decreasing trend in average CNI dose by year: at the end of the first year, the mean dose of TAC was 9.3±5.4 mg/day and 282.1±118.3 mg/day for CYC, decreasing to 5.2±3.6 and 158.7±57.8 mg/day in the third year, and 4.8±7.3 and 144.2±58.4 mg/day in the fifth year. At the end of the first (n=455) and second year (n=408) post-transplant, the most common IS regimens were TAC/prednisone/mycophenolate mophetil (MMF) (19.1% in both years), TAC/prednisone/azathioprine (15.6% at first year and 14.7% at second year) and CyC/prednisone/azathioprine (13.2% at first year and 14.0% at second year). By the end of the fifth year (n=141), however, the most common IS regimen was TAC/prednisone/mycophenolate sodium (MFS; 31.9%), followed by CyC/prednisone/MFS (7.8%) and TAC/prednisone/MMF (7.1%). **CONCLUSIONS:** Tacrolimus was the CNI of choice for the majority of *de novo* kidney transplant patients in 2004. The main IS therapy regimens during the first post-transplant years was tacrolimus/prednisone/mycophenolate mophetil.

PUK20

EARLY DETECTION, SCREENING, AND MANAGEMENT OF CHRONIC KIDNEY DISEASE AMONG ACTIVELY EMPLOYED – AN INTEGRATED POPULATION HEALTH MANAGEMENT APPROACH

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OBJECTIVES: The employer burden of CKD in terms of lost productivity, short and long term disability use, and high total health care costs has been well-documented and warrants an employer-sponsored population health management program to improve the health and lives of the workforce. Georgia Power Company (GPC) has implemented a chronic care management program aimed at early identification, disease awareness, and counseling of employees through on-site screenings. **METHODS:** Individuals are offered voluntary participation in the CKD management program with their PCPs and nephrologists depending upon their risk and CKD stage. Health outcomes including, clinical, resource utilization, and self-reported health status and productivity are compared pre- and post- program implementation. **RESULTS:** Preliminary results at the 6-month mark show that: a) 2,589 employees were screened, 638 (25%) met program criteria for participation and 110 (17.2%) agreed to participate in the study; b) among the current enrollees, 17% have diabetes and 51% have hypertension; c) mean eGFR rates are 61.27, and HbA_1C levels of 7.7, and a mean BMI of 30.5 indicating a population at high risk for developing CKD; d) participants reported missing on average 10.5 hours/week due to their CKD; and e) baseline total health care expenditures were $19,776 per member per year indicating a high cost population as well. **CONCLUSIONS:** CKD is a high-cost disease for GPC. Resources invested in creating novel CKD management programs to identify, raise awareness, and manage CKD are a worthwhile investment for employers.

PUK21

PATIENT CHARACTERISTICS ASSOCIATED WITH INITIATION OF OVERACTIVE BLADDER (OAB) DISCUSSION WITH A PHYSICIAN

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OBJECTIVES: Many patients with OAB attempt self-management and are reluctant to initiate an OAB discussion with a physician. We sought to identify patient characteristics associated with patient initiation of an OAB discussion with a physician. **METHODS:** Of 24,866 respondents of the 2009 National Health & Wellness Survey, an internet-based questionnaire on healthcare attitudes, behaviors, and outcomes, 2750 recontacted respondents qualified for and completed a longitudinal survey. Eligible subjects (≥18 y) had an OAB Awareness Total score of >14 (men) or >16 (women) or used an OAB prescription medication. Exclusion criteria included current pregnancy or catheter use, hematuria, urinary tract infection symptoms, benign prostatic hyperplasia (BPH), use of BPH medication, or prostate cancer. Analysis of proportions and logistic regression analysis (2-tailed $P<0.05$ significance level) identified patient characteristics associated with initiation of OAB discussions with a physician. **RESULTS:** 1325 of 2750 (48%) OAB patients reported initiating an OAB discussion with a physician. These respondents (mean age 52 y) were predominantly female (65%) and white (71%). Significant variables associated with initiation of an OAB discussion were divorced/separated/widowed vs single, more familiar with OAB, a longer duration of bladder control symptoms, lower SF-12 Physical Component Summary score, better daily activity function, greater pill burden, and regular physician contact (Table). Patient age, income, employment status, and health insurance coverage were not significantly associated with a patient-physician OAB discussion. **CONCLUSIONS:** Patients are more likely to initiate an OAB discussion with their physician if they have regular contact with the physician, a longer duration of symptoms, are familiar with OAB, and have worse physical quality of life. Socioeconomic variables or drug insurance coverage were not significantly associated. These findings suggest that the physician relationship is important for help seeking behavior; and there is a need for early patient education on OAB symptoms and treatments.

