BACKGROUND: Management of type 1 diabetes (T1D) places a high burden on people living with the disease. This survey aimed to identify unmet needs in current T1D therapy, and ascertain how patients view the risk to benefit ratio of sotagliflozin as adjunct therapy to insulin.

METHODS: An online survey, carried out in November 2017, was sent to 2,084 adults with T1D who had registered in the dQ&A Market Research USA Diabetes Research Panel. A “Jobs-to-be-Done” analysis was used to produce a relative ranking of the unmet needs based on importance and satisfaction with current therapy. Conjoint analysis, a technique that simulates the real-world decision-making process, was used to determine patients’ preferences for sotagliflozin as adjunct therapy to insulin.

RESULTS: 1313 (63%) completed, valid surveys were received and included in this analysis (median age of participants: 53 [20–86] years; median diabetes duration: 30 [2–75] years). Overall, the highest ranking unmet needs identified were 1) simple and predictable diabetes management, 2) improved glycemic control (glycated hemoglobin [A1C] <7.0%), 3) spending more time in target blood glucose range (70–180 mg/dL), and 4) weight loss. When specifically testing features of sotagliflozin as an adjunct therapy to insulin, the survey revealed weight change as the most important attribute (25%), followed by time in target blood glucose range (18%); getting A1C to goal and chance of yeast infection were ranked equal third.

CONCLUSIONS: This unmet needs analysis highlights patient desire to simplify T1D management and improve glycemic control. Patients viewed sotagliflozin as able to address some of these needs, particularly by promoting weight loss and increasing time in target glucose range. Thus, the results indicate that patients with T1D view the addition of sotagliflozin as adjunct therapy to insulin as favorable after considering its potential risks and benefits.
Poster #2

GLYCEMIC CONTROL AND RISK FACTORS FOR ADULTS WITH TYPE 1 DIABETES (T1D): BASELINE DEMOGRAPHICS AND CLINICAL CHARACTERISTICS OF MORE THAN 30000 US PATIENTS FROM T1PCO STUDY

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Background: Although the incidence of T1D among adults is increasing in the US, beyond recent reports from registry data, there are limited real-world data describing the disease burden and unmet need in this patient population.

Objective: This retrospective study aimed to describe baseline demographics and clinical characteristics of the overall adult population with prevalent T1D from a large US electronic health records database.

Methods: Patients included in the T1PCO study had ≥1 T1D diagnosis (250.x1, 250.x3, E10) and were classified as T1D using the validated algorithm developed by Klompas et al, with a diagnosis of T1D during the study identification period (7/1/2014-6/30/2016, first diagnosis as index date). Patients were ≥18 years at the index date, had disease duration ≥24 months, no pregnancy, and had ≥1 insulin prescription and ≥1 A1C measurement during baseline (12 months prior to index). Outcomes were summarized using descriptive statistics.

Results: A total of 31430 patients were included in the study: mean age 45.9 years at index date; 48.9% female; 88.1% Caucasian; 7.0% African American; 57.5% commercially insured; 7.6% Medicaid insured; 15.7% Medicare insured; 14.1% current smokers; and 25.4% former smokers. At baseline, 79.9% of patients were not meeting glycemic goals (A1C ≥7.0%). Mean BMI at baseline was 28.3 kg/m2; 31.8% were obese (BMI ≥30 kg/m2), including 13.3% who were extremely/severely obese (BMI ≥35 kg/m2). Of the study patients, 33.7% had a most recent systolic blood pressure ≥130 mmHg, and 13.4% had an estimated glomerular filtration rate <60 mL/min/1.73m2. Additionally, 45.1% of patients had a diagnosis of hypertension and 52.1% a diagnosis of hyperlipidemia; 17.7% had a history of depression, and 25.4% used antidepressant/antianxiety medication. The prevalence rates of microvascular complications indicated that 10.1% of patients had neuropathy, 9.8% nephropathy, and 18.0% retinopathy. Severe hypoglycemia occurred in 5.2% and diabetic ketoacidosis (DKA) in 6.0% of patients during the 12-month baseline period.

Conclusions: To our knowledge, this is the largest real-world study of more than 30000 US adults with T1D; the outcomes reveal that the majority of individuals are not meeting glycemic goals, are overweight or obese, and commonly experience hypertension, depression, microvascular complications, severe hypoglycemia, and DKA. These results align with findings from the T1D exchange, and further highlight the significant disease burden of T1D and a large unmet need to improve disease management.

Sponsorship: Sanofi.
POSTER #3
SCREENING FOR SEVERE HYPOGLYCEMIA IN TYPE 1 DIABETES MELLITUS IN AN OUTPATIENT PEDIATRIC POPULATION
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Objectives: The purpose of this study was to implement a risk profile to prospectively identify youth with type 1 diabetes mellitus (T1D) at risk of severe hypoglycemia (SH). We hypothesized that subjects with risk factors such as prior SH, a high frequency of nocturnal hypoglycemia, and impaired hypoglycemia awareness would have a high rate of SH within the following year. If confirmed, an accurate risk assessment can lead to the efficient application of interventions that will reduce the risk of future SH, as referenced in the recent Type 1 Diabetes in Children and Adolescents a Position Statement by the ADA.

Methods: 196 subjects (from a cohort of 404) completed 1 year follow up for SH, defined as a seizure, coma or loss of consciousness in the setting of presumed hypoglycemia (ISPAD guidelines). Patients completed a questionnaire that queried about SH, nocturnal hypoglycemia, and hypoglycemia unawareness. Comparisons were made using paired t-tests and McNemar tests, where appropriate.

Results: Of the 404 enrolled, 13 subjects indicated on the initial questionnaire SH in the prior three months. In the univariate analysis, those who were more likely to have recent SH had more nocturnal hypoglycemia defined as ≥2 nights in a 3 mo period (P=0.006) and less hypoglycemia awareness (P=0.030). With regard to insulin management, those with SH had a lower insulin sensitivity factor (P=0.012) and higher proportion of basal insulin (P=0.003).

26 of subjects reported SH during the 12 month interval. In univariate analysis, subjects were more likely to experience SH with a lower total daily dose of insulin (P=0.002) or more blood glucose checks (P=0.005). In addition, subjects with a lower HbA1C at baseline were more likely to have SH (P=0.020). Nights with hypoglycemia and hypoglycemia awareness at baseline were not significantly different for prediction of events over 12 months.

