Short Report

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Comparing characteristics and outcomes between hospitalized adults on a pea protein or dairy/soy protein formulas: initial findings

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Enteral formulas are an essential part of nutrition support to prevent or treat malnutrition and minimize hospital length of stay (LOS). Yet not all formulas are tolerated and may leave nutritional needs unmet. Unique pea protein plant-based formulas (PPPBF) are nutritionally complete and have accumulated evidence of good tolerance, but impact on health economic outcomes (HEO) is largely unknown. **Aim:** To examine differences in patient and clinical characteristics and HEOs of hospitalized adults using PPPBF versus dairy and/or soy protein (DSP) formulas to inform further research. **Materials & methods:** Retrospective comparative cohort study examined real-world data (Premier Healthcare Database) from adults (≥18 year) admitted to US hospitals who were prescribed a formula between 1 January 2020 and 30 September 2023. Patient and clinical characteristics and HEOs were compared between the PPPBF and DSP groups by unadjusted descriptive analysis. **Results:** Preliminary analyses were conducted on inpatients (n = 65,338 DSP; n = 243 PPPBF) from 60 US hospitals. PPPBF (versus DSP) group was younger (mean [SD] 63.6 [17.0] vs 66.7 [17.3] years; $p = 0.006$) and had a higher diagnosis rate for malnutrition, weight loss, food allergies, irritable bowel syndrome and/or inflammatory bowel disease on admission. Overall, formula intake was primarily oral but higher in PPPBF versus DSP (100 vs 78.3%, $p < 0.001$). Charlson Comorbidity Index indicated PPPBF (versus DSP) was sicker (median 4.0 vs 3.0; $p < 0.001$). Yet PPPBF group had shorter LOS (by ~2 days; $p < 0.001$) and lower mortality rate by discharge (5.8% vs 11.5%; $p = 0.005$) without significant difference in 90-day readmission/outpatient visit rates after discharge (unadjusted comparisons). **Conclusion:** Preliminary evidence in hospitalized adults observed a shorter LOS in PPPBF users, despite higher baseline acuity and without significant difference in readmission/outpatient visit rates compared (unadjusted) to DSP users. Adjusted analyses and further research are needed.

Plain language summary: A comparison between two groups of hospitalized adults based on the formula they used: initial findings

What was the aim of this research? To identify and compare preliminary clinical and healthcare resource use differences between hospitalized adults who consumed pea protein plant-based formulas (PPPBF) or dairy and/or soy protein (DSP) formulas for further study.

How was the research carried out? Real-world deidentified data previously collected by Premier Healthcare Database included adults in US hospitals who were prescribed a formula over 3-year study period (2020–2023). Study groups were assigned based on formula used: PPPBF or DSP. Patient and clinical characteristics and health economic outcomes, like hospital length of stay, were compared between groups.

What were the results? Preliminary analyses were performed on large dataset from 60 US hospitals (DSP = 65,338; PPPBF = 243). The PPPBF group was younger and sicker than DSP group based on measures related to risk of death, nutritional status and gastrointestinal function. Initial results showed the PPPBF group had a shorter length of stay, lower rate of death in the hospital and similar percentage of hospital readmissions or outpatient visits after discharge compared with the DSP group. Further testing to confirm these preliminary findings is underway.

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What do the results of the study mean? The use of PPPBF, as an alternative to DSP formulas, to supplement nutritional intake in the hospital may have benefits for the patient and healthcare system despite greater illness severity and nutritional risk as observed in this study. In this preliminary study, those in the PPPBF group left the hospital sooner and had comparable rates of readmissions or outpatient visits compared with DSP group. More testing of these findings is underway.

Shareable abstract: Preliminary unadjusted study findings suggest that hospitalized adults using a fiber containing formula made with a unique yellow pea protein may use less healthcare resources (due to ~2 day earlier hospital discharge) than those using formulas made with dairy and/or soy protein, despite being sicker at baseline. Further testing of these preliminary results is underway.

