

# Non-seizure Symptoms, Mental Health Comorbidities, and Quality of Life in Patients Reporting Focal Onset Seizures

Joanne M. Wagner<sup>1</sup>, Bhagyashree Oak<sup>2</sup>, Brittany Smith<sup>2</sup>, Amod Athavale<sup>2</sup>, Jeffrey R. Skaar<sup>2\*</sup>, Alvin Ong<sup>1</sup>, Cynthia Harden<sup>1</sup>

<sup>1</sup>Xenon Pharmaceuticals Inc., Vancouver, BC, Canada; <sup>2</sup>Trinity Life Sciences, LLC, Waltham, MA, United States; \*Affiliation at the time of study design and completion

## INTRODUCTION

- Approximately 3 million adults in the U.S. have epilepsy and an estimated 60% of the total epilepsy population experience focal onset seizures (FOS) <sup>1-5</sup>
- Patients with FOS are primarily treated with antiseizure medications (ASMs); however, nearly one third of patients are not well-controlled on treatment and high rates of adverse events (ranging from 7-31%) have been reported <sup>6-8</sup>
- Anxiety and depression are also common comorbidities associated with epilepsy that can further exacerbate the burden of illness and may require additional care or support <sup>9</sup>
- The burden of epilepsy, treatment-related adverse events, and comorbidities can negatively impact patients' quality of life (QoL); patients may experience trouble with employment, independence, and activities of daily living <sup>10</sup>
- The Quality of Life in Epilepsy-10 (QOLIE-10) is a 10-item questionnaire specifically designed to evaluate quality of life in patients with epilepsy; scores range from 0 to 100, with higher scores indicating more favorable QoL<sup>11</sup>
  - Mean QOLIE-10 scores between 33.3 and 43.9 have been reported for patients with epilepsy in previous literature <sup>12-15</sup>
- Despite existing knowledge on the burden of epilepsy, a substantial knowledge gap remains in our understanding of the real-world experiences of patients with epilepsy reporting FOS, including their self-perceived burden of illness (BOI) and QoL

## OBJECTIVES

- To examine the self-reported burden of illness and overall quality of life of patients reporting FOS

## METHODS

- A cross-sectional study employing a 30-minute, customized, web-enabled questionnaire was conducted from July to September 2023 to assess symptomatology, treatment, comorbidities, and QoL of patients reporting FOS; the study was institutional review board (IRB)-exempt (Advarra, Columbia, MD)
  - QoL was assessed using the validated QOLIE-10 instrument <sup>11</sup>
- Cognitive interviews (n=4) were conducted to ensure the questionnaire was clear and understandable for patients reporting FOS
- Patients were recruited via either a patient panel or their physician at the point of care, using the following criteria:

Inclusion	Exclusion
<ul style="list-style-type: none"><li>18 years of age or older and residing in the United States</li><li>Self-reported physician diagnosis of FOS for at least 1 year</li><li>Experiencing ≥ 1 seizure in a typical month</li><li>Have used (currently or previously) at least 2 ASMs and are currently taking at least 1 ASM for at least 1 month</li></ul>	<ul style="list-style-type: none"><li>Currently enrolled in a clinical trial for FOS</li><li>Experiencing seizures secondary to drug or alcohol use, ongoing infection, neoplasia, demyelinating disease, degenerative neurological disease, metabolic illness, progressive structural lesion, encephalopathy, or progressive central nervous system disease</li></ul>
- Patient panel:** Patients applied to be part of the third-party vendor panel based on having a physician diagnosis of epilepsy. The vendor validated the epilepsy diagnosis before confirming panel enrollment. These patients then participated in the survey screener to verify they met the inclusion and exclusion criteria.
- Physician at point of care:** Physicians were provided with the study inclusion and exclusion criteria and used them to select patients to recruit for the study. Patients then participated in the survey screener to verify they met the inclusion and exclusion criteria.
- Data were analyzed using descriptive statistics in Q Research Software 5.12.4.0

