

Development of a Conceptual Model and Review of Patient- and Observer-Reported Outcome Measures in Atopic Dermatitis

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BACKGROUND

- Atopic dermatitis (AD) is a chronic, itchy, inflammatory skin disorder that affects both children and adults.
- Overall, AD affects approximately 15% to 30% of children and 2% to 10% of adults.¹
- Prevalence is higher, and on the rise, in industrial nations,^{2,3} and varies by age group and geographic region.^{1,4,5} However, ranges for these demographic characteristics may vary between countries.
- Emphasis on patient-focused drug development has increased interest in capturing the patient voice. Where patient input cannot be reported, caregiver input may be used.
- Since AD affects children and adults, both observer- and patient-reported outcomes (ObsROs and PROs, respectively) need to be considered in the assessment of the condition.

OBJECTIVES

- The objectives of this review were to:
 - Develop a literature-driven conceptual model for AD
 - Identify existing PRO and ObsRO measures that assess the literature-based AD concepts

METHODS

- A targeted search of the literature was conducted using Embase, Patient-Reported Outcome and Quality of Life Instruments Database (PROQolid), and PubMed to identify PRO and ObsRO measures that assess AD-related signs/symptoms and associated impacts.
 - Key words used in the searches included “atopic dermatitis”; “patient-reported outcomes”; “signs”; “symptoms”; “impact”; “observer-reported outcomes”
- Abstracts were retrieved and screened to identify potentially relevant articles.
- Relevant articles were then retrieved and reviewed in full for signs, symptoms, and impacts, as well as outcome measures assessing these domains.
- These concepts were organized into a conceptual model, and identified measures were evaluated to classify concepts assessed by each measure.

RESULTS

Signs, Symptoms, and Impacts Conceptual Model

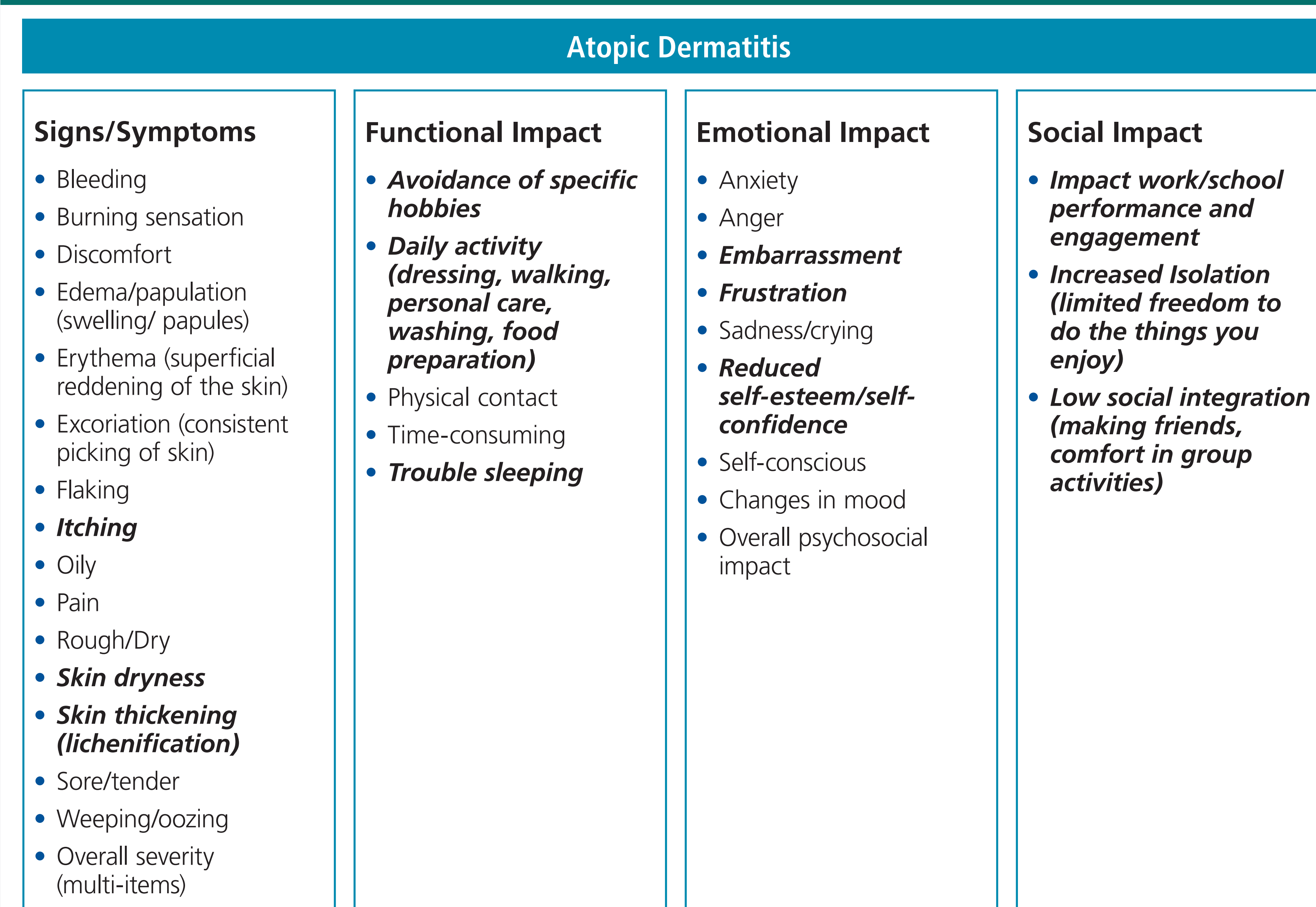
- Based on literature, AD-related concepts included signs/symptoms, functional impacts, emotional impacts, and social impacts.
- Figure 1** presents the literature-based conceptual model developed in order to summarize these concepts.
- The most commonly found sub-concepts for signs/symptoms of AD were itching, skin dryness, and skin thickening.
- Impact on daily activity, trouble sleeping, and avoidance of specific hobbies were the most commonly reported sub-concepts under functional impacts.
- Frustration, embarrassment, and reduced self-esteem/self-confidence were common emotional impacts.
- Isolation, low social integration, as well as a negative effect on work/school performance and engagement were frequently reported as social impacts.