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Background

Enteral nutrition (EN), provided by tube or oral feedings, is a cornerstone of nutritional support for hospitalized patients who cannot meet their nutritional needs [1]. Carefully planned and monitored enteral feeding plans are essential to minimize malnutrition risk and optimize patient outcomes [2,3]. In the hospital setting, malnutrition elevates the risk of infections, pressure injuries, prolonged mechanical ventilation, anemia, compromised cardiac and respiratory functions, leading to increased length of hospital stay and mortality [4–8]. Thus, the availability of an enteral formula to meet nutritional requirements while optimizing tolerance and metabolic support is critical.

The high prevalence of malnutrition following hospitalization (20–45%) highlights the critical need for timely interventions by a registered dietitian to implement nutrition risk screenings, assessments and interventions during and after hospital stays [9]. EN initiated early, ideally within 24–48 h of admission, improves clinical outcomes, especially in critically ill patients [10,11]. Selection of an appropriate enteral formula, however, depends on multiple factors, including individual needs and preferences, underlying medical conditions and gastrointestinal (GI) tolerance [12]. Since the 1960s, dairy protein-based formulas (derived from cow's milk proteins such as casein and/or whey) have been the standard of care for EN patients as they provide a complete protein source. Soy protein-based formulas later became the first widely used plant-based alternative, also offering a complete source of protein. Initially, these formulations were deliberately fiber-free or "low residue" in an attempt to minimize fecal output; despite updated clinical practice guidelines invalidating this, fiber-free formulas remain in use. Given the prevalence of food allergies and growing evidence of the potential negative environmental effects from heavy reliance on dairy and soy, yellow pea protein has emerged as a possible alternative. Recent studies have investigated a unique fiber-containing, yellow pea protein plant-based formula (PPPBF) and its effects on gastric emptying, GI tolerance, prebiotic activity, production of beneficial gut metabolites and patient and caregiver reported outcomes. This research suggests these formulations may improve GI tolerance, support patient adherence, enhance prebiotic activity and promote moderate gastric emptying (relative to casein- or whey-based formulas), while also providing dietary fiber and a low allergen profile – attributes that address issues historically associated with traditional EN formulas [13–15]. Tailoring nutrition therapy to individual patient needs and preferences is replacing the 'one-size-fits-all' approach to EN [16].

There is an increasing body of evidence of healthcare cost benefits related to the timely achievement of an individual's EN goals. Patients who reach their EN goals may be transferred out of the intensive care unit setting and/or discharged from the hospital sooner resulting in lower costs for the healthcare system [17,18]. However, symptoms of GI intolerance can impede the successful delivery of the enteral formula, delay the patient's attainment of the goal infusion rate/nutritional requirements, and postpone hospital discharge. The prevalence of enteral feeding intolerance (EFI) is substantial in the hospital setting, estimated to occur in 30.5–65.7% of hospitalized patients (more adults than pediatrics) [19,20]. GI related medications are used to help manage EFI symptoms, which add additional costs. Thus, efforts to find EN formulas to aid in GI tolerance have the potential to improve quality of life as well as minimize healthcare resource utilization (HCRU).

For decades, EN studies centered largely on dairy and soy protein-based formulas, given that these were essentially the main options available (apart from very specialized or elemental amino acid formulas). A gap, therefore, exists in research focused on pea protein plant-based enteral formula use. The primary objective of this study was to use real-world data to assess the differences in health economic outcomes between hospitalized adults who received a

unique pea protein plant-based formula (PPPBF, Kate Farms™) and those who received a formula made with dairy and/or soy protein (DSP) formulas. The secondary objective was to compare patient and clinical characteristics and other HEOs between the PPPBF and DSP groups to identify differences to investigate in further analyses. This short report presents initial descriptive, unadjusted findings to inform further research.

