HOME III

Measurement properties of outcome measurements for atopic dermatitis signs

Jochen Schmitt, Stefanie Deckert, Sinead Langan, Ake Svensson, Laura von Kobyletzki, Kim Thomas, Phyllis Spuls

San Diego, April 6-7, 2013

Background

Harmonizing Outcome Measures for Eczema

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DECEMBER 2007

What are the best outcome measurements for atopic eczema? A systematic review

Jochen Schmitt, MD, MPH,[a] Sinead Langan, MD,[b] and Hywel C. Williams, PhD, FRCP,[b]

Objective: to identify and critically appraise all named outcome measurements specifically designed for AD to measure disease severity

ADAM	Atopic Dermatitis Assessment Measure
ADASI	Atopic Dermatitis Area and Severity Index
ADSI	Atopic Dermatitis Severity Index
BCSS	Basic Clinical Scoring System
EASI	Eczema Area and Severity Index
FSSS	Four Step Severity Score
IGADA	Investigators´ Global Atopic Dermatitis Assessment
Leicester	Leicester index
NESS	Nottingham Eczema Severity Score
OSAAD	Objective Severity Assessment of Atopic Dermatitis
POEM	Patient-Oriented Eczema Measure
RL Score	Rajka and Langeland Score
SA-EASI	self-administered Eczema Area and Severity Index
SASSAD	Six Area, Six Sign Atopic Dermatitis severity score
SCORAD	Severity Scoring of Atopic Dermatitis index
SIS	Skin Intensity Score
SSS	Simple Scoring System
TBSA	6-area Total Body Severity Assessment
TIS	Three Item Severity Score
W-AZS	(Polish acronym for atopic dermatitis severity score)

TABLE I. Psychometric properties and scale quality criteria considered in this review

Name of quality item	Definition of quality item	Measurement of quality item	Criteria for rating "adequate"	Criteria for rating "acceptable"
Construct validity:	Does the scale measure the hypothetical construct (objective severity of AE) it should?			
(a) convergent	(a) Are 2 outcome measurements that are presumed to measure the same latent construct correlated?	(a) and (b) Confirmatory factor analysis, Structural equations modeling (correlation of coefficients)	(a) Factor loading/ correlation coefficient >0.70	(a) Factor loading/ correlation coefficient 0.60-0.69
(b) divergent	(b) Are 2 outcome measurements that are presumed to measure different constructs not (highly) related?		(b) factor loading/ correlation coefficient <0.70	(b) Factor loading/ correlation coefficient 0.71-0.85
Content validity	Are the domains adequate to measure the construct in question? Are the items representative of the domain they are supposed to measure?	Rating by experts and consumers	Expert/consumer says yes for at least 90% of all items	Expert/consumer says yes for 70% to 89% of all items
Internal consistency	Are the different domains/items of the scale interrelated?	Cronbach α*	≥0.90 (individual patients) ≥0.70 (groups)	0.70-0.89 (individual patients) 0.60-0.69 (groups)
Interobserver reliability	Do 2 or more independent investigators achieve the same result?	(a) Correlation coefficient (b) κ† (c) Coefficient of variation (d) ANOVA (% variance explained by observer)	(a) >0.80 (b) >0.60 (c) <20% (d) <10%)	(a) 0.60-0.80 (b) 0.41-0.60 (c) 20% to 30% (d) 10% to 20%
Test-retest reliability	Do 2 assessments by one investigator in the same patient yield the same result?	(a) Correlation coefficient (b) Percentage variation (c) Coefficient of variation	(a) 0.90 (b) <5% (c) <10%	(a) 0.80-0.90 (b) 5% to 10% (c) 10% to 20%
Sensitivity to change	Can clinically relevant changes be detected by this measurement?	Correlation of changes in 2 or more outcome measurements of the same construct	>0.80	0.60-0.80
Acceptability	Is the measurement practical enough to be applied in: (a) everyday clinical practice (b) clinical trials	Time to administer	 (a) <3 min (b) <7 min	 (a) 3-5 min (b) 7-10 min

Criteria for recommendations

A total relative score ranging from 0% to 100% was calculated for each outcome measurement

Score	Recommendation	Reason
> 90%	highly recommended	measurement is valid & reliable
70-90%	recommended	measurement meets most validity criteria
50-69%	acceptable but not recommended	validity criteria only partly met
30-49%	not recommended	significant validity criteria are not met or have not been evaluated
< 30%	not acceptable	measurement is invalid or has not been validated

Recommendations

Recommendation	Outcome measurement
highly recommended	
recommended	EASI, SCORAD, POEM
acceptable but not recommended	IGADA, NESS, SA-EASI, SASSAD, TIS
not recommended	ADAM, ADASI, BCSS, Leicester Index, RL Score, SSS
not acceptable	ADSI, FSSS, OSAAD, SIS, TBSA, WAZ-S

JACI 2007; 120:1389-98

Objectives of systematic review

1. To systematically assess measurement properties of outcome measurements for atopic dermatitis **signs**

2. To identify outcome measures for atopic dermatitis signs
   - that meet the predefined criteria (*OMERACT Filter*) to be recommended for the measurement of signs in future atopic dermatitis trials
   - that have the potential to be recommended in the future depending on the results of further validation studies
   - that do **not** meet the predefined criteria to be recommended and therefore should **not** be used any more.

3. To provide the evidence base
   - for an international consensus process to further standardize the assessment of atopic dermatitis signs in clinical trials.
   - for an international consensus process to prioritize further research concerning atopic dermatitis signs outcome assessment.

Methods

Harmonizing Outcome Measures for Eczema

A priori study protocol

www.crd.york.ac.uk/Prospero/display_record.asp?ID=CRD42013003935

PROSPERO
International prospective register of systematic reviews

NHS
National Institute for Health Research

Systematic review of measurement properties of outcome measurements for atopic eczema signs

Jochen Schmitt, Sinead Langan, Stefanie Deckert, Marjolein de Bruin-Weller, Ake Svensson, Laura von Kobyletzki, Kim Thomas, Phyllis Spuls

Citation
Jochen Schmitt, Sinead Langan, Stefanie Deckert, Marjolein de Bruin-Weller, Ake Svensson, Laura von Kobyletzki, Kim Thomas, Phyllis Spuls. Systematic review of measurement properties of outcome measurements for atopic eczema signs. PROSPERO 2013:CRD42013003935 Available from http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42013003935

Review question(s)
1. To systematically assess measurement properties of outcome measurements for atopic eczema signs.

2. To identify outcome measures for atopic eczema signs:

a) that meet the predefined criteria to be recommended for the measurement of signs in future atopic eczema trials;

b) that have the potential to be recommended in the future depending on the results of further validation studies;

c) that do not meet the predefined criteria to be recommended and should therefore no longer be used.

3. To provide the evidence base:

a) for an international consensus process to further standardize the assessment of atopic eczema signs in clinical trials;

Options
Print
PDF

Share

Revision Notes
Revision History
Feb 27 2013 3:36PM

Research question

…divided by PICOS-criteria

Which

(P) atopic dermatitis

(I and C) not applicable

(O) outcome measurements exist to assess **disease severity** and were investigated regarding to

(S) measurement properties?

Inclusion and exclusion criteria for study selection

	inclusion	exclusion
Population	atopic eczema (syn: eczema, atopic, dermatitis, neurodermatitis)	all others
Outcome	clinical signs	• exclusively symptoms, quality of life or other domains investigated • biomarker or skin physiology measures as comparators
Study Design	• validation studies or inauguration • papers with at least one of the following measurement properties: content validity, construct validity, internal consistency, reliability, senisitivity to change, floor or ceiling effects, interpretability, acceptability	• articles that report an eligible scale without any explicit validation • linguistic validation • studies which assess discriminant validity only

Systematic literature search

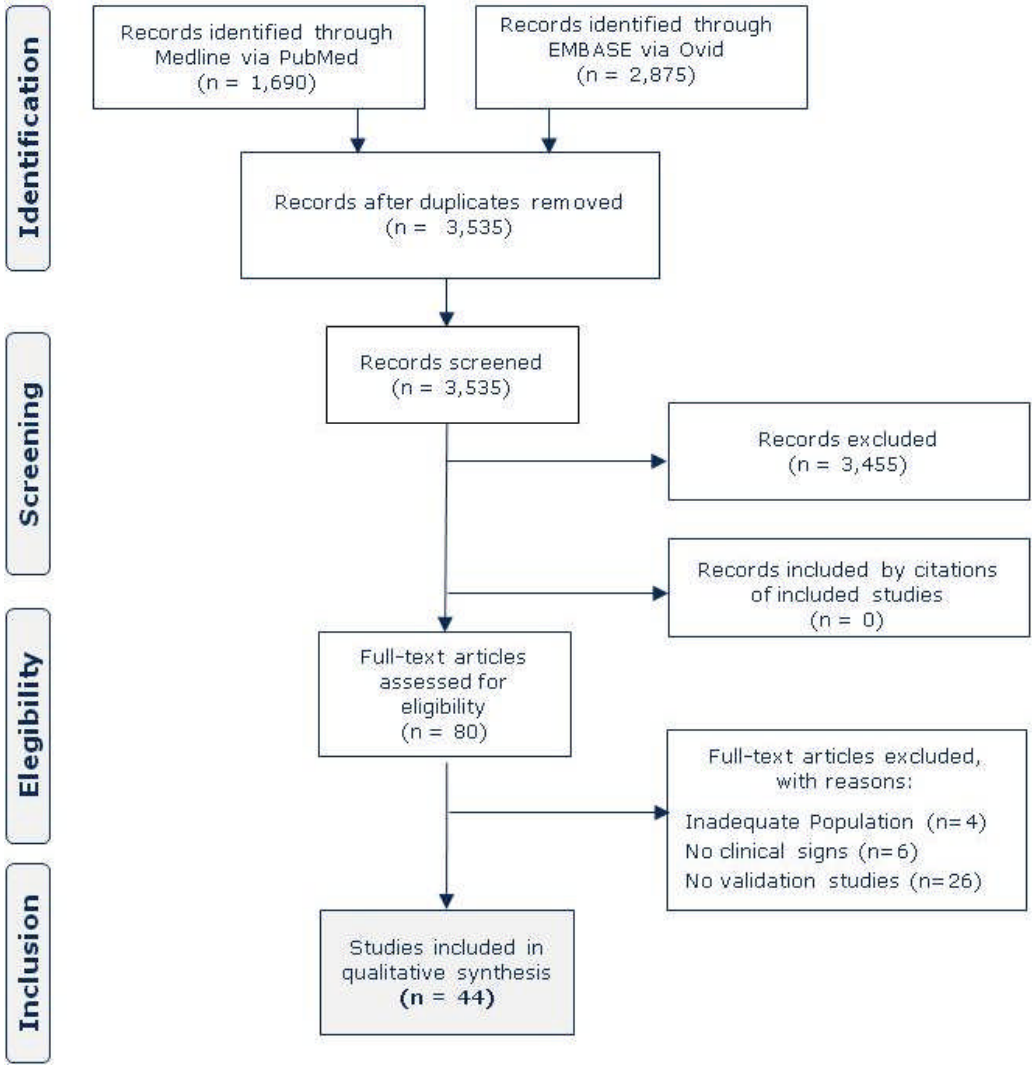
- **Systematic electronic search**
  - Medline via PubMed and EMBASE via Ovid (up to Oct 1st 2012)

