Optimizing the management of atopic dermatitis with a new minimal disease activity concept and criteria and consensus-based recommendations for systemic therapy

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Background, objective, and methods

**Background:** Inconsistent criteria are used to identify patients with AD who are candidates for—and assess response to—systemic therapy, and evidence suggests that current T2T treatment targets are insufficient to ensure optimal treatment outcomes.

**Objective:** To develop optimized and practical criteria for identifying patients who should receive systemic therapy, including definitions of treatment goals, treatment failure, and disease severity.

**Methods:** An executive steering committee of 7 international experts agreed that there is a lack of evidence on patients’ treatment goals, needs, and expectations, and initiated a global, ethnically, and culturally diverse patient research study (N=88).

- 9 regional sub-committees were also created to gain perspectives from different regions worldwide.

87 experts from 44 countries contributed to the initiative, which included 46 virtual meetings, discussions on a virtual secure platform, and modified eDelphi voting on expert recommendations.

Experts rated their agreement with a series of recommendations for AD management using a 10-point Likert scale:

- **10** Strongly agree
- **9** Agree
- **8** Moderately agree
- **7** Mildly agree
- **6** Slightly agree
- **5** Slightly disagree
- **4** Mildly disagree
- **3** Moderately disagree
- **2** Disagree
- **1** Strongly disagree

Consensus was pre-defined as ≥70% of all respondents rating their agreement as 7, 8, 9, or 10.

Strong consensus was defined as ≥90% agreement.

AD, atopic dermatitis; T2T, treat-to-target
Results: Consensus-based recommendations for systemic therapy

- Expert perspectives and patient insights led to the development of 34 patient-focused clinical recommendations on disease severity assessments, treatment goals, and targets for clinician- and patient-reported outcomes, long-term disease control, and a novel MDA concept.

- The MDA concept was created using a patient-centric approach and combines T2T principles with shared decision-making.

- The MDA concept was pre-defined as ≥70% of all respondents rating their agreement as 7, 8, 9, or 10. Strong consensus was defined as ≥90% agreement.

- Patients are asked which AD feature(s) are most important to them.

- The clinician chooses a reporting measure that gives an overall assessment of the patient’s condition.

- The clinician chooses treatment targets based on:
  - Patient-reported measures that reflect the patient’s choice of AD features
  - The clinician-reported measure

Consensus agreement was reached for all recommendations in one round of voting.

30 of 34 of the recommendations reached “strong” consensus.

77 of the invited 87 experts participated in eDelphi voting.

89% 100% 88%

BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator Global Assessment; MDA, minimal disease activity; SCORAD, SCORing Atopic Dermatitis

*Consensus was pre-defined as ≥70% of all respondents rating their agreement as 7, 8, 9, or 10. Strong consensus was defined as ≥90% agreement.

*From itch, skin appearance/condition, sleep disturbance, mental health, skin pain, and impact on daily life.
Results and discussion: A novel MDA concept and criteria in AD

Treatment targets are chosen from a list of “moderate” and “optimal” targets based on discussions between the clinician and patient

- Achievement of “optimal” targets is defined as MDA
- Experts also agreed that:
  - Treatment response can be considered inadequate if the agreed targets are not met within 3–6 months; treatment modification or escalation should then be considered (91% agreement)
  - Systemic therapy should be considered in patients with moderate-to-severe AD who have failed to achieve the agreed targets with topical medications or phototherapy, particularly if this is affecting their QoL (96% agreement)
  - Physicians and patients/caregivers should aim for optimal treatment targets to optimize disease control and patient outcomes when possible (100% agreement)

These criteria and patient-focused clinical recommendations will help to identify and monitor patients with AD who could benefit from systemic therapy

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Moderate target</th>
<th>Optimal target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome measure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At least 1 of the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EASI</td>
<td>EASI 75 or EASI ≤7 (moderate to severe)</td>
<td>EASI 90 or EASI ≤3</td>
</tr>
<tr>
<td>SCORAD</td>
<td>SCORAD 50 or SCORAD ≤24 (moderate to severe)</td>
<td>SCORAD 75 or SCORAD ≤10</td>
</tr>
<tr>
<td>IGA and BSA</td>
<td>IGA ≤2 and 50% BSA improvement</td>
<td>IGA 0/1 and BSA ≤2%</td>
</tr>
</tbody>
</table>

*Targets are for all AD severities, unless otherwise specified
CDLQI, Children’s Dermatology Life Quality Index; DLQI, Dermatology Life Quality Index; HADS, Hospital Anxiety and Depression Scale; HADS-A, HADS-Anxiety; HADS-D, HADS-Depression; IDQOL, Infants’ Dermatitis Quality of Life; NRS, numeric rating scale; QoL, quality of life; POEM, Patient-Oriented Eczema Measure