standard OS extrapolation methods which fit ‘traditional’ parametric survival distributions to patient-level data, two different methods were explored in the model development stage. The first method (OS extrapolation) allows for a formal comparison with AIC, but allows extrapolation in line with the clinical interpretation. The ‘parametric curves’ approach allows for a statistically better fit with the patient level data using conventional AIC criteria. Both methods are in line with long-term observations of immuno-therapy patients in a more suitable way.

M03
A METHODOLOGICAL FRAMEWORK FOR DEVELOPING MODELS OF WHOLE DISEASE AREAS TO INFORM RESOURCE ALLOCATION DECISIONS

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OBJECTIVES: A conventional economic evaluation involves piecewise comparisons of competing interventions at a single point in a broader care pathway. METHODS: This approach is subject to several problems: a) there remains an ongoing debate surrounding the appropriateness of threshold-based decision rules and whether their repeated use will maximise health, b) restricting the model scope to a single decision point does not always reflect other adoption decisions elsewhere in the disease pathway may be treated as independent of the problem under consideration, and c) the absence of model development guidance leads to inconsistencies between analyses addressing similar decision problems. In light of these problems, this study puts forward the notion of “Whole Disease Modelling.” This involves simulating whole disease and treatment pathways within a single model, from preclinical disease through to diagnosis and referral, adjuvant treatment, follow-up, potential recurrence, palliative treatment, end-of-care and eventual death. A methodological framework has been developed based on three key principles: 1) the model boundary should be broad, and should capture all relevant aspects of the disease and its treatment; 2) the model should be developed such that the decision node is conceptually transferable across the pathway; and 3) the costs and consequences of service elements should be structurally related. RESULTS: Case study applications in colorectal cancer services suggest that Whole Disease Modelling is feasible and may provide a consistent platform for economic analysis at virtually any point in a disease pathway using multiple economic decision rules. CONCLUSIONS: The value of the approach may be realised when: multiple decision problems require different economic analysis at a single time point; services are subject to rapid innovation and the model can be re-used; a substantial proportion of currently provided value is realised when: multiple decision problems require in-situ development and the model can be re-used; a substantial proportion of currently provided value may be realised when: multiple decision problems require a consistent platform for economic analysis at virtually any point in the disease pathway.

M04
OUTCOMES BEYOND HEALTH

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OBJECTIVES: The aim of this study was to investigate whether broadening the evaluative space in an economic evaluation would lead to other outcomes, and hence policy recommendations. METHODS: Two discrete choice experiments (DCE) were conducted in a population of patients who had been treated for varicose vein disease (N=390) either by foam sclerotherapy or surgical stripping. In the Health DCE the treatments were described in terms of health outcomes attributes only (based on the EQD dimensions). In the Extended DCE the treatments were described in terms of the same health outcomes attributes and other aspects (Waiting time, Probability of retreatment and Nature of treatment). The differences in the levels were collected in a clinical trial and entered into the preference models to calculate the difference in utility between those treatments. The AU in both models was standardised on a [1-1] scale. The incremental costs of foam sclerotherapy versus surgical stripping, as observed in the clinical trial, amounted to €1123. RESULTS: All attributes were statistically significant, except for Waiting time and Probability of retreatment. The relative importances and the ranks of the health attributes differed between the models. The patients preferred surgical treatment if only health outcomes were considered, while the patients preferred dermal treatment if all aspects of the disease were considered in the choice: AUhealth = 0.0109, AUextended = 0.3971. When incremental utility was based on health outcomes only alone, the incremental cost-utility ratio was €30,027. When incremental utility was based broader outcomes, the incremental utility ratio indicated dominance. CONCLUSIONS: The results suggest that recommendation for policy would change if not only health outcomes but also broader outcomes are considered. The results confirm that a restriction to health outcomes in the (economic) evaluation of health care leads to the maximization of health, but not necessarily to the maximization of benefit in a broader sense.

