

**Food Standards Agency Research Project B13008**

**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**

***FINAL REPORT***

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## LIST OF ABBREVIATIONS

ACC	Aerobic Colony Counts
ATP	Adenosine Triphosphate
AV	Audio Visual
CAPI	Computer Assisted Personal Interviewing
CMW	Community Midwife
DN	Day Nursery
DNM	Day Nursery Managers
DNN	Day Nursery Nurses
DNS	Day Nursery Staff
DoH	Department of Health
EFSA	European Food Safety Authority
EH	Environmental Health
EHO	Environmental Health Officer
FAO	Food and Agriculture Organisation
FSA	Food Standards Agency
GI	Gastro-intestinal
GP	General Practitioner
HCA	Healthcare Assistant
HMW	Hospital Midwife
HN	Hospital Nurses
HV	Health Visitors
IRAS	Integrated Research Application System
MHCA	Maternity Healthcare Assistant
MREC	Multi-Centre Research Ethics Committee
NCT	National Childbirth Trust
NDNA	National Day Nurseries Association
NHS	National Health Service
NI	Northern Ireland
HPA	Health Promotion Agency
PCTs	Primary Care Trusts
PFM	Powdered Formula Milk
PIF	Powdered Infant Formula
R&D	Research and Development
RLU	Relative Light Units
RTF	Ready to Feed
RTU	Ready to Use
SCBU	Special Care Baby Units
SD	Standard Deviation
SEG	Socio Economic Group
UHT	Ultra Heat Treatment
UK	United Kingdom
UNICEF	United Nations (International) Children's Fund
UWIC	University of Wales Institute Cardiff
VAS	Visual Analogue Scale
WAG	Welsh Assembly Government

## TERMS OF REFERENCE APPLICABLE TO THIS REPORT

<u>Preparation</u> of powdered formula milk	Refers to adding the powder to the water
<u>Handling</u> powdered formula milk	Refers to what you do with the made-up powdered formula milk once powder and water have been mixed together
<u>Storage</u> of powdered formula milk	When mixed powder and water is not fed to infant immediately and kept for feeding at a later time
Socio economic group (SEG)	Classification scale for classifying people into five groups, one subdivided (A, B, C1, C2, D, E). The composition of the classes brought together, as far as possible, people with similar levels of occupational skill. (National Statistics, 2005)
Risk	The term risk may be used in a variety of contexts, e.g. high-risk food' and high-risk consumer which accounts for the severity of a hazard as well as the probability of its occurrence (Dillon <i>et al.</i> 2001).
Vulnerable and 'at risk' populations	Sections of the population with an increased susceptibility to food poisoning/infectious disease
Target audience	An audience to whom communications are directed. The target audience is defined in terms of demographic and psychographic characteristics, such as age, sex, education, income, habits, attitudes and other lifestyle characteristics
Indirect contamination.	Passage of pathogens via an intermediary vehicle to a previously uncontaminated or cooked food. The main vehicles are hands, equipment, utensils, surfaces and cloths (Worsfold and Griffith, 1996).
Potentially contaminated.	A material/food/surface that in its natural state is not contaminated with pathogenic micro-organisms, however, as a result of other actions/activities during domestic food preparation may become contaminated has been referred to as being.
Adequate hand-washing and hand drying.	Immediate thorough hand-washing after touching raw chicken using hand hot water and soap/detergent, followed by effective drying using a clean, hand towel or disposable paper towel (no contamination of the kitchen before washing and no touching of the tap before washing, and no contamination of kitchen items within kitchen before washing) (Griffith <i>et al.</i> 1999a).
Inadequate hand-washing and hand drying.	Failure to implement adequate hand-washing and hand drying (as stated above).
Adequate washing and drying of equipment and utensils.	Adequate washing/drying of utensils (particularly after preparation of raw chicken) includes applying an abrasive scrubbing action with hot water, detergent and a clean cloth followed by rinsing and drying using a clean T-towel or disposable paper towel (Griffith <i>et al.</i> 1999a).
Inadequate washing and drying of equipment and utensils.	Failure to implement adequate washing and drying of equipment and utensils (as stated above).
Clean hand towel or tea-towel.	A tea-towel or hand towel that is considered to be 'clean' when it has <i>not</i> been previously in contact with potentially contaminated hands that have either not been washed or inadequately washed, or has been used to wipe a kitchen work surface.
Potentially contaminated hands.	Hands that have been unwashed and/or dried or inadequately washed and/or dried after direct or indirect contact with raw chicken
Potentially contaminated utensils.	A utensil that has been unwashed/dried or inadequately washed and/or dried after direct or indirect contact with raw chicken
Clean	Visibly free from obvious soil or food. When the numbers and type of micro-organisms (microbial load) is at an acceptable level for use. (Dillon <i>et al.</i> 1999).
Social Marketing	'Social marketing is the application of commercial marketing technologies to the analysis, planning, execution and evaluation of programs designed to influence the voluntary behaviour of target audiences in order to improve their personal welfare and that of society' (Andreason, 1995).
Attitudes	An attitude is typically viewed as being an underlying variable that is assumed to guide or influence behaviour (Fishbein and Ajzen, 1975). It can be defined as 'a learned predisposition to think, feel and act in a particular way towards a given object or class of objects' (Ribeaux and Pobbleton, 1978). Attitudes can be positive and negative. In the context of this report a negative attitude relates to caregiver failure to agree with recommended practices for safe preparation, handling and storage or powdered infant formula feeds. In addition negative attitudes relate to overall use of powdered infant formula and associated information provision.

## EXECUTIVE SUMMARY

### RATIONALE AND OBJECTIVES

The purpose of this project was to obtain data detailing how parents and professional caregivers (including National Health Service (NHS) hospital and community caregivers and day nursery staff) manage the safety aspects of infant formula preparation and storage. The initial objectives of this study are as follows:

1. Produce a report reviewing research methods used in this study.
2. Obtain qualitative data from consumers and relevant caregivers concerning beliefs, attitudes and practices relating to infant feeding with powdered infant formula inside and outside the home.
3. Obtain quantitative data detailing powdered infant formula advice given by health visitors.
4. Obtain quantitative data from 200 consumers (parents bottle feeding infants aged less than 6 months with powdered formula) on beliefs, attitudes, risk perceptions and self-reported practices.
5. Analyse the microbiological quality of 100 prepared powdered infant formula feeds and observe hygiene practices.
6. Track the time temperature profile of 100 feeds prepared by parents.
7. Obtain quantitative data detailing beliefs, attitudes, risk perceptions and self-reported practices used by caregivers in hospital baby units.
8. Obtain quantitative data detailing beliefs, attitudes, risk perceptions and self-reported practices used by caregivers in nurseries.
9. Track the time temperature profile of 25 feeds served in nurseries.
10. Model the data obtained from the time temperature profiling of consumers and nurseries.

*Initial findings from objective (2) indicated midwives were important healthcare professionals who provide advice and information to parents during pregnancy and immediately after infants have been born. Therefore, this caregiver group was included in qualitative and quantitative parts of the study.*

### APPROACHES USED

- Qualitative data detailing parents', hospital nurses', health visitors', hospital and community midwives' and day nursery nurses' attitudes, beliefs and self-reported practices related to powdered infant formula and preparation, handling and storage behaviours and sources of powdered infant formula information were obtained from moderated focus groups undertaken across the UK.
- Quantitative data detailing attitudes, beliefs, risk perceptions and self-reported practices was obtained from postal questionnaires distributed to day nurseries and NHS hospital nurses and midwives across the UK.
- Quantitative data detailing attitudes, beliefs, risk perceptions and information provision was obtained from postal questionnaires distributed to NHS health visitors and community midwives across the UK.
- Parents' powdered infant formula preparation, handling and storage behaviours were determined using direct observation in a model domestic kitchen. Reconstituted powdered infant formula feeds, prepared feeding bottles and kitchen surfaces were subsequently analysed to determine microbiological quality.
- Time temperature profiling of reconstituted powdered infant formula feeds in day nurseries and inside/outside of parents' homes using validated methods and miniature dataloggers.
- Model the time-temperature profile to project growth of *Enterobacter sakazakii* (*Cronobacter*) using specialised software and expertise at Wageningen University, The Netherlands.

## KEY FINDINGS

### **Powdered infant formula preparation, handling and storage behaviours inside & outside the home.**

- Cumulatively, UK parents reported and demonstrated use of a variety of methods for preparation, handling and storage of powdered infant formula inside and outside the home. Although all feeds were observed and reportedly prepared with boiled water, many reported methods /practices were not in accordance with current guidance provided by the UK Department of Health (DoH) and Food Standards Agency (FSA).
- All parents expressed positive attitudes towards preparation of safe powdered infant formula for their infant(s). However, negative attitudes towards some practices and methods required to achieve this were identified which could contribute to non-compliance and have implications for microbiological safety.
- Reconstitution of powdered infant formula milk in advance of feeding was found to be common practice inside and outside of the home (35-40% parents) and modelling of the time temperature data from reconstituted feeds stored for 12-24 hours indicated high levels of predicted growth of *E.sakazakii* (*Cronobacter*) in made-up feeds stored at ambient temperature.
- Many parents also reported awareness of the current recommendations to prepare one feed at a time for immediate feeding. Almost all parents and NHS caregivers considered this was difficult and impractical to implement. In addition, there was a widespread lack of understanding *why* preparation of individual feeds is now recommended, when making feeds up in advance in the past was considered acceptable, more practical to implement and perceived to be non-problematic.
- The majority of parents and NHS caregivers considered judgement of cooled, boiled water temperature  $>70^{\circ}\text{C}$  to be difficult. Cooling boiled water for longer than 30 minutes was frequently reported, observed in the model kitchen and during time-temperature studies. Many parents believed the recommendation was intended to prevent scalding infants from feeding feeds that were too hot as opposed to reasons for safety.
- A common practice reported and observed for preparation of powdered infant formula feeds involved preparation of boiled tap water in cleaned and sterilised/disinfected bottles (being stored at refrigerated or room temperatures) with addition of powdered formula when ready for immediate feeding. The majority of parents reported they believed that implementation of this practice was following guidelines by making 'one feed at a time' and similarly this practice was reportedly advocated by many community midwives and health visitors and day nursery staff. However, use of this method means that powdered formula is mixed with water  $<70^{\circ}\text{C}$  before feeding, which is contrary to FSA/NHS UK recommendations and has implications for microbiological safety.
- Findings have illustrated the diversity of attitudes and perceptions that parents have towards specific handling, preparation and storage behaviours and microbial safety of powdered infant formula use inside and outside of the home.
- Results indicate that parents 'cut corners' with required preparation practices, especially as the infants age increases, indeed, 43% parents reported they were more careful with how they prepared their infants' feeds when they first started preparing powdered formula.
- The most common observed cleaning malpractices implemented by parents included failure to rinse all bottles and components after washing in hot water and detergent. In addition, almost all (90%) of parents failed to clean the inside and outside of the screwcap, outside of teats and around the outerrim of the feeding bottle. The screwcap and outerrim threads are key bottle locations known to harbour food residues and micro-organisms if inadequately cleaned.
- Common disinfection/sterilisation malpractices implemented included failure to follow all manufacturer's instructions for disinfection/sterilisation equipment, particularly failing to load the



disinfection/steriliser unit according to instructions and failure to allow for 'cooling time' after completion of disinfection/sterilisation cycles and before removal of items from units.

- The majority of participants did not wash and dry their hands adequately at key powdered infant formula preparation steps as recommended by the FSA/DoH and handling of bottle components after disinfection/sterilisation, which could lead to cross contamination was carried out by a large number of parents.

#### **Powdered infant formula preparation, handling and storage behaviours in UK hospitals.**

- Ready-to-use (RTU)/ready-to-feed (RTF) formula (in glass bottles) was predominately determined as the type of formula used as an artificial feed in maternity departments, but also in neonatal/special care baby units (SCBU) and paediatric departments. Specialist and non-specialist powdered infant formula feeds were more frequently prepared/used for feeding in neonatal, SCBU and paediatrics departments.
- Hospital nurses in neonatal/SCBU and paediatrics reported longer periods of time (>4 hours) that they considered RTU/RTF formula can be safe, open and in-use for feeding than hospital midwives (~1 hour) in maternity departments. Reported responsibility for monitoring the time RTU/RTF formula bottles were in use was variable between departments. For example, in maternity departments, 88% hospital midwives/maternity healthcare assistants (MHCAs) reported it was the parents' responsibility to monitor the length of time the RTU/RTF formula was open and 'in-use'; whereas 95% of hospital nurses in neonatal/SCBU and paediatric departments/healthcare assistants (HCAs) reported that it was the responsibility of the nurse to monitor RTU/RTF formula opening and 'in use' times.
- Locations for the preparation of powdered infant formula feeds was variable between hospitals. In the majority of hospitals, all feeds are prepared in ward/department kitchens or at the patient/infants bedside; however, in some hospitals, feeds are prepared in central feeds units.
- In neonatal/SCBU and paediatric departments and in central infant feed units, powdered infant formulae (specialist and non-specialist) is reportedly reconstituted using bottles of sterile water (at ambient temperature).
- Hospital caregivers reported that there are instances when parents bring formula milk powder, reconstituted feeds and prepared (cleaned and sterilised) empty feeding bottles in from home for feeding in hospital. Furthermore, it was reported that parents do sometimes prepare their infants' feeds in hospital. Such practices were reportedly more common in neonatal/SCBU and paediatric departments than in maternity.
- Cumulatively, the majority of NHS caregivers perceived recommended practices to reduce the risk of illness from feeding with powdered formula milk to be important. However, practices associated with preparing one feed at a time, feeding reconstituted feeds immediately after preparation and reconstitution using boiled water cooled for <30 minutes/at >70°C were not considered to be important by up to 18% of NHS caregivers.
- Less than half of all NHS caregivers surveyed were aware of infection control policies that included powdered infant formula. 'Policies' that were cited were associated with the United Nations (International) Children's Fund (UNICEF) Initiative and/or general hygiene.

#### **Powdered infant formula preparation, handling and storage behaviours in UK day nurseries.**

- Considerable variability was reported in methods used to manage and handle powdered infant formula between and within UK day nurseries, for example, 55-61% day nursery staff reported that made-up bottles of powdered formula are brought to nurseries, 34-41% reported that empty bottles, (ready for use) are bought to nurseries and 35-47% reported that prepared ready for use bottles are bought to

nurseries with boiled water, ready for addition of the formula. Data indicate national and regional differences in reported methods. For example, in Wales, Scotland and Northern Ireland, use of powdered infant formula reconstituted by parents at home before nursery appears to be a more frequent practice.

- More than half of day nursery staff indicated that reconstituted powdered infant formula feeds (made-up at home) are frequently brought to nurseries, for storage and use throughout the period of infant care, which may for >10 hours. Methods used for carrying reconstituted powdered infant formula feeds to nurseries may encourage microbial growth.
- Nearly half of day nursery staff considered it acceptable for powdered formula to be made-up in advance and stored in the refrigerator all day before feeding, however, time temperature profiling of reconstituted feeds showed that no feeds achieved <5°C during storage which has implications for microbiological safety.
- Another common method reported for managing powdered formula feeds in day nurseries was parent preparation of feeding bottle and boiled water (at home) and provision of powdered formula in a separate (sometimes measured out) container. The powdered formula feeds are then reconstituted immediately before feeding, removing the need for storage of reconstituted feeds. However, use of this method means that powdered formula is mixed with water <70°C before feeding, which is contrary to FSA/NHS UK recommendations and has implications for microbiological safety.
- More than 20% of day nursery nurses lacked knowledge of correct refrigeration temperatures.
- The majority of day nursery nurses believed that they knew all of the precautions necessary for safe preparation and storage of powdered infant formula. However, few nursery nurses demonstrated knowledge of recommended handling, preparation and storage behaviours and almost all were unaware of the current guidelines.
- The majority of day nursery staff (including managers) believed powdered infant formula is a sterile product before the tin is opened and most were unaware of the association with *Cronobacter* spp. (*E.sakazakii*) and/or *Salmonella*.
- Large proportions of day nursery staff reported never receiving up-to-date information about powdered infant formula guidelines and only a third of day nursery managers reported awareness or recalled seeing the FSA Guidance for Healthcare Professionals
- Although 65-72% of day nursery staff reported their nursery had a policy in place covering safe preparation, handling and storage of powdered infant formula; other study findings have indicated that such reported 'policies' may be unstructured and limited.
- Training about powdered infant formula use in day nurseries was reportedly scarce and usually conducted by day nursery managers who reported rarely receiving information/updates about safe preparation, handling and storage of powdered infant formula. Day nursery managers (as well as nursery nurses) reported negative attitudes towards recommended practices and were unaware of microbial risks associated with powdered formula.

#### **Parent & caregiver awareness of microbiological hazards associated with powdered infant formula.**

- A lack of knowledge and negative attitudes towards microbiological hazards associated with powdered infant formula was determined among parents, day nursery staff and to a slightly lesser extent, NHS caregivers. Nearly three-quarters of parents and 45-77% of NHS caregivers believed that powdered infant formula is a sterile product before the tin has been opened.
- Parents' confusion and misconceptions have been identified about the length of storage time of opened cartons of RTU formula and reconstituted powdered infant formula.

- Judgements of optimistic bias, the illusion of control, personal invulnerability and confidence in current practices associated with powdered infant formula preparation have been identified among all caregiver groups. Such judgements may impede intervention effectiveness and need to be considered in the design of risk communication strategies.

#### **Information provision to parents about safe preparation and handling of powdered infant formula.**

- A *substantial variability* in provision of information to parents about powdered infant formula feeding, preparation, handling and storage was determined among NHS caregivers.
- Almost all NHS hospital midwives, hospital nurses, health visitors and community midwives reported they were in contact with infants being fed using infant formula. However, NHS caregivers indicated variable (and often negative) attitudes towards provision of information and advice about powdered infant formula to parents.
- The majority of mothers reported a lack of adequate information provision from NHS professionals about preparation, handling and storage of powdered infant formula; all reported a huge amount of information about breastfeeding being available and given to them from midwives and health visitors.
- Many NHS caregivers (up to 71%), in each caregiver group, reported that bottle feeding mothers/parents were not given as much time or support and information as breast feeding mothers.
- Substantial discrepancies were identified between parents' perceived need for information about powdered infant formula and NHS caregivers' provision of adequate information for needs. Most NHS caregivers believed they provided adequate information to meet parents' needs, but most parents reported they needed more support and advice about how to manage the safety of powdered formula milk feeds.
- Parents who were aware of the new recommendations reported they required additional support and advice about *how* to implement them in realistic scenarios; parents also wanted to know *why* recommended practices should be implemented.
- Although almost all (94-99%) health visitors and community midwives reported that it was important to give powdered infant formula information to mothers when changing from breast feeding to formula feeding, many mothers reported that when they changed such feeding practices no information/advice was given.
- Health visitors reported that they encountered considerable confusion amongst parents regarding correct practice in the preparation of powdered infant formula feeds; this confusion was compounded by the belief amongst health visitors, community midwives and parents that recommended practices are not consistent between sources (NHS, FSA, National Childbirth Trust (NCT), supermarkets, formula manufacturers etc).
- NHS caregivers working in the community (particularly health visitors) reported experiencing difficulties providing accurate information to non-English speaking clients due to time constraints, lack of availability of interpreters and lack of availability of pictorial interventions.
- Few parents recalled being given DoH/NHS Bottle Feeding leaflets and large proportions of NHS caregivers reported lack of availability which was variable between countries and regions.

#### **Training and sources of powdered infant formula information reported by NHS caregivers.**

- Few (<31%) NHS caregivers reported they had 'ever' had training about microbiological risks associated with powdered infant formula and <20% reported they had received any such training in the past three years (since 2006/2007).

- Information about breastfeeding was reportedly updated more frequently to all caregiver groups, than powdered infant formula. Overall, ~50% of all caregivers reported never receiving updated information about powdered formula milk use and feeding.
- Reported awareness or recollection of FSA/DoH and WHO powdered infant formula guidance notes was limited among all NHS caregivers (26-40%) and lowest among hospital midwives (26%) and more widespread among health visitors.
- Representatives from powdered infant formula manufacturers (known as ‘formula reps’) were considered by some NHS caregivers (particularly in the community) for providing information to be useful, important and needed by caregivers to inform parents about up-to-date powdered infant formula guidelines, microbiological risks associated with formula and effect of consumption on the digestive system. However the majority of caregivers reported they are now not allowed to contact such ‘formula reps’ directly for information.
- Breast feeding coordinators/infant feeding coordinators (reportedly often responsible for implementation of the UNICEF Baby Friendly Initiative within hospitals) were cited by many NHS caregiver groups as gatekeepers to powdered infant formula information.

### **Infant feeding policies and the UNICEF Baby Friendly Initiative.**

- Policies for infant feeding are present in many hospitals and reported to be based upon the UNICEF Baby Friendly Initiative and focus upon breastfeeding.
- Almost all NHS caregivers reported the influence of the Baby Friendly Initiative – the majority of caregivers who did not work for accredited hospitals/workplaces either had obtained a certificate of commitment or informally followed ‘Baby Friendly rules’.
- The majority of NHS caregivers reported that they promote breastfeeding ‘*more than they used to*’ and that the influence of the UNICEF Baby Friendly Initiative has a substantial impact upon their roles.
- NHS caregivers reported variable opinions and attitudes towards the implementation and conformance to the Baby Friendly Initiative. For example, the majority of hospital nurses/who were supportive of the need and importance for breast feeding, believed the Baby Friendly Initiative was ‘*too extreme*’ and ‘*detrimental*’ to bottle feeders. Other NHS caregivers, particularly community midwives and health visitors reported restricted provision of information to parents about powdered infant formula; others reported they believed adhering to ‘Baby Friendly rules’ undermined professional judgement.
- Less than half of respondents in each NHS caregiver group reported awareness that their workplace has an infant feeding policy that included powdered infant formula.

**Table 1.1 FSA study objectives, targets and achievements.**

	Objective	Achievement	Additional comments related to implementation
01	Produce a report reviewing research methods used in this study.	FSA objective achieved	No comment
02	Obtain qualitative data from consumers and relevant caregivers (health visitors, day nursery nurses and hospital nurses) concerning beliefs, attitudes and practices relating to infant feeding with powdered infant formula inside and outside the home.	FSA objective achieved and exceeded In addition to the original FSA objective, additional focus groups with hospital and community midwives in England and Wales also undertaken.	~ 6 months delay to the study while NHS Multi-Centre Research Ethics Committee (MREC) and hospital Trust and Primary Care Trust (PCT) and departmental approvals obtained.
03	Obtain 100 questionnaires detailing quantitative data about powdered infant formula advice given by health visitors.	FSA objective achieved and exceeded In total, 426 questionnaires were obtained from health visitors	Additional work and consequent delays incurred while obtaining MREC amendment approval and NHS PCT and departmental approvals.
04	Obtain quantitative data from 200 consumers (parents bottle feeding infants with powdered formula, aged less than 6 months) on beliefs, attitudes, risk perceptions and self-reported practices.	FSA objective achieved	No comment required
05	Analyse the microbiological quality of 100 prepared powdered infant formula feeds and observe hygiene practices.	FSA objective achieved and exceeded Observations of preparation of 300 infant feeding bottles/feeds for feeding (including 100 reconstituted feeds); Data from over 1000 microbiological and Adenosine triphosphate (ATP) samples.	Considerable delays encountered due to move and set up of model kitchen from Colchester Avenue campus to the Food Industry Centre (FIC), Llandaff followed by technical audio visual and software/hardware problems.
06	Track the time temperature profile of 100 feeds prepared by parents.	FSA objective achieved and exceeded In total, 145 time temperature profiles of reconstituted feeds stored in advance of feeding were obtained.	Implementation linked to objective 05 and thus associated delays.
07	Obtain 100 questionnaires detailing quantitative data about beliefs, attitudes, risk perceptions and self-reported practices used by caregivers in hospital baby units.	FSA objective achieved and exceeded In total, 291 questionnaires were obtained from hospital nurses (in SCBU/neonatal and paediatric departments). In addition to the original FSA objective, 266 questionnaires were obtained from hospital midwives and 232 questionnaires obtained from community midwives.	Additional work and consequent delays incurred while obtaining MREC amendment approval and NHS hospital and departmental approvals.
08	Obtain 100 questionnaires detailing quantitative data about beliefs, attitudes, risk perceptions and self-reported practices used by day nursery nurses in nurseries.	FSA objective achieved and exceeded In total, 339 questionnaires were obtained from day nursery nurses In addition to the original FSA objective, 224 questionnaires were obtained from day nursery managers	No comment required
09	Track the time temperature profile of 25 feeds served in nurseries.	FSA objective achieved and exceeded In total, 55 time temperature profiles were obtained.	No comment required
10	Model the data obtained from the time temperature profiling of consumers and nurseries.	FSA objective hopefully achieved	Delays with data analysis (illness and unknown issues) at Wageningen has meant continued delays. Source data was sent to them later in the study than initially envisaged due to delays outlined in 06.

# CHAPTER 1

## INTRODUCTION

### 1.1. BACKGROUND

#### 1.1.1 Infant feeding with powdered infant formula milk.

In the UK, it is estimated that after 4-10 weeks of age 75% of babies are exclusively fed on formula milks or are receiving a combination of breast and formula milk; these figures, which represent infant feeding practices in many westernised populations highlight the fact that most babies in the UK are fed wholly or in part on breast milk substitutes (Hamyln *et al.* 2002). Therefore the microbiological safety of formula preparation and handling is of relevance and considerable importance to parents and caregivers in homes, hospitals and day nurseries.

The risk to infants from powdered infant formula milk has received increased attention in recent years due to possible contamination with pathogens such as *Cronobacter spp.*<sup>1</sup> [formerly *Enterobacter sakazakii*] and *Salmonella* (EFSA, 2004). Prevention of infection requires care in the production/manufacturing of the formula product, the containers it is stored in, as well as how it is reconstituted and subsequently handled prior to feeding. Recommended procedures from the Government and a range of other sources on the safe preparation and use of powdered infant formula in the home are available to parents, however, relatively little is known about the safety practices used in the preparation and storage of powdered infant formula amongst caregivers and parents inside and outside of the home.

To maximise powdered infant formula safety a World Health Organisation/Food and Agriculture Organisation (WHO/FAO) risk assessment of powdered formula milk (WHO/FAO, 2004) stated a need to reduce the level of microbial contamination in powdered infant formula through heating prior to use, a need to minimize the chance of contamination of reconstituted powdered infant formula during preparation and a need to minimize the risk of microbial growth following reconstitution, prior to consumption. The UK Department of Health (DoH) and Food Standards Agency (FSA) recommend that powdered formula is re-constituted ‘*using boiled water cooled to no less than 70°C*’ and ‘*fresh for each feed*’ (DoH, 2008; FSA, 2007). Such practices should destroy potential pathogens in the powdered infant formula and reduce the risk of microbial survival and/or multiplication before feeding.

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<sup>1</sup> In 2008, *Enterobacter sakazakii* was reclassified as 6 species in a new genus – *Cronobacter* gen. nov. within the Enterobacteriaceae. To avoid any confusion arising from this taxonomic change the designation *E. sakazakii* (*Cronobacter spp.*) is used throughout this report (FAO/WHO, 2008).

Safe powdered infant formula prepared in the home may be achieved by parents equipped with adequate/correct knowledge, positive attitudes and a motivation to comply with and implement desired recommendations/behaviours that can minimise microbial risks. This in turn requires appropriate health education and risk communication concerning potential problems and the necessary control measures. A key to the design of effective educational initiatives that will be implemented is an understanding of factors that influence hygiene and safety behaviours.

### **1.1.2 Microbiological risks associated with feeding infants powdered infant formula.**

*'Intrinsic contamination of powdered infant formula with E.sakazakii (Cronobacter spp.) and Salmonella has been a cause of infection and illness in infants including severe disease, and can lead to serious developmental sequelae and death'* (FAO/WHO, 2004).

Reconstituted powdered infant formulas are considered to be a food class of high risk because of the susceptibility of the infant population to enteric bacterial pathogens, severe response to enterotoxins and increased mortality (Rowan and Anderson, 1998). Powdered infant formula is not a sterile product and once reconstituted provides an ideal growth medium for spoilage and pathogenic bacteria. The latter includes *E. sakazakii* (*Cronobacter* spp.), a relatively rare cause of invasive infection with high death rates in neonates (Himelright *et al.* 2002).

*E. sakazakii* (*Cronobacter* spp.) is a motile, non spore forming Gram negative facultative anaerobe (Iversen and Forsythe, 2003). The International Commission for Microbiological Specification of Foods ranked *E. sakazakii* (*Cronobacter* spp.) as a 'severe hazard for restricted populations, life threatening or substantial chronic sequelae or long duration' (ICMSF, 2002). The virulence of *E. sakazakii* (*Cronobacter* spp.) varies between strains (Lehner & Stephan, 2004) and little is known about its dose response characteristics. Studies have shown that in reconstituted dried infant formula the organism is highly thermotolerant, which has considerable implications for manufacture and subsequent preparation, use and storage (Weir, 2002).

During the past several years, *E. sakazakii* (*Cronobacter* spp.) has received increased attention (Edelson-Mammel *et al.* 2005) as a public health concern and cases of *E. sakazakii* (*Cronobacter* spp.) infections due to contaminated infant formula have been reported in a number of developed countries (INFOSAN, 2005). *E. sakazakii* (*Cronobacter* spp.) has caused disease in all age groups, however, from the age distribution of reported cases infants (children aged less than 1 year old) appear to be mainly at risk and data have indicated that babies aged less than 5 months old, particularly neonates, babies that are preterm, low birth weight or immuno-compromised are most likely to fall victim (FAO/WHO, 2004). Mortality rates from *E.*

*sakazakii* (*Cronobacter* spp.) infection have been reported to be 50-75% (Nazarowec-White and Farber, 1997), although this is also reported to have declined to <20% in recent years (FAO/WHO, 2004). Based on the available information in 50-80% of cases, powdered infant formula is both the vehicle and source (direct or indirect) of *E. sakazakii* (*Cronobacter* spp.) induced illness.

There are three main routes by which *E. sakazakii* (*Cronobacter* spp.) can enter infant formula through the following ((FAO/WHO, 2004):

- the raw material used for producing the formula
- contamination of the formula or other dry ingredients post-pasteurisation
- contamination of the formula as it is reconstituted by the caregiver prior to feeding

A number of studies have determined contamination rates of *E. sakazakii* (*Cronobacter* spp.) in powdered infant formula. In the UK, Iversen & Forsythe, (2004) isolated *E. sakazakii* (*Cronobacter* spp.) from 2/82 samples of powdered infant formula milk and 3/72 samples of milk powder. In Canada, *E. sakazakii* was isolated from up to 12% of retailed dried infant formula samples (Nazarowec-White and Farber, 1997). This has implications both for the quality assurance procedures during manufacture and how the product will be subsequently prepared and stored by the end users. Current FAO/WHO Codex microbiological specifications (CAC, 1979) for powdered infant formula limit the number of coliforms, which includes *E. sakazakii* (*Cronobacter* spp.), however it is considered that ‘*although such criteria may prevent a number of outbreaks, it does not confer a sufficient level of safety*’ (FAO/WHO, 2004). Even low levels of contamination of *E. sakazakii* (*Cronobacter* spp.) are considered to be a risk factor, given the potential for multiplication during the preparation and holding time prior to consumption of reconstituted formula (INFOSAN, 2004). An expert meeting recommended that Codex revise such standards to include establishing a microbial specification for *E. sakazakii* (*Cronobacter* spp.) (FAO/WHO, 2004).

*E. sakazakii* is known to have good long term survival properties (Edelson – Mammel & Buchanan, 2004) and has been isolated from a range of home, food production and healthcare environments (Vasavada, 2005; Khandai, *et al.* 2004). A review of cases and outbreaks of *E. sakazakii* (*Cronobacter* spp.) infection in premature babies and neonates found that the organism was isolated from food/formula preparation items such as blenders, bottle cleaning brushes and spoons (Muytjens and Kollee, 1990). Research has also shown that the organism is able to grow on infant feeding equipment (Iversen, *et al.* 2004). Low populations (1cfu/ml) of *E. sakazakii* (*Cronobacter* spp.) in reconstituted formula may grow to potentially hazardous levels (>10<sup>7</sup> cells/ml) when stored at room temperature for 10 hours – such levels would be reached sooner in formula held at 35-37°C (Nazarowec-White and Farber, 1997; Pagotto *et al.* 2003). Furthermore, *E. sakazakii* (*Cronobacter* spp.) can grow slowly at some refrigerator temperatures

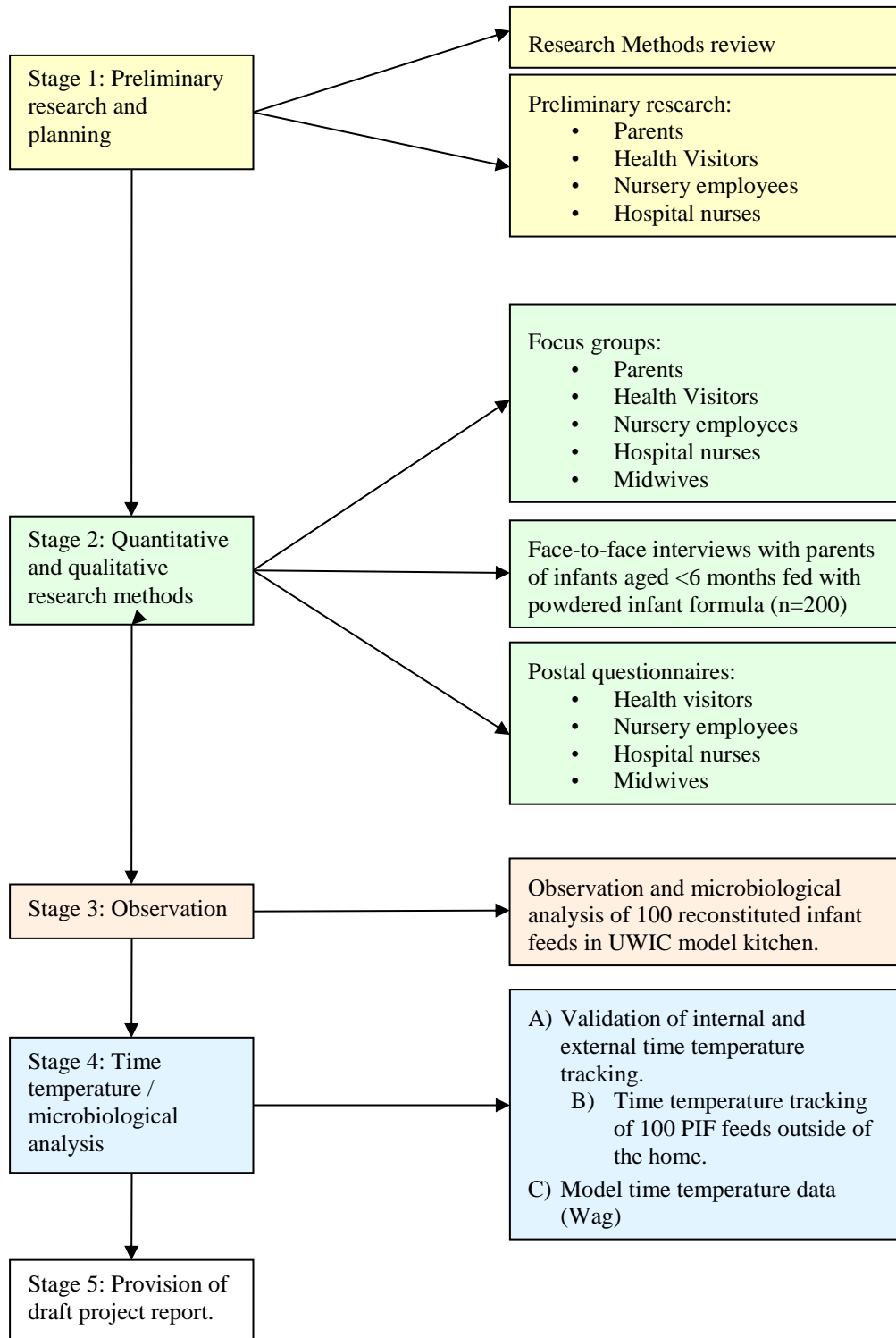


(Iversen, *et al.* 2004), especially if they are not operating below 5°C. Studies have found that large numbers (21-25%) of consumers' refrigerators exceed recommended temperatures (Van Garde and Woodburn, 1987; Daniels, 2001) therefore providing conditions that encourage the proliferation of organisms such as *E. sakazakii* (*Cronobacter* spp.) to potentially dangerous levels. The growth and survival properties of *E. sakazakii* (*Cronobacter* spp.) on preparation and feeding equipment and in reconstituted formula has implications for the importance for adequate decontamination of feeding utensils after use and proper temperature control of reconstituted formula.

Infant feeding bottles and components can act as transfer sites for pathogenic microorganisms. Therefore, effective cleaning and sterilisation/disinfection of feeding bottles and components is important to prevent contamination of the formula as it is reconstituted by the caregiver prior to feeding. As some of the potential consumers (premature and low birth weight babies) may have reduced immunity, the management of the reconstitution process and subsequent storage prior to use are particularly important. The latter may be especially significant when feeding is not immediately after feed preparation.

Given the increasing importance of powdered infant formula and associated microbiological risks, the project has the following aims and objectives (see Figure 1.1 for overall plan of study).

**Figure 1.1 Overall Plan of Study**



## **1.2 PROJECT AIMS AND OBJECTIVES**

### **1.2.1 Parents**

- Assess and analyse consumers' qualitative and quantitative beliefs, attitudes and awareness related to powdered infant formula safety, preparation, handling and storage, hygiene, microbial risks, practices recommended for safety and sources of information.
- Assess and analyse consumers' self-reported practices in powdered infant formula preparation, handling, reconstitution and storage inside and outside of the home.
- Observe consumer practices in the preparation and reconstitution of 100 infant feeds.
- Microbiologically analyse the content of 100 reconstituted infant feeds.
- Monitor the time temperature history of 100 reconstituted feeds.
- Model time temperature profile data for potential growth of *E. sakazakii* (*Cronobacter* spp.).

### **1.2.2. Day nurseries**

- Assess and analyse day nursery caregivers' qualitative and quantitative beliefs, attitudes and awareness related to powdered infant formula safety, preparation, handling and storage, hygiene, microbial risks, practices recommended for safety.
- Assess and analyse nursery self reported practices in infant formula preparation, handling, reconstitution and storage of powdered infant formula in UK day nurseries.
- Monitor the time temperature history of 25 reconstituted feeds fed in day nurseries.
- Model time temperature data for potential growth of *E. sakazakii* (*Cronobacter* spp.).

### **1.2.3 Health visitors**

- Assess qualitative and quantitative health visitor beliefs and attitudes relating to powdered infant formula preparation and storage in terms of: importance, risk, hygiene, responsibility and communication.

### **1.2.4 Hospital nurses**

- Assess qualitative and quantitative hospital nurse beliefs and attitudes relating to powdered infant formula preparation and storage in terms of: importance, risk, hygiene, responsibility and communication.

### 1.3 PROJECT RESEARCH QUESTIONS.

- What do consumers know about powdered infant formula preparation? What are consumer attitudes, perceptions and beliefs about reconstitution, hygiene, storage and risk inside and outside of the home?
- What information do consumers receive regarding powdered infant formula preparation and storage? Source of information? How do consumers perceive current advice in terms of adequacy?
- Which practices do consumers implement during preparation of powdered infant formula in terms of bottle preparation and reconstitution of the formula?
- Using the time temperature history of a range of consumer prepared feeds; based on data obtained, assess potential for the growth of *E. sakazakii* (*Cronobacter* spp.).
- What do day nursery employees know about powdered infant formula preparation? What are day nursery employee attitudes, perceptions and beliefs about reconstitution, hygiene, storage and risk?
- What training do day nursery employees receive regarding powdered infant formula preparation and storage?
- Which behaviours do day nursery nurses implement during preparation and storage of powdered infant formula?
- How do health visitors communicate information on powdered infant formula safety and hygiene to consumers?
- What are health visitors' attitudes, perceptions and beliefs about powdered infant formula safety and provision of information?
- What infection control practices are used in hospitals? If practices are in use, determine knowledge and attitudes towards them.
- How do hospital nurses communicate information about powdered infant formula safety and hygiene to consumers?
- What are hospital nurses' attitudes, perceptions and beliefs about powdered infant formula safety and provision of information?

## CHAPTER 2

### USE OF POWDERED INFANT FORMULA INSIDE & OUTSIDE THE HOME: A QUALITATIVE ANALYSIS OF PARENTS' AND CAREGIVERS BELIEFS, ATTITUDES, RISK PERCEPTIONS AND SELF-REPORTED PRACTICES

#### 2.1 INTRODUCTION

##### 2.1.1 Background

An in-depth understanding of parent and caregiver beliefs, attitudes, risk perceptions and self-reported practices is required to determine how powdered infant formula (PIF) is prepared, handled and stored in different environments, to find out what information is provided to parents and caregivers about preparing and handling PIF and find out *why* reported practices are implemented and *why* parents and caregivers think or feel in the way that they do. This data will also inform latter stages of this study (Chapters 3, 4 and 5).

Used alone or in combination with other methods, the aim of focus groups is to get closer to participants' understanding of, and perspectives on certain issues (Millward, 1995). This facilitates the understanding of attitudes, perceptions, beliefs, and values that individuals have as well as uncertainties and ambiguities in group thought processes. In addition, focus groups can identify the normative understandings that groups of consumers draw to reach a collective judgment (Bloor *et al.* 2002). Focus groups can be especially effective in exploring people's perception of risk – the group discussion provides an opportunity to evaluate how those perceptions are linked to personal attitudes and characteristics (Desvousges and Smith, 1988).

Focus groups have been widely recommended as a means to construct questionnaires (Converse and Presser, 1986; Rossi *et al.* 1983). Indeed, prior to drafting and piloting a larger survey study focus groups may be used in the early days of the study for exploratory purposes to inform the later stages of the study. This exploration will typically be wide ranging but may concentrate on certain priority topics, on generating contextual data or on everyday group language (Bloor *et al.* 2002). There are three ways that focus groups can contribute to the creation of survey items (Morgan, 1993): (a) by capturing all the domains that need to be measured in the survey; (b) by determining the dimensions that make up each of these domains; (c) by providing item wordings that effectively convey the researchers' intent to the survey respondent.

##### 2.1.2 Aims and objectives

The overall aim of this part of the project was to obtain qualitative data from 16 focus groups with consumers and relevant caregivers (health visitors and hospital nurses) concerning beliefs,

attitudes and practices relating to infant feeding with PIF inside and outside the home. The more specific objectives were to:

- Obtain formal NHS Ethical Approval, NHS Trust Approval and local management approval to undertake focus groups with NHS staff.
- Design, construct and pilot focus group discussion guides.
- Organise and co-ordinate 16(+2) focus groups around the UK with NHS caregiver groups, parents and day nursery nurses.
- Determine caregiver perceptions of risks associated with PIF, self-reported practices related to preparation, handling and storage of PIF feeds inside and outside the home and caregiver roles and responsibilities related to PIF handling/information provision/receipt.

Preliminary research and findings from parent, hospital nurse and health visitor focus groups indicated that hospital and community midwives were key caregivers providing information about infant feeding at antenatal and postnatal stages. Therefore additional focus groups (n=2) were undertaken with hospital and community midwives throughout the UK.

Data obtained from this part of the project informed face to face interviews (Chapter 3), day nursery postal questionnaires (Chapter 4) and health visitor, hospital nurse and hospital and community midwife questionnaires (Chapter 5).

## **2.2 METHODS**

Implementation of the focus groups was undertaken by the researcher in UWIC in conjunction with the market researchers and field staff from Beaufort Research (subcontractors within the study). Beaufort Research is an independent market research company based in Cardiff, and have worked professionally and successfully with UWIC in the past undertaking qualitative and quantitative research studies (Redmond *et al.* 2001; Redmond *et al.* 2005).

Beaufort Research interviewers, trained to meet the BS7911 criteria were used to recruit focus groups. In accordance with the BS7911 (based on ISO 9000) Beaufort Research provided standard guidelines for the recruitment and hosting of group discussions. The standard specifies best practice for every aspect of their business and therefore includes fieldwork, data processing and executive elements. In addition, Beaufort Research staff were compliant with the Code of Conduct of the Market Research Society (MRS).

For an overview of the plan of methods used for the collection of qualitative data from parents and day nursery nurses for this component of the study see Figure 2.1 and for an overview of

the plan of methods used for the collection of qualitative data from NHS professionals for this component of the study see Figure 2.2.

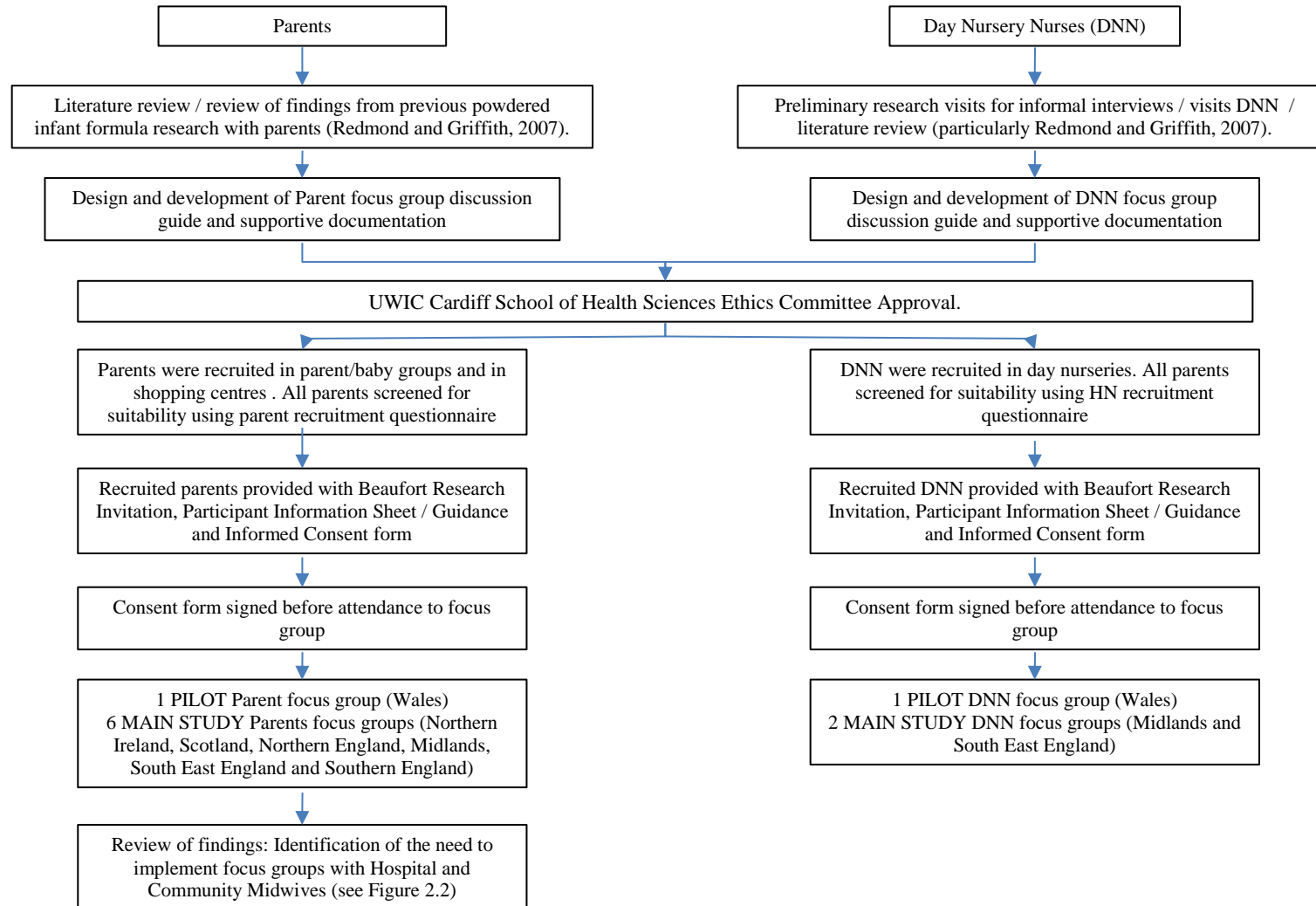
### **2.2.1 Design, development and piloting of the focus group discussion guides.**

Design and development of the focus group discussion guides (Appendix 2.1 and 2.2) was based on preliminary investigative visits and meetings with health visitors, hospital nurses (in paediatric, neonatal and maternity departments), hospital staff in ‘milk kitchens’, infant feeding advisors (in hospitals) and day nursery managers and staff in day nurseries. For some preliminary investigative visits, informal interviews were undertaken to ascertain key practices and subjects of relevance to safety when preparing, handling and using PIF in the different environments. In addition, previous literature detailing microbiological risks associated with the use of PIF were reviewed, including previous consumer and day nursery based research related to preparation of infant feeding bottles for feeding (Redmond and Griffith, 2007).

Each focus group with professional caregivers began with an open-ended discussion about roles and responsibilities for preparation of formula milk and for parents – a brief word association with PIF. For all groups, perceptions of the microbiological risks associated with PIF were ascertained, as well as any concerns, determination of most important actions required to achieve safety and perceptions of recommended practices. NHS caregivers were asked about previous training and information sources about PIF; parents’ perceptions of intervention sources and materials were obtained. Parents and day nursery nurse group discussions focused upon reported handling, preparation and storage behaviours and related attitudes to practices carried out with PIF inside and outside of the home. Health visitor and midwife groups included sections related to antenatal and postnatal care – including information provision. All professional caregiver groups were asked about PIF policies in their establishment and potential influences of external initiatives.

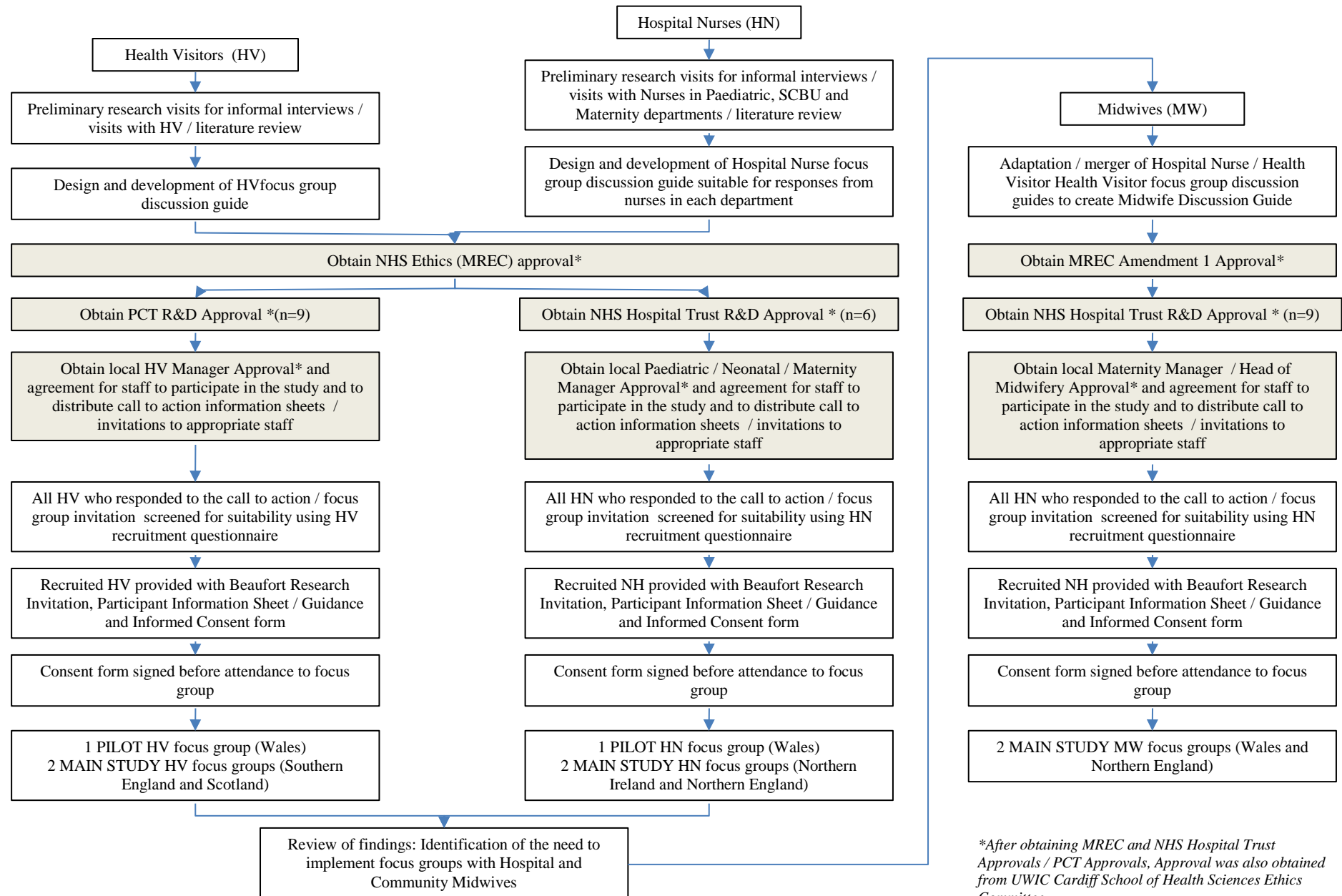
Before the discussion guide was used for the main focus groups throughout the UK, pilot focus groups were carried out in Wales with each caregiver group under study. After pilot focus groups, discussion guides were amended as necessary; for example, in some cases discussion guides were shortened, in other cases selected stimulus materials amended.

**Figure 2.1 Overview of the plan of methods used to implement focus groups with parents and day nursery nurses.**





**Figure 2.2 Overview of the plan of methods required to implement focus groups with NHS professionals.**



## 2.2.2 Determination of focus group sample specification and locations in the UK (pilot and main study).

The sample specification of parents outlined in Table 2.1 was designed to achieve six groups of parents including five groups of mothers and one group of fathers (all of whom feed babies aged less than 6 months with PIF). One of the mothers' focus groups only included 'at risk' babies (no minimum age, mix of social grades). 'At-risk' babies were defined as pre-term and low weight babies – not clinically immuno-compromised. No grandparents or alternative carers were included in the study. All parent groups included a mix of motivations (planned to feed on formula/unplanned) and recruitment ensured representative inclusion of ethnic minorities. Half of all respondents in each group used PIF for feeding for all infant feeds; half of respondents used PIF feeding at least once a day.

