# Characterizing the Experience of Excessive Daytime Sleepiness in Patients with Idiopathic Hypersomnia: PCR44 Implications for Measuring Daytime Sleepiness with the Epworth Sleepiness Scale (ESS) in a Clinical Trial (NCT05156047)

# Background

- Idiopathic hypersomnia (IH) is characterized by hypersomnolence with excessive daytime sleepiness (EDS) being the cardinal symptom (Arnulf et al. 2019)
- Objective sleepiness measures may not appropriately quantify EDS; thus, their value in evaluating changes in EDS is uncertain (Arnand and Bonnet 2019)
- The Epworth Sleepiness Scale (ESS) (Johns 1991) is the most frequently used patient-reported outcome measure (PROM) of EDS in sleep disorder clinical practice and research
- The ESS assesses EDS by asking respondents to rate their propensity for falling asleep in 8 situations on a 4-point scale; total score >10 indicates EDS (Figure 1)

# Objectives

- Elicit qualitative descriptions of how EDS is experienced by individuals with IH
- Understand how the response options to the ESS are understood among individuals with IH
- Map the content of the ESS to the qualitative descriptions of EDS as provided by individuals with IH

# Methods

Qualitative interviews with a subset of participants with IH (n=61) who were consecutively recruited at the completion of study NCT05156047

1:1 semi-structured interviews (≈ 60 mins) conducted at the end of the last study visit via video conference

### **Concept Elicitation**

- Participants described their experience living with IH before they enrolled in the study
- Interviewer probed further for details as appropriate

#### **Cognitive Interview**

- Interviewer elicited qualitative data, via think aloud techniques, about how participants differentiated between and selected their
- between and selected their responses to the ESS
- Participants rated the relevancy of IHSS content to their experience
- Interviews were recorded and professionally transcribed; however, technical difficulties precluded 1 interview from being transcribed
- Transcripts (n=60) were analyzed following principles in line with applied thematic (content) analysis (Guest et al 2012) to identify the qualitative descriptions of how participants experienced EDS in their daily lives and how they interpreted the ESS response options
- Identified EDS themes were mapped to the ESS items to assess the conceptual coverage of the ESS

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## **Table 1. Participant Characteristics**

Characteristic	Interviewed (n=60)	Not Intervie (n=79)
Age (years), mean (SD)	38.5 (10.9)	41.1 (12.
Sex, n (%) female	48 (80.0)	62 (78.5
Race, n (%) White/Caucasian	54 (90.0)	69 (87.3
Baseline ESS Score <sup>1</sup> , mean (SD)	16.3 (3.2)	16.7 (7.9
Baseline IHSS Score <sup>2</sup> , mean (SD)	34.1 (5.8)	33.1 (7.9
Baseline PGI-S (EDS) <sup>3</sup> , mean (SD)	3.9 (0.70)	3.8 (0.70
Baseline CGI-S (IH) <sup>3</sup> , mean (SD)	3.7 (0.60)	3.6 (0.60

Abbreviations: CGI-S = Clinician Global Impression of Severity; EDS = excessive daytime sleepiness; ESS = Epworth Sleepiness Scale; IHSS = Idiopathic Hypersomnia Severity Scale; PGI-S = Patient Global Impression of Severity

<sup>1</sup>Ranges from 0 to 24 with scores  $\geq$ 16 indicating severe EDS

<sup>2</sup>Ranges from 0 to 50 with scores >26 indicating severe symptoms;

<sup>3</sup>5-point verbal rating scale ranging from 1 (none) to 5 (very severe)

### Figure 2. ESS Conceptual Coverage

Sitting and Reading	"Pretty much anytime I get home from work and I just essen stay still, like <b>watching TV, lay down, read a book, anythi</b> <b>like that, I'd probably be out within like 15 minutes</b> with even knowing it." " <b>If I'm sitting quietly</b> and I'm doing something that's not interesting to stimulate me at all, <b>I'll fall sleep</b> ."
Watching TV	"Reading or watching movies was difficult for me because I wasn't able to stay awake. I would doze off within 5, 10 minutes." "It's tough watching movies in the evening or TV shows, because I'd fall asleep."
Sitting Inactive in Public	"I've fallen asleep <b>in church</b> . I've fallen asleep <b>standing up</b> <b>while waiting for a table at a restaurant</b> . I've fallen asleep <b>the toilet</b> ." "I found myself <b>on campus sleeping in numerous differer</b> <b>areas</b> that perhaps one should not be sleeping all the time."
As a Passenger in a Car	"I'd be like, <b>'Okay, now I get a chance, because I'm the</b> <b>passenger, to fall asleep for a little bit and take a nap."</b> "If I'm doing this for more than, like, 20 minutes, I'm going to out. <b>Like sitting in a car.</b> "
Lying Down to Rest	"I would have to <b>take naps during the day in my car or in</b> <b>different room at in my office</b> ." "I had to <b>get crafty with how my classes were scheduled</b> that I would have <b>time to nap in between them</b> ."
Sitting and Talking	"I would often need naps in the middle of the day. "Like if there was a birthday party or something, everyone that I start nodding off at 8 or 8:30." "When I'm having these conversations with my girlfriend some friends, I'll start, like, dozing off."
Sitting after Lunch	"I would try to <b>just not eat</b> because I felt like <b>if I was eating</b> <b>would make me even more groggy</b> ." "I do okay in the mid-morning hours until just <b>after lunch</b> , be then in the afternoon, that's when <b>it tends to hit me a lot</b> ."
At a Stop in a Car or Bus	"At red lights, I would fall asleep and I had bumped into a couple cars because I fell asleep at a red light." "When I was at a traffic light, I would hit that brake button I would take a nap I would even have dreams."

Epworth Sleepiness Scale
Name:Today's date:
Your age (yrs):Your gender (Male = M, Female = F):
How likely are you to doze off or fall as leep in the following situations, in contrast to just feeling tired?
This refers to your usual way of life in the past week
Use the following scale to choose the <b>most appropriate number</b> for each situation:
0 = no chance of dozing 1 = <b>slight chance</b> of dozing
2 = moderate chance of dozing 3 = high chance of dozing
It is important that you answer each item as best as you can.
Situation Chance of Dozing (0-3)
Sitting and reading
Sitting inactive in a public place (e.g., a theater or a meeting)
As a passenger in a car for an hour without a break
Lying down to rest in the afternoon when circumstances permit
Sitting and talking to someone
In a car or bus, while stopped for a few minutes in traffic
THANK YOU FOR YOUR COOPERATION
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# Results

- Baseline characteristics of interviewed patients and those who were not interviewed were similar (Table 1)
- 98% of interviewed patients with IH spontaneously reported experiencing EDS
- Descriptions from patients about their experience with dozing off during the day mapped to the activities / situations presented on the ESS (Figure 2)
- Patients described differentiating ESS response options by thinking about how the likelihood of them falling asleep, or the amount of effort needed to maintain wakefulness, varied in each situation (**Figure 3**)
- One theme that emerged was the interplay between dozing off and activity level; more physical engaging activities were associate with less chance of dozing; more sedentary actives were associated with more change of dozing

# Conclusions

- ESS items map to descriptions of situations in which interviewed patients with IH reported experiencing EDS
- Because interviewed IH patients had experienced EDS in these situations. they were indeed able to accurately report their likelihood to fall asleep in these situations
- Patients with IH were able to accurately interpret ESS item content and response options

#### This evidence supports the utility of the ESS as an endpoint measure for assessing the severity, and changes in the severity, of EDS in clinical trials among patients with IH

### REFERENCES

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