REAL-WORLD EVIDENCE SOLUTIONS
INSIGHTS FROM ISPOR
LOOKING BACK AT VIENNA
LOOKING FORWARD TO BOSTON
As a long-time, prominent participant, Kantar Health was proud to deliver more than two dozen research posters at the ISPOR 19th Annual European Congress. Some posters featured the innovative use of patient-centric data leveraging EQ-5D, wearable devices and EHRs. These studies demonstrate how the industry and Kantar Health together can use real-world evidence as the foundation to improving patient outcomes.

We’re excited to share the latest research during ISPOR’s 22nd Annual International Meeting at Boston. Kantar Health offers a holistic approach to providing real-world evidence solutions, pooling scientifically based primary research and non-interventional studies, epidemiology data and world-class syndicated patient data assets. We also conduct patient preference studies to support clinical development, patient engagement, physician communication and education and patient-physician decision making.
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## REAL-WORLD EVIDENCE SOLUTIONS

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FEATURED RESEARCH
Gaucher disease (GD) is an autosomal recessive disorder caused by a mutation in the glucocerebrosidase gene. Patients with this orphan disease exhibit a broad range of symptoms and disease severity that manifest at all ages. GD-related complications and outcomes include hepatomegaly, splenomegaly, bone events and cytopenia. In this research, our team sought to characterize a population-based cohort of patients with GD relative to the general population and to describe sociodemographic and clinical differences by disease severity, as defined by the use of enzyme replacement therapy (ERT).

The prevalence of type 1 GD, the most common form of the hereditary lysosomal storage disorder, is far higher among people of Ashkenazi Jewish descent than it is in other populations. A cross-sectional study of 500 patients with GD was conducted using the electronic health records (EHR) database from Clalit Health Services, the largest health service organization in Israel, accounting for over 50% of its population. Disease prevalence was calculated using the Clalit population and adjusted to Israel’s population in 2014. Disease management was classified as ERT+ (the purchase of at least one ERT at any time) or ERT- (never treated with ERT). By 2014, 41.2% of all patients with GD in the Clalit EHR database had been treated with ERT.

Our analyses found that the majority of GD patients were 18 years and over, primarily Jewish, and of higher socioeconomic status relative to the general population. Prevalence, however, was especially high among people aged 34 and older compared with the age-standardized mean. Sociodemographic and clinical characteristics, such as smoking and body mass index, were fairly similar between those who had and had not initiated ERT treatment. ERT group differences were observed for disease-related complications such as anemia and thrombocytopenia but not for preexisting complications.

This is the first study to detail socioeconomic and clinical data on a large, population-based GD cohort using a comprehensive real-time EHR database. Monitoring such a cohort is important to understanding disease burden and outcomes in a real-world population.

To read more about the study, see our research poster, which was presented at the ISPOR 19th Annual European Congress.
The American Diabetes Association (ADA) indicates that the agents used to treat type 2 diabetes mellitus (T2DM) should be based on patient considerations, including efficacy, costs, potential side effects, weight, comorbidities, hypoglycemia risk and patient preferences. Following the U.S. Food and Drug Administration’s (FDA) approval of a new generation of ultra-long-acting basal insulins (ULABI), we sought to evaluate the patient profiles of those using the new ULABI, as well as those using older long-acting basal insulin (LABI) and oral antidiabetic medications (OAD).

To profile T2DM patients, we employed a retrospective observational study design using a large U.S. ambulatory electronic health records (EHR) database. More than 20,000 patients in the study met our diagnosis and prescription inclusion criteria. In addition to demographics, patients’ comorbidities, weight, body mass index (BMI) and HbA1c were also assessed. For the analysis, patients were divided by treatment regimen, including LABI, LABI+OAD and ULABI groups. Those using the newer insulin therapies represented the smallest group, comprising 19% of the total sample.

Our findings revealed that a higher percentage of males versus females used ULABI treatments, and these patients had a lower mean age than those using LABI and LABI+OAD treatments. We found that patients who were overweight or obese and had sleep apnea and hypertension were associated with higher usage of ULABI versus LABI treatment. Those using LABI+OAD versus LABI treatment were more likely to be overweight or obese and without sleep apnea, depression and common diabetic comorbidities.

