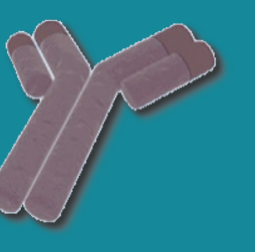


Understanding the experiences of people living with chronic pruritus of unknown origin: Development of a disease conceptual model

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CPUO



Introduction

- Chronic pruritus of unknown origin (CPUO) is characterized by an itch of indeterminate etiology lasting longer than six weeks.^{1,2}
- CPUO is a highly debilitating condition with moderate to severe impact on patients' health-related quality of life³; however, there is no effective treatment for the disease.⁴
- Additionally, there is a significant lack of data on how patients with CPUO experience and describe their signs, symptoms, and impacts on their lives.
- Understanding patient perspectives could be crucial for future drug development and treatment strategies.⁵

Methods

Study Design and Population

- This non-interventional, qualitative study involved concept elicitation (CE) interviews with adult patients with CPUO in the United States (US).
- Inclusion criteria were as follows:

- Adults (18-90 years old) with clinician confirmed diagnosis of chronic pruritus (CP) for ≥6 months that affected at least two bodily areas (e.g., legs, arms, or trunk).
- Clinicians assessed that CP was of unknown origin.
- History of insufficient control of the CP as determined by the investigator.
- History of moderate-to-severe itch as determined during the verbal screening based on the Patient Global Impression of Severity scale.
- One-to-one, telephone or web-based interviews were conducted between November 2022 and September 2023.
- During the interviews, all patients were asked about the symptoms and impacts of CPUO that they had experienced, and which symptoms and impacts they found to be the worst.
- Saturation of concept was evaluated by arranging patient transcripts chronologically and checking subsequent transcripts until no new concept emerged.
- All de-identified transcripts were uploaded, coded, and analyzed following a content analysis approach using ATLAS.ti.
- A conceptual disease model (CDM) was developed for CPUO based on patients' experiences about symptoms and impacts.

Objective

- This study aimed to explore patients' experience with CPUO and develop a CDM.



Conclusions

- The concepts identified during the interviews supported the development of a holistic CDM and highlighted a variety of skin symptoms causing sleep disturbance and frustration to patients.
- As the underlying mechanism of the disease remains to be confirmed, systematic subjective assessments of patients' symptoms and quality of life in clinical trials are essential.

Results

Patient and clinician characteristics

- In total, 20 patients with CPUO were included in the study with a mean age of 42.7 years. (Table 1) 42.7 years. Participants were predominantly female (n=14/20, 70%), White (n=10/20, 50%) or Asian (n=8/20, 40%), and non-Hispanic (n=19/20, 95%). Most of the patients self-rated their health status as "good" (n=14/20, 70%).

Table 1. Patient demographic and clinical characteristics

Characteristics	Total (n=20)
Age (years), mean (SD)	42.7 (22.4)
Female, n (%)	14 (70)
Ethnicity, n (%)	
Hispanic or Latino	1 (5)
Race, n (%)	
American Indian or Alaska Native	1 (5)
Asian	8 (40)
Black or African American	1 (5)
White	10 (50)
Other dermatological conditions, n (%)	
Acne	8 (40)
Hives (urticaria)	8 (40)
Other	3 (15)
No other dermatological conditions diagnosed	6 (30)
Self-rated general health*, n (%)	
Very good	3 (15)
Good	14 (70)
Fair	3 (15)
Poor	0

