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Guidelines for the Preparation and Handling of Expressed and Donor Breast Milk and Specialist Feeds for Infants and Children in Neonatal and Paediatric Health Care Settings



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Foreword

The safe feeding of hospitalised infants and children is paramount in enhancing their clinical outcome. Quality assurance is essential at all stages of preparation, handling, delivery and administration of feeds containing expressed breast milk (EBM), powdered infant formula (PIF) and/or formula for special medical purposes. This revised document provides the guidelines for all health care facilities to adopt locally and from which to devise their own internal monitoring and audit trail.

These guidelines are based on current research and scientific evidence where available together with best practice from experienced practitioners. This edition extends to the preparation of feeds in neonatal intensive care units (NICU) considering the handling of maternal and pasteurised donor breast milk as well as expanding beyond paediatric hospitals with a special feed unit to include health care facilities where there is no designated feed preparation room.

The desired outcome is that all infants and children within a health care setting receive optimal nutrition prepared in a safe manner and that all the staff working within the health care facility have guidelines to prepare safe feeds.

This document will be reviewed in 3 years or as new evidence emerges.

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Frequently Used Abbreviations

BMF – Breast Milk Fortifier
FSA – Food Standards Agency
FSMP – Formula for Special Medical Purposes
HACCP – Hazard Analysis Critical and Control Point
MEBM – Maternal Expressed Breast Milk
NEC – Necrotising Enterocolitis
NICU – Neonatal Intensive Care Unit
PDBM – Pasteurised Donor Breast Milk
PIF – Powdered Infant Formula
RTF – Ready to Feed
RTH – Ready to Hang
SFU – Special Feed Unit
UK – United Kingdom
WA – Working Appendices
WHO – World Health Organisation

Definitions

Aseptic Technique: a set of specific practices and procedures performed under carefully controlled conditions with a goal of minimising contamination by pathogens

Cleaning: a process that physically removes contamination and many micro-organisms using a detergent

Decontamination: any process that renders an item safe and fit for re-use

Disinfection: a process that reduces the number of micro-organisms to a level at which they are not harmful. Spores will not usually be destroyed

Pasteurisation: the partial sterilisation of foods at a temperature that destroys harmful micro-organisms without major changes in the chemistry of the food

Pathogen: A bacterium, virus, or other microorganism that can cause disease

Sanitise: to make sanitary by cleaning or sterilisation

Sterilisation: a process that removes or destroys all micro-organisms, including spores

Section One

Introduction

Breast feeding is the preferred method of feeding infants including the preterm and hospitalised infant. Breast milk provides the proper balance of nutrients and transfers immune factors to protect the infant in early life. Preterm infants often require additional nutrients including breast milk fortifiers in breast milk.

When breast milk is unavailable for the infant in health care facilities, nutritionally appropriate ready to feed (RTF) formulas should be used as these are commercially sterile. Infants and children requiring specialised feeds, formulated to meet their individual and clinical needs, should receive the appropriate RTF product where available in preference to powdered products. Industry continues to manufacture more sterile liquid feed options which are available to health care facilities. RTF formulas remain free of microbiological contamination before opening providing the container is intact and stored appropriately.

In the absence of RTF products, many infants and children are prescribed individualised feeds requiring the use of a powdered formula and/or supplement. Powdered formulas and supplements enable the provision of specialised nutrition that;

- meets clinical needs (these may be disease specific)
- improves growth
- allows the provision of ideal nutrition within a fluid restriction

Powdered feed products are not sterile; they can be intrinsically contaminated with pathogens [1]. PIF conform to appropriate microbiological specifications. For PIF in international trade, these specifications were recently revised by Codex Alimentarius Commission (CAC 2008) [2].

Powdered feeds are a food source and once reconstituted become a medium for bacterial proliferation. This concern was heightened after the increase in the notification of serious cases and outbreaks of disease caused by *Cronobacter spp* [3]. This problem is especially serious in vulnerable infants (preterm, low birth weight, immunocompromised, in the first two months of life) [4]. To address this issue, the World Health Organisation (WHO) issued guidelines for the safe preparation, storage and handling of powdered infant formula (PIF) [5] in 2007.

When a liquid alternative is not available, the preparation of powdered formulas requires careful handling to avoid contamination and minimise growth of micro-organisms. These guidelines provide instruction on the best practice from available scientific evidence and current practice within the UK to control the critical factors which influence possible microbial growth in prepared formulas; these include;

- formula preparation technique
- cleanliness of formula preparation environment and equipment
- maintaining appropriate hanging and feeding times
- making regular tubing changes
- complying with expiry dates
- using an aseptic technique at each stage when preparing feeds

The quality of water used in the preparation of feeds in care settings needs to be controlled and monitored. Recent neonatal mortalities linked to *Pseudomonas aeruginosa* in water from contaminated taps have been investigated [6, 7].

Section Two

Physical Facilities

Powdered feeds must be prepared in a specific location away from the bedside with adequate space and equipment [8]. The area for the preparation of specialised feeds must ensure the preparation and delivery of safe feeds using an aseptic technique [9] as well as minimising airborne contamination (as from open windows, vents). A room that is routinely used for a function necessitating similar requirements for cleanliness and equipment can provide an acceptable work area.

Where there is a high demand for specialised feeds, as in paediatric hospitals, a separate room for the preparation and handling of powdered feeds is recommended. This is designated the Special Feed Unit (SFU).

During the preparation of powdered feeds, there must be no other activity in the SFU or designated area. Access to the SFU is restricted to minimise the risk of cross-infection and tampering of feeds.

2.1 The Special Feed Unit

The area and equipment layout should follow the logical flow of materials through the storage, production and clean-up process as well as facilitating efficiency at each stage. The SFU should consist of storage, preparation, clean-up and office areas.

2.1.1 Storage

This room should ideally be separate from the preparation room. It should be shelved with all feed products stored above floor level. The temperature should be ambient without large variations in temperature. Daily records of the room temperature should be monitored (Appendix 1WA). Products should be stored in a manner allowing adequate air flow. The expiry dates of stock must be checked regularly and stock rotated when storing to avoid the use of out of date products. The expiry dates of all products must be checked before use.

Where the storage is integrated within the preparation area the above criteria continue to apply. There must be a designated area for feed storage and a separate area for cleaning equipment.

2.1.2 The Office

There should be a designated area for receiving orders, record keeping and label preparation. In larger units, there should be space for a telephone/ fax machine, computer terminal, printer and stationery store.

2.1.3 The Preparation Area

The preparation area contains a stainless steel work surface, a hand wash sink with hand free taps, anti-bacterial hand wash and drying facilities, storage for utensils and current feeds being used, and refrigerators for holding the prepared feeds. Utensils and currently used feed products should be stored in closed cupboard(s). Depending on the procedures required by the individual health care facility, optional equipment used in the preparation room may include a pasteuriser, blast-chiller and freezer. There should be provision for water for feed preparation to meet national and institutional standards. Adequate electric outlets with sufficient power should be provided for the equipment within the room and be compliant with local standards. Electric outlets for the refrigerators and freezers should be backed by emergency generators in cases of power failure. Lights within the unit should be enclosed and allow adequate illumination for accurate feed production. Clean air should be supplied through the ventilation system. Floors, walls and ceilings should be of a material that can be easily maintained clean. The unit must be cleaned daily and deep cleaned on a weekly basis (Appendix 2WA). All waste bins must be covered, foot operated and emptied daily.

2.1.4 The Clean-up Area

This can be a designated area within the preparation room or in larger units situated in a separate area. In the former, the processes of preparation and clean-up must be separated by time and space. Small equipment can be cleaned in a dish washer or sterilised in an autoclave. When a dishwasher with an 82°C final rinse cycle is used, a single sink for pre-rinsing is sufficient [9]. If bottles are re-used, a two or three compartment sink with bottle-washing brushes and a rinse nozzle is suggested.

A stainless steel three compartment sink allows for washing, rinsing and sanitising. Dedicated food compatible cleaning supplies must be stored away from feed products and equipment.

2.2 Facilities without a Separate Feed Preparation Room

A section of the food production area or dedicated space in a nursery can be designated a feed preparation area. When choosing an area, all construction considerations of standard food preparation must be followed. To minimise clean-up area requirements, only single use bottles should be used. The preparation equipment should be sanitised in standard dishwashing equipment following local policy or autoclaved by the hospital's sterilisation department.

In a shared preparation area, other activities should finish before feed preparation starts. Food supplies must be removed and work surfaces thoroughly washed, rinsed and sanitised using approved food compliant chemicals. The mixing equipment should be used solely for feed preparation and the supplies should be removed from clean storage and brought to the preparation area. Only personnel involved in feed preparation should be in the area during feed production. They should follow an aseptic technique and place prepared feeds directly into a designated refrigerator after cooling the feeds. The refrigerator should not contain other food supplies; if this is not possible, feeds should be stored in covered plastic storage boxes separate from food supplies with separate boxes for feeds containing breast milk.

Section Three

Equipment and Supplies

3.1 Equipment

All equipment and utensils used within the preparation room should be made of stainless steel or other non-absorbent material. They must be easily cleaned and decontaminated and withstand temperatures of a commercial dishwasher [10] in a SFU. Strong and persistent biofilms can form on surfaces such as steel, plastic, silicone and latex [11]. Proper cleaning and decontamination of the equipment used in feed preparation is essential to avoid *Cronobacter spp* biofilms contaminating subsequent feeds if not removed.

Written guidelines should be produced outlining the regular scheduled checking and monitoring of maintenance for any equipment used during the preparation and storage of feeds produced in the SFU (Appendix 3WA).

3.1.1 Refrigerator, blast-chiller and freezer

Prepared feeds must be chilled rapidly and stored at 2-4°C. This is essential for the safe storage of feeds. *Cronobacter spp* can grow very quickly at temperatures between 6-47°C [12]. All prepared feeds are an excellent growth medium for bacteria due to their high moisture and nutrient content, and warm temperatures support optimal bacterial growth. Rapid chilling minimises the time that feeds are in danger of microbial growth.

Commercial refrigerators are recommended in a SFU; these should allow temperature monitoring and adequate air circulation. The most efficient way of cooling feeds efficiently is by the use of a

blast-chiller; this is advised in larger units. It is not uncommon for domestic refrigerators to be above the recommended 4°C storage temperature [13, 14] and these must be carefully monitored where used and data acted on accordingly.

If maternal expressed breast milk (MEBM) is stored and fortified in the feed preparation room, a freezer that holds the milk at -20°C is needed. A commercial grade freezer with external thermometer and alarm systems is recommended [9].

Refrigerator and freezer temperatures should be checked and recorded daily (Appendix 4WA) to monitor fluctuations in temperature. Feeds must be discarded if operational temperatures are not within the recommended range (refrigerator: 2-4°C; freezer: <-20°C).

3.1.2 Dishwasher

In a SFU, a commercial dishwasher is recommended. This should reach a temperature of 66-74°C and a rinse temperature of 82-91°C. Use of the facility's foodservice dishwasher is not recommended. Where a dedicated dishwasher is not available, controlled practices to avoid cross contamination must be implemented.

3.1.3 Utensils

Equipment and utensils used for the preparation of feeds must be easily decontaminated and facilitate the use of the aseptic technique. This includes items such as measuring and mixing devices, scales, trays, spoons, sieves, bowls and jugs. Blenders should be avoided. Bottles and teats are for single use only unless they can be sterilised or decontaminated adequately. All devices used for MEBM must be sterilised between uses.

3.1.4 Transportation Equipment

Transportation equipment must cover the bottles of feed, be easily cleaned and maintain the feeds at 4°C or below to allow safe transportation to the wards and units within the facility. The temperature of the transport equipment should be checked daily before use and monitored.

3.2 Supplies

Tap water that is freshly boiled and cooled to 70-80°C should be used for feed preparation (see section 5). Commercial bottled water (with accepted electrolyte content) should never be used to make feeds unless boiled first according to the criteria in section 5.

The formulas and proprietary products should be available in the preparation room. These should be obtained from reputable sources. Once opened, packages should be dated and stored in closed cupboards or the refrigerator as appropriate. Any damaged products together with out of date stock must be disposed of. Once prepared, it is recommended that feeds have tamper-proof tabs to ensure their authenticity. This can be via safety strips or heat sealed lids on the bottles.

Cleaning supplies must be approved for food service use by the health care facility's infection prevention and control department. These must be stored separately from feed ingredients.

3.3 Facilities without a Feed Preparation Room

Feed preparation should be in a designated space with equipment dedicated specifically for feed production. The equipment should include the following: facility approved sanitising solution, hand gel, sterile water, disposable measuring devices for liquids, scales, container with lid to mix feeds, individually wrapped spoon for mixing, bottles, and waterproof labels and refrigeration for feeds not used straight away.

