EXPERT SURVEY FOR INCREMENTAL COST-EFFECTIVENESS RATIO (ICER) THRESHOLD RANGE IN KOREA: DISCRETE CHOICE EXPERIMENTS

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OBJECTIVES: This study was performed to elicit ICER threshold range in Korea and to investigate the magnitude of relative influence of main attributes to reimbursement decision. METHODS: This study was based on experts survey using discrete choice experiments (DCE). DCE is stated preference method, in which respondents are requested to express preferences for sets of hypothetical choice alternatives constructed according to experimental design principles. Total 39 respondents (22 from the government, 17 from industry) were responded to this survey among 95 selected experts who were working in pharmacoeconomics field. We identified 6 attributes (disease severity, availability of alternative therapy, burden of disease, ICER, uncertainty of cost-effectiveness ratio and budget impact) which are considered as main decision factors for reimbursement decision. Literatures related to reimburse- ment decision in Australia, UK, Canada and Korea were comprehensively investigated to elicit these attributes. 18 choice sets having two alternatives were selected using fractional factorial design (FFD). Each coefficient of 6 attributes and probabilities of a recommendation response by ICER range were estimated. RESULTS: Total 1346 observations were analyzed using probe model. 4 attributes (severity, burden, alterna- tive, ICER) significantly influenced on respondents’ choice on reimbursement decision (p < 0.010). If the disease is severe and rare, the probability of recommending the alternative therapy is higher. The lower ICER, the higher the probability of choosing the alternatives. ICER range threshold from survey results is 70,000,000 KRW approximately. Industry group were excluded in the analysis, the figure reduced to 40,000,000 KRW. CONCLUSIONS: This study showed that severity, burden, alternative, ICER is important factor for reimbursement decision in Korea as well expected. The ICER threshold estimated from this study between the estimators from previous studies. The study design and respondent characteristics could affect these figures.

IMPACT OF MISSING DATA ON POTENTIAL CONFIDENTIORS IN PERINATAL PHARMACOEPIDEMIOLOGICAL STUDIES USING ADMINISTRATIVE DATABASES

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OBJECTIVES: Administrative databases are increasingly being used in perinatal phar- macoepidemiological studies. Although such studies have increased statistical power, they are prone to biases due to lack of information on potential confounders. Hence, the objective was to quantify the degree of bias introduced by the lack of data on smoking status and maternal pre-pregnancy weight in the association between gestational exposure to antidepressants and the risk of low birth weight (LBW) infants.

METHODS: The Quebec Pregnancy Registry was used to sample a cohort of women who had delivered a liveborn singleton, and answered a self-administered question- naire on lifestyles during pregnancy and family history. The association between antidepressant use during pregnancy and the risk of LBW was calculated using the questionnaire data. Percent bias in the Registry estimate was calculated using Shmerson’s method. RESULTS: Overall, the unadjusted estimate (Regis- try) of the association between antidepressant use during pregnancy and the risk of LBW was 1.16 (p < 0.05). Adjusting for smoking status resulted in an estimate of 0.99 (p > 0.05), and for maternal pre-pregnancy weight, 1.19 (p < 0.05). The percent bias introduced by the non-adjustment for smoking and maternal pre-pregnancy weight during only the Registry data was 13%, and did not change the direction of the effect. CONCLUSIONS: Although data on potential confounders are often missing in perinatal pharmacoepidemiological studies using administrative databases, the bias that results for the non-adjustment does not necessarily invalidate findings.

HOW TO GAIN HIGH DATA QUALITY IN A NON-INTERVENTIONAL TRIAL USING THE LIVE-COM STUDY AS EXAMPLE

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OBJECTIVES: The increasing scientificness and complexity of non-interventional studies is facing new operational and quality management aspects to gain high level quality data and results. Therefore it is crucial to implement quality measurements as part of the overall study design. METHODS: A non-interventional, comparative multicenter, representative cross sectional cost evaluation study was conducted (LIVE- COM). The study was prospecively, documented and the observation data was used retrospectively. Documentation, reporting and verification of data were performed in order to improve the quality of the study. Baseline data was analyzed for mean, min and max values and compared to 2000, the base year. The number of claims was compared to the number of actual treatments. The difference of the actual and expected claims was calculated. RESULTS: The concept has been validated using detailed data from the German Association of Research-Based Pharmaceutical Companies and according to Good Epidemiological Practice. A detailed study plan, containing scientific objectives and statistical methods was developed before start of study and approved by the responsible Ethics Committee. In addition a feasibility assessment of the case record forms and PRO-instruments was performed in advance. A total of 4000 randomly selected primary care units were invited to participate in LIVE-COM. Throughout the study a close telephone monitor- ing with the sites was implemented, also to ensure the collection of the PRO data from the patient. A detailed in-house review of the case record forms, double data entry, cross calulations and source data verification at 10% of the sites was implemented.

