1.434 Caregiver-Reported Real-World Use of Cannabidiol (CBD) and Effects on Seizures and Caregiver Burden: Results From the CARE-EpiC Survey

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Introduction

- In June 2018, the US Food and Drug Administration approved Epidiolex®, a plant-derived, highly purified pharmaceutical formulation of cannabidiol (CBD) for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), and tuberous sclerosis complex (TSC)[1]
- In addition to a reduction in the frequency of seizures, a caregiver survey (BECOME) reported that CBD treatment for patients with LGS or DS may offer non–seizure-related benefits, including improvements in cognition, communication ability, behavior, physical functioning, daily activities, and sleep[2]
- Caregivers play a crucial role in the lives of patients with epilepsy, providing essential support and care. Nearly one-third of caregivers experience depression symptoms and substantial economic burden, especially when caring for patients with frequent seizures[3]
- **C**aregiver **A**nalysis of **R**eal-world **E**pidiolex® in **E**pilepsy **C**ontext (CARE-EpiC) was a descriptive, observational, cross-sectional survey designed to understand the real-world implications of CBD treatment from the caregiver's perspective. The study involved caregivers of dependents with different treatment-resistant epilepsy conditions, including those for which Epidiolex® is approved
- Here, we report the caregiver burden experienced across caregiver subgroups, including by community, sex, and caregiving responsibility

Objectives

- **Primary objective:** To describe caregivers' perceptions about their dependents' experience with CBD, based on:
  - Real-world use of CBD
  - Perceived benefits of CBD on the caregiver and their dependent's condition
  - Caregiver burden
- **Exploratory objective:** To explore potential caregiver-reported outcomes associated with passively collected wearables data based on:
  - Steps
  - Activity
  - Resting heart rate
  - Sleep duration

Methods

- **Enrollment:** Adults in the US aged ≥18 years who self-identified as a caregiver of a dependent taking CBD for the treatment of epilepsy or a seizure condition consented and were enrolled. A total of 346 participants interacted with the survey; 210 eligible participants completed the survey; 204 were included in the analysis
- **Survey design**
  - A one-time cross-sectional survey (55 questions) was conducted on the Evidation platform, which gathers information related to dependents (characteristics, treatment experience, medical journey, and epilepsy condition) and caregivers (experience and burden)
  - Respondents who perceived benefits with CBD were subsequently asked to detail the benefits they observed
  - Caregiver burden was measured using the Burden Scale for Family Caregivers–short version (BSFC-s); a maximum score of 30 represents a greater burden
  - Wearables data to assess caregiver activity level were collected for 1 year, retrospectively
- **Outcomes analysis:** Outcomes were evaluated overall and for the following subgroups. Descriptive statistics are reported; no inferential statistics were planned or conducted

Race/ethnic communities	Sex	Caregiver responsibility
• Underrepresented communities – Hispanic or Latino, Black and African American, Asian, other, and multiple • Not underrepresented, including White	• Male • Female	• Sole caregiver • Shared caregiving responsibilities

Results

Dependent characteristics

Table 1. Summary of overall dependent characteristics

Characteristics	Overall (N=204)	Community		Sex		Caregiving responsibility	
		Underrepresented caregivers (n=78)	Not underrepresented caregivers (n=120)	Female (n=111)	Male (n=90)	Shared (n=160)	Sole (n=44)
Seizure frequency, n (%)							
<1 seizure per week	91 (45)	31 (40)	60 (50)	45 (41)	45 (50)	66 (41)	25 (57)
Co-occurring conditions, n (%)							
Neuropsychiatric conditions	172 (84)	70 (90)	96 (80)	93 (84)	77 (86)	132 (83)	40 (91)
Chronic health conditions	149 (73)	65 (83)	78 (65)	76 (69)	71 (78.9)	114 (71)	35 (80)
Behavioral/physical/developmental challenges	165 (81)	64 (82)	95 (79)	91 (82)	71 (79)	131 (82)	34 (77)
No concomitant medication for seizures, n/N (%)	26/184 (14)	7/69 (10)	19/109 (17)	15/111 (14)	11/81 (14)	21/160 (13)	5/44 (11)

Real-world use of CBD

Figure 1. Duration of CBD use by dependents

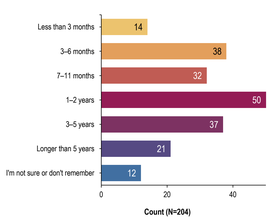


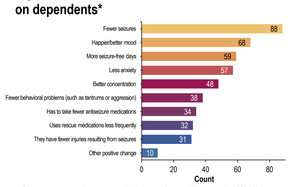
Table 2. Distribution of dependents based on the duration of CBD use – subgroup analysis