Urinary/Kidney Disorders – Research on Methods

PUK22

LEVELING THE PLAYING FIELD: A CASE STUDY ON TECHNICAL PRECISION IN COMPARATIVE EFFECTIVENESS RESEARCH FOR CLINICALLY LOCALIZED PROSTATE CANCER (PC)

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OBJECTIVES: Determine the impact of correcting for different definitions of prostate-specific antigen (PSA) recurrence when analyzing relative effectiveness of seven treatments for localized PC; Emphasize the importance of clinical input and real-world data in ensuring modeling accuracy. **METHODS:** We conducted two lifetime cost-utility analyses comparing men undergoing open, laparoscopic, or robot-assisted radical prostatectomy, 3-dimensional conformal or intensity-modulated radiation therapy, brachytherapy, or combined external-beam radiation and brachytherapy. We constructed a Markov model quantifying lifetime costs and quality-adjusted life years (QALYs) for men with localized PC in low-, intermediate-, and high-risk strata. Post-treatment PSA recurrence is defined differently for surgical versus radiation treatments. In Study 1, we made clinically-based corrections in time between recurrence and metastasis, the basis for time-to-disease-progression (biochemical failure [BCF]) calculations, to account for the different definitions. In Study 2, these corrections were not made. **RESULTS:** In "corrected" analyses, surgery tended to yield more QALYs and lower costs than radiation, with minimal differences among surgical modalities. Compared to a base case assuming a 4-year increment between the surgery and radiation modalities in the median time from BCF to metastasis, "uncorrected" analyses yield surgical costs relatively overstated by 3 to 11%; QALYs understated by 1 to11%; life expectancy understated by <1% to 8.5%; metastasis overstated by 17 to 36%; and PC death overstated by 17% to 43%. Results are generally greater with larger corrections and outcomes discounted to net present value. **CONCLUSIONS:** "Without correction" results do not affect conclusions about relative costs for all patients or QALYs for low-risk patients. They do affect QALY conclusions for intermediate- and higher-risk patients, yielding erroneous conclusions on the relative superiority of radiation versus surgical treatments. Without correction, the same incorrect conclusions would be reached for survival, metastasis, and PC death. Literature and real-world data were used to validate the corrections.

PUK23

METHODOLOGICAL CONSIDERATIONS FOR COST-EFFECTIVENESS ANALYSIS OF ONABOTULINUMTOXINA IN PATIENTS WITH NEUROGENIC DETRUSOR OVERACTIVITY

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OBJECTIVES: Selection of an appropriate modeling structure is a key consideration in economic evaluations. Factors that influence the choice of modeling structure include data availability and consensus within the clinical community regarding clinically meaningful definitions of treatment response and defined and measureable health states. In the absence of an agreed consensus, selecting a model structure is challenging. We explored two model structures to assess the cost-effectiveness of onabotulinumtoxinA for the treatment of urinary incontinence (UI) due to neurogenic detrusor overactivity (NDO). **METHODS:** The merits and limitations of a model based on treatment response versus an absolute model structure were considered. In the response model, health states were defined by precise trial outcomes (percent reduction in UI episodes from baseline). In the absolute model, health states were defined by categories of UI episodes/week. In the absence of clinically meaningful cutoffs, we plotted health-related quality of life (HRQoL) scores versus UI episodes to derive meaningful cutoffs for health states based on HRQoL. **RESULTS:** In the response model, response was defined as a ≥50% reduction in UI episodes. The primary limitation with this approach is the heterogeneity within 'non-responder' patients (e.g. patients with either a 0% or a 49% reduction are both 'non-responders'). No clear health state cutoffs were observed with respect to HRQoL and UI episodes for the absolute model. Health states were defined on percentile distribution within the trial population: dry, 0-25% [1-14 UI episodes/week], >25%-75% [15-32 UI episodes/week], and >75% [>32 UI episodes/week]. The primary limitations to this approach are the inability to capture health improvement within health states and the lack of clinical relevance for health states based on percentiles. **CONCLUSIONS:** In the absence of clinical consensus, model structure selection should be a key consideration to capture the true economic value of a therapy.

