

The medication adherence rate scores of the patients at academic hospital ( $4.35 \pm 1.31$ ), corporate hospital ( $4.38 \pm 1.10$ ) and government hospital ( $4.16 \pm 1.28$ ). **CONCLUSIONS:** The overall mean medication adherence rate score of the patients is  $4.34 \pm 1.23$  and there is no significant difference in mean scores among hemodialysis centres ( $p 0.722$ ). 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 which is a chronic debilitating condition characterized by pelvic pain, urinary urgency, and urinary frequency. It affects around 0.7–1 million people in the US and mostly middle aged women. Diagnostic criteria developed for research are not efficient and missing 60% of all cases. Uncertainty surrounds definition, etiology, diagnosis, natural history, true prevalence, and most effective treatment(s). **METHODS:** Literature review results were used to design semi-structured telephone interviews to elicit concepts of importance for IC/PBS patients on functioning and life. Interviews were held with clinical experts and UK patients until saturation of concepts. Transcripts were analyzed thematically. **RESULTS:** Two clinical experts and 30 female patients were interviewed. IC/PBS was defined as a chronic pain syndrome that may begin as a pathologic process in the bladder in most (but not all) patients. Pain and frequency were reported as the most bothersome symptoms. Relationships, activities, energy levels, and psychological impact were reported to be the key areas of impact. 'Not being able to do what I used to', 'worry about toilet access', 'impact on work life', and 'impact on family / home life' were mentioned as having the greatest impact. A broad range of treatments was reported with a broad range of treatment side effects. The experts' results contributed the following: pain drives frequency and younger people report a heavier burden. **CONCLUSIONS:** The conceptual framework of this study contributes to the understanding of IC/PBS. IC/PBS has a profound and debilitating effect on all aspects of patients' lives, from preventing them to work over participating in family life and traveling to being house-bound with greatly impacted change in roles and self-perceptions, leading to feelings of being 'not-normal' causing anxiety, depression and even suicidal tendencies.

## URINARY/KIDNEY DISORDERS – Health Care Use &amp; Policy Studies

## PUK17

## RETROSPECTIVE STUDY OF UTILIZATION PATTERNS OF OVERACTIVE BLADDER THERAPY IN MEN IN A COMMERCIALLY INSURED POPULATION: THE EARLY US MIRABEGRON EXPERIENCE

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**OBJECTIVES:** The medical management of men with Lower Urinary Tract Symptoms often involves agents targeting bladder outlet obstruction (BOO) such as  $\alpha$ -blockers or 5- $\alpha$  reductase inhibitors (5ARI). However, overactive bladder (OAB) symptoms may coexist with BOO. This study aims to describe the baseline characteristics of men who utilize OAB [mirabegron and antimuscarinics (AM)] therapy and sequential and combination use of various urologic medication classes. **METHODS:** Data from a US commercial database were analyzed for men starting OAB therapy between 10/01/12 and 12/31/13. Men were grouped by initiation of mirabegron or AM. A 12-month retrospective analysis was conducted with patients defined as naive or experienced to AM therapy 12-month period prior to index. Baseline demographics and comorbid conditions were compared. Concomitant BOO medications, in use at baseline, initiated, or discontinued during the 90 days pre/post index date of mirabegron or AM, were analyzed. **RESULTS:** More men on mirabegron saw a urologist (75% vs 35%), more likely to have BOO diagnosed (66% vs 49%) and use in free combination with  $\alpha$ -blockers (26% vs 17%) and 5ARI (7% vs 4%) therapy versus AM. Baseline characteristics showed mirabegron patients were older (64 vs 59) and had a higher Elixhauser comorbidity index (4.7 vs 4.0) compared with AM patients. Baseline health resource utilization (HRU) was higher among the mirabegron cohort for urodynamics (58% vs 29%), cystoscopy (25% vs 19%), polypharmacy (10.4 vs. 8.2) and overall outpatient visits (11.4 vs 8.5). More mirabegron patients had prior prostate (7.6% vs 5.8%) and OAB (3.9% vs 0.7%) surgical therapy 12-months prior to index compared to AM patients. **CONCLUSIONS:** Male patients receiving mirabegron showed distinct baseline characteristics. Patients managed by urologists were often more complicated with greater baseline HRU. Additional studies to model the impact of patient characteristics on outcomes in those prescribed mirabegron and AMs may be helpful.

