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 COMMERCIALLY INSURED PATIENTS IN THE UNITED STATES

Grabner M[1], Abbott S[2], Nguyen M[2], Chen Y[1], Quimbo R[1]
[1]*HealthCore, Inc., Wilmington, DE, USA,* [2]*Valeritas, Inc., Bridgewater, NJ, USA*

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 Database℠, 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

Dalal MR[1], Frimpter J[2], Pan C[3], Stewart J[4], Johnstone B[2], Gemmen E[5], Reed J[6], Vlajnic A[2]
[1]*Sanofi US, BRIDGEWATER, NJ, USA,* [2]*Sanofi US, Bridgewater, NJ, USA,* [3]*Pro Unlimited, Boca Raton, FL, USA,* [4]*Sanofi Canada, Laval, QC, Canada,* [5]*Quintiles Outcome, Rockville, MD, USA,* [6]*Outcome, A Quintiles Company, Cambridge, MA, USA*

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 ANTIDIABETIC DRUGS: THE EXPERIENCE OF AIFA MONITORING REGISTRY

Montilla S[1], Sammarco A[1], Trotta MP[1], Siviero PD[2], Xoxi E[2], Pani L[2]
[1]*Italian Medicines Agency, Rome, Italy,* [2]*Italian Medicines Agency (AIFA), Rome, Italy*

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 peptide1(GLP-1) receptor agonists (incretin-mimetics) and orally-administered inhibitors of dypeptidylpeptidase-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 analogous (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, ANTIDIABETIC MEDICATION USE, AND GLYCEMIC CONTROL IN DIABETIC NURSING HOME RESIDENTS WITH MODERATE TO SEVERE CHRONIC KIDNEY DISEASE

Wu N[1], Greene M[2], Oderda G[3]
[1]*United BioSource Corporation, Lexington, MA, USA,* [2]*Georgia State University, Atlanta, GA, USA,* [3]*University of Utah, College of Pharmacy, Salt Lake City, UT, USA*

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/1.73m^2. 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

Chen SY[1], Alas V[1], Greene M[2]
[1]*United BioSource Corporation, Lexington, MA, USA,* [2]*Georgia State University, Atlanta, GA, USA*

OBJECTIVES: To assess the association between non-concordant use of oral anti-diabetic 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-

1.71) or re-admission (HR: 0.89, 95% CI: 0.78-1.02). **CONCLUSIONS:** The higher risk of severe hypoglycemic events and re-admission associated with non-PI-concordant OAD treatment after being discharged among hospitalized T2DM patients with moderate to severe CKD suggests prescribing patterns that consider renal impairment may be important from both clinical and economic perspectives.

PDB103

ORAL ANTIDIABETIC USE AMONG NURSING HOME RESIDENTS WITH DIABETES AND MODERATE TO SEVERE CHRONIC KIDNEY DISEASE

Wu N[1], Yu X[2], Greene M[3], Oderda G[4]
[1]*United BioSource Corporation, Lexington, MA, USA,* [2]*United Biosource Corporation, lexington, MA, USA,* [3]*Georgia State University, Atlanta, GA, USA,* [4]*University of Utah, College of Pharmacy, Salt Lake City, UT, USA*

OBJECTIVES: To assess the rate of non-concordant use of oral anti-diabetic drugs (OAD) according to National Kidney Foundation (NKF) guidelines and drug package inserts (PI) among nursing home (NH) residents with diabetes and moderate to severe chronic kidney disease (CKD). **METHODS:** Long-term care administrative database with medical and pharmacy claims information was analyzed. Residents with diabetes and moderate to severe CKD who remained in NHs for at least 90 consecutive days between 2008 and 2011 were selected. Residents with moderate to severe CKD was identifed if they had at least one glomerular filtration rate <60 ml/min/1.73m^{2}in the 1 year prior to or during the 90-day period. Concordance was analyzed among residents that filled at least 1 prescription for OAD during the first 90-day continuous stay. If at least 1 of the OADs prescribed was not concordant to NKF or PIs, then that resident was classified as non-concordant. **RESULTS:** Of the 730 diabetic residents with diabetes and stage 3-5 CKD, 186 residents used the OADs included in the NKF guidelines during their 90-day stay in a NH. Of the 186 residents, 135 (72.6%) received the OADs in accordance with NKF guidelines, and 77 (41.4%) received the medications in accordance with their respective PIs. There was no significant difference in the age, gender, and educational status and NH facility location distribution among NKF and PIs concordant and non-concordant groups. However, residents in NKF concordant group were more likely to be Hispanic (32.6 vs. 13.7%, p<0.05) compared to NKF non-concordant group. **CONCLUSIONS:** The findings suggest that significant proportion of the OAD-treated residents with moderate to severe CKD, received at least one OAD prescription that was not concordant to NKF guidelines or PIs. Efforts should be made to more closely monitor OAD treatments of NH residents

