ages mentioned below were not measured with this instrument due to lack of hands on experience by the author. TreeAge ProSuite was included as a gold standard comparator for HE. A Linkart scale (1 to 5) was used to grade each item. RESULTS: Thirteen packages were found and considered in this review. Among the best software (including at least three characteristics of the selection criteria) suitable for HE modeling were AnyLogic, Arena, SAS Simulation Studio, Simio, Simul8 and TreeAge. Average grades (ordered from less expensive to most expensive) were as follows: Simul8-Basic, 3.89; TreeAge ProSuite, 3.07; Arena-Basic, 3.00; Simul-Pro1fl700, 4.43.

CONCLUSIONS: This work tried to create a list of items to objectively measure the characteristics of HE modeling software. At this point results of the graded packages represent the views of the author. This instrument may be a useful tool when deciding between different packages to buy. Future work is required for this instrument to be assessed by other modeling experts.

PRM15
VALIDATING AN ONLINE CALCULATOR FOR EVALUATING HEALTH INTERVENTION OPTIONS USING THE ANALYTIC HIERARCHY PROCESS (AHP)
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OBJECTIVES: To evaluate an online calculator for analyzing and scoring health intervention options using the analytic hierarchy process (AHP). METHODS: A web-based calculator was developed that generates priority scores using the Analytic Hierarchy Process as well as various AHP statistics and graphs. AHP is designed to assist in decision-making situations involving multiple attributes by making judgments about the relative importance of key attributes and then specifying a preference for each decision alternative on each attribute. The web-based software is freely available at: www.healthstrategy.com (HDS). The tool was compared to an MS Excel calculator and a Teknome which can be downloaded from: http://peo-

ple.revoluedu.com/kardi/tutorial/AHP. These two software options were evaluated against results from a published health economics paper from Nuijten and Kosa that utilized AHP on three antidepressant choices around the three main factors of budget impact, therapeutic value, and cost-effectiveness.

RESULTS: The published cost-effectiveness values for the AHP calculator were compared to the Teknomo and HDS calculators as follows on factor weights: Budget Impact (0.28, 0.28, 0.28), Cost Effectiveness (0.07, 0.07, 0.07), Therapeutic Value (0.65, 0.64, 0.64). Overall scores (composite weights) the published paper compared with the Teknomo and HDS calculators as follows: New Drug (0.49, 0.56, 0.56), SSR1 (0.26, 0.18, 0.18), TCA (0.25, 0.26, 0.26). CONCLUSIONS: Both software approaches provided basic statistics and graphs often found in AHP reports. For basic scoring, the HealthStrategy and Teknomo approaches provided similar results, but overlaid somewhat with the published paper that used additional sub-factors on some attributes. For future research, additional datasets should be explored, sensitivity analyses should be performed on key variables, and comparisons should be made with more comprehensive software and multi-attribute utility approaches.

Research on Methods – Patient-Reported Outcomes Studies

PRM16
VALIDATION AND PSYCHOMETRIC EVALUATION OF A 5-ITEM MEASURE OF PERCEIVED SOCIAL SUPPORT
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OBJECTIVES: Previous researchers (Ren, 1999) have used a 5-item shortened version of the Medical Outcomes Study Social Support Scale (MOSSS, Sherborne, 1991), but the measurement properties of this brief measure have not been established. We filled this gap by evaluating the psychometric properties of a 5-item perceived social support tool (SS-5) and testing its use against a paper and web-based administration modes. METHODS: The SS-5 and other questionnaire measures were administered to a sample of adults recruited through newspaper and web-based advertisements in 8 US cities. Participants were randomized to complete the SS-5 on either paper or computerized format followed by a one-week retest. The intraclass correlation coefficient (ICC) was calculated to assess reproducibility of the SS-5 and equivalence between administration modes. Cronbach’s alpha was calculated to assess internal consistency. To assess known group differences, differences in means and standard deviations between mentally ill and healthy groups were evaluated. RESULTS: The 258 participants that completed the baseline assessment, 251 (97%) completed the retest. Mean ages of participants was 48.6 years, 61% were female, and 71% were Caucasian. Participants included 44% married or living with a partner; 24% had never been married. The mean SS-5 score was 17.3 ± 4.9, and the ICC between paper and web-based was 0.89. Reproducibility was strong (ICC = 0.92), and the instrument was internally consistent (alpha = 0.88). The SS-5 significantly discriminated between participants living with a partner and those living alone (means: 19.1 vs. 15.9; p < 0.001) and tertiles of the LOT-R. The correlation of SS-5 scores to the full MOSSS was 0.91. CONCLUSIONS: The SS-5 was observed to have adequate reproducibility and internal consistency, and demonstrated appropriate group discriminations. Validity. Equivalence between paper and web-based administration was demonstrated.

