Establishing a patient-centered definition of atopic dermatitis flare: insights from a modified eDelphi study

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**Background:** Atopic dermatitis (AD) flares and their management are a significant unmet research and treatment need. The term “flare” is commonly used to describe AD disease activity, but there has been little work done to understand the meaning of this term from the patient perspective in research or clinical settings, hindering an effective patient-healthcare provider (HCP) relationship and patient-centered care. The potential for, and recurrence of flares contributes to marked patient anxiety and negative emotional sentiment, making flare reduction a highly sought-after treatment outcome for patients.
Objectives: The objective of this study is to establish patient-reported attributes associated with AD flares to develop a more patient-centered definition to support real-world decision-making and enhance AD outcomes.

Methods: Following in-depth qualitative work with patients to develop Delphi items, a modified eDelphi process was conducted January-June 2023 with focus group participants recruited from the National Eczema Association (NEA) Ambassador program. The aim of the Delphi was to determine the most/least important aspects of an AD flare from their perspective. Participants rated 98 flare-related statements on a 1-9 scale (1-3 = not important, 4-6 = important but not critical, 7-9 = critically important), indicating their importance to defining AD flares, alongside several other questions about flaring. Consensus for a statement was defined a-priori as ≥70% rating 7-9 and <15% rating 1-3. Statements reaching consensus were subsequently evaluated by participants in a ranked pair exercise resulting in a final list of statements important to include in a definition of flare from the patient perspective. A subsequent national survey distributed by NEA assessed broader patient agreement with the working concepts essential to a definition identified in the modified eDelphi exercise, with stratified analysis to assess variations in agreement among respondent sub-groups.

Results: Twenty-six participants completed the eDelphi process, with 15/98 statements achieving ranked consensus on critical flare attributes. Survey responses (n=631) confirmed agreement with 12/15 statements; no statement received 100% agreement by all participants. The 3 statements with the highest agreement were: “when my
symptoms take significantly more of my attention than normal,” “a worsening of physical symptoms associated with AD,” and “a worsening of itching associated with AD.” Statements ranked as the most important to a definition were “acute worsening of AD symptoms”, “a change in physical health that interrupts my day-to-day”, and “an “eruption” on the body”. Consensus results were similar across most subgroups of interest with the exception of those whose eczema was mild, those who completed some high school, and those who identified as Native American/Alaskan Native. Most participants (80%; 503/631) found existing flare definitions inadequate, with only 53% (334/631) indicating agreement with their HCP on what an AD flare is.

**Conclusion:** This study found that current definitions of AD flare based on HCP assessment of signs or the clinical reaction to AD (e.g. treatment escalation) resonate poorly with most adult AD patients and differ from concepts achieving consensus by study participants. The patient perspective deviated most significantly from existing definitions in terms of how a flare can negatively impact lifestyle and be associated with greater preoccupation. However, despite achieving conceptual agreement for several statements, patient perspectives varied, highlighting the importance of individualized discussions in clinical settings. This study suggests that a patient-centered flare definition can potentially enhance care and treatment efficacy in AD management as current definitions fail to capture what is meaningful to patients. Understanding nuanced patient perspectives is vital for individualized care and shared decision-making. Future efforts should focus on developing assessment tools and outcome measures based on
patient-identified flare attributes, facilitating better treatment monitoring and personalized care delivery.

**Keywords:** flare, patient-perspective, HCP-alignment, consensus.
Focus Group Qualitative Interviews (Previous Study)

- n=29: Conducted qualitative interviews with AD patients, resulting in a conceptual framework of AD flare containing 6 key concepts.

Statement Development

- m=28: The same focus group participants (less 1) from the previous interviews rated importance of 99 statements for a patient-centered definition of AD flare.

Modified eDelphi Consensus Activities

- n=27: Focus group participants discussed and independently re-rated statements that were close to reaching consensus or received a rating of ‘do not understand’.

Survey Validation

- n=631: Survey administered broadly to AD patients. Participants rated agreement level with the final statements from the modified eDelphi. Participants rated the statements for relative importance and were asked their perspectives on AD flare definitions.

Ongoing Work

- 1 participant dropped out during each step:
  - 1 participant dropped out after the focus group interviews.
  - 1 participant dropped out after the modified eDelphi consensus activities.
  - 1 participant dropped out during the survey validation.

Overall, the study involved 27 participants for the modified eDelphi, 631 participants for the survey validation, and 29 participants for the focus group interviews.