Challenges of Developing an Observable Parent-Reported Measure: A Qualitative Study of Functional Impact of ADHD in Children

Louis S. Matza, Mary Kay Margolis, Linda S. Deal, Kimberly F. Farrand, M. Haim Erder

Value in Health, March 2017
DOI: https://dx.doi.org/10.1016/j.jval.2017.02.010

Abstract

Background
Informant-reported outcome measures, usually completed by parents, are often administered in pediatric clinical trials with the intention of collecting data to support claims in a medical product label. Recently, there has been an emphasis on limiting these measures to observable content, as recommended in the US Food and Drug Administration guidance on patient-reported outcomes. This qualitative study explores the concept of observability using the example of childhood attention-deficit/hyperactivity disorder (ADHD).

Methods
Concept elicitation interviews were conducted with children (aged 6–12 years) diagnosed with ADHD and parents of children with ADHD to identify concepts for a potential parent-reported measure of the functional impact of childhood ADHD. The observability of each concept was considered.

Results
Of the 30 parents (90% females; mean age = 42.0 years), 24 had a child who was also interviewed (87.5% males; mean age = 9.6 years). Areas of functional impact reported by parents and/or children included the following: 1) functioning within the home/family, 2) academic performance, 3) school behavior, 4) social functioning, 5) emotional functioning, and 6) decreased self-efficacy. Parents cited many examples of direct observation at home, but opportunities for observation of some important areas of impact (e.g., school behavior and peer relationships) were limited.

Conclusions
Findings illustrate the substantial functional impairment associated with childhood ADHD while highlighting the challenges of developing informant-reported outcome measures limited to observable content. Because ADHD has an impact on children’s functioning in a wide range of contexts, a parent-report measure that includes only observable content may fail to capture important aspects of functional impairment. Approaches for addressing this observability challenge are discussed.