The medication adherence rate scores of the patients at academic hospital (4.35 ± 1.31), corporate hospital (4.39 ± 1.0) and government hospital (4.16 ± 1.28). CONCLUSIONS: The overall mean medication adherence rate score of the patients is 4 ± 1.4 and there is no significant difference in mean scores among hemodialysis centres (p = 0.72). The health care professionals need to educate the patients about their disease state and importance of adherence to prescribed medications.

PUK16

CONCEPTUAL FRAMEWORK IN INTERSTITIAL CYSTITIS / BLADDER PAIN SYNDROME

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OBJECTIVES: This study aimed to build a conceptual framework in patients with IC/PBS with the help of clinical experts (n = 14) in addiction treatment. The objectives of this study was to resource the framework associated with LAIT in KT patients in Spain. METHODS: A systematic literature review was conducted using Medline, PsycINFO and BVS to identify Spanish studies published between 2009 and 2013 focusing on LAIT and KT. Following the review a questionnaire was developed to explore HRU associated with LAIT. Six national experts in KT from Spain completed the survey and the data was analyzed using Computer Assisted Qualitative Data Analysis (CAQDAS). HRU was estimated independently for suspected LAIT, suspected CHR, confirmed CHR and graft loss. RESULTS: Suspected LAIT and CHR were associated with additional HRU quantified by additional nephrology and immunosuppressive blood-level monitoring, and 2 measurements of anti-HLA antibodies (Luminex), 1 ultrasound scan and 1 kidney biopsy. Confirmed CHR was associated with additional HRU such as increases in the number of follow-up visits from 1 visit every 4–6 months to 1 visit every 4–6 months, associated monitoring and testing (bloods, ultrasonography, donor-specific antibodies, proteinuria). A proportion of these patients are treated with intravenous immunoglobulin, rituximab and plasmapheresis, and kidney biopsy to check whether CHR is resolved. Finally, most CHR episodes, up to 60%, cause graft loss with increased HRU associated with intensive patients' follow-up to prepare the return to dialysis and renal replacement therapy. CONCLUSIONS: The lack of adherence to immunosuppressive treatment may lead to CHR and graft loss with an associated increase of healthcare resource utilization.

PUK19

COMPARATIVE EVALUATION OF PCR-RFLP OF SSU RNA AND CWP GENE FOR DETECTION OF CRYPTOSPORIDIUM SPECIES IN PATIENTS WITH POST RENAL TRANSPLANT DIARRHOEA

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OBJECTIVES: To study the utility of SSU RNA and CWP gene PCR-RFLP for the detection of C. meleagridis and C. andersoni in diarrhoea. METHODS: 845 stool samples from 323 patients in renal transplant (RT) recipients and 50 healthy controls between January 2006 and August 2011 were examined for Cryptosporidium by Modified Ziehl–Neelsen stain and fast (Kinyoun’s) staining technique. A 908 bp PCR fragment was extracted and was subjected to PCR-RFLP for species detection in cases positive for Cryptosporidium by microscopy. RESULTS: Cryptosporidium was detected more commonly among the RT recipients than healthy controls (23/323, vs. 0%, respectively; p < 0.001). All the Cryptosporidium positive cases (23/23) were detected using the PCR-RFLP of SSU RNA gene, 15/23 were C. hominis and 8/23 were C. parvum. Only 17/23 cases were detected by CWP genes of which 9/17 were C. hominis and 8/17 were C. parvum. By comparing the SSU & CWP gene PCR-RFLP with microscopy as the gold standard, SSU gene PCR-RFLP proved to be more sensitive & specific (100%) than CWP sensitivity & specificity of CWP PCR-RFLP was 73% and 100% respectively. C. meleagridis and C. andersoni were not detected using the CWP gene. CONCLUSIONS: Cryptosporidiosis is more common in RT recipients. The most common species was Cryptosporidium hominis. SSU RNA PCR-RFLP is more suitable for identification of Cryptosporidium species than CWP.

PUK20

VALUATION OF COMPARATIVE EFFECTIVENESS RESEARCH QUESTIONS BASED ON IDENTIFICATION OF THE MOST RELEVANT OUTCOMES TO IMPROVE CLINICAL PRACTICE: AN APPLICATION OF MCDCA TO DIALYSIS RESEARCH PLANNING

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OBJECTIVES: To prioritize comparative effectiveness research (CER) questions to improve home dialysis practice using a multicriteria decision analysis (MCDCA) framework. METHODS: Candidate CER questions (n = 28) were generated and refined in PICO format by an international network of nephrologists (n = 28) using a nominal group process. The EVIDEF framework was adapted to include 11 criteria to assess the value of these research questions to improve practice from a holistic standpoint, including the impact, context and outcomes of the CER question, feasibility of study, economics and implementation of study findings. Quality of evidence to be generated was also included as a criterion, with consideration of 13 subcriteria outlining the risk of bias and precision. First, participants were asked to weight each criterion independently of the research questions. Second, for each research question, participants assigned a score for each criterion. Average overall values of CER questions were obtained by combining weights and scores using a linear model. RESULTS: Participants assigned the highest importance to the following criteria: Impact on survival and other major clinical outcomes, Unmet needs, and Feasibility of the CER question. Value of CER questions varied between 48% and 73% of maximum value on the MCDCA scale. 61% q criteria estimates (> 70%) were obtained for research questions exploring the association between vascular access or dialysis selection process and mortality/morbidity. Ranking had excellent face validity for all criteria. Results of this ranking process were used to prioritize research questions. CONCLUSIONS: The international network of nephrologists: Holistic MCDCA provides a useful tool for comparative effectiveness research to ensure prioritization of CER questions with highest benefits for improving clinical practice, as illustrated by this application for home dialysis.
**PCN1**