In addition, the following recruitment requirements were satisfied:

- three groups of first time parents and three groups of subsequent parents
- four younger groups (aged 18-30 years) and two older groups (aged 31-45 years)
- two groups<sup>2</sup> of (socio economic groups) SEGs ABC1 and four groups of SEGs C2DE

**Table 2.1 Sample specification and location of parent focus groups.**

Group	Age (years)	SEG <sup>2</sup>	Parental Status	Motivation*	Location
Parents – mothers - PILOT	31-45	ABC1	First time	Planned	Wales
Parents – fathers	31-45	ABC1	Subsequent	Planned	Southern England
Parents – mothers	18-30	C2DE	Subsequent	Unplanned	Midlands
Parents – mothers	31-45	C2DE	First – time	Unplanned	Scotland
Parents – mothers	18-30	ABC1	First – time	Planned	Northern Ireland
Parents – mothers	18-30	C2DE	First – time	Unplanned	South East England
Parents – mothers of 'at risk babies'	18-45	Mixed	Mixed	Mixed	Northern England

\*Planned or unplanned feeding with PIF

Sample specification and locations where focus groups of professional caregivers can be found in Table 2.2. All such respondents were involved professionally with infants aged less than 6 months or provide advice and help to parents on the preparation, storing and feeding of PIF milk.

<sup>2</sup> Socio economic groups (SEGs) Classification scale for classifying people into five groups, one subdivided (A, B, C1, C2, D, E). The composition of the classes brought together, as far as possible, people with similar levels of occupational skill. (National Statistics, 2005)

- Day nursery nurse focus groups - included some who make up PIF in the nurseries – others who accept reconstituted feeds for storage and feeding throughout the time in the nursery (maximum of two nursery nurses from an individual day nursery in each group).
- Health visitor focus groups – included health visitors who provide information/advice to parents with infants aged less than 6 months (maximum of two health visitors from the same health centre or GP practice).
- Hospital nurse focus groups – included a mixture of nurses from following wards/units/departments – special care baby units (SCBUs)/neonatal units, maternity wards, paediatric units (maximum of two nurses per ward).
- Hospital and community midwife focus groups – included a 50:50 mix of hospital and community midwives for each group (maximum of two midwives per hospital/ward).

**Table 2.2 Sample specification and location of professional caregiver focus groups: day nursery nurses, health visitors, hospital nurses and hospital and community midwives.**

Group	Location
Day nursery nurses - PILOT	Wales
Health visitors - PILOT	Wales
Hospital nurses- PILOT	Wales
Day nursery nurses	South East England
Day nursery nurses	Midlands
Health visitors	Southern England
Health visitors	Scotland
Hospital nurses	Northern England
Hospital nurses	Northern Ireland
Hospital and community midwives	Wales
Hospital and community midwives	Northern England

### 2.2.3 NHS Approvals

Before implementation of focus groups involving NHS staff, NHS approval had to be obtained from NHS Ethics and local NHS hospital Trusts and Primary Care Trusts (PCTs), as well as at a local management level in each department where hospital staff asked to participate in the study may work. For a flow chart indicating stages of obtaining NHS approvals see Appendix 2.2.

Firstly, NHS Ethics Approval was required from the Multi-Centre Research Ethics Committee (MREC) for Wales. This provided ethical approval for more than one research centre (i.e. PCTs and Hospital Trusts) across the UK. The MREC approval letter with list of 19 documented items of approved documentation required for the application can be found in Appendix 2.2.

Focus groups were all implemented before the introduction of the IRAS (Integrated Research Application System) NHS application system for obtaining Trust approvals in the UK. In total, applications for approval were submitted to 24 NHS Trusts – many of which had separate research and development (R&D) processes/application forms for different regions within the Trust. Each NHS Trust had a unique application system (with some commonalities). For some processes, a link person, who worked at management level within the hospital, had to be agreed and established as a ‘responsible clinician’ to oversee implementation of the research in the hospital(s). In other instances, written local management approval from departmental managers had to have been agreed before the R&D approval could progress. In other instances, local management/departmental approval would be sought after R&D approval had been granted. Approvals from PCTs were required for health visitor involvement in the project and approvals from NHS hospital Trusts were required for hospital nurse, midwife involvement. For some (not all) hospital Trusts, research and field staff from Beaufort and UWIC who were part of the study and likely to come into contact with NHS staff as a result of this study required Honorary Contracts (from R&D) (even though none of the work (including recruitment) was conducted on NHS property). All approval applications were ‘Site Specific Exempt’.

Once written R&D Approval to proceed with the research had been obtained from each R&D department, managers/leads (e.g. Head nurses, Leads for Children’s Services, Directorate managers for Women’s and Children’s Health, Heads of SCBU/Paediatrics and Heads of Midwifery) for individual departments (paediatrics, neonatal/SCBU, maternity and health visiting) were contacted to seek approval for staff under their management to be invited to participate in the MREC and R&D approved focus groups. In addition, departmental managers were asked to distribute ‘call-to-action invitations’ to relevant staff members (see Appendix 2.2) for recruitment. At this stage, some local managers refused approval – a selection of anonymised reasons for local management approval can be found in Table 2.3.

Throughout all approval processes, particularly at the local management level, it was made very clear that the study was concerned with issues related to the safety of PIF use and what associated information is given to them. In addition, all managers at all stages were informed:

- 1) This was an independent study for the UK FSA about the microbiological safety of PIF preparation and handling
- 2) The study had no links or connections to commercial PIF companies
- 3) The study was not advocating feeding infants with PIF (or any formulas) nor advocating increased provision of information about PIF.

Initial reluctance from departmental managers/leads (particularly from maternity departments) for allowing staff participation in the focus groups included issues such as the study would involve open discussion about use of PIF – which was in some cases discouraged and almost a ‘taboo’ subject in some departments. In addition, managers/ leads reported concerns that staff (therefore associated department) participation in the study could affect/undermine/hinder ‘Baby Friendly’<sup>3</sup> accreditation or efforts being made to achieve accreditation status. In response to this, the UK Baby Friendly Initiative (UNICEF) headquarters in London were contacted (March, 2008) and informed that the study was being implemented. They were sent all relevant documentation about the focus group and postal questionnaire (Chapter 5) components of the project and were specifically asked if they considered staff/departmental participation in the focus groups would undermine current/working efforts towards ‘Baby Friendly’ status. As a result, the Deputy Director at the Baby Friendly Initiative was fully supportive of the study and provided assurances (which they said could be passed onto departmental managers/point of contact) that staff participation in the study would not affect accreditation status. This information was thereafter passed on to all departmental managers where local management approval was sought.

**Table 2.3 Some of the reasons offered for refusing approval for staff participation in FSA focus groups to discuss safety of powdered infant formula.**

NHS Staff	Reason for refusal
Consultant midwife	‘As a midwife in a hospital which prides itself on its ‘Baby Friendly’ status, it is hard to see how this fits in with our current remit???’ (email)
Midwifery manager	‘Incensed’ that the FSA should fund a research study about infant feeding without addressing breast feeding, even though she acknowledged that the focus of the study was the microbiological safety of powdered infant formula feeds. As a result of this opinion nurses and midwives from/associated with maternity departments in three hospitals had to be excluded from participation in the study (despite R&D Trust approval – granted with the support of the same manager). (Telephone)
Head of Midwifery	‘the midwifery team are not able to support this research programme on the advice of our Consultant Midwife’. (email)
Area Public manager (health visitors)	‘Unfortunately due to the current situation within our service we ...are unable to participate on this occasion. We are currently undertaking numerous audits within our PCT and this combined with current staffing pressures has resulted in this decision’ (email)

<sup>3</sup> *The Baby Friendly Initiative is a worldwide programme of the World Health Organization and UNICEF. It was established in 1992 to increase and prolong breastfeeding and ‘reverse the trend towards use of infant formula’. Initiatives are implemented in UK requiring requirements for compliance in hospital and at a community level, using the ten steps to successful breast feeding\* and to practise in accordance with the International Code of Marketing of Breastmilk Substitutes (UNICEF website 2009).*

*\*Step 7: Give newborn infants no food or drink other than breast milk, unless medically indicated*

## **2.2.4 Participant recruitment**

Beaufort Research was responsible for all recruitment fieldwork. Between 8-10 participants were recruited for each focus group. Overall, ~150 participants were recruited for this stage of the study.

### ***2.2.4.1 Recruitment of parents and day nursery nurses.***

Managers and persons running day nurseries and baby groups were contacted by field researchers to ask permission, and arrange a convenient time for recruiting day nursery nurses and parents for focus groups in selected UK locations. In addition, ‘on-street’ recruitment of parents was undertaken (e.g. outside shopping centres). Once screened using the recruitment questionnaires, the recruits were given a participant information/guidance sheet and personal invitation with details of time/location of the group. Signed consent was obtained from all parents and day nursery nurses prior to attending the focus group. For all parent/day nursery nurse documentation related to recruitment and consent see Appendix 2.1.

### ***2.2.4.2 Recruitment of NHS health visitors, hospital nurses and hospital and community midwives.***

In accordance with MREC and NHS Trust/local management approval requirements, department managers/leads (paediatrics, neonatal/SCBU, maternity) were sent ‘Call to Action Invitations’ to distribute to relevant nursing and maternity staff (see Appendix 2.2). All responses were screened to these invitations by the field department at Beaufort Research, using the recruitment questionnaire.

For health visitor recruitment, health visitor managers (in approved PCTs) distributed a letter (provided from UWIC) via email to all health visiting staff to inform them that this study was taking place, and that they may be contacted directly by telephone<sup>4</sup> by Beaufort Research field researchers to be invited to take part in the study. The letter also included important details indicating that MREC, NHS Trust R&D and local manager (named) approval had been granted for health visitor participation. (Absence of this approval during the preliminary stages of the project resulted in many health visitors refusing to speak to the UWIC researcher about background information about their job/responsibilities etc.). Health visitor managers also distributed ‘Call to Action’ invitations to all health visitors in areas where focus groups were planned.

As was the case for parents and day nursery nurses, the NHS staff recruits were given a participant information/guidance sheet and personal invitation with details of time/location of

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<sup>4</sup> Contact details sourced and compiled in UWIC from publically available GP Surgery/Clinic information on the Internet (February/March 2008).

the group. Signed consent was obtained from all NHS staff prior to attending the focus group. For all NHS staff documentation related to recruitment and consent see Appendix 2.1.

### **2.2.5 Focus group organisation and coordination**

Each group was professionally moderated by Beaufort Research using specific discussion guides (written by UWIC and agreed by Beaufort). Discussion groups were held in rooms in hotels and public houses, outside of normal working hours (9-5pm) and consisted of between six and ten participants. Participants were seated facing each other around a table in relaxed circumstances and provided with refreshments. Each group was moderated by a non-biased, trained professional (from Beaufort) and co-moderated by the researcher from UWIC. All focus group discussions were recorded using digital recorders and each focus group lasted between 90-120 minutes (all participants signed to give consent that the discussion could be recorded). All focus group participants were given an incentive (£30 for parents/£40 for professionals) for taking part in the study, to cover time and transport expenses.

#### ***2.2.5.1 Parents***

Seven focus groups were held in the private function rooms of hotels in Wales (pilot), Scotland, Southern England, Northern Ireland, Northern England, The Midlands and South East England. In total, 50 parents attended groups (46 mothers and 4 fathers).

#### ***2.2.5.2 Day nursery nurses***

Focus groups were held in private function rooms of hotels in Wales (pilot), England (The Midlands) and South East England. In total, 24 day nursery nurses attended groups (8 per location), representing ~14 different day nurseries.

#### ***2.2.5.3 NHS health visitors***

Focus groups were held in the private function rooms of hotels in Wales (pilot), Scotland and Southern England. In total, 29 health visitors attended groups (10 in 2 locations and 9 in 1 location). Some health visitors who participated in the focus groups were from Trusts/areas which were 'Baby Friendly' accredited, others were not. The discussions included some health visitors who had received varying levels of 'Baby Friendly' training.

#### ***2.2.5.4 NHS hospital nurses***

Focus groups were held in private function rooms of hotels in Wales (pilot), Northern Ireland and Northern England. In total, 29 hospital nurses attended groups (10 in 2 locations and 9 in 1 location). Nursing staff recruited for the study included healthcare assistants (HCAs), maternity healthcare assistants (MHCAs), nursery nurses, paediatric nurses, neonatal and SCBU nurses – all of whom are involved in the preparation, handling or storage of PIF or advising about infant feeding infants aged less than 6 months in hospitals.

Hospital staff attending the focus group in Wales were from hospitals working towards 'Baby Friendly' accreditation (i.e. have a certificate of commitment) and a 'Baby Friendly' accredited hospital. Nurses from the focus group in Northern Ireland were from a 'Baby Friendly' Accredited hospital. Nurses attending the focus group in Northern England were from hospitals that were not 'Baby Friendly' accredited; however, both hospitals reported working according to the 'Baby Friendly rules'.

#### **2.2.5.6 NHS midwives**

Two focus groups were held in the private function rooms of hotels in Wales and Northern England. In total, 17 midwives (community and hospital) attended groups. Midwives who attended the focus group in Wales were from six hospitals, all of which were either fully 'Baby Friendly' accredited or reportedly working under the rules of the Baby Friendly Initiative. Midwives who attended the focus group in Northern England were from two hospitals, neither of which were 'Baby Friendly' accredited, however, staff who participated in the focus groups from both of these hospitals reported working according to 'Baby Friendly rules'.

#### **2.2.6 Analysis of focus groups**

A detailed content analysis of all transcriptions was carried out by the researcher at UWIC. Common PIF, handling, preparation, storage and information provision issues were highlighted in transcripts and then grouped. Analysis of the transcriptions involved use of NVIVO qualitative software.

### **2.3 RESULTS**

The need to obtain MREC and NHS approvals for implementation of NHS caregiver focus groups around the UK caused delay for implementation of this part of the study (resulting in the study being frozen for 6 months, as agreed with the FSA). However, on completion this part of the study did exceed FSA objectives by including additional hospital and community midwives focus groups.

Approximately 30 hours of focus group transcriptions were obtained from this part of the study involving discussions between ~50 parents, ~80 NHS healthcare professionals and ~30 day nursery nurses.

The following results detail summarised focus group findings denoting parents' and caregivers' perceptions of PIF, factors that may influence implementation of important behaviours required for safety, self-reported preparation, handling and storage practices and information related to the provision of advice and where appropriate, receipt of professional training. For additional supporting quotations evidencing research findings see corresponding table reference.



### 2.3.1 Parents - cumulative focus group findings

- The age of an infant was reported to influence the number of feeds required; parents reported a requirement to make a larger number of feeds (smaller quantities) for younger infants. The majority of mothers reported feeding their infants 5-6 bottles of PIF during a 24 hour period (including one during the night).
- Most parents reported *'doing everything by the book'* for the first few weeks of preparing PIF – but found recommended practices too time consuming, resulting in *'corners being cut'*. Parents with more than one child also reported they were less *'neurotic'* about hygiene and following guidelines for their second infant (Table 2.4 part A).

*'You do everything by the book for those first few weeks, because you think you are going to kill them and then after a week, you think I have just been doing everything by the book. And I mean it's just so time consuming that you do then you start to cut corners the older they get ....by the time, you have got to your second kid, they are just deprived [laughing].'*

- Mothers who had more than one child reported they usually implemented the same infant feeding practices (if using formula) as they had for their first baby, particularly if they encountered no problems; this was particularly the case for preparation of feeds 12-24 hours in advance.

[when asked why PIF feeds are prepared in advance] *'Just because ..... I had done it with my first..... if it had done any harm ..... and there isn't anything to say do not'*

- A cumulative opinion in many parent focus groups was the need to let infants *'have a few germs'* and that it was possible to be *'too clean'*.
- Many mothers reported that they usually prepared PIF feeds themselves and were confident that practices they implemented were safe; the majority of mothers did not trust their partners to reconstitute the powdered formula feeds *'properly'* or as hygienically/safely as themselves. However, in some households it was the fathers' responsibility to clean, sterilise and prepare all of the feeds (Table 2.4, part B)

[Prefer to do it myself] ----- *'Just because I know I suppose, I feel responsible to do it, I know that I've done it this way, done it that way I don't have to worry about it. If they've [husband] not done this and not done that'*

#### 2.3.1.1 Self-reported preparation, handling and storage practices

- Methods that parents reportedly implement to prepare, handle, store and feed PIF inside and outside of the home are **variable**, although all feeds were reportedly prepared with boiled water.
- Implementation of practices that do not meet current recommendations (i.e. malpractices) were reported by parents in all focus groups.

### *Preparation, handling and storage of powdered infant formula in the home*

- The majority of parents reported preparation of PIF feeds in the same area of the kitchen as other foods (including raw meat/chicken etc). As a measure to ensure surface hygiene, some parents reported placing a tea towel on the surface where and when feeds were prepared (Table 2.4, part C).

*'I will usually put a clean, like tea towel down before I put all my bottles on them'.*

- Almost all mothers reported boiling the water for preparation of infant feeds in the kettle. However, subsequent practices were extremely variable. For example, some parents reported leaving the water to cool in the kettle before pouring into the bottle and adding the formula, others poured it straight into the bottle to cool and then mixed the formula, others poured it straight into the feeding bottle and mixed with the formula straight away (Table 2.4, part D).

*'Boil the kettle, put the water into the bottle, and then put the formula in [straightaway]'.*

*'I let it cool in the kettle' .... 'It'd be about an hour I would leave it sitting, but it would be sealed, it would be in one of those filter things'*

*'Mine's poured into a jug and left to cool'*

- Other mothers reported less common practices such as pouring the boiled water into a jug to cool down before pouring into the feeding bottle(s) and boiling water in a saucepan, cooling it at room temperature, then in the fridge, then pouring into a plastic bottle, which is then stored outside of the fridge ready for preparation of the feed when needed (Table 2.4 part E).
- For PIF feeding in the home, some mothers reported making up one feed at a time, others boiled the water and stored it in prepared feeding bottles at room temperature or in the fridge until required for feeding, when the powder would be added (Table 2.4 part F).

*'I would put the water in the bottles and keep the water in the fridge, and then mix the formula for each feed when you need it.....all those bottles are there full of water just ready for the powder to go in' .....* *'I do too, like about five hours later, ..... I just pour the powder into the water'*

*'I make them up in the morning and that's it for the day'*

*'I do it four at a time'*

*'I do mine individually'*

- Mothers also reported they reconstituted enough feeds for 12-24 hours in advance and stored in the fridge until required. Some also reported storage of feeds in the door of the fridge and other reported confusion regarding the length of time made-up feeds could be used for, once out of the refrigerator (Table 2.4 part G).

*'I make the milk for 24 hours'*

*'they say 24 hours you can keep it for 24 hours, refrigerated'*

*'I make them all with the milk in them and then just leave them in the fridge, and then warm them up when I need them'*

*'If I am staying in all day or in home, I would be home at feed times, I would do at five.... I'll keep them overnight and I'll just, for that day or twelve hours maximum, they have got to be in the fridge'*

*'Just leave them on the side until the bottle is at room temperature and then put them in the fridge'*

- It was reported that the maximum length of time that reconstituted feeds had been stored for was 24 hours – however, more likely storage times were 9-12 hours.

*'Never longer than 24 hours, never ever longer than 24 hours. I don't even think it has been near 24 hours, but I always know the time because I write the time on them'*

*'Max 12 hours' .... 'It would be about 9, 10 hours, I never let them go so it's longer than 12 hours'*

- Storage of made-up feeds and prepared water at room temperature was reported in some cases to be influenced by the infant, who may only feed on the made-up formula at room temperature – in which case reconstituted feeds would not be placed in the fridge for storage or cooling, but would be left at room temperature to cool (after reconstitution) until ready for feeding.

*'Well, I think it depends on what you want to do, like whether your child has the bottle, when they want the bottle, do they have it warmed up or not because Connor will only have his bottles at room temperature. So I always make all my bottles up, just the water to let them cool down and leave them at room temperature, so it's just water and if you are going out, I have just got the bottles at room temperature and I just add the formula.'*

- Very few parents reported consideration of refrigeration temperatures and none reported measurement/monitoring refrigeration temperatures.

[know what their fridge temp is] *'Oh, God, no'*. [All laugh]

[know what temp their fridge should be] *'No' .... 'Cold'*

*'My fridge beeps if it's out of range so I know it's all right.'*

- Variable practices were reported for cooling reconstituted PIF feeds – some of which were intended for immediate feeding, others for storage and later feeding. Most common practices reported included holding the warm feed under a tap of cold water and/or placing the warm feed in a jug of cold water. Some parents reported they leave the made-up feed to cool by leaving it on the work surface at room temperature (Table 2.4 part H).

*'Sometimes I have to run it under cold water, the bottle, I just keep it in a wee pot of cold water just to cool it down, but if he's crying for it and he wants it and it's still really warm, I just ...run it under the water tap just to cool it down'*

*'I leave mine out to cool down, just on the side.... [for]....about two hours'*

- Variable methods were reported for reheating PIF feeds. Most common reasons for the need for reheating included for feeding after storage of made-up feed or water in the refrigerator or for feeding after reconstitution of the PIF with water stored at room temperature or water that has cooled for a long time in the kettle. Most commonly reported reheating methods reported included using a microwave, using a bottle warmer (which was reported to usually take too long) and placing the made-up feed in a jug of hot/boiling water. Other methods reported placing a feed in a bowl in a saucepan of boiling water (Table 2.4, part I).

*..... it's just as easier keeping it at room temperature where you're going to have to have it in for maybe say 30 seconds to a minute, take it out and then it out and it's ready'*

*'I have a bottle warmer' ... 'It's good in theory but they take like eight minutes apparently to... who can wait eight minutes to feed a baby, I can't, not when they're screaming the house down'*

*'I was not using microwave before, I was doing just boil water from the kettle and put in the bowl, then drop my bottle in that for about five to six minutes, but sometime they be so hungry you can't wait that much and I just go for the microwave, but I don't do it like every time. I do it when he is hungry and then I just go microwave.'*

#### *Preparation, handling and storage of powdered infant formula away from the home*

- For PIF feeding away from the home parents reported variable practices. Some reported taking a measured quantity of boiled water in a prepared bottle, powder in a separate container (sometimes upturned in the formula bottle with water). Others reported taking an empty sterilised bottle, powder in a separate container and obtain boiled water when out and others reported taking sterilised bottles and cartons of ready-to-use (RTU) formula. Some parents reported reconstituting the feed before leaving the home and taking it with them (sometimes in a cool bag with cool packs, other times in an insulated bag to keep the feed warm and at other times in a normal bag (i.e. no cool/warm insulation).
  - Using sterilised bottle with boiled water and container with PIF (Table 2.4 part J):

*'I use a small ...pot.... it is easy, I just put my three spoons in each of them [sections of the pot], so I know I have like three time I can use them [ie enough powder for three feeds] and then just have my water this side and my empty bottles'*
  - Using reconstituted PIF prepared in advance (Table 2.4 part K):

*'I find that when I've made up two bottles, when I put them in this thermal bag, the time his next bottle is, the bottles are still, they're just going cold, so it's a nightmare trying to find someone where you can heat the bottles up, especially if you're out. .... 'They can keep them warm or keep them cold. They're better at keeping them cold than they are keeping them warm [laughing]. It's just like normal, say if you leave a bottle there and put one in the bag, it'll probably go cold at the same time. There's not much difference there. I always take my bottles out cold.'*
  - Using RTU formula (cartons) (Table 2.4 part L):

*'I just take a bottle with me, a sterilised bottle, and then buy the formula when I'm out, the ready made stuff....the cartons'*
- Practices for dealing with PIF when on holiday were reported. Some parents indicated they used RTU cartons when abroad (sometimes bought in holiday location, others taken in the suitcase from the UK). Other parents reported taking the infant formula powder and preparing bottles as they would at home – except for not using tap water – buying and boiling bottled mineral water.

*'I made two or three up and kept them in the fridge, and it said not to do on that on the carton packet.....but I did that... [laughing]....for convenience, you know, if you're going out somewhere for the day, then it's easier'*

[use of RTU cartons on holiday] *'They're definitely perfect if you're going on holiday'*

*'I took a tin with me and just ... bought bottles water.....bottled water, I just boiled it in a wee kettle'*

- Parents reported storage of reconstituted feeds away from the home for up to 4 hours.

*'About four hours' .... 'Three or four hours' 'Two hours' 'Four hours'*

*'Oh when I'm out? If it's in a thermal bag I would say three hours, three or four hours, but when I'm at home after two hours I haven't used the same milk'*

- Parents reported practices that they implemented for dealing with PIF feeds during the night. Some prepared bottles of boiled water and stored them next to the bed with required quantities of infant formula powder and mixed the two when required for feeding (the same practice that was implemented during the day time). Others reported they would use reconstituted feeds during the night – sometimes stored at the bedside, sometimes stored in the refrigerator.

*'I make the night feeds up because he has 3 – 12am, 3am and 6am, I make them up before I go to bed and I take the last one up with me, the first one up with me and then I go down and get the others out the fridge [in the night].'*

- Most important practices reported by parents to ensure PIF is safe included the following:

*'That your bottles are properly cleaned' .... 'Cleaning and sterilising them'*

*'the water I think, the water as well, sort of freshly boiled water'*

*'that they haven't been made up for too long. They haven't been there sitting for too long'*

- Misunderstandings were determined regarding use of UHT RTU formula. Some parents believed the RTU formula to be the same as reconstituted powdered formula. Instructions on cartons of formula indicate it is acceptable to store the RTU formula for 24 hours (refrigerated) and this caused confusion for parents who could not understand why reconstituted PIF should be made-up one at a time and used immediately. Parents believed that the two types of formula could be stored in the same way for the same length of time (Table 2.4, part M).

*'See these wee cartons and the wee jars, obviously they've been made somewhere before, you know what I mean? So what's the difference in making a bottle that morning, and making a fresh one that night? Well, I can imagine that it'd still be okay to give him if it's kept cool enough'*

**Table 2.4 Parents reported preparation, handling and storage of powdered infant formula in the home and away from the home**

	Parent quotes
A. Preparation of powdered infant formula for first and subsequent infants	<p><i>'at first you are unsure aren't you, so you listen to other people' .... 'You just think they are a lot more fragile when you first get them, when you first come out of that hospital you think they are so fragile and then after a [while], you think 'God, you know, they are a bit more sturdy than what you think - and then by the time they get a bit older .....they are so sturdy. As I say the new one comes and you forget that they are so titchy and little again. So yeah, it is probably the time and the effort and all the rest of it, that when you have got the other one then. The first one as you say you had all this time and they are sat there and you can dote around but then when you have got another one to keep an eye on. As you say that's probably for half the time for quickness, as you say.'</i></p> <p><i>'I was a bit more, fussy the first time'</i></p> <p><i>'I did everything [making up individual feeds] with my first, but with the second, anything goes' .... 'Poor second children'</i></p> <p><i>'When you are then back at work you have got everything else [to deal with] and as you say I found myself cutting corners then .... 'I hate cutting corners' .... 'It's a flat big circle now'</i></p>
B. Person responsible for preparation of infant feeds in the home.	<p><i>'It will be shared always' ... 'On the weekends mine would do it, because that's my time off' ... 'I don't trust mine. [laughing]'</i></p> <p><i>'Sometimes you have to step in if they're not quite doing it right and you can hear your voice all the time, I think "that's not the way to do that but I'll let him do it".'</i></p> <p><i>[Prefer to do it myself] ----- 'Just because I know I suppose, I feel responsible to do it, I know that I've done it this way, done it that way I don't have to worry about it. If they've [husband] not done this and not done that'</i></p> <p><i>'He would do it, but I [prefer to do it because I] know that it's been done properly' . .... 'I do it myself'</i></p> <p><i>'My husband likes really have a go, we have got a microwave steriliser and there was a really funny smell one day and he basically blew it up, I had to go and buy a new one, he just didn't read the instructions that he hadn't put enough water in and put it on far too long' ..... 'so it costs you double' ..... 'I said, what, did you read the instructions? No, it's like him saying no. I know he would do it but I just don't trust him ... to get it right'</i></p>
<i>Self-reported preparation, handling and storage of powdered infant formula in the home</i>	
C. Area of home kitchen for preparation of formula feeds.	<p><i>[do you have separate areas for bottle/food preparation] 'No'</i></p> <p><i>'where I actually prepare my formulas, there's no food prepared there at all, so I don't actually prepare any of our food there, it's a separate space'</i></p>
D. Self-reported practices implemented post boiling water for preparation of powdered infant formula feeds.	<p><i>'I'll put it straight into a bottle when it's boiled' 'I leave mine in the kettle'</i></p> <p><i>'Sometimes I will leave it in the kettle' .... 'See, I don't because you get stupid men ....who boil the kettle again'</i></p> <p><i>'Well, I put the water in straightaway and then put the formula in straightaway, I do and I would just mix it' ... 'I never use the boiled water because they tell you that will just sort of kill any of the vitamins and whatever is in there. So yeah, make it probably more colder rather than hotter'</i></p> <p><i>'Mine depends on how long the kettles been left for, it's sometimes, if it's just the right temperature then from where I have previously used it. I will just fill it up and make it straightaway. If it's been done and it's gotten cold, I will put so much of that water and then boil and top it up. So I mean I have got the cold boiled water and then just top it up with the hot one, now it's the right temperature then to use straightaway'</i></p>
E. Less common reported powdered infant formula preparation practices related to boiling and cooling of water prior to reconstitution with powdered infant formula.	<p><i>'I will put it into a jug of water to cool down'</i></p> <p><i>'I boil it on the gas..... my mum been tell me that, it is not enough boil when you boil in the kettle, you need to let boil ..... white come out, you know it's really boiled. I let it boil for ten minutes actually' 'I have one special one [saucepan] to boil water' .... 'I just keep it to cool down for 30 minutes [in the saucepan], about 30 minute, and then I put it [cooled water in the saucepan] into the fridge until I need to use and when I need I just take it out and put in another bottle, mineral water [bottle] if I have which is empty, just fill it up and then every time I need to use it just pour in my [feeding] bottle..... when it is nearly finished I do the same thing, it lasts me for nearly two days. So then keep it outside [of the fridge], I don't need to keep it in the fridge. Every time I just have to do the milk, I just pour in my bottle in the formula'</i></p>

**Table 2.4 Continued.**

	Parent quotes
<p>F. Variable reported methods for preparation of powdered infant formula feeds in the home.</p>	<p><i>'as long as I know it's going in sterile and that's it's been boiled beforehand, and then it's been sealed with the lid, so it's nice and sterile of they're okay, and then give him his feed'</i></p> <p><i>'I put them in the fridge' ..... 'I just sit them there, mine just sits there'</i></p> <p><i>'When I used to make the bottles like that when he was younger, it was always in the door of the fridge'</i></p> <p><i>'It's always the same, I make them [bottles of water] up and they're sitting there ready to go because he's so hungry all the time. If I think he's going to need a bottle in five minutes, you wouldn't have no time to make it up for him, so it's sitting there ready to go, it's at room temperature, put in the formula, give it a good shake up and that's it.</i></p> <p><i>'I put mine straight into the bottle and then just leave it to cool down..... with the tops on'</i></p> <p><i>'I do a whole day .... then I have to put them in the fridge'</i></p> <p><i>'With the first, I did, I used make them all up ready but now you get told to do it'</i></p> <p><i>'Do the water'</i></p> <p><i>'I will just put the water in'</i></p> <p><i>'Do your water and then add the formula'</i></p> <p><i>'I tip the water and then put the milk in later on'</i></p> <p><i>'I only do one. Yeah because I'm not sure, it might be stupid that I'm asking, that I thought if you make up for a whole day, for example you make one bottle it's only good for like a couple of hours'</i></p>
<p>G. Reported methods for preparation of powdered infant formula feeds for 12-24 hours time.</p>	<p><i>'I make it for half the day, because I might make two, there might be one in the fridge already, and that will be her next bottle and then I will make another two, so that will make three in the fridge ..... I won't make all five at a time for the day'</i></p> <p><i>'I do mine for all day'</i></p> <p><i>'I make mine up for the whole day'</i></p> <p><i>'24 hours in the fridge'</i></p> <p><i>[where made-up feeds were stored in the fridge] 'In side panels, you know you have your side panels ...on the door of the fridge'</i></p> <p><i>'they said that you can keep the milk, if like the baby, like sometimes they don't have all of it you can keep four hours outside. No three hour outside, no one hour outside, but if you keep it in the fridge it will be four hours, if the baby haven't finished the bottle you can't throw it every time, so you can keep it one hour outside, otherwise you throw it, or four hours in the fridge. So if you count it to be make about 24 hours you can leave it'</i></p>
<p>H. Reported methods for cooling of reconstituted feeds</p>	<p><i>'I would run it under the tap or in a jug'</i></p> <p><i>'Put them in the fridge and then warm them up'</i></p> <p><i>'I've got some cold water in a jug and I just put the bottle in there ...or just leave the tap running if you need it quickly, so it's warm'</i></p> <p><i>'I put them in cold water and cool them down quickly'</i></p>
<p>I. Reported methods for reheating of powdered infant formula feeds before feeding.</p>	<p><i>'I boil the kettle, put it in a jug then pour the water and then let it stand for a couple of minutes. I was told not to do it in the microwave because it has got hot spots'</i></p> <p><i>'I do it in the microwave, but if I haven't got a microwave I put it in the bowl, put boiling water in the bowl and then put it in like that to warm it up. A lot of people say, oh not to use microwaves, but I use a microwave and I find it fine.'</i></p> <p><i>'Put a bit of water in a pot, put it over the stove ..... so it's not directly in hot water, the steam just comes up'</i></p> <p><i>'if you're re-heating it again, and you get caught doing something and you've left it in for that split second too long, you've then got to go back and put it under a cold tap, you've got this screaming baby, you have to warm it up and then cool it down, and then make sure it's the right temperature'</i></p>

**Table 2.4 Continued.**

	Parent quotes
<i>Self-reported preparation, handling and storage of powdered infant formula away from the home</i>	
J. Reported use of a sterilised bottle with boiled water and container with powdered infant formula	<p><i>'I make three up in the morning, just water, ready for as and when I need it. If I'm out and about during the day, I'll have the wee dispenser with me, that's in the car and I'll take it with me if I need it. I won't always rush home to give him his feed'</i></p> <p><i>'I take the milk separately'</i></p> <p><i>'if you are going out then I make as many [feeding bottles with boiled water in] as I need but if I am in the house, you do make them up as you go along, just depends what you are doing, don't you? And where you are going, you know if you know you are going to be out all day, then you have got to take enough bottles so have to make up a certain extent'</i></p> <p><i>'I make two up and put them in the thermal bags. You see your little pot there, with that and then when she needs it, pour that in'.</i></p>
K. Reported use of reconstituted powdered infant formula feeds away from the home	<p><i>'I've got these ice things, you put them in the freezer, I think they're like gel things and I put them in my bag to keep the [reconstituted] milk cool and they say you can, if your milk is not room temperature, you can only have your milk room temperature for an hour, but if they are cold you can still keep them for longer, like in the fridge you can keep them for 24 hours, so if you've got them in your bag and they're still refrigerated because they are still cold, then obviously you can still use them for the time that they're supposed to be refrigerated..... It's like little gel things that you put next to your bottle to keep it cool, so it's always cold'</i></p> <p><i>'I take mine ready made'</i></p> <p><i>'Because I pre make the bottles, if I am only going into certain or I know that she is only going to need one bottle while I am out. I will just take my pre made one but if I know I am going to be out all day, I just don't want the bottle already made with me all day. I will buy cartons'.</i></p>
L. Reported use of RTU formula feeds away from the home	<p><i>'Just because if I'm out, I prefer those wee cartons and I think they're the best things since sliced bread, I love them. Just pouring them in, it's great'</i></p> <p><i>'When I go out I use the carton, ready to use cartons. If I don't take them out, they stay in the fridge until I use them, they don't go cold, hot, cold, hot. I take the ready to use whenever I'm out'</i></p> <p><i>'I do mine [sterilised bottles with boiled water] all in the morning and put them in the fridge but if I am going out, I can't take the fridge, so I take the..... carton'</i></p>
M. Misunderstandings between storage of opened UHT RTU cartons of formula and reconstituted powdered formula.	<p><i>'Yeah, so I don't see what the difference is between that [the RTU carton] and making up a bottle and putting it in the fridge'</i></p> <p><i>'I wasn't told [about not making feeds up in advance of use]. I don't understand it because the cartons, you could open the carton and you can leave the carton for 24 hours in the fridge.</i></p> <p><i>'[re making up PIF feeds in advance] it's only as same as the cartons, they are formulas, keeping the carton on the shelf all the day' ..... 'they're in shops they are not always in the fridge, are they?'</i></p>

### **2.3.1.2 Microbial risks and concerns associated with powdered infant formula**

- Virtually all parents believed PIF was a sterile product – justified by the way the product has been sealed and the assumption that the product is manufactured and packaged in a sterile environment. Many parents (not all) believed however, that once the seal has been broken and the tin opened, that the product then was not sterile.

*'you would assume that it's packed in a sterile environment' ..... 'Aye, you would imagine so' ..... 'and hopefully you're not going to tell us something different! [laughing]'*

*'It is until you open it' .... 'Its all been sealed, vacuumed, so it is until you open it'*



### **2.3.1.3 Powdered infant formula recommendations**

- Many mothers were aware of the current PIF preparation and storage guidelines, however, reported confusion about implementation. This was particularly with regards to 1) determination of the exact temperature (i.e.>70°C) of cooled, boiled water to be added to powdered formula during reconstitution and 2) the recommendation to make one feed at a time, when in the past it was considered that no problems occurred from making feeds 12-24 hours in advance and stored in the fridge.
- Preparation of one feed at a time, when required, was considered to be unachievable and impractical all of the time. It was also reported to be very time consuming and the necessity to do so was frequently questioned and as a consequence reportedly not implemented. It was considered to be much easier to make up more than one feed and store reconstituted feeds in the fridge until required for use.
- If parents had heard of the recommendation to allow the boiled water to cool for 30 minutes before mixing with the PIF, the vast majority considered this was to ensure the water was not too hot to feed the baby with. None reported awareness of the need to destroy any micro-organisms present/reduce risk of illness. As boiled water cooled for <30 minutes will on most occasions be too hot to feed an infant safely, parents reported allowing the water to cool for longer before making up the feed for immediate feeding, and adapting the recommendations/their practice to suit the needs and perceived safety of the feed for their infant.

### **2.3.1.4 Information sources**

- Overall, the majority of mothers reported a lack of information provision from NHS professionals about preparation, handling and storage of PIF; all reported a huge amount of information being available and also given to them from midwives and health visitors about breast feeding.
- The majority of mothers indicated that advice about preparation, handling and storage of PIF should be included in antenatal/parentcraft classes; in addition, many mothers indicated they would have liked such information before their baby was born (Table 2.5, part B).

*'Before you have your baby .... they should discuss it like they do with breast feeding'*

*'I didn't want breastfeed, I wanted to start on formula, but your health visitors try and push you and they say 'wait because you might feel differently once your baby is born" so you don't really get a lot of information before'*

*'I think it would be a good idea for it [PIF preparation] to be covered in antenatals, that they do actually show you how to do it'*

- Mothers reported being given little, if any (for the majority of cases), information while in hospital about preparation and handling of PIF feeds. As the RTU glass bottles of formula are used in hospitals mothers reported any advice (sometimes inconsistent between staff) about formula feeding was related to feeding with the RTU bottles and how to hold the infant while feeding (Table 2.5, part B).

*'they do give you some pack like bounty pack, there was nothing about formula milk. Actually I think in hospital they just push you on breast feeding, that's what they do'*

*'When you have to ask for a bottle in the hospital they take longer and...it's like you've committed a crime isn't it?'*

*'when I was in the hospital, the wee bottles, they told me you could use them again for up to two hours' ..... 'I was told within an hour, so it's weird we have different sort of opinions'*

- Mothers who reported being given a formula feeding demonstration in hospital reported a demonstration of feeding the infant for a RTU feed, not preparation (and feeding) of a PIF feed.

*'they done the first feed and done the whole demonstration and everything.... just the ready made [formula] ..... how to feed her and where you should hold her, and then I was just left to it'*

- Almost all mothers (excluding those of at-risk babies) were given no information about PIF preparation, handling and storage during their stay in hospital for the birth of their infant. In hospital, mothers reported that midwives were more interested in encouraging breastfeeding.

*'I don't remember anybody ever telling me how to make a bottle, I don't'*

*'in the hospital..... they won't tell you any information of bottle feeding. They'll only tell you information on breast feeding then and straightaway .... you are already thinking, oh I am in the wrong. So then you do, as you say you don't feel that they give you all the stuff on it'*

- Mothers of 'at-risk' infants (all who had been in SCBU/neonatal or paediatric departments) reported being given information, advice and one-to-one demonstrations from paediatric/neonatal/SCBU staff regarding cleaning, sterilisation of feeding equipment and preparation of PIF feeds before their infant was discharged from hospital. Parents reported this provision of information etc. with a positive attitude.

- All parents reported postnatal home visits from community midwives and health visitors (although some reported up to four week gaps between visits from the midwife and health visitor when feeding changes were implemented).

*'At first it's your midwife and then after the baby is ten days [old], then the health visitor will visit you' ..... 'The health visitor only comes round once and then you can visit them at the clinic every week'*

- Mothers perceived midwives and health visitors to be key information providers relied upon for information and advice about infant health etc; however, a **substantial variability** in provision of information to parents about PIF feeding, preparation, handling and storage from these providers was observed by the variability in parents' attitudes and beliefs regarding the adequacy of information about PIF that they received. Some parents reported occasions where the advice from NHS caregivers was contrary to recommendations (Table 2.5, part D).

*'I found the midwives and the health visitors just completely contradict what they are both saying'*

*'I remember, xxxxx's midwife said "make them up individually". My midwife was like, "No, no, it's fine, make them up, put them all in the fridge and then you can warm them up when she needs them" so some midwives can give [different information].'*

- Some parents believed they did not need to be given any information about PIF from health professionals, while others considered the information they had been given/told from their midwife or health visitor was adequate for their needs, other parents reported their midwife/health visitor made them feel that infant feeding with formula was like feeding with 'poison' or disapproved of and as a consequence provided no supportive advice or information.

*'you're told that it's poison really aren't you'*

- The lack of PIF advice was not understood by parents, given the availability of formula to them in hospitals and supermarkets etc.
- Many mothers reported that when they changed from breast feeding to formula feeding with no information/advice given to them by the midwife or health visitor.

*'I actually didn't talk to anybody about formula milk before because I was so keen on breast feeding I suppose I didn't even think about it, but I knew the shop was only up the road if I did need milk then I could go and pick one up'*

*'I didn't really read much about formula feeding with the first one, because in my own head I was so adamant that I wanted to breast feed. So I didn't read anything about bottle feeding or anything until it all started to go wrong and then I still didn't really it was just a case of manage and make do really'*

- Many parents reported that their main source of information about PIF preparation, handling and storage was the instructions on the PIF milk tin (Table 2.5 part E).

*'I think you just get into your own ways. I just basically read the instructions on the back of the formula box' 'No [one told me how to make up the formula], I think I read the back of the tin'*

- In addition to parents' mothers, friends were important and influential sources of advice (Table 2.5 part F).

*'I have always gone by what my mum's done, so I have had advice and my mum has always done it that way, so I would just do it the same as mum has always done so'*

*'My mom, friends and just anyone really. Whoever wants to help me'*

- The majority of parents suggested they would have liked more information and advice from the midwives and health visitors about preparation, handling and storage of PIF. In addition receipt of such advice was considered to be important.

*'I think it [having information about how to prepare and handle PIF] is important, because we are using the formula milk and we don't even know how to, people is telling us how to do it, or you reading it. Before introducing something, it is better to give proper advice I think'*

*'You just want the facts, you just want to be allowed to make your own informed decision and that's it'*

- A minority of parents recalled having seen specific bottle feeding leaflets provided by DoH/Welsh Assembly Government (WAG)/Scottish Executive and The Health Promotion Agency (HPA) Northern Ireland. Few parents reported being given both ‘Birth to Five’ and ‘Pregnancy’ Books (in England, Wales and Northern Ireland). In some instances lack of availability of information sources was reported.

[Re birth to 5/pregnancy books] *‘The midwife said to me, we don’t have enough so you will have to get them at the clinic, but they didn’t have also’*

- Some parents perceived branded information leaflets/materials to be a form of advertising. Others who had received information from the brand of formula they had selected to feed their infant considered it to be trustworthy and this increased their confidence in use of the product.

*‘When I was receiving from SMA, I was feeling more confident because they are the one producing the milk and they are telling me when to stop one and to start the other one, I was more confident. I know they know what they are doing and they are more protected, we are more protected by it, but still they are the one producing’*

- Information about formula feeding and infant/pregnancy related issues was considered to change ‘all of the time’, resulting in parents becoming more ‘blasé’ to messages. Some parents noted that recommended practices had changed since their mothers had fed them – particularly related to preparation of feeds in advance. There was a lack of understanding why feeds still could not be reconstituted in advance when such a practice was considered to do no harm in the past (Table 2.5, part G).

*‘It’s strange because like, when my mum fed me it was okay to do it like that, and we’ve all been brought up okay, it just seems to be like a modern way of doing things that they change it all the time and now they say, you’re supposed to make up the bottles as you go along, but it was fine for me, it was fine for my brother and fine for most people’*

**Table 2.5 Parents’ perceptions of microbial risks associated with powdered infant formula and sources of powdered infant formula information**

	Parent quotes
A. Perceived sterility of powdered infant formula.	<p>[think PIF is sterile product] <i>Yes</i> [all agree].</p> <p><i>‘You like to think it is, don’t you?’</i></p> <p><i>‘There are quite a few seals and everything’</i></p> <p><i>‘obviously now every time you open it, there’s germs getting in, but your bottles are sterile so it should be fine’</i></p> <p><i>‘I think with all the health and safety procedures that are in processing factories and things like that now, that is has to be [sterile].</i></p> <p><i>‘Again it is the name that you think ‘Well it is baby food and they know what they are doing’ and you trust them don’t you?’</i></p> <p><i>There is bound to be something that they are going to find in the future’ .... ‘You get a report for everything, so there will be a scare at some point in the future but if it was to come about now .... I don’t think I would take it too seriously because as you say there is always something’</i></p>

**Table 2.5 (continued)**

	Parent quotes
<p>B. Antenatal advice about preparation, handling and storage of powdered infant formula</p>	<p><i>'I was really nervous about going to classes because I definitely wasn't breast feeding, and there's such a big focus on it and I thought they were going to be "why not?"'</i></p> <p><i>'they did actually do the whole bottle feeding as well as the breast feeding, because they can be seen to be discriminating'</i></p> <p><i>'I had more time to read though, when I was pregnant. You know, once the baby is born you just, you haven't got time too. Well you are not even functioning properly half the time so to sit down and read information, so I definitely did all my reading with both of them, before'</i></p> <p><i>'I found with my antenatal they were very much pushing breastfeeding again, and yeah there was one girl in my group who said she planned to bottle feed from the beginning and she was basically ignored and carried on talking about breastfeeding, and it's "Well why are you doing that?" and there was no support for her on that'</i></p> <p><i>[in another mothers' antenatal class] 'there were a big group of breastfeeding mums and there was like three or four of us, and then like you said, you're left out'</i></p> <p><i>'No [demonstration of how to make up a PIF feed in antenatal classes], they just tell you about it.....they would advise you to clean, sterilise and make up a bottle, and that's why I sort of do it the way I do it, just from them telling us'</i></p>
<p>C. Powdered infant formula advice provided in hospitals</p>	<p><i>'Basically they said "are you breast feeding or bottle feeding? Are you bottle feeding?", I said "yes", "there you go", that was dealing with me'</i></p> <p><i>'when you are in hospital they give you those little jars with the teats on and everything, you don't have to worry about sterilisation'</i></p> <p><i>'The information you get is all breast is best and everything. They don't tend to put a lot of bottle things in because I think they think, well if we give this new information on the bottle, you are going to think. Oh, actually it's not that bad, well I might do the bottle feeding, so I think they have tried to get you to do the breast unless you ask specifically like for bottle feeding'</i></p> <p><i>'They tell you now when you make up a bottle in the hospital so after an hour of you opening it that it's dead and so you are going to kill them if you give it to them'</i></p>
<p>D. Information provision from health visitors and midwives</p>	<p><i>'on the tins of milk it says, 'make each feed up as you need them', but then my health visitor said, make a bulk up otherwise.... she said, "Why are you making up separately?"; She said, "Make them in bulk and store them in the fridge", because I was making them up like one by one for like two weeks and it was absolutely killing me. She came in and she said, "Just make them up in bulk" and then after that it's... I've always done that'</i></p> <p><i>'The midwife, health visitor at the hospital, because they are the people you rely on, you trust,'</i></p> <p><i>'I was advised not to [by health visitor] so I'm only going by you know, this is my first child and I don't have anyone else to advise me, so I was told not to so I don't'</i></p> <p><i>'I found the health visitor more helpful than the midwife'</i></p> <p><i>'I did find a bit of conflicting information with some of them'</i></p>
<p>E. Powdered infant formula tins as a main source of information about preparation, handling and storage of powdered infant formula feeds.</p>	<p><i>'I had to read the instructions as to how to do it and the same with how often to feed him, there was no advice for that at all, it was a case of, you had to muddle along by yourself. 'It is misleading on the actual boxes as to what you can do with it. ....Because to start off with I thought, well to start off with I was using the individual feeds and not using the powdered milk and that was fine, that could be in the fridge for 24 hours and it actually said on the box. Whereas on the formula I use, it doesn't say on the box that it can stay in the fridge for 24 hours...'</i></p>
<p>F. Parents' mothers and friends as a source of powdered infant formula information.</p>	<p><i>'I'm trying to pick up bits of sort of helpful advice from all over really at first. A first time mum you're like, "What do I do?" everything is just a mess, you've got stuff everywhere, but then you kind of, just kind of know, just a mother's instinct I suppose. You just learn because you have to really' 'The way my mum was telling me how to do things'</i></p> <p><i>'My boyfriend, he has two grown up children and this was our first baby together, but I mean, it was him that showed me how to make up a bottle. No one showed me'</i></p>
<p>G. Reported changes in recommended methods for preparation, handling and storage of powdered infant formula.</p>	<p><i>'I think it's changed. My mum.....she made all the bottles in the morning, and every morning she made up the whole bottles for the whole day' .... 'She was really surprised and said "oh no, you have to make them up every time, so I think it's just changed now. But I used see them in the hospital, you were told to never to make them up'</i></p> <p><i>'it's like when you're pregnant you're told what not to eat, but it's completely to what your friends told you the year before, so I think it just changes so constantly, you get a bit blasé about what they say' 'But everything changes all the time'</i></p>

## 2.3.2 Day nursery nurses – cumulative focus group findings

### 2.3.2.1 Roles and responsibilities

- Most nursery nurses reported caring for infants aged three months or older and none cared for infants aged less than 8 weeks. The frequency of caring for infants aged less than six months was variable and most nursery nurses reported that periods of time would elapse when no infants aged less than six months would be in the nursery.

*‘Each child brings about three bottles of milk. Sometimes we have the children that come in at quarter past seven and go home at half five so there’s always like the extra bottle there for them just in case they need it’*

- Nurseries were variable in size and offered variable hours of care (up to ~10 hours a day) and variable available ‘sessions’.
- Different methods for allocating care for individual infants were reported. Some nurseries reported implementing a ‘key child/worker system’ whereby an individual nursery nurse would be assigned and responsible for specific infants ‘*The ratio is one adult to three children*’ (one adult to three babies ratio was reported as the standard). Infants in other nurseries were reported to be cared for by ‘*whoever is free*’.
- No nursery nurses in any of the focus groups reported there being a designated person responsible for preparation, handling or monitoring of formula feeds.

*‘We take it in turns, the early shift for the morning bottles and then whoever is free to do them’*

### 2.3.2.2 Self-reported practices: feeding infants aged less than 6 months in day nurseries

- No nursery nurses reported awareness or adherence to any standard policies and official codes of practice for feeding infants with powdered formula milk in nurseries where they worked. However, all nurseries reported implementation of ‘standard practices’ and many reported policies and procedures which were specific and unique for individual nurseries.
- It was reported that the new recommendations for preparation and storage of reconstituted formula milk has not changed the infant formula handling policy of most of the nurseries. For many of the nurseries, nursery nurses reported that parent requests were of greater importance than formal recommendations or unique nursery policies.
- Variable methods of preparation, storage and feeding the PIF were reported between and within nurseries. Some nurseries reported implementing the choice of method requested by the parents, other nurseries would specify a particular procedure that all infant feeds would be dealt.
- Cumulatively, generic methods reported included the following:

***a) Parents bring reconstituted formula to the nursery for use throughout the period of care (which could be up to ~10 hours).***

This practice was encouraged (or indicated as a required method for attendance) by many of the nurseries where the respondents worked. All feeds brought into nurseries were required to be labelled with just the infant’s name (labelling was usually undertaken by

the parents). Nursery nurses reported that, on arrival to the nursery, the temperature of reconstituted feeds was variable, ranging from very hot (i.e. having just been made-up) to very cold (i.e. having been stored in the refrigerator for a period of time). It was reported that parents would bring the feeds to the nursery in all manner of bags ranging from changing bags, 'thermo/cool bags', ruck-sacks and most commonly, carrier bags.

*'The bottles are mixed in with all sorts' 'They [parents] don't bring them in cool bags' 'they're just bringing [the reconstituted milk in bottles in] carrier bags and they bring them in their backpacks that they bring in' . 'You get some parents that just bring their nappies and whatever in a plastic carrier bag and it's like "there you go"'*

Different nurseries reported variable procedures for receipt of reconstituted feeds when parent/infant arrived at the nursery; in most instances feeds would be placed in the refrigerator 'immediately' by a member of staff, or if too hot, left at room temperature to cool (for unmeasured, variable lengths of time) prior to refrigeration. After feeding, used, empty bottles (sometimes rinsed) were placed into the infants bag or box to be taken home for the parents to clean and disinfect for re-use.

It was reported that this practice is less time consuming for staff in the nurseries and also ensured infants would not be fed the wrong type of milk which they may be allergic to (which was reported as an important safety concern by most nursery nurses).

This practice also enabled infants to be fed with bottles and teats prepared by the parents for feeding. In these cases it was therefore was not the nurseries' responsibility to clean and disinfect bottles and components.

This practice facilitated circumstances whereby bottles of reconstituted formula may not have been used (i.e. fed to the infant) during the course of the day. On some occasions, parents would take remaining formula (full feeds and partly fed feeds) home when they came to collect their infant. This practice concerned many nursery nurses, who indicated that, beyond offering their own opinion that subsequent feeding of such feed may not be safe, there was nothing else they could do as ultimately, the parent would make feeding decisions for the infant.

