CLINICAL AUDIT

Appropriate prescribing of specialised **infant formula** for **cows' milk protein allergy**

Valid to December 2019

bpac nz
better medicine

Background

Specialised infant formulae subsidised on the pharmaceutical schedule, i.e. partially or extensively hydrolysed formula, amino-acid formula, are only appropriate for infants with cows' milk protein allergy who are unable to be breast fed.

Cows' milk protein allergy (CMPA) is an immunologically mediated adverse reaction to cows' milk protein, with a prevalence of approximately 2% in infants aged under two years. Allergic reaction to cows' milk protein can be IgE or non-IgE mediated, and the spectrum of reactions ranges from immediate anaphylaxis and food allergy reactions to delayed effects such as atopic eczema. Diagnosis can be challenging, and it is generally recommended that children with suspected CMPA are referred to a paediatrician for assessment.

In New Zealand, more expensive and last-line amino-acid formula products, e.g. Elecare; Neocate; Vivonex, are being prescribed as an early option. Pharmaceutical dispensing data indicates that many infants with CMPA are prescribed an amino acid formula without an initial trial of an extensively hydrolysed formula (or soy if the infant is aged more than six months).

The use of amino acid formula as an early option is inconsistent with international guidelines, which suggest that only around 5–10% of infants with CMPA require an amino acid formula. As amino acid formula is also significantly more expensive than other options (approximately five to six times the cost of extensively hydrolysed formula per 100 mL), the continuing high uptake of amino acid formula in New Zealand is unsustainable.

Choosing the right formula

The age of an infant and the clinical characteristics of the CMPA should determine the type of infant formula most appropriate as an initial option. If CMPA is likely, an elimination challenge can be initiated. Cows' milk should first be eliminated from the mother's diet in infants who are breastfed. If this is not possible, or for infants who are not breastfed, the first-line choice of formula is extensively hydrolysed formula, e.g. Pepti-Junior. Soy formula can be trialled in infants aged over six months as an alternative first-line option.

Some infants with significant gastrointestinal symptoms that do not improve after this trial may benefit from a further trial using amino acid-based formula. These recommendations are summarised in Table 1 below.

If none of these formulae are tolerated, an elemental feed may be trialled; these would be the most costly option, however. Other formulas such as goats'-milk based, lactose-free and partially hydrolysed formula are not suitable for infants with CMPA.

When to choose amino acid formula

For the majority of infants with CMPA, extensively hydrolysed formula, (or soy if the infant is aged more than six months) should be considered first. Amino acid formula should only be considered as a first line-option in infants with CMPA following anaphylaxis or a confirmed diagnosis of eosinophilic oesophagitis. ESPGHAN* 2012 estimates that approximately 10% of infants with CMPA do not tolerate extensively hydrolysed formula, and amino acid formula would therefore be required.[2]

* European Society for Paediatric Gastroenterology, Hepatology and Nutrition

Encouraging re-challenge of other options

Children with CMPA may develop tolerance to cows' milk as they get older. According to ESPGHAN 2012, approximately 50% of affected children develop tolerance by age one year, more than 75% by the age of three years, and greater than 90% are tolerant at age six years.[2]

Regular re-challenge is recommended to avoid continuing with an unnecessarily restrictive diet. The optimal interval for re-challenge is dependent on several factors including age, severity of symptoms and evidence of an immunological reaction to CMPA.

References

1. Kemp AS, Hill D, Allen K, et al. Guidelines for the use of infant formulas to treat cows' milk protein allergy; An Australian consensus panel opinion. Med J Aust 2008;188(2):109–112.
2. Koletzko S, Niggemann B, Arato A et al. Diagnostic approach and management of cow's-milk protein allergy in infants and children: ESPGHAN GI committee practical guidelines. JPGN 2012;55:221-9.

