

The development and implementation of a care bundle aimed at reducing the incidence of NEC

A care bundle to reduce the incidence of necrotising enterocolitis (NEC) was designed and implemented across the 17 neonatal units in the East of England Perinatal Network with the ultimate aim of reducing the incidence of NEC. The project called for significant changes in practice across a wide geographical area and involved neonatal, midwifery and allied healthcare professionals. This article describes the care bundle development process and implementation strategies required to bring about the changes involved. Data collection is continuing to determine whether implementation has been successful in reducing the incidence of NEC.

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necrotising enterocolitis; care bundle; change management; audit; compliance

Key points

- Radbone L., Birch J., Upton M.** The development and implementation of a care bundle aimed at reducing the incidence of NEC. *Infant* 2013; 9(1): 14-19.
1. Feeding practices and delivery of care, aimed at reducing NEC rates, were standardised across the East of England.
 2. Ambitious improvements require the efforts of effective change agents who use small cycles of change and regular feedback to bring changes to fruition.
 3. Adequate resources, planning for sustainability and open, frequent communication are vital for long-term project success.

Necrotising enterocolitis (NEC), an inflammatory disease of the bowel, is a major cause of morbidity and mortality in infants born before 32 weeks of gestation or with a birthweight less than 1500g¹.

Over the past 20 years, despite significant advances in neonatal care, the incidence of NEC in very low birthweight (VLBW) infants has not changed markedly, presumably in part due to improved survival rates. The mortality rate in confirmed NEC remains greater than 20%^{2,3}.

The NEC care bundle was developed in response to concerns from clinicians in the East of England about a perceived increase in the incidence of NEC in their local units. With the exact aetiological factors contributing to the development of NEC still widely debated, the Perinatal Network decided to develop a network-wide project across all 17 of the East of England's neonatal units (**FIGURE 1**), using care bundle methodology. The primary aim was to reduce the incidence of NEC across the region.

Project lead and dietetic time was funded by the Perinatal Network and managers leading local changes were offered protected time, as resources allowed.

Care bundles

Care bundles are a group of evidence-based interventions related to a disease or care process that, when executed together, result in better outcomes than when implemented individually⁴. They are a quality improvement tool focusing on a



FIGURE 1 The East of England Perinatal Network comprises the Eastern and Bedfordshire and Hertfordshire networks with two units also belonging to the North East London network.

particular patient group or disease process. Care bundles encourage collaborative working and behavioural changes and allow for the development of new insights on care processes, resulting in improved clinical and often improved organisational outcomes. Care bundle elements must be evidence-based and widely regarded as being best practice, while at the same time being simple to implement and part of day-to-day practice.

Data collection on NEC incidence

At the beginning of 2010 a data review was carried out across the East of England Perinatal Network using the Standardised

Electronic Neonatal Database (SEND) to establish the incidence of NEC between 2007 and 2009. In the absence of a national definition for NEC, and in order to capture a broad understanding of the number of babies treated for suspected or confirmed NEC, SEND data was reviewed using the crude criteria of any baby with a SEND recorded diagnosis of:

- Suspected NEC
- Confirmed NEC
- Having received metronidazole at any point of the neonatal admission.

Results showed that between 2007 and 2008 there was an increase of more than 3% of all neonatal admissions fulfilling the above criteria.

A multidisciplinary team (MDT) with neonatal, surgical, dietetic and allied health professional representation from most neonatal units within the network was brought together. As the care bundle was developed, additional expertise was sought from relevant stakeholders including midwifery teams, lactation specialists and departmental leaders.

An initial scoping exercise was undertaken to understand the range in practices relating to the management and treatment of NEC, the existence, scope and use of unit feeding guidelines and milk preparation.

The findings of the scoping exercise showed significant variation across the network in resources relating to dietetic support, the content and use of enteral feeding guidelines as well as milk kitchen facilities, milk preparation standards and feeding practices. Variation in feeding practice focused particularly on the timing of commencement of feeds, volume and frequency of trophic feeds, the interval between feeds, the rate of increasing feed volume in the at-risk population and the type of milk used for first feed³.

The care bundle development process continued with a robust literature review encompassing 15 factors implicated in the development of NEC (TABLE 1). Although high-level evidence was sought on each theme, only three were identified as elements that would meet the care bundle criteria of being simple to implement, widely regarded as best practice and day-to-day interventions. These three elements were: the use of maternal breast milk to initiate feeding; the prevention of infection; and the use of standardised feeding strategies.

