



CASE CLOSED?

Diagnosing Idiopathic Hypersomnia Beyond the Usual Suspects

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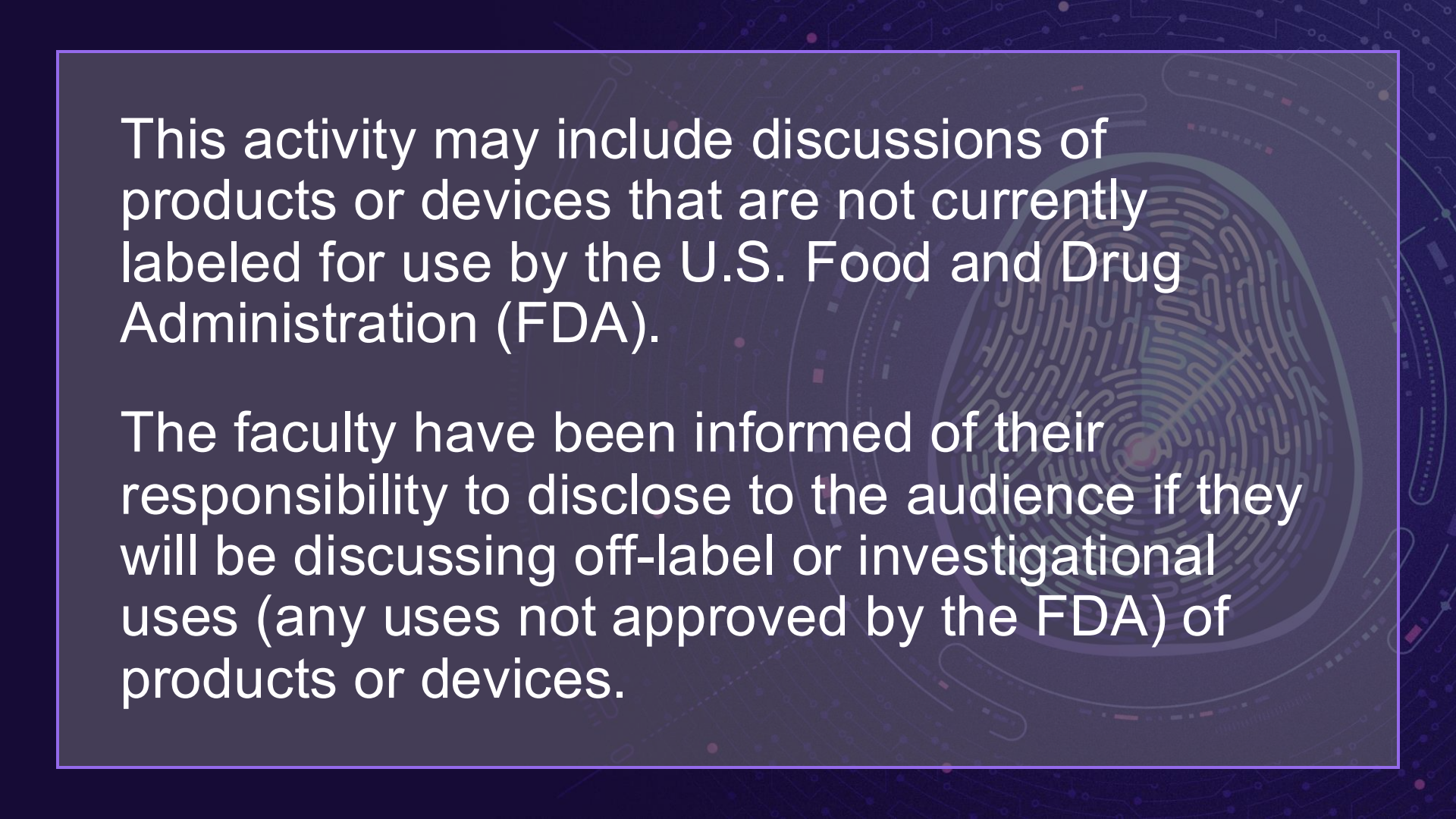
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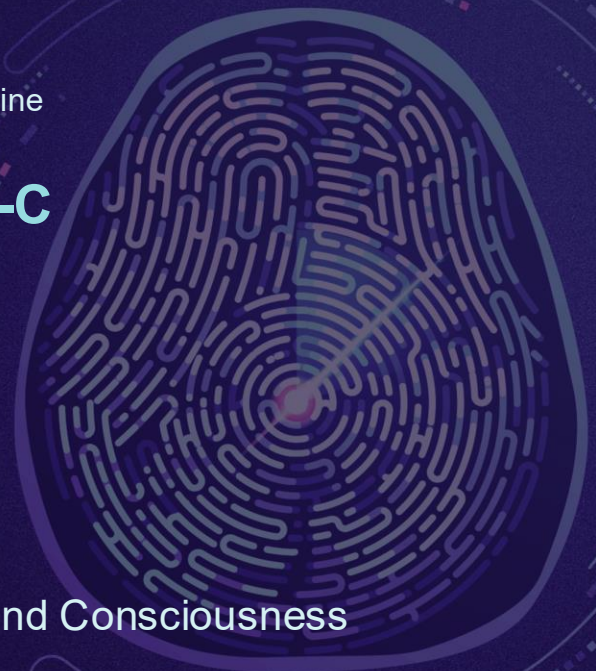
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All identified conflicts of interest have been mitigated.

Disclosures

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Research Support—Funding for REVITALYZ clinical trial provided by Avadel Pharmaceuticals (2/2025-4/2025)

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All identified conflicts of interest have been mitigated.

LEARNING OBJECTIVES

1

Evaluate the latest efficacy and safety data for current and emerging therapies for patients with IH

2

Integrate appropriate guideline-recommended diagnostic criteria and comprehensive assessments into practice when there is clinical suspicion of IH to improve early and accurate diagnosis

3

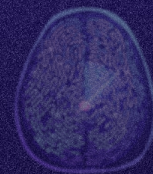
Identify the nature of overlapping symptoms of IH and other hypersomnia disorders

Idiopathic Hypersomnia Landscape

*Disease Burden, Diagnostic
Framework, Approved
Therapy, and Investigational
Agents That Could Change
the Picture*



Idiopathic Hypersomnia (IH) Is Too Often Missed or Mislabeled



> 60%

of people with IH are initially
misdiagnosed

69%*

experience > 1 year delay to
diagnosis

~20%

wait ≥ 10 years for an accurate
diagnosis

The Clinical Consequence

IH is commonly misattributed to mood disorders and may be confused with other central disorders of hypersomnolence, especially NT2; insufficient sleep syndrome must also be excluded in the diagnostic workup. Delayed diagnosis prolongs impaired daily functioning, cognitive burden, work/school disruption, and reduced QoL.

*Data from a U.S. patient survey of adults with IH (N = 290); 69% is derived from the 1-2 year, 2-5 year, 5-10 year, and ≥ 10 year categories combined.

IH = idiopathic hypersomnia; NT2 = narcolepsy type 2; QoL = quality of life.

Whalen M, et al. *Sleep*. 2022;45(Suppl 1):A175-A176. Boulanger T, et al. *Sleep Adv*. 2024;5(1):zpae059. Dauvilliers Y, et al. *Sleep Med Rev*.

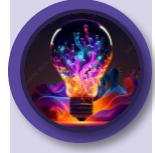
2022;66:101709. Stevens J, et al. *Nat Sci Sleep*. 2023;15:593-606.



