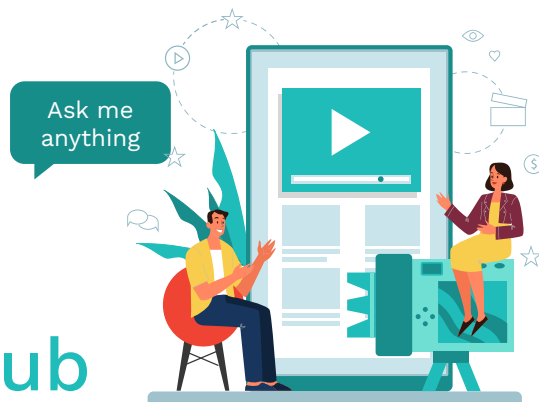


DiME

Virtual Journal Club



Nocturnal scratch: A study bringing patient input into development of novel digital measures

September 20, 2023, 11 am ET



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But first, housekeeping

- Please note today's session is being recorded
- To ask a question for discussion during Q&A, please:
 - Either 'raise your hand' in the participant window and come off mute when the moderator calls on you, or
 - Type your question into the chat box
- Slides and recording will be available after today's session

Key Points

1. What matters to patients
2. Methods
3. Study population
4. Inclusion & Exclusion Criteria
5. Results
6. Discussion
7. Publication contents

NOCTURNAL SCRATCH



Digital Measures Development

*Advancing nocturnal scratch
as a digital endpoint for atopic
dermatitis*

Founding Project Partners

abbvie

janssen | PHARMACEUTICAL COMPANIES OF
Johnson & Johnson

NOVARTIS

Pfizer



Project Collaborators

Advancing Innovation
in Dermatology

almirall

gsk
GlaxoSmithKline



Lilly

sanofi

Expert Partners:



National
Eczema
Association

GLOBAL PARENTS
FOR ECZEMA RESEARCH
RESEARCH • SUPPORT • CHANGE

Duke
UNIVERSITY



Harvard
Business
School

BOSTON
UNIVERSITY

Health Outcomes **Insights**
Getting targeted answers to patient behaviour and outcomes



NOCTURNAL SCRATCH



Digital Measures Development



LEARN MORE



Patient Research

- Data and evidence from mixed methods research
- Conceptual framework



Measures Terminology & Ontology

- Data and evidence supporting technical definition
- Evidence-based ontology



Deployment to Clinical Trials

- 10 tools supporting successful operational implementation
- Case studies



Payer Acceptance

- Translating patient value to commercial value
- Modeling potential increases in drug utilization
- Key insights & action items

What matters to patients

Digital Biomarkers

Digit Biomark 2020;4:69-77

DOI: 10.1159/000509725

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Viewpoint Review Article

Digital Measures That Matter to Patients: A Framework to Guide the Selection and Development of Digital Measures of Health

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Digital Measures That Matter to Patients: A Framework to guide the Selection and Development of Digital Measures of Health

Digit Biomark 2020;4:69-77 = DOI:10.1159/000509725

Critical Patient Input

Meaningful Aspect of Health

Aspect of a disease that a patient a) does not want to become worse, b) wants to improve or c) wants to prevent

- May be shared across some conditions and diseases



What do you wish that you could do, but your condition prevents you from doing it?

What part of your life is most frustratingly impacted by your condition?

Concept of Interest

Simplified or narrowed element that can be practically measured

- Patients may have different symptoms
- Symptoms may vary over time
- Symptoms relevance may vary over time



What are the symptoms that most impact your ability to do these activity?

Outcome to be measured

Specific measurable characteristics

- Measures may be relevant to multiple symptoms
- Asses technical specification of sensor and whether it is suitable for measuring this outcome in this population



Do these measures make sense to you?

Endpoint

Health research only; Precisely defined, statistically analyzed variables

- Sensors may support multiple measures & endpoints



How much change do we need to see in this symptom before it really starts to make a positive difference in your life?

This figure was adapted from original work by Evidation Health, with permission. This figure illustrates patient considerations that should drive digital measure selection and development, these should precede technical considerations [8]. Additional information on subsequent technical considerations are available at [36, 37, 38]

What matters to patients

Critical Patient Input

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- *May be shared across some conditions and diseases*



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Why is it important?

