PSY10

A NOVEL APPROACH TO ADJUST FOR THE IMPACT ON SURVIVAL RESULTING FROM PATIENT CROSS-OVER FROM CONTROL TO EXPERIMENTAL TREATMENT IN CLINICAL TRIALS

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OBJECTIVE: Clinical trials are often the best source of efficacy data for economic evaluations of medical interventions. However, their reliability can be compromised when patients cross-over from control to experimental treatment. In two trials evaluating lenalidomide (Len) plus high-dose dexamethasone (Dex) vs Dex alone (MM-009/010) in patients with multiple myeloma (MM), 47% of patients in the Dex alone group were switched to Len +/– Dex at disease progression or following study unblinding. Given the significant efficacy benefits of Len + Dex over Dex alone, the trial data will overestimate the survival with Dex alone biasing the results. **METHODS:** External data from the UK Medical Research Council (MRC) MM-IV, V, VI, and VIII trials enrolled between 1980 and 1997 were used to derive an equation reflecting survival without lenalidomide, including prognostic variables to enable adjustment for differences between the MRC and MM-009/010 trials. Applying the MRC equation to the MM-009/010 Dex patient characteristics yielded expected median survival time without cross-over to Len +/– Dex. This was used to calibrate the economic model for the Dex alone group by correcting the scale parameter of the underlying Weibull survival equation, estimated from MM-009/010, assuming the shape parameter remained the same. **RESULTS:** Of 873 MRC patients, 826 died. Exponential survival fit the data, with age, MM performance status, M-protein level, B2M level and time to progression as predictors. Applied to MM-009/010 Dex patient characteristics, this yielded a median survival of 14.9 months (95%CI: 12.3–18.0) (compared to 31 months (95%CI: 25.7–35.1) observed with cross-over in MM-009/010). Incorporating the corrected survival function into the economic model resulted in an estimated incremental 2.8 life-years and 1.9 QALYs gained per patient treated with Len + Dex vs Dex alone. **CONCLUSION:** Using external data to adjust estimation equations can mitigate the impact on economic evaluations resulting from cross-over or other distorting factors in clinical trials.

PSY11

EVALUATION OF ACETAMINOPHEN EXPOSURES REPORTED TO A REGIONAL POISON CONTROL CENTER FOR ADULT PATIENTS

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OBJECTIVE: To describe patient characteristics, doses taken, reason for exposure, time of exposure, treatment and severity of poisoning in adults with acetaminophen-related exposures reported to a regional poison control center (RPCC). **METHODS:** A retrospective review was conducted of all acetaminophen exposures that occurred between October 31, 2000 and October 31, 2003 in adults over 18 years of age who were managed by a RPCC. Data collected included patient demographics, amount ingested, severity of exposure, time since exposure, treatment, reason for exposures, exposure site, and caller site. **RESULTS:** There were 175 exposures to acetaminophen; 72% were females and 28% were males in the study population. There was no significant difference between the mean age of females (31.2 ± 14.0) and males (30.9 ±12.3) in years. The mean dose of acetaminophen taken was 18.7 ± 20.4 grams and no significant difference in the amount ingested between males and females. The majority of the callers seeking information on acetaminophen ingestion were health care professionals (68%). The mean time between the exposure and the call made to the RPCC was 11.27 ± 18.54 hours. Fifty percent of the patients received acetylcysteine therapy, 27.4% received decontamination (e.g., activated charcoal), and 22.3% received other interventions for the treatment of acetaminophen poisoning. Females (72.4%) were more likely (p < 0.001) to take intentional overdoses than males (27.6%). The most common acetaminophen exposure site was patient's own residence (96%). The majority of the exposures were acute (86.9%) rather than chronic poisoning. **CONCLUSION:** The main reason for acetaminophen exposure was intentional and females were more likely to ingest intentionally than males. Contacting the RPCC for advice generally occurred beyond the time for optimal acetylcysteine effectiveness. The majority of the exposures were due to acute poisoning.