Feeds must be cooled quickly. In the absence of a blast-chiller, this can be achieved by:

- holding the bottles under cold running water ensuring that the water is below the level of the lid.
- cooling the bottles in a container of cold water or ice ensuring that the water level is below the level of the lid and that the bottles do not tip over.

The outside of the bottle should then be dried and a label attached with the child's identification details.

Section Four

Personnel

The production of safe and accurate feeds by a SFU requires staff in administrative, supervisory and technical roles. All staff must be trained and skilled in their respective duties.

The operational management of the SFU or feed preparation area should be the role of a professional such as a registered dietitian or a registered senior nurse. The SFU should be assigned a supervisor experienced with the aseptic technique and SFU operations. SFU technicians should be competent in comprehension and written English and be numerate.

The number of employees will depend on the volume of work within each facility. A sufficient number of trained staff should be available to provide seven-day cover for the SFU accounting for planned and unplanned leave.

Productivity measures for SFU staff have not been published to date. Most of the work time involves standing. Staff should access and update local manual handling training especially in relation to lifting and carrying products. Staff should be instructed to immediately report any illness they experience with symptoms of gastro-intestinal disturbance, pyrexia, respiratory infections, skin lesions and sores. Local policies for managing illness must be adhered to.

4.1 Personal Hygiene and Clothing

All staff must meet the guidelines of the facility to maintain appropriate personal hygiene and dress code. In the SFU, aseptic clothing is essential as a uniform or theatre blues. Staff should have a separate area to change into their uniform. Disposable aprons and hats should be worn and be put on before hand washing. Sterile gloves are recommended when handling MEBM or to cover cuts. Shoes must be closed, nonslip and comfortable. Eating and drinking is prohibited in the feed preparation area.

4.2 Training

A written training policy should be developed and implemented [15] (Appendix 5WA). New starters should have an induction period of sufficient duration and content to enable their competency in feed production [16] such that feeds are produced accurately and without bacterial contamination.

All staff preparing feeds should maintain food hygiene qualifications in line with local policy.

4.3 Personnel in Facilities without a Feed Preparation Room

All employees who prepare feeds, including nursing staff, and handle MEBM should have documentation of an annual competency in feed preparation. This should include:

- the use of standard feed recipes
- hand decontamination before feed preparation
- aseptic technique for feed preparation
- labelling requirements
- cleaning techniques
- appropriate storage of feeds and EBM
- stock control

Section Five

Feed Preparation and Handling

The appropriate preparation and handling of feeds for infants and children in health care settings is crucial to the delivery of a safe and accurate feed. It is essential that local written guidelines are implemented and that these are monitored. There should be full traceability of prepared feeds in health care settings.

5.1 WHO Guidelines for safe Preparation, Storage and Handling of Powdered Infant Formula

In 2007 WHO published guidelines for the safe preparation, storage and handling of PIF [5]. Where possible, PIF should be made fresh for immediate consumption. Specific advice in relation to formula for special medical purposes (FSMP) has not been issued by the Food Standards Agency (FSA). It is considered best practice to adhere to the WHO guidelines when preparing FSMP.

The WHO guidelines also consider the precautions to take in the advance preparation of large quantities of feeds in care and institutional settings where it is impractical from a man-power and financial perspective to make individual feeds. Detailed procedures for powdered formula preparation are given. Modified feeds with multiple ingredients are made for a 24-hour period, using the aseptic technique, to ensure accuracy. In health care settings tamper proof lids/seals are recommended for all prepared feeds.

5.2 Aseptic Technique

The aseptic technique must be followed in the preparation of all feeds in health care settings to control the microbiological quality of the feed. Prior to feed preparation, work surfaces must be cleaned with a food-grade anti-bacterial sanitising solution. During feed preparation, there should be no admittance of allied staff to the feed preparation room and no other activities taking place. The aseptic technique combines hand decontamination with the no touch technique to exclude contact contamination from personnel, work surfaces, equipment and environment [17]. Each health care facility should have written guidelines for the aseptic technique (Appendix 6WA).

A clinical incident form must be submitted when any of the stages within the production, handling, storage and dispensing of feeds produced by the SFU or facility are not met.

Clinical risk assessment should occur in each SFU or specified feed production area to highlight potential hazards (refer to section 9). This documentation should be kept within the local procedure/guideline folder.

5.3 Feed Recipes and Labels

Written or printed instructions for the preparation of feeds within the SFU must be authorised by a registered and appropriately trained paediatric dietitian.

All feeds must carry an identifying label. The minimum information to be included on a label is:

- patient name
- hospital number
- ward/location
- feed name including additives
- expiry date and time

Additional information can include volume, percentage of ingredients, 'for enteral use only', 'refrigerate until used'.

5.4 Ingredient Water

The WHO and United Kingdom (UK) Department of Health recommend reconstituting PIF with previously boiled tap water cooled to $\geq 70^{\circ}\text{C}$ for all infants (≤ 12 months) [5,18]. This fresh water should come from the cold water tap. In practice this equates to boiling one litre of water and allowing it to cool for 30 minutes in a covered container. Care must be taken to avoid scalds. This evidence has been used as best practice to make up formula for special medical purposes within the SFU in the UK. Risk assessment modelling found that reconstituting PIF with $\geq 70^{\circ}\text{C}$ water to result in a $>100,000$ fold reduction in risk [19]. Such made up feeds must be stored in the refrigerator for no longer than 24 hours from the time of reconstitution

The use of $\geq 70^{\circ}\text{C}$ tap water to reconstitute formula can cause some loss of vitamins. The small amount of experimental evidence available on the effects of heat on vitamin content in PIF and other formula products suggests that the loss is small and is less with shorter durations of heat exposure [20].

The addition of hot water ($\geq 70^{\circ}\text{C}$) to PIF could activate any bacterial spores (especially *Bacillus cereus*) that may be present in the powder [21]. Reports suggest that this likelihood is minimised if the reconstituted feed is rapidly cooled after making and either fed immediately or refrigerated at $\leq 4^{\circ}\text{C}$ [21]. The variation in killing rates of bacteria in reconstituted feed below 70°C has been published by the FSA [2].

Commercial sterile water can be used following the above temperature guidance. Commercial bottled waters may contain a high level of certain minerals. In emergency situations it is recommended that only bottled waters with a sodium (Na) level of less than 200mg per litre and a sulphate (SO_4) of less than 250mg per litre are used to make up feeds; these should be boiled before use for infants under 6 months of age (NHS, 2011) [22, 23].

5.5 Formula Mixing

Formula and feed containers should be handled under aseptic technique. Powdered or decanted liquid feeds should only be used when there is no suitable alternative sterile feed available. All feed products should be checked to ensure their integrity; products with damaged packaging should be returned to the supplier. Clean sterilised or disinfected mixing equipment should be used to prepare each type of feed to avoid cross contamination.

Any feed containing MEBM must be made up at the end of formula preparation after work surfaces have been cleaned and fresh equipment used.

Prepared feeds should not be frozen and thawed as freezing can cause irreversible physical changes.

5.5.1 RTF Formula and Concentrated Liquid Formula

Check both the expiry date and that the seal is intact before the use of such products. Shake well, clean the lid before opening and measure the required amount using an accurate measure. The top of the container should not be touched with hands during this process. Opened feed can be covered and stored in the original containers in the refrigerator according to the manufacturer's directions; the container must be labelled with the expiry date and time.

5.5.2 Powdered Formula

These can be additives or formula used when a nutritionally comparable sterile liquid feed is unavailable. The expiry date should be checked. Where available, these are measured by weight using a scientific scale accurate to one decimal place. The manufacturer's scoop inside the container should be removed aseptically and discarded; scoops should only be used where there are no accurate weighing scales.

Measure the ingredient water according to the feed instructions and add to the powder. Mix well with a spoon, fork or whisk. Opened containers should be covered, labelled with the expiry date and stored in a cool dry area for up to one month.

5.5.3 Feeds containing Probiotics

Probiotics are live micro-organisms which colonise the gastrointestinal tract and can bestow benefit to the host. There are reported significant impacts of probiotics reducing the incidence and severity of necrotising enterocolitis (NEC) [24]. There is also emerging evidence for the use of specific probiotics in acute gastroenteritis [25] as well as in improving tolerance in infants with cow's milk protein allergy [26, 27]. Probiotics can be given as a dosed supplement; they are increasingly being added to FSMP. As probiotics are inactivated by hot water, the reconstitution of a feed containing probiotics would fall outside of current WHO feed reconstitution recommendations and a local risk assessment would be needed. Where facilities are able to make individual fresh feeds with FSMP containing probiotics for immediate consumption; these should be reconstituted after the preparation of feeds without probiotics to minimise cross contamination and made by adhering to a strict safe preparation technique. Although probiotics are generally regarded as safe, there are clinical conditions in which their use requires special caution, such as prematurity, immunocompromised patients, critically ill patients, those with a central venous catheter, cardiac valvular disease and short-gut syndrome [28]. In a large facility with a SFU preparing feeds for a 24-hour period, FSMP containing probiotics need to be made with water of $\geq 70^{\circ}\text{C}$; the probiotics will be inactivated. Randomised controlled trials in this field together with safe procedures for the use of probiotics in tube feeding are awaited [29].

5.5.4 Pre-thickened Feeds & High Fat Feeds

For compositional reasons, several FSMP cannot be reconstituted with water at $\geq 70^{\circ}\text{C}$.

Manufacturers recommend that pre-thickened (anti-reflux) infant formula with added corn starch, carob bean gum or rice are made up with boiled water cooled to room temperature to avoid clumping. Thickened feeds have only been shown to be moderately effective in treating gastro-oesophageal reflux in healthy infants [30]. Where these products have been prescribed to aid in improving gastro-oesophageal reflux, they should be used under medical supervision and the risks considered in reconstituting in line with the guidance of the manufacturer for a 24-hour feed.

Manufacturers of FSMP with a high fat content for use in a ketogenic diet, recommend reconstituting using warm water ($45\text{-}50^{\circ}\text{C}$) to dissolve the powder easily. A local risk assessment together with a strict safe preparation technique should be in place.

5.5.5 Electrolytes

Electrolytes should be added at ward level and administered by trained nursing staff. Where a local policy allows for their addition in the SFU, all staff should be trained and assessed competent at measuring small volumes. All electrolyte additions should be checked and counter signed.

5.6 Pasteurisation

The pasteurisation of feeds is not routinely recommended. This is due to the potential alteration of nutritive and physical characteristics. Feeds containing amino acids or peptides are nutritionally compromised by pasteurisation [31].

There is an absence of evidence supporting or disputing the pasteurisation of specialised feeds and modified enteral feeds. Some of the larger children's hospitals in the UK have adopted the pasteurisation of feeds for at risk groups as best practice. These include preterm infants, low birth weight infants, neonates (infants <28 days of age), immuno-compromised children and those on powdered jejunal feeds. For these groups the feeds are heated to a temperature of 67°C for 4 minutes and rapidly cooled to a safe temperature. Pasteurisers must be data logged to ensure that correct temperatures are reached.

Literature does however support the use of pasteurised donor breast milk (PDBM) especially for the preterm infant [32, 33]. PDBM has been shown to reduce the incidence of necrotising enterocolitis (NEC) by four-fold in preterm infants and improves feed tolerance [34, 35]. In this pasteurisation process, human milk is heated to 62.5°C for 30 minutes and is rapidly cooled to a safe temperature.

5.7 Chilling and Storage of Feeds in the SFU

Once made, prepared feeds must be rapidly cooled and either fed immediately or refrigerated at ≤4°C. In healthcare establishments producing large numbers of feeds, a blast-chiller is recommended. A blast-chiller should cool feeds to ≤4°C within 15 minutes. Without a blast-chiller, feeds are cooled by placement in a container of cold or iced water ensuring that the level of the cooling water is below the lid of the bottle/container. Once cooled, the containers are dried and stored in a dedicated refrigerator with an alarmed temperature gauge. The temperature of prepared feeds should be maintained at ≤4°C until used.

5.8 Care and Maintenance of Facilities and Equipment

The work area and equipment in the SFU or feed preparation area must be kept clean and organised. Written guidelines should be in place for the maintenance of a clean unit. All equipment and work surfaces must be thoroughly cleaned after use. Any spillages should be wiped up straight away with a clean disposable cloth. Cleaning schedules should be written for each unit (Appendix 2WA).

Bacteria such as *Cronobacter spp* which can be found in powdered formulas are able to form strong biofilms on feeding equipment including bottles, screw caps and feeding tubes. *Cronobacter spp* can attach and grow on surfaces such as latex, silicon and stainless steel [36, 37, 38]. Biofilms can inhibit cleaning and disinfection as well as being a source of contamination for subsequent feeds if inadequately cleaned equipment is used. Biofilms can persist on these surfaces for long periods of time and cannot be removed from feeding tubes [38]. Thorough cleaning and disinfection is essential [39]. Food grade disinfectants should be used according to manufacturer's directions.

