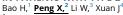
VALUE IN HEALTH | DECEMBER 2023 \$43

Objectives: The objective of this study was to identify the most common clinical endpoints used for assessing treatment efficacy in nonalcoholic fatty liver (NAFL) and nonalcoholic steatohepatitis (NASH) by analysing ongoing, completed, and earlystage clinical trials related to these conditions. Methods: Clinical trials focusing on NAFL/NASH were analysed using data from ClinicalTrials.gov. Trials in the third, fourth, or undetermined phase with over 50 participants where included while device testing, diet restriction, surgeries, and diagnostics were excluded. Trials were tagged and grouped based on outcome measures and the most common primary and secondary outcomes across all trials were identified. Results: The initial search has provided 505 results for pre-screening. After filtering towards adopted criteria, the spectrum was limited to 76 trials out of which 51 concerned mainly NASH/NAFL and in remaining 25 NASH/NAFL was considered in the background. The investigated studies included 27 phase IV and 29 phase III clinical trials. 35 studies were completed with total 4233 participants and average follow up of around 27 weeks. After the review process, 86 unique primary and 174 secondary endpoints were identified. All of the enlisted endpoints were connected towards measuring the fat content of the subject or its liver. The most common primary endpoints were lowering NAFLD Activity Score NAS (21 trials), improvement of fibrosis (11 trails),resolution of NASH/NAFL (8 trials); and secondary endpoints: BMI (16 trails), alanine transaminase level ALT (13 trials), measure of aspartate aminotransferase AST (11 trials). Conclusions: Many clinical trials investigating various treatments for NASH are ongoing. They differ in terms of the considered outcomes. Awareness of this diversity and knowledge of the most common endpoints will allow for more efficient clinical comparisons and economic modelling in the future.

CO159

A BAYESIAN NETWORK META-ANALYSIS (NMA) FOR EVALUATING THE RELATIVE EFFICACY OF DUAL THERAPY COMBINATIONS OF DAPAGLIFLOZIN AND METFORMIN IN PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM)

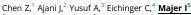


¹Sun Yat-sen University, Shanghai, 31, China, ²Sun Yat-sen University, 广州市, China, ³Health Economic Research Institute, School of Pharmacy, Sun Yat-sen University, Guangzhou, Guangdong, China, ⁴Sun Yat-sen University, Guangzhou, Guangdong, China

Objectives: This study aims to utilize Bayesian network meta-analysis (NMA) to assess the relative efficacy of dapagliflozin add-on to metformin as a dual therapeutic strategy for managing T2DM. The main emphasis is on comparing the outcomes of this dual therapy approach with both placebo and other SGLT2 inhibitors used in combination with metformin. Methods: A Bayesian NMA with random effects model has been conducted to estimate the relative efficacy of dapagliflozin when administered at various doses and frequencies in combination with metformin. Pertinent data related to changes in HbA1c levels from the baseline were extracted for analysis. The assessment of relative efficacy was conducted by evaluating the mean differences (MD). Results: Following a systematic review of the existing body of literature, the study encompassed a selection of 20 randomized controlled trials, all of which provided outcomes for a minimum duration of 16 weeks. The reduction in HbA1c levels demonstrated a significant increase when dapagliflozin at doses of 2.5mg QD, 5mg QD, and 10mg QD was administered alongside metformin, as compared to the combination of metformin with a placebo. The mean difference between the three treatment regimens compared to placebo were -0.388 (-0.625, -0.158), -0.507 (-0.682, -0.340) and -0.523 (-0.683, -0.382). However, no statistically significant difference was observed in the efficacy endpoint of HbA1c reduction compared with other SGLT2 combined with metformin. Conclusions: This study synthesized direct and indirect evidence to establish indirect comparisons of dual therapy combinations of different SGLT2 inhibitors and metformin. The result indicates that irrespective of the medication's dosage and frequency, the therapeutic impact of dapagliflozin in conjunction with metformin exhibited a considerably superior efficacy compared to metformin as a standalone treatment. The variance in effectiveness among distinct SGLT2 and metformin regimens may be discernible in facets beyond HbA1c.

