The cohort included 33,951 individuals. We found it surprising how much risk of death healthy individuals have. To measure utility (predictive) prior odds to optimize the posterior risk of death for even mild MS improvements and accepted more risk for severe MS and greater disease improvements. The lowest mean score was for mild MS improvement (0.082; 95% CI [0.045-0.120]). The highest score was for substantial MS improvement given severe MS (0.382; 95% CI [0.295-0.469]). Only education significantly affected utility for mild improvement in mild MS (p = 0.03). Individuals with bachelor’s degree or less had 7.7% higher score than post-graduates.

CONCLUSIONS: We found it surprising how much risk of death healthy individuals were willing to accept (8–38%). This is much greater than the 1/1000 actual risk for natalizumab in MS treatment, which the FDA removed from the market. MS patients voiced preferences helped get that drug back on the market, showing importance of shared health decision-making. The FDA and physicians might find it difficult to approve or prescribe drugs with 38% risk of death. However, these preferences indicate that healthy individuals may be less risk-averse than the FDA or physicians, emphasizing the importance of including the public when weighing risks and benefits of drugs.

**R2A**

**RISK OF DIABETES ASSOCIATED WITH THE USE OF ATYPICAL ANTIpsychotics IN CHILDREN AND ADOLESCENTS: A TEXAS MEDICARE STUDY**

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OBJECTIVES: To examine the risk of developing diabetes among children and adolescents who received atypical antipsychotic drug. MEIHDS: This study is a retrospective cohort analysis using 2003-2004 Texas Medicaid claims data. Patients were included in the cohort if they met the following criteria: 6 to 18 years of age, new users of atypical antipsychotics and had not received a diagnosis of diabetes (ICD-9-CM code: 250.xx) or a prescription claim of an anti-diabetic drug both before and one month after the initiation of an antipsychotic treatment. Risk of newly developed diabetes following antipsychotic treatment was observed during a 1 month follow-up period. Kaplan-Meier survival curves and Cox proportional-hazards regression model were employed to examine the time dependent risk (hazard) of diabetes and hazards ratios were obtained. Age, gender, race and exposure to other diabetogenic medications were included in the analysis. RESULTS: A total of 40% patients were identified as new atypical antipsychotic users. The average age of the cohort was 11 years, most of the patients were male (65%), and Hispanics (36.5%). Cox-proportional hazard model analysis revealed no significant association between use of atypical antipsychotics and risk of diabetes (Hazard Ratios = 1.11, 95% CI = 0.81-1.53). Children in the older age group of 15-18 years, females and Hispanics had higher risk of developing diabetes. Concurrent treatments with corticosteroids, beta-blockers, thiazides and antiprerenals were also associated with increased incidence of diabetes.

CONCLUSIONS: Our results indicate that there is no increase in the risk of developing diabetes in pediatric patients receiving atypical antipsychotics. The discrepancy in the findings between adults and children implies that psychotropic medications might function differently in pediatric population from adults. It is necessary to comprehensively assess the risks associated with common off-label medications, such as atypical antipsychotics, in children and adolescents.

**R3A**

**A BAYESIAN DECISION-ANALYTIC ECONOMIC MODEL TO OPTIMIZE ALLOCATION OF RISK IN PAY-FOR-PERFORMANCE PAYMENT ARRANGEMENTS**

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OBJECTIVES: Performance-based payment arrangements for innovative drugs seek to allocate financial risk of interventions between manufacturers and payers. Given operational challenges in monitoring real-world outcomes, effective risk sharing mechanisms may require precision of incremental survival/value-adjusted life years (QALYs) conditional on surrogate markers, for example, complete remission (CR) or partial remission (PR). In accepting a risk-sharing arrangement that reimburses only for remitters, payers should minimize the “false-positive” (FP) risk: early remitters who subsequently have limited QALYs. Manufacturers should minimize the “false-negative” (FN) risk: early non-remitters who subsequently have prolonged QALYs.

A Bayesian decision framework can be used to choose among multiple likelihood (predictive) priors to optimize the posterior economic risk trade-off for payers and manufacturers. METHODS: A Bayesian decision-analytic, hypothetical data-based, cost-effectiveness model was developed. Prior probabilities and QALYs were assigned for CR, PR, and 1-month survival, assuming treatment costs. A plausible prior likelihood (predictive) structure represented the ROC relationship between the sensitivity and specificity of CR/PR in predicting survival. Expected (posterior) probabilities of survival, conditional on CR/PR, were generated. At a threshold of $10,000/QALY, the cost-effectiveness of the intervention, conditional on achieving CR/PR, and an optimal sensitivity-specificity trade-off was derived. RESULTS: At a hypothetical treatment cost of $5,000/month for a 4-month cycle, a minimal FP of 13% (maximum specificity of 87%) and a minimal FN of 33% (maximum sensitivity of 67%) emerged as necessary (predictive) priors. Some payers and manufacturers respectively to ensure viable risk-sharing. At higher sensitivity, payer risk did not meet the reimbursement threshold, while at higher specificity, manufacturers would assume excessive financial risk. Other illustrations will be discussed. CONCLUSIONS: Manufacturers should propose evidence-based payment arrangements that utilize clinical trial data to develop economic implications of being at various points on the ROC curve in order to optimize the trade-offs between payer and manufacturer incentives.