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Home use of breast milk fortifier to promote postdischarge growth and breast feeding in preterm infants: a quality improvement project

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ABSTRACT

To improve the postdischarge growth of exclusively breastfed preterm infants, born weighing ≤ 1.8 kg, by using breast milk fortifier (BMF) supplements postdischarge until 48 weeks' gestational age. A quality improvement (QI) project involving plan–do–study–act (PDSA) cycles. A tertiary surgical neonatal unit. Preterm infants weighing ≤ 1.8 kg at birth. We completed four PDSA cycles to develop and improve an electronic patient information sheet to promote the use BMF beyond discharge. Safety, feasibility and attitudes of parents to home BMF were assessed using questionnaires. A retrospective audit (July 2015–September 2017) was completed investigating the effects of home BMF on growth up to 1 year of age. Change in SD scores for weight for age, length for age and head circumference of age at various time points compared with those at birth were calculated. Compared with baseline measurements (infants born October 2012–November 2013), the QI project resulted in improved growth (measured as the change in SD score from birth, cSDS) at discharge for weight (cSDS -0.7), head circumference (cSDS 0.4) and length (cSDS 0.8), and at 1 year for weight (cSDS 0.9) and length (cSDS 0.8). Home BMF appeared to be safe, and parents found its use acceptable. QI methods facilitated the successful integration of BMF into routine clinical care after discharge, improving the growth trajectory of exclusively breastfed preterm infants discharged home, as well as supporting breast feeding in this vulnerable population group.

INTRODUCTION

Problem description

The successful implementation of comprehensive nutrition guidelines on our neonatal unit (NNU) has seen improvements in nutrient intake and a reduction in growth failure during NNU stay and at the point of discharge.^{1,2} However, there remained ongoing concern about growth failure in exclusively breastfed infants once discharged home.

A retrospective review of 36 exclusively breastfed preterm infants born ≤ 1.8 kg between October 2012 and November 2013 (mean \pm SD score (SDS) gestational age and weight at birth 30.2 ± 2.1 weeks and 1.33 ± 0.31 kg, respectively) demonstrated a fall in SDS for weight between birth and 35 weeks of 0.52 . This coincides with the time around which most exclusively breastfed infants will start to transition to breast feeding and so stop receiving breast milk fortifier (BMF). By discharge, infants had fallen further, with a change in SDS between birth

What is already known?

- Preterm infants have higher nutritional requirements than those born at term.
- Breast milk fortifier (BMF) is available for in-hospital use only and used to enrich breast milk to meet nutritional requirements in infants weighing ≤ 1.8 kg at birth.
- BMF is stopped prior to discharge.

What this study adds?

- Using quality improvement methods, it was possible to successfully implement the use BMF in infants weighing ≤ 1.8 kg at birth into routine clinical care after discharge.
- Growth trajectory of exclusively breastfed preterm infants discharged home on BMF was improved.
- Parents and healthcare professionals found the use of home BMF supplement to be acceptable, feasible and safe.

and discharge of -1.0 ($p < 0.001$ compared with 35 weeks, see [figure 1A](#)). A similar pattern was also seen for length with an SDS of -1.44 ([figure 1B](#)) but not head circumference (HC) with an SDS of -0.53 ([figure 1C](#)), which did show improvements in head growth between 35 weeks and discharge.

Available knowledge

Although maternal breast milk (MBM) is the preferred feed for preterm infants during the first 6 months of life,^{3–5} conferring multiple health advantages,^{6,7} it does not contain sufficient protein and minerals to support adequate growth.⁸ Therefore, during their stay in the NNU, a commercially available BMF specifically designed to enhance the nutritional content of breast milk, by providing additional protein and micronutrients, including calcium and phosphorus,⁹ is usually added to MBM. A recent survey of practice surrounding the use of BMF during NNU stay suggested it could potentially protect breast feeding on discharge.¹⁰

Postnatal growth failure is common among preterm infants with a reported incidence of up to 45%¹¹ and has been associated with longer term consequences, including poorer neurocognitive and scholastic outcomes.¹² As such, optimising growth around the time of discharge is important to improve



