patterns, and rates of comorbid conditions that exist in patients treated on each regimen. These estimates can be used to calculate and project cost of therapy for patients suffering from HIV/AIDS.

**BURDEN OF BRONCHIAL ASTHMA: FAMILY EXPENSES FOR CHILD’S DISEASE**

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**OBJECTIVES:** The object of the present assay was to analyze the type and amount of expenses for the family with a child suffering from bronchial asthma living in Vladivostok between 1996–1998.

**METHODS:** 500 families with asthmatic children were surveyed retrospectively and anonymously.

**RESULTS:** Direct expenditures for the child’s disease were 10,98 ± 0.94% of annual income. Pharmacotherapy was the main expense item (75,96 ± 1.2%). Drug expenses for one child were US$302, 86 ± 10, 4 in 1996, US$356, 72 ± 19, 8 in 1997. In 1998 the dollar amount of pharmacotherapy didn’t change greatly (US$344, 4 ± 20, 2) but a slump in exchange value of the ruble without an adequate increase of ruble income led to expenses growing as a percentage of family income (22, 1 ± 2, 1%). Self-control means expenditures appeared in 1997 and by the end of 1998 19 ± 2,25% of families had sustained them. Doctor visits and sanatorium and health resort expenses per child were 7–8% of direct expenditures for asthma. Less than 5% of families have the means to buy an air cleaning apparatus and hypoallergic linen. The unit price is US$100–2100 but annual income of a family with an asthmatic child in Vladivostok in 1997 was US$3493 ± 50, 4, in 1998 – US$2996 ± 94, 5. Owing to the child’s disease one of the parents in a third of families either had to be totally unemployed or take low qualified work that aggravated financial loss. Annually 12,2 ± 2,1 disablement days fall on the family because of asthma.

**CONCLUSIONS:** In order to evaluate a family’s real means to follow medical recommendations it’s necessary to take into consideration family expenses for asthma. Economic state aggravation in the country in August 1998 led to abrupt reduction or interruption of basic asthma therapy in 37, 86 ± 4, 36% families for financial reasons, 82, 8 ± 1, 67% of parents find the disease to be a considerable financial burden for the family.

**RANDOMIZED CLINICAL STUDY METHODOLOGY ISSUES**

**CROMOGLYCATE THERAPY IN CHILDREN WITH MODERATE BRONCHIAL ASTHMA**

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**OBJECTIVES:** To investigate the cost-effectiveness of using an increased dose of disodium cromoglycate versus switching to budesonide treatment in those children with moderate asthma whose symptoms cannot be controlled with the recommended dose of cromoglycate.

**METHODS:** An open, randomized, parallel group design clinical trial was conducted at 20 study centres. After a 4-week run-in period, 131 children with uncontrolled symptoms were randomized either to the treatment of increased disodium cromoglycate 4 × 40 mg daily or budesonide 2 × 200 µg daily for a 12-week treatment period. An intention-to-treat analysis was performed. Efficacy variables were the morning PEF value and the number of symptom free days. The economic analysis was based on a societal perspective. Protocol driven costs were excluded from the analysis. Direct costs were measured as costs of study medication, rescue medication, non-protocol driven visits, and number of days stayed at hospital. Indirect cost measurement was based on time missing from school. A sensitivity analysis was carried out on resource use data to test final cost-effectiveness.

**RESULTS:** The morning PEF value increased more from baseline in the budesonide group (30.8 vs. 10.6; p = 0.01). The average number of symptom free days was higher in the budesonide group (65.7 vs. 59.5; p = 0.09). The average cost of therapy was lower in the budesonide group (HUF 7844 vs. HUF 16962; p < 0.0001). The cost per symptom free day was HUF 119 in the budesonide group and HUF 285 in the cromoglycate group.

**CONCLUSIONS:** Budesonide treatment was the dominant strategy as it led to both superior clinical outcomes and cost savings.

**COST-MINIMIZATION ANALYSIS OF TWO TRIPLE REGIMENS FOR THE TREATMENT OF HELICOBACTER PYLORI-RELATED PEPTIC ULCER DISEASE**

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**OBJECTIVES:** To investigate the cost-effectiveness of using a triple regimen (ranitidine, cimetidine, and clarithromycin) and non-triple regimen (ranitidine, cimetidine, and tetracycline) in patients with Helicobacter pylori-related peptic ulcer disease.

**METHODS:** A cost-minimizing analysis was carried out on resource use data to test final cost-effectiveness.

**RESULTS:** The average cost per patient was $450 in the triple regimen and $350 in the non-triple regimen. The cost per symptom free day was $200 in the triple regimen and $100 in the non-triple regimen.

**CONCLUSIONS:** The triple regimen is more cost-effective than the non-triple regimen.

**COST-EFFECTIVENESS ANALYSIS OF BUDESONIDE VERSUS DISODIUM**

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**OBJECTIVES:** To investigate the cost-effectiveness of using an increased dose of disodium cromoglycate versus switching to budesonide treatment in those children with moderate asthma whose symptoms cannot be controlled with the recommended dose of cromoglycate.

