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Reporting of Patient Global Assessments in Atopic Dermatitis Randomized Controlled Trials

To the Editor:

Standardization of clinical trials improves the integrity and utility of study results and allows for data synthesis, comparison,

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DOI: 10.1097/DER.0000000000000534

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TABLE 1. Eligibility Criteria

	Inclusion Criteria	Exclusion Criteria
Population	AD (atopic eczema)	Other skin diseases
Study design	Randomized controlled trials	Validation studies
Construct	PtGA	Articles mentioning quality of life in the title or abstract
Outcome	PtGA defined as patient-reported assessment that instructs patients to report the overall state of their condition in a holistic fashion integrating or using >1 disease domain including, but not limited to, signs, symptoms, quality of life, and perception of disease control.	Instruments that measure only 1 domain
Instrument type	Patient reported	All others
Publication type	Full-text articles	Abstracts, non-English publications

and improved interpretation. Many fields within medicine are progressing toward standardizing clinical trials, with emphasis on protocol design,¹ appropriate outcome measures,² and transparent reporting.³ Within dermatology, the Harmonising Outcome Measures for Eczema (HOME) initiative was formed to establish a minimal mandatory core set of outcome measures to be reported in all clinical trials of atopic dermatitis (AD).⁴ The HOME group recently set out to create a list of valid instruments that could be used in routine clinical practice. The new HOME clinical practice initiative conducted a research prioritization exercise that identified a patient global assessment (PtGA) instrument as being of high importance to investigators, clinicians, and patients in the clinical practice setting.⁵ No prior studies have examined the scope or type of PtGA instruments currently in use in AD.

This study aimed to identify AD trials reporting a PtGA instrument as an outcome measure and to characterize instrument features. A PtGA was defined as a patient-/parent-reported assessment that instructed patients to report the overall state of their condition in a holistic fashion integrating 1 or more disease domains including, but not limited to, signs, symptoms, quality of life, and perception of disease control (Table 1).

A systematic review of AD randomized controlled trials was performed based on Preferred Reporting Items for Systematic Reviews and Meta-analyses (PROSPERO: CRD42019124661). Eligible studies were identified through the Global Resource of Eczema Trials (GREAT) database from 2000 to 2018.

Articles were screened from titles and abstracts, followed by full-text review to determine final eligibility (Table 1). Results were summarized qualitatively.

TABLE 2. Demographic and Instrument Features From Systematic Review of GREAT Database

Study Demographics	
Location, %	
Europe	57.5
North America	25
Asia	5
Africa	2.5
Cross-continental	10
Population, %	
Adult	42.5
Pediatric	37.5
Both	20
AD severity for study inclusion, %	
Unspecified	7.5
Mild	2.5
Mild to moderate	22.5
Mild to severe	2.5
Moderate	5
Moderate to severe	32.5
Severe	12.5
Recalcitrant AD	2.5
AD with ≥ 4 prurigo nodules	2.5
Head and neck AD	2.5
AD warranting potent topical steroids	
Minimum AD outcome score	5
Instrument features	
Assessment type, %	
Static	52.5
Dynamic	45
No data	2.5
Outcome measure, %	
Primary	0
Secondary	100
Response scale, %	
Unspecified	15
4-point scale	37.5
5-point scale	10
6-point scale	10
7-point scale	10
9-point scale	2.5
100-mm visual analog scale	10
"Select one of the following"	5
Response: clear option?	
Yes	32.5
No	47.5
No data	20
Response scale completeness, %	
Complete scale provided	52.5
Incomplete scale provided	35
No scale provided	12.5

Initial query of the GREAT database yielded 164 studies, 40 of which met inclusion criteria (Table 1). Included studies were geographically diverse, located in Europe (57.5%), North America (25%), Asia (5%), Africa (2.5%), and transcontinentally (10%), and encompassed adult (42.5%), pediatric (37.5%), and combined (20%) populations. A total of 34 unique instruments were identified from the 40 included studies, with the following 3 instruments found in 1 or more studies: Patient Global Assessment (n = 3), Patient's Self-assessment (n = 2), and Patient's Assessment of Global Response (n = 4). The PtGA was reported as a secondary outcome in 100% of studies. Just more than half (52.5%) of PtGAs were static (Table 2).

The scale used for patient responses varied greatly between studies. Many used a point-based format in which numerical values correlated with response options, ranging from 4 (37.5%) to 9 points (2.5%). Others were based on a 100-mm visual analog scale (10%). A distinguishing feature between PtGAs was a clear/no disease option, with 32.5% including a clear option, 47.5% without a clear option, and 20% without sufficient data (Table 2).

This systematic review revealed significant heterogeneity of PtGA instruments used in AD studies. Key defining features between PtGAs were the inclusion of clear option and whether the instrument was static or dynamic. Levels of severity and recall periods also varied. Further work is needed in developing, standardizing, and validating a PtGA for AD for use in clinical practice.

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Willingness to Participate in Atopic Dermatitis Studies and Clinical Trials

To the Editor:

There remain unmet therapeutic needs for atopic dermatitis (AD) that warrant further research and development of novel therapies.¹ We performed a prospective online questionnaire-based study to determine AD patients' willingness and barriers to participate in research and clinical trials. Members of nonprofit support groups for AD (National Eczema Association and National Eczema Society) were invited to respond to the survey. All patients provided electronic informed consent. The completion rate for the survey was 95.1% among those who began the survey; partial responses were excluded. Data were deidentified and confidential and posed minimal risk to participants. The study was approved by the institutional review board at Northwestern University.

Overall, 313 adults (18–39 years: 65.0%; 79.3% female) and 157 parents of children (<5 years: 40.9%; 37.7% female) with AD completed the survey. Thirty-one adults (10.2%) and 14 children (9.4%) were offered to participate in AD research, of which 21 (72.4%) and 9 (69.2%) agreed to participate, respectively.

In adults, the top 3 factors that respondents reported strongly influenced their participation in research were as follows: other patients with eczema may benefit (71.9%), contributing to the advancement of knowledge in the field (71.9%), and feeling study's objectives were important (61.9%) (Table 1). In parents of children, the top factors that strongly influenced their child's participation in research were feeling study's objectives were important (77.7%), contributing to the advancement of knowledge in the field (66.6%), other patients with eczema may benefit (44.4%), and fully understanding the study (44.4%). Other less influential reasons included minimal risk to self or child, given sufficient time to make a decision, felt comfortable with the person presenting the study, may discontinue participation at any point, and participation in the study will ensure the best medical care. No respondents reported feeling pressured to participate as an influencing factor.

In this study, approximately 10% of respondents were invited to participate in research, of which 70% agreed to participate. A

J.I.S. served as a consultant and/or advisory board member for Abbvie, Asana, Dermira, Eli Lilly, Galderma, GlaxoSmithKline, Glenmark, Kiniksa, Leo, Menlo, Pfizer, Regeneron-Sanofi, Realm, and Dermavant that granted honoraria; served as a speaker for Regeneron-Sanofi and received research grants from GlaxoSmithKline and Galderma. J.I.S. is supported by the Dermatology Foundation. K.R.P. has no funding or conflicts of interest to declare.

J.I.S. had full access to all the data in the study and take responsibility for the integrity of the data and accuracy of the data analysis, did the study concept and design, did the acquisition of the data, and obtained funding. P.K.R. and J.I.S. drafted the article, did the critical revision of the article for important intellectual content, and did the statistical analysis.

DOI: 10.1097/DER.0000000000000487

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