## RESULTS

### Sample Description

Table 1. Demographics and Baseline Characteristics of Patients Reporting FOS

	Study Population (N=170)
Age, mean (SD)	42.6 (10.9)
Female, n (%)	92 (54.1%)
Race, n (%)	
White	99 (58.2%)
Black	26 (15.3%)
Other	45 (26.5%)
Employed Full- or Part-time, n (%)	80 (47.1%)
Annual Household Income < \$60,000, n (%)	74 (43.5%)
Number of Years Living with Epilepsy, mean (SD)	11.3 (12.4)
Time since epilepsy diagnosis, n (%)	
1-5 years ago	69 (40.6%)
6-10 years ago	52 (30.6%)
10+ years ago	49 (28.8%)
Seizure Types and Epilepsy Syndromes Reported <sup>a</sup> , n (%)	
FOS	170 (100.0%)
Primary Generalized Seizures (PGS) <sup>b</sup>	79 (46.5%)
Non-epileptic Psychogenic Seizures	19 (11.2%)
Lennox-Gastaut Syndrome (LGS)	19 (11.2%)
Developmental and Epileptic Encephalopathy (DEE)	14 (8.2%)
Combination of Seizure Types and Epilepsy Syndromes Reported <sup>a</sup> , n (%)	
FOS only	74 (43.5%)
FOS + PGS	54 (31.8%)
FOS + PGS + other*	25 (14.7%)
FOS + other*	17 (10.0%)

<sup>a</sup> Patients were asked, "Which type of healthcare provider is currently managing/ treating your epilepsy?" and allowed to reported more than one type of healthcare provider; <sup>b</sup> Patients were asked, "Has a neurologist ever diagnosed you with any of the following seizure types?" and allowed to report physician diagnosis for more than one type of epilepsy/seizure type; <sup>c</sup> Primary Generalized Seizures was defined as, "Seizures that start on both sides of the brain at the same time and cause loss of awareness from the start of the seizure. Primary generalized seizures are sometimes called grand mal seizures. This type of seizure has no warning or confusion at the start of it." <sup>d</sup> Patients were asked, "With regards to your epilepsy, do you have someone who helps care for you on a day-to-day basis?"; \*Other seizure types and epilepsy syndromes reported include non-epileptic psychogenic seizures, Lennox-Gastaut Syndrome (LGS), and Developmental and Epileptic Encephalopathy (DEE)

- Patients had been living with epilepsy for an average of 11.3 (12.4) years and 97.1% of patients reported a neurologist, epileptologist, or both were managing their epilepsy (Table 1)
- Of the 170 patients reporting FOS who participated in the survey, only 43.5% of patients reported having only FOS; Primary Generalized Seizures (PGS) was the most reported concomitant seizure type (46.5%) (Table 1)

### Comorbidities

Figure 1. Top Self-Reported Physician-Diagnosed Comorbidities for Patients Reporting FOS