Conclusions: In diverse cohort of T1D, this study presents the complex and changing nature of predicting a subject’s risk for SH in the future 12 months. Review of hypoglycemia unawareness in the preceding months did not help identify at risk youth for SH and further prospective studies are needed to identify additional risk factors.
The leading cause of death in pediatric patients with type 1 diabetes (T1D) is ketoacidosis (DKA), typically caused by insulin omission. In 2015, Children’s Healthcare of Atlanta launched a prevention program for children under 21 years of age who had at least 2 episodes of DKA in the preceding 12 months. Using phone calls, e-mail, and in-person visits, a nurse, psychologist, and social worker collaborated with the family, school, and endocrinology team to deliver education and services to enhance diabetes management and avert DKA. Because of the importance of these services for patient care, the program was operationalized rather than developed into a randomized, controlled study. This allowed a wider range of at-risk children to be helped but also posed some unique challenges to statistically measuring the program’s impact on reducing DKA risk. First, the method for the selection of a control group needed to be considered. Using the hospital database, records were retrieved for visits for 2011 to 2018 for any pediatric patients who had two DKA’s in twelve months, but either had not been in the support program, had declined participation in the program, or had withdrawn from the program. Challenges for control group selection included the options of (1) restricting the time period of the hospital visits of the control group to be contemporary with the program (2015 to 2018 visits only), which produced a smaller sample size; (2) increasing the time period to use visits back to 2011, so that a larger sample could be obtained, allowing for matching with the treatment group using propensity scores; (3) determination of criteria for inclusion in the control group. Second, the best statistical approach needed to be researched. Several options were considered: (1) logistic regression (DKA or not) using variables which were significantly different in the control and treatment groups, including presenting creatinine level, presenting glucose level, and DKA severity, along with group membership (control or treatment); (2) propensity matching of similar variables, followed by regression using the control and treatment group membership as the predictor; (3) using the propensity matching scores as covariates in an analysis of covariance with treatment and control membership as the independent variables. Depending on the approach, the outcomes varied widely, ranging from no significant relationship to an odds ratio of getting a DKA in the control group being 2.64 times higher than the treatment group (preliminary results and subject to change with further analysis). Comparison of the findings for the different methods, advantages of each, and decisions on the control sampling time frame will be shared.
Background: Many patients on basal insulin do not reach recommended blood glucose goals in a timely manner despite repeated titration of their insulin dose and the availability of other medications. In this survey the differences in patient and healthcare provider priorities and perceptions regarding their insulin therapy regimen and escalation approaches were explored.

Methods: A quantitative survey was completed online by 305 patients with T2D on BI >1 year and 240 HCPs (endocrinology and PCP). The questionnaire aimed to determine similarities and differences between HCPs and patients for their: treatment priorities; expectations in time to reach A1c goals; impact of not reaching goals; and willingness to change their therapy regimen to reach A1c goals while on basal insulin. A small qualitative survey (n=40 participants) was done in advance of the quantitative survey to refine the language and test for risk of social desirability bias in survey responses.

Results: The quantitative survey revealed the similarities and differences in patients’ and HCPs’ viewpoints and priorities. Top 3 priorities for patients were: maintaining goals long term (62%), staying healthy (44%), avoiding weight gain (43%) vs HCPs: avoiding side effects (55%), treatment affordability (53%), maintaining goals long term (45%).

In this survey, 35% of both patients and HCPs reported that A1c goals are achieved slower than expected; 49% of patients believed they will not reach goals after starting BI; 61% are willing to reach the goal faster; 80% indicated frustration about slow treatment progress. Also, 42% of patients vs 16% of HCPs expected to reach goal in 1-5 years, but both groups indicated preference for reaching goal in 6-12 months. In patients, 37% are willing to strive for their A1c goal, more than HCPs believe (16%); 46% would visit their HCP more often vs. 17% expected by HCPs; 40% of patients are willing to change medication vs. 18% (HCPs); 45% of patients would try a different injectable product vs 34% (HCPs). Only 17% of patients expect no additional medications within 12 months of starting basal insulin, but 68% of HCPs expect not to make changes in that time. 29% of Endo’s vs. 16% of PCPs anticipated reaching ≥ 100U/d BI dose via titration. In patients, 61% felt frustrated not reaching goal on BI, whereas HCP estimated only 36% of their patients were frustrated.

Conclusion: This survey highlights that patients are willing to do more than their HCPs expect. A better understanding of these differences in preferences, beliefs and perceptions could help deliver better outcomes for patients with T2D who are currently not reaching their glycemic goals, and diminish issues such as over-basalization and other complications.
Background: Understanding the barriers to treatment intensification or continuation in patients with inadequately controlled type 2 diabetes (T2D) may help to provide individualized treatment options and communication with a patient-centered perspective.

Objective: Identify barriers to treatment intensification or continuation using a patient-level survey among patients (aged ≥ 65 years) with inadequately controlled T2D (glycated hemoglobin [A1C] ≥ 8.0%), who had either discontinued insulin therapy or did not intensify treatment.

Methods: Three cohorts of Medicare Advantage patients with T2D were identified from the Humana Research Database (1/1/2016–6/31/2016). Patients had suboptimal A1C (≥ 8.0%) and: were using 2 oral antidiabetes drugs without treatment advancement (Cohort 1); were using basal insulin but had not added another injectable therapy or increased their insulin dose by > 10% (Cohort 2); or had discontinued basal insulin (≥ 90 days gap in therapy) irrespective of A1C level (Cohort 3), in a 6-month period. Cohort-specific surveys were conducted by telephone (8/7/2017–9/29/2017), focusing primarily on treatment intensification barriers in 4 key areas: injection/pain, health, lifestyle, and provider. Descriptive statistics were used to report the survey results.

Results: 305 of those eligible (4.9%) completed the survey. Inability to contact patients was the main reason for not completing the survey. In Cohort 1, (138 respondents; mean age 75.1 years; 49.3% female) the most frequently identified barrier was patients’ preference for other methods to control T2D (90.6%), followed by a belief that their T2D was under control (78.3%). In Cohort 2, (114 respondents; mean age 74.4 years; 61.6% female) the most frequently identified barrier was being comfortable or familiar with the current insulin dose (95.6%), followed by a belief that the cost of insulin or other injectables is too high (72.8%). In Cohort 3, (53 respondents; mean age 72.4 years; 64.2% female) the most frequently identified barriers were patients’ belief that their T2D was under control (66.0%) and the cost of insulin is too high (64.2%).

