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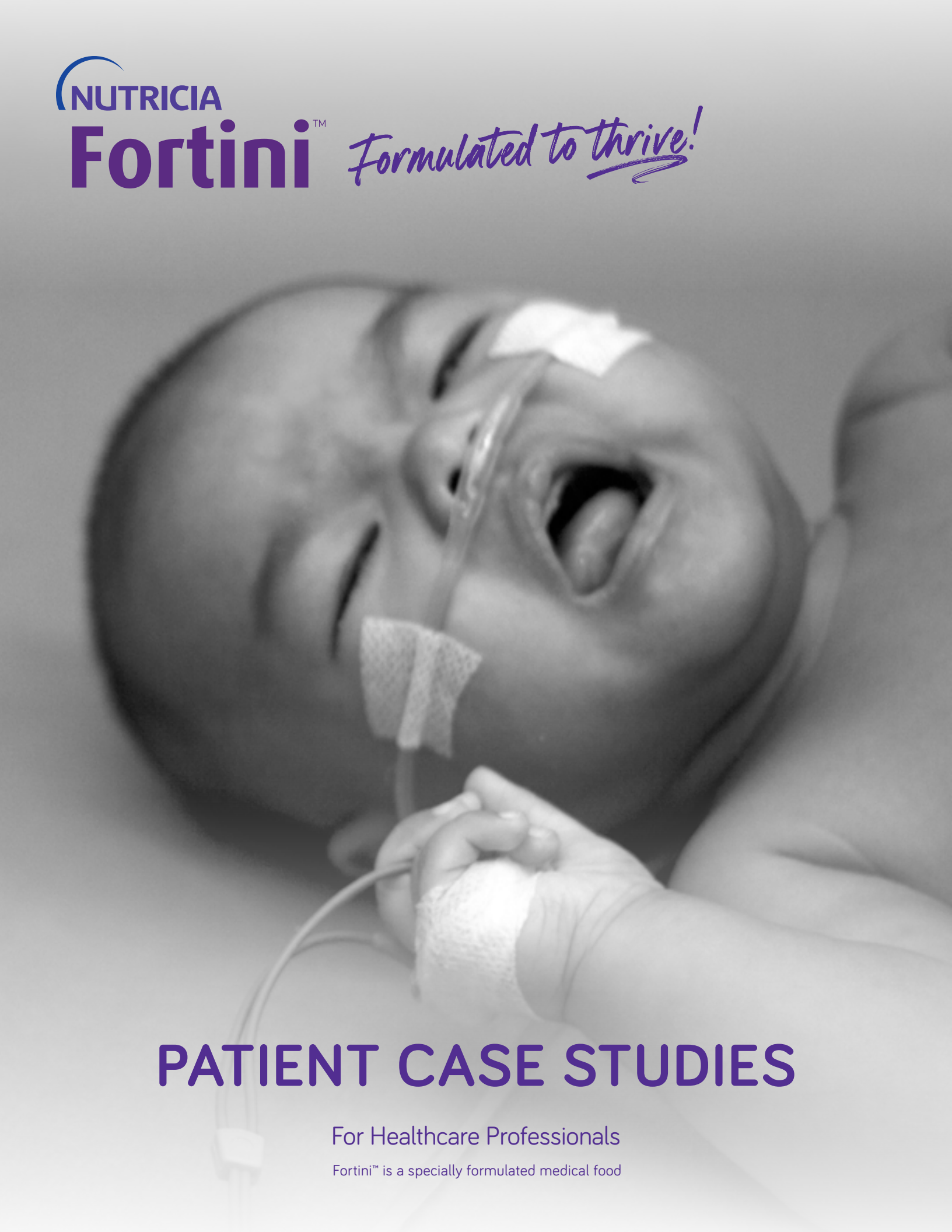
Fortini™ *Formulated to thrive!*