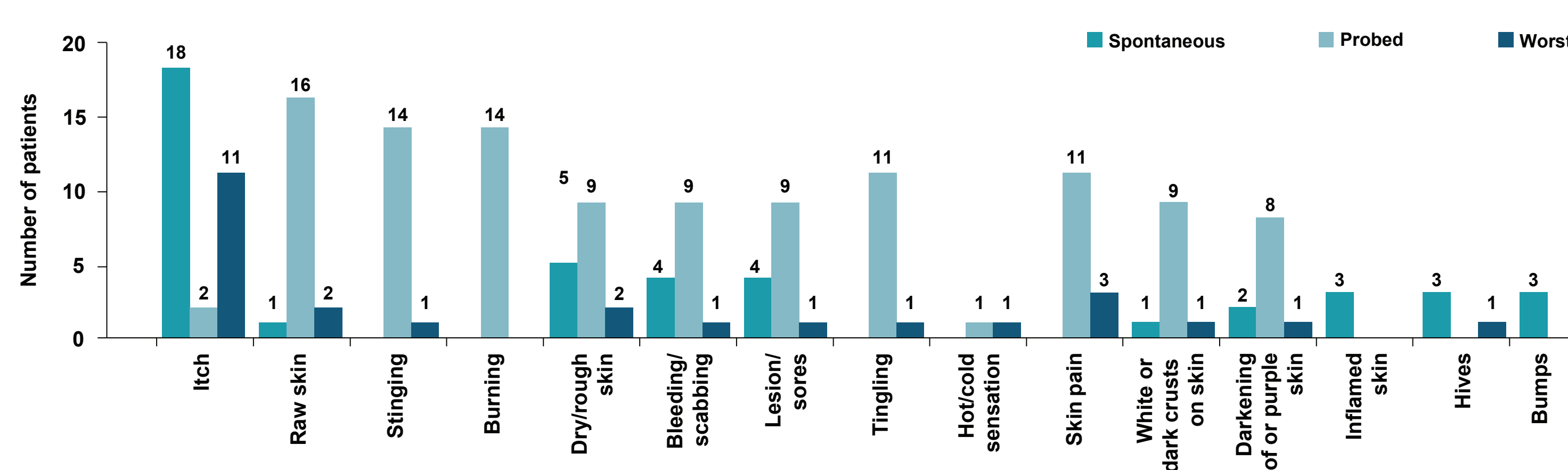
n, Number of patients; SD, Standard deviation

*As rated within the past month.

Symptoms and signs of CPUO

- Patients reported 21 symptoms in total. The most frequently reported symptom was itch (n=20), followed by raw skin (n=17), dry skin (n=14), stinging (n=14), burning (n=14), bleeding (n=13), lesions (n=13), tingling (n=11), hot and cold sensation (n=11), skin pain (n=11), crust on skin (n=10), and darkening of the skin (n=10). (Figure 1)
- Itch was spontaneously reported symptom by majority of the patients (n=18), whereas raw skin (n=16), stinging (n=14), burning (n=14) were reported when probed by most of the patients. (Figure 1)
- Itch was reported as worst symptom by most of the patients (n=11), followed by skin pain (n=3), raw skin (n=2), and dry/rough skin (n=2). (Figure 1)