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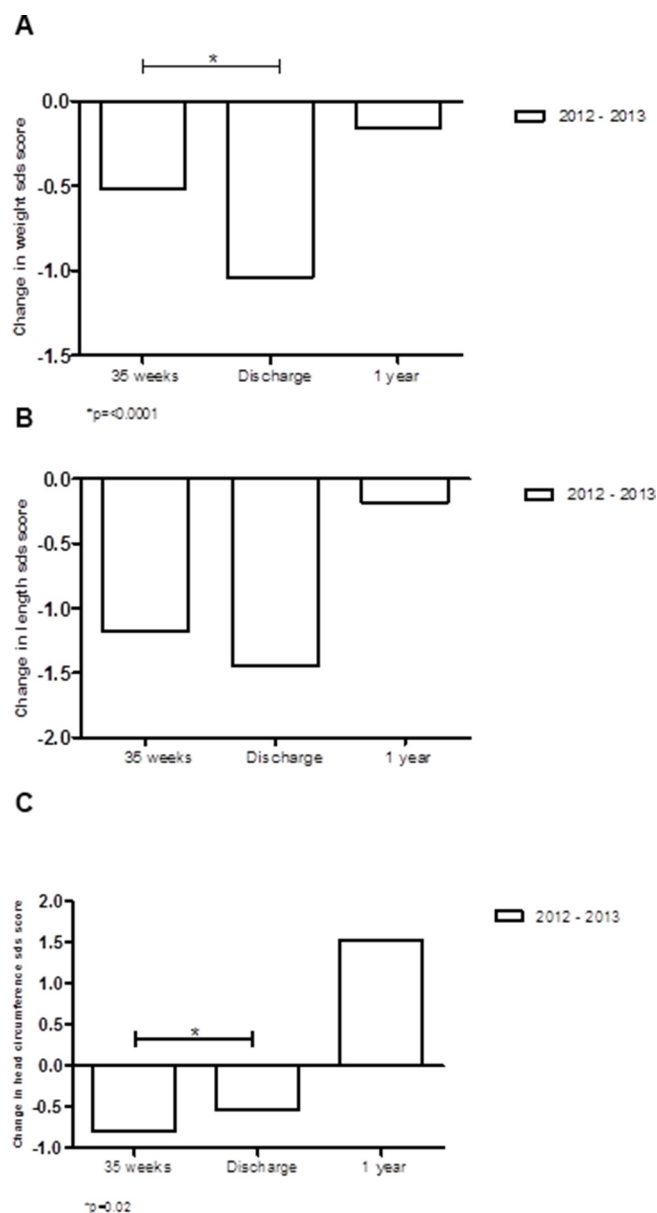


Figure 1 Change in SDS from birth to 35 weeks, discharge and 1 year for (A) weight, (B) length and (C) head circumference in 2012–2013. SDS, SD score.

longer term outcomes. For formula-fed preterm infants, the use of specialist nutrient enriched preterm formula milks is recommended until a postmenstrual age (PMA) of up to 52 weeks.¹² As BMF is not used routinely after discharge, it is usually stopped as preterm infants transition from MBM via nasogastric tube to oral breast feeds, meaning they potentially have a period of suboptimal nutrition around and beyond discharge. Growth failure in breastfed preterm infants around discharge is therefore common and often necessitates supplementation with preterm formula alongside breast feeding.¹² However, the use of infant formula top-ups in preterm breastfed infants has been shown to erode maternal confidence and increase anxiety around breast feeding leading to early breast feeding cessation.¹³

Rationale

Whilst BMF is used routinely in NNUs, anecdotally there is little clinical experience using them beyond discharge in the

community, and BMF cannot currently be prescribed by general practitioners (GPs). BMF can, however, be provided by the NNU for use at home under their supervision. The use of BMF for 12 weeks following discharge in preterm infants has been shown to have a positive effect on growth at 1 year without impacting on breastfeeding rates.¹⁴ Therefore, in view of the potential benefits of BMF on growth and the negative impact of formula top ups on breastfeeding rates, we felt that the routine use of BMF beyond discharge had the potential to address these issues, in addition to promoting breast feeding.