RESULTS: In total 1731 patients with signed informed consent were included in the study at 138 study centres in Germany. Overall only 1.3% of the documented patient data showed missing values and the validity of the data was high. Only in rare cases imputation algorithms were applied or data were excluded from analyses. CONCLU- SION: The implementation of data quality management procedures and close contact with the study sites can deliver high quality data comparable to clinical studies. 1Long Acting Insulin Glargine Versus Insulin Detemir Cost Evaluation Comparison.
testing vaccination strategies. One of the main benefits is that for parameterization and identification no abstract values are used, so objectivity and traceability are assured.

**PMC13**

**CRITICAL REVIEW OF ECONOMIC MODELS IN TYPE 2 DIABETES** Yi Y1, Bergman R1, Burton LT2, Philips Z1

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OBJECTIVES: To identify and critically appraise cost-effectiveness models developed to model type 2 diabetes (T2D) treatments and to assess which types of treatment effects they capture. METHODS: A systematic search was performed in MEDLINE, EMBASE, Centre for Reviews and Dissemination databases at the University of York, and Health Economic Evaluation Database for the period to September 2008. The websites of Health Technology Assessment (HTA) bodies in different countries were also screened for relevant models. For each of the identified original models, details of the structure, data in- and outputs and consistency were extracted and critically appraised using published criteria. RESULTS: 78 articles and 41 HTAs reporting relevant economic evaluations were identified. There were ten models with multiple publications, and a further ten models with one associated publication. The critical review demonstrated that most of the existing models had the same fundamental structure, used similar microsimulation techniques and were based on the same key data sources. However, the process for identification of relevant data and their synthesis, as well as the selection of outcomes was, at times, inconsistent and lacked transparency. The models differed according to which diabetes complications and treatment-related adverse events were captured. For example, just one model incorporated changes in patient weight, despite the fact that weight gain can be a side effect of some treatments, and weight loss a potential benefit of others. CONCLUSIONS: Whilst many economic models exist in T2D, most share common features such as the model type. Identified shortcomings are lack of transparency in data identification and evidence synthesis as well as the selection of the modelled outcomes. Future models should aim to include all relevant treatment outcomes, whether these relate to effects on underlying diabetes and its complications or to short- or long-term side effects of treatment.

**PMC14**

**SEROTYPE-SPECIFIC TRANSMISSION DYNAMICS OF INVASIVE PNEUMOCOCCAL DISEASE AFTER VACCINATION WITH 7-VALENT PNEUMOCOCCAL CONJUGATE VACCINE** Snedecor SS1, Botzemian PM2, Strutton DR3

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OBJECTIVES: After the introduction of the 7-valent pneumococcal conjugate vaccine (Prevnar®) in the US, the incidence of invasive pneumococcal disease (IPD) caused by the 7 vaccine serotypes declined dramatically in vaccinated children as well as unvaccinated adults (via herd effect benefit). In 2008, a transmission dynamic equation model was developed to capture direct and indirect vaccination effects. This model accurately predicted the total incidence of IPD (caused by all serotypes) after Prevnar® introduction. This original model was refined in the present analysis to predict the dynamics of IPD caused by specific serotypes. METHODS: The model simulates the acquisition of asymptomatic carriage of pneumococci and the development of non-fatal and non-fatal IPD among vaccinated and unvaccinated individuals aged 2–4, 5–17, 18–64, 65–95, and > 65 years old. Categories of pneumococcal serotypes include PCV7-type (4, 6B, 9V, 14, 18C, 19F, and 23F) and non-PCV7-type (all other serotypes). The model was calibrated by approximating serotype-specific US IPD surveillance data from the years 1998–2008. RESULTS: The previous model structure fit the disease incidence caused by the PCV7 serotypes quite well, but was inadequate to predict increases in disease caused by the non-PCV7 serotypes due to serotype replacement. Additionally, the surveillance data showed limited increase in IPD caused by non-PCV7 serotypes in the vaccinated <2-year-old group. A subsequent recalculation and reformulation resulted in a revised model able to replicate closely the observed IPD incidence stratified by pneumococcal serotypes. CONCLUSIONS: The revised model validates the accuracy of the original model to replicate the incidence of IPD caused by PCV7 serotypes and may be used to predict the future incidence of disease given the increases in IPD caused by non-PCV7 serotypes.