PODIUM SESSION III:
FLOATING THRESHOLDS AND BY PASSES: RISK SHARING AND PATIENT ACCESS

RS1
LITERATURE REVIEW ON PATIENT ACCESS SCHEMES, FLEXIBLE PRICING SCHEMES AND RISK SHARING AGREEMENTS FOR MEDICINES

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OBJECTIVES: To identify existing knowledge about the costs and benefits, assessed either quantitatively or qualitatively, of performance based reimbursement, risk sharing schemes, patient access schemes, and flexible pricing schemes for pharmaceuticals. METHODS: A systematic literature review was conducted using Medline, PubMed and the Cochrane Database of Systematic Reviews from the period January 2000 to 2011. This review included “fixed pricing”, “patient access schemes”, and “performance-based reimbursement” were searched in titles and abstracts. RESULTS: The search provided 62 records and after screening the number was reduced to 31. After full assessments of these studies, a total of 24 formed the basis of the review. More than 40 per cent of the publications referred to the Multiple Sclerosis Risk Sharing Scheme implemented in the UK since 2002. The review did not identify any cost benefit analysis evaluating the overall economic impact of schemes in monetary terms. All studies discussed costs and benefits qualitatively and in some cases, when known, some costs were re-portered. Schemes’ key stakeholders were health service employees, companies, regulators – bear different costs and benefits and conflicting incentives may arise. Costs and benefits widely vary depending on the characteristics of the scheme. CONCLUSIONS: There is lack of consensus on the welfare consequences of the schemes, their social desirability and identified benefits are open to significant costs and the overall balance remains unclear. Further research is necessary: a) to assess in a transparent way to what extent the transactional costs and administrative burden are shared between payers and pharmaceutical companies, as they constitute an important barrier for the implementation of the schemes, and b) to aid design of a successful Value Based Pricing system for new medicines in the UK, given the similar principles that underpin outcome-based schemes where prices are set to match “real world” NHS value in practice.

RS2
COST-EFFECTIVENESS OF END-OF-LIFE, LIFE-EXTENDING INTERVENTIONS: NICE’S COST-EFFECTIVENESS THRESHOLD EXPLORED

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OBJECTIVES: It is widely recognised that the National Institute for Health and Clinical Excellence (NICE) in the UK employs cost-effectiveness thresholds in health technology appraisal decision-making. This incremental cost-effectiveness ratio (ICER) threshold has been topic of much debate and is estimated to lie around £30,000 per quality-adjusted life-year (QALY) gained. In December 2008, NICE appeared to consider the threshold had been reached for end-of-life interventions. METHODS: All NICE technology appraisals issued between December 2008 and June 2011 were reviewed. The appraisals in which end-of-life considerations were implemented were identified and ICERs from these appraisals were extracted. RESULTS: In total 39 single technology appraisals were published in the timeframe considered. Of these, only 13 fulfilled the end-of-life criteria, all concerning treatments for cancer. The final ICERs of these 13 interventions ranged from £31,800 to £68,000, although 10 out of 13 manufacturers employed patient access schemes to lower these values. Both the highest ICER that was approved and the lowest ICER that was not approved were £94,300 per QALY gained. Interestingly, both of these appraisals concerned interventions for the treatment of advanced renal cell carcinoma, implying that other factors must have been taken into account by NICE to reach this judgement. CONCLUSIONS: Cost-effectiveness seems to be the most important consideration for NICE in their health technology appraisals. For end-of-life, life-extending treatments, the cost-effectiveness threshold appears to lie around £50,000 per QALY. However, review of individual appraisals shows that other factors such as uncertainty in the estimates and unmet need are also taken into account in NICE’s decision-making.

RS3
EVIDENCE, PROCESS OR CONTEXT? EXAMINING THE FACTORS THAT DRIVE COVERAGE DECISIONS OF PHARMACEUTICALS BY HEALTH TECHNOLOGY ASSESSMENT BODIES IN EUROPE

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OBJECTIVES: In Europe, Health Technology Assessment (HTA) bodies produce coverage decisions that guide public funding of pharmaceuticals. This analysis examines how and weights those factors that drive HTA coverage decisions, focusing on the National Institute for Health and Clinical Excellence (NICE) in England and Wales, the Scottish Medicines Consortium (SMC), the Dutch College for Zorgverzeker-ingen (CVZ), and the French Haute Autorité de Sante (HAS). METHODS: A dataset of approximately 100 HTA coverage decisions by NICE, SMC, CVZ and HAS from the period 2004-2009 was created, containing more than 30 clinical, economic, process and socio-economic factors extracted from published HTA reports. A three-cate-
gory outcome variable was used, defined as the decision to ‘recommend’, ‘restrict’ or ‘not recommend’ a technology. Multivariate analyses were conducted to assess the relative contributions of the explanatory variables on coverage decisions both within and between HTA bodies. RESULTS: Different combinations of clinical/eco-
nomic evidence, process and socio-economic factors drive HTA coverage decisions by NICs, SMIC, CVZ and HAS. In addition, the same factor may behave differently across different HTA bodies, even the outcome of the coverage decision. The analysis further suggests there is a significant difference between HTA bodies in the probability of reaching a ‘restrict’ or ‘not recommend’ decision outcome relative to a ‘recommend’ out-
come, adjusted for evidence, process and context factors. CONCLUSIONS: This analysis contributes to the understanding of factors driving HTA coverage deci-
sions by examining multiple European HTA bodies, enhancing the comprehensive-
ess of the factors examined through descriptive and multivariate analyses and by identifying and weighting the key drivers of the coverage decisions made by the four HTA bodies between 2004 and 2009. This research further provides relevant insights for the ICDF on good practice in decision-making, pharmaceuti-
cals, and implications for collaboration between European HTA bodi-
es. **RS4**