PATIENT CASE STUDIES

For Healthcare Professionals

Fortini™ is a specially formulated medical food

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Fortini™

Formulated to thrive - Fortini™ Infant can help turn growth setbacks into epic comebacks

30 calories/fl oz energy- & nutrient-dense term infant formula specifically calibrated for term infants with or at risk of **failure to thrive**

Clinically shown to promote catch-up growth in disease- and non-disease-related growth failure[1,2]

Equivalent tolerability to 20 kcal/fl oz standard infant formula[3,4]

Nutritionally complete with the right balance of fluid, protein, and energy

Powered by protein: 2.6 g of protein per 100 kcal; 10.3% of energy from protein meets WHO/FAO/UNU guideline to support lean tissue gain for catch-up growth[5]

Made in Europe, supported by 7 clinical studies, and trusted for over 20 years†

Lower osmolality than 30 kcal/fl oz concentrated standard formula[6] (360 vs. 460-507 mOsm/kg H_2O)

Fortini Infant is for the dietary management of term infants and young children from 0 to 18 months of age or up to 19.8 lbs (9 kg) with or at risk of growth failure, increased energy requirements, and/or fluid restrictions due to conditions such as:

- Congenital heart disease
- Chronic lung disease
- Respiratory syncytial virus
- Neurological syndrome or neuro-disabilities
- Cystic fibrosis
- Non-organic failure to thrive

† In other countries, Fortini is known as Infatrini™

1. Clarke, et al. J Hum Nutr Diet. 2007;20:329-39. 2. Eveleens, et al. J Hum Nutr Diet. 2019;32:3-10. 3. Cui, et al. JPEN J Parenter Enteral Nutr. 2018;42:196-204. 4. van Waardenburg, et al. Clin Nutr. 2009;28:249-55. 5. World Health Organization; Food and Agriculture Organization of the United Nations; United Nations University. Protein and amino acid requirements in human nutrition: report of a joint FAO/WHO/UNU expert consultation. 2007. 6. Third party laboratory testing of standard infant formulas commercially available in United States. Eurofins, Madison, Wisconsin.

Fortini is for use under medical supervision. Clinicians should regularly monitor for adequate nutrient and fluid status by reviewing nutrient intake and needs, anthropometry, symptoms, and micronutrient status.

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PATIENT CASE STUDIES

Case Study	Author	Child's Age & Gender	Diagnosis	Weight & Feeding History	Summary	Page
A	Chris Smith Senior Paediatric Dietitian, Royal Alexandra Children's Hospital, Brighton, UK	7 weeks -12 months female	Ventricular Septal Defect (VSD)	Fortini started at 7 weeks. Weight was 2-9th centile at 10 weeks. Surgery occurred at 14 weeks, with steady improvement in weight starting at 17 weeks. By 39 weeks weight approached the 50th centile.	Following surgery, she managed volumes better orally and the NG tube was removed. At 17 weeks, the weight pattern began to significantly improve. Solids were started at 18 weeks and the opportunity was taken to fortify her foods with Fortini to maximize her intake. Her weight gain pattern continued to improve and she gained on average 12 g/kg/day crossing up the centiles to her proportional position. At 39 weeks, Fortini was phased out.	4-5
B	Carolyn Patchell CF Specialist Dietitian Birmingham Children's Hospital	7-25 weeks female	Cystic Fibrosis	At birth, patient was on the 9th centile for weight, length and head circumference. By 12 weeks she had fallen well below 0.4th centile. Patient was breastfed at birth, but started supplemental formula feedings at 4 weeks of age due to poor weight gain. Following her diagnosis of CF, patient was changed to Fortini. By 25 weeks her weight had increased to the 0.4th centile, on continuous overnight feeds and bolus NG feeds with Fortini during the day.	The use of a high-energy formula, Fortini, given by bottle and NG tube, alongside treatment for cystic fibrosis, including PERT and sodium supplementation, supported her growth and enabled her to gain weight, and grow in length and head circumference, at a rate sufficient to catch up to her genetic potential within 13 weeks of commencing management.	6-7
C	Dr. Rosan Meyer Paediatric Dietitian, London	9 months female	Gastroenteritis Failure to thrive Behavioral feeding difficulties	Standard formula was introduced as a supplement at 4 months, and weaning at 20 weeks. Weight dropped 700 g at 7 months of age following gastroenteritis. Fortini was started due to faltering growth and poor intake.	Instead of standard infant formula, an energy-dense infant formula (Fortini) was recommended and the target volume for the family was set at 500 mL per day (23 kcal/kg additional), in addition to the breast feeding at night. This provided a 23 kcal/kg/day and 0.6 g/kg/day additional protein. Within 4 weeks of following this regime, weight gain had increased from the 9th to 25th centile.	8-9
D	Carolyn Patchell CF Specialist Dietitian Birmingham Children's Hospital	Birth - 12 months male	Cystic Fibrosis	Patient's weight dropped from the 75th centile at birth to 9th centile by 3 weeks of age. His weight increased after starting Fortini Infant. Following a chest infection it fell to the 25th centile. Growth subsequently improved and at 12 months his weight was between the 75th and 91st centile.	Patient changed back to Fortini at 16 weeks, starting solids at 6 months and with supplemental Fortini. He stayed on Fortini until 12 months, when he transitioned onto full fat cow milk. Use of high-energy formula, such as Fortini, for this baby ensured that he achieved optimal growth despite his increased energy requirements.	10-11

