control, sham-operated, Captopril, low dose TGP and high dose TGP respectively. The pressure-overload method was adopted by abdominal aorta ligation to induce the CHF. Furthermore, collagenfibers detected by picrosirius red staining and expression of NF-kB, TGF-β1 by immunohistochemistry and observed under a polarized microscope and assessed by image-pro plus 6.0. Matrix metalloproteinase's (MMP)-2, -9 mRNA levels by reverse transcription PCR (RT-PCR), the concentration of angiotensin II was determined by radioimmunoassay and ELISA was employed to determine the cytokine IL-1β. ***Results:*** It was observed that TGP could relieve myocardial remodeling in rats induced by abdominal aorta ligation and decrease the level of angiotensin II and I/III collagen ratio, pathogenic cytokines and inhibit the expression and activities of MMPs. ***Conclusions:*** Consequently, the observations suggested that myocardial remodeling was mediated by the NF-κB pathway.

Alternative Medicine & Nutrition - Patient-Centered Research

PAM10
SIGNIFICANCE OF STOOL TESTS IN CHILDREN WITH COW'S MILK PROTEIN ALLERGY

Lendvai-Emmert D,[1] Emmert V,[2] Fusz K,[1] Prémusz V,[1] **Boncz I,**[1] Tóth GP[2]
[1]*University of Pécs, Pécs, Hungary,* [2]*Erzsébet Teaching Hospital and Rehabilitation Institute, Sopron, Sopron, Hungary*

Objectives: The most common food allergy in children is cow's milk protein allergy (CMPA). The aim of this research is to observe gastrointestinal changes induced by this nutritional allergy and to monitor the effect of dairy elimination diet on these symptoms. ***Methods:*** Children with symptoms suggesting CMPA were included in this study (n=47). The investigation was performed at the Balassa János County Hosptital in Szekszárd, Hungary. Stool samples were collected from the children at the time of the diagnosis, and after 3 months of elimination diet. During visits, a self-edited questionnaire was filled by the parents. Stool samples were evaluated using Bristol stool scale and Quantum Blue fecal calprotectin (FC) rapid test. ***Results:*** In the entire study population (n=47, mean age:7.36 years, 42.6 % female), no significant difference in FC values was observed before (mean: 73.98 μg/g, SD: 71.12) and after (mean: 68.11 μg/g, SD: 74.04) elimination diet (p=0.21). However, after dividing the participants into two subgroups according to the questionnaires, the following was observed: a significant decrease in FC values ($p<0.001$) was detected in children who strictly followed the diet (n=35) comparing the first (mean: 84.057 μg/g, SD: 79.48) and the second (mean: 41.114 μg/g, SD: 34.24) stool sample. Evaluating the results of Bristol stool scales before eliminaion diet, 36.2% of the study population presented with normal stool, 63.8% had stool abnormalities. After 3 months of elimination diet, the former results changed as the following: 93.6% showed normal stool, 6.4% still had constipation or diarrhea. ***Conclusions:*** According to our data, FC can be an objective parameter in monitoring of allergic colitis in children with CMPA. Significant improvement in symptoms can only be expected after a strict diet. Beneficial effects of elimination diet on the gastrointestinal symptoms can also be confirmed using the Bristol stool scale among children with CMPA.

PAM11
DEVELOPMENT AND EVALUATION OF THE BLOOD DEFICIENCY QUESTIONNAIRE (BDQ)

Jingnan L,[1] Yu L,[2] **Chen ZH,**[1] Cui BH,[1] Li Q,[2] Zhang HY[2]
[1]*Liaoning university of Traditional Chinese Medicine, Shenyang, China,* [2]*Affiliated Hospital of Liaoning university of Traditional Chinese Medicine, Shenyang, China*

Objectives: To develop and evaluate the blood deficiency questionnaire(BDQ) which provide an effective clinical efficacy evaluation tool for patient self-evaluation. ***Methods:*** The theoretical framework and initial BDQ were established by literature review and semi-structured interview. After a pilot study, the final BDQ with 3 domains including 'brain blood deficiency (BBD)' 'heart blood deficiency (HBD)' and 'meridian, collateral body constituents blood deficiency (MCBD)' was developed. Confirmatory factor analysis (CFA) was used to evaluate the construct validity of BDQ. Discriminant validity was evaluated by T-test between two groups. Internal consistency reliability was assessed using Spearman correlation coefficients and Cronbach's α coefficients. Test-retested reliability was evaluated by Spearman correlation coefficients. ***Results:*** The scale consisted of 11 items which included 'dizziness' 'avoid thinking because dizzy' 'need a break because dizzy' 'forgetfulness' 'palpitation' 'dream more' 'bad complexion or yellowed' 'dazzling or dry eyes' 'dry skin' 'numbness of limb skin' and 'limb restraint', and the additional menstrual information. The results of T-Test were significant which the BDQ can distinguish normal people from patients. In CFA, items were divided into 3 factors (KMO=0.812, $p<0.001$). The Cronbach's α coefficient of total scores was 0.821, and the Spearman correlation Coefficients between items and total scores were good (0.420-0.766). The Spearman Correlation coefficients of test-retested reliability were significant (0.518 -1.0). ***Conclusions:*** In this study, 3 domains with 11 items and the additional menstrual information in the BDQ were developed. The BDQ is a reliable and valid instrument for evaluating blood deficiency in the clinical.

