

# Assessment of Healthcare Resource Utilization in Patients With Exocrine Pancreatic Insufficiency in the PACT-CP Registry

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## INTRODUCTION

- Chronic pancreatitis (CP) is a disease of the pancreas most frequently associated with causing exocrine pancreatic insufficiency (EPI)<sup>1,2</sup>
- Despite the impaired quality of life and increased morbidity and mortality associated with the condition, EPI remains underdiagnosed and undertreated<sup>2</sup>
- To identify the needs and experiences of patients with CP/EPI who are receiving pancreatic enzyme replacement therapy (PERT), a prospective, patient-driven registry was developed to collect data from patients and their providers
- Because little information is currently available discussing healthcare resource utilization of patients with CP/EPI, findings from this registry may help identify patterns of healthcare resource utilization

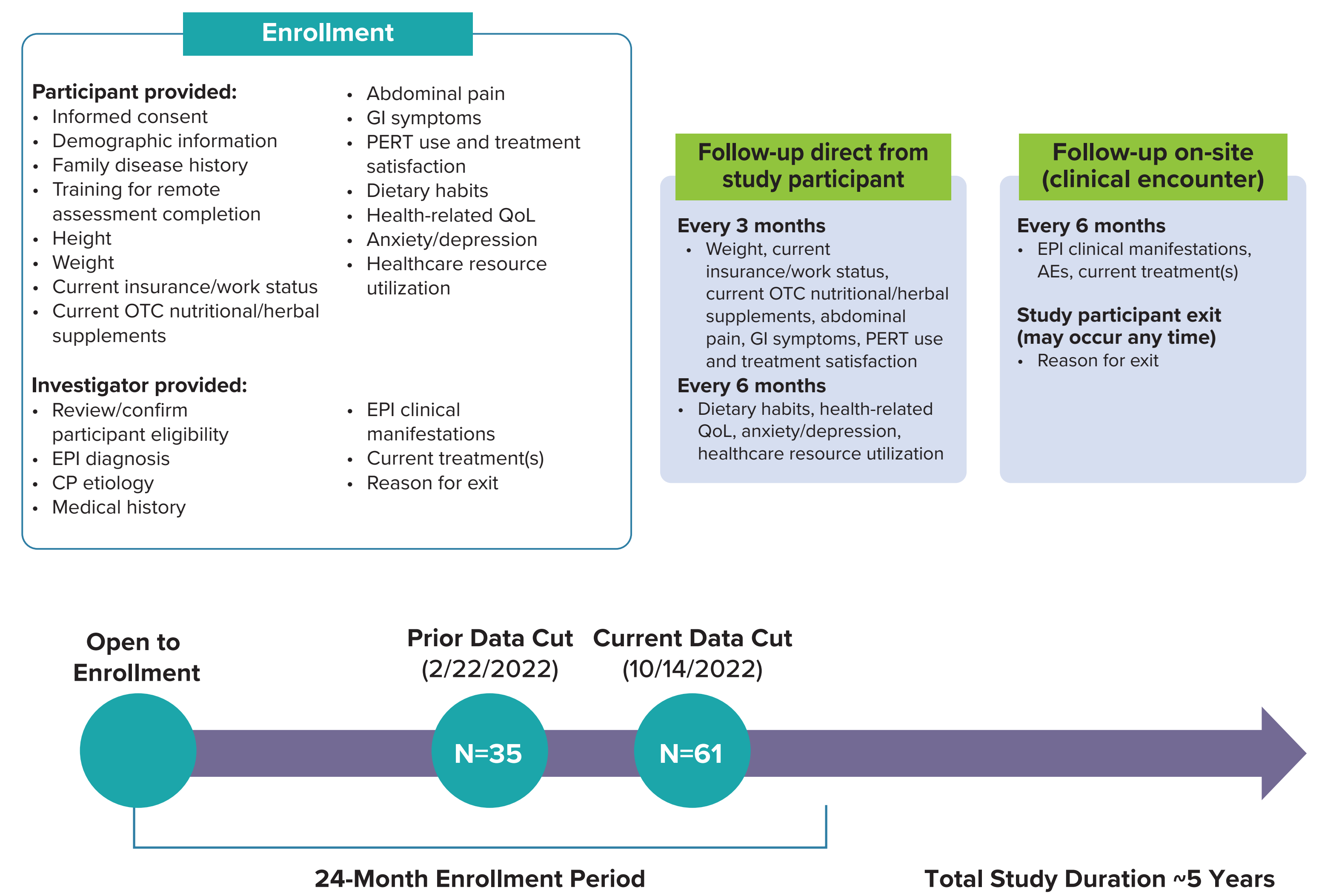
## OBJECTIVE

- To better understand EPI and its impact on healthcare resource utilization through analysis of real-world experience data collected from a traditional registry of patients with EPI who are PERT, and their gastroenterologists

## METHODS

- This is a prospective, longitudinal, noninterventional US study spanning ~5 years
  - Recruitment to occur over 24 months
  - Inclusion of ~20 gastroenterology practices
- Assessments were collected at prespecified time points (Figure 1)
- Adults with suspected or confirmed EPI due to diagnosed CP or recurrent acute pancreatitis, who were receiving PERT, and were under the care of a practicing gastroenterologist at enrollment were eligible
- Patients with a history of cystic fibrosis, fibrosing colonopathy, or pancreatic cancer/malignancies were excluded
- All data were summarized descriptively

Figure 1. Study Design and Schedule of Assessments



Abbreviations: AE, adverse event; CP, chronic pancreatitis; EPI, exocrine pancreatic insufficiency; GI, gastrointestinal; OTC, over-the-counter; PERT, pancreatic enzyme replacement therapy; QoL, quality of life.