5.9 Feeds Made Up Outside of SFU Hours of Operation

Local procedures should be written for feed orders made outside of the normal operational hours of the SFU. Where medically appropriate, RTF products should be dispensed until modular feeds are prepared from the SFU. When FSMP are required, an emergency cupboard containing specialised feeds should be located within the facility and the feeds made as stated in section 3.3.

5.10 Irregularities in Feed Preparation and Storage

The Department of Health reiterated its position to follow current best practice on the safe preparation of powdered infant formula milks in 2013 [40].

Written guidelines should be in place to report and investigate all errors in the feed preparation, feed storage and/or feed delivery mechanism. These must be considered according to local policy.

Local records should be kept regarding the personnel preparing a feed and the checks made during this process. Records should be retained in accordance with local policy

Section Six

Storage, Collection and Handling of Maternal Expressed Breast Milk (MEBM) and Pasteurised Donor Breast Milk (PDBM)

If it is not possible for an infant to breastfeed in hospital due to prematurity, infant or maternal ill health or maternal wishes, the mother should be supported to express her breast milk. Hand expressing is a valuable skill and should be taught as soon as possible following delivery so that new mothers who are separated from their baby can start to express within the first 4-6 hours of birth. Manual or electric pumps may also be used. Easy access to hospital grade electric pumps will be needed by most lactating mothers of hospitalised infants and pumps with adjustable suction that have been designed and sold as suitable for communal use should be readily available. Frequent expressing (8-10 times in 24 hours) including a night time expression will facilitate the initiation of lactation and help to maintain a good milk supply [41]. In the early days and weeks following an infant's birth the mother may express more milk than her infant needs. She should be encouraged and supported to maintain her milk supply as it may be more difficult to increase lactation at a later stage. Dual pumping (in which both breasts are expressed at the same time) is advisable [42], especially once a mother is familiar with the use of the electric pump.

When insufficient MEBM is available, pasteurised donor breast milk (PDBM) obtained from a human milk bank operating to nationally recognised standards [43] is an alternative option and is the recommended alternative for preterm infants [41, 44]. A list of UK milk banks is available from the UK Association for Milk Banking [45] together with information on the milk banks that supply PDBM to hospitals that wish to obtain it.

In situations where an infant is able to feed at the breast, providing supplementary feeds via a supplemental nursing system or nasogastric tube rather than by cup or teat will help to maximise an infant's time at the breast and so help to promote lactation.

Expressed breast milk is not sterile and may be contaminated by both commensal and pathogenic micro-organisms during its collection, handling and storage. Applying a hazard analysis and critical control point (HACCP) approach to systematically identify, evaluate and control significant hazards will limit the contamination of breast milk and prevent multiplication of any organisms that are present [46].

6.1 Expressing Breast Milk

- 6.1.1 Support mothers to express at the cot side. This will reduce the time they are separated from their baby/ies and can help to promote lactation [47].
- 6.1.2 A comfortable dedicated room equipped with electric breast pumps should also be made available for mothers to express their milk [47].

- 6.1.3 Provide written and verbal instructions to each mother explaining how to express breast milk by hand [40] as well as how to use and decontaminate the expressing equipment and how to label and store breast milk [46].
- 6.1.4 Demonstrate effective hand washing techniques and provide written and illustrated guidance for mothers. Explain that hand washing prior to and after expressing breast milk is an effective means of minimising contamination of the milk with harmful micro-organisms. In addition, washing the breasts daily and a daily change of bra that has been washed using a hot machine cycle or in hot water is recommended.
- 6.1.5 The availability of a range of sizes of breast pump shields will help to ensure mothers receive optimal support for expressing and prevent nipple trauma caused by ill-fitting equipment. A mother may need different shield sizes as her lactation progresses [48].
- 6.1.6 Provide sufficient electric breast pumps for use in hospital so that mothers can express breast milk whenever they need to or are ready to [49]. Suitable locations for electric breast pumps will include all postnatal facilities, neonatal and paediatric unit wards and family overnight rooms as well as dedicated expressing rooms.
- 6.1.7 Ensure electric breast pumps are routinely checked and maintained by clinical engineering staff in accordance with manufacturers' instructions and local equipment protocols to ensure they are working safely and effectively and that milk has not been allowed to enter the pump's casing or its mechanism.
- 6.1.8 Initially provide sterile expressing equipment (collecting set and tubing) to all new mothers wishing to express their milk. This can be:
- a new, sterile set that has been purchased for single use (disposable)
 - a new sterile set for a single user with cleaning/decontamination between each use followed by disposal once no longer required by the user
 - a sterile set that will subsequently be sterilised between every use and/or between users
- 6.1.9 Adhere to the manufacturers' instructions for decontaminating or sterilising all parts that come into contact with the mother and with her milk as long as they are in accordance with locally agreed infection control protocols. The use of the wash, rinse, dry method is appropriate in most circumstances. The microbiological quality of the rinse water is an important consideration and if unknown or not in compliance with guidance sterile water should be used for the final rinse. If additional decontamination is required chemical disinfection has lower quality assurance than heat based methods [50, 51, 52].
- 6.1.10 Any plastic storage boxes used by individual mothers for storing breast pump equipment should be washed, rinsed and thoroughly dried every 24 hours.
- 6.1.11 If brushes are provided to aid the cleaning of equipment these should be single person use, labelled with the user's name and allowed to dry between each use. Decontamination should be as for breast pump collection sets. Toothbrushes can provide a cheap alternative to bottle brushes.

Discussion of Cleaning, Decontaminating and Sterilising Equipment

Cleaning of the pump collection set followed by sterilisation between each use will help to minimise the risk of expressed breast milk becoming contaminated during its collection. However, autoclaving is costly, it is not suitable for all materials and it reduces the active

performance life of the individual component parts. When performed off site losses of equipment and delays in it being ready for re-use may occur. It is not a sustainable method of minimising contamination for most hospital neonatal, paediatric and postnatal wards.

Washing equipment with warm water and detergent, rinsing thoroughly in running water that is of good microbiological quality drying thoroughly followed by dry storage is the appropriate decontamination method for most circumstances. The importance of complete drying of all parts should be highlighted when teaching staff and parents about this method.

The mother should use a plastic bowl provided to her for this sole purpose and not place the items directly in the sink. The individual parts need to be rinsed well with cool water to remove all detergent residues and, unless the quality of the rinse water is known to be suitable following routine checks on its microbiological quality, sterile water should be used for the final rinse. The equipment should be completely dried using clean paper towel before being stored on more clean paper towel in a plastic box and covered with additional paper towel to absorb any hidden residual moisture. The plastic box should be clearly labelled with the mother's or infant's name and stored where it will not be used in error by another mother. The safety of this system is dependent upon good hygiene practices overall, on the quality of the rinse water and on the equipment being thoroughly dried prior to storage to avoid the growth of pathogenic micro-organisms. The additional use of a steam method once every 24 hours is also sometimes recommended or the equipment discarded and replaced at set time intervals (e.g. every few days or weekly) as an added precaution.

Dishwashing equipment used on a hot cycle is also employed in some hospitals however a means of keeping each mother's equipment separate is required and checks made to avoid the risks of excess salt residues.

Steam generating stand-alone equipment, so called 'steam sterilisers', are sold for the domestic market but are in use in some hospitals. These present a hazard if manufacturers' instructions for use are not followed, including a scalding risk, and if not dried between each use. They decontaminate but do not sterilise. They are not intended for communal hospital use and will not meet hospital sterilisation equipment standards.

The use of microwave ovens to decontaminate breast pump collection sets comprises two main systems. One requires the separated previously washed and rinsed parts to be placed in a designated plastic bowl with a set volume of water prior to heating in the microwave oven for a recommended time. The second utilises a specially provided plastic bag to which a set volume of water is added. The bags are intended for single user only and the manufacturers provide guidance on the number of times each bag should be used before being replaced with a new one. If it is the role of the mothers to take responsibility for decontaminating their own sets then each mother should be provided with clear instructions and a practical demonstration to reduce the risk of scalding accidents and facilitate compliance with manufacturers' instructions. The provision of multiple microwave ovens may be required and these will need to be checked, cleaned and maintained.

6.1.12 Responsibility for ensuring the breast pump collection equipment that is provided is cleaned and dried, is not left unattended and does not become mixed up with anyone else's may be assigned to each mother or to designated members of staff.

6.1.13 Breast pump tubing does not need to be sterilised or decontaminated between each use, however the outside of the tubing should be cleaned with a sanitised wipe and mothers advised that if milk or moisture enters the tube this should immediately be brought to the attention of staff and the tubing replaced. If milk has entered the tube whilst the breast pump is in use the pump should be taken out of action to await investigation by the clinical engineering department or the manufacturer.

- 6.1.14 Communal electric breast pumps should have no visible signs of damage and should be cleaned externally before and after every use by each user together with the surface that the pump stands on. *This is to remove milk splashes and contamination that results from general handling.*
- 6.1.15 Provide sanitised wipes next to every breast pump to facilitate the cleaning of pumps and surrounding areas.
- 6.1.16 Mothers with a known infection should be provided with a dedicated electric breast pump and their collection sets disposed of or autoclaved following local infection control protocols once they are no longer in use by the mother. The pump should also be decontaminated prior to its re-use, including, in accordance with manufacturer's instructions, the replacement of internal tubing if required.
- 6.1.17 The external surfaces of communal breast pumps should be cleaned every day in accordance with manufacturers' instructions by a member of staff and care taken to ensure any areas that are not easily accessible are also cleaned.

6.2 Breast Milk Storage

When a mother expresses more breast milk than is immediately required for a feed, appropriate handling and storage of the milk is required. Storage may include in a refrigerator and/or in a freezer depending on the mother's lactation and ability to be with her baby. It is likely that mothers will express breast milk both at home and in hospital.

- 6.2.1 Provide dedicated fridges and freezers in suitable locations for storing MEBM.
- 6.2.2 Hospital milk storage fridges and freezers should be lockable or housed in a locked room if they are not constantly supervised. To help prevent milk errors and to promote best practice for the handling and storage of breast milk, only staff should have access to fridges and freezers containing breast milk from more than one mother.
- 6.2.3 Ensure fridges and freezers are fitted with temperature alarms and externally visible temperature monitoring.
- 6.2.4 Fridges should maintain a temperature of 2-4°C.
- 6.2.5 Freezers should maintain a temperature of <-20°C.
- 6.2.6 Validate the internal temperatures of breast milk fridges and freezers at least every 6 months.
- 6.2.7 The internal temperature of all hospital breast milk storage fridges and freezers should be recorded twice a day and the record maintained for 2 years. Appropriate action is required if the recorded temperatures fall outside the recommended range.
- 6.2.8 Provide written instructions to parents on how best to transport breast milk.
- 6.2.9 Breast milk for babies in hospital should be collected in labelled, sterile containers provided by the hospital.
- 6.2.10 Containers of milk should be placed in a clean plastic bag e.g. food bags prior to placing into an insulated bag or box for transporting to the hospital.

- 6.2.11 Provide mothers with sterile, tamper evident breast milk containers that meet current health and safety standards with respect to plastic components. Currently this includes absence of Bisphenol A which is banned from feeding bottles sold in the UK and other EU countries [53].
- 6.2.12 If evidence of the sterility of breast milk containers is not visible on the packaging it should be requested from the manufacturer.
- 6.2.13 Provide containers in a range of sizes to enable mothers to use ones which most closely match the volume of milk being collected. Providing large containers to mothers who are expressing small volumes can be demoralising for them and also takes up additional storage space in the fridge or freezer.
- 6.2.14 Advise mothers not to overfill the container and to leave room for the milk to expand if frozen.
- 6.2.15 Provide mothers with printed labels that include the name and medical notes/hospital number of the infant and space for additional information. Printed labels help to prevent identification errors. Details of any medications taken by the mother in the 24 hours prior to expressing may be useful as long as this will not be seen by other parents or visitors.
- 6.2.16 The date and time the milk was expressed should be added by the mother.
- 6.2.17 Details of any additives (e.g. breast milk fortifier) and/or the date and time of thawing if relevant should be added as appropriate.
- 6.2.18 In the absence of printed labels and for the addition of information use indelible ink or biro. This helps to prevent information becoming illegible e.g. due to condensation on thawing.
- 6.2.19 Use 'alert' stickers in the event of the presence of mothers or infants with the same or similar names.
- 6.2.20 Use barcode traceability with inbuilt safety checks or institute a system for the recording of the double checking of breast milk feeds. This is to minimise the risk of breast milk errors. The use of barcode name labels that can be checked using a barcode reader when feeds are prepared and at the cot side prior to giving a feed and that use an audible alarm in the event of a mismatch help to prevent breast milk feeding errors [54]. The ISBT 128 codes are internationally agreed.
- 6.2.21 In the absence of barcode labelling and checking, every feed should be double checked by a member of staff at the point of making up the feed if milk has been transferred from the original labelled container. It should also be checked at the cot side by a member of staff or by one of the infant's parents prior to feeding. Recording this additional check on the feeding chart will help to minimise the chances of a baby being given the wrong feed.
- 6.2.22 Expressed breast milk should be stored in single expression aliquots. In the event of a mother expressing large volumes of milk, it is advisable to decant some of these into smaller volumes. This will prevent excessive handling of individual containers during the preparation of multiple feeds and also avoid having to defrost larger than needed volumes at a later stage.