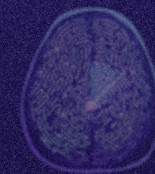


Patient Advocate Becky

Video Clip:



Approved and Key Emerging IH-Relevant Trials



Agent	Class/Target	Phase	Current Status
Low-sodium oxybate	GABA-B/oxybate	Approved (adult IH)	FDA-approved for IH in adults (Aug 2021); only FDA-approved therapy for adult IH; LCM + real-world studies ongoing
Sodium oxybate ER; once-nightly*	GABA-B/oxybate	Phase III (IH)	FDA-approved for cataplexy or EDS in adults with narcolepsy (May 2023); phase III in adult IH ongoing
Alixorexton (ALKS 2680)*	OX2R-selective agonist	Phase II (IH)	VIBRANCE-3 phase II study in adult IH ongoing; estimated primary completion June 2026
TAK-360*	OX2R-selective agonist	Phase II (IH)	Recruiting phase II study in adults with IH
Cleminorexton (ORX750 + additional OX2R agonists)*	OX2R-selective agonist	Phase IIa (NT1/NT2/IH)	CRYSTAL-1 phase IIa includes participants with IH

*This agent is not currently indicated for the treatment of IH.

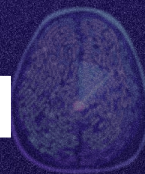
GABA-B = gamma-aminobutyric acid type B; LCM = lifecycle management; ER = extended release; EDS = excessive daytime sleepiness; OX2R = orexin 2 receptor; NT1 = narcolepsy type 1.

Sodium oxybate [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761061s000lbl.pdf.

Calcium, magnesium, potassium, and sodium oxybates [package insert].

https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/212690s011lbl.pdf. ClinicalTrials.gov Identifiers: NCT06812078 and NCT06752668.

Low-Sodium Oxybate: Phase III in Adult IH



Parameter	Phase III
Design	Phase III, multicenter, placebo-controlled, double-blind randomized-withdrawal study following a 10-14-week open-label titration/optimization period and 2-week stable-dose period
Population	Adults age 18-75 with IH meeting ICSD-2 or ICSD-3 criteria; N = 154 enrolled (safety population), N = 115 randomized (modified intention-to-treat population)
Primary endpoint	Change in ESS from end of stable-dose period to end of 2-week double-blind randomized withdrawal; ESS worsened on placebo withdrawal but remained stable on low-sodium oxybates (LS mean difference -6.5 points; 95% CI, -8.0 to -5.0; $p < 0.0001$)
Key secondaries	Key secondary endpoints PGI-C and IHSS both favored low-sodium oxybates (both $p < 0.0001$)
Most common AEs	Nausea (22%), headache (18%), dizziness (12%), anxiety (11%), vomiting (11%)
Safety summary	No deaths and no new safety signals in IH relative to the known oxybate profile; boxed warning for CNS depression and abuse/misuse
Regulatory outcome	FDA-approved on August 12, 2021 for the treatment of IH in adults; first and only FDA-approved therapy for adult IH

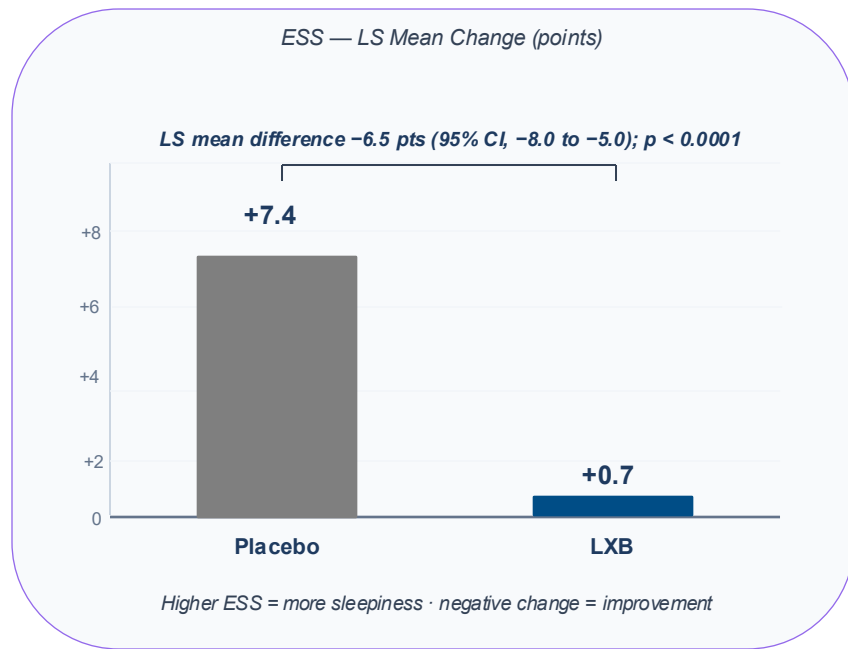
AE = adverse event; CI = confidence interval; CNS = central nervous system; ESS = Epworth Sleepiness Scale; ICSD-2/3 = International Classification of Sleep Disorders, second/third editions; IHSS = Idiopathic Hypersomnia Severity Scale; LS = least squares; PGI-C = Patient Global Impression of Change; REMS = Risk Evaluation and Mitigation Strategy.

Dauvilliers Y, et al. *Lancet Neurol*. 2022;21(1):53-65. Calcium, magnesium, potassium, and sodium oxybates [package insert].

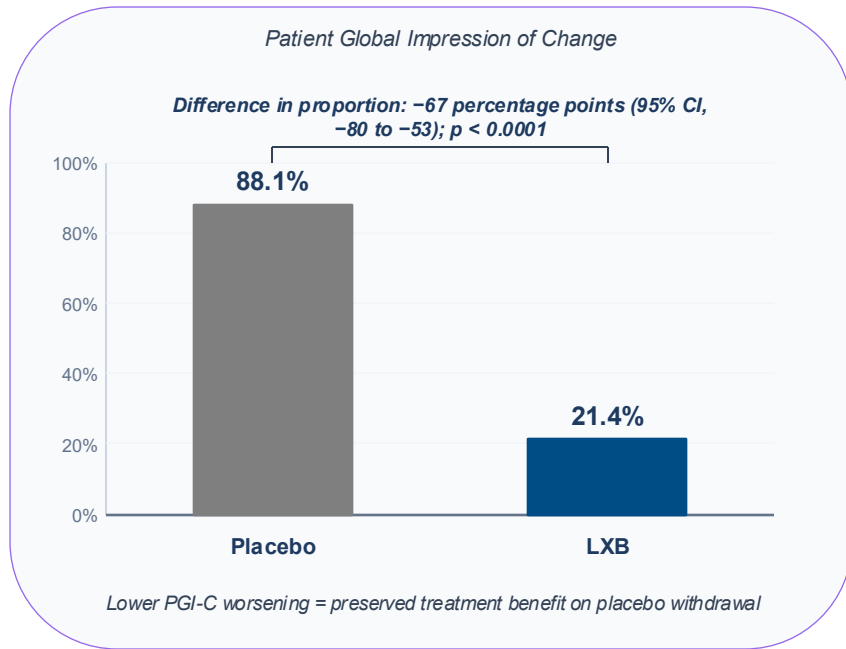
https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/212690s011lbl.pdf.

