Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company’s public news and information website.

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immunomodulators among patients with ankylosing spondylitis (AS), psoriatic arthritis (PsA), ulcerative colitis (UC), Crohn’s disease (CD), lupus (SLE), and psoriasis (PsO). We restricted the cohort based on the economic integrated Research Database. Adult patients with AS, PsA, UC, CD, SLE, and PsO who initiated AT (TNFi, non-TNFi biologics, other pharmacotherapies) from 7/1/2016-8/31/2018 and had continuous enrollment >6 months before and ≥12 months after index date (first AT claim date) were included. The algorithm criteria used healthcare resource utilization proxies associated with inadequate clinical response. Baseline characteristics associated with IR were identified via logistic regressions. **Results:** Patients were identified as having IR to their index AT if during the 12month period before index date they had ≥1 of the following: ≥10 AT claims in 2 consecutive periods of days covered <80%, switched/added a new AT, added a new conventional immunomodulator, increased dose/frequency of AT, had ≥1 glucocorticoid injection/infusion, addition/dose increase of oral glucocorticoids, or use of new pain medication; additional disease-specific criteria included: (PsO/PsA) use of a new topical treatment, actinotherapy, or retinoids; (SLE) intravenous immunoglobulin; (AS) spinal procedures; (UC/CD) GI surgery. Sample sizes and IR frequencies were: AS:N=646, 65%; PsA:N=1,433, 77%; UC:N=1,692, 63%; CD:N=2,437, 62%; SLE:N=448, 84%; PsO:N=4,952, 70%. Across all diseases, IR was mostly driven by low adherence. Certain baseline patient characteristics (e.g. higher age, conventional immunomodulator usage) were associated with IR. **Conclusions:** Using adaptations to a validated claims algorithm that proxies for inadequate clinical response, the proportions of AS, PsA, UC, CD, SLE, and PsO patients with IR ranged from 62-84%. Health plan claims data appears useful to classify IR in these patients and additional research should be done to further validate the algorithm adaptations in a clinical setting.

**PMU55 A NEW APPROACH TO SURVIVAL CURVE TAIL CORRECTIONS: THE AGE-MATCHED LIFE TABLE (AMLT) METHOD**

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When survival analyses are utilized in decision analytic models the tails of survival curves are often checked against mortality from general population life tables to ensure hazards from the disease-specific survival curves are not incongruent (less than) than the general population. This approach uses the average age of the modeled population and corresponding age-specific mortality from life tables with updates to mortality as the model cycles. This approach works when the model population is homogeneous in terms of age. However, in a heterogeneous population the “wall of human mortality” can cause the average age approach to overestimate the hazards of model population sans disease. An alternate methodology that recreates the model population using survival of multiple age groups rather than a single can provide more accurate hazard adjustments. The impact of the traditional method and the new age-matched life table (AMLT) method is compared in an illustrative example. In the AMLT method, the age distribution of the modeled population is used to distribute patients into reasonable age groups. Next, lifetime survival for the same population sans disease within each age group is calculated from life tables. Finally, the age groups are rolled up based on the population surviving in each year and group to create survival/hazard estimates for an age-matched cohort. A survival analysis utilizing mortality data following kidney transplant from the United Kingdom Transplant Registry was conducted. The mean age of patients in the cohort was 45.4 years and age distribution was 0-17 =6.4%, 18-34=12.8%, 35-49=47.5%, 50-64=19.9%, and ≥70=13.4%. Utilizing the average age approach resulted in tail-corrected mean survival of 24.70 years. Using AMLT resulted in tail-corrected mean survival of 26.82 years, a difference of 21.2 years. This methodology will provide more accurate survival tail corrections in models when the population is heterogeneous in terms of age.