A retrospective case note review of babies with suspected or confirmed NEC

- Use of donor breast milk in prevention of NEC
- Use of maternal milk in prevention of NEC
- Early vs late feeding
- Trophic feeding
- Fortifiers and milk additives
- Blood transfusions
- Enteral feeding regimens in prevention of NEC
- Reflux and the use of anti-reflux medication
- Supplementation of feeds
- Use of probiotics
- Feeding with a UAC/UVC in place
- Kangaroo care
- Resistant infection outbreak leading to clusters of NEC in affected units
- Oral lactoferrin for prevention of NEC
- Role of calprotectin in diagnosing NEC

TABLE 1 Factors implicated in the development of NEC, the basis for a literature review. Terms: UAC = umbilical artery catheter, UVC = umbilical venous catheter.

in 2009 was undertaken to look for themes from the East of England population. The criteria for inclusion in the case note review were refined to any baby who had a minimum of both seven days intravenous antibiotics and seven days of being nil by mouth for suspected or confirmed NEC. Details of babies meeting these criteria were identified from SEND and confirmed by each unit against their own SEND database and local admission book. A detailed case note review was then carried out for each baby meeting the criteria.

Using these criteria there were a total of 112 episodes of NEC in 102 babies in 2009, an incidence of 1.16 per 100 admissions⁶. Known and suspected predisposing factors for NEC were included within the review, eg gender, presence of a patent ductus arteriosus (PDA), presence of umbilical lines, the type of milk being fed at the onset of NEC, timing of blood transfusions, stool history and other factors. No clear trends in these factors were identified in the East of England population.

The working group recognised that, while mothers of preterm babies do frequently start expressing breast milk, maintaining the use of expressed breast milk (EBM) or breastfeeding in the longer

term and on discharge is more challenging. Therefore it was decided that a two-pronged approach, ensuring both early and long-term provision of breast milk, should be adopted. The final care bundle elements were therefore:

- Facilitating the use of maternal breast milk to initiate feeding through the commencement of early expression
- Promoting the long-term use of maternal breast milk through ongoing support for expression and breastfeeding
- Following a standardised enteral feeding guideline
- Prevention of infection through the use of an aseptic non-touch technique (ANTT) when preparing milk feeds.

Strategies to support the implementation of the care bundle

Unsuccessful mobilisation or engagement of leaders is a key factor in the failure of change projects⁷. A recognised model described by Bevan presents change as two divisions – anatomical change and physiological change⁷.

Anatomical change can be described as the structures (processes) employed to realise change, eg clear definition of the project, a top down approach, correct scale and pace of change and ensuring sustainability from the start. Physiological change can be described as processes that create a higher purpose and deeper meaning for staff, a connection with their values and a creation of hope and optimism about the future.

One or two 'champions' drawn predominantly from the neonatal nursing teams were identified as key links for the teaching, implementation and change cycle processes in each unit. Lactation specialists and infant feeding co-ordinators as well as medical and midwifery colleagues supported the champions in their role. To facilitate engagement and allow for multidisciplinary discussion of the evidence behind the chosen interventions, the project leader and neonatal dietitian responsible for writing the enteral feeding guideline, undertook teaching sessions across the network units.

Nursing care plans and 'top tips' for expressing breast milk were key tools to support implementation of the two elements relating to expressing and breastfeeding support. An ANTT milk preparation prompt was designed to guide staff through the milk preparation process

for use in milk preparation areas. To aid simplicity of use, the standardised enteral feeding guidelines included two algorithms (**APPENDIX 1**). The standardised enteral feeding guideline was developed by a specialist neonatal dietitian with the support of a MDT that included representation from across the region. Guidance was evidence-based as far as possible, but where evidence was insufficient or poor quality, guidance was based on regional consensus and national best practice. The first algorithm detailed feed volume and advancement rates based on the assessed risk of NEC (high, moderate or standard based on defined clinical criteria). The second provided guidance on milk choice and breast milk fortification.

To further support the change process, information folders, posters, electronic presentations and monthly electronic newsletters were produced. A letter was sent to chief executives, medical directors and commissioners to outline the project aims and to secure their support. The use of parent stories and a focus on reducing the incidence of a devastating disease through the provision of optimal, evidence-based feeding practices were some of the 'physiological' aspects of the strategies used.

Implementation of the care bundle took place during January and February of 2011 following a formal regional launch.