## RESULTS

### Demographics and Baseline Characteristics

- As of October 14, 2022, 61 patients were enrolled (Table 1)
- Most patients enrolled in the registry were non-Hispanic, White, and male
- 29 patients reported having experienced unintentional weight loss
- 4 patients had a familial history of CP

Table 1. Patient Demographics and Characteristics

| Characteristic              | Total N=61   |
|-----------------------------|--------------|
| Patient demographics        |              |
| Age (years), median (range) | 63.5 (31–83) |
| Sex, n (%)                  |              |
| Male                        | 29 (47.5)    |
| Female                      | 25 (41.0)    |
| Race, n (%)                 |              |
| White                       | 40 (65.6)    |
| Black or African American   | 7 (11.5)     |
| Asian                       | 2 (3.3)      |
| Other                       | 4 (6.6)      |
| Ethnicity, n (%)            |              |
| Hispanic or Latino          | 7 (11.5)     |
| Not Hispanic or Latino      | 47 (77.0)    |

- Alcohol (susceptibility/progression), tobacco smoking, and diabetes mellitus were common etiologies/comorbidities (Table 2)
- Weight loss (37.7%), clinical steatorrhea (31.1%), and abnormal fecal elastase-1 test (23.0%) were frequently used as evidence for EPI diagnosis

Table 2. Disease Characteristics at Baseline

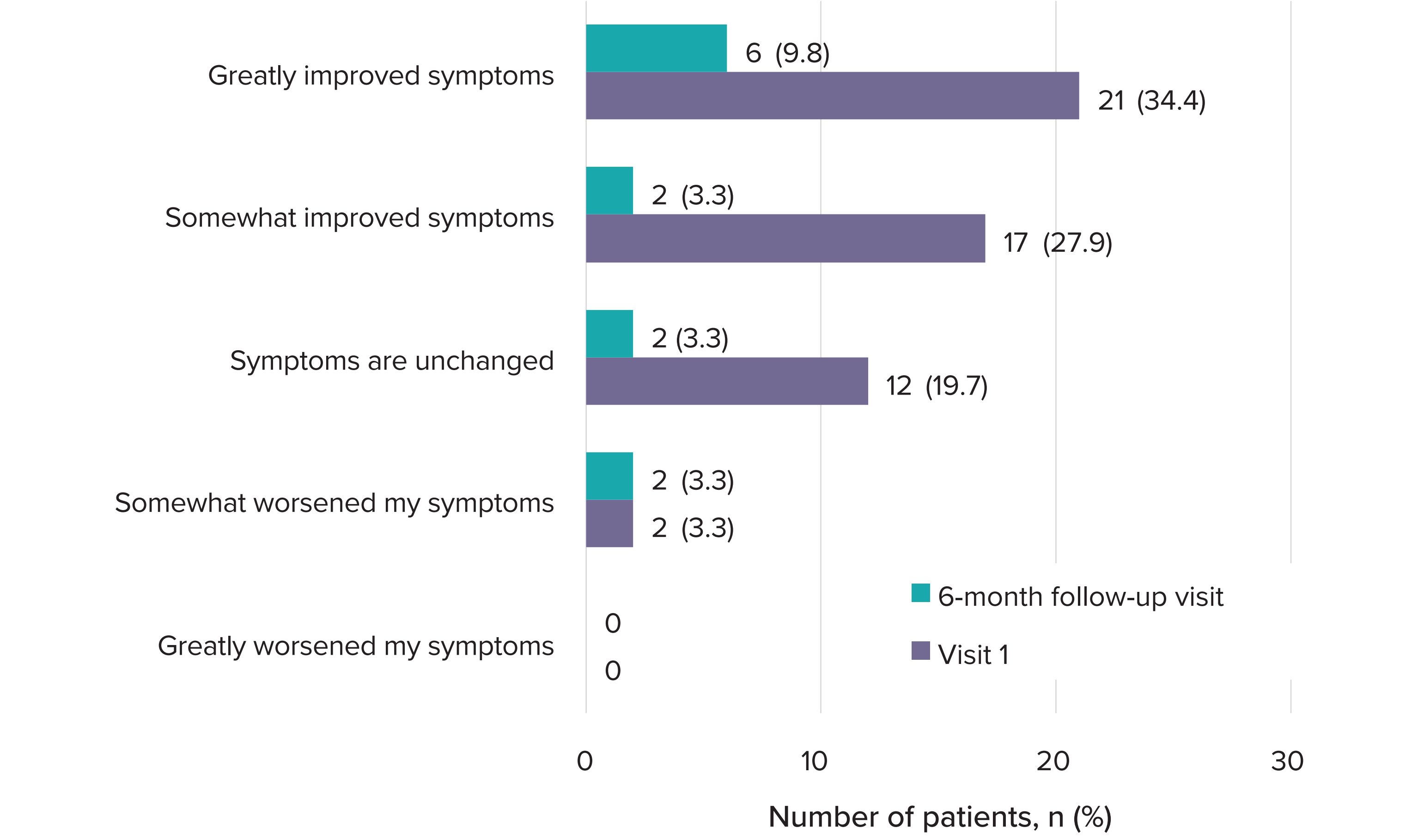
| CP Etiology <sup>a,b</sup> , n (%)                                | Total N=61 |
|---|------------|
| Toxic-metabolic   |            |
| Alcohol (susceptibility/progression)                              | 25 (41.0)  |
| Tobacco smoking   | 11 (18.0)  |
| Hyperlipidemia (fasting >300 mg/dL, nonfasting >500 mg/dL)        | 5 (8.2)    |
| Medications   | 2 (3.3)    |
| Hypercalcemia (total calcium levels >12.0 mg/dL or 3 mmol/L)      | 2 (3.3)    |
| Toxins, chronic kidney disease (stage 5, end-stage renal disease) | 2 (3.3)    |
| Toxins, other   | 1 (1.6)    |
| Toxins, other, not otherwise specified                            | 1 (1.6)    |
| Not applicable  | 30 (49.2)  |
| Metabolic, other  |            |
| Diabetes mellitus   | 17 (27.9)  |
| Not applicable  | 44 (72.1)  |
| Idiopathic  |            |
| Late onset (>35 years of age)                                     | 32 (52.5)  |
| Early onset (<35 years of age)                                    | 3 (4.9)    |
| Not applicable  | 26 (42.6)  |

