

Clinical Outcome Assessments (COA) Qualification Program
DDT COA #000099: Child Asthma Diary (CAD)
August 25, 2017 Update

Introduction

Asthma is one of the most common diseases in the industrialized world, estimated to affect 7% of children, and has a profound impact on functioning in everyday activities. The goals of asthma treatment have broadened beyond managing traditional clinical markers of disease severity and now include a focus on the benefits of treatment in terms that are most meaningful to patients.¹

Asthma clinical trials in adults often rely on patient reports of daily symptoms through diaries, along with traditional assessments of lung function. Pediatric assessments of asthma symptoms in children under age 12 can be complex. Previous research and discussions with FDA have suggested that because parents are not always with their child, and because children under age 12 may or may not be able to reliably self-report some symptoms, an innovative method to assess asthma symptoms needs to be used.^{2,3}

A draft symptom diary has been developed by the Pediatric Asthma Working Group within Critical Path Institute's (C-Path) PRO Consortium; this diary is meant to be co-completed by parents and their children who would answer the questions together so that both perspectives are included in each answer. Detailed instructions to the parents, who will complete the diary with their child, have also been developed. This co-completion approach has not yet been tested for its feasibility.

The purpose of this protocol is to provide an overview of the methods that will be used to assess the feasibility of the co-completed symptom diary, compared to a more traditional approach of a parent-administered diary for the younger children (4 through 7), diary self-completion for older children (8 through 11), and parent observer ratings of symptoms across the age range that are reported independently of the children's reports.

Objectives

The primary objective of the present study is to assess the feasibility of the co-completed symptom diary, compared to traditional methods of pediatric diary completion. Specific objectives of the study are as follows:

1. To conduct a training session for the parents on how to co-complete and administer the diary to their child, facilitate self-completion by the older children, and complete the ObsRO diary
2. To have the parents complete or ensure completion of the diaries, using varying modes of administration, counterbalanced to avoid bias, so they can adequately assess the feasibility of each mode

3. To conduct qualitative focus groups with the parents to assess the feasibility of each mode of diary administration (co-completed versus interview administered for children ages 4 through 7, self-completed for children ages 8 through 11, and ObsRO diary completed by the parents of children ages 4 through 11)
4. To make final recommendations regarding the feasibility of the different modes of administration for the diary

References:

1. National Institutes of Health (2007). National Asthma Education and Prevention Program Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma (NIH Publication No. 08-5846).
2. Matza LS, Patrick DL, Riley AW et al. Pediatric Patient Reported Outcomes Instruments for Research to Support Medical Product Labelling: Report of the ISPOR PRO Good Research Practices for the Assessment of Children and Adolescents Task Force. *Value in Health* 2013; 16 461-479.
3. U.S. Department of Health and Human Services FDA Center for Drug Evaluation and Research, U.S. Department of Health and Human Services FDA Center for Biologics Evaluation and Research, U.S. Department of Health and Human Services FDA Center for Devices and Radiological Health, "Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims," 2009.