Materials & methods

Data source & study design

This retrospective comparative cohort study was conducted using real-world data from the Premier Healthcare Database (PHD) [21]. The PHD includes hospital administrative data from healthcare systems across the US. In accordance with the HIPAA Privacy Rule, disclosed data from the PHD are considered deidentified per US Code of Federal Regulations (CFR) 45 Part 164.514(b)(1) through the 'Expert Determination' method. The study was not considered human subjects research and it was determined to be exempt from IRB oversight by a central IRB under US CFR 45 Part 46.106(d)(4). Study inclusion criteria were defined as adult patients (≥18 years) who had a hospitalization in one of the reporting sites and evidence of use of any brand of EN formula between 1 January 2020 and 30 September 2023. For each patient, the index visit was defined as the first hospitalization within the time period that also included an EN formula order. Study participants were assigned to one of two groups based on their EN formula order. The PPPBF group sought to include participants who received any Kate Farms brand of formula (Standard 1.0, Standard 1.4, Peptide 1.0, Peptide 1.5).The dairy and/or soy protein (DSP) formula group sought to include participants who received 'all other brands' of formulas with these protein sources, with or without fiber, and excluded specialized DSP formulas that didn't have a comparable formula in the PPPBF group (e.g., immunomodulating or reduced calorie).

Data & study outcomes

The primary outcome was length of stay (LOS) of the index visit, as this is a measure of HCRU and is influenced by the successful tolerance of the EN/dietary regimen during the admission. This study compared two groups, both of which received a nutritional formula during hospitalization, rather than comparing a treatment group with a non-treatment group. Additionally, the collection of data on the percentage of inpatient days involving any formula use helped to minimize immortal time bias. Secondary outcomes included in-hospital deaths by index visit discharge and clinical end points measured during the 90-day post-index visit follow-up (all-cause hospital readmissions, all-cause outpatient medical visits). Patient and clinical characteristics (present on admission and/or reported during index visit) included demographics and data such as enteral formula use, CCI score/comorbidities, GI-related medication use, GI intolerance symptoms and nutritional status (based on weight loss/malnutrition diagnosis). The CCI score was calculated using a combination of the original and updated methods [22,23].

Statistical analyses

Descriptive statistics are presented as mean (standard deviation [SD]) and median (interquartile range [IQR]) for continuous variables or as count (%) for categorical variables. Unadjusted statistical comparisons between groups for categorical or binary variables were performed using Pearson's Chi-squared test or Fisher's exact test when expected cell counts were small. Welch's two-sample *t*-test was performed for age, and the Wilcoxon rank sum test was performed for count variables, as they are typically not normally distributed. Significance was determined at a p-value < 0.05. Statistical analyses were performed using R version 4.4.1.

Results

Demographics at index visit admission (Table 1)

During the study period, 65,581 patients receiving EN formulas were identified (65,338 DSP, 243 PPPBF) across 60 US hospitals. The mean (SD) age was 66.7 (17.3) and 63.6 (17.0) years for DSP and PPPBF groups, respectively ($p = 0.006$). Overall, the study population was mostly male (51.7%), white (72.4%), non-Hispanic or Latino (96.8%), and had Medicare as their primary insurance payer (64.5%).

Clinical characteristics during index visit (unless specified) (Table 2)

Of the 243 patients identified and grouped into the PPPBF group, 100% of them had used Standard 1.4 which was also a fiber-containing formula. Table 2 presents unadjusted comparisons of clinical characteristics, including measures of medical acuity, between formula groups. The median CCI score was higher in the PPPBF group

Table 1. Demographics at index visit admission; n (%) unless specified.

	DSP (N = 65,338)	PPPBF (N = 243)	p-value
Sex			0.106†
Female	31,561 (48.3%)	130 (53.5%)	
Male	33,777 (51.7%)	113 (46.5%)	
Age (years)			
Mean (±SD)	66.7 ± 17.3	63.6 ± 17.0	0.006‡
Median (IQR)	69.0 (57.0, 79.0)	66.0 (53.0, 76.0)	
Age categorized (years)			0.154†
18–39	5860 (9.0%)	28 (11.5%)	
40–64	20,065 (30.7%)	82 (33.7%)	
65+	39,413 (60.3%)	133 (54.7%)	
Race			<0.001§
White	47,304 (72.4%)	157 (64.6%)	
Asian	1224 (1.9%)	4 (1.7%)	
African–American	12,537 (19.2%)	72 (29.6%)	
Other	4273 (6.5%)	10 (4.1%)	
Ethnicity			0.714§
Hispanic or Latino	2108 (3.2%)	6 (2.5%)	
Not Hispanic or Latino	63,230 (96.8%)	237 (97.5%)	
Discharge status			<0.001†
Home/health	32,182 (49.3%)	170 (70.0%)	
SNF, ICF or long-term care	20,029 (30.7%)	46 (18.9%)	
Other	4533 (6.9%)	11 (4.5%)	
Transferred to acute care	1075 (1.6%)	2 (0.8)	

