

## Abstracts

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and 0.0099 (SE = 0.0085; 90% CI: 0.00002, 0.028) under one of the Beta-based estimators, while other Beta-based estimators produced similar results. Our simulation results revealed substantial advantage of the Beta-based estimators over OLS when the true incremental effect is large, but this advantage dissipates as the incremental effect gets smaller. **CONCLUSIONS:** One and two-part Beta regression models can provide substantial benefits, both in terms of bias and efficiency, over traditional OLS regression in modeling quality of life data such as EQ5D only when the true incremental effects are large but not when they are small. Our case study confirms these conclusions. Further exploration is required to provide definite ranges of incremental effects where alternative methods are to be preferred.

#### CONCEPTUAL PAPERS & RESEARCH ON METHODS – Patient-Reported Outcomes Studies

PMCS1

##### TESTING THE ROLE OF TIME IN AFFECTING THE UNIDIMENSIONALITY IN EQ-5D USING THE 2002–2003 MEDICAL EXPENDITURE PANEL SURVEY (MEPS): A FACETS MODEL APPROACH

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**OBJECTIVES:** To evaluate the measurement property of the EQ-5D and to test the role of time in affecting the unidimensionality in EQ-5D. **METHODS:** We extracted a sample from the two-year panel (2002–2003) in Medical Expenditure Panel Survey (MEPS). Respondents were included if they completed the EQ-5D, were  $\geq 18$  years of age and were diagnosed with any of the top ten most prevalent chronic conditions using ICD-9-CM ( $n = 1428$ ). Data sets using point-in-time were constructed to analyze the EQ-5D 1) cross-sectional two repeated measures for each respondent. For measures and, 2) longitudinal cross-sectional study, we used Rasch rating scale model. For longitudinal analysis, we applied FACETS model by parameterizing time with the hypothesis that time plays a significant role in characterizing the unidimensionality of the EQ-5D. Unidimensionality was evaluated using the goodness-of-fit of the EQ-5D items to the measurement models. Time severity effect was examined via item  $\times$  time interactions to evaluate the measurement invariance property of the EQ-5D. **RESULTS:** Results from both point-in-time measures revealed that the mental health item “anxiety/depression” consistently showed misfit in all chronic conditions (INFIT/OUTFIT mean square  $> 1.3$ ). Results from longitudinal analysis demonstrated that including time rendered improved model fit as unidimensionality of the EQ-5D was achieved in eight out of ten chronic conditions. There was significant time severity effects ( $p < 0.05$ ) indicating that the EQ-5D items were endorsed differently over time. **CONCLUSIONS:** Most analysis of health measures suggest unidimensionality fails because mental health and physical health items tend to form different scales. Our findings suggest that time mediates unidimensionality and that physical health and mental health are linked through time. As time is essential to all chronic disease prognoses, controlling for time in a longitudinal study of health measurement is important for proper assessment on the measurement properties of health instruments.

PMCS2

##### CULTURAL ADAPTATION AND VALIDATION OF A HEALTH RELATED QUALITY OF LIFE QUESTIONNAIRE : FUNCTIONAL OUTCOMES OF SLEEP QUESTIONNAIRE

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**OBJECTIVES:** The aim of this study was to determine the reliability and validity of the Functional Outcomes of Sleep Questionnaire (FOSQ) for the Turkish population. **METHODS:** A total of 200 university students participated. A total of 52% of them were men, 48% of them were women. A total of 43% of them lived in the dormitory and 57% of them lived in the apartments. Data were collected with a sociodemographic form, FOSQ, and SF-36. Cronbach's Alfa was used to assess reliability and factor analysis to assess dimensionality. The SF-36 was used for concurrent validity. **RESULTS:** The internal consistency coefficient (Cronbach's alpha) of FOSQ was 0.90. Factor analysis of the scale revealed that it was composed of three factors with Eigenvalues  $> 2.0$ , accounting for 57.6% of the total variance. All items of the Turkish FOSQ had a factor load ranging from 0.413 to 0.731. There was a strong relationship between Functional Outcomes of Sleep Questionnaire, and SF-36. **CONCLUSIONS:** The culturally adapted Functional Outcomes of Sleep Questionnaire had good validity and reliability, making it a potentially useful outcome measure in the evaluation of insomnia patients in Turkey.

