



BACKGROUND

- Amino acid-based (AA) formulas play a significant role in the dietary management of children with cow's milk protein allergy, multiple food allergies or malabsorptive conditions.
- In February 2022, after a voluntary recall of Abbott Nutrition's powdered infant formulas¹, the US faced prolonged formula shortages, including AA formulas of which there were limited alternatives for medically complex children with specialized nutritional needs.
- Switching to alternative formulas can cause concerns related to a potential impact on tolerance and other outcomes. Formula intolerance can lead to poor nutritional outcomes, increased healthcare resource utilization (HCRU) and economic impact.

OBJECTIVE

- This study assessed HCRU and associated costs in children that switched hypoallergenic AA formulas during a nationwide formula recall.

METHODS

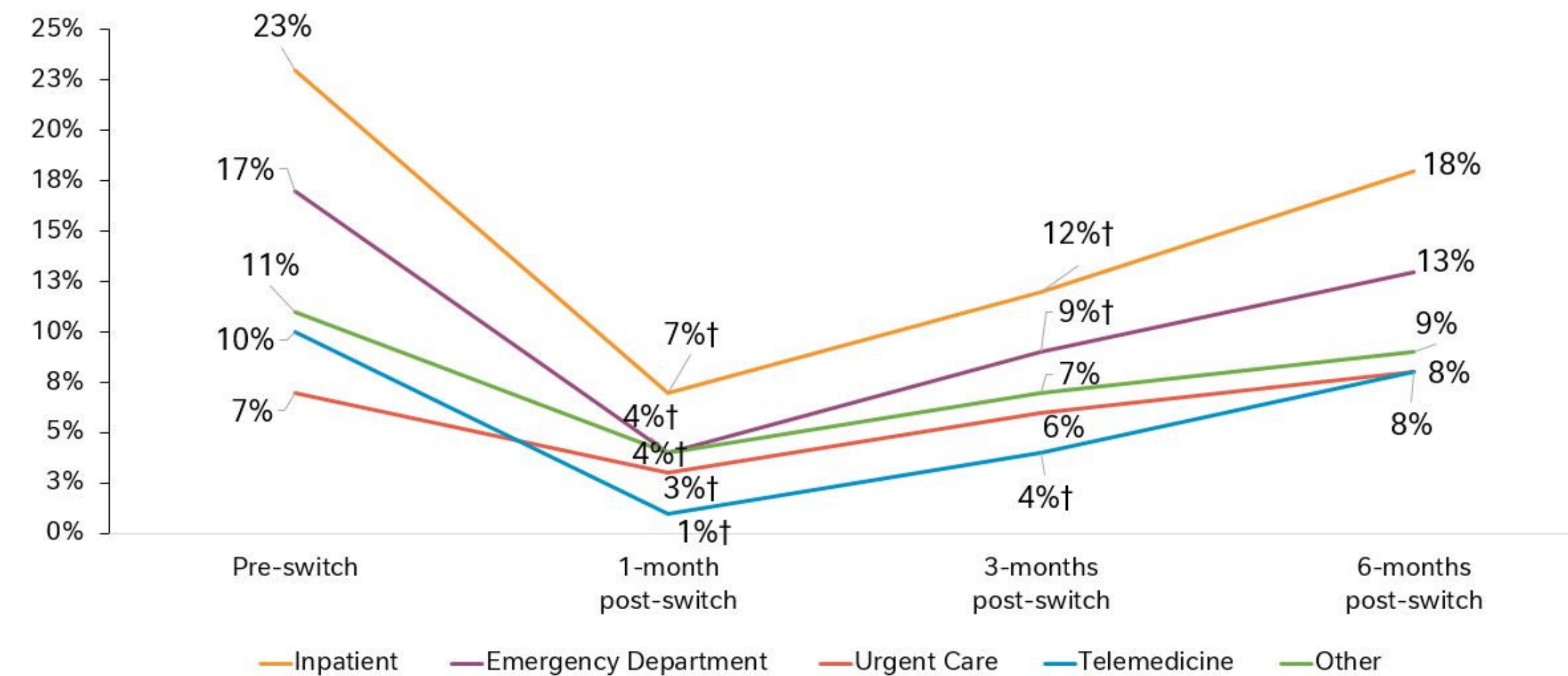
- Retrospective study (June 2021 to April 2023) using nationally representative US claims data obtained from the Decision Resources Group Real World Evidence Data Repository.
- Inclusion criteria were children (≤ 18 years of age) with a history of receiving EleCare[®] or EleCare[®] Jr formulas (AAAF, Abbott Nutrition, US) and having switched to Alfamino[®] Infant or Alfamino[®] Junior formulas (NAAF, Nestlé HealthCare Nutrition, US), in post-acute care.
- Patient characteristics, GI intolerance and allergy symptoms are previously reported.²
- HCRU and associated costs with emergency department (ED), inpatient, outpatient, urgent care (UC), telemedicine and other visits were captured.
- Outcomes were compared in 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).
- Results were presented as mean (SD) or N (%). Outcomes at pre-switch and post-switch periods were compared using Chi-square or t-tests.