Conclusions: The major barriers to treatment intensification or continuation in patients with T2D on oral therapy are those related to lifestyle and health, while patients on basal insulin selected barriers related to insulin injection and cost. Adoption of a patient-centered approach including education, frequent communication, and shared decision-making between patients and providers to navigate appropriate T2D management may help remove barriers and therefore improve outcomes.
POSTER #7
BOOT CAMP LEVERAGES REAL WORLD EMR DATA TO GENERATE EVIDENCE OF IMPACT ON TYPE 2 DIABETES CARE MANAGEMENT

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Objective: Randomized controlled trials (RCTs) are the gold standard for generating evidence for diabetes care management (DCM) best practices. Translating evidence from RCTs into real world clinical settings is challenging. We have implemented a pragmatic, patient-centered, technology-enabled diabetes boot camp in support of primary care practices in a health care system. Real world data extracted from electronic medical records (EMR) was leveraged for outcomes analysis.

Research Design and Methods: Adults with type 2 diabetes and Hgb A1C > 9.0% identified and referred via the EMR participated in the 90 day diabetes intervention. Diabetes self-management education and algorithm-driven medication management were offered from 5 hub sites. Two initial in-person visits were with system Certified Diabetes Educators (CDEs) under the supervision of diabetes specialists. Patients received a cellular-enabled blood glucose (BG) monitoring system (Telcare™) that transmitted near-real-time blood glucose values to a team dashboard. Subsequent weekly ongoing management virtual visits (telephone or text) were provided. Encounters were documented in the EMR (Centricity, then Cerner) using templates built with maximized use of structured data fields. Participants’ data was compared with that of concurrent, propensity-matched (1:1) chart controls receiving standard diabetes care. All data analyzed was extracted from the EMR and system databases. HbA1c at 90 days, risk for hospitalizations, and costs were examined.

Results: A total of 366 participants, majority (81%) Black, 62% female, mean age 56.7 years, 60% Medicare or Medicaid, and referred from 35 practices, completed the Boot Camp. Their EMR data was compared to that of 366 controls. Baseline mean HbA1c for cases and controls respectively were 11.2% and 11.3% , and at 90 days were 8.1% and 9.9% (p<0.001). Reduction in risk for 90 day all-cause hospitalizations among boot camp participants was - 77%, compared to an increase of + 58% for chart controls, p=0.036. A boot camp participant is projected to save $3,086.40 annually in averted hospitalization costs based on actual system cost data.

Conclusions: We implemented a real world intensive DCM intervention in a health care system. All clinical, utilization and cost data were available in the EMR and system databases as part of regular care and were extracted and analyzed to generate evidence of the program’s effectiveness. Significant improvement in glycemic control and health care utilization as compared to standard of care were
observed. The real world evidence generated has been instrumental in securing ongoing funding and support from the system to sustain and spread the program.

**POSTER #8**

*GLYCEMIC OUTCOMES AND PERSISTENCE OF BASAL INSULIN AND GLP-1 RA AMONG PATIENTS WITH TYPE 2 DIABETES: SIMULTANEOUS VS SEQUENTIAL INITIATION*

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This real-world retrospective observational analysis was conducted from a US regional (Louisiana and Texas) electronic medical record (EMR) database: Research Action for Health Network (REACHnet). We evaluated glycemic control outcomes after simultaneous or sequential initiation of basal insulin (BI) and glucagon-like peptide 1 receptor agonist (GLP-1 RA) in patients with type 2 diabetes (T2D) uncontrolled (A1C ≥7%) on oral anti-diabetes drugs (OADs). Three cohorts of patients were defined as follows: Cohort 1, patients initiating BI and GLP-1 RA simultaneously (n=109); Cohort 2, patients initiating BI followed by GLP-1 RA within 90 days (n=301); and Cohort 3, patients initiating BI followed by GLP-1 RA after 90 days (n=459). Baseline characteristics were very similar across the cohorts, including mean A1C (10.3%, 10.3%, and 10.2% in Cohorts 1, 2, and 3, respectively), with similar comorbidities such as dyslipidemia, hypertension, and obesity. Mean A1C decreased in all 3 cohorts in the 12 months from the index date (date of first BI injection), but the majority of patients did not reach A1C goal <7%. The greatest mean A1C reductions occurred within the first 6 months with simultaneous administration (Cohort 1, –2.18%), followed by addition of GLP-1 RA within 90 days (Cohort 2, –1.77%), and addition of GLP-1 RA after 90 days (Cohort 3, –1.24%). This order was maintained at 12 months: Cohort 1 (–1.66%), Cohort 2 (–1.46%), and Cohort 3 (–1.32%). Persistence (i.e. non-discontinuation of index treatments) at 12 months was 74.3%, 73.8%, and 80.0% in Cohorts 1, 2, and 3, respectively. Kaplan–Meier survival curves (KM-curves) also demonstrated that the simultaneous approach to treatment resulted in the greater proportion of patients achieving A1C <7% at 12 months (33.4%, 24.5%, and 20.9% in Cohorts 1, 2, and 3, respectively). Pairwise log-rank tests on KM-curves indicated a statistically significant difference between Cohorts 1 and 3 (p=0.0186), but not between Cohorts 1 and 2, or between Cohorts 2 and 3. In conclusion, this retrospective analysis in patients with T2D uncontrolled on OADs suggests that simultaneous initiation of BI and a GLP-1 RA resulted in significantly better glycemic control than sequential initiation of BI followed by GLP-1 RA after a 90 day timeframe.

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POSTER #9
A RETROSPECTIVE REAL WORLD EVIDENCE STUDY ON GLYCEMIC GOAL ACHIEVEMENT WITHIN 2 YEARS POST BASAL INSULIN INITIATION IN THE US
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The probability of reaching glycemic goal of A1C <7% in patients with type 2 diabetes and A1C ≥7% who initiated basal insulin (BI) following oral therapy was investigated using real world data extracted from the Optum Humedica EMR database. The study cohort consisted of 70,288 patients who met inclusion criteria. Index date was defined as the time of initiating BI, and baseline A1C reading was defined as being obtained within 90 days prior to and including the Index date. Key baseline characteristics included: mean age, 59 years; mean BMI, 34.1 kg/m²; mean A1C, 9.8%; mean FPG, 190.6 mg/dL; male, 53.0%; 74.8%, 14.2%, and 2.3% were Caucasian, African American, and Asian American, respectively. In the 6 months prior to initiation of BI, there was a rapid increase in mean A1C from ~8.5% to 9.8% while on oral therapy.

After BI initiation, mean A1C rapidly declined to ~8.2% after 3 months and remained steady through 24 months. The Kaplan–Meier curve for reaching the first event of glycemic control (A1C <7%) showed a steep slope in the first 12 months, but remained flat during the next 12 months. Patients with higher baseline A1C were less likely to achieve glycemic goal. Lower baseline A1C was associated with longer persistence of index medications: mean duration was 574.1, 489.3, and 479.3 days for sub-cohorts with baseline A1C ≥7% and <8%, ≥8% and <9%, and ≥9%, respectively.