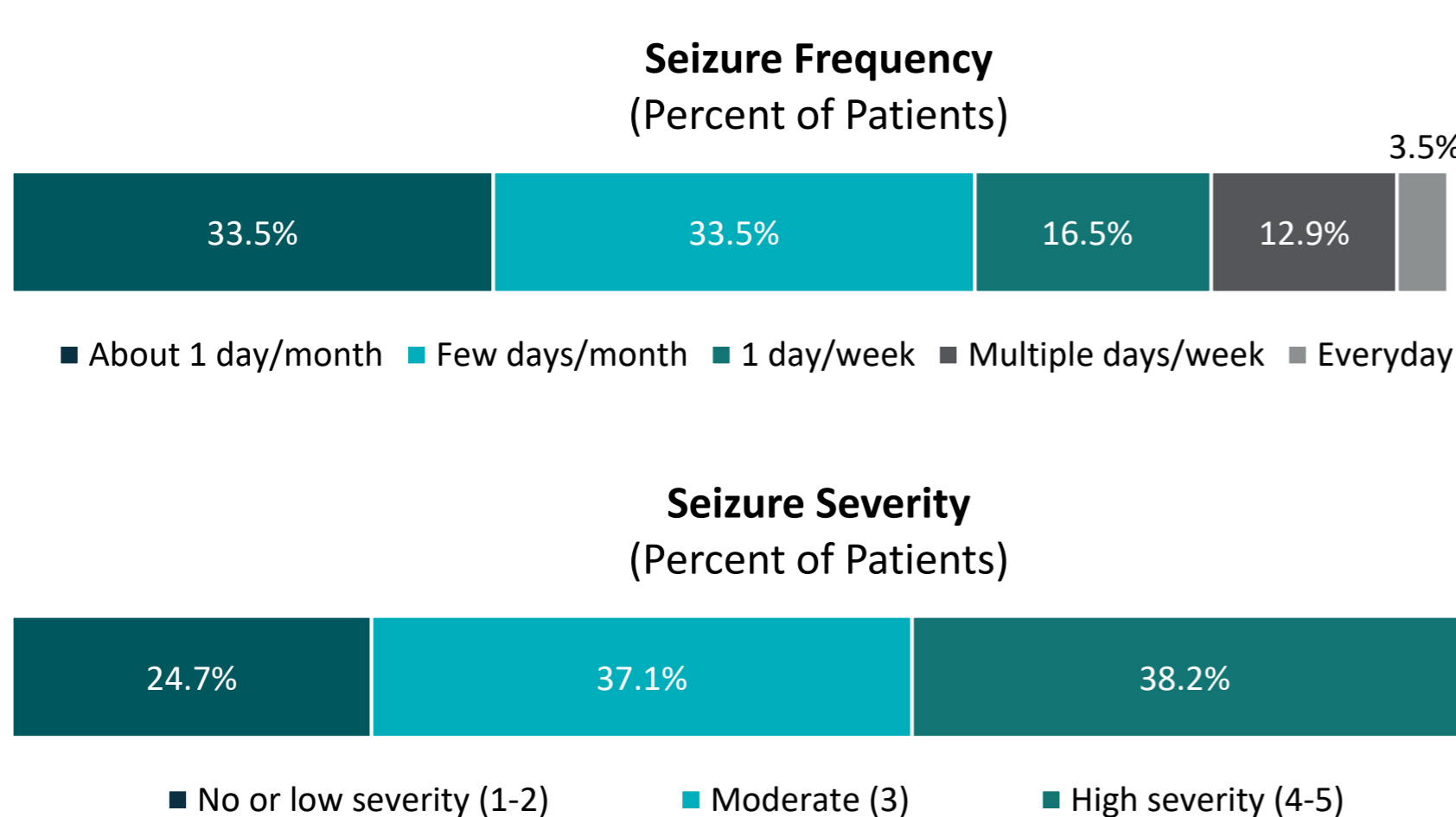


Footnotes: Question: Other than epilepsy, which of the following conditions have you been diagnosed with by a doctor? Please think about all diagnoses you have received to present date; additional comorbidities reported include: allergies (32%), high cholesterol (22%), obesity (19%), diabetes (14%), hypertension (13%), chronic pain (13%), GI disorders (12%), arthritis (12%), interictal dysphoric disorder (12%), stroke (8%), ADHD (6%), respiratory disorders (5%), learning disability (5%), autism (4%), and musculoskeletal disorders (3%), other (multiple sclerosis [1%], asthma [1%], hypertriglyceridemia [0.5%], osteoporosis [0.5%], insomnia [0.5%], Charcot Marie Tooth disease [0.5%], mitochondrial disorder [0.5%], Ehlers Danlos syndrome [0.5%], Postural Orthostatic Tachycardia Syndrome [0.5%], chronic kidney disease [0.5%], chondrosarcoma [0.5%], syringomyelia [0.5%], dystonia [0.5%], lupus [0.5%])

- The mean number of comorbidities reported was 3.1 (SD 1.9)
- Anxiety, migraines, and depression were the top reported physician-diagnosed comorbid conditions by patients (Figure 2)

### Seizure-Related Symptom Burden

Figure 2. Self-Reported Seizure Frequency and Severity for Patients Reporting FOS



Footnotes. Questions: For each symptom you currently experience, please indicate how often you experience it; For each symptom you currently experience, please indicate the current severity of each symptom (rating scale 1-5; 1 = not at all severe, 5 = extremely severe).