Alternative Medicine & Nutrition - Real World Data & Information Systems

PAM12
ESTIMATING EXCESS HEALTHCARE COSTS OF MALNOURISHED PATIENTS IN A LEARNING COLLABORATIVE OF U.S. HOSPITALS

Belowich ES, Maxim R, Valladares AF, Kilgore KM
Avalere Health - An Inovalon Company, Washington, DC, USA

Objectives: Malnutrition carries significant economic burden to the U.S. healthcare system. This study extrapolates excess costs using national cost estimates, associated with increased length of stay (LOS) and 30-day readmissions experienced by patients with a malnutrition diagnosis compared to non-malnourished patients in a real-world sample of 56 U.S. hospitals. ***Methods:*** We identified two cohorts of patients using ICD-10-CM codes: 421,125 patients and 296,023 patients, with a variable tag of LOS and 30-day readmission, respectively. Both cohorts included 26,428 patients with a medical diagnosis of malnutrition ≥ 18 years-old upon admission. A 2016 national claims-based analysis by the Healthcare Cost and Utilization Project calculated costs for 1.45M inpatients with malnutrition in 2016, representing 5.27% of the 27.6 million total non-maternal and non-neonatal stays. To evaluate the total excess costs among malnourished patients to the healthcare system, we calculated excess cost per patient associated with increased LOS and 30-day readmissions ($12,635 and $3,700, respectively) and extrapolated that over the total patient cohorts. ***Results:*** Our analysis indicates that a medical malnutrition diagnosis amounts to excess costs of $333.92M and $16.86M, associated with increased LOS and readmission within 30 days of discharge, respectively. Our data shows 82.76% of malnourished patients were above the median LOS, compared to 47.79% of non-malnourished patients who were above the median LOS ($p-<0.0001$). Average readmission rate among malnourished patients is 17.24%, compared to non-malnourished patients with an average readmission rate of 9.24%, ($p<.0001$). ***Conclusions:*** Our analysis using a first of its kind aggregate real-world dataset of patients identified with malnutrition supports previously reported claims data demonstrating the excess costs associated with malnutrition in hospitalized adults. These findings support the need for a call to policymakers to adopt policies incentivizing providers to focus on these patients. Identifying and treating malnutrition may provide substantial savings to the U.S. healthcare system.

Patient Behavior Studies

PB1
PATIENT-REPORTED CONCERN, UNDERSTANDING AND LIFESTYLE MANAGMENT OF NON ALCOHOLIC STEATOHEPATATIS PATIENTS: A 12-COUNTRY REAL WORLD STUDY

Higgins V,[1] **Piercy J,**[2] Williams R,[3] Bacon K,[1] Jackson J[1]
[1]*Adelphi Real World, Bollington, CHE, UK,* [2]*Adelphi Real World, Bollington, UK,* [3]*Sunovion Pharmaceuticals, Marlborough, MA, USA*