Baseline characteristics associated with higher probability of reaching glycemic goal of A1C <7% included: ages 18 to 34 years or 55 to 64 years; male gender; Caucasian race; and non-Hispanic ethnicity. Patients with baseline A1C ≥8% and <9%, or A1C ≥9% had lower probability of reaching glycemic goal, as well as those with comorbidities such as coronary heart disease, neuropathy, peripheral vascular disease, and retinopathy (which could have been indicative of longer duration of disease).

These results from a large representative EMR database in the US suggest that the 12-month time point following basal insulin initiation remains an important trigger in considering therapeutic advancement. If an A1C goal of <7% is not achieved at 12 months from initiation, it is unlikely that this glycemic goal will be achieved within the next 24-months. For clinicians, it is important to realize that the likelihood of achieving control diminishes precipitously after 12 months, and they may wish to consider additional options to help patients achieve glycemic control.
POSTER #10

INNOVATIVE TAILORED MICROLEARNING APPROACH TO INSULIN SELF-MANAGEMENT EDUCATION SHOWS HIGH ENGAGEMENT LEVELS AMONG DIVERSE ADULTS

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Self-management education for adults with type 2 diabetes (T2DM) improves knowledge, skills and motivation; yet, new strategies to more effectively educate patients and improve adoption of insulin therapy are still needed. We conducted a prospective, non-randomized multi-center pilot, using a novel Patient Experience Cloud to deliver microlearning education focused on survival skills, insulin injection technique, and lifestyle management. Consented T2DM adults, age 20-70 years, were presented an online library of 56 education videos (1-4 minutes each). Pre and post surveys of self-reported attitudes towards insulin and patient activation measures (using the validated PAM scale) were obtained. The study enrolled 201 patients: 78 Non-Hispanic Whites (NHWs), 74 African Americans (AAs), 39 Hispanic Whites (HWs) and 10 Other. Of these, 181 (90%) were engaged (defined as completing baseline surveys and watching 4+ videos). The number of videos viewed differed by race, p=0.012; with median number of 23 for AAs, 13 for NHWs and 5 for HWs. One week later, 83 participants (41%) continued engagement via viewing and completion of post questionnaires. Highest engagement was seen among AAs (51%) versus 40% of NHWs and 26% of HWs. Overall attitudes towards insulin improved significantly, with a mean change of 0.29 points (on a 6 point Likert scale, 95% CI 0.02 to 0.56, p=0.03). Similarly, the PAM score increased significantly after viewing (by 0.17 point on a 4 point scale, 95% CI 0.08 to 0.26, p<0.001), independent of race. After viewing culturally tailored microlearning delivered via a cloud platform, patient attitudes towards insulin and activation measures for self-care improved significantly. This novel approach should be further investigated for its ability to improve adherence to insulin and glycemic outcomes.
Hypoglycemic events during basal insulin (BI) treatment, recorded by physicians in US electronic health records in real-life practice, were used to predict hypoglycemia rates in people with T2DM prescribed BI analogs. Based on large-scale real-world data (Optum Humedica), a predictive model (implementing machine learning and controlling for >160 baseline demographic and clinical variables) was developed and validated for each drug-specific cohort (patients treated with a specific BI). Overall, models predicted similar severe hypoglycemia (defined by ICD-9/10 codes, plasma glucose <54 mg/dL, intramuscular glucose administration, or natural language processing of clinical notes) rates when switching from another BI to second-generation BI analogs Gla-300 or IDeg, with median hypoglycemia rates of 21.00 and 21.15 per hundred patient-years [PHPY], respectively, and a difference vs Gla-300 of $-0.11$ (95% confidence interval [CI]: $-5.94; 6.47$; 1-sided p-value: 0.492). This subanalysis focuses on severe hypoglycemia rates in clinically vulnerable subgroups of patients (with prior hypoglycemia, renal insufficiency, and aged $\geq 65$). Numerically, the highest rates were found in the subgroup with prior hypoglycemic events: 52.01 and 43.64 PHPY for Gla-300 and IDeg, respectively; difference vs Gla-300 (95% CI): 8.26 (−6.44; 26.67); p-value: 0.859. The models predicted no statistically significant differences in media rates of severe hypoglycemia between Gla-300 and IDeg in any of the at-risk subgroups (for patients with moderate/severe renal impairment: 30.75 and 31.64 PHPY, respectively; difference vs Gla-300 [95% CI]: $-0.89$ [−10.03; 10.32]; p-value: 0.430; for patients $\geq 65$ years of age: 22.52 and 26.43 PHPY, respectively; difference vs Gla-300 [95% CI]: $-3.75$ [−11.28; 5.66]; p-value: 0.200). In summary, using real-world data, these predictive modeling results show similar rates of severe hypoglycemia when switching to either Gla-300 or IDeg, in subgroups of patients with T2DM at high risk of hypoglycemia.
**POSTER #12**

**A RANDOMIZED PROSPECTIVE PRAGMATIC REAL-WORLD CLINICAL TRIAL OF INSULIN GLARGINE 300 U/ML (Gla-300) VS OTHER BASAL INSULINS (BIs) IN INSULIN-NAIVE PATIENTS WITH TYPE 2 DIABETES (T2D): 6-MONTH ANALYSIS OF THE ACHIEVE CONTROL STUDY (NCT02451137)**

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Background: RCTs have established the efficacy of various BI preparations for T2D, but their real-world effectiveness has not yet been fully established. Second-generation BIs such as Gla-300 may offer improved glycemic control with lower hypoglycemia risk. Pragmatic prospective trials using randomization allow assessment of BIs in a broad primary care population, providing valuable insights on clinical outcomes, safety, and resource utilization of various treatment strategies for HCPs and payers.

Objective: ACHIEVE Control is a pragmatic clinical trial comparing the effectiveness and safety of Gla-300 vs other BIs used in a standard of care (SoC-BI) setting in insulin-naive patients with T2D inadequately controlled on ≥2 OADs or glucagon-like peptide-1 receptor agonists after ≥1 year of treatment.

Methods: Insulin-naive patients with T2D (ICD10 E11.x), age ≥18 years, A1C 8.0-11.0%, under continuous care for ≥1 year before the index date were randomized to Gla-300 or SoC-BI in conjunction with optional patient support programs. This US study was powered to demonstrate superiority of Gla-300 in achieving the composite primary endpoint of proportion of patients reaching individualized HEDIS A1C targets (<8.0% if age ≥65 years or with defined comorbidities, <7.0% otherwise) without documented symptomatic (blood glucose ≤70 mg/dL) and/or severe hypoglycemia over a 6-month period. Secondary endpoints included change from baseline to 6 months in A1C, fasting plasma glucose (FPG), body weight (BW), and BI dose.