## CONCLUSION

- Patients with epilepsy reporting a diagnosis of FOS reported a high seizure frequency and severity despite currently taking ASMs
- In addition to seizure burden, the most common self-reported non-seizure symptoms were mood issues and fatigue/lack of energy, which could negatively impact a patients' QoL
- Patients also reported multiple diagnosed comorbidities, including anxiety and depression, further illustrating the broad burden of epilepsy and impact on QoL
- Reduced quality of life, documented by the QOLIE-10 scores, illustrates the substantial burden of illness and treatment experienced by patients reporting FOS

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### Non-Seizure-Related Symptom Burden

Figure 3. Top Self-Reported Non-Seizure Symptoms for Patients Reporting FOS

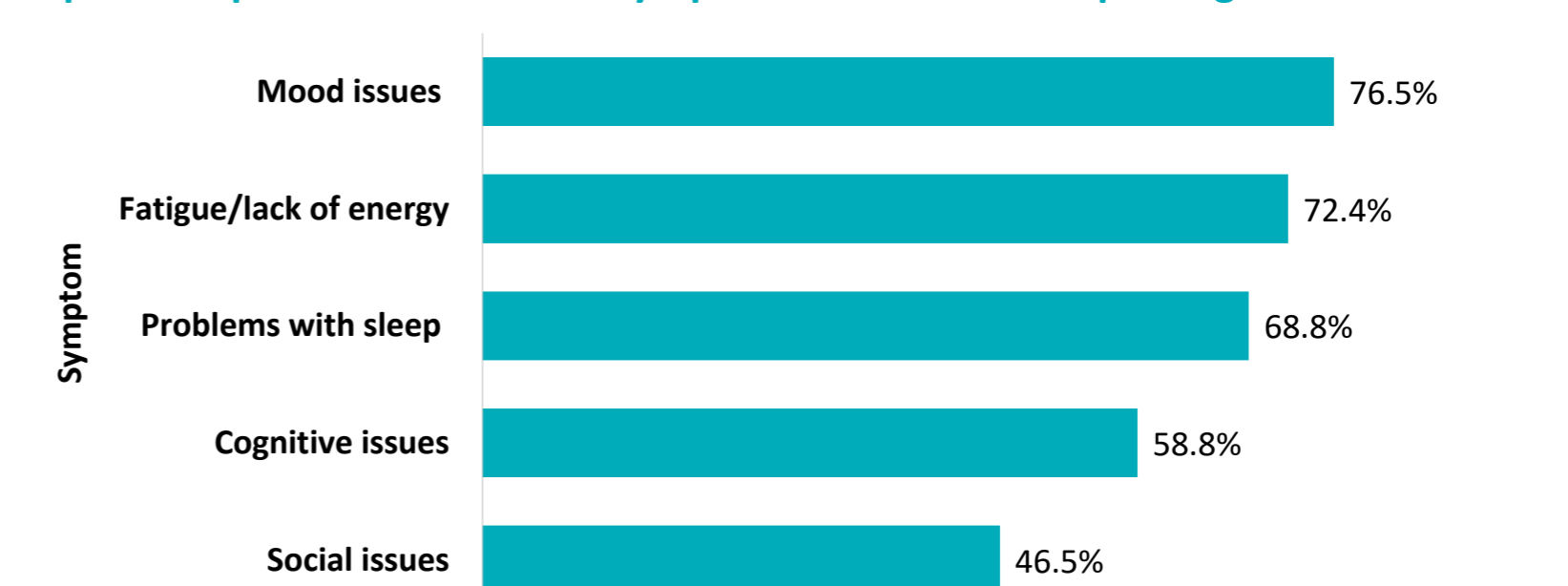


Figure 4. Self-Reported Frequency of Non-Seizure Symptoms for Patients Reporting FOS

