

# Comprehension of the Urticaria Activity Score (UAS) Measure and Patient Guidance Document: Qualitative Interviews with Adults and Adolescents with Chronic Spontaneous Urticaria (CSU)

PCR240

Maurer M,<sup>1,2</sup> Skaliky AM,<sup>3</sup> Wang Y,<sup>4</sup> Eseyin O,<sup>3</sup> Stefan M,<sup>3</sup> McLaren J,<sup>4</sup> Rane PB<sup>4</sup>

<sup>1</sup>Institute of Allergology, Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany; <sup>2</sup>Fraunhofer Institute for Translational Medicine and Pharmacology ITMP, Allergology and Immunology, Berlin, Germany; <sup>3</sup>Evidera, Inc., Bethesda, MD, USA; <sup>4</sup>Amgen Inc., Thousand Oaks, CA, USA

## Background

- Chronic spontaneous urticaria (CSU), formerly known as chronic idiopathic urticaria, is characterized by the occurrence of itchy wheals/hives, angioedema, or both for six weeks or more in the absence of a specific trigger.<sup>1,2</sup>
- The Urticaria Activity Score (UAS) is a patient-reported outcome (PRO) measure that has two questions that assess the signs and symptoms of CSU. The first question asks respondents how intense their itch has been over the past 24 hours, and the second question asks respondents to report the number of wheals/hives they have had over the past 24 hours. Daily UAS scores are summed over seven consecutive days to create the weekly UAS (UAS7), with higher scores indicating greater disease severity.<sup>3,4</sup>
- To ensure the use of patient-friendly terminology, the original UAS questionnaire was adapted to explain the lesser-known term “wheals” in the United States (US) with the developer’s permission.
- Additionally, a Patient Guidance Document was developed with specific instructions to aid completing the adapted UAS questionnaire and minimize variability in individuals’ responses.
- Multiple anchor scales were also drafted to help interpret the meaningful within-patient score change for use in future trials.

## Objective

- The objective of the study was to conduct interviews among individuals with CSU to assess patient understanding of the:
  - Adapted\* version of the UAS questionnaire (**Figure 3**)
  - Patient Guidance Document for Completing the UAS Questionnaire
  - Patient Global Impression of Severity (PGI-S) and Patient Global Impression of Change (PGI-C) Items\*\*

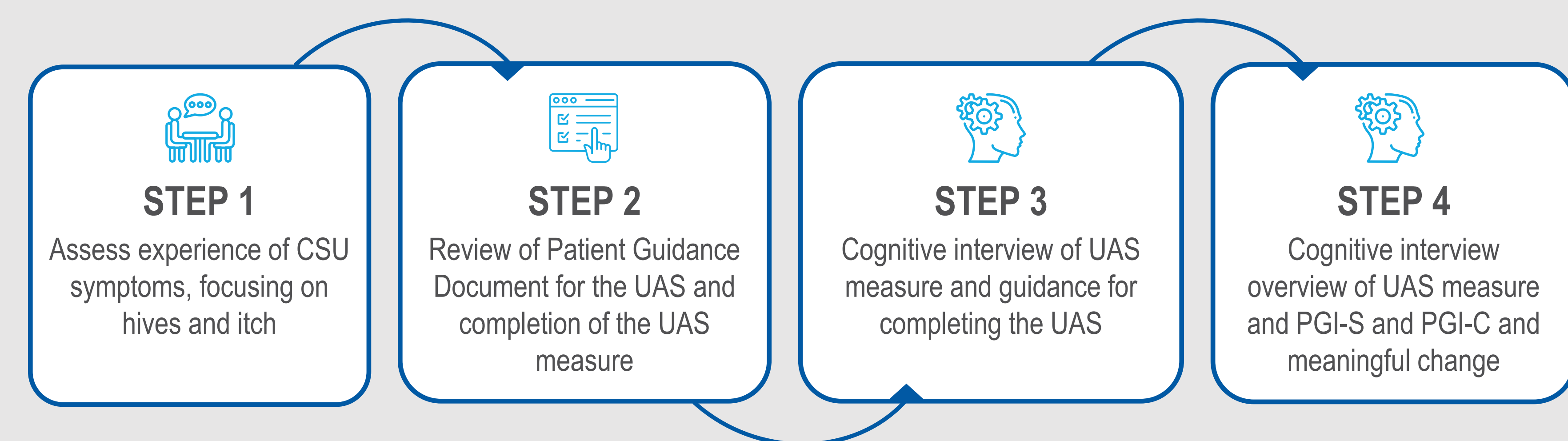
## Study Design

- This was a non-interventional, cross-sectional, qualitative study involving concept elicitation and cognitive interviews with adults and adolescents with CSU.
- Thirty, one-time interviews were planned with 12-17 years old (n=15) and 18 and older (n=15). Eligibility included clinician-confirmation of CSU, and experience of itch and hives for ≥6 weeks. The interview study was conducted between November 2022 and March 2023 in the US.