Figure 1. Number of patients reporting each sign/symptom



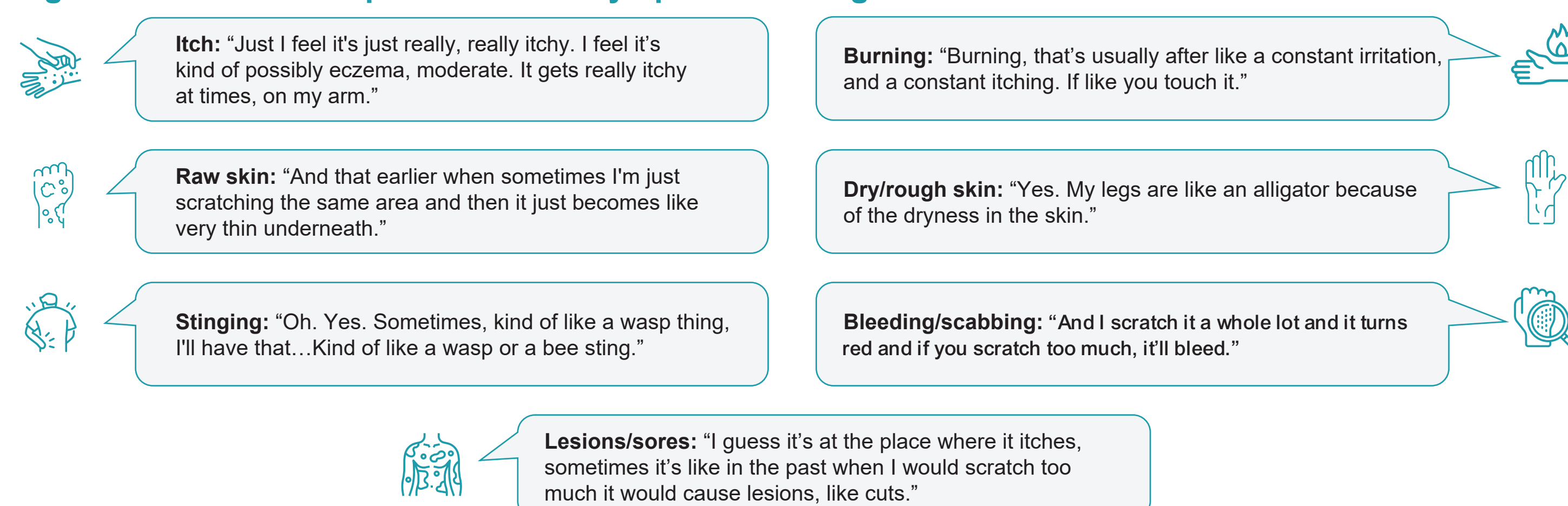
Spontaneous: Number of patients who reported the symptom spontaneously.

Probed: Number of patients who reported the symptom after being probed.

Worst: Number of patients who rated the symptom more than one "worst symptom".

- Description of patient symptom and signs are illustrated in Figure 2.

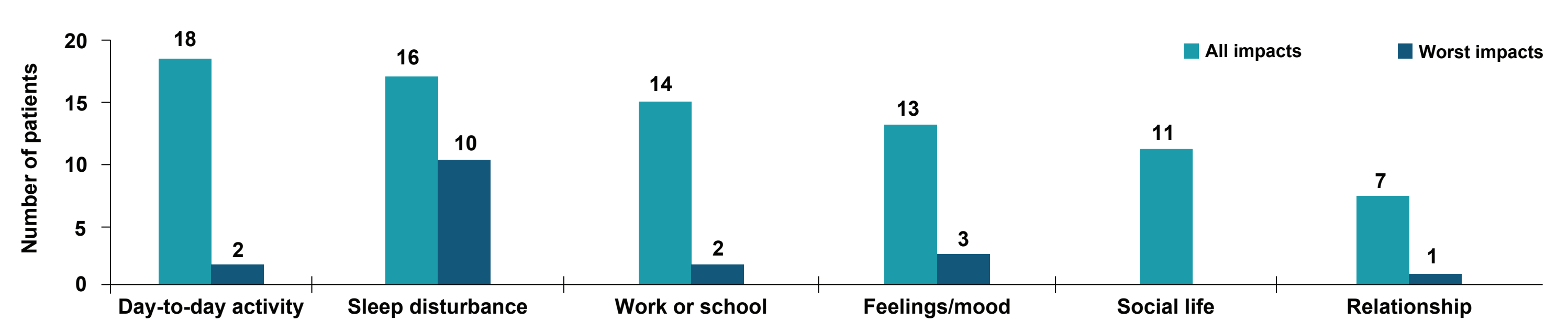
Figure 2. Patient description of CPUO symptoms and signs



Impacts of CPUO

- In total, the following six impact domains were identified: negative impact to patient's day-to-day activities (n=18), sleep (n=16), work/school (n=14), feelings/mood (n=13), social life (n=11), and relationships (n=7). (Figure 2)
- Sleep disturbance was reported as the worst impact (n=10), which included impact on sleep quality, time needed to fall asleep, and duration of sleep. (Figure 2)