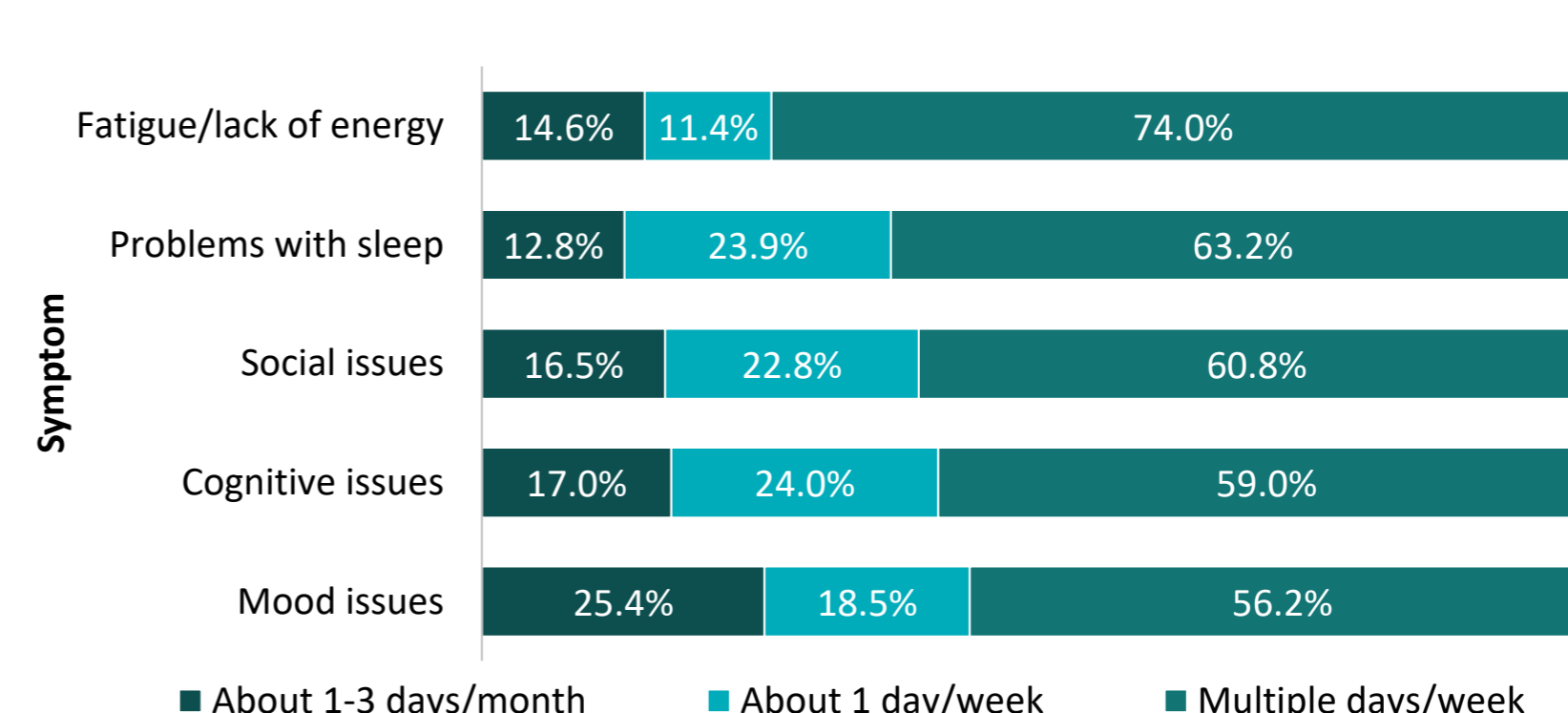
