



The Role of Foods for Special Medical Purposes

An infant perspective



Martha Hughes, Scientific and Regulatory Executive
British Specialist Nutrition Association Ltd.; www.bsna.co.uk; @BSNA_UK

At any age, for a variety of reasons, an individual can experience periods when food alone, or modification of the diet, is not successful in meeting the body's nutritional requirements. Foods for special medical purposes (FSMPs) are foods which have been formulated to help meet the nutritional or dietary needs of patients living with a disease, disorder or medical condition when this situation arises. This article discusses infant foods for special medical purposes (iFSMP), the importance of these products in the management of diseases and medical conditions and why these products should be accessible, including on prescription.

Adequate nutrition during infancy is essential to ensure growth, health and development.¹ Undernutrition, which can be caused by an underlying illness or condition, can be detrimental for an infant and have long-lasting implications for the health of the child.²

The World Health Organisation (WHO) recommends that babies are exclusively breastfed until six months of age, after which breastfeeding is complemented with the appropriate introduction of solid foods until two years of age.² But for those infants whose nutritional requirements cannot be met by breastmilk or standard formula alone due to an underlying medical condition or disorder, there is a diverse range of specialist products available. These products are known as infant foods for special medical purposes (iFSMP).

iFSMPs are specialised products specifically formulated, processed and intended for the exclusive or partial feeding of infants and young children. They should be used under medical supervision, making sure that the infant and/or child is receiving the appropriate nutritional support to ensure optimal growth and development, either in an acute clinical situation or for chronic conditions. These conditions can vary greatly in terms

of their permanence, severity and impact on day-to-day life. The age of their introduction also varies, with some medical conditions being detected at birth by newborn screening (e.g. PKU), to others which may have a later onset or diagnosis, e.g. between 6-12 months, such as cow's milk protein allergy.

Conditions which may require the use of an iFSMP

Some conditions for which an iFSMP may be used are listed below:

Food allergy

Cow's milk protein allergy (CMPA) is the most common food allergy in infants and young children, where a response is triggered by one or both of the proteins casein and whey, which are found in milk. There are two types of CMPA:

1. Immediate or IgE-mediated allergy
2. Delayed or non IgE-mediated allergy

In infancy, exposure can occur through breastfeeding (via cow's milk protein in the maternal diet), through standard infant formula, or when weaning occurs and solids are introduced. Worldwide, CMPA is reported to affect 1.9% to 4.9% of infants and children.³

CMPA is a highly complex food allergy which can affect the skin, respiratory and gastrointestinal systems. In worst case scenarios, CMPA can lead to admission to accident and emergency (A&E) and/or paediatric intensive care units due to anaphylaxis and can potentially lead to death. It is important that those affected by CMPA are diagnosed and managed appropriately. For confirmed CMPA, strict avoidance of cow's milk protein is currently the safest strategy for management, i.e. elimination of cow's milk protein for either the child or the breastfeeding mother, via an elimination diet. Re-introduction of milk, under healthcare professional supervision, is often feasible further down the line.

iFSMPs can be prescribed to manage CMPA. These formulae can either be an extensively hydrolysed formula (eHF) or an amino-acid based formula (AAF), as stated by National Institute for Health and Care Excellence (NICE) and the Milk Allergy in Primary Care (MAP) Guideline.^{4,5}

EHF are based on cow's milk which is extensively broken down into smaller peptides that are less well recognised by the immune system.⁶ They are available either as whey-based or casein-based formulae and are tolerated by the majority of infants and children (90%) with CMPA.

AAFs are an alternative for children who cannot tolerate eHFs, or those with severe symptoms.⁷

Lactose intolerance

Lactose intolerance is caused by an inability to digest the carbohydrate lactose because of a decreased or absent lactase activity. Lactose intolerance in infants typically only lasts from a few days up to a few weeks. The symptoms of lactose intolerance are gastrointestinal and can cause loose stools, abdominal pain, flatulence, bloating and discomfort. It is during this time that specific formulae containing an alternative carbohydrate source to the lactose present in standard formula can play a vital role in ensuring the continued nourishment, development and health of the child. Although lactose intolerance can cause similar symptoms, it should not be confused with cow's milk protein allergy.

Pre-term

Due to advances in antenatal care, an increasing number of pre-term babies are surviving. These babies are vulnerable, and specialist paediatric dietitians have a critical role to play in making sure that the diet of these infants is effectively managed. Expressed breastmilk supplemented by a breastmilk fortifier is the preferred method

of feeding. However, mothers of pre-term infants may be under particular stress, which may affect their milk supply. If so, a specialist ready to feed pre-term formula may be required;⁸ which typically contains higher levels of energy, a higher protein: energy ratio and higher levels of key micronutrients, such as iron and vitamin D, compared with standard formula. These formulae are designed to support the increased metabolic requirements of pre-term infants.

Post-discharge

Most pre-term infants have nutrient and growth deficits at hospital discharge. If a pre-term infant is receiving breastmilk when discharged from hospital, the breastmilk should be fortified appropriately.^{8,9} If an infant is formula fed at hospital discharge and is suboptimal weight, a nutrient-enriched post-discharge formula is recommended.⁹ This is a nutritionally complete catch-up formula, specifically designed to provide nutritional support for pre-term, low birthweight infants when discharged from hospital.⁹ It can be used in combination with breastfeeding. As post-discharge formulae contain higher levels of energy, protein and calcium compared to standard formulae, careful monitoring of weight gain is recommended.⁹ Once the infant has reached an appropriate proportional weight, a post-discharge formula will no longer be needed and the infant should transition onto a standard term formula or, if possible, breastfeeding.

