

PMD17**ASSESSMENT OF QUALITY OF LIFE IN CHILDREN: METHODOLOGICAL AND CONCEPTUAL ISSUES**Matza LS¹, Swensen A², Flood E¹, Secnik K²¹MEDTAP International, Bethesda, MD, USA; ²Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: Researchers are gradually becoming more aware of the unique challenges of assessing health outcomes among children, including health-related quality of life (HRQL). Like adults, children experience impacts of illness and treatment beyond purely medical effects. More pediatric HRQL research is necessary to identify these broader outcomes and provide a thorough understanding of children's health status. Thus, the purpose of this presentation is to review recent pediatric pharmaceutical regulatory developments and discuss methodological and conceptual issues relating to the assessment of children's HRQL. **METHODS:** Computerized literature searches were conducted in MEDLINE, HealthSTAR, and PSYCH-INFO from 1990 to 2002. Internet searches were conducted to identify regulatory developments. To empirically examine the HRQL impact of a childhood psychiatric disorder, baseline data from a clinical trial of children with ADHD were compared with normative data. **RESULTS:** Over 200 abstracts were located, and 80 relevant articles were selected for detailed review. Commonly used instruments included the Child Health Questionnaire. Several methodological issues were identified, including when to use parents as proxy respondents and the age at which children can recognize and report their HRQL. Consideration should be given to the content, language, presentation style, and response choices in order to ensure that child-report measures are age-appropriate. One conceptual issue involves the interaction of children's HRQL and social contexts, including family and peer systems. The empirical analyses suggested that ADHD, one example of a psychiatric disorder, has a serious impact on children's HRQL ($p < 0.0001$). **CONCLUSIONS:** There are numerous methodological and conceptual issues unique to research on HRQL in children. Based on brief empirical analyses, it is recommended that future research examine the impact of psychiatric disorders, as well as medical conditions, on children's HRQL. Finally, we advocate additional regulation to encourage assessment of pediatric health outcomes among children as an integral part of drug development.

PMD18**THE INTERNATIONAL HEALTH-RELATED QUALITY OF LIFE OUTCOMES DATABASE (IQOD) PROGRAMME—WHQ AND PGWBI DATABASES: REFERENCES VALUES FOR CROSS-CULTURAL COMPARISONS**

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With the increased number of multinational clinical trials and epidemiological studies using Patient-Reported Outcomes (PRO), the need of cross-cultural reference values for analysis and interpretation has arisen. **OBJECTIVE:** The International Health-related Quality of Life Outcomes Database (IQOD) Programme aims at creating scores and standardizing analysis and interpretation for health-related quality of life questionnaires. **METHODS:** Data were collected from multiple clinical trials and epidemiological studies conducted worldwide. The IQOD Programme Phase I involves the Women's Health Questionnaire (WHQ), the Psychological General Well-Being Index (PGWBI), and the Minnesota Living with Heart Failure Questionnaire (MLHF). These instruments represent three types of PRO: generic, condition, and disease specific instruments, selected for their linguistic adaptation into several languages, their reliability and validity, and their extensive use. Descriptions of population, analysis and interpretation provide reference values in different population groups and per country. **RESULTS:** Data collection and specification include the elaboration of the merging rules in order to incorporate the results of multiple studies while building the databases. IQOD-WHQ collected data among 9023 women (mean age: 52 years), using the 37-item version of the WHQ, were analysed and interpreted. Pre, peri and post-menopausal women reference values have been established for 6 languages, 10 European countries and USA. WHQ's scoring has been reviewed with the author and a 23-item short-form WHQ has been developed. IQOD-PGWBI database includes data of 11 286 patients (mean age: 46 years) living in 19 countries, speaking 15 languages with symptomatic GERD, HTA, chronic constipation, colorectal cancer, digestive problems and several co-morbidities. IQOD-MLHF data collection is being finalized. **CONCLUSION:** IQOD-WHQ and IQOD-PGWBI databases analysis provides reference values for comparison of PRO data across populations (countries and languages), cultures and condition severity. Ongoing and future work in IQOD focus on creating similar reference values for IQOD-MLHF and other PRO.

PMD19**A CRITICAL REVIEW OF HEALTH-RELATED PRODUCTIVITY MEASURES**Prasad M¹, Shih YCT¹, Wahlqvist P², Shikiar R³¹MEDTAP International Inc, Bethesda, MD, USA; ²AstraZeneca R&D Mölndal, Mölndal, Sweden; ³MEDTAP International Inc, Seattle, WA, USA

OBJECTIVES: Health impairment often leads to work impairment in the form of both absenteeism and presenteeism, which is reduced productivity at work. To date, few instruments are available to measure this impact. The objective of this study was to review and evaluate instruments designed to measure health-related productivity at work. **METHODS:** A literature search was conducted