

# GASTROINTESTINAL INTOLERANCE AND HEALTHCARE RESOURCE UTILIZATION IN CHILDREN WITH MOTILITY DISORDERS RECEIVING A WHEY PEPTIDE-BASED ENTERAL FORMULA IN POST-ACUTE CARE: A RETROSPECTIVE ANALYSIS

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## BACKGROUND

- Gastroesophageal reflux disease (GERD) and gastroparesis (GP) are common gastrointestinal (GI) motility disorders in children, characterized by symptoms such as heartburn, regurgitation, nausea, vomiting, and abdominal pain<sup>1,2</sup>
- Enteral nutrition may be required to manage severe GERD or GP in children who fail to meet nutritional goals through oral intake<sup>3,4</sup>
- 100% whey peptide-based formulas (w-PBF) have been associated with improvements in signs and symptoms of GI intolerance in children<sup>5,6,7</sup>

## OBJECTIVE

 This study assessed GI intolerance symptoms and healthcare resource utilization (HCRU) in children with GERD and/or GP prescribed w-PBF in a post-acute care setting

## METHODS

- Retrospective analysis of US medical claims data for patients prescribed w-PBF (Peptamen Junior<sup>®</sup> formulas, Nestlé HealthCare Nutrition, US) between January 2013 and July 2023, using de-identified, patient-level data from the Decision Resources Group Real World Evidence Data Repository (Clarivate)<sup>8</sup>
- Inclusion criteria:  $\geq 1$  to <18 years of age, prescribed w-PBF for  $\geq$ 7 days in post-acute care, history of enteral feeding formula use
- Exclusion criteria: parenteral nutrition usage, palliative, and/or end-of-life care
- The pre-and post-index periods were defined as 1 year before the first w-PBF claim date and the last record documented within the study period at 1-, 3-, 6- and 12-months post-index, respectively
- GI intolerance symptoms (constipation, diarrhea, abdominal pain, nausea, vomiting, flatulence gagging & retching and abdominal distention) and HCRU outcomes (visits to healthcare providers) were compared between the 1-year pre-index and post-index periods using chi-square test

## RESULTS

## GI INTOLERANCE SYMPTOMS

- **GERD**:

## GP:

# HEALTHCARE RESOURCE UTILIZATION

- GERD:

## Post-index (months) GERD Pre-index 12 N (%) N (%) N (%) N (%) N (%) Any intolerance 665 (65) 227 (22) **<0.001** 344 (34) 486 (48) **<0.001** 24 (11) <0.001 55 (16) <0.001 93 (22) <0.001 153 (31) **<0.001** < 0.001 134 (13) 16(2) Abdominal pain 182 (18) 27 (3) <0.001</th> 52 (5) <0.001</th> 80 (8) <0.001</th> 128 (13) <0.001</th> Constipation 373 (37) 99 (10) <0.001 180 (18) <0.001 238 (23) <0.001 304 (30) <0.001 Diarrhea 184 (18) 37 (4) <0.001 72 (7) <0.001 99 (10) <0.001 134 (13) <0.002 153 (15) 20 (2) <0.001 35 (3) <0.001 < 0.001 56 (5) <0.001 84 (8)

# (N=1,019)≥3 Intolerance events 253 (38) Abdominal distention Gagging and retching 95 (9) 16 (2) < 0.001 31 (3) < 0.001 49 (5) < 0.001 72 (7) 0.063 Nausea and vomiting 439 (43) 106 (10) <0.001 171 (17) <0.001 224 (22) <0.001 277 (27) <0.001

Abbreviations: GERD, gastroesophageal reflux disease; GP, gastroparesis; w-PBF, 100% whey peptide-based formula. †Chi-square test (pre-index vs post-index); alpha=0.05 level of significance

## References

1. Saliakellis, E., et al. Annals of Gastroenterology. 2013; 26:204-211. 2. Friedman, C., et al. J Clin Nutr and Diet 2021; 7(4):1-6. 6. Elfadil OM, et al. JPEN 2022; 46:626-634. 7. Minor G, et al. Global Ped Health 2016; 3:1-6. 8. Clarivate. Real world data. Available at: https://clarivate.com/products/real-world-data/#dynamics 9. Sun, J. W., et al. American Journal of Epidemiology. 2021; 190(5):918-927. Presented at Digestive Disease Week, May 18-21, 2024, Washington DC. Sponsored by Nestlé HealthCare Nutrition, Inc.

