# Content Validity of the Atopic Dermatitis Symptom Scale (ADerm-SS) and Atopic Dermatitis Impact Scale (ADerm-IS) in Adolescents to Assess the Symptoms and Impacts of Atopic Dermatitis

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**Objectives:** Atopic dermatitis (AD) is characterized by pruritus, redness, and skin pain, and can lead to disrupted sleep, limitations on daily activities, difficulty concentrating, and feelings of frustration and self-consciousness. Informed by best measurement practices, two patient-reported outcome (PRO) questionnaires – the Atopic Dermatitis Symptom Scale (ADerm-SS) and the Atopic Dermatitis Impact Scale (ADerm-IS) – were developed to measure symptoms and impacts of moderate-to-severe AD in adults 18 years and over. The ADerm-SS uses a 24-hour recall period to measure 11 AD symptoms such as itch while awake, itch while asleep, skin pain, skin flaking, and skin cracking. The ADerm-IS uses 10 items to measure AD-related impacts: three items use a 24-hour recall period to measure AD's impact on sleep and seven items use a 7-day recall period to measure other impacts such as limitations to household activities, physical activities, and social activities, as well as emotional impacts such as embarrassment and sadness. Both the ADerm-SS and ADerm-IS use an 11-point numerical rating scale (NRS) for each item (range 0-10; higher scores indicating worse symptoms/impacts). The objective of this study was to evaluate the relevance, comprehensiveness, and comprehensibility of the questionnaires for adolescents with moderate-to-severe AD (i.e. content validity).

**Methods:** Adolescents (12-17 years old) with moderate-to-severe AD were recruited to participate in 90-minute hybrid concept elicitation/cognitive debriefing interviews. A diagnosis of moderate or severe AD (Validated Investigator Global Assessment Scale for AD score ≥3) was required. Participants spontaneously reported the symptoms and impacts of AD they experienced, then completed the ADerm-SS and ADerm-IS, and then provided feedback on the instructions, items, and response options of the questionnaires. Interviews

were audio-recorded, transcribed verbatim, anonymized, and analyzed using qualitative and quantitative methods.

**Results:** Twenty adolescents (mean age of 14.9 years; 50% male; 55% white; 45% severe AD) participated in the interviews. A total of 12 symptoms and 22 impacts were reported. The most frequently reported symptom was itch (n=20, 100%), which was also reported as the most bothersome symptom; other frequently reported symptoms included rash, dry skin, and skin flaking. The most frequently reported impact was sleep interference (n=15, 75%); physical activity limitations, difficulty concentrating, and leisure activity limitations were also frequently reported. Adolescents reported having experienced the symptoms and impacts measured by the ADerm-SS and ADerm-IS and found the questionnaires to be comprehensive, reporting that they did not consider any important symptoms and impacts missing. Adolescents also found the questionnaires to be comprehensible, being able to read, understand, and provide meaningful responses to the instructions, items, and response options.

**Conclusions:** Results provide confirmatory evidence that the ADerm-SS and ADerm-IS are relevant, comprehensive, comprehensible, and appropriate for use in adolescents with moderate-to-severe AD. The ADerm-SS and ADerm-IS were originally developed for adults, and these qualitative results provide support for the content validity of this younger age group in line with best measurement practices summarized in regulatory guidelines. Quantitative evaluation of the ADerm-SS and ADerm-IS scores from a Phase 3 clinical trial will provide further evidence of their reliability, validity, and interpretability.

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