**BONE SAFETY PROFILE OF DENOSUMAB THERAPY: A PHARMACOVIGILANCE CHARACTERIZATION ANALYSIS**

**ALAB**

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**OBJECTIVES:** Denosumab is a biologic approved in June 2010 to treat bone tumors and hypercalcemia of malignancy. This study characterizes bone-related safety signals of subcutaneous atypical femoral fractures (SAF) and osteonecrosis of the jaw (ONJ) in relation to denosumab therapy. **METHODS:** The FDA Adverse Event Reporting System (AERS) was used to detect signals of SAF and ONJ in relation to denosumab therapy. Adverse event reports submitted between July 2010 and December 2013 were retrieved and disproportionality reporting of SAF and ONJ was calculated by Empirical Bayes Geometric Mean (EBGM). Denosumab-event pairs with EBGM 95% confidence interval (CI) above 1.35 were considered signals of SAF and ONJ excess. **RESULTS:** A total of 26,216 adverse event reports submitted for denosumab during the analysis period, corresponding to 30 for SAF and 721 for ONJ. Denosumab was significantly associated with more than expected reporting of SAF (EBGM = 17.5, 95% CI: 9.67-30.30) and ONJ (EBGM = 26.9, 95% CI: 20.3-35.80) compared to other drugs. The majority of denosumab users who experienced both events were females, and average age was 69 years (SAF SD±9.0, ONJ SD±13.1). 12 SAF and 65 ONJ events lead to hospitalization. **CONCLUSIONS:** SAF and ONJ are potential risks of denosumab therapy. Patients with thigh or hip pain should seek immediate medical help, and periodic dental and maxillofacial evaluations should be performed before and during denosumab therapy. Pharmacoepidemiologic studies are recommended to further characterize these risks, as some patients were treated with other medications, including systemic corticosteroids at the time of event occurrence.

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**PCN2**

**META-ANALYSIS OF THE SAFETY OF SIPULUCEL-T IMMUNOTHERAPY IN PROSTATE CANCER**

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**OBJECTIVES:** Sipuleucel-T is an autologous active cellular immunotherapy designed to reduce the risk of death in patients with prostate cancer. The aim of this study was to evaluate the safety of Sipuleucel-T for patients with prostate cancer. **METHODS:** PubMed, EMBASE and the Cochrane Central Register of Controlled Trials were searched through January 10, 2015. Criteria for inclusion were randomized, placebo-controlled clinical trials on Sipuleucel-T patients receiving three infusions, 36 months follow-up and the availability of outcomes data for adverse events. The primary outcome was the total number of adverse events. Secondary outcomes were examined eighteen specified adverse events. Two investigators selected studies independently and assessed the quality of studies using the Jadad scale. Point estimate with 95% confidence interval was used. Fixed-effect or random-effect models were used to consider heterogeneity. **RESULTS:** Five clinical trials encompassing 1031 patients were included. The overall adverse event rate was 1.02% (95% CI 0.75 to 1.30). Multivariate Cox proportional hazards regression models were used to consider heterogeneity. **CONCLUSIONS:** Sipuleucel-T significantly increased the risk of selected adverse events in patients with prostate cancer. Although many adverse events were transient, patients and providers should consider the potential risk of treatment with Sipuleucel-T.

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**PCN3**

**TREATMENT FOR CHEMOTHERAPY-RELATED COGNITIVE DYSFUNCTION:**

**REVIEW OF THE LITERATURE**

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**OBJECTIVES:** Chemotherapy-related cognitive dysfunction (CRCD), colloquially known as ‘chemo fog’ or ‘chemo brain,’ describes the impact of chemotherapy on cognitive functioning in domains ranging from memory to expressive language. CRCD is generated by interactions between direct and indirect effects of chemotherapy on the nervous system, may occur at some level of intensity in as many as 75% of patients who have undergone chemotherapy, and impacts quality of life, educational/occupational outcomes, and social functioning. Management of CRCD includes both pharmacological and non-pharmacological therapies. **METHODS:** To better understand the range of treatments that have been studied for CRCD, and their relative efficacy, a comprehensive review of the published literature was undertaken. A MEDLINE search was conducted for relevant articles published in English between January 2005 and December 2014. The search was limited to studies describing trials of interventions to manage or treat CRCD using non-pharmacological interventions. **RESULTS:** Of 162 records retrieved, 11 described interventions targeting CRCD. Pharmacological therapies used included entyfrotopin, dexamethasone, galabila, and pycnogenol. Half of the studies focused on breast cancer. Most resulted in small, statistically significant findings, but two studies of etoposide and pycnogenol trial had significant results. All 3 of the non-pharmacological studies focused on patients with breast cancer, two using a form of cognitive-behavior therapy (CBT) and the third studying a yoga program. **CONCLUSIONS:** The review found a large number of trials investigating the potential of interventions for managing the extent of the cognitive impairment, and describing etiological theories, such as the relationship of CRCD to fatigue and anemia. However, there was a paucity of well-designed, sufficiently powered studies of potential treatments, given the extent of the problem and its impact on patient functioning. This is an area of clear patient need which warrants further scientific study.