*'you've got the ones [feeding bottles] that come in ready-made that can be in there all day. Sometimes we send them home again, they [the babies] don't have [drink] all of the feed ... and they [the bottles of made-up feed] come in and out of the fridge quite a few times'*

*'some of them [babies], we've given them milk at say 12:30 for example, it's been on the side, all of us know not to give it to them because it's now four o'clock, they'll [the parents] come to pick up [their infant] and "this is his bottle, it's dead now don't give it to him", [the parents say] "oh no it's fine don't worry about it", "okay" but then its kind of like "well that's your child, I can give my opinion" do you know what I mean, obviously I may have thrown it away but they say take the bottle home'*

***b) Nursery staff to reconstitute all powdered formula feeds within the nursery when needed or at the start of every day.***

Nursery nurses reported that an increasingly common practice (particularly by young, first time parents) was that parents would bring a prepared (i.e. disinfected) feeding bottle

to the nursery with either boiled water inside or empty for the nursery staff to boil the water just before feeding. For both scenarios, either a container with measured amount(s) of formula or new (preferably sealed) tins of powdered formula would be brought into the nursery for the staff to reconstitute feeds as and when required.

For circumstances where boiled water was brought to the nursery in prepared bottles, the powder would be added to the cold water when required, and reheated by immersing the made-up feed in either an electric bottle warmer or a jug of hot water.

Some nurseries provide all of the powdered formula in the nursery (and include it as part of the nursery fee), other nurseries request parents to provide ('preferably' sealed) tins of formula for their infant. When sealed tins are brought into the nursery, some nursery nurses reported that the infant's name and date of opening tin were written on the tin and it was the responsibility of the nursery nurses to ensure the powder was used within four weeks of opening.

*'we prefer them if they're going to bring them in they bring sealed, not ready opened' ... 'we know when we've opened them we put the date on and then that's it, the recommended time that's all we'll have it for'*

Other nursery nurses reported they did not know the maximum length of time that opened powdered formula tins should be stored for.

The practice of nursery nurses making up feeds as required was perceived as preferable for some nurseries who reported that younger infants required a smaller quantity of feed more often which when made-up in the nursery as required would result in less wastage.

Some nurseries provided bottles and teats; others asked parents to provide bottles and teats.

Some nursery nurses expressed concerns in cases where parents brought in their own disinfected/sterilised bottles for the nursery staff to make the formula in and feed the infant. The nursery nurses considered that if the bottles had not been disinfected/sterilised properly by the parents, resulting in the infant becoming ill, they themselves would be blamed for lack of appropriate hygiene when preparing the feed and feeding the infant.

*'parents are sterilising the bottles at home and bringing them in, I think that process highlights something because you don't really know how sterile those bottles are. You're preparing the feeds so if there is contamination it's going to be easier for it to happen. Really the sterilising of the bottles and the feeds should go together by the same person really ... from a sort of safety hygiene point-of-view.' .... 'Cause they could blame you, couldn't they, for not being hygienic in the kitchen' .... '95% of the time we would get the blame'*

- Overall nursery nurses reported that in most cases, the method and timing of formula reconstitution and subsequent feeding was largely led and instructed by the parents.
- Some nurseries encouraged/stipulated that parents reconstitute formula to bring to the nursery to feed throughout the day.
- It was reported that increased numbers of particularly young, first time parents, were requesting nurseries to make the formula up throughout the day. It was believed that this was a result of parent awareness of the new guidelines. However, parents who already had



older children were reported to prefer to bring powdered formula already reconstituted for feeding throughout the whole day.

- It was reported that reconstituted formula was never taken out of any of the nurseries during the day, for example, when infants were taken for walks outside the nursery.
- Some nursery nurses reported a preference for disinfecting bottles and making the reconstituted feeds for infants in the nursery so they could be confident themselves that the formula was safe for feeding.

*'I'd rather do it myself, I would, 'cause I know it's fresh, you've made it yourself, it's fresh. You don't know how long, that bottle could have been in their fridge the night before or something'*

- Some nursery nurses indicated concern regarding the cleanliness of bottles of reconstituted formula brought into the nursery by parents to feed the infants, due to the presence of visible debris in the bottle.

*'you look at the bottles and you can see the grime around the bottles and you look at the milk and you can see the lumps in the bottom of the milk and we can't give that child that milk but we have to because it's what ...' 'You're relying on the parents, you know' ..... 'Yeah, and it's their formula milk and you know that that hasn't been done fresh, but there's nothing you can do about it'*

- For scenarios where parents bring their own infant feeding bottles to the nursery, after feeding, nursery nurses reported that bottles and components were either rinsed in water or washed using detergent and water or neither, and then placed in the infants 'box' or 'bag' for the parents to take home and prepare for re-use.

*'we just used to send bottles home for parents to wash' .... 'we don't sterilise the bottles' .... 'They go home for the parents to wash' ..... 'We just wash them out and then put them pack in the children's bags and then they go home with the children'.*

- Most nursery nurses reported to have a small kitchen or kitchen area for use for preparing and storing infant feeds.
- For most instances the kitchens were reported to be extremely small with a limited work surface space.
- Fridges were reportedly present in most (not all) kitchens and in some cases were designated for storage of PIF. However, some nursery nurses reported that such fridges were also used for storage of staff lunches and other children's foods. When asked whether the feeds kitchen was used for other tasks a respondent replied:

*'It's meant to be but we do use it for like storing our dinners in the fridge [laughing], we're not meant to but it's easier than going all the way to the portacabin in the morning to put your things in the fridge up there' .*

*'We've got a separate fridge, we've got a big fridge with all the food and then a separate little milk fridge just for the milk' .*

- Day nurses also considered it to be acceptable to store other foods alongside formula milks in the fridge.

*'As long as you keep it all separate, because we keep our formula milks on the bottom shelf and then the food on the top shelf, and the food's always wrapped up in cling film as well' .*

- Nursery nurses from a number of nurseries reported monitoring and recording of the temperature of the fridge used for storing PIF feeds. The reason(s) given for monitoring fridge temperature were not related to microbiological safety of the feeds.

*'We mark it down morning and night, every day' .... 'who ever cleans up the milk kitchen at the end of the day will write it down then' ..... 'just to check it and make sure it's not broken or something like that'*

- One nursery, which was connected to a large gym chain, did not have a fridge. However, it was reported that in this nursery parents frequently brought reconstituted bottles of formula milk for infants to consume while the infant was in the nursery and the parent(s) were in the gym. In such cases the made-up feeds were stored at room temperature until required for feeding. This period of time was reported to be usually <2 hours.
- Kitchens were used for preparation of older children's foods, staff tea/coffee and also as a storage area (e.g.) for boxes of nappies.
- All nursery nurses reported that none of the kitchens in their nurseries were used for preparation of raw meat/poultry etc – in most cases main food preparation areas were undertaken in a central kitchen. All nursery nurses reported that the fridges were in constant use: *'Ours is in constant use all the time, [opening and closing the fridge] every couple of minutes'*.

### **2.3.2.3 Knowledge and self reported practices**

- Many of the nursery nurses indicated their knowledge of preparation and handling of PIF came from their own experiences of feeding their own infants.
- Nursery nurses demonstrated knowledge of parts of the preparation process including allowing boiled water to cool for <30 minutes before adding the formula powder, and using a tin of powdered formula for no more than one month after breaking the seal.
- In all focus groups some nursery nurses demonstrated knowledge of basic hygiene principles/procedures. For example, use of separate cloths for different tasks in the nursery, although most reported use of paper towels as they recognised that cloths may harbour bacteria (Table 2.6, part A).
- Misconceptions were apparent regarding the storage of reconstituted powdered formula milk. One nursery employee believed made-up formula should be left at room temperature *'you should make them and leave them [made-up bottles of formula] out at room temperature'* , whereas the majority knew to avoid storage of made-up formula at room temperature. Some recalled concern when seeing parents carry bottles of reconstituted formula in holders on pushchairs etc Table 2.6, part B).
- A variety of practices were reported regarding storage of reconstituted feeds at room temperature, in many cases storage of made-up feeds was implemented due to requests

from individual parents. It was reported that some parents whose babies prefer their feeds to be at an ambient temperature also bring RTU feeds to the nursery.

*'Some [babies] like it at room temperature' 'We've had them [parents] where they [parents] just want it [the reconstituted powdered formula feed] given at room temperature, they say "leave the bottle on the side"' 'I've got a couple of babies that don't like warm temperature, they like it at room temperature, and the mothers come in and they say "keep it in the cupboard, it'll be fine", so they're in the cupboard for like at least five hours..... and they like them at that temperature'.*

*'Most of the parents that like it at room temperature bring those cartons'*

#### **2.3.2.4 Attitudes, beliefs and perceptions towards powdered infant formula**

- The majority of day nursery nurses believed PIF to be a sterile product and did not believe formula could possibly be contaminated with any bacteria

*'I would hope the tin and everything was sterile' .... 'if you keep the lid on it's [sterile]'*

*'I think it is sterile though because if it wasn't then they [the babies] could have cows milk because that's not sterilised, that's why you can't have cows milk because it's not sterile'*

- Some nursery nurses considered there would be no point in disinfecting/sterilising bottles etc if the powdered formula itself was not sterile. Only one nursery nurse recognised that PIF was not a sterile product and expressed implications of this:

*'that's why you've got to use boiled water so all the germs are killed'*

- Some nursery nurses believed that there would be no point of manufacturing formula if it wasn't a sterile product and none had heard of *E. sakazakii* – some were indignant at the suggestion that PIF may be contaminated with bacteria if they had never heard of it before and some could not see the point of manufacturing PIF if it was not a sterile product.

*'I've worked with children for 15 for years and never heard of it'*

*'Never heard of that, no, so why make it'*

*'It's something new they've brought up that there's gonna shock'..... 'If there's a risk that that could be in there and we're doing everything to prevent that child from getting ill by sterilising ..... but they're going to get diarrhoea because that's in there, why is it in formula milk ... and why such a big thing now'*

- Some nursery nurses reported that they could not rely on other nursery employees to be 'as hygienic as themselves'

*'I think in a nursery in general it's very tricky because you know yourself your own hygiene levels and needs but you can't rely on every other team member to be following and adhering to the same policy and the same things'*

- Some nursery nurses reported concerns regarding feeding formula to infants in the nursery that had been reconstituted in parents' homes and also using bottles sterilised at parents' homes. They reported they did not know how long the bottle had been made-up for or if the sterilisation etc had been done properly. Some reported that bottles brought to the nursery with made-up feed were visually dirty with 'grime', but they still fed the baby with the

bottle as it's what the parent requested and considered to be acceptable. Another nursery reported they wouldn't accept such practice and would telephone the parent and say they couldn't/wouldn't feed such formula to the baby.

- Most nursery nurses preferred to make formula up themselves in the nursery.  
*'it is a good peace of mind if you do it yourself and you know it's fresh and you know it's good, but then it saves time when they [parents] do it'*
- All nursery nurses reported trusting formula companies as providers of credible information and manufacture of a safe product.
- Most nursery nurses perceived that parent requests frequently determined the preparation, handling and storage practices implemented within the nursery.  
*'well you can give your opinion, you can inflict your advice but if they then turn around and say "well no it's fine", "okay then"' 'At the end of the day it's their child and their preference, what they want goes really' 'personally what I think doesn't come in to it' 'what they [parents] want goes'*
- Many nursery nurses believed that generic 'germs' were good to build infants immune systems.  
*'I think a baby needs something to build up his immune system'.  
'You can only protect them so much'*

#### **2.3.2.5 Information sources/training**

- Most nursery nurses reported having no formal training about preparation or handling of PIF.  
*'Not on bottle feeding, no, because they employ you to expect to know things anyway don't they?'*
- Some (particularly younger nursery nurses) reported having been shown how to prepare bottles/reconstitute powdered formula when they started working in the nursery by a more experienced member of staff, but none reported any formal generic or nursery specific training (Table 2.6, part C).
- Many of the nursery nurses indicated that information sources about preparation and handling of PIF had been seen/encountered during their personal experiences of feeding their own infants and not in their capacity as a nursery nurse working with babies in a day nursery (Table 2.6, part C).
- A new member of staff from college was reported more likely to have been given more up-to-date information about infant feeding *'just the baby unit we did in college'* than members of nursery staff who trained longer ago.
- Nursery nurses reported they do have weaning courses, but not specific training or information about preparation and storage of powdered formula milk. They suggested training/information about powdered formula milk would be good.  
*'I think it would be good perhaps if they did do something like that' 'At least it could perhaps cover yourself a bit more I suppose'*

- No nursery nurses were aware of or familiar with FSA recommendations for safe PIF preparation, handling and storage etc. They believed such information would be distributed to or sought by the nursery manager who would filter out issues that were relevant/important to them. In some instances it was reported that managers would pick out parts they considered to be relevant and present the information on a board.

*'if we had these sent to us, they'd go to the office.....the manager would have these..... and it would be whether she thought that we needed to know'*

- Some day nursery nurses reported to have been on hygiene courses, which appeared to be connected with their nursery. They perceived the issues regarding food safety and formula preparation to be different, but reported asking questions about formula preparation and handling and issues related to their nursery during the course.

*'not about formula milk because we all go on food & hygiene courses but that's got nothing to do with formula milk'*

*'We did a food and hygiene certificate but it doesn't really cover making up feeds..... It's more about storage and fridge temperatures and preparation of foods and cleanliness.'*

- Some nursery nurses indicated they would like additional information about preparation, handling and storage of powdered formula milk as they considered things had changed and updates would be good. Other nursery staff indicated that they did not want further training.
- In some instances, nursery nurses reported that their managers had searched the internet for Codes of Practice detailing formula preparation and handling for their nursery to adhere to.
- Nursery nurses reported trusting formula companies as a source of information about their product; however, none reported had ever been approached or been in any contact with any formula reps.
- A primary source of information regarding preparation, handling and storage of PIF was reported as following the instructions on the side of a tin of formula.
- Some nursery nurses believed that the health visitors were responsible for changing PIF preparation, handling and storage recommendations, and it was suggested that health visitors should brief day nursery staff (as well as parents) on updated information and current recommendations

*'if the health visitors are changing things it would be good if they could perhaps come and brief everybody so we're all singing from the same hymn sheet, it wouldn't be a bad thing and that way we're keeping up with I suppose what's expected, but I think they'll always change no matter what we're doing'. 'Health visitors should have more input with the nurseries 'cause a lot of children go to nursery now'..... 'Or even somebody on behalf of the health visitor 'cause I know they're very stretched and I know they're very busy, but there could be somebody that could perhaps come round and just make sure'*

- Nursery nurses reported that they believed the reason that parents now bring the powder and sterilised bottle (with or without boiled water) to the nursery is a result of advice that health visitors have given to parents.

*'most young parents now, since the health visitors have been telling them ..... they're bringing the powder milk and get you to do it on demand'*

- When parents ask day nursery nurses about recommendations related to formula preparation, handling and storage they (the day nursery nurses) suggest the parent(s) ask their health visitor.

*' "speak to the health visitor" cause they're constantly changing things, I mean even though we're updated not everywhere is and what you could be saying might have recently changed again'*

- Most nursery nurses reported that they didn't think it was their role to advise or tell parents about recommended practices – most reported they thought parents should already know as they will have been making up feeds prior to coming to the nursery.
- Nursery nurses (unprompted) volunteered perceptions of two key health professionals who may provide advice about infant feeding. Such perceptions were largely based on personal experience of the nursery nurses having their own children. Health visitors were more highly regarded than midwives, due to provision of inconsistent information.
- The majority of nursery nurses indicated that recommendations have changed since their formal training in (e.g.) college to become a nursery nurse.

*'New' recommendations were perceived by some to be difficult to implement:*

*'I think it's ridiculous to be honest' because 'You'd be making up all the time'*

*Others questioned why they would want to change current practices*

*'we don't want to change things because we know it will be for the worse'.*

- Opinions regarding how achievable current recommendations are to implement in a day nursery were defended by previous experience of no problems of illness resulting from bottles of made-up powdered formula milk being made in advance of feeding. For example:

*'Since I was a kid like I've said, my mum probably gave me a bottle, kept them for eight hours, it didn't do me any harm did it?'*

- There was a strong perception observed though all of the focus groups that recommended practices change all the time; this was particularly apparent among nursery nurses who had children who had been fed using PIF. The change in recommended practices was strongly associated with a negative attitude, as implementation of 'new' changes now would need to be changed again in the future.
- The majority of day nursery nurses perceived that guidelines and advice about recommendations for preparation, handling and storage of powdered formula milk were inconsistent and conflicting. Furthermore, different sources of information would advise different practices: *'We're constantly getting different information from different people'*.
- Nursery nurses also considered that information was always changing and that it was difficult to keep up to date.

- Most nursery nurses reported that they would like to receive updated information regarding PIF preparation, handling and storage. The majority requested universal information that is consistent between organisations/information providers.
- Most preferred information sources were the DoH and NHS. The majority of nursery nurses reported they trusted the FSA, their local health authority (particularly health visitors) and formula companies more than organisations such as the NCT and UNICEF (the Baby Friendly Initiative) and GPs and midwives.

*'you've obviously got to give some thought just to the formula brands because they're telling you how to make up their type of milk'*

[on advice provided by a formula company] *'You're going to trust them more wouldn't you? You put your trust in them by buying their product anyway don't you?' 'it's a lot of money for them if anything went wrong, ..... you'd hope they wanted it to be just as safe as we do' .... 'Otherwise they'd be losing a lot of millions wouldn't they?'*

- The majority of day nursery nurses considered that not enough information is available to them about PIF, however all were confident in current practices.
- Most nursery nurses perceived that sourcing updated information about PIF preparation etc was the responsibility of their employer.

**Table 2.6 Day nursery nurse comments about powdered infant formula hygiene, storage of feeds and training**

	Day nursery nurse quotes
A. Awareness of basic hygiene principles.	<i>'We've got anti-bac spray and green paper towels, we never use a cloth because the cloth carries germs, so it's anti-bac spray, green paper towel and in the bin. Then we do what we've got to do and it's clean it again.'</i>
B. Day nursery nurse recalled observations about how reconstituted powdered infant formula feeds are sometimes stored by parents.	<i>'they've got little bottle holders now on the pushchairs and they'll just go out shopping all day and they'll give them some and stick it back in the pushchair .....that would make alarm bells ring - I don't think that's what you should be doing because bacteria can fester at room temperature with mixed milk' .</i>  <i>'a lot of parents make them up in the morning and go out shopping, taking a couple of bottles with them in the bag and not recognising that they can't really be carried around at room temperature'</i>
C. Day nursery nurse training about powdered infant formula	<i>'I've never had any training on how to make a bottle.'</i> <i>'You sort of get shown once and that's it really.....on your first day of starting really and then you pick it up'</i>  <i>'Senior member of staff shows you'..... 'Yeah, the head of the room'</i>  <i>[When you start working in the nursery] you have to go through making [powdered formula milk] with the trainer, go and making the feeds and that, to be seen making a feed....but that was sort of like work place sort of experience.....while training you had to write about it and things like that but not proper food hygiene.....you get achieved certificate, it's for the workplace'</i>  <i>'I think it depends on the person who's new, if it's a really young girl from college then you would.....If somebody's old there that's had children they know how to do it anyway'</i>  <i>'Everything's different from what I've learnt when I was at college 10 years ago, it's completely different, it's like the formula hasn't changed at all in that time but the practices change'</i>

### 2.3.3 NHS health visitors – cumulative focus group findings

- Many health visitors reported they believed their role was to inform mothers-to-be/new parents of the recommended guidelines based on up to date research findings – whether this be regarding breast feeding or artificial feeding. It was also considered that parents ultimately should make the choice regarding which method of feeding/practices to implement.
- A common belief among health visitors was that there is a lot of inconsistent information and advice provided about recommended practices for feeding with PIF from different organisations (Table 2.7, part A).

*‘There are three guidelines, there’s the World Health Organisation and there’s the Department of Health, and what it says on the back of a tin..... and Birth-to-Five says differently, and then you’ve also got other family members, mother-in-laws, etc, etc, chipping in with this or that or the other, and friends chipping in, so it goes round and round’*

- Due to the perceived inconsistent recommendations regarding best practice, many health visitors reported finding it confusing and difficult to know the right way of preparing and handling formula (Table 2.7, part B).

*‘it’s confusing to us really’ ‘Very confusing for us’*

- Health visitors reported that they encountered considerable confusion amongst parents regarding correct practice in the preparation of PIF feeds, particularly regarding the temperature of the boiled water. Health visitors reported that many mothers are allowing the water to cool down longer than the recommended 30 minutes. Confusion and misunderstandings were reported to have been more prevalent in recent years since advice has been changed and revised.

*‘Quite a majority of mine - the thing about clinic at the moment is talking to them about formula feeding - they’re all totally confused. Up until a year ago, they were making bottles up for 24 hours, put them in a fridge, keeping them there, then all of a sudden things changed and they were told to make them up one at a time. Then some of them made them up with the water and put the water in the fridge, add the powder after, or go to ready feed when they’re out. They’re all doing everything differently.’ ....*

- In some areas/trusts health visitors reported that they and other health professionals (e.g. midwives) are not ‘allowed’ to talk about artificial feeding to prospective parents. This was perceived by health visitors to be unrealistic and not practical as large percentage of their client base bottle feed with PIF.

*‘artificial feeding now is taboo, you’re not allowed to mention it....you’re to encourage to breastfeed, so that is a big problem’ ‘mums who are artificial feeding are discriminated against’ .*

- Sources of up-to-date information for health visitors regarding the microbiological safety of PIF preparation were reported to be non-existent or limited. In many cases health visitors reported having to contact formula reps (even though they are officially not allowed) to get correct, current and required information to be able to answer client questions and also



provide accurate, up-to-date advice. Health visitors acknowledged that formula reps represented individual companies in the market, but their experience has shown that the information and advice the reps provide is invaluable and not necessarily easily available elsewhere, particularly regarding the physiological effect of powdered formula in babies.

- Many health visitors reported that by the time they make the first home visit feeding practices are already established

*‘it’s too late sometimes when you’re in at day 14’ .*

- Some health visitors reported observing malpractices regarding formula feeding which had not been noticed or advised upon by previous healthcare professionals visiting the clients at home between discharge from hospital and the health visitors first visit, for example

*‘I saw a bottle that was full with eight ounces of milk made up at a birth visit, and stared at it for a bit and said, ‘why have you got eight ounces of milk there?’ , and he didn’t know, this dad, and made it up and he thought it was alright to make that eight ounces and keep using it all day, and he’d been doing that for two weeks when I got there, and nobody else had picked up on that’ .*

### **2.3.3.1 Roles and responsibilities**

- Many health visitors reported they believed their role was to inform mums-to-be/new parents of the recommended guidelines based on up to date research findings – whether this be regarding breast feeding or ‘artificial feeding’. It was also considered that parents ultimately should make the choice regarding which method of feeding/practices to implement.
- Health visitors reported it was their responsibility to provide a service to families by promoting health to mothers and their infants which they considered to be a wide remit. Therefore, they need up to date and accurate information to advise and help parents make best choices. It was perceived that this gets lost in the Baby Friendly Initiative and promotion of bottle feeding (Table 2.7, part C).

*‘if our role is to promote health then health is so wide, it’s not our job to tell people that they should do this or they should, it’s to have the information, all the information at our fingertips to help them make the best choices ..... for them, and I think that gets lost in things like the baby feeding and breastfeeding initiatives and what have you, and you come up against a real evangelicals about how you do it, and what works for one will not work for everyone and they forget, I think they forget that’*

- Health visitors perceived their role to include an advisory service which includes answering parent questions about infant feeding, which frequently included feeding with PIF. However, many reported that professionally they frequently didn’t have the required up to date information to answer questions accurately and satisfactorily, which at times would make them look and feel foolish.

*‘I think it’s our role to be able to answer their questions, and that’s where I find sometimes when you don’t have that information, they come to you with a question and professionally you don’t have the up to date information’*

*‘And how stupid do you look, “I’m sorry I can’t give you that information”, you just look like an idiot’ .*

- Health visitors considered it important and part of their role to give their clients information about formula feeding from an impartial source, based on well researched and real evidence – they believed they should be able to give this kind of information to parents, however, the majority reported this information is currently unavailable to them.

*‘I think there is an impartiality issue and I think what we’re saying is that we need real research, real evidence, good information on formula, bottle feeding, sterilisation, that doesn’t come from partial sources, so we should be able to give that information -but not coming from a logo-ed company-, so that we can say “well there’s this that applies to all of these [brands of formula] that you could use”, and it’s not, I think that’s what we would, what I would want!’ .*

**Table 2.7 Health visitor comments related to powdered infant formula recommended ‘best practice’ and responsibilities as an information provider**

	Health visitor quotes
A. Inconsistent guidelines about powdered infant formula preparation, handling and storage.	<p><i>‘they all had slightly different takes on the same thing’</i></p> <p><i>‘Actually at the update, they had quite a few of the different ones [sets of guidelines], they vary. There was a comparison as to the advice that was being given out by the different people, and they were all different. They had about three or four different ones, and there was not one single bit of consistency’</i></p>
B. Confusion and misunderstandings about powdered infant formula preparation, handling and storage ‘best practice’.	<p><i>‘That’s the one thing that’s coming up quite frequently recently.....do they make it up each feed; do they put it in the fridge? Do they just make it up for 24 hours? And the guidelines for us are confusing’.</i></p> <p><i>‘I think there’s a lot of confusion about how to make up a bottle, from the temperature of the water particularly, because people have been given information over the last three years which has changed regularly. A lot of mums aren’t using the hotter temperature, the 70 degrees; they’re actually letting the water cool down in the kettle much longer than half an hour.’</i></p> <p><i>‘I’m not surprised they’re confused!’ ..... ‘I do say, it is a <u>real</u> grey area at the minute’.</i></p>
C. Health visitor responsibility to provide parents with powdered infant formula information.	<p><i>‘I just think it’s our job to inform people what the research is, and like everything it’s their choice; you’re there as a professional to tell them what the information, what the research is. You can only give them guidelines to point out the risk, point out the fact that it’s probably more with vulnerable babies that the risk is there, however small, and the risk is there’</i></p> <p><i>‘We’re not there to police people.....we are an advisory service, and they can take that advice if they want or choose’</i></p> <p><i>‘in our area, it’s not that they [management] can’t say anything about bottle feeding, because about 80% of people bottle feed so, but they[management] might say “well read the instructions on the side of the tin”, now that assumes that they [parents] can read....or that English is their first language’ .</i></p>

### 2.3.3.2 Antenatal health care

- It was reported that ‘in an ideal world’ health visitors would like to meet all prospective mothers antenatally – this was considered by health visitors from each focus group as best practice. But all health visitors indicated this was not possible in reality because they are very busy due to the problem of their large client caseloads. Antenatal visits were more than often perceived by health visitors to be best practice and a good opportunity to give information about breast feeding (as noted in the Baby Friendly Initiative guidelines).

- Some health visitors reported it is their PCTs aim to see all prospective mothers antenatally (first or subsequent children) according to the ‘Family Needs Assessment programme’ or ‘Child Health Programme’ – but this is reported to be currently unachievable due to lack of staff.
- Health visitors from all focus groups indicated that meeting prospective mothers antenatally was not common practice and rarely would take place in the clients home (unless flagged up as a special needs case/issues relating to child protection). Health visitors reported that home visits were targeted according to need.

*‘For me its a time issue and now I would liaise with the midwives and anybody that’s flagged up as having an issue of some sort I will go and see them, but it’s very much a targeted antenatal service now for us’*

- Health visitors from all focus groups indicated that antenatal contact with prospective mothers was variable. Health visitors from some areas/trusts telephone or send letters to all parents antenatally and then it is up to the parents to respond and attend a meeting with health visitors/parentcraft clinic at a health centre. Health visitors considered that many women do not perceive the need to see health visitors before the birth, so although all women are contacted by telephone or invited to an appointment, less than 50% reportedly turn up.

*‘We meet some of our antenatals at joint parent class sessions with the midwife, and we write out to them all to offer them contact, whether it’s by telephone or one to one, they don’t all uptake it and if they don’t uptake it ..... we don’t follow them up’.*

- Some health visitors considered it their role to advise and only promote breastfeeding antenatally, where-as other health visitors did consider it part of their role to mention and talk about feeding using PIF.

*‘It should be our role to mention it and ask them if they’ve got the advice, and I feel that if everything’s being done properly up to that stage..... it should be in antenatal’*

- Parentcraft/antenatal classes were reportedly offered in all of the areas where focus groups were held. In the majority of cases health visitors contributed to the running of the classes with midwives.

*‘we always do ours as a group, again it’s if they opt to come, if they don’t opt and they’re not flagged up, we won’t be seeing them’*

- Health visitors in all focus groups indicated variable attitudes and opinions as to whether PIF/bottle feeding should be included in parentcraft/antenatal classes. In ‘Baby Friendly’ accredited areas/trusts (or areas/trusts trying to achieve accreditation), bottle feeding is not allowed to be talked about in antenatal classes – this was perceived to be a big problem by some health visitors.

*‘in the antenatal class they are not allowed to talk about bottle feeding, so that we’ve found to be a problem really, so that’s off the agenda, whereas in the past.... We used to show them how to make up feeds and things’*

- Other health visitors who expressed stronger feelings towards breast feeding considered that there was no need to discuss artificial feeding antenatally ‘*it's something we don't need to discuss antenatally*’.
- Some health visitors indicated they believed bottle feeding should be discussed in parentcraft or antenatal groups. Omission of information about PIF and bottle feeding in such classes was reported to leave many prospective mothers with no ‘education’ of recommended practices and this was perceived by some (not all) health visitors to be a problem and means of discrimination.

*‘I think at an early point antenatally as in, i.e., when they're at their parent craft, when they have decided, “next week we're doing the breastfeeding” or “next month we're doing breastfeeding folks”, they should also be saying “and there's also the bottle feeding discussion” .....It should be a feeding conversation.....I think they should be given a whole session to look at the why's and safety of that’ .*

*‘I think sometimes the women vote with their feet as well don't they? In the parent craft session, if it's breastfeeding and they know they are not wanting to do that then they don't go, but then they're left with nothing, and that's a problem’*

- If health visitors do meet with prospective mothers antenatally, information regarding infant feeding was reported to be usually focused around breast feeding. One health visitors reported a typical conversation would involve asking the mother if she intends to breast feed, if not, they may have to promote positive pros and benefits of breast feeding.

*‘Well if it's antenatal, are they going to breastfeed? (Laughs) If they're not going to breastfeed, we have to encourage them to breastfeed. [all laughing]. Tell them all the pros and the benefits, but obviously you know, I mean I haven't done an antenatal visit for so long (laughs)’.*

- Health visitors reported that they considered information midwives currently give to parents regarding formula preparation, handling and storage to be non-existent or inadequate at the antenatal stage – it was believed that this was due to breast feeding/the Baby Friendly Initiative; some health visitors considered such information should be included in antenatal classes.

*‘I had a friend whose wee one is now 15 months, and she actually said at her antenatal class somebody asked “how do I use a sterilising unit?” And the midwife point blank said “I'm not allowed to talk about that”, so they got no information on artificial feeding’*

*‘it [preparation and storage of PIF] is a real grey area at the minute, and it comes from the midwives, the fact that they just give the leaflets...and don't do anything anything else....and whereas years ago they used to.....be part of the antenatal classes....’*

### **2.3.3.3 Postnatal health care**

- Health visitors reported that the community midwife is the first healthcare professional to make a home visit to a new mother and infant, usually within 24 hours of discharge from hospital. It is the community midwife who then is responsible for provision of advice and information to the new parents until passed on to the health visitor. (Although in some areas health visitors reported combining home visit work and ‘piggyback’ with the midwives).

- Health visitors prioritise home visits for first-time mothers and usually make the first home visit on the 10-11th day, post discharge from hospital, once passed on by the community midwife.
- The number of home visits was reported to depend on needs of the client and infant. Visits were reported to be more frequent if mother has had a caesarean section, had trouble breast feeding or infant had a low birth weight. Health visitors reported the frequency of visits to be ‘needs lead’, according to client caseload, and would be discussed with the mother during the first home visit.
- The frequency of health visitors home visits, location of meeting and duration of meeting/visit was needs lead – several health visitors reported daily and lengthy visits to support the breast feeding mothers.
- The most common infant feeding scenarios that health visitors reportedly deal with include a) established bottle feeding and b) the change from breast feeding to bottle feeding. For the established bottle feeders, some health visitors perceived it too late to introduce information regarding recommended handling, preparation and storage practices

*‘it’s too late sometimes when you’re in at day 14’ .*

*‘A lot of mine start breastfeeding, not a lot, but a higher proportion start but by the time I’ve got in there, they’re already on the bottle’.*

- Some health visitors reported observing malpractices regarding formula feeding which had not been noticed or advised upon by midwives visiting the client’s home between discharge from hospital and the health visitors first visit, for example:

*‘I saw a bottle that was full with eight ounces of milk made up at a birth visit, and stared at it for a bit and said, ‘why have you got eight ounces of milk there?’, and he didn’t know, this dad, and made it up and he thought it was alright to make that eight ounces and keep using it all day, and he’d been doing that for two weeks when I got there, and nobody else had picked up on that.’*

- Health visitors reported they often do not make home visits until two weeks after birth and in many cases feeding/sterilisation already established

*‘if we’re lucky, they’ll have read the tins’ .*

- A small number of health visitors reported that if the infant is being bottle fed they will ask how PIF feeds are being made-up and talk through recommended practices

*‘If I’ve got a first visit I’ll do a notification, if somebody’s bottle feeding, I always just quickly go through and make sure that they’re doing what I think they should be doing in terms of how they’re making up the feed’*

*‘I really make sure it’s an important part of the primary birth visit, to spend a good five or 10 minutes talking about everything we’ve spoken about [preparation of PIF and non sterile]’ .*

*‘I always ask them about how they’re preparing the feed, if they’re not buying the ready to feed cartons, which some of them in the beginning are, and then suddenly they come six weeks down the line “well how do I make up powdered milk?” Because they’ve been using the cartons until they’ve got themselves into some sort of routine, and then they need to know how to make up the milk’*

- Health visitors reported that if there are no problems with the new infant's weight or breast feeding during the first home visit, subsequent visits to the client's home are not made and future contact is made in the clinic/health centre if the new mother and baby attend.

*'I think after that first notification visit, you negotiate with the mum if the baby has put weight on? Are there breastfeeding issues? Other issues? And then I'd go back, otherwise probably not unless there was a problem, I don't tend to go back'.*

- In some areas/trusts, health visitors strongly promote postnatal 'drop-ins' to clinics/health centres as point of contact rather than home visits because of stretched resources. The problem they found with this is that some new mothers who don't necessarily need to be seen come to lots of groups, where as ones who need to be seen don't come at all.

*'some of the mums will go to everything ..... they will go to groups every day of the week if they were around'..... 'others actually don't turn up and then those are the harder to reach ones'*

*'we have a postnatal one and two drop ins per week and we have to strongly promote them' ... 'Because we can't get around everyone'..... 'we do more home visits because our clientele largely don't come to groups'..... 'So you do have a kind of two tier, and that's based on your assessment, who's going to come along to something and who you need to home visit, and the two can work together or work separately, but it depends on the area very much, what your client looks like'*

*'I think it would be fair to say though that resources are very stretched so that initial assessment at notification, yeah you can work with where they're at, but I mean we have a drop in/forum that we've run for years where we, and we strongly promote that as our contact point'*

- Some health visitors reported that clinics and drop in groups were usually held in venues that were inappropriate for demonstrations. In addition there was not enough time to provide such information and provision of information about bottle feeding is not looked upon favourably by management due to the drive to increase breast feeding and become 'Baby Friendly' accredited/adhere to the Baby Friendly Initiative requirements.

*'We haven't got time; and also it's not an appropriate venue because most of us are doing sort of postnatal weigh ins and things, so it's not a venue that you can actually discuss sterilising with, there are just too many coming through' 'And I think also now there's the association with bottle feeding' 'No, it's frowned upon' 'It wouldn't be allowed, not with Baby Friendly'*

- In the clinics/drop-ins/surgery – usually health visitors only deal with immunisations and baby checks at 8 weeks.

*'We have to have drop ins because our GP's insist on doing the six week check ..... if we stepped back and didn't do a drop in we probably wouldn't see them, and there isn't a venue in our area that would be large enough to accommodate the numbers that would turn up, our postnatal group's bursting out of the clinic room at the seams, at the moment we have about 17 a week, and the drop ins are probably between 30 and 40 a week, and if we didn't have those the mums wouldn't have anywhere to go'*

- Some health visitors reported that information about PIF feeding is given to parents in postnatal clinics, but only if the parent asks for the information. However, if feeding is discussed it is more likely to be how much feed is given rather than microbiological safety

issues regarding preparation, handling and storage. Issues regarding preparation and handling of PIF would normally be addressed in the home.

*‘sometimes you get “he’s taking seven ounces every three hours, what should I do about that?” So it’s that kind of advice but not actually preparing’ ..... ‘That’s the kind of thing you’d probably address at home’*

- Health visitors reported that mothers can meet health visitors and talk to healthcare professionals about feeding issues at breast feeding and baby massage support groups, however some health visitors reported that such groups were run by midwives who were not allowed to talk about artificial feeding to them.

*‘things like the breastfeeding support group because the Midwives are not allowed to talk to them about it’ ... ‘The midwives aren’t allowed to talk about artificial feeding, in fact we’re not allowed to speak to anybody about that [laughter]’ ..... ‘It depends very much on the midwife’ .*

- In one area of the UK where health visitors worked, a new framework for health visiting was currently under discussion – whereby all mothers and infants are required to be visited by the health visitors on four occasions to the clients home within a period of 6 months, however, health visitors in the focus group indicated they did not know how this number of home visits could be achieved due to their large caseloads.

*‘Four home visits by the health visitor – it’s not your staff nurse, it’s not your nursery nurse, it’s your health visitor at home, four visits within six months’ .*

#### **2.3.3.4 Role compared to/associated with other health professionals**

- Health visitors reported they liaise with community midwives on a regular basis – particularly as, in most cases, clients have to be discharged by the community midwife before the health visitor can make the first home visit. Health visitors reported increased liaison with midwives for clients who require additional care/attention – in such cases there may also be liaison with social workers. Occasionally health visitors reported they also liaise with GPs and hospital midwives.

*‘I would liaise with the midwives and anybody that’s flagged up as having an issue of some sort’*

*‘If there were child protection issues sometimes you might have done a joint visit with the midwives or with the social worker’*

*‘We do [have contact] with the midwives’ .... ‘We don’t normally have contact with the midwives in the hospital where they’ve had the baby.’ ..... ‘We’ve got access to the notes that they’ve [clients] had, and some of the notes are in the hospital.’*

*‘our midwives [community] are seeing the same people that we then take over from, and we have a communication form that’s left in the home, so if there are any problems, they’ll talk to us personally and tell us as well’*

- Communication between midwives and health visitors was reported to be variable and usually at the time of handover/discharge from midwife to health visitor.

*‘We’re supposed to meet with the midwives once a month’ ..... ‘But that also depends, because I work such a wide geographic patch, that I could be meeting with six or seven different midwives’ .....  
‘I can’t meet with every midwife’*

*‘We tend to communicate, I mean it’s good as the ‘midwife and the health visitor’ ..... they do tend to hand over a bit, have a ... discussion about what this mum’s doing with her feeding or what her thoughts, what her difficulties are, GPs even, it can depend really because a lot of parents I find still medicalise a lot of things, and they turn up at the GP wanting a bit of nutritional advice and they say “speak to your health visitor”’*

- Health visitors in all focus groups believed that hospital and community midwives do not provide sufficient information and advice about handling, preparation and storage of PIF or preparation of bottles for infant feeding.
- Some health visitors indicated a strong belief that consistent information about formula feeding is provided to parents between health visitors, but not consistent between midwives and health visitors. This which was considered to be a big problem. Furthermore, other health visitors indicated that content/delivery of bottle feeding information varies between midwives.

*‘it’s consistent between health visitors but it’s not consistent between midwives and health visitors; that’s where the big problems are .*

*‘The information varies from midwife to midwife’.*

- Many health visitors considered the lack of information provision to parents about feeding infants with powdered formula to be a big problem – many health visitors reported this lack of information provision was influenced by the UNICEF Baby Friendly Initiative.

*‘the midwives are not fed any information about bottle feeding, not at all, they’re not allowed to...because of Baby Friendly’*

- Health visitors reported they considered the midwives have the opportunity for intervention with new/prospective mothers before the baby is born or in the first few days/weeks after the birth, yet do not provide information about bottle feeding – only promotion of breast feeding. Whereas some (most) health visitors considered themselves to offer more proactive advice and information, including some demonstrations where necessary (time allowing) about preparation and handling of PIF and sterilisation practices.

*‘You’re to encourage to breastfeed’ ..... ‘the midwives have the intervention first, they will tell them [parents/mothers] very specific advice about breast feeding, and either something or nothing generally about bottle feeding, and just hand them a leaflet. Whereas from birth onwards if we’re involved, then whether they want to sterilise stuff because they’re breast feeding, or whether they want to make up feeds or sterilise it because they’re bottle feeding, then we’ll actually do more of a one to one and won’t rely totally on just a leaflet’*

- Some health visitors believed the hospital midwives should teach parents how to prepare a feed before the mother leaves hospital. However, some health visitors reported that parents quite often leave hospital with incorrect bottle feeding information or reporting they don’t know how to make up a feed:



*'often they come out with incorrect information or you know, and there's a lot of "I don't know how to make up a feed"'* .

Many health visitors considered that information about bottle feeding should be given to mothers in hospital:

*'that information should be given really in the hospital when the baby's born, and they've decided not to breast feed'* .

*'What I think is interesting is that in our area folks often know about making up the feed or they think they know, the midwives have talked to them and they come in and we ask about making the feeds and .... we say "well what do you do?", and they say "powder in first and then pour the water in", and so they've actually had that information in a number of different forums if you like, but they still haven't actually got it right'* .

- Health visitors considered that GP's, midwives and health visitors were the health professionals that have the biggest influence over parents regarding feeding babies. They believed that GP's have an inadequate knowledge regarding this subject:

*'they ask them and then the GPs ring us up..... GPs offer very incorrect advice'* .

- Some health visitors believed the midwives were most influential because the community midwife is responsible for care of mother and infant during the period of time from bringing the baby home and in the first few weeks. During this time health visitors reported is when most mothers start to bottle feed:

*'I just think most of the bottle feeders have already decided or started bottle feeding before we even go there, so they're under the care of the midwife'* .

*'Because they're the first to contact' .... 'They're catching them early'*

- Other health visitors considered 'the health visitor' was the most influential because some parents feel under pressure to breast feed from the midwives and the health visitors allows them to make the choice more freely.

*'some women do feel pressured by midwives'..... 'I just want to give information so that we can give an informed choice'*

- Health visitors reported that many parents tell them they have felt pressured to breast feed from the midwives – some reported they have encountered parents who are frightened to talk to their midwife about bottle feeding which was therefore believed to be a barrier to receiving advice. This may create a situation where people who are uninformed about safe PIF preparation, handling and storage practices, may implement unsafe practices and are afraid to ask about best practice.

*'some people, you go in and they're actually frightened because the midwife's coming later and they want to give a bottle'*

- Health visitors reported that parents quite often hide formula feeding issues from the health visitors and particularly the community midwives regarding moving from breast feeding to PIF feeding, due to feelings of fear and guilt. Many health visitors reported seeing implementation of bad practices as a result.

*‘Sometimes they don’t even tell you they’ve stopped breastfeeding because they feel guilty...and then they’re not actually making the feeds up properly; they don’t know how to sterilise the bottles and everything properly, and then suddenly they get oral thrush and you think right, you start asking them again about sterilisation and then it sort of comes out, but they don’t want to tell you’ ..... ‘It’s just definitely got more of a problem since the Baby Friendly. [all strongly agree]’*

*‘Do you not find they [mothers] get to day 10 and tell the midwife whatever?, because the amount of visits I’ve done recently where the midwife will tell me they’re breastfeeding but you walk in the door and all the questions are about formula milk?.....that’s what I’m finding because I do laugh and go “well the midwives are only there 10 days, what do you want to do?”, and usually they’re onto formula milk at that point, even if they’re ‘exclusively breastfeeding’ according to the midwife’*  
*‘It’s just definitely got more of a problem since the Baby Friendly. [all strongly agree]’*

### **2.3.3.5 Microbial risks associated with powdered formula milk**

Knowledge and awareness of microbiological risks with preparation, handling and storage of PIF was variable and limited amongst health visitors.

- There was considerable disagreement between health visitors as to whether PIF is a sterile product. Some health visitors could not see the point of preparing disinfected bottles/feeding equipment etc if the powder itself was not sterile.

*‘I would hate to think that we were farting around with anything else if it wasn’t sterile in the first place, what a waste of time’.*

Whereas others believed that the reason for adding the PIF to the boiled water at >70°C when making feeds was to ensure the reconstituted feed was safe to consume.

*‘I thought that’s why we have to make up every feed freshly, and that’s why the water had to be hot, because when the powder hits it, it actually sterilises the powder for that feed’*

- Some health visitors believed that the formula was sterile until the tin is opened; others reported they had never thought about it *‘I have never thought about it’*, however, recognised that once the tin was open it couldn’t remain sterile due to extrinsic contamination from the scoop, placed in and out of the tin.

*‘But once you take the top off, you’re putting things in and out, the spoon isn’t sterile, then it’s not a sterile product’.*

- Health visitors indicated they believed the majority of parents considered PIF to be a sterile product and suggested that they are surprised when (if) informed otherwise; they also reported they believed many would not have considered whether it was or wasn’t a sterile product.

*‘They’re surprised when you tell them it’s not’ ..... ‘a lot of them don’t understand what sterile is’ ..... ‘I don’t think it enters their head. I don’t think they actually don’t realise that it’s not sterile. I don’t think it actually enters their head to actually dispute the fact that this feed is something that’s the same as everything else in their cupboard’.*

- Those that believed PIF was a sterile product also believed that all packaged foods were sterile before consumption.

*‘Packaged food I assume is sterile before you eat it’.*

- Some health visitors reported their source of information as to whether PIF was a sterile product was the information on the tins of formula – although many of the older health visitors repeatedly indicated they could not read the information on the tins as it was too small.
- Some health visitors reported disbelief that PIF could be contaminated with bacteria when leaving the factory, post manufacture, although some reported recollection of *Salmonella* being associated with PIF.

*‘It’s almost unforgivable that any tin would come out of a factory with something like that in it’ ‘we don’t know, if it’s there, then it’s a disgrace’.*

Whereas some recognised it is not manufactured in a sterile environment:

*‘And also it’s not made in a sterile environment is it?’*

- The health visitors who were more aware of the microbiological hazards associated with PIF were those who had stronger opinions about breastfeeding, and were ‘Baby Friendly’ trained and reported to acquire such information through the Baby Friendly Initiative. Furthermore the perception of risk expressed by these health visitors, associated with feeding infants with PIF was greater than health visitors who were not directly involved in the Baby Friendly Initiative.
- Few health visitors considered intrinsic contamination of the PIF and reported the potential for bacteria to grow in the powder.

*‘My concern about the milk is actually the storage actually, because the bugs are growing in the powder’.*

- Some health visitors indicated an awareness of *E.sakazakii* and *Salmonella* and association with PIF, whereas the majority hadn’t heard of *E.sakazakki* and did not link *Salmonella* with formula milk.
- All health visitors in one focus group reported they had heard of *E.sakazakki*:

*‘That’s that Japanese one’ ‘That’s the bug that could be found in the dried milk....’*

Half of another focus group of health visitors had heard of *E.sakazakki*, and one health visitor who believed she had heard of it, reported knowledge of an adult who experienced the illness resulting from the bacteria. It was recognised as being a gut infection associated with hospitals which could be cured with antibiotics within 48 hours. Health visitors reported they wouldn’t tell parents about *E.sakazakki*.

*‘we don’t want to frighten them’. ‘I wouldn’t name it [to parents]’*

- Recollection of the names of bacteria associated with PIF was poor among most (not all) health visitors.

*'It's got that campylobacter or some Japanese name of bacteria..... it begins with a C anyway!'* .....

*'Something Japanese (laughing)' .....* *'Escherek-ee—ii...'* .....

- Many health visitors perceived bacteria names as being funny and commonly referred to microbial contaminants as 'bugs'.

- The presence of bacteria in PIF was likened to 'weevils' that may be present in flour.

*'if you think about it, you get weevils in the flour don't you? So why don't get it in milk powder?'*

- Some health visitors considered that in their experience they do not see infants getting GI problems, even though they see parents implementing malpractices, so therefore the risks of resultant illness were not significant.

*'If they're not getting gastroenteritis, where's the problem? If we're not actually seeing children suffer with that, then it isn't a big issue is it?'*..... *'Even if they do fill their bottles up under the tap'.*

- The microbiological risks associated with PIF were considered to be very low by health visitors as they recalled no recent outbreaks; furthermore health visitors recalled such issues in the past had been predominantly associated with premature infants and hospitals. Two health visitors in separate focus groups recalled the Farley's *Salmonella* outbreak.

*'I don't think we've had any problems with them really. There've been no deaths or anything; no babies really who've had contaminated milk for a long, long time now.'* *'The research was premature babies wasn't it, and their birth weight'* *'The two deaths in this country were from infected incubators'* *'So premature and at risk, vulnerable'* *'And the last major outbreak we had was with Farley's back in 1985, where it was found to have salmonella in it'.*

*'...they had trouble with salmonella at one time didn't they, one of them [formula companies].'*

- Some health visitors believed that the problems and risks associated with PIF and GI infections did exist, (for example *'In the wrong hands, bottle feeding is positively dangerous'*), but GI rates couldn't be too high and too big a problem else it would be reported in the media.

*'It's not something that's hitting the press is it?'*

- All health visitors reported they had not been educated specifically about microbiological risks associated with preparing, handling and storing PIF. The only education they reported was regarding basic cleaning and sterilising practices as paediatric nurses or midwives (general nurses do not receive the same training).

- Health visitors who used to be paediatric nurses reported they were taught how to make up feeds to reduce bacteria.

*'Paediatric .... I was taught how to make up feeds but the reason you're doing that is to reduce the bugs, but I didn't get any formal training on bugs'*

### ***2.3.3.6 Knowledge, perceptions and concerns associated with powdered formula milk preparation, handling and storage***

- Most health visitors reported an understanding of requirements for preparation of PIF.

- Cumulatively there was a conflict in attitudes and beliefs between health visitors with regards to necessity and safety of preparation of powdered infant feeds one at a time as required (including night feeds and when away from the home), as opposed to making feeds up in advance.
  - Some health visitors considered practices involving preparation of PIF away from the home kitchen were unsafe, for example in coffee shops or in the middle of the night in a different part of the house.
 

*‘.....if they're taking out a cold bottle of water from a fridge that was boiled in the morning, leave it on the landing, then they've got their powder which they're shoving in, in the middle of the night, and then warming it up with the bottle warmer, that's grossly unsafe’. ‘I see them in town trying to do it darling, there's milk powder all over the place, there's water here’ .... ‘It's dangerous’.*
  - Alternatively some health visitors reported they would prefer for a bottle of PIF be reconstituted while the parent was awake, the evening before and be careful with practices rather than *‘bumbling around half asleep’* – a practice that was perceived to increase microbial risks.
  - Other health visitors considered the practice of making one feed up at a time to be preferable due to the acknowledgement (by some health visitors) that bacteria may be present in the powdered feed. She believed the risk of microbial growth in the formula is minimised/alleviated when one feed is being made-up at a time for immediate feeding – although microbial growth in the feed was equated with potential growth in the powder (which may or may not have been reconstituted) (Table 7.8, part A).
- When unprompted, health visitors perceived important concerns associated with feeding with PIF was the concentration of the formula fed to infants as well as the reduced potential for the bonding process by feeding with powdered formula milk (as opposed to breast feeding).
- ‘Concerns’ about the use of powdered formula milk were mainly nutrition orientated, especially from the health visitors who were ‘Baby Friendly’ trained and appeared to be very pro-breast feeding. The same health visitors also believed there was an increased risk of gastroenteritis associated with feeding babies with PIF.
 

*‘there's obviously more chance of gastroenteritis, especially with our more vulnerable families, making up the feeds properly, sterilising the bottles’*
- A particular concern relating to use of powdered formula milk was associated with ‘target families’ i.e. parents with learning difficulties. One health visitors reported a ‘target family parent’ making up a large quantities of formula up, storing it at room temperature and making it last as long as possible.
 

*‘The target families..... especially ..... people with learning difficulties’ ..... ‘keeping one bottle out, making one big bottle and keeping it going’*
- Health visitors demonstrated knowledge of the >70°C recommendation and some recalled the recommendation to cool boiled water for 30 minutes (although some believed the boiled

water should be cooled for an hour before reconstituting the powder). Health visitors also considered that it was very difficult for people in their homes to know whether water used for preparing PIF was above 70°C (Table 7.8, part B).

*'How many people in the houses are going to know when it's 70 degrees, it's just ridiculous isn't it?'*

*'I think that's confusing because you're told that to kill the bug and I can't remember the name of it, it has to be at 70 degrees; how do you know when it's 70 degrees, you know? Excuse me. Have you got a thermometer?'*

- Some health visitors indicated they thought it was very difficult for parents to make formula up fresh for every feed, especially when away from the home e.g. on shopping trips. Other health visitors reported that even when parents were at home all of the time, they themselves wouldn't want to be making up a new bottle for every feed, particularly when the baby may be screaming for the feed and having to wait.

*'I think people aren't at home to make them up freshly each time, and you get really stressed out, the fact that they've got to go out shopping and they take out the baby' 'even if I was at home all day, I wouldn't want to be making up a bottle feed for every feed, it would drive me nuts'*

- With regards to preparation of food in advance, health visitors reported that they were frequently told by mothers that either the infant's grandmother used to prepare PIF up to 24 hours before use, or this was a practice implemented for the mother's first infant. This 'argument' was frequently used to challenge the new recommendations of preparing one feed at a time. One health visitor indicated she would respond by saying that method was implemented in the olden days and she wouldn't recommend it now, however, she felt that all she could do was inform the parent of best practice, it was not possible to ensure it was implemented.

*'I don't think that I actually would recommend it, I would say "in the olden days we used to" and they'll tell us "My mum used to do this", or "when I had my first baby I used to do that, is that alright?", "well no, actually the current practice is this...". 'With this making up of the formula milk [one feed at a time], they say "have I really, really, really got to do this?", and I will say "if you can't bear to do it, and it is difficult, then you must make sure that your washing technique, that your sterilising technique, and you're keeping bottles in the middle of the fridge." So you're giving them informed advice'*

- The most important practices to ensure that made-up PIF is safe were considered by health visitors to be washing and sterilising techniques and handwashing.