## PUK18

## LACK OF ADHERENCE TO IMMUNOSUPPRESSIVE TREATMENT IN KIDNEY TRANSPLANT PATIENTS: ESTIMATION OF ASSOCIATED HEALTH RESOURCE UTILIZATION

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**OBJECTIVES:** The Lack of Adherence to Immunosuppressive Treatment (LAIT) has been associated with Chronic Humoral Rejection (CHR) and decreased graft survival which can increase Health Resource Utilisation (HRU). Prevalence of LAIT has been reported to range between 7.4% and 41.8% of Spanish Kidney Transplant (KT) patients and published studies suggest LAIT may cause up to 20–50% of CHR episodes in Spain. The objective of this study was to estimate the resource utilization 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 KT and LAIT. 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 nephrologist visits, heightened 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 1–2 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 COWP GENE FOR DETECTION OF CRYPTOSPORIDIUM SPECIES IN PATIENTS WITH POST RENAL TRANSPLANT DIARRHOEA

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**OBJECTIVES:** To study the utility of SSU rRNA and COWP gene PCR-RFLP for the detection of *C. parvum*, *C. hominis*, *C. meleagridis*, and *C. andersoni*. **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 acid-fast (Kinyoun's) staining technique. DNA 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. 0/50, respectively;  $p=0.005$ ). All the Cryptosporidium positive cases (23/23) were detected using the PCR-RFLP of SSU rRNA gene, 15/23 were *C. hominis* and 8/23 were *C. parvum*. Only 17/23 cases were detected by COWP genes of which 9/17 were *C. hominis* and 8/17 were *C. parvum*. By comparing the SSU & COWP gene PCR-RFLP with microscopy as the gold standard, SSU gene PCR-RFLP proved to be more sensitive & specific (100%) than COWP (sensitivity & specificity of COWP PCR-RFLP was 73.9% and 100% respectively). *C. meleagridis* and *C. andersoni* were not detected in any case. **CONCLUSIONS:** Cryptosporidiosis is a common cause of diarrhea in RT recipients. The most common species was Cryptosporidium hominis. SSU rRNA PCR-RFLP is more suitable for identification of Cryptosporidium species than COWP.

## PUK20

## PRIORITIZATION OF COMPARATIVE EFFECTIVENESS RESEARCH QUESTIONS BASED ON IDENTIFICATION OF THE MOST RELEVANT OUTCOMES TO IMPROVE CLINICAL PRACTICE: AN APPLICATION OF MCDA 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 (MCDA) framework. **METHODS:** Candidate CER questions ( $n=13$ ) were generated and refined in PICO format by an international network of nephrologists ( $n=28$ ) using a nominal group process. The EVIDEM 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 highest importance to the following criteria: Impact on patient 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 MCDA scale. Highest value 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 planning for the international network of nephrologists. **CONCLUSIONS:** Holistic MCDA 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.

## RESEARCH POSTER PRESENTATIONS - SESSION IV

DISEASE-SPECIFIC STUDIES  
CANCER – Clinical Outcomes Studies

## PCN1

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

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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 subtrochanteric atypical femoral fractures (SAF) and osteonecrosis of the jaw (ONJ) in relation to denosumab therapy. **METHODS:** The FDA Adverse Event Reporting System 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 disproportional reporting of SAF and ONJ was calculated by Empirical Bayes Geometric Mean (EBGM). Denosumab-event pairs with EBGM 95% confidence interval lower limit  $\geq 2.0$  are considered signals of SAF and ONJ excess reporting compared to other drugs in the database. Events were defined by the Preferred Terms of the Medical Dictionary for Regulatory Activities, and denosumab was defined by the Anatomical Chemical Therapeutic Classification. **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=9.67-30.0) and ONJ (EBGM=26.9, 95%CI=20.1-35.9) compared to other drugs. The majority of denosumab users who experienced both events were females, and average age was 69 years (SAF SD=9.5; ONJ SD=11.3). 12 SAF and 65 ONJ events lead to hospitalization; 25 and 14 ONJ events contributed to patient disability and death, respectively. Other factors could have lead to these serious outcomes, including comedication and comorbidities. **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. Pharmacoeconomic 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.

