

Study Summary: Health Economic Impact: Reduced cost of care with AAF Switch during formula shortage

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 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.

Objectives

This study assessed costs related to healthcare resource utilization (HCRU) in children that switched hypoallergenic amino acid-based formulas during the nationwide formula shortage.

Study Design

A retrospective study using nationally representative US claims data obtained from the Decision Resources Group Real World Evidence Data Repository (Clarivate), which covers 98% of US health plans, including medical and pharmacy claims.

Patient characteristics, comorbidities, HCRU and costs of care were assessed in children ≤ 18 years; with a history of receiving EleCare® or EleCare® Jr formulas (AAAF, Abbott Nutrition, US) and having switched to Alfamino® Infant or Alfamino® Junior formulas (NAAF, Nestlé HealthCare Nutrition, US); in post acute care settings between June 2021 and April 2023.

Methods

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), and 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

402 children (40% female; mean [standard deviation (SD)] age 5.3 [4.7] years) from all US regions, switched from AAUF to NAAF. The most common comorbidities pre-switch were GI conditions (51%), congenital conditions (49%) and developmental delays (27%).

Among 355 patients (88%) with ≥ 1 comorbidity, the mean (SD) pediatric comorbidity index (PCI) score was 4.8 (3.4).

(Table 1)

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

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 2)

Table 2. Multivariate Costs Comparisons By Different Place Of Service

Place of Service (visits)	Children (N= 402)						
	Pre-Index value	1 Month Post-Index value	p-Value*	3 Months Post-Index value	p-Value*	6 Months Post-Index 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 AAUF to NAAF during the 2022 formula shortage, suggesting potential clinical benefits with a change from AAUF to NAAF.^{2,3} Furthermore, this transition was previously associated with a significant reduction in healthcare visits, where all included children had significantly fewer ED, inpatient, UC, telemedicine, or other services at 1-month post-switch compared with pre-switch ($p < 0.05$), and significant reductions in mean total number of visits were also observed at 3-months post-switch (76 vs 45, $p < 0.001$).³

Conclusion

Significant reduction in cost of care was observed in children in the post-acute care setting who switched to NAAF (Alfamino® Infant or Junior by Nestle Healthcare Nutrition, US) from AAAF (Elecare® Infant and Junior by Abbott Nutrition, US) 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.

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

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

Study summary prepared by Nestlé Healthcare Nutrition.

The poster presented at AAAAI 2024 may be accessed online:

<https://www.nestlemedicalhub.com/sites/default/files/2024-06/AAAAI%2024%20Alfamino%20poster.pdf>

The complete abstract may be accessed online:

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