<sup>a</sup>Selected chronic pancreatic etiology; other categories not shown include genetic, autoimmune, recurrent and severe acute pancreatitis, obstructive, and other. <sup>b</sup>Multiple options may be selected for individual participants. Abbreviation: CP, chronic pancreatitis.

### PERT Use

- At both the first and 6-month follow-up visits, patients reported a median of 6 pills of PERT taken per day
- Patients generally reported PERT greatly or somewhat improved symptoms (Figure 2)
- 47 (77.0%) patients reported taking their PERT or enzymes every day

Figure 2. Impact of PERT Use on Symptoms<sup>a</sup>



<sup>a</sup>Multiple options may be selected for individual participants. Abbreviation: PERT, pancreatic enzyme replacement therapy.

### Healthcare Resource Utilization

- The median number of ER visits was numerically lower at the 6-month follow-up visit compared with visit 1 (Table 3)
- At visit 1, patients (n=49) had a median number of 3 healthcare provider visits over the past 3 months
  - At the 6-month follow-up visit, patients (n=10) had a median number of 2.5 healthcare provider visits over the past 6 months
- At the first visit, patients reported needing a median of 4 sick days (n=18) if they were employed full-time and a median of 0 sick days (n=4) at the 6-month follow-up visit

Table 3. Healthcare Resource Utilization per Visit

| Healthcare Resource Utilization  | Total N=61 |
|--|------------|
| Visit 1  | n=54       |
| Needed ER visits over the past 3 months, n (%)                               | 13 (21.3)  |
| Median number of ER visits over the past 3 months (range)                    | 3 (1–5)    |
| Needed hospitalization visits over the past 3 months, n (%)                  | 11 (18.0)  |
| Median number of hospitalizations over the past 3 months (range)             | 1 (1–4)    |
| Median number of days of hospitalization stay over the past 3 months (range) | 4 (1–60)   |
| 6-month participant follow-up  | n=12       |
| Needed ER visits over the past 6 months, n (%)                               | 4 (6.6)    |
| Median number of ER visits over the past 6 months (range)                    | 2 (1–2)    |
| Needed hospitalization visits over the past 6 months, n (%)                  | 1 (1.6)    |

Abbreviation: ER, emergency room.

## LIMITATIONS

- Data collected for the 6-month follow-up period are currently limited due to the sample of patients who have reached this time point in the study; additional data are anticipated as the registry continues to accrue patients and additional follow-up visits occur
- Only descriptive statistics were available for this current data set

## CONCLUSIONS

**These findings indicate that most patients were adherent to PERT and that rates of healthcare resource utilization decreased over time**

*Further analyses are needed to confirm possible associations and trends seen between registry participation and improvements over time in PERT adherence, decreased healthcare resource utilization, and reduction in sick days taken by patients*

**There was a substantial decrease in workplace absenteeism over time**

**Future analyses of this ongoing registry will help further clarify areas of unmet needs in EPI**

## References

- Capurso G, et al. *Clin Exp Gastroenterol*. 2019;12:129-139.
- Diéguez-Castillo C, et al. *Medicina (Kaunas)*. 2020;56(10):523.

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