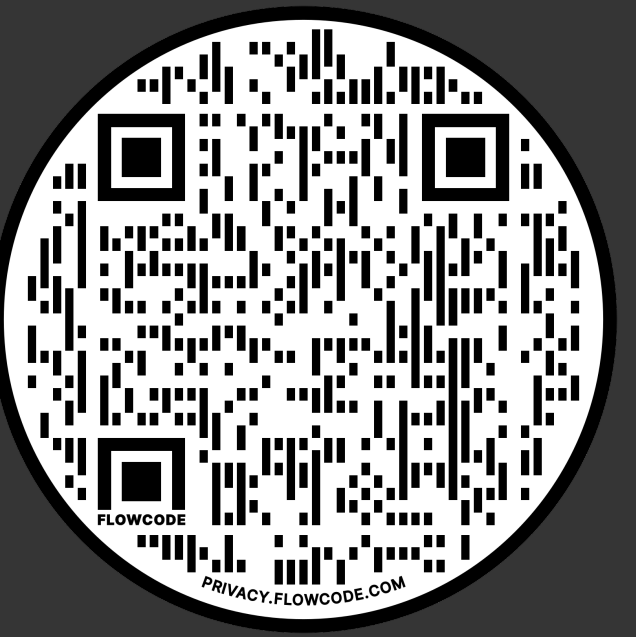


Understanding the Patient Experience With Sodium Oxybate Therapy for Narcolepsy



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BACKGROUND

Excessive daytime sleepiness (EDS) and cataplexy are 2 of the most common symptoms affecting people with narcolepsy. Although medications for treating these symptoms have existed for decades, sodium oxybate (SO) was the first to demonstrate efficacy in relieving both symptoms in clinical trials.¹ It does so by addressing disrupted nighttime sleep. Before the advent of once-nightly SO, the therapy involved twice-nightly dosing. However, the need to wake to take the second dose presents risks for patients, including potentially dangerous dosing administration errors, such as early second doses.² Moreover, suboptimal adherence to medications that improve EDS, such as SO, is common for people with narcolepsy.³ This study examined concerns about SO in the narcolepsy community using social listening (SL)⁴ and a survey.

METHODS

A proprietary SL analytics engine that uses natural language processing, including a custom clinical entity recognition model leveraging a medical ontology, was employed on 226,046 posts/comments from Reddit and Facebook. The model's outputs were used to identify posts/comments that mentioned a second SO dose and then to construct a co-occurrence network of substances and clinical findings to identify relationships among them. The engine also employed a large language model to detect posts/comments discussing challenges associated with taking a second dose and those mentioning any type of injury or accident. In addition, patient experiences with SO were collected using a survey and interviews.