**PMU56 HEALTH ECONOMIC EVALUATION ALONGSIDE STEPPED WEDGE TRIALS: A METHODOLOGICAL SYSTEMATIC REVIEW AND RECOMMENDATIONS OF APPROPRIATE METHODS**

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**Objectives:** Recently, there has been an increase in use of the stepped wedge trial (SWT) design in the context of health services research, due to its pragmatic and methodological advantages over the parallel group design. Our objectives were twofold: review the statistical methods used when conducting economic evaluations alongside SWTs and make a proposal for appropriate methods to use. Methods: A methodological systematic literature search was conducted (up to February 2020) in the PubMed, Scopus, Cochrane and NHS-SEED databases to find and evaluate studies where there was an intention to conduct an economic evaluation alongside a SWT. Results: 54 studies were identified and included in this review. 54 studies were published protocols, 8 economic evaluations and 7 studies reporting full trial results. Included studies varied in terms of their reporting of statistical methods, in both detail and methodology. There were 34 studies that did not report any statistical analysis of treatment effects and only 16 studies reported appropriate methods, mainly using some form of mixed/multilevel models, seemingly unrelated regression and Bayesian techniques with Monte Carlo simulation. The remaining studies failed to appropriate account for clustering, correlation or adjusted for time. Conclusions: The use of appropriate statistical methods that account for time clustering, and correlation between costs and outcomes is an important part of SWT health economics analysis and in particular we recommend the use of one of the following methods: hierarchical/multilevel models, seemingly unrelated regressions, two-stage bootstrap methods and bivariate Bayesian models. We also propose the extension of the CHEERS checklist in order to encourage transparent reporting of economic evaluations alongside SWTs.

**PMU57 ASSESSMENT OF KNOWLEDGE ON HEALTH ECONOMICS AND OUTCOMES RESEARCH IN CENTRAL ASIA COUNTRIES**

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**Objectives:** The present study examined level of health economics and outcomes research (HEOR) knowledge in Central Asia countries, assessing what expert in this field think and know about HEOR and how they used it in their work. Methods: A new age-matched life table (AMLT) method is compared in an illustrative example. Correlation analyses was performed to identify possible associations between HEOR topics self-assessed level and responders demographic data, level of knowledge and preferred method for delivery of this knowledge. Results: Survey data collected from 74 responders. The huge gap between science and action was identified in field interpretation of health economic evaluation and patient-reported outcomes, which was amounted 2.48 ± 1.52 and 2.56 ± 1.58 accordingly. The least gap on knowledge was amounted for systematic review and meta-analysis applications (mean = 0.98 ± 0.66). Also, self-perceived unmet needs on HEOR knowledge were smallest in field of understanding of types of health care costs. The 65 % of responders preferred to receive knowledge related to HEOR topics through academic continuing education and distance learning programs. Correlation analyses was performed to identify possible associations between HEOR topics self-assessed level and responders demographic data. Conclusions: The lack of gap on HEOR knowledge allowed current unmet needs on knowledge in perceptions among responders. This study provide clarification of the needs and topics of the educational programs for sustainable development of HEOR in Central Asia countries. The results of our study help, in a larger sense, to navigate society towards achieving the HEOR knowledge.

**Multiple Diseases - Organizational Practices**

**PMU58 AMERICANS’ HEALTH PRIORITIES DURING THE COVID-19 PANDEMIC**

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**Objectives:** To examine how Americans’ opinions of the relative seriousness of various health problems have changed over time and to quantify the public’s preferences for research prioritization. Methods: We conducted a survey that asked respondents to rate the seriousness of 80 health problems on a four-point Likert scale (“very serious problem,” “somewhat serious problem,” “not too serious of a problem,” or “not a problem at all”). Results were compared to past surveys from 2001 and 2013 that examined the same set of health problems (with the exception of COVID-19). The survey also included 15 MaxDiff questions that asked respondents to rate the seriousness of 80 health problems on a four-point Likert scale (from 1 to 4). Correlation analyses was performed to identify possible associations between health problems self-assessed level and responders demographic data. Conclusions: The lack of gap on HEOR knowledge allowed current unmet needs on knowledge in perceptions among responders. This study provide clarification of the needs and topics of the educational programs for sustainable development of HEOR in Central Asia countries. The results of our study help, in a larger sense, to navigate society towards achieving the HEOR knowledge.
PMU59
PREDICTORS AND HEALTH RELATED QUALITY OF LIFE ASSOCIATED WITH RENAL DISEASES IN CANCER PATIENTS IN UNITED STATES
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Objectives: Cancer survivors are projected to increase from 16.9 million people in 2019 to 22.2 million people in 2030. Cancer patients are exposed to more nephrotoxic agents than general population and are hence at a higher risk of developing kidney complications and renal diseases. Renal diseases in cancer patients are associated with a negative prognostic factor for overall survival, worse health-related quality of life (HRQoL) more healthcare utilization. This study determines the predictors of renal diseases and health-related quality of life (HRQoL) associated with renal diseases in cancer patients.