These analyses may help inform physicians in assessing T2DM patients’ characteristics when evaluating treatment plans.

To read more about the study, see our research poster, which was presented at the ISPOR 19th Annual European Congress.

REFERENCE:
Since 2011, the National Commission for Incorporation of Technologies (CONITEC), a governmental body in Brazil, has been involved in evaluating and incorporating health technologies in the healthcare system. CONITEC requires specific criteria for health technology assessment (HTA) requests. Our team sought to explain CONITEC’s reports regarding how requests are evaluated and how budget impact models and economic studies determine and influence their decisions.

We analyzed reports published up to June 9, 2016, including more than 200 reports submitted from public entities, pharmaceutical companies, medical societies, non-identified submitters and others. The data assessed included type of request, submitter, type of economic analyses reported and CONITEC’s decision.

Our analyses found that of all reports published by CONITEC, 86% comprised decisions regarding incorporations. The other reports referred to decisions regarding exclusion of technologies or approval of guidelines. Although CONITEC requires economic analysis (EA) as part of a complete submission for incorporation, less than half of all reports included it, with cost-effectiveness analysis (CEA/CUA) accounting for 82% and cost-minimization analysis (CMA) accounting for 18% of those that did contain EA.

Most of those including EA (66%) came from pharmaceutical companies, with only 12% coming from public entities. Two-thirds of all reports analyzed included budget impact analysis (BIA).

Among reports receiving positive recommendations for incorporation, 74% were submitted from public entities, while 10% were submitted from pharmaceutical companies. Among those receiving negative comments for incorporation, 24% were submitted by public entities, while 63% were submitted by pharmaceutical companies.

Interestingly, despite CONITEC’s requirement criteria, more complete submissions had a lower approval rate than those not containing EA or BIA. Only 22% of the reports approved included EA, while 71% included BIA. Of those reports not approved, 68% included EA, while 82% included BIA.

Overall, BIA was included more often than EA. New technologies included in our analyses were incorporated in the Brazilian healthcare system without assessment of economic value in most cases. Based on our research, it was not possible to determine the criteria that guided CONITEC’s decisions regarding the incorporation of new technology. The need for inclusion of EA in submissions should be reinforced to standardize and enhance transparency in CONITEC’s decision-making process.

To read more about the study, see our research poster, which was presented at the ISPOR 19th Annual European Congress.
IMPACT OF BURDENSOME CHRONIC CONDITIONS ON HEALTH-RELATED QUALITY OF LIFE AMONG EUROPEANS

ANALYSIS OF EQ-5D-5L VAS SCORES

It is held that European countries vary considerably in both lifestyle and healthcare delivery systems, so the impact of a given condition may also vary considerably according to a patient’s country of residence. Because few large-scale surveys measure health status or health-related quality of life (HRQoL) across multiple countries with the same methodology, our study set out to assess HRQoL decrement in the five major markets of the European Union associated with impactful diseases and also whether the burden associated with each disease differs by country.

A general population survey of 80,600 adults aged 18 and older from France, Germany, Italy, Spain, and the UK was conducted using data from the 2016 National Health and Wellness Survey (NHWS), which was primarily fielded via the internet. HRQoL was measured with the visual analog score (VAS) from the EQ-5D-5L, and five conditions – cardiovascular disease, cancer, obesity, osteoarthritis and diabetes – were selected on the basis of having high burden.

Although all five conditions were associated with significant decrements within each country, the magnitude of the decrement varied across the countries. For example, cardiovascular disease was associated with larger decrements in Germany and the UK than in France and Spain, while the decrement associated with cancer was lower in the UK than in France, Germany, or Italy.

While the analysis did not provide a reason for these differences, the study has highlighted that the impact of chronic conditions varies significantly across Europe. Therefore, policymakers should seek to optimize the allocation of healthcare resources for the improvement of HRQoL by relying on country-level rather than pan-European studies of disease burden where feasible.