RESULTS

SURVEY DATA

Private Facebook Group and Subreddit r/Narcolepsy

226,046
POSTS & COMMENTS EVALUATED

AUG 2011 – OCT 2022
DATE RANGE

FIGURE 1. CHALLENGES WITH SECOND DOSE

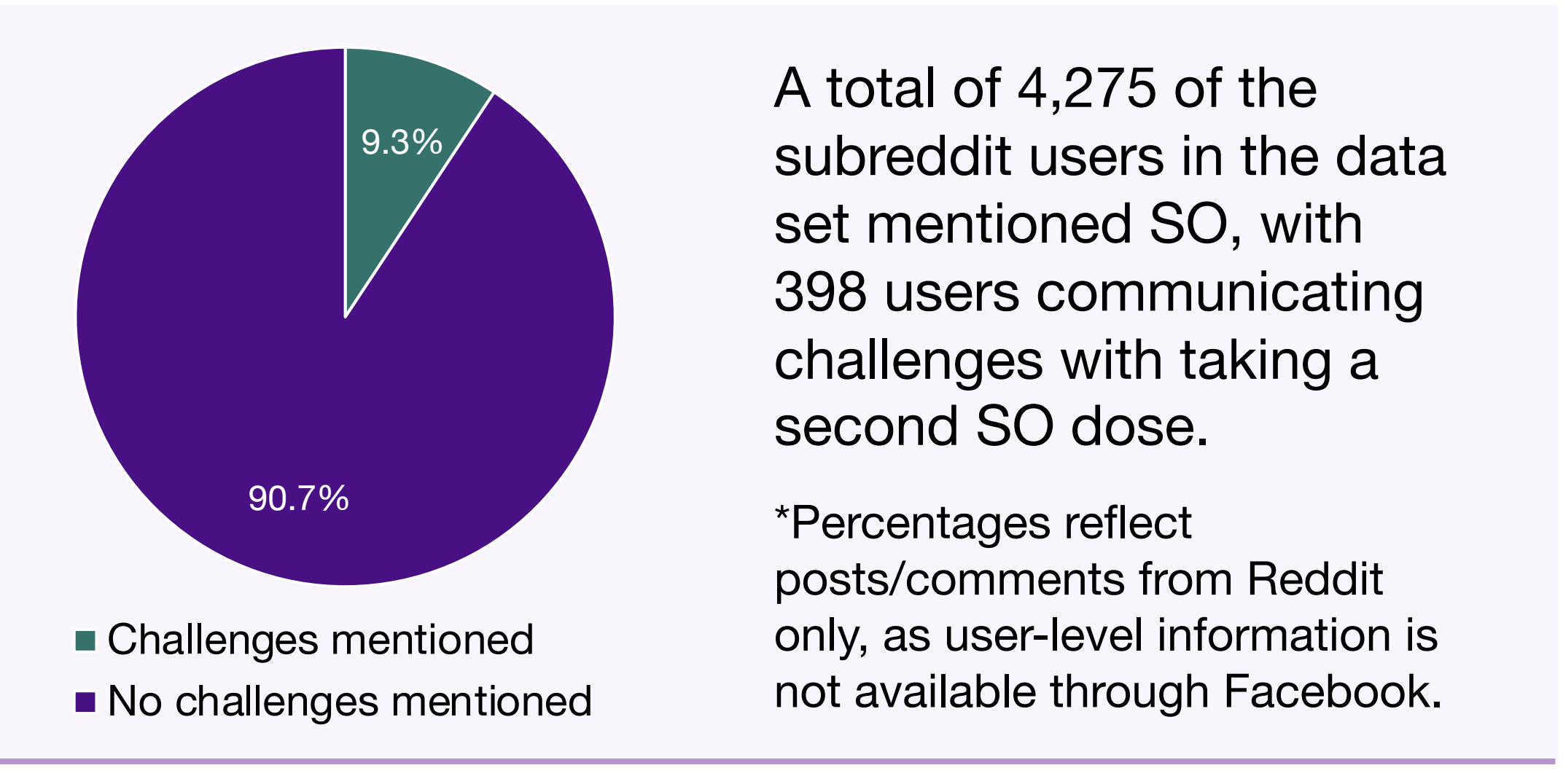


FIGURE 2. CO-OCCURRENCE NETWORK

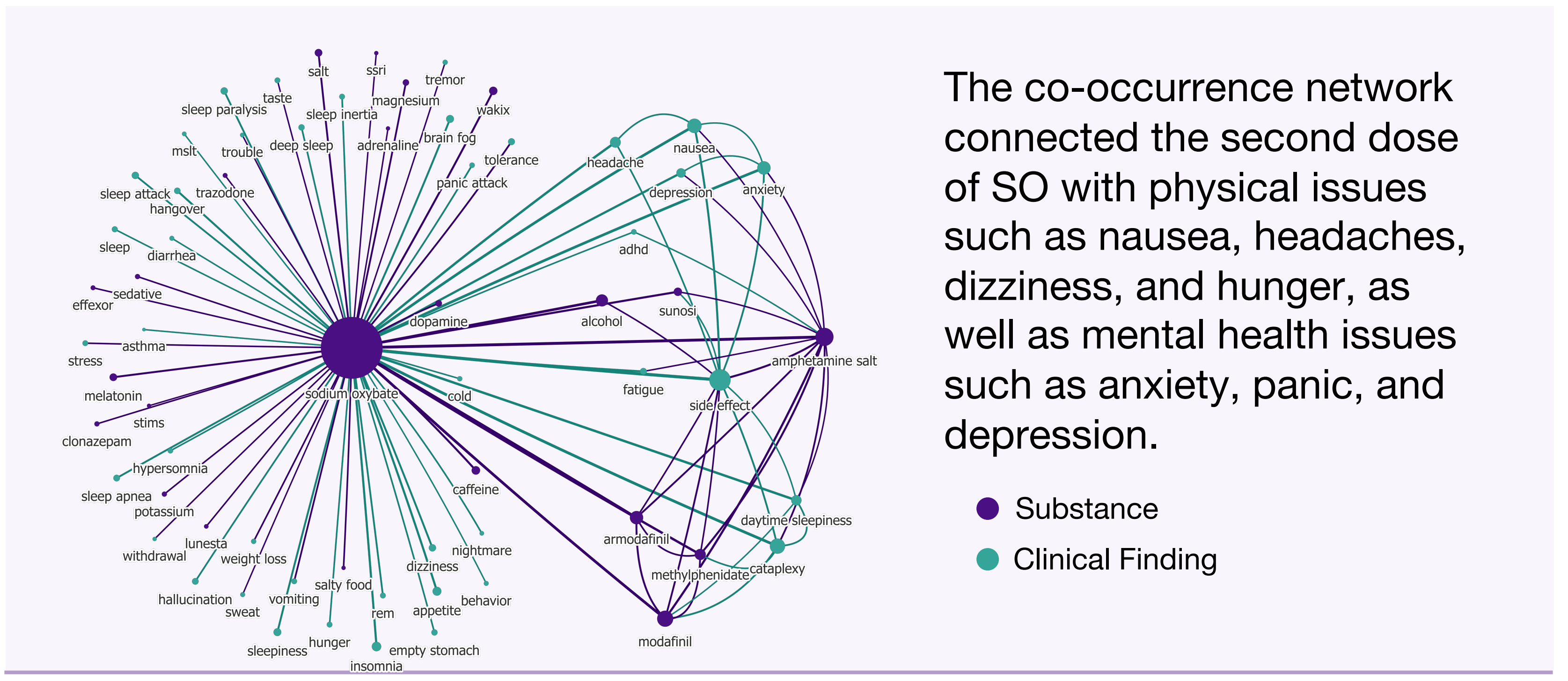


TABLE 1. SODIUM OXYBATE AND INJURY CONTINGENCY TABLE

Mention	Count	Post/Comment Mentions Any Type of Injury or Accident?		Total
		Yes	No	
Second dose of SO	Actual	67	1,068	1,135
	Expected	33.82	1,101.18	
SO, but not second dose	Actual	726	21,436	22,162
	Expected	660.31	21,501.69	
Does not mention SO	Actual	5,942	196,807	202,749
	Expected	6,040.87	196,708.13	
TOTAL		6,735	219,311	226,046

A G-test was used to test the independence of mentions of injury and mentions of SO (and dose) in posts/comments. With a test statistic of $G = 34.47$ and 2 degrees of freedom, the test resulted in $P < .00001$, indicating a statistically significant ($P < .05$) association. Of posts/comments that mention a second dose of SO, 5.90% also mention an injury or accident, compared with 3.28% of posts/comments that mention SO without mentioning the second dose and 2.93% of posts/comments that do not mention SO at all. However, the effect size, Cramér V, is 0.014, indicating that the association, while statistically significant, is not strong.

SURVEY DATA

3 Private Facebook Groups and Discord Servers
Patients: **85** Caregivers/care partners: **2**

Sex Assigned at Birth	Diagnoses
Female: 65	Type 1: 45
Male: 20	Type 2: 40
Intersex: 1	Unsure: 2
Prefer not to answer: 1	

