cardiovascular death and hospitalizations for HF. However, decision makers need to determine whether its benefits are worth the additional costs, given the low-cost generic status of current standard of care.

METHODS:

Using a Markov model, we projected lifetime clinical and economic outcomes of sacubitril/valsartan versus enalapril for 66-year-old patients with HF in Singapore. Key health states included New York Heart Association (NYHA) classes; patients in each state incurred a monthly risk of hospitalization for HF and cardiovascular death. Probabilities of events were based on the PARADIGM-HF trial. The uncertain treatment effect of sacubtril/valsartan in Asian patients was modelled using a hazard ratio (HR) of 1 as upper limit in sensitivity analyses. Utilities were obtained from published literature. Local national epidemiological and cost data were applied. Analyses were conducted from the Singapore healthcare payer's perspective. Both one-way and Probabilistic Sensitivity Analyses (PSA) based on 10,000 Monte Carlo simulations were performed.

RESULTS:

Compared to enalapril, sacubitril/valsartan was associated with an incremental cost-effectiveness ratio (ICER) of SGD74k (USD52k) per quality-adjusted life year (QALY) gained. The cost-effectiveness of sacubitril/valsartan was highly dependent on its effectiveness in reducing the risk of cardiovascular death. However, this was uncertain, particularly in the Asian subgroup, where results were not statistically significant. In sensitivity analyses using results from Asian patients, the ICERs ranged from SGD41k (USD30k) to SGD1.3 million (USD 0.94 million) per QALY gained. PSA showed the probability of sacubitril/valsartan being cost-effective was below 1 percent, 12 percent and 71 percent at thresholds of SGD20k (USD14k), SGD50k (USD36k) and SGD100k (USD 72k) per QALY gained, respectively.

CONCLUSIONS:

Given the uncertain ICER, sacubtril/valsartan may not provide good value for money compared to enalapril in reducing cardiovascular morbidity and mortality in patients with HF at the current daily cost. Our study highlights the cost-benefit trade-off that healthcare professionals and patients face when considering HF therapy.

OP118 Cost-Effectiveness Analysis Of Molecular Profile Selection For Advanced Head And Neck Cancer

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INTRODUCTION:

Relapsed/metastatic head and neck squamous cell cancer patients are offered a combination of platinum-based chemotherapy (PF, cisplatin-fluorouracil) plus cetuximab regimen (PF+C) according to results of the EXTREME trial (1). However, two economic evaluations showed that addition of cetuximab was not cost-effective.

This study aimed to evaluate the cost-effectiveness of a putative predictive molecular test (MT) to identify and treat only patients potentially responsive to cetuximab when added to PF.

METHODS:

A Markov model was developed to compare both health and economic outcomes of PF+C regimen administered to all patients (PF+C ALL) versus the regimen administered only to MT-positive patients (PF+C POS).

The model considered the following health states: partial/complete response with/out mild/severe adverse events (AEs), progression and death. Rates of progression and survival, response rates to systemic treatment and adverse events were retrieved from the EXTREME trial (1). According to Mesía et al. (2), we assumed that addition of cetuximab to PF would not negatively affect life quality compared to PF alone, and

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the baseline utility coefficients for disease control and progression were assumed as .67 and .52, respectively.

Only direct costs estimated from the Italian Health Service perspective were included (tariffs and Diagnosis Related Group - DRG - reimbursements).

The model was evaluated according to a cut-off of sensitivity at 85 percent and specificity at 70 percent. A 3 years horizon was chosen. Life expectancy, quality-adjusted life years (QALYs) and costs were discounted at 3.5 percent annually.

RESULTS:

Applying the World Health Organization (WHO) cost-effectiveness threshold of 3 times the gross domestic product for Italy (EUR66,402), PF+C POS resulted a cost-effective choice in comparison to PF+C ALL for a MT cost lower than EUR5,750.

CONCLUSIONS:

Adding cetuximab to PF only to patients positive to a predictive test may be cost-effective. Efforts should be spent to build such a test upon existing evidences in order to save resources for the health systems and spare unnecessary toxicities to patients.

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OP119 Advanced Therapy Medicinal Products: Are Current Health Technology Assessment Methods Suitable?

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INTRODUCTION:

There is considerable excitement around the development of regenerative medicines (or advanced therapy medicinal products, ATMPs), with the expectation that they may bring substantial clinical gains and offer cures for previous debilitating and fatal diseases. However, high costs mean that Health Technology Assessment (HTA) and reimbursement decisions are challenging for payers and manufacturers, even when the therapies are expected to offer good value for money.

In Europe, seven ATMPs have market authorization, yet only one has achieved national level reimbursement. Statistics such as these put HTA bodies under pressure to review their methods and consider how these can apply to regenerative medicines.

METHODS:

We present a review of one example, from the United Kingdom's National Institute for Health and Care Excellence (NICE), who commissioned an external organization to undertake a mock appraisal of a hypothetical ATMP using standard methods. The therapeutic area chosen for the mock appraisal was chimeric antigen receptor (CAR) T-cell therapy for treating relapsed or refractory B-cell acute lymphoblastic leukaemia.

RESULTS:

The role of uncertainty was a key consideration within the report, yet we found that the presentation of uncertainty within the mock appraisal was misleading for decision makers.

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