## PATIENT CHARACTERISTICS (Table 1)

• The study included 1,019 patients with GERD and 113 patients with GP

 Children with GERD and GP had a mean of 4.7 and 5.1 comorbidities, respectively

 Significantly fewer children with GERD experienced any or  $\geq 3$  intolerance events at all timepoints (both p≤0.001)

• Significant reductions in all analyzed GI intolerance symptoms were observed for at least 6 months post-index, with significant reductions of abdominal distention and pain, constipation, diarrhea, flatulence, nausea and vomiting sustained up to 12 months (p≤0.05) (Table 2)

• Significantly fewer children with GP experienced any or  $\geq 3$  intolerance events up to 6 months post-index (both p≤0.05)

 Reductions in all GI intolerance symptoms for at least 3 months post-index were observed, with significant reductions in nausea and vomiting, abdominal distention and flatulence up to 12 months post-index (p≤0.05)

• Significant reductions in the percentages of patients requiring healthcare visits were observed for all visit types for at least 1-month post-index, with emergency department visits and inpatients visits sustained for 12 months (p≤0.05) (Figure 1)

# Table 1: Patient characteristics and comorbidities

Age, mean (SD) years

Female n (%)

Most common comorbidities, n (%)

Congenital malformations

Developmental delays

Nausea/vomiting

Cardiovascular conditions Number of comorbidities, mean (SD)

PCI score, mean (SD)

Abbreviations: GERD, gastroesophageal reflux disease; GI, gastrointestinal; GP, gastroparesis; PCI, Paediatric Comorbidity Index; SD, standard deviation.

 Mean numbers of emergency department (4 vs 3 visits), inpatient (24 vs 14), and urgent care (3 vs 2) visits per patient were significantly reduced up to 12 months post-index compared with pre-index (p≤0.05). Data for other time points not shown.

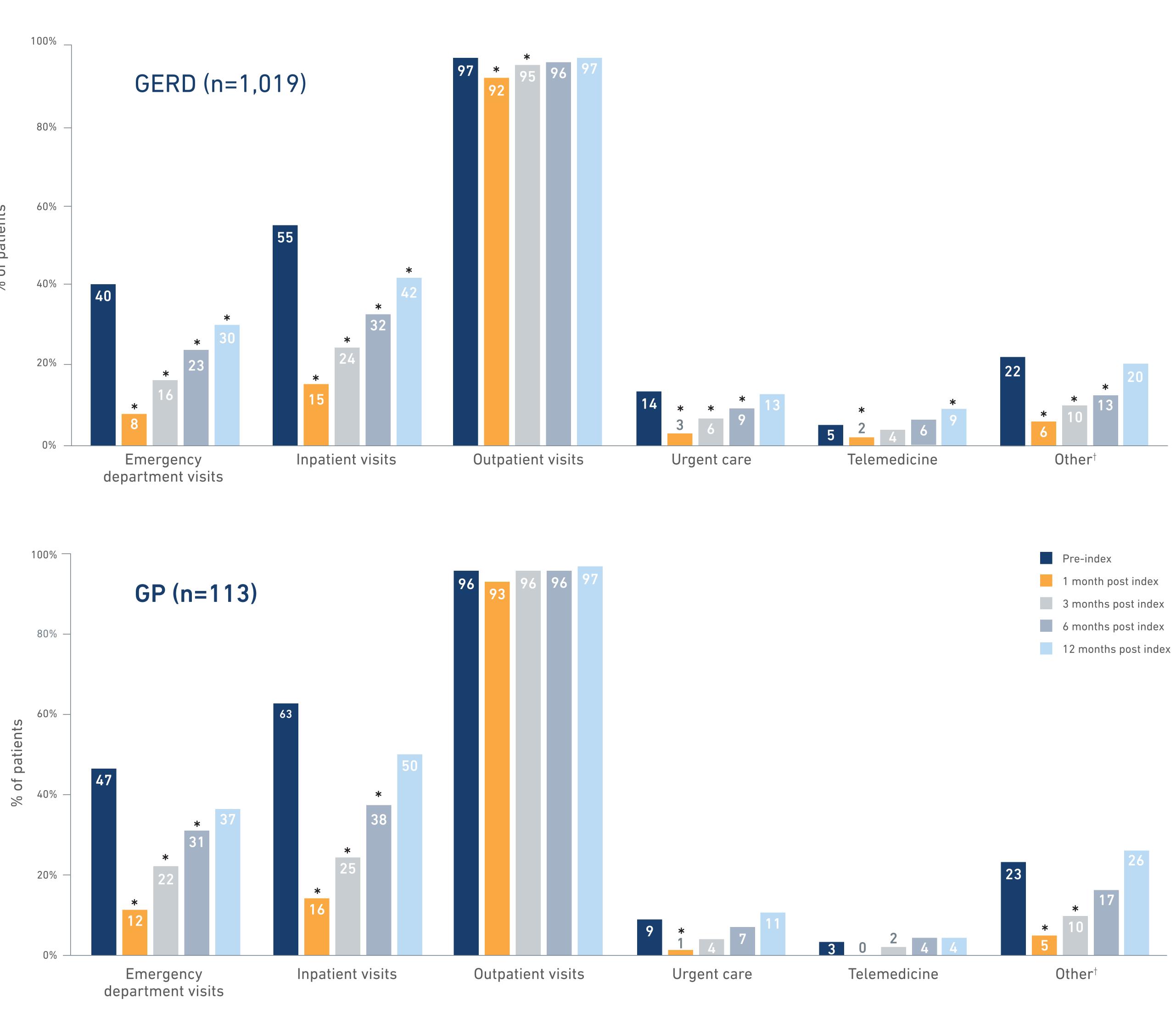
GP:

- Significant reductions in the percentage of patients requiring HCRU were observed 1 to 6-months post-index across multiple visit types, including emergency visits, inpatient visits, urgent care, and other visit types ( $p \le 0.05$ ) (Figure 1)
- Mean numbers of emergency department (4 vs 2 visits), inpatient (26 vs 10), and outpatient (70 vs 48) visits per patient were significantly reduced up to 6 months post-index compared with pre-index (p≤0.05). Data for other time points not shown.

## Table 2: Gastrointestinal intolerance among children with GERD or gastroparesis receiving w-PBF

GERD (N=1,019)	GP (N=113)
5.2 (4.4)	7.6 (5.0)
471 (46)	67 (59)
683 (67)	64 (57)
485 (48)	46 (41)
439 (43)	64 (57)
337 (33)	39 (35)
4.7 (2.4)	5.1 (2.6)
7.5 (4.3)	7.9 (4.9)

## Figure 1: Healthcare resource utilization among children with GERD (top) or gastroparesis (bottom) receiving w-PBF



Abbreviations: GERD, gastroesophageal reflux disease; GP, gastroparesis; w-PBF, 100% whey peptide-based formulas.  $p \le 0.05$ . Chi-square test (pre-index vs post-index), alpha=0.05 level of significance. <sup>†</sup>Other places of service include assisted living, intermediate care, and facilities not identified on the submitted claim.

	Pre-index	Post-index (months)							
GP F (N=113)		1		3		6		12	
	N (%)	N (%)	p†	N (%)	p†	N (%)	p†	N (%)	p†
Any intolerance symptoms	85 (75)	47 (42)	<0.001	60 (53)	<0.001	67 (59)	<0.011	72 (64)	0.060
≥3 Intolerance events	47 (55)	6 (13)	<0.001	12 (20)	<0.001	21 (31)	<0.001	33 (46)	0.051
Abdominal distention	28 (25)	3 (3)	<0.001	5 (4)	<0.001	8 (7)	<0.001	12 (11)	0.005
Abdominal pain	46 (41)	11 (10)	<0.001	15 (13)	<0.001	24 (21)	0.002	36 (32)	0.167
Constipation	52 (46)	20 (18)	<0.001	32 (28)	0.006	37 (33)	0.041	43 (38)	0.225
Diarrhea	30 (27)	7 (6)	<0.001	13 (12)	0.004	20 (18)	0.109	29 (26)	0.880
Flatulence	31 (27)	3 (3)	<0.001	7 (6)	<0.001	10 (9)	<0.001	14 (12)	0.005
Gagging and retching	9 (8)	1 (1)	0.010	2 (2)	0.030	3 (3)	0.075	6 (5)	0.423
Nausea and vomiting	65 (58)	25 (22)	<0.001	31 (27)	<0.001	39 (35)	<0.001	47 (42)	0.017



# CONCLUSION

- The use of w-PBF in children with GERD or gastroparesis was associated with significant reductions in GI intolerance symptoms and HCRU
- This data supports the use of w-PBF in children with GI motility disorders who require enteral nutrition support in post-acute care