Low-Sodium Oxybate: Primary and Secondary Data in Adult IH

PRIMARY ENDPOINT — ESS CHANGE DURING 2-WEEK RANDOMIZED WITHDRAWAL



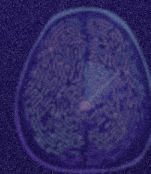
SECONDARY ENDPOINT — PGI-C — % worsened (minimally, much, or very much worse) at end of withdrawal



LXB = low-sodium oxybate.

Adapted from Dauvilliers Y, et al. *Lancet Neurol.* 2022;21(1):53-65.

Once-Nightly Sodium Oxybate ER* (REVITALYZ): Study Design at a Glance



Randomized-withdrawal design: participants are stabilized on once-nightly oxybate, then randomized to continue active treatment or switch to placebo.



PRIMARY ENDPOINT

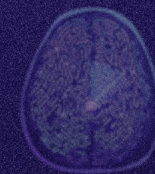
Change in ESS total score from end of the stable-dose period to end of the 2-week double-blind randomized withdrawal (assessed ~week 14)

KEY SECONDARY ENDPOINTS

PGI-C, IHSS, CGI-C, and FOSQ-10

*This agent is not FDA-approved for the treatment of IH. This agent would be the first new IH dosing paradigm since low-sodium oxybate (2021); registered trial design and endpoints are shown here, with peer-reviewed efficacy/safety results anticipated to follow.
CGI-C = Clinical Global Impression of Change; FOSQ-10 = Functional Outcomes of Sleep Questionnaire.
ClinicalTrials.gov identifier: NCT06525077. BusinessWire. 2026. https://www.businesswire.com/news/home/20260512566395/en/Alkermes-Announces-Positive-Topline-Results-From-REVITALYZ-Phase-3-Study-Evaluating-LUMRYZ-sodium-oxybate-Extended-Release-in-Adults-With-Idiopathic-Hypersomnia#xd_co_f=YzA5MmViNDMtZDQ0NS00MTU0LTk5Y2EtMWFjYmY4MjYyNmU5~.

Once-Nightly Sodium Oxybate ER* (REVITALYZ): Phase III in Adult IH

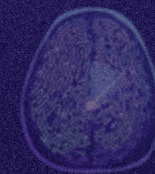


Parameter	Phase III
Design	Phase III, multicenter, double-blind, placebo-controlled, randomized-withdrawal study of once-at-bedtime oxybate in adults with IH: ~10-week open-label dose titration (4.5 g up to 9 g) → 2-week stable-dose period → 2-week double-blind randomized withdrawal, followed by an open-label safety extension (~42 weeks total)
Population	Approximately 150 adults age 18-75 with IH; total ESS > 11 and average nightly total sleep time > 7 hours at screening; eligible whether initiating oxybate or transitioning from existing oxybate therapy; stable stimulants/alerting agents permitted
Primary endpoint	Change in ESS total score (LS mean) from the end of the open-label stable-dose period to the end of the 2-week double-blind randomized withdrawal (assessed at ~week 14) Placebo group showed statistically significant worsening vs participants continuing sodium oxybate ER ($p < 0.0001$)
Key secondaries	PGI-C, IHSS, and a measure of functional outcomes of sleep (worsening on placebo vs maintenance on active treatment during randomized withdrawal) Both worsened significantly with placebo vs continued sodium oxybate ER ($p < 0.0001$)
Most common AEs	The most common treatment-emergent AEs (occurred in $\geq 10\%$ of participants) were nausea, anxiety, headache, dizziness, and vomiting
Safety summary	No new safety signals observed in the IH population. Current approved-product labeling carries a boxed warning for CNS depression and abuse/misuse
Regulatory outcome	Once-nightly sodium oxybate ER is FDA-approved (May 2023) for cataplexy or EDS in narcolepsy (age 7+) *This agent is not approved for the treatment of IH. REVITALYZ is designed to support a potential supplemental indication in IH. Enrollment completed Dec 2025; topline results are pending

DBRW = double-blind randomized withdrawal.

Sodium oxybate [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761061s000lbl.pdf. ClinicalTrials.gov Identifier: NCT06525077. BusinessWire. 2026. https://www.businesswire.com/news/home/202605112566395/en/Alkermes-Announces-Positive-Topline-Results-From-REVITALYZ-Phase-3-Study-Evaluating-LUMRYZ-sodium-oxybate-Extended-Release-in-Adults-With-Idiopathic-Hypersomnia#xd_co_f=YzA5MmViNDMtZDQ0NS00MTU0Lk5Y2EtMWFjYmY4MjYyNmU5~.

Active IH Trials



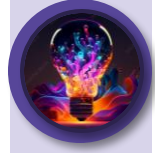
Agent	Mechanism	Lead Indication	Phase + Lead Study	IH-Relevance Note
Alixorexton (ALKS 2680)	OX2R-selective agonist	IH	Phase II (Vibrance-3)	Only named OX2R agonist with an active dedicated IH efficacy study; estimated primary completion July 2026; public topline timing not confirmed
TAK-360	OX2R-selective agonist	IH/NT2	Phase II (IH; NCT06812078)	Active IH dose-finding study recruiting
ORX750	OX2R-selective agonist	IH/NT1/NT2	Phase IIa (CRYSTAL-1)	Includes an IH cohort in an early proof-of-concept crossover study



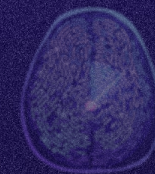


Patient Advocate Haley

Video Clip:



The Diagnosis Sets the Direction



The Argument

- IH now has one FDA-approved therapy in adults, with additional mechanisms under investigation that include OX2R agonism and histaminergic wake-promotion. As therapeutic options diversify, **diagnostic mislabeling matters more** because the wrong label can delay both appropriate workup and access to the right treatment pathway.
- The more options exist, the more a misdiagnosis costs the patient: **access to the right mechanism depends on the label**. If a patient is diagnosed with IH rather than narcolepsy, treatment eligibility and future therapeutic options may differ.



Patient Cases: What Would You Do?

*Audience, Community/Rural
Clinician, KOL, AI, and Faculty
Responses to Two Patients with
IH*





PATIENT CASE

Elena Brooks

- 29-year-old graduate student and part-time laboratory technician referred for 12-18 months of persistent daytime sleepiness, difficulty waking, fatigue, and worsening concentration/work/school performance
 - Sleeps 9-10 hours on weeknights, up to 12 hours on weekends, wakes unrefreshed
 - 2-4 sequential alarms to get up; 45-90 min disorientation after waking
 - Reports pervasive mental fog, slowed processing, reduced ability to complete coursework and protocols
 - 1-2 unplanned naps/day, 60-120 min; naps are not restorative and may occasionally worsen alertness
 - 2-3 caffeinated beverages daily with limited benefit

- Targeted history/prior psychiatric framing:
 - Drinks alcohol rarely; no cannabis or illicit substances
 - Not a shift worker
 - Primary care provider prescribed sertraline 50 mg daily; after 10 weeks, no meaningful improvement in daytime sleepiness, sleep inertia, or function
 - Describes symptoms as “still tired when I wake up” and “never fully on”
 - Frustrated that symptoms are framed as stress, burnout, or mood-related
 - Wants a clear diagnostic plan and realistic expectations



PATIENT CASE

Elena Brooks

Laboratory and Mood Screening

Primary care workup was limited to general lab screening, and no sleep-specific evaluation has yet been performed.