("**dermatitis, atopic"**[MeSH] OR atopic dermatitis[tiab] OR atopic eczema[tiab] OR eczema[MeSH] OR eczema[tiab] OR "neurodermatitis"[MeSH] OR Neurodermatitis[tiab])
AND
((“**Severity of Illness** Index”[mh:noexp] OR “Severity of Illness Index”[tiab] OR ((severity[tiab] OR severe[tiab]) AND (scor*[tiab] OR measure*[tiab] OR item[tiab] OR index[tiab] OR instrument[tiab] OR questionnaire[tiab] or scal*[tiab] or tool*[tiab] or assessment[tiab])))….
AND
(**instrumentation[**sh] OR methods[sh] OR Validation Studies[pt] OR Comparative Study[pt] OR “psychometrics”[MeSH] OR psychometr*[tiab] OR clinimetr*[tw] OR clinometr*[tw] OR “outcome assessment (health care)”[MeSH] OR outcome assessment[tiab] OR outcome measure*[tw]……
NOT
(“animals”[MeSH Terms] NOT “humans”[MeSH Terms])

Systematic literature search

- **Systematic electronic search**
  - Medline via PubMed and EMBASE via Ovid (up to Oct 1st 2012)
- **Hand search**
  - search of reference lists of studies included and key articles on this topic

Flow Chart


Identification
Records identified through Medline via PubMed (n = 1,690)
Records identified through EMBASE via Ovid (n = 2,875)
Records after duplicates removed (n = 3,535)
Screening
Records screened (n = 3,535)
Records excluded (n = 3,455)
Records included by citations of included studies (n = 0)
Elegibility
Full-text articles assessed for eligibility (n = 80)
Full-text articles excluded, with reasons:
Inadequate Population (n=4)
No clinical signs (n=6)
No validation studies (n=26)
Inclusion
Studies included in qualitative synthesis (n = 44)

Data extraction and quality assessment

- Data extraction and assessment for each “substudy”
- independent quality assessment
  - **methodological quality of included studies** based on COSMIN checklist → rating: a 4-point scale → “worse score counts”
  - **rating of scale quality** (see handout)

Four categories of recommendation

A) Outcome measure meets **all requirements** to be recommended for use.

B)Outcome measure meets **two or more quality items**, but performance in **all other required quality items is unclear**, so that the outcome measure has the potential to be recommended in the future depending on the results of further validation studies.

C)Outcome measure has **low quality in at least one required quality criteria** (≥1 rating of “minus“) and therefore is not recommended to be used any more

D)Outcome measure has **(almost) not been validated**. Its performance in all or most relevant quality items is unclear, so that it is not recommended to be used until further validation studies clarify its quality.

Results

Harmonizing Outcome Measures for Eczema

Summary of studies

- 15 instruments identified to assess AD clinical signs
- published between 1989 and 2012
- most studies were conducted in the USA, UK, and NL
- most studies were performed on SCORAD (n=21) and EASI (n=10)
- study population consisted of more than 1,500 patients for both SCORAD and EASI including infants, children, and adults

No. of validation substudies per scale

Quality item (name)	SCORAD	TIS	EASI	SASSAD	POEM	BCSS	ADAM	ADASI	ADQ	OSAAD	SSS	W-AZS	Unnamed sale 1	Unnamed sale 2
Content validity	3	2	2	2	3	1	1	2	1	1	2	2	2	2
Construct validity	17	3	8	2		1			1	3	1			
Internal consistency	7	1	2		1		1							
Intra-observer reliability	1		1	1	1									
Inter-observer reliability	11	5	3	1		1	1			1	2		1	1
Sensitivity to change	2		2		2					1				
Floor or ceiling effects	2	2		1						2	1			
Interpretability	2	1												
Acceptability	3	1	1	1	1			1	1	1				

Summary of scale domains and items (scale content)

Name of scale	Items of signs domain													Consideration of intensity and extent of signs		Other domains		
	erythema	edema / induration / papulation	oozing/ crusting / weeping/ exudation	excoriation	lichenification	dryness	scaling	cracking / fissuring	vesicles	(de)pigmentation	flaking	bleeding	erosions	only intensity of signs	intensity AND extent of signs	Symptoms	Epidermal function	Complications
ADAM, 1999	•			•	•		•								•	•		
ADASI, 1991	•	•	•		•		•								•	•		
ADQ, 2008	•		•			•	•	•							•	•		
BCSS, 1995															•			
EASI, 1998	•	•		•	•										•			
OSAAD, 2003	•		•	•	•										•		•	
POEM, 2004			•			•		•			•	•		frequency of signs		•		
SA-EASI, 2002	•	•		•		•									•	•		
SASSAD, 1996	•		•	•	•	•		•							•			
SCORAD, 1993	•	•	•	•	•	•									•	•*		
SSS, 1989	•	•	•	•	•		•		•	•					•	•		
TIS, 1999	•	•		•										•				
W-AZS, 2005	•	•	•				•		•	•			•		•	•		
Unnamed 1	•	•			•	•							•		•	•		•
Unnamed 2	•				•	•							•		•	•		•

Two key studies on content validity …

A cooperative effort of the Clinical Epidemiology Unit of the Istituto Dermopatico dell'Immacolata Istituto di Ricovero e Cura a Carattere Scientifico (IDI-IRCCS) and the Archives of Dermatology

Measuring Atopic Eczema Severity Visually

Which Variables Are Most Important to Patients?

Carolyn R. Charman, BM, BCh, MRCP; Andrea J. Venn, PhD; Hywel Williams, MSc, PhD, FRCP; Michael Bigby, MD

Background: There is wide variation in the objective visual variables used to measure atopic eczema severity in clinical trials, making comparison and interpretation of results difficult.

Objective: To provide a rationale for simplifying and standardizing objective atopic eczema scoring by investigating which visual variables provide the best measure of disease severity from the patient's perspective.

Setting: The dermatology outpatient department at the Queen's Medical Centre, University Hospital in Nottingham, and 5 local general practices.

Patients: One hundred eighty individuals with atopic eczema.

Interventions: Clinical examination with scoring of 7 clinical signs and disease extent, followed by regression analyses of visual variable scores against a patient-rated measure of current disease severity.

Results: Objective measurements account for only a quarter of the variation in patient-rated disease severity. Three clinical signs were independent predictors of patient-rated disease severity: excoriations, erythema, and edema/papulation. Disease extent measurements do not reflect patient-rated disease severity in a linear manner, with mean severity scores increasing little above 30% body surface area involvement.

Conclusions: From the patient's perspective, the measurement of 3 clinical signs—excoriations, erythema, and edema/papulation—provides as much information about current atopic eczema severity as more complex scoring systems that measure multiple clinical signs and disease extent. The simplicity of the Three Item Severity score, a previously published atopic eczema score based on measurement of these 3 clinical signs, makes it a suitable tool for research studies or clinical practice.

Arch Dermatol. 2005;141:1146-1151

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Content validity: Expert and consumer survey

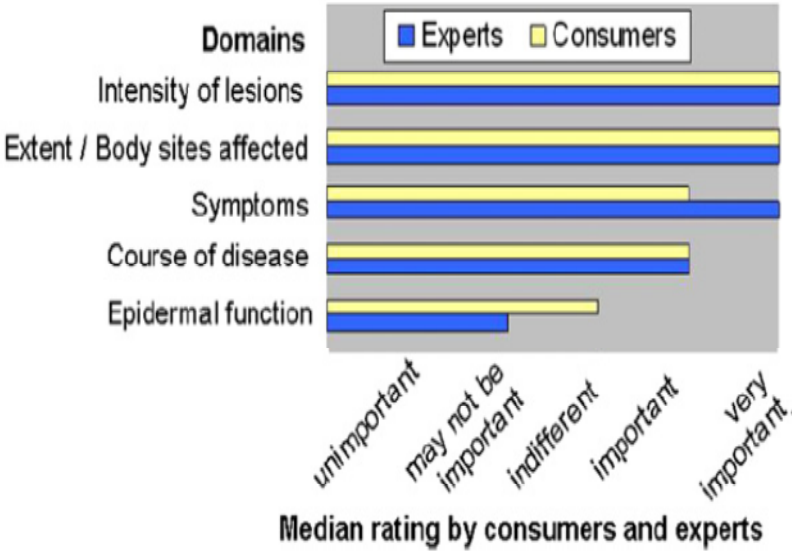
a) Are the domains adequate to measure the severity of AD?

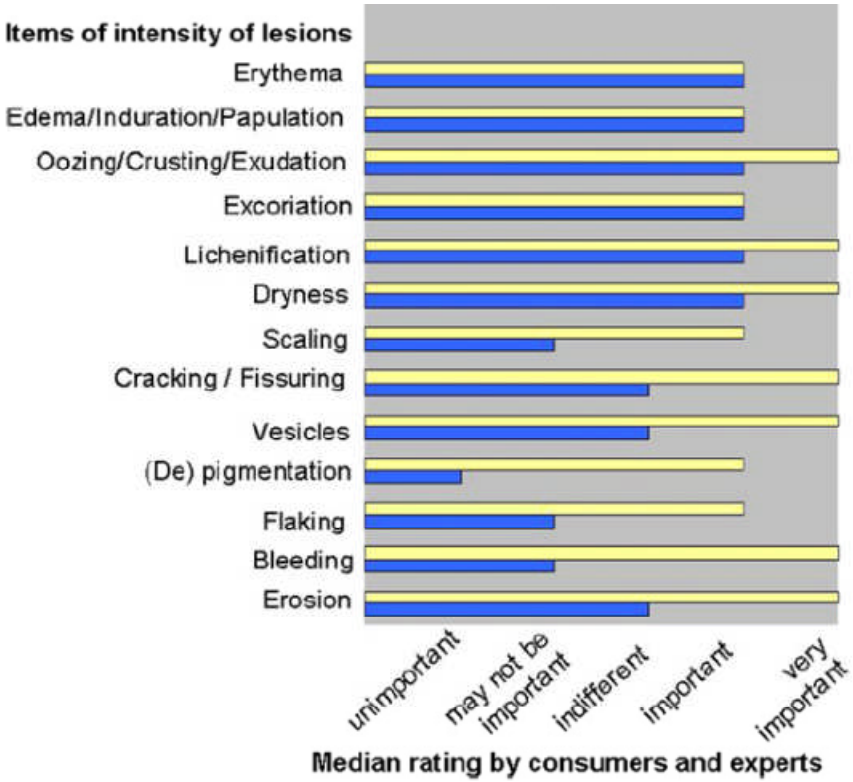
b) Are the items representative of the domain they are supposed to measure?