RESULTS

- Study included 402 children (40% female; mean [standard deviation (SD)] age 5.3 [4.7] years) from all US regions, that switched from AAAF 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). Nearly half of children (49%) had a PCI score of ≥ 4 .

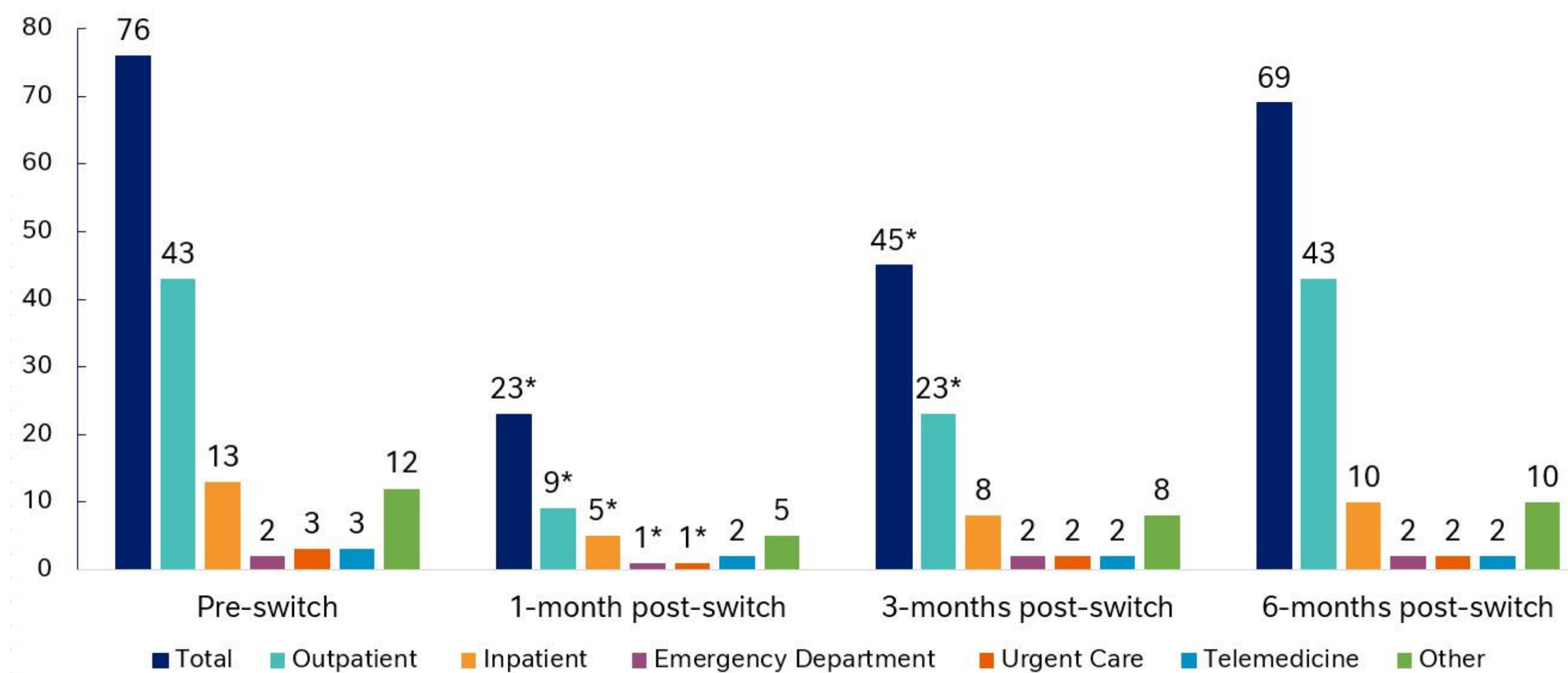
Transition of AA infant formulas during nationwide recall was associated with a significant reduction in healthcare visits and associated costs

FIGURE 1. PERCENTAGE OF PATIENTS REQUIRING CARE BY PLACE OF SERVICE



†Chi-square test; alpha=0.05 level of significance (pre-switch vs post-switch); Outpatient visits were 100% at each study timeperiod