Assessment	Result	Interpretation
CBC	Within normal limits	Anemia excluded as driver of fatigue
TSH	Within normal limits	Thyroid dysfunction excluded
Ferritin	Within normal limits	Iron deficiency/RLS association excluded
Vitamin D (25-OH)	Within normal limits	Common reversible fatigue contributor addressed
PHQ-9	8 (mild)	Depressive symptoms present but not severe; overlaps EDS items
GAD-7	3 (minimal)	Anxiety unlikely to be primary driver



PATIENT CASE

Elena Brooks

Medications and Pertinent Clinical Information

Assessment	Result	Interpretation
Sertraline 50 mg daily	×10 weeks, no symptomatic benefit	<i>Adequate trial duration; REM-suppressant (will affect MSLT interpretation)</i>
Hypnotics/benzodiazepines	None	<i>No medication-induced hypersomnolence</i>
Opioids/cannabinoids	None	<i>Excluded</i>
Stimulants/wake-promoting agents	None	<i>Drug-naïve for this indication</i>
Substance misuse/head trauma	None reported	<i>Secondary causes of hypersomnolence unlikely</i>
Cataplexy history	None on directed review	<i>No clear cataplexy identified; diagnostic significance remains unresolved without full reassessment</i>

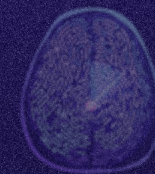


AUDIENCE POLLING

Which initial assessment approach most appropriately clarifies whether her symptoms reflect IH, a primary mood disorder, or insufficient sleep syndrome?

- A. Administer the ESS, initiate a 2-week sleep diary with actigraphy, and reassess the symptom cluster including prolonged sleep time, severe sleep inertia, unrefreshing naps, and brain fog
- B. Administer the IHSS as the primary screening tool
- C. Rely on prior PHQ-9 and GAD-7; refer directly for PSG
- D. Refer to psychiatry for additional assessment before any sleep-focused evaluation
- E. Refer directly for overnight PSG followed by next-day MSLT
- F. Reinforce sleep hygiene counseling and reassess in 3 months

What Patients Need Clinicians to Hear



This is not just “being tired”

65% reported trouble staying awake or “never feeling fully awake”

53% say that “it is very hard to get out of bed even with alarms”

51% reported brain fog/trouble thinking clearly

The wrong explanation often comes first

42%: symptoms were commonly attributed to depression/stress/burnout

40% were told to simply get more sleep



The diagnostic journey is hard to navigate

42%: barriers getting a referral to a sleep specialist

30%: barriers knowing how to describe the symptoms clearly

26%: barriers finding a treatment/management plan that helps

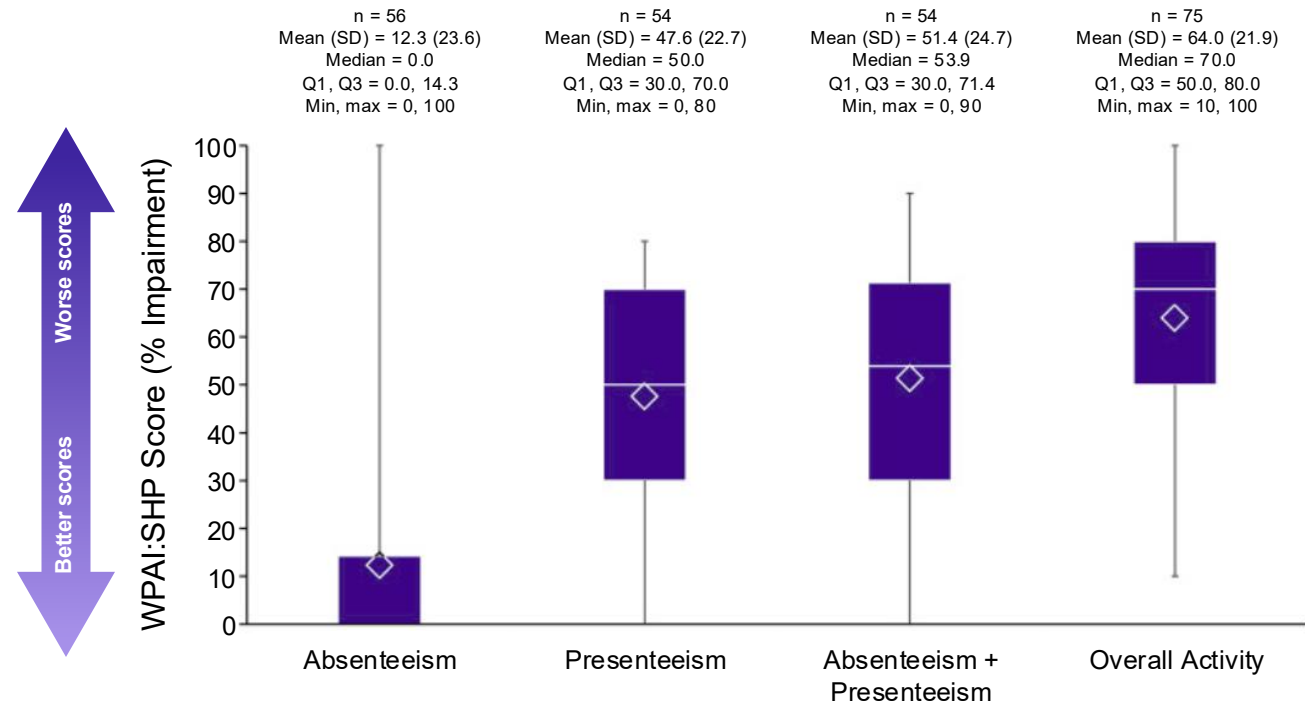
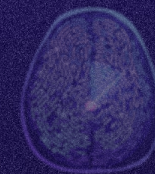
What patients say would have helped earlier

54%: more targeted questions about waking up, naps, brain fog, and long sleep time

47%: clearer explanations of how IH differs from depression or other conditions

39%: a symptom checklist, diary, or tracking tool

Functional Impact of IH: ARISE Survey



Takeaway

IH imposes a **clear, quantifiable burden** on work and daily function, especially presenteeism, overall work-productivity impairment, and nonwork activity impairment.

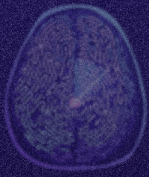
- Presenteeism: mean 47.6%
- Overall work-productivity impairment: mean 51.4%
- Overall activity impairment: mean 64.0%

These data support **earlier** diagnostic workup and **stronger** documentation of functional impact.

WPAI:SHP scores in all participants. The bottom and top edges of the box indicate the first and third quartiles, the line inside the box is the median, and the marker inside the box is the mean. The whiskers extending from the box indicate the minimum and maximum values.

Stevens J, et al. *Nat Sci Sleep*. 2023;15:593-606.