PUK24

USE OF BIOMARKERS IN PROPENSITY SCORE MATCHING TO MITIGATE CHANNELING BIAS IN A RETROSPECTIVE COHORT OF ESRD PATIENTS

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OBJECTIVES: Retrospective analyses are inherently subject to bias. Techniques such as propensity score matching (PSM) can function as pseudo-randomization. The PSM, however, is often done solely using administrative claims data. We tested the hypothesis that claims alone would provide inadequate matching when compared to claims plus relevant biomarkers. **METHODS:** We used databases from a large dialysis organization to obtain two cohorts of dialysis patients prescribed different drug therapies within the same class. The cohorts were first matched on demographics and comorbidities only. The same cohorts were then rematched, adding baseline biomarkers (albumin, corrected calcium, Kt/V, normalized protein catabolic rate (nPCR), parathyroid hormone (PTH), phosphorus) to the PSM. We used generalized mixed models (GMM) to determine if treatment was associated with lab outcomes over a 16-week period, run separately on both PSM cohorts. **RESULTS:** The first PSM cohorts did not differ on baseline demographic and comorbid variables, but significant differences existed in four (nPCR, phosphorus, calcium, PTH) of the six baseline biomarkers excluded from the match (all $p< 0.01$). When biomarkers were included in the PSM, there were no significant differences between groups on any baseline measures. GMM analysis showed a significant

association between drug and lab outcomes for the cohort matched on demographic and comorbid information only ($p<0.001$). There was no significant association in the cohort matched on biomarkers plus comorbid and demographic variables ($p=0.414$). **CONCLUSIONS:** PSM using administrative claims alone left considerable channeling bias in the sample, and erroneous conclusions were drawn from subsequent GMM analysis. Inclusion of biomarkers in the PSM removed this bias and yielded non-significant GMM results. Administrative claims data without biomarkers may not be sufficient for conducting PSM.

POSTER SESSION II:
SELECTED HEALTH CARE TREATMENT STUDIES

Medical Device/Diagnostics – Clinical Outcomes Studies

PMD1
IMPACT OF VAGUS NERVE STIMULATION (VNS) THERAPY ON CLINICAL OUTCOMES AND COSTS IN MEDICAID PATIENTS WITH DRUG-RESISTANT EPILEPSY

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OBJECTIVES: This study evaluated the benefits of VNS Therapy on health resource utilization (HRU), epilepsy-related comorbidities, and costs over time in drug-resistant epilepsy patients in a clinical practice setting. **METHODS:** An open-cohort pre-post analysis was conducted using Medicaid data from FL, NJ, IA, MO, and KS (January 1997-June 2009). Patients had ≥1 neurologist visit with epilepsy diagnosis (ICD-9 345.xx, 780.3, or 780.39), ≥1 procedure for VNS Therapy implantation, ≥1 anti-epileptic drug (AED), ≥6 months of pre- and post-VNS Therapy continuous enrollment. The 6-months preceding VNS Therapy implantation was designated as Pre-VNS Therapy period. Post-VNS Therapy period was designated from the date of VNS Therapy implantation until removal of device, death, or Medicaid disenrollment. Univariate and multivariate Poisson regressions (incidence rate ratios [IRR] and 95% confidence intervals [CI]) compared HRU and epilepsy-related comorbidities and GLM models estimated cost differences between the pre- and post-VNS Therapy periods. Costs were adjusted to $2009 using medical care component of the consumer price index. **RESULTS:** Of the 1655 patients, mean age was 29.4 years and 51.4% were males. Compared to Pre-VNS Therapy period the incidence of hospitalizations and emergency room (ER) visits decreased over time during Post-VNS Therapy period (Trend: 0.9238, p<.0001 and Trend: 0.9526, p<.0001, respectively). Generalized tonic-clonic seizure events showed a decreasing trend during Post-VNS Therapy period than Pre-VNS Therapy period (adjusted IRR: 1.23 [CI: 1.03-1.46] in Q1 to 0.17 [CI: 0.11-0.27] in Q12). During Post-VNS Therapy period, average total health care costs decreased from $42,540 (Q1) to $14,316 (Q12). After 1.5 years, cost savings in Post-VNS Therapy period started to outweigh total costs of VNS Therapy device and implantation procedures. **CONCLUSIONS:** To conclude, VNS Therapy is associated with decreased HRU and common epilepsy-related comorbidities, such as hospitalizations, ER visits and generalized tonic-clonic seizure events, resulting in net cost savings for public payers after about 1.5 years.