To read more about the study, see our research poster, which was presented at the ISPOR 19th Annual European Congress.
As wearable devices continue to grow in popularity, the application of data collected from them in the healthcare setting is being examined. Wearable devices collect users’ number of steps, pace at which steps were taken, and sleep patterns. We sought to evaluate passively collected biometric data from wearable devices connected with participant questionnaire data to reveal valuable insights on their overall condition, stress levels and restfulness.

To conduct this research, we provided activity trackers to nearly 100 participants in France and the UK, collecting their biometric data over a two-week period. During this time, participants also completed a mobile-based questionnaire every other day, indicating their physical condition, stress level and restfulness. Each questionnaire was matched with the corresponding days of biometric data for each participant.

The majority of participants’ responses indicated good overall physical condition. Our analyses found that participants who reported a better overall physical condition took more steps per day than the participants’ average (8,342 versus 7,563). These participants also slept an average of 18 more minutes per night than those who reported “OK” or “mediocre” overall physical condition. Minor differences regarding participants’ stress levels were also observed, with participants who indicated they were never stressed or stressed some of the time taking more steps and sleeping longer than those who were stressed all or most of the time; however, these results were not statistically significant. Restfulness was not linked to participants’ number of steps but was linked to how long they had slept, with those feeling well or perfectly rested sleeping 31 minutes longer than those who felt somewhat or not at all well rested.

Our results prove that biometric data are correlated with overall physical condition, stress level and restfulness, and collecting these data can add valuable insights to healthcare research studies regarding patients’ quality of life.

To read more about the study, see our research poster, which was presented at the ISPOR 19th Annual European Congress.
As one of the most common forms of blood cancer, several new therapies for multiple myeloma (MM) have become available in recent decades that can improve patient survival. Patients are being treated longer and are receiving multiple lines of treatment, and while the new agents could improve patients’ health-related quality of life (HRQoL), they are also associated with adverse events that could have an impact on HRQoL.

While patient HRQoL is a key consideration in MM management and the evaluation of new therapies, the data available on real-world HRQoL for patients with MM is limited, especially in France. This research set out to assess the HRQoL for patients with MM by treatment line in a real-world setting in France.

An observational, cross-sectional, multicenter study was conducted in France with 41 physicians and 445 patients with MM, selected on the basis of an assigned quota. All patients for whom the physician completed a case report form were invited to complete three validated HRQoL questionnaires: EQ-5D/EQ-VAS, EORTC QLQ-C30 and QLQ-MY20.

Overall, the three HRQoL instruments used in this study generated consistent data, further validating their use in patients with MM. Our research found that patients with advanced MM who were receiving later lines of therapy had worse HRQoL than those at earlier treatment lines. HRQoL scores for patients receiving supportive care showed the biggest difference compared with those for patients at other treatment lines, which highlights the need to ensure that patients receive active treatment for as long as possible. Response to treatment was associated with better HRQoL, and Grade 3 or 4 adverse events were associated with worse HRQoL.

These data demonstrate the importance of effective treatment options in MM that result in better levels of response and delayed disease progression and that minimize adverse events so that HRQoL in patients with MM can be preserved.

To read more about the study, see our research poster, which was presented at the ISPOR 19th Annual European Congress.

This study was sponsored by Amgen.
REAL-WORLD TREATMENT PATTERNS IN METASTATIC AND/OR UNRESECTABLE GASTRIC CANCER PATIENTS IN BRAZIL

Gastric cancer is a leading cause of cancer-related deaths worldwide, with over 20,000 new cases in 2016 in Brazil alone. Despite the high prevalence and malignancy of this disease, limited data are available on the treatment and management of care for Brazilian patients with advanced gastric cancer (AGC) after failure of first-line treatment. To address this information gap, our client sought to examine the care and clinical profile of these patients as well as their use of healthcare resources.

In order to assess the care and clinical profiles of patients with gastric cancer in Brazil, we employed a retrospective audit of medical charts from five centers in Brazil, all of which met the Ethics Committee’s approval. Patient data were summarized using qualitative and quantitative variables, and statistical analyses were performed.

After consolidating patient records to meet our exclusion criteria, patients’ demographic and clinical characteristics were evaluated. Our sample included patients in both the public healthcare system and the private setting. Twenty-five percent of patients evaluated had more than one metastatic site at the time of diagnosis, with the majority of patients in Stage IV. The number of patients receiving first- and second-line treatment was recorded, including about 20 regimens for each line of treatment. Survival data were analyzed with the Kaplan-Meier model, including several prognostic factors.