**THE INTERIM CANCER DRUGS FUND – HOW TO NOT SPEND £50 MILLION**
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OBJECTIVES: The Cancer Drugs Fund (CDF) was established in April 2011 by the UK government, with a pledge of £200 million additional funding for each of the next 3 years to increase patient access to high cost oncology drugs in England. As an interim measure, £50 million was distributed between the 10 strategic health au-
thorities (SHAs) to be used to improve the prioritisation of the four HTA bodies. Remaining budget is expected to be reclaimed by the Department of Health (DH) for the next financial year. CONCLUSIONS: This research aimed to identify how the interim CDF (ICDF) was spent, and to discuss how this could impact utilization of the CDF. METHODS: Data regarding the funding allocated to each SHA from the ICDF and how much of this money had been spent by March 31, 2011 were obtained from SHA websites. Missing data were accessed through freedom of information requests. RESULTS: Overall, there were over 2700 applications to the fund, with an average approval rate of 91%. Over the 6 month period covered by the ICDF, approximately £21 million was spent across the 10 SHAs in England, this constituted 42% of the £50 million allocated. There was a sig-
nificant increase in the amount spent by each SHA; the highest under-spend was in the South West, where 75% of funds remained unallocated. Several SHAs reported the forecasted costs for continuing treatment beyond March 2011; these constituted 48-77% for injury requiring neurological intervention. Other rules, such as New Orleans criteria, NEXUSS, NCSW and SIGN produce similar sensitivities but with lower and more variable specificity values. CONCLUSIONS: This research can provide useful information for optimizing the allocation process ensuring that the highest quality treatments receive the necessary funding to help patients. The CDF also provides a unique opportunity to learn from this interim measure in order to improve decision-making in future levels of funding.

**POSTER SESSION I**

**SELECTED HEALTH CARE TREATMENT STUDIES**
Medical Device/Diagnostic – Clinical Outcomes Studies

**PMD1**

**ND-YAG LASER INCIDENCE RATE COMPARISON OF THREE MONOFOCAL INTRAOCULAR LENSES (IOL) 36 MONTHS AFTER CATARACT SURGERY IN FRANCE**
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OBJECTIVES: The aim of this study was to compare the 36-month Nd-Yag laser (a technique of posterior capsular opacification, the most frequent complication of cataract surgery) incidence rate of three monofocal IOLs: Acrysof SN60WF (Alcon), Akreos AO-MI-60 (Baush & Lomb) and Hoya YA-608B (Hoya). METHODS: This is a retrospective study conducted at 3 French sites. Each centre implanted at least two of the above IOls. Patients had to have uncomplicated cataract surgery with at least 2 years of follow-up. Patients implanted with one of the above IOls were picked up at random from the surgery theatre registry. Medical data were retrieved from patient charts. 36-months post surgical data were obtained from the surgeon’s medical record and anterior/posterior ophthalmologic examination performed in post-surgery. Time to Nd-Yag laser analysis was carried out using Kaplan-Meier survival curves. Confounding variable imbalances were adjusted with a stepwise Cox model. The statistical unit is the eye. RESULTS: 126 eyes were implanted with Acrysof, 89 with Akreos and 85 with Hoya. Patients with Acrysof were younger than Hoya and Akreos groups (P = 0.0005). The results remained unchanged when the analysis was re-
stricted to the events occurring during the first 36 months (HR = 2.20; P = 0.0005, HR = 3.67; P = 0.0001, respectively). Adjusting for confounding variable imbalances did not change the results. CONCLUSIONS: This analysis conducted at 36 months suggests that following usual surgical practice, Acrysof eyes had significantly less Nd-Yag laser capsulotomy than those implanted with Hoya and Akreos. Conse-
sequently, Acrysof eyes were less exposed to Nd-Yag laser complications and ex-
perienced lower post-surgical treatment costs.