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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INTRODUCTION

- Atopic dermatitis (AD) is characterized by pruritus, redness, and skin pain,[1,2] can lead to disrupted sleep, limitations on daily activities, difficulty concentrating, and feelings of frustration and self-consciousness[3]
- Two patient-reported outcome (PRO) questionnaires have been developed in adults 18 years and over, using best measurement practices to assess symptoms and impacts of moderate to severe AD:
  - –The Atopic Dermatitis Symptom Scale (ADerm-SS) contains 11 items measuring the severity of AD symptoms at their worst, using a 24-hour recall period and an 11-point numerical rating scale (NRS) from 0=no symptom to 10=worst symptom
  - –The Atopic Dermatitis Impact Scale (ADerm-IS) contains 10 items measuring the impact of AD on various aspects of quality of life. Three items use a 24-hour recall period, and 7 items use a recall period of the past week. All items use an 11-point NRS from 0=no impact to 10=worst imaginable impact
- Content validity (i.e., relevance, comprehensiveness, and comprehensibility) of the ADerm-SS and ADerm-IS has been demonstrated among adults; the goal of the current research is to provide evidence for content validity among adolescents (aged 12–17 years) with moderate to severe AD

OBJECTIVES

- To provide qualitative evidence that the concepts assessed by the ADerm-SS and ADerm-IS are relevant and appropriate for adolescents with moderate to severe AD
- To evaluate the ability of adolescents to read, understand, and respond to the ADerm-SS and ADerm-IS

METHODS

- Regulatory guidelines and best scientific measurement practices require qualitative research evidence showing relevant and important aspects are being measured by the questionnaires that can be meaningfully interpreted and responded to[4-6]
- To demonstrate content validity, adolescents aged 12–17 years old with a diagnosis (Validated Investigator Global Assessment Scale for AD score ≥3) of moderate-to-severe AD were recruited to participate in 90-minute hybrid qualitative concept elicitation and cognitive debriefing interviews
  - –During the concept elicitation portion of the interview, participants were asked to spontaneously report the symptoms and quality of life (QoL) impacts of AD they experienced, as well as which symptoms were the top five most bothersome and which impact they considered the most important
  - –During the cognitive debriefing portion of the interview, participants completed the ADerm-SS and ADerm-IS, then provided feedback on the questionnaires' instructions, items, and response options
- Interviews were audio-recorded, transcribed verbatim, anonymized, and analyzed using qualitative and quantitative methods

RESULTS

- 20 participants (ages 12.1 – 17.7 years, 50% female, 55% White/Caucasian) completed interviews; demographic and disease characteristics of participants are presented in **Table 1**

Table 1.Demographic and disease characteristics of participants

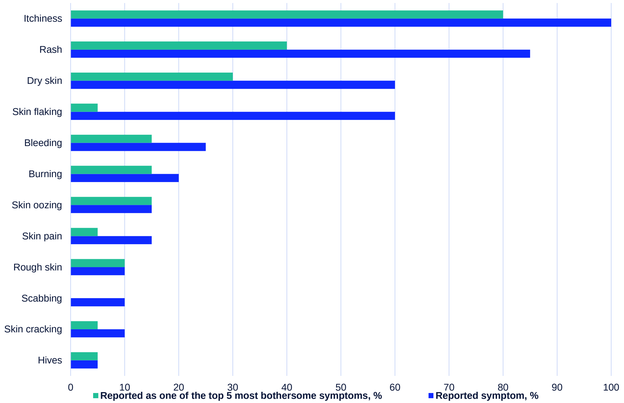
Characteristic	Total (N=20) n (%)	Characteristic	Total (N=20) n (%)
Age (in years)		**Race**	
Range	12.1 – 17.7	White/Caucasian	11 (55%)
Mean (SD)	14.9 (1.9)	Black/African American	7 (35%)
Gender		American Indian or Alaska Native	1 (5%)
Male	10 (50%)	Other	1 (5%)
Female	10 (50%)	**vIGA-AD scores**	
Ethnicity		Moderate (score of 3)	11 (55%)
Not Hispanic/LatinX	19 (95%)	Severe (score of 4)	9 (45%)
Other	1 (5%)		

SD = standard deviation; vIGA-AD = Validated Investigator Global Assessment of Atopic Dermatitis.

