The standard treatment of this condition involves a major open surgery. For patients currently ineligible for surgery, medical management is the only option. The UGT1A1 pharmacogenetic test can potentially inform irinotecan dose selection and reduce the incidence of neutropaenia, a key adverse event of irinotecan-based chemotherapy in advanced colorectal cancer (CRC). Neutropae-dose selection and reduce the incidence of neutropaenia. This study aimed to assess the cost-effectiveness of UGT1A1 testing and identify key parameters driving cost-effectiveness.

OBJECTIVES: Rituximab (Rmb), imatinib (lmt) and extra-corporeal photopheresis (ECP) are palliative treatment options used in patients with chronic graft-versus-host disease (cGVHD) who fail previous lines of treatment. The purpose of the study was to assess the cost-effectiveness of ECP in patients with cGVHD in Spain. METHODS: A Microsimulation model was built to estimate the clinical and economic consequences of ECP versus Rmb or lmt for 1000 hypo-thetical patients. Model probabilities concerning the efficacy of ECP, Rmb and lmt and severity degree per organ affected were obtained from literature. Treatment pathways and adverse events were evaluated taking into consideration expert opinion. Local data on costs (Euros 2010) and use of health resources were also validated by clinical experts. An annual 3% discount rate was applied to costs and outcomes. The perspective was the Spanish National Health System and time horizon was 5 years. RESULTS: Differences in improvement when ECP is used showed a gain at first year of 6.2% and of 6.7% against Rmb and lmt, respectively. The higher efficacy for ECP compared to lmt was 0.011-0.014 Quality Adjusted Life Years at the first year and 0.062-0.094 at year five compared to Rmb or lmt. Results showed that higher acquisition cost of ECP vs lmt was compensated at 9 months by higher efficacy and vs Rmb was partially compensated (5178 year 5). After 9 months, ECP was dominant vs lmt. The incremental cost-effectiveness ratio of ECP versus Rmb was 29,667 €/QALY gained and 24,442 €/QALY gained at year 2.5. The probabilistic sensitivity analysis showed robustness of results, being the ECP cost-effective in 70% of the simulated cases at year 5 (threshold of €30,000/QALY gained).

CONCLUSIONS: ECP as third-line therapy for cGVHD is a more cost-effective com-pared to Rmb or lmt.

ECONOMIC EVALUATION OF THE UGT1A1 PHARMACOGENETIC TEST TO INFORM DOSE SELECTION OF IRINOTECAN-BASED CHEMOTHERAPY Shaburudin FH, Elliott KA, Tappenden P, Payne K 1
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OBJECTIVES: The UGT1A1 pharmacogenetic test can potentially inform irinotecan dose selection and reduce the incidence of neutropaenia, a key adverse event of irinotecan-based chemotherapy in advanced colorectal cancer (CRC). A pharmacokinetic model for CRC patients with neutropaenia has a negative impact on health and its management uses healthcare resources. The UGT1A1 test identifies patients at low-, intermediate- or high-risk of grade 3/4 neutropaenia. High-risk patients can be prescribed lower doses to reduce the incidence of neutropaenia. This study evaluated the cost-effectiveness of UGT1A1 testing and identify key parameters driving cost-effectiveness. METHODS: An economic model of UGT1A1 testing to predict grade 3/4 neutropaenia compared to standard care was developed over a lifetime horizon from the UK NHS perspective. Treatment pathways were informed by a national survey of clinical experts (n=44). The model was populated with data from: systematic reviews of the effectiveness and utility literature, a micro-costing observational study (n=48 pa-tients) and CRC expert (n=55) elicitation. RESULTS: UGT1A1 testing was cost-sav-ing and resulted in lower incidence of grade 3/4 neutropaenia. For a cohort of 100 patients, the test was estimated to save £14,500, avoid 4.4 neutropaenic episodes, gain 0.06 life-years and 0.05 QALYs. The probability that the test was cost-effective at willingness-to-pay thresholds between £20,000 and £30,000 per QALY gained was above 95%. These findings were specific to model assumptions and specifications. Sensitivity analysis (probabilistic and one-way) suggested that the main driver of cost-effectiveness was the effect of irinotecan dose reduction on survival. Value of information analysis indicated a low value of future research to reduce parameter uncertainty (5 year population EVPI: £31,564). However, assumptions affecting model structure had a comparatively greater impact on cost-effectiveness. CONCLUSIONS: This analysis modelled NHS-relevant clinical treatment pathways and provided potentially useful evidence for UK decision-makers. Structural model assumptions rather than parameter inputs had a larger impact on cost-effectiveness.