PDB104

ADHERENCE TO ADA HBA1C TESTING FREQUENCY AND ANTIDIABETIC THERAPY GUIDELINES IMPROVES PATIENT OUTCOMES

Lian J, Liang Y
Novo Nordisk Inc., Princeton, NJ, USA

OBJECTIVES: The aim of this retrospective study is to evaluate the adherence of type 2 diabetes (T2DM) patients starting drug treatment to the ADA guidelines on HbA_{1C}testing and treatment modification and determine its impact on treatment outcomes. **METHODS:** Data was obtained from a large health care plan claims database between July-2008 to December-2011. Eligible patients were aged ≥18 years with ≥2 T2DM diagnoses (ICD-9CM codes 250.x0, 250.x2), and were drug-naïve for ≥6 months before the first antidiabetic drug (termed "index treatment") was required. Patient adherence to the HbA_{1C} testing guideline was defined as an initial HbA_{1C} test within 105 days of the index treatment and subsequent tests within 105 or 195 days of the previous test depending on the result (≥7 or <7%, respectively). Adherence to the drug modification guideline was defined as a change in treatment within 45 days of HbA_{1C} ≥7%. Patient outcome after one year was evaluated using the HbA_{1C}values closest to 365 days after index treatment. **RESULTS:** Of the 14,164 patients who met the study criteria, 4,419(31.20%) met the testing criteria for drug modification (HbA_{1C} ≥7%). Of these patients, 546(12.36%) met the recommended testing frequency, 934(21.14%) adhered to the drug modification guidelines, and 117(2.65%) met both guidelines. The odds ratio of a patient achieving the HbA_{1C} target (<7%) who adhered to the testing guideline was 4.66 compared with a patient who did not meet the testing guideline. Furthermore, the odds ratio of a patient in this population achieving the HbA_{1C} target was 4.95 when both guidelines were met, as compared with a patient who met neither guideline. **CONCLUSIONS:** Adherence to ADA guidelines on HbA_{1C} testing frequency and therapy modification correlated with improved outcomes one year after initial drug treatment.

PDB105

RELATIONSHIP BETWEEN SELF-MONITORING OF BLOOD GLUCOSE AND TREATMENT PROGRESSION IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

Wade RL[1], Kindermann SL[1], Hou Q[2], Dirani R[3]
[1]*Cerner Research, Culver City, CA, USA,* [2]*Cerner Research, North Kansas City, MO, USA,* [3]*LifeScan, Inc., West Chester, PA, USA*

OBJECTIVES: To evaluate the relationship between self-monitoring of blood glucose (SMBG) test strip utilization and medication intensification in Type 2 diabetes mellitus (T2DM). **METHODS:** A retrospective study of Marketscan data examined patients with T2DM with ≥2 prescription claims or a 90-day supply of at least one non-insulin antihyperglycemic (AH) agent during a 4-month baseline period between July 1, 2006 to December, 31, 2009. The first claim for an AH was the index date. Patients were classified by number and dosage of AH agents, and by their utilization of SMBG test strips during the baseline period. Utilization of AH agents and insulin was assessed during follow-up between months 6-12 post-index. Medication intensification included an increase between baseline and follow-up in the number of AH classes used, an increase in dose, or the addition of insulin. An analysis of medication intensification from baseline to follow-up between users and non-users of SMBG test strips at baseline was conducted using chi-square analysis. **RESULTS:** Among 824,461 patients selected, 482,854 used one, 258,477 used two, and 83,130 used three AH agents at baseline. SMBG test strip use was observed in 28.3% of the entire population, with 17.0% using >4 test strips weekly. The following treatment changes occurred from baseline to follow-up: no change 67.9%, a decrease in AH classes 13.0%, an increase in AH classes 15.4%, initiating insulin 2.5%, and increasing dose 6.8%. The utilization of SMBG test strips at baseline in patients with no change or a decrease in medication intensification during follow-up was 28.0%, which was significantly different compared to SMBG use in patients with an increase in AH classes (29.1%), patients initiating insulin (32.8%), and in patients increasing dose (30.6%) (all P<0.001). **CONCLUSIONS:** The use of SMBG test strips is associated with medication intensification among users of AH therapy in T2DM.

