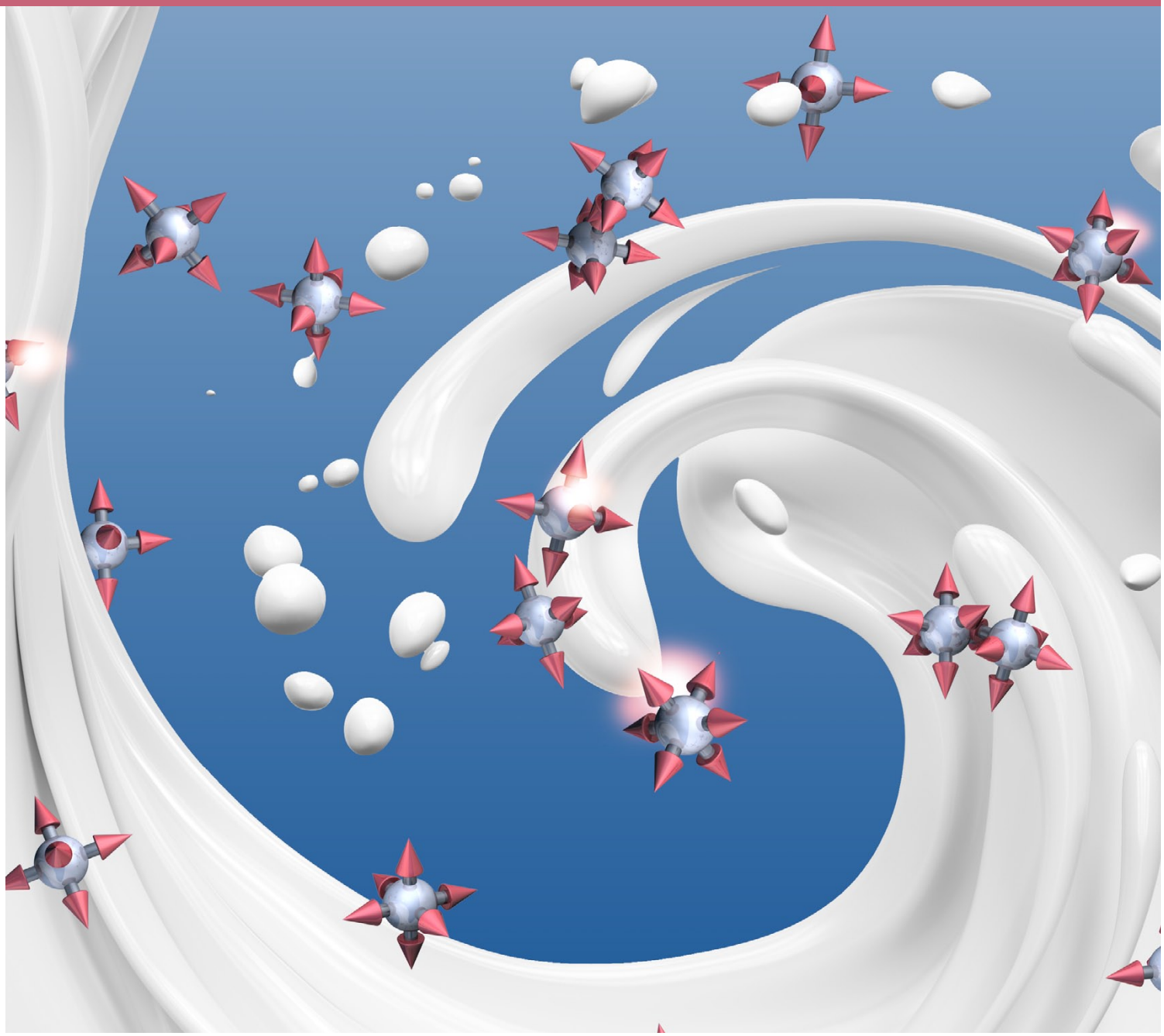
CLINICAL AUDIT

Appropriate prescribing of **amino acid formula in infants with cows' milk protein allergy**



Valid to December 2024

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This audit helps health professionals in primary care identify infants who have been prescribed amino acid formula to assess whether this is appropriate and to ensure that they have attempted re-challenge or an appointment has been scheduled with a specialist if they will be aged over 12 months at their next Special Authority renewal.