Nutricia North America supports the use of breast milk wherever possible.

CASE STUDY A

A CASE OF FEEDING DIFFICULTIES IN A CARDIOLOGY INFANT

Chris Smith, Senior Paediatric Dietitian, Royal Alexandra Children's Hospital, Brighton, UK

CLINICAL PRESENTATION

The family noticed within a few weeks that this patient was struggling with feeds and although support was provided the mother felt breastfeeding was unsuccessful and changed to exclusive standard infant formula feeds. The local health visitor observed difficulty with feeding and gave standard advice. At 4 weeks of age, she was admitted with a viral illness and during the admission the medical team observed her to be tachypneic. Various diagnostic tests including an echocardiogram were arranged which confirmed a Ventricular Septal Defect (VSD).

FEEDING HISTORY

At this stage her feeding pattern and volumes were sporadic and her weight had not increased significantly from birth. Her intakes were on average 110 mL/kg/day providing 75 kcal/kg/day. At 7 weeks, after consistently unsuccessfully achieving adequate volumes to meet her target requirement of 120kcal/kg/day, a specialized formula designed for catch-up growth was introduced. This was built up over 3 days with decreasing the frequency of standard infant formula and replacing bottles with Fortini.

There were no signs of poor tolerance in terms of gastrointestinal symptoms or a change in frequency of stools, however her tolerance to volumes through tiring remained. Her discharge from hospital was being delayed by failure to achieve adequate milk volumes and the decision was made for nasogastric tube (NGT) placement. The family were trained and she was discharged on 3 hourly feeds offered orally first over 20 mins with the remainder given as a gravity bolus via the NGT.