*'I think the sterilising technique, the washing and the sterilising technique must be the most important thing, because milk will grow bugs. You've got to get rid of those bugs before you make the next feed up' .... 'And the washing of hands before you start, and this is what worries me when I'm out and about, these mums, they're sitting in the café slurping their tea, they've got a bottle of water and they open the tin and they're shovelling it in, that's got to be more dangerous than clean hands, clean surface, make them up and cool quickly – it's got to be'*

- One health visitor reported a clear understanding of need to wash feeding items after use before sterilising.

*'You've got to wash them first, I mean, that's with the bottles isn't it? It's no good sterilising it, they haven't given it a good wash at all'*

- They reported that in most instances parents do boil tap water used for reconstituting PIF, but some recognised that domestic kettles do not ‘sterilise’ the water. To sterilise water some health visitors believed it would need to be boiled for 10 minutes and that would destroy any bacteria present in the water.
- Health visitors expressed concern about the temperatures of parents’ refrigerators, and some reported an understanding that PIF is stored for up to 24 hours, feeds may not be stored at the correct temperature. Some health visitors reported lack of knowledge of correct refrigeration temperatures, for example:

*‘the fridge has to be a certain degree.... it has to be 10degrees’*

**Table 2.8 Health visitor comments related to recommended powdered infant formula practices**

	Health visitor quotes
A. Comments related to preparation of powdered infant formula feeds one at a time.	<p><i>‘Personally I think make up one at a time.....because I’m concerned about the bugs growing. I’m sure that I’ve attended one of the UNICEF’s conference’s where they gave us some information about, as soon as that’s opened the bugs arrive, they’re multiplying straight away, as soon as that lid’s off’. ‘even in dried powder, I’m almost certain that the bugs are rife, they’re growing’</i></p> <p><i>‘if you’re looking at last week’s temperature which hit 27, if you’ve got a bottle in your bag sometimes in your bag, not even in a cool bag some of these mums, the babies are safer if the mums make it up where they go’</i></p> <p><i>‘isn’t that to do with the bugs growing though?’</i></p>
B. Comments related to the <70°C recommendation for cooling of boiled water	<p><i>‘Boil the kettle, wait an hour’ ..... ‘It depends on the size of the kettle’</i></p> <p><i>‘.... they say, if people wanted to go out shopping and they weren’t going to a friends or whatever; if they were going into town, where are you going to get freshly boiled water?’</i></p> <p><i>..... ‘Just take it in a thermos don’t they?’ ..... ‘A dedicated thermos; well that’s not going to be at the right temperature ... but they said you can make it up at home and then stick it quickly under the tap to quickly reduce its temperature, and you can then stick it in the cool bag, but once it went over the four hours, no good. .... Or put water in the bottle, take the powder with you, warm the water up and then put your powder in, but you still can’t guarantee getting it back to 70 degrees.’</i></p>

### 2.3.3.7 Malpractices health visitors reported seeing in parents’ homes

- Health visitors in all focus groups reported that they believed many parents did not always read the instructions on tins of powdered formula milk.
- Health visitors recognised that basic hygiene is needed during preparation and handling of PIF feeds. Many also reported seeing very unhygienic kitchens on their visits – which in some instances they reported having to ‘close their eyes to’. Some health visitors reported seeing some very dirty houses which have given them concern about hygiene issues associated with preparation of the PIF feed.
- Health visitors reported that many mothers haven’t a clue about formula feeding when they leave hospital.

*'they come out [of hospital] and they don't know a thing; they haven't got a clue, so we have to pick up the pieces ....invariably we haven't got enough time to go through it [in clinics] so we have to arrange a home visit...but if you're pushed [for time] it is quite difficult' .*

- Health visitors in all focus groups indicated that if mothers have had previous children fed using PIF, and experienced no problems they are likely to implement the same preparation and storage practices again.

*'I mean the mums who've had babies before have done it quite safely before when maybe their children have not had salmonella and gastroenteritis or thrush because they've done it cleanly and safely and they sterilise things properly.....and stored properly' .*

*'When people are on their second and third baby, when you tell them about the changes in the rules they, I mean I've had a lot of people say "that's nonsense" and they've continued to make them up and store them in the fridge'*

- Some health visitors recognised the difference between RTU and PIF feeds, whereas others considered RTU feeds as the same as PIF:

*'making it up... except that will have a hole in the top and stand in the fridge'*

- Health visitors reported parent misunderstandings between use and particularly storage of RTU UHT milks in hospitals, RTU UHT milks in cartons and reconstituted PIF milk. Storage instructions on the RTU formula in cartons indicated once opened cartons should be kept refrigerated for up to 24 hours. Whereas recent guidelines recommend reconstituted powdered formula milk to be made-up immediately before use – avoiding prolonged storage.

*'that's another confusion because they use the readymade in hospital and they don't realise that that's different to what you make up from the tin when you get home. So because they see it just, the bottles that are closed; they're just left in hospital, they think when they make it up they can leave it for hours as well, because nobody's told them they're different' .*

- Some of the storage malpractices health visitors reported that they see include the following:

*'some are still making the day's [bottles of reconstituted PIF] up, leaving them on the side sealed and then sticking them in the fridge and bringing them out one by one' . .*

*'quite a lot are using the microwave to heat it [bottle of reconstituted PIF] up .*

*'it has to be in a certain place in the fridge..... at the back of the fridge, not in the door of the fridge, but not everybody's going to do that' .*

*'A lot of ours just take a wee couple of feeds away with them on a trip' .... 'they just put them in a cool bag' .... 'Yeah, made up, that's what they do, they don't faff' ..... 'And I dare say there's some who don't even bother doing that [laughter] "in the bag!"' .*

- Some of the hygiene related malpractices health visitors reported that they see include the following:

*'I feel like cleaning most of my fridges'*

*'I've certainly visited some very, very dirty houses where actually I would far rather they were breastfeeding because you wonder how well they're cleaning bottles and sterilising them, and washing their hands and the teats, you know babies who very quickly get oral thrush because they're not washing the teats' .*



*'pets, cats, and the cat walking across the kitchen surfaces'*

*'Not washing their hands'*

*'Tea towels that have never been washed'*

*'They're using their hands rather than the tongs, the little tongs, or emptying a bottle out..... the dirty milk and just pouring some kettle water in and swilling it around and then proceed to make up a feed, and you're going [all laugh]. And they're looking at you like you're talking rubbish'*

- Some of the preparation and feeding malpractices health visitors reported that they see include the following:

*'One of mine.....they're just bunging in the powder, sticking it under the hot tap and giving it a shake, and this baby is fine.....and you think "you really shouldn't do that" and she'd say "why, she's a healthy baby, what do you lot know?"'*

*'they're still putting a rusk in the final bottle'*

### **2.3.3.8 Powdered infant formula information**

#### *General*

- Health visitors in all focus groups considered it was part of their role to inform parents of preparation, handling and storage of PIF if the health visitors considered such information was necessary/relevant for the parent (see 2.3.3.1).
- Information about feeding with PIF is reportedly not volunteered to mothers who are successfully breast feeding, unless they are specifically asked for advice or the infant has a considerable weight drop and artificial feeding is required as a top up feed to increase the infant's weight. However, some health visitors thought bottle feeding information should be given to all parents, even if they are successfully breast feeding.
- Some health visitors very strongly believed that talking to parents about bottle feeding and safe preparation, handling and storage of PIF was NOT likely to make them NOT breast feed.

*'I think it's such a disgrace to women's intelligence to think that by not telling them about bottle feeding, will make them breast feed. Not having Farley's written on your pen will encourage somebody to breast feed, rubbish. These are intelligent women, most of them, and they should be given all the information and make their own informed choice.'*

- Other health visitors believed that there is enough information available for parents to support formula feeders – but still indicate they promote breast feeding.

*'I think there's a lot of information about formula feeding out there, and we need more information and support about breast feeding, which is the safest and best way to feed a baby.'*

- Some health visitors thought that parents should be told how difficult it is to bottle feed in an effort to increase breast feeding rates.

- Health visitors reported that there is so much information and advice to give parents at the primary birth visit, each subject of which is equally important, and it is difficult to know where to put the emphasis.

*‘What’s more important, a five minute discussion on cot death? Or a five minute discussion on making up bottles feeds? Or a five minute discussion on.....; there’s so much information that you have to give to these parents at a primary birth visit, and it’s all equally important, but where to give that emphasis is difficult’ .*

- Health visitors reported that immediately after the birth parents are bombarded with information and advice about care of their new infant, and therefore some considered it better to discuss infant feeding issues antenatally and reinforce subjects during the first home visit (if an antenatal visit/contact is made).
- Some health visitors recognised the need to support bottle feeding mothers.

*‘it’s true that they do need more support when they’ve decided to bottle feed postnatally. They do need more support on the safety of giving formula milk, because it’s an unsafe, potentially unsafe milk to give if it’s not given correctly.’*

- Many health visitors reported that parents *‘quite often ignore the advice you give them anyway but at least you give them the information’*.
- Perceptions of the bottle feeding/PIF preparation, handling and storage information and advice for parents were variable between health visitors. Some believed that there is currently enough information available, others considered there was insufficient information.

*‘I think there is enough information out there, I think we possess enough information to support women in their formula feeding if that’s what they need to have the information on – I mean we all promote breast feeding’*

*‘There’s enough information out there about formula feeding’.*

Other health visitors (particularly the ‘Baby Friendly’ health visitors) thought there was too much information available. Those who considered that there was insufficient information available believed this to be the case because of the emphasis on encouraging breast feeding.

### *Approach*

- Some health visitors reported they did not ask how the prospective mother was planning to feed her baby, they only gave information regarding breast feeding. The reason for this was that they believed many prospective mothers chose to bottle feed because they were not aware of the benefits of breast feeding.

*‘I don’t actually ask that question “how are you planning to feed your baby?”, I just give information about breast feeding’*

*‘you tend to give them information about breast feeding, not bottle feeding’*

- One health visitors reported if she knew that a baby was being bottle fed, she would have automatically informed the mother regarding preparation, handling and storage of PIF. This would be done by *‘you’d say “how are you making up the feed?”, or “have you got a*

*steriliser? How are you cleaning your bottles?''.* In many cases assessment of preparation etc efficacy would be done by self-reported practices and visual assessment of preparation environment.

### *Information provision*

- Health visitors from all focus groups also reported informing mothers of the new recommendations and 'best practice', but also talking about realistic and achievable practices which may be contrary to the recommendations. Most health visitors believed that how the parent decided to make the formula up was ultimately up to them (Table 2.9, part A).

*I was just going say the guidelines, I usually start with the quote "the government guidelines suggest that you should be doing it one at a time, I'm not telling you you have to do it one at a time, you do for you but that is what the guidelines ..... I'm not saying that's what you must do", I think we're there to provide the information because at the end of the day you can say anything to these mums and they can tell you to get lost, they don't have to take anything you say'*

- Health visitors reported that they and parents they are advising who have had previous children often rejected/questioned the need to make one feed up at a time when preparation of enough feeds to last 24 hours for previous children has been convenient and resulted in no problems. This was reported as a common impediment to implementation of the new guidelines.
- Some health visitors indicated they would not inform the mother of specific practices, but would be included in a general discussion. *'you wouldn't be going through them and say "I've got to tell you about this, this and this", it would be through the general discussion'* . Further investigation would occur if the infant was vomiting or not gaining weight.

*'I think certainly if the baby comes in and they've been vomiting or want ever else, you then sort of say "are you making up the feeds okay, how are you managing that?''.*

- Overall, the health visitors considered that it was important to provide parents with informed advice and important to be realistic, but they could not dictate what the parents must do.

*we're aiming for the safest practice in the reality of life.'*

Many believed that making feeds one at a time was not realistically achievable

*'The mums who are tired, they're not going to go down and.... boil the kettle and wait for half an hour with a screaming baby, where they're nodding off to sleep at two in the morning. We've got to be realistic surely.'* *'we're aiming for the safest practice in the reality of life'*

- Health visitors reported they have to be realistic in their expectations of parent hygiene, for example, if a house was extremely dirty, the client would be encouraged to clean a small area for preparation of the PIF.
- Information was mainly given to mothers, but sometimes to fathers too – it would depend who was in the house or listening during the time of the home visit (if a home visit was made).

- Information provided to clients was usually tailored according to considered 'need'. For example, a mother who had previous children may be given less information if the health visitors believed she knew what she was doing.

*'I think it's a very individual piece of information that we give. It's on a need to know for each client'  
 ..... 'If you've got a lady that's had two or three children before and has bottle fed them; they  
 know what they're doing'*

*Health visitors reported advice: feeding with formula when away from the home*

- Advice health visitors in all focus groups reported giving to parents about feeding babies away from the home mainly consisted of using RTU formula milks in cartons (Table 2.9, part B).
- Other health visitors recommended taking boiled water in a designated flask and measured amounts of formula and making up the feed when they are ready to feed the infant. Others recommended getting boiled water from a café etc and reconstituting with powder as would be done at home. A few health visitors recommended reconstituting the powdered formula feed before leaving home (Table 2.9, part B).
- If parents are going on holiday involving a flight, one health visitor reported she advised to take prepared bottles and the powdered formula and get boiled water from somewhere and make the feed up as they would at home (Table 2.9, part C).

*Health visitors reported advice: feeding with powdered formula during the night*

- Health visitors in all focus groups discussed issues of preparation of PIF in advance and feeding reconstituted feeds during the night. Many suggested they considered preparation of the feed during the evening before to be preferable and storing the reconstituted powdered feed before feeding rather than making up fresh in the night (Table 2.9, part D).

*'what I weigh up as well, if you've got a knackered mum who at 12 o'clock at night is making yet another bottle, is she going to be as safe at that time as she was at nine o'clock in the morning when she made a batch? You're weighing up that as well, and if she's then put her fingers all around it, it's not quite as clean or as sterile as it should be, that for me, that's what I would weigh up with the mum and how they are'*

**Table 2.9 Health visitor comments related to powdered infant formula advice**

	Health visitor quotes
<p>A. Information provision about recommended practices.</p>	<p><i>'We tell them best practice, I do tell them best practice and say "I've told you the right way, what's considered the best way, but how ever you do it is up to you".'</i></p> <p><i>'I don't stress it [guidelines] too much to mothers; I always say, well I'm just saying the guidelines and those are what they, and obviously they don't, they're not going to do that'</i></p> <p><i>'I advise her to do what she thinks is best'</i></p> <p><i>'I think we need to give them the guidelines, make them aware of...'</i></p> <p><i>'They can say yes to do it and then do exactly the opposite'</i></p> <p><i>'We're not there to police people'</i></p> <p><i>'We are an advisory service, and they can take that advice if they want or choose'</i></p> <p><i>'I've a mother who has got triplets... and she said "you're not telling me I've got to make this up fresh are you, every feed?", and I said "no, absolutely not".....this is what I'm supposed to tell you, and this is what I think we'll tell you". I mean, you've got to be able to have a life haven't you?'</i></p>
<p>B. Information provision about use of RTU formula feeds and feeding infants with formula when away from the home..</p>	<p><i>'Recommend when they start out to use ready-made or make it up where ever they go from scratch. Since this new research, if it's just an infrequent event, to try and use the readymade'.</i></p> <p><i>'Take the carton'</i></p> <p><i>'Quite often they take the ready to feed cartons with them'</i></p> <p><i>'It depends on their income I think, you have to temper your advice to what you think they can actually 'A', manage and 'B', afford I think.' ..... 'Some of them are not going to be able to afford the cartons' ..... 'If you've got a wee premi baby it's probably worth the expensive using the ready cartons' .</i></p> <p><i>'A holiday I'd say travelling, if they can, use the ready to feed'</i></p> <p><i>'Make it up or take a readymade bottle'. 'Or use a flask'.</i></p> <p><i>'A lot of them use flasks and the little containers'</i></p> <p><i>'I had a poor mum came to our first time mums group with that and the bottle, and she touched the flask with her thumb and it went all over the place, and she was like "that was measured" and burst into tears, I mean we had a kettle, we had to boil some water for her but if they're out and about somewhere on a park bench or wherever and that happens, the cartons are probably the better option because they're not fiddling about with trying to keep the cap sterile and the teat sterile while they tip the powder in.' .</i></p>
<p>C. Information provision about feeding with formula on flights.</p>	<p><i>'nowadays, what I'm tending to tell them is to just take the powder and get some boiled water when they get somewhere. And that's the information that's come out from the airlines, is that you can't take readymade cartons through security with you' .</i></p> <p><i>'Take the tins, put the tins in the luggage' .</i></p>
<p>D. Information provision about feeding with powdered infant formula during the night.</p>	<p><i>'I quite often say to them, at night time to make up the night time feeds before they go to bed, because you know what you're like in the morning yourself ....., bleary eyed and not with it'</i></p> <p><i>There is a 'safety aspect of doing it in the middle of the night when you're tired'</i></p> <p><i>'Fancy doing all that [following guidelines for preparation of powdered formula feed] in the middle of the night when you're half asleep' .</i></p> <p><i>'I would rather they did the process well and at the time than a bit sort of haphazardly, because we've all done that' .</i></p> <p><i>'knowing they're not doing it correctly, you'd have to give them, you know, so if they're taking out a cold bottle of water from a fridge that was boiled in the morning, leave it on the landing, then they've got their powder which they're shoving in, in the middle of the night, and then warming it up with the bottle warmer, that's grossly unsafe, then taking a cold bottle from the middle of the fridge and heating it up' .</i></p> <p><i>'It was the storage that was the problem, and then the make up of the feed, especially if you wanted to go out or it was at night time, and what do you do if you're upstairs? Do you stagger downstairs because not many parents will stagger downstairs. They're either going to take readymade bottles upstairs, or they're going to take hot water in some form upstairs which won't be at the right temperature'</i></p> <p><i>The night time feeds .....they were suggesting a dedicated flask of hot water that somebody takes up to the bedroom, and that has its own inherent hazards in itself to them and to the baby .</i></p>

- It was also suggested that for breast feeding mothers, the introduction of PIF feeds commonly occurs ~6-8 weeks for the night feed.

*'by six or eight weeks they're introducing some, one bottle at night, very common'*

- Other health visitors reported that some fill flasks of boiling water the night before and reconstitute the powdered formula when feeding is needed (Table 2.9, part D).

*'...then you've got other mums who want to do it absolutely to the letter and they fill their thermos flask, put them with the hot water and they've got it to the right temperature and that's by their bed, and their little pot is near the bottle, everything is just there because they can't sleep, I don't think, if they don't do it absolutely to the letter, so it just varies so much'.*

### *Demonstrations*

- Health visitors in one focus group reported occasionally demonstrating handling/preparation of PIF if parents required it whereas health visitors in another focus group indicated that if the parent really wanted to be shown what to do, they wouldn't do a demonstration of best practice, but let them prepare a feed and talk through correct behaviours etc.

*'I wouldn't demonstrate it, I would let them do it but talk them through it if they really really wanted'*

- Some health visitors reported 'getting around the problems' of not being allowed to demonstrate PIF preparation etc in classes that they do so in the homes if necessary.

*'I think we get round probably by doing it in the home' 'A one to one.' 'You have to do it.'*

- Demonstration of practices in classes is seen to be undermining breastfeeding.

*'It's seen as undermining breastfeeding.'*

- Some health visitors reported that the bath and feed demonstration is only offered in one hospital on certain days of the week, so as many mothers with new baby are only in hospital for less than 24 hours, many do not get offered the demonstrations. The demonstrations would usually be done by the MHCA.

- Health visitors felt that years ago info about preparation of powdered formula feeds was given to parents before leaving hospital. Nowadays parents are reported to '*have nothing*' and '*they leave hospital not knowing a thing*' about bottle feeding.

- Some health visitors considered if mothers were shown how to or actually made-up PIF in hospital instead of using ready-to-use feeds in hospital it would help to promote correct practice for when clients returned home. Others thought that nursery nurses did currently show mothers how to make PIF feeds up in hospitals, therefore they thought that all mothers received a demonstration before leaving hospital; this perception was based on practice that was implemented many years ago when a few respondents worked in the hospitals.

*'I thought that the nursery nurse used to show them.....the nursery nurse years ago used to show the mums how to make a bottle up'*

*'years ago ....before they were discharged you had everything; you had them all in the nursery before they were discharged; 'how do you make up a bottle?', get them all doing it. Now there's nothing; they come out and they don't know a thing; they haven't got a clue, so we have to pick up the pieces there, and they do ask in clinics don't they when they come? [all agree] And invariably we haven't got enough time to go through it so we have to arrange a home visit which is fine, but if you're pushed it is quite difficult. So it is a grey area and it's something I don't feel is adequately, well, the information isn't correct'*

- Health visitors reported they would rarely have a display in health centres/surgeries about PIF feeding, whereas would more likely display information about breast feeding.

#### *Consistency of information*

- Health visitors believed that official sources of information e.g. from the NHS, DoH and other organisations detailing recommendations and guidelines for preparation, handling and storage of PIF were inconsistent.

*'There are three guidelines, there's the World Health Organisation and there's the Department of Health, and what it says on the back of a tin..... and Birth-to-Five says differently, and then you've also got other family members, mother-in-laws, etc, etc, chipping in with this or that or the other, and friends chipping in, so it goes round and round'*

- Due to the inconsistent recommendations for best practice, many health visitors reported finding it confusing and difficult to know the right way of preparing and handling formula.

*'it's confusing to us really' 'Very confusing for us' 'We weren't aware, someone told us, we didn't know'*

#### *Other influences about information provision to parents*

- Health visitors from all focus groups reported that they experience problems with providing accurate information to non-English speaking clients. Interpreting (sometimes unofficial – usually by other family members, other times use of official interpreter) was considered to be time consuming.

*'It also depends if you're going to have to use an interpreter as well'..... 'which takes about 50% longer'*

- Health visitors reported they were not sure if information being advised is actually translated.

*'you're at a loss to know whether they are translating exactly what you're saying' .*

- Other health visitors reported problems in providing written information for non-English speaking clients. Some health visitors indicated that the problem of language barriers could be overcome with the DoH bottle feeding leaflets which include big pictures – however then health visitors encountered the problem of limited resources and did not always have such leaflets readily available.

- Health visitors reported also having to consider clients' cultural ways of life, such as use of water and wastage.
- Health visitors from all focus groups indicated infants' grandmothers often provided information to the mother and they believed such information often was conflicting to the advice they, as a health visitor, were providing. In some cases health visitors believed the grandmothers may have a greater influence on parents and this may contribute to the failure of some to implement new PIF preparation guidelines. Health visitors considered provision of information and advice about infant feeding from friends and family to be a hindrance.

*'you've also got the grannies sometimes in these houses who are saying, as soon as you've gone out the door, "no, this is what you do", and you just feel it and know that the mum is only getting the information from dad and granny.'*

*'Granny..... not always the best [source of information]!'*

*'I think extended family are probably the biggest influence aren't they, the older ones.'*

*'because gran's told them to do that'*

- No health visitors reported giving branded information/advice to parents about PIF or bottle feeding to ensure that they do not advertise or promote any specific formula products. Some indicated that just because there is a company name or associated character (e.g. teddy bear associated with Heinz – Farley's formula) present on the information source they did not believe that parents would automatically go and buy the product.

*'I really don't think that the women look at it and think "oh, this leaflet's been done by SMA, therefore I'm going to give my baby that milk", it's an insult to women's intelligence'.*

Whereas other health visitors were concerned about the '*subliminal advertising*' used in information sheets associated with specific formula companies.

- Different policies for 'being allowed' to be in contact with formula reps were reported.
- 'We have different policies for different areas'*
- It was reported that all new parents receive a 'Birth to Five book' from the NHS which includes a few pages detailing preparation, handling and storage of PIF.

### **2.3.3.9 Powdered infant formula policy and the Baby Friendly Initiative**

- All health visitors in all focus groups were aware of the UNICEF Baby Friendly Initiative.
- 'UNICEF Baby Friendly guidelines as well, to try to promote breast feeding.'*
- Some health visitors worked in accredited Trusts/areas, others worked in areas which were working towards accreditation and others were not yet directly associated with the Baby Friendly Initiative/had not received 'Baby Friendly' training. All health visitors indicated that their work as healthcare professionals advising parents (predominantly mothers) about infant feeding was affected in some way by the initiative.
  - Attitudes towards the Initiative were variable between health visitors. Some health visitors had received 'Baby Friendly' training, attended UNICEF conferences and were very much



in support of the initiative, whereas others considered it an impediment to provision of important feeding information to mothers.

- No formal policies about advising health visitors about PIF preparation, handling and storage were reported in any focus groups – any policies related to infant feeding were based on the Baby Friendly Initiative which predominately is a policy for breast feeding.
- Health visitors perceived the Baby Friendly Initiative as being not very friendly to formula-fed babies and an Initiative which can make life quite difficult for health visitors given that a large proportion of their client base are being fed using PIF.
- Many health visitors considered implementation of the Baby Friendly Initiative/concepts to be *'over the top'*, and result in a lack of information about artificial feeding being available and provided to health visitors and consequently to parents. Furthermore health visitors in all groups reported caring for mothers who felt considerable guilt and failure for feeding their baby with formula. Furthermore, as a result of the breast feeding emphasis, health visitors from different focus groups reported they themselves felt guilty when discussing PIF with clients as they are not supposed to do so under the Initiative.

*'It's over the top. It makes you feel guilty and it makes the mothers feel guilty.'*

*'It's over the top'*

*'That's what they (mothers) say, they all say that.'*

*'The fact that they're (mothers) bombarded with all this information in hospital; 'you've got to breastfeed because it is best', and they're not given any other information, and the guilt trips they go on when they come out, and as Sally has said, that they don't, they hide it'*

*'And they feel a terrible failure'*

*'I think it is the guilt and the lack of information about artificial feeding, which are the two main things that have come out of the breastfeeding initiative'*

*'It can lead to an inequality as we've just been discussing, the bottle feeding is really left alone, and for people who are choosing to use that method, they need to do it safely and I suppose it's our job to make sure that they are doing it safely to keep the baby well.'*

*'I don't think they should be stigmatised in a way, and I think that's how a lot of mums feel about it, they're almost apologising that they can't, wont, don't want to breastfeed, the mums who tell you "I absolutely hate it" are nearly in tears because they feel so guilty and that to me is completely wrong.'*

*'I think what a lot of our mums say is antenataly that they're not given information about how difficult it will be or the realities of it.'*

*'I think some of that adds to the guilt that parents feel if they can't breastfeed because the message they're getting is so heavily biased to breastfeeding, that if they can't do it and they feel that we're not able to give them much straightforward advice, I mean we do when they ask questions, but yeah I think it kind of gives them an impression that it's frowned upon because it's certainly frowned upon for us to give.'*

- All health visitors reported they are now not supposed/allowed to speak to formula milk reps as part of the Baby Friendly Initiative. However, despite this many health visitors in all of the focus groups reported they do secretly contact reps for up-to-date information about the

guidelines, recommendations and any changes to the products. Many reported they feel guilty doing so, but are not being influenced by any brand name and do not promote any brands of formula, ever.

*'With management, it's partly to do with Baby Friendly that they don't want us to see milk reps, but it's also, it's a bit insulting to our intelligence because we're not swayed by any rep.'*

*'It's over the top. It makes you feel guilty and it makes the mothers feel guilty.'*

- NHS management were perceived to have blinkered view of breast feeding which some health visitors disagreed with as they considered it to be wrong to not give formula feeding mothers information about their selected type of infant feeding.

*'I just made a decision..... to see reps because I see it as an extension of your education; you keep updated, and I just think it's a very, very blinkered view to just block that out totally. Yes, breast is best, it will always be best but you can't offer these artificially feeding women a second rate service, and that's what is happening.'*

- Health visitors reported that mothers were put under pressure by midwives to breast feed, as midwives are required to increase breast feeding rates, which may contribute to achieving 'Baby Friendly' accreditation.

*'I think they're [mothers] put under pressures from the midwives, they've [midwives] got to keep their breastfeeding statistics up to a certain level, they've got to provide the breastfeeding support groups, they've got to be seen to be promoting it and they've got to be seen to have a certain percentage in their area who are doing it, and it's not...'*

*'So that's wrong pressure isn't it.'*

*'And that's come right now because they have to, I've been told recently haven't I? That they've got to increase it from something like 30 to 50% in the next six months.'*

- Health visitors reported that because of the Baby Friendly Initiative midwives frequently were not given information about the risks associated with preparation, handling and storage of PIF.

*'The midwives are not fed any information about bottle feeding, not at all, they're not allowed to - because of Baby Friendly'*

- Health visitors who had attended the UNICEF Baby Friendly Initiative workshops/conferences appeared to be more knowledgeable about the microbiological risks associated with feeding infants with PIF. However, this was discussed in the focus groups more as a negative aspect of formula feeding and a reason for breast feeding, as opposed to using knowledge of the risks to enable safe preparation of powdered formula feeds.

*'I'm concerned about the bugs growing. I'm sure that I've attended one of the UNICEF's conference's where they gave us some information about, as soon as that's opened the bugs arrive, they're multiplying straight away, as soon as that lid's off' .*

### **2.3.3.10 Powdered infant formula preparation, handling and storage recommendations**

- Health visitors considered that the reason the new recommendations were introduced was to ensure the information providers cover themselves.

*‘I think it’s a kind of “we told you so” if something does go wrong, “we told you so, this is what we’ve told you to do”’*

- New recommendations were reported to cause frustration among health visitors. For example *‘they drive me mad’*. All health visitors were frustrated at the changes, and perceived frequency of changes made to the recommendations. Some health visitors reported they do not bother learning the current recommendations as they will have changed in 6 months time.

*‘it’ll all be changed in another six months, I wouldn’t bother learning it’.*

Other health visitors indicated the new recommendations have caused some difficulties for health visitors as some had been discouraging behaviours which are now recommended.

*‘We’ve been trying for ages, I mean it’s quite common; I’ve got quite a lot of families..... before any of this even changed, and they used to use a flask of water, and I’ve been saying, “no, no, no” [overtalking/laughing], and it’s [the new recommendations] telling them, yeah it’s okay, they can stick it in a flask. But for the last two years prior to this, I’ve been telling them, trying to stop them using the flask’.*

- Some health visitors believed the main reasons recommendations had changed in the UK was because two infants died after consuming PIF in Spain.

### **2.3.3.11 Training and information sources**

#### *Training and updates*

- All health visitors indicated they had never received specific training about the microbiological risks associated with PIF. The majority indicated that their training occurred years ago and that now they relied on irregular/infrequent updates e.g. at sector meetings (which not all health visitors attend) or formula manufacturer reps – who they aren’t supposed to communicate with.
- All health visitors reported that they get regular updates on breast feeding.
- Most health visitors reported that as professionals, they get information about PIF feeding from dietetic departments who receive updates every two years about formula milk. However, dieticians are also not allowed to speak/see formula manufacturer reps.
- Many health visitors indicated that a useful source of updated information for healthcare professionals such as themselves is the ‘Community Practitioner’, the health visitor magazine.

- Health visitors indicated they received no formal ‘health visitor’ training, although the majority of health visitors were previously trained as midwives. Those who had no training at all had read the instructions included on the packaging of the different packets of formula, so that they were aware of the instructions and additional information.
- Health Visitors received training days which are topic-based and if training was about feeding (as opposed to wound healing or resuscitation) it was usually about breast feeding. It was felt that there was no time or opportunity to ask about formula feeding issues. Furthermore, to ask questions about formula feeding was perceived by health visitors to be inappropriate.
- Some health visitors reported they would not go to their feeding advisor to ask about PIF – particularly in areas/Trusts that are very ‘Baby Friendly’ orientated.

*‘I have to say in your training you get nothing and you come out, you get nothing, they refuse to talk to you, the infant feeding advisors, about it, and you get all these questions so I actually just put a pile of questions together and I say “please come and talk to me because I don’t know where else to go”, .... okay they’re representing their company and I accept that, I don’t use their products, I don’t advocate for any formula milk, but he gave me this information about, when do you go onto hungrier milk? What the difference is in the bowels, the constipation and how and what mum should expect in their baby, the information has been worth its weight just equally as much as the breastfeeding advice and information’.*

- Health visitors reported they believed they should be treated as professionals and make decisions about appropriate information to give to parents/clients. However they described a ‘strangling of information’ that actually reaches them as a health visitor.
- As health visitors don’t receive PIF information from proper/official sources (which usually would come as an email) they reported they would usually look on the internet.
- Frequently health visitors reported that their knowledge of PIF preparation, handling and storage has come from their own personal experience of having children.

*‘Most of us have had kids & we’ve all done it, yeah, have we all done it [made feeds up in advance]?.... How many of us have done it and not had a problem? [all agree]..... But obviously we can’t say that to clients, that we did it’*

- Many health visitors indicated that they wanted more information about PIF, however they did not have time to source and read it themselves.

*‘I’d love to go away and read all the evidence that says, but I have other priorities’*

#### *Sources of information for health visitors*

- Although health visitors were not supposed to see PIF representatives, some do because they perceive the reps as being the primary and only accessible source of information. Infant feeding advisors were reported as being very difficult to get hold of.
- Health visitors reported that the reps they’ve seen (and known for many years) were not trying to promote their brand to them – more likely answering important questions.

- When health visitors do obtain information from formula reps and management find out they aren't happy and get into trouble. Nevertheless the health visitor still see these reps as a reliable source of information. When health visitors have been challenged by their managers about communicating with a formula rep they were informed to refrain from further contact and told to 'look on the internet' or seek advice from their 'infant feeding advisor' or 'breast feeding advisor'.
- Some health visitors wanted more information from formula companies, and believed that they (the formula companies) must do research regarding the rate of microbial growth in reconstituted feeds and whether it is actually safe to make up PIF for 24 hours or not. One health visitor confirmed that she, and other health visitors, did not have this information.

*'The formula companies must do lots of research into how the rate that bugs grow when once the bottle has been made up. Couldn't we have more information on that from formula companies? So we know what advice to give parents. Should it be just make one feed young people at a tome? Or is it really safe to make up 24 hours bit you know, I'd like more information about how the rate, how fast these bugs are growing in the bottles, but we haven't got that information, I haven't got that information'.*

- Although health visitors seeing and speaking to formula manufacturer reps was not allowed, many health visitors reported that they considered PIF information from reps to be useful. In many cases health visitors reported having contacted formula reps to get correct, current and required information to be able to answer client questions and also provide accurate, up-to-date advice. Health visitors acknowledged that formula reps represented individual companies in the market, but their experience has shown that the information and advice the reps provide is invaluable and not necessarily easily available elsewhere. Many health visitors reported being 'reprimanded' if their contact with reps was discovered.

*'they've stopped the Reps being allowed to speak to the midwives and that happened a long time ago, and us, and I've just recently had a rep who dropped into the surgery because he hadn't been able to speak to our infant feeding advisors, who're supposed to be the people that they do speak to and then they give the information to us, and I had a very nasty email wanting his name, and when he came, and how he turned up, and why he came to the base, and why he hadn't made an appointment with them, and I emailed back to say, well he just happened to be passing on the off chance, I've known him for 20 years because I was a midwife before i was health visitor and he stopped to chat and said he hadn't been able to get hold of the infant feeding advisors'..*

*'I find them really useful actually'.*

- Most health visitors believed that the DoH and the FSA would be an unbiased source of information, whereas formula companies may provide biased information – although they believed that formula companies wouldn't lie, just provide an optimistic point of view.

*'They shouldn't lie though should they?' ..... 'They can be optimistic' ..... 'But they all say "our milk grows bugs at a slightly different temperature from someone else's milk" won't they?'*

*'Shouldn't it be the Foods Standards Agency that actually give us that information?' ... 'Of course, it's excellent'*

- The very enthusiastic 'Baby Friendly' health visitors wanted more information regarding the risks of formula feeding to give to parents alongside the benefits of breast feeding. It

appeared that this information would be used as a tool to promote breast feeding and present PIF as risky product, as opposed to educate about safe preparation, handling and storage practices.

- Health visitors believed that having information about safe preparation, handling and storage of PIF was useful, however, some believed that the reps just wanted health visitors to advertise the product - which is something they reported they would never do.

*'the worrying thing is, is the reps want us as health professionals to advertise their products' 'we never do that [all agree] I never see them, but even if you did, you wouldn't.' 'I'd let them come and I listen to what they've got to say and I'd take any freebies that they've got'.*

Other health visitors reported attending meetings and conferences run by formula companies where no brand name was mentioned.

*'I went to a SMA conference and they didn't mention SMA once'*

- Some health visitors reported they were not allowed to use/have any items in work with a formula company logo:

*'we're not allowed to have a pen from them though, nobody's got SMA written on it'*

One of the reasons given for this was so the health visitors or parents are not influenced to advocate/use any specific formula product.

*'In our new breast feeding policy, we won't be able to advertise formula companies'.*

#### **2.3.4 NHS hospital nurses– cumulative focus group findings**

- Nurses from five different hospitals attended the 'hospital nurse' focus groups (n=3). Nurses from each of the maternity departments, paediatric departments, neonatal departments and SCBU were represented.
- Considerable differences in the use, perceived acceptability and preparation of PIF was observed during focus group discussions between nurses from maternity departments, paediatric departments, neonatal departments and SCBU.
- Overall, formula use in paediatric departments, neonatal departments and SCBUs was perceived by nurses as acceptable. Even in 'Baby Friendly' hospitals, nurses believed part of their role was to inform all parents (breast and bottle feeders) about safe preparation, handling and storage of PIF. All nurses from these departments recognised that breast feeding is best for infants, however did not enforce and 'push' this on parents as they perceived was done so in maternity.
- Maternity ward nurses were considerably more supportive of the Baby Friendly Initiative and implemented policies and 'rules' reportedly without exception. All maternity nurses reported that they are not allowed to discuss, suggest or encourage formula feeding with mothers. They also indicated that nowadays they never demonstrated PIF preparation or sterilisation practices (although they reported they used to in the past) – this was due to the Baby Friendly Initiative and lack of time.

### **2.3.4.1 Roles and responsibilities**

- Nurses believed that health visitors and particularly midwives are the most influential people providing information to parents about infant feeding.

*'Midwives and health visitors ....because they're the first point of contact for most mothers and then in the community the health visitor takes over from the midwife, ....and even antenatally the midwife will have discussed methods of feeding with mum'*

*'the midwife would be the biggest influence ..... because they're still the first point after the birth'*

*Reported role of infant feeding coordinator*

*'They do all the parent craft and antenatally as regards breastfeeding. They'd assist the mothers and they also deal with staff education for breastfeeding. 'Then they'd come and see the parents, someone who is postnatally, that are having difficulties, and I think maybe go over to paed's wards'*

- Neonatal/paediatric nurses considered that it was part of their role to advise parents about PIF if they were already bottle feeding.

*' if they're bottle feeding definitely'*

### **2.3.4.2 Self-reported practices: preparation, handling and storage of powdered formula milk**

#### *Maternity departments*

- In most instances, RTU formula (in small glass bottles) is the feed available for non-breastfeeding mothers. A sterile teat (individually packaged) is screwed onto the glass bottle for single use. It was reported that such feeds are usually stored in a locked cupboard out of sight to meet with 'Baby Friendly' requirements.

*'we've got a main storeroom which is locked unless some people leave it open, and then people can just walk in and have whatever they want. And then we've got like a smaller milk kitchen which we just put out basically a box [of RTU feeds], they come in boxes of 24, the 'ready to feed' and then we put out a box of everything, well the main ones anyway like SMA, Cow & Gate, Aptamil, boxes of water.' ..... 'when they [the parents] first come [to the ward] we show them all around, take them there and we show them where the milk kitchen is and where everything is kept on the wards then, and they help themselves then'.*

Some nurses reported that in this maternity department, parents are allowed to access this milk kitchen to take RTU formula feeds:

*'The thing is it wouldn't work because if we had like 25 patients and they're all feeding four hourly and like there's only five nurses, they're all like "Excuse me, can you get a bottle?" you'd end up being like "No, No I can't, I'm setting up an IV, I'm doing this", it just wouldn't work.'*

*'you're not supposed to keep bottles stocked up by any of their beds because that's advertising, we're not allowed to do that with the breastfeeding. They've got to have one bottle at a time'*

- All nurses working on maternity wards reported that no PIF was allowed on the wards (unless for reasons such as religion). Some hospitals reported that mothers sometimes brought their own RTU cartons of formula in (size of carton not obtained) for feeding.

*'We don't prepare it on maternity ward'*

*'We also use cartons because a lot of mums have chosen Aptamil and the hospital doesn't supply it, so the mother's have to bring in their own cartons..... it's just that the hospital doesn't supply it and they have to bring in their own'.*

- Nurses working on maternity wards reported they do not have the facilities for cleaning and sterilising infant feed equipment, or reconstitution of powdered milk formula feeds.
- In addition, on maternity wards, other than feeding the RTU formula out of the glass bottles nurses reported they would use syringes or small cups.

*'Well they would use wee cups or a syringe to top up breast-feeding babies'*

- On the maternity ward, if parents who are not breastfeeding choose not to use the RTU formula in glass bottles they are advised to bring their own powdered formula into the ward, however such practice seldom occurred (not at all in some hospitals).

*'They've got to bring their own; we don't have any [powdered] tinned milk at all available. I have known one or two women but they've been of different religions and have different beliefs, so they bring their own powder in, but it's in very, very few cases, but most mums... [use the RTU glass bottles of formula] - the most popular milk we use is Cow & Gate and SMA and a lot of mums decide before they come in what they're going to use and they have their bottles already at home and their tins of whatever milk they're going to have for when they get home, so when they come in it's normally more Cow & Gate or SMA [RTU].'*

- RTU feeds were reported by most nurses to be allowed to be 'in-use' (i.e. opened and suitable for feeding), at room temperature for up to 1 hour. However, other nurses reported that different brands of RTU feeds (according to instructions on the bottle) could be opened and fed for up to 4 hours, others thought the feed could only be used within 30 minutes of opening.

*'it depends [on the formula brand].....on maternity we tell everyone it's an hour so it's not sitting about, even though it says four hours on the back, just to make sure'*

*'you've got an hour'*

*'I've got a feeling the SMA has changed hasn't it ?..... its half an hour'*

- Monitoring of the length of time RTU feeds are opened (fed on the maternity ward) was reported to be usually the responsibility of the mother.

*'On maternity it would be the mums and it would be marked on their wee sheet, you know last fed'*

- Reheating of RTU formula feeds for feeding was reported in all focus groups. The common method used for reheating feeds was using a jug of boiled water. For health and safety reasons, reheating practices were not allowed to be undertaken at the bedside, only in the designated maternity milk kitchen (which was reported to be alongside wards).

*'they're [the RTU formula feeds] stored at room temperature, but they're heated in a jug of water' ..... 'Even though .... we've got a kitchen and there's a kettle in there and they can heat the bottles there, but they're not supposed to take the hot water then to the bedside ..... it's all to do with health & safety'*



*Paediatric departments, neonatal departments and SCBU*

- In addition to the standard glass bottles of RTU formula, a wide variety of specialist PIF powders were reportedly used in paediatric and neonatal departments and SCBU.

*'We've got the specialist milk, but we're encouraged to only keep the ready to feed now because of hygiene reasons.'*

*'we don't have the facilities to stock powdered milk'*

- Nurses frequently reported the need to decant RTU formula milk and prepared specialist feeds into smaller bottles or plastic cups, or syringes or enteral feeding bags or into bottles brought in by parents for feeding infants etc.

*'Tube feeds we would use quite a lot.'*

*'Sometimes the mum might say, "Oh he feeds well from this bottle" we'd have to have different teats and stuff, so you might transfer into a sterilised bottle that the parents have brought in.'*

The reported periods of time that prepared specialist feeds and opened cartons or bottles RTU formula feeds could be 'in use'/at ambient temperature was variable.

[For RTU formula] *'An hour'..... 'and they used to be four, it said on the bottle, but now it's down to an hour.'..... 'Yes, some are four and others are two'..... 'It depends on the type, Nutraprem is one hour. All the Cow & Gates are one hour and the SMAs are four hours.'*

The maximum reported hang times for feeding bags was: *'Usually four hours and no more'*

This time was reported monitored: *'because you only put the 4 hour amount in and then it beeps'*

In neonatal and paediatric departments, nursing staff were reported to be responsible for monitoring times when a RTU/prepared feed was 'in use'/at ambient temperature.

*'We would, the nurse looking after the baby and we would label it when it was open'*

*'It's just the nurse responsible for feeding that baby, to make sure that it was discarded after an hour.'*

*'Because it's generally us that feed the baby, or we measure out the feeds and then say to the parents, "that's the feed for that time".'*

- In paediatric wards, some (not all) hospitals reportedly allow parents to bring the PIF used to feed the infant at home, into the hospital. In some cases such feeds are made-up in the room where the infant is ill, on other occasions the hospital requires a new, sealed tin of feed to be brought into the ward and feeds to be reconstituted in a ward kitchen by ward staff (usually nursery nurses or health care assistants). In most cases it was reported that the nursing staff would make the feeds up – not the parents.

*'They're [parents are] not allowed to [make powdered formula up themselves because] they're not allowed in the kitchen.....It would be the all the nurses [who make up the formula]. (Paediatrics)*

*'we would make up powdered formula....just rarely' (Paediatrics)*

*'They're made up prior to each feed by the nurse responsible'. 'We have ....a 'clean store' where we would make up feeds' [on the ward] (Neonatal)*

*'it would be the nurse responsible or the nursing auxiliary' ... 'just in the [ward] kitchen'.... 'It's not very big, about 8ftx6ft'..... 'we have two fridges, one completely for milk...a fridge for milk..... we*

*have a lot of children with special needs and they would be on some milks and you would store them in between feeds' (Paediatrics)*

*'Our parents aren't allowed in the kitchen' ..... 'If we give them a carton then they open it, then they've got to decant it into a bottle and we've got put their name on and then lock it back in the fridge once it's opened. If they don't use it all, if the child just wants a little bit of it..... [it can stay in use for] It's usually 12 hours' (Paediatrics).*

- Preparation, handling and storage of specialist PIF feed was variable between hospitals. Some hospitals have a Central Infant Feeds Unit whereby all feeds are prepared for 24 hours use by a designated person who transports prepared feeds to required wards (or via taxi to other hospitals) where the reconstituted feeds are stored in refrigerators.

*'Well on our ward obviously we've got the milk kitchen and they're all like, we have recipes, which obviously xxx [the milk kitchen manager] makes up, so that obviously specialised feeds so there's obviously quite a few being bottle fed and some breast fed'.*

- Other hospitals have (in some cases in addition to the central feeds unit) kitchens on the wards where feeds are made-up by ward staff. In some cases these kitchens are designated for only preparation and storing specialist powdered feeds, in other cases the kitchens may also be used for preparation of simple meals, storage of staff lunches, making staff coffees etc.
- Specialist and non-specialist made-up powdered formula feeds were reportedly prepared using bottles of sterile water (stored and prepared at ambient temperature) in central feeds units and ward kitchens.

*'We just use sterile water bottles, and you put the appropriate amount in our scoops then and that's how we do it.' ..... 'They're the Cow & Gate kind of bottle, only a sterile bottle'. 'And syringes for measuring the water' and 'We've got the scoop in the tins'*

- Nurses reported that their ward kitchens were 'monitored' by infection control – however, other than indicating that fridge temperatures are monitored on a daily basis, no other 'monitoring' details were provided :

*'infection control was in it the other day... .they come. .every two years now' [neonatal]*

- Refrigerators for storage of reconstituted infant feeds in paediatric/neonatal/SCBU were reported by some nurses as being specifically for such feeds, others shared with other foods and even staff lunches. Some nurses reported monitoring and recording refrigerator temperatures.

*'the temperature for the fridge is recorded and that's checked every morning.....[by]..... person in charge each morning records temperatures of the fridge and the freezer'. [neonatal]*

- It was indicated in all focus groups that the length of time tins of specialist (and when used, non-specialist) PIF in use are monitored by nurses writing the date of opening the tin on the tin itself and then discarding open tins after a period of one month.

*'We always put date of opening on it' 'It's a month isn't it?'*

- In some cases in paediatric wards nurses reported that parents bring in sterilised bottles for the RTU formula (in glass bottles) to be decanted into to feed the infant. Alternatively, plastic bottles and teats used for feeding in hospitals are reportedly re-used by parents. In both cases cleaning and sterilising efficacy was the responsibility of the parent.

*'The plastic bottles are but the teats we throw away' ..... 'because they're obviously staying in like a bit longer with us, some can stay in for weeks at a time and whatever, we give them all the Milton tank and the parents, if they tend to wash the EBM bottles out, they wash the teats out as well, so it's just like washing one of your normal teats out, like if you buy it from Asda or something they're made of the same stuff, so they just wash it out with the washing up liquid and the teat brush we've got in, and they just chuck it in the Milton, it's the same sort of thing'*

However, the glass bottles (used for RTU formula) with teats are reportedly never re-used:

*'Not the bottles. Once they've used the bottles, if it's left we just throw it away, we don't keep the bottles' ..... 'The cartons, we've just been told, because we've just started to get them all in cartons and if a mother was told, because most of them come in 200mls now, so if they had a little baby that just took a little bit, you've got to decant what's left and put it in a sterile bottle, write the child's name and date of birth and what time and when it was opened. I think you can keep it up to 12 hours, in the fridge obviously'*

- Parents were reported to have no participation in preparation of powdered infant foods in the paediatric department ..... *'until the demonstration before they go home'*

*'I think what's hard for them is, when they come in, like I had a parent today, had just been used to making her own and she's come in today and you've got to explain to them, that you can't really make your own up in our kitchen, and it's got to be made for you. "Well I do it at home" and then you've got sit down and talk to them.'*

- In paediatric wards, because infants will have been home for a few weeks they frequently are used to being fed with warmed formula – so the nurses often reported to having to warm up formula feeds on the ward frequently using boiled water in a jug.

*'In a jug of hot water'      'Boil the kettle and..[place made-up/RTU feed]...in a jug'*

*'Because they're older, they'll refuse it if you give it to them at room temperature, they'll just be like, "what's this?" ..... It depends on the baby.'*

The time the feed was being reheated was not monitored:

*'you just keep on taking it in and out [laughing]..... for a few minutes'. 'It's not very long because it's already at room temperature, so it doesn't take very long'*

*'you just feel it, and if it was too hot'      'you just keep testing it on your wrist'*

For infants in special care, nurses reported:

*'Sometimes what we do with the babies that are incubators, you may take the amount out into a syringe 20 minutes before and then just warm it in the incubator so it comes up to incubator temperature, and then feed it, so only out for about 20 minutes before'*

- Two out of the five of the hospitals where nurses attended focus groups from had central milk kitchens (Hospital X and Hospital Y). In Hospital X it was reported that each paediatric and neonatal ward also has its own ward kitchen (Table 2.10, part A).

*'The way that we do it is we have this special milk kitchen which is a highly sterile room, so we don't make feeds as they're needed, we make a batch for 24 hours, and we have a pasteurizer, so each milk that we make for any patient is pasteurised and then stored in a fridge, so that milk is good for 24 hours. So we can send that milk to wherever it's needed as long as it's then kept in a [locked] fridge, that milk is good to use' (Hospital X)*

**Table 2.10 Hospital nurse comments related to hospital milk kitchens**

A. Hospital nurse comments about hospital milk kitchens.

*'Every ward has to have a locked fridge, where the milk's collected by a member of staff from that ward, it comes direct from me [milk kitchen manager], into that fridge and then the milk's used throughout the day. We've actually got a bottle sealer now, so it's all tamper proof, so I seal it and then the milk's not opened until later on, but that's why we have the pasteurizer because it's the same principle, exactly the same as you would with your cow's milk, you wouldn't drink your milk straight from a cow, so it gives a little bit longer life because it's pasteurised. We have standard recipes, we have millions of different kinds of milks and you can mix anything with anything to that child's requirements, so that child, especially from oncology and from renal, they've got everything in that one milk. The dietician writes out [the formula recipe] but we also have standard formulas as well, where we just calculate what the feed is and what's needed and then we just calculate it, make it. Again it's pasteurised and then straight off to the ward. The pasteurizer heats the milk, it all goes into the same bottles [the prepared feeds are decanted into the same shape bottles], then into the pasteurizer which heats the milk to 68 degrees for a length of six minutes, which kills anything, any germ, any bacteria that could have gotten into that, even though we're in a very sterile room, you still have airborne bacteria which would breed in the milk and obviously milk's notorious for bacteria. So it heats it up for a certain length of time which kills anything that shouldn't be in the milk. It then very slowly cools it, so when it comes out the pasteuriser it's the exact temperature to be stored in a fridge, it's cold when it comes out and then the wards collect it and take it straight off to their fridges, where it stays.'* (Hospital X)

*'It's took a long time to get it going hasn't it? ..... 'It has, it's took a long time to perfect' (Hospital X)*

*'Monitoring of the safety of feeds prepared in this milk kitchen: 'two samples go to micro-biology everyday..... one of them is un-pasteurised sample of the same thing, and one of them is a pasteurized sample. They both go off to microbiology everyday, then I get the results back and they tell me if my pasteuriser is working, if my room's clean or whatever. If we start getting bad results back it's like, we have to swab everything because they'll be something in the room that we're getting the bacteria from. We did have an episode a few months ago and it was actually something in our dishwasher, so we had to have a different detergent for the dishwasher put in and since then, touch wood, everything has been great. Because we send the two samples off, we know that we've got a very sterile environment' (Hospital X)*

*Re labelling of feeds in Hospital X: 'we write the date and we write the time that the milk has come out of the pasteuriser because the time doesn't start from the milk's made, it starts from when the milk comes out the pasteuriser, so we write the time on that the milk come out of the pasteuriser and it's good till that time the following day. Then after that it's just got to be discarded.'* (Hospital X)

*In our hospital 'we have a milk kitchen to prepare it ....we've got a special milk kitchen which a dietician orders all the milk for all the patients on the unit, and they come up with a crate and deliver all the milk every morning, so that's why they've stopped the formulas because there's no need theoretically to.'* (Hospital Y)

*Made up formula feeds come from 'CPU, the Central Production Unit - they come [made up powdered feeds are delivered] every day, every day, we're talking about Monday to Friday now' ..... 'I have boxes of them empty and full for feeds every day, for the patients, for the milk kitchen' ..... they are delivered 'once a day, unless the dietician's phone and request some more' .... and are 'just put in the fridge in the kitchen .... and stored for up to 24 hours .... [each feed] is labelled with the patient's name, hospital number. When it comes up from the kitchen it's like a big hospital sticker.... it's a printed sticker that comes out of the like machine with all their details on it and what milk it is, when it was made up and it says, "do not use after 12 midday the next day".' If the feed is not used by the time indicated on the sticker it is reportedly 'Chucked away, poured in the sink and then the bottle's thrown in the bin' (Hospital Y)*

### 2.3.4.3 Microbial risks and concerns associated with powdered infant formula

- Safety and hygiene were perceived to be important to nurses and they were often concerned about feeding and preparation practices once infants leave the hospital and go home, although few nurses indicated that once parents left the hospital, how feeds were prepared was not their problem.