PMD2
A META-ANALYSIS OF BIOMARKERS AND DIAGNOSTIC IMAGING IN ALZHEIMER'S DISEASE

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OBJECTIVES: Mild Alzheimer's Disease (AD) is often difficult to differentiate from mild cognitive impairment (MCI) or non-AD dementias. A multitude of diagnostic biomarkers and advanced imaging strategies have been developed to aid in the diagnosis and management of AD. Examples of biomarkers include total tau, phosphorylated tau (Ptau), and the 42 amino acid form of beta-amyloid ($A\beta_{1-42}$) and imaging strategies include MRI, FDG-PET, SPECT and CT. We sought to systematically review and meta-analyze the published evidence on key test characteristics of major diagnostic strategies in AD. **METHODS:** A systematic review was undertaken to locate all studies of biomarkers or diagnostic imaging for AD published in English from January 1990 to March 2010. Meta-analysis was performed using a bivariate mixed-effects binary regression model. We calculated sensitivity (SN), specificity (SP) and area under the receiver operating curves (AUROC), with confidence and prediction contours in order to formulate best estimates of SN and SP of commonly used diagnostic tests for AD. **RESULTS:** Of 1,840 unique studies identified, 119 presented primary data sufficient for analysis. For each diagnostic method, SN and SP were calculated against non-demented controls, non-AD dementias with and without MCI, if available. Compared to non-demented controls, FDG-PET demonstrated the highest AUROC (0.96), with 90% SN (95%CI 84% to 94%) and 89% SP (95% CI 81% to 94%). FDG-PET also was most accurate in discriminating AD from demented controls (including MCI) with AUROC 0.91, and 92% SN (95%CI 84% to 96%) and 78% SP (95% CI 69% to 85%). For discrimination of AD from non-AD dementias (excluding MCI), CSF Ptau and SPECT produced identical AUROC (0.86) with 79% and 86% SN and 80% and 81% SP, respectively. **CONCLUSIONS:** Diagnostic strategies for AD show wide variation in test characteristics and some show promise for clinical practice.

PMD3
PARTIAL RESPONDERS IN SCHIZOPHRENIA

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OBJECTIVES: Despite well conducted treatment, schizophrenic patients often remain symptomatic. Although multiple studies studied resistant patients, no data are available on partial responders (PR). The purpose of this study is to compare clinical, quality of life (QoL), cost of PR versus non symptomatic patients (full responders=FR), and to assess the evolution of PR. **METHODS:** An analysis was performed based on a sample of patients in France and UK followed prospectively over 2 years. At baseline, resistant as well as acute exacerbated patients were excluded. Symptomatic patients were defined according to 3 clinical criteria: CGI score ≥ 4 and PANSS score ≥ 60 (with 3 items < 4). Evolution was assessed over the 2 years period. The following information was collected using standardized validated instruments: psychotic symptoms, depression, side effects, compliance, functioning, specific and generic QoL, resource utilisation. **RESULTS:** 93 (19%) patients were identified as PR and 284 (59%) as FR out of 484 patients. The population of PR was well discriminated at baseline period when compared to FR. Clinical symptoms including depression and side effects, compliance, functioning, QoL are more severe in PR than in FR. Cost of management of PR appears significantly higher than FR. Patients identified as PR remained PR over the 2 years period. The change of prescription including switch, dosage increase or therapy augmentation is similar between PR and FR. **CONCLUSIONS:** The PR is a stable population overtime with higher clinical burden and increased management cost compared to FR. The lack of specific treatment pattern raises the issue of the need for specific disease management strategy of PR and related assessment of such intervention.

