Re: Position statement on the use of amino-acid based formula (AAF) - A response from PIID subspecialty of Hong Kong College of Paediatricians towards direct-to-consumer advertising of a special infant formula.

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Background:

There is an increasing prevalence of food allergy in Asia populations including mainland China and Hong Kong. This upsurge results in an unmet need for improved allergy health services in our region. Amino-acid based formulae (AAF) has been traditionally used as a treatment formula for cow's milk allergy. However, AAF is reported to be useful as a form of elimination diet for treating different forms of food hypersensitivity and other immunologically-based gastrointestinal conditions.

In children, one of the most difficult areas is food allergy-induced eczema. Due to the long waiting time for allergy consultation, some experts advocate that an empirical trial of AAF for 2-4 weeks may help in supporting the diagnosis of cow's milk allergy and relieving allergic symptoms. Nonetheless, it is highly debatable whether such proposal justifies such direct consumer marketing strategy.

In general, in our clinical practice, AAF (Neocate for example) are clearly indicated as special formulas that are prescribed by paediatric specialists and clinical dietitians. For families that cannot afford this expensive dietetic treatment, we can cover it by disability allowance or other social security subsidy. In places like Australia, families will be reimbursed through insurance for such specialised treatment when specialists endorsed the use of AAF in their children.

Our views:

1) AAF is a special infant formula with market-price being 4-5 times more expensive than usual infant formulae. Direct-to-consumer advertising should be discouraged from both consumer and professional perspectives.

2) All national infant feeding guidelines do not recommend AAF for primary allergy prevention or as a starter formula in children weaning from breast feeding.

3) In infants at risk for allergy (e.g. strong family history), partially hydrolysed formula is recommended as a supplement if breast feeding alone is deemed inadequate or inappropriate.

4) AAF is considered an elimination diet with both diagnostic and therapeutic implications. It is important to note that elimination and reintroduction of cow's milk and dairy products should be undertaken with advice from medical specialists, particularly in children with severe allergic symptoms.

5) Though AAF is considered nutritionally comparable to all other normal infant formulas in terms of supporting growth and development, there is a potential harm for using it uncensored for all children. Most children do not fulfill the indications for AAF. Recent studies suggest that complete avoidance may increase food allergy prevalence. The complete forms of food protein (e.g. cow's milk protein) should be introduced during the window period of 4-6 months of age in order to achieve immune tolerance.

6) As AAF are unpalatable, clinical experience suggests that expert guidance to stressful parents is needed when switching babies from normal formula to AAF.

7) Following the diagnosis of cow's milk allergy, we recommend the following nutritional options:

1. Soy-based formula

Around 50-80 per cent of children with cow's milk allergy can tolerate soy-based formulae. However, this option is not suitable for children who are also allergic to soy protein.

Recommended / adopted age limits for offering soy formula by various professional bodies:

No age restriction	Older than 6 months of age
Hong Kong public sector	Australia [1] expert opinion
Australia [1] PBAC	ESPGHAN GI Committee (Europe)[3]
American Academy of Pediatrics [2]	World Allergy Organisation (WAO)[4]
	BSACI (UK) [5]

2. Extensively hydrolysed formula (EHF)

EHF contains cow's milk protein that has been treated with enzymes to break down most of the proteins that cause allergic symptoms in infants with cow's milk allergy (brands include Alfare and Pepti-Junior). These formulas are supplements of first choice in cow's milk-allergic children. However, the minority of children unresponsive to EHF will need to be switched to AAF. Extensively hydrolysed formulas are less allergenic than partially hydrolysed formulas, and all national guidelines do not recommend the latter for the treatment of cow's milk allergy.

3. Amino acid-based formula

This special formula is necessary in around 10 per cent of children with cow's milk allergy (brands include Neocate, Elecare). Virtually all children with cow's milk and soy allergy will be tolerant to AAF.

8) Other immunologically-based disorders that are indications for AAF include:
Food protein-induced enterocolitis syndrome (FPIES)
Eosinophilic disorders of GI tract (EoE, EoG, etc)
Remark: Some may regard these two conditions together with cow's milk-induced anaphylaxis as absolute indications for AAF.

Conclusions:

With the above deliberations, our PIID subspecialty strongly objects direct-to-consumer marketing strategy for AAF. Through public education and evidence-based clinical guidelines, we recommend AAF as a special milk formula treatment only for infants and children with severe or refractory cow's milk allergy and several other immunologically-based gastrointestinal conditions.

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