FDA rejects Verily filing for wrist-worn Parkinson's clinical trial device

Published June 14, 2021

- “A change in rigidity or finger tapping in the MDS-UPDRS Part III cannot be directly interpreted as being **meaningful to patients**. However, a change in speech, eating and dressing (as assessed in the MDS-UPDRS Part II) represents meaningful change in how patients function in daily life,” FDA wrote.

Methods

- **Qualitative patient interviews**
 - 1-hour interview with unbiased associated sociology researchers
- **Quantitative survey**
 - Web-based electronic survey

Study population

- **Qualitative patient interviews**

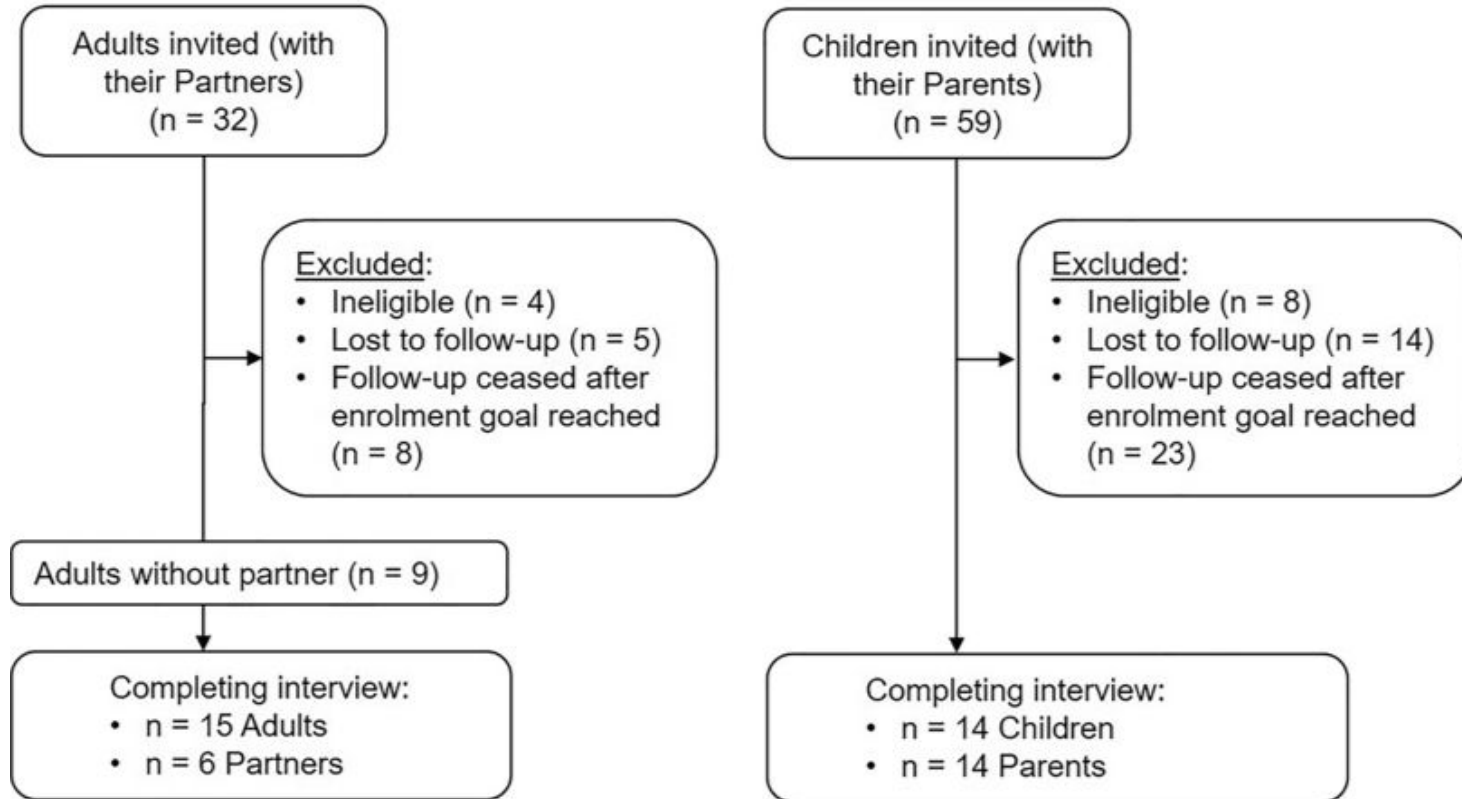
- “Adults” - adults with AD ≥ 18 years old
- “Partners” - adult caregivers/spouses/partners of adults with AD
- “Children” - children 7–17 years old with AD
- “Parents” - adult primary caregivers of a child with AD

