OBJECTIVES: to estimate economic consequences and patients acceptance of a program proposing a switch toward self-injection of a recombinant Human erythropoietin (r-HuEPO) NeoRecormon with Reco-Pen® in a population of adult patients on dialysis. METHODS: A cost-minimisation study was performed in a societal perspective to assess the economic consequences of the program proposing Reco-Pen®, to facilitate self-injection in patients requiring a treatment with r-HuEPO. A random national sample of French patients in maintenance dialysis or in pre-dialysis were selected. A nurse was dedicated in each centre to educate and assist patients during the study period. Direct costs of injecting r-HuEPO before and after the program were estimated including purchase of the device and erythropoietin, time spent by nurses for injection and education of patients or caregivers. Data were collected on all relevant items retrospectively and prospectively during a 2-month follow up period. An acceptance study was conducted including self-evaluation of pain during injection, easiness of use and satisfaction. RESULTS: One hundred twenty-four patients in 42 centres were enrolled in Fall 2001. Eighty-seven percent of patients were in maintenance therapy and the rest in correction phase. The satisfaction scores were positive in 80% of patients in terms of improved autonomy and comfort and 93% declared themselves ready to go on using the pen. The self-injection rates grew from 21% to 53%. The switch to Reco-Pen® of 100 patient x year was associated with an economic gain of €22,449 broken down as following: €18,725 corresponding to the benefit on r-HuEPO purchase cost, €3,500 corresponding to the costs avoided by reducing the number of injections performed by office-based nurses, and €224 due to the reduction of total time spent by nurses in the centres. CONCLUSIONS: The short-term acceptance of self-injection with Reco-Pen® in a program proposing the assistance of dedicated nurses is high and associated with an overall economic benefit.

THE ECONOMICS OF PHOSPHATE BINDERS IN RENAL DIALYSIS: A TWO-STAGE STRATEGY FOR MANAGING HYPERPHOSPHATEMIA

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OBJECTIVES: Because the outcomes and cost of caring for patients with ESRD are of major concern, we analyzed claims data of patients receiving exclusively either Calcium Acetate (CA) or Sevelamer HCl (SHCl). METHODS: From the California Medicaid (Medi-Cal) program we compared 1401 ESRD patients who were prescribed CA and 192 who were prescribed SHCl during a 2-year period. RESULTS: For this population, the median daily dose and cost were 4447 mg ($0.55) for CA and 4030 mg for SHCl ($2.88), a significant difference by multivariate regression analysis that controlled for patient demographics, co-morbidities, hospital admissions, and time on binder. Not unexpectedly, comorbid conditions such as COPD, diabetes, heart disease, and hypertension were significantly associated with costs and number of hospital admissions. However, in patients who had been prescribed binder for at least 12 months, there was no statistically significant association between choice of binder, cardiovascular and other co-morbidities, downstream medical resource utilization or costs. Moreover, there was no difference between the binders with regard to time to first hospitalization as well as the number of hospital admissions. For a hypothetical cohort of 1000 ESRD patients treated over a 2-year period, the use of CA as a first-line agent, switching to SHCl only patients who become hypercalcemic, would save almost $1.4 million with no change in patient morbidity. Savings would be substantially greater if the same approach is followed for the entire US dialysis population. CONCLUSION: The choice of phosphate binder does not have a significant impact on the medical costs (except cost of phosphate binder), or number of hospitalizations, or time to hospitalization during follow-up for patients with ESRD. However, implementing a 2-stage strategy for phosphate binders has the potential to significantly reduce the cost of managing hyperphosphataemia in ESRD patients without having any detrimental effects on this population.

COMPARING SENSITIVITY TO CHANGE BETWEEN I-QOL AND SF-36 IN A POPULATION WITH URINARY INCONTINENCE

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OBJECTIVE: To report comparisons of the sensitivity to change between a condition-specific quality-of-life measure (I-QOL, specific to urinary incontinence) and a generic health status measure (SF-36). METHODS: Incontinent female patients completed the I-QOL and the SF-36 measures at screening, pre-treatment, and four subsequent follow-up visits during participation in a multicenter, double-blind, placebo-controlled randomized trial to assess the efficacy of duloxetine in the treatment of incontinent female patients with stress and mixed incontinence. Sensitivity analyses were conducted using baseline and week 6 data (or last observation carried forward if participant was an early dropout). Only responders to stress pad test (25% decrease), incontinent episodes (25% decrease) and perceived global improvement (a little better) were evaluated. I-QOL scores and SF-36 scores are both transformed onto a 0 – 100-point scale. RESULTS: For individuals having a decrease in pad weight of at least 25%, change scores of the SF-36 ranged from 0 (General Health) to 4 points (Bodily Pain, Physical Functioning, Role Emotional, and
Role Physical) compared to a 9-point increase in I-QOL total score. Those with a 25% decrease in incontinent episodes had improvements ranging from 0 (General Health) to 5 points (Physical Functioning) compared to a 10-point improvement in the I-QOL score. Those that self-reported “a little” improvement in their urinary condition had improvements of 6 points on the I-QOL and +1 to 2 in 7 of the 8 subscales of the SF-36. CONCLUSION: In a clinical trial, condition-specific measures can provide greater sensitivity and offer a clearer interpretation.