Methods: This was a retrospective cross-sectional study with data obtained from 2009 – 2018 Medical Expenditure Panel Survey for cancer patients above the age of 18. HRQoL is determined by Mental Component Summary (MCS) and Physical Component Summary (PCS) using Short Form 12 item (version 2). Unadjusted and adjusted analyses were done using t-test, chi square tests, multivariable linear and logistic model while controlling for covariates. All analyses were weighted to get national estimates with $p<0.05$ in SAS v9.4.

Results: of the 11,820 cancer patients, 1,069 were diagnosed with a renal disease. Significant predictors ($p<0.05$) for renal disease were Female (OR = 1.73), Hispanic (OR = 1.84), Black (OR = 2.01), High School Education (OR = 1.43), Living in south (OR = 0.76), Low income (0.91). Adjusted mean PCS and MCS score for cancer patients with renal disease was 40.2 and 47.6 respectively. Mean PCS and MCS score for cancer patients with renal disease was 45.1 and 41.8 indicating worse HRQoL ($p = 0.02$).

Conclusions: Race, sex, education, census region and income were found to be the significant predictors of renal disease in cancer patients. HRQoL in cancer patients with renal disease is worse as compared to patients with just cancer diagnosis.

PMU60
ASSESSING THE READABILITY OF PATIENT-REPORTED OUTCOME MEASURES IN TRIALS FOR DRUGS WITH RECENT FDA APPROVAL
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Objectives: When using patient-reported outcome (PRO) measures, the language must be understood by patients. This can be tested empirically with qualitative studies or measured by evaluating readability. Readability, the ability of an individual to understand written text, can be measured using a variety of standard indices. However, evidence suggests that measurement and reporting of readability metrics is not standard practice in PRO measure development. Here, we evaluated the readability of PRO measures from FDA submissions for products approved fourth quarter, 2020. PROs were included that were listed in the approved labeling or medical review, as presented on the Drugs@FDA database. Supplemental information about the outcomes measured in pivotal trials was extracted from clinicaltrials.gov. Selected PROs were processed by editing the text to remove headings, footers, and response options and combining item stems and questions to form complete sentences. Microsoft Word was used to calculate Flesch Reading Ease (range 0-100, higher scores indicate greater readability); 60-70 is considered “plain English”; and Flesch-Kincaid Grade Level (based on US educational levels, average American scores between 7th and 8th grade). Results: Thirty products received FDA approval during 4Q2020. Specific information on PRO measures was provided for 4 products, with 12 PROs; 11 PROs were readily available and included in the analysis Flesch Reading Ease averaged 69.4 (range: 52.0, 90.3) and Flesch-Kincaid Grade Level averaged 6.88 (range: 3.4, 10.4). Although no consensus exists for acceptable readability, many view 6th grade as an appropriate maximum level, or reading ease score of 60-70.

Conclusions: Present results indicate that, although PROs included in FDA submissions are acceptable on average, there is substantial variability. Some PROs may present a challenge to the average reader. Further work is needed on the most appropriate methods for developing readable PRO measures and for assessing readability of existing measures.