PDB106

UTILIZATION TRENDS OF VARIOUS FORMULATIONS OF TESTOSTERONE: AN ANALYSIS OF THE RAMQ DATABASE

Lachaine J[1], Beauchemin C[1], Lapierre ME[1], Snow LA[2]
[1]*University of Montreal, Montreal, QC, Canada,* [2]*Abbott, St-Laurent, QC, Canada*

OBJECTIVES: Testosterone is mainly used as androgen replacement therapy. The purpose of this study was to describe utilization trends of various testosterone formulations in a real life setting, using the RAMQ database. **METHODS:** Male patients covered by the Quebec provincial drug reimbursement program (RAMQ) who had used at least one formulation of testosterone in the period from June 1, 2003 to March 31, 2011 were selected. Characteristics of the treatments were analyzed, including switches from one formulation to another. A 1:1 control group matched for age of patients not using any formulation of testosterone was created and incidence of co-morbidities in patients in the study group was compared to the control group. **RESULTS:** Among a random sample of 125,000 patients covered by the drug plan, 723 males used at least one formulation of testosterone (0.57%). The average age was 57.2 years (SD=14.4). A total of 7 different formulations of testosterone were used by these patients. The most frequent formulations used during the study period were Andriol® (48.4%) and Androgel® (41.4%). Testosterone formulations were mainly prescribed by GPs (73%), endocrinologists (11.9%) and urologists (7.5%). About 32% of patients used more than one formulation during the study period. Among patients who switched from one formulation to another, switching to Androgel was the most frequent trend. Average treatment persistence varied from 147 days with Testim® to 674 days with Androgel. Prevalence of many co-morbidities was significantly higher amongst these patients compared to the control group. Co-morbidities included mental disorders (63.2%), hyperlipidemia (63.8%), hypertension (51.2%), articulation pain (32.1%) back pain (31.4%), HIV (6.2%) and migraine (6.6%). **CONCLUSIONS:** Patients on androgen replacement therapy have significantly more co-morbidities than controls. A significant proportion of patients will switch to a different formulation of testosterone over time, Androgel being the most frequent choice.

SENSORY SYSTEMS DISORDERS – Clinical Outcomes Studies

PSS1

THERAPEUTIC TRIAL OF INTRALESIONAL INJECTION OF MYCOPHENOLATE MOFETIL IN PSORIASIS VULGARIS: CLINICAL, HISTOPATHOLOGICAL AND IMMUNOHISTOCHEMICAL EVALUATION

Ashoush NN
British University in Egypt, Cairo, Egypt

OBJECTIVES: Systemically administered mycophenolate mofetil (MMF) has a beneficial effect in psoriasis patients. The purpose of the current study was to investigate the efficacy and safety of intralesional MMF in ordinary psoriasis vulgaris and to find out the best regimen of treatment. **METHODS:** In hundred plaque psoriasis patients, response to different concentrations (3.125, 6.25, 12.5 and 25 mg/ml) of MMF have been objectively evaluated and compared to control (5% dextrose). Patients were divided into two groups, group (A): patients who were injected once every two weeks for six weeks and group (B): patients who were injected once every week for six weeks. Patients were followed up clinically, histopathologically, and immunohisto-chemically for CD3. **RESULTS:** Maximum response to MMF was achieved 8 weeks after initiation of therapy. There was significant reduction of erythema, thickness, scaliness (P≤0.01) but not surface area (P=0.152) compared to control. Histopathologically, there was significant reduction in scores of parakeratosis, acanthosis, dilatation of papillary vessels and density of dermal mononuclear infiltrate. Immunohistochemical semi-quantitative analysis revealed variable, but in general, obvious degree of reduction in the density of CD3+ cellular infiltrate (i.e. T-cells) at the eighth visit compared to the first visit in all specimens examined. No significant difference could be seen in the efficacy of different concentrations with different regimens. No systemic or local adverse effects were noted apart from mild and transient burning sensation especially with higher concentrations. **CONCLUSIONS:** Intralesional MMF could be adopted as a safe and effective adjunctive line of treatment especially in localized plaque psoriasis.

PSS2

COMPARING TREATMENT PATTERNS AND EFFICACY OF RANIBIZUMAB FOR PATIENTS WITH AGE-RELATED MACULAR DEGENERATION (AMD): A META-ANALYSIS

Jiang S, Park C, Barner JC
The University of Texas at Austin, Austin, TX, USA