FIGURE 2. MEAN NUMBER OF VISITS TO DIFFERENT PLACE OF SERVICE

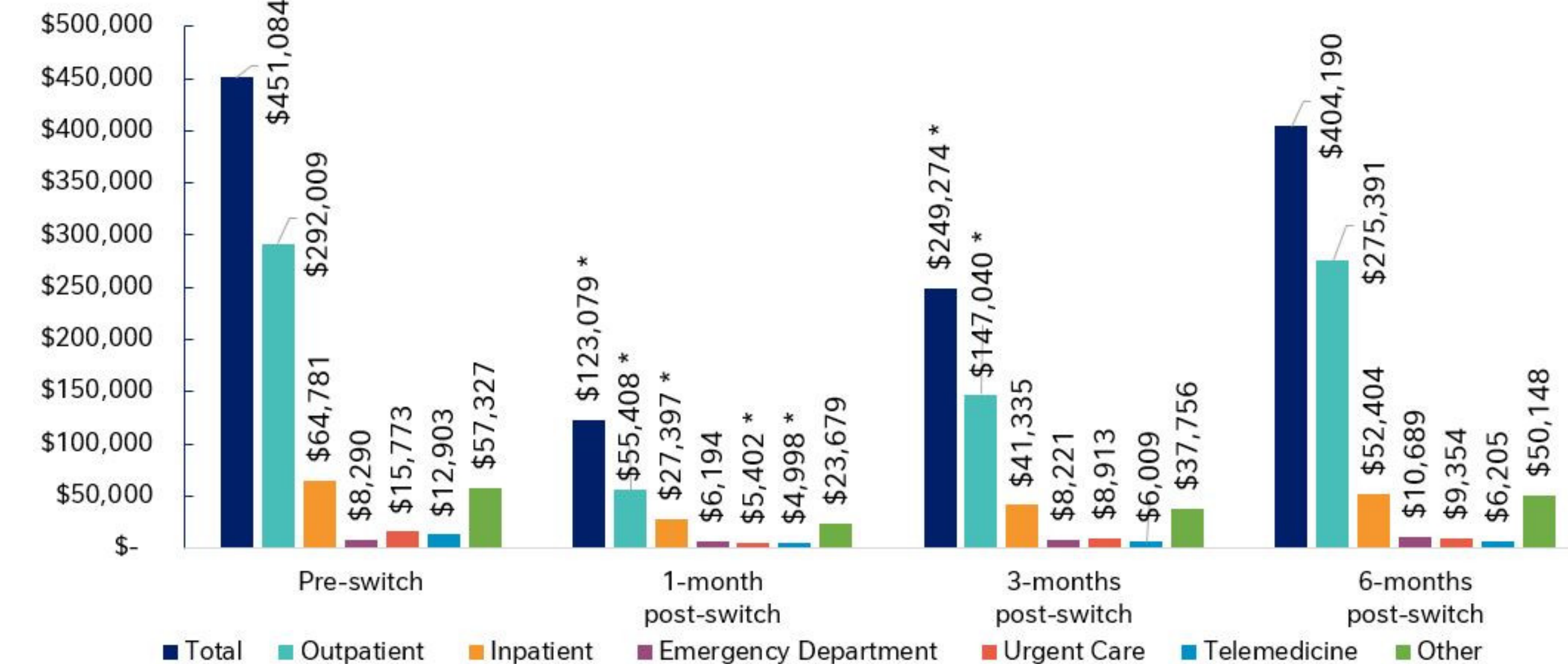


*t-Test; alpha=0.05 level of significance (pre-switch vs post-switch)

RESULTS

- As expected in this patient population, all children recorded outpatient visits at all study time-periods, although significantly fewer patients required ED, inpatient, UC, telemedicine, or other services at 1-month post-switch compared with pre-switch ($p < 0.05$). A significant reduction was maintained for ED, inpatient, and telemedicine visits at 3-months post-switch ($p < 0.001$) (Figure 1).
- Mean total visits ($p < 0.001$), outpatient ($p < 0.001$), inpatient ($p = 0.004$), ED ($p < 0.001$) and UC ($p = 0.014$) visits per patient were significantly lower at 1-month post-switch.
- Significant reductions in mean total number of visits and outpatient visits were also observed at 3-months post-switch ($p < 0.001$) (Figure 2).

FIGURE 3. COSTS COMPARISONS BY DIFFERENT PLACE OF SERVICE



*t-Test; alpha=0.05 level of significance (pre-switch vs post-switch)

- Total costs associated with these healthcare visits were \$123,079, \$249,274 and \$404,190 at 1-, 3- and 6-months post-switch, respectively; compared to \$451,084 pre-switch.
- Decreased HCRU resulted in significant ($p < 0.05$) reductions in total costs associated with post-acute care visits up to 3-months post-switch (Figure 3). There was no significant difference in visits and associated costs at 6-months post-switch.

CONCLUSIONS

- During the 2022 infant formula shortage, children who switched to NAAF had a safe and effective transition.
- Significant reductions in HCRU and associated costs up to 3 months were observed after switch to NAAF from AAAF.

REFERENCES

- (1) The White House. 2022. FACT SHEET: President Biden Announces Additional Steps to Address Infant Formula Shortage. May 12, 2022; <<https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/12/fact-sheet-president-biden-announces-additional-steps-to-address-infant-formula-shortage>>; (2) Cekola P et al. (2023) NASPGHAN. Oct 4-7;77(1), S552