Care bundle delivery

It is widely accepted that active staff involvement is essential for quality improvement in an organisational setting⁸. All members of the MDT were involved in the delivery of the care pathway. The pathway commenced prior to delivery for a woman in threatened preterm labour and ended at discharge. Support for breastfeeding continued throughout the inpatient stay and, in units where community teams existed, into the home environment.

Partnership working between neonatal and maternity teams was apparent early on in the project. Encouragement of early breast milk expression was increasingly initiated by neonatologists, either at or prior to delivery, and was no longer seen as only a nursing or midwifery role. Neonatal nursing and medical teams along with dietetic colleagues agreed the initial feeding plan based on clinical criteria, which was regularly re-assessed through clinical review, and nursing observation of

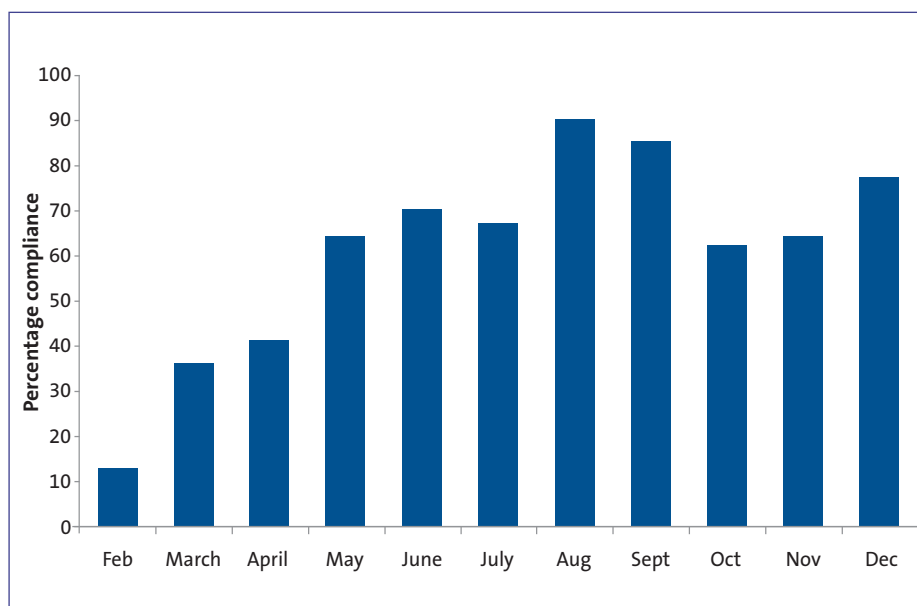


FIGURE 2 Network compliance with all four care bundle elements, 2011.

feed tolerance. Lactation consultants have been key drivers for the implementation of the care bundle and in some units have led the initiative across neonatal and maternity services.

Aims of the NEC care bundle

The primary aim of the project was to reduce the incidence of NEC in the East of England. With the small number of cases involved, it was recognised that demonstrating this would be a statistical challenge. Due to the nature of the interventions, a number of secondary aims were identified which included:

- To achieve high rates of compliance with the four care bundle elements
- To measure the impact of the care bundle elements on preterm breastfeeding rates
- To measure the impact of the bundle on length of stay
- To measure parent satisfaction⁹.

Audit of compliance

Compliance with the care bundle was audited throughout the first year of implementation. Ten randomly selected babies born at less than 35 weeks' gestation were audited each month by local champions or network personnel using a consistent network-wide audit form. An 'all or none' approach was adopted, with the expectation that every aspect of each element had to be met to be considered fully compliant.

Units progressed to a three-monthly audit when 100% compliance was achieved in all four elements for two consecutive months. It was generally considered that

the bundle had been well embedded once this level of compliance had been reached.

At this point audit criteria were changed and compliance requirements heightened with the expectation that breast milk expression would commence within six hours of delivery to achieve full compliance along with the previous criteria. This was part of a staged approach to improving practice and bringing it in line with best evidence⁶, while recognising the number of changes the initial implementation criteria demanded. As anticipated, the percentage compliance with all four elements dipped while units worked towards achieving the stricter criteria. Three units were able to maintain the high compliance rates despite these increased expectations.

The audit tool was used to measure unit compliance with the bundle and to evaluate use of the network enteral feeding guideline. The audit tool ascertained accuracy on classification of babies into the three NEC risk categories and adherence to guidance on feed management following this classification. Deviations from the guidance, both justified and non-justified were recorded. The tool also supported the identification of non-audited feeding trends across the network, including time to first feed and milk used for first feed.