PRM17
DEVELOPMENT AND VALIDATION OF A HEALTH RELATED QUALITY OF LIFE INSTRUMENT TO MEASURE THE IMPACT OF OVER-THE-COUNTER PRODUCT USE AND ASSOCIATED ADVERSE EVENTS
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OBJECTIVES: A self-administered questionnaire was developed to evaluate health related quality of life (HRQoL) with over-the-counter (OTC) product use and HRQoL with OTC product use associated adverse drug events (ADRs). Validity and reliability was assessed to determine psychometric properties of these new instruments.

METHODS: The questionnaire was developed as part of a cross sectional study in an elderly population and included content based on existing literature and discussions with expert panel. HRQoL OTC product use (9 items) and HRQoL OTC ADR scale (9 items) was measured using a 5-point Likert scale (strongly agree to strongly disagree). The questionnaire was tested on a pilot sample to evaluate legibility, response burden, and comprehension. Seniors residing in retirement homes or visiting senior community centers and using OTC products participated.

Reliability was evaluated on the basis of internal consistency. Concurrent validity was evaluated by comparing scores obtained with an existing general health status measure (GHS). Data were collected and analyzed using SAS v9.2. RESULTS: A total of 157 seniors completed the survey yielding a response rate of 66.5%. The mean age of the sample was 75.1 (±7.4) years with majority female (56.2%) and white (67.5%). Of the total sample, 22.9% had an adverse event due to OTC use. The reliability coefficient was very high for the two scales, namely, HRQL OTC product use scale (0.95) and HRQL OTC ADR scale (0.92), with mean summary scores of 4.6 ± 1.6 and 0.52 ± 0.6, respectively. The GHS measure was significantly correlated with HRQL OTC product use (r = 0.3, p < 0.001) and HRQL OTC ADR (r = 0.5, p< 0.01) scores. In addition, both scales were significantly correlated with each other (r = 0.7, p < 0.001).

CONCLUSIONS: Both scales exhibit excellent reliability and validity. Further assessment using other products and different populations would help increase generalizability of these instruments.

PRM18
CAN UTILITIES EXCEED 1.0? EMPIRICAL EVIDENCE OF THE CEILING EFFECT
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OBJECTIVES: There is some debate about whether utilities can exceed 1.0. This assumption has important ramifications regarding which statistical methods are appropriate. One convention is to use utility scores up to 1.0 (full health) and the descriptive health state corresponding to ‘full health’ differs across instruments. The objective of this research is to examine the extent to which the value for ‘full health’ differs between the SF-6D and the EQ-5D and to explore the existence of a ceiling effect for utilities. METHODS: The 2000-2003 Medical Expenditure Panel Survey was used to identify respondents who completed the SF-6D and the EQ-5D. Predicted EQ-5D and SF-6D scores were regressed on SF-12 scores and sociodemographic characteristics. The regression equations were then used to predict EQ-5D and SF-6D scores. The two series of predicted scores were compared and 107 to examine ceiling and floor effects. Nineteen individuals had a score of 1.0 on the EQ-5D and only 7% on the SF-6D. The SF-6D exhibited significant floor effects with the lowest value at 0.340 compared to 0.594 for the EQ-5D. Based on the Tobit predicted scores, a value of 1.0 on the SF-6D corresponds to a value of 1.2 on the EQ-5D. This result suggests that the sensitivity of the 46% of individuals with a score of 1.0 on the EQ-5D would actually have utility scores greater than 1.0 on a scale without such a pronounced ceiling effect. Likewise a 0.34 on the SF-6D corresponds to 0.03 on the EQ-5D, suggesting a floor effect for the SF-6D. CONCLUSIONS: Statistical estimation should incorporate censored
regression methods to address ceiling and floor effects evident both theoretically and empirically. Also, future descriptive systems and tariff valuation processes should incorporate values that exceed ‘full health’ (1.0) as is currently done for ‘death’ (0.0).

PRM19
NON-RESPONSE BIAS IN A SURVEY ASSESSING PATIENTS’ MEDICATION AND HEALTH BELIEFS
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OBJECTIVES: To assess the potential for non-response bias. We recommend using multiple measures of patients’ medication and health beliefs. Non-response bias by adherence status and medication persistence may be necessary.

RESULTS: A final survey response rate of 24.25% was achieved. Survey non-responders had statistically significantly lower medication adherence than responders. Median costs (p=0.003), less prescription knowledge (p=0.007), and less trust in their prescribing physician (p=0.02). CONCLUSIONS: Our study found evidence of non-response bias in a survey assessing patients’ medication and health beliefs. Non-response bias by adherence status can be important. The objectives of medication beliefs. We recommend using multiple survey levers to increase response rate among non-adherent patients to reduce the potential for non-response bias.