PMU61
STATE OF BYOD: LESSONS IN ACCEPTABILITY AND COMPLIANCE FROM 35 TRIALS
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Objectives: Interest in bring-your-own-device (“BYOD”) studies has risen rapidly since the start of the global COVID pandemic. To better inform our understanding of patient acceptability and compliance in BYOD, we conducted a retrospective review of clinical trial operational data. Methods: Operational data was analyzed from 35 clinical trials from 2017 to the present in the US and EU collecting eCOA data using BYOD; some trials also provisioned handheld devices for participants who chose not to use BYOD. Key outcomes of interest were: % of patients requesting provisioned device and compliance rates. Sub-group analysis was conducted by phase and therapeutic area, sample size permitting. Results: The 35 trials included pivotal phase II/III and phase IV/observational/long-term safety studies. The most-represented therapeutic areas were CNS (20%), hematology (11%), dermatology (11%), pulmonology (9%), women’s health (9%), and virology (9%). Combined, they included 18,171 sites and 69,037 participants; 15 trials (43%) did not offer provisioned devices to participants (i.e., 100% BYOD). Of the 20 trials (57%) that offered provisioned devices to participants, device provisioning rates ranged from 10%-75% (median 20%). Overall compliance for patient-completed assessments ranged from 85% to 92%. Trials that domains, improvements were observed with odevixibat, while with placebo, 3 of 4 domains had an average compliance of 92%.

Conclusions: BYOD is increasingly recognized as a feasible and practical methodology for collecting eCOA data in clinical trials, especially in indications that require frequent and/or acute data collection (e.g., children, burn patients). Since mobile technology is widely available, with broad access to mobile phones/other devices, it is not surprising that we found minimal differences in subject compliance with diary completion between studies that did and did not offer a provisioned device, however, this should be explored further to discern any potential differences based on patient characteristics and/or reporting frequency.

PMU62
IMPROVED QUALITY OF LIFE IN CHILDREN WITH PROGRESSIVE FAMILIAL INTRAHEPATIC CHOLESTASIS FOLLOWING 24 WEEKS OF TREATMENT WITH ODEVIXIBAT, AN ILEAL BILE ACID TRANSPORTER INHIBITOR: RESULTS FROM THE PHASE 3 PEDIFIC 1 STUDY
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Objectives: Patients with progressive familial intrahepatic cholestasis (PFIC) have debilitating symptoms that can impact many aspects of their and their families’ quality of life (QoL). Key findings from PEDIFIC 1 have been previously described; briefly, the ileal bile acid transporter inhibitor odevixibat improved serum bile acids, pruritus, and several sleep parameters in children with PFIC1 and PFIC2. Here, we describe the effect of odevixibat on QoL, assessed as an exploratory outcome.

Methods: Randomized children (n=62) received placebo or odevixibat (40 or 120 mg/kg/day). To assess QoL, caregivers of patients ≥2 years old completed the Pediatric QoL Inventory (PediQL) questionnaire, which outputs a total score (summarizing patient functioning in physical, emotional, social, and school domains) and a family impact (FI) total score (comprising physical, emotional, social, and cognitive functioning as well as communication, worry, daily activities, and family relationship domains). Here, mean score changes from baseline to week 24 are presented for both patient functioning in physical, emotional, social, and school domains) and a family impact (FI) total score.

Results: Odevixibat improved patient and family QoL, parallel to previously described improvements in clinical signs and symptoms. When comparing odevixibat versus placebo FI total (14.3 vs 5.6, respectively) and domain scores (physical: 18.9 vs 8.1; emotional: 13.4 vs 7.9; social: 13.5 vs 8.5; cognitive: 16.4 vs 3.2; communication: 8.3 vs –4.4; worry: 12.8 vs 7.9; daily activities: 21.1 vs 9.3; family relationships: 10.9 vs 2.1).

Conclusions: Odevixibat improved patient and family QoL, parallel to previously described improvements in clinical signs and symptoms. Overall, odevixibat represents a potential noninvasive option to treat patients with PFIC and improve QoL.