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

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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 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.

Keywords: ADHD, concept elicitation, functional impairment, informant-reported outcome measures, observability, parent report, qualitative research.

Introduction

Although many patient-reported outcome (PRO) instruments have been developed for pediatric populations [1–5], younger children may not be able to read a questionnaire, understand the relevant concepts, or provide reliable and valid responses. For these situations, an alternative approach is to administer an informant-reported measure, most commonly completed by a parent. A recent PRO Good Research Practices Task Force Report of the International Society of Pharmacoeconomics and Outcomes Research [6] suggested using the term *informant-reported measure* as a general term for instruments completed by people, other than the child, who provide information related to the child. Informant-reported measures can include both observable and nonobservable content.

For assessing clinical trial outcomes and informing medical product labeling, the International Society of Pharmacoeconomics and Outcomes Research Task Force report and the US Food and Drug Administration PRO guidance [7] recommend that informant-reported measures for assessment of children who cannot respond for themselves should focus on behaviors and characteristics that can be directly observed by the informant. In response to these recommendations, outcomes researchers are increasingly focused on developing informant-reported measures of child functioning that include only observable content [8–11], which have recently been called "observer-reported outcomes" [12].

Consequently, a qualitative study was recently conducted to examine whether it would be useful to develop a parent-reported measure of the impact of childhood attention deficit/hyperactivity disorder (ADHD) while focusing only on observable content.

Conflicts of interest: L. S. Deal, K. F. Farrand, and M. H. Erder were employed by the sponsor at the time data collection was conducted. L. S. Matza is employed by Evidera, Inc., a company that received support from Shire Pharmaceuticals for time spent conducting this study. M. K. Margolis was employed by Evidera, Inc., at the time the study was conducted.

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Development of this potential measure was discontinued for two reasons. First, the areas of impact reported by parents and children had largely been covered in previously developed instruments [13–17]. Second, it became apparent that parents were not able to directly observe some of the most common and important ways that ADHD affects children's functioning. The results of this qualitative study have important implications for the development of informant-reported measures focusing on observable content. The qualitative study described in this article provides an opportunity to explore the concept of observability and highlight the challenges of developing informant-reported outcome measures that are limited to observable content.

Methods

Overview of Study Design

This was a qualitative study involving semistructured, one-on-one, in-person, concept elicitation interviews with children who have been diagnosed with ADHD and with their parents. All interviews focused primarily on the impact of ADHD on children's functioning. Parents were also asked about the observability of the concepts they reported.

Study Participants

Participants were recruited from four clinical sites in the United States that focused on treatment of childhood ADHD (Durham, NC; Houston, TX; Las Vegas, NV; and Midlothian, VA). To be eligible, children were required to be 6 to 12 years old and have a diagnosis of ADHD. Parents were required to be at least 18 years old; be a parent or guardian of a child aged 6 to 12 years with ADHD; be currently living with the child; and have been the primary guardian for at least 6 months. Children were excluded if they had participated in a clinical trial within the past 6 months or if they had a comorbid psychiatric diagnosis of major depressive disorder, psychosis, bipolar disorder, pervasive developmental disorder, an anxiety disorder, or an Axis II disorder. Parents were excluded if their child met these exclusion criteria. Parents and children were also excluded if they had any impairment (e.g., cognitive, sight, or hearing) that would interfere with the interview. Only one parent reporting on each child was permitted to participate. Whenever possible, both a parent and his or her child were interviewed, but parents were permitted to participate even if their child did not.

Qualitative Interview Procedures

Study procedures were approved by an independent ethics review committee (Schulman IRB, protocol ID 5810). Before the interviews, an interviewer obtained written informed consent from the parent and assent from the child. Parents and children were interviewed separately according to semistructured interview guides (one guide for parents and another for children; see both guides in Appendices A and B in Supplemental Materials found at http://dx.doi.org/10.1016/j.jval.2017.02.010) drafted on the basis of literature review and interviews with seven clinicians who treated ADHD.

After introductory questions on ADHD symptoms, respondents were asked open-ended questions about the impact of ADHD. This open-ended section was designed to elicit concepts spontaneously from the respondents, without suggestions from the interviewers regarding possible domains of impact. Open-ended questions for parents included "What is the impact of your child's ADHD?" and "Can you think of any other ways ADHD has an impact on your child's life?" Questions for children included "What do you think ADHD is?"; "What effect does ADHD have on your life?"; and "Does your ADHD stop you from doing things or make things harder?"

After the open-ended questions, the respondent was asked about potential ADHD impact in four general areas: 1) home/family, 2) school, 3) social functioning, and 4) emotional functioning. These areas were selected on the basis of a draft conceptual model, which was developed on the basis of literature review [18–27] and interviews with seven clinicians (three PhD psychologists and four physicians from a range of geographic locations including Cleveland, OH; Herndon, VA; Las Vegas, NV; Houston, TX; Bradenton, FL; Lubbock, TX; and Durham, NC; mean years of practice was 23.6 ± 2.3). To differentiate between observable and nonobservable aspects of children's functioning, parents were asked how they learn about the child's functioning (e.g., "What indicates to you that your child's ADHD has had impact on his/her social life?"; "How do you know this information?"; and "Do you observe this yourself, or do you hear about it from someone else?").

Other Study Measures

Each parent completed sociodemographic forms and rated his or her child's ADHD symptoms on the ADHD Rating Scale-IV, home version [28]. For each participant, a recruiting site staff member completed a form to report ADHD diagnosis *DSM-IV-TR* code, current medications, and comorbid conditions. The treating clinician at the site completed the Clinical Global Impression Scale to rate ADHD symptom severity (single-item scale ranging from 1 [normal, not at all ill] to 7 [among the most extremely ill]).

Qualitative Data Analysis

Quotations from interview transcripts were coded using ATLAS.ti version 5.3 Scientific Software Development, Berlin, Germany. A coding dictionary included codes for concepts and themes reported by respondents in the interviews. A coding leader trained two coders, one who coded child transcripts and another who coded parent transcripts. The first three transcripts for each coder were also coded by the coding leader to ensure consistent understanding and application of the codes.

Using ATLAS.ti, codes were assigned to the relevant text in each transcript to categorize quotations according to concepts or themes. Coded text resulted in qualitative output that organized participants' statements in themes. These statements were tracked in a concept-tracking table used to document saturation, which is the point in the interview process at which no new themes, concepts, or terms are introduced [29].

Results

Sample Description

Of the 30 parents who were interviewed, 24 had a child who was also interviewed. All children and parents were interviewed separately and simultaneously, except for one parent who requested to observe her child's interview. In this case, the parent was interviewed first so that she could answer questions without bias that could result from watching and hearing her child's responses. After the parent completed her interview, the child was interviewed while the parent observed from a separate room through a one-way mirror. Demographic characteristics are presented in Table 1.

All children had a diagnosis of ADHD in their medical charts (*DSM-IV-TR* code 314.00 or 314.01), and all were receiving medication treatment for ADHD. The most commonly reported medications were stimulants: dexmethylphenidate (10 of the 30 children discussed by parents; 33.3%), methylphenidate