expected, TX is the most convenient treatment, as regards cost-effectiveness estimates. PD is also preferred to HD. National Health System authorities should, therefore, favor PD over HD. If that is the case, a Budget Impact Analysis would help to assess to which extent such approach would be worthy.

PUK8

FESOTERODINE IS COST-EFFECTIVE FOR THE TREATMENT OF OVERACTIVE BLADDER: RESULTS OF AN ECONOMIC MODEL

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OBJECTIVES: Health economic analyses are used routinely to evaluate a number of types of health care interventions and are required for all new pharmaceuticals by many national and regional health authorities. These analyses assess the implications of projected outcomes and costs of a new drug treatment and are often used as a tool to guide decisions about pharmaceutical development and consumption. As an illustrative example, an overview of the components and construction of an economic model is presented here using the costs and outcomes associated with fesoterodine (FESO), a new antimuscarinic that has been shown to be safe, tolerable, and effective for the management of overactive bladder (OAB) in adults. **METHODS:** Economic evaluations comparatively assess the costs in terms of resources consumed and consequences of drug (eg, FESO therapy). The type of analysis illustrated is a cost utility analysis (CUA), which focuses particular attention on the costs and incremental health improvement attributable to fesoterodine. The costs of treatment are measured in monetary units and include medical costs purchased by the health care system, including physician visits, diagnostic and laboratory tests, hospitalizations, and so forth. Other costs consist of the patient's out-of-pocket expenses for goods and services outside of the medical sector, such as incontinence pads. Unpurchased resources consumed by patients with OAB include lost productivity while at work or lost time from work owing to the condition. Health improvement due to FESO is measured by quality-adjusted life years (QALYs, pronounced "qualies"). The QALY is a measure of health outcome, which assigns to each period of time a weight, ranging from zero (death) to one (perfect health) corresponding to the quality of life during that period. The need for incorporating QALYs, rather than life years or expectancy, is due to the observation that many medical interventions, such as those for OAB, are not associated with premature death but with changes in morbidity and quality of life. Finally, the central outcome in a CUA is the cost utility ratio, the difference in the costs of the 2 alternatives divided by the difference in QALYs. This ratio is essentially the cost of an additional QALY when using 1 intervention compared with an alternative. **RESULTS:** A CUA was created examining the costs and benefits of FESO demonstrated in a 12-week, randomized, double-blind, placebo- and active-controlled clinical trial. Comparators were FESO 4 mg/d, FESO 8 mg/d, extended-release tolterodine 4 mg/d (TOL), and solifenacin (SOL). SOL was not included in the clinical trial, therefore efficacy data were obtained from the published literature. Medical costs of OAB (antimuscarinic drugs, physician visits, laboratory tests, and OAB-related comorbidities), patient out-of-pocket costs (incontinence pads), and productivity costs (lost productivity at work and lost time from work) were all considered. Health-related quality of life data were collected during the trial via the King's Health Questionnaire (KHQ). Using a published algorithm, responses to the KHQ were transformed into QALYs. The time frame of the analysis was extended from the 12-week trial period to 52 weeks, and the total expected costs and the expected QALYs for each intervention were used in 2-way comparisons. The QALYs gained were 0.0111, 0.0115, 0.0124, and 0.0143 for TOL, SOL, FESO 4 mg, and FESO 8 mg, respectively. The overall costs were £1294, £1344, £1362, and £1424 for FESO 8 mg, SOL, FESO 4 mg, and TOL, respectively. **CONCLUSIONS:** Economic analyses are used by decision makers in conjunction with clinical and other information to decide which drug therapy provides the best economic value. The results of our economic analysis suggest that FESO may result in fewer overall costs and greater QALYs gained than treatment with TOL or SOL for the management of patients with OAB and incontinence.