Specific aims

We developed a quality improvement (QI) project aimed at improving growth in exclusively breastfed preterm infants (≤ 1.8 kg at birth) postdischarge by introducing the routine use of BMF beyond discharge. We chose to target preterm infants ≤ 1.8 kg at birth as these are the group that have higher nutritional requirements as set out by current European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) recommendations.⁹

METHODS

Context

Southampton Neonatal Unit is a tertiary NNU with surgical, cardiac and other specialist services.

Interventions

A multidisciplinary Neonatal Nutrition team, together with weekly nutrition ward rounds has been established on our unit since 2011. However, infants discharged home were not discussed during ward rounds and were managed by the neonatal community nursing team. Existing practice was to stop BMF prior to discharge in infants whose mothers were planning to exclusively breast feed, usually at around 34–35 weeks once breast feeding was underway. Postdischarge nutrition support from a neonatal dietitian for such infants was reactive rather than proactive, often occurring once an infant had already experienced a significant decline in growth. At this point, breast feeds were often ceased or reduced in place of preterm infant formula top-ups.

It was clear that some changes to current practice were required in order to prevent this ‘supervised malnutrition’ and encourage more women to continue breast feeding their infants. A QI project was therefore developed in 2015 by key stakeholders including consultant neonatologists with a special interest in nutrition, neonatal dietitians, the nursing breast feeding lead and the neonatal community nursing team, with the aim of formalising the use of BMF at home alongside breast feeding after discharge. In 2015, an updated neonatal nutritional guideline was implemented on the unit that recommended that BMF supplementation was commenced for all infants ≤ 1.8 kg at birth, in line with ESPGHAN recommendations.⁹ This policy was therefore extended to include those infants exclusively breast feeding postdischarge. Of note, while the previous published study had mixed powdered BMF with half of the infant’s estimated daily feed volume given in addition to breast feeds (often using bottles),^{14 15} we chose to give the BMF as ‘shots’, with a sachet of BMF mixed with a small volume of MBM to be given at regular intervals during the day just before a breast feed.

We undertook four ‘Plan–Do–Study–Act’ (PDSA) cycles focused on establishing the practice of home BMF use in a way that was practical and acceptable to parents and staff (supplementary file 1). This was based around the introduction of an

electronic patient record (EPR) entry and parent information sheet that aided decision making around and delivery of BMF at home and measured the impact on growth and breastfeeding rates. Where infants demonstrated growth failure, they were reviewed by the neonatal dietitian and an individualised nutrition care plan implemented.

Measures

Growth

The primary quantitative outcome measure used in this QI project was longitudinal growth, measured by the change in SDS for weight, length and HC between birth and each of 35, 40 and 48 weeks PMA and 1 year of age corrected for prematurity. Measurements were performed in accordance with local standard operating procedures and WHO guidelines.¹⁶ Infants were weighed naked; weight was measured to the nearest 0.1 kg using a digital scale. Recumbent length was measured to the nearest 0.1 cm for all infants using an infantometer (Seca 416; Birmingham, UK). While on the NNU infants were measured weekly by the neonatal nursing staff. Once discharged and on home BMF, infants had their growth regularly assessed by the neonatal community nursing team. Beyond this point and up to 1 year of age, measurements were carried out by children's outpatient nurses at routine outpatient appointments.

Infants with a weight of ≤ 1.8 kg at birth gestation who were discharged home from the NNU exclusively breast feeding were identified using the hospital admissions database (Badgernet, Clevermed, Edinburgh). Data on growth were extracted. In addition, the hospital EPR system was used to collect growth data from outpatient and community reviews after discharge. Measurements were converted into SDS based on the UK Neonatal and Infant Close Monitoring growth chart reference data.¹⁷

Breastfeeding rates

Breastfeeding status was recorded as part of clinical follow-up and entered onto the hospital EPR.