SYSTEMIC DISORDERS/CONDITIONS—Cost Studies

PSY12

PROJECTED COST OF CARDIOMETABOLIC RISK FACTORS IN COMMERCIALLY INSURED NORMAL AND OVERWEIGHT PRIMARY CARE PATIENTS

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OBJECTIVE: To determine the economic impact of increased prevalence of cardiometabolic risk (CMR) factors including high blood pressure (BP), loss of glycemic control (DB), high triglycerides (TG) and decreased high density lipoproteins (HDL) in commercially insured overweight patients [Body Mass Index (BMI) > 27 kg/m2] compared to normal weight (18 ≥ BMI < 27 kg/m2). **METHODS:** Patients 18–65 years old were identified from an electronic medical record database (EMR) with CMR factors designated by prescription orders or ICD-9 codes and grouped into normal or overweight categories. Similar patients with CMR factors were identified in Medstat MarketScan® administrative claims database. Using a multivariate two-part regression model, costs from this database were estimated for CMR factors. Probabilities of being normal or overweight from the EMR database were applied to the estimated costs to obtain per patient total annual medical costs for CMR factors stratified by normal and overweight groups. **RESULTS:** A total of 75,578 patients with CMR factors were identified in the EMR. Normal [18,213 (24%)] versus overweight patients [57,365 (76%)] were distributed as follows: BP, 29% vs. 71%; DB, 19% vs. 81%; TG, 25% vs. 75%; HDL, 37% vs. 63%; any 2 CMR factors, 13% vs. 87%; any 3 CMR factors, 9% vs. 91%; and all 4 CMR factors, 6% vs. 94%. Estimated costs from the claims database were: high BP, $1630; DB, $1748; high TG's, $638; low HDL, $1474; and $2606, $2801, $3191 for 2, 3, and 4 CMR factors, respectively. Applying the probability of normal or overweight and the estimated costs to the distribution of CMR factors resulted in an

increased projected annual cost of $998 per overweight person with CMR factors. **CONCLUSION:** CMR factors are more prevalent and lead to significantly greater costs in an overweight population. Weight loss interventions of overweight patients may potentially decrease CMR factors and their associated costs.

PSY13

THE HEALTH CARE COST EFFECTS OF DIABETES AMONG OBESE AND MORBIDLY OBESE ADULTS IN THE UNITED STATES

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OBJECTIVE: To determine the extent to which diabetes among obese and morbidly obese subjects affects health care costs, and to determine whether obesity and morbid obesity remain predictors of health care costs after controlling for diabetes. **METHODS:** Data from the Medical Expenditure Panel Survey (MEPS) for 2000–2004 are examined. Multivariate models are estimated to predict the probability of incurring any health care costs and health care costs incurred. These models include obesity and morbid obesity, diabetes, age, education, occupation category and race. Models are estimated separately by gender. Estimates of out-of-pocket, insurer, and total costs are obtained. Both per capita and national aggregate cost estimates are obtained. **RESULTS:** Both out-of-pocket costs rise dramatically among obese and morbidly obese subjects who are diabetic. Relative to healthy weight individuals, out-of-pocket costs for obese diabetics increase by $1002 per annum for females and $1051 for males. The cost increases are even greater among morbidly obese diabetics—$1551 for females and $1555 for males. Insurer costs increase for obese diabetics are $3897 for females and $3651 for males. Among morbidly obese diabetics, these cost increases total $7302 for females and $8008 for males. The aggregate out-of-pocket costs of obesity total $9.7 billion, of which $8.2 billion, or 85%, are incurred by obese or morbidly obese diabetics. Aggregate costs to insurers total $56.3 billion, of which $32.2 billion, or 57%, are due to obese or morbidly obese diabetics. **CONCLUSION:** Obese and morbidly obese diabetics account for a disproportionate share of health care costs among the obese population as a whole. Efforts to prevent diabetes in this population and to reduce diabetes among obese and morbidly obese individuals will lead to very substantial cost savings to insurers and consumers.