*'we can't control what parents do once they get home, all we can do is control what happens in hospital'.*

*'I suppose the only concerns you would have in the neonatal unit is ....you're not sure what they're going home to, do they sterilise the bottles properly and things, but in the hospital it's okay but then you might worry about when they go home. Because now we're getting a lot of mothers who aren't even speaking English and you just wonder how do they understand, although we use interpreters like it's a bit difficult'*

*'Once they've left the hospital it's not our problem'*

- Focus groups discussions revealed variable knowledge and awareness that PIF is not a sterile product, before and after the tin has been opened. Some nurses believed that PIF is a sterile product; others believed that once opened, the product could not be sterile (Table 2.11, part A), for example one nurse said *'It's just sterile until you take the lid off.'*
- None of the nursing auxiliary/nursery nurses and healthcare assistants in any of the focus groups had heard of *E.sakazakii*.

*'Does it live in xxxxxxxx [nearby city] [laughing]? It sounds horrible'*

*'I'm sure that's a special in Chinatown [laughing]'.*

- A small number of more experienced nurses who attended the groups reported awareness of *E.sakazakii* and also an association with *Salmonella* (Table 2.11, part B).
- Some nurses recognised the potential for microbiological risks associated with feeding babies aged less than 6 months with PIF, for example, some showed awareness that the recommendations not to prepare feeds in advance was to prevent the opportunity for microbial growth in PIF (Table 2.11, part C).

**Table 2.11 Hospital nurse perceptions of the microbiological risks associated with powdered infant formula**

	quotes
A. Perception of powdered infant formula sterility.	<p><i>'it would have to be really'</i></p> <p><i>'It's vacuum packed' ..... 'It's been sealed' .....</i></p> <p><i>'Sealed in the factory, so... are you telling us it's not [laughing]?' </i></p> <p><i>'It maybe made up in your sterile environment, as soon as you take the lid off that's it.'</i></p> <p><i>'the powder's not sterile'</i></p> <p><i>'Once opened it can't be'</i></p> <p><i>'you've got to put your fingers in to get the scoop, no matter how clean it is you always lose it and you've got to get it in'</i></p> <p><i>' as soon as you open it, you're exposing it, it's everything that's going in, aren't you?'</i></p> <p><i>'Even when the lid's on, no I agree you, it's not sterile powder'</i></p>
B. Awareness of <i>E.sakazakii</i> and/or <i>Salmonella</i> .	<p><i>'It must come from the milk somewhere'</i></p> <p><i>'the babies can be actually very sick with it and require isolation and all with Enterobacter and they try and isolate them from other babies, and it involves antibiotic therapy and everything, so you can get a very sick babies with it'</i></p> <p><i>'I'm sure I've heard of it somewhere along the lines, which is the reasons as to why they changed the way of making up the formula, which was why you couldn't make the formula up and store in advance.'</i></p>
C. Perceived risk of microbial growth from inadequate storage.	<p><i>'Of course there is .....if you don't use clean equipment, you could get bacteria, so yeah there would be more risk than breastfeeding I would imagine' 'Their immune systems are still immature. So if they get an infection they're more likely to be sick'</i></p> <p><i>'The bacteria breeding, adding the formula and leaving it standing round, and not using it straightaway'</i></p>

#### **2.3.4.4 Information provision about the safe use of powdered infant formula**

- In all focus group discussions the majority of nurses repeatedly indicated that support, discussion and information to give parents about safe use of PIF was limited. Many nurses expressed frustration at this (Table 2.12, part A).

*'We're not allowed to push it [information about bottle feeding]' ..... 'Even with a bottle feeder you can't give it' ..... 'That's dangerous isn't it?' .... 'But that's not giving people the choice is it'*

- Some nurses reported that there were occasions when they considered that giving an infant a small amount of formula would be beneficial to the infant (although not necessarily medically necessary), but they reported that they are not allowed to give information about formula or suggest feeding with formula at all.

*'even though deep down in your heart you want to say to that mum, when it's screaming, it's not been fed in 24hours, you really want to say, please can we just give it a little bit of formula or whatever, you've just got to bite your tongue.....You've got to bite your tongue and that's when you start running into problems, like you see, when their levels drop, then in special care and it's just, then their temperatures' drop and then that's when their days start to become even longer, going longer and you just think, for the sake of like a 3ml top up [with formula], just... they wouldn't get that in probably a whole day's feeding off the breast' ... 'You're fine if you've got our*

*male consultants, but if you've got our female consultant she would be standing there, "You will not give any formula milk..."*

*'But at the end of the day it's you've got to give people information and let them choose what they wish to do'*

*'I believe in individual choice' ..... 'You're not allowed to promote it at all' 'because you're supposed to promote breastfeeding, so you're not allowed to actually advertise it or promote it' (paediatric/neonatal)*

- Nurses reported they considered it important to give parents verbal information and the correct advice and also explain why certain practices are advised and why recommendations have changed. In addition, the way information is conveyed was considered important, so that parents don't feel like they are being forced into certain practices.

*'Verbal always sinks in more because they're not, they say they'll read a leaflet but they're not going to, they just chuck it in their bag. And like there's always something better to do or the baby is keeping them occupied, and as long as you'd be telling them, they've either listened or they've looked like they've listened and you can say, they've been told you can write in their notes they've been told, and that's the best you can do'*

*'I think the secret is not only to tell them, but say, "I'm not being funny, but do you know the reason why" and once you've put actually the reason behind, that is when it actually sinks in, "We have to do it this way because there was once a risk factor and I believe it could have ended up in a death". It isn't, they're not being awkward, they're actually telling you for a reason. Tell people why, don't just say, "Do this, this and this" but if you put it why the reason they say, that's what sticks with them, they think, "Ooh well I better not do that".'*

- Nurses working in SCBU/neonatal units reported that parents/mothers are always given a demonstration as to how to safely prepare and handle PIF (as well as sterilise feeding bottles/components) before they leave hospital. This was less commonplace in paediatrics, but it was reported if (for example) it was a 'new mum' (Table 2.12, part C).

*'It's done routinely on every discharge.....a full mixed demonstration....' (Neonatal/SCBU)*

*'Unless of course it was a new mum .....and maybe they're giving up breastfeeding, and then we would have teach them how to make a formula feeds, so that would be, when they in for a little time.' ..... 'But that wouldn't be on a regular basis' (Paediatrics)*

*'we never sort of teach mothers what to do, we used to years ago, we used to do demonstrations of how to make feeds..... we'd take mums into the nursery and say to the mothers in the afternoon "come up", and they sit in like a circle and you would have everything to show them, but we just don't now, it's all breast now. We don't do anything do we?' 'It's a shame really isn't it?' 'Yeah, they have a leaflet and the midwives when they do a discharge will go through that leaflet with them, but us we don't, do we?' 'I think it's wrong' 'I know we haven't got the time but I still think they should show patients..... because you have like young girls coming in and if they haven't got a parent, if they haven't got their mum around or a Nan around to help them, they've got nobody you know, it is a bit unfair for the young girls' 'Some haven't got a clue' (Maternity)*

- Nurses reported that they did not tell parents about the specific names of microorganisms, but would inform about ‘general infection’. Nurses were concerned that parents sometimes were overloaded with information about different subjects, of which bottle feeding was not always a priority. The most important messages for ensuring safety considered by nurses include the following:

*‘Make them as you need’*

*‘Boiled water cooled before adding the powder’*

*‘Let the boiled water cool before adding the powder’*

*‘Washing your hands, you know mums normally change the baby’s nappy and then they go up there to feed and you’re like, “No, wash your hands, you’ve touched a nappy wash your hands”’*

*‘A clean surface’*

*‘I suppose you tell them about general infection but you don’t use the named organisms’*

*‘You can sometimes overload them with information, there’s so much to tell them and if you go down the line of starting to tell them about that, they’ll never take the baby home [laughing].’*

- Nurses reported they considered it important to give parents written information about bottle feeding – however, in many cases they were not now permitted to do so – especially to mothers breastfeeding when they leave hospital. Provision of written information was variable between hospitals, although nurses most often reported the photocopied UNICEF sterilisation sheet as being the information they would be most likely to give bottle feeding parents (if anything). Some nurses reported that the UNICEF sheet was given to bottle feeding parents in the Bounty Pack. It was also reported that in the past all parents used to receive branded PIF leaflets from PIF companies in the Bounty pack, however, now such information was not allowed (Table 2.12, part D).

*‘We’re not even allowed the leaflets for bottle feeding anymore’ .....*

*‘I don’t think we have a choice, because it used to be the Bounty Bags, the new mums had all that information but now everything to do with bottle feeding was taken out of it and we’re not allowed at all.’*

- Paediatric and neonatal nurses reported they frequently have to advise about PIF handling and preparation issues that they consider the health visitors and midwives should have already addressed. Nurses also considered that as midwives are reportedly understaffed, this made it difficult for them pass on information to parents.

*‘They probably do but sometimes the parents don’t actually take it all in, so they come back to you and they say, “Can you tell me that again” and then you have to go through it more simply with them’*

[whether midwives provide enough information about formula feeding to parents]

*‘Probably not now because they’re so under staffed and so many patients, it’s very difficult to find the time’*

- Nurses also believed that information about formula feeding was provided to mothers in the antenatal period, six weeks after birth when a drop in the breastfeeding rate is reported.

*‘Although I think a lot is discussed now at the parent craft classes, and the antenatal period’*



*'there's quite a drop in breastfeeding about six weeks post delivery, you know it would be the health visitors at that stage'*

- Nurses reported that some parents intended to implement PIF practices their mothers taught them. However, given that recommended PIF practices have changed in recent years, such information may not be in line with current recommendations which may have implications for safety.

*'Because one mum went home the other week and she said, she'd learn off her mum, I said, "But it's changed now", she said, "Oh has it?", so I give her a leaflet and explained, she was just going to listen to her mum, but her mum from years ago'*

**Table 2.12 Hospital nurse comments related to provision of information about safe use of powdered infant formula**

	Quotes
A. Hospital nurses provision of information about powdered infant formula.	<p><i>'I think the only time we can really discuss it is when the mum either from the very beginning has decided she's going to bottle feed, or has decided and her heart set on changing from breastfeeding to bottle feeding, but even then you've got to discuss everything, from the beginning of breastfeeding to the point that they're up to and then discuss what help and what advice we can give them to continue and try and discuss like their problems before even going to like, "Okay what bottles do you want now?" But if a mum comes up and from the very beginning she says that she's bottle feeding then we can start discussing things like, "Well have you got bottles at home, have you got a steriliser? Do you know which way to make the formula up?" that type of thing, and then we can give them some bottle feeding leaflets. But until then we can't say, we're not even really supposed to say, "Are you breast or bottle feeding?" They're supposed to tell you.'</i></p> <p><i>'We're not even allowed the leaflets for bottle feeding anymore' ..... 'We had to fight for ours... I think we just thought, if they're adamant they're bottle feeding then we can just give them a little bit of advice, but again, there's still more information on the ward on breastfeeding than what there is on bottle feeding.'</i></p> <p><i>'A couple of weeks ago it was 'breastfeeding week' so .....you have to do your boards and things, and you're allowed to do it for breastfeeding week, but I couldn't do it for like a formula, really honestly I would have my head in my hands.'</i></p>
B. Importance of providing the correct advice to parents and reasons why powdered infant formula recommendations have changed.	<p><i>'And some of them don't speak English, so it's quite hard then'</i></p> <p><i>'I think as long as you advise the parents on how to do it, or how they should be doing it, whatever they're going to do, when they get home...'</i></p> <p><i>'Of course our hands are tied as well because we can only explain but like in their terms, on their level, we're told in a sense whatever is, the up to date method then we have to put that across to them but in a level so that they understand. Even if you do bring up in, like a joking manner, I know years ago you used to make them all up and leave them and you were done for the day, but we're not like that now, you'd have to be up... Just talk to them on their level, so that they can understand but we can't, as much as sometimes we want to say, "Well we know when you get home you're not going to do the things that we've told you to do, but our hands are tied in the fact that it might be one week we're telling somebody something, but two weeks later it could have changed, because we have to do exactly what, information we're given". ..... 'But then that's when you say, the information has changed because there's obviously been an incident and that's the only way they would change it.....something horrible must have happened somewhere, and that's why it's been changed, it's not to be awkward...'</i></p> <p><i>'Oh yeah that's what I'm saying, we do say that, but we do get the women who just come back at you and go, "I done it five year ago, never done my kids any harm". You can tell them everything you're supposed to tell them, you can give them the information, they can give them like an example of an incident that could have occurred or could occur which is the reason why they've changed all '</i></p>

**Table 2.12 continued**

	Hospital nurse quotes
<p>(continued)</p> <p>B. Importance of providing the correct advice to parents and reasons why powdered infant formula recommendations have changed</p>	<p><i>'You think, sometimes we're too forceful because then they come back and "They're making me do this, they're making me do that".'</i> <i>'Nobody makes you do anything, you give people the information and allow them to choose, but if you don't give them the correct information and the reasons behind the information then really...'</i></p> <p><i>these guidelines and all the information and everything, and then they just come up and they hit you with something that you just say...?</i></p> <p><i>No, but then you say to them, "You've just been very lucky then, that's all I can say, because Gastroenteritis in child can kill, and that's what happens when you don't wash your hands or you don't do the job properly", that's what you say, "well I'm very surprised and you've been very lucky then because I have seen cases where they haven't listened". Don't let them get away with that, throw one back at them, say, "You haven't dealt with a sick child".'</i></p>
<p>C. Demonstrations to show how to prepare powdered infant formula.</p>	<p><i>'there's always a feeding demonstration before the mums go home... there's also written information given, special leaflets for bottle feeding and things, so they get verbal and written'</i> and this happens <i>'Usually at their bed or just in the ward'</i> (Neonatal/SCBU)</p> <p><i>'In addition to providing a demonstration some nurses considered it important to 'writing everything down and [provide them with] written information so that they have something to refer to if they forget. There have been a couple of occasions when mothers have taken the teats from the steriliser and rinsed them under the cold tap [laughing]...because they don't like babies to taste [e.g. cold water sterilising solution]'</i> (Neonatal/SCBU)</p> <p>A maternity nurse reported <i>'We used to make them up for demonstrations, but now we don't we just talk through it all because we don't have any milk to do any demonstrations with and there's nowhere to take them. You'd have to do it at the bed and bring the kettle and... [because of] ...health and safety. We didn't have the sterile water before, we used to just show them with the kettle, we used to just disguise tins of smash by putting it in an SMA tin [laughing].'</i></p>
<p>D. Provision of written information to parents about bottle feeding/powdered infant formula preparation, handling and storage.</p>	<p><i>'they get a leaflet, they get a pack of three different leaflets, things on cot death, and either, we've got two boxes with two different packs made up and one with the bottle feeding leaflet in and ones with the breastfeeding and every mum gets one, regardless of which way she's feeding on discharge'</i></p> <p><i>'It's important that they get it. As I say they do get a sheet then that tells them how to prepare the feed and how to sterilise all their equipment'</i></p>

#### **2.3.4.5 Powdered infant formula policy and the Baby Friendly Initiative**

- Cumulatively, in all departments, breast feeding is a priority and 'encouraged' as soon as infants are born. Policies for breast feeding are present in hospitals and based upon the UNICEF Baby Friendly Initiative. This policy primarily affects staff that have contact with breast feeding women: midwives, healthcare assistants and health visitors, paediatric and neonatal nurses and all medical staff.
- Nurses in all focus groups from all hospitals reported variable opinions and attitudes towards the implementation and conformance to the Baby Friendly Initiative.

*'I think it has good points and bad points to be honest'*

- The majority of nurses, who were supportive of the need for breast feeding, believed the Baby Friendly Initiative was '*too extreme*' and '*detrimental*' to bottle feeders. Most nurses (particularly from paediatrics and neonatal/SCBU) reported that they believed it was important for all mothers to have a free choice with regards to her chosen method of infant feeding, and that all mothers should be provided with all the information they needed to

make informed choices including information about PIF, not just breast feeding. Nurses working in paediatrics/neonatal/SCBU indicated that they believed that the method of infant feeding should be the parent's choice, and breastfeeding was strongly encouraged in maternity departments.

*'I think the Baby Friendly Initiative, as much as I support breastfeeding, is quite detrimental.'*

*'it's like well if you don't breast, we don't want to know you, and that's not fair'.....'and they're pushing and pushing the breastfeeding'*

*'whilst it's great and try and support mums [with breastfeeding] ...by shoving it down their throat and it not working...'*

*'They're trying to push the breastfeeding, but a lot of mums aren't having any of it, and we believe in freedom of choice don't we really'. (Paediatrics)*

*'It's the parent's choice, we don't influence them anyway' (Paediatrics)*

*'It's more influenced on maternity I think than ours' (Paediatrics)*

*'They've had the mothers in tears, the midwife saying "go onto breast feed....I think a lot of them feel pressured, they think they're doing the wrong thing' (Paediatrics/Neonatal)*

- All nurses reported that as a result of the Baby Friendly Initiative they now *'promote breast feeding more than they used to'*. Furthermore, nurses reported they risked having their *'heads chopped off'* by their managers if they gave breast feeding mothers information about PIF. They reported *'sometimes you just have to bite your tongue'* not to offer a small top up of formula when a mother is struggling to breast feed and her infant won't stop screaming. Formula feeds are only allowed to be offered in hospital, according to the Initiative, if medically advised. Nurses reported this as being frequently influenced by the consultant working at the time, some of whom will avoid giving formula milk unless as a last resort.

*'If a mother is breastfeeding or intending to breastfeed information about powdered infant formula is not provided: 'you're only allowed to [talk about formula feeding] if it's medical intervention. We have somebody medical has to say "You need to top up with SMA". That's Baby Friendly as well, you're not allowed to' ..... 'They [parents] would have to ask it [formula to feed their baby]'*

- Nurses from 'Baby Friendly' accredited hospitals reported that mothers have to sign consent *'for their baby to receive supplementation'* i.e. formula when not medically advised.
- One of the requirements for implementation of the Baby Friendly Initiative is to have no formula, branded products, branded items or posters advocating recommended PIF practices on view in the wards (all departments). This was perceived by nurses to be extreme for staff to *'hide'* such items. Despite this, nurses reported that they trusted formula manufacturers as providers of information about PIF.

*'we are promoting breastfeeding more, when we had the Baby Friendly, when it started you know your formula feeds are not in view of the parents, it's all kept away and when you're going to get the bottle are they seeing anything. There are no posters or anything, we're not allowed to promote a specific feed' ..... 'We're not even allowed to use a pen that says SMA or anything, and [re the milk companies taking them away for weekends], we're not allowed to do that now [laughing].'*

*‘the Breastfeeding Co-ordinator asked me to remove milk from our middle bay where we have all our babies, and I said, “No”, because I said, “We don’t have the proper storage, all babies are in there, you’re running around and you don’t have time to walk down to the corridor to the store”, and I said, “I really am sure it doesn’t have that much of an effect on whether or not they’re going to change”. It’s maybe wrong of me but I thought, no.’*

- Nurses reported the impact the Baby Friendly Initiative has had on their role in the hospital and in the hospital where they work:

*‘On a drip for two days, mothers stressed out crying, feeling like they’re the bad one ..... it’s getting that happy medium’.*

*‘I suppose you’re getting a lot more babies with low sugars, high belly ribbons, dehydrated...’*

*‘I suppose the fact that the formula feeds now aren’t as evident, they’d used to be set out and you just helped yourself. They only do bottle feeding demonstrations to bottle feeders, not breast feeders’*

- None of the nurses in the focus groups reported an infant feeding policy for their ward/hospital with regards to feeding or preparation and storage with infant formula. A nurse from one hospital reported that there was a written procedure for sterilisation methods and making up and storing powdered formula feeds. Nurses in all hospitals represented indicated that policies were in place for breast feeding.

*‘a written procedure on sterilisation and making up of feeds’ ..... ‘they cover ..... the storage of all milks and also sterilisation ....the storage of breast milk, frozen breast milk, defrosting’*

(Paediatrics/Neonatal)

#### **2.3.4.6 Preparation, handling and storage recommendations**

- Nurses in different areas of the UK had variable reported knowledge of current recommendations for preparation, handling and storage of PIF.
- Nurses reported that they were often asked why the recommendations had changed and why should they change their practices which they may have implemented for a previous infant.

*‘A lot of mummies would “How with my last child I could have made them all up and now I can’t?”’*

*‘we’re supposed to be explaining to them about making up like bottles for every individual feed, but if you’ve got a mum who’s got like a 7 or 8 year old and them have come in and they have a baby and they go, “Oh I done it years ago, it never done him any harm” and they’ll just go ahead and they’ll do and they’ll rack them up in the fridge’*

- Some nurses thought that the recommendations to prepare one feed up at a time were realistically unachievable for some parents.

*‘But thinking practically, my first job was looking after triplets at home and you made up the bottles for 12 hours. What do you do in that situation you just get up at 3 o’clock in the morning, 4 o’clock, 5 o’clock they wake up, so it can be difficult, if it was you personally. But we obviously tell them that they have to adhere to the guidelines’.*

*'Well I think it is yes, because even if they're away from home, they can still bring their bottle of sterile water with them and if you explain and give them enough information and the same likewise at night time'*

- Nurses also recalled occasions when they had seen parents handling/storing powdered infant feeds using practices that were contrary to the recommendations. Nurses also recalled observing parents who attempted to achieve the recommended practices.

*'At our last ward meeting some of the girls were identifying that parents were bringing in a whole load of readymade bottles in from home and we had to say, "Sorry, you can't use them, you have to chuck them out"..... they had them in their bag, like their baby bag with them and the baby was admitted and they had three or four feeds in there..... I suppose they thought, "Right I've a hospital appointment, I'll stick a couple of bottles in" ..... 'we do tell them to keep their powder and the water separate and just when you're about to feed the baby mix the two together. They are told that'. ..... 'All you can do at the end of the day is give advice, and as long as you've given the correct advice'*

*'I was sitting in the Nightcare Café the other and there was a girl with a screaming baby, like she was an older mum, maybe 40 or something and she had a flask with her boiled water, she had her little plastic tub with a scoop, she had the teat everything, she got everything out, the baby's screaming all the time, she was frantic. The mother was harassed, she undone the teat, put it down on the table, she would have been better having brought it readymade.'*

*'They make like six bottles for 24 hours and... make them for through the night and that, there's no way I'm getting up at 3 in the morning and putting on with the kettle ...'*

- Many nurses demonstrated knowledge of the new recommended PIF preparation, handling and storage practices; however, some recognised the difficulties parents may experience in implementation.

*'They're not supposed to make them in advance now'*

*'if you're making up all your feeds, if like in the old days where they'd make up all their feeds, they'd probably make them all up, leave them for a while until they were fully cooled and then put them in the fridge.' ..... , 'Yeah that's right, I used to do that with mine' .... 'They've stopped that because that case of meningitis wasn't it? And they stopped making up them for 24hours now, you're only mean to make one as you go'*

*'that's the advice we're giving to the parents going home as well, freshly made up'*

*'I certainly say never ever pre-boil a kettle that's been boiled before. .... We also say as well, once the kettle's boiled leave it for...leave it for about a half an hour 45 minutes'*

*'It's possible, but it's difficult isn't it?' .... 'Just the inconvenience really; people are ignorant, they don't realise, it's not their, their lack of education'*

- Many nurses indicated that to avoid preparation of reconstituted feeds in advance of use, that they suggested that parents prepare the boiled water in a prepared feeding bottle and just add the powder at the time of feeding (even though the boiled water is likely to be cold/ambient temperature).

*'They're not supposed to make them in advance now'..... You know they used to, they make the bottles' ..... 'but you can have your boiled water in the room and all you have to do is put the powder in. I can't see what the problem is with that.'*

*'but they do have a sterile bottle with boiled in through the night, and that will not go off' ....*  
*'you can still sterilise a bottle and put boiled water and leave it on the side all the day and it's not going to come to any harm if it's got the lid on, so really I don't think that's a typical task, all you've got to do is pick up one bottle and mix it as and when you need it. '*

#### **2.3.4.7 Training and information sources for nurses**

- Nurses reported variable methods/training routes to achieve their current nursing position – some achieved Nursing NVQ levels 2 and 3, others trained as a general nurse, midwife and then neonatal nurse, while others reported 'general experience'. Most reported on the job training and 'we just train each other.'
- Many nurses indicated that in the past, formula reps used to be a useful source of information to them about PIF. All nurses reported not having much, if any, contact with them now.

*'Not so much now, they don't allow them in [laughing] only a special license'*  
*'the milk companies, the bottle feeding ones, no we weren't allowed to use them, we had to get rid of them all'*

*'They're [formula companies] not allowed to [give us information], we're not allowed to have anything that says SMA or Cow & Gate or anything'*

- For hospital X milk kitchen, the milk kitchen manager indicated that unless specific training had been obtained there was restricted access to the milk kitchen itself.
- Although no formal training had been received, paediatric and neonatal nurses in one hospital indicated that information about the latest PIF preparation, handling and storage recommendations had reached them (even if not as formal training).

*'Unless you've had a proper training programme and I've signed it off on training, unless you've had these and I've actually signed you off as competent, you're not allowed to go in. We have a file and we do updated training every year, so every member of staff that uses the kitchen has to have had a full training programme with myself.'*

*'We were told that you can't premix...there had been an incident.....we then all got informed about it, which is why we had to change the way were to advise mums about the way to make bottles up when they went home.'*

- Some nurses indicated they are never given training about issues related to PIF, while others recalled their only training about PIF was when they received their initial nursing training 'many years ago'. Other nurses said that they knew if new information was available that it would be recorded in a file in a location available to all staff, so it was up to the individual to keep up to date 'if things change'.

*'I suppose when we trained' 'years ago we did, yeah'*  
*[updated training about powdered infant formula] 'Not at all'*

*'If there's any new research then we have a hot file don't we and it's all in there if things change..... It's in the staff room for everyone, for all the staff to look at' .... 'it's up to you if you open it and look at it'*

## 2.3.5 NHS midwives (hospital and community) – cumulative focus group findings

### 2.3.4.1 Roles and responsibilities

- All hospital and community midwives in focus groups perceived themselves to be the main and most influential health professional that has contact with prospective mothers during pregnancy and in the first weeks after the birth.
- First contact with prospective mothers was reported to be with the community midwife, usually in the 8-10<sup>th</sup> week of pregnancy and then usually meeting with first time mothers about ten times and second (or more) time mothers 6-7 times before the birth. Usually the first visit (during pregnancy) was reported to be in the mothers' home and subsequent contact may be in the home or in clinics or parentcraft classes. Frequency of visits was often rated according to whether they were rated as a low or high risk pregnancy.

*'It depends whether they're a high or low risk pregnancy, we would assess that at the first visit. If they have a medical problem or a previous complicated delivery, we might probably see them twice more, but really 16 weeks, 25, 28, 31, 34, 36, 38 40, so nine to 10.' .... 'That's the minimum' .... 'There's the NICE guidelines but if they've had babies before, cut out the 25 and the 31 and the 40 weeks'*

- After discharge from hospital, the community midwife reportedly makes the first home visit within 24 hours. Most postnatal visits were reported to occur in the home. Frequency and duration of visits varied between Trusts and was also variable between mothers and was based on needs assessment. Midwives reported that breast feeders usually needed increased numbers of home visits and support.

*'First time mums we go for the first few days every day, and then we tend to say 'we'll leave it two or three days now but if you need us ring us and we can come back'. Obviously with the breast feeders we're there, we live there really!'*

*'Unless there's major problems with the partner, we're not allowed to go into the home; we deal with them at the clinics (postnatal visits)'*

- Midwives reported infrequent meetings with health visitors however all of the health visitors are reportedly linked to GP surgeries and linked to midwives, so patient information gets passed over. Some health visitors reported that feeding is not a main topic of discussion, unless there are major problems.

*'Meetings with the health visitor about once a month just in case there's any issues with anybody that you want to discuss or you've got any worries or anything like that. Don't really talk about feeding unless they've had severe problems with feeding'*

*'Usually most health visitors are linked up with the midwives in the surgeries, so you know your pregnant mums, you know your vulnerable, anybody you've got concerns about, they've been involved because the health visitors have to make contact with the woman antenatally, so they should have met them at least once. And then we would hand them over, "Mrs Blog's is breast feeding, bottle feeding, no problems, lots of problems".'*

- Midwives reported that they did perceive their role to include providing information about infant feeding. However some midwives were more focussed on promotion of breastfeeding, whilst others felt that an open choice of feeding was better (what is best for other and infant). Other midwives strongly believed that bottle feeding mothers should be voluntarily given as much support and information about feeding with PIF as the breastfeeders.

*'breastfeeding should be encouraged from when they're born'*

*'unless they ask, but as we said right at the beginning, our role is to promote the best and the best with the knowledge that we've got is breast feeding. So you promote the benefits from the maternal point of view as well as the benefits from the people point of view'*

*'I think it should be' ... 'I think we should be' .... 'I think if they're bottle feeding we should be' ... 'We put so much effort into telling them how to breast feed and how to do this and how to do that, and then as soon as they want to bottle feed we're like 'oh there's the information, off you go'.' ..... 'And there's so many things that can go wrong with the bottle feeding like giving too much powder or too little powder' ..... 'They deserve the same treatment as anybody who's breast feeding' .... 'Otherwise you alienate them don't you? Because they deserve the same information, why should they be segregated?'*

#### **2.3.4.2 Self-reported practices: preparation, handling and storage of formula milk**

- In hospital, midwives reported they are never involved in preparation and handling of PIF as only the RTU formula is used on the wards – this was considered to be a straightforward method for feeding with formula. Alternatively, midwives reported that infants were occasionally fed using a cup or syringe. They reported that they encounter parents who have problems going from use of RTU formula in hospital to having to make the powdered formula feeds up when they arrive home.

*'No cartons just the glass bottles' ..... 'Which are stored 'in the milk cupboard.....in a locked cupboard'*

*'for bottle feeding, they're just using pre-packed'*

*'It's pretty straightforward really' 'It takes the hassle out of making up a feed doesn't it?'*

*'What I've found is some people in certain areas will take the glass bottles home and the teats and you go there the next day and they've sterilised them. And we always tell them 'don't take any of this milk home now, you can't use it again' because of course once it's opened you've got to use it within an hour. And I've seen them in the steriliser and I'm like 'no''*

*'On the maternity ward, other than breastfeeding and feeding using the RTU glass bottles, infants are fed using 'sometimes in a cup or in a syringe if we're just topping up a breast feeder or something, 5mls'*

- Midwives reported that the RTU formula feeds could be used within 1-2 hours of opening. It was reported that usually it was the mother's responsibility to monitor this length of time (midwives would be too busy).

*'Two hours' .... 'An hour' .... 'We say one hour'*



*'Probably the mums' .... 'midwives are so busy really, they wouldn't really....' ..... 'They're [the mums are] given that information when they start off'*

- It was reported that sometimes infants required RTU feeds to be warmed before feeding. The method reportedly used to achieve this was immersing an unopened RTU formula bottle in a jug of hot water. Nursing staff or midwives reportedly implemented this practice (not the mothers).

*'Sometimes if they don't take it very well.....awkward feeders' .... 'You have to get it a bit warmer but they don't tend to do it' ..... 'We usually do it for them....because they can't have hot water on the wards. We just put it in some warm water.' .... 'Unopened like that, and then take it to them when it's warmed.... for a few minutes'*

Recording of such warming practices was reported *'whoever did it would write in the notes that the feed was warmed and taken'*

#### **2.3.4.3 Microbial risks associated with powdered infant formula**

- Some midwives believed that PIF is not sterile once the seal of the tin has been broken; some believed that it is not sterile when the seal is intact.

*'As soon as the foil is broken it's not is it? If the lids been off and their hands have been in it and I don't know what'*

*'I don't think it is [sterile]'*

*'It can't be can it [sterile]?''*

*'the whole thing about making up, making up as you need them, I thought that's why that came in because they found bacteria'*

*'There's a bacteria in it and as soon as it mixes with the water then they start to grow..... and even like a fridge temperature isn't cold enough apparently to kill that bacteria'*

*'Use the made up formula in your breast. Sorry.'*

- Midwives reported they thought that the majority of parents believe that it is a sterile product.

*'I think they often think it is sterile'*

*'I think they do because the bottles sterile I think that's just the mindset you're in, everything you're doing is.'*

*[do they think its sterile product ?] 'No, just clean' ..... 'I've never thought about it actually' .....*

*'Once it's opened it's not going to be sterile' ..... 'It can't be sterile once it's opened'*

*'No [i don't think its sterile before the container has been opened], I think it's prepared in huge batches on factories. [laughs] it is isn't it?' ..... 'It must be done under clean procedures'*

*'I've never really thought about it.'*

*'Well, you find things anyway' ..... 'Bugs'*

- One midwife reported that she perceived the microbiological risk of the feed to be associated with the method of preparation and hygiene.

*'I think it depends on the making up of it and everything, the hygiene, if they're doing it properly. I think it's more like you said the hygiene of it rather than, it depends if they've had that bottle there for three days and then decided to give it to them.'*

- Limited awareness of *Enterobacter sakazakii* was determined in both midwife focus groups. Two midwives reported recollection of an association with *Salmonella*.

*'Good grief!' [All laugh].*

*'Is it a Japanese name?'*

*'No. the first bit yes, but no sakazakii' ..... 'Any cousin to coxsackie?'*

*[have they heard of E.sakazakii] No [all agree]. 'No' [all agree]*

*[Salmonella association] 'That it's one of the bacteria that can grow in it'*

*'I've heard of it'*

#### **2.3.4.4 Information provision**

##### *Antenatal information provision*

- Usually no information about PIF is given to mothers during pregnancy from community midwives, unless the prospective mother brings the subject up/asks the midwife questions about it. Even if a mother tells the midwife she intends to bottle feed using PIF, the midwife has to give her a 20 minute talk (under the 'Baby Friendly rules') about the benefits of breast feeding (which the mother has to sign a declaration to evidence that she has been given the information). Individual midwives admitted that they did sometimes discuss formula feeding before the birth, if the mother is adamant she intends to formula feed. A midwife from one hospital reported that they do ask about feeding intention, however, mothers are still given breast feeding information after either response.

*'We just say about breast feeding as well, we don't do bottle feeding at all.'*

*'Well we mention breast feeding, well we give them breast feeding information, a booklet.'*

*'And that's the breast feeding talk and we give them a leaflet then and we've got to sign it all off with them, it takes about twenty minutes'*

*'In XXXXXX they do ask at 36 weeks in the birth plan, how do you intend to feed your baby? And then they give the information, but if they intend to bottle feed you still give them the breast feeding information'*

- Parentcraft classes were reportedly offered to all prospective parents at approximately weeks 28/32 of pregnancy onwards while the duration of the class varied between trusts. Some trusts ran classes that were 1-2 hours each week for six weeks, others offered one or two day classes (one of which would be focussed on breast feeding). No information about PIF is reportedly included in parentcraft classes due to the Baby Friendly Initiative as well as health and safety issues regarding boiling a kettle. Demonstrating PIF preparation was 'seen' to be promoting bottle feeding according to the Baby Friendly Initiative, and therefore not allowed.

*'We invite them to parent craft classes, that's the first time, usually after 28 weeks and that's when it would normally be discussed, but we don't physically show them how to make up feeds. We give them the leaflet and the information. But we do breast feeding workshops as well, and for those who haven't quite made their mind up what they want to do, they often come to that. And for those that definitely want to breast feed, we do those monthly'*

*'We do breast feeding workshops as well, so they come to those, that's from 32 weeks onwards and parent craft again we discuss breast feeding at parent craft' ..... 'Never formula feeding'*

[Re parent craft classes in one hospital trust – inclusion of formula?] *'No' ..... 'It's just breast feeding' ..... 'It's breast feeding or nothing'*

However another midwife (while working for a different trust reported including information of PIF preparation and cleaning/sterilisation of feeding bottles.

*'The class that I did in XXXXX, well, it was split into about a million different pieces but you talked about breast feeding and then you talked about making formula and sterilisation and that was included there but they don't do that in XXXXXX'*

- During the delivery of an infant the hospital midwives reported they are not allowed to ask how the mother is going to feed the infant, they (the midwives) have to assume the mother will breast feed. Even when mothers have indicated they intend to bottle feed using formula, hospital midwives in the hospital will still encourage them to breast feed.

(Hospital P) *We don't ask them, we're not even allowed to ask at delivery 'how are you going to feed?' ..... 'We've got to assume they're breast feeding'*

*'Are you going to breast feed?' means 'You really want to breast feed don't you?'*

(Hospital Q) *We do ask them what they want to, you know, are they breast feeding or bottle feeding? We do say those dreaded words'*

- Information provision to bottle feeding mothers in hospital was variable between hospitals/individual midwives. When some mothers and their infants are discharged from hospital the breast feeding mothers are reportedly not given any information about PIF and bottle feeding mothers are reportedly sometimes given a Bottle Feeding leaflet (DoH or WAG if available) and UNICEF information sheets instructing how to prepare a feed and/or sterilise bottles (photocopied A4 sheets of paper). Some midwives reported they usually asked bottle feeding mothers if they knew how to make up a feed etc and others reported discussing the process with mothers before discharge. They indicated that the breastfeeding mothers had considerably more support and information about breastfeeding.

*'Nothing to do with bottle feeding it's all the breast feeding leaflets'*

*'On discharge from hospital if they're bottle feeding we also just discuss it with them, we've got leaflets that we send them home with if they're definitely bottle feeding'*

*'the breast feeding mums go home with packs like that, every book about breast feeding you can imagine. And there's a number if you need us for this and a number if you need us for that, and the bottle feeders are just going 'you're bottle feeding, off you go' .... 'and support groups as well, they've got support groups' ..... 'and they've had those hours of support as well actually in the hospital when you go in to help them breast feed' .... 'It's not fair, it's not fair on them because they are treated differently really because they're not given the same time and information'*

- Midwives reported that they would like to give more information to parents about formula preparation. They reported that provision of bottle feeding information is unlikely due to 'Baby Friendly' commitments. Midwives also indicated that they believed that providing mothers with a leaflet about how to safely prepare PIF was unlikely to change the way they chose to feed their infant.

*'they're not likely to do it, the Baby Friendly now in most of the hospitals round here, they wouldn't allow that' .... 'No. The thing is it's not like one little leaflet is going to make them change their mind about the way they want to breast feed, they won't want to feed. 'It's not going to sway them if they want to breast feed' ..... 'People really want to breast feed or they really don't, if somebody really wants to breast feed one leaflet's not going to change their mind' ..... 'I think a leaflet might be okay, I think a full on discussion might undermine it a bit'.*

*'it's the freedom to be able to do it really'*

*'It needs to be more of an equal balance I suppose, doesn't it, rather than the big gap there is'*

*'I think it's too late [to give them information about formula feeding] when they're at home because they will have been at home at least one night before we go in, they need something in between' ...*

*'If they're formula feeding, they need to know how to do it before they go home'*

*'I think it should be there somewhere because if they go home and they change then they could be doing things wrong' .... 'they should have it there should they need it' ..... 'More than likely they change at three o'clock in the morning when they're delirious'*

- The majority of midwives indicated that breastfeeding mothers were not given any information about PIF – even if she asked for information about formula feeding.

*'Oh god no' .... 'If we know they're breast feeding we don't mention it' ..... 'The leaflets ready for the bottle feeders, and the leaflets ready for the breast feeders and depending how they're going home that's the information they get'*

*'I have mentioned it before. Sometimes you know they're only breast feeding them in the hospital, as soon as they go home they've got bottles waiting and most of them will tell you 'I've got formula at home just in case'. Most of them will say it to you, and if they say that to you I say to them 'well do you know how to make up the bottles properly then in case you do decide to change your mind?' Because it's better to tell them that they know than upset the child's stomach by not feeding them properly because a lot of people add the water to the formula instead of the other way round and it just doesn't work properly then'*

*'I would say to a breast feeding mum "why do you need to know? It's almost having confidence in what you're doing, and lets' worry about what might happen or not happen when the times comes' ..... 'If some women say "I'm going to breast feed for so long, but then I'm going to go back to work, and I want to know how to give formula'*

- Midwives recognised that bottle feeders are treated differently and that it isn't fair that they are not given the same time and amount of support and information as breast feeding mothers.

*'It's not fair; it's not fair on them [bottle feeders] because they are treated differently really because they're not given the same time and information'*

- Midwives reported they believed information given to parents about formula feeding was variable between midwives. Some midwives would go into considerable detail whereas others assumed parents know enough about it.
- All midwives reported knowledge and advising parents of recommended practices, such as the need to make feeds up fresh, one at a time and allow boiled water to cool for no more than 30 minutes, follow instructions on the tin etc. Midwives advised parents to use cartons of RTU formula when away from the home.

*'Just say 'prepare your area first, make sure it's clean, wash your hands before you start'.'*

*It's always got all the instructions on the tin. I always found if you follow the instructions on the tin you'll be fine*

*'I think if you prepare the feed as it's needed that's what we tell everybody' .... 'Freshly boiled water, use within half an hour, make up the feeds and use that feed then within an hour' ... 'and don't make up more than one bottle' .... 'and most of them look at you really stupid and say 'have I got to do that during the night as well?' 'yes'' ..... 'People still do make a lot of bottles' .... 'Yeah they do and it doesn't matter what you tell them' ... 'especially if they've had kids before'*

*'You wouldn't be able to tell the name but you will tell them that they can get bacteria, but they will just switch straight off'*

- All midwives agreed that *'we can give them [parents] the advice, but its up to them [parents] what they do with it'*

*'I think they listen to you, sometimes you can tell they're thinking 'go now so I can just do what I want to do' and next time you go there you just see four bottles lined up' ... 'That's the information you give them and what they do with that information is up to them' ... 'If we say that we've documented it and we're asked to do anything else they'd like to ask or they're happy' .... 'As long as it's documented' .... 'There's only so much you can do isn't there?' ... 'there's only so much you can do, you give them all the information then it's up to them at the end of the day, it's their choice'*

*'just say to them 'look, all we can do is advise you'' ..... 'Yeah as long as you've given them everything'*

*'We give them the information but they've often made their minds up [about how to feed their infant]' .... 'but sometimes, from our point of view, if we don't give them the correct information then they don't have a choice to change it. And I think it depends on the way you sell it, you don't ask them how they're going to feed, you tell them the benefits and say "we will support you", and it gives them an opportunity to think with the correct information on how you're going to feed, and then you don't want to say "well, that's not as good as".'*

*'In my opinion I think they've got to let them choose once they have the information, and then support them in which ever they do. And I don't think you should have to say "you can't bottle feed, you won't give babies any accreditation if you do. What you need to say is "If you're going to do it and you've made your mind up, let's show you how to do it properly, so that you're not putting yourself or your baby at risk".'*

- Midwives reported that they frequently observed that parents reconstituted feeds in advance of use – and would have them 'lined up in the door of the fridge'. They reported they would reiterate recommendations, even if they did not think such practices were

necessary and had not implemented the recommendations themselves when they had fed their own infant with PIF. They were aware they could be accountable to the advice they give the mother and thus would stick to the recommendations.

*'I know midwives who've said 'put it in the back of the fridge because in the door the temperatures not as constant so at the back of the fridge will be alright for the night' and I think 'oh god' ..... 'but then it comes back and I'm really worried about the repercussions of 'well the midwife told me it was fine to put it in the back of the fridge and now he's got a bad tummy'.*

*'I suppose like you say you're accountable then if something does go wrong, I suppose.'*

- Midwives reported that providing information to mothers about infant feeding could be challenging because of language barriers.

*'I actually had a Polish couple that don't speak any English and were actually using, they had brought bottles in from home but as she was trying to express to them, and I went round the corner and thought 'oh gosh she can't sterilise them'. So I had to try and explain to them and luckily they had the Polish bottle looking through it, so I found the steriliser and pointed to the page 'read that'.*

*But it can be difficult with people not from round here, communication'*

*'They can read and write, that's fine, and it's not a problem. But if you've got a lot of women who English isn't their first language, they're all written in English. Or if you have some women who have learning... the reality is, there's a lot of women with undiagnosed learning disabilities, and they're the ones that you need to...' .... 'Or mental health problems' .... '... or mental health problems, and you really need to spend a lot of time with them'*

- Midwives recalled that demonstrations of how to prepare a bottle of PIF used to happen in the past, but not in recent years. Some midwives reported that this was as a result of the Baby Friendly Initiative and doing a demonstration was reportedly seen as promotion of bottle feeding. Other midwives reported it was a result of health and safety regulations. The majority of midwives indicated that demonstrations of how to safely prepare PIF feeds did not happen. Some midwives reported that demonstrations of how to prepare infant feeds were necessary, particularly when there are language barriers.

*'Well this is the thing; four years ago they didn't have the Baby Friendly. We did it and then obviously it came in ..... and it [doing bottle feeding demos] was gone then ..... Because it's seen as promoting bottle feeding isn't it'*

*'I think it was something you did do years ago [do demonstrations]. [all agree] A midwife when you were training, you had to do it because you were teaching people and it used to be an afternoon job, demonstrate how you do something in a room full of eight women or something' .... 'The breast feeding [all parents/mums], we don't now'*

*'At one stage the nursery nurse had started giving demonstrations of how to do it but it's awkward because then you've got health and safety with having to boil a kettle and just things like that, so that got a bit awkward'*

*'if people are bottle feeding already just to make sure they know how to do it. But like I said health and safety have said if you want to boil the kettle and show them and things like that, they just don't tend to do it' ..... 'they think it's to make it baby friendlier'*

*'Sometimes I've done it with a family who can't speak English and with the interpreter there because they couldn't read the box so we had to demonstrate, demonstrate the sterilising, what to do and where to put it and stuff like that.'*

*'if we showed them wrong we'd be in big trouble wouldn't we?'*

[Do they do demos to breastfeeding Mums] *'No.' .... 'If they asked I would but not... if they asked but they don't usually'*

- Many midwives reported that they believed some mothers were afraid to talk to them about feeding their infant with PIF due to the focus on breast feeding. In addition, midwives reported that they considered too much pressure was put on mothers to breastfeed (which was perceived to be wrong) and as a consequence impeded provision of information about safe formula feeding.

*'Too much pressure's put on women to breast feed and they feel inadequate if it doesn't work. It's not their fault that it doesn't work and they feel guilty and they break their hearts when they have to give the baby a bottle and they shouldn't.'*

*'they feel put under pressure to do it really, the rest of you find the same? ..... 'think it's because we make such a fuss as well, there's always a form to sign to say that you've talked about it so everybody has to have the same speech even if they don't want to'*

*'I think they're frightened to tell you that they don't want to, they are. And then even when they're in floods of tears in the middle of the night and they'd love to give this baby a bottle but they're too frightened to actually say to you. And you were not allowed, you were thinking it personally'*

*'I do think they there's really pressure on women to breast feed.'*

*'I think because you put so much pressure on breast feeding and especially if they've started breast feeding and they've changed their minds' ..... 'Some of them are almost too afraid, they wait until they go home from hospital because they think they're going to be judged by the hospital staff. So if they go home they just say 'oh well I was breast feeding but I'm bottle feeding', they just pass over it really quickly as if so you haven't got chance to say anything' ..... 'I had a couple of women actually who would be too scared to go home from hospital because the community midwife has said 'you have to breast feed' they were really upset'*

#### **2.3.4.5 Powdered infant formula policy and the Baby Friendly Initiative**

- Midwives reported that the Baby Friendly Initiative has a massive impact upon their role. Implementation of the Initiative relies on them following a set of rules and these influence what they can tell or talk to parents/mothers about (e.g. they do not ask a mother how she intends to feed her infant or even mention PIF feeding/preparation etc).

[Impact of BF upon role as a midwife] *'Oh yes, massive amount' ... 'It's the rules what you are allowed, we're not allowed to ask 'how are you going to feed?' that's where all this has come from' .... 'You're not allowed to mention bottle feeding, that's where it all comes from.....we don't tell them [bottle feeders] anything' ... 'They do get a raw deal really, you're not allowed to tell them anything' .... 'It's not fair'*

*'Like I say, it's not fair, we should be able to give information from both sides and then say we do advocate breast feeding but it's just not fair really'*

*'I think the women have their babies, they're too frightened to say to you 'I want to do bottle feeding' and then they're not likely to succeed at breast feeding'*

*'I think for many years when they were going for Baby Friendly, we were frightened to share the information with them. But I think now that seems to have taken a bit of a back seat. I think we're much better at encouraging the women to make their own choice and then supporting them with their choice.'*

- Midwives reported they are under pressure to increase breast feeding rates – and are reminded of proportions each month from their managers *'come on girls, our numbers are flagging'*. However, the midwives reported they can only do so much; *'ultimately it is the mothers choice how she feeds her infant'*.

*It's just the rule we work by isn't it?' .... 'that's how it is' ..... 'Make sure we get more numbers this month girls, come on now, our numbers are flagging' ..... 'Well it's like recruiting isn't it? You're recruiting people'*

- One midwife described the impact of the Baby Friendly Initiative on her role as *'It takes away your professional judgement sometimes – as you are a bit like a puppet saying what you've been told you're allowed to say'*.

- The impact of implementation of the 'Baby Friendly rules' was reported by midwives to put pressure on mothers and prevents midwives from providing information that they may want to provide to parents about PIF feeding.

*'I think it's too much pressure to put on the women, and like I said they feel like a failure then because they can't do it. Because they can have all the will in the world but if their baby won't go on and won't do it then there's only so much we can do to help them'*

*And it is a bit, if they say 'what about bottle feeding?' you go [stammers] 'sorry I can't recommend and I can't, I can't really it's up to you. All I can say is these are the benefits of breast feeding and you make your own choice'*

*'the information sheets have had the bottle feeding information removed, and they're formula adverts. At one time we used to give them in the Bounty Packs, we stopped giving them for a while because they had milk product adverts in...' ..... 'now we're using the Bounty packs again because they've taken the milk product information out. But if the women ask you, we'll give them it but it's not actually in their pack' ..... 'It was because of the Baby Friendly Initiative'*

- Midwives working in one hospital reported that since their management has changed in the past few years, the push for 'Baby Friendly' accreditation has reduced. This was reportedly perceived as a positive thing as now they support mothers in whatever feeding method they choose.

*'There doesn't seem to be the push to get the accreditation. We still don't know, we're midwives but we're not dictated to as to what information we can give the women, which we were a few years ago'*

*..... 'It was from high up within the Trust. It was from the head of Midwifery at the time .*

*[laughs]..... 'Management' ..... 'They said we must not talk to the formula reps...' ..... 'and we mustn't give the women information....' '... and the implication was that if we talk to them, we were telling them all to bottle feed and you're like "hello".' 'it was just a step too far really' ..... 'There's a different management structure now and I think people realised you cannot force*



women to breast feed just because you want accreditation. We have to support women whatever they choose’.

- Midwives from another hospital indicated their guidelines state ‘It’s not in our guidelines, our postnatal guidelines, to offer formula feed if they’re breast feeding unless it’s indicated medically.’

#### **2.3.4.6 Preparation, handling and storage recommendations**

- Midwives learned of the new recommendations from different sources. Some reported they saw the DoH/WAG leaflets and UNICEF sheets provided to hospitals to be given to parents. Others encountered the new recommendations in professional journals.

*‘It was in the journals beforehand...’*

- They also reported awareness of key new recommendations and also reported problems that they hear from parents when attempting to follow recommendations, for example when making individual feeds up at a time, waiting for the boiled water to cool when their infant is screaming, wanting its feed.

*‘that’s the thing ..... when the baby’s screaming and I’ve got to wait for the water to cool’*

- Some midwives reported recognition of why the new recommendations to not make feeds up in advance are in place. However, they reported they found it difficult telling parents not to implement practices that they themselves had used for feeds with their own children with no consequences. This related specifically to reconstituting PIF feeds in advance of feeding, especially as they believed it did not do their own children any harm.

*‘Well it’s hard to tell them that when it’s something I did myself’*

*‘it never did my kids any harm, after I finished breast feeding I bottle fed but then, I don’t know, it’s difficult. It’s not for us to really make judgment on, it’s for us to give them the information that we’re told to give and to let them get on with it’ .... ‘I was the same, I done what you done, I done the same with my children and it is difficult because you do feel like saying ‘well they’ll be alright’ but you can’t, we’ve got to give the evidence what we’re told*

*‘it’s a difficult one, because it never did my kids any harm’*

#### **2.3.4.7 Training**

- All midwives reported they rarely, if ever, received information or ‘updates’ about PIF preparation, handling and storage, however, they reported they frequently received update information about breast feeding and other health issues. They all reported they would like to be updated about PIF and importantly would like the freedom to be able to act upon it.

*‘I think regular updates about it [safe preparation and handling of powdered infant formula are needed] because you get regular updates about breast feeding, some about bottle feeding because I’ve never had children, some people have just breast fed, they don’t know how to make a bottle’*

- Training about bottle feeding and preparation and handling of PIF was frequently reported to have only taken place during midwifery training in college, which for some midwives was a number of years ago.
- Updated information about issues such as bottle feeding were reportedly obtained from professional magazines (e.g. The British Journal of Midwifery), rather than the NHS Trust that they work for.

*'Usually from professional magazines, rather than from the Trust. It will filter down through but it's usually you've found about it from the professional journals first. And then you may get it direct from the Trust.'*

## 2.4 SUMMARY OF FINDINGS

### 2.4.1. Parents

- Methods that parents reportedly implement to prepare, handle, store and feed PIF inside and outside of the home are **variable**, although all feeds were reportedly prepared with boiled water.
- Parents in all focus groups reported implementation of PIF preparation, handling and storage practices that are contrary to current recommendations for safe powdered infant formula use.
- For PIF feeding in the home, some mothers reported making up one feed at a time, others boiled the water and stored it in prepared feeding bottles at room temperature or in the fridge until required for feeding, when the powder would be added. Others reported they reconstituted enough feeds for 12-24 hours in advance and stored in the fridge until required. Very few parents reported consideration of refrigeration temperatures and none reported measurement/monitoring refrigeration temperatures.

Other mothers reported less common practices such as boiling water in a saucepan and pouring into a plastic bottle/other container stored in the fridge ready for preparation of the feed when needed.

- For PIF feeding away from the home parents reported variable practices. Some reported taking a measured quantity of boiled water in a prepared bottle, powder in a separate container (sometimes upturned in the formula bottle with water). Others reported taking an empty sterilised bottle, powder in a separate container and obtain boiled water when out and others reported taking sterilised bottles and cartons of RTU formula. Some parents reported reconstituting the feed before leaving the home and taking it with them (sometimes in a cool bag with cool packs, other times in an insulated bag to keep the feed warm and at other times in a normal bag (i.e. no cool/warm insulation).
- Most parents reported '*doing everything by the book*' for the first few weeks of preparing PIF – but found recommended practices too time consuming, resulting in '*corners being cut*'.

