rigorous qualitative research. This approach combines grounded theory methods and is underpinned by an overarching phenomenological framework. It is used to develop PRO items and scales that possess content validity and the ability to yield a measurement model for psychometric testing. This paper will present: 1) The rationale for the combination of these two schools of qualitative research; 2) the current tools that are used that include semi-structured interviews, a computerized software package, theoretical sampling, saturation and grounded theory data analysis methods; 3) examples of successful application of qualitative research to PRO development; and 4) future applications of qualitative research in upcoming/planned clinical trials.

PM3

THE VALIDITY AND RELIABILITY OF A PARENT-CHILD DYAD APPROACH TO UTILITY AND QUALITY-OF-LIFE ASSESSMENT IN CHILDREN

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OBJECTIVES: In children, utility and health-related quality of life (HRQOL) measurements may be influenced by age, cognitive ability and disease severity. Parents are often proxy respondents. The objectives were to assess the validity and reliability of a parent-child dyad utility and HRQOL assessment wherein children and parents are interviewed together to assess the child's HRQOL. **METHODS:** The Health Utility Index (HUI), PedsQL Core and Asthma Modules and the Pediatric Asthma Quality of Life Questionnaire (PAQLQ) were administered to 93 asthmatic children aged 8 to 15 years and their parents in a joint dyad interview. All questions were directed at the child to assess the child's utility and HRQOL. Questionnaires were scored normally. A pre-tested structured guide was available to interviewers. To assess construct validity of the dyad approach, Spearman correlations were calculated between HUI attributes and questionnaire domains associated with physical function and with emotional function. Test-retest reliability was assessed with an intra-class correlation coefficient (ICC) in 28 children who remained clinically stable between baseline and follow-up assessments at 5 months. **RESULTS:** Among the parent-child dyads, the HUI2 Mobility attribute was significantly correlated ($p < 0.05$) with the PedsQL Core Physical ($r = 0.41$) and the PAQLQ Activities ($r = 0.32$) domains. The HUI2 Emotion attribute was significantly correlated ($p < 0.05$) with the PedsQL Core Emotion ($r = 0.39$), the PedsQL Core Social ($r = 0.34$), the PedsQL Asthma Communication ($r = 0.21$) and the PAQLQ Emotion ($r = 0.25$) domains. For clinically stable children, significant ICCs between baseline and follow-up were observed for the HUI2 Total ($r = 0.53$), PedsQL Core Total ($r = 0.70$), PedsQL Asthma Symptoms ($r = 0.84$), PedsQL Asthma Treatment ($r = 0.51$), PAQLQ Activity ($r = 0.75$) and PAQLQ Emotion ($r = 0.76$) domains. **CONCLUSIONS:** The parent-child dyad demonstrated moderate construct validity and moderate to strong test-retest reliability in generic and disease-specific questionnaires. This approach may be a valid alternative to relying on parent proxies for assessing children's utility and HRQOL.