Patient- and Observer-Reported Outcome Measures

- A total of 9 PRO and ObsRO measures for use in pediatrics (n=2), adults (n=6), as well as both pediatrics and adults (n=1), were identified and reviewed (**Table 1**).
- Of the 9 dermatology-specific measures that were identified, only 1 (the Quality of Life Index for Atopic Dermatitis [QoLIAD]) was specific to AD.
- The QoLIAD evaluates 9 sub-concepts, which represents 27% of the literature-based concepts, while the Dermatology-Specific Quality of Life Instrument (DSQL) for Contact Dermatitis evaluates 18 sub-concepts, which represents 55% of the literature-based concepts that were identified.
 - While the DSQL evaluated more literature-based concepts that were relevant to AD, it is important to note that it is not an AD-specific measure.

RESULTS (CONT.)

Figure 1. Conceptual Model of Literature-Based Concepts



Note: Bolded items represent the most frequently reported sub-concepts

Table 1. Patient- and Observer-Reported Outcome Measures Frequency of Concepts

Tool	PRO vs ObsRO or ClinRO	AD- vs dermatology-specific	Adult vs pediatric	Symptoms	Functional Impact	Psycho-social Impact	Social Impact	Total Frequency of Concepts	
								n	%
Quality of Life Index for Atopic Dermatitis ⁷	PRO	AD-specific	Adult	None	<ul style="list-style-type: none"> Daily activity Physical contact Time-consuming 	<ul style="list-style-type: none"> Anxiety Embarrassment Reduced self-esteem/self-confidence Sadness/crying Self-conscious 	<ul style="list-style-type: none"> Low social integration 	9	27%
Itch Visual Analog Scale ⁸	PRO	Dermatology-specific	Adult	None	<ul style="list-style-type: none"> Itching 	None	None	1	3%
Itch Numeric Rating Scale ⁸	PRO	Dermatology-specific	Adult	None	<ul style="list-style-type: none"> Itching 	None	None	1	3%
Itch Verbal Rating Scale ⁹	PRO	Dermatology-specific	Adult	None	<ul style="list-style-type: none"> Itching 	None	None	1	3%
DSQL instrument for contact dermatitis ¹⁰	PRO	Dermatology-specific	Adult	<ul style="list-style-type: none"> Burning sensation Discomfort Dryness Itching Oily Pain Sore/tender 	<ul style="list-style-type: none"> Avoidance of specific hobbies Daily activity Trouble sleeping 	<ul style="list-style-type: none"> Anger Embarrassment Frustration Reduced self-esteem/self-confidence Self-conscious 	<ul style="list-style-type: none"> Increased isolation Low social integration Negative impact on work/school performance and engagement 	18	55%
Patient-Oriented Eczema Measure ¹¹	PRO	Dermatology-specific	Adult	<ul style="list-style-type: none"> Bleeding Flaking Itching Rough/Dry Weeping/oozing 	<ul style="list-style-type: none"> Trouble sleeping 	None	None	6	18%
Dermatitis Family Impact Questionnaire ¹²	ObsRO	Dermatology-specific	Pediatric	None	<ul style="list-style-type: none"> Daily activity Trouble sleeping 	<ul style="list-style-type: none"> Overall psychosocial impact 	None	3	9%
Infants' Dermatitis QoL Index ¹³	ObsRO	Dermatology-specific	Pediatric	<ul style="list-style-type: none"> Overall severity (multi-items) 	<ul style="list-style-type: none"> Daily activity Trouble sleeping 	<ul style="list-style-type: none"> Changes in mood 	None	4	12%
Eczema Area and Severity Index ¹⁴	PRO and ObsRO	Dermatology-specific	Adult/ Pediatric	<ul style="list-style-type: none"> Edema/papulation Erythema Excoriation Skin thickening 	None	None	None	4	12%

Key: AD – atopic dermatitis; DSQL – Dermatology-Specific Quality of Life; ObsRO – observer-reported outcome; PRO – patient-reported outcome; QoL – quality of life.

CONCLUSION

- Based on the literature, AD-related concepts include signs/symptoms and associated impacts (ie, functional, emotional, social).
- The identified PRO and ObsRO measures were primarily developed for research purposes, as opposed to making regulatory decisions.
- While existing PRO and ObsRO measures include some of these AD concepts, the quality of the measures was not assessed.
- There appears to be a lack of comprehensive AD-specific measures, and future research should focus on a gap analysis.

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