- **Quantitative survey**

- “Adults”
- “Parents”

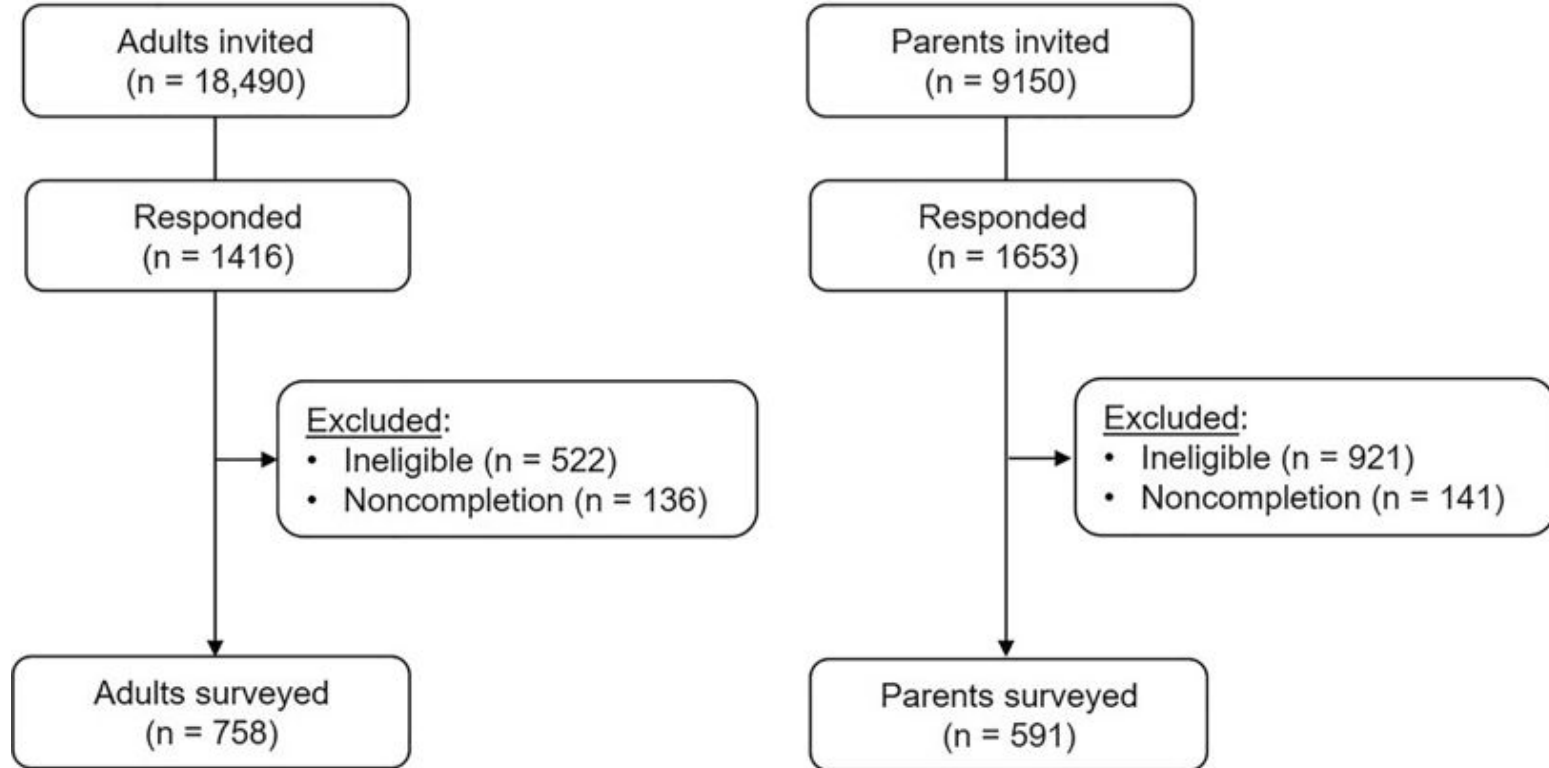
Study population

Qualitative patient interviews



Study population

Quantitative survey



Powered by:

Inclusion & Exclusion Criteria

- **Inclusion Criteria:**

- Patients self-reported with atopic dermatitis, and caregivers for patients diagnosed with atopic dermatitis
- Patient's itch self-assessment (overall) => 1 on itch numerical rating scale (NRS)
- Ability to perform study assessments in English language & provide informed consent

- **Exclusion Criteria:**

- Patients with other skin condition than atopic dermatitis
- Patients with overall itch self-assessment =0
- Patients who fail to provide informed consent

Results & Analysis

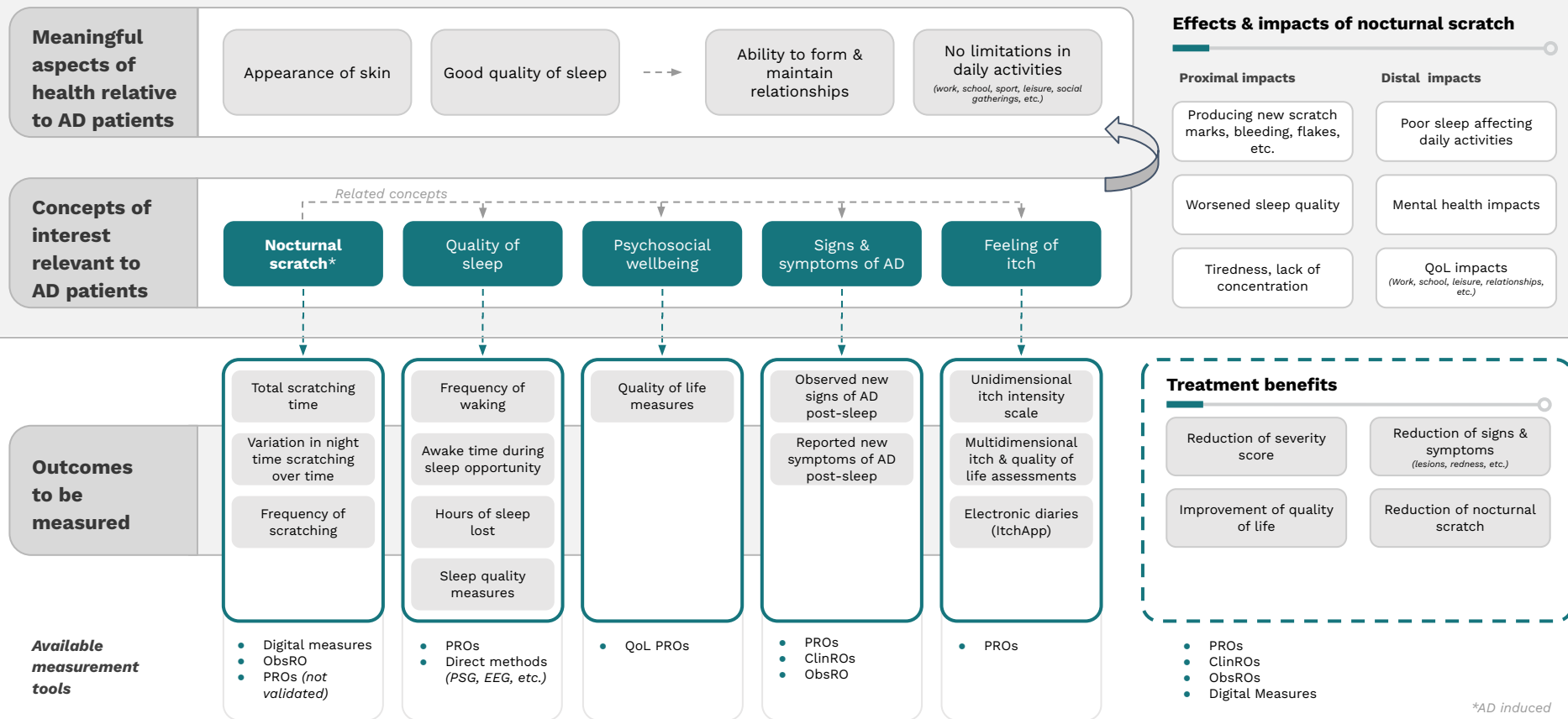
- **Qualitative interviews**