Core Epidemiology and Patient Burden



Domain	What the Evidence Shows	Clinical Implication
Prevalence	Diagnosed IH remains rare in U.S. adults: annual prevalence ~10.5-12.1 per 100,000; all-time lookback prevalence 32.7-49.0 per 100,000 in claims data	Rare diagnosis, but likely underrecognized; recognition and diagnostic workup remain the bottleneck
Age of onset	Typical onset between adolescence and young adulthood (age 15-20); symptoms often chronic and stable	Misattribution to school stress, circadian preference, or mood symptoms may delay correct diagnosis
Diagnostic delay	61% reported prior misdiagnosis; 69% reported > 1-year delay in diagnosis; 19% reported ≥ 10 years to diagnosis	Delayed diagnosis prolongs inappropriate labeling and years of untreated disability; years of inappropriate therapy (antidepressants, stimulants)
Functional impact	ARISE showed substantial work and activity burden: mean absenteeism 12.3%, presenteeism 47.6%, overall work productivity impairment 51.4%, and daily activity impairment 64.0%	Measurable occupational and academic cost; strengthens case for expedited workup
Symptom profile	Core burdensome symptoms extend beyond EDS and include severe sleep inertia/sleep drunkenness, long sleep duration or nonrestorative sleep, prolonged unrefreshing naps, and daytime cognitive dysfunction/brain fog	ESS alone is insufficient; pair ESS with IHSS, sleep diary/actigraphy, and a structured symptom history to distinguish IH from depression, insufficient sleep syndrome, and NT2

Foundational Framework

ICSD-3-TR Criteria for Idiopathic Hypersomnia



All of the following must be present:*

- Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months
- Cataplexy is absent
- MSLT shows < 2 SOREMPs, or no SOREMPs if REM latency on the preceding PSG is ≤ 15 minutes
- Presence of at least one:
 - (1) $\text{MSLT} \leq 8$ min; or
 - (2) total 24-hour sleep time ≥ 660 min (typically 12-14h) on 24hr performed after correction of chronic sleep deprivation, or actigraphy with sleep diary/log averaged over ≥ 7 days of unrestricted sleep
- Insufficient sleep syndrome ruled out, ideally with sleep diary $\pm$ actigraphy when clinically needed and/or documented lack of improvement after adequate sleep extension
- Hypersomnolence/MSLT findings are not better explained by another sleep disorder, circadian rhythm sleep-wake disorder, medical disorder, mental disorder medication/substance use or withdrawal

*Criteria A-F must be met; criterion D requires at least 1 of the 2 objective findings above.

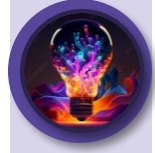
ICSD-3-TR = International Classification of Sleep Disorders, Third Edition, Text Revision; MSLT = Multiple Sleep Latency Test; SOREMP = sleep-onset rapid eye movement period; REM = rapid eye movement; PSG = polysomnography.

American Academy of Sleep Medicine [AASM]. 2023. <https://aasm.org/clinical-resources/international-classification-sleep-disorders/>. Krahn LE, et al. *J Clin Sleep Med*. 2021;17(12):2489-2498. Dauvilliers Y, et al. *Sleep Med Rev*. 2022;66:101709.



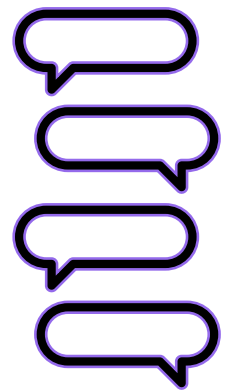
EXPERT FACULTY

Live Discussion



Decision Point

Patient Case: Elena Brooks



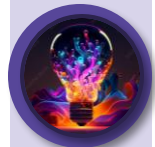


COMMUNITY/RURAL KOL

Audio Recording: Case 1 Elena



E Refer directly for overnight PSG followed by next-day MSLT



- Enough information that any of the other options would be delaying what needs to take place – the sleep study
- Depression does not make sense given her PHQ-9 is 3
- Never seen or heard of a patient with overwhelming hypersomnia with no depression symptoms otherwise
- Symptoms tend to convey a classic sleep disorder
- Use screening scales to rule out depression or other mood disorders during that initial patient visit
- Insufficient sleep syndrome unlikely as patient is getting excessive yet unrestful sleep



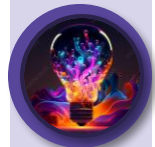
COMMUNITY/RURAL KOL

Audio Recording: Case 1 Elena



A Administer the ESS, initiate a 2-week sleep diary with actigraphy, and reassess the symptom cluster including prolonged sleep time, severe sleep inertia, unrefreshing naps, and brain fog

- Reflex with daytime sleepiness is to think OSA first, but no evidence
- Presence of long sleep that does not refresh, morning sleep inertia, unrefreshing naps, and cognitive fog; none of which is consistent with OSA
- Diary and actigraphy indicates whether or not it is insufficient sleep
- IHSS not something reached for in primary care
- Mood scores only mildly elevated
- Repeat referral to psychiatry would be a mistake
- Want sleep document before PSG and MSLT





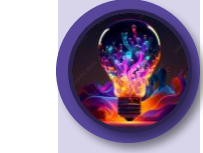
COMMUNITY/RURAL KOL

Audio Recording: Case 1 Elena



A Administer the ESS, initiate a 2-week sleep diary with actigraphy, and reassess the symptom cluster including prolonged sleep time, severe sleep inertia, unrefreshing naps, and brain fog

- ESS and sleep diary is what is currently done in office
- Determine if she is getting enough sleep prior to sending for hours of testing
- Symptoms are not consistent with OSA
- Since she already failed an antidepressant trial, would not repeat
- Going straight to sleep study should be preceded by prep first





Additional Community KOL Responses for Case 1 Elena



RESPONDENT 1

B

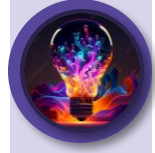
Administer the IHSS as the primary screening tool



RESPONDENT 2

A

Administer the ESS, initiate a 2-week sleep diary with actigraphy, and reassess the symptom cluster including prolonged sleep time, severe sleep inertia, unrefreshing naps, and brain fog



RESPONDENT 3

A

Administer the ESS, initiate a 2-week sleep diary with actigraphy, and reassess the symptom cluster including prolonged sleep time, severe sleep inertia, unrefreshing naps, and brain fog





KOL: Kiran Maski, MD, MPH

Video Recording: Case 1 Elena

A Administer the ESS, initiate a 2-week sleep diary with actigraphy, and reassess the symptom cluster including prolonged sleep time, severe sleep inertia, unrefreshing naps, and brain fog

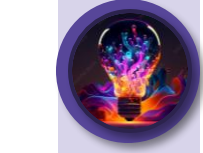




KOL: Yves Dauvilliers, MD, PhD

Video Recording: Case 1 Elena

B Administer the IHSS as the primary screening tool





KOL: John Carter, MD

Video Recording: Case 1 Elena

A Administer the ESS, initiate a 2-week sleep diary with actigraphy, and reassess the symptom cluster including prolonged sleep time, severe sleep inertia, unrefreshing naps, and brain fog





AI: ChatGPT 5.2

User-Fed Response: Case 1 Elena



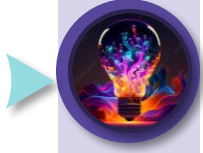
New chat → Here's the case's subjective, objective, and plan/multiple choice question. Based on the information provided, which answer choice would you choose and what is your brief rationale for your chosen answer and unchosen options?

A Administer the ESS, initiate a 2-week sleep diary with actigraphy, and reassess the symptom cluster including prolonged sleep time, severe sleep inertia, unrefreshing naps, and brain fog

Rationale: This patient's history is highly suggestive of IH. However, a diagnosis of IH requires documentation that: 1) she is obtaining adequate sleep; 2) symptoms are not due to chronic sleep deprivation; and 3) another sleep disorder is not responsible.