Figure 2. Number of patients reporting each impact

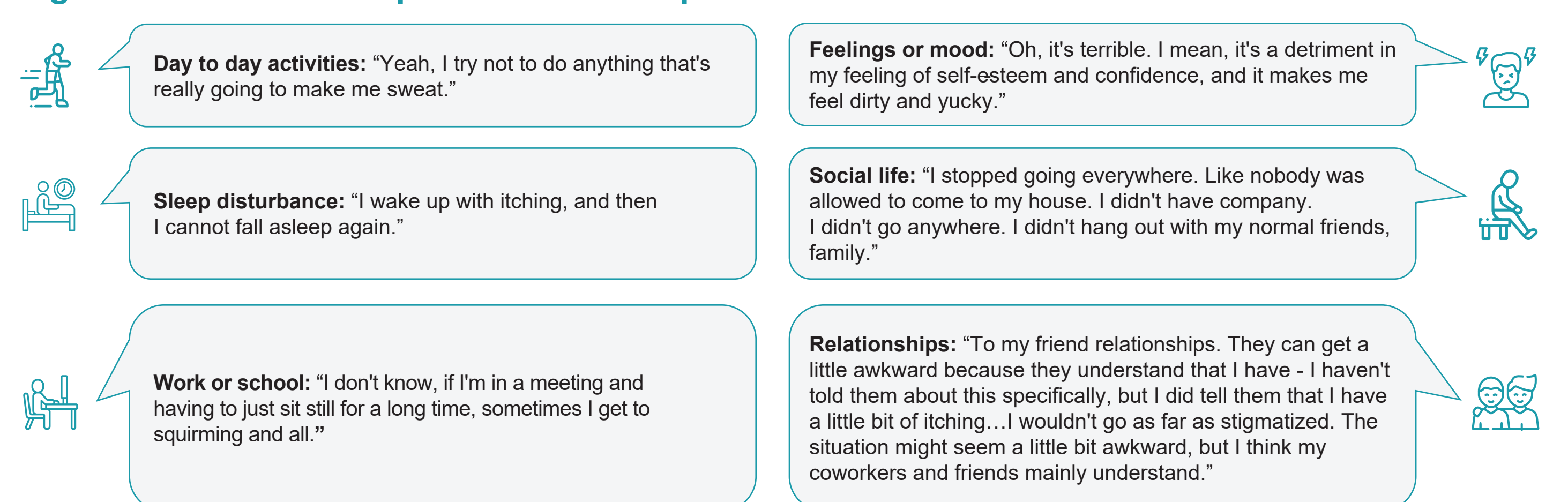


All impacts: Total number of patients who reported the impact.

Worst impacts: Number of patients out of the total who rated the impact as worst. Some patients reported more than one "worst impact".

- Description of patient impacts are illustrated in Figure 3.