The audit captured information on the use of the specific breast milk expression log designed for the project and on dissemination of the regional breastfeeding information leaflet. Reasons for non-compliance with the breast milk expression elements were also recorded.

The milk preparation audit tool captured information on whether the specified ANTT was used to prepare the feeds. This was self-audited by staff as feeds were prepared.

FIGURE 2 shows network percentage compliance with the care bundle (comprised of all care bundle elements) in the first 11 months of the implementation period. The decline in compliance after August reflects the transition of some units to the stricter audit criteria for early expression. Throughout this time period, compliance with the ANTT guidance element was consistently high while cross-network compliance with the standardised enteral feeding guideline element increased steadily month-on-month throughout 2011.

Each unit received an individualised end-of-year report detailing feedback on local compliance with the NEC care bundle since implementation in January 2011 and providing specific feedback and points for practice on use of the enteral feeding guideline.

The future of the care bundle

The care bundle has become a formal element of practice across the region with elements incorporated into a user-friendly nutrition pathway (**APPENDIX 1**), incorporating all documentation relating to the processes involved and providing an easy auditable trail. This document is transferable from unit to unit and supports a consistent approach to nutritional care across the East of England. Early outcomes for NEC rates, mortality and morbidity are currently being measured along with feeding practice trends identified in year

one. These and the results of the secondary aims of the care bundle will be published at a later date.

All four care bundle elements have become embedded practice within the neonatal units in the East of England. Wider health professional groups within the MDT are now undertaking roles traditionally undertaken by specific groups of staff. Implementation of the standardised care pathway and feeding guidelines appear to have resulted in earlier, safer, more consistent feeding practices for preterm infants. It has removed guesswork and enhanced staff confidence when making decisions about feeding and has led to the increased use of breast milk for the initiation of feeding in moderate and high risk babies (**FIGURE 3**).

What has the care bundle project taught staff?

Implementation of standardised practice across a network is possible. There is willingness within individual units to accept, embrace and contribute positively to changes in practice. Where clinicians and local teams have identified this, the change process is made considerably easier. However, to be successful, there has to be recognition that network projects need to be led by individuals with dedicated time. They have to be thoroughly planned, include appropriate representation and be carried out within realistic time frames. Where appropriate, professional contact groups for key disciplines should be established to harness the specific approaches they offer a project, adding depth to the work. Communication and

ongoing engagement are crucial aspects of project management with particular attention being given to keeping staff informed of progress and developments without a communication overload.

Training was delivered by the project leaders and then disseminated across the unit by a locally-based champion. The champions were able to directly influence the success of the project in their own unit by embracing and leading on the proposed change strategy. This process offers multiple rewards including: change brought about by local individuals who understand the culture of their teams; opportunities for career development for leaders; recognition for individuals for their successes; and opportunities for units to benchmark themselves against each other and share good practice.

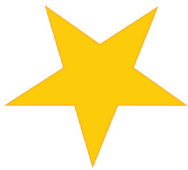
Those who take on the rewarding challenge of leading network change need patience, flexibility and a supportive and positive approach. Considerable time will be spent advising local change agents and providing essential and timely support to maintain engagement. Adequate resources, planning for sustainability and open, frequent communication are vital for long-term project success.

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Unit level and risk category	Four months post implementation	12 months post implementation
Level 3 – High	100	100
Level 3 – Moderate	76	91
Level 3 – Standard	35	60
Level 2 – High	67	70
Level 2 – Moderate	58	67
Level 2 – Standard	38	19
Level 1 – High	73	100
Level 1 – Moderate	69	83
Level 1 – Standard	37	32

FIGURE 3 The use of expressed breast milk (EBM) for initiation of feeding: percentage of babies receiving EBM as first feed.