PM4

EVALUATION OF A THEORY OF GLOBAL HEALTH PREFERENCE FORMATION

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The multi-attribute health status (MAHS) approach to developing indirect utility measures assumes that health preferences are formed from the simultaneous consideration of multiple health dimensions. We propose an alternative view that theorizes the formation of health preferences is mediated by global impressions of quality of life (QL). This study compared the theory of global health preference formation (GHPF) with the MAHS approach for explaining time trade-off utilities. A total of 1432 cancer patients completed the EORTC QLQ-C30 and valued their own current health. A mediation analysis was performed using latent variable models relating health preferences to QLQ-C30 domains. Founded on the MAHS approach, Model I described health preferences using the physical, role, cognitive, emotional, and social functioning domains (PF, RF, CF, EF, and SF, respectively) and the fatigue (FA), pain (PA), and nausea/vomiting (NV) symptom domains. Model II related the QL domain to the same functioning and symptom domains. Consistent with the GHPF framework, Model III purported that QL mediated associations of health preferences with functioning and symptoms. Ignoring QL, health preferences were related to PF ($b = 0.041/p = 0.050$), SF ($b = 0.057/p = 0.028$), and EF ($b = -0.054/p = 0.001$). Model II: QL was positively related to RF ($b = 0.222/p = 0.001$), EF ($b = 0.116/p = 0.001$), SF ($b = 0.257/p < 0.001$), FA ($b = 0.245/p < 0.001$), and PA ($b = 0.123/p = 0.001$). Model III: QL was positively related to health preferences ($b = 0.117/p < 0.001$). Controlling for QL, the only functioning or symptom domain related to health preferences was EF ($b = -0.067/p < 0.001$). Significant indirect effects representing differences between direct effect estimates for Models I and III were observed for RF ($b = 0.026/p = 0.001$), EF ($b = 0.014/p = 0.002$), SF ($b = 0.030/p < 0.001$), FA ($b = 0.029/p = 0.003$), and PA ($b = 0.014/p = 0.002$). Model III provided a significantly better fit than Model I ($p < 0.001$). The MAHS approach yields misspecified models of health preferences since QL mediates associations of the latter with functioning and symptoms. Our framework has far-reaching implications for utility assessment and warrants further research.

PODIUM SESSION III

RESEARCH IN ADHERENCE AND COMPLIANCE I

AC1

THE ASSOCIATION BETWEEN IMPROVEMENTS IN DRUG ADHERENCE AND SHORT-TERM SERVICE UTILIZATION AND COSTS IN A MEDICAID POPULATION

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OBJECTIVE: More than one-third of patients with diabetes exhibit poor adherence with recommended drug regimens. While poor adherence is associated with excess morbidity and mortality, it is important to realize that better adherence may also affect short-term health care costs. This research quantifies the effects of improvements in medication adherence on short-term health services utilization and their associated costs. **METHODS:** Data from Florida: A Healthy State (FAHS), a Medicaid disease management program developed jointly by Pfizer Inc. and the state of Florida targeting chronically ill Primary Care Case Management

Program beneficiaries. The sample contains 5000 diabetes patients who were continuously eligible for Medicaid benefit and FAHS for at least 2 years. Medication adherence was measured with the Medication Possession Ratio (MPR) for diabetes-specific prescriptions, statins, and ACEs/ARBs. MPR was calculated separately for the first 12 months (baseline) and the following 12 months (follow-up). Costs were similarly summed over the 12 month intervals of baseline and follow-up. Estimation was performed with first-difference and conditional logistic regressions. **RESULTS:** Improvement in MPR between baseline and follow-up was reflected in lower inpatient, emergency room (ER), and total non-drug costs. A 10% improvement in MPR for hypoglycemic medications reduced inpatient costs by \$127.97 ($p = 0.002$), ER costs by \$3.72 ($p = 0.003$), and total non-drug costs by \$116.00 ($p = 0.009$) over 12 months. This reduction in inpatient costs was the result of a shorter average length of stay: a decrease of 0.2 ($p = 0.03$) day per 10% increase in MPR. Finally, a 10% improvement in adherence with statins reduced the probability of being hospitalized by 4.3% ($p = 0.01$). **CONCLUSION:** This research demonstrates the existence of significant short-term savings related to the improvement of medication adherence among persons with diabetes.