## Methods

- Study participants were recruited from US clinical sites and online CSU patient communities. A semi-structured hybrid concept elicitation/cognitive interview telephone interview was conducted.
- Figure 1** outlines the procedures. Study participants were first asked about their CSU symptom experience. The Patient Guidance Document was then reviewed by participants before completing the adapted UAS measure. Cognitive interviews of the adapted UAS measure and guidance document ensued to assess comprehension, followed by review and discussion of the PGI-S and PGI-C items and discussion of interpretation of minimal meaningful change on the UAS and PGI-C.
- The study was approved by Advarra, a central Institutional Review Board.

Figure 1. Interview Flow



Abbreviations: CSU = chronic spontaneous urticaria; PGI-C = Patient Global Impression of Change; PGI-S = Patient Global Impression of Severity; UAS = Urticaria Activity Score

\*Adapted version of UAS: permission was obtained from the developer to modify the UAS to include patient-friendly terminology for wheals. No further modifications were made to the UAS as it does refer to “itch” and not “pruritus”.

\*\*Three PGI-S items: CSU overall, itch, and wheals. Each item was rated on a five-point scale (none, mild, moderate, severe, very severe). Three PGI-C items: CSU overall, itch, and wheals. Each item was rated on a seven-point scale (very much improved, much improved, minimally improved, no change, minimally worse, much worse, very much worse). The PGI-S and PGI-C items were assessed during a seven-day period.

## Key Takeaways

- Key components of the adapted UAS measure were well understood by adult and adolescent participants, including the recall period, items, and response options, especially when provided with the additional instruction from the Patient Guidance Document for completing the questionnaire.**
- Results support the content validity of the adapted UAS and provide valuable suggestions for improving the Patient Guidance Document, which can be used in future clinical trials.**

Figure 3. Feedback on UAS Questions

**Item 1**

Please select the score that represents the intensity of your itch over the past 24 hours.

22/22, 100% understood instructions, item concept, recall period, and response scale

Please choose one answer:

- None
- Mild (present but not annoying or troublesome)
- Moderate (troublesome but does not interfere with normal daily activity or sleep)
- Intense (interferes with normal activity or sleep)

“The explanation next to the severity of—or the intensity was helpful, like if it interferes with the everyday activity or, yeah, I felt like in the parentheses what explained—I felt like that was helpful.” (100-107 Adult Female)

**Item 2**

Please select the score that corresponds to the number of wheals (hives) you have had over the past 24 hours.

22/22, 100% understood instructions, item concept, recall period, and response scale

For a group of overlapping hives, count as separately as best as possible.

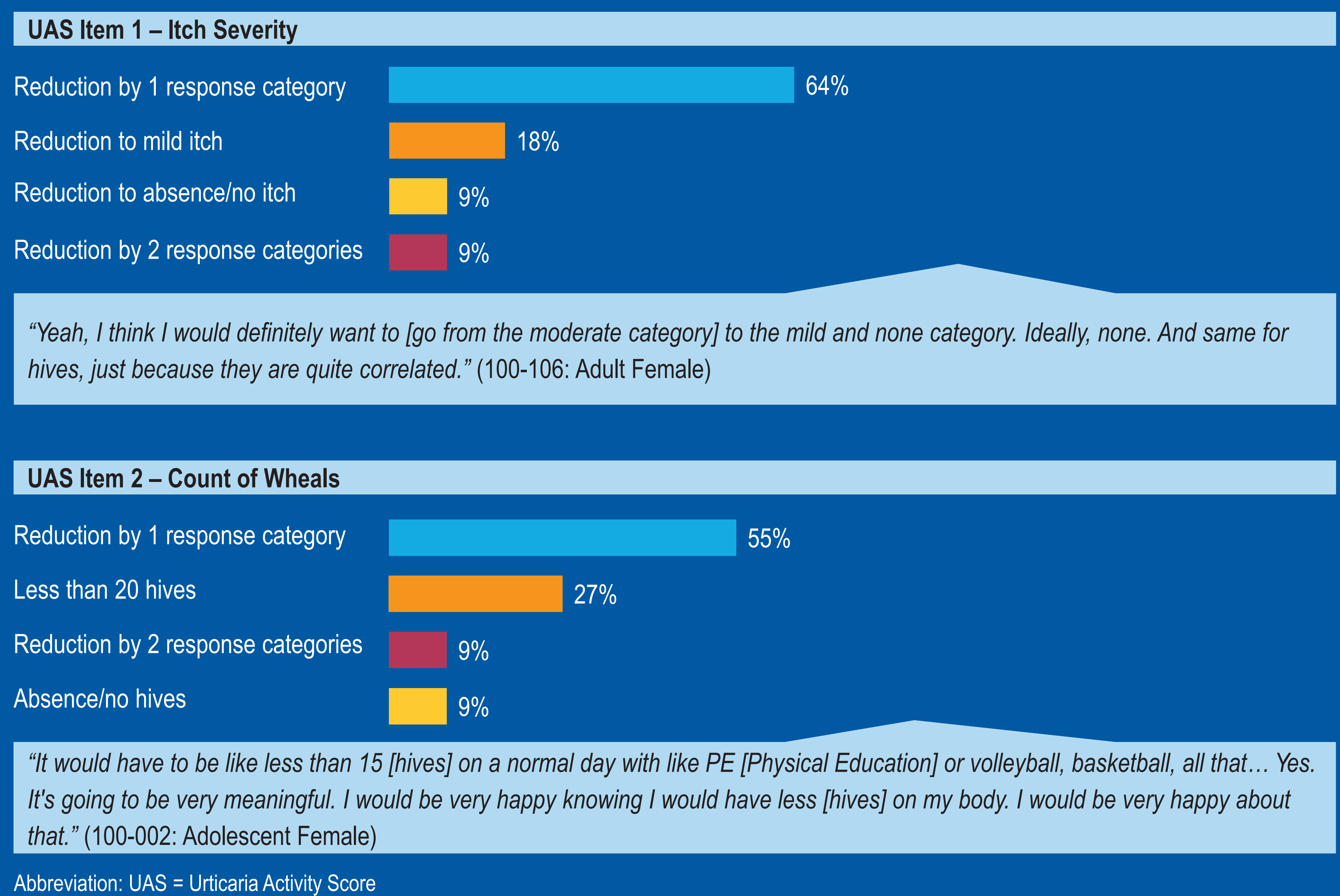
Please choose one answer:

- None
- <20
- 20–50
- >50

“[They are] easy. Less than 20 is behind 20, like 19 to 1. And [<50] is like 49. They [the response categories] helped me.” (100-002 Adolescent Female)

Abbreviation: UAS = Urticaria Activity Score

Figure 4. UAS Items—Meaningful Change

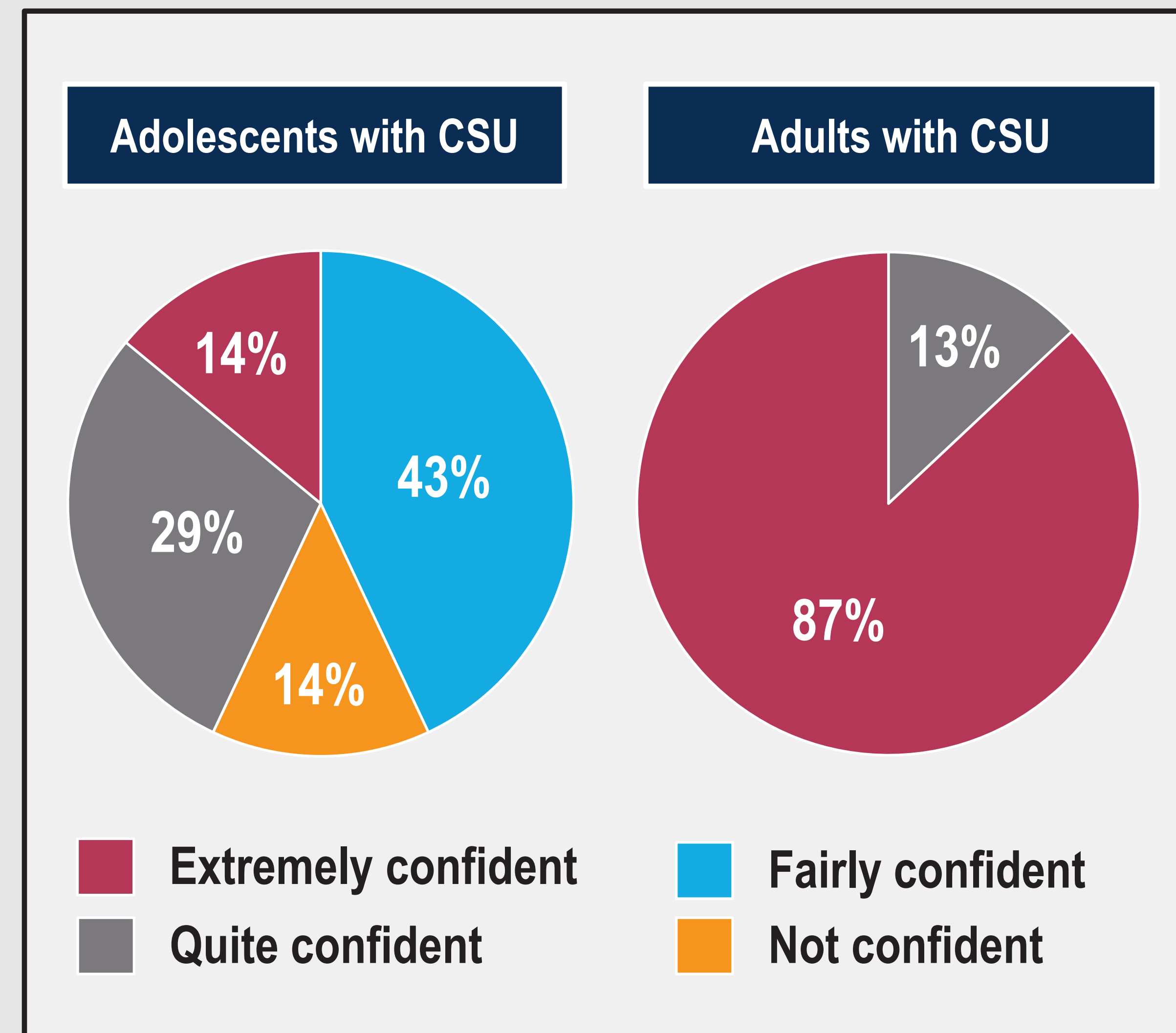


## Results

### Demographics and Clinical Characteristics

- Twenty-two participants were interviewed for the study; 68.1% were ≥18 years of age and 31.8% were 12–17 years of age.
- The mean age of the study population was 34 ± 17.9 years. Most of the study sample were female (63.6%), non-Hispanic (77.3%), and White (77.3%).
- Participants were diagnosed with CSU on average 3 ± 3.0 years ago and were on treatment for an average of 2.7 ± 2.3 years.
- Figure 2** outlines the diverse health literacy levels of adults and adolescents in the sample.

Figure 2. Health Literacy



Abbreviation: CSU = chronic spontaneous urticaria

### Concept Elicitation

- Saturation of CSU concepts was reached within the first five interviews for itch and hives.

### The Adapted Urticaria Activity Score

- All participants were able to describe the UAS items in their own words and demonstrated clear understanding of the Itch and Wheals item.
  - Itch:** All participants liked the parenthetic impact descriptions for mild, moderate, and severe response options for the itch item. Six participants (n=6/22, 27%) provided suggestions for adjusting the impact description.
  - Wheals:** Only four adults (18.1% of total sample) were familiar with the term “wheals,” but all participants understood the meaning of “wheals” given that “hives” was provided in the parentheses.
    - Participants described that counting hives over a 24-hour period was difficult. However, participants reported estimating the number of hives based on the response categories: none, <20, 20–50, or >50 hives.
- Most adults (n=13/15, 87%) and adolescents (n=4/7, 57%) reported that having a one-level improvement in the respective UAS items 1 and 2 would be a significant change in their CSU