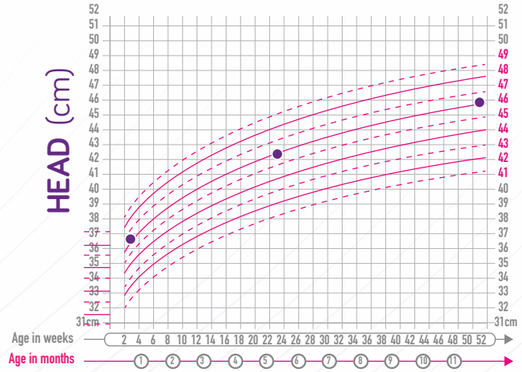
WEIGHT HISTORY

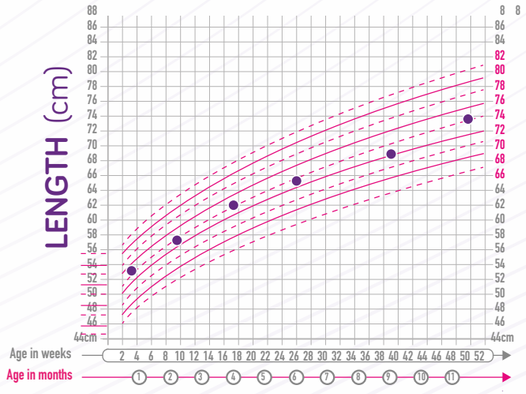
After 3 weeks post discharge and establishment of high-energy formula (10 weeks of age), her weight gain velocity trend had stabilized and her weight gain was now steadily tracking between 2nd-9th centile. Overall the family reported tolerance was good and tube feeds were still required. She had weekly weight checks via the health visitor and stayed in contact with the Dietetic team via community nurse reviews and consultant outpatient reviews.

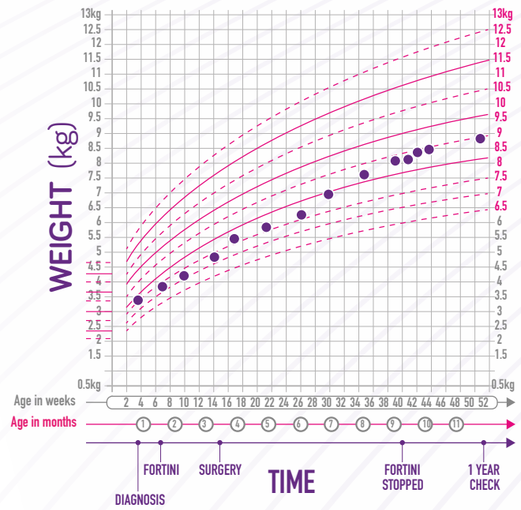
Cardiac surgery was agreed for several months later unless required sooner. At 13 weeks, she went into cardiac failure and at 14 weeks surgical repair was completed. Following surgery, she managed volumes better orally and the NG tube was removed. At 17 weeks, the weight pattern began to significantly improve. Solids were started at 18 weeks and the opportunity was taken to fortify her foods with Fortini to maximize her intake.

CONCLUSION

Her weight gain pattern continued to improve and she gained on average 12 g/kg/day crossing up the centiles to her proportional position. At 39 weeks (see WHO growth chart), Fortini was phased out and she returned to a standard infant formula. Weekly weights were taken for the following 3 weeks by her health visitor and her weight pattern and velocity were successfully maintained.







CASE STUDY B

USE OF HIGH-ENERGY FORMULA IN AN INFANT WITH A LATE DIAGNOSIS OF CYSTIC FIBROSIS, SEVERE RESPIRATORY INFECTION AND FALTERING GROWTH

Carolyn Patchell, CF Specialist Dietitian, Birmingham Children's Hospital

CLINICAL PRESENTATION

The patient presented to her local district general hospital aged 7 weeks, suffering from significant faltering growth and loose stools. She was the first of non-identical twins, her twin brother being well. She was seen by a general pediatrician and admitted to hospital where she had blood and urine tests, ultrasound scans and cardiac assessment.

At the time, abnormalities included a low albumin level and anemia, requiring blood transfusion. She was discharged from hospital at 8 weeks of age, however was readmitted with signs of respiratory distress and a diagnosis of parainfluenza at 12 weeks of age.

During this admission, she was assessed by a respiratory consultant, who was concerned that she had symptoms consistent with cystic fibrosis.

Patient had been screened for cystic fibrosis under the newborn screening program, and the results were negative at that time.

Genetic bloods were requested, which returned a positive diagnosis of cystic fibrosis, with genotype ΔF508: c.489+1G>T.

Stool was sent to the laboratory for fecal-1 elastase, but given her history of loose frequent stools, up to 8 times daily, she was started on pancreatic enzyme replacement therapy (PERT), pancrelipase, at 2500 units per feeding, while results were awaited.