Background

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

CMPA is an immunologically mediated adverse reaction to cows' milk protein, with a prevalence of approximately 2–3% in children before the age of three years. Allergic reaction to cows' milk protein can be IgE or non-IgE mediated, and there is a wide spectrum of possible reactions, ranging from mild gastrointestinal manifestations through to anaphylaxis. Diagnosis can be challenging, and it is generally recommended that children with suspected CMPA are referred to a paediatrician for assessment.

For further information on diagnosing CMPA, see: "Managing cows' milk protein allergy in infants" see: **www.bpac.org.nz/2019/cmpa.aspx**

Despite being highly tolerable, AAF is approximately three times more expensive to produce than eHF, and eHF will be sufficiently hypoallergenic in the majority of infants with CMPA.[1, 2] In New Zealand, this more expensive and "last-line" AAF is currently being overprescribed. The expected prescribing ratio for eHF to AAF should be approximately 3:1, pharmaceutical dispensing data from 2019 indicates that under the current subsidy criteria it is an almost 1:1 ratio.

Choosing the right formula

The age of the infant and the clinical characteristics of the CMPA should determine the type of formula most appropriate as an initial option. However, in the majority of cases, eHF is recommended as the first-line choice of infant formula for CMPA (Table 1).[4, 5] CMPA symptoms resolve in approximately 90% of infants that transition to eHF.[6] Soy-based formula is not funded in New Zealand but is comparable in price to standard cows' milk formula.

Other formulas such as goats'-milk based, lactose-free and partially hydrolysed formula are not suitable for infants with CMPA, and "milk beverages", such as rice or almond milk, are nutritionally inadequate and therefore not recommended as a substitute for breast or cows' milk.[6]

Table 1: Appropriate choice of formula feed in infants with CMPA syndromes in primary care.[4,7]

Syndrome	First choice	Second choice (if first not tolerated)
IgE		
Acute allergic reaction (non-anaphylactic)	eHF or soy* (if aged >6 months)	eHF (if soy was trialled first) or AAF†
Anaphylaxis	AAF (with urgent referral)	–
Mixed immune response (IgE- and non-IgE)		
Atopic dermatitis (eczema)	eHF or soy* (if aged >6 months)	eHF (if soy was trialled first) or AAF†
Non-IgE		
Eosinophilic oesophagitis	AAF	–
Food protein-induced enterocolitis syndrome	eHF	AAF
Food protein-induced proctocolitis	eHF	AAF
Gastrointestinal syndromes, GORD, allergic eosinophilic gastroenteritis, food protein-induced enteropathy, constipation, severe irritability (colic)	eHF or soy* (if aged >6 months)	eHF (if soy was trialled first) or AAF†

* Soy formula is not funded but may be used as an alternative to eHF for some infants with mild CMPA symptoms.

† eHF must first be trialled first for 2–4 weeks and found to be inappropriate due to severe intolerance, allergy or malabsorption.

AAF, amino acid formula; eHF, extensively hydrolysed formula; GORD, gastro-oesophageal reflux disease

When to choose amino acid formula (AAF)

For the majority of infants with CMPA, eHF (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 and:[8]

- Anaphylaxis
- Eosinophilic esophagitis
- Severe intolerance, allergy or malabsorption on eHF
- Growth faltering, particularly with multisystem involvement and multiple food exclusions

It is estimated that only 10% of infants with CMPA will require AAF.[5]