### The Patient Guidance Document

- Participants found the guidance document “helpful” and “easy to understand.” They especially appreciated the instructions for determining and counting hives over a 24-hour recall period. Suggestions for improvement included adding a picture to aid in counting hives.
- PGI-S and PGI-C**
  - Only a few participants (n=2/22, 9.1%) considered that seven-day recall would be a bit difficult or less accurate than daily.
  - All participants considered that a seven-point PGI-C scale was useful for capturing change and could differentiate “very much,” “much,” and “minimally” improved change in CSU, itch, and hives.
  - All participants considered that a five-point PGI-S scale (“none,” “mild,” “moderate,” “severe,” “very severe”) was useful for capturing CSU, itch, and hives severity.

## Conclusions

- The interviews confirmed that itch and hives were relevant and important to patients’ CSU sign and symptom experience.
- Study participants reported that they used a 24-hour recall period when responding to the adapted UAS questionnaire. When asked to describe the items in their own words, all participants were able to do so and demonstrated clear understanding. One level of change was agreed by most adults and adolescents for an improvement to be meaningful on either UAS item.
- The guidance document was deemed important to help patients complete the adapted UAS questionnaire and maximize the comprehensibility of the instrument across individuals with varying health literacy levels.
- A five-point PGI-S and seven-point PGI-C were widely endorsed to capture disease severity and change.
- The study demonstrated the content validity of the adapted UAS for individuals ≥12 years of age and provided supportive evidence that the UAS is a fit-for-purpose PRO for use in trials for CSU.

## Limitations

- The final sample (n=22) included fewer than the planned number of participants (n=30). Saturation results, however, demonstrated that concept saturation was reached; indicating a sufficient sample size for content validation.

## Disclosures & Funding

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