Characteristics		Up to 6 months n (%)	>6 months n (%)
Community	Underrepresented caregivers (n=78)	22 (28)	51 (65)
	Not underrepresented caregivers (n=120)	28 (23)	86 (72)
Sex	Female (n=111)	28 (25)	77 (69)
	Male (n=90)	22 (24)	62 (69)
Caregiving responsibility	Shared (n=160)	37 (23)	112 (70)
	Sole (n=44)	15 (34)	28 (64)

- 69% of caregivers reported their dependent had taken CBD for >6 months (**Figure 1**)
  - Fewer dependents of caregivers belonging to underrepresented communities and sole caregivers have taken CBD for >6 months compared with other groups (**Table 2**)
- 86% of caregivers reported their dependent was currently taking another prescribed antiseizure medication, in addition to CBD

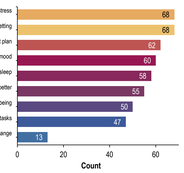
Perceived benefit of CBD

Figure 2. Perceived benefit of CBD use on dependents*



*Data corresponds to caregivers who responded 'Yes' to reporting any positive changes since CBD initiation.

Figure 3. Perceived benefit of CBD use on caregivers*



- 78% of caregivers noticed positive changes in their dependent's condition since starting CBD (data not shown)
- 78% of caregivers noticed positive changes about their own experience since their dependent started taking CBD (data not shown)
  - Male caregivers and sole caregivers reported positive changes about their own experience more often than female caregivers and shared caregivers, respectively (Scan QR code for Supplemental Table 5a)
  - Overall, 64% of caregivers reported that the average duration of their dependent's seizures has decreased since initiating CBD treatment (Scan QR code for Supplemental Table 5b)

Caregiver experience and burden

Figure 4. Impact on daily caregiving activities on caregivers' well-being

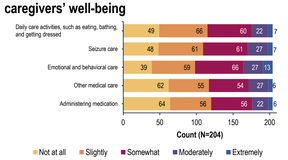


Table 3. Caregiver burden – subgroup analysis

Characteristics		BSFC-s score, mean (SD)
Overall (N=204)		14.1 (6.8)
Community	Underrepresented caregivers (n=78)	14.4 (7.2)
	Not underrepresented caregivers (n=120)	13.7 (6.4)
Sex	Female (n=111)	13.2 (5.7)
	Male (n=90)	15.1 (7.8)
Caregiving responsibility	Shared (n=160)	14.1 (6.7)
	Sole (n=44)	14.2 (6.7)

BSFC-s, Burden Scale for Family Caregivers–short version. Scores range from 0 to 30; higher scores indicate higher caregiver burden.

- Overall, caregivers reported experiencing a mean (SD; range) caregiver burden score of **14.1 (6.8; 0–30) out of 30** on the BSFC-s
- **Emotional and behavioral care (81%)** was the care activity with the **most negative impact on caregivers' well-being** (**Figure 4**)
  - Underrepresented or male caregivers experience more burden compared with others represented in the study (**Table 3**)

Perceived benefit of CBD - caregiver subgroup outcomes (Scan QR code for Supplemental Table 5a and Figures 5 and 6)

- 4% more male caregivers observed positive changes in their dependent compared with female caregivers
- 7% more caregivers who belong to underrepresented communities reported positive changes in their own caregiving experience compared with those who do not belong to an underrepresented community
- 14% more sole caregivers observed positive changes in their own caregiving experience compared with those who share caregiving responsibilities

Wearables data insights (based on the past 1 year)

Table 4. Wearables data by subgroups

Characteristics	Community		Sex		Caregiving responsibility	
	Underrepresented caregivers, mean (SD) [n]	Not underrepresented caregivers, mean (SD) [n]	Female, mean (SD) [n]	Male, mean (SD) [n]	Shared, mean (SD) [n]	Sole, mean (SD) [n]
Step count	6371.0 (3832.4) [59]	7809.4 (4578.9) [101]	6063.4 (3383.7) [99]	9352.7 (4921.2) [64]	7531.6 (4303.1) [128]	6375.7 (4495.9) [38]
Active minutes	67.2 (81.6) [17]	106.9 (101) [34]	78.1 (90.2) [28]	116.2 (102.1) [23]	Insufficient data available*	
Resting heart rate	64.2 (7.8) [22]	62.2 (8.9) [55]	64.6 (9.4) [43]	60.5 (6.8) [34]	62.1 (8.5) [64]	66.0 (8.1) [14]
Sleep duration, min	Insufficient data available*		378.3 (77.7) [23]	367.7 (105.1) [21]	Insufficient data available*	

*Insufficient data to draw between-group comparisons.