Rule outs

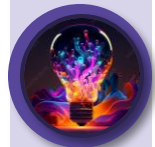
IHSS: is not the preferred initial screening tool
PHQ-9 and GAD-7: evaluate mood and anxiety symptoms, not hypersomnolence disorders
Refer to psychiatry: her symptoms are dominated by sleep, not mood
Overnight PSG and next-day MSLT: should occur after documenting sleep; REM-suppressing meds should be discontinued before MSLT
Sleep hygiene counseling: no evidence poor sleep hygiene is causative





Patient Advocate Caitlin

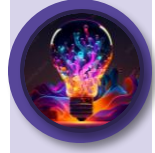
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Patient Advocate Haley

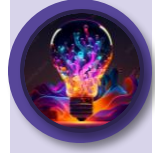
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Patient Advocate Becky

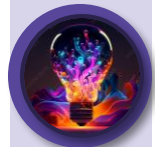
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Case Perspective Summary

Case 1 Elena



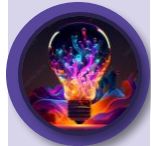
Most Appropriate Assessment Approach	Community/Rural	KOLs	AI
Administer the ESS, initiate a 2-week sleep diary with actigraphy, and reassess the symptom cluster including prolonged sleep time, severe sleep inertia, unrefreshing naps, and brain fog	4	2	1
Administer the IHSS as the primary screening tool	1	1	—
Rely on prior PHQ-9 and GAD-7; refer directly for PSG	—	—	—
Refer to psychiatry for additional assessment before any sleep-focused evaluation	—	—	—
Refer directly for overnight PSG followed by next-day MSLT	1	—	—
Reinforce sleep hygiene counseling and reassess in 3 months	—	—	—



FACULTY DISCUSSION

What have we learned from Elena's case?

- **Diagnostic delay has real costs:** functional decline and QoL loss while the workup stalls
- **Red flags hide in plain sight:** long sleep, sleep inertia, and unrefreshing naps were reframed as stress or mood
- **Ask about sleep, then dig deeper:** quantify sleep duration, wake difficulty, nap quality, and sleep inertia
- **A mild PHQ-9 is not the diagnosis:** overlapping EDS may inflate it, and a failed antidepressant trial can argue against mood as primary
- **No single test stands alone:** pair ESS and IHSS with a sleep diary/actigraphy and PSG → MSLT for a full clinical picture
- **Check confounders before testing:** REM suppressants can distort MSLT



A Practical Diagnostic Algorithm for Suspected IH



1. Recognize

Chronic EDS ≥ 3 months despite adequate sleep; long sleep time, severe sleep inertia, unrefreshing naps

2. Characterize and screen

Symptom history + ESS and IHSS; screen mood (PHQ-9); reconcile medications/substances

3. Exclude mimics

Insufficient sleep (1-2-wk diary $\pm$ actigraphy, sleep extension), OSA, medication/substance, circadian, medical/psychiatric

4. Objective testing

Overnight PSG, then next-day MSLT after ≥ 7 days unrestricted sleep; taper REM suppressants first



Reaching the Diagnosis (ICSD-3-TR)

IH confirmed when all are met:

- MSLT mean sleep latency ≤ 8 min and/or 24 h total sleep time ≥ 660 min
- Fewer than 2 SOREMPs; or no SOREMPs, if the REM latency on the preceding overnight sleep study (PSG) was ≤ 15 min
- Cataplexy absent
- Not better explained by another disorder, medication/substance, or insufficient sleep

Branch points

- ≥ 2 SOREMPs $\rightarrow$ evaluate for narcolepsy
- Symptoms resolve with adequate sleep $\rightarrow$ insufficient sleep syndrome
- Explained by OSA, medication, circadian, or psychiatric cause $\rightarrow$ treat that condition and reassess

IHSS and ESS: What Each Scale Measures



Attribute	Epworth Sleepiness Scale (ESS)	Idiopathic Hypersomnia Severity Scale (IHSS)
What it measures	Subjective propensity to doze in 8 everyday situations – a single sleepiness dimension; does not capture sleep inertia or long sleep time	Severity, frequency, and functional impact of the 3 core IH symptoms: EDS/naps, prolonged unrefreshing night and day sleep, and sleep inertia
Items and score range	8 items; total score 0-24	14 items; total score 0-50
Interpretation/cut-offs	> 10 suggests excessive daytime sleepiness (not diagnosis-specific)	≥ 22 discriminates untreated IH from controls (sensitivity 91%, specificity 94%); severity: mild 0-12, moderate 13-25, severe 26-38, very severe 39-50
Disease specificity	Generic across sleep disorders; cannot distinguish IH from OSA, narcolepsy, or insufficient sleep	Developed and validated specifically for IH
Treatment responsiveness	Responsive to change in sleepiness; used as a primary endpoint in IH trials	Responsive to treatment; used as a key secondary endpoint in IH trials
Best use in practice	Quick screen and tracking of overall sleepiness	Characterize the full IH symptom burden and monitor response – use alongside, not instead of, the ESS

Differentiating IH From Depression and Mood Disorders



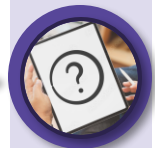
Clinical Feature	Idiopathic Hypersomnia	Depression/Mood Disorder
Predominant complaint	Irrepressible daily sleepiness with long, unrefreshing sleep; sleepiness is the primary, persistent disturbance	Low mood/anhedonia is primary; hypersomnolence is one of several symptoms and tends to fluctuate with mood
Daytime naps	Often long (1-4 h) and characteristically unrefreshing	Frequently short or absent; daytime lying down may reflect low drive rather than true sleep propensity
Sleep inertia and long sleep time	Severe sleep inertia (sleep drunkenness) and long sleep time are hallmark features	Less prominent; early morning awakening or insomnia is common
Objective testing (PSG/MSLT)	Long total sleep time; MSLT mean sleep latency ≤ 8 min in many (not all) patients, with < 2 SOREMPs	MSLT often shows normal or long sleep latency; objective sleepiness frequently not confirmed
Response to antidepressants	EDS, sleep inertia, and long sleep time persist despite an adequate antidepressant trial	Hypersomnolence typically improves as mood improves with adequate treatment
Overlap to remember	Depressive symptoms are common in IH (up to ~two-thirds screen positive on PHQ-9); comorbidity is not causation	PHQ-9 sleep/energy items overlap with EDS and can inflate scores; screen for an underlying sleep disorder



AUDIENCE POLLING REVISITED

Now, what would you do next?

- A. Administer the ESS, initiate a 2-week sleep diary with actigraphy, and reassess the symptom cluster including prolonged sleep time, severe sleep inertia, unrefreshing naps, and brain fog
- B. Administer the IHSS as the primary screening tool
- C. Rely on prior PHQ-9 and GAD-7; refer directly for PSG
- D. Refer to psychiatry for additional assessment before any sleep-focused evaluation
- E. Refer directly for overnight PSG followed by next-day MSLT
- F. Reinforce sleep hygiene counseling and reassess in 3 months





PATIENT CASE

Daniel Mercer

- 37-year-old man, software engineer, is referred for reevaluation after a prior assessment for presumptive OSA
 - Symptoms have persisted for 5-6 years with progressive functional impact
 - Describes “never feeling fully awake” with mental fog, difficulty sustaining attention at work
 - Sleeps ≥ 8 hours on weeknights and often 10-11 hours on weekends, still wakes unrefreshed
 - 45-90 min of poor wakefulness despite multiple alarms
 - Daytime naps 30-90 min on 3-4 days/week, minimal restorative benefit
 - Symptoms interfering with work performance and daily functioning
 - Wants to understand what evaluation is needed to clarify diagnosis
- Prior workup/targeted history:
 - Prior HSAT did not show OSA
 - Presents believing narcolepsy is likely after reading about it online
 - No clear cataplexy
 - No muscle weakness with laughter, surprise, or strong emotion
 - No head drops, jaw sag, or knee buckling
 - No paralysis on awakening
 - No consistent hypnagogic hallucinations
 - Occasional vivid dreams; no dream enactment
 - Main symptom pattern remains long sleep time, severe morning sleep inertia, persistent foggy, and nonrestorative naps