## PCN2

## META-ANALYSIS OF THE SAFETY OF SIPULEUCEL-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 examined eighteen specified adverse events. Two investigators selected studies independently and assessed the quality of studies using the Jadad scale. Point estimates with a 95% confidence interval were generated. Fixed-effects or random random-effects models were based on the evaluation of heterogeneity. **RESULTS:** Five clinical trials encompassing 1031 patients were included. The overall adverse events relative risk (RR) was 1.02 (95% CI 1.00 to 1.05, p=0.091). For the secondary outcomes, differences were detected between Sipuleucel-T and placebo on chills (RR 4.87; 95% CI 2.50 to 6.78, p=0.000; 904 patients), fatigue (RR 1.20; 95% CI 1.01 to 1.43, p=0.035; 1031 patients), pyrexia (RR 5.40; 95% CI 1.90 to 15.35, p=0.002; 1031 patients), headache (RR 2.68; 95% CI 1.75 to 4.10, p=0.000; 1031 patients), influenza like illness (RR 3.07; 95% CI 1.48 to 6.36, p=0.003; 681 patients), myalgia (RR 2.24; 95% CI 1.26 to 4.00, p=0.006; 681 patients), nausea (RR 1.40; 95% CI 1.05 to 1.88, p=0.023; 1031 patients), vomiting (RR 1.86; 95% CI 1.21 to 2.88, p=0.005; 856 patients) and dyspnea (RR 3.72; 95% CI 1.34 to 10.36, p=0.012; 350 patients). **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.

## 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 generally attributed to the direct or indirect effects of chemotherapy on the central nervous system, may occur at some level of intensity in as many as 75% of patients who have undergone chemotherapy, and impacts patient quality of life, educational/occupational achievement, 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 sources 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 161 records retrieved, 11 described interventions targeting CRCD. Pharmacological therapies used included erythropoietin, dexamethylphenidate, ginkgo

biloba, and pycnogenol. Half of the studies focused on breast cancer. Most resulted in statistically non-significant findings, but two studies of erythropoietin and the 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 studies documenting the problem of CRCD, discussing innovative ways of measuring 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.

## PCN4

## HYPOFRACTIONED RADIOTHERAPY IN THE TREATMENT OF EARLY BREAST CANCER: SYSTEMATIC REVIEW AND META-ANALYSIS

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**OBJECTIVES:** To evaluate short and long term effects of hypofractionated radiation therapy in women with early stage breast cancer, after undergoing breast conservative surgery. **METHODS:** We searched for randomized controlled trials in Embase, Medline, Cochrane Library and Lilacs comparing unconventional versus conventional fractionation. The authors performed data extraction independently. Disagreements were resolved by consensus. Random-effects risk ratios (RR) were calculated comparing patients randomized to unconventional with those to conventional fractionation. Periods before and after five years of treatment were considered. **RESULTS:** Five trials reported on 7,802 women. The studies were of medium to high quality. Unconventional fractionation did not affect, until five years and after five years, respectively: (1) local recurrence RR 0.90 (95% CI 0.68 to 1.18, P = 0.44) and RR 0.98 (95% CI 0.83 to 1.17, P = 0.86); (2) distant recurrence (RR) 1.04 (95% CI 0.73 to 1.46, P = 0.84) and RR 1.02 (95% CI 0.79 to 1.32, P = 0.88); (3) mortality RR 0.89 (95% CI 0.77 to 1.05, P = 0.16) and RR 0.96 (95% CI 0.89 to 1.08, P = 0.48); (4) disease-free survival RR 0.96 (95% CI 0.78 to 1.18, P = 0.69) and RR 0.96 (95% CI 0.84 to 1.09, P = 0.49); (5) cardiac ischemia RR 0.73 (95% CI 0.34 to 1.57, P = 0.42) and RR 0.61 (95% CI 0.33 to 1.15, P = 0.13); (6) rib fracture RR 1.02 (95% CI 0.25 to 4.20, P = 0.98) and RR 1.08 (95% CI 0.26 to 4.53, P = 0.91); (7) pulmonary fibrosis RR 2.42 (95% CI 0.50 to 11.71, P = 0.27) and RR 0.97 (95% CI 0.89 to 11.21, P = 0.07). **CONCLUSIONS:** Using hypofractionated radiotherapy regimens does not affect any of the outcomes analyzed in women with early stage breast cancer, after undergoing breast conservative surgery.