- Mothers who had more than one child reported they usually implemented the same infant feeding practices (if using formula) as they had for their first baby, particularly if they encountered no problems; this was particularly the case for preparation of feeds 12-24 hours in advance.
- A cumulative opinion in many parent focus groups was the need to let infants ‘*have a few germs*’ and not be ‘*too clean*’.
- Misunderstandings were determined regarding use of UHT RTU formula. Some parents believed the RTU formula to be the same as reconstituted powdered formula.
- The majority of consumers perceive themselves to be responsible for food safety during their own food preparation, but also perceive manufacturers to have responsibility for the safety of the foods that they produce.
- Many parents reported that their main source of information was the instructions on the PIF milk tin. In addition, parents’ mothers and friends were also important and influential sources of information.
- Almost all mothers (excluding those of at-risk babies) reported being given no information about PIF preparation, handling and storage during their stay in hospital for the birth of their infant. In hospital, mothers reported that midwives were more interested in encouraging breastfeeding.
- The majority of parents suggested they would have liked more information and advice from the midwives and health visitors about preparation, handling and storage of PIF.
- Overall, the majority of mothers reported a lack of information provision from NHS professionals about preparation, handling and storage of PIF; all reported a huge amount of information being available and also given to them from midwives and health visitors about breast feeding.
- Mothers perceived midwives and health visitors to be key information providers about infant health. However, a **substantial variability** in provision of information to parents about PIF feeding, preparation, handling and storage from these providers was observed by the variability in parent attitudes and beliefs regarding the adequacy of information about PIF that they received.
- Many mothers reported that when they changed from breast feeding to formula feeding they were given no information/advice by the midwife or health visitor.
- Mothers of ‘at-risk’ infants (all who had been in SCBU/neonatal or paediatric departments) reported being given information, advice and one-to-one demonstrations from paediatric/neonatal/SCBU staff regarding cleaning, sterilisation of feeding equipment and preparation of PIF feeds before their infant was discharged from hospital. Parents reported this provision of information with a positive attitude.

#### 2.4.2 Day nursery nurses

- Variable methods of preparation, storage and feeding the PIF were reported between and within nurseries.

- Methods implemented for preparation, storage and feeding of PIF were frequently led and instructed by parents, even if the nursery nurses did not believe such practices to be appropriate.
- All day nursery nurses were responsible for safe handling, reconstitution, storage and feeding of PIF to infants aged less than 6 months. Many reported misconceptions of safe storage of reconstituted powdered feeds and a lack of knowledge and awareness of microbiological issues. Many day nursery nurses believed that PIF is a sterile product.
- Few nursery nurses reported knowledge of recommended handling, preparation and storage behaviours and almost all were unaware of the current guidelines.
- Although day nursery nurses reported wanting to receive information/updates about safe handling, preparation, storage and feeding of PIF, the majority perceived that recommendations were constantly changing and difficult to keep up to date with. All reported that they were confident with the safety of their current practices and did not perceive a need for change.

### **2.4.3 Health visitors**

- Many health visitors reported they believed their role was to inform prospective mothers/new parents of the recommended guidelines based on up to date research findings – whether this be regarding breast feeding or artificial feeding. The infant feeding priority for many health visitors was to advise and encourage breast feeding.
- The frequency of health visitor contact, home visits and provision of advice to clients was commonly based on an ongoing individual assessment of need. Although standards and best practice regarding frequency and duration of visits are present for some areas/Trusts, all health visitors reported that their heavy caseload restricted their role.
- A common belief among health visitors was that there is a lot of inconsistent information and advice provided about recommended practices for handling, preparation, storage and feeding of PIF from different organisations. This resulted in many health visitors finding it confusing and difficult to know the right way of preparing and handling formula, and thus advising best practice.
- Health visitors reported that they encountered considerable confusion amongst parents regarding correct practice in the preparation of PIF feeds – particularly regarding the temperature of the boiled water. Confusion and misunderstandings were reported to have been more prevalent in recent years since the advice on infant formula has been changed and revised. This is particularly related to the recommendation to prepare one feed at a time and temperature of boiled water when mixed with the powder.
- In some areas or trusts, health visitors reported that they and other health professionals (e.g. midwives) are not ‘allowed’ to discuss artificial feeding to prospective parents. This was perceived by health visitors to be problematic, unrealistic and not practical as a large percentage of their client base bottle feed with PIF.

- Health visitors from all focus groups reported that information about PIF preparation, handling and storage is not provided to parents in antenatal/parentcraft classes.
- Some health visitors indicated that they do not discuss PIF at all unless a parent asks them about it.
- All health visitors were aware of the UNICEF Baby Friendly Initiative which was reported to impact upon their role as a provider of health information to prospective mothers/new parents. Attitudes towards the initiative were variable. Some health visitors were very much in support of the initiative, whereas others considered it an impediment to provision of important feeding information to mothers.
- Sources of up-to-date information for health visitors regarding the microbiological safety of PIF preparation were reported to be non-existent or limited. In many cases health visitors reported having to contact formula reps (even though they are officially not allowed) to get correct, current and required information to be able to answer client questions and also provide accurate, up-to-date advice.
- Many health visitors reported that by the time they make the first home visit, feeding practices are already established. Some health visitors reported observing malpractices regarding formula feeding which had not been noticed or advised upon by previous healthcare professionals.

#### **2.4.4 Hospital nurses**

- Considerable differences in the use, perceived acceptability and preparation of PIF were observed during focus group discussions between maternity departments, paediatric departments, neonatal departments and SCBU.
- Cumulatively, in all departments, breast feeding was a priority and ‘encouraged’ as soon as infants are born. Policies for breast feeding were present in hospitals and based upon the UNICEF Baby Friendly Initiative. This policy primarily affects staff that had contact with breast feeding women: midwives, healthcare assistants and health visitors, paediatric and neonatal nurses and all medical staff.
- Nurses in all focus groups from all hospitals reported variable opinions and attitudes towards the implementation and conformance to the Baby Friendly Initiative.
- The majority of nurses, who were supportive of the need for breast feeding, believed the Baby Friendly Initiative was ‘*too extreme*’ and ‘*detrimental*’ to bottle feeders.
- All nurses reported that a result of the Baby Friendly Initiative is that they now ‘*promote breast feeding more than they used to*’. Formula feeds were only allowed to be offered in hospital, according to the initiative, if medically advised.
- Overall, formula use in paediatric departments, neonatal departments and SCBUs was perceived by nurses as acceptable. All nurses from these departments recognised that breast feeding is best for infants, however did not enforce and ‘push’ this on parents as they perceived this was done so in maternity wards.

- Maternity ward nurses were considerably more supportive of the Baby Friendly Initiative and implemented policies and ‘rules’ reportedly without exception. All maternity nurses reported that they are not allowed to discuss, suggest or encourage formula feeding with mothers.
- Nurses believed health visitors and midwives were the most influential people providing information to parents about infant feeding.
- None of the nurses in focus groups reported an infant feeding policy for their ward/hospital with regards to feeding or preparation and storage with infant formula, policies were only in place for breast feeding.

#### *Maternity departments*

- On all maternity wards no PIF was allowed (unless for reasons such as religion). On such wards, mothers who formula fed could usually only use the RTU formula (in small glass bottles). Monitoring of the length of time feeds were opened was usually the responsibility of the mother.
- Nurses working on maternity wards reported they do not have the facilities for cleaning and sterilising infant feed equipment, or reconstitution of powdered milk formula feeds.

#### *Paediatric departments, neonatal departments and SCBU*

- In addition to the standard RTU glass bottles of formula, a wide variety of specialist PIF powders are used in paediatric and neonatal departments and SCBU.
- Preparation, handling and storage of specialist PIF feeds was variable between hospitals. Some hospitals have a Central Infant Feeds Unit, whereby all feeds were prepared for 24 hours use by a designated person who transports prepared feeds to required wards (or via taxi to other hospitals) where the reconstituted feeds were stored in refrigerators. Other hospitals have (in some cases in addition to the central feeds unit) kitchens on the wards where feeds were made-up by ward staff. In some cases these kitchens were designated for only preparation and storing specialist powdered feeds, in other cases the kitchens were also used for preparation of simple meals, storage of staff lunches, making staff coffees etc.
- Refrigerators for storage of reconstituted infant feeds in paediatric/neonatal/SCBU were reported by some nurses as being specifically for such feeds, others shared with other foods and even staff lunches. Some nurses reported monitoring and recording refrigerator temperatures.
- Nurses frequently reported the need to decant prepared feeds into smaller bottles or plastic cups for feeding or enteral feeding bags etc.
- In paediatric wards, some hospitals allow parents to bring the PIF used to feed the infant at home, into the hospital. In some cases such feeds are made-up in the room where the infant is ill, on other occasions the hospital requires a new, sealed tin of feed to be brought into the ward and feeds to be reconstituted in a ward kitchen by ward staff (usually nursery nurses or health care assistants).

- In some cases in paediatric wards nurses reported that parents bring in sterilised bottles for the RTU formula (in glass bottles) to be decanted into to feed the infant. In such cases cleaning and sterilising efficacy was the responsibility of the parent.
- Nurses from paediatric and neonatal departments in some hospitals, reported giving all formula feeding mothers demonstrations regarding formula preparation and sterilisation before leaving hospital.

#### **2.4.5 Hospital and community midwives**

- All hospital and community midwives in focus groups perceived themselves to be the main and most influential health professionals that have contact with prospective mothers during pregnancy and in the first weeks after the birth.
- First contact with the community midwife is usually in the 8-10<sup>th</sup> week of pregnancy and they usually meet with first time mothers about ten times and second (or more) time mothers 6-7 times before the birth. Usually the first visit (during pregnancy) is in the mothers' home and subsequent contact may be in the home or in clinics or parentcraft classes. After the birth the first home visit is within 24 hours of discharge.
- Usually no information is reportedly given to mothers about PIF during pregnancy from Community Midwives, unless the prospective mother asks for information.
- Parentcraft classes are reportedly offered to all prospective parents, however it was reported that no information about PIF is included due to the Baby Friendly Initiative as well as health and safety issues. Demonstrating preparation of PIF feeds was reportedly 'seen' to be promoting bottle feeding and therefore not allowed.
- Midwives reported that the Baby Friendly Initiative has a substantial impact upon their role, in some cases reportedly undermining professional judgement about giving PIF advice. Implementation of the Initiative relies on them following a set of rules and these influence what they can tell parents/mothers about (e.g. they do not ask a mother how she intends to feed her infant or even mention PIF feeding/preparation etc). Midwives reported they are under pressure to increase breast feeding rates.
- All midwives reported they rarely, if ever, received information or updates about PIF preparation, handling and storage, however, they reported they frequently received update information about breast feeding and other health issues. They all reported they would like to be updated about PIF and importantly would like the freedom to be able to act upon it.
- During the birth, hospital midwives reported they are not allowed to ask how the mother is going to feed the infant, they (the midwives) have to reportedly assume the mother will breast feed. Even when mothers have indicated they intend to bottle feed using formula, hospital midwives reported they will still encourage breastfeeding.
- In hospital, midwives reported they are never involved in preparation and handling of PIF as only the RTU formula is used on the wards.
- When mothers and their infants are discharged from hospital the breast feeding mothers are reportedly not given any information about PIF; bottle feeding mothers are reportedly given

a bottle feeding leaflet (if available) and UNICEF photocopied sheets instructing how to prepare a feed and sterilise bottles.

- Some midwives considered it to be unfair that bottle feeding mothers are not given the same time/support and information as breast feeding mothers.
- Many midwives reported that they believed some mothers were afraid to talk to them about feeding their infant with PIF due to the focus on breast feeding.



## CHAPTER 3

### USE OF POWDERED INFANT FORMULA INSIDE & OUTSIDE THE HOME: A QUANTITATIVE ANALYSIS OF PARENTS' BELIEFS, ATTITUDES, RISK PERCEPTIONS AND SELF-REPORTED PRACTICES.

#### 3.1 INTRODUCTION

##### 3.1.1 Background

For the majority of formula feeding parents it is their responsibility to prepare feeding bottles and reconstituted PIF to feed their infant(s), therefore, they have the best opportunity to mitigate any risk. However, in a smaller number of cases, other people may prepare and or store PIF feeds, e.g. day nursery or hospital staff, and they, also have an important role to play (see Chapter 4 and 5). Most homes represent a less structured environment than those found in healthcare establishments and there may be times, due to social or other requirements/conditions, when preparation or storage of PIF may be less than ideal.

Studies have indicated that up to 70% of consumers' refrigerator temperatures exceed the recommended  $<5^{\circ}\text{C}$  (Van Garde and Woodburn, 1987; Daniels, 2001; Johnson *et al.* 1998). This could provide conditions that allow proliferation of organisms such as *E. sakazakii* (*Cronobacter* spp), in reconstituted formula to potentially dangerous levels. In a study involving parents making children's sandwiches for consumption in school, time temperature abuse (as measured by data loggers) indicated considerable potential for microbial growth (Worsfold and Griffith, 1997). Furthermore, substantial research has found that consumers frequently implement general hygiene malpractices and take risks during normal food preparation (Redmond & Griffith, 2003a). Similar concerns regarding temperature abuse and implications of unsafe behaviours may also apply to prepared PIF. Information on how consumers perceive the risks associated with PIF as well as beliefs on how to prepare and store infant feeds, especially when outside the home environment, is needed.

In this chapter, issues about consumer beliefs, attitudes, self-reported practices related to PIF preparation and storage inside and outside of the home (identified from focus groups in Chapter 2) will be investigated quantitatively.

### **3.1.2 Aims and objectives**

The initial aim of this part of the study was to determine parents' attitudes and perceptions towards PIF behaviours. However, qualitative data informing this component of the study (Chapter 2) indicated the variability of parents' perceptions of information sources and spokespersons providing PIF preparation and handling information, therefore this was included in the quantitative part of the project.

By conducting face-to-face interviews with 200 consumers (parents bottle feeding infants with powdered formula, aged less than 6 months) in England and Wales, the more specific objectives of this part of the study include the following:

- Quantify parents' self-reported PIF preparation, handling and storage practices.
- Investigate influencing factors as to why parents implement unsafe preparation, handling and storage behaviours when dealing with PIF inside and outside of the home.
- Analyse parents' perceptions of risk, control and responsibility for themselves and for others.
- Determine parents' perceptions of information sources and methods of communication about safe preparation and use of PIF.

## **3.2 METHODS**

For an overview of the plan of methods used for collection of quantitative data from parents for this component of the study see Figure 3.1.

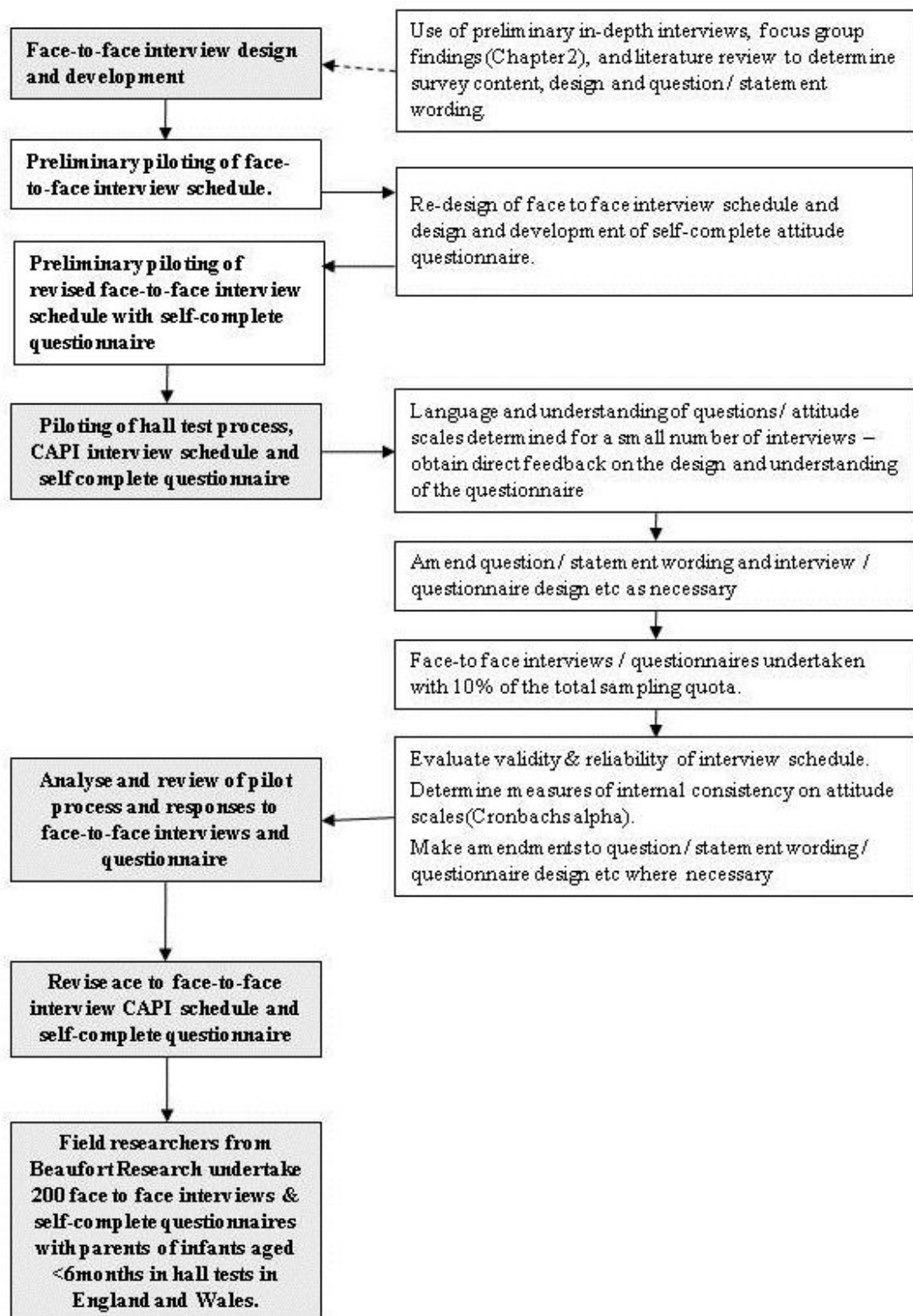
### **3.2.1 Development of the piloted face-face interview schedule**

Qualitative research with UK parents and caregivers (Chapter 2) and a review of PIF microbiological data were used to prioritise important PIF safety handling and storage issues. The interview schedule assessed self-reported behaviours, determined attitudes and perceptions towards PIF safety in the home and PIF information. A variety of question types were used including multiple choice, 5-point Likert rating scales, 10-point attitude scales, pre-coded open questions and closed questions. Stimulus materials (recent PIF interventions) from a number of sources were also included.

### **3.2.2 Ethics**

Ethical approval was obtained from the Cardiff School of Health Sciences Ethics Committee (UWIC) before implementation of this component of the study.

**Figure 3.1 Face-to-face interview plan of methods**



### 3.2.3 Data collection

All face-to-face interview fieldwork was undertaken by the field research team from a local market research agency - Beaufort Research Ltd. (Cardiff) using a Computer Assisted Interview Technique (CAPI). The CAPI method requires use of laptop computer/specialised CAPI computer which displays the interview schedule enabling respondents' replies to be directly keyed in. After each response the next relevant question is automatically displayed – if necessary, errors are indicated (Bowling, 2000). It is reported that use of CAPI enhances the quality of data collection, for example, potential errors made by interviewers (e.g. inaccurate routing) can be minimised by the use of such techniques (Bowling, 2000). Software used for CAPI allows the flow of the questionnaire to be customised, based on the answers provided, as well as information already known about the participant. In addition, the customisation allows questions to be received in a random order to avoid biases. Use of this method has been successfully utilised in a previous nationwide consumer food safety survey for the FSA (Redmond *et al.* 2005).

The content and question design of a recruitment questionnaire and face-to-face interview schedule was provided by UWIC to Beaufort Research for piloting, scripting and routing in the CAPI software (NIPO) and implementation of the main study. Fieldwork undertaken by Beaufort Research was in accordance their quality control procedures including ISO20252.

The initial plan for data collection was face-to-face interviewing in parents' homes with recruitment taking place in GP surgeries/clinics (requiring MREC and NHS approvals). Times would then be arranged for interviewers to travel to parents' homes to conduct the interview. However, after discussions with Beaufort Research, this was considered to be impractical and therefore not feasible. Using this approach may have resulted in the interview period being implemented over a considerably longer period of time – whereby the potential for recruited parents to be unavailable or reluctant to continue with the pre-arranged interview once the interviewer arrives at their home, requiring re-visits or returning to recruitment locations and starting the recruitment process again. The alternative methodology of 'hall-tests' was suggested by Beaufort Research (in which they were experienced and had used in other similar types of projects), which overcame the logistical problems of the in-home methodology and provided the same high quality face-to-face data capture method. It was suggested that using this methodology, the sample was more robust given that it was likely to be less clustered than the in-home approach.

The implementation of the hall tests involved hiring halls in the centre of Cardiff/Bristol. Recruitment was carried out by field interviewers on the street outside the venue. Criteria were

defined by the recruitment questionnaire and willing parents were brought into the hall to participate in the study.

### **3.2.3.1 Pilot testing**

Pilot testing followed recommended procedures (Breakwell *et al.* 1995) using 10% of the total sample. Initial pilot testing of the interview schedule indicated that it was too lengthy for implementation. To address this, but not lose the potential for data collection about certain topics, the interview schedule was shortened considerably and a paper based self-complete questionnaire was designed and developed (by UWIC) to be completed by all participants, in addition to the interview. the questionnaire solely consisted of attitude statements (strongly agree- strongly disagree/perceived importance) using Likert-like scales.

Hall tests for pilot face-to-face interviews using CAPI technique with self-complete questionnaires were undertaken on 17th November 2008, over a period of six hours at St. Davids Hall, Cardiff, Wales. Beaufort Research staff present for the pilot testing included a field interview manager, a technical support officer, senior quantitative researcher, four trained field researchers with laptops with CAPI software scripted for the PIF study and two field researchers on street for recruitment. The UWIC researcher also attended to make observations.

The piloting process was critically assessed for feasibility and timing, understanding of terminologies used and instructions for implementation of the on screen CAPI survey. As a result of piloting the hall test process, interviews and questionnaire it was determined that parent participation in the study took ~30 minutes which was considered and agreed to be satisfactory by Beaufort Research and UWIC.

Main amendments to the process included the need for field researchers to be briefed more clearly to only recruit parents feeding their infant (aged less than 6 months) with POWDERED infant formula – not just ready-to-use infant formula; an additional showcard was provided to field researchers to use during recruitment. To alleviate the potential for terminology misinterpretation relating to PIF preparation and use, supportive written instructions with images were developed and displayed alongside all questionnaire completion and interview implementation. Interviewer briefing notes were also refined by Beaufort Research.

Post-pilot, amendments to the CAPI schedule included refinement of the wording of some questions, inclusion of additional response options and a number of scripting issues and refining of routing programming. Amendments to the paper based self-complete questionnaire included refinement of the wording of several attitude statements to alleviate ambiguities and provision of more detailed instructions supported with corresponding images.

An initial analysis of data collected from the pilot study was undertaken using SPSS (Version 17.0) and Microsoft Excel (2007). Internal reliability was calculated for the piloted attitudinal data using Cronbachs Alpha.

The revised and final versions of the field interviewer briefing notes, recruitment questionnaire and show card, participant information sheet, consent form, supportive participant information card, CAPI interview schedule and self-complete attitude questionnaire can be found in Appendix 3.

### ***3.2.3.2 Main study data collection and analysis***

For the main study, all field researchers were provided with briefing notes (Appendix 3) and were supervised by the field manager and a specialist quantitative researcher from Beaufort Research to ensure reliability and consistency throughout.

Four hall tests were held in Cardiff at St David's Hall and The Thistle Hotel over a period of five days (including a Saturday) and then in centrally located venues in Bristol city centre, over a period of four days. Hall test venues were selected based on their proximity to shops such as Mothercare and Boots, as well as suitability for market research purposes. All hall tests were implemented in November-December, 2008.

Using the screening recruitment questionnaire and show card (see Appendix 3), parents (with infants aged less than 6 months) were recruited (on-street, outside hall test venues) to participate in the hall-tests in Bristol, England and Cardiff, Wales. Quota controls on age groups and SEG were applied and sampling was designed to obtain a representative sample of parents who feed their infant with PIF at least once a day.

Recruitment criteria included the following:

- parent of infant aged less than 6 months
- aged between 16-45 years
- feed their infants with PIF at least once a day

In addition to the quota controls on age groups and SEG, the sample aimed to achieve inclusion of 90% mothers: 10% fathers and >50% parents who exclusively feed their infant (aged 0-6 months) with PIF.

Consumer groups such as grandparents and other family members were excluded from this study due to cost and time limitations.

After recruitment, parents were provided with a participant information sheet (Appendix 3) and asked to sign the informed consent form (see end of recruitment questionnaire in Appendix 3) before being taken to the hall test. Parents were given refreshments and childcare facilities were made available when required. All parents were provided with a supportive information card (with terms of reference etc) (see Appendix 3) and the self-complete attitude questionnaire (Appendix 3) to complete. Immediately after completion of the questionnaire, field researchers implemented the CAPI interview. On completion, parents were given a £10 Boots voucher as a token of thanks for participation.

### 3.2.4 Data analysis

An analysis of interview data was undertaken using SPSS (Version 15.0) and Microsoft Excel (2007).

## 3.3 RESULTS

### 3.3.1 Sample Specification and background data (n=200)

Overall, 200 face-to-face interviews and attitude questionnaires were completed. Eighty-seven percent of respondents were female and the demographic breakdown according to age group and SEG can be seen in Table 3.1. Forty-two percent of respondents were aged 16-24 years, 46% were aged 25-34 years and 12% aged 35-45 years. It can be seen that 12% of respondents were SEG AB, 30% C1, 18% C2 and 40% DE.

**Table 3.1 Demographic breakdown of the respondent sample (n=200)**

Demographic		Socio-Economic group n (%)				Total n (%)
		AB	C1	C2	DE	
Age	16-24	6 (3.0)	14 (7.0)	12 (6.0)	51 (25.5)	83 (41.5)
	25-34	13 (6.5)	34 (17.0)	19 (8.5)	27 (13.5)	93 (46.5)
	35-45	4 (2.0)	13 (6.5)	5 (2.5)	2 (1.0)	24 (12)
Total		23 (11.5)	61 (30.5)	36 (18.0)	80 (40.0)	200 (100)

Data presented in Table 3.2 states that 21% of parents interviewed were parents of infants aged 1-2 months, 37% had infants aged 3-4 months and 42% had infants aged 5-6 months.

**Table 3.2 Age of infant fed by parent (n=200)**

Age of infant	n=200 n (%)
1 months (0-4 weeks)	22(10)
2 months (5-8 weeks)	23 (11)
3 months (9-12 weeks)	41 (21)
4 months (13-16 weeks)	32 (16)
5 months (17-20 weeks)	41 (21)
6 months (21-24 weeks)	41 (21)

Forty-six percent of parents who participated in this component of the study were on maternity leave and data presented in Table 3.3 indicate their employment status (for parents on maternity leave, working status before/after leave period was recorded).

**Table 3.3 Sample employment status (n=200)**

	Male (n=27) n (%)	Female (n=173) n (%)	Total (n=100) n (%)
Unemployed	5 (3)	31 (15)	36 (18)
Employed full time (30 hours a week or more)	15 (7)	54 (27)	69 (34)
Employed part time (less than 30 hours)	4 (2)	34 (17)	38 (19)
Full time housewife	1 (<1)	42 (21)	43 (22)
Part time housewife	0	1 (<1)	1 (<1)
Full time student	0	4 (2)	4 (2)
Part time student	0	3 (1)	3 (1)
&Refused	2 (1)	4 (2)	6 (3)

Seventy-nine percent of parents reported feeding their infant exclusively with PIF and 21% of parents reported combination feeding (breast feeding and PIF feeding).

Findings presented in Table 3.4 indicate current reported feeding practices, compared with planned practices and feeding practices implemented within the first two weeks of the infant's birth. Half of the respondents planned to breast feed, 36% planned to exclusively formula feed and a further 12% planned to use PIF in conjunction with breast feeding. The data also illustrates that more than half of parents (56%) reportedly used PIF to feed their infant within the first two weeks after the birth.



**Table 3.4 Reported current feeding method, feeding method when infant was first born (within first two weeks) and planned feeding method (n=200)**

	Current practices n=200 n (%)	Practices when infant was first born (within first two weeks)	Planned feeding practice (n=198*)
Exclusive formula feeding	158 (79)	88 (44)	72 (36)
Mostly formula feeding, partly breastfeeding	14 (7)	10 (5)	
Equal formula feeding and breastfeeding	5 (2)	8 (4)	24 (12)
Mostly breastfeeding, partly formula feeding	23 (12)	7 (3)	
Exclusive breast feeding		87 (44)	100 (50)

\*2 respondents=don't know

Cumulatively, 85% (169/200) of parents reported currently feeding their infant with PIF for 'all or most feeds' and 15% (31/200) fed infants with PIF at least once a day.

The majority 95% (191/200) of respondents' infants were born in hospital and 5% (9/200) born at home.

Data in Table 3.5 indicates that more than half (56%) of respondents were first-time parents. Less than one percent of respondents reported having at least one other child aged <1 year, 10% had at least one other child aged 1-2 years, 13% 3-4 years, 6% 5-6 years and 14% had at least one other infant aged 6 years and above.

**Table 3.5 Reported age of respondents' eldest child**

	n=200 n (%)
Not applicable – only have one child	112 (56)
Up to one year	1 (<1)
1-2 years	20 (10)
3-4	26 (13)
5-6	13 (6)
6+ years	28 (14)

The majority of respondents (44%) reportedly fed their infants 5-6 bottles of PIF each day (see Table 3.6); however, some parents (1-2%) reported feeding their infants up to 10-12 bottles a day.

**Table 3.6 Usual number of powdered infant formula feeds reportedly fed to infants (aged less than 6 months) within 24 hours**

	No. of PIF feeds <i>n</i> (%)
1	15 (8)
2	8 (4)
3	15 (8)
4	38 (19)
5	36 (18)
6	52 (26)
7	17 (8)
8	13 (6)
9	2 (1)
10	1 (<1)
12	2 (1)
No response	1 (<1)

### **3.3.2 Attitude determination: powdered infant formula preparation, handling & storage**

Cumulatively, parent attitudes towards PIF preparation & storage practices were more positive than negative. However, 24% of parents expressed overall neutral or negative attitudes suggesting that uncertainties may exist about current recommended procedures.

A significant negative correlation was identified between age group and attitudinal response ( $r=-0.224$ ;  $p<0.01$ ). This suggests that younger parents (16-24 years) have a more positive cumulative attitude to PIF safety and correct practices than older parents (35-44 years). No correlation was determined between social class and cumulative attitudinal responses ( $r=0.118$ ;  $p>0.05$ ) and no significant difference was identified between cumulative attitudinal responses and gender ( $Z=-0.923$ ;  $p>0.05$ ).

#### ***3.3.2.1 Attitudes towards microbial risks associated with powdered infant formula, perceived efficacy and other issues***

Data in Table 3.7 illustrates identification of widespread misconceptions among parents regarding the sterility of PIF and potential for pathogenic contamination. Sixty nine percent of parents believed PIF was a sterile product and 18% were unsure; 81% were unaware of PIF contamination with *Salmonella*. A significant difference ( $Z = -2.803$ ,  $p<0.01$ ) of attitudes between ‘first time parents’ and ‘parents with other children’ was identified towards perceived sterility of PIF - before the tin has been opened. More ‘parents with other children’ believed PIF is sterile before opening the tin than ‘first time parents’. Similarly, a positive correlation ( $r = 0.145$ ,  $p<0.05$ ) was determined between perceived sterility of PIF and age of infant.

Positive correlations were determined between the perceived sterility of PIF once a tin had been opened and respondent age group and SEG (see Table 3.8). Main findings included the finding that a larger proportion of parents (54%) from SEG DE believed an open tin of PIF was sterile, compared to 28% of parents from SEG AB.

The majority of parents (>94%) were confident in the safety of PIF feeds they prepared and also believed they knew all of the safety precautions necessary for making-up safe feeds. Such perceptions may impede upon potential education effects to improve safety behaviours.

Significant differences ( $p < 0.05$ ) between attitudes expressed by formula feeding parents who use PIF feeding in conjunction with breast feeding can be seen in Table 3.8. Findings suggest that a larger proportion of parents (82%) who feed their infant exclusively with PIF believe it is easy to implement all of the recommended practices every time a bottle of PIF is made-up, than parents who use PIF in conjunction with breast feeding (68%). In addition, more parents (93%) who feed PIF in conjunction with breast feeding were confident that they way they prepare PIF is safe (and will not cause their infant illness) compared to exclusive formula feeders (83%).

Significant associations ( $p < 0.05$ ) were determined between SEG and perceived ease of implementing recommended practices every time a bottle of PIF milk is made-up and perceived confidence when preparing PIF to ensure safety. Findings indicated that parents from SEG DE were more likely to agree (81%) that it is easy to implement recommended safety practices, than parents from SEG AB (71%).

The majority of parents (84%) cumulatively reported that they trusted their partner to prepare their infants PIF milk safely. However, a significant difference ( $Z = -2.263$ ,  $p < 0.05$ ) was identified between male and female respondents, whereby a larger proportion of females disagreed with the statement, indicating they did not trust their male partner to prepare their infants formula milk safely.

Forty three percent of respondents (85/200) indicated they were more careful with how they prepared infant feeds when they first started preparing formula for their infant. However, a similar portion of parents disagreed (44%), indicating they believed their current practices are equally as careful as when they started preparing formula for their infant. Significant associations between this attitude and SEG, and age group of respondents have been identified (see Table 3.8).

Overall, 70% of parents considered that formula manufacturers are ultimately responsible for the safety of PIF (see Table 3.7).

**Table 3.7 Consumer attitudes towards powdered infant formula, perceived efficacy and other issues related to powdered infant formula safety (A) (n=200)**

Attitude statement		Strongly agree/agree n (%)	Neither agree/disagree n (%)	Strongly disagree/ disagree n (%)
Microbial hazards	Once a tin of powdered infant formula has been opened the powder is not sterile (n=196).	56 (28)	67 (34)	73 (36)
	Before opening a tin of powdered infant formula the powdered milk is sterile (n=197).	138 (69)	36 (18)	21 (10)
	There is no association between <i>Salmonella</i> and powdered infant formula (n=196).	45(22)	117 (59)	34 (17)
Perceived efficacy	I think I know all of the safety precautions necessary for safe preparation and storage of powdered formula milk (n=200).	192 (95)	5 (3)	3 (2)
	It is easy to implement all of the recommended practices every time I make up a bottle of powdered formula (n=200).	157 (78)	25 (13)	18 (9)
	I am confident that the way I prepare powdered formula milk is safe (i.e. will not cause my baby illness) (n=199).	188 (94)	10 (5)	0
	I have no concerns about the safety of the made-up formula milk that I feed to my baby (n=199).	146 (73)	24 (12)	29 (14)
Other issues	I trust my partner to prepare my baby's formula milk safely (n=198)	168 (84)	11 (5)	18 (9)
	I was more careful with how I prepared my baby's feeds when I first started preparing formula for my baby, than I am now (n=200)	85 (43)	26 (13)	89 (44)
	Formula manufacturers are ultimately responsible for the safety of powdered formula milk (n=200)	140 (70)	43 (21)	17 (9)

*Percentage responses for some attitude statements may not add up to 100 due to non responses.*

**Table 3.8 Statistical difference between attitude responses (A) and gender, different age groups, SEGs, current feeding practice, first or subsequent time parents and age of baby**

♦Comparisons of responses according to gender, first or subsequent infants and current feeding practice (exclusive PIF feeding or combination PIF and breast feeding) using Mann Whitney U test statistic<sup>5</sup>.

†Comparisons of responses according to age group, SEG, age group of infant using Spearmans *rho* correlation coefficient<sup>6</sup>.

	Gender♦	Current feeding practice♦	First or subsequent infants♦	Age group†	SEG†	Age of infant†	England/Wales♦
<i>Microbial hazards</i>							
Once a tin of PIF has been opened the powder is not sterile (n=196).	-	-	-	R=0.170*	R=0.170*	-	-
Before opening a tin of PIF the powdered milk is sterile (n=197).	-	-	Z=-2.803**	-	-	R=0.145*	-
There is no association between <i>Salmonella</i> and powdered infant formula (n=196).	-	-	-	-	-	-	-
<i>Perceived efficacy</i>							
I think I know all of the safety precautions necessary for safe preparation and storage of powdered formula milk (n=200).	-	-	-	-	-	-	-
It is easy to implement all of the recommended practices every time I make up a bottle of powdered formula (n=200).	-	Z=-2.347*	-	-	R=-0.162*	-	-
I am confident that the way I prepare powdered formula milk is safe (i.e. will not cause my baby illness) (n=199).	-	Z=-1.999*	-	-	R=-0.120*	-	-
I have no concerns about the safety of the made-up formula milk that I feed to my baby (n=199).	-	Z=-1.999*	-	-	-	-	-
<i>Other issues</i>							
I trust my partner to prepare my baby's formula milk safely (n=198)	Z=-2.263*	-	-	-	-	-	-
I was more careful with how I prepared my baby's feeds when I first started preparing formula for my baby, than I am now (n=200)	-	-	-	R=0.154*	R=-0.179*	-	-
Formula manufacturers are ultimately responsible for the safety of powdered formula milk (n=200)	-	-	Z=-2.438*	-	-	-	-

\* = p<0.05; \*\* = p<0.01

<sup>5</sup> The Mann Whitney test is a non-parametric test used when a comparison of two samples is made to determine whether responses come from the same or different underlying populations (Elmes *et al.* 1995)

<sup>6</sup> Spearmans *rho* is a non parametric test used to correlate ordinal data that are related by definition (Coolican, 1999)

### ***3.3.2.2 Attitudes towards preparation, handling and storage behaviours***

The majority (98%) of parents indicated positive attitudes towards using boiled water for reconstituting PIF, although only 63% reported the water used (before boiling) was fresh from the tap (see Table 3.9). Less than 50% of parents considered measuring the cooling time between boiling the water and mixing with the PIF to be important. Attitudes indicating the perceived difficulty in judging the water temperature when adding PIF were split; however, 62% of parents considered such judgment difficult or were undecided.

The most significant attitudinal differences determined with regards to the preparation of PIF were between parents exclusively feeding with PIF and parents using PIF in conjunction with breast feeding (see Table 3.10).

A misconception identified in qualitative research (Chapter 2) was with regards to storage of reconstituted PIF and opened containers of RTU formula. Data from this part of the project indicated that 50% of parents believed reconstituted PIF could be stored for the same length of time as opened cartons of RTU infant formula.

Attitudes towards cooling practices showed that nearly three quarters (71%) of parents were happy to cool a bottle of the reconstituted PIF at room temperature. A significant difference ( $p < 0.05$ ) in responses between 'first time' and 'subsequent time' parents was identified with regards to this attitude. A larger percentage of parents (74%) feeding their infant exclusively with PIF agreed they were happy to cool made-up PIF at room temperature than parents feeding PIF in conjunction with breast feeding (60%).

Large proportions (56-64%) of parents indicated negative attitudes towards the acceptability for PIF feeds that had been prepared and stored in advance of use (Table 3.9). This may suggest that corresponding unsafe practices (contrary to current recommendations) may be commonly implemented.

Significant associations ( $p < 0.05$  and  $p < 0.01$ ) were identified between attitudinal responses towards storage and preparation of reconstituted feeds in advance of use (see Table 3.10). The most significant association ( $r = -0.182$ ,  $p < 0.01$ ) was a negative association between SEG and attitude towards the ease of making up PIF feeds at home to take away from the home and feed when needed. Findings indicated that more parents (71%) from SEG DE agreed that taking reconstituted PIF feeds out to feed away from the home was easier than making them up when out (16% disagreed), whereas 52% from SEG AB were in agreement that reconstitution of PIF in advance was easier and 43% disagree with this statement.

**Table 3.9. Consumer attitudes towards important preparation, handling and storage behaviours (B) (n=200)**

Attitude statement		Strongly agree/agree n (%)	Neither agree/ disagree n (%)	Strongly disagree/ disagree n (%)
Preparation of PIF	Measurement of the time between when the kettle has boiled and when the boiled water is added to the formula is not important (n=197)	54 (27)	48 (24)	95 (47)
	It is difficult to judge the actual temperature of water when it is mixed with the formula powder (n=194)	81 (41)	42 (21)	71 (36)
	The [boiled] water used to make up my baby's formula feeds is always fresh from the tap (n=198)	125 (63)	7 (3)	66 (33)
	Following preparation and storage instructions on tins of powdered formula is not essential (n=200)	37 (18)	21 (11)	142 (71)
	Removal of all milk debris from a used feeding bottle is always easy (n=197)	130 (65)	34 (17)	33 (16)
	All of the utensils (e.g. scoop and knife) used to measure the powdered formula are always washed and sterilised before use (n=198).	150 (75)	17 (9)	31 (15)
	It is important to always use boiled water to make up powdered formula for my baby (n=200).	196 (98)	1 (<1)	1 (<1)
Storage and Cooling	Made-up powdered formula milk can be safely stored for the same length of time as opened cartons of ready-to-use formula (n=198).	53 (27)	45 (22)	100 (50)
	I am happy to cool a made-up bottle of powdered formula milk at room temperature (n=197).	142 (71)	27 (13)	28 (14)
Preparation of PIF in advance of use.	It is acceptable to make up bottles of powdered formula milk in advance of use (n=198).	116 (58)	30 (15)	52 (26)
	It is difficult to always make fresh bottles of powdered formula to feed my baby (n=199).	101 (56)	28 (14)	70 (35)
	When feeding my baby away from the home it is easier to make bottles of formula at home and take them with me, than make them up when I am out (n=198).	127 (64)	19 (9)	52 (26)

*Percentage responses for some attitude statements may not add up to 100 due to non responses*

**Table 3.10 Statistical difference between attitude responses (B) and gender, different age groups, SEGs, current feeding practice, first or subsequent time parents and age of baby**

♦Comparisons of responses according to gender, first or subsequent time parents and current feeding practice (exclusive PIF feeding or combination PIF and breast feeding) using Mann Whitney U test statistic.

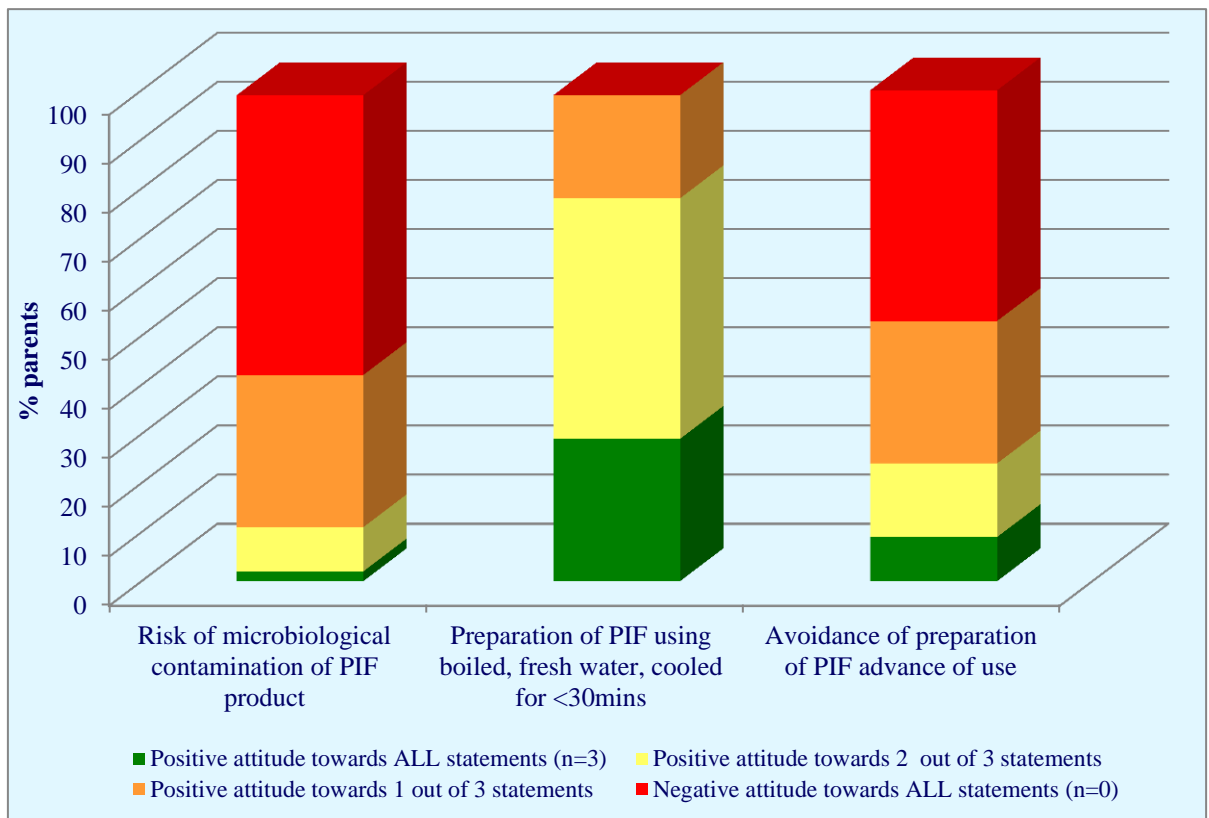
†Comparisons of responses according to age group, SEG, age group of infant using Spearmans *rho* correlation coefficient.

	Gender♦	Current feeding practice♦	First or subsequent infants♦	Age group†	SEG†	Age of infant†	England/Wales♦
<i>Preparation of PIF</i>							
Measurement of the time between when the kettle has boiled and when the boiled water is added to the formula is not important. (n=197)	-	-	-	-	-	-	-
It is difficult to judge the actual temperature of water when it is mixed with the formula powder (n=194)	-	-	-	-	-	R=0.165*	Z=-2.296*
The water used to make up my baby's formula feeds is always fresh from the tap (n=198)	-	-	-	-	-	-	Z=-2.518*
Following preparation and storage instructions on tins of powdered formula is not essential (n=200)	-	Z=-2.932**	-	-	-	-	-
Removal of all milk debris from a used feeding bottle is always easy (n=197)	-	Z=-2.932**	-	-	-	-	-
All of the utensils (e.g. scoop and knife) used to measure the powdered formula are always washed and sterilised before use (n=198).	-	Z=-2.367*	-	-	-	-	-
It is important to always use boiled water to make up powdered formula for my baby (n=200).	-	-	-	-	-	-	-
<i>Storage and cooling</i>							
Made-up powdered formula milk can be safely stored for the same length of time as opened cartons of ready-to-use formula (=198).	-	-	Z=-1.969*	R=0.217**	R=-0.143	-	-
I am happy to cool a made-up bottle of powdered formula milk at room temperature (n=197).	-	-	Z=-2.522*	-	-	-	-
<i>Preparation of PIF in advance of use</i>							
It is acceptable to make up bottles of powdered formula milk in advance of use (n=198).	-	-	-	R=0.158*	-	-	-
It is difficult to always make fresh bottles of powdered formula to feed my baby (n=199).	-	-	-	-	-	-	-
When feeding my baby away from the home it is easier to make bottles of formula at home and take them with me, than make them up when I am out (n=198).	-	-	-	R=0.162*	R=-0.182**	-	-

\*\* = p<0.01; \* = p<0.05



**Figure 3.2. Frequency of positive attitude responses towards aspects of powdered infant formula microbiological safety (n=200)**



*Microbial hazards*

Once a tin of PIF has been opened the powder is not sterile  
 Before opening a tin of PIF the powdered milk is sterile.  
 There is no association between *Salmonella* and PIF.

*Preparation of powdered infant formula using boiled, fresh water cooled for <30 minutes*

Measurement of the time between when the kettle has boiled and when the boiled water is added to the formula is not important.  
 The water used to make up my baby’s formula feeds is always fresh from the tap.  
 It is important to always use boiled water to make up powdered formula for my baby.

*Avoidance of preparation of powdered infant formula advance of use*

It is acceptable to make up bottles of powdered formula milk in advance of use.  
 It is difficult to always make fresh bottles of powdered formula to feed my baby.  
 When feeding my baby away from the home it is easier to make bottles of formula at home and take them with me, than make them up when I am out.

Data presented in Figure 3.2 illustrates that few parents (<30%) have positive attitudes towards all important behaviours and issues (investigated in this study) that may influence safe PIF feeding in and away from the domestic environment.

### 3.3.3 Attitude determination: information sources

Cumulatively, attitudinal data indicates that some parents do feel they were given enough information about how to prepare and store PIF. However, considerable proportions of parents also reported the following:

- they would have liked more information about how to prepare and store PIF (35%)
- they felt insufficient information is available to parents about feeding with PIF (35%)
- they felt they needed information about safe preparation and storage of PIF (26%)
- up to 27% parents considered information given about PIF from NHS professionals (such as hospital staff, community midwives and health visitors) was inadequate for their needs.

Sixteen percent of parents reported they prepare/ store PIF differently to advice they have been given and 15-32% of parents considered advice and instructions from different sources are not consistent. More than half of parents believe that the recommendations for safe preparation and storage of PIF are always changing.

A significant difference between ‘first time parents’ and ‘parents with other children’ was identified ( $Z = -2.714$ ,  $p < 0.01$ ) (see Table 3.12) and the attitude towards perceiving the need for/liking to have more information about how to prepare and store PIF safely. Unsurprisingly, more first time parents (44%) agreed that they would have liked more information, compared to 25% of ‘parents with other children’. Similarly, a significant difference ( $Z = -2.025$ ,  $p < 0.05$ ) was determined between the same groups of respondents and the attitude towards perceived availability of information for parents about feeding infants with powdered formula milk. Sixty one percent of first time parents considered there was not enough information available to them, compared with 28% of parents with other children.

A significant difference ( $z = -3.050$ ,  $p < 0.01$ ) was identified between parents exclusively feeding with PIF and parents breast feeding in combination with PIF feeding. Findings indicated 58% of parents breast feeding in conjunction with PIF feeding thought they needed information about safe preparation and storage of formula milk, whereas only 29% exclusively formula feeding thought that they needed information.

A significant positive association ( $r = 0.315$ ,  $p < 0.05$ ) was determined between age groups of parents and attitude responses. Results showed that parents 25-35 years (71%) and 36-45 (64%) were significantly more likely to prepare and store powdered formula milk differently to advice given to them than parents aged 16-24 years (54%).

**Table 3.11 Consumer perceptions and attitudes towards sources of information about how to prepare and handle powdered infant formula (C) (n=200)**

Attitude statement	Strongly agree/agree n (%)	Neither agree/disagree n (%)	Strongly disagree/ disagree n (%)
Parents are not given enough advice and support about how to safely prepare and store formula feed (n=199).	68 (34)	58 (29)	73 (36)
Advice and instructions about preparation and storage of powdered formula milk is consistent from different sources (n=194).	101 (51)	64 (32)	31 (15)
I would have liked more information about how to prepare and store powdered formula for my baby (n=195)	71 (35)	58 (29)	66 (33)
NHS health professionals should not give advice to all parents about safe preparation and storage of powdered formula milk (n=196).	24 (12)	23 (11)	149 (75)
I am happy to receive information about preparation and storage of powdered formula milk from formula manufacturers (n=199).	160 (79)	23 (12)	16 (8)
The way I prepare and store powdered formula milk is the same way as my mother used to (n=199)	45(22)	117(59)	34(17)
<sup>X</sup> Information I was given about powdered infant formula feeding from hospital staff was adequate for my needs (n=145)	93 (46)	27 (13)	25(13)
<sup>Y</sup> Information I was given about powdered infant formula feeding from the community midwife was adequate for my needs (n=155)	125 (62)	19 (10)	11(5)
<sup>Z</sup> Information I was given about powdered infant formula feeding from the health visitor was adequate for my needs (n=161)	118 (59)	25 (12)	18 (9)
There is not enough information available to parents about feeding babies with powdered infant formula (n=199)	73 (36)	56 (28)	70 (35)
I was given enough information about safe preparation and storage of powdered formula milk (n=199)	125 (62)	35 (17)	39 (20)
I needed information about safe preparation and storage of powdered formula (n=198)	82 (26)	44 (22)	101 (51)
The way I prepare or store powdered formula milk is different from any advice given to me (n=195).	33 (16)	38 (19)	124 (62)
Recommendations for safe preparation and storage of powdered infant formula are always changing (n=199).	104 (52)	73 (36)	22 (11)

X= Parents reported that they had acquired no information from the hospital staff= 54/200 (27%)

Y= Parents reported that they had acquired no information from the community midwife = 43/200 (22%)

Z= Parents reported that they had acquired no information from the health visitor = 37/200 (18%)

*Percentage responses for some attitude statements may not add up to 100 due to non responses*

**Table 3.12 Statistical difference between attitude responses (C) and gender, different age groups, SEGs, current feeding practice, first and subsequent time parents and age of baby**

♦Comparisons of responses according to gender, first or subsequent infant and current feeding practice (exclusive PIFfeeding or combination PIF and breast feeding) using Mann Whitney U test statistic.

†Comparisons of responses according to age group, SEG, age group of infant using Spearmans rho correlation coefficient.