- **12 consumers:** 4 adult patients, 4 patients aged 8-14 years, 4 caregivers of patients aged 1-7 years
- **6 clinical experts** not involved in scale development

→ Assessment of content validity of all **domains** and **items** included in the outcomes identified on 5-point Likert scale

Content validity of domains and items





Summary of scale domains and items (scale content)

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ADAM, 1999	•			•	•		•								•	•		
ADASI, 1991	•	•	•		•		•								•	•		
ADQ, 2008	•		•			•	•	•							•	•		
BCSS, 1995															•			
→ EASI, 1998	•	•		•	•										•			
OSAAD, 2003	•		•	•	•										•		•	
POEM, 2004			•			•		•			•	•		frequency of signs		•		
→ SA-EASI, 2002	•	•		•		•									•	•		
SASSAD, 1996	•		•	•	•	•		•							•			
→ SCORAD, 1993	•	•	•	•	•	•									•	•*		
→ SSS, 1989	•	•	•	•	•		•		•	•					•	•		
→ TIS, 1999	•	•		•										•				
W-AZS, 2005	•	•	•				•		•	•			•		•	•		
Unnamed 1	•	•			•	•							•		•	•		•
Unnamed 2	•				•	•							•		•	•		•

Summary of psychometric properties of measures for clinical signs of eczema

Quality item (name)	SCORAD	TIS	EASI	SASSAD	POEM	BCSS	ADAM	ADASI	ADQ	OSAAD	SSS	W-AZS	Unnamed sale 1	Unnamed sale 2
Content validity	+	+	+	+/-	-	-	+/-	+/-	-	-	+/-	+/-	+/-	-
Construct validity	+	+/-	+	+	n.r.	-	n.r.	n.r.	+/-	+/-	?	n.r.	n.r.	n.r.
Internal consistency	+/-	+/-	+	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Intra-observer reliability	n.r.	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Inter-observer reliability	+	+/-	+/-	+/-	n.a.	+	+/-	n.r.	n.r.	+	?	n.r.	+	+
Sensitivity to change	+	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	?	n.r.	n.r.	n.r.	n.r.
Floor or ceiling effects	+	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	+	+	n.r.	n.r.	n.r.
Interpretability	+	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Acceptability	+/-	+	n.r.	+	+	n.r.	n.r.	+	+	-	n.r.	n.r.	+	+
RECOMMENDATION	**B**	**B**	**B**	**B**	**C**	**C**	**D**	**D**	**C**	**C**	**D**	**D**	**D**	**C**

(+) positive rating indicating „adequate“ scale quality; (+/-) intermediate rating indicating “intermediate” scale quality; (-) negative rating indicating “inadequate” scale quality
n.r.: not reported

Categories of recommendation:

A) Outcome measure meets all requirements to be recommended for use.
B) Outcome measure meets two or more quality items, but performance in all other required quality items is unclear, so that the outcome measure has the potential to be recommended in the future depending on the results of further validation studies.
C) Outcome measure has low quality in at least one required quality criteria (≥1 rating of “minus“) and therefore is not recommended to be used (as a measurement of eczema signs) any more.
D) Outcome measure has (almost) not been validated. Its performance in all or most relevant quality items is unclear, so that it is not recommended to be used until further validation studies clarify its quality.

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Construct validity	+	+/-	+	+	n.r.	-	n.r.	n.r.	+/-	+/-	?	n.r.	n.r.	n.r.
Internal consistency	+/-	+/-	+	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Intra-observer reliability	n.r.	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Inter-observer reliability	+	+/-	+/-	+/-	n.a.	+	+/-	n.r.	n.r.	+	?	n.r.	+	+
Sensitivity to change	+	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	?	n.r.	n.r.	n.r.	n.r.
Floor or ceiling effects	+	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	+	+	n.r.	n.r.	n.r.
Interpretability	+	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Acceptability	+/-	+	n.r.	+	+	n.r.	n.r.	+	+	-	n.r.	n.r.	+	+
RECOMMENDATION	**B**	**B**	**B**	**B**	**C**	**C**	**D**	**D**	**C**	**C**	**D**	**D**	**D**	**C**

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Internal consistency	+/-	+/-	+	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Intra-observer reliability	n.r.	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Inter-observer reliability	+	+/-	+/-	+/-	n.a.	+	+/-	n.r.	n.r.	+	?	n.r.	+	+
Sensitivity to change	+	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	?	n.r.	n.r.	n.r.	n.r.
Floor or ceiling effects	+	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	+	+	n.r.	n.r.	n.r.
Interpretability	+	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Acceptability	+/-	+	n.r.	+	+	n.r.	n.r.	+	+	-	n.r.	n.r.	+	+
RECOMMENDATION	**B**	**B**	**B**	**B**	**C**	**C**	**D**	**D**	**C**	**C**	**D**	**D**	**D**	**C**

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Construct validity	+	+/-	+	+	n.r.	-	n.r.	n.r.	+/-	+/-	?	n.r.	n.r.	n.r.
Internal consistency	+/-	+/-	+	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Intra-observer reliability	n.r.	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Inter-observer reliability	+	+/-	+/-	+/-	n.a.	+	+/-	n.r.	n.r.	+	?	n.r.	+	+
Sensitivity to change	+	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	?	n.r.	n.r.	n.r.	n.r.
Floor or ceiling effects	+	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	+	+	n.r.	n.r.	n.r.
Interpretability	+	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Acceptability	+/-	+	n.r.	+	+	n.r.	n.r.	+	+	-	n.r.	n.r.	+	+
RECOMMENDATION	**B**	**B**	**B**	**B**	**C**	**C**	**D**	**D**	**C**	**C**	**D**	**D**	**D**	**C**

(+) positive rating indicating „adequate“ scale quality; (+/-) intermediate rating indicating “intermediate” scale quality; (-) negative rating indicating “inadequate” scale quality
n.r.: not reported

Categories of recommendation:

A) Outcome measure meets all requirements to be recommended for use.
B) Outcome measure meets two or more quality items, but performance in all other required quality items is unclear, so that the outcome measure has the potential to be recommended in the future depending on the results of further validation studies.
C) Outcome measure has low quality in at least one required quality criteria (≥1 rating of “minus“) and therefore is not recommended to be used (as a measurement of eczema signs) any more.
D) Outcome measure has (almost) not been validated. Its performance in all or most relevant quality items is unclear, so that it is not recommended to be used until further validation studies clarify its quality.

Summary of psychometric properties of measures for clinical signs of eczema

Quality item (name)	SCORAD	TIS	EASI	SASSAD	POEM	BCSS	ADAM	ADASI	ADQ	OSAAD	SSS	W-AZS	Unnamed sale 1	Unnamed sale 2
Content validity	+	+	+	+/-	-	-	+/-	+/-	-	-	+/-	+/-	+/-	-
Construct validity	+	+/-	+	+	n.r.	-	n.r.	n.r.	+/-	+/-	?	n.r.	n.r.	n.r.
Internal consistency	+/-	+/-	+	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Intra-observer reliability	n.r.	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Inter-observer reliability	+	+/-	+/-	+/-	n.a.	+	+/-	n.r.	n.r.	+	?	n.r.	+	+
Sensitivity to change	+	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	?	n.r.	n.r.	n.r.	n.r.
Floor or ceiling effects	+	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	+	+	n.r.	n.r.	n.r.
Interpretability	+	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Acceptability	+/-	+	n.r.	+	+	n.r.	n.r.	+	+	-	n.r.	n.r.	+	+
RECOMMENDATION	**B**	**B**	**B**	**B**	**C**	**C**	**D**	**D**	**C**	**C**	**D**	**D**	**D**	**C**

(+) positive rating indicating „adequate“ scale quality; (+/-) intermediate rating indicating “intermediate” scale quality; (-) negative rating indicating “inadequate” scale quality
n.r.: not reported

Categories of recommendation:

A) Outcome measure meets all requirements to be recommended for use.
B) Outcome measure meets two or more quality items, but performance in all other required quality items is unclear, so that the outcome measure has the potential to be recommended in the future depending on the results of further validation studies.
C) Outcome measure has low quality in at least one required quality criteria (≥1 rating of “minus“) and therefore is not recommended to be used (as a measurement of eczema signs) any more.
D) Outcome measure has (almost) not been validated. Its performance in all or most relevant quality items is unclear, so that it is not recommended to be used until further validation studies clarify its quality.

Eczema area and severity index (EASI)

EASI: Area of Involvement

0	1	2	3	4	5	6
No eruption	<10%	10% - 29%	30% - 49%	50% - 69%	70% - 89%	90% - 100%

Erythema	**(E)**
0 – None	
2 – Moderate	(erosion, crust) Several linear marks of skin with some showing evidence of deeper skin injury (erosion, crust)
3 – Severe	Many erosive or crusty lesions
Lichenification	**(L)**
0 – None	
1 – Mild	Slight thickening of the skin discernible only by touch and with skin markings minimally exaggerated
2 – Moderate	Definite thickening of the skin with skin markings exaggerated so that they form a visible criss-cross pattern
3 - Severe	Thickened indurated skin with skin markings visibly portraying an exaggerated criss-cross pattern

Head / Neck	(E + I + Ex + L) x Area[1] x 0.1	(+ + +) X X 0.1 =	
Trunk	(E + I + Ex + L) x Area[1] x 0.3	(+ + +) X X 0.3 =	
Upper limbs	(E + I + Ex + L) x Area[1] x 0.2	(+ + +) X X 0.2 =	
Lower limbs	(E + I + Ex + L) x Area[1] x 0.4	(+ + +) X X 0.4 =	
EASI	Sum of the above four body areas		Total Score=

Author	**Content Validity** Method	Result	Interpret.	Study base	COSMIN score
Charman, C.R. et al. 2005	Simple and multiple linear regression analysis of items on patient global assessment (bother)	SLR: all 4 clinical signs of the EASI (erythema, edema/ papulation, excoriations, lichenification) are significantly associated with global bother score MLR: excoriations, edema/ papulation, and erythema are independently related to patient-rated disease severity.	(+)	180 children and adults (mild to severe)	excellent
Schmitt et al. 2007	Rating of importance of domains and items of outcome measures on 5-point Likert scale	Median rating of all three SCORAD domains, and each of the items of signs domain (erythema, edema, oozing, excoriation, lichenification, dryness) rated as "important" or "very important"	(+)	12 consumers (patients and caregivers) and 6 clinical experts	fair
Conclusion: 2 studies assessed content validity of the EASI items, indicating adequate content validity. ➔ Content validity of the EASI: **adequate** ➔ Quality of evidence: excellent to fair					