Parental survey

A parental survey was developed containing questions on basic demographics together with 13 questions on parental breastfeeding experiences, ease of using BMF at home and availability of information, with dichotomous answers and Likert scale-based questions (online supplementary file 2). Verbal consent was obtained from the parents/nominated carer for each participant for the anonymous parental survey.

Dietitian survey

An electronic neonatal dietitian survey was developed (supplementary file 3), focusing on the use of and attitudes towards BMF in preterm infants during inpatient stay and postdischarge. A link to the survey was distributed via the Paediatric British Dietetic Association Neonatal Dietetic Interest Group.

Analysis

Growth outcomes before and after the QI project were compared using an independent samples Mann-Whitney U test, with a p value of <0.05 was considered significant. Analysis was carried out using Stata IC V.12.

Ethical considerations

The use of home fortifier was applied to all infants who met the criteria as part of a change in practice brought about through the QI project. It was therefore the study of a clinical practice change using QI methodology and not an interventional study, with no ethical approval required. Growth data were collected as part of a registered audit of the new practice. Opinion regarding ethical review was sought from a local ethics committee regarding the anonymous parental and dietetic surveys and felt to be unnecessary in the context of service evaluation.

RESULTS

PDSA cycle 1: July–November 2015

Our initial intervention was to implement a change in practice that ensured all exclusively breastfed preterm infants with birth weight of ≤ 1.8 kg discharged with BMF sachets to be given until 44–48 weeks' gestational age. The QI group, together with parents, codesigned an EPR patient information sheet (PIS) template on the hospital EPR platform that could be used by the neonatal community nursing team to record and guide the use of BMF at home, with a hand-held copy given to parents. It provided eligibility criteria for home BMF and instructions on mixing up a dose ('shot') of fortifier for the infant (figure 2). Four or six fortifier doses per day were recommended for up to 44 or 48 weeks' gestational age, depending on an infant's current growth trajectory. Feedback on the clarity and utility of the PIS were collected during this period.

PDSA cycle 2: December 2015–February 2016

The BMF PIS was amended in response to parental and nursing feedback indicating it was unclear regarding which supplementation strategy infants were on, which was causing parental

<p>Does my baby need to still have breast milk fortifier at home?</p> <ul style="list-style-type: none"> • < 35 weeks—only crossed 1 growth line from birth weight/ length/ head circumference: Aim to give 4 x fortifier shots per day until he/ she is 44 weeks of age • < 35 weeks—crossed ≥ 2 growth lines from birth weight/ length/ head circumference: Aim to give 6 x fortifier shorts per day until he/ she is 48 weeks of age <p>How do I make a fortifier shot?</p> <ul style="list-style-type: none"> • A dose of breastmilk fortifier 'is made with 1 sachet of Breast milk Fortifier mixed with 10ml Breast milk • Give the 10ml of breastmilk fortifier as a cup feed followed by a full breast feed

Figure 2 First version of the electronic patient record information sheet.

Does my baby need to still have breast milk fortifier at home?

- < 35 weeks –only crossed 1 growth line from birth weight
☒ Aim to give 4 x fortifier doses per day until **44 weeks of age**
- < 35 weeks –crossed ≥ 2 growth lines from birth weight
☒ Aim to give 6 x fortifier doses per day until **48 weeks of age**

Fortifier is only available from the hospital and the Home Team Nurses or Dietitian will provide it for you.

How do I make a fortifier shot?

- A dose of breastmilk fortifier 'is made with 1 sachet of Breast milk Fortifier mixed with 10ml Breast milk
- Give the 10ml of breastmilk fortifier as a cup feed followed by a full breast feed

Figure 3 Second version of the electronic patient record information sheet.

anxiety. Tick boxes were added next to the supplementation strategy in addition to simplifying the remaining information (figure 3). The new leaflet was introduced, and the collection of verbal feedback on the practice for parents and nursing staff continued. The NNU uses a commercially available BMF as per the manufacturers' instruction for inpatients. On discharge, we recommended that four sachets of BMF were added to 40 mL of expressed breast milk, with 5 mL administered orally before each breast feed or eight times per day. This provided an additional 191 kcal, 6 g protein, 111 mg phosphorus and 192 mg calcium per day.