Results: 3,304 patients at 407 sites (167 sites identified in collaboration with insurance providers) were randomized to receive Gla-300 (n=1,651) or SoC-BI (n=1,653). Baseline characteristics were similar between groups. At 6 months, Gla-300 met prespecified criteria for superiority vs SoC-BI in achieving the composite primary endpoint (31.3% vs 27.9%; P=0.03 for superiority). A1C change from baseline to 6 months was -1.41% for Gla-300 and -1.36% for SoC-BI (P=0.32). The difference in hypoglycemia events rate between groups did not reach statistical significance (RR=0.92 [0.71, 1.19]). There were no differences between Gla-300 and SoC-BI for FPG, BW change, BI dose, or treatment-emergent adverse events.

Conclusions: In this randomized prospective pragmatic trial, a Gla-300-based approach was superior to SoC-BI for the attainment of individualized A1C targets without hypoglycemia at similar BI dose and with similar BW change. This is the first pragmatic trial to study real-world comparative effectiveness and safety of Gla-300 and provide valuable insights for HCPs and payers.
Background: Many patients (pts) with T2D treated with oral anti-hyperglycemic drugs (OADs) or glucagon-like peptide-1 receptor agonists (GLP-1 RAs) experience suboptimal A1C levels, and could benefit from basal insulin (BI) therapy. Insulin glargine 300 U/mL (Gla-300) is a long-acting second-generation BI analog indicated to improve glycemic control in adult pts with diabetes.

Objective: Compare effectiveness of Gla-300 vs insulin glargine 100 U/mL (Gla-100) in pts with T2D newly initiating BI in real-world (RW) clinical settings.

Methods: Data from insulin-naive adult pts with T2D initiating Gla-300 or Gla-100 treatment from 03/01/15 to 12/31/16 were extracted from electronic medical records in the Predictive Health Intelligence Environment database representing 39 integrated health care delivery networks. Inclusion criteria were: using 1 OAD or GLP-1 RA in 12-month baseline (BL) period prior to BI initiation (index date); 6 months of follow-up; and 1 A1C value within 6 months prior to index date and during follow-up (> 90 days). Propensity score matching (PSM) 1:2 was conducted on BL demographic and clinical characteristics for pts in the two cohorts. A1C levels and hypoglycemia events were determined at 3-6 and 6 months of follow-up, respectively. PROC MIXED with repeated measures was used to compare mean A1C reductions and hypoglycemia event rate difference between arms. Goal attainment was compared using Cochran-Mantel-Haenszel test.

Results: 1,044 pts initiating on Gla-300 and 15,901 pts initiating on Gla-100 were eligible; after PSM, 1,044 and 2,088 pts were in Gla-300 and Gla-100 arms, respectively. BL demographic and clinical characteristics in matched pts were similar except for payer type, which was controlled in all models. A1C reductions were 1.52% in Gla-300 arm and 1.30% in Gla-100 arm (difference between arms: P = 0.003); adjusted mean hypoglycemia event rate difference between arms was 0.109 events per pt per year for Gla-300 vs. Gla-100 (P = 0.077). Pts in Gla-300 arm were more likely to attain A1C goals of < 7.0% (25.0% vs. 21.5%, respectively; P = 0.029) and < 8.0% (55.0% vs. 49.2%; P = 0.002). Significantly more pts in Gla-300 arm reached A1C goals of < 7.0% (21.9% vs. 17.4%, respectively; P = 0.003) and < 8.0% (49.1% vs. 41.8%; P = 0.0001) without experiencing hypoglycemia.

Conclusions: Gla-300 vs Gla-100 initiation in insulin-naive pts with T2D in RW clinical settings is associated with greater A1C reduction and increased attainment of A1C goals of < 7.0% and < 8.0%, as well as a trend toward fewer hypoglycemia events at 6-month follow-up.

Sponsorship: Sanofi.
POSTER #14

COMPARABLE GLYCEMIC CONTROL AND HYPOGLYCEMIA OUTCOMES IN ADULT PATIENTS WITH TYPE 2 DIABETES (T2D) INITIATING INSULIN GLARGINE 300 U/ML (Gla-300) VS INSULIN DEGLUDEC (IDeg) IN REAL-WORLD CLINICAL PRACTICE: DELIVER NAIVE D STUDY

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Objective: This retrospective, observational study compared clinical outcomes in insulin-naive adults with T2D initiating Gla-300 or IDeg in a real-world clinical setting.

Methods: Electronic medical records from the Predictive Health Intelligence Environment database (IBM® Explorys, US) were analyzed (3/1/2015–3/31/2018). Key inclusion criteria were: insulin-naive adults with T2D on oral antihyperglycemic drugs and/or a glucagon-like peptide-1 receptor agonist during 12-month baseline; ≥1 basal insulin prescription during identification period (first prescription = index date); ≥1 A1C value during 6-month baseline; and >90 days during 6-month follow-up. Propensity score matching (PSM) 1:1 was conducted on baseline demographics, clinical characteristics, and other factors (e.g. insurance type) for patients in the 2 cohorts. Endpoints were: A1C change and A1C target (<7.0% and <8.0%) attainment during follow-up; hypoglycemia (ICD-9/-10-CM and/or plasma glucose ≤70 mg/dL, all events or events associated with an inpatient/emergency department [ED] encounter); and proportion of patients discontinuing therapy.

Results: Before PSM, 1277 patients initiating Gla-300 and 653 patients initiating IDeg were eligible. After PSM, baseline demographics and clinical characteristics were similar in matched groups (Gla-300, N=638; IDeg, N=638). When comparing matched Gla-300 and IDeg groups, mean A1C reductions were similar (1.67% vs 1.58%, respectively; p=0.51), as was attainment of A1C goals <7.0% (23.82% vs 27.43%; p=0.20) and <8.0% (55.02% vs 57.05%; p=0.63). Comparing the Gla-300 versus IDeg groups at 6 months fixed follow-up, adjusting for baseline hypoglycemia as a covariate, the incidences of all hypoglycemia (10.34% vs 11.13%; p=0.75) and inpatient/ED hypoglycemia (2.04% vs 2.51%; p=0.42) were similar. With variable follow-up, incidences of all hypoglycemia (adjusted hazard ratio [HR] 1.02; p=0.93) and inpatient/ED hypoglycemia (adjusted HR 0.84; p=0.67) were similar between the groups, as was all hypoglycemia (rate ratio [RR] 0.88; p=0.33) and inpatient/ED hypoglycemia event rate (RR 0.63; p=0.15). A similar proportion of patients in the Gla-300 versus IDeg groups discontinued therapy (29.15% vs 32.60%; adjusted HR 0.86; p=0.14).