Eczema area and severity index (EASI)

Author	Construct Validity				
	Method	Result	Interpret.	Study base	COSMIN score*
Housman et al. 2002	Pearson EASI vs. SA-EASI	r = 0.62 acute SA-EASI and acute EASI; r= 0.60 chronic SA-EASI and chronic EASI r = 0.17-0.30 VAS components acute SA-EASI with similar components acute EASI; r = 0.32-0.45 VAS components chronic SA-EASI with similar components chronic EASI;	(+/-) with chronic SA-EASI (+/-) with acute SA-EASI	47 children (severity of AD not reported)	good
Mazzotti et al. 2005	Spearman SA-EASI vs. oSCORAD	r = 0.71	(+) SA-EASI with oSCORAD	35 children (moderate to severe)	fair
Mazzotti et al. 2008	Spearman SA-EASI vs. oSCORAD	r = 0.71	(+) SA-EASI with oSCORAD	98 children (moderate to severe)	fair
Rullo et al. 2008	Spearman EASI vs. SCORAD at 2 timepoints	r =0.881 to 0.930	(+) with SCORAD	42 children (mild to severe), 2 investigators	fair
Shim et al. 2011	Pearson EASI vs. itching intensity (VAS-itch)	r = 0.169 EASI vs. VAS-itch r = 0.346 EASI and VAS-sleep	(-) with VAS-itch	83 children and adults	fair
Tremp et al. 2011	Spearman EASI vs. digital images (SCORADdig and EASIdig)	r = 0.921 baseline, r = 0.887 after 12 weeks (unclear if result relates to SCORAD or EASI)	(+) with digital images	48 adults (mild to severe)	poor
van Velsen et al. 2010	Pearson and Spearman SA-EASI vs. oSCORAD and SA-EASI vs. SASSAD	r = 0.61 SA-EASI vs. oSCORAD r = 0.37 SA-EASI vs. SCORAD signs domain r = 0.43 SA-EASI vs. SASSAD	(+/-) SA-EASI with oSCORAD (-) SA-EASI with SCORAD signs domain (-) SA-EASI with SASSAD	60 children (moderate to severe)	fair
Yang et al. 2010	Pearson EASI vs. SCORAD, EASI vs. SASSAD	r = 0.84 EASI vs. SCORAD; r = 0.86 EASI vs. SASSAD	(+) with SCORAD (+) with SASSAD	50 children (mild to severe)	fair
Conclusion: 8 studies assessed construct validity of the EASI correlating the EASI and SA-EASI with other measures for AD severity; The EASI correlates well with the SCORAD and SASSAD, correlation between EASI and SA-EASI is intermediate. ➔ Construct validity of EASI: **adequate;** ➔ Construct validity of SA-EASI: **intermediate** ➔ Quality of evidence: poor to good					

* Box F: hypothesis testing

Eczema area and severity index (EASI)

Author	Internal Consistency				
	Method	Result	Inter-pretation	Study base	COSMIN score
Barbier et al. 2004	Spearman	Correlation between EASI components 0.612 and 0.816; correlation of lichenification with other items not as good as between other items.	(+/-)	1550 children (mild to moderate)	poor
Rullo et al. 2008	Cronbach's alpha	0.944 (no information in methods)	(+)	42 children (mild to severe)	fair
Conclusion: 2 studies, only one study assessed Cronbach's alpha, but methods unclear ➔ Internal consistency of EASI **adequate**; ➔ quality of evidence: fair to poor					

Eczema area and severity index (EASI)

Author	**Intra-observer reliability (test-retest)**				
	Method	Result	Inter-pretation	Study base	COSMIN score
Hanifin et al.2001	Linear regression of day 1 score against day 2 score (mixed effect model)	Age ≥ 8 years: regression coefficient 0.996 Age < 8 years: regression coefficient 0.657 (1 patient did not have stable disease)	(+)	20 children and adults (mild to severe) 15 trained observers	poor
Conclusion: 1 study on intra-observer reliability of the EASI. ➔ Intra-observer reliability of EASI: **adequate** ➔ Quality of evidence: poor					

Author	**Inter-observer reliability**				
	Method	Result	Interpretation	Study base	COSMIN score
Hanifin et al. 2001	EASI total score: correlation coefficient of reliability EASI items: kappa	correlation EASI day 1: 0.71; day 2: 0.76; kappa erythema: 0.49 - 0.496 kappa infiltration: 0.226 - 0.269 kappa excoriation: 0.449 - 0.495 kappa lichenification: 0.383 - 0.435	EASI (+/-) Erythema (+/-) Infiltration (-) Excoriation (+/-) Lichenification (+/-)	20 children and adults (mild to severe), 15 trained observers	poor
Mazzotti et al. 2005	Spearman assessment of SCORAD signs by physician vs. SA-EASI signs by caregivers	Erythema: 0.42 Excoriation: 0.43 Dryness: 0.29 Other items <0.1	SA-EASI: Erythema (+/-) Dryness (-) Excoriation (+/-) Other items (-)	35 children (moderate to severe); 3 untrained observers	fair
Rullo et al. 2008	Wilcoxon Test	No significant differences between 2 observers at baseline and after treatment	Not possible	42 children (mild to severe); 2 observers unclear whether trained or not	poor
Conclusion: 3 studies assessed inter-observer reliability of the EASI / SA-EASI; 1 study indicates intermediate inter-observer reliability of the EASI, the assessment of infiltration appears to be less reliable than other items. One study indicates inadequate inter-observer reliability of the SA-EASI. 1 study does not allow conclusions ➔ Inter-observer reliability of EASI: **intermediate;** Inter-observer reliability of SA-EASI**: inadequate** ➔ Quality of evidence: fair to poor					

Eczema area and severity index (EASI)

Author	Sensitivity to change				
	Method	Result	Inter-pretation	Study base	COSMIN score
Barbier et al. 2004	change from baseline to day 8; no reference scale used	median change 3.9	Not possible	1078 children (mild to moderate)	poor
Schram et al. 2012	Investigator global assessment used (or patient global assessment) as reference. Used area under the curve (AUC) for ROC curves and MCID calculated as absolute changes for 1 point change in global assessment	AUC: 0.67 [0.60 - 0.76] MCID: 6.6 [SD 5.9]	(+)	42 adults (severe)	fair
Conclusion: 2 studies assessed sensitivity to change of the EASI; 1 study indicates adequate sensitivity to change of the EASI. ➔ Sensitivity to change of EASI: **adequate** ➔ Quality of evidence: fair to poor					

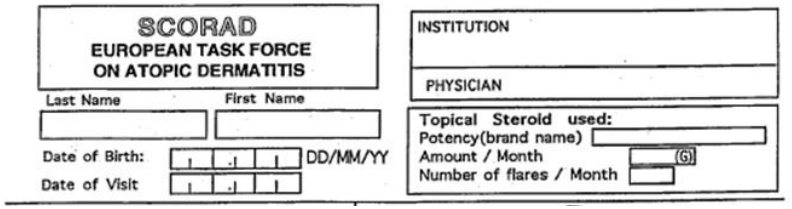
Eczema area and severity index (EASI)

Author	Floor- and ceiling effect			
	Method	Result	Interpretation	Study base
Conclusion: No studies were identified that assessed floor- and ceiling effect of the EASI ➔ Floor- and ceiling effect of the EASI: **unclear**				

Author	Interpretability			
	Method	Result	Interpretation	Study base
Conclusion: No studies were identified that assessed interpretability of the EASI ➔ Interpretability of the EASI: **unclear**				

Author	Acceptability / ease of use			
	Method	Result	Interpretation	Study base
Mazzotti et al. 2005	Unclear	"SA-EASI was easily understandable and managed by all involved patients" (sentence from discussion section)	Not possible	35 children (moderate to severe)
Conclusion: 1 study assessed acceptability / ease of use of the SA-EASI, but does not allow any firm interpretation. No study assessed ease of use of the EASI ➔ Acceptability / ease of use of the EASI: **unclear** ➔ Acceptability / ease of use of the SA-EASI: **unclear**				

Severity Scoring of Atopic Dermatitis Index (SCORAD)


SCORAD
EUROPEAN TASK FORCE
ON ATOPIC DERMATITIS

Last Name First Name

Date of Birth: DD/MM/YY

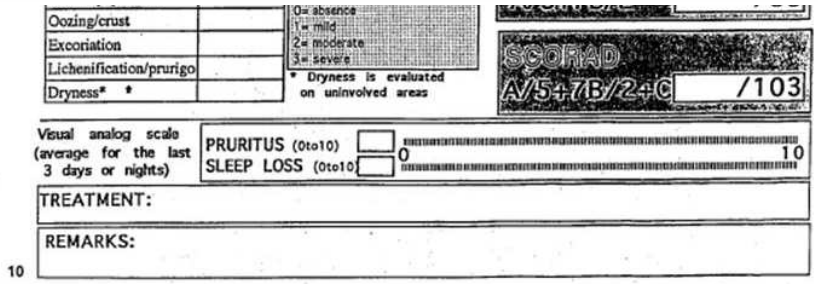
Date of Visit

INSTITUTION

PHYSICIAN

Topical Steroid used:
Potency(brand name)
Amount / Month (G)
Number of flares / Month

Author	Content Validity				
	Method	Result	Interpret.	Study base	COSMIN score
Charman, C.R. et al. 2005	Simple and multiple linear regression analysis of items on patient global assessment (bother)	SLR: all 4 clinical signs of the EASI (erythema, edema/ papulation, excoriations, lichenification) are significantly associated with global bother score MLR: excoriations, edema/ papulation, and erythema are independently related to patient-rated disease severity.	(+)	180 children and adults (mild to severe)	excellent
European Task Force on Atopic Dermatitis 1993	consensus within a group of experts	Not reported	Not possible	25 experts from the European Task Force on Atopic Dermatitis	poor
Schmitt et al. 2007	Rating of importance of domains and items of outcome measures on 5-point Likert scale	Median rating of all three SCORAD domains, and each of the items of signs domain (erythema, edema, oozing, excoriation, lichenification, dryness) rated as "important" or "very important"	(+)	12 consumers (patients and caregivers) and 6 clinical experts	fair
Conclusion: 2 studies assessed content validity of the SCORAD domains and items; 1 study indicates adequate content validity of the SCORAD domains and all items of the signs domains. ➔ Content validity of total SCORAD and SCORAD signs domain: **adequate** ➔ Quality of evidence: excellent to poor					


Oozing/crust
Excoriation
Lichenification/prurigo
Dryness* *

0= absence
1= mild
2= moderate
3= severe

* Dryness is evaluated on uninvolved areas

SCORAD
A/547B/24C /103

Visual analog scale (average for the last 3 days or nights)

PRURITUS (0to10)
SLEEP LOSS (0to10)
0 10

TREATMENT:

REMARKS:

10

Severity Scoring of Atopic Dermatitis Index (SCORAD)

Author	Construct Validity				
	Method	Result	Interpret.	Study base	COSMIN score*
Angelova-Fischer et al. 2005	Spearman SCORAD vs. OSAAD	r = 0.76 before treatment; r = 0.62 after treatment (21 days later)	(+/-) with OSAAD	32 adults (moderate to severe)	fair
Carel et al. 2008	Pearson SCORAD vs. ADQ	r=0.64 before treatment; r=0.39 after treatment	(-) with ADQ	68 children at admission and 36 children at discharge (mild to severe)	fair
Cosickic et al. 2010	Spearman SCORAD vs. TIS	r= 0.531	(-) with TIS	261 children (mild to severe)	fair**
Hachisuka et al. 2009	Spearman oSCORAD vs. OSAAD, SCORAD vs. OSAAD	r=0.619 oSCORAD vs. OSAAD; r= 0.619 SCORAD vs. OSAAD:	(+/-) with OSSAD	22 children and adults (mild to severe)	poor
Mazzotti et al. 2005	Spearman oSCORAD vs. SA-EASI	r = 0.71	(+) with SA-EASI	35 children (moderate to severe)	fair
Mazzotti et al. 2008	Spearman oSCORAD vs. SA-EASI	r = 0.71	(+) with SA-EASI	98 children (moderate to severe)	fair
Rullo et al. 2008	Spearman SCORAD vs. EASI at 2 timepoints	r =0.881 to 0.930	(+) with EASI	42 children (mild to severe), 2 investigators	fair
Sprikkelman et al. 1997	Cohen's kappa SCORAD vs. BCSS	K = 0.38	(-) with BCSS	82 children and adults (severity of AD not reported)	fair
Stalder et al. 2011	Pearson SCORAD vs. PO-SCORAD	r = 0.67 at T0; r = 0.79 at T28 Change score correlation r = 0.71 (T28 - T0)	(+) with PO-SCORAD	471 children and adults (mild to severe)	fair
Sugarman et al. 2003	Spearman SCOARD vs. OSAAD	r = 0.63	(+) with OSAAD	38 children mild to severe	
Tremp et al.2011	Spearman SCORAD and EASI vs. digital images (SCORADdig and EASIdig)	r = 0.921 baseline, r = 0.887 after 12 weeks (unclear if result relates to SCORAD or EASI)	((+) with digital images)	48 adults (mild to severe)	poor
van Velsen et al. 2010	Pearson and Spearman oSCORAD vs. SA-EASI	r = 0.61 oSCORAD vs. SA-EASI r = 0.37 SCORAD signs domain vs. SA-EASI	(+/-) oSCORAD with SA-EASI (-) signs domain with SA-EASI	60 children (moderate to severe)	fair
Vourch-Jourdain et al. 2009	Spearman SCORAD vs. PO-SCORAD	r = 0.27 at T0; r = 0.61 at T18, r = 0.46 combined visits	(-) with PO-SCORAD	33 children and adults (severity of AD not reported)	fair
Weisshaar et al. 2008	Spearman Itch vs. oSCORAD	r = 0.32 age 0 - 7 yrs r = 0.30 age 8 - 12 yrs r = 0.38 age 13-18 yrs	(-) oSCORAD with itch Score	823 children (severity of AD not reported)	fair
Willemsen et al. 2009	Spearman SCORAD vs. TIS	r=0.76-0.84	(+) with TIS	66 children (mild to severe)	fair**
Wolkerstorfer et al. 1999	Spearman SCORAD vs. TIS	r = 0.86	(+) with TIS	126 children (mild to severe)	fair**
Yang et al. 2010	Pearson SCORAD vs. SASSAD; SCORAD vs. EASI	r = 0.92 SCORAD vs. SASSAD r = 0.84 SCORAD vs. EASI	(+) with SASSAD (+) with EASI	50 children (mild to severe)	fair

Conclusion: 14 studies assessed construct validity of the SCORAD correlating the SCORAD with other measures for AD severity; although the evidence is not completely consistent, the SCORAD appears to measure the same construct as the TIS, the EASI, the SA-EASI, but a different construct then the OSSAD, the ADQ, and the BCSS. The degree of correlation between the SCORAD and the PO-SCORAD is unclear.

- ➔ Content validity of SCORAD and objective SCORAD: **adequate**
- ➔ Quality of evidence: fair to poor

* Box F: hypothesis testing; ** as the TIS is part of the SCORAD there is an "independency problem", this was not considered an important methodological flaw in the study design.

(+) positive rating indicating „adequate" scale quality; (+/-) intermediate rating indicating "intermediate" scale quality; (-) negative rating indicating "inadequate" scale quality
Not possible: according to predefined criteria

Severity Scoring of Atopic Dermatitis Index (SCORAD)

Author	Internal consistency				
	Method	Result	Inter-pretation	Study base	COSMIN score
European Task Force on Atopic Dermatitis 1993	PCA[1]	2 uncorrelated components both including different clinical signs	(+/-)	88 children (mild to severe)	poor
Hachisuka et al. 2009	Spearman	oSCORAD - pruritus: 0.69	(+/-)	22 children &adults (mild to severe)	poor
Haeck et al. 2012	Pearson	oSCORAD - symptoms: 0.18	(+/-)	54 adults (severe)	poor
Hon et al. 2006	Spearman	signs - extent: 0.86; signs - pruritus: 0.38 signs - sleep loss- 0.34	(+/-)	182 children (mild to severe)	poor
Pucci et al. 2005	Pearson	signs - extent: 0.64; signs - symptoms: 0.46 SCORAD highly correlated with each domain (r = 0.71 to 0.91)	(+/-)	63 children (mild to severe)	poor
Rullo et al. 2008	Cronbach's alpha	0.974 (no information in methods)	(-)[2]	42 children (mild to severe)	fair
Schaefer et al. 1997	PCA[1]	Three independent components (without clear patterns)	(+/-)	171 children (mild to severe)	poor
Conclusion: 7 studies, only one study assessed Cronbach's alpha, but methods unclear ➔ Internal consistency of SCORAD (total and signs domain **intermediate**); ➔ Quality of evidence: fair to poor					

[1] Principal Components Analysis; [2] Modified version of SCORAD (a total score of more than 103 was achieved)

Severity Scoring of Atopic Dermatitis Index (SCORAD)

Author	Intra-observer reliability (test-retest)				
	Method	Result	Inter-pretation	Study base	COSMIN score
European Task Force on Atopic Dermatitis 1993	2-way ANOVA	>= 70% probability to be scored identically for all signs	Not possible	10 pictures of training atlas (mild to severe), 10 trained observers	poor
Conclusion: 1 study which does not allow conclusions about intra-observer reliability of the SCORAD. ➔ Intra-observer reliability of SCORAD: **unclear** ➔ Quality of evidence: poor					

Author	Inter-observer reliability				
	Method	Result	Interpretation	Study base	COSMIN score
European Task Force on Atopic Dermatitis 1993	2-way ANOVA	"overall agreement good"; poorest agreement for edema/papulation: 54% probability to be scored identically by 2 investigators	(-) for edema/ papulation; not possible for other items	10 pictures of training atlas (mild to severe); 10 trained observers	poor
Angelova-Fischer et al.2005	Variance between observers	Coefficient of variation 4.75 (SD 4.23) [median SCORAD 56.8]	(+)	32 adults (moderate to severe); 3 trained observers	poor
Carel et al. 2008	ICC	0.99 (95%CI 0.96 to 1.00)	(+)	15 children (mild to severe); 2 observers (unclear whether trained)	poor
Kunz et al. 1997	Unclear	"overall, extent of lesions (…) showed interobserver variability mostly for patients with lesions of moderate intensity involving 20-60% of body surface"	Not possible	19 children and adults (variable severity); 12 observers (unclear whether trained)	poor
Mazzotti et al. 2008	ICC	0.84 for extent domain	(+) for extent	98 children (moderate to severe); 3 untrained observers	fair
Oranje et al. 1997	Comparison of rating by 22 dermatologists and 69 other investigation in relation to 3 experts (gold standard); Euclidean Distance[1]	Dermatologists: 67.5 to 81.8 % within range of experts for clinical signs; Others: 69.7 to 82.2 % within range of experts for clinical signs; Euclidian distance of extent domain significantly greater in non-dermatological investigators	Not possible	Training atlas (photos) based on 817 children (variable severity); 3 experts (trained) have trained 91 non-expert investigators	poor
Rullo et al. 2008	Wilcoxon Test	Significant differences between 2 observers at baseline and after treatment	Not possible	42 children (mild to severe); 2 observers unclear if trained or not	poor
Schaefer et al. 1997	MANOVA	Statistically significant differences between observers in total SCOARD, signs domain, lichenification, excoriation; no significant difference in edema, oozing, erythema; dryness not reported	Not possible	171 children (mild to severe); 9 trained investigators	poor
Sprikkelman et al. 1997	Wilcoxon signed-rank test; Limits of agreement (mean ± 2 SD of the difference between observers)	Statistically significant differences between observers in edema/population, erythema, excoriations; no significant difference in extent; other items of signs not reported; Limits of agreement SCORAD: -0.28 ± 7.49	Not possible	34 children and adults; 2 trained investigators	poor
Willemsen et al. 2009	Cohen's kappa	Kappa (total SCORAD) = 0.665 (visit 1) to 0.776 (visit 2, at 3 to 4 weeks)	(+)	2 trained investigators, 66 children	good
Wolkerstorfer et al. 1999	Cohen's kappa	Kappa (total SCORAD) = 0.82	(+)	20 children (mild to severe) 3 trained investigators	poor
Conclusion: 11 studies assessed inter-observer reliability of the SCORAD; 5 studies indicate adequate inter-observer reliability of the total SCORAD. One study indicates that the assessment of edema/ population on photos may not be reliable. 5 studies do not allow conclusions ➔ Intra-observer reliability of total SCORAD: **adequate;** intra-observer reliability of signs domain**: intermediate)** ➔ Quality of evidence: good to poor					

[1] The Euclidean Distance is the distance between the evaluations of each investigator and the average expert score (Kaufmann & Rousseeuw, 1990). Within this study, the Euclidean Distance was calculated for the surface of the lesions.