- Caregivers from underrepresented communities had a numerically lower step count and active minutes and a numerically higher resting heart rate in comparison with those from not underrepresented communities
- Male caregivers had a numerically higher step count, more active minutes, and a numerically lower resting heart rate compared with female caregivers
- Sole caregivers had a numerically lower step count and a numerically higher resting heart rate in comparison with caregivers who shared caregiving responsibilities (**Table 4**)

Limitations

- The study did not include a comparator group, and the results are based on caregivers' recall bias
- Only caregivers whose dependents were currently taking CBD were included in the survey; these caregivers may have been more likely to report improvements than those who did not benefit or who discontinued CBD
- Only caregivers who reported positive benefits overall were asked about their perceived benefits of CBD
- The perception of caregivers on the benefit of CBD included those who did not know or remember the duration of CBD (n=12)

Conclusions

- The CARE-EpiC study suggests that high caregiver burden (including physical, emotional, and behavioral care) resulted in negative impact on activity, emphasizing the need for additional support, especially for those from underrepresented communities and sole caregivers
- Among caregivers who reported a positive change, most reported fewer seizures and better mood in their dependents after CBD initiation
  - A majority also reported a reduction in their dependent's seizure duration since starting CBD
- Caregivers who perceived positive changes in their own caregiving experience reported reduced stress, and improved mood and sleep after their dependents started CBD

References: 1. Epidiolex® (cannabidiol) oral solution. Prescribing information. Jazz Pharmaceuticals, Inc., 2024. Accessed August 9, 2024. https://pp.jazzpharma.com/pi/epidiolex.en.USPI.pdf. **2.** Berg AT, et al. *Epilepsy Res.* 2024;200:107280. **3.** Hussain SA, et al. *Epilepsia.* 2020;61(2):319–329. **4.** Graessel E, et al. *BMC Geriatrics.* 2014;14(23):1-9.

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Table 5a. Perceived impact of CBD use on dependents and caregivers

Perceived impact in dependent experience after starting CBD		Community		Sex		Caregiving responsibility	
		Under-represented caregivers (n=78)	Not under-represented caregivers (n=120)	Female (n=111)	Male (n=90)	Shared (n=160)	Sole (n=44)
Have you noticed any positive changes about the person you care for since they started taking CBD?	Yes	61 (78.2%)	93 (77.5%)	84 (75.7%)	72 (80.0%)	121 (75.6%)	38 (86.4%)
	No*	5 (6.4%)	17 (14.2%)	14 (12.6%)	9 (10.0%)	21 (13.1%)	2 (4.5%)
	I'm not sure	12 (15.4%)	10 (8.3%)	13 (11.7%)	9 (10.0%)	18 (11.3%)	4 (9.1%)
Have you noticed any positive changes about your own caregiving experience since the person you care for started taking CBD?	Yes	63 (80.8%)	89 (74.2%)	85 (76.6%)	70 (77.8%)	119 (74.4%)	39 (88.6%)
	No*	9 (11.5%)	19 (15.8%)	16 (14.4%)	12 (13.3%)	24 (15.0%)	4 (9.1%)
	I'm not sure	6 (7.7%)	12 (10.0%)	10 (9.0%)	8 (8.9%)	17 (10.6%)	1 (2.3%)

*Respondents who said 'No' on the perceived impact of CBD use were not probed further to understand the "why."

Table 5b. Perceived impact of CBD use on dependent's seizure duration

Perceived impact in dependent's seizure duration	Community		Sex		Caregiving responsibility	
	Under-represented caregivers (n=78)	Not under-represented caregivers (n=120)	Female (n=111)	Male (n=90)	Shared (n=160)	Sole (n=44)
Average duration of seizures has decreased	49 (62.8%)	79 (65.8%)	68 (61.3%)	61 (67.8%)	103 (64.4%)	28 (63.6%)
Average duration of seizures has stayed the same	25 (32.1%)	31 (25.8%)	36 (32.4%)	22 (24.4%)	45 (28.1%)	14 (31.8%)
Average duration of seizures has increased	4 (5.1%)	10 (8.3%)	7 (6.3%)	7 (7.8%)	12 (7.5%)	2 (4.5%)

References: 1. Epidiolex® (cannabidiol) oral solution. Prescribing information. Jazz Pharmaceuticals, Inc., 2024. Accessed August 9, 2024. https://pp.jazzpharma.com/pi/epidiolex.en.USPI.pdf. **2.** Berg AT, et al. *Epilepsy Res.* 2024;200:107280. **3.** Hussain SA, et al. *Epilepsia.* 2020;61(2):319–329. **4.** Graessel E, et al. *BMC Geriatrics.* 2014;14(23):1-9.

