PSSII

PAYER NEEDS IN EMERGING MARKETS: HOW SHOULD THESE NEEDS BE INCLUDED IN DERMATOLOGY DRUG DEVELOPMENT PLANS?
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OBJECTIVES: Health technology assessment (HTA) is a rapidly growing field, and countries in the Asia-Pacific and Latin America regions are in the process of developing economic assessment guidelines for pharmaceutical products. The objective of this evaluation was to determine how emerging market payer needs should be included in drug development plans.

METHODS: Payer needs were evaluated for Brazil, China, India, Japan, and South Korea. Dermatology was chosen as the exam model area, as the need for evidence is large and important markets for dermatology. Based on the results, a process map was developed outlining the steps and timeline for including country-specific needs in drug development plans. Additionally, key survey questions were developed for country-specific input.

RESULTS: Brazil has a formal HTA body, CONITEC (Comissao Nacional de Incorporacao de Tecnologias), which makes appraisal decisions based on cost-effectiveness and budget impact analysis. Similarly, South Korea has a formal process for assessing cost-effectiveness or cost minimization analysis. India is primarily a self-pay market for dermatology but has proposed pharmacoeconomic guidelines (ISPOR 2013) for formal assessments. In China, health economic (HE) data are required in negotiations for high-price products at the provincial or city level but not at the central level. Japan has no formal HE data requirements. Topics for key country survey questions included disease prevalence, economic burden, treatment guidelines, drug listing procedures, HTA decisions for current therapy, and key comparators.

CONCLUSIONS: Timely inclusion of payer needs in the drug development process is critical for market access with emerging markets.

URINARY/KIDNEY DISORDERS – Clinical Outcomes Studies

PUK1

TREATMENT PATTERNS OF URINARY INCONTINENCE IN THE PRESENCE OF COMORBIDITIES
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OBJECTIVES: Urinary incontinence (UI) is an undertreated condition. We examined the likelihood of receiving UI treatment in subjects having UI alone and UI along with different comorbidities. METHODS: This was a retrospective cross-sectional study of a 10% random sample of IMS LifeLink data from 2001-2011. Subjects were aged > 18 years and continuously enrolled 6 months pre and post their first index UI claims. The databases searched for scholarly articles were PubMed and Medline. Only research studies written in English which met the inclusion criteria were considered. A random effects model was used to test the hypothesis of equality in mean treatment outcomes. RESULTS: A total of 21 studies with a combined sample size of 17,099 patients were used in the review. Patients who received FD did not have a better HRQoL compared to patients receiving HD. However, the HRQoL of Tx patients was significantly better than that of HD patients in the improvement of incontinence. The overall mean differences were 0.11, 95% CI (0.09, 0.55) and 0.29, 95% CI (0.09, 0.50) respectively, and were statistically significant. CONCLUSIONS: The findings support the assertion that Tx patients experience significantly improved quality of life compared to HD patients but only in the physical and psychological domains. Findings on the effectiveness of FD compared to HD as a treatment modality were inconclusive.

PUK2

META-ANALYSIS OF IL-2 RECEPTOR ANTAGONIST (IL-2 Ra) AS INDUCTION THERAPY IN PEDIATRIC RENAL TRANSPLANTATION
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OBJECTIVES: Therapy with interleukin-2 receptor antagonists (IL-2Ra) has resulted in significantly decreasing numbers of acute rejection episodes in adult renal transplant recipients. Acute rejection remains a major threat for graft failure resulting in increased immunosuppression and attendant comorbidities. There are limited data available regarding use of IL-2Ra in pediatric kidney recipients. This study aims to systematically identify and summarize the effects of using IL-2Ra for induction therapy in pediatric renal transplantation.

METHODS: Databases, reference lists, and abstracts of conference proceedings were searched extensively to identify relevant RCTs from January 1991-August 2012 in all languages using following terms “kidney transplantation” “renal transplantation”, “IL-2Ra”. Twenty-eight trials were identified of which eight (N=893) satisfied inclusion criteria; including patients less than 19 years old; with comparison of IL-2Ra to placebo or as an addition to standard therapy or as an alternative to standard therapy. Key clinical events included were graft survival and acute rejection. Heterogeneity was assessed using I² statistic. With P<0.05, fixed effects model was used. RESULTS: Seven studies were included in the analysis (n=462). The mean 1-year survival was 93.4% (range 85.8%-97.8%) with IL and did not receive treatment. The odds of receiving treatment was only influenced by those with multiple sclerosis, Parkinson’s diseases or stroke subjects with those with (OR = 1.64, p<0.001).

CONCLUSIONS: Current guidelines recommend treatment for UI in the presence of multiple sclerosis, Parkinson’s diseases or stroke and our data suggest that treatment resembles guideline recommendations.

PUK3

SCHEMIA TIME ON RENAL ALLOGRAFT SURVIVAL: EFFICACY OF MACHINE PERFUSION
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OBJECTIVES: To evaluate the efficacy and safety of machine perfusion for human kidneys obtained from living or cadaveric donors for transplantation. METHODS: We searched for systematic reviews (SR) of clinical trials that compared machine perfusion and static cold storage for renal graft preservation in the Cochrane Library, Centre for Reviews and Dissemination, Medline (via Pubmed) and LILACS databases. We included RCTs suited for Health Technology Assessment (HTA) in economic analyses. The quality of the evidence and strength of recommendation were evaluated according to the GRADE system. RESULTS: We included eight studies: five SR and three HTA. The SR did not show statistically significant differences in graft survival, form a reduction in health related quality of life and that certain bladder management options are cost-effective.