Severity Scoring of Atopic Dermatitis Index (SCORAD)

Author	**Sensitivity to change** Method	Result	Interpret.	Study base	COSMIN score
Angelova-Fischer et al. 2005	Assessment before and after treatment	Not reported	Not possible	32 adults (moderate to severe)	poor
Schram et al. 2012	Investigator global assessment used (or patient global assessment) as reference, Used area under the curve (AUC) for ROC curves and MCID calculated as absolute changes for 1 point change in global assessment	SCORAD: AUC: 0.70 [.61-.78] MCID: 8.7 (SD 7.8) objSCORAD (signs & extent): AUC: .73 [.70-.77] MCID: 8.2 (8.7); no differences between children and adults	(+)	143 children and adults (moderate to severe)	excellent
Conclusion: 2 studies assessed sensitivity to change of the SCORAD; 1 study indicates adequate sensitivity to change of the total SCORAD and objective SCORAD. ➔ Sensitivity to change of total SCORAD: **adequate** sensitivity to change of objective SCORAD**: adequate** ➔ Quality of evidence: excellent to poor					

Severity Scoring of Atopic Dermatitis Index (SCORAD)

Author	**Floor- and ceiling effect**			
	Method	Result	Interpretability	Study base
European Task Force on Atopic Dermatitis 1993	distribution of total score and domain scores according to 2 alternative formulas	total SCORAD (RES1): normally distributed; intensity (signs) normally distributed; extent skewed to left	(+)	88 children (mild to severe)
Schaefer et al.1997	histogram	<15% achieved highest and lowest scores	(+)	171 children (severity of AD not reported)
Conclusion: 2 studies assessed floor- and ceiling effect of the SCORAD suggesting adequate score distribution in two pediatric population ➔ Floor- and ceiling effect of the SCORAD and the signs domain: **adequate**				

Author	**Interpretability**			
	Method	Result	Interpretation	Study base
Kunz et al.1997	Consensus report (Consensus method unclear)	mild: <15 moderate 15 - 40 severe >40 10 points can be added for functional impairment according to investigator's judgement	(+) (objective SCORAD)	23 experts from different European countries
Oranje 2011	Not reported	mild: <25 moderate 25 - 50 severe >50	(+) SCORAD	Not reported
Conclusion: 2 studies assessed interpretability of the objective SCORAD and the SCORAD suggesting ranges for mild, moderate, and severe AD. ➔ Interpretability of the SCORAD and objective SCORAD: **adequate**				

Author	**Acceptability / ease of use**			
	Method	Result	Interpretability	Study base
European Task Force on Atopic Dermatitis 1993	Not reported	"about 10 minutes"	(+/-)	88 children (mild to severe)
Schaefer et al. 1997	time to complete	less than 10 minutes	(+/-)	171 children (severity of AD not reported)
Vourch-Jourdain et al.2009	Feasibility questionnaire	48% less than 5 minutes; 96% less than 10 minutes; considered "not at all difficult" by 83%; described as "not taking much time" by 98%	(+) PO-SCORAD	33 children and adults (severity of AD not reported)
Conclusion: 3 studies assessed acceptability / ease of use of the SCORAD and PO-SCORAD suggesting *at least* acceptable ease of use of the SCORAD and adequate ease of use of the PO-SCORAD. ➔ Acceptability / ease of use of the SCORAD: **intermediate** ➔ Acceptability / ease of use of the PO-SCORAD: **adequate**				

Three Item Severity Scale (TIS)

Author	Content Validity				
	Method	Result	Interpret.	Study base	COSMIN score
Charman, C.R. et al. 2005	Simple and multiple linear regression analysis of items on patient global assessment (bother)	SLR: all 3 clinical signs (erythema, edema/papulation, excoriations) are significantly associated with global bother score MLR: excoriations, edema/papulation, and erythema are independently related to patient-rated disease severity.	(+)	180 children and adults (mild to severe)	excellent
Schmitt et al. 2007	Rating of importance of domains and items of outcome measures on 5-point Likert scale	Median rating of all three TIS- items rated as "important" or "very important"	(+)	12 consumers (patients and caregivers) and 6 clinical experts	fair
Conclusion: 2 studies assessed content validity of the TIS, indicating adequate content validity. ➔ Content validity of the TIS: **adequate** ➔ Quality of evidence: excellent to fair					

Author	Construct Validity				
	Method	Result	Interpret.	Study base	COSMIN score*
Cosickic et al. 2010	Spearman TIS vs. SCORAD	r= 0.531	(-) with SCORAD	261 children (mild to severe)	fair**
Willemsen et al. 2009	Spearman TIS vs. SCORAD	r=0.76-0.84	(+) with SCOARD	66 children (mild to severe)	fair**
Wolkerstorfer et al. 1999	Spearman TIS vs. SCORAD	r = 0.86	(+) with SCORAD	126 children (mild to severe)	fair**
Conclusion: 3 studies assessed construct validity of the TIS; 2 studies indicate adequate and 1 study indicates inadequate construct validity. ➔ Construct validity of TIS: **intermediate** ➔ Quality of evidence: fair					

* Box F: hypothesis testing; ** as the TIS is part of the SCORAD there is an "independency problem", this was not considered an important methodological flaw in the study design.

(+) positive rating indicating „adequate" scale quality; (+/-) intermediate rating indicating "intermediate" scale quality; (-) negative rating indicating "inadequate" scale quality
Not possible: according to predefined criteria

Three Item Severity Scale (TIS)

Author	Internal Consistency				
	Method	Result	Interpretation	Study base	COSMIN score
European Task Force on Atopic Dermatitis 1993	PCA [1]	2 uncorrelated components within the SCORAD; TIS items in one component (component 1; dermatitis)	(+/-)	88 children (mild to severe)	poor
Conclusion: 1 study informs internal consistency of the TIS. This study was not designed to validate the TIS and did not calculate Cronbach's alpha. However, the TIS-items appear to be in one component and thus measure one single construct which is some indication for internal consistency of the TIS. ➔ Internal consistency of TIS: **intermediate** ➔ Quality of evidence: poor					

[1] Principal Components Analysis

Author	Intra-observer reliability (test-retest)				
	Method	Result	Interpretation	Study base	COSMIN score
Conclusion: no study on intra-observer reliability of the TIS could be identified. ➔ Intra-observer reliability of TIS: **unclear**					

Author	Inter-observer reliability				
	Method	Result	Interpretation	Study base	COSMIN score
European Task Force on Atopic Dermatitis 1993	2-way ANOVA	"overall agreement good"; poorest agreement for edema/papulation: 54% probablitiy to be scored identically by 2 investigators	(-) for edema/papulation; not possible for other items	10 pictures of training atlas (mild to severe); 10 trained observers	poor
Schaefer et al. 1997	MANOVA	Statistically significant differences between observers in excoriation; no significant difference in edema/population and erythema	Not possible	171 children (mild to severe); 10 trained investigators	poor
Sprikkelman et al. 1997	Wilcoxon signed-rank test	Statistically significant differences between observers in all three TIS-items	Not possible	34 children and adults; 2 trained investigators	poor
Willemsen et al. 2009	Cohen's kappa	Kappa = 0.604 (visit 1), Kappa = 0.464 (visit 2, at 3 to 4 weeks)	(+) visit 1 (+/-) visit 2	66 children (mild to severe), 2 trained investigators	good
Wolkerstorfer et al. 1999	Cohen's kappa	Kappa TIS = 0.58; excoriation: 0.56; erythema: 0.52; edema/population: 0.41	(+/-)	20 children (mild to severe) 3 trained investigators	poor
Conclusion: 5 studies assessed inter-observer reliability of the TIS; 2 studies indicate intermediate to adequate inter-observer reliability of the TIS, the assessment of edema/population on pictures of a training atlas appears to be not adequately reliable. 2 studies do not allow conclusions. ➔ Inter-observer reliability of TIS: **intermediate** ➔ Quality of evidence: good to poor					

Three Item Severity Scale (TIS)

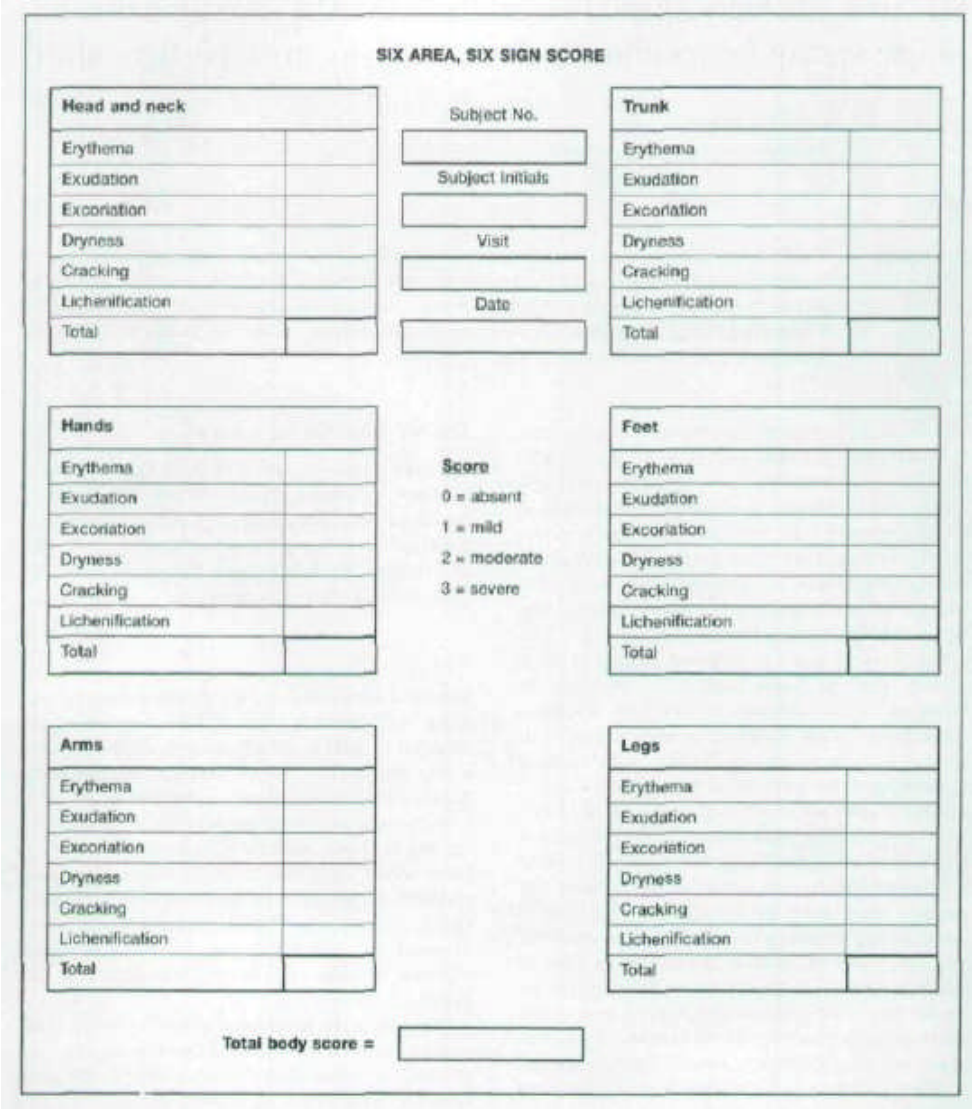
Author	Sensitivity to change				
	Method	Result	Inter-pretation	Study base	COSMIN score
Conclusion: no study on sensitivity to change of the TIS could be identified. ➔ Sensitivity to change of TIS: **unclear**					