Objectives: There is currently a lack of real-world evidence regarding non-alcoholic steatohepatitis (NASH) patient perceptions and experience of their condition. This study investigated differences between patients with advanced fibrosis (AF-NASH; fibrosis stage 3-4) and early fibrosis (EF-NASH; fibrosis stage 0-2) regarding concerns about NASH, degree of knowledge, associated impact and motivation to change lifestyle. ***Methods:*** Data derived from cross-sectional 2018/19 Adelphi NASH Disease Specific Programme (France, Germany, Italy, Portugal, Spain, UK, US, Canada, Australia, Japan, Saudi Arabia, UAE). Physicians completed questionnaires describing 2-8 NASH patients. Fibrosis severity categorized using peer-reviewed, retrospectively-applied fibrosis scores (AF-NASH >12.1kPa or EF-NASH < 6.5kPa) based on vibration-controlled transient elastography results. Voluntary patient assessments measured impact of NASH on concerns, knowledge and lifestyle changes. All differences stated were significant ($p\leq0.05$). ***Results:*** 734 NASH patients were included (77% AF-NASH vs. 23% EF-NASH). Mean age 55.3 years; mean BMI 32.7. AF-NASH patients reported more concerns about living with NASH (44%/35%), difficulties with liver (36%/18%) vs. EF-NASH patients. AF-NASH patients more frequently reported NASH affected family/social life (7%/1%), appearance/confidence (15%/8%), motivation (14%/5%) and feelings about future (18%/5%). 71% of patients received lifestyle advice. Despite physicians having suggested lifestyle interventions to AF-NASH patients for longer than EF-NASH patients (32/20 [months]), the former self-reported not receiving enough information vs EF-NASH patients (15%/5%). Physicians reported AF-NASH patients found it difficult to implement exercise advice vs EF-NASH patients (70%/81%). Fewer AF-NASH patients vs EF-NASH patients reported making a greater effort to improve health (13%/22%) and increase daily exercise (3%/9%). ***Conclusions:*** Whilst AF-NASH patients appear more concerned/impacted by NASH overall vs. EF-NASH patients, they do not appear to be motivated into making

associated lifestyle changes, despite physician suggestions. Physician/patient education around the importance of correctly managing the disease could help reduce humanistic and psychological burden of NASH, especially as disease progresses.

PB2
ADHERENCE TO INJECTABLE ANTIDIABETIC THERAPIES (IAT) AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM) IN CHINA: RESULTS FROM A CROSS-SECTIONAL SURVEY STUDY

Chen T,[1] **Zhou L,**[2] Ma X,[3] Wu H,[3] Cai B,[4] Tong J,[5] Liu X,[4] Ji Q[1]
[1]*The First Affiliated Hospital, the Air Force Medical University, Xi'an, China,* [2]*Lilly Suzhou Pharmaceutical Co., Ltd. Shanghai Branch, Shanghai, 31, China,* [3]*Lilly Suzhou Pharmaceutical Co., Ltd. Shanghai Branch, Shanghai, China,* [4]*IQVIA, Shanghai, China,* [5]*IQVIA, shanghai, 31, China*

Objectives: To assess medication adherence and associated factors among T2DM patients receiving IAT. ***Methods:*** 500 T2DM patients receiving IAT were included in PURPOSE study conducted in 12 representative cities across China from Dec. 2018 to Jan. 2019. Patient adherence level was measured with 5-item Medication Adherence Report Scale (MARS-5). According to MARS-5=25/<25, adherence was classified into perfect/imperfect. Multivariate logistic regression models were performed to explore factors influencing adherence, with demographic variables as fixed covariates in each model. Statistical analysis was performed using R software, version 3.5.2. ***Results:*** The mean (SD) age of participants was 55.1 (11.8) years, with 7.6 (6.4) years of disease duration. Of the total patients, 391 (78.2%) used insulin and 109 (21.8%) received glucagon-like peptide-1 receptor agonist (GLP-1 RA). 97.2% of GLP-1 RA users were treated with daily injection. The median (IQR) MARS-5 score was 23 (19-24) for all patients, 23 (20-25) and 22 (19-24) for GLP-1 RA users and insulin users, respectively. The percentage of perfect adherence among GLP-1 RA users was slightly higher than insulin users but not significant different (30.3% vs. 21.7%, P=0.08). Multivariate logistic regressions showed that better adherence was found associated with longer time since IAT initiation (OR=1.01, 95%CI:1.00-1.02), higher satisfaction with current IAT (OR=1.10, 95%CI:1.04-1.17), not reusing needle (OR=1.10, 95%CI:1.01-1.20), higher degree of agreement with "fully complying with prescriptions helps controlling blood sugar" (OR=1.10, 95%CI:1.05-1.14) and "good glycemic control can delay the onset of complications" (OR=1.12, 95%CI:1.07-1.18). Patients with concerns about weight gain (OR=0.83, 95%CI:0.75-0.92), injection site reaction (OR=0.88, 95% CI:0.81-0.95) and daily injection (OR=0.92, 95%CI:0.85-0.99) or having business travel during the last half year (OR=0.87, 95%CI:0.77-0.97) showed poorer adherence. ***Conclusions:*** Both the attributes of IAT and patient-related factors have significant impact on adherence. A user-friendly IAT with lower injection frequency, less site reactions, and less side effects of weight gain would help improve treatment adherence.