PATIENT CASE

Daniel Mercer

Sleep-Specific Assessments and Mood Screening

Assessment	Result	Interpretation
Medication status	No current stimulant, wake-promoting agent, or antidepressant use	<i>Current symptom burden is not being actively modified by alerting or antidepressant therapy</i>
PHQ-9	6 (mild)	<i>Mild depressive symptoms present; does not independently explain the full hypersomnolence picture</i>
GAD-7	4 (minimal)	<i>Anxiety unlikely to be primary driver</i>
ESS	18/24	<i>Severe excessive daytime sleepiness</i>
HSAT	Negative for OSA	<i>Prior OSA screen unrevealing; does not establish the cause of hypersomnolence</i>
Swiss Narcolepsy Scale/directed cataplexy inventory	Negative for cataplexy	<i>No clear cataplexy signal on screening; clinical significance remains unresolved without full sleep-focused reassessment</i>

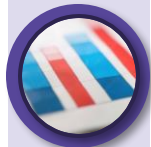
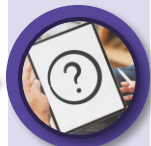




AUDIENCE POLLING

What is the most appropriate next diagnostic step?

- A. Proceed directly to overnight PSG followed by next-day MSLT
- B. Obtain a 2-week sleep diary and actigraphy and reassess while formal testing is pending
- C. Obtain a detailed current symptom history, document adequate sleep with a 2-week sleep diary and actigraphy, and perform an overnight PSG followed by next-day MSLT
- D. Administer the ESS and a validated hypersomnia questionnaire and manage based on score





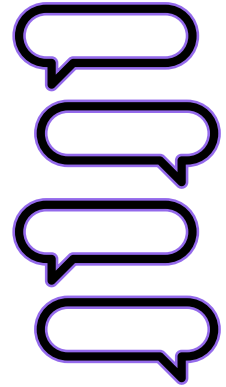
EXPERT FACULTY

Live Discussion



Decision Point

Patient Case: Daniel Mercer





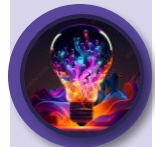
COMMUNITY/RURAL KOL

Audio Recording: Case 2 Daniel



A Proceed directly to overnight PSG followed by next-day MSLT

- Patient has a significant ongoing history of:
 - Hypersomnolence
 - Unrestful sleep
 - ESS is very high
- Functional impairment due to his symptoms is evident
- No or minimal evidence of medical- or substance-related issues contributing to symptoms





COMMUNITY/RURAL KOL

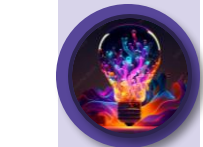
Audio Recording: Case 2 Daniel



C

Obtain a detailed current symptom history, document adequate sleep with a 2-week sleep diary and actigraphy, and perform an overnight PSG followed by next-day MSLT

- Severe ESS, negative HSAT, no cataplexy
- Symptoms not consistent with narcolepsy
- Positive for long sleep, severe inertia, unrefreshing naps, and brain fog, which is more consistent with IH than narcolepsy
- Immediate PSG and MSLT skips documenting adequate sleep
- Diary and actigraphy alone insufficient, need objective tests
- Questionnaires cannot distinguish narcolepsy from IH
- Teaching point: negative HSAT does not rule out sleep disorder





COMMUNITY/RURAL KOL

Audio Recording: Case 2 Daniel



C Obtain a detailed current symptom history, document adequate sleep with a 2-week sleep diary and actigraphy, and perform an overnight PSG followed by next-day MSLT

- Negative HSAT yet still sleepy
- Full, proper workup is needed
- Confirm if history indicates adequate sleep first, then PSG and MSLT
- Score on questionnaire alone insufficient for diagnosis
- Skipping sleep documentation would undercut testing



Additional Community KOL Responses for Case 2

RESPONDENT 1

C Obtain a detailed current symptom history, document adequate sleep with a 2-week sleep diary and actigraphy, and perform an overnight PSG followed by next-day MSLT

RESPONDENT 2

C Obtain a detailed current symptom history, document adequate sleep with a 2-week sleep diary and actigraphy, and perform an overnight PSG followed by next-day MSLT

RESPONDENT 3

C Obtain a detailed current symptom history, document adequate sleep with a 2-week sleep diary and actigraphy, and perform an overnight PSG followed by next-day MSLT

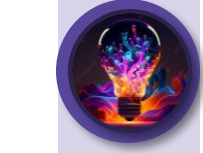




KOL: Kiran Maski, MD, MPH

Video Recording: Case 2 Daniel

C Obtain a detailed current symptom history, document adequate sleep with a 2-week sleep diary and actigraphy, and perform an overnight PSG followed by next-day MSLT

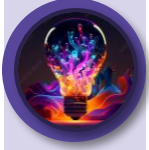




KOL: Yves Dauvilliers, MD, PhD

Video Recording: Case 2 Daniel

- C** Obtain a detailed current symptom history, document adequate sleep with a 2-week sleep diary and actigraphy, and perform an overnight PSG followed by next-day MSLT

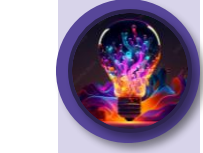




KOL: John Carter, MD

Video Recording: Case 2 Daniel

- C** Obtain a detailed current symptom history, document adequate sleep with a 2-week sleep diary and actigraphy, and perform an overnight PSG followed by next-day MSLT





AI: ChatGPT 5.2

User-Fed Response: Case 2 Daniel



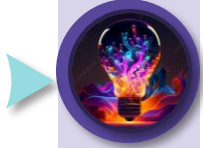
New chat → Here's the case's subjective, objective, and plan/multiple choice question. Based on the information provided, which answer choice would you choose and what is your brief rationale for your chosen answer and unchosen options?

X Obtain a detailed current symptom history, document adequate sleep with a 2-week sleep diary and actigraphy, and perform an overnight PSG followed by next-day MSLT

Rationale: Daniel's history strongly suggests IH, clues including long sleep duration, severe sleep inertia, unrefreshing naps, brain fog, severe sleep per ESS, no cataplexy, and negative HSAT for OSA

Rule outs

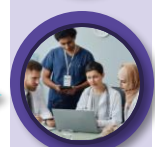
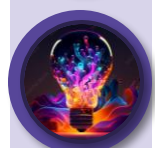
Overnight PSG + next-day MSLT: current guidelines recommend documenting sleep adequacy beforehand
Two-week diary and actigraphy: ESS score, functional impairment, and negative OSA warrant definitive sleep testing
Administer ESS and hypersomnia questionnaire: questionnaires do not diagnose IH; they quantify symptoms, measure severity, and track treatment response



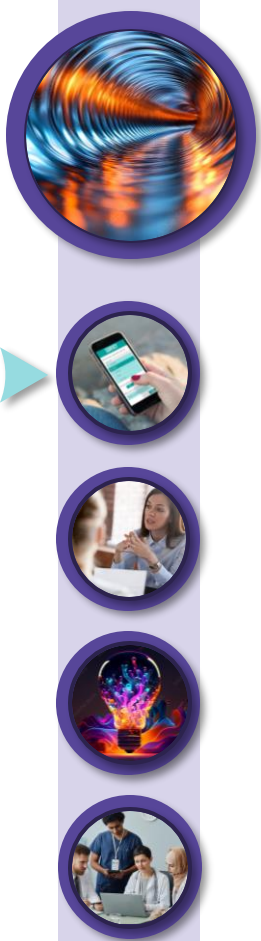


Case Perspective Summary

Case 2 Daniel



Most Appropriate Assessment Approach	Community/Rural	KOLs	AI
Proceed directly to overnight PSG followed by next-day MSLT	1	—	—
Obtain a 2-week sleep diary and actigraphy and reassess while formal testing is pending	—	—	—
Obtain a detailed current symptom history, document adequate sleep with a 2-week sleep diary and actigraphy, and perform an overnight PSG followed by next-day MSLT	5	3	1
Administer the ESS and a validated hypersomnia questionnaire and manage based on score	—	—	—

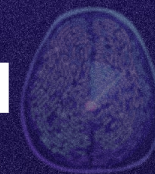


FACULTY DISCUSSION

What have we learned from Daniel's case?