Figure 3. Patient description of CPUO impacts



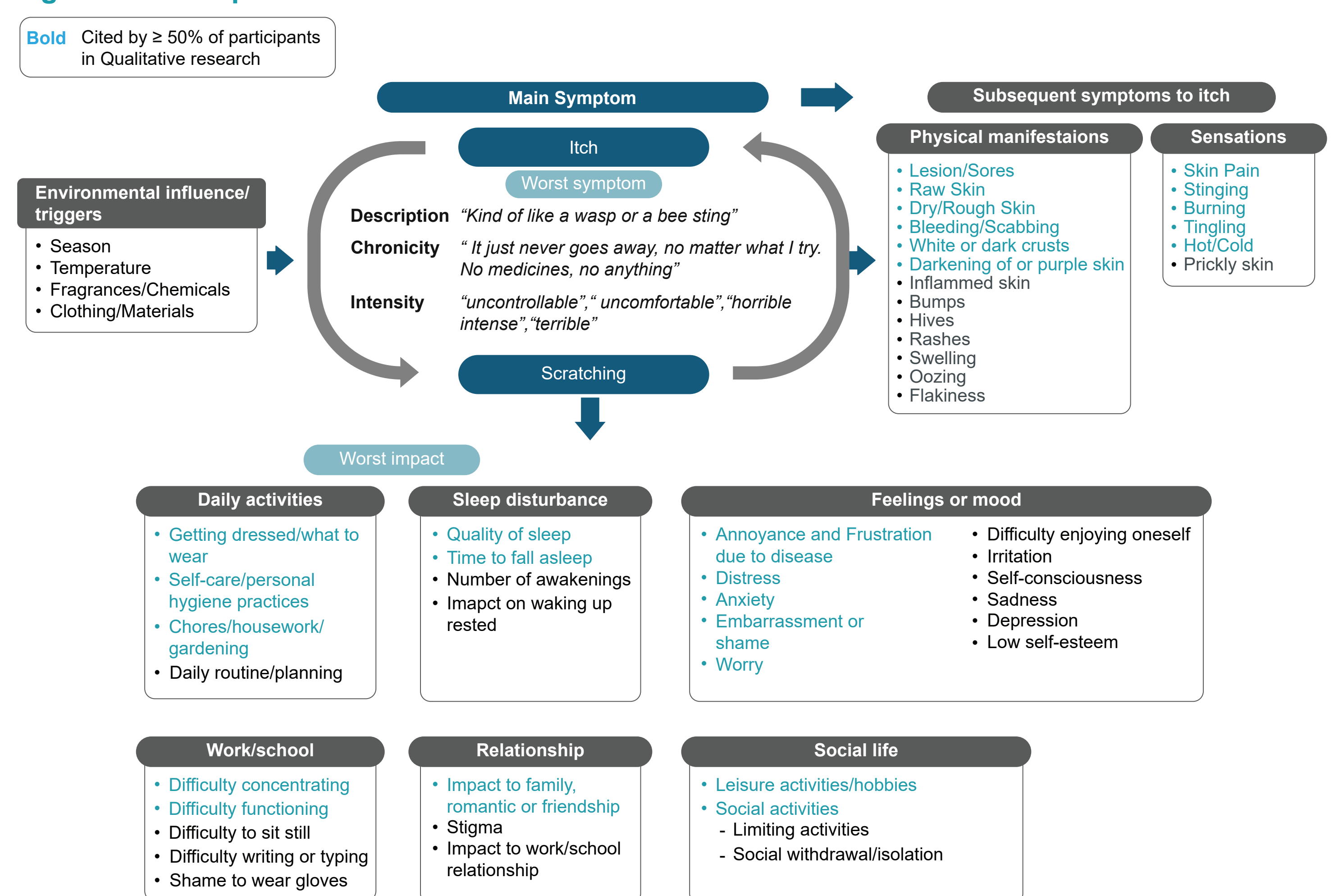
Conceptual saturation

- Most of the concepts (76%) appeared within the first five interviews and only four new skin-related concepts appeared in the subsequent 15 interviews; it was determined that saturation of symptom concepts had been reached at this point.
- About 63% of impact concepts were described by the third interview, and 88% of impact concepts were reported by the seventh interview. The last two impact concepts, irritation and difficulty sitting still, were mentioned during the 17th interview by one patient. We conclude that saturation of impact concepts was reached, as no new impact concepts emerged in the three subsequent interviews.

Conceptual disease model of CPUO

- A CDM of CPUO developed based on responses received from patients is depicted in Figure 4.

Figure 4. Conceptual disease model of CPUO



CPUO, Chronic pruritus of unknown origin

Limitations

- The key concepts emerging from the interviews may not be generalizable to all patients worldwide with CPUO because of potential selection bias as all participants were from the US.
- The preferences and experiences of participants who completed the interviews may be systematically different from those who did not wish to participate in the study, suggesting a non-response bias.

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CONFLICTS OF INTEREST

AM, CDB, and KB: Employees of Evidera. ASM: Employee of ICON plc. EM: Employee of Regeneron. EZ, ADB, MP, DB, and EB: Employees of Sanofi.

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