Encouraging re-challenge of other options

In most cases, CMPA is a self-limiting condition; resolving between the ages of one to three years in many children.[3] In addition, most children have a reduced requirement for milk once they are aged over 12 months and should be able to progress to solids as their primary source of nutrition, meaning that dependence on AAF can be avoided or reduced. Therefore, in the long-term it is important to regularly review and consider a cows' milk challenge to avoid unnecessary dietary restriction.[4,5] This is required for AAF Special Authority subsidy renewals (which are valid for six months), in addition to trialling other non-AAF formula options, i.e. eHF and soy. The optimal interval for re-challenge is dependent on several factors including age, severity of symptoms and evidence of an immunological reaction to CMPA.

From 1 July, 2020, the existing Special Authority approval for AAF will be replaced, and applications for children 12 months of age and older will need to be made by a paediatrician, paediatric gastroenterologist or paediatric immunologist, or by a dietician on the recommendation of one of these specialists. Primary care will now need to ensure children likely to still be using AAF and who will be aged 12 months at their next renewal are referred to a dietician, paediatrician, paediatric gastroenterologist or paediatric immunologist before this time.

Audit plan

Summary

Identify infants in the practice who have been prescribed AAF in the previous twelve months. Assess whether they have documented evidence of an indication for AAF, whether they have previously trialled another formula, and whether they have attempted re-challenge or an appointment has been scheduled with a specialist if they will be aged over 12 months at their next Special Authority renewal.

Criteria for a positive outcome

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

1. A documented diagnosis of CMPA
2. Evidence in their notes that they have an indication for AAF: anaphylaxis, eosinophilic oesophagitis, or eHF is inappropriate due to severe intolerance, allergy or malabsorption
3. Evidence in their notes that they have been re-challenged on cows' milk, a re-challenge is planned, or an appointment has been scheduled with a specialist if they will be aged over 12 months at their next renewal

Audit standards

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

References

1. PHARMAC. Proposal to change access to amino acid infant formula. Available from: https://www.pharmac.govt.nz/news/consultation-2019-07-16-infant-formula/ (Accessed Nov, 2019).
2. Special Foods Sub committee of the Pharmacology and Therapeutics Advisory Committee (PTAC). Minutes of the meeting held 22 July 2015. Available from: https://www.pharmac.govt.nz/assets/ptac-special-foods-subcommittee-minutes-2015-07.pdf (Accessed Nov, 2019).
3. Flom JD, Sicherer SH. Epidemiology of cow's milk allergy. Nutrients 2019;11:1051. doi:10.3390/nu11051051
4. Venter C, Brown T, Meyer R, et al. Better recognition, diagnosis and management of non-IgE-mediated cow's milk allergy in infancy: iMAP—an international interpretation of the MAP (Milk Allergy in Primary Care) guideline. Clin Transl Allergy 2017;7:26. doi:10.1186/s13601-017-0162-y
5. Fox A, Brown T, Walsh J, et al. An update to the Milk Allergy in Primary Care guideline. Clin Transl Allergy 2019;9:40. doi:10.1186/s13601-019-0281-8
6. Lifschitz C, Szajewska H. Cow's milk allergy: evidence-based diagnosis and management for the practitioner. Eur J Pediatr 2015;174:141–50. doi:10.1007/s00431-014-2422-3
7. Vandenplas Y. Prevention and management of cow's milk allergy in non-exclusively breastfed infants. Nutrients 2017;9:731. doi:10.3390/nu9070731
8. Meyer R, Groetch M, Venter C. When should infants with cow's milk protein allergy use an amino acid formula? A practical guide. The Journal of Allergy and Clinical Immunology: In Practice 2018;6:383–99. doi:10.1016/j.jaip.2017.09.003

Audit data

Eligible people

Any infant that has been prescribed AAF.

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 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 AAF 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.

Identifying opportunities for Audit of Medical Practice

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

Once a set of priorities for change have been decided on, an action plan should be developed to implement any changes.

Taking action

It may be useful to consider the following points when developing a plan for action (RNZCGP 2002).