PDSA cycle 3: September–December 2017:

During the third cycle an anonymised parental survey was carried out in order to understand the factors influencing the effectiveness of the intervention from parents' perspectives. A national survey of BMF practices among neonatal dietitians was also undertaken. In addition, a retrospective audit of the postdischarge growth up to 1 year of age corrected age was carried out for all infants who had been discharged home on BMF since the start of the project (July 2015–September 2017).

PDSA cycle 4: January–April 2018

For the final cycle, the PIS was further amended in response to parental feedback, focusing on making the preparation and administration of BMF easier and more convenient. The PIS was simplified to include just one time point (48 weeks and all breastfed infants weighing $1 \leq 8 \text{ kg}$ at birth). It was recommended that parents made up the BMF all at once and refrigerated it for use throughout the day. Further iterative changes were made: four sachets to be used in a 24-hour time period, made up once to a volume of 40 mL and administered as a slow 5 mL bolus up to eight times per day (online supplementary file 4: Information sheet on BMF).

Outcomes: postdischarge growth

The retrospective audit of preterm infants discharged home on BMF since the start of the project (July 2015–September 2017) included 29 infants with a mean \pm SD gestational age and weight at birth of 29.7 ± 2.8 weeks and 1.23 ± 0.32 kg, respectively (see table 1 for patient characteristics). The change in SDS between birth and 35 weeks PMA, discharge, 48 weeks PMA and 1 year

corrected for prematurity for weight, HC and length are shown in figure 4A–C, respectively.

Figure 4A shows that in the post-QI 2015–2017 cohort, overall there were improvements in growth trends for weight, length and HC. In particular, the change in SDS for weight at discharge was -0.7 and 1 year was 0.9 corrected for prematurity, so is more positive, suggesting that BMF use prior to discharge reduced growth failure and promoted growth post-discharge. For length, figure 4B shows a reduction in the fall in SDS between birth and discharge length, with a fall of -0.8 in the post-QI cohort, and a positive change in SDS of 0.8 at 1 year. Figure 4C shows a positive in change SDS between birth and discharge for HC of 0.41 and of 1.8 at 1 year in the post-QI cohort, replacing the fall that was seen previously in the pre-QI cohort.

Outcomes: breastfeeding rates

The aggregated rate for breast feeding in England on discharge following an infants' birth was 44.3% (95% CI 44.1% to 44.6%; January–March 2017). Within our local area (Southampton City), 76% of mothers had initiated breast feeding following their baby's birth, with 50% of women continuing to breast feed at 6–8 weeks after birth.¹⁸ In this cohort of preterm infants, 37.5% of mothers continued to breast feed at 8 weeks post-term and 9.4% at 1 year of age (table 2). We were unable to assess the effect of BMF supplementation on promoting and protecting

Table 1 Characteristics of infants included in the study

Characteristics	Number (%)
Male	17 (59)
Necrotising enterocolitis	0 (0)
Late-onset sepsis	0 (7)
Severe Intra Ventricular Haemorrhage (\geq grade 3)	0 (0)
Caesarian section	19 (66)
Multiple pregnancy	7 (24)
Chronic lung disease at 36 weeks	9 (31)
Patent ductus arterious requiring treatment	3 (10)
Severe retinopathy of prematurity	0 (0)
Intrauterine growth restriction (\leq 10th percentile for weight)	5 (17)