- 49 interviews
 - 15 Adults, 6 Partners, 14 Children, 14 Parents
- Analyzed according to FDA guidance for patient centric drug development
"Methods to Identify What is Important to Patients Methods to Identify What is Important to Patients"

- **Quantitative survey**

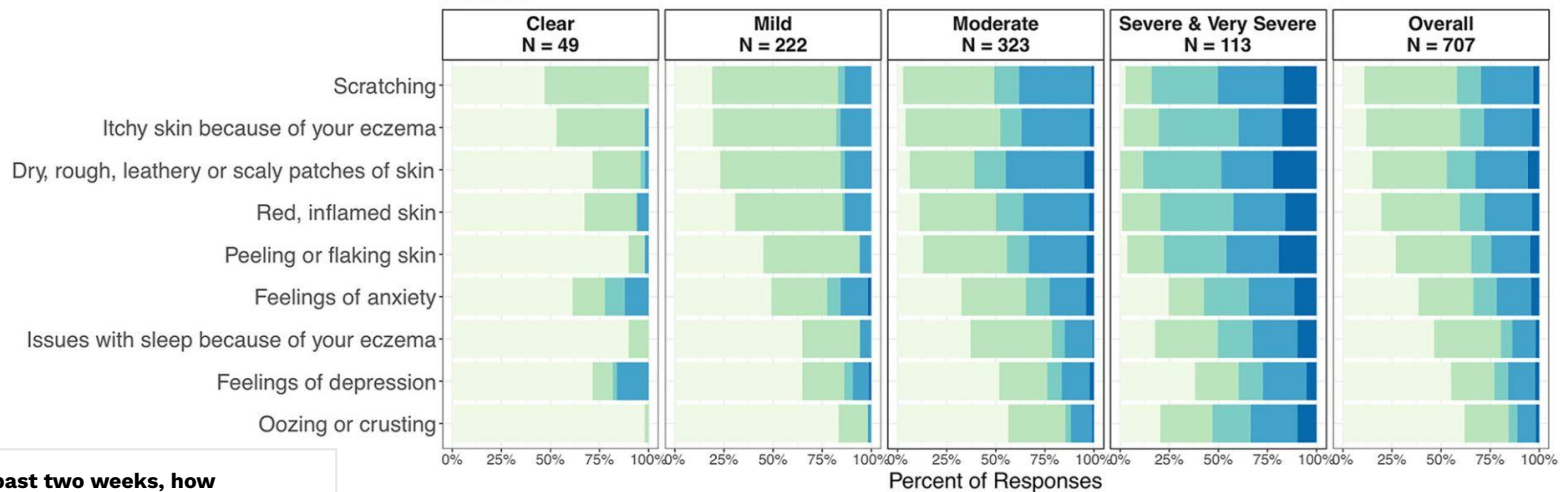
- 1349 survey participants
 - 758 Adults, 591 Parents
- Descriptive statistics
- Raw data available:
<https://dimesociety.org/access-resources/digital-measures-nocturnal-scratch/#research>

Meaningful Aspects of Health: Conceptual Model for Nocturnal Scratching in Atopic Dermatitis (AD) Patients

