

# BUDGET IMPACT OF MANAGING COW MILK ALLERGY IN AUSTRALIA

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## INTRODUCTION

- Cow milk allergy (CMA) is an adverse reaction to protein in cow's milk involving the immune system [1], with an estimated incidence of 2-3% in western industrialised countries [1-4]. This equates to 6,150 newly-diagnosed infants in Australia per year.
- Symptoms of CMA generally appear within the first few months of life. An infant can experience symptoms either immediately or up to several days after milk ingestion [2-4]. There are three types of allergic reactions to cow's milk:
  - Quick onset (immediate) in which infants develop symptoms within minutes to one hour after ingestion of small volumes of cow's milk. These are typically IgE mediated reactions. Symptoms may include urticaria, eczema, facial swelling, vomiting, diarrhoea and wheeze. Severe reactions may result in anaphylaxis.
  - Slow onset (intermediate) in which infants develop vomiting or diarrhoea several hours after ingestion of moderate amounts of cow's milk.
  - Late onset in which infants develop eczema, vomiting, bloody stools, colic, diarrhoea or irritability after 24 hours, or up to several days after ingestion of normal volumes of cow's milk. These are generally T-cell mediated reactions. Most children will outgrow this form of allergy by 2 years of age.
- Mothers of affected infants who are being breast-fed are advised to eliminate dairy products from their diet under the close supervision of a dietician. Clinical nutrition preparations for bottle-fed infants with CMA include soy-based milk, extensively hydrolysed formulas (eHF) and amino acid formulas (AAF), such as Neocate, which is a complete hypoallergenic infant formula.

- The objective of this study was to estimate the budget impact of current clinical practice for managing CMA in Australia, from the perspective of payers.

## METHODS

- A decision model was constructed, depicting the treatment patterns and associated resource use of managing 6,150 newly-diagnosed infants <1 year of age with CMA over the first six months following referral to a specialist. Within the model patients are stratified according to whether they present with:
  - Bloody stools
  - Gastrointestinal enteropathies
  - Failure to thrive
  - Eosinophilic oesophagitis
  - Atopic conditions
  - Acute IgE reactions
  - Severe IgE reactions
- The gaps in the published evidence base on healthcare resource use pertaining to managing CMA was estimated following a series of interviews with Australian paediatricians (n=15), paediatric gastroenterologists (n=7) and paediatric immunologists/allergists (n=8).
- National unit costs of resources at 2006/07 prices [5,6] were applied to the resource utilisation estimates in the model to estimate the healthcare costs and consequences associated with each treatment pathway over the first six months following referral to a specialist.

## RESULTS

- All affected infants are initially seen by their GP. Using information obtained from the published literature [7] and clinician interviews, it was estimated that GPs refer 50% of their CMA infants to a paediatrician, 32% to a paediatric gastroenterologist and 17% to a paediatric immunologist/allergist. Additionally, paediatricians subsequently refer 40% of their CMA referrals to a paediatric gastroenterologist (20%) and a paediatric immunologist/allergist (20%).
- Most breast-fed infants would continue to be breast-fed, although their mothers would be placed on a cow milk elimination diet. In some instances the infant would have their diet supplemented with eHF or AAF. The initial diet for bottle-fed infants is summarised in Figure 1.

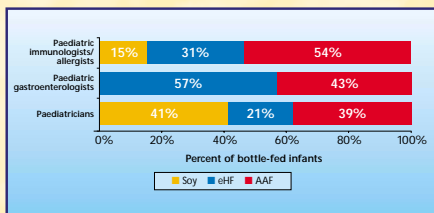


Figure 1: Initial diet for bottle-fed infants, stratified by clinical specialty.

- It was assumed that 9% of patients would be intolerant to soy and 29% would be intolerant to eHF, based on an epidemiological study we have undertaken among 1,000 infants with CMA in the community in the UK [8].
- CMA sufferers who are intolerant to soy have an 80% and 20% chance of being switched to an eHF and AAF respectively by paediatricians. In contrast, paediatric gastroenterologists would generally switch all patients who are intolerant to soy to an eHF, whereas paediatric immunologists/allergists would generally switch 85% of patients to an eHF and 15% to an AAF. All clinicians would switch patients to an AAF if they are intolerant to an eHF.
- The six-monthly healthcare cost following the initial specialist visit was estimated to be \$1,150 (95% CI: \$966; \$1,550) per patient. However, this varied according to the presenting symptoms (Figure 2).
- The taken time for a CMA sufferer to be put on an appropriate diet and achieve symptom resolution was estimated to be 12 (95% CI: 6; 19) days. However, this varied according to the presenting symptoms, ranging from as little as 7 days for those presenting with bloody stools to 25 days for those presenting with atopic conditions.

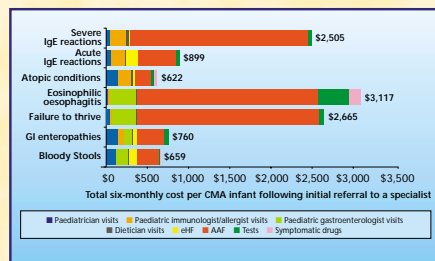


Figure 2: Distribution of the six-monthly healthcare costs stratified by presenting symptoms.