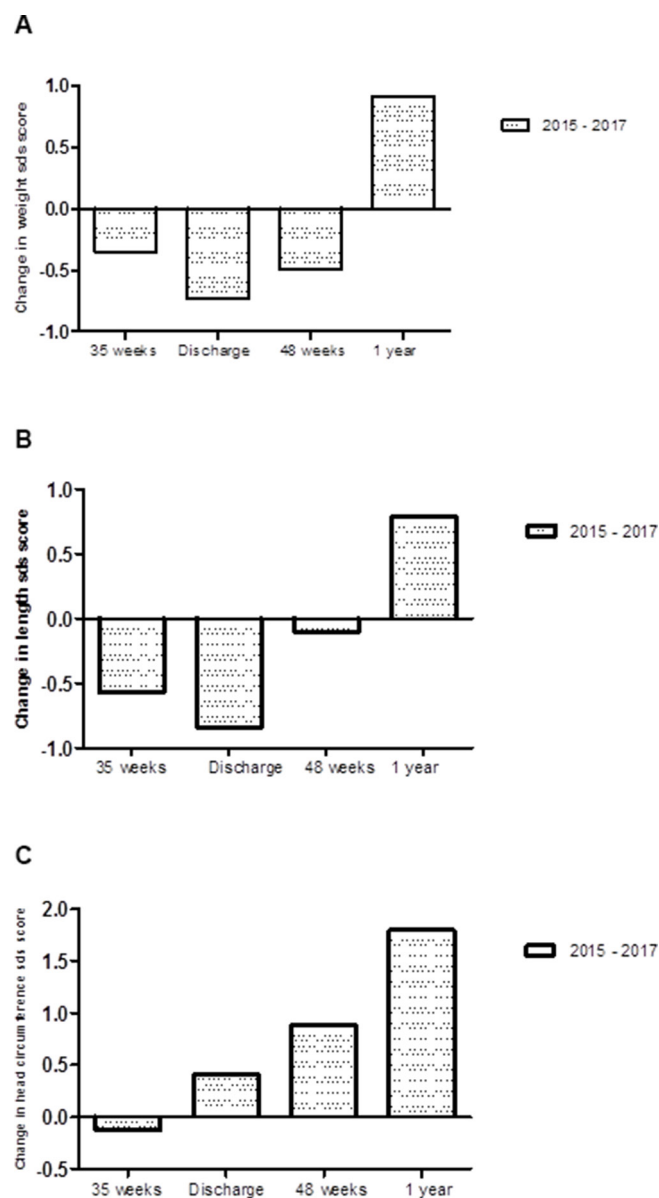


Figure 4 Change in SDS from birth to 35 weeks, discharge and 1 year for (A) weight, (B) length and (C) head circumference in 2015–2017. SDS, SD score.

breast feeding as breast feeding information was not available from the retrospective cohort.

Outcomes: parental survey

There was a 34% (11/32) response rate to the parental questionnaire. Ninety-one per cent of parents reported giving the BMF post discharge as prescribed 'most of the time' or 'always'. The three most commonly stated 'best things' about giving BMF were: helping weight gain, helping take the pressure off if an infant had not breast fed well, and the small volumes required. The three most commonly stated 'worst things' about giving BMF were: preparation difficulties, concerns about it going 'off' if it was out of the fridge for too long, and that it was difficult to administer. Parent reported symptoms and associations with BMF are shown in table 3, demonstrating that parents associated BMF use with weight gain and occasionally with constipation. Otherwise symptoms were minor and generally not felt to be associated with BMF.

Table 2 Breastfeeding rates of preterm infants discharged on breast milk fortifier

	Percentage of breast feeding at 40 weeks' gestation	Percentage of breast feeding at 8 weeks post-term	Percentage of breast feeding at 1 year of age
Yes	78.1	37.5	9.4
No	18.8	40.6	40.6
Unknown	3.1	21.9	50.0

Outcomes: dietitian survey

Sixty-six per cent (27/41) of UK dietitians completed the online dietitian questionnaire. Ten were neonatal specialist dietitians, with the remainder paediatric dietitians who provided a NNU service. Only 3% (1/27) routinely used BMF for breastfed infants postdischarge, with 30% (8/27) reporting occasional use. There was no consistency between centres as how to make up BMF, the necessary daily dosage or the duration of supplementation post-discharge. Although many dietitians felt it would be easier for GPs to prescribe BMF in a community setting, there was concern regarding inappropriate use.