Anti-reflux

Reflux, or gastro-oesophageal reflux, is when the contents of the stomach move back into the oesophagus and may return into the mouth. It is common for this to happen in infants during or immediately after feeding. However, when the volumes of returned feed are significant and the infant has additional symptoms, such as excessive crying, poor growth and regular vomiting, then either an anti-reflux formula, which is pre-thickened or thickens in the stomach, or a feed thickener added to standard formula may be required to manage the condition.

The role of the healthcare professional for FSMPs for infants and young children

All iFSMPs should be used under the guidance of a healthcare professional.

Healthcare professionals are uniquely qualified to advise on the correct use of nutritional products for infants and

“At any age, for a variety of reasons, an individual can experience periods when food alone, or modification of the diet, is not successful in meeting the body's nutritional requirements.”

children. The choice of the most appropriate iFSMP for each patient will vary as every clinical situation is different and requires specific nutritional considerations. Dietitians will also ensure that sufficient nutrients are being provided to safeguard appropriate growth and development. As infants have relatively high nutritional needs and growth trajectories, their nutritional support should be constantly monitored. One size does not fit all: as children grow and develop, their nutritional needs change, therefore they may need different nutritional inputs at different times. Moreover, some conditions are characterised by periods of relapse and remission, e.g. Crohn's disease, which makes ongoing monitoring even more important. The value of good paediatric dietetic advice in these situations cannot be underestimated.

Not only is a medical condition stressful for the infant, it can be very upsetting for parents. Conditions such as gastro-oesophageal reflux, lactose intolerance and CMPA can be significantly distressing and frightening for the parents of children who suffer from them.¹⁰ Any concerned parent should be encouraged to see their doctor to make sure that the appropriate feeding options are discussed, including specialist infant formula, so that the condition can be professionally managed. This eliminates the risk that a parent or guardian does not receive appropriate specialist medical advice about the dietary management of their child, thus putting the health of the baby at risk.

Prescriptions of specialist infant formulae are at risk within certain clinical commissioning groups. For example, proposals have included restrictions to

soya-based infant formula, thickened infant formula, formulae for lactose intolerance and formulae for CMPA. It is clear to see that these specialist products play a vital role in safeguarding the health and development of vulnerable infants and children and, as iFSMPs are highly regulated by EU legislation and supported by robust evidence, healthcare professionals and patients can trust in the efficacy and quality of the products available.

Conclusion

Putting nutrition at the heart of patient care

The appropriate use of FSMPs for infants under medical supervision, following screening and assessment and accompanied by regular monitoring, should form an integral part of dietary management of diseases, disorders and medical conditions both in the hospital and in the community. Without the support of iFSMPs, infants may have their nutritional status compromised, making them more prone to related complications.

BSNA supports:

- FSMPs for infants and children to be recognised as an integral part of the management of diseases, disorders and medical conditions which require nutritional support
- FSMPs specifically for infants and children to be accessible to all patients who need them. All care pathways should clearly identify how and when FSMPs should be used to help manage patients' conditions
- FSMPs for infants and children to be prescribed and used when needed, and for patients to be regularly reviewed and monitored by a healthcare professional.

About the British Specialist Nutrition Association

BSNA is the trade association representing the manufacturers of products designed to meet the particular nutritional needs of individuals; these include specialist products for infants and young children (including infant formula, follow-on formula, young child formula and complementary weaning foods), medical nutrition products for diagnosed disorders and medical conditions, parenteral nutrition and gluten-free foods on prescription. www.bsna.co.uk

References: **1.** World Health Organization (2009). Infant and Young Child Feeding: Model Chapter for Textbooks for Medical Students and Allied Health Professionals. SESSION 1. The importance of infant and young child feeding and recommended practices. Geneva: World Health Organization. Accessed online: <https://www.ncbi.nlm.nih.gov/books/NBK148967> (April 2017). **2.** World Health Organisation (2016). Infant and young child feeding. Accessed online: www.who.int/mediacentre/factsheets/fs342/en (April 2017). **3.** Fiocchi A, et al. (2010). World Allergy Organization (WAO) diagnosis and rationale for action against Cow's milk allergy (DRACMA) guidelines. *World Allergy Organ J.* 3(4): 57-161. **4.** NICE (2015). Cows' milk protein allergy in children - Scenario: Confirmed cows' milk protein allergy. Accessed online: <https://cks.nice.org.uk/cows-milk-protein-allergy-in-children#scenario:1>. Accessed (March 2017). **5.** The MAP Guideline (2013). Accessed online: <http://cowsmilkallergyguidelines.co.uk/the-map-guideline> (January 2017). **6.** Ludman S, Shah N, Fox A (2013) Managing cows' milk allergy in children (clinical review). *BMJ*; 347: f5424. **7.** Baker G, Meyer R, Reeves L (2014). Food fact sheet: suitable milks for children with cows milk allergy. The British Dietetic Association. Accessed online: www.bda.uk.com/foodfacts/home#medical_conditions (April 2017). **8.** Agostoni C, et al. (2010). Enteral Nutrient Supply for Preterm Infants: Commentary From the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition Committee on Nutrition. *JPGN*; 50: 85-91. **9.** Aggett PJ, et al. (2006). Feeding preterm infants after hospital discharge: a commentary by the ESPGHAN Committee on Nutrition. *JPGN*. 42(5): 596-603. **10.** Lozinsky AC, et al. (2015). Cow's Milk Protein Allergy from Diagnosis to Management: A Very Different Journey for General Practitioners and Parents. *Children*. 2: 317-329.