Conclusions: In insulin-naive adults with T2D, initiation of Gla-300 or IDeg therapy resulted in similar improvements in glycemic control, and comparable hypoglycemia outcomes and discontinuation rates in the real-world clinical setting. These findings are consistent with the results of the first recently completed head-to-head randomized controlled trial of Gla-300 versus IDeg in this field.

Sponsorship: Sanofi.
POSTER #15
REAL-WORLD GLYCEMIC CONTROL DATA FROM THE INITIAL LAUNCH OF THE ONDUO VIRTUAL DIABETES CLINIC

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Background: Access to comprehensive diabetes care—education, behavior change, and endocrinologic consultation—is limited in many parts of the US. By combining mobile app technology, continuous glucose monitoring (CGM), and a coordinated team of clinicians, the Onduo Virtual Diabetes Clinic (VDC) provides comprehensive diabetes management services without office visits and in real-time. These services range from lifestyle coaching and internet-connected blood glucose monitoring to endocrinologic consultation and medication management. Here, we report initial glycemic results of a real-world, commercial pilot launch of the VDC in South Carolina, Georgia, and Arkansas across urban and rural geographies.

Methods: Patients with Type 2 diabetes enrolled in the VDC online and made primary contact with a health coach via a mobile app. Baseline HbA1c values were collected by FDA cleared at-home tests or lab report from enrollees. Patients received diet and lifestyle coaching by mobile chat in accordance with an AADE-based curriculum and, where appropriate, medication management by telemedicine according to ADA guidelines. After a minimum of 80 days after the baseline HbA1c, a follow-up HbA1c was requested. Change in HbA1c was analyzed in two sub-groups pre-specified according to baseline HbA1c: 1) 6.0-7.9%, 2) >= 8.0%. Patients missing a baseline or follow-up A1c were excluded from the analysis.

Results: In the initial program launch 133 patients returned baseline and follow-up HbA1c values. Sub-group 1 maintained blood glucose control with a mean change in HbA1c of +0.13 (n=89, p=0.094) and sub-group 2 improved blood glucose control with a mean change in HbA1c of -1.34 (n=44, p < 0.001).

Conclusions: These preliminary, real-world glycemic data suggest that the Onduo VDC can both maintain glycemic control in individuals with HbA1c 6.0-7.9% and improve glycemic control in those with HbA1c >= 8.0%.
POSTER #16

USING GOOGLE CLOUD AND PREDICTIVE ANALYTICS TO PROMOTE INFLUENZA VACCINATION AMONG PEOPLE WITH DIABETES

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Background: Although influenza vaccination is recommended for people with type 1 & 2 diabetes, uptake is suboptimal, often leading to complications & hospitalizations. Vaccine acceptance is influenced by several psychosocial & behavioral factors, including one’s knowledge of flu & vaccination beliefs. We used novel data sources to understand predictors of vaccination adherence among countries & subpopulations

Methods: We used VaxiTrends, a proprietary dataset, to identify variables influencing vaccine uptake among adults in the U.S., China, France, Mexico, and U.K. We combined the data with NH Interview Survey results, which offer insights into health behaviors of Americans with diabetes. This information was aggregated with data from Google’s FluTrend, which signals flu incidence, & Google Trends Application Programming Interface, which tracks search keyword popularity by location & date in a de-identified fashion. Cluster analyses indicated factors most positively & negatively associated with acceptance & adherence

Results: Our analysis indicates that targeted interventions focusing on country-specific drivers of flu vaccination adherence among subpopulations of people with diabetes could lead to an increase in vaccination rates of up to 5%. In France, Mexico & U.K., relationships with HCPs were most predictive of vaccination adherence, while in the U.S., reminders & strategies addressing affordability concerns were key predictors. In China, encouragement from relatives, convenient options for receiving vaccinations & education to counter fear of flu vaccination may have the greatest impact. Within countries, we found some patient subgroups were more amenable to vaccination than others

Conclusion: By identifying country-specific behavioral drivers of flu vaccination & most receptive subgroups, we can design more tailored interventions to increase uptake.
Influenza causes substantial morbidity in people with Diabetes; annual vaccination is recommended. We conducted a retrospective cohort study of influenza-related outcomes (IRO) among fully insured Type 2 diabetics from a large US payer over a 1 year period covering the 2016-17 influenza season. We used bivariate analysis (54,656 diabetics, mean age 54.8 yr, s.d. = 10.2) to compare IRO’s inferred from claims data against IRO’s for 113,016 age and gender matched non-diabetics.

People with Diabetes had more influenza events (influenza specific ICD-9 and ICD-10 codes, 1.96% vs 1.37%, p<0.001), and were prescribed more influenza antivirals per 100 people (27.1 vs 22, p<0.001). Within 2-weeks before and 4-weeks after a medical claim for influenza, the diabetic population with influenza had more observed hyperglycemic events than in a comparable non-influenza period in the same year (3.81% vs 2.18%, p<0.001), and also experienced substantial increases in pneumonia, sepsis and coronary disease (5.5% vs 0.7%, 5.5% vs 3.5%, 1.6% vs 0.3% respectively, p<0.001), as well as more outpatient antibiotic use per 100 people (54.5 vs 16.9, p<0.001).

8.2% of Type 2 Diabetes patients (vs. 9.1% controls, p<0.001) used commercially available activity and sleep trackers, sharing data through a wellness platform powered by the insurer. Activity trackers showed that people with Diabetes slept fewer hours compared to controls (6.48 vs 6.69 hrs, p<0.001), and had statistically significant changes in sleep and walking habits in the days around an influenza event as compared to baseline (about 2% more of the night spent restless and 10,000 fewer steps).

This is the first population scale study to use medical claims linked with activity tracking data to quantify the behavioral and clinical effects of influenza in Type 2 Diabetes patients. These data highlight the impact of influenza on glycemic control and the daily lives of the Diabetic population, and reinforce the need for annual influenza vaccine, as recommended by the WHO and other global public health bodies.

This study was sponsored by Sanofi.
POSTER #18

PHYSICAL ACTIVITY IMPACTS METABOLIC HEALTH VIA INSULIN RESISTANCE

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Introduction: There has been a significant increase in the prevalence of type 2 diabetes, obesity, and metabolic unhealthiness in the U.S population over the past decade. We hypothesized that physical activity is running counter to the increasing trend.