PMD4
PERCEPTION OF IRON DEFICIENCY IN CLINICAL PRACTICES: MULTIDISCIPLINARY FRENCH SURVEY (SUPFER SURVEY)

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OBJECTIVES: To assess the perception of iron deficiency and describe the management of iron deficiency in clinical practices. **METHODS:** Physicians were randomly selected from a professional directory. They reported in a questionnaire the estimated frequency of iron deficiency and anemia among their patients, the biological exams performed for iron deficiency diagnosis and the conditions of use of intravenous iron. The survey analysis was performed on 358 questionnaires (return rate: 12%) from physicians of different areas of expertise (anesthesia, intensive care, surgery, n=67; gynecology, obstetrics, n=122; oncology, hematology, radiotherapy, n=39; hepato-gastroenterology, internal medicine, geriatrics, rheumatology, n=130). **RESULTS:** Out of 86% (309/358) of the physicians reported cases of iron deficiency. For 63% of them (223/358), the frequency of anemia among their patients was more than 10%. Survey responders were 25% (89/358) to report that they systematically explored iron deficiency and 61% (217/358) only if anemia had been previously diagnosed. Severe iron deficiency, is treated with oral iron in 75% (269/358), 39% (141/358) with intravenous iron and 20% (70/358) with transfusion. For 70% of the physicians who prescribe intravenous iron (148/213) the limit threshold of hemoglobin for prescription of intravenous iron of 8 g/dL (median). In contrast with hemoglobin level, serum ferritin and transferrin saturation, were infrequently performed (15% [31/213] and 5% [11/213], respectively). The use of erythropoiesis-stimulating agents was reported by 44% (156/358) of physicians with systematic iron supplementation for only 47% (74/156) of them. **CONCLUSIONS:** One of the main results of this survey is the apparent equation between iron deficiency and anemia in many physicians. Thus, most physicians report that intravenous iron is used when hemoglobin is at a median value ≤ 8 g/dL, Therefore, iron deficiency is considered only within a context of severe anemia for many physicians.

PMD5
OUTCOME STUDY OF DRUG ELUTING STENT (DES) VERSUS BARE METAL STENT (BMS) IN HONG KONG: A 6-MONTH PILOT STUDY

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OBJECTIVES: This pilot study was to evaluate and compare drug eluting stent (DES) and bare metal stent (BMS) in 1) clinical outcome; 2) humanistic outcome; and 3) economic outcome, in patients undergoing percutaneous coronary intervention (PCI). **METHODS:** All patients undergo PCI in Prince of Wales Hospital during August 1 to October 31, 2009 were recruited. Clinical outcome was measured by the occurrence of major adverse cardiac events (MACE), which is defined as cardiac death, non-fatal MI and target lesion revascularization. An EQ-5D questionnaire was used to measure the baseline quality of life before the stent placement, and six months post PCI. Procedural cost including the instruments, medications and hospitalization, as well as all cardiac related follow-up for the first six months was recorded. Cost to reduce one MACE (ICER) and cost to gain one quality-adjusted life-year (QALY) was calculated to assess the cost-effectiveness of DES. **RESULTS:** A total of 50 patients (n=22 and n=28 for DES and BMS respectively) were enrolled into our study. MACE in 6 month was 5% in DES (n=1) versus 7% (n=2) in BMS respectively (p=0.701). In DES group, the utility score showed significant improvement in six months than baseline (0.92, IQR 0.80–1.00 vs. 0.69, IQR 0.22–0.77, p=0.001), while there were no significant improvement for BMS group (0.87, IQR 0.73–1.00 vs. 0.81, IQR 0.66–1.00, p=0.337). ICER calculated was HKD$17,112 and cost per QALY gained was HKD$142,600. six-month total medical cost was similar, HKD$92,440±58,566 for DES (median=$74231) versus $95,223±64,301 for BMS (median=$76475) respectively, p=0.875, the higher procedural cost of DES group was balanced by lower follow-up and hospitalization cost, when compared with BMS group. **CONCLUSIONS:** The quality of life of patient underwent placement with DES