WEIGHT HISTORY

At birth patient weight, length and head circumference were on the 9th centile, however at 12 weeks of age, her weight was 2.73 kg, significantly below 0.4th centile, length and head circumference had also crossed centiles to <0.4th centile and 0.4th centile, respectively.

FEEDING HISTORY

Patient was breastfed at birth, but was started on supplemental feeds of a whey-based infant formula at around 4 weeks of age, when concern was raised regarding her slow weight gain, and was weaned onto full bottle feeds by 8 weeks of age.

She was described as being a hungry baby, taking up to 220 mL/kg/day (up to ~146 kcal/kg/day) of bottle feeds.

At the time of her diagnosis, her respiratory symptoms were making it difficult for her to feed, she was floppy, and disinterested in feeding. The feeding volume had reduced significantly to 50 mL/kg/day, she was therefore commenced on nasogastric feeding to support her, and her feeds were changed to a high-energy feed, Fortini, to help manage her poor growth.

During the admission, she was also started on full treatment for cystic fibrosis, including additional fat-soluble vitamins, and sodium chloride supplementation, given to replace sodium chloride losses through her sweat.

Her parents were trained to give feeds via the nasogastric tube, and she was discharged home, on 175 mL/kg/day Fortini (175 kcal/kg/day). This was given as 3-hourly feeds, given as bottle and NG feeds, with 2500 units pancrelipase per feeding (6800 units/kg/day) to help manage her malabsorption.

At 16 weeks of age, she was gaining 200 g per week, however she developed a further respiratory exacerbation, requiring admission to Birmingham Children's Hospital.

She was desaturating during bolus feeds, and so feeds were given as a continuous feed, at 175 mL/kg daily, with PERT, given orally every 3 hours.

Urinary sodium was checked as a marker for sodium status and her sodium supplements were adjusted in relation to her weight gain.

Despite her severe respiratory distress, the patient continued to gain weight and was discharged home, requiring oxygen support at night, on an overnight feed of Fortini, given for 10 hours, plus 3 daytime bottles, with supplemental NG feeding, at 170 mL/kg/day (170 kcal/kg/day). She was unable to complete her feeds orally, becoming tired after a small volume by bottle. She was floppy and showed signs of developmental delay, due to severe undernutrition. Her weight on discharge was 4.15 kg, length 55.5 cm, taking her closer to the 0.4th centile.

The patient was seen in clinic aged 25 weeks, having remained stable at home, and had increased weight further to 5.2 kg (0.4th centile), her length and head circumference had also increased to 0.4th centile and 25th centile, respectively.

The improvement in her nutritional status led to an improvement in her development and muscle tone, and advice was given to start weaning solids, with appropriate PERT.

CONCLUSION

This patient was failing to gain weight due to a delayed diagnosis of cystic fibrosis, associated malabsorption, and recurrent chest exacerbations, which increased her energy requirements.

The use of a high-energy formula, Fortini, given by bottle and NG tube, alongside treatment for cystic fibrosis, including PERT and sodium supplementation, supported her growth and enabled her to gain weight, and grow in length and head circumference, at a rate sufficient to catch up to her genetic potential within 13 weeks of commencing management.

CASE STUDY C

FALTERING GROWTH AND BEHAVIORAL FEEDING DIFFICULTIES FOLLOWING ACUTE GASTROENTERITIS

Dr. Rosan Meyer, Paediatric Dietitian, London

CLINICAL PRESENTATION

A 9-month-old baby girl was referred to the dietitian for faltering growth reportedly resulting from behavioral feeding difficulties.

HISTORY

The history reported by the parents revealed she was born at full term at a weight of 3.48 kg (50th centile) with a length of 51 cm (>50th centile).