6.3 Storing Breast Milk Prior to Arrival at the Hospital

- 6.3.1 It is usually preferable for breast milk to be stored in a home refrigerator rather than frozen at home prior to transporting to the hospital.

- 6.3.2 Refrigerated breast milk should be used within 48 hours of being expressed [55]. If it will not be transported to the hospital in time for it to be safely used fresh (i.e. within 48 hours) it should be frozen as soon as possible after expressing.
- 6.3.3 Advise mothers to ensure their home fridge is clean and that it is operating at 2-4°C. Mothers should be asked to let a member of staff know if their fridge is routinely warmer than 4°C and advised that the refrigerated storage time of the milk after expressing be reduced to 24 hours. If the temperature of the home fridge is not known or warmer than 8°C it will not be suitable for storing breast milk for a sick or preterm infant and in this case the milk should be chilled by placing in a cool bag filled with coolant blocks (from the freezer). The coolant blocks should be replaced with frozen ones directly from the freezer every 6-8 hours however the milk should be transferred to the hospital fridge as soon as possible and used within 24 hours of being expressed. Alternatively, if it is not possible to transport it within 24 hours it may be frozen immediately at home and transported frozen to the hospital. As a general rule however, fresh milk is preferred over thawed milk and its use should be encouraged.
- 6.3.4 Advise mothers that breast milk should not be stored in the door of the fridge.
- 6.3.5 Containers of breast milk should be placed in a new (preferably sealable) polythene bag or a clean plastic box with a lid before being placed in a home fridge or freezer. This is to protect them from being handled unnecessarily or from becoming contaminated by other foods. It also enables all containers to be moved without additional handling when being transferred to an insulated container for transporting to the hospital.

6.4 Transporting Breast Milk

- 6.4.1 Protect containers of breast milk from contamination using a new/clean paper (locker) or plastic bag whilst being transported within the hospital e.g. from postnatal ward to neonatal unit
- 6.4.2 Use an insulated cool bag and frozen coolant blocks/ice pack(s) for transporting breast milk during journeys longer than a few minutes
- 6.4.3 Care should be taken to ensure the temperature of the milk is maintained throughout the journey by avoiding placing the cool bag next to a car heater, or the parcel shelf.
- 6.4.4 Advise mothers to always place containers of breast milk in a new or clean polythene bag or in a clean plastic box before placing in the cool bag/box. This is to protect the container from becoming contaminated; it will also avoid milk residues on the outside of the containers contaminating the interior of the cool bag.
- 6.4.5 Fill any spaces in the cool bag/box with frozen coolant blocks/ ice packs to help to maintain the temperature of the frozen or chilled milk throughout the journey.
- 6.4.6 Similar procedures should be in place whenever frozen or chilled milk is transported between hospitals or from hospital to home.
- 6.4.7 Always clean cool boxes internally and externally between use e.g. with disinfectant wipes and use a clean plastic bag or liner to prevent cross contamination in cool boxes that are used communally by the hospital/unit/ward.

- 6.4.8 Whenever breast milk is being transported between hospitals or within a hospital between wards, the transport container should be clearly labelled with details of the contents, the destination address and that the contents should be transferred to a fridge/freezer immediately on arrival at the destination.
- 6.4.9 The use of tamper evident insulated transport containers is recommended for when breast milk is transported by non-hospital staff e.g. paid or volunteer couriers.
- 6.4.10 On arrival at the hospital the fresh, chilled or frozen milk should be checked and transferred immediately to the ward or unit fridge or freezer or to a central storage facility if available. If the milk has not been transported appropriately and has not remained chilled or frozen a decision based on the condition of the baby, the temperature of the milk and the stocks of MEBM otherwise available should be made. *If frozen breast milk has just started to thaw but remains largely frozen it can be transferred to the freezer and stored as usual. Otherwise transfer to the refrigerator to complete the thawing process. In the event that partially thawed breast milk would have to be discarded because it wouldn't be used within the safe storage time a decision based on the clinical condition of the baby may be made. For example, the milk may be refrozen but only used at a later date when the baby has been discharged from hospital. Alternatively, if there will be insufficient milk available then refreezing the milk and using it may be a preferred option. As long as the milk was not fully thawed, bacterial growth will not have started however the quality of the milk may have been impaired.*

6.5 Appearance of Breast Milk

- 6.5.1 The appearance and colour of breast milk will change, especially in the first few days. Initially the early milk or colostrum may be clear, yellow or tinged brown, green or a rusty colour. As long as collection and storage recommendations outlined above have been met this can be safely fed to the baby.
- 6.5.2 If breast milk is tinged pink with blood and this continues for more than 2 expressions or if larger quantities of blood on a single occasion are apparent advise the mother to seek specialist help from a midwife, obstetrician, International Board Certified Lactation Consultant (IBCLC) or from her GP.

6.6 Storage and Use of Breast Milk in Hospital

- 6.6.1 Appropriately stored refrigerated MEBM leads to minimal changes in immune components such as secretory IgA, lactoferrin and white blood cells [56].
- 6.6.2 Use the aseptic non-touch technique (ANTT) every time a milk feed is prepared [57].
- 6.6.3 Avoid exposure of breast milk to light except where necessary for preparation of feeds and during feeds [58].
- 6.6.4 Support mothers to continue to express frequently even if their breast milk is temporarily not being used or they are expressing more than their infant needs. This will help to ensure their milk supply does not diminish.
- 6.6.5 Initially use any available colostrum in the order it was expressed. Subsequently, where possible, fresh breast milk, expressed closest to the time of the feed should be used. This ensures optimal nutritional quality of the breast milk and its immunological contents will reflect the mother's and infant's recent exposure to infectious micro-organisms as a result of the entero-mammary pathway [59]. This is the means by which a mother's breast milk rapidly contains antibodies to infectious micro-organisms that the mother has recently ingested, or

inhaled. Where any surplus colostrum or very early (transitional) breast milk has been stored frozen it is also advisable that the infant receives this but at the same time ensuring that most of the daily feed is with freshly expressed milk.

- 6.6.6 Avoid unnecessary handling of feeds by not mixing or combining expressions of milk from a mother unless to make up a feed for immediate use. In hospital it is better to store all expressions separately.
- 6.6.7 Milk from different mothers should be kept separate at all times using individual labelled trays, plastic boxes with lids, sealable plastic bags and separate drawers in freezers. This will help to prevent milk errors. If it is not possible to separate milk in this way due to lack of fridge or freezer storage space, plastic bags should be used to separate the milks and consideration given to increasing such storage.
- 6.6.8 Freshly expressed breast milk may be kept at room temperature (up to 26°C) for up to 4 hours [59]. However, if it will not be used within this time for a feed, it should be refrigerated immediately following expression. If breast milk is kept at room temperature and subsequently not used it should be discarded. For this reason, unless a feed is imminent, it is advisable for breast milk to be refrigerated immediately after being expressed even if it is expected to be used within 4 hours.
- 6.6.9 Fresh breast milk can be stored in a refrigerator for up to 48 hours at 2-4°C [55]. This will include any time in the mother's home fridge and whilst being appropriately transported. Research evidence has shown that breast milk can be stored for longer in the refrigerator [56] including up to 8 days [60]. However, when storing breast milk in a communal fridge that is being frequently accessed on a neonatal unit and when feeding immuno-compromised and extremely preterm infants a cautionary approach is best adopted. Furthermore, whilst refrigerated milk is preferable to thawed milk it is also the case that freshly expressed breast milk is optimal. Prolonged storage (24-48 hours) should only be required in circumstances where a mother cannot visit every day.
- 6.6.10 Any breast milk that will not be required for a feed within the 48 hours recommended storage time should be frozen as soon as possible, preferably within 24 hours. It is usually apparent within 24 hours if refrigerated milk will be required for feeding to a baby. Where a mother is expressing frequently and if the milk is able to be brought to the hospital every day, the stored milk can be frozen as soon as sufficient of the more freshly expressed milk is available. Good communication about her milk supply between the mother and the nursing staff is very important.
- 6.6.11 Breast milk may be stored frozen at -20°C for up to 3 months for an infant who is hospitalised [61]. If freezer temperatures are not maintained at -20°C (e.g. in the ice box of a fridge or in an old or small freezer) the maximum storage time should be reduced to 2 weeks.
- 6.6.12 Mothers should be advised that once their baby has been discharged home, the safe frozen storage time can be increased to six months at -20°C if the storage conditions are suitable and so they should not discard milk that is more than 3 months old [62].
- 6.6.13 All containers of milk should be clearly labelled using pre-printed labels and /or indelible ink prior to placing in the fridge or freezer.

- 6.6.14 Use a named, clear, new plastic bag for storing containers of breast milk in a freezer drawer or on a freezer shelf. This will facilitate removal from the freezer, help to prevent containers being placed in the wrong drawer or with someone else's milk and help to prevent buildup of frost around the containers.
- 6.6.15 Ensure freezer facilities do not become overcrowded and that frost and ice buildup is kept to a minimum and isn't allowed to accumulate around the containers of milk.
- 6.6.16 Defrost and clean freezers every 2 months.
- 6.6.17 Clean fridges internally once a week or more frequently in the event of spillage and deep clean every 3 months.
- 6.6.18 Clean fridges and freezers externally daily or more frequently as required. Decontaminating the door or door handle each time the fridge and freezer doors are opened and closed will help to prevent cross infection.
- 6.6.19 Discard breast milk using a designated sink (such as in 'dirty' utility room) and flush with greater quantities of water. Alternatively dispose of breast milk via the hospital's clinical waste system. Discarding large quantities of breast milk is sometimes necessary for example if a baby dies or if a mother is not able to store the milk following her baby's discharge home. Breast milk that is less than 3 months old may be suitable for donation to a milk bank. Information about this is available from the UK Association for Milk Banking [45].
- 6.6.20 Do not use a hand washing sink for disposing of breast milk or for washing expressing equipment.
- 6.6.21 Used and empty breast milk containers should be discarded as clinical waste or it may be possible for them to be sent for recycling as part of recyclable plastic hospital waste but only if all patient identification labels have been removed.

6.7 Thawing and Warming Feed

- 6.7.1 Only use water free methods for thawing and warming feeds. This is to prevent contamination of feeds with water borne organisms which can lead to outbreaks of infection. Containers tip over easily when standing in water and this can lead to ingress of water and possible contaminants into the feed.
- 6.7.2 Clearly label thawed milk with the 'use by' date and time.
- 6.7.3 The following methods are recommended for thawing frozen MEBM:
- Place container(s) of frozen breast milk in a fridge to thaw slowly. This may take up to 12 hours or more depending on the temperature of the fridge and the volume of milk. Ensure the thawing milk is clearly labelled and placed in a suitable container such as a plastic box or foil tray to prevent drips of condensation reaching other containers of milk.
 - Frozen milk may be thawed at room temperature if needed more quickly. This will usually take 0.5-4 hours depending on the room temperature and the volume of milk. Care should be taken to check the contents every 30 minutes and the milk transferred to a fridge once thawed/almost thawed. It isn't always possible to note the exact time when the milk has fully thawed. If thawing breast milk at room temperature it is advisable to place it in the fridge prior to complete thawing i.e. when some ice crystals remain. This is to prevent the temperature of the milk and therefore bacterial levels rising.
 - If using an electric milk thawing/warming device follow manufacturer's instructions for its use and cleaning to prevent cross contamination and overheating.

- 6.7.4 Microwave ovens should not be used to thaw or warm breast milk [63, 64]. Microwaves cause 'hot spots' in the milk which can lead to scalds. The immunological quality of the milk also deteriorates when heated in a microwave.
- 6.7.5 Thawed milk should be stored in a fridge and used within 12 hours of complete thawing i.e. from the point at which no ice remains in the milk. Alternatively, for ease of recording, if thawing the milk in the fridge, use within 24 hours of placing the container of frozen milk in the fridge.
- 6.7.6 Breast milk should be kept at room temperature for as little time as possible to prevent microbial growth. In the absence of electric milk warming equipment (warm air devices) a feed should generally take no more than 30 minutes to reach a suitable feeding temperature although large volume feeds may take longer. It should not be necessary to keep breast milk at room temperature for more than 2 hours. Do not keep more than one feed at room temperature for an infant. In the event of an unforeseen delay in feeding, always use feeds within 4 hours of being removed from the fridge [65, 66]. Do not return milk to the fridge. Discard unused feeds.
- 6.7.7 Gently agitate the container prior to giving a feed to gently mix any contents that may have separated.