Medications
Currently taking SO therapy: 68
Previously taken SO therapy: 19

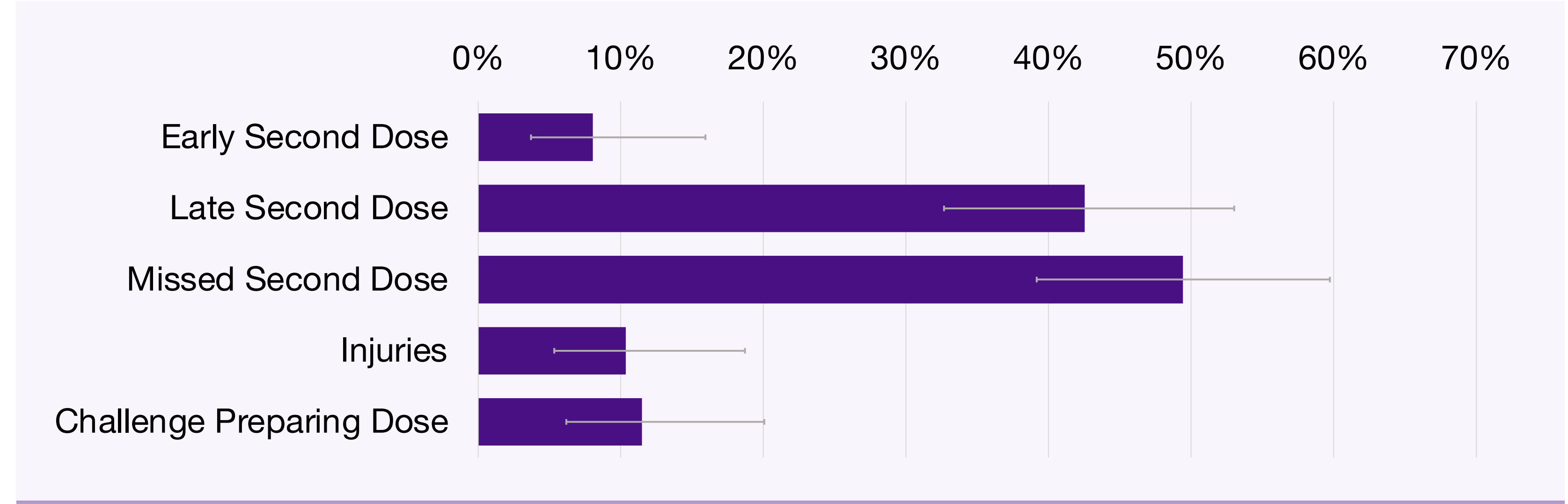
OCTOBER 2022 – NOVEMBER 2022
DATE RANGE

TABLE 2. BELIEF THAT SO WOULD BE SAFER AS A SINGLE DOSE (N = 87)

Response	%
Strongly agree	46.0
Agree	29.9
Neither agree nor disagree	11.5
Disagree	5.7
Strongly disagree	6.9

When asked if a once-at-bedtime, premeasured SO dose would be safer, ~76% of respondents agreed or strongly agreed (95% CI, 65.8%-83.7%).

FIGURE 3. PROPORTION OF PATIENTS REPORTING ISSUE OCCURS AT LEAST MONTHLY



Patients and caregivers were asked if they had experienced any of the following while on SO therapy, and if so, how frequently: taking the second dose early, taking the second dose late, accidentally missing the second dose entirely, getting injured after waking for the second dose, and having challenges with preparing their dose. Sample proportions and 95% CIs for the true proportion of patients experiencing these challenges at least monthly are shown in Figure 3.

CONCLUSION

Patient experiences with SO therapy (especially regarding the second dose) were assessed by collecting and analyzing survey results and conversations in patient-oriented narcolepsy social media communities. Evidence from both suggests that the inherent risks associated with the need to wake for a second dose in the middle of the night, especially with missed doses and late doses, are common and have negative impacts on patients' physical health, mental health, and quality of life. Moreover, SL revealed a statistically significant, albeit weak, association between mentions of the second dose of SO and mentions of injuries/accidents.

FUTURE DIRECTIONS

Although the network revealed connections between second SO dose mentions and specific physical and mental health issues, it does not reveal the context of these mentions—that is, whether they related to aspects of second dose administration (e.g., missing the dose, taking it early/late) or simply to the disease itself. A deeper dive with the analytics engine might show that the association in the survey results between specific challenges with the second dose and specific symptoms (e.g., increased EDS) is latently present in online patient conversations. This would present further evidence of such associations in this study and provide evidence that SL can be used to investigate such topics in a cost- and time-effective manner, all while presenting no burden to the disease community.



