

PCV115

DEVELOPMENT OF A CONCEPTUAL MODEL FOR EARLY HEALTH TECHNOLOGY ASSESSMENT OF TISSUE-ENGINEERED HEART VALVES

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OBJECTIVES: In-situ tissue-engineering provides a promising method to create living heart valves with the potential to grow, repair and last a lifetime. The objective of the present study is to develop a conceptual model (CM) that can be used to investigate the requirements for tissue-engineered heart valves (TEHV) to become cost-effective compared to current surgical and transcatheter heart valve substitutes (HVS). **METHODS:** The development of the CM was based on recommendations from the ISPOR-SMDM Modeling Good Research Practices Task Force-2. After scoping the decision problem, a draft CM was developed based on clinical guidelines and discussion within a small workgroup. This model was compared with existing models for cost-effectiveness of HVS, found by systematic literature search. It was further discussed with a Delphi panel of cardio-thoracic surgeons, cardiologists and a biomedical scientist (n=10). Delphi panelists were first interviewed individually to discuss the CM structure. Thereafter, they completed online surveys in order to reach consensus between panelists. **RESULTS:** Health states included in the CM are 'alive without complications', cerebrovascular accident, myocardial infarction, vascular complication, bleeding, acute kidney injury, atrial fibrillation, pacemaker implantation, prosthetic valve dysfunction, prosthetic valve thrombosis, prosthetic valve endocarditis, 'alive after complications' and dead. Predictors of transition probabilities between the health states are included; age, gender, NYHA functional class, left ventricular function, renal impairment, and diabetes. Relevant outcome measures included health-related quality of life, event occurrence, event-free survival, mortality and costs. **CONCLUSIONS:** The CM provides the foundation of a microsimulation model that will be used to estimate the cost-effectiveness of TEHV compared with current HVS. The results will be used to inform stakeholders about the requirements for TEHV to become cost-effective. This information can help bio-tech companies to decide about further development of TEHV, focus on the most promising target groups, set realistic performance-price goals, and design and manage a reimbursement strategy.

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A COST-EFFECTIVENESS STUDY ON THE INCREASED INTAKE OF POTASSIUM AND VITAMIN B2 AMONG ADULTS IN CHINA

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OBJECTIVES: The World Health Organization guidelines recommend that an increase of potassium intake reduce blood pressure in adults. In addition, intervention with vitamin B2 has been shown to lower blood pressure in patients with genotype, specifically in hypertensive patients with premature cardiovascular disease (CVD) homozygous for the 677C→T polymorphism (TT genotype) in the gene encoding for the enzyme methylenetetrahydrofolate reductase. In the Chinese northern region, the prevalence of this TT genotype was estimated to be 35% of the population. Furthermore, 26% of adults are hypertensive and 20% adults will experience a CVD episode. This study aims to evaluate the impact of increased intake of potassium and vitamin B2 have on blood pressure, CVD events and quality-of-life among Chinese adults older than 45 years old. Furthermore this study assesses the costs and cost-effectiveness of achieving this impact via the consumption of a fortified milk product. **METHODS:** An analytical decision model was used to quantify and compare three strategies against the current intake of the at-risk-population: 1) Increased potassium intake level 2) Increased vitamin B2 intake level 3) Combined increased vitamin B2 and potassium intake levels. The effectiveness of these strategies in incrementing vitamin B2 and potassium were determined by patient level data and the Framingham methodology. All costs and epidemiological data were collected from the literature. **RESULTS:** All strategies led to statistically significant health outcomes due to the preventive effect of increased intake of potassium and vitamin B2 also resulting in a significant Quality Adjusted Life Years gain over the baseline. Each strategy is shown to be cost-effective or highly cost-effective with the largest effect being the combined increased intake of potassium and vitamin B2. **CONCLUSIONS:** The strategy of the combined increased intake of vitamin B2 and potassium is highly cost-effective thereby preventing CVD events and saving costs to the health system.

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CLINICAL AND ECONOMIC IMPACTS OF THE USE OF A PRESCRIPTION ASSISTANCE SOFTWARE FOR VITAMIN K ANTAGONIST TREATMENT IN FRENCH MANAGEMENT OF ATRIAL FIBRILLATION AND VENOUS THROMBOEMBOLIC EVENTS

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OBJECTIVES: Vitamin K Antagonist (VKA) have traditionally been the main treatment for thromboembolic event prevention in atrial fibrillation (AF) and for the treatment of venous and pulmonary thromboembolic events (VTE) and the prevention of their relapses. A close patient monitoring with the determination of the INR (International Normalized Ratio) is needed during the AVK treatment, to avoid adverse thrombotic or hemorrhagic events. The improvement of the time spent in the therapeutic range (TTR), depending on INR results, has previously been studied in France with the use of a prescription assistance software (PAS). The use of this PAS improves the TTR from 58.46% to 71.79%. The objective of the