	Gender ♦	Current feeding practice ♦	First or subseque- nt child♦	Age group†	SEG†	Age of infant†	Englan d/Wale s♦
Parents are not given enough advice and support about how to safely prepare and store formula feed (n=199).	-	-	-	-	-	-	-
Advice and instructions about preparation and storage of powdered formula milk is consistent from different sources (n=194).	-	-	-	-	-	-	-
I would have liked more information about how to prepare and store powdered formula for my baby (n=195)	-	-	Z=-2.714 **	-	-	-	-
NHS health professionals should not give advice to all parents about safe preparation and storage of powdered formula milk (n=196).	-	-	-	-	-	-	-
I am happy to receive information about preparation and storage of powdered formula milk from formula manufacturers (n=199).	-	-	-	-	-	-	-
The way I prepare and store powdered formula milk is the same way as my mother used to (n=199)	-	-	-	-	-	-	-
Information I was given about powdered infant formula feeding from hospital staff was adequate for my needs (n=145)	-	-	-	-	-	-	-
Information I was given about powdered infant formula feeding from the community midwife (n=155)	-	-	-	-	-	-	-
Information I was given about powdered infant formula feeding from the health visitor was adequate for my needs (n=161)	-	-	-	-	-	-	-
There is not enough information available to parents about feeding babies with powdered infant formula (n=199)	-	-	Z=-2.025*	-	-	-	-
I was given enough information about safe preparation and storage of powdered formula milk (n=199)	-	-	Z=-2.231*	-	R=0.187*	-	-
I needed information about safe preparation and storage of powdered formula (n=198)	-	Z=-3.050 **	Z=-2.316*	-	-	-	-
The way I prepare or store powdered formula milk is different from any advice given to me (n=195).	-	Z=-2.265*	-	R=0.315 **	R=-0.277 **	-	-
Recommendations for safe preparation and storage are always changing (n=199).	-	-	-	-	R=- 0.157*	-	-

\*\* = p<0.01; \* = p<0.05

### 3.3.4 Perceptions of risk, control, responsibility and hygiene consciousness

Perceptions of risk and control identified determined in this section demonstrate judgements of optimistic bias and the illusion of control. Data presented in Table 3.13 and Figure 3.3 indicated the following:

- Ninety percent of parents believed there was a very low risk of infant illness after feeding PIF they had prepared; risk of illness was perceived to be greater if feeds were made-up by 'other parents', day nursery staff & hospital staff.
- Parents considered themselves to have more control over the safety of PIF feeds they prepared, than other parents, day nursery & hospital staff.
- More parents perceived themselves to have responsibility for the safety of their baby's feeds than other caregiver groups (other parents, day nursery staff and hospital staff).
- Parents also considered themselves to be more conscious of hygiene when preparing infant feeds than other caregiver groups (other parents, day nursery staff, hospital staff).

Parents perceived hospital staff to have the lowest amount of control over hygiene and safety in infant feeds, the lowest amount of responsibility for safety and the lowest level of hygiene consciousness when compared with other caregiver groups. Day nursery staff were perceived to be associated with the lowest level of hygiene consciousness and the highest risk for illness resulting from drinking powdered formula milk. Although other parents fared better for all variables, respondents themselves considered themselves to have more control, responsibility, hygiene consciousness and less risk of associated illness.

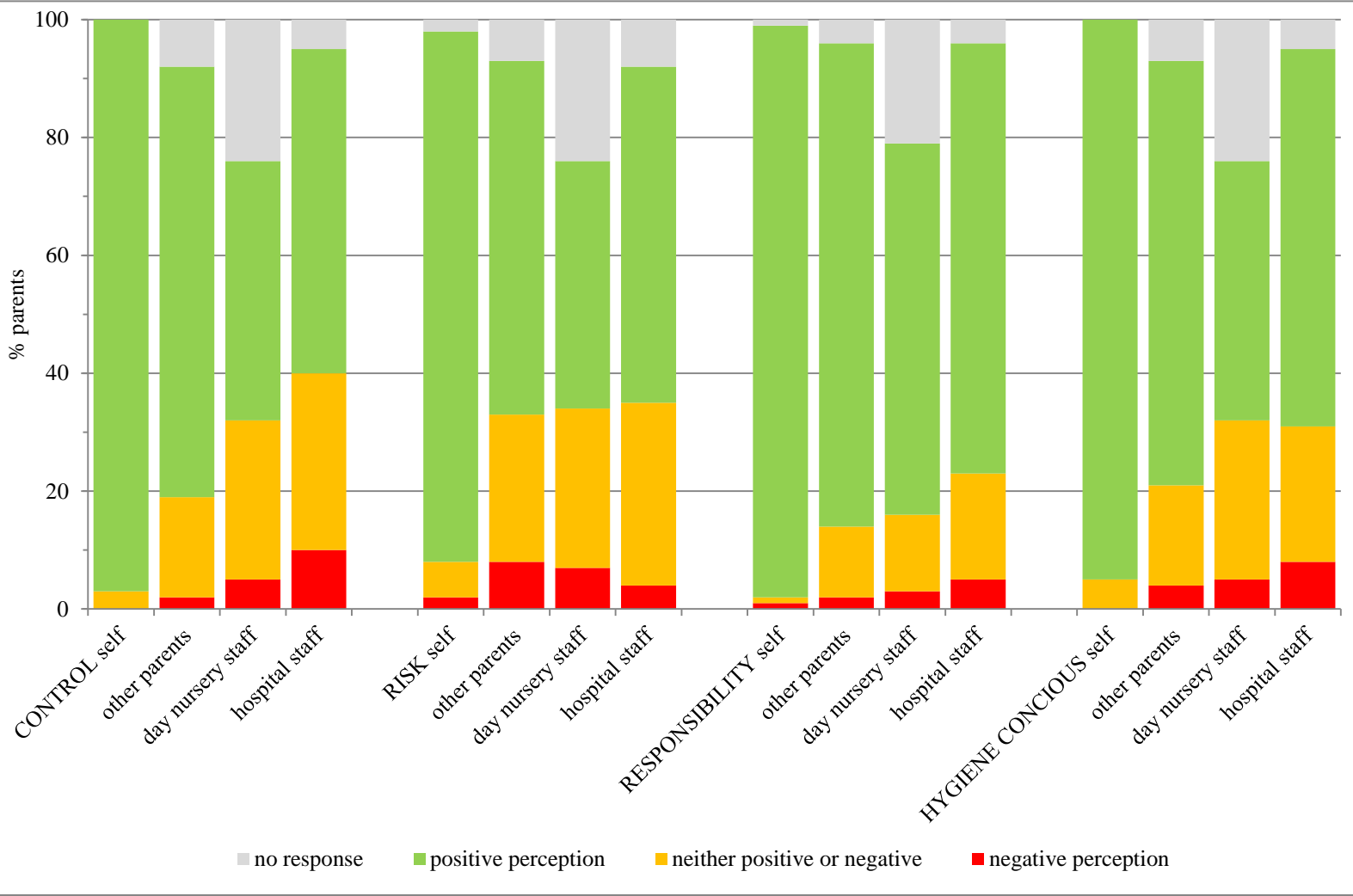
Using Spearman's rank *rho* correlation coefficient, further analysis of the data indicated:

- A positive correlation ( $p < 0.01$ ) was determined between different caregiver groups and perception of responsibility for safety of infant feeds.
- A positive correlation between personal control over the safety of infant feeds and control that other parents have for infant feeds ( $r = 4.01$ ,  $p < 0.01$ ), day nursery nurses ( $r = 1.92$ ,  $p < 0.01$ ) and hospital staff ( $r = 1.71$ ,  $p < 0.05$ )
- A negative correlation was identified between perceived self control and perceived risk of illness resulting from infants drinking PIF reconstituted by self. Parents who perceived themselves to have full or nearly full control over the safety of their preparation of PIF also perceived a lower risk of their infant getting ill from drinking PIF that they had prepared/made-up.

**Table 3.13. Perceptions of risk, control, responsibility and hygiene consciousness during preparation of powdered infant formula (n=200)**

Assessment of perceived risk, control and responsibility (key to ranking)	Caregivers	Sample who stated values 1-3. n (%)	Sample who stated values 8-10. n (%)	Mean ranking (SD)	Don't know/no response n (%)
What do you consider to be the risk of illness to your baby from drinking made-up powdered infant formula prepared by.....[insert each of the following caregivers]? (1= Very Low Risk, 10= Very High Risk)	... <i>yourself</i>	180 (90)	4 (2)	1.8 (1.9)	3 (2)
	... <i>other parents</i>	120 (60)	15 (8)	3.9 (3.2)	14 (7)
	... <i>day nursery staff</i>	83 (42)	14 (7)	5.5 (3.8)	48 (24)
	... <i>hospital staff</i>	114 (57)	8 (4)	3.7 (3.0)	16 (8)
How much control do you think ... [insert each of the following caregivers]..... have over hygiene and safety when preparing your baby's feeds? (1= No control ; 10=Full control)	... <i>yourself</i>	0	193 (97)	9.6 (0.9)	0
	... <i>other parents</i>	3 (2)	145 (73)	8.9 (2.0)	16 (8)
	... <i>day nursery staff</i>	9 (5)	88 (44)	8.4 (2.6)	47 (24)
	... <i>hospital staff</i>	19 (10)	109 (55)	7.7 (2.7)	9 (5)
How much responsibility do you think ... [insert each of the following caregivers]..... have for the safety of their baby's feeds? (1=No responsibility; 10=Full responsibility)	... <i>yourself</i>	1 (<1)	194 (97)	9.7 (0.9)	0
	... <i>other parents</i>	3 (2)	163 (82)	9.1 (1.8)	8 (4)
	... <i>day nursery staff</i>	5 (3)	126 (63)	9.2 (2.1)	41 (21)
	... <i>hospital staff</i>	9 (5)	145 (73)	8.6 (2.3)	8 (4)
How conscious of hygiene do you think ... [insert each of the following caregivers].....are when preparing your/other baby's feeds? (1=Not at all conscious; 10=Very conscious)	... <i>yourself</i>	0	189 (95)	9.5 (1.1)	0
	... <i>other parents</i>	8 (4)	144 (72)	8.6 (2.0)	14 (7)
	... <i>day nursery staff</i>	10 (5)	88 (44)	8.4 (2.5)	47 (24)
	... <i>hospital staff</i>	15 (8)	128 (64)	8.1 (2.5)	10 (5)

Figure 3.3 Perceptions of risk, control, responsibility and hygiene consciousness during preparation of powdered infant formula (n=200).



### 3.3.5 Importance of implementation of recommended powdered infant formula preparation and handling behaviours

Parents were asked to rate how important they considered implementation of key PIF preparation behaviours which are recommended by FSA and NHS for safety (see Table 3.14). Perceived importance of practices related to general hygiene, washing, rinsing and sterilising feeding bottles was high, with 82-94% of parents considering such practices as being ‘very important’. However, less than half of parents (44-48%) considered other key practices required to ensure PIF safety as equally important; for example, 32% of parents failed to consider mixing the PIF with boiled water, cooled for <30 minutes to be important, 28% of parents also did not consider feeding the made-up PIF immediately after preparation to be important and 34% of parents did not think it was important to make up one feed at a time.

**Table 3.14 Perceived importance for implementation of key powdered infant formula preparation and handling behaviours (n=200)**

	Very important n (%)	Fairly important n (%)	Neither n (%)	Not very important n (%)	Not at all important n (%)
• Clean the preparation area every time you prepare a bottle of powdered formula milk feed. (n=200)	164 (82)	30 (15)	3 (2)	2 (1)	0
• Wash and dry your hands every time you prepare a bottle of powdered formula milk feed. (n=199)	179 (90)	17 (8)	3 (2)	0	0
• Wash feeding bottles and components with detergent and hot water before sterilising. (n=198)	179 (90)	12 (6)	6 (3)	0	1 (<1)
• Rinse washed feeding bottles and components with running water before sterilising. (n=198)	167 (84)	23 (12)	6 (3)	1 (<1)	1 (<1)
• Sterilise feeding bottles and components before use. (n=199)	188 (94)	9 (5)	2 (1)	0	0
• Mix milk powder with boiled water that has cooled for less than 30 minutes. (n=198)	94 (47)	38 (19)	44 (22)	17 (9)	5 (2)
• Feed the made-up powdered formula <u>immediately</u> after preparation (once at a suitable temperature). (n=197)	96 (48)	44 (22)	41 (20)	12 (6)	4 (2)
• Prepare one feed at a time. (n=199)	87 (44)	44 (22)	36 (18)	19 (10)	13 (6)

*NB: % may not add up to 100% due to non response*



Statistical differences/associations between importance ratings and groups of respondents can be found in Table 3.15. Further analysis of data indicated a significant difference between England and Wales for perceived importance of preparing one PIF at a time. Seventy one percent of Welsh parents (Cardiff) reported that this practice was very important/fairly important compared to 60% of English respondents (Bristol). Further positive correlations between responses can be found in Table 3.15.

**Table 3.15 Statistical difference between responses to perceived importance and gender, different age groups, SEGs, current feeding practice, first and subsequent time parents and age of baby**

♦Comparisons of responses according to gender, first and subsequent time parents and current feeding practice (exclusive PIF feeding or combination PIF and breast feeding) using Mann Whitney U test statistic.

†Comparisons of responses according to age group, SEG, age group of infant using Spearmans rho correlation coefficient.

	Gender♦	Current feeding practice♦	First and subsequent time parents♦	Age group†	SEG†	Age of infant†	England/Wales♦
• Clean the preparation area every time you prepare a bottle of powdered formula milk feed.	-	Z=-2.060*	Z=2.068*	-	R=-0.185**	-	-
• Wash and dry your hands every time you prepare a bottle of powdered formula milk feed.	-	Z=-2.400*	-	-	-	-	-
• Wash feeding bottles and components with detergent and hot water before sterilising.	Z=-2.430*	Z=-2.100*	-	-	R=0.148*	-	-
• Rinse washed feeding bottles and components with running water before sterilising.	Z=-2.649**	-	-	-	-	-	Z=-3.143**
• Sterilise feeding bottles and components before use.	-	-	-	-	-	-	-
• Mix milk powder with boiled water that has cooled for less than 30 minutes.	-	-	-	-	-	-	-
• Feed the made-up powdered formula <u>immediately</u> after preparation (once at a suitable temperature).	-	-	-	-	-	-	-
• Prepare one feed at a time.	-	-	-	-	-	-	Z=-2.299*

\*\* = p<0.01; \* = p<0.05

**Table 3.16 Positive correlations between parent responses to their perceived importance for implementation of key preparation and handling behaviours (n=200)**

	Clean the preparation area every time you prepare a bottle of powdered formula milk feed.	Wash and dry your hands every time you prepare a bottle of powdered formula milk feed.	Wash feeding bottles and components with detergent and hot water before sterilising.	Rinse washed feeding bottles and components with running water before sterilising.	Sterilise feeding bottles and components before use.	Mix milk powder with boiled water that has cooled for less than 30 minutes.	Feed the made-up powdered formula <u>immediately</u> after preparation (once at a suitable temperature).	Prepare one feed at a time.
Clean the preparation area every time you prepare a bottle of powdered formula milk feed.								
Wash and dry your hands every time you prepare a bottle of powdered formula milk feed.	$p<0.01$							
Wash feeding bottles and components with detergent and hot water before sterilising.	$p<0.01$	$p<0.01$						
Rinse washed feeding bottles and components with running water before sterilising.	$p<0.01$		$p<0.01$					
Sterilise feeding bottles and components before use.	$p<0.01$	$p<0.01$	$p<0.01$	$p<0.01$				
Mix milk powder with boiled water that has cooled for less than 30 minutes.	$p<0.01$	$p<0.01$	$p<0.01$		$p<0.01$			
Feed the made-up powdered formula <u>immediately</u> after preparation (once at a suitable temperature).			$p<0.05$		$p<0.01$	$p<0.01$		
Prepare one feed at a time.						$p<0.05$	$p<0.01$	

### 3.3.6 Self-reported powdered infant formula preparation, handling and storage practices

#### 3.3.6.1 Preparation, handling and storage in the home

Self-reported practices associated with preparation, handling and storage of PIF in the home have been determined. Findings have indicated:

- 78% (155/200) of parents reported preparation of the powdered formula feeds in the same area or same work surface where they/other household persons prepare foods suggesting a potential risk of cross contamination
- 44% of parents reported feeding 5-6 bottles of PIF to their infant within 24 hours. The maximum number of PIF feeds reportedly fed during 24 hours was 12 feeds.

The majority (64%) of parents reported they reconstitute individual feeds (i.e. mix water and PIF) as and when required for feeding and >35% (67/200) of parents reported to always or sometimes prepare PIF feeds in advance of use; 29%` parents reported reconstitution of 2-4 feeds at a time (maximum number of feeds prepared at one time = 12).

Data presented in Table 3.17 indicates that 6% of parents reported reconstitution of enough PIF feeds for 12 hours feeding and a further 6% of parents reported reconstitution of PIF feeds for up to 24 hours.

**Table 3.17 Number of powdered infant formula feeds prepared when more than one feed is made-up at a time for 12-24 hours (n=28/200)**

	n=200 n (%)	No. of PIF feeds made-up	n=200 n (%)
Enough feeds for 12 hours	13 (6)	3	5 (3)
		4	4 (2)
		5	2 (1)
		6	2 (1)
Enough feeds for 24 hours	12 (6)	4	5 (3)
		5	1 (<1)
		6	4 (2)
		8	1 (<1)
		10	1 (<1)
Other (3 at a time)	3 (2)	na	na

All respondents (n=200) reported they boil tap water in a kettle for reconstitution of PIF (no respondents reported use of tap water that had not been boiled or bottled water): 51% reported boiling the water and pouring it into the feeding bottle straight away; 46% reported boiling the water and allowing it to cool in the kettle (of whom 13% reported cooling for more than 30 minutes) and then pour into the feeding bottle; 3% boil the water and the pour it into a jug or flask before required for use.

- 17% reported to pour boiled water into the bottle straight away, add the powdered formula, cool quickly and feed immediately.
- 12% reported to pour boiled water into the bottle straight away, leave the boiled water in the bottle to cool at room temperature and then add powdered formula when ready for feeding (of these 57% reported adding the powder to the boiled water within 30 minutes of boiling; 43% reported adding the powder to the boiled water more than 31 minutes after boiling).
- 6% reported pouring boiled water into the bottle straight away, leaving it to cool at room temperature, then adding powdered formula and storing the reconstituted PIF at room temperature until required for feeding.
- 23% reported cooling the boiled water in the kettle, pouring the cooled water into the bottle and adding the PIF and feeding immediately.
- 15% reported to cool the boiled water in the kettle, pour the cooled water into the bottle and add PIF and store in the fridge until required for feeding.
- 5% reported cooling the boiled water in the kettle, pouring the cooled water into the bottle and adding the PIF and storing at room temperature until required for feeding.

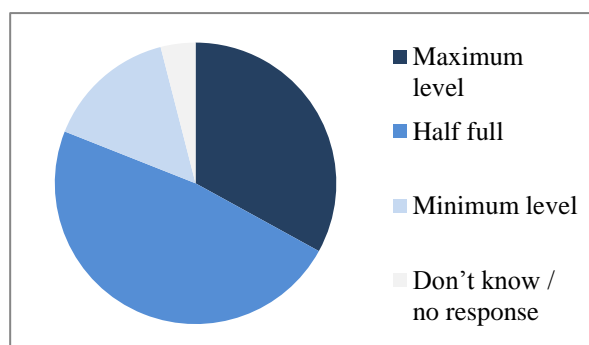
Once PIF has been reconstituted ( $n=200$ ):

- 52% of parents reported feeding the reconstituted PIF immediately after reconstitution (i.e. no storage).
- 23% reported storing reconstituted PIF in the fridge before required for feeding; 12% reported storing reconstituted PIF at room temperature before feeding.

Data related to quantities of water reportedly boiled can be seen in Figure 3.4. The majority of parents reported boiling the kettle at least half full (48%).

More parents reported pouring boiled water into feeding bottles immediately after boiling rather than adhering to DoH advice by allowing boiled water to cool in the kettle before use. Of those that did cool boiled water in a kettle, a quarter reported cooling times longer than the recommended 30 minutes (DoH, 2008). Data suggests that large proportions of PIF feeds are reconstituted using boiled water that is likely to be  $<70^{\circ}\text{C}$ . This has implications for the microbial safety of the end-product. Other reported malpractices included storage of feeds at room temperature until required (12%) and reheating feeds more than once (3%).

**Figure 3.4 Quantities of water reportedly boiled in kettles (n=200)**



The main persons responsible for the preparation of feeding bottles and PIF feeds can be seen in Table 3.18. A summary of data presented in this section is found in Figure 3.5.

**Table 3.18 Self-reported practices: main person(s) responsible for preparation of feeding bottles/reconstitution of powdered infant formula feeds in respondent households (n=200)**

In your household, who is <u>mainly</u> responsible for .....	Self n (%)	Partner n (%)	Both n (%)	Other family member* n (%)
....preparing/making up the powdered infant formula?	130 (65)	9 (4)	60 (30)	1 (<1)
....cleaning bottles and equipment after use?	132 (66)	8 (4)	58 (29)	2 (1)
...sterilising bottles and equipment for re-use?	132 (66)	8 (4)	59 (30)	1 (<1)

\*Other au pair/other family member

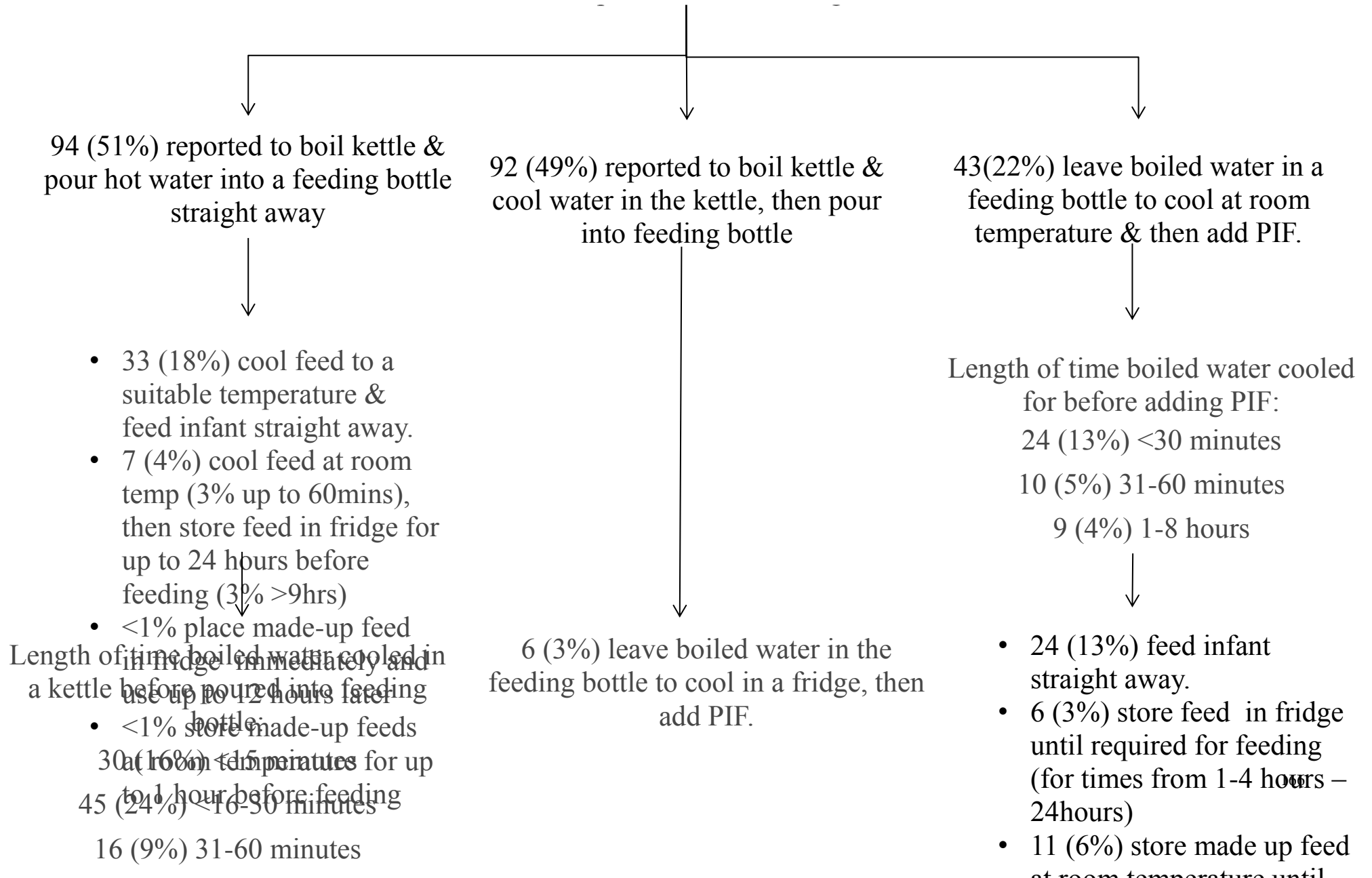
Data presented in Table 3.19 indicates the maximum length of time parents reported they stored reconstituted PIF for use in the home. The majority (47%) reported feeding PIF within 30 minutes of reconstitution; however, 22% reported maximum storage times of more than 4 hours (unspecified temperature/conditions).

**Table 3.19 Maximum reported times reconstituted powdered infant formula has been kept for use within the home.**

Storage time	% of whole sample (n=200)
<30 minutes	47%
31-60 minutes (1 hour)	7%
61-120 minutes (2 hours)	13%
121-240 minutes (4 hours)	9%
241-480 minutes (8 hours)	5%
481-720 minutes (12 hours)	3%
721-1440 minutes (24 hours)	8%
>1441 minutes (24 hours, 1 minute)	6%

2% unusable data/no response

89 (48%) poured cooled, boiled water into feeding bottle and immediately added PIF



### 3.3.6.2 Cooling and reheating reconstituted powdered infant formula feeds

Self reported behaviours related to cooling reconstituted PIF feeds for feeding, were determined and findings are presented in Table 3.20. The majority (45%) of parents reported cooling practices, involving placement of the reconstituted feed in a bowl of cold water or hold the bottle containing made-up feed under a running tap of cold water (40%). Thirteen percent of parents (27/100) reported they leave the made-up feed out at room temperature until it is sufficiently cool before feeding.

**Table 3.20 Methods used for cooling reconstituted powdered infant formula feeds (for feeding)**

Cooling practice	n (%)
Leave it at room temperature until it is sufficiently cool	27 (13)
Hold it under a running tap of cold water	79 (40)
Place it in a bowl of cold water	90 (45)
Not applicable - don't have to cool made-up formula down before giving to baby	4 (2)

Reconstituted feeds prepared in advance of use (stored at ambient temperature or in the fridge) or feeds prepared with cooled/cold boiled tap water may require reheating before feeding. The majority (85%) of parents indicated they implemented reheating methods. Findings are presented in Table 3.21. The most common methods reportedly implemented to reheat PIF feeds include in a jug/bowl of hot water (47%) in the microwave (19%) and in an electric bottle warmer (13%). Three percent of parents reported that they have reheated a reconstituted feed up more than once.

**Table 3.21 Methods used for reheating reconstituted powdered formula feeds (for feeding)**

Reheating practice	n (%)
In a jug/bowl of hot water	95 (47)
Running it under a hot tap	3 (2)
In an electric bottle warmer	26 (13)
In a microwave	39 (19)
Leave at room temperature	4 (2)
Not applicable - don't need to heat because warm enough to give to baby	20 (10)
Not applicable - give to baby cold	6 (3)
Discard and make up a new feed	3 (2)
Don't know	4 (2)

### 3.3.6.3 Preparation, handling and storage of powdered infant formula away from the home

Parents reported variable methods with regards to dealing with PIF feeding when away from the home (see Table 3.22). The most common method reported (45% of parents) was reconstitution of a bottle of PIF feed at home and taking it out away from the home. Other methods reported included:

- Taking a cleaned and sterilised feeding bottle with a carton of RTU PIF (20%),
- Taking a cleaned and sterilised feeding bottle with a container of measured out PIF and a flask of boiled water to reconstitute feed as and when required (18%),
- Taking the prepared feeding bottle and a container with measured PIF and asking for boiled water in food establishments or similar (13%),
- Taking a bottle with prepared water and adding the powder when needed (1%).

For parents who reported taking reconstituted bottles of made-up PIF out with them to feed their infant (90/200) (Table 3.22), the reported storage methods are presented in Table 3.23.

**Table 3.22 Self-reported methods used to deal with feeding with powdered infant formula when away from the home e.g. on a shopping trip**

Self reported practice	n (%)
Make up a bottle of powdered formula milk at home and take it with you	90 (45)
Take a bottle that has been sterilised and a ready-to-use carton of formula	39 (20)
Take a bottle that has been sterilised, a container with measured powdered formula & flask of boiled water - make formula up to feed immediately.	36 (18)
Take a bottle that has been sterilised, a container with measured powdered formula & ask for boiling water in a food establishment or similar. Make formula up to feed immediately.	26 (13)
Breast feed	4 (2)
Take a feeding bottle with prepared water and add powder when needed	2 (1)
Other	3 (2)

The majority (52%) of parents reported using an insulated compartment of a baby bag or similar to keep the PIF feed warm until feeding time or use a carrier bag/normal bag – no insulated/cool bag for storage (30%). Only 4% of parents reported using a cooler bag compartment with freezer packs and 4% also reported placing the feed in the bottle holder of a pram or pushchair until required.



**Table 3.23 Self-reported methods used to store reconstituted powdered infant formula when away from the home e.g. on a shopping trip (n=90)**

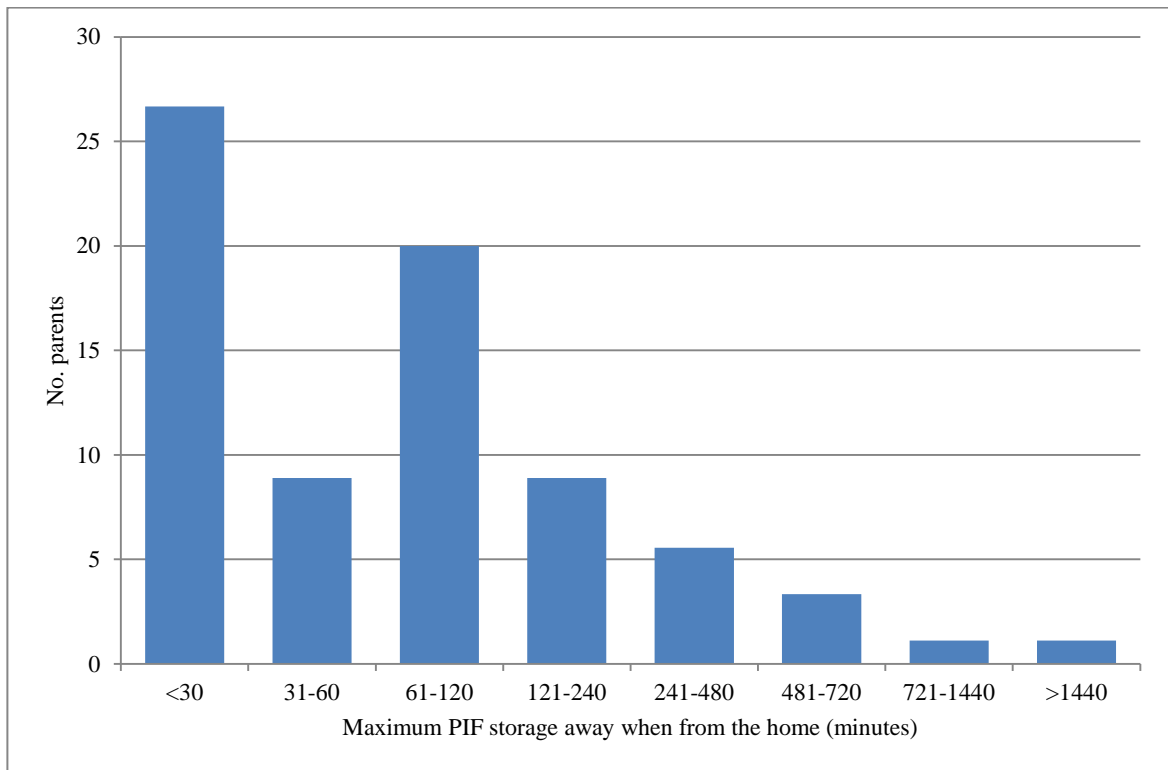
	n (%)	% of whole sample (n=200)
In an insulated bag/compartment of a baby bag to keep the bottle warm	47 (52)	23
In a cool bag/compartment of a baby bag with frozen cool packs	4 (4)	2
In a cool bag/compartment of a baby bag (no frozen cool packs)	8 (8)	4
In the bottle holder on a pushchair/pram	4 (4)	2
In a carrier bag/other general bag/handbag/rucksack/general compartment of a baby bag	27 (30)	14

Parents reported maximum times for when reconstituted PIF feeds had been stored for when away from the home see Table 3.24 and Figure 3.6. Data shows that 27% of parents reported the maximum storage time was <30 minutes, a further 38% reported maximum storage times were between 1-4 hours, and 11% of parents reported maximum storage times have been over 8 hours and over and up to 24 hours.

**Table 3.24 Maximum reported times that reconstituted powdered infant formula has been stored for when away from the home e.g. on a shopping trip**

Storage time	n (%) of parents who reported taking reconstituted powdered infant formula away from the home for feeding (n=90)	% of whole sample (n=200)
<30 minutes	24 (27)	12
31-60 minutes (1 hour)	8 (9)	4
61-120 minutes (2 hours)	18 (20)	9
121-240 minutes (4 hours)	8 (9)	4
241-480 minutes (8 hours)	5 (6)	3
481-720 minutes (12 hours)	3 (3)	2
721-1440 minutes (24 hours)	1 (1)	<1
>1441 minutes (24 hours, 1 minute)	1 (1)	<1

**Figure 3.6 Maximum reported times that reconstituted powdered infant formula has been stored for use within and for use when away from the home e.g. on a shopping trip**



A positive correlation ( $r=0.510$ ;  $p<0.01$ ) was determined between reported maximum lengths of time reconstituted PIF is stored inside and outside of the home, suggesting that parents who store feeds for longer periods of time within the home are likely of implementing the same practice when away from the home.

#### ***3.3.6.4 Preparation, handling and storage of powdered infant formula for infants in day nurseries***

Only 1% (2/200) parents reported their infant (aged less than 6 months) attended a day nursery, therefore limited results were obtained from this section of the interview. One of the parents reported taking reconstituted PIF feeds to the nursery for storage and feeding through the day and the second parent reported taking measured amounts of powdered formula to the nursery with a prepared feeding bottle each day (feeds would be made-up when needed during the nursery when required).

Detailed information about the preparation, handling and storage of PIF in day nurseries is discussed in Chapter 4 and Chapter 8.

#### ***3.3.6.5 Self-reported practices and attitudes/perceptions towards powdered infant formula recommendations***

A comparison of self reported practices and attitudes/perceptions towards corresponding practices that are recommended by the FSA and the NHS to reduce microbiological risks can be seen in Table 3.25. Findings suggest larger proportions of parents perceived practices to be more important than self-reported implementation. For a comparison with observed behaviours, see Chapter 6.

**Table 3.25 Self-reported practices and attitudes/perceptions towards powdered infant formula recommendations**

Recommended practices <sup>▲</sup>	Self-reported practice	Perceived importance/attitude
Clean surface thoroughly on which to prepare the feed.	85% parents reported that they clean* the work surface where they prepare/make-up bottles of powdered infant formula.	97% parents perceived implementation to be very important/important.
Wash hands with soap and water, then dry.	90% parents reported washing hands every time they prepared/made-up a powdered infant formula feed.  73% reported use of hot running water with soap/bowl of hot soapy water.  49% parents reported drying their hands after hand washing every time they prepared/made-up a powdered infant formula feed, using a paper towel or unused hand towel.	98% parents perceived implementation to be very important/important.
Allow boiled water to cool to no less than 70°C before adding to the powder/using water for less than 30 minutes after boiling.	43% reported using boiled water that had cooled for >30 minutes to reconstitute powdered infant formula feeds.	66% parents perceived implementation to be very important/important.  47% considered that <i>'measurement of the time between when the kettle has boiled and when the boiled water is added to the formula is not important'</i> .
Each bottle should be made-up fresh for each feed (i.e. freshly boiled water – not water boiled and stored for any length of time).	66% parents reported feeding reconstituted powdered infant formula immediately after preparation (once at a suitable temperature).	70% parents perceived implementation to be very important/important  56% parents considered that <i>'it is difficult to always make fresh bottles of powdered formula to feed my baby'</i>

<sup>▲</sup>Sources= FSA (2007) and NHS (2007)

*\*reported use of hot water and detergent and/or antibacterial/sanitiser sprays – representing implementation of adequate and inadequate methods*

### 3.3.7 Information about powdered infant formula

#### 3.3.7.1 Recommendations for safe preparation, handling and storage of powdered infant formula

Data presented in Table 3.26 shows the proportions of the parents that were aware of PIF preparation and handling recommendations. It can be seen that 84-87% of parents were aware of surface ‘cleaning’ and handwashing/drying requirements; however, it appears they were less familiar with specific recommendations related to PIF reconstitution and use. For example, 62% were aware of the recommendation to allow boiled water to cool to no less than 70°C before addition of PIF to the water. Eight three percent of parents were aware each bottle should be made-up fresh for each feed and nearly three quarters of parents were aware of the recommendations to discard feed that had not been used up within two hours.

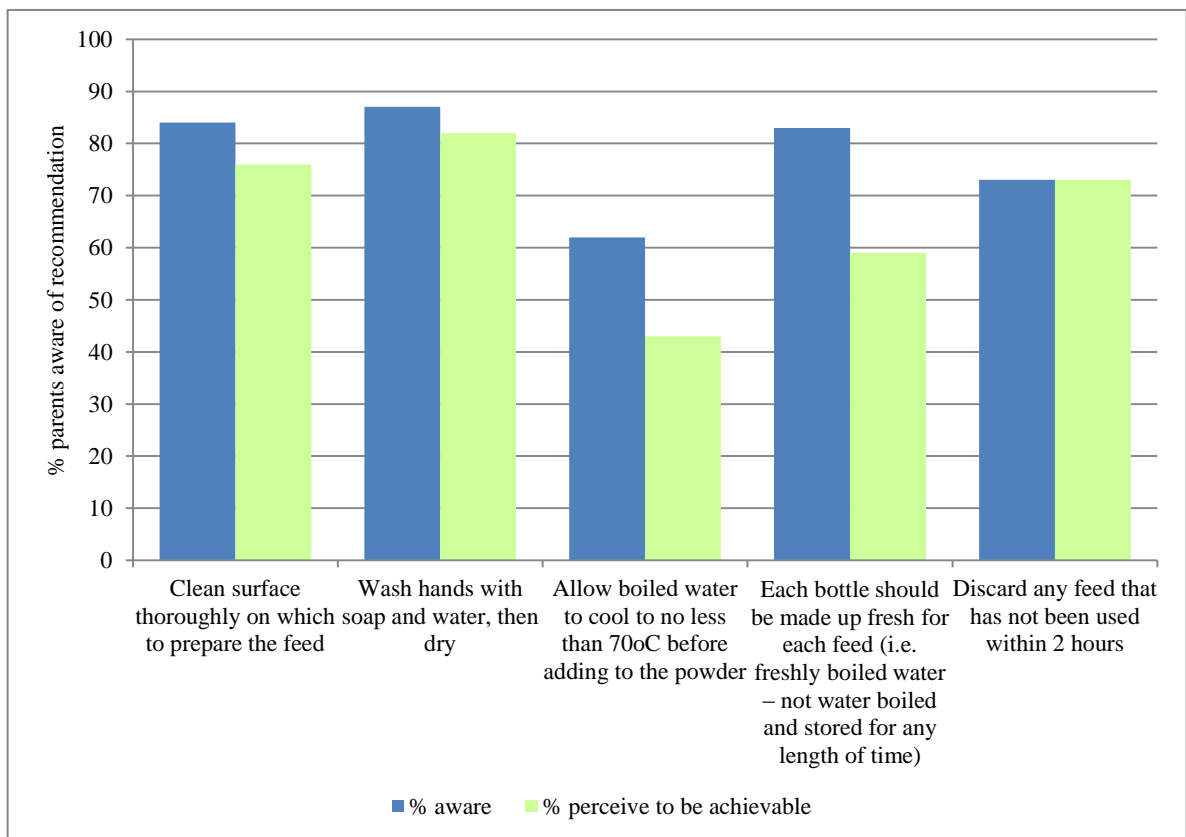
**Table 3.26 Awareness of powdered infant formula preparation, handling and storage recommendations compared with perception of how the recommendation is realistically achievable (n=200)**

	Parents aware of recommendation n (%)	Parents consider recommendation realistically achievable n (%)
Clean surface thoroughly on which to prepare the feed	168 (84)	155 (76)
Wash hands with soap and water, then dry	174 (87)	164 (82)
Allow boiled water to cool to no less than 70°C before adding to the powder	124 (62)	86 (43)
Each bottle should be made-up fresh for each feed (i.e. freshly boiled water – not water boiled and stored for any length of time)	165 (83)	118 (59)
Discard any feed that has not been used within two hours	146 (73)	146 (73)

For cleaning and hand decontamination, 76-82% of parents considered implementation of such recommendations achievable. However, more than half of parents (57%) considered cooling boiled water to no less than 70°C before the addition of PIF to be realistically unachievable. A similar response pattern is seen for preparation of individual and fresh feeds – whereby more parents reported awareness of the recommendation (83%) than considered it reasonably achievable (59%). A comparison of responses indicating recommendation awareness and perceived implementation is illustrated in Figure 3.7.

A comparison of data from Tables 3.25 and 3.26 indicates differences between awareness of recommendations and corresponding self reported PIF preparation practices and attitudes towards such practices.

**Figure 3.7 Awareness of powdered infant formula preparation, handling and storage recommendations compared with perception of how the recommendation is realistically achievable (n=200)**



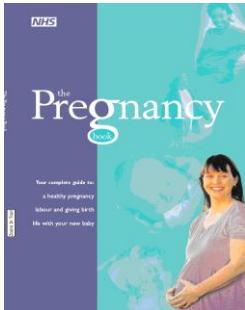
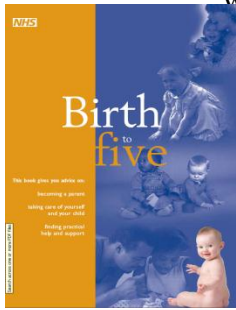
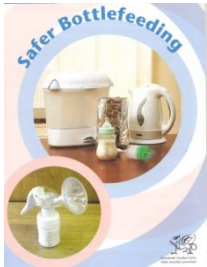
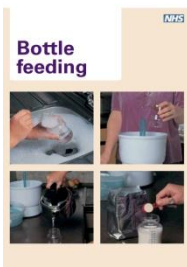
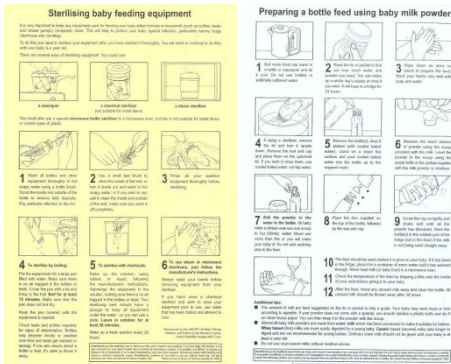
### ***3.3.7.2 Experience of preparation, handling and storage of powdered infant formula information***

During the CAPI interviews, respondents were shown on-screen images of PIF interventions provided in England and Wales. Eighty seven percent (175/200) of parents recalled seeing at least one of the NHS pregnancy or Birth to Five books (few parents recorded having seen/been given both books). Of those who recalled seeing these books, 55% reported referring to them for information about preparation, handling and storage of PIF; only 29% rated the information as being very useful.

Only 25% of respondents reported seeing/being given the bottle feeding leaflet – (only 12% of Welsh parents compared to 37% of English parents). Of those who had seen this information source, 71% reported referring to it for PIF preparation and handling/storage information and 57% rated the information as very useful.

Forty percent of parents reported seeing/being given the UNICEF information sheet, with 75% of whom reported referring to it for PIF information and 63% reporting the source to be very useful.

**Table 3.27 Awareness and reported use of powdered infant formula preparation, handling and storage information (n=200)**

Information Sources	n (%) respondents who had encountered/seen information sources (see left)	Of the parents who reported previously seeing the sources: n (%) respondents reported referring to the books for information about preparation/handling/storage of PIF	Of the parents who reported previously seeing the sources: n (%) rated information about formula feeding in the book 8-10 (1= not at all useful; 10=very useful)
 	Wales 91/100 (91) England 84/100 (84) Total = 175/200 (87)	97/175 (55)	50/175 (29)
 	Wales 12/100 (12) England 37/100 (37) Total 49/200 (25)	35/49 (71)	28/49 (57)
	Total 81/200 (40)	61/81 (75)	52/81 (63)



### 3.4 SUMMARY OF FINDINGS

- Overall, UK parents reported carrying out **variable methods** used to prepare, handle and store PIF inside and outside the home. Many parents reported methods/practices that are contrary to current UK DoH and FSA PIF preparation and handling recommendations.
- Parents expressed negative attitudes towards key risk-reducing behaviours required for PIF safety, suggesting corresponding unsafe practices may be commonly implemented.
- Many parents perceived recommended PIF practices to be important, however, smaller proportions of parents reported practicing corresponding behaviours.

#### 3.4.1 Powdered infant formula preparation, handling and storage behaviours

- Parents expressed variable and negative attitudes towards practices associated with cooling of boiled water to  $>70^{\circ}\text{C}$  (and judgement of water temperature) for reconstitution of PIF feeds. Many parents reported that they frequently did not cool boiled water to temperatures  $>70^{\circ}\text{C}$  for reconstitution. This has implications for the microbial safety of the end-product.
- A third of parents did not consider the following behaviours to be important to ensure PIF safety: preparing PIF with boiled water cooled for  $<30$  minutes, feeding reconstituted PIF immediately after preparation and making up one feed at a time.
- The majority of parents considered it to be acceptable for PIF to be prepared and stored in advance of use. Attitudinal data concurred with self-reported data which indicated large proportions of parents prepare reconstituted PIF in advance of use.
- The most common method for dealing with PIF feeds away from the home was reported to be making up PIF feeds at home to take out.
- The majority of parents who reported reconstituting PIF feeds for feeding away from the home also reported storage practices which would have microbial implications for safety. Larger proportions of parents from social class DE were more likely report implementation of this practice.
- Misconceptions were identified about ‘safe’ storage of opened cartons of RTU UHT formula (with instructions indicating storage for 24 hours in a refrigerator) and reconstituted PIF (recommendation indicating no storage and immediate feeding after reconstitution). Parents perceived instructions to be contradictory and caused confusion as the RTU UHT formula and the reconstituted PIF were perceived by many parents to be the ‘*same*’.

- Fewer parents from SEG DE who used PIF for feeding in conjunction with breastfeeding found implementation of all recommended practices ‘easy’, compared to exclusively formula feeding parents from SEG AB; however, parents using a combination of feeding methods were more confident that the formula they prepare is safe.
- Older parents (aged 35-45 years) were significantly associated with negative attitudes towards PIF safety and implementation of recommended practices.

### **3.4.2 Microbial risks**

- Widespread negative attitudes were expressed towards microbiological risks associated with PIF & preparation of PIF feeds in advance. For example, nearly three-quarters of parents reportedly believe that PIF is a sterile product before the tin is opened – this included more parents from SEG DE and age group 35-45 years.

### **3.4.3 Perceptions of risk, control, responsibility and hygiene consciousness**

- Judgements of optimistic bias, the illusion of control and personal invulnerability associated with PIF preparation have been identified.
- Parents perceived hospital staff to have the lowest amount of control over hygiene and safety of infant feeds, the lowest amount of responsibility for safety and the lowest level of hygiene consciousness when compared with other caregiver groups.
- The majority (70%) of parents considered that ultimately the safety of PIF was the responsibility of manufacturers. Failure to recognise personal responsibility for the safety of PIF feeds may not only impede upon intervention efforts, but also result in a negative assumption that ‘others’ have ensured complete safety of powdered formula milk feeds. Thus, necessary safety control measures that are required during formula preparation may not be implemented, which subsequently increases the risk of illness.

### **3.4.4 Information provision/sources**

- Considerable numbers of parents (particularly first time parents) reported they felt that insufficient information regarding preparation and handling of PIF was available and would have liked more information.
- Many parents believed that information and recommended PIF practices were always changing – which undermined the content and credibility of the information.

- Parents with older children believed they did not need more information about safe preparation and handling of PIF – however, such information may be needed if recommendations have changed since the birth of their first infant.
- The majority of parents recalled being given or seeing at least one of the NHS Pregnancy/Birth to Five books. However, limited recall was reported for bottle feeding leaflets especially in Wales, where only 12% of formula feeding parents recalled seeing or receiving this information source.

## CHAPTER 4

### PREPARATION, HANDLING AND STORAGE OF POWDERED INFANT FORMULA IN UK DAY NURSERIES

#### 4.1 INTRODUCTION

##### 4.1.1 Background

Data has shown that in recent years there has been an increase in women returning to work after childbirth. In the UK it is reported that two thirds of mothers now return to work after having a baby, this is an increase of 50% since 1988, when less than half (45%) went back (Callender *et al.* 1997). Similarly, US data indicates that in 1994, 52% of mothers returned to work after 6 months after the birth of their first child, compared to 14% in 1965 (NCBA, 2001). This has led to an increase in demand for nurseries and day care centres. Currently, 14,500 day nurseries in the UK provide care for nearly one million under fives (NDNA, 2006).

Nurseries and day care centres, whilst possibly more structured than the home, are unlikely to have infection prevention policies and practices, or information and trained staff. This, in conjunction with the frequency and large numbers of PIF feeds fed/handled in day nurseries make day nursery staff an important caregiver group to include in this study.

##### 4.1.2 Aims and objectives

The aim of this part of the study was to obtain quantitative data from 100 UK day nursery nurses who look after and feed PIF to infants aged less than 6 months in the nursery, and to detail caregiver beliefs, attitudes, risk perceptions and self-reported practices related to PIF use in day nurseries. The more specific objectives were to:

- Quantify how PIF is prepared, handled and stored in UK day nurseries.
- Investigate influencing factors as to why caregivers implement unsafe preparation, handling and storage behaviours when dealing with PIF inside and outside of the home.
- Analyse day nursery caregivers' perceptions of risk, control and responsibility for themselves and for others.
- Determine day nursery caregivers' information sources and training about safe preparation and use of PIF.

## **4.2 METHODS**

For an overview of the plan of methods used for collection of quantitative data from day nurseries for this component of the study see Figure 4.1.

### **4.2.1 Development of the day nursery questionnaire**

Qualitative research with day nursery nurses (Chapter 2) and a review of PIF microbiological data and previous day nursery observation and microbiological research (Redmond and Griffith, 2007) were used to prioritise important PIF safety handling and storage issues.

The self-complete questionnaire determined background information including kitchen facilities available in the day nursery, self-reported behaviours, assessed attitudes and perceptions towards PIF safety in day nurseries and training/information about PIF that day nursery staff received.

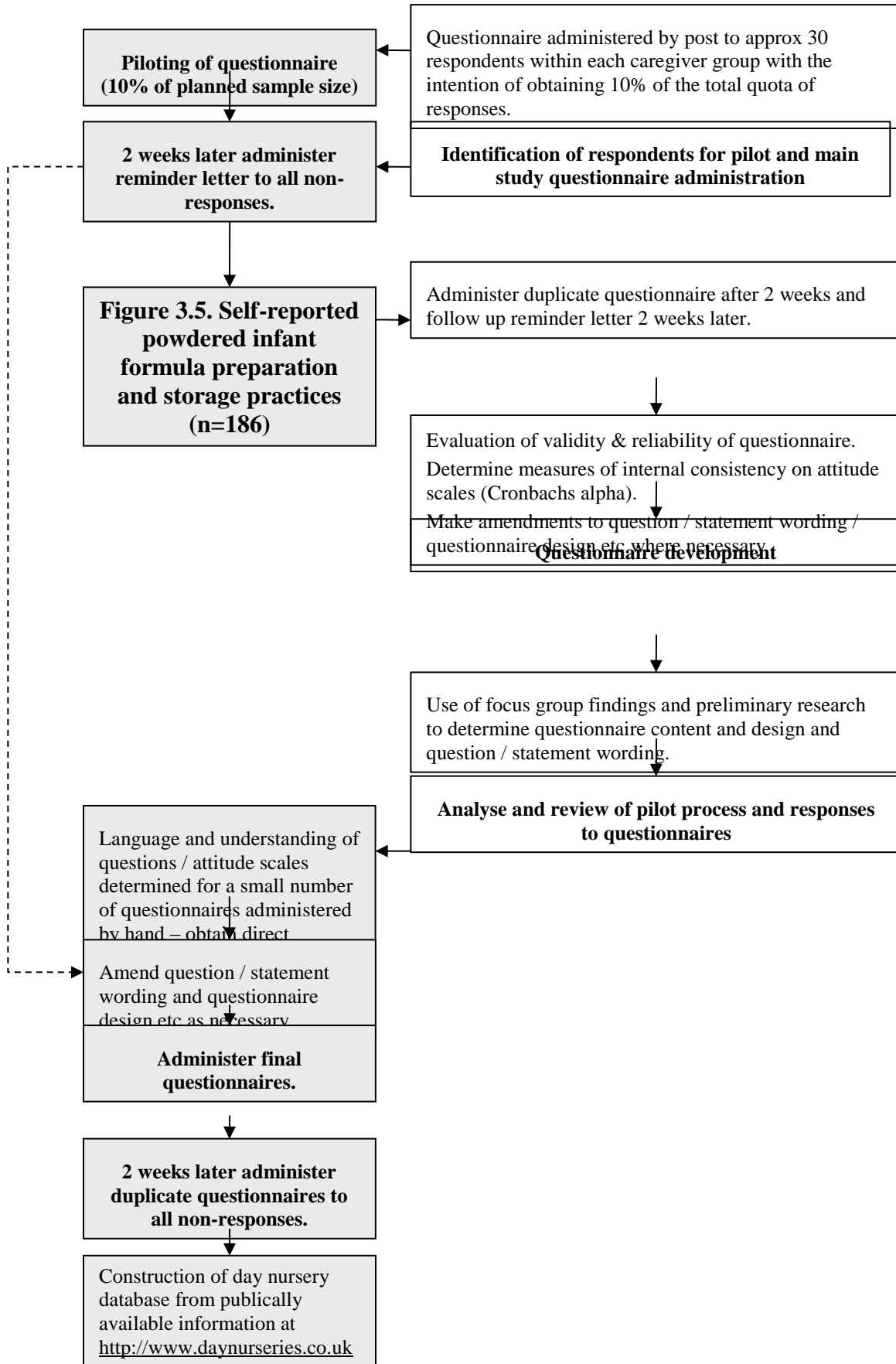
Attitudes and risk perceptions were assessed using five point Likert-type rating scales (strongly agree to strongly disagree) and a variation of a visual analogue scale (VAS) (Bowling, 2000). Attitude responses given on a Likert-type rating scales provided ordinal data and no assumption of equal intervals was made. The variation of a VAS included a horizontal line bound with adjectives at either end e.g. 'Very low risk and very high risk' (Bowling, 2000). A numerical scale was displayed at regular intervals along the line (from 1 to 10) to help respondents intuitively understand the scale (Bowling, 2000). This data was considered as ranked, ordinal data. Respondents were required to circle a number along each line to indicate how strongly they feel about the given statements.

