INFECTION – Clinical Outcomes Studies

COST AND QUALITY OF LIFE ISSUES ASSOCIATED WITH PROTEASE INHIBITOR-BASED COMBINATION THERAPY IN SOUTH AFRICA

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OBJECTIVES: To systematically analyze the literature to assess the economic and health-related quality of life (HRQoL) impact of adverse events (AEs) related to the addition of protease inhibitors (PI) to standard of care (SOC) for the treatment of hepatitis C (HCV). METHODS: A literature search (2000-Present) was conducted to identify and analyze clinical trials for PI triple therapy (PITT = PI + SOC) and SOC (PEGINFoR/RBV for 48 weeks). HRQoL and safety data were synthesized by study design, sample characteristics, and AEs. Economic and resource use data were synthesized in an economic analysis of AEs in PITT vs. SOC. Costs (2009) were derived from published literature. RESULTS: Twenty-three SOC and 7 PITT trials were identified. Statistically significant (p < 0.05) changes from baseline were most often seen in trials of SOC in the following domains: vitality, depression, physical limitations, and fatigue. The following 4 PITT-related AEs could be linked to HRQoL domains: anemia and depression were linked to fatigue and vitality, and headache and rash were linked to physical limitations. In terms of economic impacts, the costs to manage a PITT-related episode of anemia, depression, diarrhea, and rash were $4285, $2387, $566, and $633, respectively. The average AE cost in PITT ranged from $1732 to $3578. Corresponding costs in SOC ranged from $1608 to $2229. The treatment costs of PITT-related AEs were 30% (range 8-40%) higher than the cost of treating SOC-related AEs. CONCLUSIONS: The costs to manage PITT-related AEs appear higher than the costs of SOC-related AEs. Since PITT is associated with higher AE rates, it can also be expected to result in worse HRQoL. Gaps in symptom burden assessment with existing instruments also exist. Future studies should incorporate the economic burden of AEs and the appropriate use of HCV-validated instruments to capture potential HRQoL differences among treatment strategies.

IMPACT OF MMWR MASS VACCINATION WITH OR WITHOUT A CATCH UP PROGRAM ON THE INCIDENCE OF VARICELLA COMPLICATIONS IN FRANCE

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OBJECTIVES: Varicella complications place a burden on health care resources, however, varicella is preventable by mass vaccination with MMVR. The impact on complications of three MMVR programs were explored. METHODS: An age-stratified dynamic model compared natural and breakthrough varicella following mass vaccination, to current cases. Age-specific complication rates (neurologic, cutaneous, pulmonary, other) were applied per case. MMVR replaced 80% of MMR over 1 year (basecase) compared to 100% of MMR with a catch-up in 11-13 year-olds (‘catch up’). In an ‘optimal’ scenario, MMVR coverage increased from 95% to 95% (1st dose) and 60% to 90% (2nd dose), MMVR replaced 100% MMVR within 1 year with a catch-up in 10 year-olds. RESULTS: MMVR decreased varicella incidence; an age shift, however, many post-vaccination cases were breakthrough cases, believed to be milder and require less resource use. Prior to MMVR: highest varicella incidence (per million-person-years of total population) was among 1-4 year-olds (7,482 cases), with 355 complications (age-specific complication rate: 4.75%). Basecase: highest incidence among 10-14 year-olds (907 natural, 633 breakthrough), with 54 complications (age-specific rate: 3.53%); 85% lower versus 1-4 year-olds. ‘Catch up’: highest incidence among 15-24 year-olds (161 natural, 398 breakthrough), with 49 complications (age-specific rate: 8.82%); 86% lower versus 1-4 year-olds. ‘Optimal’ highest incidence among 15-24 year-olds (22 natural, 80 breakthrough), with 9 complications; 97.5% lower versus 1-4 year-olds. Assuming breakthrough cases have 10% of complications of natural cases, the incidence in the basecase, catch-up and optimal scenarios, respectively, becomes: 3.4, 18 and 3 complications per case. The impact of varicella complications in older age groups, the reduction in varicella cases significantly reduced the incidence of complications. The ICER remained below €16,000 (direct costs). CONCLUSIONS: Mass varicella vaccination is predicted to significantly reduce varicella and complication cases. As many vaccine era cases will be breakthrough, burden to patients and health care systems may be reduced further.

HOW LONGITUDINAL PATIENT RECORDS CAN HELP PUBLIC HEALTH AUTHORITIES IN THE MANAGEMENT OF RAPIDLY GROWING EPIDEMICS: THE EXPERIENCE OF FLU A/H1N1 IN FRANCE

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OBJECTIVES: In the context of an epidemic, public health authorities need to have real-time information of the disease propagation to make appropriate decisions. We present our experience in using centralized electronic patient records in the early detection and follow-up of Flu A/H1N1 epidemic in France. METHODS: We used Longitudinal Patient Data (LPD), which is a dynamic centralized database of more than one million anonymous patient records uploaded regularly by a network of 1300 representative general practitioners and pediatricians in France. The trends of seasonal influenza, Flu A/H1N1 and flu-like syndrome diagnoses are traced and compared with the reports published by Sentinel Network, a group of trained physicians employed by public authorities. RESULTS: The trends of seasonal influenza, Flu A/ H1N1, and flu-like syndrome obtained from LPD database show a very close similarity with those published by Sentinel Network (Pearson’s correlation coefficient = 0.97). The seasonal pattern of the incidence of influenza and flu-like syndrome were less similar in 2007/2008 compared to 2009 and 2008/2009 (Pearson’s correlation coefficient =0.60), which can be explained by an overdeclaration of all kinds of flu by the doctors during the second half of 2009. There was also a close similarity between seasonal Flu, approved Flu A/ H1N1, and flu-like syndrome trends with a peak incidence in late November 2009. There was also a close similarity between seasonal Flu, approved Flu A/ H1N1, and flu-like syndrome trends with a peak incidence in late November 2009. CONCLUSIONS: The LPD data matched very closely the results published by the company during 2005 to 2007. Potential DDIs between ARVs were identified and classified according to a clinical significance rating. The clinical significance ratings of potential DDIs are described in three degrees of severity, identified as major, moderate and minor as described by Tatro. (RSA Rand/RUS$ = 6.3895 on 31 December 2007). RESULTS: Antiretroviral drug interactions were 0.91% of all documented ARV prescriptions claimed during the three years at a total cost of N = R 5 758 783 544 (1.92%). The average cost of antiretroviral prescriptions decreased with 4.19% from 2005 (R524.40 ± 178.79) to 2007 (R502.41 ± 161.19). ARV prescriptions by prescribed for general international market prices. The cost of PITT dosing was decreased by 12.33% in 2005 to 24.62% in 2007. Those prescribed by specialists increased from 15.46% in 2005 to 35.30% in 2006 and decreased to 33.16% in 2007. The highest percentage of ARV prescriptions with potential DDIs and DDIs not according to the recommended ARV dosing guidelines identified in ARV regimens between lopinavir/r/ritonavir at PDD 1066.4 mg/264 mg and efavirenz at PDD 600 mg prescribed to patients 19 to 45 years. These regimens were mostly prescribed by general practitioners as compared to specialists. CONCLUSIONS: There is need for more education of prescribers to be aware of the potential medicine-prescribing errors associated with highly active antiretroviral therapy which could lead to treatment failures, development of resistance and DDIs.

IMPACT OF SVR IN SOUTH AFRICA

Antiretroviral drug interactions on prescriptions prescribed by practitioners set up by public authorities.

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