Understanding the Patient Experience With Sodium Oxybate Therapy for Narcolepsy

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Affiliations: ¹TREND Community, Philadelphia, PA, USA; ²PWN4PWN, Tampa, FL, USA; ³Geisinger Commonwealth School of Medicine, Geisinger Medical Center, Janet Weis Children's Hospital, Danville, PA, USA; ⁴Johns Hopkins Medical Institutions, Johns Hopkins All Children's Hospital, St. Petersburg, FL, USA

Limits: 500 words (includes introduction, materials and methods, results, conclusions, and acknowledgments), current 500

Topic: Narcolepsy

Presentation type: Poster

Introduction: Narcolepsy is a chronic sleep disorder defined by excessive daytime sleepiness, impaired rapid eye movement sleep, disrupted nighttime sleep with frequent waking, and several molecular biomarkers; it may also be accompanied by cataplexy. Narcolepsy has no cure and affects both men and women. This research used natural language processing (NLP) with social media listening to better understand patient experiences in the narcolepsy community with taking sodium oxybate (SO) therapy.

Materials and Methods: A combination of social media listening and survey methods was employed. A proprietary analytics engine that incorporates NLP analyzed 25,018 posts/comments shared by 15,280 participants during August 2011 to October 2022 in 2 narcolepsy communities: a subreddit, r/Narcolepsy, and a private Facebook group. A clinical entity recognition tagger leveraging a medical ontology was used to build a co-occurrence network and identify relationships between entities. We filtered conversations that mentioned (1) second dosage (e.g., second dose, 2nd) and (2) SO (e.g., Xyrem, SO) to build a unique co-occurrence network for all conversations discussing second doses of SO. Patient experiences with SO were then documented by surveying and interviewing community members and analyzing the stories and experiences they shared on social media.

Results: A total of 4,275 of the subreddit users mentioned SO and 398 (9%) used language consistent with having challenges in taking a second SO dose. The co-occurrence network revealed that second SO dose was comentioned with physical (e.g., nausea, headache) and mental health (e.g., anxiety, depression) conditions. A group of 87 users from the private Facebook group were then surveyed (n = 85 patients, n = 2 caregivers). Missing the second dose was reported by 75% of patients (65% at least monthly). The most common reported impacts of missing doses were poor sleep quality, increased daytime sleepiness, work/school absences, and

brain fog affecting next-day functioning. Regarding whether they suffered injuries resulting from waking to take a second dose of SO, 32% responded yes (33% of these respondents at least monthly). Delayed dosing (>4 hours after) was another issue reported by 59% (74% at least monthly). Impacts of this delayed dosing led to school/work tardiness and missed responsibilities. Patients reported adverse effects with SO therapy, including mental health issues (especially depression), racing heart, muscle spasms, acid reflux, bedwetting, and eating problems. Seventy-six percent of the respondents strongly agreed or agreed that a single bedtime dose of SO would be safer.

Conclusions: Converging evidence from both the social media and survey results suggests that the need to take the second dose of SO is associated with various sleep-related issues and disruption for people with narcolepsy and their caregivers. Daily functioning, physical and mental health, injuries, and quality of life were affected. These impacts are present both for missed second SO doses and doses taken more than 4 hours after the first dose.

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Disclosures

Matthew Horsnell, Enming Zhang, Rachele Cook, Lauren Dougherty, and E. Robert

Wassman are employees of and own stock options in TREND community. Our clients are pharmaceutical and biotechnology companies including, but not limited to, Horizon

Therapeutics, Chiesi Global Rare Disease, Novartis, Harmony Biosciences, and Avadel. **Allison**

Foley Shenk and Frederik Ascencion have no conflicts of interest to disclose. **Anne Marie**

Morse is a consultant for Harmony Biosciences and Jazz Pharmaceuticals; has served on

advisory boards and speakers bureaus for Jazz Pharmaceuticals; has received grant funding from

NIH/NIMH; has served as an advisor for Epilog, Neura Health, and the American Sleep Apnea

Association; and was a REST-ON site PI for Avadel Pharmaceuticals. **Luis E. Ortiz** has served

on an advisory board for Avadel Pharmaceuticals. **Christopher DeFelice and Maria Picone** are

owners of and own stock options in TREND Community. Our clients are pharmaceutical and

biotechnology companies including, but not limited to Horizon Therapeutics, Chiesi Global Rare

Disease, Novartis, Harmony Biosciences, and Avadel.

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Meeting Information

World Sleep

October 21–25, 2023

Rio de Janeiro, Brazil