CO160

BURDEN OF ILLNESS AND TREATMENT PATTERNS OF ADULT PATIENTS WITH ADVANCED OR METASTATIC GASTRIC/GASTROESOPHAGEAL JUNCTION CANCER: A SYSTEMATIC LITERATURE REVIEW



¹Amgen, Tampa, FL, USA, ²MD Anderson Cancer Center, Houston, TX, USA, ³Amgen Inc., Thousand Oaks, CA, USA, ⁴Oxford PharmaGenesis, Oxford, UK,

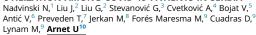
⁵Amgen, Rotkreuz, Switzerland

Objectives: Gastric and gastroesophageal junction cancer (G/GEJC), represents the fifth most common malignancy and the fourth leading cause of cancer-related death worldwide. This study aimed to identify published evidence on treatment patterns, real-world clinical and economic outcomes, and humanistic burden in previously untreated, unresectable, locally advanced and/or metastatic G/GEJC patients. **Methods:** A systematic literature review was conducted following the PRISMA 2020 guideline. The MEDLINE, Embase, and Cochrane Library were searched electronically for articles on 24 June 2022, supplemented by hand searches of congress abstracts, health technology assessments, relevant regulatory documents, and treatment guidelines. Searches included all interventions regardless of regulatory approval and were limited to English language. Interventional or preclinical studies, case series,

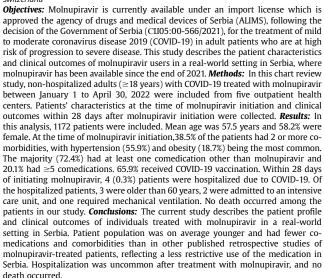
case reports, and editorial articles were excluded. Reporting focused on publications published since 2012, with large sample size (n=150). **Results:** Of the 1721 identified publications, data from 53 publications were extracted and included in this review. Majority of the publications (n=49) reported data from single-country studies; 25 from Asian countries and 8 from the US. Treatment patterns were reported in 37 publications, with combinations of fluoropyrimidines and platinum being the most commonly used regimens. S-1 was almost exclusively used in Asian countries. Most studies (n=40) reported real-world clinical outcomes with an estimated median OS ranging from 6.4 to 18.9 months. Economic burden was reported in 5 studies which showed a significant financial impact of advanced G/GEJC on patients, caregivers and healthcare providers. **Conclusions:** Across studies, patients with advanced or metastatic G/GEJC had poor survival outcomes. There is limited real-world data available on the humanistic burden of advanced G/GEJC. Due to the search timeframe, the identified studies did not capture real-world outcomes of recently approved immuno-oncology therapies.

CO162

MORE SERBIA: MOLNUPIRAVIR REAL WORLD UTILIZATION AMONG COVID-19 PATIENTS IN SERBIA







CO165

VALIDATION OF HIGH RISK CRITERIA IN MEDICATION RECONCILIATION IN MAJOR ORTHOPEDIC SURGERY: A DELPHI STUDY

Luque J, ¹ Cavalheiro M, ¹ Silva P, ¹ Filipe H, ² Falcao F, ² Caldeira D, ³ Costa J, ³ Fernandes R, ³ Pereira I, ⁴ Lavrador M, ⁴ Castel-Branco MM, ⁴ Fresco P, ⁵ Fernandez-Llimos F, ⁵ Duarte G, ¹ Rodrigues M, ⁶ Capoulas M, ⁷ Santos C⁷

¹Hospital Da Luz Lisboa, Lisboa, Portugal, Portugal, ²University of Lisbon, Pharmacy Faculty, Lisboa, Portugal, Portugal, ³University of Lisbon, Medicine Faculty, Lisboa, Portugal, Portugal, ⁴University of Coimbra, Pharmacy Faculty, Coimbra, Portugal, Portugal, ⁵University of Porto, Pharmacy Faculty, Porto, Portugal, Portugal, ⁶Instituto Universitário Egas Moniz, Lisboa, Lisboa, Portugal, ⁷Luz Saúde, Lisboa, Portugal

Objectives: Medication reconciliation(MR)is relevant in the transitional care, however, given the limited resources, it is necessary to identify the patients who can benefit most from this activity. Our aim was to validate the criteria that identify patients at high risk of experience medication errors and error-related adverse events undergoing major orthopaedic surgery. *Methods:* The Delphi technique was used through a questionnaire carried out in 3 phases (April-June 2023)to obtain consensus on the inclusion criteria. These were previously defined by a multidisciplinary team, based on the probability of risk of the adverse event to happen.Each expert rated the criteria according to a 5-point Likert scale, and consensus was assumed if 50% of the mean responses were ≥4 (inclusion) or <2 (exclusion). It was possible to suggest the inclusion of new criteria. *Results:* 10 experts from 4 Faculties of Pharmacy and Medicine were invited. In the first phase,9 responses were obtained