analysis was to develop two cost effectiveness models taking into account the new management of the treatment of AF and VTE in France. The clinical and cost benefits of VKA (with/without the use of a PAS) has been evaluated versus new oral anticoagulants (NOAC): dabigatran, rivaroxaban and apixaban. **METHODS:** A Markov model was built for the treatment of AF and a decision tree for the treatment and prevention of VTE. In the VKA arms, both models integrate the possibility to adjust the percentage of time spent by patients within INR therapeutic range. In the VTE model, outcomes were expressed in cost per avoided event whereas in the AF model in cost per QALY. **RESULTS:** In both models, apixaban is the strategy producing the least thromboembolic and hemorrhagic events whereas AVK strategies are the cheapest treatments (2 to 2.5 times less than NOAC treatments). The use of the software for the treatment and prevention of VTE allows to save €3,192 per avoided event and for the AF treatment €7,557 per extra QALY gained and €6,688 per avoided event. **CONCLUSIONS:** Based on French guidelines for economic evaluation, apixaban and VKA + PAS are efficient strategies in AF.

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A NEW COST-EFFECTIVENESS MODELLING APPROACH IN CHRONIC HEART FAILURE WITH REDUCED EJECTION FRACTION

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OBJECTIVES: As new therapies for chronic heart failure with reduced ejection fraction (HFrEF) emerge, health technology assessments (HTAs) will require cost-effectiveness analyses to inform decision making. The objective was to develop a model framework for evaluating the cost-effectiveness of LCZ696, a novel oral therapy proposed for the treatment of HFrEF. **METHODS:** A systematic literature review was performed. Searches were conducted in MEDLINE, EMBASE, EconLit, and Cochrane Library databases, with supplementary hand searching of conferences and HTA websites. Of 63 distinct analyses identified, 33 used decision-analytic models. Structures were most commonly described as Markov models (n=27), but methods employed were heterogeneous. The health states most frequently employed were 'alive' and 'dead', with outcomes such as hospitalization or New York Heart Association (NYHA) class distribution most commonly considered within the 'alive' state. **RESULTS:** A 2-state Markov model with 'alive' and 'dead' states was developed using three multivariate regression models to predict the risks of mortality, hospitalisation and the trajectory of health-related quality of life over time within the 'alive' state. NYHA class was not used as a basis for health states, as the extrapolation of clinical improvements beyond the observed data was considered clinically implausible. Parametric survival models, negative binomial models and multilevel models are used to predict mortality, hospitalisation, and HRQL, respectively, allowing extrapolation to a lifetime time horizon. The model of HRQL attempts to capture the effects of baseline characteristics, hospitalisation, adverse events and time on EQ-5D. Clinical experts were consulted to validate the regression models and their respective predictions. **CONCLUSIONS:** The new framework employs similar methods to decision analytic models developed previously in heart failure, however models health-related quality of life as a function of time directly, thereby providing a parsimonious approach with improved clinical plausibility compared to other model structures in the literature.

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COST-MINIMIZATION ANALYSIS OF RIVAROXABAN IN COMPARISON TO ENOXAPARIN PLUS WARFARIN FOR THE TREATMENT OF VENOUS THROMBOEMBOLISM (VTE) UNDER THE PRIVATE HEALTHCARE SYSTEM PERSPECTIVE

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OBJECTIVES: Venous thromboembolism (VTE) which comprises deep vein thrombosis (DVT) and pulmonary embolism (PE) is associated with a significant health-care burden. Currently, the standard of care is parenteral low molecular weight heparin (enoxaparin) plus warfarin. Rivaroxaban is an oral anticoagulant that does not require dose adjustment or routine coagulation monitoring, bringing an important advantage for the treatment of VTE. The EINSTEIN clinical program of rivaroxaban showed that, overall, hospitalized patients who received initial treatment with rivaroxaban for DVT and PE had a significantly shorter length of stay compared to patients who received enoxaparin/VKA. Therefore, the aim of this study was to compare the direct costs of treatment with rivaroxaban versus enoxaparin/warfarin. **METHODS:** A cost-minimization analysis (CMA) was chosen once the EINSTEIN program showed that rivaroxaban is non-inferior to enoxaparin/VKA with regards to efficacy for treatment of VTE being possible to consider that there is no difference in outcomes. Perspective was from the Brazilian private healthcare system and time horizon was one year. Costs related to hospitalization, outpatient management and adverse events were obtained by micro-costing approach and resource use captured from literature and expert panel. Costs were expressed in 2015 prices and exchange rate used was \$1.00USD=3.00BRL. **RESULTS:** Rivaroxaban use resulted less expensive than enoxaparin+warfarin in the treatment of VTE. Estimated total cost of treatment for one patient with VTE is \$2,079 with rivaroxaban and \$2,716 with enoxaparin+warfarin. The greater difference in costs was for treatment of PE, which was \$688.57 less for rivaroxaban. For DVT treatment, estimated savings for rivaroxaban was \$561.46. Robustness of the model was tested in a deterministic univariate sensitivity analysis in which all results remained cost saving. **CONCLUSIONS:** Rivaroxaban is a cost-saving alternative compared to the current practice for the treatment of VTE under the perspective of the Brazilian private healthcare system.