI-DIABETIC DRUGS: THE EXPERIENCE OF AIFA MONITORING REGISTRY

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OBJECTIVES: Type-2 diabetes is the most common metabolic disease in Italy and in developed countries. It is the sixth leading chronic disease by diffusion with a crude prevalence of 4.9%. It is estimated that about 3,000,000 Italians suffer from this pathology. In the last decade, the new class of incretin-based therapies entered the arena, but their place in therapy remains difficult to determine

because of limited long-term clinical data on both effectiveness and safety, and the high cost of therapy. Both injectable glucagon-like peptide-1 (GLP-1) receptor agonists (incretin-mimetics) and orally-administered inhibitors of dipeptidylpeptidase-4 (DPP-4) produce a significant improvement in glycemic control especially when combined with metformin, similar to other second-line therapies, but additional advantages with respect to weight gain and overall hypoglycemia. In 2008 AIFA established a Monitoring Registry through which collecting and monitoring the safety and the efficacy profiles of new antidiabetic drugs. **METHODS:** Data collected from the Monitoring Registry from 2008 to 2011 were analyzed. An estimation of population enrolled, NHS-expenditures and median cost for patients were calculated for the antidiabetic drugs which entered in the Registry. **RESULTS:** AIFA Antidiabetic Monitoring Registry enrolled 135,954 patients for the period of observation. 79,211 patients (58%) were treated with DPP-4 (saxagliptin, vildagliptin and sitagliptin associated or not with metformin) and 56,743 patients (42%) with GLP-1 analogues (liraglutide and exenatide) with an economic NHS burden on Registry respectively equal to €34,675,414 (55%) and €28,649,091 (45%). The daily mean cost per patient related to the drugs included in the Registry was around €3. **CONCLUSIONS:** The safety and efficacy profiles of drugs monitored in the Italian real-world clinical practice are similar to those recorded during phase 2-3 registration clinical trials. Data collected through Registry allows performing a cost-effectiveness analysis and a cost-impact for NHS comparing both the monitored drugs among them and the other therapeutic treatments

PDB101

PATIENT CHARACTERISTICS, ANTI-DIABETIC MEDICATION USE, AND GLYCEMIC CONTROL IN DIABETIC NURSING HOME RESIDENTS WITH MODERATE TO SEVERE CHRONIC KIDNEY DISEASE

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OBJECTIVES: To describe the demographic and clinical characteristics, antidiabetic medication use and glycemic control among diabetic nursing home (NH) residents with moderate to severe chronic kidney disease (CKD). **METHODS:** Long term care administrative data with linked clinical and functional assessments, demographic information, laboratory results and pharmacy claims were analyzed. Residents with diabetes who remained in NHs for at least 90 consecutive days in 2008-2011 and had at least one estimated glomerular filtration rate (eGFR) test and one glycated hemoglobin (HbA1c) test within 1 year of the continuous stay were selected. Residents with moderate to severe CKD were identified if they had an eGFR less than 60 mL/min/1.73m². Resident demographic characteristics, comorbidities, and functional status were summarized. Use of antidiabetic medications was assessed for the first 90-day period of the continuous NH stay. Proportion with glycemic control was also assessed. **RESULTS:** Of the 1005 long-stay diabetic NH residents, 338 (33.6%) had moderate to severe CKD. CKD residents were on average 74.4 ± 11.1 years old and majority of them were females (59.8%). Common comorbidities included hypertension (93.2%), depression (77.8%) and anemia (56.2%). 72.8% of the residents were receiving ≥9 medications. Less than half (42.0%) of the residents received oral antidiabetic drugs (OAD) or glucagon-like peptide-1 agonist, and a higher proportion received insulin (61.8%). The most commonly used OAD was sulfonylurea (22.2%), followed by metformin (13.3%). The average HbA1c was 7.0 ± 1.5; 59.8% had HbA1c <7%, 19.2% had HbA1c >7% and ≤8%, 11.8% had HbA1c >8% and ≤9%, and 9.2% had HbA1c >9%. **CONCLUSIONS:** The prevalence of moderate or severe CKD is high in long-stay diabetic nursing home residents. Less than two thirds of the residents with CKD had glycemic control. Medication therapy management to achieve better glycemic control should be considered for NH residents particularly among those with CKD.

PDB102

ASSOCIATION OF SEVERE HYPOGLYCEMIC EVENTS AND HOSPITAL READMISSION WITH TREATMENT NON-CONCORDANCE TO GUIDELINES AND PRESCRIBING INFORMATION IN HOSPITALIZED PATIENTS WITH TYPE-2 DIABETES AND STAGE 3-5 CHRONIC KIDNEY DISEASE

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OBJECTIVES: To assess the association between non-concordance use of oral antidiabetic drug treatment (OAD) according to National Kidney Foundation (NKF) guidelines and prescribing information (PI) and severe hypoglycemic events and hospital re-admission in hospitalized type 2 diabetes mellitus (T2DM) patients with stage 3-5 chronic kidney disease (CKD). **METHODS:** This study analyzed electronic health records from integrated health systems across the U.S. Adult T2DM patients with stage 3-5 CKD, who were hospitalized between 2008 and 2011, were identified from medical diagnoses, dialysis procedures, or laboratory findings. OADs prescribed on the discharge date were evaluated and considered not concordant if any were not prescribed according to NKF guidelines or PI. Separate Cox-proportional hazards models were used to evaluate the associations of NKF and PI non-concordance with re-admission and severe hypoglycemic events controlling for patient demographic and clinical characteristics, respectively. **RESULTS:** A total of 1712 patients (mean age: 68.4; 50.5% female; 69.6% stage-3 CKD) met the criteria for NKF guidelines evaluation and 1552 patients (mean age: 68.2; 50.5% female; 70.6% stage-3 CKD) for PI evaluation. The non-concordance rate was 36.4% for NKF and 71.8% for PI. After adjusting for patient characteristics, patients who were not concordant to PI were more likely to have severe hypoglycemic events (HR: 1.62, 95% CI: 1.11-2.37) and re-admission (HR: 1.36, 95% CI: 1.16-1.61) after being discharged. On the other hand, we did not find any statistically significant associations between non-NKF-concordance with severe hypoglycemic events (HR: 1.29, 95% CI: 0.98-