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

- Identifying barriers can provide a basis for change
- What is achievable – find out what the external pressures on the practice are and discuss ways of wdealing 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

It is important to review the action plan developed previously at regular intervals. It may be helpful to review the following questions:

- Is the process working?
- Are the goals for improvement being achieved?
- Are the goals still appropriate?
- Do you need to develop new tools to achieve the goals you have set?

Following the completion of the first cycle, it is recommended that the doctor completes the first part of the Audit of Medical Practice summary sheet (Appendix 1).

Undertaking a second cycle

In addition to regular reviews of progress with the practice team, 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 practices complete the remainder of the Audit of Medical Practice summary sheet.

The Royal New Zealand College of General Practitioners

Claiming credits for Continuing Professional Development (CPD)

This audit has been endorsed by the RNZCGP as an Audit of Medical Practice activity (previously known as Continuous Quality Improvement – CQI) for allocation of CPD 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 CPD programme.

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

Record your completion of the audit on the **CPD Online Dashboard**, under the **Audit of Medical Practice section**. From the drop down menu select "**Approved practice/PHO audit**" and record the audit name.

General practitioners are encouraged to discuss the outcomes of the audit with their peer group or practice.

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).

The Royal New Zealand College of General Practitioners
Te Whare Tohu Rata o Aotearoa
Endorsed CPD Activity

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bpac nz
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www.bpac.org.nz/audits

Data sheet – cycle 1

Amino acid formula in infants with cows' milk protein allergy

Patient prescribed AAF	A Patient has documented diagnosis of CMPA?	B Evidence that patient has an indication for AAF: anaphylaxis, eosinophilic oesophagitis? ***or*** eHF is inappropriate due to severe intolerance, allergy or malabsorption?	C Evidence that patient has been re-challenged on cows' milk, or a re-challenge is planned? ***or*** an appointment has been scheduled with a specialist if they will be aged over 12 months at their next renewal?	D **Positive outcome?** tick in column A + B + C
	✔ / ✘	✔ / ✘	✔ / ✘	✔ / ✘
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			Total:	

AUDIT RESULT: Total column D **divided** by number of patients audited × 100 = **%**

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

Data sheet – cycle 2

Amino acid formula in infants with cows' milk protein allergy

Patient prescribed AAF	A Patient has documented diagnosis of CMPA?	B Evidence that patient has an indication for AAF: anaphylaxis, eosinophilic oesophagitis? ***or*** eHF is inappropriate due to severe intolerance, allergy or malabsorption?	C Evidence that patient has been re-challenged on cows' milk, or a re-challenge is planned? ***or*** an appointment has been scheduled with a specialist if they will be aged over 12 months at their next renewal?	D **Positive outcome?** tick in column A + B + C
	✔ / ✘	✔ / ✘	✔ / ✘	✔ / ✘
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			Total:	

AUDIT RESULT: Total column D **divided** by number of patients audited × 100 = **%**

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

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APPENDIX 1

SUMMARY SHEET
Audit of medical practice (CQI activity)

Topic:
Appropriate prescribing of amino acid formula in infants with cows' milk protein allergy

Date:

Activity designed by (name of organisation, if relevant):
Bpac^{nz}

Doctor's name:

Results discussed with peer group or colleagues?
☐ Yes ☐ No

Date:

FIRST CYCLE

DATA: Date of data collection:

CHECK: Describe any areas targeted for improvement as a result of analysing the data collected. (If the findings have any implications for health equity, please include this.)

ACTION: Describe how these improvements will be implemented.

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

AUGUST 2016

SECOND CYCLE

DATA: Date of data collection:

CHECK: Describe any areas targeted for improvement as a result of analysing the data collected. (If the findings have any implications for health equity, please include this.)

ACTION: Describe how these improvements will be implemented.

MONITOR: Describe how well the process is working.

COMMENTS:

AUGUST 2016