PUK9

COST OF OVERACTIVE BLADDER IN THE UNITED STATES

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OBJECTIVES: Existing projections of the cost of overactive bladder (OAB) in the United States (US) are incomplete and outdated. We sought to determine the cost of OAB in the US from a societal perspective, incorporating direct medical, direct non-medical, and indirect costs. **METHODS:** We developed a prevalence-based model with data on age- and sex-specific OAB prevalence, health care utilization, other components of care, and productivity. Using data from the five most recent years of medical literature, practice guidelines, Medicare and managed care fee schedules, and expert panel input, we calculated the annual per capita and total US costs. Direct costs were calculated as the product of the age/sex-specific probability that a care component is used, the age/sex-specific number of units used, and its unit price. Indirect costs (lost productivity) were calculated based on the human capital model and governmental census data. We applied current age/sex-specific prevalence rates, treatment patterns, and costs to US census population projections to project costs of OAB in 2015 and 2020. **RESULTS:** Mean total annual per capita cost in 2007 was $1991, comprised of $1500 (direct medical), $66 (direct non-medical), and $426 (indirect). Given that about 34 million people in the US have OAB, the total national cost is $68.2 billion (B) ($51.4B direct medical, $2.3B direct non-medical, and $14.6B indirect). Mean total annual per capita costs in 2015 and 2020 would be $2010 and $2036 respectively. Given projections of ~39 million and 42 million people with OAB in 2015 and 2020, total national costs would be $78.8B and $85.4B, respectively. **CONCLUSIONS:** These data suggest that the economic burden of OAB is about five-fold higher than older, non-comprehensive estimates. Inasmuch as 75% of this cost is for direct medical care, it is important that opportunities be explored to improve the value of available therapies.

PUK10

ECONOMIC IMPACT OF A LOW-PROTEIN DIET AIMING TO DELAY THE HAEMODIALYSIS TREATMENT IN PATIENTS WITH CHRONIC-RENAL-FAILURE

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OBJECTIVES: Chronic kidney disease is a progressive condition that results in significant morbidity and mortality. Dietary

protein restriction slows the progression of kidney disease delaying the dialysis treatment. The cost of treatment of end-stage renal disease is high and increases with age. Therefore, delaying the start of renal replacement therapy with hemodialysis and improving the patient's quality of life are two primary goals justifying the use of protein-restricted diets. The aim of the study was to evaluate the economic impact of a low-protein diet (0.6 gr proteins/kg, body weight/day) with the intent of delay the haemodialysis treatment in patients with advanced chronic-renal-failure. **METHODS:** The study was a naturalistic, longitudinal retrospective Cost of Treatment study. Patients were enrolled during the 2005 and followed up until 2007 or the beginning of haemodialysis treatment. Direct health care resources attributable to disease management (drugs, ambulatory care, day case treatments, hospitalizations, specialist visits, diagnostics and laboratory exams) were quantified using National Health Service (NHS) tariffs expressed in Euro 2008. NHS perspective was adopted. Health-related quality of life information were also collected using SF-36 questionnaire at the enrolment and at the end of the observation period. **RESULTS:** We enrolled 30 patients (males 60%, mean age of 56.5 ± 13.9 y.o.) from the Nephrology Department of the University "Federico II" of Naples, with a mean follow-up of 12.7 ± 7.5 months. The average monthly cost of care was €1075.6 ± 925.2 per patient, mainly because of hospitalization which represented the 45.0% of the expenses. SF-36 results showed a quality of life stable during the observation period and quite similar to the general population. **CONCLUSIONS:** This is the first study evaluating the economic impact of law-protein diet in patients with CRF in Italy. The protein-restricted diets helps to delay initiation of hemodialysis sessions, which substantially increase treatment costs and negatively impacts quality of life.

PUK11

A COST-UTILITY ANALYSIS OF SOLIFENACIN 5 MG AND SOLIFENACIN 10 MG VERSUS TOLTERODINE ER 4 MG IN THE PHARMACOLOGICAL TREATMENT OF PATIENTS WITH OVERACTIVE BLADDER (OAB)