Methods: We identified metabolic healthy (MH) and metabolic unhealthy (MUH) participants of National Health and Nutrition Examination Surveys (NHANES) conducted between 1999-2010 (unweighted N=9316, MH=4846, MUH=4470), and examined “lifestyle” differences, physical activity and sedentary behavior, between the metabolically healthy and metabolically unhealthy participants. Metabolic unhealthiness was defined as having 2 or more cardiometabolic abnormalities: high triglycerides, decreased HDL-C, high c-reactive protein, high fasting glucose, insulin resistance, use of a lipid lowering therapeutic and blood pressure control therapeutic.

Results: We found significant differences in physical activity levels between metabolically healthy and unhealthy individuals. Overall, we found that physical activity was protective of metabolic health (OR=0.86, 95%CI 0.78-0.94). On examination of individual markers of metabolic unhealthiness, we found that physical activity was protective in the case of blood glucose levels (OR = 0.9, 95% CI 0.82-0.97), insulin resistance (OR = 0.84, 95% CI= 0.78-0.89), and body mass index (ES = -0.11 , 95% CI 0.1-0.12), but did not significantly impact blood pressure, inflammation (c-reactive protein), triglycerides and HDL. We found that while sedentary behavior was not a significant contributor to overall metabolic unhealthiness, it did significantly increased the odds of elevated C-reactive protein levels (OR =1.21, 95% CI 1.01-1.45) and increased insulin resistance (OR=1.32, 95% CI 1.06-1.64), and increased body mass index (ES =0.05, 95% CI 0.03-0.07)

Discussion: Prevalence of elevated blood glucose levels, insulin resistance and obesity in the U.S showed significant increases between 1999-2010 (p < 0.0001). As expected, physical activity is strongly associated with of metabolic health but this association is mainly through fasting glucose and insulin resistance and not other indicators of metabolic health, such as blood pressure or HDL-C. Physical activity prevention efforts may selectively impact insulin resistance rather than other cardiometabolic risk factors.
POSTER #19
MULTI-COHORT TRANSCRIPT WIDE ASSOCIATION STUDY IDENTIFIES GENES ASSOCIATED WITH AEROBIC AND ANAEROBIC INTERVENTION AND PROSPECTIVE FREE-LIVING ACTIVE ENERGY EXPENDITURE

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Introduction: Physical activity is associated with decreased risk for many chronic and acute conditions and is increasingly used as a therapeutic intervention for diabetes, cardiovascular disease among others. In this study, we aimed to identify common changes in expression of genes due to aerobic and anaerobic physical activity and investigated the efficacy of the identified exercise intervention signature in predicting prospective “real life” activity and sedentary behavior.

Methods: We performed a multi-cohort analysis of twenty publically available datasets (N=638) to identify a set of genes differentially expressed by physical activity intervention. We replicated our results in five independent interventional cohorts (N=245) validation sets with a mix of healthy subjects and subjects with metabolic syndrome, including a control set. We next investigated the association of the PA signature genes in under “free-living” conditions in 432 twins using accelerometry data.

Results: We identified a 23-gene set that discriminated between pre- and post-exercise samples from healthy and adults with metabolic syndrome with an average AUC of 0.75. We found that there was no significant difference between the mean PA scores for pre- and post-physical activity samples (GSE59088-Control, p=0.8, N=12) in the control set where subjects were part of a control group that did not perform any physical activity. Finally we assessed prospective association of the physical activity signature in a “free-living” observational twins cohort (N=418) with samples from blood, adipose and skin tissues to assess. Our results show that the PA signature can (1) discriminate pre-exercise samples from post-exercise samples, (2) is significantly correlated with prospective active energy expenditure, and (3) has a significant inverse association with sedentary behavior. Further, our results show that a subset of the PA signature genes is attenuated even with lower levels of activity measured in free-living conditions.

Discussion: As chronic conditions such as diabetes and obesity reach epidemic status (Butterfield et al. 2016; “WHO | Diabetes” 2016, “WHO | Obesity and Overweight” 2016), there is a pressing need to not only gain better understanding of the molecular mechanisms that govern physical activity but to also develop better diagnostic tools that can calibrate physical activity at the molecular level. Such an understanding/diagnostic tools can lead to more precise exercise and treatment plans, reducing patient risk for chronic conditions such as diabetes.
POSTER #20
WHEN RWE COMES TO MARRY CVOTS: THE CVD-REAL STUDY
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Recently the role of real-world evidence (RWE) has expanded rapidly, with attention from multiple authorities (FDA/EMA) developing guidance for the use of RWE in regulatory decisions. Public-private consortia (e.g. IMI GetReal) comprising pharmaceutical companies, academia, regulators, patient groups and small- and medium-sized enterprises have shown how robust methods of RWE data collection can be developed and adopted earlier in pharmaceutical R&D and healthcare decision-making. However, consensus on best practice in the application of RWE to clinical practice, regulatory decisions and reimbursement remains elusive. As a result, RWE is often confined to a supportive/confirmatory role to randomized controlled trials (RCTs), especially in the development of clinical guidelines.

Real-world data sources, methods, study designs and analytic tools have improved dramatically, increasing the ability to produce meaningful results that complement evidence from RCTs. One example that illustrates this is the effect of type 2 diabetes (T2D) medications on cardiovascular (CV) risk. Recent CVOTs have demonstrated a significant reduction in major adverse CV events, death, and hospitalizations for heart failure (HHF) with sodium-glucose cotransporter-2 inhibitors (SGLT-2i) in patients with T2D and established CV disease (CVD).

CVD-REAL is an innovative, large, international, comparative effectiveness, pharmaco-epidemiologic study evaluating CV outcomes associated with SGLT-2i vs other glucose-lowering drugs (oGLDs) in patients with T2D. CVD-REAL pooled de-identified administrative/medical records of >700,000 patients from 12+ countries across 4 major world regions (North America, Europe, Middle East, Asia Pacific) from a total population of ~5M T2D patients. SGLT-2i patients were matched 1:1 using propensity score methodology with those receiving oGLDs to minimize confounding by indication and establish well-balanced baseline characteristics across treatment groups. In contrast to RCTs (and in line with what would be expected in a broadly representative T2D population) most patients didn’t have established CVD. Use of SGLT-2i vs oGLDs was associated with lower risk of death, HHF, death or HHF, myocardial infarction and stroke. Results were consistent across countries and patient demographics/characteristics, and remained stable after multiple sensitivity analyses, effectively complementing and extending data from CVOTs.

