COST EFFECTIVENESS OF SWITCHING TO SECOND LINE THERAPY WITH LOPINAVIR/RITONAVIR (LPV/R) IN KENYA Simpson KN¹, <u>Dietz B²</u>, Rahim S³, Rajagopalan R³

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OBJECTIVES: Recent reports from the DART study (Chimbete et al, CROI 2008. poster 642) indicate substantial immunological responses for patients failing a first-line regimen who switch to a protease inhibitor (PI)-based antiretroviral (ARV) regimen with LPV/r. However, the long-term health and economic consequences expected from this switch in ARV are not known. This study will examine the cost effectiveness of using 2nd line therapy in Kenya. METHODS: We used a Markov model to combine population data on CD4+ T-cell response, infectious disease events, death rates, health-related quality of life, cost of care, and drug costs to estimate the cost effectiveness of switching to a LPV/r regimen, as compared to remaining on a first failed NNRTI regimen, or to discontinuing all ARV drugs. These treatment options are compared in the base estimate assuming a cost of \$500/ year for LPV/r, \$200/year for first-line regimen, \$3 per CD4+ T-cell test, concurrent use of cotrimoxazole, 4% annual drop out from therapy, and a 10% annual incidence of malaria in Kenya. RESULTS: The base model estimates an improvement of 19 months in average survival for the LPV/r group at an incremental cost effectiveness ratio (ICER) of \$1483/OALY. The ICER increases to \$1571/OALY if dropout rate is 16%, and to \$1517 if CD4 tests cost \$25, the survival benefit decreases to 13.3 months and the ICER is \$1393/OALY gained when we assume no use of cotrimoxazole. CONCLUSIONS: Under the WHO benchmark for cost effective ICERs based on two times a country's per capita GDP, with Kenya's 2007 GDP of \$1700 (International Monetary Fund) a switch to a LPV/r regimen using very stringent clinical or immunological failure criteria appears to be quite cost effective for a country such as Kenya.

DOES COMBINING ANTIRETROVIRAL AGENTS IN TO A SINGLE DOSAGE FORM (CO-FORMULATIONS) ENHANCE QUALITY OF LIFE OF HIV/AIDS PATIENTS – A COST UTILITY STUDY

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OBJECTIVES: Combining various antiretroviral agents into one single pill has been a strategy to reduce the pill burden thus enhance medication adherence among HIV/ AIDS patients. The study aims to analyze the cost effectiveness and cost utility of the co-formulated fixed dose (FXD) strategy over multiple free dose combination (FRC) of antiretroviral agents from a health care system's perspective. METHODS: The Medical Expenditure Panel Survey (MEPS; 2001-2006) was used to identify HIV/ AIDS patients (ICD-9-CM code 042, 043, V08) on at least one active antiretroviral medication. Patients on FXD were matched in 1:1 ratio with FRC group using propensity score method. All medical costs excluding those paid by patients and families were included. A patient without any ER visit was taken as the effectiveness measure. Utility was measured using SF-6D scores based on the SF-12 questionnaire. RESULTS: Nine FXD formulations were in the market from the period from 2001 to 2006. One hundred and seventy HIV patients were identified as study population of which 53%(n = 92) were on at least one FXD formulation during the study period. Upon matching, 70 patients from FXD had a match from the FRC group. Both groups had no significant differences in terms of socio-demographic characteristics and health status. Fifty three patients (76.09%) in FXD did not have an ER visit versus 46 (65.82%) in the FRC. The mean annual cost for FXD patients was \$15,749.91 and \$11,890.01 for FRC patients. The mean utility for FXD group was 0.6741 and 0.6112 for FRC group. The Incremental cost-utility ratio for the FXD treatment over FRC treatment was \$45,586.13 per QALY. CONCLUSIONS: This study concludes that co-formulating antiretroviral drugs in a combination therapy enhances the quality of life in HIV/ AIDS patients and is cost effective as per the generally accepted threshold of \$50k per OALY.

COST-EFFECTIVENESS OF MARAVIROC FOR HIV IN MEXICO

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OBJECTIVES: Maraviroc (MVC) is the first CCR5 antagonist licensed for antiretroviral therapy of patients with CCR5-tropic HIV-1. The objective of this study was to predict the long-term clinical impact and cost-effectiveness of MVC in treatmentexperienced adults with HIV/AIDS in Mexico. METHODS: The AntiRetroviral Analysis by Monte Carlo Individual Simulation (ARAMIS) model was adapted to the Mexican context to predict clinical and economic outcomes of treating with optimized background therapy (OBT) versus testing for viral tropism status and treating with OBT ± MVC accordingly in treatment-experienced adults in Mexico. Baseline characteristics and efficacy were from the MOTIVATE trials' screening cohort. Costs and population mortality data were specific to Mexico collected from the Social Security Mexican Institute (IMSS). Results were reported from the perspective of health care payers using a 5% rate for discounting. Utility values for the quality adjustment of survival were obtained from published literature. Deterministic sensitivity analyses were conducted by means of repeat microsimulations. RESULTS: Compared to treatment with OBT alone, treatment with OBT \pm MVC contingent on tropism test result increased projected undiscounted life expectancy and discounted qualityadjusted life expectancy from 7.54 to 8.71 years and 4.42 to 4.92 quality-adjusted life years (QALYs), respectively, at an incremental cost of \$21,329 USD. The resultant incremental cost-effectiveness ratio (ICER) was \$42,429 USD per QALY gained. The ICER was considerably lower when MVC was modeled as a protease inhibitor replacement in individuals with HIV susceptible to \leq 2 omponents of OBT (\$29,737 USD); the ICER was higher in individuals susceptible to \geq 3 OBT components (\$67,171 USD). CONCLUSIONS: In treatment-experienced individuals with HIV/AIDS in Mexico, a strategy of OBT \pm MVC contingent on tropism test result may be costeffective compared to OBT alone, particularly in individuals with limited options for active ART.