†Pearson's Chi-squared test.
‡Welch's two sample *t*-test.
§Fisher's exact test.
DSP: Dairy and/or soy protein formula group; ICF: Intermediate care facility; IQR: Interquartile range; PPPBF: Pea protein plant-based formula group; SD: Standard deviation; SNF: Skilled nursing facility.

($p < 0.001$), with 20.6% having a score of 9 or above (highest category of mortality risk), compared with 8.7% in the DSP group. Higher rates of 'Any Malignancy' and 'Metastatic solid tumor' diagnoses in the PPPBF group (than the DSP group) were also noted. Further, upon admission to the index visit, the PPPBF group was more likely to present with a diagnosis of malnutrition, weight loss, food allergies, irritable bowel syndrome and/or inflammatory bowel disease (all $p < 0.05$) than the DSP group. The median percentage of inpatient days involving formula use, relative to the entire hospital stay, was similar between the formula groups (45.5% DSP vs 42.9% PPPBF, $p = 0.928$). Most of the formula intake for both groups was via ONS (versus tube feedings) but was statistically higher in the PPPBF group (243 [100%] PPPBF; 51,564 [78.3% DSP]; $p < 0.001$).

Formula group differences were also found in GI-related issues and nutritional status (see Table 2). Patients in PPPBF group (compared with DSP group) were more likely to report one or more GI intolerance symptom (flatulence, abdominal pain, constipation, diarrhea and/or nausea/vomiting) upon admission to the hospital index visit (present on admission) and during the index visit (both $p < 0.001$). GI medication use varied between groups as well. Specifically, patients in the PPPBF group (versus DSP group) were more likely to receive antidiarrheals (9.9% vs 6%) and antiemetics (64.2% vs 55.5%), and less likely to receive H2 antagonists (15.6% vs 29.1%) or laxatives (56.8% vs 65.3%, all $p < 0.05$). Last, the occurrence of malnutrition/weight loss (a combined measure) was higher overall in the PPPBF group, but a larger absolute increase in the percentage of affected individuals was observed in the DSP group during the index visit.

Study outcomes (Table 3)

Outcomes by index visit discharge (unadjusted comparisons)

Preliminary analyses indicated patients in the PPPBF group had a LOS that was approximately 2 days shorter than the DSP group (median [IQR] 6.0 [4–10] vs 8.0 [5–15] days, $p < 0.001$; Table 3). The percentage of in-hospital

Table 2. Clinical characteristics during index visit (unless specified).