PB3
DISCORDANCE BETWEEN PSYCHIATRISTS AND THEIR PATIENTS ON DISEASE SEVERITY AND TREATMENT OUTCOMES IN SCHIZOPHRENIA

Keenan A,[1] Lin D,[2] Joshi K,[2] Shepherd J,[3] Bailey H,[3] Wright J,[3] Meakin S,[3] Kim E[2]
[1]*Janssen Global Services, LLC, Titusville, NJ, USA,* [2]*Janssen Scientific Affairs, LLC, Titusville, NJ, USA,* [3]*Adelphi Real World, Bollington, CHE, UK*

Objectives: To assess discordance between psychiatrists and their patients with Schizophrenia in relation to disease severity and treatment outcomes. ***Methods:*** A cross-sectional survey of psychiatrists and their patients with schizophrenia was conducted across the US, France, Spain, Japan and China between July and December 2019. Participating psychiatrists completed a patient record form (PRF) for their next 10 consulting adult patients with schizophrenia, with the same patients voluntarily completing a patient self-completion form (PSC). Both PRF and PSC surveyed on patients' clinical characteristics, severity of illness and treatment outcomes. Kappa analysis was used to calculate agreement between psychiatrists and patients. ***Results:*** A total of 456 psychiatrists provided data on 4189 patients, of which 2275 completed a PSC. Results were derived from matched PRF and PSC pairs. Discordance was observed between psychiatrists and their patients with Schizophrenia on patient's severity of illness (kappa = 0.1744) and level of improvement on treatment (kappa = 0.2035) using Clinical Global Impression (CGI) scale. Compared to patients, psychiatrists tended to underrate patients' severity of illness (16.6% of patients considered markedly/severely/extremely ill by psychiatrists, compared to 30.3% by patients themselves) and overrate the patients' level of improvement on treatment, (72.0% of patients considered much/very improved by psychiatrists, compared to 46.9% by patients themselves). Where patients were not always compliant with schizophrenia treatment, psychiatrists tended to underestimate "taking medication is inconvenient" (6% psychiatrist reported vs 22% patient reported; kappa = 0.0909) and "do not see improvement on medication" (20% psychiatrist reported vs 49% patient reported; kappa = 0.0033) as key reasons for non-compliance. ***Conclusions:*** A disconnect was observed between psychiatrists and their patients with Schizophrenia on their respective perception of severity of illness, level of improvement and reasons for non-compliance with treatment, which could lead to sub-optimal treatment. Future research should investigate factors associated with such discordance.

PB4
PROJECT HERCULES: A PATIENT LED PARADIGM IN EVIDENCE GENERATION FOR HTA IN DUCHENNE MUSCULAR DYSTROPHY

Crossley E,[1] Chandler F,[2] Godfrey J,[3] Fischer R,[4] Furlong P,[4] Abrams K,[5] Carlton J,[6] Mumby-Croft J,[7] O'Hara J,[8] Powell PA[6]
[1]*Duchenne UK, London, UK,* [2]*Alcmena Consulting Ltd, London, UK,* [3]*JG Zebra Consulting, London, UK,* [4]*Parent Project Muscular Dystrophy (PPMD), Hackensack, NJ, USA,* [5]*ISPOR, Lawrenceville, NJ, USA,* [6]*University of Sheffield, Sheffield, UK,* [7]*Source Health Economics, Oxford, OXF, UK,* [8]*HCD Economics, Daresbury, UK*

Objectives: Project HERCULES is an international patient led multi stakeholder collaboration developing tools and evidence supporting HTA for new treatments for Duchenne Muscular Dystrophy (DMD) including a bespoke Quality of Life metric, a natural history model, a burden of illness study and a core economic model. The evidence reflects patient experience and patients and patient organisations can shape the framework for HTA in DMD. This has led to a new paradigm for developing evidence for HTA and an improved understanding of DMD impacting on HTA decisions. ***Methods:*** Project HERCULES is led by Duchenne UK with a core team including two parents of boys with DMD, one of whom is also a health economist. This unique combination brings health economics and HTA expertise combined with the lived patient experience to deliver this ambitious health economics research programme. Patient organisation leadership enables access to data sources and expertise which may be inaccessible for individual researchers. An iterative approach to the individual workstreams ensures each workstream has high levels of patient involvement, shaping outcomes to embody actual patient and family experience. ***Results:*** This patient led approach has led to each workstream of Project HERCULES better reflecting the true impact of DMD:

- Identification of a previously undefined disease stage between the traditional stages of late ambulatory and early non ambulatory
- Development of a bespoke Quality of Life metric
- An economic model encompassing the actual experience of patients and families
- A burden of illness study focussing on what is most impactful on patients and families.
- Identification of future research priorities reflecting what is important to patients.

Conclusions: Project HERCULES has demonstrated the potential impact of patient led evidence generation in a rare disease for use in HTA.