PRK13
DEVELOPMENT OF A QUESTIONNAIRE TO ASSESS QUALITY OF CARE IN DUTCH DIALYSIS CENTERS
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OBJECTIVES: Dialysis patients have a chronic renal insufficiency. For these patients process characteristics of their treatment are important. Therefore this study aimed at the development and testing of a questionnaire to assess the quality of care in Dutch dialysis centers from the patients perspective: the Quality of Care in Dialysis centers (QCD) questionnaire. METHODS: In a literature study possible sets of dimensions were identified. Four focus group sessions were organized, with 27 patients in total. The results from the focus groups were transformed into a 68-item test version of the QCD. This version was discussed with four nephrologists and seven patients. A ‘visual analogue scale’ (VAS) was added to determine overall satisfaction. The final test version was sent to 300 patients in a postal setting. Factor analysis was applied and item reductions were conducted. RESULTS: Statistical analyses was based on 140 out of the 162 returned questionnaires. The results from the factor analysis confirmed the use of the set of dimensions with the dimensions: doctors, nurses, other staff members, and facilities. The test version of the QCD instrument, was found to be both construct valid and content valid. The instrument is reliable, with Cronbach’s alpha of $\alpha = 0.91$, $\alpha = 0.86$, $\alpha = 0.85$ and $\alpha = 0.83$ for four factors. After item reduction 36 items and the VAS remained. Each dimension consists of 8 specific items and one item about the overall satisfaction with that dimension. The 36-item QCD is also content valid, construct valid and reliable ($\alpha = 0.83$ and $\alpha = 0.84$ for two factors). CONCLUSIONS: The QCD can be used in Dutch dialysis centers. Further research will be conducted to establish preference weights per dimension on the basis of the VAS scores. These preference weights can be applied in benchmark procedures to assess the quality of care in a dialysis center.

PRK14
PERCEIVED RISK, VALUE AND QUALITY OF LIFE FOR PATIENTS WITH OVERACTIVE BLADDER: DEVELOPMENT OF A PERCEIVED VALUE SCALE
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OBJECTIVES: Prevalence rates of 16% have been reported for overactive bladder (OAB). Despite the high prevalence of overactive bladder (OAB), it is both an under-diagnosed and underreported condition; less than one half of community-dwelling persons with urinary incontinence consult physicians about the problem. Once symptoms develop many individuals explore treatment options through a variety of channels depending on symptom severity, perceived risk and the perceived value gained from taking appropriate action. The purpose of this study was to develop a self-administered questionnaire to measure perceived value for patients presenting with symptoms of OAB. Psychometric evaluation of this questionnaire for scale development included item development, item reduction and item analysis to assess reliability and validity. METHODS: A questionnaire consisting of 18 items was used for the study. Prior to inclusion items were evaluated for both content and face validity to ensure that they adequately represented the value domain. The sample consisted of 50 patients from a large clinic having symptoms of OAB. To be included, participants were either male or female and were not taking medications to treat their symptoms. Females had to be pre-menopausal with no controls implemented for hormone replacement therapy. Data were obtained via telephone using trained interviewers. RESULTS: The Kaiser-Meyer-Olkin (KMO) Measure of Sampling Adequacy for the final principal components analysis was 0.774. The Bartlett Test of Sphericity was significant (0.0001), indicating the appropriate use of exploratory factor analysis. Item reduction was accomplished by examining item to total correlations and factor loadings. Oblique rotation was used to obtain a final factor solution consisting of four items, which explained 60% of the variance. Cronbach’s alpha was 0.78 for the value scale. CONCLUSIONS: A scale to assess perceived value was developed that after undergoing psychometric evaluation satisfied the criteria for scale reliability and validity.

PRK15
DISEASE-SPECIFIC PATIENT-REPORTED OUTCOME MEASURES IN URINARY INCONTINENCE
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Urinary incontinence (UI) is a multi-faceted disease that may significantly impact patients’ daily lives and health-related quality of life (HRQoL). Most recently, a number of measures applying various approaches have been