	DSP (N = 65,338)	PPPBF (N = 243)	p-value
Percentage of inpatient days with any formula use			
Mean (±SD)	47.7% ± 27.7%	47.9% ± 27.8%	
Median (IQR)	45.5% (25.0, 66.7%)	42.9% (25.0, 66.7%)	0.928†
Enteral intake, n (%)			
Oral feedings	51,164 (78.3%)	243 (100%)	<0.001‡
Tube feedings	14,174 (21.7%)	0 (0%)	<0.001‡
CCI score			
Mean (±SD)	4.0 ± 3.1	4.9 ± 3.8	
Median (IQR)	3.0 (2.0, 6.0)	4.0 (2.0, 8.0)	<0.001†
CCI score (categorized), n (%)			<0.001‡
0	7935 (12.1%)	24 (9.9%)	
1–4	33,102 (50.7%)	111 (45.7%)	
5–8	18,624 (28.5%)	58 (23.9%)	
9+	5677 (8.7%)	50 (20.6%)	
CCI comorbidities, n (%)			
Myocardial infarction	8780 (13.4%)	25 (10.3%)	0.151‡
Congestive heart failure	20,050 (30.7%)	53 (21.8%)	0.003‡
Peripheral vascular disease	6834 (10.5%)	32 (13.2%)	0.169‡
Cerebrovascular disease	10,564 (16.2%)	27 (11.1%)	0.032‡
Dementia	9308 (14.2%)	14 (5.8%)	<0.001§
Chronic pulmonary disease	22,089 (33.8%)	74 (30.5%)	0.270‡
Rheumatic disease	2409 (3.7%)	10 (4.1%)	0.731§
Peptic ulcer disease	2203 (3.4%)	6 (2.5%)	0.591§
Diabetes with chronic complications	13,457 (20.6%)	45 (18.5%)	0.424‡
Diabetes without chronic complications	7814 (12.0%)	32 (13.2%)	0.562‡
Hemiplegia or paraplegia	3985 (6.1%)	7 (2.9%)	0.031§
Moderate or severe renal disease	32,118 (49.2%)	106 (43.6%)	0.085‡
Any malignancy	9932 (15.2%)	93 (38.3%)	<0.001‡
Moderate or severe liver disease	5114 (7.8%)	19 (7.8%)	>0.999§
Mild liver disease	3337 (5.1%)	18 (7.4%)	0.108§
Metastatic solid tumor	4699 (7.2%)	55 (22.6%)	<0.001‡
HIV disease	439 (0.7%)	3 (1.2%)	0.226§
Other conditions, n (%)			
Food allergies	1153 (1.8%)	23 (9.5%)	<0.001§
Irritable bowel syndrome	996 (1.5%)	8 (3.3%)	0.035§
Inflammatory bowel disease (UC, Crohn's disease)	2327 (3.6%)	16 (6.6%)	0.022§
GI-related medications, n (%)			
Antidiarrheals	3939 (6.0%)	24 (9.9%)	0.012‡
Antiemetics	36,266 (55.5%)	156 (64.2%)	0.006‡
H2 antagonists	19,015 (29.1%)	38 (15.6%)	<0.001‡
Proton pump inhibitors	33,584 (51.4%)	123 (50.6%)	0.807‡
Laxatives	42,658 (65.3%)	138 (56.8%)	0.005‡
Prokinetic	7032 (10.8%)	26 (10.7%)	0.975‡

†Wilcoxon rank sum test.
‡Pearson's Chi-squared test.
§Fisher's exact test.
CCI: Charlson Comorbidity Index; DSP: Dairy and/or soy protein formula group; GI: Gastrointestinal; PPPBF: Pea protein plant-based formula group; IQR: Interquartile range; SD: Standard deviation; UC: Ulcerative colitis.

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Table 2. Clinical characteristics during index visit (unless specified) (cont.).

	DSP (N = 65,338)	PPPBF (N = 243)	p-value
Present on admission: GI intolerance, n (%)			
Report of ≥1 GI intolerance symptoms	7654 (11.7%)	49 (20.2%)	<0.001‡
Flatulence	76 (0.1%)	0 (0%)	>0.999§
Abdominal pain	496 (0.8%)	5 (2%)	0.040§
Constipation	5208 (8.0%)	28 (11.5%)	0.041‡
Diarrhea	1419 (2.2%)	14 (5.8%)	0.001§
Nausea and vomiting	1102 (1.7%)	11 (4.5%)	0.003§
Reported during index visit: GI intolerance, n (%)			
Report of ≥1 GI intolerance symptoms	11,831 (18.1%)	64 (26.3%)	<0.001‡
Flatulence	161 (0.2%)	1 (0%)	0.452§
Abdominal pain	661 (1.0%)	6 (2.5%)	0.039§
Constipation	7995 (12.2%)	41 (16.9%)	0.028‡
Diarrhea	2652 (4.1%)	14 (5.8%)	0.189§
Nausea and vomiting	1657 (2.5%)	16 (6.6%)	<0.001§
Present on admission: nutritional status, n (%)			
Malnutrition	12,885 (19.7%)	62 (25.5%)	0.024‡
Weight loss	3621 (5.5%)	22 (9.1%)	0.017‡
Malnutrition and weight loss	14,361 (22.0%)	69 (28.4%)	0.016‡
Reported during index visit: nutritional status, n (%)			
Malnutrition	14,218 (21.8%)	63 (25.9%)	0.116‡
Weight loss	3712 (5.7%)	22 (9.1%)	0.024‡
Malnutrition and weight loss	15,696 (24.0%)	70 (28.8%)	0.082‡