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OBJECTIVES: The aim of this study was to assess the cost-effectiveness of solifenacin (5 mg/10 mg) relative to tolterodine ER 4 mg in the treatment of patients with overactive bladder (OAB), from the perspective of the UK (NHS) health care system. **METHODS:** This was a cost-utility analysis based on a one-year decision-tree model. A systematic review and meta-analysis of efficacy data was performed to obtain estimates for clinical effectiveness. The benefits of treatment were measured according to resolution of OAB symptoms and subsequent improvement in health-related quality of life (HRQoL). Treatment success was defined separately for urgency, frequency and incontinence. Definitions of treatment success were no urge episodes, eight or fewer micturitions and no incontinence episodes per 24 hours respectively. Incremental cost-effectiveness ratios (ICERs) were estimated separately for each symptom. HRQoL values were taken from published sources. Treatment persistence data and data for the proportion of solifenacin patients receiving the higher dose, 10-mg formulation were obtained from the DIN-LINK database. The analysis was undertaken from the perspective of the UK NHS and included costs directly associated with the treatment of OAB, i.e. cost of antimuscarinics, GP consultations and consultations in an outpatient clinic; cost data was taken from NHS published sources (at 2007/2008 prices). Resource utilisation was based on expert opinion. **RESULTS:** ICERs fell below £15,000/QALY in all analyses: £6,406/QALY, £9,065/QALY and £14,374/QALY for urgency, frequency and incontinence outcomes, respectively. ICERs remained below the threshold of £30,000/QALY throughout univariate sensitivity analyses. **CONCLUSIONS:** Treatment with solifenacin 5 mg/10 mg is likely to be a cost-effective treatment strategy relative to tolterodine ER 4 mg in the UK healthc are setting.

PUK12

A COST-UTILITY ANALYSIS OF SOLIFENACIN 5 MG AND 10 MG VERSUS FESOTERODINE 4 MG AND 8 MG IN THE PHARMACOLOGICAL TREATMENT OF PATIENTS WITH OVERACTIVE BLADDER (OAB) IN THE UK NHS

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OBJECTIVES: The aim of this study was to assess the cost-effectiveness of solifenacin (5 mg/10 mg) relative to fesoterodine (4 mg/8 mg) for OAB, from the perspective of the UK (NHS) health care system. **METHODS:** A cost-utility analysis was undertaken using a one-year decision-tree model. Estimates for clinical effectiveness were obtained from a systematic review and meta-analysis. Treatment success was defined separately for urgency, frequency and incontinence. Definitions of treatment success were no urgency episodes, eight or fewer micturitions and no incontinence episodes per 24 hours. Incremental cost-effectiveness ratios (ICERs) were estimated separately for each symptom. Treatment persistence rates for solifenacin and the percentage of patients requiring the higher-dose formulation of solifenacin were taken from the DIN-LINK database. In the absence of these data for fesoterodine, in the base case analysis treatment persistence and the percentage of patients requiring the higher dose formulation of fesoterodine were assumed to be equal to that for solifenacin. Utility values for the calculation of Quality Adjusted Life Years (QALYs) were taken from published sources. The analysis included costs directly associated with OAB treatment, i.e. antimuscarinic therapy, GP consultations and outpatient contacts; cost data were taken from NHS published sources (2007/2008 prices). Resource utilisation was based on expert opinion. **RESULTS:** In the base-case analysis, solifenacin resulted in a cost-effective treatment strategy compared with fesoterodine for urgency and frequency outcomes being both more effective and less costly. Fesoterodine was more effective but more expensive than solifenacin for incontinence, with an ICER of £84,686/QALY. **CONCLUSIONS:** This analysis suggests that fesoterodine does not provide a cost-effective treatment option relative to solifenacin at a cost-effectiveness threshold of £30,000/QALY for the resolution of urgency, frequency and incontinence in patients treated for OAB.

PUK13

EXPANDED CRITERIA DONORS IN RENAL TRANSPLANTATION: RESULTS OF ECONOMIC EVALUATION

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OBJECTIVES: At present, expanded criteria donors suppose up to 40–50% of the renal transplant. The aim was to evaluate cost-utility difference between standard criteria donors (SCD) versus expanded criteria donors (ECD) at the first year of kidney transplant. **METHODS:** Patients were collected in the waiting-list for renal transplant in our region from January 1, 2003 to December 31, 2005. Clinical and demographic variables, transplant costs and EQ-5D tariff, as a generic perceived state of