were conducted using a leading PBM's research sample that contains prescription claims from 3.9 million beneficiaries. Continuously eligibles for 1997 and 1998 were included. A mapping algorithm was developed to link each of 27 diseases with their corresponding medication classes using Standard Therapeutic Class and/or Hierarchical Ingredient Code List codes. A weight system was developed based on relative costs derived using multivariate regression. The second-year drug costs were predicted based on the first-year demographic and CDS scores. To assess the accuracy of the prediction models, a random split-sample method was applied. **RESULTS:** The revised CDS was moderately correlated with age ($r = 0.42$) and had a high year to year correlation of 0.83. It performed significantly better in explaining variations in and predicting costs than the demographic model. Adjusted R-Square for fitting was fourfold higher: 0.65 vs. 0.15 for log-transformed costs (0.32 vs. 0.06 for actual dollars). **CONCLUSION:** The revised CDS is better than demographics in explaining the variations in prescription drug costs and predicting the future costs, however further validation work is required. We plan to compare the revised CDS with the old version to determine the incremental improvement in predicting both drug and medical cost.

PMT4

METHODOLOGICAL ISSUES IN ESTIMATING DISEASE PROGRESSION: IS MARKOV MODEL THE BEST METHOD?

Shih YCT[1], Ke XT[2]
[1]MEDTAP International, Bethesda, MD, USA; [2]Department of Health Services Research and Management, Texas Tech University, Health Sciences Center, Lubbock, TX, USA

Markov model is a technique for analyzing events that repeat or extend over a long period of time. It has been widely applied to examine the progressions of disease with well-defined "markers" such as HIV. Most studies using Markov models suffer from a major limitation of the "no-memory" assumption. **OBJECTIVE:** This study uses HIV cases as an example to demonstrate an alternative disease progression model: a history- and duration-dependent transition probability model. **METHODS:** This general transition probability model captures patient's history of disease states (history-dependency) by categorizing HIV patients into three types, stable, progress, and recess, based on whether the patients had the same disease state, a less severe state, or a more severe state at the previous cycle. For patients with a history of "stable" disease states, duration in that state was also included in the model (duration-dependency). Data from the Multicenter AIDS Cohort Study (MACS) was used to model the disease progression of HIV patients in four US cities since 1984. Five disease states were constructed using ranges of the CD4/CD8 ratio as the "marker". They are: >0.63, 0.42–0.63, 0.31–0.42, <0.31, and death. The cycle length is 6 months. **RESULTS:** Compared with estimates obtained from either Markov chain or Markov process models, this general transition probability model yields better prediction of life expectancies and allows more flexibility in modeling the disease progression. **CONCLUSIONS:** By refining the disease progression process, our transition probability model provides a better way to evaluate the effectiveness as well as cost-effectiveness of treatment alternatives and/or impacts from alternative health policies.

PMT5

DEVELOPMENT OF MULTI-LANGUAGE PATIENT OUTCOME ASSESSMENTS

Rentz AM[1], Trudeau E[2], Schmier JK[1], Dubois D[3], Jones R[4], Marquis P[2], Willian MK[4], Revicki DA[1]
[1]Center for Health Outcomes Research, MEDTAP International, Bethesda, MD, USA; [2]MAPI Research Institute, Lyon, France; [3]Janssen Pharmaceutica, Beerse, Belgium; [4]Janssen Pharmaceutica, Titusville, NJ, USA

OBJECTIVES: Inclusion of patient outcome assessments in international clinical trials necessitates that cross-culturally valid instrument data be pooled across countries. Our primary objective is to discuss the development of patient outcome assessments for use in international trials of patients with upper gastrointestinal disorders. **METHODS:** We reviewed the literature and conducted interviews with subjects and clinical experts prior to developing symptom and quality of life (QOL) instruments for patients with upper GI disorders. The instruments were reviewed by clinical experts and cognitive debriefing of subjects was performed. Following these procedures, forward and backward translation of the instruments into twenty languages was performed. **RESULTS:** A total of approximately 120 subjects with gastroesophageal reflux disease, dyspepsia, or gastroparesis and 12 clinical experts from six countries were interviewed to determine symptoms and QOL issues they deemed important. The resulting instruments are the Patient Assessment of Upper GastroIntestinal Disorders-Symptom Severity Index (PAGI-SYM) and Quality of Life Index (PAGI-QOL). The PAGI-SYM contains 37 items and six modules representing heartburn, reflux/regurgitation, nausea/vomiting, abdominal pain/discomfort, bloating/early satiety/fullness and other symptoms. The PAGI-QOL has 49 items divided into two sections, QOL and a general section. The QOL section is comprised of seven modules: daily activities, concentration/sleep, social activities, clothing, diet, relationships, and psychological state/emotions. The general section contains six items measuring severity of GI problems, satisfaction, and relief. **CONCLUSION:** Outcome measures for international trials should undergo comprehensive development and rigorous linguistic validation processes. Initial psychometric testing is currently underway to ensure the instruments will behave appropriately across countries.