†Wilcoxon rank sum test.
‡Pearson's Chi-squared test.
§Fisher's exact test.
CCI: Charlson Comorbidity Index; DSP: Dairy and/or soy protein formula group; GI: Gastrointestinal; PPPBF: Pea protein plant-based formula group; IQR: Interquartile range; SD: Standard deviation; UC: Ulcerative colitis.

Table 3. Study outcomes.

	DSP (N = 65,338)	PPPBF (N = 243)	p-value
Outcomes by index visit discharge			
Length of stay for index visit (days)			
Mean (±SD)	11.9 ± 11.2	8.7 ± 8.7	
Median (IQR)	8.0 (5.0, 15.0)	6.0 (4.0, 10.0)	<0.001†
Deaths, n (%)	7519 (11.5%)	14 (5.8%)	0.005‡
Clinical end points during 90-day post-index visit follow-up			
All-cause hospital readmission, n (%)	14,212 (21.8%)	52 (21.4%)	0.894‡
All-cause outpatient medical visits, n (%)	19,407 (29.7%)	81 (33.3%)	0.216‡

†Wilcoxon rank sum test.
‡Pearson's Chi-squared test.
DSP: Dairy and/or soy protein formula group; IQR: Interquartile range; PPPBF: Pea protein plant-based formula group; SD: Standard deviation.

deaths by index visit discharge was also lower in the PPPBF group compared (unadjusted) to the DSP group (5.8% vs 11.5%, p = 0.005; Table 3). The initial comparisons between formula groups showed those in the PPPBF group were more likely to be discharged to home or home health services than the DSP group, whereas those in the DSP group were more likely to be discharged to a skilled nursing facility or long-term care (see Table 1).

Clinical end points during 90-day post-index visit follow-up (unadjusted comparisons)

In these preliminary analyses, no statistical differences were found between the DSP and PPPBF groups in the percentage of all-cause inpatient readmissions (21.8% vs 21.4%, p = 0.894) or all-cause outpatient medical visits (29.7% vs 33.3%, p = 0.216) within 90-days of hospital discharge, respectively (see Table 3).

Discussion

Adult inpatients receiving a unique pea protein plant-based formula had a 2-day shorter LOS despite being more ill when compared (unadjusted) to a group of adult inpatients using dairy and/or soy protein formulas in our preliminary study analyses. Despite a higher CCI score, the PPPBF group also had a lower percentage of deaths (in unadjusted comparisons) than the DSP group during index visit and similar percentages of all-cause inpatient readmissions and all-cause outpatient medical visits within 90 days of hospital discharge. This study was an initial step in the research of the users and usage of PPPBF versus DSP formulas in hospitalized adults and associated HEOs. These preliminary findings identified, described and quantified unadjusted differences between groups for further study.

Hospital LOS and readmissions are vital qualitative checkpoints for healthcare systems, including the Hospital Readmission Reduction Program, which penalizes hospitals with high rates of readmissions for certain conditions within 30 days. Facilities can benchmark their performance against others using this metric and share it with the public [24]. Registered dietitians can help to optimize hospital performance metrics by the early identification, treatment and as possible, prevention of malnutrition. Studies have documented the benefits of EN support on improving nutritional status as well as helping to reduce LOS, readmission rates and reduce healthcare costs [25–28].

