

**DO HIGH-INCOME GROUPS IN PAKISTAN UNDERSTAND THE CONCEPT OF GENERIC MEDICINES?**

PIH53

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**OBJECTIVES:** High income groups in Pakistan resort to private health care settings for consultations and treatment modalities but only 5% of them have Social Health insurance coverage. As 77% of medicine expenditures are out-of-pocket payments in Pakistan, it is imperative to assess the understanding, perception, and attitude of this privileged group towards cost-effective alternatives. **METHODS:** In order to have an in depth evaluation of the issue qualitative methodology was adopted. a combination of purposive and snowball sampling was used to conduct face-to-face semi-structured interviews, which were then audio-taped, and transcribed verbatim. As sample size in qualitative research revolves around the attainment of point of saturation, no new themes emerged after the interview of 8 respondents. **RESULTS:** Thematic content analysis identified four major themes; appropriate knowledge of generic medicines, negative perception towards generic medicines, negative attitude towards generic medicines, and future recommendations which should be directed towards the maintenance of quality and efficacy of generic alternatives. Interestingly, all the respondents managed to explain generic medicines with reference to patent expiry. Regarding perception all of them expressed negative views and considered quality and safety as questionable domains in generic medicines. All the respondents cited negative concerns towards generic medicine utilization and harbored the notion that "low cost relates compromised quality." Majority of the respondents expressed that future strategies should be directed towards educated high income group to build confidence for generics and this should be possible until and unless the local manufacturers in Pakistan make themselves compliant with WHO Good Manufacturing Practices (GMP). **CONCLUSIONS:** The respondents showed excellent understanding towards generic medicines. They exhibited negative concerns and attitudes towards generic medicine utilization. Still there is room for improvement, provided the confidence is built in consumers regarding generic medicines quality and efficacy, which in turn will pave the way for their quality utilization.

**METFORMIN FOR THE TREATMENT OF CHILDHOOD OBESITY: A SYSTEMATIC REVIEW AND META-ANALYSIS**

PIH54

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**OBJECTIVES:** Childhood obesity associates with significant morbidity and premature death; its prevalence has increased greatly during the past three decades; and it is recognized as a worldwide public health problem. However, the efficacy of treatments for childhood obesity remains unclear. In recent years the use of metformin, an insulin sensitizer, has aroused a great interest for the treatment of obesity in adults. Our aim was to assess the efficacy and safety of metformin for childhood obesity. **METHODS:** Systematic review of literature and meta-analysis of randomized controlled trials in obese subjects age  $\leq 19$  years without diabetes or other morbidities. Structured electronic searches of published studies until March 2010 were performed. Changes in the Body Mass Index (BMI) were considered our main outcome measure of efficacy whereas metabolic parameters such as insulin levels, glucose, HOMA, lipid profile and leptin levels were considered as secondary outcomes. Safety parameters included adverse events and losses from adverse effects. Individual studies were graded using published methodologies. Pooled estimates of effect and confidence intervals were derived using a fixed effects model and tested for heterogeneity. Consistency across studies was evaluated by means of the I-square statistic. **RESULTS:** Seven trials met the inclusion criteria. All trials compared metformin with placebo and used behavioural co-interventions. Average follow-up was six months. Though with small sample sizes, methodological quality of trials was adequate. Meta-analysis showed that compared to placebo, metformin provided a significant decrease in BMI ( $-1.90$  ( $-3, -.8$ ). No statistical significant differences were found in secondary outcomes. Main adverse effects were digestive, no serious adverse events were reported. **CONCLUSIONS:** Available evidence suggests that, added to behavioural interventions, metformin is a relatively safe and effective treatment for childhood obesity in the short term. Further research with longer follow-up periods is needed to solve this important health issue. Partially supported by Spanish National I+D Program.

**BPH PATIENTS TREATED WITH PHYTOTHERAPY: RESULTS AT 6 MONTHS**

PIH55

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**OBJECTIVES:** Assess the impact of the treatment of urinary disorders of the lower urinary tract related to benign prostatic hypertrophy (BPH) using medical treatment under actual conditions of use. **METHODS:** A pragmatic cohort of 420 patients treated medically, was followed up for 6 months, using several validated questionnaires: IPSS, MSF4, and SF12. **RESULTS:** 267 patients treated with Serenoa Repens were evaluated, the mean age was  $64.3 \pm 8.6$  years, and on average the diagnosis had been made 18 months previously. At 6 weeks, the IPSS was significantly improved in this group ( $P < 0.0001$ ). This improvement in the IPSS score between 6 weeks ( $11.98 \pm 5.11$ ) and inclusion ( $14.58 \pm 5.65$ ) was 2.6 points. An improvement was also observed at 3 months. At 6 months, the p-value was also significant ( $P < 0.0001$ ). The improvement in the IPSS score between 6 months ( $8.20 \pm 4.12$ ) and inclusion ( $14.65$