PRM20
TRENDS IN UTILITY ELICITATION METHODS: DIRECT VERSUS INDIRECT METHODS
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OBJECTIVES: To identify trends in the use of direct and indirect utility elicitation techniques in published cost-effectiveness analyses. METHODS: We analyzed data extracted from cost-effectiveness analyses (CEAs) included in the Tufts Medical Center Cost-effectiveness Analysis Registry, a database with detailed information on CEAs published in the peer-reviewed medical and economic literatures. Using studies from 1991-2008, we analyzed the proportion of utility weights elicited using direct elicitation methods, type of direct or indirect elicitation method, source of weights, age of the population affected by the disease, and disease category. RESULTS: For CEAs published from 1991 to 2008, 42% of utility weights were elicited using direct elicitation methods, 35% using indirect methods, and methods were not reported for 23%. During this time, the proportion of direct and indirect remained similar. For direct methods in adults, the rating scale remained most common (50% for ‘91-93 and ‘06-08). For direct methods in child health, author/cli-
cien judgment was most common in earlier years (91%) compared with the standard gamble later (31%). For indirect methods, the most common method in recent years was the EQ-5D for adults and the HUI for children. Trends in the identified source of utility weights demonstrated an increase in patient or community members as the source accompanied by a decline in clinicians or authors as the source. Specific characteristics of utility weights were missing for 60% of utility weights depending on the year. CONCLUSIONS: Trends over time show increasing adherence to guideline recommendations. A substantial proportion of CEAs using direct elicitation methods in recent years suggests there may be a central role for direct elicitation for certain populations or types of health. The high proportion of studies lacking details for health utilities suggests greater attention needs to be paid toward providing transparency in utility weights for published cost-effectiveness analyses.

PRM21
CONVERTING PAPER VERSIONS OF PATIENT REPORTED OUTCOME INSTRUMENTS TO ELECTRONIC VERSIONS: IDENTIFYING THE REQUIRED STEPS
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OBJECTIVES: To provide a preliminary description of existing Patient Reported Outcome (PRO) study requirements. However, there are a number of PRO instruments that are only available in paper version. Researchers may be unaware of steps required for converting paper to electronic versions and that different steps may be required pending on level of modification involved. The PROMO study intends to provide guidance for identifying required steps in converting paper to ePRO and to identify FDA’s PRO Guidance as a resource. METHODS: Required actions can be determined with input from the following: original author, psychometrician, FDA reviewer, etc. It is the Researcher’s responsibility to determine the action plan on received input. Actions to dem-onstrate measurement equivalence include: clinical reviews, cognitive debriefs, usability testing, equivalence testing and full psychometric testing. Since the decision is determined based on the magnitude of modification, it is important to distinguish each level of modification. This session will provide examples with application to FDA’s PRO guidance.

RESULTS: Examples such as changing wording from “circle yes/no” to “press 1 for yes, press 2 for no”, clinical review, small scale cognitive and usability testing would likely be recommended. Medium – modifications such as changing sentence structure or format; or for a given survey, some minor additional modifications may be required. Large – modifications such as removing items or scales anchors, changing question wording, a full validation study and large scale usability testing would likely be necessary. CONCLUSIONS: Classification of level of modification is based on the potential effect on the original version’s meaning. Demonstration that the modified version has either equivalent or superior psychometric properties is required in respect to the original version is important, as failure to do so may result in serious consequences for trials where the modified version is used.

PRM22
STAGES OF NON-PERSISTENCE: A NOVEL WAY OF FRAMING LONGITUDINAL PERSISTENCE TO CHRONIC MEDICATIONS
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OBJECTIVES: The objective of this study is to propose and provide preliminary evidence of validity of a novel, staging approach for framing longitudinal persistence to chronic medications. The BEI model suggests health utility improves in naïve patients, whereas patients on an established treatment regimen are more likely to experience to the index drug class was measured using pharmacy claims data over 12 months. A multivariate general linear model with a negative binomial distribution and log-link function was used to determine the significant predictors of adherence. Kaplan-Meier estimates of survival (persistence) curves were used to assess the time to discontinuation, and the multivariate Cox proportional hazards model was used to identify significant predictors of non-persistence. To assess differences between early vs. late responders, medication beliefs were compared across timing quartiles based on survey response date (date signed minus date mailed). RESULTS: A final survey response rate of 24.25% was achieved. Survey non-responders had statistically significantly lower medication adherence than responders. As assessed by the log-rank test, the Kaplan-Meier estimates of the persistence of non-responders was statistically significantly higher (indicating better persistence) than the one for non-responders. These results were confirmed by the multivariate Cox proportional hazards model for time-to-discontinuation compared to early survey responders, late responders reported less persistence (p=0.003), less prescription knowledge (p=0.008), and less trust in their prescribing physician (p=0.02). CONCLUSIONS: Our study found evidence of non-response bias in a survey assessing patients’ medication and health beliefs. Non-response bias by adherence status can be important. The objectives of medication beliefs. We recommend using multiple survey levers to increase response rate among non-adherent patients to reduce the potential for non-response bias.