Abstracts

USE OF PROPENSITY SCORE METHODOLOGY IN CARDIOVASCULAR DEVICE TRIALS: U.S. FOOD AND DRUG ADMINISTRATION PERSPECTIVES
Muni N, Yue L
U.S. Food and Drug Administration, Rockville, MD, USA

OBJECTIVE: Randomized, controlled trials (RCTs) are considered to be the gold standard of scientific evidence to assess safety and effectiveness of cardiovascular devices. However, RCT use is challenging to implement in certain device trials, due to logistical and ethical reasons. The FDA understands that assessment of device technologies must balance the competing demands of scientific and ethical reasons. The FDA understands that assessment of device technologies must balance the competing demands of scientific and ethical reasons. The FDA understands that assessment of device technologies must balance the competing demands of scientific and ethical reasons.

RESULTS: As an alternative to conventional covariate adjustment as well as propensity score methodology, the use of propensity score modeling, a full pre-specification of covariates to be included and the model to be used is recommended to minimize the concern of bias introduced by post hoc model development. RESULTS: Furthermore, sensitivity analysis should be performed to demonstrate the robustness of study outcome in the face of hidden bias due to unmeasured or unquantifiable covariates. Lastly, it is recommended that conventional covariate adjustment as well as propensity score adjustment should be performed to demonstrate consistency of outcomes between techniques.

CONCLUSION: Propensity score methodology has increased in popularity for covariate adjustment in non-randomized cardiovascular device studies. However, there are limitations to this methodology, which must be fully appreciated to avoid erroneous inferences from study data. Randomized trials are still preferred and strongly encouraged whenever possible, especially for the evaluation of novel cardiovascular devices.

A BUDGET IMPACT MODEL FOR EPLERENONE IN THE TREATMENT OF HEART FAILURE POST MYOCARDIAL INFARCTION
Tabberer M, Duorden M
1Pfizer Ltd, Tadworth, Surrey, UK; 2Keele University, Keele, Staffordshire, UK

OBJECTIVES: The Eplerenone Post-Acute Myocardial Infarction Heart Failure Efficacy and Survival Study (EPHESUS) showed that the addition of eplerenone to optimal medical therapy reduced both morbidity and mortality in patients with acute myocardial infarction (AMI). This study demonstrated that the addition of eplerenone to standard care in the UK National Health Service (NHS). METHODS: Within the model the efficacy of eplerenone is based on the EPHESUS study. This is applied to UK epidemiological data on the incidence of AMI, proportion of survivors developing heart failure and their prognosis. UK drug acquisition costs and NHS hospital inpatient costs and average length of stay for England are included. All costs are expressed in pounds sterling. The model estimates the incremental costs and benefits of adding eplerenone to standard care in heart failure resulting from AMI from the perspective of NHS health care decision makers over a three-year period. Input variables include population, incidence of AMI and annual rate of eplerenone uptake. RESULTS: If all eligible patients are treated in an NHS Primary Care Trust of population 250,000, the estimated cost per life year saved is 6,701 pounds in year three, for an additional expenditure of £256,959. This level of treatment results in a reduction of 101 bed days for re-hospitalisations due to heart failure, at a cost per bed day avoided of €1207. CONCLUSIONS: With hospital inpatient care the biggest single health care cost in heart failure, reduction in hospitalisation is a key priority within the UK NHS. Models such as the one described here enable the economic consequences of using a new drug to be identified and clarify the role of drug treatment in delivering NHS priorities.

COST-EFFECTIVENESS OF EPTIFIBATIDE IN NSTEMI PATIENTS IN POLAND
Dewilde S, Opolski G, Brown R
1The MEDTAP Institute at UBC, Brussels, Belgium; 2Medical Academy, Warsaw, Poland; 3MedTap Institute at UBC, London, UK

OBJECTIVES: To estimate incremental cost-effectiveness of adding a GPIIb/IIIa inhibitor (eptifibatide) to percutaneous coronary intervention (PCI) and standard medical management (MM) versus PCI + MM alone in Poland for patients with non-ST-elevation myocardial infarction (NSTEMI) at high risk of recurrent ischemia or cardiovascular death. METHODS: A Markov model was constructed to estimate the additional costs and benefits of a GPIIb/IIIa inhibitor on top of standard care. The model has 4 disease states (no event, post-ischemia, post-MI, death) and two tunnel states (refractory ischemia, non-fatal MI). PCI + MM include beta blockers, ACE inhibitors, aspirin, heparin and clopidogrel. The model takes the Polish national health payer perspective and runs for the expected lifetime of the patient. The effectiveness parameters were taken from a 6-month GPIIb/IIIa clinical trial and extrapolated to 45 years with an estimated Weibull function. Event and follow-up costs are based on assumed treatment patterns. The results of the model were expressed in total (discounted) costs and life years per patient, and incremental cost per life year gained. A series of one-way sensitivity analyses have been conducted on the major model inputs. RESULTS: The lifetime discounted costs for the base case analysis are 13,856 PLN per patient for the PCI + MM group and 15,570 PLN for the eptifibatide group (a difference of 1714 PLN). The use of eptifibatide provides an additional average of 0.05 year of life per patient compared with PCI + MM. The incremental cost-effectiveness ratio for the lifetime model, with