In the literature, a higher CCI score has been associated with a longer inpatient LOS in adults [29]. In this study, the PPPBF (versus DSP) group was observed to have a higher medical acuity based on a higher median CCI score and a higher prevalence of individuals reporting $\geq$1 GI intolerance symptom, diagnosis rates of malnutrition, weight loss, irritable bowel syndrome, inflammatory bowel disease and food allergies, and serious comorbidities like 'malignancy' and 'metastatic solid tumor'. Yet this higher acuity in the PPPBF group was not accompanied by a higher percentage of in-hospital deaths, longer LOS or higher hospital readmission rates/outpatient medical visits when compared with the DSP group in preliminary analyses (descriptive, unadjusted comparisons). These outcome differences and potential economic benefits observed between formula groups in this study are noteworthy but should be interpreted with caution until the contribution of the baseline differences identified in this study are tested at the same time. Further analysis is in development.

The role of EN support has been undervalued in the treatment of both acute and chronically ill patients, even though global research has shown that malnutrition and nutrient deficiencies worsen conditions and lead to higher healthcare costs. When intake by mouth is tolerated, the use of oral nutrition supplements (ONS) can avoid the cost and burden of feeding tubes by the patient and healthcare system, and have demonstrated clinical and cost benefits by extending lives of malnourished older hospitalized patients at a low additional cost of $524 per life-year saved in the United States [30]. Additionally, ONS use among hospitalized Medicare patients aged 65 and older is associated with better outcomes and reduced healthcare expenses [31]. Yet in the outpatient/home setting in the United States, ONSs are not reimbursed or covered by the majority of government or private medical insurance policies despite demonstrated clinical and economic benefits [30,31]. EN support, and as possible ONS, are relevant options for providers looking for affordable, evidence-based nutrition strategies [31]. Enteral formula intake as ONS was higher in the PPPBF (versus DSP) group (Table 2), however, it was the primary route of intake for both groups. In the inpatient setting, insurance covers nutritional formula regardless of delivery route, so patient payer types were not relevant to formula ordering, recommendations or prescribing in this study.

Similar to other retrospective studies using hospital administrative databases, our study had some known and suspected limitations. For example, our dataset may be subject to hospital reporting practices, with outliers, missing or incomplete data (e.g., items not billable or reimbursable) and lack clinical details that could impact the characteristics and outcomes studied (e.g., frequency and involvement of registered dietitians, EN used prior to admission, readmissions/outpatient medical visits outside of the hospital system's database parameters). Our preliminary results focused on outcome differences in the PPPBF versus DSP groups, but future research may perform sensitivity analysis to explore outcome differences in PPPBF versus DSP groups across different formulas (e.g., standard, peptide), age groups, and other relevant subgroups. The PPPBF group is noted to have a smaller and more heterogenous sample than the DSP group but this investigation was the first to evaluate a fiber-containing yellow PPPBF in hospitalized adults, so there was no scientific rationale to restrict analysis of the PPPBF cohort by geographic location; accordingly, the statistical plan included all available PPPBF data across sites. In parallel, strict data governance policies and safe data handling requirements prevented excluding data based on geography or hospital system, ensuring compliance while maximizing the use of all collected data. Finally, because hospital dietetic practices aim to follow uniform, evidence-based nutrition guidelines (which define criteria for initiating

oral or tube feedings), one can expect minimal differences in clinical practice patterns between sites and across formula groups, further supporting the decision to analyze an unrestricted, comprehensive dataset.

The descriptive, unadjusted analyses reported in this initial study identified differences in patient characteristics between the PPPBF and DSP formula groups, but these characteristics were not adjusted for in the outcome comparisons. This is an important but expected limitation to these early study results. Further, smaller sample size in one arm may yield lower power in the statistical tests. Future studies involving adjusted or matched analysis will be able to address the difference in patient characteristics between the two groups, and a larger PPPBF sample may improve the power of the tests.

These preliminary study findings help fill a gap in this area of literature, inform further research and develop deeper understanding. These findings are intended to inform our next study which will test group differences identified for an impact on study outcomes and, as appropriate, be controlled for in adjusted analyses (for adjusted exponentiated coefficients, 95% confidence intervals). From this study, we also identified additional data points that would be useful for future prospectively designed studies and those which can help to further control for potential immortal time bias.

