The Role of Foods for Special Medical Purposes for Infants

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Supporting infants with unique dietary needs

Foods for special medical purposes for infants, or iFSMPs, play a vital role in supporting vulnerable infants with specific conditions to obtain the essential nutrients they require day to day. Alongside that, healthcare professionals (HCPs) play an invaluable role in the management of these conditions.

iFSMPs are medical foods, specifically formulated and produced for a medical need and intended for the exclusive or partial feeding of infants and young children to be used under medical supervision; they may also be known as specialist formula milks.

It is well established that breastfeeding is the best way to feed a baby, being important for the mother and baby. The World Health Organization (WHO) recommends that babies are exclusively breastfed until six months of age, thereafter appropriate complementary foods should be given whilst continuing to breastfeed up to the age of two or beyond.[1]

HCPs play a vital role in supporting families sensitively through the realities of infant feeding. When a child is sick or experiencing health complications, the desire and importance for a mother to breastfeed, or provide breastmilk, should not be overlooked. However, breastfeeding can be challenging, especially if a mother is under stress, and not everyone is able to breastfeed. For specific health conditions, when breastmilk is not an option, iFSMPs may be used. These have been specifically developed to meet an infant's nutritional requirements. They are safe, rigorously monitored and tightly regulated.[2]

Why an iFSMP may be needed

Nutrition plays an essential role in growth, health and development of babies.[4] When not supported adequately, an underlying illness or condition can lead to malnutrition, nutritional deficiencies and failure to thrive. This can lead to long-lasting health implications.[1]

For babies born prematurely, or with a medical condition, or who develop a disease, disorder or medical condition, providing breastmilk is extremely important and needs to be fully supported where appropriate. For some infants, however, due to factors including clinical condition, or parent/carer choice, an iFSMP may be required. These are highly regulated medical foods and should always be used under the advice and monitoring of a HCP.[3] Where a specialist milk is required, every effort should be made to combine with breast milk, unless clinically contraindicated.

Conditions where an iFSMP may be required

There is a range of iFSMPs available to address several conditions which babies can experience; it is essential that infants receive the appropriate formula for their individual requirements. The conditions for which an iFSMP may be used can vary greatly in terms of their permanence, severity and impact on day-to-day life. The age at which they may be introduced also varies, with some medical conditions being detected at birth by newborn screening, such as phenylketonuria (PKU), and others having a delayed diagnosis, such as cows' milk protein allergy (CMPA).

Preterm infants

In the UK nearly 58,000 babies are born prematurely, and many are also born critically ill.[5] Babies born prematurely or critically ill may not initially be able to feed directly from the breast or bottle and may need to be fed via a nasogastric tube or an intravenous line (IV). They often have additional nutritional needs, with growth and development of the gastrointestinal tract and neuromotor systems being a priority.[6, 7] The preterm infant's diet may incorporate fortified human milk from the infant's own mother, which can help reduce the incidence of morbidities, such as necrotising enterocolitis and sepsis.[7] However, if breastmilk (either a mother's own milk or donor breast milk) is insufficient or unavailable, a formula designed specifically for premature infants should be used and is a good nutritional option due to its higher caloric density and protein content, when compared with standard infant formula.[8] Neonatal dietitians have a critical role to play in making sure that the diet of these infants is effectively managed.

Gastro-oesophageal reflux (GOR) and gastro-oesophageal reflux disease (GORD)

Gastro-oesophageal reflux (GOR) is a common medical condition affecting at least 40% of infants.[9] It typically occurs during or immediately after feeding, with noticeable regurgitation. For breastfed infants, this need not adversely affect breastfeeding and is likely to improve with age.[9] A breastfeeding assessment should be carried out by a suitably trained expert. When reflux is significant and additional symptoms such as excessive crying, pain/discomfort and poor growth are observed, this may be diagnosed as gastro-oesophageal reflux disease (GORD) and can be a serious medical concern. NICE guideline [NG1] provides guidance on when anti-reflux formula should be trialled.[9] For formula fed babies, an anti-reflux formula, which is pre-thickened or thickens in the stomach, or a feed thickener added to expressed breastmilk or standard formula, may be required to manage this condition (e.g. containing a starch thickener, or locust/carob bean gum). In up to half of cases, GORD is associated with CMPA, with some comparable symptoms observed.[10]

Cow's milk protein allergy (CMPA)

The prevalence of CMPA varies in the literature; this could be partially due to differences in study designs and methodology of reporting CMPA. However, it is thought CMPA is one of the most common food allergies in young children, affecting 1.8–7.5% of infants during the first year of life.[11] It is an allergic reaction to one or both proteins, casein and whey, found in milk. CMPA can be categorised as immediate (IgE-mediated) or delayed (non-IgE-mediated).[12] Symptoms are wide ranging and can include red itchy rashes and swelling of the lips, face and eye area, eczema and hives, respiratory symptoms, and gastro-intestinal issues. In rare cases, consumption of products containing cows' milk can cause anaphylaxis, leading to fatalities. It is important that those affected by CMPA are diagnosed and managed appropriately by a HCP.[12, 13]