AC2

PATTERNS OF DIABETES MEDICATION AND TEST ADHERENCE IN A MEDICAID DISEASE MANAGEMENT PROGRAM

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OBJECTIVE: The failure to maintain adherence to recommended medication and testing regimens is associated with excess morbidity and mortality among diabetics. This presentation focuses on the adherence patterns of diabetics enrolled in Florida: A Healthy State (FAHS), a Medicaid disease management program. **METHODS:** Attention is given to the baseline characteristics of program participants, and the association between them and baseline adherence to hypoglycemic agents, ACEI, ARB, Statins, and annual tests (HbA1C, lipids, microalbumin, retinal exam). A matched-group comparison examined changes in patterns of medication and test adherence at follow-up for those enrolled in the nurse care management module. **RESULTS:** A total of 8432 diabetic adults were continuously enrolled for 24 months. Multivariate models evaluating their baseline adherence to hypoglycemics, ACEI, ARB, Statins and recommended tests were fit. Those who were adherent to one class of diabetes-related medication were 1.5 to 3.5 times more likely to be adherent to another class of diabetes-related medication. Baseline adherence to recommended tests was associated with 50% greater odds of adherence to hypoglycemics, ACEI and Statin. The profile of the 2597 (31%) moderate and high risk participants that enrolled in the nurse care management module was significantly different than that of non-enrollees. Participants had more comorbidities, greater service utilization and costs, and lower medication and test adherence. In a matched-group comparison, nurse care management was associated with improved odds of: filling at least one script during the study period among those who were not using diabetes medications at baseline, adherence to insulin among those using diabetes medications at baseline, and adherence to recommended testing **CONCLUSION:** A pattern of overall adherence behavior was observed at baseline. Participation in nurse care management improved adherence to recommended diabetes medication and testing regimens. It is believed that these results can be generalized to other Medicaid populations.

AC3

DEPRESSIVE SYMPTOMATOLOGY, MEDICATION PERSISTENCE, AND ASSOCIATED HEALTH CARE COSTS IN OLDER ADULTS WITH INSOMNIA

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OBJECTIVE: The effect of insomnia along with the decreased cognitive functioning associated with aging is a serious concern within the elderly (65 years and older) population. We examined the association of patient health care utilization and depressive symtomatology with medication adherence in insomnia in Medicare-HMO enrolled elderly patients. **METHODS:** This was a retrospective, longitudinal cohort study which included elderly patients (65 and older) enrolled continuously for 1–5 years in the Medicare HMO. Medication possession ratio was used to estimate the adherence in insomnia medication. Different MPR thresholds (0.8, 0.6, 0.4 and 0.2) were used to determine non adherence. Associations between depressive symptoms, medication adherence and health care costs were assessed using ordinary least square multiple regressions. **RESULTS:** A total of 2068 patients with a primary diagnosis of insomnia were included in the study. Sixty percent of these patients had depressive symptomatology. The severity of comorbidity (Charlson index) was 4 and the patient perception of quality of life (Short Form-12 scores) were between 79 and 82. The prevalence of non adherence was 70% even with a low MPR of 0.2. Insomnia patients with depressive symptoms were 92% less likely to be adherent to their insomnia medications ($p < 0.05$). After controlling other variables, we found MPR was a good predictor of total health care costs (10% increases in MPR for every 2% decrease in total health care costs, $p < 0.001$). **CONCLUSION:** We found strong associations between depressive symtomatology, medication adherence, and health care costs in elderly patients with insomnia. Disease and risk management programs in managed care settings should be used to optimize the medication adherence in the elderly.

AC4

THE COST OF NON-ADHERENCE TO ASTHMA TREATMENT GUIDELINES AMONG A LOW-INCOME COHORT

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OBJECTIVE: Investigate the effects of non-adherence by providers to the National Institutes of Health treatment guidelines on the costs of care for children and adults with asthma. The Guidelines recommend providing access to rescue medications but restricting their overuse through controller medications. **METHODS:** Pediatric (6–19 years) and adult (20–64 years) patients with a prescription for an albuterol inhaler (AI) or an inhaled corticosteroid (ICS) and a diagnosis for asthma between January 1, 2001 and December 31, 2005 were identified from the Utah Medicaid population. Patients were observed for ninety days following the first prescription and classified into three groups on the basis of AI use and ICS prescription, as following: 1) less than three canisters of AI (appropriate); 2) three or more canisters of AI (inappropriate); 3) no AI use but a prescription for ICS (inappropriate). Once categorized as adherent (group 1) or non-adherent (groups 2, 3), direct medical costs were estimated for children and adults for one year using generalized linear two-part regression models adjusting for demographics, comorbidities, smoking status, seasonal effects and year. **RESULTS:** Of the final sample ($N = 4751$), children comprised 40.4%