Poster# 632

Reduced Cost of Care Associated with Switching Hypoallergenic Amino Acid-Based Formulas During 2022 US Nationwide Formula Shortage

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BACKGROUND

- In February 2022, during a nationwide pediatric formula shortage[1] it was necessary for some children to switch formulas, including amino acid-based formulas (AAFs).
- AAFs are hypoallergenic, provide complete nutrition and effective dietary management for cow's milk protein allergy, multiple food allergies, malabsorption, and related gastrointestinal and allergic conditions.
- While switching formulas can cause concerns related to potential intolerance, increased healthcare resource utilization (HCRU) and associated costs, limited data exist on the actual impact.

OBJECTIVE

- This study assessed multivariate costs related to HCRU in children that had to switch AAF during a nationwide formula shortage.

METHODS

- Retrospective study (June 2021 to April 2023) using nationally representative US claims data obtained from the Decision Resources Group Real World Evidence Data Repository.
- Inclusion criteria:
  - children ≤ 18 years of age in post-acute care,
  - history of receiving EleCare® or EleCare® Jr formulas (AAAF, Abbott Nutrition, US), and
  - switched to Alfamino® Infant or Alfamino® Junior formulas (NAAF, Nestlé HealthCare Nutrition, US)
- HCRU were defined as emergency department (ED), inpatient, outpatient, urgent care (UC), telemedicine and visits to other places of service.
- Outcomes compared:
  - 6-months pre-index (index defined as the date patients switched from AAAF to NAAF),
  - post-index (last record in study period at 1-, 3- and 6-months post-switch).
- Descriptive statistics were presented as mean [standard deviation (SD)] or N(%).
- Multivariate costs associated with HCRU after adjusting for age, sex, and pediatric comorbidity index (PCI) were compared in pre-index and post-index time periods.

RESULTS – TABLE 1

- 402 children (60% male; mean [SD] age 5.3 [4.7] years) from all US regions that switched from AAAF to NAAF.
- The most common comorbidities pre-switch were gastrointestinal (GI) conditions (51%), congenital conditions (49%) and developmental delays (27%).
- Of 355 patients (88%) with ≥1 comorbidity, the mean [SD] pediatric comorbidity index (PCI) score was 4.8 [3.4]. Nearly half of children (49%) had a PCI score of ≥4 .

RESULTS – TABLE 2

- Total mean adjusted costs associated with healthcare visits decreased significantly (p<0.001) from $679,401 (pre-switch) to $92,923, $244,305 and $416,063 at 1-, 3- and 6-months post-switch, respectively.
- Mean adjusted costs associated with outpatient visits decreased significantly (p<0.001) from $654,087 (pre-switch) to $89,460, $234,968 and $399,343 at 1-, 3- and 6-months post-switch, respectively.
- Significant cost reductions (p<0.001) were observed for inpatient, emergency department, urgent care, telemedicine and other visits at all post-index periods.

Table 1. Patient Characteristics (N=402)

	N (%)
Age †	
0-1 Year	49 (12)
1-3 Years	174 (43)
4-8 Years	102 (25)
9-13 Years	43 (11)
14-18 Years	34 (8)
Gender	
Male	243 (60)
Comorbidities	
GI Conditions	205 (51)
Congenital Malformations	198 (49)
Developmental Delays	107 (27)
Pediatric Comorbidity Index, Weighted Score ≥4	196 (49)

† Age was calculated at the index date

Transition of amino acid-based formulas during nationwide shortage was associated with a **significant reduction in cost of care**

Table 2. Multivariate Costs Comparisons By Different Place Of Service

Place of Service (visits)	Children (N= 402)						
	Pre-Index	1 Month Post-Index		3 Months Post-Index		6 Months Post-Index	
	value	value	p-Value*	value	p-Value*	value	p-Value*
Total	$ 679,401	$ 92,923	**<0.001**	$ 244,305	**<0.001**	$ 416,063	**<0.001**
Outpatient	$ 654,087	$ 89,460	**<0.001**	$ 234,968	**<0.001**	$ 399,343	**<0.001**
Inpatient	$ 13,498	$ 1,846	**<0.001**	$ 4,845	**<0.001**	$ 8,914	**<0.001**
Emergency Department	$ 2,358	$ 322	**<0.001**	$ 875	**<0.001**	$ 1,592	**<0.001**
Urgent Care	$ 1,176	$ 161	**<0.001**	$ 460	**<0.001**	$ 726	**<0.001**
Telemedicine	$ 1,349	$ 184	**<0.001**	$ 525	**<0.001**	$ 1,011	**<0.001**
Other	$ 6,933	$ 948	**<0.001**	$ 2,633	**<0.001**	$ 4,478	**<0.001**

Significant differences vs pre-index are shown in bold. *Multivariate t-Test; alpha=0.05 level of significance (pre-switch vs post-switch).

DISCUSSION

- GI intolerance and allergy symptoms were previously reported to have significantly decreased with a switch from AAAF to NAAF during the 2022 formula shortage, suggesting potential clinical benefits with a change from AAAF to NAAF.[2,3]
- Furthermore, this transition was previously associated with a significant reduction in healthcare visits[3]

CONCLUSIONS

- Significant reduction in cost of care was observed in children in the post-acute care setting who switched to NAAF from AAAF as a necessity during the 2022 nationwide formula shortage.
- These results build on previous research by showing significant reductions in costs associated to healthcare visits were maintained after adjusting for age, sex, and PCI score.

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References: [1] US FDA. Abbott Voluntarily Recalls Powder Formulas Manufactured at One Plant. Available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/abbott-voluntarily-recalls-powder-formulas-manufactured-one-plant. Accessed 30 May 2023; [2] Cekola P, et. al *JPGN* 2023;77(1): A 761, S552-553; [3] Desai A., et al. *JPGN* 2023;77(1): A 748, S538-539

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