To conclude, CVD-REAL shows how well-designed large pharmaco-epidemiologic comparative effectiveness studies provide insight into current clinical practice and complement RCT data with a tangible impact on clinical practice.
**POSTER #21**

**PREDICTING RECURRENT CVD EVENTS AMONG ADULTS WITH STABLE CVD: A NEW RISK MODEL BASED ON THE POOLED NIH COHORTS**

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Background: Estimating downstream risk for cardiovascular disease (CVD) events among those with known CVD is important, as it can influence estimated treatment benefit, cost effectiveness, and treatment selection.

Purpose: To develop a prediction model to estimate the risk of recurrent CVD events among adults with known atherosclerotic CVD.

Methods: Pooled data from the Atherosclerotic Risk in Communities (ARIC) study, Cardiovascular Health Study (CHS), and Framingham Original and Offspring Studies were used to identify adults with known CVD (prior myocardial infarction [MI], angina, coronary revascularization, stroke, transient ischemic attack, or peripheral arterial disease). Multivariable Cox regression was used to develop a model for hard CVD events (MI, stroke, or cardiovascular death) at 5 years.

Results: Overall 1835 adults with known CVD were included in the analysis. Over 5 years, the CVD event rate was 4.1 per 100 person-years. The final model included age, race, sex, diastolic blood pressure, non-high-density lipoprotein cholesterol, creatinine clearance, statin use, blood pressure medication use, peripheral arterial disease, heart failure, diabetes (on insulin, on orals, no diabetes), and history of stroke or MI in the prior 5 years. Model risk estimates varied widely among patient risk deciles (from under 10% to >50%) and were calibrated with observed risk. After bootstrap correction, model discrimination (c-index) was 0.70 (95% confidence interval 0.67–0.73).

Conclusion: Using readily available demographic and clinical characteristics, risk for recurrent CVD events can be accurately estimated among those known CVD. Targeting those at highest risk may help improve the selection and cost-effectiveness of CVD therapies.
**POSTER #22**

**MULTIMORBIDITY PROFILE OF OLDER ADULTS WITH DIABETES**

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Introduction: Nearly 25% of adults aged 65 or older have diabetes, and the aging of the overall population has been a significant driver of the diabetes epidemic. Individuals with diabetes often present with co-occurring chronic conditions, such as cardiovascular disease. In older adults, diabetes also co-occurs with functional limitations (FL) and geriatric syndromes (GS). Multimorbidity (MM) has been widely defined as the co-occurrence of 2 or more chronic conditions. In this study, we aimed to expand the definition of MM by also accounting for FL and GS. We then describe the MM profile and sociodemographic characteristics of older adults with diabetes.

Methods: We conducted a cross-sectional study using data from the 2010 Health and Retirement Study linked to 2010-2011 Medicare data. Individuals age 65 years or older were identified as diabetic if they had a self-report of diabetes and if they had diabetes based on the Chronic Condition Warehouse algorithm. Excluding proxy respondents and individuals who died before the 2010 HRS interview, there were a total of 1,858 persons with diabetes in the study population. We conducted a descriptive analysis to describe the MM burden and the sociodemographic characteristics of our study population; additionally we stratified by the count of conditions constituting multimorbidity (CCMM).

Results: Of the 1,858 persons with diabetes in our study, about half (50.4%) were under age 75, 43.5% were men, 30.6% were non-Hispanic Black or Hispanic, and 13.9% were on Medicaid or dually eligible Medicare-Medicaid beneficiaries. When examining MM, 79% of our study population presented with additional chronic conditions, FL, as well as GS, whereas only 0.4% had none of these conditions, 3.7% had one CCMM, and 16.9% had 2 CCMM. With regards to CCMM count, 69.5% presented with at least 6 conditions, including 27% with 10 or more conditions. More than one third (34.8%) of our study population who presented with 10 or more conditions were 85 years or older. Similarly, higher counts were observed among women than among men, and among those with lower income and/or educational attainment than among those with higher income and/or educational attainment.

Discussion: Our findings indicate that functional limitations and geriatric syndrome considerably add to the multimorbidity burden in older adults with diabetes. This study highlighted the importance of characterizing multimorbidity in broader terms rather than limiting its definition to the co-occurrence of chronic conditions alone. Further analysis will be conducted using association rule mining to identify the combinations of CCMM.
Objective: Diabetes Mellitus (DM) has been shown to be associated with osteoarthritis (OA). However, previous evidence was mainly focused on knee or hip OA regardless of the impact of diabetes as a systemic disease. This metabolic disturbance is associated with low grade inflammation that may affect any part of the body including joints. DM may be associated with generalized OA (GOA; multiple joints) rather than localized OA (LOA; 1 or 2 joints). Therefore, the purpose of this study is to examine the prevalence of DM in people with GOA compared to LOA.

Methods: A retrospective review of de-identified data was performed for patients who were seen between 2013 and 2017 in a tertiary medical center using a clinical data repository system (i2b2). A query was built to select patients who have diagnoses codes using international classification of disease 9th and 10th revisions. Each patient must have at least 2 diagnostic codes of OA separated by at least one day to be included. Index date was set as the first diagnosis date of either LOA or GOA. These codes include primary GOA, primary LOA and DM. Patients were excluded if they had diagnoses codes for cancer, type 1 diabetes, rheumatoid arthritis, fibromyalgia, gout or secondary OA. Other variables included in the analysis were: age, sex, race; diagnoses codes for depression, anxiety, sleep disorders; and medication list (+/- 90 days of the index date of OA). The main outcome was the presence of either GOA or LOA diagnoses codes. Chi square and logistic regression were used at a .05 alpha level.

Results: Data from 3884 patients (mean age = 66.40±11.01, 60.9% women) included patients with GOA (n=1274) and LOA (n=2610). The prevalence of DM among patients with GOA was significantly greater (25.9%) compared to the prevalence of DM among patients with LOA (12.1%); (p<0.001). The final model of logistic regression showed that DM was significantly associated with GOA (odds ratio 2.16, 95% confidence interval 1.70 -2.76, p<0.001) after controlling for covariates including age, sex, race, depression, anxiety, sleep disorders, and medications (for pain, DM, hypertension, dyslipidemia and depression).

Conclusion: This study found higher prevalence of DM in people with GOA when compared to LOA, and people with diabetes are about 2 times likely to have GOA. This study did not control for body mass index, and the results should be interpreted with caution. Because people with DM appear to be at higher risk of GOA, they may benefit from an interdisciplinary approach to prevent the development of arthritis in multiple parts of the body. Further research is required to explore this association using objective measures for OA severity, taking into account the extent to which DM is controlled.
POSTER #24
EVALUATION OF REAL WORLD DATA TO MEASURE THE EFFECTIVENESS OF HYPERBARIC OXYGEN THERAPY FOR DIABETIC WOUND HEALING

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Abstract withdrawn by author.