DISCUSSION

Summary

This QI project aimed to improve the growth of exclusively breastfed preterm infants born weighing ≤ 1.8 kg as they transitioned to oral feeds from 35 weeks to discharge and beyond, by implementing the use of BMF as a supplement to breastfeeding postdischarge. The use of BMF in this way as part of a QI project was associated with improvements in weight, head and length growth between 35 weeks and discharge, with further improvements in weight and length growth by 1 year of age corrected for prematurity. Feedback from staff and parents was vital in ensuring the feasibility, utility and success of home BMF use. Evaluation of parental views formally using a questionnaire revealed that they found home BMF acceptable, practical and safe. Parents also felt home BMF had a positive impact on growth, though reported some negative aspects relating to the volume of expressed breast milk required, lack of written information and the complicated nature of mixing BMF sachets each time. The national dietitian survey found that providing BMF to preterm infants postdischarge is uncommon, with some concern about allowing GPs to prescribe BMF in the community, although there is no evidence to support this concern.

Table 3 Parental reports of symptoms in relation to breast milk fortifier (BMF) postdischarge

Moderate to severe symptoms	Rates of moderate to severe symptom reported by parents (%)	Symptom felt to be completely related to BMF by parents (%)	Problems with tolerance to BMF reported to dietitians (%)
Vomiting	36	0	4
Diarrhoea	0	0	0
Constipation	27	18	4
Discomfort/crying	45	9	0
Weight gain	73	27	30
Sleeping better	18	0	0
Other: reflux	18	9	4

Interpretation

ESPGHAN specifically recommends that preterm infants receive supplements after discharge to ensure an adequate nutrient supply.^{9 19} This QI project meets this recommendation while supporting and protecting breast feeding among this vulnerable patient cohort.¹⁹ To our knowledge, this is the first study to evaluate the use of BMF given as small 'shots' or boluses beyond discharge in a community setting in the UK. While a previous Canadian study has used powdered BMF beyond discharge in the community, it was mixed with substantial volumes of milk (around half the infant's feed volume) and often given in addition to breast feeds as bottles. We believe using BMF as small boluses in this way has the potential to further protect breast feeding in this population.^{14 15}

Ensuring good communication between parents, the breast-feeding lead, community nursing team, dietitian and neonatal consultants was integral to the process, and the feedback enabled iterative changes to be made to the written information as part of PDSA cycles. Including their input, particularly around the practical aspects of administering the BMF and written information, helped to increase support and embed this into routine practice. Despite this, we did encounter some confusion around the written information and how much to give and when, which was attributed to the fact it was not feasible to include every member of the community nursing team. As the current and more convenient way of making up BMF does not comply with manufacturers' recommendations, we did encounter some unexpected staff resistance, which required us to develop a summary table of evidence from the literature to support the change in practice.

Limitations

The audit of growth following the implementation of the QI project was completed in a small number of infants, and the effects seen at 12 months may be due to the natural course of preterm growth. It is also relevant to note that in the post-QI cohort, compared with the pre-QI cohort, significant reductions in the fall in SDS from birth were already present at 35 weeks for HC and length, suggesting these infants were already on an improved growth trajectory prior to commencing the additional BMF supplements. It is therefore hard to ascertain the effect of home BMF in isolation. These improvements at 35 weeks may be the result of further iterations to local nutrition guidelines between 2012 and 2016. In order to overcome this ideally, more data would need to be collected over a longer period in a larger group, ideally as part of a randomised controlled trial in order to confirm our findings.

CONCLUSION

QI methods facilitated the successful integration of BMF into routine clinical care, improving the growth trajectory of exclusively breastfed preterm infants discharged home. This led to the development of a new local care pathway that improves longitudinal growth as well as supporting, promoting and protecting breast feeding in this vulnerable population group. This project has enabled the development of a standard way of providing BMF to this population, which was found to be safe, acceptable and feasible by both parents and healthcare professionals. Due to the encouraging results gained by this project, it is necessary to ensure this improvement methodology and interventions are shared throughout the wider neonatal network and further afield as necessary and tested in a larger controlled trial.

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