- **A prior label can anchor and mislead:** a negative HSAT neither excludes OSA nor explains his sleepiness
- **Delay compounds impairment:** 5-6 years “never fully awake” before anyone reopened the workup
- **ESS is necessary but not sufficient:** ESS 18/24 confirms severe EDS but is nonspecific – it cannot separate IH from OSA, narcolepsy, or insufficient sleep; pair it with the IHSS and a full symptom history
- **IH vs NT2:** lookalikes need objective separation
- **Depression overlap and ruling out insufficient sleep:** PHQ-9 of 6 is mild and does not explain the full picture
- **Diagnosis is the gateway to treatment:** 5-6 years of progressive impairment shows the cost of delay

Differentiating IH From OSA, Insufficient Sleep, and Medication-Related Causes



Mimic or Cause	Distinguishing Features vs IH	How to Confirm or Exclude
OSA	Snoring, witnessed apneas, obesity; nonrestorative sleep with EDS but usually without severe sleep inertia or long sleep time; may coexist with IH	Overnight PSG (AHI). Treat OSA first; persistent EDS with normal sleep duration after adequate therapy warrants workup for a central disorder of hypersomnolence
Insufficient sleep syndrome	Chronic curtailed sleep with marked weekend/vacation “catch-up”; symptoms resolve with adequate sleep – an explicit ICSD-3-TR exclusion for IH	1-2-week sleep diary ± actigraphy documenting habitual short sleep; reassess after a structured sleep-extension trial
Medication- or substance-related	Sedating agents (antihistamines, benzodiazepines, opioids, some antidepressants/antipsychotics), alcohol, or withdrawal can cause or worsen hypersomnolence	Reconcile medications and substances; REM suppressants (e.g., antidepressants) can confound the MSLT; therefore, taper appropriately before testing when feasible
Diagnostic principle	IH is a diagnosis of exclusion; these causes must be ruled out before it is made	Layer symptom history + sleep diary/actigraphy + overnight PSG with next-day MSLT; revisit prior labels when symptoms don't fit

AI tool Claude Opus 4.8 was utilized to assist in content development and graphic layout. Reviewed by Siddharth Mohan.

AHI = apnea-hypopnea index.

AASM. 2023. <https://aasm.org/clinical-resources/international-classification-sleep-disorders/>. Lammers GJ, et al. *Sleep Med Rev*. 2020;52:101306.

Dauvilliers Y, et al. *Sleep Med Rev*. 2022;66:101709. Krahn LE, et al. *J Clin Sleep Med*. 2021;17(12):2489-2498.



AUDIENCE POLLING REVISITED

Now, what would you do next?

- A. Proceed directly to overnight PSG followed by next-day MSLT
- B. Obtain a 2-week sleep diary and actigraphy and reassess while formal testing is pending
- C. Obtain a detailed current symptom history, document adequate sleep with a 2-week sleep diary and actigraphy, and perform an overnight PSG followed by next-day MSLT
- D. Administer the ESS and a validated hypersomnia questionnaire and manage based on score





Patient Advocate Haley

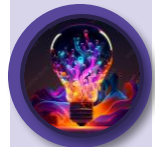
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Patient Advocate Caitlin

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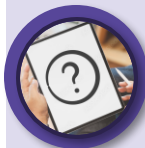
CME OUTFITTERS



Case Closed

Turning Complexity Into Clarity in IH Care

IH care demands earlier recognition, accurate diagnosis, and readiness for an evolving treatment landscape.



Diagnostic delays impose a measurable and preventable burden

Overlapping symptoms with mood disorders and other sleep conditions drive diagnostic delays; raising clinical suspicion early is the first step



ICSD-3-TR criteria are a starting point, not a finish line

A layered approach combining objective testing, validated scales, and a thorough symptom history is necessary to reach an accurate diagnosis

The correct label unlocks the correct treatment pathway

A misdiagnosis of depression or NT2 delays access to it and to emerging therapies

An expanding pipeline makes getting the diagnosis right more consequential than ever

With new therapeutic options emerging, accurate diagnosis matters more than ever; the right label connects patients to the right treatment at the right time



Put information into action!

Takeaways from this program can be implemented into your practice to improve patient care.

- **Improve** clinician confidence in differentiating IH from depression/mood disorders, NT2, OSA, and insufficient sleep syndrome when evaluating chronic EDS
- **Increase** the proportion of patients with suspected IH who receive a guideline-concordant workup; i.e., structured symptom history, validated scales (ESS and IHSS), sleep diary/actigraphy, and overnight PSG followed by next-day MSLT
- **Increase** the use of validated patient-reported measures, such as the IHSS and ESS, to characterize sleep inertia, long sleep time, and unrefreshing naps at diagnosis and to track treatment response over time
- **Reduce** diagnostic delay by reassessing $\geq 15\%$ more patients carrying a presumptive depression or NT2 label for an underlying central disorder of hypersomnolence when symptoms persist despite treatment

QUESTIONS & ANSWERS

The background of the slide is a dark purple color. It features a large, faint, stylized fingerprint in the center-right area. Overlaid on the fingerprint and the rest of the background are intricate, glowing circuit-like patterns in shades of blue and purple, resembling a complex network or data flow.

**Thank you for joining us.
Don't forget to collect your credit.**

Additional Resources

Visit www.cmeoutfitters.com
for clinical information and
certified educational activities



Visit the **Sleep Disorders Hub**

Free resources and education to educate
health care professionals and patients

<https://www.cmeoutfitters.com/practice/sleep-disorders-hub/>



**This activity was created in collaboration
with the Hypersomnia Foundation**



To learn more and access
additional resources,
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Thank you for your participation!



*To receive credit, participants must register an account and apply for credit within 10 days of the live activity. For questions or technical difficulties, please contact info@cmeoutfitters.com.

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2. Complete the post-test and evaluation at the conclusion of the webcast
3. Enter your **ABIM ID number** and **DOB** (MM/DD) on the evaluation, so credit can be submitted to ABIM



CME for MIPS Improvement Activity

How to Claim This Activity as a CME for MIPS Improvement Activity

- Actively participate today by responding to ARS questions and/or asking the faculty questions
- Complete the post-test and activity evaluation at the link provided
- Over the next 3 months, actively work to incorporate improvements from this presentation into your clinical practice
- In approximately 3 months, complete the follow-up survey from CME Outfitters



CMEO will send you confirmation of your participation to submit to CMS attesting to your completion of a CME for MIPS Improvement Activity.

CASE CLOSED?

Diagnosing Idiopathic Hypersomnia Beyond the Usual Suspects

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