## PCN5

## RISK OF CARDIOTOXICITY AND ALL-CAUSE MORTALITY IN BREAST CANCER PATIENTS AFTER ADJUVANT CHEMOTHERAPY OR HORMONAL THERAPY

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**OBJECTIVES:** The purpose of this study was to estimate incidence of and identify factors associated with cardiotoxicity, defined as heart failure and/or cardiomyopathy, and all-cause mortality in breast cancer patients undergoing adjuvant chemotherapy or hormones. **METHODS:** A retrospective, population-based cohort study of 108,672 women ( $\geq 66$  years of age) newly diagnosed with breast cancer from 2001-2009 was conducted using the Surveillance, Epidemiology, and End Results (SEER)-Medicare-linked database. Adjuvant chemotherapy were classified as mutually exclusive groups: trastuzumab-based, anthracycline-based, anthracycline and trastuzumab-based, taxane-based, and other chemotherapy. Propensity score matching adjusted for differences in patient characteristics across treatments. The final sample included a total of 11,250 women. Multivariable Cox proportional hazards regression models estimated hazard ratios (HRs) of cardiotoxicity and all-cause mortality with adjustment for inverse probability weights, sociodemographics, cancer characteristics, comorbidities, surgery and radiation, region, and year at diagnosis. **RESULTS:** Compared with hormones, risk of cardiotoxicity was higher in patients treated with anthracycline and trastuzumab-based (adjusted HR=1.87; 95% confidence intervals [CI]=1.51-2.33), trastuzumab-based (HR=1.32; 95%CI=1.14-1.52), and anthracycline-based (HR=1.14; 95%CI=1.03-1.27) regimens, respectively. Certain baseline characteristics were significant predictors of cardiotoxicity, including demographics (older age (vs.  $\leq 70$ ), non-Hispanic black), cancer characteristics (advanced stage), comorbidities (cardiovascular conditions or renal failure), year at diagnosis, and West region (vs. Northeast). Additionally, risk of all-cause mortality was higher in patients treated with taxane-based (HR=1.54; 95%CI=1.43-1.67) regimens compared to hormones. Baseline characteristics including sociodemographics, cancer characteristics, cardiovascular or renal failure comorbid conditions, year at diagnosis, and South region were significant predictors of all-cause mortality (all P<0.05). **CONCLUSIONS:** Women with breast cancer treated with trastuzumab-based and/or anthracycline-based regimens had increased cardiotoxicity risk compared with hormones, while those treated with taxane-based regimens had higher rates of all-cause mortality. Types of chemotherapy are associated with increased risk of cardiotoxicity and all-cause mortality. Practitioners should further evaluate treatment and patient characteristics for risk mitigation strategies.

## PCN6

## RACIAL/ETHNICITY DISPARITIES IN THE ASSOCIATION BETWEEN DIABETES AND PANCREATIC CANCER IN THE ELDERLY MEDICARE POPULATION

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**OBJECTIVES:** Although the relationship between diabetes and risk of pancreatic cancer are well-documented, limited research has examined whether racial/ethnicity differences accounted for the association between diabetes and pancreatic cancer. The aims of this study were to 1) assess whether diabetes is associated with pancreatic cancer in the elderly Medicare population, and 2) identify if any racial/