6.8 Continuous Feeds

- 6.8.1 MEBM or PDBM which is fed via a tube should hang for a maximum of 4 hours and the container used to administer the feed changed every 4 hours [67]. The amount of feed to be hung should be carefully calculated to avoid wastage.
- 6.8.2 For optimal delivery of fat content of breast milk feeds, syringe drivers should be placed vertically [68, 69]. Fat globules rise and will be delivered first; hence minimising adherence to surfaces.

6.9 Additives to Breast Milk

- 6.9.1 Breast milk fortifiers (BMF) and any other additives should be added to MEBM or PDBM aseptically [70].
- 6.9.2 Additives should be added as close to the time of a feed as possible [71].
- 6.9.3 If fortified breast milk would otherwise be wasted, it may be stored at 2-4°C for a maximum of 12 hours however avoid such prolonged storage wherever possible [71]. The commonly fortified minimum volume is 50ml breast milk and this is often more than is needed for a single feed. To fortify a smaller volume accurately, fully dissolve a sachet in 3-4 ml breast milk and then use only the required amount (using a sterile syringe) to add to the reduced volume of milk. For example, use half of the fortifier and breast milk mixture and make it up to 25ml total for a full-strength feed. Discard the remaining concentrated mix. This will reduce wastage of valuable stocks of a mother's milk and reduce storage time prior to feeding.
- 6.9.4 No significant difference in bacterial growth has been found between MEBM with or without BMF added [72, 73].

6.10 Medications and Mother's Milk

As some medications are contraindicated for use by breastfeeding mothers, maternal medications should be checked with the ward or unit's hospital pharmacy department. Information about medications and breast milk is also available from the Breastfeeding Network [74] website and from their Drugs and Breast milk Helpline.

6.11 Maternal Illness and Breast Milk

- 6.11.1 Mothers should be advised to express or continue to express breast milk wherever possible.
- 6.11.2 When a mother is not able to visit her baby because she is unwell, arrangements should be put in place to transport any breast milk she expresses at home, in hospital or elsewhere to the unit or ward where her baby is being cared for (see 6.4.).
- 6.11.3 If a mother is known to be suffering from gastroenteritis/diarrhoea and or vomiting she should be advised/reminded about hospital visiting protocols. Although the mother may not be able to be with her baby on the ward or unit, her expressed breast milk, if appropriately expressed and stored, can be fed to her baby. Remind the mother of the essential hygiene standards that need to be maintained at all times when expressing breast milk.
- 6.11.4 Mothers who have a primary CMV infection or a reactivation may be infectious [75]. Take microbiological advice on testing and feeding in high risk infants. The routine use of freezing or pasteurisation of breast milk to avoid transmission of CMV has been suggested for preterm infants born <32 weeks. However, no consensus has been reached as to whether the consequent delays that would occur in the availability of maternal milk and the loss of immune factors particularly in pasteurised milk are justified by the overall benefits to a minority of infants.
- 6.11.5 Being Hepatitis B positive is not a contraindication to breastfeeding [76]. Ensure the baby is appropriately vaccinated and given immunoglobulin if required.
- 6.11.6 Mothers who are known to be Hepatitis C antibody positive with detectable virus who wish to breastfeed should be advised that the risk of transmission is unknown but appears to be extremely low [77, 78] and that they will be supported to breastfeed. Ensure mothers are well supported practically to help them achieve optimal positioning and attachment as additional precautions may be required in the event of suffering from cracked or bleeding nipples and expert advice should then be sought on an individual basis.
- 6.11.7 Mothers who are infectious should not use a communal breast pump and extra precautions should be taken to isolate their breast milk during refrigerator and freezer storage.

6.12 Ante-natally Expressed Colostrum

- 6.12.1 Expressing colostrum ante-natally, after 37 weeks gestation, may be recommended in some circumstances.
- 6.12.2 Ante-natally expressed colostrum should be collected and frozen immediately in small named and date labelled containers that are suitable for breast milk storage. The containers of colostrum should be protected from contamination by food or other substances by placing in a clean plastic lidded container.

6.12.3 If required, the colostrum samples can be transported, stored and used in accordance with the recommendations in this guideline for colostrum/ breast milk that has been expressed post-natally i.e. use within 12 hours of thawing.

6.13 Breast Milk Error

An agreed protocol should be in place in the event of breast milk being fed to the wrong baby.

6.14 Donor Breast Milk

Donor breast milk is breast milk that has been expressed by a mother and provided freely to a human milk bank to be fed to another mother's child. Human milk banks collect, screen, store, process and distribute pasteurised donor breast milk (PDBM).

NICE Clinical Guideline 93 (Donor breast milk banks; the operation of donor breast milk bank services) published in 2010 provides recommendations for the operation of donor breast milk bank services [43]. The safety of donor milk is dependent upon the implementation of all the recommendations in the guideline.

- 6.14.1 PDBM should be obtained from a milk bank listed on the UK Association for Milk Banking (UKAMB) website [45].
- 6.14.2 All containers of PDBM should be labelled as PDBM together with the name of the milk bank that it was obtained from, the batch or unique identity number, the expiry date and once thawed, the date and time it was thawed [43].
- 6.14.3 The milk bank supplying PDBM should be asked to confirm in writing that it has implemented the recommendations in NICE CG93.
- 6.14.4 PDBM should be transported between the milk bank and its destination (usually a hospital) in a transport container that has been validated by the milk bank and the courier company/organisation for the journey time.
- 6.14.5 Only courier services using appropriately trained personnel and that have a written agreement with the hospital and/or the milk bank should be used to transport PDBM.
- 6.14.6 Tamper evident insulated transport containers that can be easily cleaned should be used and a new liner used for every journey. PDBM should not be placed directly into a transport container. Use of a new polythene bag facilitates transport and helps to minimise handling of the containers.
- 6.14.7 Separate insulated transport containers or cool boxes should be used for MEBM and PDBM and they should be clearly labelled.
- 6.14.8 Milk banks should only supply PDBM to hospitals or neonatal units that agree to comply with the tracking procedures for PDBM [43].

6.14.9 A record of who receives each container of PDBM should be maintained [34]. The introduction of barcode traceability using the ISBT 128 coding for products of human origin will facilitate full traceability of DBM [79]. For each container of DBM the following should be documented:

- the recipient baby's name, NHS number and date of birth, and the date administered
- the batch/container number and the date the donor milk was used in the patient/record of each baby
- the condition of the donor milk on arrival following transport (should be fully frozen)
- the storage conditions

Full traceability of donor milk from donor to recipient is made possible by combining the milk bank's tracking records and those of the user hospital.

6.14.10 The frozen storage, thawing and warming of PDBM should be carried out as for MEBM.

6.14.11 Once thawed, store PDBM for no more than 24 hours at 4°C or lower. Discard if not used within this time.

6.14.12 All staff recommending the use of PDBM to parents should receive relevant training and be aware of milk bank procedures including the screening and recruitment of donors to enable them to obtain informed consent for its use.

6.14.13 When PDBM is obtained from a milk bank, the unit/hospital/individual user should not then provide it to a different user without first informing the milk bank so they can amend their records. Milk banks are required to keep a record of the hospital that the PDBM was supplied to. The user hospital then should keep the record of which baby receives each container of PDBM.

6.15 Storage Times for MEBM and PDBM

The overriding principal should be for breast milk to be warm or at room temperature for as short a time as possible to minimise the opportunity for bacterial proliferation.

	Freshly expressed MEBM stored at room temp	MEBM stored in fridge at 2-4°C	MEBM removed from fridge prior to feed, then brought to room temp	MEBM frozen and stored at -20°C	Thawed MEBM stored at 2-4°C	Thawed MEBM kept at room temp prior to feeding	Thawed PDBM at 2-4°C	Thawed PDBM at room temp prior to feeding
MEBM for baby in hospital	Up to 4 hours	Up to 48 hours. If not required, freeze as soon as possible and within 24 hours	2-4 hours. A maximum of 2 hours is optimal	Up to 3 months	12 hours from when fully thawed	2-4 hours. A maximum of 2 hours is optimal	-	-
PDBM	-	-	-	-	-	-	24 hours	2-4 hours. A maximum of 2 hours is optimal
MEBM for baby at home	Up to 6 hours	Up to 8 days if stored at 2-4°C, up to 3 days if stored at 5-10°C. Freeze as soon as possible after expressing if to be stored for more than this.	Up to 4 hours	Up to 6 months	If thawed in fridge 12 hours once fully thawed.	Up to 4 hours	-	-

Section Seven

Delivery of Feeds and Storage at Ward/Unit Level

7.1 Delivery of Feeds

Transporting reconstituted feeds increases the risk of bacterial proliferation. Local guidelines must be produced for the safe transportation of prepared feeds. Equipment that prevents contamination of feeds and maintains a safe temperature should be used to deliver feeds. If transport takes more than 30 minutes, it is recommended that feeds are transported under refrigerated conditions [5]. A cool box with ice packs or chilled trolley are suitable transportation. A local system to monitor the adequacy of temperature control of feeds at the time of delivery should be established.

Before placing feeds in the delivery vessel, feed labels should be checked against the individualised patient feed order.

On arrival at the ward or unit, feeds should be placed immediately into the designated refrigerator.

7.2 Discarding Formula

Any feeds remaining in the refrigerator from the previous 24 hours or expired feeds should be discarded in line with local policy. The latter should identify who is responsible for this task and how feeds are discarded.

7.3 Feed Storage

The designated feed storage area or refrigeration should only be used to store prepared feeds and MEBM. It should be securable to prevent unauthorised access to feeds and possible tampering. The temperature of the refrigerator must be monitored and recorded daily; incorrect refrigerator temperatures should be promptly acted upon. The frequent opening of unit refrigerators can result in unsafe storage temperatures [14]. These refrigerators should be deep cleaned each three months.

It is best practice to store MEBM below other feeds or, if there is insufficient space, feeds containing MEBM should be stored inside separate containers (see section 6.6).

Where it is impractical to have separate feed and food storage refrigerators, feeds should be placed in sealed containers/bags and stored on the shelves above the food items to avoid cross contamination.

Feeds taken from the ward/unit refrigerator to the patient area must not be returned to the storage refrigerator if unused and should never be given to another patient.

Section Eight

Feeding the Child and Feed Management at Ward/Unit Level

Once feeds are safely refrigerated at the patient care unit, the nursing staff then become responsible for ensuring that appropriate handling techniques are observed. Written local policies should be in place to ensure that safe and appropriate feed handling, administration of the feed and care of the feeding tube occur; all of these stages should be monitored.

8.1 Feed Handling

Feeds should be handled on a clean, dry, disinfected surface. Hand decontamination with soap and water should be used before handling feeds, bottles and other feeding devices. Care must be taken to avoid touching the rim of feed containers/bottles with the hands.

8.2 Warming Feeds

Warming a feed will allow accelerated bacterial growth.

Feeds which are administered continuously through enteral tubes should not be warmed. Oral and bolus feeds for full-term infants and older children need not be warmed unless a preference is shown for feeds at room temperature. Warming bolus feeds to room temperature is not needed except for preterm infants.

The best practice for warming feeds is by water free methods including electric warming devices (see section 6.7).

Microwave ovens must never be used to warm feeds because of the danger of overheating and the production of hot spots [80].

8.3 Feed Administration

The nursing staff or carer must verify the feed label before feeding the prepared feed to an infant or child. If the feed has been warmed, the temperature should be checked by testing a few drops on the inside of the caregiver's wrist.

Bottle feeds – discard any feed remaining after one hour of starting the feed.

Tube feeds – assemble the feeding system on a clean, dry, disinfected surface avoiding contact with the parts that come directly into contact with the feed. Good hand decontamination and an aseptic technique for filling and changing the reservoir must be employed. Prepared feeds should be hung for a maximum of 4 hours or according to local policy. Commercial closed paediatric feed systems can be hung for longer according to the manufacturer's advice. The giving set should be changed on a 24-hourly basis except in high risk and premature infants where the giving set should be changed 4-hourly [81]. Bottles, teats and syringes should be for single use following local policy. Any additions such as electrolytes or medication must only be added by trained staff in compliance with local medicines policy.

Local tube feeding guidelines should be followed regarding the use of the giving sets, the feed hanging times, the maintenance and duration of insertion of enteral feeding tubes as well as the care, use and maintenance of enteral feeding pumps.

8.4 Discharge Planning

Prior to discharge, parents and carers should be educated and trained in the techniques of hand decontamination, feed preparation and feed administration. A local policy and competency checks should be developed in line with the WHO guidelines [5]. For more complex multi-component feeds, it is desirable to demonstrate the safe mixing of these feeds in a designated clean area and a feed recipe for home should be produced. The rationale for this practice in minimising the risk of infection from micro-organisms and ensuring accurate measurements must be emphasised.