The gold standard is to calculate feeds according to each babies individual weight. However the weight banding tables below can also be used

For staff use only:
Hospital number:
Surname:
First names:
Date of birth:
NHS no: / /
Use hospital identification label

Birth weight	Gestation	Date and time of first feed	Trophic volume (if applicable)	Starting volume (mls per kg)	Frequency of feeds	Date 150ml/kg achieved

Reason for deviation: _____
Reason for the change of category: _____

Date of change						
Volume						
Frequency of feeds						

- ✓ THE FEEDING PLANS below show the maximum starting and advancing milk volumes by weight and maximum recommended increases
- ✓ All feeding plans are to be used in conjunction with the East of England enteral feeding guideline and algorithms 1 and 2
- ✓ Commence feeds as soon after birth as possible based on clinical assessment

HIGH RISK NEONATES

Stage of feeding (Frequency and volume)	Birth weight (grams)															
	< 600	600	700	850	950	1050	1150	1300	1400	1500	1750	1850	2100	2400	3000	>3500
Trophic Feeds	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.8	2.0	2.5	3.0
Starting volume on first day of advance	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.8	2.0	2.5	3.0
Increase every 12 hours	0.2	0.3	0.3	0.4	0.4	0.4	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.9	1.0	1.3
	0.4	0.6	0.6	0.8	0.8	0.8	1.0	1.0	1.2	1.4	1.4	1.6	1.8	2.0	2.6	3.0

MODERATE RISK NEONATES

Feed Frequency :	Birth weight (grams)															
	1000	1100	1200	1300	1400	1500	1600	1700	1800	1900	2000	2100	2200	2300	2400	2499
Starting volume on first day of feeding (ml)	0.8	0.9	1.0	1.0	1.1	1.2	1.3	1.4	1.5	1.5	1.6	1.7	1.8	1.9	2.0	2.0
Increase every 12 hours	0.6	0.7	0.7	0.8	0.85	0.95	1.0	1.05	1.10	1.12	1.25	1.3	1.35	1.45	1.5	1.5
	1.2	1.4	1.5	1.6	1.7	1.9	2.0	2.1	2.2	2.4	2.5	2.6	2.7	2.9	3.0	3.0

STANDARD RISK NEONATES

✓ The starting volume plan for standard risk babies is 30 - 60ml/kg/day. Feeds should then be increased 30 ml/kg/day as tolerated.

NHS Neonatal Networks

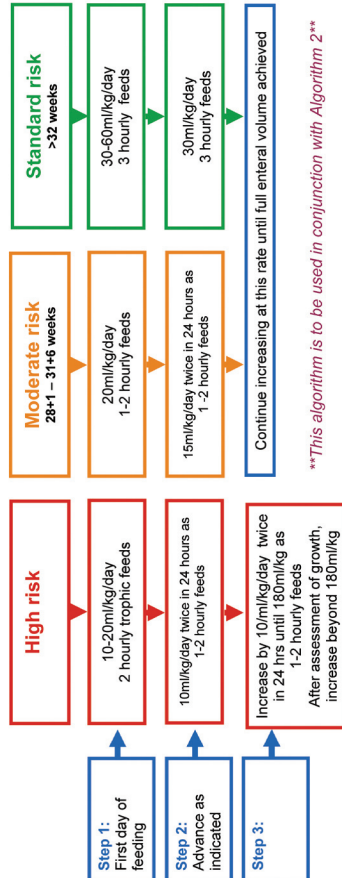
For staff use only:
Hospital number:
Surname:
First names:
Date of birth:
NHS no: / /
Use hospital identification label

Nutrition Care Pathway

Algorithm 1:

Initiating and advancing enteral feeds

- ✓ Commence feeding as close to birth as possible following individual clinical assessment
- ✓ Maintain trophic feeds in high risk infants as long as clinically indicated
- ✓ Infants can move between risk categories following individual clinical assessment



This algorithm is to be used in conjunction with Algorithm 2

Please manage my feeding as:

High Risk Moderate risk Standard Risk

High risk: Infants will generally be considered high risk if they meet the criteria below

-28 weeks gestation at birth	Severe SGA infants (<0.4 th percentile and >34 weeks gestation)
<1000g at birth	Indomethacin or Ibuprofen for PDA
Unstable/hypotensive ventilated neonates	Complex congenital cardiac disease
Perinatal hypoxia-ischaemia with significant organ dysfunction	Dexamethasone treatment
Preterm SGA infant (<2nd centile and <34/40 gestation at birth)	Polycythaemic infants
Absent/reversed end-diastolic flow in infants born <34/40	

Re-establishment of feeds following NEC	Date of Introduction:	April 2012
Serious congenital gut malformations (e.g. gastroschisis)	Review date:	April 2015
	Version:	NCP 001

Algorithm 2: Choice of milk

✓ **Fresh maternal breast milk is the first milk of choice for all infants unless clearly contraindicated**