PMCS3

##### SHOULD AN SF-10 REPLACE THE SF-12?

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**OBJECTIVES:** To evaluate the item measurement property of the SF-12v2™ and the merits of the physical and mental health component scales (PCS and MCS) using Rasch model. **METHODS:** We extracted a sample from the 2005 Medical Expenditure Panel Survey (MEPS). We included respondents who had completed the SF-12v2™, were  $\geq 18$  years of age and were diagnosed with any of the top ten most prevalent chronic conditions using the primary ICD-9-CM ( $n = 5151$ ). Rasch analyses were applied repeatedly in subgroups on all SF-12v2™ items as a 12-item scale as well as on PCS

and MCS items separately as two 6-item scales. Items were evaluated using the Rasch model fit statistics to examine 1) whether or not the 12 items measure a unidimensional construct and 2) whether or not PCS items measure a physical health construct and MCS items measure a mental health construct. **RESULTS:** In the 12-item scale, the two mental health (MH) items “Have you felt calm and peaceful” and “Have you felt downhearted and depressed” consistently demonstrating misfit in all subgroups (infitt/outfit mean square  $> 1.3$ ). By subdividing the PCS and MCS items into two separate 6-item scales, all six MCS items had good model fit including the two MH items. On the other hand, two PCS items concerning respondents' general health and bodily pain showed misfit to the Rasch model. **CONCLUSIONS:** The SF-12v2™ items do not form a unidimensional scale as the two MH items did not fit with other ten items. However, there are tradeoffs treating PCS and MCS as two distinctive scales as PCS items had a reduced fit. A generic SF-10 for adult population may be a unidimensional component of the SF-12v2™ and could serve as a brief health survey instrument that improves upon the SF-12v2™.

PMCS4

##### ARE YOUNG CHILDREN ABLE TO MAKE TRADE-OFFS? A QUALITATIVE STUDY OF CHILDREN AGED 6 TO 12 YEARS AND THEIR PERCEPTIONS OF INFLUENZA VACCINATION

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**OBJECTIVES:** This study explored children's perceptions of influenza and their ability to make trade-offs among flu vaccine attributes. **METHODS:** A qualitative study was performed to inform the development of a conceptual model on children's perceptions of influenza vaccination. Interviews were conducted by a trained interviewer using an interview guide. A thematic analysis was conducted to understand perceptions of influenza and vaccination including influenza vaccine attributes such as efficacy, side effects, and mode of administration. Study subjects were children aged 6 through 12 years from the Washington, DC area. **RESULTS:** A total of 28 children (two males and two females per year of age) participated. Parents reported that 75% of the children had previously been vaccinated against the influenza virus. Knowledge of influenza varied among children; some were unable to describe influenza-illness, while others described it as a virus and were able to list specific symptoms. Once influenza was described by the interviewer, all children demonstrated a basic understanding of the illness. Efficacy, risk of side effects and mode of administration were found to impact children's decision to be vaccinated. Children as young as 8-years old were able to differentiate low, medium and high risk of side effects and showed the ability to make rational and consistent tradeoffs between vaccines with differing levels of efficacy, chance of side effects and/or mode of administration. Under certain vaccine scenarios, each child was willing to be vaccinated. **CONCLUSIONS:** Children may be able to make decisions pertaining to influenza vaccination. Young children appear to understand the concept of risk and are able to make trade-offs among influenza vaccine attributes.

PMCS5

##### IMPACT OF THE FDA DRAFT GUIDANCE ON PATIENT REPORTED OUTCOMES (PRO) LABEL CLAIMS FOR APPROVED DRUG PRODUCTS IN THE US: HAS IT MADE A DIFFERENCE?

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**OBJECTIVES:** To determine the influence of the FDA Draft PRO Guidance on obtaining PRO label claims, for drug products in the US, since its release in February 2006. **METHODS:** Package inserts (indication, clinical trials sections) and medical review sections from publicly available summary basis of approvals (SBA) for FDA approved drug products named by the MAPI PROLabels database as having a US-based PRO label claim between February 2006 and August 2008 were reviewed. **RESULTS:** Of 33 products reviewed, 44 PRO claims were granted. Signs and symptoms (SS) represented the majority ( $n = 32$ ; 73.7%) of the claims. Within this category, the greatest number of claims were pain-related (primarily based on a VAS or NRS rating scale) and more than half of all SS claims were based on a patient diary. After SBA review for the 24 drug products identified with an available medical review, 13 products were found to have collected additional PRO within the context of the registration trial (reported in the medical review) that did not result in a PRO claim; of these, 6 had PROs reported to have statistically significant results and 2 of these (Voltaren and Fentora) reported clinically meaningful results. Both products were reviewed by the same FDA Division of Anesthesia, Analgesia, & Rheumatology (DAAR) and are indicated for pain. Of the 33 products reviewed, the Pulmonary and Allergy Products reviewing division reviewed the most products (nine) and allowed the most PRO claims (eleven) in the label. Of the 33 products reviewed, SEALD was involved in 4 product SBA reviews. **CONCLUSIONS:** Evidence suggests that since the release of the Draft PRO Guidance, many PRO claims continue to be approved by FDA reviewing divisions; however, the reviewing divisions are not always adhering to the current standards when assessing PRO data for a claim.