She was exclusively breastfed until 4 months of age when a supplemental cow milk formula was introduced. Patient was not that keen on bottle feeding, however with perseverance she accepted 200 mL of formula every night in addition to breast milk. At 20 weeks of age complementary foods were introduced, following the UK Department of Health guidelines,[1] which reportedly went well. At this stage she was receiving only 1 breast milk feeding per day at night and the rest of the nutrients came from the infant formula. Growth continued along the birth centiles.

At 7 months she however became unwell with acute diarrhea and vomiting, which lasted 10 days. During the acute period she only wanted breast milk and had some rehydration fluid prescribed by the pediatrician. She lost 700 g during this illness and dropped 1 centile in weight; however her length continued to track along the birth centile. Mum was extremely concerned about this weight drop and started to feed her every 2 hours, which was recommended by granny, with either infant formula or some solids, aiming to increase the catch-up weight gain.

The patient refused the majority of feeds offered, by sealing her mouth and pushing the spoon away. Mealtimes became extended (45-60 min), with her protesting to sit in the highchair and requiring significant distraction to get her to eat any food. Although food intake was low, they still managed to get her to drink 500 mL of formula. A follow-up weight indicated that her weight had dropped further, now to 2 centiles from her previous weight 8 weeks before. The length measurement also indicated 1 centile drop.

The dietitian identified the cycle of events that have led to the feeding difficulty which results in the faltering growth (Figure 1) and identified areas that needed to be addressed to improve the situation. This included the following:

- Ensuring sufficient energy and protein as recommended by the WHO/FAO/UNO guidelines on catch-up growth[2]
- Provision of vitamins and minerals that are essential for growth and development[3]
- Improving feeding routine at home

It was recommended that instead of standard infant formula, an energy-dense infant formula (Fortini) should be used and the target volume for the family was set at 500 mL per day (23 kcal/kg additional), in addition to the breast feeding at night. This provided a 23 kcal/kg/day, 0.6 g/kg/day additional protein at an optimal of energy from protein at 10.3%.[2] A multivitamin and mineral supplement was also commenced to provide her with sufficient vitamin D, zinc and iron as well as other micronutrients to support catch-up.[3,5] Advice on mealtimes was given. Within 4 weeks of following this regime, weight gain had increased from the 9th to 25th centile. Although the patient still consumed smaller volumes, she now happily sat in the highchair and would open her mouth for a couple of spoons before wanting to self-feed.

CONCLUSION

There are many lessons to be learned from this case study. The first is the occurrence of "behavioral feeding difficulties" in young infants, which according to Rommel et al.[6] is more frequently observed in children >2 years of age and below this age mostly has an organic cause. Five common triggers have been found identified for the development of feeding difficulties, which include:[7,8]

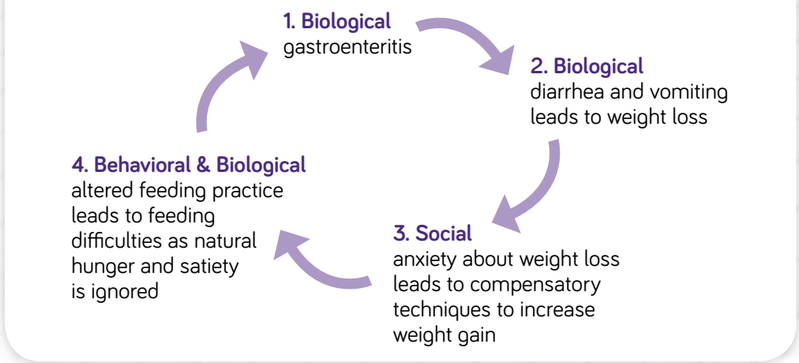
- Size – i.e. failure to thrive or faltering growth
- Transitioning – i.e. transitioning from puree to lumpy food
- Organic disease – i.e. chronic or acute illness
- Mechanistic feeding – i.e. feeding at specific intervals irrespective of hunger or satiety
- Post traumatic – i.e. a severe event, including choking, anaphylactic reaction

The second lesson is that feeding difficulties often have a medical cause, that may not be chronic, but acts as a trigger.[7] In this case, a common childhood illness (trigger 2), led to growth faltering (trigger 1) which in turn caused a change in feeding practice (trigger 4) and the only way this child could signal that this was going against her normal hunger/satiety and also her normal development was to refuse the feeds/ food, which then in turn became her normal routine.

