Development of the Initial Version of the Asthma Daily Symptom Diary

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Background

• The Asthma WG aims to develop a self-reported symptom diary for adults and adolescents with a diagnosis of mild to severe persistent asthma
• The FDAs Patient-Reported Outcome (PRO) Guidance recommends that PRO instrument development is based directly on patient input
• A review of prior qualitative research showed asthma was characterized by three core symptom domains: breathing symptoms (e.g., difficulty breathing, shortness of breath, wheezing), chest symptoms (e.g., tightness, pressure, pain), and cough-related symptoms (e.g., coughing)
• A review of existing asthma symptom measures demonstrated that there is currently no instrument for the measurement of patient-centered symptoms of asthma which meets standards specified in the FDA PRO Guidance for labeling claims (Nelsen et al., 2014)

Methods

• This study followed the recommended PRO development process described in the FDA Guidance for industry titled “Patient-Reported Outcome Measures: Use in Medical/Product Development to Support Labeling Claims” (a PRO Guidance)

Conceptual Framework Development

• Methods
  • Background: study design, including the target population and key demographic and clinical characteristics
  • Conceptual Framework Development
  • Methods
    • Review of qualitative literature regarding asthma symptomatology
    • Scientific Advisors: Adelphi Values, the WG’s contract research partner (e.g., frequency, intensity, duration) were the primary focus of exploration
    • Item Generation
      • Results: Items were drafted which reflected how patients described symptoms in their own words
      • Item generation was held among members of the Asthma Working Group, Adelphi Values, and the scientific advisors
      • Result of the concept elicitation interviews were discussed; items were drafted which reflected how patients described symptoms in their own words

Patient-Reported Symptoms

• Eight symptoms emerged as ‘core asthma symptoms’ based on their frequency of spontaneous report: wheezing, breathlessness, chest tightness, chest pain, and pressure/weight on chest; 2) Cough Symptoms: cough and mucous/phlegm
• Core symptoms included 1) Breathing Symptoms: difficulty breathing, shortness of breath and wheezing; 2) Chest Symptoms: chest tightness, chest pain, and pressure/weight on chest; and 3) Cough Symptoms: cough and mucous/phlegm

Literature Review

• Literature review was conducted to: 1) understand qualitative work conducted to date among asthma patients and 2) understand currently available asthma PRO measures

Conceptual Framework Development

• The conceptual framework was informed by the literature review described above, as well as information made available to the WG from a previously conducted literature review and focus groups related to asthma control

Protocol Design

• The development of the protocol and semi-structured interview guide were based on the conceptual framework
• A panel of asthma experts reviewed the draft study protocol and provided input into the study design, including the target population and key demographic and clinical characteristics

Table 1. Participant Demographics and Clinical Characteristics (n=55)

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Conclusion

• The Asthma Daily Symptom Diary is a new PRO measure based on patients’ direct experiences of asthma
• The Asthma Diary Symptom Diary is developed, may potentially support product labeling claims related to reduction of symptom severity or of symptom free days over a study interval
• Future research will involve testing the draft items to ensure that adolescents and adults with asthma find them relevant, understandable, and comprehensive

References


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