S44 VALUE IN HEALTH | DECEMBER 2023

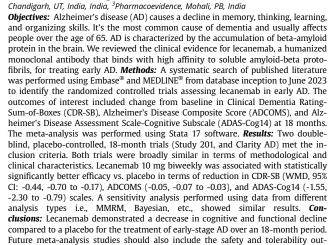
and consensus was reached on 18 criteria: polypharmacy, anticoagulants, oral chemotherapy (not hormone therapy),immunosuppressants,antiretrovirals, (pyridostigmine and neostigmine),insulin, corticoids, neuroleptics, antiarrhythmics, digoxin, carbamazepine, phenytoin, valproate, thyroid drugs, anti-glaucoma therapy, anti-aggregants and urgent surgery. Systemic antifungals and opioids were suggested. In the second phase, 8 experts responded. Consensus was reached on 6 criteria: anti-parkinsonics, beta-blockers, age ≥65 years, length of stay ≥5 days, opioids and systemic antifungals. In the last phase, 6 experts responded and 1 criterion reached consensus: sulfonylureas. At the end,3 criteria did not reach consensus: anxiolytics, angiotensin converting enzyme inhibitor or angiotensin II receptor antagonists and calcium channel blockers. Conclusions: We developed and validated a list of 25 criteria to identify patients at high risk of experience medication-related adverse events undergoing major orthopedic surgery. These criteria may help improve human resource management for clinical pharmacy activities by prioritizing patients who would benefit most from MR. This methodology could be replicated in other clinical areas.

CO166

EFFICACY OF LECANEMAB IN PATIENTS WITH EARLY ALZHEIMER DISEASE: A SYSTEMATIC REVIEW AND META-ANALYSIS



¹Pharmacoevidence, SAS Nagar Mohali, PB, India, ²Pharmacoevidence,



comes. Further, longer-term studies are needed to evaluate the effectiveness and

CO168

A PROPENSITY SCORE-BASED COMPARISON OF TEPOTINIB VERSUS IMMUNOTHERAPY WITH/WITHOUT CHEMOTHERAPY, USING REAL-WORLD DATA IN PREVIOUSLY UNTREATED *MET* EXON 14 (*MET*EX14) SKIPPING NON-SMALL CELL LUNG CANCER (NSCLC)

safety of lecanemab for the treatment of early-stage AD.

Hook E, Batteson R,² Christopoulos P,³ Guisier F,⁴ Ekman S,⁵ Hatswell A,² Vioix H⁶

¹Delta Hat Limited, Nottingham, NGM, UK, ²Delta Hat Limited, Nottingham, UK, ³Thoraxklinik and National Center for Tumor Diseases at Heidelberg University Hospital, Heidelberg, Germany; Translational Lung Research Center Heidelberg (TLRC-H), Member of the German Center for Lung Research (DZL), Heidelberg, Germany, ⁴Univ Rouen Normandie, LITIS Lab QuantIF team EA4108, CHU Rouen, Department of Pneumology and Inserm CIC-CRB 1404, F-76000 Rouen, France, ⁵Karolinska University Hospital/Department of Oncology-Pathology, Karolinska Institutet, Stockholm, Sweden, ⁶Merck Healthcare KGaA, Darmstadt, Germany

Objectives: With the approval of immunotherapies (IOs) and IO combinations with chemotherapy (IO+chemo), several IO-based treatment options are available for non-oncogenic NSCLC. However, in specific mutations such as METex14 skipping, observational studies suggest IOs do not perform as well, and no evidence exists for IO+chemo in this population. By pooling seven real-world datasets of patients with METex14 skipping NSCLC (the TOGETHER study), we are able to compare IO-based treatments to tepotinib, a selective MET inhibitor. Methods: TOGETHER includes 289 previously untreated patients, 47 of whom received IO, and 26 IO+chemo, facilitating comparisons with the 164 previously untreated patients from the tepotinib VISION study (NCT02864992). Time-to-event outcomes are compared with the November 2022 data cut-off of VISION, using propensity scoring to account for differences in patient characteristics based on clinical input; reweighting IO treatment data to match VISION. Results: After weighting, patient and disease characteristics were balanced across groups, with no statistical differences observed. Patients who received tepotinib had longer progression-free survival (PFS, median 8.7 months)

than patients receiving IO (median 3.6, Cox Hazard Ratio (HR) 0.56 [95% confidence interval (CI): 0.37, 0.85]) and IO+chemo (median 6.7, HR 0.43 [95% CI: 0.43, 1.12]). Overall survival comparisons marginally favored tepotinib (median 21.3 months) over IO (median 19.0, HR 0.85 [95% CI: 0.57, 1.28]), and IO+chemo (median 19.3, HR 0.97 [95% CI: 0.57, 1.66]). *Conclusions:* Although the introduction of IO has led to a step change in non-oncogenic NSCLC, in patients with *MET*ex14 skipping NSCLC, consistent with published observational data, we find time-to-event outcomes to be shorter. Despite limited patient numbers, the evidence presented suggests similarly patterns for IO+chemo. Estimated PFS is longer with tepotinib, while evidence on overall survival remains uncertain and confounded by subsequent treatment use, but does suggest a differential outcome for any treatment in isolation.