Author	Floor- and ceiling effect			
	Method	Result	Interpretation	Study base
Willemsen et al.2009	Distribution graphically displayed	<15% achieved highest and lowest scores	(+)	66 children (mild to severe),
Wolkerstorfer et al.1999	Distribution graphically displayed	<15% achieved highest and lowest scores	(+)	20 children (mild to severe)
Conclusion: 2 studies assessed floor- and ceiling effects of the TIS suggesting adequate score distribution in pediatric populations. ➔ Floor- and ceiling effect of the TIS: **adequate**				

Author	Interpretability			
	Method	Result	Interpretation	Study base
Willemsen et al. 2009	Not reported	mild: 0-2 moderate: 3-5 severe: 6-9	(+)	66 children (mild to severe),
Conclusion: 1 study assessed interpretability of the TIS suggesting ranges for mild, moderate, and severe AD. ➔ Interpretability of the TIS: **adequate**				

Author	Acceptability / ease of use			
	Method	Result	Interpretation	Study base
Willemsen et al. 2009	Mean time to assess	43 seconds (range 7 to 170 seconds)	(+)	66 children (mild to severe), 2 trained observers
Conclusion: 1 study assessed acceptability / ease of use of the TIS indicating very short time to assess. ➔ Acceptability / ease of use of the TIS: **adequate**				

Six Area Six Sign Atopic Dermatitis Score (SASSAD)



SIX AREA, SIX SIGN SCORE

Head and neck	
Erythema	
Exudation	
Excoriation	
Dryness	
Cracking	
Lichenification	
Total	

Subject No.

Subject Initials

Visit

Date

Trunk	
Erythema	
Exudation	
Excoriation	
Dryness	
Cracking	
Lichenification	
Total	

Hands	
Erythema	
Exudation	
Excoriation	
Dryness	
Cracking	
Lichenification	
Total	

Score
0 = absent
1 = mild
2 = moderate
3 = severe

Feet	
Erythema	
Exudation	
Excoriation	
Dryness	
Cracking	
Lichenification	
Total	

Arms	
Erythema	
Exudation	
Excoriation	
Dryness	
Cracking	
Lichenification	
Total	

Legs	
Erythema	
Exudation	
Excoriation	
Dryness	
Cracking	
Lichenification	
Total	

Total body score =

Six Area Six Sign Atopic Dermatitis Score (SASSAD)

Author	Content Validity				
	Method	Result	Interpret.	Study base	COSMIN score
Charman, C.R. et al. 2005	Simple and multiple linear regression analysis of items on patient global assessment (bother)	SLR: all 6 SASSAD-items (erythema, oozing/crusting, excoriations, dryness, lichenification, cracking) are significantly associated with global bother score MLR: erythema, excoriations, and edema/population [NOT INCLUDED IN SASSAD], are independently related to patient-rated disease severity.	(+/-)	180 children and adults (mild to severe)	excellent
Schmitt et al. 2007	Rating of importance of domains and items of outcome measures on 5-point Likert scale	Median rating of all SASSAD-items except cracking rated as "important" or "very important". Cracking rated as "indifferent" by experts.	(+/-)	12 consumers (patients and caregivers) and 6 clinical experts	fair
Conclusion: 2 studies assessed content validity of the SASSAD items, indicating intermediate content validity of the SASSAD items. Content validity of the SASSAD is not adequate, because edema/population which is independently related to patient-rated disease severity is not included. The SASSAD-item "cracking" was not rated as important by experts. ➔ Content validity of the SASSAD: **intermediate** ➔ Quality of evidence: excellent to fair					

Author	Construct Validity				
	Method	Result	Interpret.	Study base	COSMIN score*
van Velsen et al. 2010	Pearson and Spearman SASSAD vs. SA-EASI	r = 0.43	(-) with SA-EASI	60 children (moderate to severe)	fair
Yang et al. 2010	Pearson SASSAD vs. SCORAD, SASSAD vs. EASI,	r = 0.92 SASSAD vs. SCORAD; r = 0.86 SASSAD vs. EASI;	(+) with SCORAD (+) EASI	50 children (mild to severe)	fair
Conclusion: 2 studies assessed construct validity of the SASSAD with objective scoring systems ➔ Construct validity of SASSAD: **adequate** ➔ Quality of evidence: fair					

Six Area Six Sign Atopic Dermatitis Score (SASSAD)

Author	Internal Consistency				
	Method	Result	Interpretation	Study base	COSMIN score
Conclusion: No studies were identified that assessed internal consistency of the SASSAD ➔ Internal consistency of the SASSAD: **unclear**					

Author	Intra-observer reliability (test-retest)				
	Method	Result	Interpretation	Study base	COSMIN score
Charman, C.R. et al. 2002	Maximum absolute intra-observer variation	8 points (maximum possible SASSAD score: 108; maximum observed SASSAD score: 63)	Not possible	6 children and adults (mild to severe), 6 trained observers	poor
Conclusion: 1 study assessed intra-observer reliability of the SASSAD, but did not report the results in an interpretable way. ➔ Intra-observer reliability of the SASSAD: **unclear** ➔ Quality of evidence: poor					

Author	Inter-observer reliability				
	Method	Result	Interpretation	Study base	COSMIN score
Charman, C.R. et al. 2002	SASSAD total score: ICC SASSAD items: weighted kappa	ICC SASSAD: 0.70; Kappa at 6 different SASSAD locations: Erythema: -0.03 to 0.25 Excoriations: 0.06 to 0.27 Lichenification: -0.01 to 0.18 Dryness: 0.02 to 0.20 Oozing/crusting (exudation): 0.08 to 0.46 Cracking: 0.07 to 0.48	SASSAD (+/-) SASSAD items (-)	6 children and adults (mild to severe), 6 trained observers	poor
Conclusion: 1 study assessed inter-observer reliability of the SASSAD indicating acceptable inter-observer reliability of the total SASSAD score, but inadequate inter-observer reliability of the SASSAD-items ➔ Inter-observer reliability of SASSAD **intermediate;** ➔ Inter-observer reliability of SASSAD items: **inadequate** ➔ quality of evidence: poor					

Six Area Six Sign Atopic Dermatitis Score (SASSAD)

Author	Sensitivity to change				
	Method	Result	Inter-pretation	Study base	COSMIN score
Conclusion: No studies were identified that assessed sensitivity to change of the SASSAD ➔ Sensitivity to change of the SASSAD: **unclear**					

Author	Floor- and ceiling effect			
	Method	Result	Interpretation	Study base
Berth-Jones 1996	Distribution of score	<15% achieved highest and lowest scores	(+)	44 infants (mild to moderate)
Conclusion: 1 study assessed floor- and ceiling effect of the SASSAD suggesting adequate score distribution in infants ➔ Floor- and ceiling effect of the SASSAD: **adequate**				

Author	Interpretability			
	Method	Result	Interpretation	Study base
Conclusion: No studies were identified that assessed interpretability of the SASSAD ➔ Interpretability of the SASSAD: **unclear**				

Author	Acceptability / ease of use			
	Method	Result	Interpretation	Study base
Berth-Jones 1996	Time to complete	< 2 minutes for trained investigators; up to 10 minutes for first time users.	(+) for trained investigators	unclear
Conclusion: 1 study assessed acceptability / ease of use of the SASSAD suggesting adequate ease of use of the SASSAD. ➔ Acceptability / ease of use of the SASSAD: **adequate**				

Correlation matrix of clinical signs scores

	ADAM	ADASI	ADQ	BCSS	EASI	OSAAD	oSCORAD	POEM	PO-SCORADR	SA-EASI	SASSAD	SCOARD	SIS	SSS	TIS	Unnamed Scales
ADAM	1															
ADASI		1														
ADQ			1													
BCSS				1												
EASI					1											
OSAAD						1										
oSCORAD						0.61	1									
POEM								1								
PO-SCORAD									1							
SA-EASI					0.60 to 0.62		0.61 to 0.71			1						
SASSAD					0.86					0.43	1					
SCORAD			0.39 to 0.64		0.88 to 0.93	0.61 to 0.76			0.46 to 0.71		0.92	1				
SIS													1			
SSS														1		
TIS												0.53 to 0.86			1	
Unnamed Scales																1

Summary of psychometric properties of measures for clinical signs of eczema

Quality item (name)	SCORAD	TIS	EASI	SASSAD	POEM	BCSS	ADAM	ADASI	ADQ	OSAAD	SSS	W-AZS	Unnamed sale 1	Unnamed sale 2
Content validity	+	+	+	+/-	-	-	+/-	+/-	-	-	+/-	+/-	+/-	-
Construct validity	+	+/-	+	+	n.r.	-	n.r.	n.r.	+/-	+/-	?	n.r.	n.r.	n.r.
Internal consistency	+/-	+/-	+	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Intra-observer reliability	n.r.	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Inter-observer reliability	+	+/-	+/-	+/-	n.a.	+	+/-	n.r.	n.r.	+	?	n.r.	+	+
Sensitivity to change	+	n.r.	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	?	n.r.	n.r.	n.r.	n.r.
Floor or ceiling effects	+	+	n.r.	+	n.r.	n.r.	n.r.	n.r.	n.r.	+	+	n.r.	n.r.	n.r.
Interpretability	+	+	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Acceptability	+/-	+	n.r.	+	+	n.r.	n.r.	+	+	-	n.r.	n.r.	+	+
RECOMMENDATION	**B**	**B**	**B**	**B**	**C**	**C**	**D**	**D**	**C**	**C**	**D**	**D**	**D**	**C**

(+) positive rating indicating „adequate“ scale quality; (+/-) intermediate rating indicating “intermediate” scale quality; (-) negative rating indicating “inadequate” scale quality
n.r.: not reported

Categories of recommendation:

A) Outcome measure meets all requirements to be recommended for use.
B) Outcome measure meets two or more quality items, but performance in all other required quality items is unclear, so that the outcome measure has the potential to be recommended in the future depending on the results of further validation studies.
C) Outcome measure has low quality in at least one required quality criteria (≥1 rating of “minus“) and therefore is not recommended to be used (as a measurement of eczema signs) any more.
D) Outcome measure has (almost) not been validated. Its performance in all or most relevant quality items is unclear, so that it is not recommended to be used until further validation studies clarify its quality.