Our findings revealed that following the failure of first-line treatment, on average, 56% of patients went on to receive second-line therapy, with 19% undergoing third-line treatment, and less than 5% undergoing fourth- and fifth-line therapy. Our analyses identified the most commonly used chemotherapy regimens for first- and second-line therapy.

Our study also shows the late diagnosis of AGC in Brazil and poor outcomes for patients. These results may contribute to developing new strategies and guidelines to address patients’ care. Awareness campaigns are also needed for both patients and physicians to diagnose AGC at earlier stages of disease.

To read more about the study, see our research poster, which was presented at the ISPOR 19th Annual European Congress.

This study was sponsored by Eli Lilly.
HER2 protein overexpression (HER2+) used to be considered a more aggressive clinical phenotype of breast cancer and was associated with a poor prognosis. However, the introduction of anti-HER2 targeted therapies has enabled significant progress in treatment and considerably improved the outcomes of patients with HER2+ breast cancer with localized or metastatic disease.

We conducted a retrospective chart review study to assess the current treatment patterns and treatment sequences used in HER2+ metastatic breast cancer (mBC) in the real-world setting. Secondary objectives were to describe the factors that contribute to the decision to prescribe an antitumoral treatment both in first- and second-line, as well as the factors that influence the choice of specific antitumoral treatment in these lines.

The study was conducted with 204 oncologists from four European countries (the UK, Spain, Italy, and the Netherlands), and 3,068 HER2+ mBC patients were documented in the cross-sectional portion of the study.

The data collected shows that first- and second-line treatment patterns are globally consistent with the European guidelines, especially for treatments recently initiated. However, the results clearly demonstrate that the treatment patterns vary significantly according to the age and performance status of the patient. In particular, younger patients received the more effective treatments while elderly patients seem to be undertreated. The results suggest a need for specific guidelines for the elderly HER2+ mBC population.

To read more about the study, see our research poster, which was presented at the ISPOR 19th Annual European Congress.
CANCER
+ Quality of Life of Patients Treated for Multiple Myeloma (MM) in France in a Real-World Setting
+ Real World Treatment Patterns in Metastatic and/or Unresectable Gastric Cancer Patients in Brazil
  Vieira F, Victorino A, Cubero D, Beato C, Minowa E, Julian G, Novick D
+ Response to Targeted Therapy and Healthcare Resource Utilization (HRU): A European Retrospective Chart Review Study in Patients with HER2+ Metastatic Breast Cancer
+ Skeletal-Related Events (SRES) and Renal Function in Patients with Symptomatic Multiple Myeloma (MM): Results from Belgium, France, Germany, Italy, Spain, Switzerland and the UK
+ The Burden of Staple Line Interventions in Colorectal Surgery in Europe
  Schiff A, Ghosh SK, Roy S, Pignot M, Fegelman E
+ Treatment Rates in Patients with HER2+ Metastatic Breast Cancer and the Factors Influencing Treatment Decisions

DIABETES
+ Characteristics of Patients with Type 2 Diabetes Mellitus Initiated on Basal Insulin Regimens: Retrospective Analysis of Electronic Health Record Data
  Lee LK, Liebert R, Hallissey B
+ Non-Adherent Behavior and Glycaemic Control in Patients with Type 2 Diabetes Treated with Insulin
  Buchs S, Weatherall J, DiBonaventura M, Wisniewski T
+ Physical Activity and Health-Related Quality of Life Among Adults with Type 2 Diabetes: Results from Wearable Fitness Trackers
  Vietri J, Witt EA, Meyer T

GASTROINTESTINAL DISORDERS
+ The Burden of Inflammatory Bowel Disease (IBD) in Japan
  Yamabe K, Kuwabara H, Umareddy I, Flores NM
+ The Humanistic and Economic Burden of Irritable Bowel Syndrome with Diarrhoea (IBS-D) by Disease Severity Among Patients in the EUS Region
  Flores NM, Tucker C, Carson R, Abel J, Liebert R