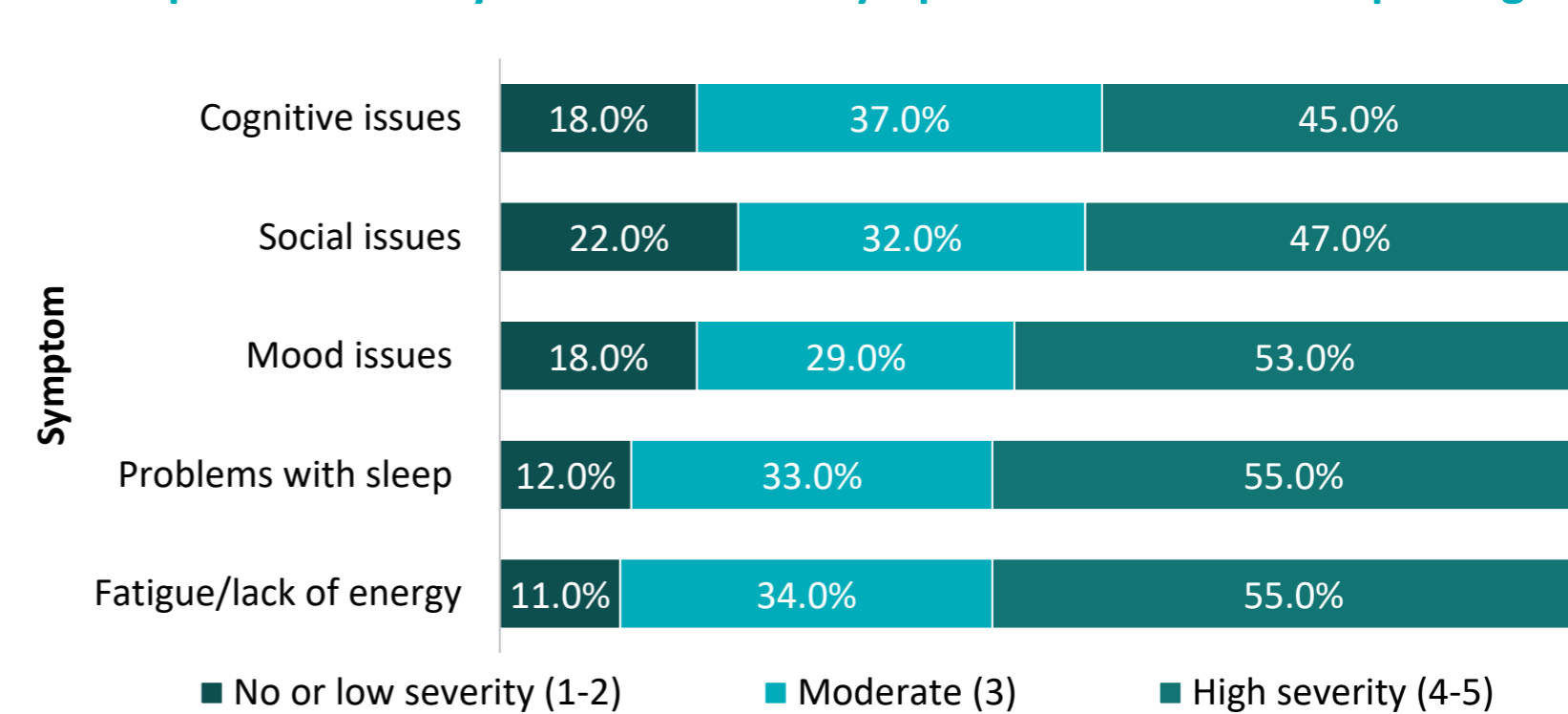


