randomised trials: RAVEL (largely patients with narrow vessels), and E-SIRIUS and SIRIUS (largely patients with long lesions). Resource costs of the initial procedures and all subsequent events were taken from NHS Reference Costs; manufacturers’ list prices were used for the devices. A utility decrement, based on EQ-5D data collected in an earlier stent trial, was included for further revascularisation based on the expected duration of symptoms prior to re-treatment. Cost-effectiveness is reported in terms of the incremental cost per additional QALY, and cost-effectiveness acceptability curves are reported showing the probability of DES being the more cost-effective at particular threshold values for an additional QALY. RESULTS: Based on clinical data from RAVEL the cost per QALY was £30,400. The corresponding results for SIRIUS and E-SIRIUS were £10,500 and £4,950, respectively. Sensitivity analysis showed that when the clinically similar mortality rates observed in the trials were incorporated into the model, they had a major impact on mean cost-effectiveness but increased uncertainty. CONCLUSIONS: The incremental cost per QALY of DES, relative to bare metal stent, was consistently below £35,000 for all sub-groups. There was considerable uncertainty surrounding cost-effectiveness suggesting additional research may be appropriate.

**CV4**

**LOWER CARDIOVASCULAR RISK ASSOCIATED WITH PIOGLITAZONE MONOTHERAPY COMPARED TO INSULIN MONOTHERAPY: A RETROSPECTIVE PROPENSITY SCORE MATCHED COHORT STUDY**

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OBJECTIVE: To investigate the cardiovascular risk associated with pioglitazone monotherapy as compared to insulin monotherapy in a large retrospective database. METHOD: Patients ≥ 18 years of age with a diagnosis of type-2 diabetes and initiated with pioglitazone or insulin monotherapy for at least 6 months with no cardiovascular events reported at baseline were selected from GE Medical Systems (GEMS) database of electronic medical records from physicians. Patients prescribed other oral anti-diabetic drugs were excluded. Cardiovascular events included one or more of the following forms of coronary artery disease: myocardial infarction, angina pectoris, unstable angina, other ischemic heart disease and surgical procedures of coronary artery bypass and angioplasty, and congestive heart failure. To avoid selection bias, patients were matched 1:1 on pioglitazone and insulin using propensity scores. Baseline demographics and clinical characteristics such as duration of disease, co-morbidities, medical therapies, and duration of treatment were included in the propensity score analysis. Logistic regression was used to calculate the odds ratio of the cardiovascular event in the follow-up period with treatment as the factor and significant (p < 0.1) baseline characteristics as the adjusting covariates in the model. RESULTS: A total of 381 patients on pioglitazone monotherapy were compared with an equal number of patients on insulin monotherapy. The crude cardiovascular event rate in the pioglitazone group was 1.84% compared with 9.71% in the insulin group (p < 0.001). The hazard ratio was 0.174 for pioglitazone (95% CI = 0.077, 0.396; p < 0.001). The significant risk reduction projected for the pioglitazone group could not be completely explained by baseline laboratory measurements of lipids, serum creatinine, systolic and diastolic blood pressure, or duration of diabetes. CONCLUSION: In a retrospective propensity-matched cohort analysis in patients with type-2 diabetes, patients treated with pioglitazone monotherapy had a significantly lower incidence of cardiovascular events than those taking insulin monotherapy.

**CANCER**

**THE STATE OF THE SCIENCE OF HRQOL ASSESSMENT IN CANCER: FINDINGS FROM THE CANCER OUTCOMES MEASUREMENT WORKING GROUP**

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OBJECTIVE: To assess the state of the science of HRQOL assessment in cancer. METHODS: The US National Cancer Institute formed the Cancer Outcomes Measurement Working Group (COMWG) made up of 35 leading experts in the field to review the state of the science of assessing three outcomes (HRQOL, patient satisfaction, economic burden) in four cancers (breast, prostate, lung, colorectal) across the continuum of care (screening/prevention, treatment, survivorship, end of life). In this presentation, the findings of the COMWG are evaluated using the Medical Outcomes Trust Instrument Review Criteria. RESULTS: The results are as follows: 1) There is currently no consensus definition or conceptual model for HRQOL; developing a stronger theoretical base would improve HRQOL measurement and interpretation; 2) While there are now well-validated HRQOL instruments, validity can be further enhanced by an integrated application of the tools from modern psychometrics—especially item response theory (IRT) modeling—survey research, and cognitive psychology; 3) A number of instruments demonstrate adequate internal reliability according to classical test theory, but reliability could be evaluated more precisely at different points along the HRQOL continuum using IRT approaches; 4) Interpretation of HRQOL findings has benefited from recent research on defining and identifying clinically important differences in instrument scores; both anchor-based and distribution-based approaches suggest changes of about 7% of a scale’s breadth are important to patients and clinicians; 5) Responsiveness of a measure is demonstrated when it is shown to detect statistically significant differences in HRQOL also large enough to be clinically important; 6) While current measurement techniques have generally proven feasible and acceptable, IRT-based computer adaptive testing may significantly decrease respondent burden without sacrificing precision; and 7) For cross-cultural assessment of HRQOL, several instruments currently meet minimum criteria. CONCLUSIONS: The current state of the science of HRQOL assessment in cancer is strong. Further development of a theoretical base and use of modern analytic techniques, including IRT, will accelerate progress.

**CN2**

**7215 COST-EFFECTIVENESS OF DIAGNOSTIC, STAGING, AND TREATMENT OPTIONS FOR MELANOMA**

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OBJECTIVES: Given the dramatic increase in the incidence of melanoma worldwide, accurate assessment of the economic value of staging and treatment options for melanoma is critically needed to guide policy making. METHODS: Cost-effectiveness (CE) evaluations published between 1990 and 2003 of diagnostic procedures and treatments of melanoma were identified via systematic searches of MEDLINE® and conference proceedings. Costs and CE ratios presented in each study were updated to