Conclusion

This descriptive study provides preliminary results that begin to address an important gap in the literature by highlighting demographic and clinical differences between adults who used a PPPBF as an oral supplement during a hospitalization compared with those who used a DSP formula as an oral supplement or via tube feeding. Additionally, these preliminary results provide a new insight into potential HCRU of PPPBF, used as an ONS, in hospitalized adults requiring nutrition support. Unadjusted comparisons between formula groups indicated that the PPPBF group had a 2-day shorter LOS than the DSP group, despite the PPPBF group presenting with higher indices of medical acuity. This unexpected finding is counterintuitive, given that more acute patients generally have longer hospital stays and has prompted additional research questions. Further research is underway.

Summary points

- Enteral nutrition can help minimize malnutrition risk and optimize patient outcomes in hospitalized patients.
- Standard of care includes dairy protein-based formulas and more recently soy protein-based formulas for plant-based alternatives, but these dairy and/or soy protein (DSP) formulas lack universal tolerance.
- Pea protein plant-based formulas (PPPBFs) are nutritionally complete and accumulating evidence of good tolerance, but impact on health economic outcomes is largely unknown.
- This retrospective comparative cohort study examined 2020–2023 adult inpatient data (deidentified) from Premier Healthcare Database who were prescribed an enteral formula.
- A total of 65,581 hospitalized adults prescribed an enteral formula were identified across 60 US hospitals and divided into two study groups based on formula: 243 in PPPBF group and 65,338 in DSP formula group.
- PPPBF group was younger and sicker than DSP group based on higher diagnosis rates of malnutrition, weight loss, food allergies, irritable bowel syndrome and/or inflammatory bowel disease, reported gastrointestinal intolerance symptoms and comorbidity index score.
- Yet the PPPBF group overall spent approximately 2 days fewer in hospital and had a lower mortality rate by discharge without a higher percentage of hospital readmissions or outpatient medical visits after discharge.
- These preliminary study findings suggest hospitalized adults using formula made with a unique yellow pea protein may use less healthcare resources than those using formulas made with dairy and/or soy protein.

Author contributions

V Millovich was responsible for substantial contributions to the design of this work, interpretation of data and writing/editing of the manuscript. IO Shingara was responsible for the interpretation of data, and writing/editing of the manuscript. GS Lopes was responsible for the analysis/interpretation of data, and critical reviewing/editing of the manuscript. M Tyagi was responsible for the analysis of data, and critical review of the manuscript. Z Cao was responsible for contributions to design of this work, analysis/interpretation of data, and critical reviewing/editing of the manuscript. CJ Valentine was responsible for substantial contributions to the design of this work, interpretation of data, and writing/editing of the manuscript. All authors are responsible for the final approval of the manuscript to be published and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Competing interests disclosure
V Millovich, IO Shingara, CJ Valentine – salaried employee of Kate Farms Inc.; shareholder. IO Shingara received consultant and speaker fees (unbranded work) from Mead Johnson Nutrition (MJN) and was on the MJN Speakers Bureau. GS Lopes, Z Cao and M Tyagi are employees of Premier, Inc., and Premier, Inc. received payment from Kate Farms to conduct this research. The authors have no other competing interests or relevant affiliations with any organization or entity with the subject matter or materials discussed in the manuscript apart from those disclosed.

Writing disclosure
No writing assistance was used in the review, writing, or editing of this manuscript.

Ethical conduct of research
In accordance with the HIPAA Privacy Rule, disclosed data from the Premier Healthcare Database (PHD) are considered de-identified per US Code of Federal Regulations (CFR) 45 Part 164.514(b)(1) through the 'Expert Determination' method. The study was not considered human subjects research and it was determined to be exempt from IRB oversight by a central IRB under US CFR 45 Part 46.106(d)(4).

Data transparency statement
This manuscript reports the results of a real-world evidence study. The protocol was not publicly registered, and the raw data are not available due to contractual restrictions. A predefined analysis plan is available upon request.

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