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THE ECONOMIC IMPACT OF MARAVIROC FOR ANTIRETROVIRAL TREATMENT-EXPERIENCED HIV-INFECTED INDIVIDUALS IN MEXICO Contreras-Hernandez I¹, Rely K², <u>Mould–Quevedo J</u>³, Davila-Loaiza G³

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OBJECTIVES: Over the past 20 years, development of antiretroviral (ARV) therapy for HIV-infection has been dynamic, with continuous development in existing new ARV drug-classes as well as the introduction of new ARV drug-classes with a new mode of action. Maraviroc (MVC) represents the first oral licensed CCR5 co-receptor antagonist. The aim of this study was to estimate the cost-effectiveness of a strategy of testing and treating with optimized-background-therapy (OBT)+MVC according to tropism test results, compared to treating with OBT alone from the Mexican payer's perspective. METHODS: A four-state Markov model was performed to estimate health and economic consequences during a time horizon of five years(6-month cycles). Effectiveness measures were progression-free-months (PFM) and quality adjusted life years (QALYs) gained. Transition probabilities and utilities were obtained from a systematic review employing international published literature(MOTIVATE-1 and -2 trials included). MVC 150 mg/day BID was used and OBT therapy could include up to six different ARV. Resource use and costs were obtained from 637 randomized hospital records from the Social Security Mexican Institute(IMSS) and official institutional databases. Costs include outpatient and inpatient services, drug, tropism test, etc. The model was validated according to international guidelines. Probabilistic sensitivity analyses were performed employing second-order Monte Carlo simulation, Acceptability curves were constructed. RESULTS: MVC+OBT showed the highest number of estimated PFM and QALYs (56.1 and 4.29) vs. OBT alone (34.5 and 2.96) (p < 0.05). Although MVC+OBT showed higher mean expected costs(US\$50,028.5 ± US\$852.8) than OBT alone (US $\$27,846.1 \pm US$ \$700.2) (p < 0.05), the incremental cost-effectiveness ratio(ICER) per QALYs resulted in US\$15,384.6[CI95% US\$9,307.6-US\$23,076.9]. Sensitivity analyses showed that MVC+OBT could be a cost-effective treatment compared with OBT alone with a probability over 80% using accepted thresholds (US\$12,500-US\$37,500). Component analyses and net monetary benefits showed the robustness of these results. CONCLUSIONS: MVC is a cost-effective option improving current ARV efficacy in Mexican individuals with few active treatment options.

INFECTION – Patient-Reported Outcomes Studies

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SELF-REPORTED PILL BURDEN AS A PREDICTOR FOR ADHERENCE IN HIV-INFECTED PATIENTS

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OBJECTIVES: To assess the association between self-reported pill burden and adherence to Antiretroviral (ARV) Therapy in HIV-infected patients. METHODS: Adults reporting HIV infection during the 2005-2007 US National Health and Wellness Surveys on at least one ARV component drug participated in this study. For the multivariate analysis, respondents needed to be on an ARV regimen that contained at least two nucleoside reverse transcriptase inhibitors and at least one protease inhibitor or non-nucleoside reverse transcriptase inhibitor. Respondents were classified as adherent if they either never missed or skipped an antiretroviral dose or did so less than once per week, and complete adherence if they never missed or skipped a dose, otherwise they were considered non-adherent. Resource use was defined by ER visits and hospitalizations. Chi-square tests were used for comparisons of percents and t-tests for comparisons of means. Logistic regression models were run controlling for possible confounders, with complete adherence the dependent variable of interest. RESULTS: A total of 788 patients were included (73.6% male, 26.4% female; average age = 43 years). The mean duration of HIV/AIDS diagnosis was 10.3 years; median number of ARV pills taken daily was 4.0, and median number of non-ARV medications was 2.0. Significantly higher percent hospitalizations (37% vs. 13%; p < 0.001) and ER visits (47% vs. 23%; p < 0.0001) respectively were reported by the non-adherent group. Using a complete adherence model, a higher number of pills decreased the likelihood of complete adherence significantly [OR = 0.945; 95% CI:(0.906, 0.986); p = 0.009]. CONCLUSIONS: Increased pill burden resulted in lower adherence to antiretroviral therapy and may lead to a negative impact on health care resource use.