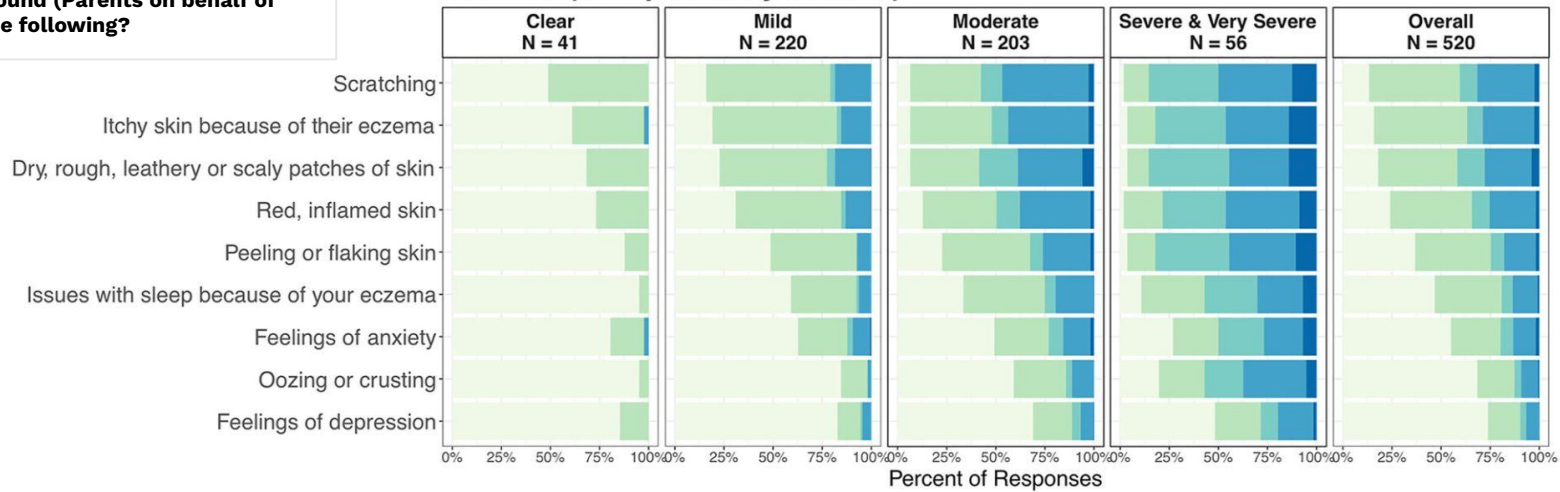


Results: close look

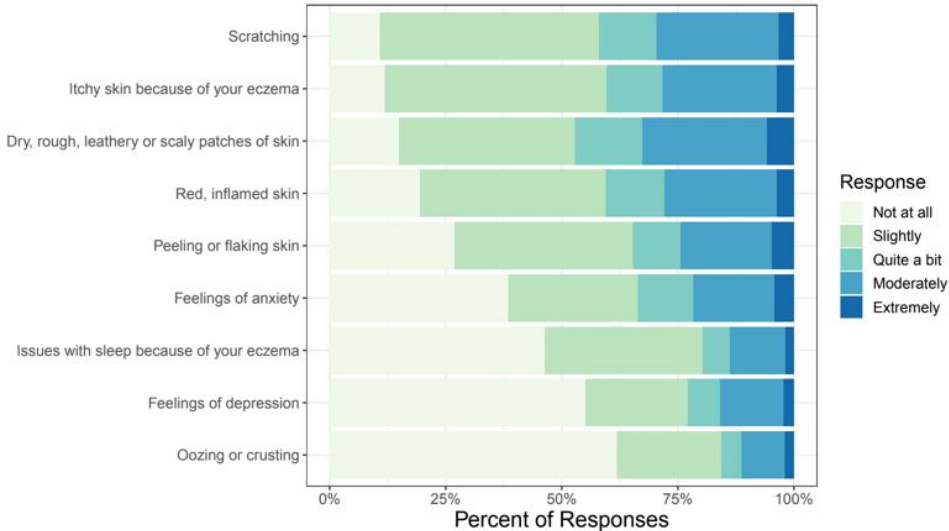
Adults



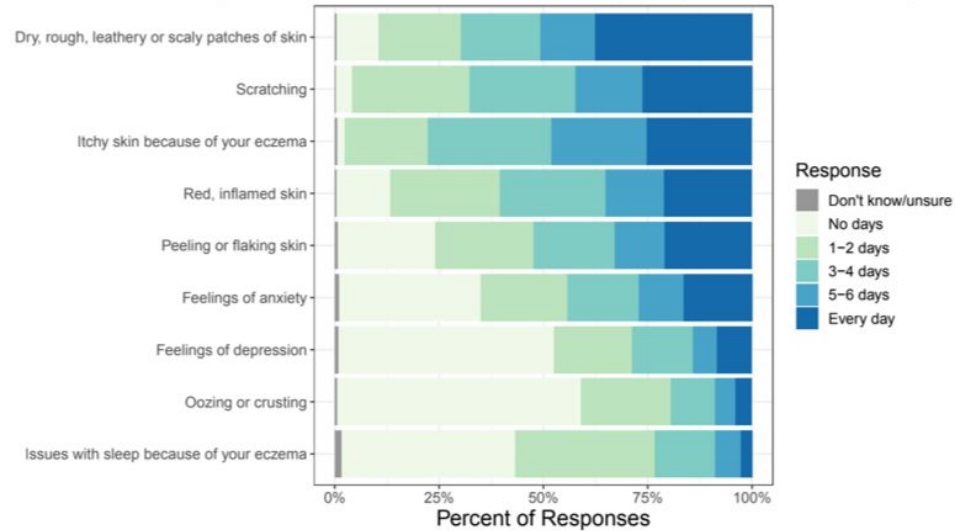
Children (as reported by Parents)



During the past two weeks, how burdensome did you find the following?



During the past two weeks, how often did you experience the following?



Results: close look

- The **most burdensome AD symptoms** reported by Adults & Parents were itchy skin; dry, rough, leathery, or scaly patches of skin; and scratching
- **Resting and sleeping** were the activities most limited by AD - by hours of sleep lost due to nocturnal scratching evaluated from the survey it's:
 - 1 h of sleep lost per night for Adults
 - 1.4 h per night for Children (as reported by Parents)
 - 1.2 h per night for Parents themselves
- 70% of Adults and 75% of Parents were **aware** of nocturnal scratching

Results: close look

- Majority of Adults (85%) and Parents (91%) ranked effectiveness of a treatment in **reducing nocturnal scratching** as important
- The ability to **measure nocturnal scratching** was ranked as valuable by 70% of Adults and 80% of Parents
- 53% Adults and 46% of Parents indicated willingness to **use technology** for this purpose (25% and 28% were unsure whether they would or not)
 - Main concerns were physical discomfort and interference with sleep

Discussion

- **The impact of nocturnal scratching on patients' lives is substantive**
- Positioning nocturnal scratching in Measures that Matter framework established it as a **potential target of novel COAs** that can leverage DHTs in their assessment
- Technology developers and manufacturers should strongly consider the **patient experience** of using the technology and data privacy

Discussion

- Future research should address
 - **correlations** between digitally measured nocturnal scratching and measures currently used in AD to understand more fully the relationship between them.