$\pm 7.01$ ) was 6.6 points. The physical dimension ( $50.97 \pm 6.45$  at inclusion) of the SF12 improved significantly ( $P < 0.001$ ) from the 6<sup>th</sup> week ( $52.63 \pm 5.20$ ), an improvement that was confirmed at 6 months ( $53.21 \pm 5.16$ ) ( $P < 0.001$ ) in comparison with inclusion ( $49.09 \pm 6.58$ ). The mental dimension ( $50.9 \pm 7.04$  at inclusion) of the SF12 improved significantly ( $P < 0.001$ ) from the 6<sup>th</sup> week ( $52.16 \pm 7.31$ ), an improvement that was confirmed between 5.45 and 6 months ( $52.50 \pm 6.69$ ) ( $P < 0.001$ ) in comparison with inclusion ( $47.09 \pm 10.82$ ). The MSF4 was unchanged. **CONCLUSIONS:** We observed an improvement in the IPSS score from the 6<sup>th</sup> week; this statistical improvement was confirmed by a significant clinical improvement in the 6<sup>th</sup> month. This favourable progression is consistent with the improvement observed for both dimensions of the SF12.

**COMPARATIVE PRICING AND REIMBURSEMENT ANALYSIS BETWEEN BULGARIA AND THE CZECH REPUBLIC**

PIH56

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**OBJECTIVES:** Comparison of regulatory rules and procedures for pricing and reimbursement of pharmaceuticals between Bulgaria and the Czech Republic (CR). **METHODS:** Medicine laws, health insurance laws, corresponding regulations stating the pricing and reimbursement procedures were reviewed. Special emphasis was devoted to the requirements for pharmacoeconomic evidences in the procedures. **RESULTS:** Both countries apply the reference pricing system for prescription medicines and the CR is among the 8 reference countries for Bulgaria, while the opposite is not the case. In Bulgaria the lowest reference price for ex-factory price setting is used, while the CR employs the average among the three lowest prices. There is also a regressive margin scale in both countries applied. In Bulgaria margins are stated for wholesalers and retailers separately, while in the CR they are negotiated between wholesalers and retailers. In both countries health insurance is obligatory. In the CR there are 11 insurance companies and in Bulgaria—only one fund. In Bulgaria reimbursement is in the form of positive drugs lists. For reimbursement of pharmaceuticals in the CR a complex external and internal referencing is employed and evaluation of innovativeness is necessary. There are 111 internal therapeutic groups defined at the 4<sup>th</sup> ATC level (e.g. statins). The reimbursement base is set as the cheapest price of medicine in the group in all 27 EU countries. There is a bonus of maximum 30% if a medicine shows superiority. In Bulgaria the reimbursement level is defined as the cheapest price per DDD for every INN. Both countries require pharmacoeconomic evidences, but there are guidelines in the CR, while Bulgaria applies only criteria for evaluation. **CONCLUSIONS:** We consider the Czech system more flexible and providing freedom for the manufacturers and distributors due to its negotiating practice and therapeutic level of reimbursement, but the process is more prolonged.

**CHALLENGES IN THE ADHERENCE AND ADOPTION OF INTERNATIONAL GUIDELINES: A SYSTEMATIC REVIEW OF THE ADHERENCE TO THE HEALTH CARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE (HICPAC) GUIDELINES FOR THE APPROPRIATE USE OF VANCOMYCIN IN CHILDREN**

PIH57

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**OBJECTIVES:** One of the most pressing problems faced by health care services is the increasing prevalence of antimicrobial resistance to vancomycin, an important antimicrobial for the treatment of infections caused by gram-positive pathogens in the severely ill patient. Inappropriate use of vancomycin encompasses serious public health consequences linked to the development of resistant species. In 1995, the HICPAC developed guidelines that delineated specific criteria for appropriate vancomycin use to reduce the improper use of antimicrobials and improve patient safety. Our aim was to evaluate and summarize the level of compliance of clinical practices with the HICPAC guidelines by assessing the appropriateness of vancomycin therapy for hospitalized critically ill children. **METHODS:** Systematic review of literature (Jan 1996-Feb 2010) and meta-analysis of studies performed in subjects aged 0–18 years. Structured electronic and manual searches were performed. The main outcome measure was the proportion of vancomycin prescribed appropriately according to the HICPAC guidelines. Appropriate/inappropriate uses were subdivided into several categories. Summary rate ratios and confidence intervals were estimated using a fixed effects model and tested for heterogeneity. Furthermore, we explored the potential reasons for non-adherence to guidelines. **RESULTS:** From 24 candidate studies, 13 publications met the inclusion criteria. Meta-analysis showed that in only 21% of patients (95% CI: 18%–23%), vancomycin prescribing and dispensing practices were consistent with the recommendations. Non-adherence to HICPAC guidelines included surgical prophylaxis, empirical use and length of therapy. Lack of awareness, lack of agreement, lack of outcome expectancy and inertia of previous practice, emerge as specific reasons for non-adherence. **CONCLUSIONS:** This study reveals that adherence to international guidelines is far from optimal with a variety of potential barriers that undermine the process. Because physician adherence is critical in translating recommendations into improved outcomes, there is an urgent need for strategies aimed at improving physician compliance with guidelines to optimize antibiotics utilization. Supported by the Spanish National I+D Program (STPY 1346/09).