Figure 5. Self-Reported Severity of Non-Seizure Symptoms for Patients Reporting FOS

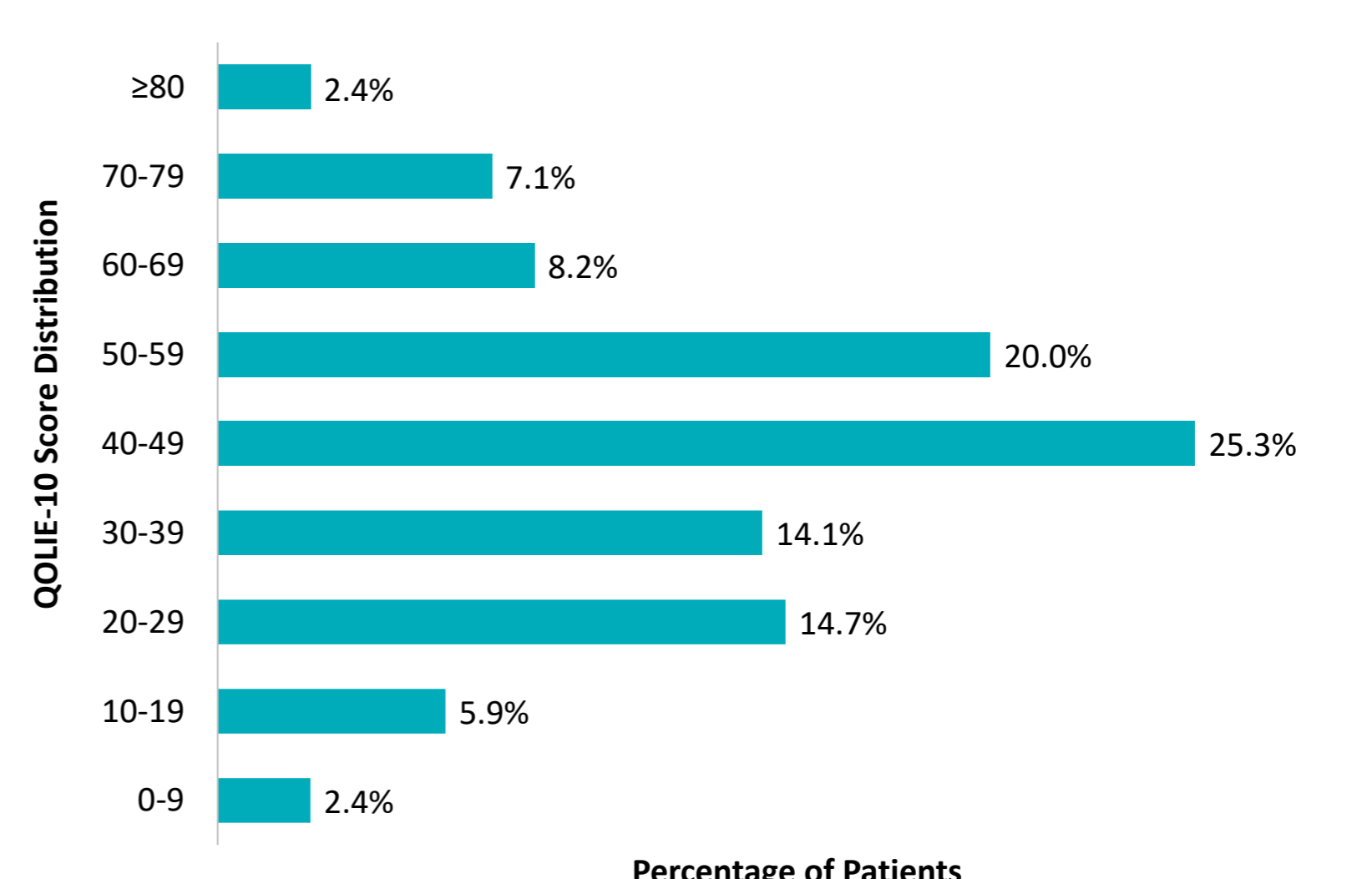


Footnotes. Mood issues were not explicitly defined in the survey instrument, but depression and anxiety were provided exempli gratia (e.g.). Questions: (Figure 2) People diagnosed with epilepsy report experiencing some of the symptoms listed below, outside of experiencing a seizure. Which of the following symptoms do you currently experience? (Figure 3) For each symptom you currently experience, please indicate the current severity of each symptom (rating scale 1-5; 1 = not at all severe, 5 = extremely severe).

- 72.9% of patients reported experiencing ≥3 non-seizure symptoms despite current treatment with ASMs
- Mood issues (e.g., depression, anxiety) were the most common (76.5%) non-seizure symptoms reported followed by fatigue/lack of energy (72.4%) (Figure 3)
- Patients reporting fatigue/lack of energy experienced this symptom regularly, with 74.0% indicating the symptom occurred multiple days per week (Figure 4)
- More than half (>53%) of patients considered their mood issues, fatigue/lack of energy, and problems with sleep to be severe (Figure 5)

### Quality of Life Burden of Epilepsy in Patients with Reported FOS

Figure 6. QOLIE-10 Score Distribution for Patients Reporting FOS



Footnotes. QOLIE-10 scores were converted to 0-100; higher scores indicate fewer problems related to epilepsy and better overall QoL

- Mean QOLIE-10 score for the entire sample was 44.5 (SD 17.5)
- 37.1% of patients had QOLIE-10 score at or below previously reported averages in the epilepsy literature (Figure 6)
- The mean QOLIE-10 subdomain scores for epilepsy effects, mental health, and role functioning were 39.9 (SD, 24.4), 49.9 (SD, 15.4), and 44.0 (SD, 22.1) out of 100, respectively

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