- Managing 6,150 newly-diagnosed infants with CMA over the first six months following referral to a specialist was estimated to result in 6,500 visits to paediatricians, 6,000 visits to paediatric gastroenterologists and 4,500 visits to paediatric immunologist/allergists.
- The six-monthly cost of managing 6,150 newly-diagnosed infants with CMA following referral to a specialist was estimated to be \$6.5 million, of which the cost of clinical nutrition preparations was found to be the primary cost driver (Figure 3).

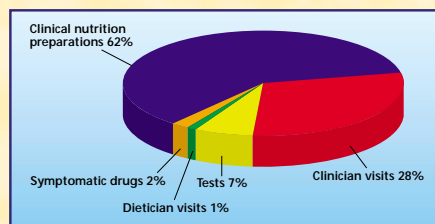


Figure 3: Distribution of the six-monthly healthcare costs of treating 6,150 newly-diagnosed infants with CMA following referral to a specialist.

- If those patients with suspected eosinophilic oesophagitis or failure to thrive are initially referred to a paediatric gastroenterologist by their GP and all other patients are initially referred to a paediatrician and all patients are initially treated with an AAF (the AAF scenario), then the six-monthly cost of managing 6,150 newly-diagnosed infants with CMA following referral is expected to be \$7.1 million.

- Additionally, managing patients according to the AAF scenario is expected to result in 10,000 additional visits to paediatricians, but 2,200 fewer visits to paediatric gastroenterologists and 2,000 fewer visits to paediatric immunologists/allergists compared to current clinical practice (Figure 4).

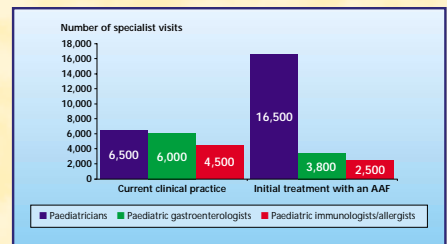


Figure 4: Number of six-monthly specialist visits associated with treating an annual cohort of 6,150 newly-diagnosed infants with CMA.

- Hence, treating all patients according to the AAF scenario instead of current practice would increase the six-monthly cost of managing 6,150 newly-diagnosed infants with CMA following referral to a specialist by \$0.6 million, but result in 4,200 fewer visits to hospital-based paediatric gastroenterologists and immunologists/allergists (see Table 1).

	Estimates for a cohort of 6,150 newly-diagnosed infants with CMA over 6 months following referral to a specialist and managed according to:		
	Current clinical practice	AAF scenario	Difference between the AAF scenario and clinical practice
Total cost	\$6.5m	\$7.1m	\$0.6m
Total number of visits to paediatricians	6,500	16,500	10,000
Total number of visits to paediatric gastroenterologists	6,000	3,800	-2,200
Total number of visits to paediatric immunologists/allergists	4,500	2,500	-2,000

Table 1: Net resource implications of switching from current clinical practice to the AAF scenario.

- Using the AAF scenario is expected to reduce the length of time for a CMA sufferer to be put on an appropriate diet and achieve symptom resolution. This was estimated to be a mean 3 (95% CI: 1; 5) days, ranging from as little as 1 day for those presenting with bloody stools to 7 days for those presenting with atopic conditions.

## DISCUSSION

- There are ~440 consultant general paediatricians in Australia and only ~30 consultant paediatric gastroenterologists and ~20 consultant paediatric immunologists/allergists [9].
- Waiting times to see a paediatrician is only a matter of days, whereas it's 3-6 months to see a paediatric gastroenterologist and 4-12 months to see a paediatric immunologist/allergist. There were only two consultant paediatric immunologists/allergists in Queensland and waiting times to see them was typically >12 months. Hence, any treatment strategy that can reduce the number of patient visits to these two clinical specialties has the potential to increase the efficiency of paediatric healthcare delivery in publicly funded hospitals in Australia.
- There are approximately 2,000 registered dietitians in Australia [10]. However, less than 200 specialise in infant feeding, paediatrics, or maternal health [11]. Additionally, according to our interviewees, mothers of affected infants would only see a dietician as part of a clinic visit to 15% of paediatric gastroenterologists and 40% of paediatric immunologists/allergists.
- Our model suggests that treating all 6,150 new CMA sufferers according to the AAF scenario instead of current practice would:
  - Increase the six-monthly cost of managing this annual cohort by \$0.6 million.
  - Increase the workload of 440 general paediatricians by some 10,000 additional visits.
  - Result in 4,200 fewer visits to the 50 consultant paediatricians specialising in gastroenterology and immunology/allergy in Australia's paediatric departments.

## CONCLUSION

Using an AAF as the initial treatment for CMA can potentially release limited hospital resources for alternative use within the Australian paediatric healthcare system.

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