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Figure 5. Perceived benefits of CBD use on dependents – caregiver subgroup outcomes

Figure 5a. By community

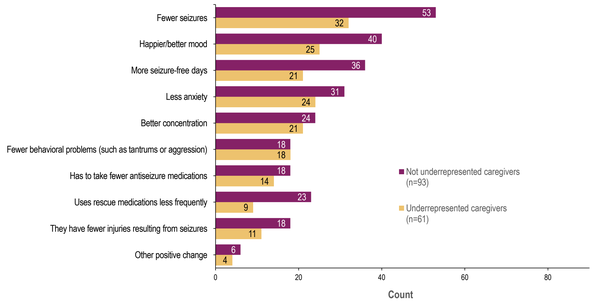
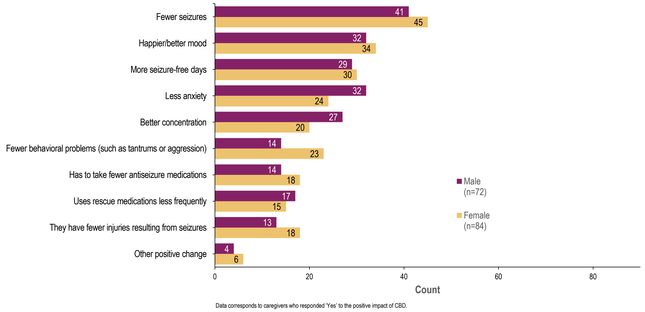


Figure 5b. By sex



Data corresponds to caregivers who responded 'Yes' to the positive impact of CBD.

Figure 5c. By caregiving responsibility

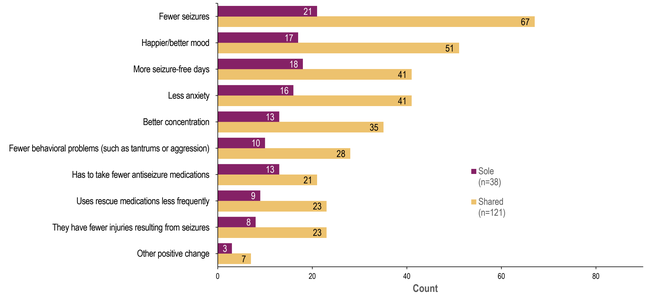


Figure 6. Perceived benefits of CBD use on caregivers – caregiver subgroup outcomes

Figure 6a. By community

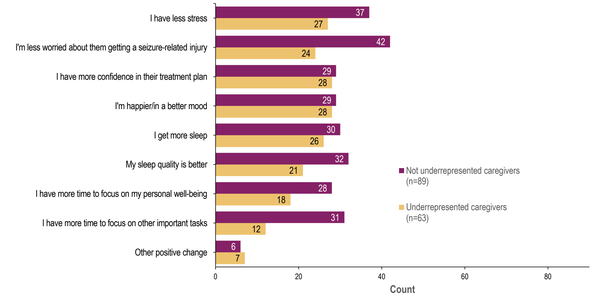


Figure 6b. By sex

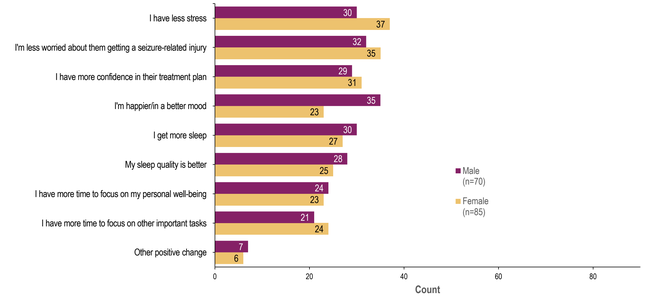
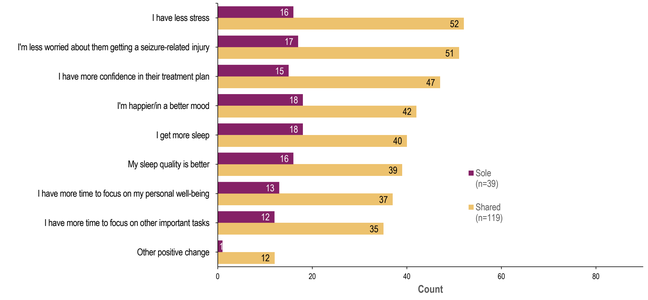


Figure 6c. By caregiving responsibility



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