HEALTH SERVICES
+ Using Advanced Modeling to Identify the Factor Structure of the Improved Health Activities Questionnaire
  Kudel I, Winget M, Vietri J
+ Economic and Humanistic Burden of Chronic Spontaneous Urticaria in Brazil: Impact on Work Productivity, Resource Utilization and Quality of Life
  Balp M, Lopes N, Tian H, Vietri J, Ensina LF

HEALTHCARE USE AND POLICY STUDIES
+ Clinical Trials Scenario in Brazil: Study and Sponsor Profiles
  Julian G, Moreira E, de Oliveira RW, Francisco FR, Ruenis AP
+ Health Technology Assessment in Brazil: Metrics from the Reports of the National Commission for Incorporation of Technologies (CONITEC)
  Lemmer T, Piedade AD, Oliveira RW, Moreira E, Julian G
+ A Cross-National Comparison of the Effect of Age and Gender on Health-Related Quality of Life (HRQL)
  Rendas-Baum R, White M, Kosinski M, Vietri J, Bjorner J
+ Impact of Burdensome Chronic Conditions on Health-Related Quality of Life Among Europeans: Analysis of EQ-5D-5L VAS Scores
  Dreyfus J, Vietri J

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MENTAL HEALTH

+ The Burden of Depression in Japan
  Yamabe K, Umareddy I, Flores NM

NEUROLOGICAL DISORDERS

+ The Association of Adherence to Disease-Modifying Drugs and Out-of-Pocket Costs in Patients with Multiple Sclerosis
  Mayer L, Smrtka JM, Gupta S, Phillips AL

+ The Burden of Parkinson’s Disease in Japan
  Yamabe K, Kuwabara H, Liebert R, Umareddy I

RESEARCH ON METHODS

+ Incorporating Biometric Data from Wearable Activity Trackers with Study Data in France and the UK
  Fink L, Chanot G, Mondry B, Normand A, Vegreville M, Bondarenko K

RESPIRATORY-RELATED DISORDERS

+ Asthma in France: Analysis of 2015 National Health and Wellness Survey Data
  Hadjijat Y, Vietri J

+ Benefits of Quitting Smoking in Japan on Working Productivity and Activity Impairment and Indirect Costs

SYSTEMIC DISORDERS

+ A Population-Based Cohort of Gaucher Disease Patients Identified Using EHR Data

+ Effects of Opioid Use With and Without Over-the-Counter Analgesics on Economic Outcomes Among Adults with Pain in the United States
  Lee LJ, Kudel I, DiBonaventura M, Shepart AL, Kellstein D

+ Indications for Prescription of Immodin®, Its Efficacy and Effect on the Most Commonly Examined Immunological Parameters
  Hrubisko M, Keszegh J, Panakova I, Marusakova E
REAL-WORLD EVIDENCE SOLUTIONS
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ADVANCING HEALTHCARE AND DRIVING BETTER PATIENT OUTCOMES

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Kantar Health is a leading global healthcare consulting firm and trusted advisor to many of the world’s leading pharmaceutical, biotech and medical device and diagnostic companies. It combines evidence-based research capabilities with deep scientific, therapeutic and clinical knowledge, commercial development know-how, and brand and marketing expertise to help clients evaluate opportunities, launch products and maintain brand and market leadership.

Kantar Health deeply understands the influence of patients, payers and physicians, especially as they relate to the performance and payment of medicines and the delivery of healthcare services. Our advisory services, built on a solid foundation of market research and data, span three areas critical to bringing new medicines and pharmaceutical products to market – commercial development, clinical strategies and marketing effectiveness.

Kantar Health operates in more than 40 countries and employs more than 600 healthcare industry specialists and practitioners, including a high number of medical doctors, epidemiologists, PhDs, PharmDs and pharmacists, and biologists, biochemists and biophysicists. We work across the product lifecycle, from preclinical development to launch, and are experts at bringing multiple stakeholders together to advance the commercialization of pharmaceutical products. Our team acts as catalysts to successful decision making in the life sciences industry, helping our clients prioritize their product development and portfolio activities, differentiate their brands and drive product success post-launch. Kantar Health is part of Kantar, the data investment management division of WPP.

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