Section Nine

Infection Prevention and Control

The primary infection prevention and control aim for feed preparation is to prevent any infant or child from ingesting micro-organisms that can result in illness. Food-borne illness can be as a result of infection or toxins produced by micro-organisms [82]. The objectives are to limit the entry of undesirable micro-organisms into sterile feeds and to limit microbial growth from non-sterile, powdered formulas during the preparation and delivery of enteral feeds.

9.1 Hazard Analysis Critical and Control Point Plan

Each establishment must have in place hazard analysis critical and control point (HACCP) guidelines for the preparation of powdered feeds and special feeds. These should address factors that influence and discourage microbial growth relating to the cleanliness of equipment, the use of the aseptic technique, storage temperatures and the handling at ward level [83] as discussed in the preceding sections (Appendix 7WA). The Bacteriocidal preparation of infant formula has been published by FSA [2] showing the rate of kill of various bacteria at different temperatures.

A multidisciplinary team should be in place in each hospital or health care setting to appropriately monitor the quality of the feed preparation process and to implement the HACCP plan. There should be documented risk assessment on the feed preparation process to ensure:

- prevention of contamination of feed products during receipt, storage before and after preparation, and administration.
- prevention of microbial proliferation during any stage of the above.
- prevention of exposure to any likely toxin that may be present in the feeds or contaminate them during the above processes.

Implementation of a HACCP approach to feed production has been shown to successfully reduce feed contamination and microbial growth [84, 85].

A recent survey by the FSA [86] looked at the behaviours of caregivers in the preparation of PIF. It was found that in several neonatal and paediatric departments, powdered infant formulae (specialist and non-specialist) are reportedly reconstituted using bottles of sterile water (at ambient temperature) as a result of the practical issues of the recommended mixing of powders with water at 70°C. Any deviation from the WHO and Department of Health recommendations would need an independent risk assessment by personnel with expertise in feed preparation.

9.2 Microbiological Sampling

There is no epidemiological evidence to support routine microbiological sampling of prepared feeds in health care facilities. Routine culturing is unlikely to detect intermittent contamination due to breaches in the preparation technique, but may be helpful in establishing trends and in evaluating root cause analysis [9].

9.3 Incident Investigation

Individual or multiple cases of infection with suspected food-borne illness from potentially contaminated feeds must be investigated and managed in line with local policies.

9.4 Environmental Health Officer Inspections

All premises specifically designated for feed preparation in health care facilities must be inspected annually (or as deemed appropriate) by an Environmental Health Officer.

9.5 Infestations

Pests carry food poisoning organisms. Any evidence of infestation must be investigated immediately by the local facilities department and dealt with accordingly.

Section Ten

Quality Assurance

The HACCP plan should be used to establish an ongoing performance improvement program (Appendix 7WA). The plan should include measurable quality indicators to monitor the salient features of feed preparation, storage, delivery and administration. In this way the feed preparation process can be audited in each establishment.

10.1 Quality Indicators

These should be objective, measurable and evidence based. They should reflect the structures, processes and outcomes in all the stages of the feed preparation process:

- structures: separate room for feed production, standard of equipment and surfaces used, staff competency.
- procedures: feed preparation staff should be appropriately trained in the aseptic technique; competency evaluations of staff (Appendices 5WA, 6WA).
- outcome: no feed-related illnesses arise, verification of disposal of expired feeds, documentation of critical incidents, temperature recommendations met.

10.2 Emergency Management Plans

Emergency management plans for unforeseen circumstances should be produced locally to accommodate the needs of infants and children receiving feeds (See Appendix 8WA).

References

1. FAO/WHO. Expert meeting on *Enterobacter sakazakii* and *Salmonella* in powdered infant formula. FAO, Rome, 16-20 June 2006.
Available from: www.who.int/foodsafety/micro/jemra/meetings/jan2006/en/
2. FSA (UK) Bacteriocidal preparation of infant formula. FSA Project B13010. December 2009. Forsythe SJ.
Available from: www.researchgate.net/publication/248707161
3. Holy O & Forsythe SJ *Cronobacter* spp. as emerging causes of healthcare-associated infection. *Journal of Hospital Infection* 2014 **86**(3) 169-177
Available from: <http://dx.doi.org/10.1016/j.jhin.2013.09.011>
4. European Food Safety Authority. Microbiological risks in infant formulae and follow-on formulae. *EFSA J* 2004, **113** 1-35.
Available from: www.efsa.europa.eu/en/efsajournal/doc/113.pdf
5. WHO/FAO. Safe preparation, storage and handling of powdered infant formula: guidelines. WHO, Geneva, 2007.
Available from: www.who.int/foodsafety/publications/micro/pif2007/en/
6. Independent Review of Incidents of *Pseudomonas aeruginosa* Infection in Neonatal Units in Northern Ireland. The Regulation and Quality Improvement Authority. Final Report 31 May 2012
Available from: www.rqia.org.uk/.../Pseudomonas%20Review%20Phase%20II%20Final.
7. Kelsey, M. *Pseudomonas* in augmented care: should we worry? *J Antimicrob Chemother* 2013
doi:10.1093/jac/dkt288
8. American Institute of Architects Academy of Architecture for Health, the Facilities Guidelines Institute. Guidelines for Design and Construction of Hospital and Health Care Facilities. Washington, DC: American Institute of Architects, 2006.
Available from: www.ashrae.org/File%20Library/.../20091215_ashraed2830220060711.pdf
9. Infant Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities. Second edition, American Dietetic Association 2011. Robbins ST & Meyers R (eds).
10. Food Hygiene: A guide for businesses. Food Standards Agency. June 2011
Available from: www.food.gov.uk/multimedia/pdfs/publication/hygieneguidebooklet.pdf
11. Kim H, Ryu JH, Beuchat LR. Attachment of and biofilm formation by *Enterobacter sakazakii* on stainless steel and enteral feeding tubes. *Appl Environ Microbiol*. 2006 **72**(9) 5846-5856.
Available from: www.ncbi.nlm.nih.gov/pmc/articles/PMC1563662/
12. Kandhai MC, Reij MW, Grogno C, van Schothorst M, Gorris LG, Zwietering MH. Effects of preculturing conditions on lag time and specific rate of *Enterobacter sakazakii* in reconstituted powdered infant formula. *Appl Environ Microbiol*. 2006 **72**(4) 2721-2729.
Available from: www.ncbi.nlm.nih.gov/pmc/articles/PMC1448981/
13. Byrd-Bredbenner C, Maurer J, Wheatley V, Cottone E, Clancy M. Food safety hazards lurk in the kitchens of young adults. *J Food Prot*. 2007 **70**(4) 991-996.
Abstract available from: <http://www.ncbi.nlm.nih.gov/pubmed/17477272>
14. Azevedo I, Regalo M, Mena C, Almeida G, Carneiro L, Teixeira P et al. Incidence of *Listeria* spp. in domestic refrigerators in Portugal. *Food Control*. 2005 **16**(2) 121-124.
Available from: smas.chemeng.ntua.gr/miram/files/publ_358_5_10_2005.pdf

15. Agostoni C, Axelsson I, Goulet O et al. Preparation and handling of powdered infant formula: A commentary by the ESPGHAN Committee on Nutrition, *J Pediatr Gastroenterol Nutr*. 2004 **39** 320-322. Available from: espghan.med.up.pt/joomla/position_papers/con_19.pdf
16. Bankhead R, Boullata J, Brantley S et al. Enteral nutrition practice recommendations. *J Parenter Enteral Nutr* 2009 **33** 122-167. Available from: www.ismp.org/tools/articles/ASPEN.pdf
17. Boyce JM, Pittet D. Guideline for hand hygiene in health-care settings: recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *Infect Control Hosp Epidemiol*. 2002 **23**(12) S3-S40. Available from: www.cdc.gov/mmwr/pdf/rr/rr5116.pdf
18. Guidance for health professionals on safe preparation, storage and handling of powdered infant formula. 2007. Food Standards Agency. Department of Health. United Kingdom. Available from: <http://www.food.gov.uk/multimedia/pdfs/formulaguidance.pdf>
19. Paoli G, Harthett E. Overview of a risk assessment model for *Enterobacter sakazakii* in Powdered Infant Formula. 2007. Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA). Available from: www.who.int/foodsafety/micro/jemra/r_a_overview.pdf
20. Leskova E, Kubikova J, Kovacikova E, Kosicka M, Porubská J et al. Vitamin losses: retention during heat treatment and continual changes expressed by mathematical models. *J Food Compos Anal*. 2006 **19**(4) 252-276.
21. World Health Organisation and Food and Agriculture Organisation. *Enterobacter sakazakii* and *Salmonella* in powdered infant formula: meeting report, MRA Series 10. Microbiological Risk Assessment Series. 2006. Available from: <http://www.who.int/foodsafety/publications/micro/mra10/en/>
22. NHS (2011). Guide to Bottle Feeding. Available from: www.dh.gov.uk
23. Osborn K and Lyons M (2010). Is bottled water really unfit for making up formula? *Community Practitioner* **83** 31-34.
24. Tarnow-Mordi W, Soll RF. Probiotic Supplementation in Preterm Infants: It Is Time to Change Practice. *JPeds* 2014 **164** (5) 959-960
25. Szajewska H, Guarino A, Hojsak I, Indrio F, Kolacek S, Shamir R, Vandenplas Y, Weizman Z. Use of probiotics for management of acute gastroenteritis: a position paper by the ESPGHAN Working Group for Probiotics and Prebiotics. *J Pediatr Gastroenterol Nutr* 2014 **58** (4) 531-439.
26. Berni Canani R, Nocerino R, Terrin G, Coruzzo A, Cosenza L et al. Effect of Lactobacillus GG on tolerance acquisition in infants with cow's milk allergy: A randomised trial. *J Allergy Clin Immunol*. 2012 **129**(2) 580-582.
27. Baldassarre ME, Laforgia N, Fanelli M, Laneve A, Grosso R, Lifschitz C. Lactobacillus GG improves recovery in infants with blood in the stools and presumptive allergic colitis compared with extensively hydrolysed formula alone. *J Pediatr* 2010 **156** (3) 397-401.
28. Hojsak I, Fabiano V, Pop TL, Goulet O, Zuccotti GV, Cokugras FC, et al. Guidance on the use of probiotics in clinical practice in children with selected clinical conditions and in specific vulnerable groups. *Acta paediatrica* (Oslo, Norway : 1992). 2018;**107**(6):927-37.

29. Braegger C, Chmielewska A, Decsi T, Kolacek S, Mihatsch W, Moreno L, Piescik M, Puntis J, Shamir R, Szajewska H, Turck D, van Goudoever J. Supplementation of infant formula with probiotics and/or prebiotics: a systematic review and comment by the ESPGHAN committee on nutrition. *J Pediatr Gastroenterol Nutr* 2011 **52** (2) 238-250.
30. Horvath A, Dziechciarz P, Szajewska H. The effect of thickened feed interventions on gastro-oesophageal reflux in infants: systematic review and meta-analysis of randomised controlled trials. *Pediatrics* 2008 **122** (6) 1268-1277.
31. Yeung CY, Lee HC, Lin SP, Yang YC, Huang FY, Chuang CK. Negative effect of heat sterilization on the free amino acid concentrations in infant formula. *Eur J Clin Nutr*. 2006 **60**(1) 136-141. Abstract available from: <http://www.ncbi.nlm.nih.gov/pubmed/11990002>
32. WHO/UNICEF. Global strategy for infant and young child feeding. Geneva, Switzerland: WHO; 2003.
33. Edmonds K, Bahl R. Optimal feeding of low-birth-weight infants: technical review. WHO 2006.
34. Boyd CA, Quigley MA, Brocklehurst P. Donor breast milk versus infant formula for preterm infants: systematic review and meta-analysis. *Arch Dis Child Fetal Neonatal Ed*. 2007 **92** F169-175.
35. Quigley M, Henderson G, Anthony MY, McGuidre W. Formula milk versus donor breast milk for feeding preterm or low birth weight infants (Review). The Cochrane Collaboration. The Cochrane Library 2007, Issue 4. CD002971.
36. Kim H, Ryu JH, Beuchat LR. Attachment of and biofilm formation by *Enterobacter sakazakii* on stainless steel and enteral feeding tubes. *Appl Environ Microbiol*. 2006 **72** 5846-5856. Abstract available from: <http://www.ncbi.nlm.nih.gov/pubmed/17172461>
37. Hurrell E, Kucerova E, Loughlin M, Caubilla-Barron J, Forsythe SJ. Biofilm formation on enteral feeding tubes by *Cronobacter sakazakii*, *Salmonella* serovars and other *Enterobacteriaceae*. *Int J Food Microbiol*. 2009 **136**(2) 227-231. Abstract available from: <http://www.ncbi.nlm.nih.gov/pubmed/19720416>
38. Hurrell E, Kucerova E, Loughlin M, Caubilla-Barron J, Hilton A, Armstrong R, Smith C, Grant J, Shoo S & Forsythe S. 2009 Neonatal enteral feeding tubes as loci for colonisation by members of the *Enterobacteriaceae*. *BMC Infectious Diseases* **9** 146. Available from: <http://www.biomedcentral.com/1471-2334/9/146/abstract>
39. Kim H, Ryu JH, Beuchat LR. Effectiveness of disinfectants in killing *Enterobacter sakazakii* in suspension, dried on the surface of stainless steel, and in a biofilm. *Appl Environ Microbiol* 2007 **73**(4) 1256-1265. Abstract available from: <http://aem.asm.org/cgi/content/full/73/4/1256?view=long&pmid=1717261>
40. Department of Health (2013). Preparation of infant formula. Available from: <https://www.gov.uk/.../advice-on-preparation-of-formula-milks-restated>
41. UK Baby Friendly Initiative; Guide to the Baby Friendly Initiative Standards www.unicef.org.uk/babyfriendly
42. Jones E & Spencer SA. Optimising the provision of human milk for preterm infants. *Arch Dis Child Fetal Neonatal Ed*. 2007 **92**(4): F236–F238.
43. NICE Clinical Guideline 93 (CG93) Donor breast milk banks: the operation of donor breast milk bank services www.nice.org.uk/guidance/CG93
44. Arslanoglu S et al. ESPGHAN 2013 Donor Human Milk for Preterm Infants; Current Evidence and Research Directions. *Journal of Pediatric Gastroenterology and Nutrition* 2013 **57** 535–542