Table 1: Syndromes associated with cows' milk protein allergy and appropriate choice of formula feed (adapted from Kemp et al, 2008).[1]

		Choice of Formula		
Syndrome	**Onset of reaction**	**First Choice**	**Second** (if first not tolerated)	**Third** (if second not tolerated)
Immediate Reaction				
Immediate Food Allergy	< 1 hour	Extensively hydrolysed formula (< 6 months) Soy (> 6 months)	Amino acid formula Extensively hydrolysed formula	 Amino acid formula
Anaphylaxis	< 1 hour	Amino acid formula with urgent referral		
Food protein-induced enterocolitis syndrome	1 – 3 hours	Extensively hydrolysed formula	Amino acid formula	
Delayed reaction				
Atopic eczema	Hours to days	Extensively hydrolysed formula (< 6 months or > 6 months with failure to thrive) Soy (> 6 months, no failure to thrive)	Amino acid formula Extensively hydrolysed formula	 Amino acid formula
Gastrointestinal syndromes: GORD, allergic eosinophilic gastroenteritis, food protein-induced enteropathy, constipation, severe irritability (colic)	Hours to days	Extensively hydrolysed formula (< 6 months or > 6 months with failure to thrive) Soy (> 6 months, no failure to thrive)	Amino acid formula Extensively hydrolysed formula	 Amino acid formula
Food protein-induced proctocolitis	> 24 hours	Extensively hydrolysed formula	Amino acid formula	
Eosinophilc oesophagitis in infants	Days to weeks	Amino acid formula		

Audit plan

Summary

Identify infants in the practice who have been prescribed amino acid formula in the previous twelve months. Assess whether they have documented evidence of an indication for amino acid formula, whether they have previously trialled alternative formula and whether they have attempted re-challenge

Criteria for a positive outcome

A patient is considered a "positive outcome" for the purposes of the audit if they have been prescribed amino acid formula, and have:

1. A documented diagnosis of CMPA
2. Evidence in their notes that they have an indication for amino acid formula: anaphylaxis, eosinophilic oesophagitis or unable to tolerate extensively hydrolysed formula
3. Evidence in their notes that they have been re-challenged on cow's milk, or a re-challenge is planned

Audit standards

A recommended standard would be for 90% of infants prescribed amino acid formula to have a valid indication for receiving this formula, if appropriate have previously tried extensively hydrolysed formula and re-challenge attempted or planned. There should ideally be an improvement in the achieved percentage between the first and second audit cycles.

Audit Data

Eligible people

Any infant that has been prescribed amino acid formula.

Identifying patients

You will need to have a system in place that allows you to identify eligible patients. Many practices will be able to identify patients by running a 'query' through their PMS system. We suggest you identify all infants who have had a prescription for amino acid infant formula in the previous 12 months.

Sample size

The number of eligible patients will vary according to your practice demographic. It is unlikely that a large number of results will be returned, but if so, take a random sample of 20 – 30 patients whose notes you will audit.

Data analysis

Use the data sheets provided to record your first and second cycles. In each data set, calculate the number of "positives" by dividing the total number of infants prescribed amino acid formula by the number of "Yes" results in the final column.

The recording of the indication should be used to help evaluate future practice and identify any areas of infant formula prescription or re-challenging that could be improved within the practice.

Undertaking a second cycle

In addition to regular reviews of progress, a second audit cycle should be completed in order to quantify progress on closing the gaps in performance.

It is recommended that the second cycle be completed within 12 months of completing the first cycle. The second cycle should begin at the data collection stage. Following the completion of the second cycle it is recommended that practitioners complete the remainder of the summary sheet.

Identifying opportunities for improving medical practice

Taking action

The first step to improving medical practice is to identify where gaps exist between expected and actual performance and then to decide how to change practice.

Decide on a set of priorities for change and develop an action plan to implement any changes.

It may be useful to consider the following points when developing a plan for action

Problem solving process

- What is the problem or underlying problem(s)?
- Change it to an aim
- What are the solutions or options?
- What are the barriers?
- How can you overcome them?

Overcoming barriers to promote change

- What is achievable – find out what the external pressures on the practice are and discuss ways of dealing with them in the practice setting
- Identify the barriers
- Develop a priority list
- Choose one or two achievable goals

Effective interventions

- No single strategy or intervention is more effective than another, and sometimes a variety of methods are needed to bring about lasting change
- Interventions should be directed at existing barriers or problems, knowledge, skills and attitudes, as well as performance and behaviour

Review

Monitoring change and progress

Expert guidelines recommend regular monitoring of growth for children with food allergy in combination with nutrition counselling. There are, however, no clear guidelines on when re-evaluation of CMPA or other allergies should occur. In practice re-trialling allergenic foods depends on clinical judgement, taking into consideration the severity of symptoms, the age of the child and other medical and social circumstances. For infants with anaphylaxis, food challenges should be performed in hospital.