Conclusions

Harmonizing Outcome Measures for Eczema

Summary of findings

- 15 instruments identified to assess clinical signs of AD
- 3 new instruments since 2007 review
- some important validation work done in past 5 years
- POEM not recommended to measure signs of AD
- EASI and (possibly) objective SCORAD are close to be recommended
- SCORAD should be reported as a profile
- TIS and SASSAD: Consensus on content validity required to determine recommendation

Suggested recommendations and research needs (I)

	Inclusion in shortlist for clinical sings measurement	Recommendation /research needs
SCORAD	yes	Clarify by consensus whether only the objective SCORAD should be included into the shortlist. Further clarify by consensus whether the SCORAD should be reported as a profile, i.e. each domain separately. Investigate intra-observer reliability. Further investigate acceptability
TIS	yes?	Clarify by consensus, if intensity of signs without assessment of the extent of signs is discriminates adequately the different degrees of AD-severity Investigate sensitivity to change and intra-observer reliability
EASI	yes	Investigate interpretability, ease of use, and floor- / ceiling effects
SASSAD	yes?	Clarify by consensus whether intermediate content validity is acceptable, if yes: close validation gaps

Suggested recommendations and research needs (II)

	Inclusion in shortlist for clinical sings measurement	Recommendation /research needs
POEM	no	Investigate within the review of measurements for clinical symptoms, possibly very well suited for clinical signs assessment
BCCS	no	Does not comply with OMERACT filter and therefore NOT recommended to be used or further investigated
ADAM	no	In light of other instruments that measure signs of AD with better content validity, and in light of unclear performance in most other quality criteria, the ADAM should not currently NOT be used and validation studies are not prioritized
ADASI	no	In light of other instruments that measure signs of AD with better content validity, and in light of unclear performance in most other quality criteria, the ADASI should not currently NOT be used and validation studies are not prioritized
ADQ	no	Does not comply with OMERACT filter and therefore NOT recommended to be used or further investigated
OSAAD	no	Does not comply with OMERACT filter and therefore NOT recommended to be used to measure clinical signs of AD. Might be adequate to assess skin physiology in research setting. For this purpose sensitivity to change needs to be investigated
SSS	no	In light of other instruments that measure signs of AD with better content validity, and in light of unclear performance in most other quality criteria, the SSS should not currently NOT be used and validation studies are not prioritized
W-AZS	no	In light of other instruments that measure signs of AD with better content validity, and in light of unclear performance in most other quality criteria, the W-AZS should not currently NOT be used and validation studies are not prioritized
Unnamed 1	no	In light of other instruments that measure signs of AD with better content validity, and in light of unclear performance in most other quality criteria, this score should not currently NOT be used and validation studies are not prioritized
Unnamed 2	no	Does not comply with OMERACT filter and therefore NOT recommended to be used or further investigated. Investigate intra-observer reliability. Further investigate acceptability and internal consistency

HOME III

Measurement properties of outcome measurements for atopic eczema signs

Jochen Schmitt, Stefanie Deckert, Sinead Langan, Ake Svensson, Laura von Kobyletzki, Kim Thomas, Phyllis Spuls

home

Harmonizing Outcome Measures for Eczema

San Diego, April 6-7, 2013

BACK-UP SLIDES

Definition of measurement properties

Content validity	The degree to which the content of an instrument is an adequate reflection of the construct to be measured.
Construct validity	The degree to which the scores of an instrument are consistent with hypotheses based the assumption that the instrument validly measures the construct to be measured
Internal consistency	The degree of interrelatedness among the items
Reliability	The extent to which scores for patients who have not changed are the same for repeated measurement under several conditions
Responsive-ness	The ability of an instrument to detect change over time in the construct to be measured
Interpretability	The degree to which one can assign qualitative meaning – that is, clinical or commonly understood connotations – to an instrument's quantitative scores or changes in scores

Summary of scale domains and items (scale content)

Name of scale	Items of signs domain													Consideration of intensity and extent of signs		Other domains		
	erythema	edema / induration / papulation	oozing/ crusting / weeping/ exudation	excoriation	lichenification	dryness	scaling	cracking / fissuring	vesicles	(de)pigmentation	flaking	bleeding	erosions	only intensity of signs	intensity AND extent of signs	Symptoms	Epidermal function	Complications
ADAM, 1999	•			•	•		•								•	•		
ADASI, 1991	•	•	•		•		•								•	•		
ADQ, 2008	•		•			•	•	•							•	•		
BCSS, 1995															•			
EASI, 1998	•	•		•	•										•			
OSAAD, 2003	•		•	•	•										•		•	
POEM, 2004			•			•		•			•	•		frequency of signs		•		
SA-EASI, 2002	•	•		•		•									•	•		
SASSAD, 1996	•		•	•	•	•		•							•			
SCORAD, 1993	•	•	•	•	•	•									•	•*		
SSS, 1989	•	•	•	•	•		•		•	•					•	•		
TIS, 1999	•	•		•										•				
W-AZS, 2005	•	•	•				•		•	•			•		•	•		
Unnamed 1	•	•			•	•							•		•	•		•
Unnamed 2	•				•	•							•		•	•		•

Eczema area and severity index (EASI)

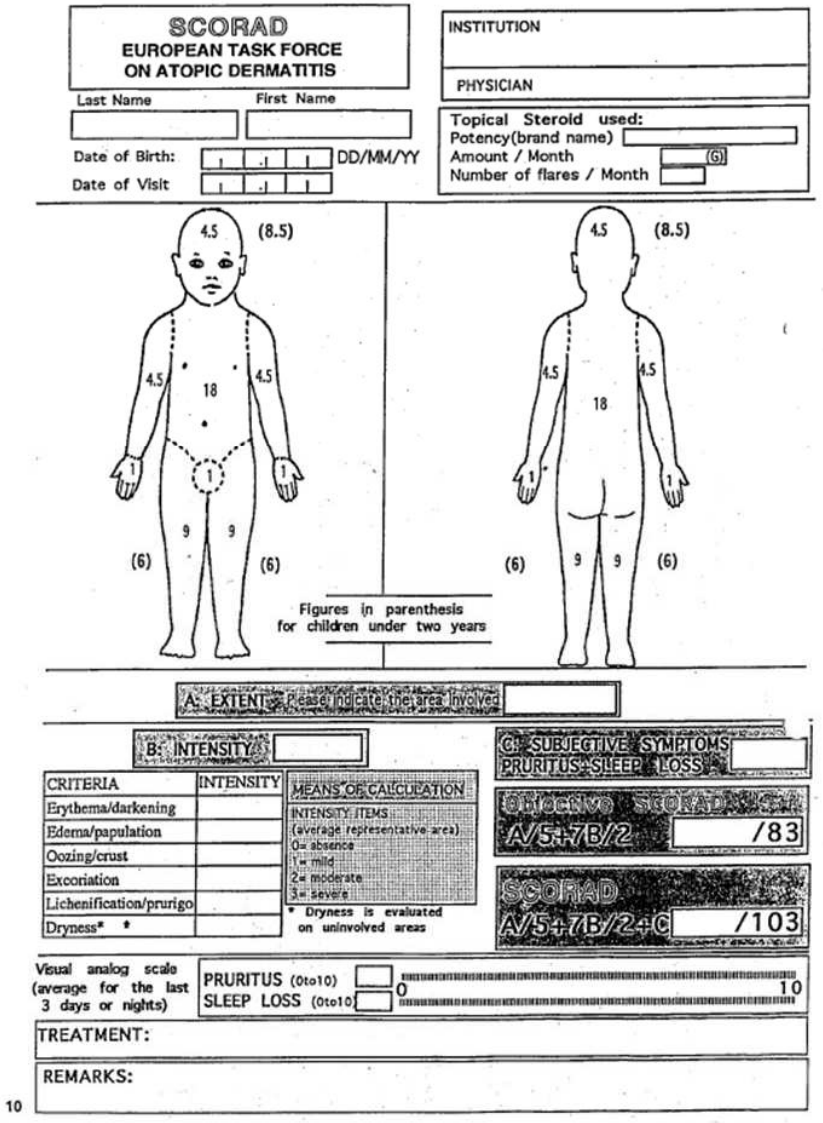
EASI: Area of Involvement

0	1	2	3	4	5	6
No eruption	<10%	10% - 29%	30% - 49%	50% - 69%	70% - 89%	90% - 100%

Erythema	**(E)**
0 – None	
1 – Mild	Faintly detectable erythema: very light pink
2 – Moderate	Dull red, clearly distinguishable
3 - Severe	Deep / dark red
Infiltration / Papulation	**(I)**
0 – None	
1 – Mild	Barely perceptible elevation
2 – Moderate	Clearly perceptible elevation but not extensive
3 – Severe	Marked and extensive elevation
Excoriations	**(Ex)**
0 – None	
1 – Mild	Scant evidence of excoriations with no signs of deeper skin damage (erosion, crust)
2 – Moderate	Several linear marks of skin with some showing evidence of deeper skin injury (erosion, crust)
3 – Severe	Many erosive or crusty lesions
Lichenification	**(L)**
0 – None	
1 – Mild	Slight thickening of the skin discernible only by touch and with skin markings minimally exaggerated
2 – Moderate	Definite thickening of the skin with skin markings exaggerated so that they form a visible criss-cross pattern
3 - Severe	Thickened indurated skin with skin markings visibly portraying an exaggerated criss-cross pattern

Head / Neck	(E + I + Ex + L) x Area[(1)] x 0.1	(+ + +) X X 0.1 =	
Trunk	(E + I + Ex + L) x Area[(1)] x 0.3	(+ + +) X X 0.3 =	
Upper limbs	(E + I + Ex + L) x Area[(1)] x 0.2	(+ + +) X X 0.2 =	
Lower limbs	(E + I + Ex + L) x Area[(1)] x 0.4	(+ + +) X X 0.4 =	
EASI	Sum of the above four body areas		Total Score=

Severity Scoring of Atopic Dermatitis Index (SCORAD)



SCORAD
EUROPEAN TASK FORCE
ON ATOPIC DERMATITIS

INSTITUTION

PHYSICIAN

Last Name First Name

Date of Birth: DD/MM/YY

Date of Visit

Topical Steroid used:
Potency(brand name)
Amount / Month (G)
Number of flares / Month

4.5 (8.5) 4.5 (8.5)
4.5 4.5 18 4.5 4.5 18
1 1 1 1
9 9 9 9
(6) (6) (6) (6)

Figures in parenthesis
for children under two years

A: EXTENT Please indicate the area involved

B: INTENSITY

CRITERIA	INTENSITY
Erythema/darkening	
Edema/papulation	
Oozing/crust	
Excoriation	
Lichenification/prurigo	
Dryness* *	

MEANS OF CALCULATION
INTENSITY ITEMS
(average representative area)
0= absence
1= mild
2= moderate
3= severe
* Dryness is evaluated on uninvolved areas

C: SUBJECTIVE SYMPTOMS
PRURITUS SLEEP LOSS

OBJECTIVE SCORAD
A/5+7B/2 /83

SCORAD
A/5+7B/2+C /103

Visual analog scale
(average for the last
3 days or nights)

PRURITUS (0to10)
SLEEP LOSS (0to10)
0 10

TREATMENT:

REMARKS:

10