OPTAR STUDY: TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI) VERSUS OPTIMAL MEDICAL TREATMENT (OMT) IN PROHIBITIVE SURGICAL RISK PATIENTS WITH SEVERE AORTIC STENOSIS (AS) – AN EXPLORATORY COST-EFFECTIVENESS ANALYSIS Telles R, Alnoudi MA, Motteram JN, Watt M, Busa MR, Farinha S, Mendes M
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OBJECTIVES: Aortic valve stenosis is a chronic and progressive valvular heart disease. The standard treatment of this condition involves a major open surgery. For patients currently ineligible for surgery, medical management is the only option available. Transcatheter aortic valve implantation (TAVI) devices recently appeared as a new less invasive treatment option. The objective of this study was to develop an exploratory cost-effectiveness analysis of TAVI vs OMT in the Portuguese Setting. METHODS: This analysis used a Markov model developed by Oxford Outcomes to assess costs and benefits of TAVI vs OMT. A short term sub-model represents the first 30 days after TAVI (cycle length of 30 days), whereas a long term model (cycle length of one month) consid-ers a 10-year time horizon. For TAVI patients the health states considered are ICU, General Wards, Home, Re-operation and Death. OMT patients are in either Home or Dead health states, receiving medication until death and at risk of co-morbidity-related hospitalisations. Portuguese NHS healthcare resources were retrospectively collected at Hospital de Santa Cruz in Lisbon for a cohort of 44 high risk AS patients (21 TAVI, 23 OMT), over a period of 11 months. Clinical parameters, transition probabilities and utility values were derived from relevant literature. Costs were taken from the Oxford Outcomes database. Treatment costs, direct and indirect, were considered. Probabilistic and one-way sensitivity analysis were performed. RESULTS: Treatment with TAVI compared to OMT increased life years by 1.7 (3.13 vs. 1.46) and quality-adjusted life years (QALYs) by 0.14 (2.33 vs. 0.80). Direct costs were 32,067 € with TAVI and 46,642 € with OMT. Incremental Cost Effectiveness Ratios (ICERs) estimated are 16,375 €/QALY and 19,180 €/QALY. CONCLUSIONS: TAVI is highly likely to be a cost-effective inter-vention for the treatment of AS in patients who are currently ineligible for surgery.

DEVELOPMENT OF A STANDARD REIMBURSEMENT DOSSIER FOR THE EVALUATION OF EFFECTIVENESS AND COST-EFFECTIVENESS OF A NEW MEDICAL DEVICE (NEBULIZER MINI-PLUS) Dózsa C, Borcsák B
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OBJECTIVES: In Hungary the re-regulated, transparent coverage system of medical aids was put into force in 2007 (after the re-regulation of coverage policy of drugs 2004). Until 2010 287 reimbursement applications were evaluated by the Office of HTA of the National Institute for Strategic Health Research. The aim of the study was to test a standard reimbursement dossier, which evidenced the effective-ness and cost-effectiveness of a new medical device (Nebulizer Mini-Plus). METHODS: According to a recommendation of the above mentioned HTA Office the combined assessment of technical functions and prices was suggested as eligible filter for the coverage of products with sufficient price-value rate. Hence the base of the study was to: compare the technical parameters of nebulizers and to use the cost-minimization analysis (CM). The study had payer’s perspective, but aspect of equity (burden of disease) was taken into consideration because of the high signif-icance of diseases of respiratory system. After the literature review and compari-son of technical parameters of nebulizers, the 2009-2010 turnover of nebulizers were analysed and the budget impact was estimated for 2011-2012, considering the business risks. RESULTS: Taking into consideration that several technical param-eters (lung deposition, particle size) of Mini-Plus exceeded other devices and its price was lower than the cheapest reimbursed device, it was expressed as the dominant alternative of compression nebulizer therapies. By its coverage the payer can reach almost 15,000 USD saving and minimally 3685 USD burden loss (reducing of co-payment) for patients until 2012. There are additionally cost-saving poten-tials of elimination of drug consumption and hospitalizations. The combined assessment of technical functions and prices (supported by CM) was a successful and eligible strategy for the evaluation of the effectiveness and cost-effectiveness of a new medical device, and can be adapted for other types of med-ical aids.

ECONOMIC EVALUATION OF THE HEARTWARE VENTRICULAR ASSIST DEVICE IN THE NHS Craig J1, Saxby RC2, Homer T2, Swartz MT2
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OBJECTIVES: End-stage heart failure is a leading cause of death; patients have a poor prognosis and low quality of life. Managing the limiting and distressing symp-toms incurs significant costs on the NHS. Therapy options are few; primarily com-bination medical therapy and, for a few patients, transplantation using a donor heart. Left ventricular assist devices (LVADs) are mechanical pumps that support the heart function. Use is increasing worldwide as more studies demonstrate clinical effectiveness, primarily from improved patient survival and quality of life. However, there are no published cost effectiveness studies. This pilot evaluates the cost-effectiveness of the HeartWare LVAD as destination therapy for patients with end-stage heart failure. METHODS: A cost-utility model compared the LVAD and costs of patients who were medically managed without a transplant (n=15) with those who received a HeartWare LVAD and no subsequent transplant (n=17). Clinical data were from a multicentre trial evaluating the safety and efficacy of the HeartWare LVAD [1] and outcomes of patients listed on the HeartWare LVAD Trans-plant Registry [2]. Utility values were from a Health Technology Assessment [3] and derived using the EQ-5D tool. Cost data came mainly from published sources. RESULTS: The results from this evaluation were patients managed with the Heart-Ware LVAD and higher costs but outcomes and those who were medically managed. At 5 years the additional cost was about £20,500 per patient and a QALY gain of 1.05, giving an incremental cost per QALY of under £20,000, below the threshold commonly adopted of £25,000 per QALY. CONCLUSIONS: The results are encouraging and suggest it is plausible that using LVADs as long-term support in patients with end-stage heart failure could be a cost-effective use of healthcare provider resources. Further research is needed to refine the clinical and cost data.