Infants ≤ 33⁺⁶ weeks gestation

Weight <2kg at birth

Weight ≥2kg at birth

Infants ≥ 34⁺⁰ weeks gestation

Breast feeding or EBM increasing to 165ml/kg/day as per algorithm 1

Expressed breast milk (EBM) increase as per algorithm 1 to 150ml/kg/day

Infant <1.5kg at birth

Once tolerating 150ml/kg/day EBM for 24 hours consider Breast Milk Fortifier (BMF)

Increase as tolerated to 165ml/kg/day

Increase to 160ml/kg/day EBM + BMF only if weight gain is poor

If insufficient or no EBM use preterm formula or Donor Breast Milk (DBM) where available (according to EOE guidelines)

Infant >1.5kg at birth

Increase as tolerated to 180ml/kg/day EBM if required to achieve weight gain

Increase to 200ml/kg/day EBM if required to achieve weight gain

If insufficient EBM use Term Infant formula

Reducing the risks of infection associated with milk feed preparation

- ✓ The Aseptic Non-Touch Technique (ANTT) prompt must be used every time a milk feed is to be prepared
- ✓ EBM / DBM must be used within 24 hours from the start of the defrosting process
- ✓ Fresh EBM can be used for 48 hours from being expressed
- ✓ EBM / DBM must not be used after being out of the fridge for longer than 4 hours

ANTT spot audit undertaken on:

>180ml/kg/day should rarely be required in infants receiving preterm formula or fortified EBM. Alternative reasons for poor growth should be examined before volumes >180ml/kg/day are implemented.

Top tips for expressing:

- ✓ Expressing is best started within the first 6 hours of delivery.
- ✓ Essential to express at least once between midnight and 06:00 hrs. Do not suggest skipping this expression to encourage a good night's sleep.
- ✓ Hand expressing is the most effective way of collecting colostrum.
- ✓ Early and frequent expressing leads to greater long term milk production.
- ✓ Mothers of preterm and sick babies should express 8-10 times in a 24 hour period until milk supply has been established.
- ✓ Avoid gaps of longer than 6 hours between expressing
- ✓ Advise double pumping where possible as this increases milk supply.
- ✓ Encourage pumping for 2 minutes after the last drop of milk has been expressed, to promote milk production.

For staff use only:

Hospital number:

Surname:

First names:

Date of birth:

NHS no: / /

Use hospital identification label

FOR STAFF AWARENESS ONLY

Day 10: Is mother expressing >350 mls milk per 24 hours? If not – refer urgently to lactation consultant and review expressing log.

Mothers should be aiming for at least 750 – 900 mls per day by day 10 in order to maximise potential for sufficient milk volumes at discharge - This is a guide and should not be used to pressure mothers.

Expressing reviewed on:	Day 3	Day 5	Day 7	Day 9	Day 10 onwards
✓					
Advice given					
Signature					

Referral to lactation specialist	Yes	No	Date:

DAY 0 - 9: CARE PLAN TO SUPPORT EARLY EXPRESSING OF BREAST MILK

Action	✓	Date	Signature
1 Benefits of breast milk discussed in relation to: <ul style="list-style-type: none"> • Reducing the incidence of bowel infections (NEC) • Protective qualities help to reduce the risk of infections • Better tolerance when compared to formula feeds • Improved neuro developmental outcomes for babies • Maternal benefits 			
2 Have maternal medications been checked and assessed as safe for use when breastfeeding? (Include prescribed, non prescribed and herbal)			
3 The following leaflets have been given: <ul style="list-style-type: none"> • East of England regional premature breastfeeding leaflet or local equivalent • BLISS leaflet "Breastfeeding your premature baby" • BLISS booklet: "Skin to Skin" with your premature baby. 			
4 Call to midwife within 4 hours post delivery to ensure mother has started hand expressing			
Time of birth: _____			
NO: (update care plan)			
5 Importance of skin to skin contact with baby (when appropriate) explained and consequent need for daily shower / bath and regular hand hygiene.			
6 Importance of frequent milk expression explained: 8-10 expressions in 24 hours for the first 2-3 weeks.			
7 Expressing log has been offered to mum for use			
Document if declined			
8 Is there a need for pump hire?			

DAY 10 TO DISCHARGE: ONGOING SUPPORT FOR EXPRESSING AND BREAST FEEDING

1 Kangaroo care, Skin to Skin or Positive Touch has been undertaken	
Please detail in notes	
2 Update action plan in clinical notes as required	

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