**PMC15**

**SCHIZOPHRENIA MODELING: MARKOV MODEL WITH MONTE-CARLO MICROSIMULATION** Dragomir A1, Angers JF1, Tarride JE2, Rouleau G1, Drapeau P1, Perreault S1

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Pharmacological strategies for schizophrenia have received increasing attention due to the development of new and costly drug therapies. Evaluating their relative costs and benefits in Canada requires modeling the natural course of schizophrenia. OBJECTIVES: To develop a Markov model with 1st-order Monte-Carlo simulations to simulate the natural course of newly diagnosed schizophrenic patients. METHODS: Six disease states were defined the Markov model; 1) first episode—FE; 2) low dependency state—LDs; 3) high dependency state—HDs; 4) Stable; 5) Well; and 6) Death. Patients’ movements between these disease states defined 17 probability transition to be estimated. The model was based on data from the Régie de l’assurance maladie du Québec and Med-Echo databases. All individuals aged 0-60 years with a newly diagnosed of schizophrenia between 1998 to 2006 were first identified by ICD-9 codes. Using this data, 5 Cox proportional hazard models for competing risks were used to estimate the 17 probabilities of transition. Validation was conducted by comparing the model’s probability transition’s predictions with the published literature. RESULTS: A total of 12,754 individuals were identified as newly diagnosed patients with schizophrenia. After the FE of schizophrenia, 69.8% of patients passed in LDS, 11.2% in HDs, 1% in death state and 18% in Well state. The mean transition probabilities after one year of follow-up were: FE to Well at 0.28 (SE = 0.10), FE to HDs at 0.01 (0.05), FE to LDS at 0.01 (0.08) and respectively FE to death at 0.01 (0.01). The corresponding values were similar to those obtained from other published models. CONCLUSIONS: This model is the first Canadian model incorporating transition probabilities adjusted for individual risk factors profiles using Canadian data. Future applications will include pricing and cost-effectiveness of new therapies for schizophrenia.

**PMC16**

**CREATING NATIONAL WEIGHTS FOR PRIVATE INSURANCE DATABASE** Baser O1, Wang L2

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OBJECTIVES: To create national weights to project a private database to the US insured population controlling not only for socio-demographic factors but also health status. METHODS: The Medicare Expenditure Survey was used as the basis of adjustment methodology. First, we subset the data source to the study population, then used multidrug logistic regression to estimate the odds of having coverage and having the weights that were applied to make the data similar to the national sample. Propensity Score Matching and Raking algorithm is combined to create the adjusted weights. The socioeconomic characteristics included in the model were the age of the head of the household, percentage of the patients who were female, race, geographic region and income level. We derived two variables to capture general health status of the member. First, Charison Index scores were generated to capture the level and burden of comorbidity. Secondly, we created an indicator variable to represent patients with chronic conditions. This variable was derived by convening two physician panel databases. Medical conditions reported by the survey sample. RESULTS: Private data were more likely to be male, white, older, and chronic (p = 0.0000). Adjusted weight values for the Commercial group ranged from 13.47 to 26.39 with median 16.35. The projected US population by private database and MEPS data were similar in terms of socio-demographic and clinical characteristics. As an outcomes measure, the predicted annual statin users from private data was 6,973,034. Statin users are predicted as 6,709,438 using MEPS data with MEPS weights. CONCLUSIONS: National projection of a private database requires adjustment from not only demographic factors but also case-mix differences related to health status. The created weights successfully balanced the population in terms of co-morbid conditions and chronic conditions as well as demographic factors.

**PMC17**

**COMPARISON OF RISK ADJUSTMENT MODELS IN OUTCOMES** Basei O1, Gint C1, Dysinger A1, Yuce H1, Akin C1, Wang L2

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OBJECTIVES: Matching and regression analysis are two approaches to estimate average treatment effect. Different matching techniques provide different results. Moreover, matching cannot control for unobserved bias. Using PropChoice algorithm and Rosenbaum bounding approach, we aim to show how to choose strongly unmixed variable must influence the selection process to undermine the implication of matching and regression analysis. METHODS: The Surveillance, Epidemiology, and End Results (SEER) Data is used for the analysis. For each patient, their hospital of care and associated hospital volume is computed. Patients in the high and low volume hospitals are matched in seven different ways in terms of demographic and clinical characteristics. Treatment costs are compared. The best technique is chosen by PropChoice algorithm. Rosenbaum bounds estimated and Mantel and Haenszel test statistics is calculated to provide evidence on the degree to which any significance results hinge on some unmeasured assumption. RESULTS: A volume cohort was constructed consisting of 19,375 female SEER-Medicare patients, aged 65+, suffering in an site and/or invasive breast cancer during 2003–2005 with surgical treatment performed at 567 hospitals. Mahalobis matching is the one who created the best balanced comparable sets. After the matching, samples were similar in terms of race, comorbidity and adjudnant therapies. Under the assumption of no hidden bias, costs were lower of the high volume hospitals. (p = 0.0000). Results were insensitive to a bias that would double the odds of being treated high volume hospitals but sensitive to a bias that would triple the odds. CONCLUSIONS: There exist several matching techniques and the results depend the type of matching chosen. One needs to choose the technique best suitable for the data. Rosenbaum bonds provides evidence on sensitivity of the estimated results with respect to unobservable factors that is not controlled by propensity score matching.

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