The last lesson to be learned is ensuring nutritional adequacy through a simple measure like changing to an energy-dense formula, which not only promotes weight gain, but has the added benefit of reducing the anxiety as parents do not need to aim for the same volume as with a standard formula and they know that their child is still receiving sufficient energy and protein at the correct level.

The patient lost 700 g during this illness and dropped 1 centile in weight; however her length continued to track along the birth centile.

FIGURE 1: CYCLE OF BIOLOGICAL, SOCIAL AND BEHAVIORAL EVENTS THAT HAVE LED TO FEEDING DIFFICULTIES AND FALTERING GROWTH[4]



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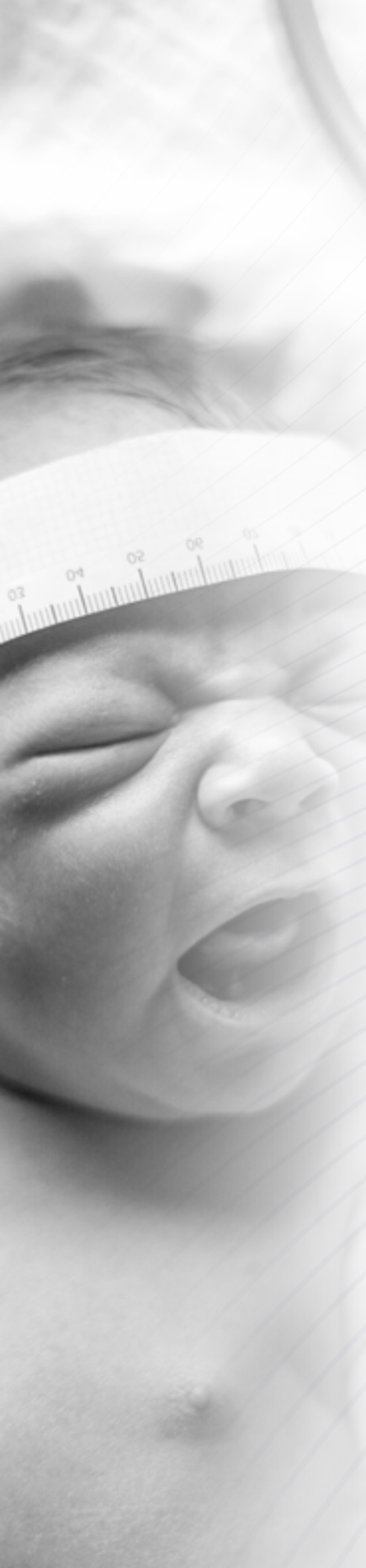

CASE STUDY D

USE OF HIGH-ENERGY FORMULA IN AN INFANT WITH CYSTIC FIBROSIS, PANCREATIC INSUFFICIENCY AND FALTERING GROWTH

Carolyn Patchell, CF Specialist Dietitian, Birmingham Children's Hospital

CLINICAL PRESENTATION

The patient presented to the hospital at 3 weeks of age. He had been suspected of having a diagnosis of cystic fibrosis following a positive newborn screening result, which was confirmed by a sweat test and positive genetic mutations (ΔF508: c.1585- 1G>A).

His birth weight was 3.75 kg (75th centile), but at the age of 3 weeks had dropped to 3.41 kg (9th centile), indicating severe faltering growth, with length on the 75th centile and head circumference was on the 50th centile.

The infant was bottle fed, taking a whey-based infant formula. He was described as being very hungry and unsettled, feeding every 2-3 hours, and taking around 285 mL/kg/day (185 kcal/kg/day) of formula. He was passing large amounts of pale, loose stool, approximately 7 times daily.