CO169

PAN-STAKEHOLDER CORE OUTCOME SET (COS)
DEFINITION FOR HEMATOLOGICAL MALIGNANCIES IN
THE FRAMEWORK OF THE EU PROJECT, HARMONY: THE
HEALTHCARE ALLIANCE FOR RESOURCEFUL MEDICINE
OFFENSIVE AGAINST NEOPLASMS IN HEMATOLOGY



¹Charité - University hospital Berlin, Berlin, Germany, ²LeukaNET e.V., Riemerling, Germany, ³Patvocates GmbH, Riemerling, Germany, ⁴Lymphoma Coalition, Mississauga, ON, Canada, ⁵Myeloma Patients Europe, Brussels, Belgium, ⁶Norwegian Medicines Agency (NoMA), Oslo, O2, Norway, ⁷MDS UK Patient Support Group, London, UK, ⁸Leukemiacare, Worcester, UK, ⁹MPN Advocates Network, Bern, Switzerland, ¹⁰University of Cambridge, Cambridge, UK, ¹¹Erasmus MC Cancer Institute, Rotterdam, Netherlands, ¹²University of Turin, Turin, Italy, ¹³Azienda Ospedaliero Universitaria Careggi, University of Florence, Florence, Tuscany, Italy, ¹⁴Masarykova Univerzita, Brno, Czech Republic, ¹⁵Universitätsklinikum Jena, Jena, Germany, ¹⁶Research Foundation FROM, Papa Giovanni XXIII Hospital, Bergamo, Italy, ¹⁷University Cologne, Cologne, Germany, ¹⁸University Hospital Ulm, Ulm, Germany, ¹⁹BMS - Bristol Myers Squibb SA, Steinhausen, Switzerland, ²⁰National Institute of Health and Care Excellence, London, UK, ²¹Hospital Universitario y Politécnico La Fe, Valencia, Spain, ²²University Salamanca, Salamanca, Spain, ²³European Hematology Association, The Hague, Netherlands, ²⁴AbbVie Deutschland GmbH & Co. KG, Wiesbaden, Germany, ²⁵Bayer AG, Berlin, Germany, ²⁶Charité - Berlin, Berlin, Germany,

Objectives: Definition of a core outcome set (COS) may improve the interpretation and comparability of future clinical trials. In the scope of HARMONY Alliance a COS, as an agreed set of outcomes for several hematological malignancy (HM) was defined. The HARMONY Alliance is a public-private European network established 2017, which currently includes 51 partners and 73 associated members from 23 countries. Methods: For COS definition, the Delphi method was used including all stakeholder groups (patients, clinicians, industry, and regulators/HTA bodies). COS were defined for nine different HMs. Conditions and criteria how to define COS were defined in study protocols, which were made publicly available for each HM through the HARMONY and COMET webpages. For outcomes especially valuable to patients, a special "patient-important criterion" was implemented. Results: For the HARMONY Delphi surveys a total of 365 individuals participated including 177 patients/patient advocates (48%), 126 clinicians (35%), 46 EFPIA/industry members (13%) and 16 regulators/members of HTA bodies (4%). In summary, for the HARMONY HMs 11 out of 59 outcomes met the consensus-in criterion in AML; 8 out of 61 in NHL; 12 out of 51 in MDS; 12 out of 58 in MM; and 17 out of 54 in CLL. For the HARMONY PLUS Delphi surveys, 161 persons participated in total including 20 patients/patient advocates (12%), 93 clinicians (58%), 39 EFPIA/industry members (24%), and 9 regulators/members of HTA bodies (6%). A detailed overview of the HARMONY and HARMONY PLUS COS will be presented at the meeting, additional to results of the latest expert panel meeting. Conclusions: To the best of our knowledge this was the first multidisciplinary approach to define COS for HMs including the views of all stakeholder groups - with a specific focus on patients' needs - a strong starting point for a harmonized application of core outcomes in future clinical and observational

CO170

TREATMENT EXPOSURE-ADJUSTED EVENT RATES (EAERS) FOR GRADE 3/4 AES ASSOCIATED WITH EMERGING AND EXISTING SYSTEMIC THERAPIES FOR MCRC WITH AT LEAST 2 PRIOR LINES OF THERAPY: INFORMING PAYER AND PATHWAY FORMULARY DECISION MAKING

Howe A,¹ Hernandez LG,¹ Paly V,¹ Eng C,² Dasari A,³ Samuel L,⁴ Kasper S,⁵ Tougeron D⁶

¹Takeda Pharmaceuticals America, Inc., Lexington, MA, USA, ²Division Hematology and Oncology, Vanderbilt-Ingram Cancer Center, Nashville, TN, USA, ³Department of Gastrointestinal Medical Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, USA, ⁴Aberdeen Royal