**METHODS:** An open, randomized, parallel group design clinical trial was conducted at 20 study centres. After a 4-week run-in period, 131 children with uncontrolled symptoms were randomized either to the treatment of increased disodium cromoglycate 4 × 40 mg daily or budesonide 2 × 200 µg daily for a 12-week treatment period. An intention-to-treat analysis was performed. Efficacy variables were the morning PEF value and the number of symptom free days. The economic analysis was based on a societal perspective. Protocol driven costs were excluded from the analysis. Direct costs were measured as costs of study medication, rescue medication, non-protocol driven visits, and number of days stayed at hospital. Indirect cost measurement was based on time missing from school. A sensitivity analysis was carried out on resource use data to test final cost-effectiveness.
OBJECTIVES: To compare the direct medical costs associated with two different regimens for the treatment of Helicobacter pylori-related peptic ulcer disease (PUD) from a hospital perspective. The efficacy of a new regimen, including ranitidine bismuth citrate, amoxycillin and clarithromycin (RAC), was recently compared in a study at a local teaching hospital with that of a regimen consisting of omeprazole, amoxycillin and clarithromycin (OAC). The study results showed no significant difference in the efficacy of the two regimens, but the cost implication of the two regimens was not examined. The drug cost of OAC (HK$364, $US 7.8HK) was 20% more than that of RAC (HK$304) for a 7-day therapy.

METHOD: Data from a controlled, randomized clinical trial conducted in Hong Kong was reanalyzed. The records of 100 patients with Helicobacter pylori-related PUD, who were previously randomized to receive either RAC or OAC, were reviewed. The hospital resources consumed during the period of PUD treatment were retrieved and studied. The total cost associated with each regimen per ulcer-healed patient was calculated and analyzed.

RESULTS: Twelve of the 100 patients were excluded from the analysis because of incomplete documentation or non-compliance with the protocol of the clinical trial. Forty-one inpatients and 47 outpatients were included in the analysis. In the inpatient group, there was no significant difference between the median direct cost associated with OAC and RAC ($13,042 and $11,622, respectively; P = 0.168). In the outpatient group, the median direct cost associated with RAC was significantly lower than that of OAC ($4,096 and $3,839, respectively; P = 0.003).

CONCLUSION: The direct medical costs associated with OAC and RAC were similar for inpatient treatment of Helicobacter pylori-related PUD but RAC was less costly in the outpatient setting.

TPC3

COST OF AML TREATMENT IN BELGIUM: RESULTS OF A RANDOMIZED TRIAL WITH AND WITHOUT FILGRASTIM USE
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INTRODUCTION: A randomised multi-centre phase III trial using Filgrastim (5 μg/kg/day until neutrophil recovery) in induction and consolidation therapy for ‘de novo’ adult acute myeloid leukaemia (AML) patients showed safety and efficacy of the drug with significant reduction in hospital duration and IV anti-infective drug therapy (Heil et al, Blood, 1997, 90, 4710–4718).

OBJECTIVE: Considering the Belgium patients enrolled in the trial to estimate the financial impact of Filgrastim use in the treatment of AML for that country.

METHODS: Retrospective data collection of resource use was obtained from the 36 Belgian patients (20 cases and 16 controls) enrolled through 3 hospitals. The data were retrieved from Case Report Forms and hospital bills. The cost perspective considered is the reimbursement authority of Belgium. A cost-minimisation model is developed including the following resource items: hospital duration, IV anti-infective drug days, lab test days, blood transfusion units, vials of Filgrastim, other drug use excluding chemotherapy, and use of other diagnostic tests (Rx, Scans). Unit costs in 1998 BEF are retrieved from the reimbursement authority (RIZIV/INAMI), the Red Cross Blood Bank, the database of the Belgium Pharmaceutical Association (APB), and a private database on cost of health care in Belgium hospitals (CECODI).

RESULTS: The cost model shows an average cost decrease of 73.31 BEF (5.7%) per patient for induction and consolidation therapy with Filgrastim. Sensitivity analysis on hospital day costs that may widely vary, shows a break-even point reached at a cost per day much lower than the minimum reimbursement cost (break-even point = 952 BEF).

CONCLUSIONS: Filgrastim use in the treatment of AML patients in Belgium is likely to induce cost savings. The cost results are conservative estimates that do not include indirect cost evaluations and quality of life improvement of the patient due to earlier hospital discharge.

TPC4

AN ECONOMIC EVALUATION OF AMLODIPINE FOR THE TREATMENT OF NONISCHEMIC DILATED CARDIOMYOPATHY: THE PROSPECTIVE RANDOMIZED AMLODIPINE SURVIVAL EVALUATION (PRAISE)
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OBJECTIVE: To evaluate the economic implications of amloidipine therapy in patients with advanced left ventricular dysfunction due to nonischemic dilated cardiomyopathy by using data from the Prospective Randomized Amlodipine Survival Evaluation (PRAISE).

METHODS: By using a decision analytic model, costs and effects were estimated for the first 2 years of observation in PRAISE and were projected for 30 years after initiation of therapy (referred to as the lifetime projection).

RESULTS: While statistical tests of the survival curves indicated that amloidipine significantly improved survival ($P < 0.001$), differences in life expectancy (amlodipine, +0.19 years (95% CI, −0.03 to 0.41 years during the first 2 years of the trial; +2.89 years, 95% CI, −0.37 to 6.14 years projected for the patient’s lifetime) were not significant. The ratios of cost per year of life saved were <$8000; those of cost per quality-adjusted year of life saved were <$14,300. The confidence intervals for the cost-effectiveness ratios indicated that for the first 2 years of the trial, amloidipine was unlikely to have ratios

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