There are also no clear guidelines on when an infant with CMPA should be weaned off a formula and when consideration should be given to changing to a less hypoallergenic formula, e.g. amino acid formula, to extensively hydrolysed formula, or extensively hydrolysed formula to soy-based, or for how long the effect of a switch should be evaluated for. However, given that most CMPA syndromes resolve over time, the requirement for on-going formula should be regularly reviewed.

Re-assessment should be on a case by case basis and it may be appropriate to consult with a paediatrician or dietitian with expertise in the management of CMPA for further advice.

The Royal New Zealand College of General Practitioners

Claiming MOPS credits

This audit has been endorsed by the RNZCGP as a CQI Activity for allocation of MOPS credits; **10 credits** for a first cycle and **10 credits** for a second cycle. General practitioners taking part in this audit can claim credits in accordance with the current MOPS programme. This status will remain in place until **December, 2019**.

To claim points go to the RNZCGP website:
www.rnzcgp.org.nz

Record your completion of the audit on the **MOPS Online credit summary**, under the **Continuous Quality Improvement/Audit of Medical Practice** section. From the drop down menu, select the audit from the list (2014 – 2017 triennium) or select "Approved practice/PHO audit" and record the audit name in "Notes", the audit date and 10 credits. 'MOPS online' can be completed by vocationally registered doctors or 'CPD online' for general registrants. Alternatively MOPS participants can indicate completion of the audit on the annual credit summary sheet which is available from the College on request.

As the RNZCGP frequently audit claims you should retain the following documentation, in order to provide adequate evidence of participation in this audit:

1. A summary of the data collected
2. An Audit of Medical Practice (CQI Activity) summary sheet (included as Appendix 1).

bpacnz
10 George Street
PO Box 6032, Dunedin
phone 03 477 5418
free fax 0800 bpac nz

bpac nz better medicine

www.bpac.org.nz/audits

Data sheet – cycle 1

Prescribing of specialised infant formula for cows' milk protein allergy

Patient	A	B	C	D	E	
	Is a confirmed diagnosis of CMPA recorded in the notes? **Y/N**	Was extensively hydrolysed formula tried first and found intolerable? **Y/N**	Does the patient have documented anaphylaxis? **Y/N**	Does the patient have eosinophillic oesophagitis? **Y/N**	Is there evidence in the notes that a re-challenge is planned or has occurred? **Y/N**	**Positive result?** ("Yes" in A + "Yes" in B, C or D + "Yes" in E)
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
					Total % of audited patients with a positive result	

Please retain this sheet for your records to provide evidence of participation in this audit.

Data sheet – cycle 2

Prescribing of specialised infant formula for cows' milk protein allergy

Patient	A Is a confirmed diagnosis of CMPA recorded in the notes? **Y/N**	B Was extensively hydrolysed formula tried first and found intolerable? **Y/N**	C Does the patient have documented anaphylaxis? **Y/N**	D Does the patient have eosinophillic oesophagitis? **Y/N**	E Is there evidence in the notes that a re-challenge is planned or has occurred? **Y/N**	**Positive result?** ("Yes" in A + "Yes" in B, C or D + "Yes" in E)
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
					Total % of audited patients with a positive result	

Please retain this sheet for your records to provide evidence of participation in this audit.

The Royal New Zealand College of General Practitioners

APPENDIX 1

Audit of Medical Practice (CQI activity) Summary Sheet

Topic:	**Appropriate prescribing of specialised infant formula for cows' milk protein allergy**
The activity was designed by (name of organisation if relevant):	**Bpac^{nz}**
Doctors Name:	

FIRST CYCLE

DATA:	Date of data collection:

CHECK:	Describe any areas targeted for improvement as a result of analysing the data collected.

ACTION:	Describe how these improvements will be implemented.

MONITOR:	Describe how well the process is working. When will you undertake a second cycle?

Please retain this sheet for your records to provide evidence of participation in this audit.

SECOND CYCLE

DATA:	Date of data collection:

CHECK:	Describe any areas targeted for improvement as a result of analysing the data collected.

ACTION:	Describe how these improvements will be implemented.

MONITOR:	Describe how well the process is working.

COMMENTS:	

Please retain this sheet for your records to provide evidence of participation in this audit.