A stool sample was sent to the laboratory for a fecal-1 elastase level, which is an indicator of pancreatic enzyme sufficiency.

While the result was awaited, as he showed signs of pancreatic insufficiency (poor weight gain, large appetite, and frequent stools), he was started on pancreatic enzyme replacement therapy (PERT) of pancrelipase, at 2500 units given before each feed (5100 units/kg/day). He was also started on sodium chloride supplements at 2 mmol/kg/day, to replace sweat sodium and chloride losses. 10 days after starting PERT, he was reviewed in clinic and was reported to continue to have a large feed intake, but was passing fewer stools, and had started to gain weight, at around 26 g daily.

He was reviewed in clinic at 6 weeks of age. His urinary sodium level was <10 mmol/L. He was still taking >260 mL/kg/day (170 kcal/kg/day) of whey-based formula, his stool frequency had reduced to 4 times daily, although they remained large and pale. His weight was 4.5 kg, showing an increase to 25th centile.

His large appetite and loose stools suggested ongoing malabsorption, and so his PERT was increased, to optimize his absorption of feed to 10,000 units/kg/day. His sodium supplements were also increased, as a low urinary sodium level is suggestive of sodium depletion.

His stool fecal-1 elastase result was <15 mcg/g, indicative of severe pancreatic insufficiency, confirming the requirement for PERT. The patient was seen in clinic again at 8 weeks of age, he had developed a cough, wheeze, and was showing signs of respiratory distress.

His feed intake had reduced to within normal limits, at around 180 mL/kg/day (117 kcal/kg/day), and he was passing 3 normal stools daily, on 9750 units/kg/day.

Despite the positive signs that his malabsorption was improved, his weight was tracking 9th - 25th centile, length continued between 50th – 75th centile, head circumference was on 50th centile.

Growth levels within the first 2 years of life are an indicator of future nutritional status and adolescent height potential, which contributes towards clinical outcomes. It is therefore imperative that children optimize their growth within the early years. Newborn screening and early life weight recovery have been associated with better adolescent growth in children with cystic fibrosis.

The patient was struggling to attain a healthy weight-for-length, so was started on Fortini at 8 weeks of age: within 1 week of starting Fortini, he had gained 250 g, and continued to gain weight at this rate, making steady progress across the centiles.

At 11 weeks of age he developed a significant cough requiring oral antibiotic treatment, and was vomiting with feeds due to the coughing and excessive respiratory secretions.

He was unable to tolerate his Fortini feeds, and was vomiting more with this than when on whey-based standard infant formula, possibly as a result of thick respiratory secretions. He was therefore changed back to whey-based infant formula until his chest symptoms had cleared. He was changed to Fortini again at 16 weeks of age.

Unfortunately during this period of time, his weight had fallen to 25th centile, length remained at the 75th centile, and head circumference at the 50th centile.

From 16 weeks of age, he remained well, and with minor adjustments of PERT and sodium supplementation, he gained weight well, reaching 50th centile at 20 weeks of age, and crossing to track >75th centile by 26 weeks of age.

Weaning solids were started at 6 months of age, given with PERT when required. He continued to track 75th centile, taking approx. 100-130 mL/kg/day (100-to-130 kcal/kg/day Fortini, plus solids).

At 12 months of age, his weight was between 75th – 91st centile, length 75th – 91st centile, head circumference 75th centile, and he was changed to full fat cow milk.

The patient failed to gain weight at an appropriate rate, despite good control of his malabsorption, with optimal use of PERT and close attention to his sodium status, due to the development of a chest infection, which increased his energy requirements.

CONCLUSION

Infants and children who have CF may require up to 150% estimated average requirement for energy, due to increased respiratory effort, and ongoing malabsorption.

Use of high-energy feeds ensured that he achieved optimal growth despite the higher energy requirements associated with CF.

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