Breastfeeding in babies with CMPA should be encouraged and adequate support from HCPs to continue the breastfeeding journey is important, especially in mothers who need to follow a cows' milk protein free diet. In formula fed infants, a specific specialist formula can be prescribed, such as an extensively hydrolysed formula (eHF).[14] These are tolerated by most infants with CMPA. However, for those who cannot tolerate an eHF, or for those with severe symptoms, an amino acid based formula (AAF), which consists of free amino acids, should be prescribed,[14] as stated by NICE and MAP guidelines.[15, 16]

Lactose intolerance

Lactose intolerance is commonly confused with CMPA as many symptoms overlap such as diarrhoea, vomiting, pain and wind. The difference is the underlying cause; where CMPA is an allergy to a protein in cow's milk, lactose intolerance is the inability to digest the carbohydrate lactose due to the lack of or absence of the enzyme lactase, needed to breakdown the sugar lactose. Mothers who breastfeed should be encouraged to continue doing so and it should be reinforced that the amount of lactose in the mother's diet will not impact the lactose content in their breastmilk. For formula fed infants, lactose free infant formulas are available.

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Lactose intolerance may be temporary or permanent, depending upon the underlying cause. Secondary lactase deficiency is the most common cause of lactose intolerance in the UK, particularly in babies and young children. Common causes of secondary lactose intolerance include long courses of antibiotics or an episode of gastroenteritis.

Faltering growth

Faltering growth refers to less than expected growth over time. The cause of faltering growth may be due to ineffective establishment of feeding, although an acute or chronic underlying disorder, such as cystic fibrosis, inflammatory bowel disease or undiagnosed diabetes mellitus shouldn't be ruled out.[17] Breastfeeding should still be encouraged but managed alongside a specialist high energy formula (in accordance with NICE QS197),[17] which provides more calories and protein than a standard infant formula, to help achieve appropriate catch-up growth.

The role of the HCP

If an infant shows signs or symptoms which indicate that an iFSMP may be required, it is essential that the infant is diagnosed and managed appropriately. Paediatric dietitians have the specialist expertise to collaborate with a GP to diagnose, advise and prescribe the appropriate product for an infant, ensuring that sufficient nutrients are provided to safeguard growth and development. As infants have relatively high nutritional needs and growth trajectories, their nutritional support should be constantly monitored by a HCP. As children grow and develop, their nutritional needs change, therefore they may need different nutritional inputs at different stages.

Not only is a medical condition stressful for the infant, but it can also be very upsetting for parents or carers.[19] Any concerned parent should be encouraged to see their GP and subsequently referred to a paediatric dietitian to ensure nutritional support is provided. This eliminates the risk of the parent/guardian receiving inappropriate advice about the dietary management of their child, which could put the health of the infant at risk.

The role of a paediatric dietitian in diagnosis, treatment and review is fundamental. HCPs involved in this area should be aware of the appropriate iFSMPs for optimal nourishment of infants with a disease, disorder or medical condition.

Prescriptions for iFSMPs

Products placed on the market as iFSMPs must meet strict legal definitions,[3] substantiated through extensive scientific research and supported with robust clinical trial data. All iFSMPs available on prescription go through a strict application process, assessed and approved by the Advisory Committee on Borderline Substances (ACBS) – the Committee responsible for advising the prescribing of foodstuffs. The ACBS takes into consideration the formulation, efficacy and cost of iFSMPs for the dietary management of clinical conditions. While some iFSMPs are only available on prescription, there are some that are available on shelf to help with conditions such as reflux, as many parents value the ability to purchase the formula their infant needs directly from retailers, based on guidance given from their HCP.

Putting nutrition at the heart of patient care

BSNA supports the following:

- The continuation, encouragement and support of breastfeeding, or provision of breastmilk, when a child is sick or experiencing health complications.
- iFSMPs to be recognised as an integral part of the management of diseases, disorders and medical conditions which require nutritional support.
- iFSMPs to be accessible to all patients who need them. All care pathways should clearly identify how and when an iFSMP should be used to help manage a patient's condition.
- iFSMPs to be used appropriately when needed, and for patients to be regularly reviewed and monitored by a healthcare professional.

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About the British Specialist Nutrition Association

BSNA is the trade association representing manufacturers of products designed to meet the particular nutritional needs of individuals; including specialist products for infants and young children (including infant formula, follow-on formula, young child formula and complementary foods), medical nutrition products for diseases, disorders and medical conditions, including oral nutritional supplements, enteral tube feeding and parenteral nutrition, as well as companies who aseptically compound chemotherapy, parenteral nutrition and CIVAS.

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