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.

**PODUM SESSION III**

**RESEARCH IN ADHERENCE AND COMPLIANCE I**

**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...