 - verification, analytic validation and clinical validation of a novel COA leveraging DHTs to measure nocturnal scratch.
- This novel outcome measure may aid research in **other pruritic conditions** that have substantial negative impact on patients' lives, such as psoriasis.

Publication includes

- Background, Objectives, Methods, Results, Discussion
- **Supporting information:**
 - Qualitative interview guides
 - Quantitative survey questions
 - Samples of verbatim responses from the participants' interviews
 - Selected survey data tables
- **Survey data available:**
<https://dimesociety.org/access-resources/digital-measures-nocturnal-scratch/#research>

Panel Discussion

**This slide will be hidden from the presentation*

- Questions for the panel:
 - The patients were the center of this research into the topic of eczema and its symptoms. Especially interviews gave us raw and personal experience with this condition and its everyday burdens. Did it create a new optics towards the lives of patients and this condition within your specific scope of work?
 - Were there some information from the collected data that stood out to you in particular?
 - One of the implications of this research is to support development of novel digitally measured clinical outcome assessments - in this case nocturnal scratching. How do you see these published findings aiding that cause? How did this research help your specific endeavors in this space?
 - What would be your advice to researchers looking to add a patient voice to their research that are thinking about doing a similar study such as this one?
 - Was this kind of mixed methods research something that informed also other areas of your research and work, perhaps in other therapeutic areas?

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Each month we will select a **manuscript tackling an important topic** in digital medicine. The DiMe Community can register to participate in an intimate discussion with the manuscript author(s).



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