45. UK Association for Milk Banking (UKAMB) www.ukamb.org / info@ukamb.org
46. Cossey V, Jeurissen A, Thelissen MJ, Vanhole C, Schuermans A. Expressed breast milk on a neonatal unit: a hazard analysis and critical control points approach. *Am J Infect Control* 2011 **39**(10) 832-8.
47. Toolkit for High Quality Neonatal Services. Department of Health October 2009 www.dh.gov.uk/publications
48. Brown, SL. Different flange sizes. Breast Pump Adverse Events: Reports to the Food and Drug Administration. *J Hum Lact* 2005 **21** (2)169-174.
49. Renfrew MJ, Craig D, Dyson L, McCormick F, Rice S, King SE, Misso K, Stenhouse E, Williams AF. Breastfeeding promotion for infants in neonatal units: a systematic review and economic analysis. *Health Technol Assess.* 2009 **13**(40) 1-146, iii-iv. doi: 10.3310/hta13400.
50. Gilks J, Gould D, Price E. Decontaminating breast pump collection kits for use on a neonatal unit: review of current practice and the literature. *Journal of Neonatal Nursing* 2007 **13** 191-198.
51. Price E, Weaver G, Hoffman P, Jones M, Gilks J, O'Brien V, Ridgway G. Decontamination of breast pump milk collection kits and related items at home and in hospital: guidance from a Joint Working Group of the Healthcare Infection Society and Infection prevention Society. *Journal of Hospital Infection* 2016 **92** (3) 213-221.
52. D'Amico CJ, DiNardo CAA, Krystofiak S Preventing contamination of breast pump kit attachments in the NICU. *Journal of Perinatal and Neonatal Nursing* 2003 **17** (2) 150-7
53. Bisphenol A EU Directive (2011/8/EU) http://ec.europa.eu/dgs/health_consumer/dyna/consumervoice/create_cv.cfm?cv_id=716
54. Dougherty D, Nash A. Bar coding from breast to baby: a comprehensive breast milk management system for the NICU Neonatal Network 2009 Sep-Oct **28**(5) 321-8.
55. Martinez Costa C, Silvestre MD, Lopez MC, Plaza A, Miranda M and Guijarro R. Effects of Refrigeration on the Bactericidal Activity of Human Milk: A Preliminary Study. *Journal of Pediatric Gastroenterology and Nutrition* 2007 **45** 275-277.
56. Slutzah M, Codipilly CN, Potak D, Clark R, Schanler RJ. Refrigerator Storage of Expressed Human Milk in the Neonatal Intensive Care Unit *Journal of Pediatrics* 2010 **156**(1) 26-28. doi:10.1016/j.jpeds.2009.07.023
57. 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.
58. Bates CJ, Liu DS, Fuller NJ, Lucas A. Exposure to light Susceptibility of Riboflavin and Vitamin A in Breast Milk to Photodegradation and Its Implications for the Use of Banked Breast Milk *InfantFeeding Acta Paediatrica*1985 **74**(1) 40-44.
59. Goldman AS. The Immune System in Human Milk and the Developing Infant. *Breastfeeding Medicine* 2007 **2** (4) 195-204. doi:10.1089/bfm.2007.0024
60. Pardou A, Serruys E, Mascart-Lemone F. Human milk banking: influence of storage processes and of bacterial contamination on some milk constituents *Biol Neonate* 1994 **65** (5) 302-309.

61. García-Lara NR, Escuder-Vieco D, García-Algar O, De La Cruz J, Lora D, Pallás-Alonso C. Effect of Freezing Time on Macronutrients and Energy Content of Breast milk. *Breastfeeding Medicine* 2012 **7** (4) 295-301. doi: [10.1089/bfm.2011.0079](https://doi.org/10.1089/bfm.2011.0079)
62. Department of Health leaflet 'Off to the best start'.
<http://www.ouh.nhs.uk/women/maternity/postnatal/infant-feeding/documents/best-start.pdf>
63. Quan R, Yang C, Rubenstein S, et al. Effects of microwave radiation on anti-infective factors in human milk. *Pediatrics* 1992: 667-669.
64. Sigman M, et al. Effects of microwaving human milk: changes in IgA content and bacterial count. *J Am Diet Assoc* 1989 **89**(5) 690-92.
65. Pittard WB, Anderson DM, Cerutti ER, Boxerbaum B. Bacteriostatic qualities of human milk *Journal of Pediatrics* 1985 **107** (2) 240-243.
66. Ogundele MO. Effects of storage on the physiochemical and antibacterial properties of human milk'. *British Journal of Biomedical Science* 2002 **59**(4) 205-211.
67. Lemons PM, Miller K, Eitzen H, Strodbeck F, Lemons JA Bacterial growth in human milk during continuous feeding. *Am J Perinatol*, 1983. **1**(1) 76-80.
68. Narayanan I, Singh B and Harvey D. Fat loss during feeding of human milk *Arch Dis Child*, 1984 **59** (5) 475-477.
69. Schanler RJ, Hurst NM. Human milk for the hospitalised preterm infant. *Semin Perinatol*, 1994 **18** (6) 476-484
70. King C, Bell S, November 2010. Discussion paper on the use of breast milk fortifiers in the feeding of preterm infants. Bliss Briefings.
Available from: <http://www.bliss.org.uk/improving-care/professional-development/bliss-briefings/>
71. Kenichiro Takahashi, Katsumi Mizuno, Kazuo Itabashi. The Freeze–Thaw Process and Long Intervals after Fortification Denature Human Milk Fat Globules. *American Journal of Perinatology* 2012 **29** (4) 283-288.
72. Chan GM. Effects of powdered human milk fortifiers on the antibacterial actions of human milk. *J Perinatol* 2002 **3**(8) 620-623.
73. Santiago MS, Codipilly CN, Potak DC, Schanler RJ. Effect of human milk fortifiers on bacterial growth in human milk. *J Perinatol* 2005 **25**(10) 647-649.
74. The Breastfeeding Network. www.breastfeedingnetwork.org.uk. Drugs and Breast milk Telephone Helpline: 0844 412 4665
75. Kurath S, Halwachs-Baumann G, Müller W, Resch B. Transmission of cytomegalovirus via breast milk to the prematurely born infant: a systematic review *Clinical Microbiology and Infection* 2010 **16** (8) 1172-1178.
76. Breastfeeding of newborns by mothers carrying hepatitis B virus: a meta-analysis and systematic review. *Arch Pediatr Adolesc Med*. 2011 **165** (9) 837-846.
- 77 Roberts EA, Yeung L. Maternal-Infant Transmission of Hepatitis C Virus Infection *Hepatology* 2002 **36** (5) S106-S113.

78. Pfaender S, Heyden J, Friesland M et al. Inactivation of Hepatitis C Virus Infectivity by Human Breast Milk. *Journal of Infectious Diseases* 2013;**208** 1943-1952.
79. ICCBBA ISBT128: www.iccbba.org
80. Hibbard R, Blevins R. Palatal burn due to bottle warming in microwave oven. *Pediatrics*. 1988 **82** 382-384.
81. Patchell CJ, Anderton A, Holden C, MacDonald A, George RH, Booth IW. Reducing bacterial contamination of enteral feeds. *Arch Dis Child* 1998 **78** 166-168.
82. Redmond EC, Griffith CJ, Riley S. Contamination of bottles used for feeding reconstituted powdered infant formula and implications for public health. *Perspect Public Health*. 2009 **129** 85-94.
83. Merriman L. Developing our HACCP plan for enteral feeding. *Future Dimensions Clin Nutr Manage*. 2001 **10** 1-9.
84. Oliviera M, Bonelli R, Aido K, Batista C. Microbiological quality of reconstituted enteral formulations used in hospitals. *Nutrition*. 2000 **16** 729-733.
85. Carvalho M, Morais T, Amaral D, Sigulem D. Hazard analysis of critical control point system approach in the evaluation of environmental and procedural sources of contamination of enteral feedings in three hospitals. *JPEN* 2000 **24** 296-300.
86. Redmond E, Griffith C. An investigation into the attitudes and behaviours of consumers and caregivers in the preparation, handling and storage of powdered infant formula inside and outside the home. Food Standards Agency Research Project B13008. Final report December 2013.

Appendix 2WA Cleaning Schedule Summary

DAILY CLEANING	WEEKLY CLEANING
All sinks and wash hand basins - including taps	Interior and top of cupboards storing feed making equipment
All work surfaces and splash back (clean before and after feed preparation)	Interior of drawers storing feed making equipment
Weighing scales	Interior and top of feed storage cupboards
Refrigerator doors and handles; refrigerator interior shelves	Interior and top of cleaning equipment cupboards
Blast-Chiller doors and handles	Trolleys including legs and wheels
Freezer doors and handles	Refrigerator interior and exterior - ensure seals are clean and in good condition
Paper towel holder, glove and gel holders (exterior)	Freezer top and sides
Cupboard doors	Blast-Chiller interior and exterior - make sure seals are clean and in good condition
Trolley shelves	Bins - interior and exterior
Bins - exterior and inside lid	Paper towel holders - interior
Windowsills	Glove and gel holders - interior
Door handles and light switches	Pipework behind pasteurisers
Telephones	Deep clean floor
Water boiler - exterior including taps, pipework and shelf	
Pasteuriser exterior - top and visible sides	
Washer drier machine exterior	
Floor	

Appendix 2WA: Special Feed Unit Daily Cleaning Record

DATE	MON	TUE	WED	THUR	FRI	SAT	SUN
WASH HAND BASIN & TAPS							
WORK SURFACES							
TROLLEYS							
FLOOR							
FRIDGE, FREEZER & BLAST-CHILLER EXTERNAL DOORS AND HANDLES							
FRIDGE INTERIOR SHELVES							
PASTEURISER EXTERIOR							
PAPER TOWEL, GLOVE & GEL HOLDERS EXTERIOR							
WEIGHING SCALES							
WASHER DRIER MACHINE EXTERIOR							
CUPBOARD DOORS							
BINS EXTERIOR & INSIDE LID							
WINDOWSILL							
DOOR HANDLES							
TELEPHONE							
LIGHT SWITCH							
WATER BOILER & SHELF							

Appendix 2WA Special Feed Unit Weekly Cleaning Record

Week beginning				
DEEP CLEAN FLOOR				
INTERIOR AND TOP OF FEED STORAGE CUPBOARDS				
INTERIOR AND TOP OF CLEANING EQUIPMENT CUPBOARDS				
EQUIPMENT DRAWERS				
INTERIOR AND TOP OF FEED EQUIPMENT CUPBOARDS				
REFRIGERATOR interior/exterior/door seals				
BLAST-CHILLER interior/exterior/ door seals				
BINS - interior & exterior				
PAPER TOWEL, GLOVE & GEL HOLDERS - interior				
PIPEWORK & SIDES OF PASTEURISER				