PSY14

ECONOMIC EVALUATION OF LENOLIDOMIDE USE FOR MULTIPLE MYELOMA IN SCOTLAND IN PATIENTS WHO HAVE RECEIVED ONE PRIOR THERAPY

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OBJECTIVE: Lenalidomide in combination with high-dose dexamethasone (Len + Dex), yields improved time to progression (TTP) and survival compared to high-dose dexamethasone alone (Dex). This study aimed to estimate long-term health and cost consequences of Len + Dex versus Dex in Scottish patients with multiple myeloma (MM) who have received one prior therapy. **METHODS:** A discrete event simulation of a patient's course following initiation of Len + Dex or Dex was developed. The model uses patient's response (complete, partial, stable disease or progressive disease) and estimates corresponding TTP and subsequent survival based on Weibull functions derived from pooled data from two Phase III randomized clinical trials and long-term outcomes of UK Medical Research Council MM trials. Adverse events and disease management costs are included. Utility by response level was obtained from literature. Patients remain on treatment until relapse. Disease management costs reflect clinical practice in Scotland. Costs and health outcomes are discounted at 3.5% per annum. In the base case, events and costs are considered over two years reflecting trial follow-up (survival is modeled until death). 1000 patients are simulated per analysis. Univariate sensitivity analyses are performed around key model parameters. **RESULTS:** The modeled median TTP is conservative with Len + Dex at 13.5 months compared with 4.7 months with Dex. This translates to QALY gains: 3.19 vs 1.39. Totals costs with Len + Dex were £56,155 compared to £3819 with Dex, leading to an incremental cost-effectiveness ratio of £28,980 per QALY. Sensitivity analyses showed that outcomes remain consistent through broad changes in key parameters. **CONCLUSION:** Lenalidomide delivers significant improvements in quality-adjusted survival in a life-limiting orphan disease and yields an estimated incremental cost per QALY which falls within a cost-effective range.

PSY15

COST-EFFECTIVENESS OF ERYTHROPOIESIS STIMULATING AGENT THERAPY BY HEMOGLOBIN TARGETS IN CHRONIC KIDNEY DISEASE

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OBJECTIVE: To evaluate the cost-effectiveness of Erythropoiesis Stimulating Agent (ESA) therapy by hemoglobin (Hb) targets (Hb < 10, 10–11, 11–12, 12–13, and >13 g/dL) in Chronic Kidney Disease (CKD) considering the complication of cardiovascular diseases (CVD). **METHODS:** Two lifetime decision analyses models for hemodialysis and pre-dialysis patients using backward induction method were developed using parameter values from published literatures and 2006 United States Renal Data System. Direct costs (anemia medication (erythopoietin or darbepoetin), hemodialysis and CVD treatment) and indirect costs (patient and caregiver time cost) were measured in 2006 US Dollars. Effectiveness was measured as quality-adjusted life years (QALYs). All costs and QALYs were discounted at 3% and cost-effectiveness was measured as incremental cost per QALYs gained (ICER). Uncertainty was evaluated using one way sensitivity analyses and threshold analyses. **RESULTS:** For hemodialysis patients who initiated treatment at age 45, higher hemoglobin targets yielded favorable ICERs ($20,050, $90,387, $67,199 and $11,216 for Hb 10–11 compared to Hb < 10, Hb 11–12 compared to Hb 10–11, Hb 12–13 compared to Hb 11–12, and Hb > 13 compared to Hb 12–13, respectively). For pre-dialysis patients, Hb 11–12 and Hb 12–13 were dominant strategies compared to Hb 10–11 and Hb 11–12, and ICER for Hb 12–13 compared to Hb > 13 was $2404. The results were more favorable for older patients and darbepoetin treatment. Results were robust to sensitivity analyses in pre-dialysis model, but sensitive to the CVD probabilities and erythropoietin costs in hemodialysis model. **CONCLUSION:** Anemia treatment with ESA therapy was cost effective even in Hb > 13 for hemodialysis patients using a threshold of ICER $120,000 compared to Hb 12–13. For pre-dialysis patients, treatment to Hb 12–13 was the most cost effective. These results showed that higher treatment targets compared to current national guidelines (maintaining Hb 11–12, not exceeding 13) are associated with favorable cost-effectiveness ratios. This is consistent with Medicare's revised payment policies for ESA treatment.