Concept elicitation

- Participants reported experiencing 12 AD symptoms (**Figure 1**); the most frequently reported were itchiness (n=20, 100%), rash (n=17, 85%), dry skin (n=12, 60%), and skin flaking (n=12, 60%)
  - –Itchiness, rash, and dry skin were also most frequently reported as among the top 5 most bothersome to participants
  - –All frequently reported and bothersome symptoms are assessed by the ADerm-SS
  - –Symptoms not assessed by the ADerm-SS (burning, rough skin, scabbing, hives) were reported by ≤20% of participants and overlap with other assessed concepts

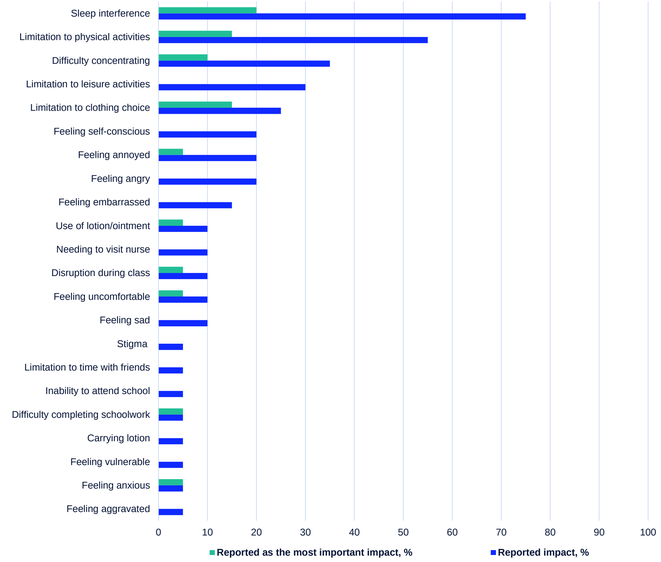
Figure 1. Atopic dermatitis symptoms reported by adolescents



Concept elicitation (continued)

- Participants reported experiencing 22 QoL impacts related to AD (**Figure 2**). The most frequently reported were sleep interference (n=15, 75%), limitation to physical activities (n=11, 55%), difficulty concentrating (n=7, 35%), and limitation to leisure activities (n=6, 30%)
  - –Sleep interference, limitation to clothing choice, and limitations to physical activities were reported as the most important impacts to participants
  - –The 3 of the 4 most frequently reported impacts and 2 of the 3 most important impacts (sleep interference, limitation to physical activities, difficulty concentrating) are assessed by the ADerm-IS
  - –Of the 8 impacts assessed by the ADerm-IS, 6 were reported by adolescents: sleep interference, limitation to physical activities, difficulty concentrating, feeling self-conscious, feeling embarrassed, feeling sad
  - –Because the ADerm-IS was originally developed for adults, concepts that may be more relevant to adolescents (e.g., limitation to leisure activities, limitation to clothing choice) are not assessed; while concepts included in the questionnaire that may be more relevant to adults (limitation to social activities, limitation to household activities) were not reported by adolescents

Figure 2. Atopic dermatitis quality of life impacts reported by adolescents



Cognitive debriefing

- Participants demonstrated that they were able to read, understand, and provide meaningful responses to the instructions and items for the ADerm-SS and ADerm-IS and reported having experienced most of the concepts assessed
- Results for the ADerm-SS are summarized in **Table 2**; results for the ADerm-IS are summarized in **Table 3**

Table 2. Cognitive debriefing summary for the ADerm-SS

Understandability	• All participants interpreted the instructions as intended by the developers • All participants understood the response scale direction and were able to select responses as intended by the developers • >75% of participants interpreted the questions as intended by the developers, except: — 8 participants were uncertain of the meaning of "skin thickening" — 7 participants were uncertain of the meaning of "skin cracking" and "skin oozing"
Relevance	• In completing the ADerm-SS, ≥80% of participants had experienced the symptoms assessed within the 24-hour recall period or prior to it, except: — 5 participants reported they had never experienced skin oozing
Comprehensiveness	• All participants reported that they did not consider any key symptoms to be missing from the questionnaire

Table 3. Cognitive debriefing summary for the ADerm-IS

Understandability	• All participants interpreted the instructions as intended by the developers • >75% of participants interpreted the questions as intended by the developers • All participants understood the response scale direction and were able to select responses as intended by the developers
Relevance	• In completing the ADerm-IS, ≥80% of participants had experienced the impacts assessed within the recall period or prior to it, except: — 8 participants reported never experiencing limitation to social activities – although this was identified by participants as being most important to assess among adolescents with AD — 7 participants reported never experiencing limitation to household activities, feeling embarrassed, or feeling sad due to AD
Comprehensiveness	• All participants reported that they did not consider any key QoL impacts to be missing from the questionnaire

CONCLUSIONS

- These qualitative results provide confirmatory evidence that the ADerm-SS and ADerm-IS, which were originally developed for adults, are relevant, comprehensive, comprehensible, and appropriate for use in adolescents with moderate-to-severe AD.
- These tools have been designed for use in clinical trials to evaluate severity of AD symptoms and impacts and may be appropriate for use in real-world clinical settings following further research.
- While this qualitative study was of a limited sample size, analysis of the scores produced by the questionnaires administered to adolescent participants in a Phase 3 clinical trial could provide further evidence of for the ability of the two questionnaires to produces scores that are reliable and valid in that patient population.

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