Appendix 3WA Planned Preventative Maintenance

Area	Minimum Standard of Maintenance	By Whom and Date
Ceilings	Inspect monthly Ensure flaking paint is removed	
Doors	Repair and replace damaged kick and fingerplates as necessary Oil hinges and self-closing mechanisms as necessary	
Drainage	Report leakage from pipes and taps as occur Repair pipes and replace washers Inspect gullies and clean out gratings	
Floors	Replace or repair damaged or uneven surfaces and open joints as necessary	
Sinks & Wash Hand Basins	Check tap fittings and waste traps weekly.	
Walls	Inspect painted walls monthly Remove flaking paint	
Windows	Check all fittings monthly Replace cracked or broken windowpanes	
Electrical Equipment	Check plugs and cables of portable appliances Service power point and wiring as Facility schedule	
Ventilation	Clean grills of air-cooling unit in preparation and clean-up room as Facility schedule	
Refrigerator, Freezer & Blast-Chiller	Check and record temperatures daily Clean refrigeration plant and associated grills twice per year Report temperature variations and faults as occur Check door linings and seals in good repair monthly	
Mechanical Dishwasher Drier	Report all faults to Line Manager as they occur	
Pasteurisers	Report all faults to Line Manager as they occur	
Painting and Wall Washing	Liaise with Facilities to provide wall washing and re-painting	
Scales	Annually within Facility contract	

Appendix 4WA Refrigerator Temperature Record

<i>Date & Time</i>	<i>Temp. °C</i>	<i>Signature</i>	<i>Action taken if needed</i>	<i>Signature</i>
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

Appendix 4WA Freezer Temperature Record

<i>Date & Time</i>	<i>Temp. °C</i>	<i>Signature</i>	<i>Action taken if needed</i>	<i>Signature</i>
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

Appendix 5WA Training Checklist

(Initial and date when discussed with employee)	INITIAL & DATE
Keys for SFU and office door code	
Identification badge	
Trust uniform (to be worn in SFU only), apron and hats	
Shoes: wear indoor shoes with toes covered	
Jewellery: no earrings, watch, bracelets; a wedding ring is allowed; no nail varnish or false nails	
Computer: how to switch on, how appropriate programs work	
Printer: how it works, production of labels	
Location and use of fax machine	
Answering the phone; message book: time of call, recording of messages	
Stock room: stock rotation, dates of stock	
Use of scales: measuring powders and liquids	
Feed instructions generated by dietitians	
Preparation prior to making feeds; use of biocidal solution	
Product names and storage areas	
Products and their mixing properties; Milkshake recipes	
Hand decontamination	
Feed preparation: reading feed instructions, aseptic technique, pouring feeds, pasteurisation and/or blast chilling	
Ingredient water >70 °C	
Which feeds to pasteurise and use of pasteurisers	
Preparation of a feed recipe including expressed breast milk	
Use of data logger	
Importance of blast chilling and use of blast chiller	
Use of fridge and freezer	
Storage of feeds in refrigerator prior to delivery to the wards	
Setting up refrigerated trolley or cool containers for delivery of feeds to unit	
Use of washer and drier	
Cleaning up after making feeds; signing for cleaning	
Checking feeds and signing for feeds	
Label production and bag preparation	
Recording temperature of fridges, freezers, feeds	
Ordering specialised feeds and ingredients	
Checking arriving stock against order	
Standard recipe book	
Rota: Hours of work, days off, overtime, sickness reporting, holiday entitlement	
Control of substances hazardous to health	
Special Feed Unit: Guidelines & Procedures Manual	
Mandatory training	
Training Needs: Basic Hygiene Course organised	
Critical Incident Reporting	

Signed (Employee) _____ Date: _____

Signed (Supervisor) _____ Date: _____

APPENDIX 6WA Competency Assessment for the Preparation of a Feed Using the Aseptic Technique

Steps of the feed preparation process	Sign where observed
Ensure door to clean preparation room is closed	
Wash hands according to Facility policy; re-wash hands at appropriate stages	
Wear hat and apron over uniform	
Clean preparation surfaces with anti-bacterial sanitising solution before making feed	
Gather recipe and ingredients: check powders are all in date	
Use new clean equipment for each feed type	
Collect supply of freshly boiled and cooled water to 70-80 °C in a covered vessel	
Make feed according to recipe	
Check labels on bottles for name/ward/date of birth/expiry date & time/feed content; check the correct number of bottles as on the recipe	
Open bottles: ensure the rims/tops of the bottles are not touched	
Pour feed out to stipulated volume (e.g. 6 x 150ml)	
Replace lids on bottles without touching the rims/tops	
If necessary, dry the outside of bottles with a clean cloth	
Use bottle sealer or apply tamper-evident seal	
Blast chill or pasteurise feed as recipe requires	
Place prepared feeds in the fridge until transferred to feed trolley for delivery to the ward	
Record the temperature of the refrigerator on the designated chart	
Wipe down surfaces after use with anti-bacterial sanitising solution	
Prepare a feed recipe including expressed breast milk	

Staff Name: _____

Assessor Name: _____

Date of assessment: _____

APPENDIX 7WA HACCP for the Preparation of Feeds in the Clean Preparation Area

Process Step	Hazard	Policy/Criterion	Monitoring Method	Action Plan (Criterion Failure)	Resources
Procurement: Contamination of enteral feeding products by chemical, microbiological, or particulate matter	<ul style="list-style-type: none"> Powdered formulas are not sterile Breakdown in quality control at point of production Improper controls in storage prior to distribution 	<ul style="list-style-type: none"> Purchase from approved, inspected and certified supplier Approved criteria for correct storage at distribution centre 	<ul style="list-style-type: none"> Monitor provider for adherence to purchasing and quality control specifications Inspect delivery on receipt Audit trail for product batch numbers received 	<ul style="list-style-type: none"> Follow recall procedures to address quality control issues Donated formula from families will not be used for patient administration Verify delivery based on receiving criteria Do not accept damaged or bulging cans or products Check expiry date according to hospital guidelines Immediately remove received products for appropriate storage 	<ul style="list-style-type: none"> SFU staff trained to inspect goods on receipt: sell by date, condition of packaging, supplier
Storage: Contamination of enteral feeding products and EBM by chemical, microbiological, or particulate matter	<ul style="list-style-type: none"> Improper storage and handling procedures 	<ul style="list-style-type: none"> Criteria for storage conditions Ensure first-in-first-out safety standards in all storage areas Identify and discard products with damaged containers/ improper labelling Date products upon opening, indicating the date on which the product expires once opened. Powders expire within 30 days of opening 	<ul style="list-style-type: none"> Monitor product and EBM expiry dates 	<ul style="list-style-type: none"> Discard products that have exceeded expiry date as noted by the manufacturer/ EBM policy Discard individual dented cans and report to manufacturer 	<ul style="list-style-type: none"> Training for SFU staff Stock control monitoring and action procedures Store room facilities: separate clean room Adequate shelving to lift products off the floor Temperature controlled room (monitored) Manual handling considerations (weight/ glass)

Process Step	Hazard	Policy/Criterion	Monitoring Method	Action Plan (Criterion Failure)	Resources
Feed Preparation: Introduction of microbes, chemicals, or particulates	<ul style="list-style-type: none"> Room Equipment Contamination Medication errors Unauthorised tampering Contaminated equipment such as bottles, jugs 	<ul style="list-style-type: none"> Building specification for SFU SFU standards for cleaning practice including decontamination and cleaning of SFU (walls, floors, equipment, utensils, bottles) Maintenance contracts for equipment (pasteuriser, dishwasher) Train SFU & dietetic staff in food handling and hygiene SFU standards of feed preparation practice: feed ordering, generation of recipe & labels, feed preparation 	<ul style="list-style-type: none"> Record cleaning process, wall washing, deep clean Audit compliance with standards of practice Tamperproof seals Double check verification of feed recipe & patient name against label and feed Data logger for pasteuriser and dishwasher 	<ul style="list-style-type: none"> Discard enteral formula ingredients in question Reject ingredients not meeting acceptable criteria Train SFU staff in enteral formula preparation methods 	<ul style="list-style-type: none"> Training competency documentation for SFU staff Pathway for feed preparation & use of EBM SFU room layout: fit for purpose (lighting, space, equipment, clean area) SFU equipment IT software for feed recipe & label generation Boiled water: boiler Precision scales to weigh powders Disposable vs recycling bottles Tamperproof sealer Dishwasher drier
Proliferation of microbes: After preparation of feeds	<ul style="list-style-type: none"> Spores germinate and microbes multiply at temperatures >4°C 	<ul style="list-style-type: none"> Discard ingredients of opened container not used within designated time period Label, seal and date opened bottles & tins indicating expiry date Blast chill and store prepared feeds at 2-4°C 	<ul style="list-style-type: none"> Monitor fridge temperature Verify accuracy of temperature control device 	<ul style="list-style-type: none"> If temperature standard (<4°C) is not met, immediately move prepared or opened products to a fridge that maintains the required temperature Discard formulas that have exceed shelf-life criteria 	<ul style="list-style-type: none"> Train SFU staff in stock management (Daily stock control of opened products) Blast-chiller, fridge, freezer

Process Step	Hazard	Policy/Criterion	Monitoring Method	Action Plan (Criterion Failure)	Resources
Refrigeration/ Transport and Delivery of feeds	<ul style="list-style-type: none"> Surviving microbes proliferate Spores can survive and grow during any inadequate refrigeration holding process Chemical and particulates cannot be destroyed 	<ul style="list-style-type: none"> Prepared enteral formulas, modular components, and open containers of enteral feeding products are sealed and labelled as to contents, patient name, room/ward number, and expiry date/time Store and hold prepared enteral feeding formulas under refrigeration at 2°-4°C in the SFU, transportation and individual patient/ ward-care refrigerators Stock check products to detect items at or near expiry date All prepared enteral formula discarded 24 hours after the production date 	<ul style="list-style-type: none"> Monitor refrigeration temperature Verify accuracy of temperature monitoring device Audit of prepared and open enteral feeds at patient level to determine expiry date of products and disposal procedures 	<ul style="list-style-type: none"> Monitor refrigeration for 4°C or less. If temperature standards are unmet, immediately move prepared or opened enteral feeding products to a refrigerator that maintains the required temperature Train employees in enteral feeding product monitoring methods. Discard formulas that have exceeded shelf-life criteria 	<ul style="list-style-type: none"> Refrigerated trolleys Fridge to store feeds at ward level

Process Step	Hazard	Policy/Criterion	Monitoring Method	Action Plan (Criterion Failure)	Resources
Power and IT support	<ul style="list-style-type: none"> Failure of networked feed management software (e.g. Electronic Dietetic Manager EDM) used to generate feed recipe, nutritional analysis and patient labels Electronic precision scales 	<ul style="list-style-type: none"> All feeds generated to have a recipe prescribed by a dietitian Feeds to be individually labelled Nutrient analysis sheet filed in patients notes at ward level Backup feed list software on separate PC and server 24/7 day access to software maintenance support Scales calibrated and maintained annually 	<ul style="list-style-type: none"> Audit of paperwork, labels and EDM sheets Maintenance records for scales 	<ul style="list-style-type: none"> Labels must be hand-written clearly to include: child's name, ward, description of contents (e.g. Scandishake; standard SMA 1 & 2% Thick & Easy; 20% RenaStart), volume of feed, date prepared, expiry date A photocopy of the feed recipe should accompany the feeds The feed recipe should be matched with the child's feed prescription chart at ward level A memo sent to the ward explaining where the recipe can be found Battery operated scales or feed recipes transferred into scoops where scales are unavailable 	<ul style="list-style-type: none"> Computer Printer and label printer Network access

APPENDIX 8WA Emergency Plan for Special Feed Unit

EQUIPMENT FAILURE	CONSEQUENCES	ACTION PLAN	IMPLICATIONS
WEIGHING SCALES	Unable to weigh ingredients	Use scoops provided	Dietitians to write recipes in scoops
FRIDGE/FREEZER	Discard any feed >4°C Not able to store fresh milk, cream, ice-cream Not able to store feeds No ice blocks to transport feeds	Use commercial supplements where possible Feeds made up as required at ward/unit level Ready to use feed used if possible Connect to emergency power supply	Stock levels and storage space – needs identifying
PASTEURISER/ BLAST-CHILLER	Untreated feeds - higher risk of contamination	Prioritise feeds made if limited access to equipment Recipes using as few additives as possible Ready to use feeds used if possible	Modify all recipes for ready to use feed where possible
HOT WATER BOILER	No boiled cooled water to mix feeds	Use bottles of sterile water For feeds that mix poorly in cold water, use boiled cooled water using a kettle	Order and keep stock of sterile bottled water
DISH WASHER /DRIER	Unable to clean equipment	All equipment to be hand washed in very hot water and detergent. Air dry.	Gloves for washing up
COMPUTER/ LABELLER	No labels Unable to retrieve feed recipe	Contact EDM support engineer Handwrite any changes on labels plus labels for new feeds Dietitians to hand write feed recipe & deliver to SFU	Obtain additional permanent marker pens
TELEPHONE/ FAX MACHINE/ E MAIL	No communications	Provide mobile phone to SFU Give information over telephone and double check recipe with ward dietitian	Mobile phone in SFU Dietitians to liaise directly with SFU staff