The day nursery questionnaire was adapted for day nursery nurse and day nursery manager completion, with the managers questionnaire including questions regarding properties, procedures, training and communication of information. The day nursery nurse questionnaire included more questions regarding reported practice.

### **4.2.2 Ethics**

Ethical approval was obtained from the Cardiff School of Health Sciences Ethics Committee (UWIC) before implementation of this component of the study.

**Figure 4.1 Plan of methods for day nursery postal questionnaire process**



## **4.2.3 Data collection**

### ***4.2.3.1 Pilot testing***

To aid development of the questionnaire, pilot testing occurred in two stages. Firstly, day nursery nurse and day nursery manager questionnaires were administered by hand to five local day nurseries. Direct feedback was obtained from staff in the nurseries which completed the questionnaires, for example understanding of instructions, recorded length of completion time, ease of respondent understanding and answering of questions/statement responses/terminologies used etc. Amendments were made to questionnaires in response to feedback. Subsequent pilot testing of the revised questionnaires and postal methodology occurred using 10% of the total sample. Therefore, questionnaires were administered to managers and day nursery nurses in local nurseries. Reminder letters and telephone calls were made as would be for the process of the main study.

An initial analysis of data collected from the pilot study was undertaken using SPSS (Version 17.0) and Microsoft Excel (2007). Internal reliability/consistency was calculated for the piloted attitudinal data using Cronbachs Alpha (0.74). For the internal consistency of a questionnaire to be reliable, Cronbachs alpha should be  $>0.7$  and  $<0.9$  (Streiner & Norman 2001). Therefore, when rounded up, the attitude response scale for this questionnaire was considered to have acceptable internal consistency.

The revised and final versions of the first mail covering letter, postal questionnaires and reminder letters can be found in Appendix 4.

### ***4.2.3.2 Sampling procedures***

The aim of this component of the study (according to the initial FSA proposal) was to obtain 100 completed questionnaires from day nursery caregivers. Previous UWIC research to healthcare and food safety professionals using a similar postal questionnaire method obtained a 27-34% response rate (Redmond *et al.* 2005). To ensure the target number of questionnaires was returned (and erring on the side of caution), the number of day nurseries sampled assumed a 15% response rate.

UK day nursery contact details used for this study were obtained from the publically available [www.daynurseries.co.uk](http://www.daynurseries.co.uk) website which is considered to be a leading, comprehensive source of UK day nurseries. All day nurseries included in the database created for this study reported that they had the facilities to care for infants aged less than 6 months (where details of age of infant care were

unavailable online nurseries were telephoned to obtain the information). Contact details from this source were provided according to county. A breakdown of the number of day nurseries registered in England, Wales and Scotland were obtained from The National Day Nurseries Association and Laing & Buisson (2008) (an independent company providing data and statistics on the UK Childcare -among others- sectors). The data indicated that 82% day nurseries were in England (see Table 4.1).

**Table 4.1 Breakdown of day nurseries in the UK**

	Total number of day nurseries	% of total no. nurseries in UK	No. of day nurseries where questionnaires administered
England	13,138 <sup>♦</sup>	82%	372
Wales	465 <sup>♦</sup>	3%	166
Scotland	2,017 <sup>♦</sup>	13%	166
Northern Ireland	261 <sup>▪</sup>	2%	166

<sup>♦</sup>source: Laing and Buisson (2008)

<sup>▪</sup> source: [www.daynurseries.co.uk](http://www.daynurseries.co.uk)

To enable broad regional comparisons, England was divided into four regions according to the Government Office county classification (<http://www.gos.gov.uk/gowm/>) (see Appendix 4).

**Table 4.2 Identification of day nurseries for the day nurseries database**

Geographical location	No. of nurseries sampled	No of day nurseries to randomly select (using random number generator websites and number day nurseries from each geographical area).
North England	93	18-19 nurseries randomly from each county on the ' <a href="http://www.daynurseries.co.uk">http://www.daynurseries.co.uk</a> ' website - some cities, some small towns/rural etc
South England	93	7-8 nurseries randomly from each county on the ' <a href="http://www.daynurseries.co.uk">http://www.daynurseries.co.uk</a> ' website - some cities, some small towns/rural
Midlands and East England	93	5-6 nurseries randomly from each county on the ' <a href="http://www.daynurseries.co.uk">http://www.daynurseries.co.uk</a> ' website - some cities, some small towns/rural
London	93	2-3 nurseries randomly from each area (37 areas in ' <a href="http://www.daynurseries.co.uk">http://www.daynurseries.co.uk</a> ' of London
Wales	166	Select 7-8 nurseries randomly from each county on the ' <a href="http://www.daynurseries.co.uk">http://www.daynurseries.co.uk</a> ' website – some cities, some small towns/rural
Scotland	166	Select 15-16 nurseries randomly from each county on the ' <a href="http://www.daynurseries.co.uk">http://www.daynurseries.co.uk</a> ' website - some cities, some small towns/rural
Northern Ireland	166	Select 27-28 nurseries randomly from each county on the ' <a href="http://www.daynurseries.co.uk">http://www.daynurseries.co.uk</a> ' website - some cities, some small towns/rural



Day nurseries were selected based on a stratified random sample (using a random number generator), based on even geographical distribution and accounting for approximate proportions of nurseries in each country (see Table 4.2). The number of nurseries sampled was based on (a) the need to achieve minimum of 25 responses from England, Wales, Northern Ireland and Scotland, (based on 15% response rate) which would allow for country comparisons *and* (b) a minimum response rate for four English regions to facilitate the potential for regional comparisons (albeit on statistically small samples if minimum response rate is achieved). It was ensured that all day nurseries compiled into the day nursery database always or sometimes cared for infants aged less than 6 months. This was achieved by consulting the ‘<http://www.daynurseries.co.uk>’ website and telephoning a large number of nurseries where online information was not available.

#### **4.2.3.3 Main study data collection**

Overall, 870 day nurseries were sent questionnaires – this represented 5.4% of all day nurseries in the UK. Each nursery was sent a covering letter, both day nursery manager and day nursery nurse questionnaires with pre-paid return envelopes. The study utilised a three tiered administration process, with subsequent follow ups two weeks after each mailing, including a second mailing with reminder letter and copy of the questionnaire and third mailing reminder letter (for non responses). All such questionnaires were distributed across the UK at once (March – May, 2009).

#### **4.2.4 Data analysis**

Data was entered into a specially designed Microsoft Access (2007) database. An analysis of all postal questionnaire data was undertaken using SPSS (Version 15.0) and Microsoft Excel (2007).

### **4.3 RESULTS**

Cumulatively, the FSA objective for this part of the study exceeded required number of questionnaires returned and additionally, questionnaires were obtained from day nursery nurses *and* day nursery managers.

#### **4.3.1 Sample Specification**

Overall, 27% of day nurseries responded to the postal questionnaire, resulting in the return of 339 day nursery nurse questionnaires and 224 day nursery manager questionnaires (see Table 4.3). Responses from some nurseries included both managers and day nursery nurses. Breakdown of responses according to geographic region/country is presented in Table 4.4

**Table 4.3 Questionnaire distribution numbers and response**

	No. of questionnaires sent (no's based on first mailings)	No of questionnaires returned	Target
Day nursery nurses	870	339	100
Day nursery managers	870	224	-
Total day nurseries	870	234	-

**Table 4.4 Geographic breakdown of responses to the day nursery questionnaire**

Location (no. nurseries)	Day nursery nurses	Day nursery managers
	No. responses (% of total responses) (n=339)	No. responses (% of total responses) (n=224)
England – London (n=93)	30 (9)	17 (8)
England – Midlands and East (n=93)	29 (8)	21 (9)
England – North (n=93)	37 (11)	26 (12)
England – South (n=93)	36 (11)	26 (12)
England (n=372)	132 (39)	90 (40)
Northern Ireland (n=116)	45 (13)	29 (13)
Scotland (n=116)	80 (24)	47 (21)
Wales (n=116)	78 (23)	54 (24)

Final follow up telephone calls to 10% of non-responses for each country/region resulted in determination of reasons for non-response and also resulted in the return of additional questionnaires. Main reasons for non response included lack of time, unavailability of suitable staff to complete the questionnaire, reports that nurseries were not currently caring for suitably aged infants at the time of questionnaire receipt and reports that nurseries did not prepare formula from powder in the nursery, so considered the questionnaire not relevant for completion.

#### 4.3.2 Background data

Overall, 58% day nursery nurses reported caring for infants aged 0-3 months and 90% also cared for infants aged 4-6 months; in 73% nurseries infant care was reported to be usually for 7-10 hours per day. Most day nurseries cared for either 0 (38-47%) or 1-3 infants aged less than 6 months at the time of responding to the questionnaire (see Table 4.5).

**Table 4.5 Number of infants aged less than 6 months in day nursery care at time of questionnaire completion**

	Day nursery nurses no. responses (%) (n=339)	Day nursery managers no. responses (%) (n=224)
0	159 (47)	85 (38)
1-3	128 (38)	84 (38)
4-6	9 (3)	10 (3)
7-9	2 (<1)	3 (1)
10-12	2 (<1)	4 (2)
13 or more	1 (<1)	1 <sup>▲</sup> (<1)
No response	37 (11)	36 (16)

<sup>▲</sup> 17 infants less than 6 months

The data presented in Table 4.6 indicates that infants aged less than 6 months are cared for 7-10 hours per day (68% day nursery nurses, 81% day nursery managers). Up to 7% of nurseries reported that infants are cared for more than 10 hours per day.

**Table 4.6 Length of time infants aged less than 6 months usually stay in the nursery**

	Day nursery nurses no. responses (%) (n=339)	Day nursery managers no. responses (%) (n=224)
Up to two hours per day	28 (8)	17 (8)
3 – 6 hours per day	144 (43)	106 (47)
7-10 hours per day	231 (68)	181 (81)
More than 10 hours per day	17 (5)	16 (7)
No response	47 (14)	20 (9)

*NB: Respondents provided more than one response*

#### **4.3.3 Day nursery kitchen facilities: day nursery nurse responses**

Overall, 95% (323/339) of day nursery nurses reported they had a kitchen/kitchen type area for preparing, handling or storing PIF feeds. Of those who reported having a kitchen/area, 34% considered the area to be ‘small’ or ‘extremely small’ with ‘limited or very small work surface space’, 52% considered it to be ‘medium sized’, with enough work surface space and 12% considered it to be large, with more than enough work surface space. Reported uses of the kitchen/kitchen area where PIF feeds are prepared/handled etc are presented in Table 4.7.

**Table 4.7 Reported uses of the kitchen/kitchen area where powdered infant formula feeds are prepared/handled (n=323)**

	No. day nursery nurses (%) (n=323)
Preparing powdered infant formula feeds	271 (84)
Cleaning used feeding bottles/teats etc	254 (79)
Sterilising used feeding bottles/teats etc	210 (65)
Storing powdered infant formula feeds	236 (73)
Preparing infant foods	278 (86)
Preparing staff food/coffees	153 (47)
As a storage area	236 (73)
Laundry	48 (15)
Other *	31 (10)

*NB: Respondents provided more than one response*

*\* warming feeds, lunch area, preparation of children's snacks and main nursery meals, staff lunches, preparation and cooking of meals, office, staff room/notice board*

The data shown in Table 4.8 indicates that not all day nurseries have a fridge for storage or sink area for preparation of feeding bottles etc. Between 24-45% of day nursery nurses indicated that they had equipment present in the nursery for sterilising feeding equipment/utensils.

**Table 4.8 Reported items present in kitchen/kitchen area where powdered infant formula feeds are prepared/handled (n=323)**

	No. day nursery nurses n (%)
Microwave	279 (86)
Kettle	294 (91)
Sink/draining board	301 (93)
Dishwasher	127 (93)
Steam steriliser	146 (45)
Cold water sterilising unit	128 (40)
Microwave steriliser	78 (24)
Fridge	301 (93)
Other *	18 (6)

*NB: Respondents provided more than one response*

*\*bottle warmer, blender, cooker/oven, freezer, toaster, washing machine*

**Table 4.9 Reported frequency of checking fridge temperature (n=323)**

	No. day nursery nurses n (%)
2 or more times a day	151 (47)
At least once a day	150 (46)
Once or twice a week	7 (2)
Once a week or more	7 (2)
Once a month or more	7 (2)
Less than monthly	5 (2)
Never	3 (1)
Don't know	8 (2)
Other *	3 (1)

\*3 times a day (morning, afternoon and late afternoon)

**Table 4.10 Knowledge of the maximum temperature that their fridge should operate to ensure food safety (n=301)**

	No. day nursery nurses n (%)
<0°C	2 (<1)
1-5°C	216 (72)
>6°C	52 (17)
Don't know	16 (5)
No response	15 (5)

Frequency data indicated that day nursery staff reportedly checked refrigerator temperatures at least once a day (Table 4.9). The majority (91%) of day nursery nurses reported that the 'checked' temperatures were written down and recorded. However, more than 20% of day nursery nurses were unaware of the maximum recommended operating temperature to ensure safety (see Table 4.10). In most cases, when temperature monitoring was undertaken, a plastic fridge thermometer was used (Table 4.11).

**Table 4.11 Reported method for monitoring day nursery refrigerator temperature (n=301)**

	No. day nursery nurses n (%)
Use of a plastic, traditional fridge thermometer	225 (75)
Use of a digital fridge thermometer	83 (28)
Ensure the dial is on the correct number	2 (<1)
Don't know	3 (1)
Other *	11 (4)
No response	26 (7)

*NB: Respondents provided more than one response*

*\*\* Use of cold water bottle – check with probe, use of a probe*

**Table 4.12 Reported frequency for cleaning the day nursery refrigerator (n=301)**

	No. day nursery nurses n (%)
Every day	82 (27)
Once or twice a week	121 (40)
Once a week or more	103 (34)
Once a month or more	14 (5)
Less than monthly	5 (2)
Don't know	6 (2)
Other *	8 (3)

*NB: Respondents provided more than one response*

*\*\* 'Every day general clean, once a week thoroughly', 'as and when needed', 'as necessary', 'as needed', 'more if spillages'*

The majority of day nursery nurses reported that refrigerators were 'cleaned' once or twice a week, although 7% reported this practice would occur either once a month/less than once a month (see Table 4.12).

#### **4.3.4 Preparation, storage and feeding of powdered infant formula in day nurseries**

The data presented in Table 4.13 indicate reported methods used for preparation, handling and storage of PIF in UK day nurseries. Findings show a considerable variability of reported practices in UK day nurseries. The most commonly reported method was reconstituted bottles of PIF being brought into the nursery from parents' homes for use throughout the day.

**Table 4.13 Reported methods used to deal with feeding infants with powdered infant formula in day nurseries**

	Day nursery nurses (n=339) No. (%)	Day nursery managers (n=138) No. (%)
Made-up bottles of powdered formula milk are brought from home to the nursery to be used throughout the day	207 (61)	77 (55)
Cartons of ready-to-use formula and sterilised bottles are brought to the nursery to be used throughout the day	154 (45)	64 (46)
Measured amounts of powdered formula and empty sterilised bottles are brought to the nursery for nursery staff to make up	114 (34)	56 (41)
Measured amounts of powdered formula and sterilised bottles with quantities of water are brought to the nursery for nursery staff to make up	160 (47)	49 (35)
Parents provide tins of powdered formula to the nursery and replace when necessary. The formula is made-up by nursery staff	157 (10)	51 (37)
Powdered formula is provided by the nursery and made-up by the nursery staff	34 (17)	20 (14)
Feeding bottles are provided and sterilised by the nursery	57	24 (17)

*NB: Respondents provided more than one response*

The data in Table 4.14 shows the geographic breakdown of reported methods used for dealing with PIF in UK nurseries. It can be seen that the most commonly reported method in England is to prepare the feeds using tins of formula provided by parents; whereas in Wales, Scotland and Northern Ireland, use of PIF prepared by parents at home before nursery appears to be more common place.

**Table 4.14 Day nursery nurse reported methods used for feeding infants with powdered infant formula in day nurseries according to country/region**

n (% of country/region)	English regions				England (total) n=132	Northern Ireland n=45	Wales n=78	Scotland n=80
	London n=30	Midlands/East n=29	North n=37	South n=36				
Made-up bottles of powdered formula milk are brought from home to the nursery to be used throughout the day	9 (30)	12 (41)	25 (68)	15 (42)	61 (46)	29 (64)	52 (67)	62 (78)
Cartons of ready-to-use formula and sterilised bottles are brought to the nursery to be used throughout the day	10 (33)	6 (21)	13 (35)	13 (36)	42 (31)	20 (44)	42 (54)	49 (63)
Measured amounts of powdered formula and empty sterilised bottles are brought to the nursery for nursery staff to make up	12 (40)	11 (38)	15 (41)	9 (25)	47 (36)	8 (18)	32 (41)	26 (33)
Measured amounts of powdered formula and sterilised bottles with quantities of water are brought to the nursery for nursery staff to make up	6 (20)	14 (48)	21 (57)	17 (47)	58 (44)	15 (33)	41 (53)	44 (55)
Parents provide tins of powdered formula to the nursery and replace when necessary. The formula is made-up by nursery staff	18 (60)	16 (55)	15 (41)	16 (44)	65 (49)	24 (53)	41 (53)	24 (30)
Powdered formula is provided by the nursery and made-up by the nursery staff	7 (23)	8 (28)	1 (3)	5 (14)	21 (16)	1 (2)	4 (5)	8 (10)
Feeding bottles are provided and sterilised by the nursery	9 (30)	12 (41)	25 (68)	15 (42)	61 (46)	29 (64)	52 (67)	62 (78)

*NB: Respondents provided more than one response*



### 4.3.5 Reconstituted powdered infant formula feeds brought to nursery

Concurring with data presented in Chapter 7, cumulative findings from this questionnaire indicate that the most common method for parents to bring reconstituted PIF feeds to nursery (as reported by day nursery nurses) (see Table 4.15) is using a non-insulated, ‘normal’ bag. Less than a third of parents reportedly use a cool bag with freezer packs and just over half (54%) reportedly use an insulated bag to keep feeds warm during transportation to nursery.

**Table 4.15 Reported methods/bags that day nursery nurses see parents bringing reconstituted powdered infant formula feeds**

	Day nursery nurses (n=207) n (%)
In insulated bag/part of baby bag to keep bottle warm	111 (54)
In a cool bag/part of baby bag with frozen cool packs	63 (30)
In a cool bag/part of baby bag (no frozen cool packs)	93 (45)
In the bottle holder on a pushchair/pram	14 (7)
In a carrier bag/other general bag/handbag/rucksack/general compartment of baby bag	168 (81)
Don't know	3 (1)
Other*	13 (6)

*NB: Respondents provided more than one response*

*\*\* Other responses: separate bottle bag; parents do not bring made-up feeds to the nursery*

Day nursery nurses reported that more reconstituted feeds brought to the nursery felt cold on arrival, however similar proportions felt warm/ambient temperature (see Table 4.16).

**Table 4.16 Reported temperature feel of reconstituted powdered infant formula feeds on arrival at the day nursery**

	Day nursery nurses (n=207) n (%)
Cold	154 (74)
Room temperature	132 (64)
Luke warm	134 (65)
Very warm	81 (39)
Don't know	4 (2)

*NB: Respondents provided more than one response*

Of the nursery nurses who reported that reconstituted bottles of PIF are brought to their nursery, 57% reported 1-5 feeds are brought in and only 1% reported between 16-20 feeds (see Table 4.17).

**Table 4.17 Reported numbers of bottles of reconstituted powdered infant formula usually brought to nurseries every day (n=207)**

	Day nursery nurses (n=207) n (%)
1-5	118 (57)
6-10	54 (26)
11-15	12 (6)
16-20	2 (1)
21 or more	0
variable	3 (1)
No response	26 (13)

Findings presented in Table 4.18 show that 85% of feeds that reportedly felt ‘cool’ on arrival at nursery are refrigerated within 15 minutes; however, feeds that feel hot/warm on arrival may be refrigerated more than two hours later.

**Table 4.18 Reported length of time between feed arrival in the nursery and refrigeration (n=207)**

	Day nursery nurses hot/warm feeds n (%)	Day nursery nurses cold feeds n (%)
Less than 15 minutes	34 (16)	176 (85)
16-30 minutes	68 (33)	8 (4)
31 minutes – 1 hour	60 (29)	4 (2)
1-2 hours	18 (9)	2 (1)
More than 2 hours	3 (1)	0
Don't know	4 (2)	2 (1)

### 4.3.6 Preparation of powdered infant formula feeds in day nurseries

Three quarters of day nursery nurses indicated that they prepare PIF feeds in their day nursery. Nearly half (161/339) reported they made feeds up every day (see Table 4.19).

**Table 4.19 Reported frequency of preparation of powdered infant formula in day nurseries (n=339)**

	Day nursery nurses n (%)
Every day	161 (47)
2-3 days a week	51 (15)
4-5 days a week	12 (4)
Once a week or more	13 (4)
Once a month or more	8 (2)
Never	83 (25)
No response	11 (3)

The greatest proportion (57%) of nursery nurses who reported preparation of PIF feeds in the nursery, prepared 1-5 feeds each day (see Table 4.20). Few day nursery nurses (2%) reported preparation of >20 feeds per day. It was noted that the number of feeds prepared was dependent upon the number of infants in care and the length of time in the nursery each day, thus the daily numbers of made-up feeds would be variable.

**Table 4.20 Reported numbers of bottles of powdered infant formula prepared/made-up/reconstituted in day nurseries (n=276)**

	Day nursery nurses n (%)
1-5	158 (57%)
5-10	71 (26)
11-15	1 (<1)
16-20	3 (2)
21-25	2 (1)
26 or more	2 (1)
variable	3 (2)
No response	38 (14)

Seventy eight percent of nursery nurses reported preparation of PIF feeds in a nursery kitchen; 8% reported preparation of feeds in a specific ‘baby room kitchen’ and other nursery nurses reported preparation of feeds in a ‘baby room’.

The data shown in Table 4.21 indicates that in only a few instances (5%) is one specific person assigned to make up feeds in day nurseries. It is reported that the responsibility for feed preparation was whoever was available (42%) or nursery staff assigned to ‘key’ infants (48%). Findings presented in Table 4.22 indicate that the majority (84%) of day nursery nurses reported that they reconstituted PIF feeds ‘as and when required’ throughout the day. However, 15% indicated they reconstitute feeds in batches or at the start of the day and store until required for use.

**Table 4.21 Reported responsibility for preparation of powdered infant formula prepared/made-up/reconstituted in day nurseries (n=276)**

	Day nursery nurses n (%)
One specific person in the nursery	15 (5)
Whoever is available	117 (42)
Individual nursery staff make formulas up for their assigned ‘key’ infant(s)	132 (48)

*Other persons responsible for making feeds include baby room staff, senior staff/supervisors, early shift staff, fully qualified nursery practitioner, member of staff assigned to kitchen duty, trained staff, students.*

**Table 4.22 Reported timing/organisation of reconstitution of powdered infant formula feeds in day nurseries (n=276)**

Powdered infant formula feeds reconstituted.....	Day nursery nurses n (%)
.....all at once at the beginning of the day	29 (11)
.....in batches throughout the day	12 (4)
.....one at a time as required for feeding individual infants throughout the day	232 (84)

*NB: % may not add up to 100% due to non responses*

The majority (97%) of day nursery nurses reported that PIF feeds were made-up with boiled water in the nursery where they worked. Forty five percent used water they boiled in the nursery and 45% used water previously prepared by the infants’ parents before arriving at the nursery. Five percent of nursery nurses reported boiling tap water and pouring it into a jug before use (see Table 4.23).

Of the nursery nurses who reported boiling the kettle for preparation of PIF feeds in the nursery (n=183), 43% reported they fill the kettle to the maximum level with water, 43% reported they half fill the kettle and 9% reported filling the kettle with the minimum level of water (the remaining reported ‘don’t know’).

Boiled water in the kettle was reportedly cooled in the kettle for <15 minutes by 39% of nursery nurses, for between 16-30 minutes by 46% of nursery nurses, between 31 minutes – 1 hour by 14% of nursery nurses and for more than 1 hour by 3% of the sample.

**Table 4.23 Reported preparation of powdered infant formula prepared/made-up/reconstituted in day nurseries: preparation/use of water (n=276)**

	Day nursery nurses responses (%)
... boil the kettle, cool boiled water in the kettle and then pour into a feeding bottle	125 (45)
... boil the kettle and pour hot water into feeding bottle(s) straight away	76 (28)
... use water in sterilised bottle prepared by infants’ parents	125 (45)
... use tap water (not boiled)	2 (<1)
... use bottled water	7 (3)
Other: Boiled tap water is poured into a jug before use (some with lid on jug)	10 (4)
Other: Boiled tap water stored in flask, made-up at the beginning of the day	1 (<1)

*NB: Respondents provided more than one response*

Reconstitution of PIF in nurseries reportedly may occur using hot boiled water, boiled water that has cooled in the nursery or water prepared by parents in infant feeding bottles, which may be stored at ambient temperature or in the fridge.

Findings in Table 4.24 show 18% of day nursery nurses reported they fed the formula to the infant straight away, 64% cooled the formula to a suitable temperature and 22% stored the formula until required for feeding.

**Table 4.24 Reported preparation of powdered infant formula reconstituted in day nurseries: practices following reconstitution of infant formula powder with water (n=276)**

	Day nursery nurses n (%)
Feed the made-up formula to the infant immediately	49 (18)
Cool the made-up formula to a suitable temperature and feed to the baby immediately	177 (64)
Warm the made-up formula to a suitable temperature and feed to the baby immediately	90 (33)
Place the made-up formula in the fridge and store until required for feeding	27 (10)
Leave the made-up formula at room temperature until required for feeding	32 (12)

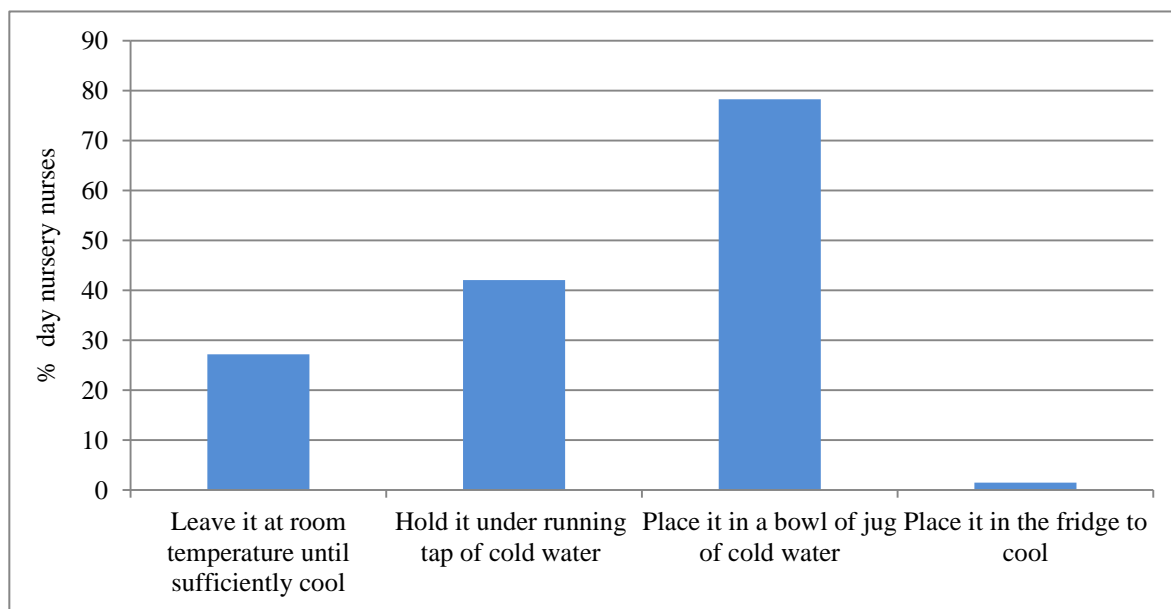
*NB: Respondents provided more than one response*

*Other 'depends upon parents' wishes', 'depends upon how child likes it'*

#### **4.3.6.1 Feeding reconstituted powdered infant formula in day nurseries: cooling practices**

Results shown in Figure 4.2 illustrate that the most common practice reported for cooling PIF feeds before feeding included placing a bottle of reconstituted formula in a bowl or jug of cold water (78%) or holding it under a tap of running cold water (42%). Twenty seven percent of nursery nurses indicated that they leave the PIF at room temperature until sufficiently cool, and 4% reported placing the warm/hot feed in the fridge to cool.

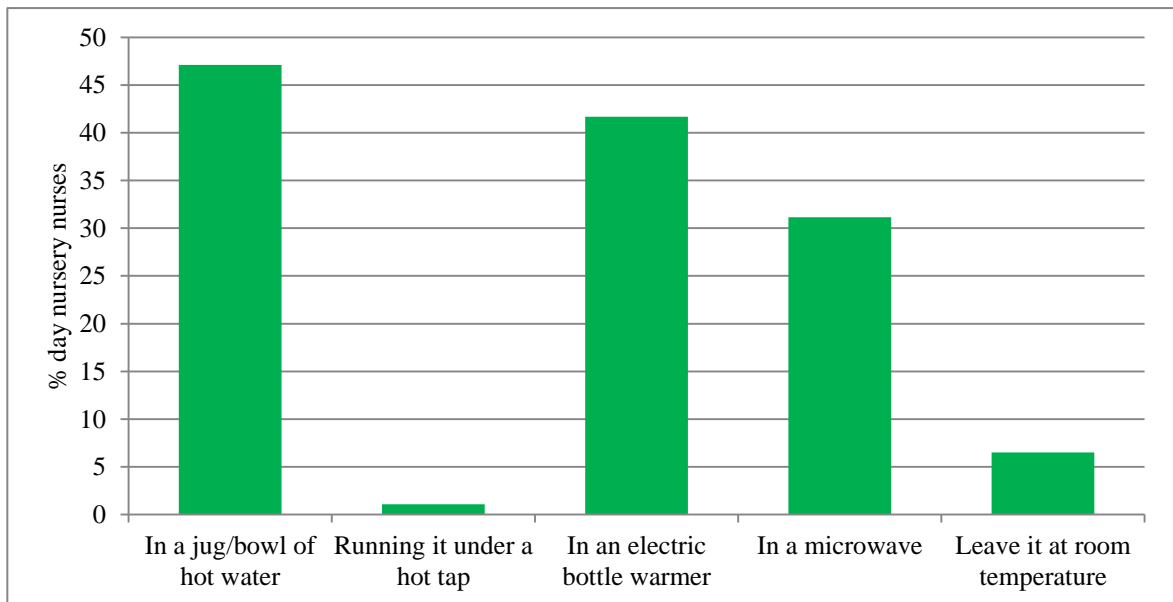
**Figure 4.2 Reported practices used for cooling reconstituted powdered infant formula feeds before feeding (n=276)**



#### 4.3.6.2 Feeding reconstituted powdered infant formula in day nurseries: reheating practices

The most commonly reported practices used to warm a PIF feed before feeding included placing the bottle of feed in a jug/bowl of hot water (47%) and using an electric bottle warmer (42%). A third of nursery nurses (31%) reported using the microwave to heat feeds up and 7% reported leaving it at room temperature (see Figure 4.3).

**Figure 4.3 Reported practices used for reheating reconstituted powdered infant formula feeds before feeding (n=276)**



### 4.3.7 Handling and storage of powdered infant formula feeds in day nurseries

The majority of nursery nurses reported storing feeds (where necessary) in the fridge – a lower proportion noted storage would be in the fridge door (see Table 4.25).

**Table 4.25 Reported locations for storage of made-up powdered infant formula feeds before feeding (n=339)**

	Day nursery nurses (%)
In the fridge door	159 (47)
Wherever there is room in the fridge	45 (13)
On a shelf near the back of the fridge	91 (27)
On a work surface	24 (7)
In a cupboard/infants box	34 (10)
Other: room temperature	2 (<1)
Other: Child’s cool bag	3 (1)
Other: Child’s bag/basket	7 (2)
Other: baby bottle fridge	7 (2)
Other: Other fridge location (salad box, shelf, bottom shelf)	7 (2)
Other: Child’s lunchbox placed into fridge	10 (3)
Other: Made-up feeds not stored	24 (7)

*NB: Respondents provided more than one response*

Eighty five percent of nursery nurses reported that made-up formula feeds were labelled in the nursery. Data indicated that attaching and writing labels on the feeds was undertaken by both parents and nursery staff. For 48% of cases it was the parents’ responsibility to label feeds and for 92% it was the responsibility of nursery staff. Information noted on the label included the infants’ name/initials (95%), date (24%), time feed reconstituted (9%) and brand of formula (4%). Other information nursery nurses reported to be noted on feed labels included the approximate time of feeding (<1%), how many scoops of formula the feed had been reconstituted with (<1%) and ‘colour bands’ (3%).

Eighteen percent of day nursery nurses reported that made-up PIF feeds that had not been drunk were kept to show parents. Of these, 67% were sometimes stored in the fridge, 33% were sometimes stored on the work surface and 41% were sometimes stored in the infants’ box/bag. In most cases, it was reported that stored, unfed PIF was taken home by the parents and 23% of day nursery nurses were happy to allow this.



#### **4.3.8 Attitudes towards powdered infant formula, perceived efficacy and other issues**

Overall, 77% of day nursery nurses and 70% of day nursery managers considered PIF to be a sterile product before opening the tin. Few day nursery nurses (15%) and day nursery managers were aware of the association between *E.sakazakii* and PIF; 28% of day nursery nurses and 24% of day nursery managers were aware of the association between *Salmonella* and PIF (see Table 4.26 and 4.27).

The majority of day nursery nurses and day nursery managers believed they knew all of the safety precautions necessary for safe preparation and storage of PIF and most also considered it was easy to implement all recommended safety practices. More day nursery managers (71%) were confident they knew all of the up to date guidelines about minimising microbiological risks associated with feeding with PIF compared to 58% day nursery nurses.

Data showed that 55% of day nursery nurses and 61% of day nursery managers indicated they did have concerns about infants experiencing stomach infections resulting from the PIF fed in the nursery where they worked.

Twenty percent of day nursery nurses and 18% of day nursery managers reported that they considered infant feeds/feeding bottles sometimes brought in to the nursery (by parents) to be unclean. Furthermore, 14% of day nursery nurses and 9% of day nursery managers reported they sometimes have to feed infants using bottles brought from infants' homes that they consider to be unclean.

**Table 4.26 Day nursery nurse attitudes towards powdered infant formula, perceived efficacy and other concerns**

	Attitude statement	Strongly agree n (%)	Agree n (%)	Neither agree/disagree n (%)	Disagree n (%)	Disagree Strongly n (%)	Don't know
Microbial hazards	Before opening a tin of powdered formula milk, the powdered milk is a sterile product (i.e. is free from all germs and bacteria) (n=320)	97 (29)	162 (48)	26 (8)	14 (4)	7 (2)	14 (4)
	<i>Enterobacter sakazakii</i> can be found in powdered infant formula (n=305)	17 (5)	33 (10)	76 (22)	2 (<1)	1 (<1)	176 (52)
	There is no association between <i>Salmonella</i> and powdered formula (n=310)	10 (3)	23 (7)	85 (25)	69 (20)	29 (8)	94 (28)
	Making up one feed at a time (fresh) for immediate feeding is <u>essential</u> to reduce the chance of illness from powdered infant formula. (n=327)	96 (28)	99 (29)	71 (21)	44 (13)	9 (3)	8 (2)
Perceived efficacy	I know all of the precautions necessary for safe preparation and storage of powdered formula milk (n=332)	134 (40)	174 (51)	16 (5)	5 (1.5)	1 (<1)	2 (<1)
	It is easy to implement all of the recommended safety practices for safe preparation of powdered infant formula (n=329)	113 (33)	189 (56)	20 (6)	5 (1)	5 (1)	10 (3)
	I am confident that I know all of the up-to-date guidelines about minimising microbial risks associated with feeding with powdered formula milk (n=326)	53 (16)	143 (42)	85 (25)	32 (9)	3 (1)	10 (3)
	I have no concerns about the safety of powdered infant formula feeds <u>prepared</u> in my nursery (n=317)	94 (28)	162 (48)	31 (9)	16 (5)	11 (3)	3 (1)
	I am not concerned about infants experiencing stomach infections resulting from powdered infant formula fed in the nursery where I work (n=323)	31 (9)	72 (21)	29 (9)	83 (19)	123 (36)	4 (1)
Other concerns	Parents sometimes bring made-up feeds/bottles, ready for feeding, to the day nursery that I consider to be unclean <sup>1</sup> (n=278)	15 (4)	53 (16)	32 (9)	108 (32)	69 (20)	1 (<1)
	I sometimes have to feed infants using bottles that parents bring from home that I consider to be unclean <sup>1</sup> (n=280)	6 (2)	41 (12)	21 (6)	126 (37)	85 (25)	1 (<1)

<sup>1</sup>Not all nurseries have parents bringing bottles/made-up feeds to nursery

Percentage responses for some attitude statements may not add up to 100 due to non responses

**Table 4.27 Day nursery manager attitudes towards powdered infant formula, perceived efficacy and other issues (n=224)**

Attitude statement		Strongly agree n (%)	Agree n (%)	Neither agree/disagree n (%)	Disagree n (%)	Strongly disagree n (%)	Don't know n (%)
Microbial hazards	Before opening a tin of powdered formula milk, the powdered milk is a sterile product (i.e. is free from all germs and bacteria) (n=218)	70 (31)	88 (39)	20 (9)	19 (9)	9 (4)	9 (4)
	<i>Enterobacter sakazakii</i> can be found in powdered infant formula (n=208)	21 (9)	39 (17)	44 (20)	1 (<1)	3 (1)	100 (45)
	There is no association between <i>Salmonella</i> and powdered formula (n=213)	3 (1)	8 (4)	56 (25)	28 (12)	28 (12)	55 (25)
	Making up one feed at a time (fresh) for immediate feeding is <u>essential</u> to reduce the chance of illness from powdered infant formula (n=221)	68 (30)	57 (25)	47 (21)	8 (4)	8 (4)	8 (4)
Perceived efficacy	I know all of the precautions necessary for safe preparation and storage of powdered formula milk (n=222)	97 (43)	103 (46)	16 (7)	5 (2)	1 (<1)	0
	It is easy to implement all of the recommended safety practices for safe preparation of powdered infant formula (n=218)	74 (33)	110 (49)	24 (11)	9 (4)	0	0
	I am confident that I know all of the up-to-date guidelines about minimising microbial risks associated with feeding with powdered formula milk (n=208)	63 (28)	97 (43)	28 (13)	11 (5)	3 (1)	3 (1)
	I have no concerns about the safety of powdered infant formula feeds <u>prepared</u> in my nursery (n=207)	61 (27)	105 (47)	18 (8)	6 (3)	6 (3)	3 (1)
	I am not concerned about infants experiencing stomach infections resulting from powdered infant formula fed in the nursery where I work (n=218)	21 (9)	42 (19)	14 (6)	53 (24)	83 (37)	4 (2)
Other issues	Parents sometimes bring made-up feeds/bottles, ready for feeding, to the day nursery that I consider to be unclean (n=164)	6 (3)	33 (15)	17 (8)	69 (31)	37 (17)	1 (<1)
	I sometimes have to feed infants using bottles that parents bring from home that I consider to be unclean (n=165)	3 (1)	18 (8)	13 (6)	81 (36)	48 (21)	1 (<1)

Percentage responses for some attitude statements may not add up to 100 due to non responses

#### **4.3.9 Attitudes towards important preparation, handling and storage behaviours**

Overall, 76% of day nursery nurses and 82% of day nursery managers reported that PIF is prepared and fed to infants according to parent instructions (see Table 4.28 and Table 4.29). It has been reported that this is the case even if contrary to recommended safe practices (Chapter 2).

Nearly half (44-47%) of day nursery managers and day nursery nurses considered it is acceptable to make up bottles of PIF in advance of use and nearly half (45-48%) of day nursery managers and day nursery nurses considered it acceptable to store made-up PIF in the fridge all day. Only 6-11% of day nursery managers and day nursery nurses considered it acceptable to store made-up PIF at room temperature for more than 2 hours.

**Table 4.28 Day nursery nurse attitudes towards important preparation, handling and storage behaviours (n=339)**

Attitude statement		Strongly agree n (%)	Agree n (%)	Neither agree/ disagree n (%)	Disagree n (%)	Strongly disagree n (%)	Don't know n (%)
Preparation of powdered infant formula feeds	Making up one feed at a time is difficult to do for every infant, <u>all</u> of the time in a day nursery (n=323)	35 (10)	48 (14)	48 (14)	126 (37)	63 (19)	3 (<1)
	Making up powdered formula feeds with cold or warm water is acceptable practice before feeding (n=322)	22 (7)	58 (17)	53 (16)	95 (28)	89 (26)	5 (2)
	It is difficult to judge the actual temperature of water when it is mixed with the formula powder (n=322)	18 (5)	92 (27)	68 (20)	101 (30)	36 (11)	7 (2)
	The time between arrival of feed at the nursery and placement in the refrigerator is not timed <sup>1</sup> (n=255)	10 (3)	55 (16)	48 (14)	82 (24)	49 (15)	11 (3)
Compliance with parent requests	I always comply with parent requests about how formula is to be prepared and fed to an infant (n=320)	123 (36)	124 (37)	47 (14)	19 (6)	7 (2)	0
	In the nursery where I work powdered infant formula is prepared/fed to infants according to parent instructions (n=330)	153 (45)	127 (37)	20 (6)	20 (6)	10 (3)	0
Storage of made-up feeds and preparation of PIF in advance of use.	It is acceptable to make up bottles of powdered formula milk in advance of use (n=321)	34 (10)	127 (37)	60 (18)	71 (21)	27 (8)	2 (<1)
	It is acceptable to keep made-up powdered formula at room temperature for more than 2 hours (n=322)	8 (2)	31 (9)	32 (9)	140 (41)	110 (32)	10 (3)
	It is acceptable to store made-up powdered formula in the fridge all day (n=326)	32 (9)	132 (39)	57 (17)	63 (19)	38 (11)	4 (1)
Nursery kitchen	The cleanliness of the kitchen area in the day nursery should be tested to ensure there are no harmful germs/bacteria present (n=330)	132 (39)	148 (44)	41 (12)	7 (2)	2 (1)	0
	There is plenty of space in the day nursery kitchen for preparation and storage of powdered infant formula feeds (n=330)	117 (35)	149 (44)	38 (11)	23 (7)	3 (<1)	0

<sup>1</sup> NO bottles/made-up feeds ever brought to nursery = 23% responses

Percentage responses for some attitude statements may not add up to 100 due to non responses

**Table 4.29 Day nursery manager attitudes towards important preparation, handling and storage behaviours (n=224)**

	Attitude statement	Strongly agree n (%)	Agree n (%)	Neither agree/disagree n (%)	Disagree n (%)	Strongly disagree n (%)	Don't know n (%)
Preparation of powdered infant formula feeds	Making up one feed at a time is difficult to do for every infant, <u>all</u> of the time in a day nursery (n=218)	33 (15)	37 (17)	31 (14)	74 (33)	39 (17)	3 (1)
	Making up powdered formula feeds with cold or warm water is acceptable practice before feeding (n=214)	6 (3)	29 (13)	28 (13)	83 (37)	66 (30)	1 (<1)
	It is difficult to judge the actual temperature of water when it is mixed with the formula powder (n=217)	6 (3)	50 (22)	33 (15)	87 (39)	38 (17)	3 (1)
	The time between arrival of feed at the nursery and placement in the refrigerator is not timed <sup>1</sup> (n=147)	6 (3)	41 (18)	17 (8)	46 (21)	46 (21)	3 (1)
Compliance with parent requests	I always comply with parent requests about how formula is to be prepared and fed to an infant (n=216)	50 (22)	71 (32)	50 (22)	39 (17)	7 (3)	0
	In the nursery where I work powdered infant formula is prepared/fed to infants according to parent instructions (n=220)	80 (36)	90 (40)	18 (8)	26 (12)	6 (3)	0
Storage of made-up feeds and preparation of PIF in advance of use.	It is acceptable to make up bottles of powdered formula milk in advance of use (n=221)	25 (11)	74 (33)	35 (16)	57 (25)	28 (13)	1 (<1)
	It is acceptable to keep made-up powdered formula at room temperature for more than 2 hours (n=217)	4 (2)	9 (4)	12 (5)	103 (46)	83 (37)	4 (2)
	It is acceptable to store made-up powdered formula in the fridge all day (n=220)	15 (7)	84 (38)	35 (16)	52 (23)	31 (14)	2 (<1)
Nursery kitchen	The cleanliness of the kitchen area in the day nursery should be tested to ensure there are no harmful germs/bacteria present (n=220)	62 (28)	107 (48)	40 (18)	5 (2)	2 (<1)	4 (2)
	There is plenty of space in the day nursery kitchen for preparation and storage of powdered infant formula feeds (n=219)	75 (34)	97 (43)	23 (10)	21 (9)	2 (<1)	0

<sup>1</sup>NO bottles/made-up feeds ever brought to nursery 77/224 respondents

Percentage responses for some attitude statements may not add up to 100 due to non responses

#### **4.3.10 Attitudes towards powdered infant formula information/sources**

The majority (92%) of day nursery managers considered it was their responsibility to obtain and inform their staff of changes to PIF preparation and storage recommendations; similarly 85% of day nursery nurses considered it was the responsibility of their manager to obtain and inform about changes to recommendations. However, data suggests that information about the new recommendations has not been sought or received by over a quarter of day nursery staff. The data indicated that 28% of day nursery nurses and 23% of day nursery managers were unaware or disagreed that recommendations of safe preparation and storage of PIF have changed in recent years (see Table 4.30 and Table 4.31).

Although 72% of day nursery nurses and 65% day nursery managers indicated the nursery where they work had a policy or systems in place for safe preparation, handling and storage of PIF, previous research (Redmond and Griffith, 2007) and Chapter 2 has suggested that reported 'policies' may be unstructured and in some cases just consist a list of 'do's and don'ts' in the kitchen.

**Table 4.30 Day nursery nurse perceptions and attitudes towards information/sources about how to prepare and handle powdered infant formula (n=339)**

Attitude statement	Strongly agree n (%)	Agree n (%)	Neither agree/disagree n (%)	Strongly disagree n (%)	Disagree n (%)	Don't know n (%)
Recommendations for safe preparation and storage of powdered infant formula have changed in recent years (n=325)	65 (19)	164 (48)	45 (13)	21 (6)	1 (<1)	29 (9)
Recommendations about preparation and storage of powdered formula milk are consistent from different sources (e.g. NHS, FSA, NCT, supermarkets, formula manufacturers etc) (n=323)	28 (8)	116 (34)	110 (32)	33 (10)	7 (2)	29 (9)
I would like to receive up-to-date information about powdered infant formula preparation and storage guidelines (n=327)	129 (38)	144 (43)	35 (10)	9 (3)	7 (2)	3 (<1)
It is the responsibility of my manager to obtain and inform me of changes to powdered infant formula preparation and storage recommendations (n=328)	83 (25)	137 (40)	62 (18)	38 (11)	6 (2)	4 (1)
It is not my responsibility to find information about updated powdered infant formula guidelines (n=326)	9 (3)	58 (17)	83 (25)	116 (34)	56 (17)	2 (<1)
I do not have time to search for information about infant feeding (n=330)	8 (2)	23 (7)	76 (22)	143 (42)	78 (23)	2 (<1)
I do not have time to read information about infant feeding (N=325)	6 (2)	7 (2)	31 (9)	161 (48)	118 (35)	2 (<1)
I think that unique policies and standards for individual day nurseries are better than national standards (n=320)	13 (4)	71 (21)	150 (44)	46 (14)	25 (7)	15 (4)
The nursery where I work has a policy and systems for safe preparation, handling and storage of powdered infant formula (n=242)	91 (27)	154 (45)	27 (8)	29 (9)	3 (1)	16 (5)
Part of my role as a nursery nurse is to give parents advice about safe preparation and storage of powdered infant formula (n=330)	42 (12)	102 (30)	96 (29)	68 (20)	21 (6)	1 (<1)
Parents often ask me about issues associated with safe preparation and storage of powdered infant formula.	11 (3)	54 (16)	96 (28)	132 (39)	31 (9)	5 (1)
I have read the Food Standards Agency guidelines for safe preparation, handling and storage of powdered infant formula.	50 (15)	142 (42)	41 (12)	65 (19)	12 (4)	10 (3)
My knowledge of powdered infant formula preparation, handling, storage and feeding is mainly from personal experience of having children.	29 (9)	66 (20)	21 (6)	72 (21)	51 (15)	2 (<1)
Following preparation and storage instructions on tins of powdered formula is <u>not</u> necessary.	3 (1)	5 (2)	14 (4)	142 (42)	164 (48)	2 (<1)



**Table 4.31 Day nursery manager perceptions and attitudes towards information/sources about how to prepare and handle powdered infant formula (n=224)**

Attitude statement	Strongly agree n (%)	Agree n (%)	Neither agree/disagree n (%)	Strongly disagree n (%)	Disagree n (%)
Recommendations for safe preparation and storage of powdered infant formula have changed in recent years (n=220)	52 (23)	117 (52)	28 (13)	2 (<1)	13 (6)
Recommendations about preparation and storage of powdered formula milk are consistent from different sources (e.g. NHS, FSA, NCT, supermarkets, formula manufacturers etc) (n=220)	26 (12)	90 (40)	49 (22)	5 (2)	15 (7)
I would like to receive up-to-date information about powdered infant formula preparation and storage guidelines (n=221)	114 (51)	92 (41)	3 (1)	1 (<1)	1 (<1)
It is my responsibility to obtain and inform my staff of changes to powdered infant formula preparation and storage recommendations (n=223)	95 (42)	113 (50)	3 (1)	2 (<1)	0
I do not have time to search for information about infant feeding (n=218)	2 (<1)	10 (5)	87 (39)	60 (27)	1 (<1)
I do not have time to read information about infant feeding (n=217)	4 (2)	5 (2)	110 (49)	81 (36)	1 (<1)
I think that unique policies and standards for individual day nurseries are better than national standards (n=217)	10 (5)	59 (26)	43 (19)	13 (6)	8 (4)
The nursery where I work has a policy and systems for safe preparation, handling and storage of powdered infant formula (n=213)	61 (27)	85 (38)	38 (17)	7 (3)	2 (<1)
Part of my role as a manager is to give parents advice about safe preparation and storage of powdered infant formula (n=220)	44 (20)	86 (38)	31 (14)	3 (1)	1 (<1)
Parents often ask me about issues associated with safe preparation and storage of powdered infant formula (n=217)	8 (4)	31 (14)	79 (35)	22 (10)	1 (<1)
I have read the Food Standards Agency guidelines for safe preparation, handling and storage of powdered infant formula (n=215)	44 (20)	118 (53)	26 (12)	4 (2)	5 (2)
My knowledge of powdered infant formula preparation, handling, storage and feeding is mainly from personal experience of having children <sup>1</sup> (n=191)	13 (6)	40 (18)	53 (24)	48 (21)	0
Following preparation and storage instructions on tins of powdered formula is <u>not</u> necessary.	5 (2)	6 (3)	80 (36)	124 (55)	0

<sup>1</sup>NO experience of having own children = 33/224

#### 4.3.11 Perceptions of risk, control, responsibility and hygiene consciousness during preparation of powdered infant formula

Data indicating perceptions of risk, control, responsibility and hygiene consciousness were determined for day nursery nurses (see Table 4.32) and day nursery managers (see Table 4.33). Day nursery nurses considered the risk of illness to an infant after drinking PIF made-up by themselves to be less than other nursery nurses, hospital staff and parents. Similarly, day nursery nurses considered they had more control over hygiene and safety and were more conscious of hygiene and safety than other nursery nurses, infants' parents and hospital staff.

**Table 4.32 Day nursery nurse perceptions of risk, control, responsibility and hygiene consciousness during preparation of powdered infant formula (n=339)**

Assessment of perceived risk, control and responsibility (key to ranking)	Caregivers	Sample who stated values 1-3. n (%)	Sample who stated values 8-10. n (%)	Mean ranking (SD)	Don't know/no response n (%)
What do you consider to be the risk of illness to infant from drinking made-up powdered infant formula prepared by.....[insert each of the following caregivers]? (1= Very High Risk, 10= Very Low Risk)	... <i>yourself</i>	6 (2)	273 (81)	9.1 (1.6)	39 (12)
	... <i>other nursery nurses</i>	6 (2)	241 (71)	8.9 (1.8)	60 (18)
	... <i>parents</i>	8 (2)	174 (51)	8.1 (2.1)	97 (29)
	... <i>hospital staff</i>	7 (2)	158 (47)	8.3 (2.1)	123 (36)
How much control do you think ... [insert each of the following caregivers]..... have over hygiene and safety when preparing infant feeds in your care? (1= No control ; 10=Full control)	... <i>yourself</i>	5 (2)	282 (83)	9.2 (1.6)	25 (7)
	... <i>other nursery nurses</i>	6 (2)	244 (72)	8.9 (1.9)	53 (16)
	... <i>parents</i>	13 (4)	226 (66)	8.9 (2.4)	68 (20)
	... <i>hospital staff</i>	16 (5)	203 (76)	8.7 (2.4)	97 (29)
How much responsibility do you think ... [insert each of the following caregivers]..... have for the safety infant feeds? (1=No responsibility; 10=Full responsibility)	... <i>yourself</i>	0	308 (91)	9.6 (<1)	20 (6)
	... <i>other nursery nurses</i>	0	291 (86)	9.6 (<1)	35 (10)
	... <i>parents</i>	1 (<1)	279 (82)	9.6 (1.1)	45 (13)
	... <i>hospital staff</i>	2 (<1)	248 (73)	9.5 (1.2)	77 (23)
How conscious of hygiene do you think ... [insert each of the following caregivers].....are when preparing infant feeds? (1=Not at all conscious; 10=Very conscious)	... <i>yourself</i>	5 (2)	304 (90)	9.5 (1.3)	24 (7)
	... <i>other nursery nurses</i>	4 (1)	262 (77)	9.3 (1.4)	53 (16)
	... <i>parents</i>	6 (2)	203 (60)	8.6 (1.9)	87 (26)
	... <i>hospital staff</i>	3 (1)	195 (57)	9.0 (1.7)	114 (34)

Day nursery nurses considered a similar level of responsibility for the safety of infant feeds made by themselves, other nursery nurses and parents and hospital staff.

Day nursery managers considered their nursery staff were associated with less risk, more control, more responsibility and more hygiene consciousness than infants' parents and hospital staff.

**Table 4.32 Day nursery manager perceptions of risk, control, responsibility and hygiene consciousness during preparation of powdered infant formula (n=224)**

Assessment of perceived risk, control and responsibility (key to ranking)	Caregivers	Sample who stated values 1-3. n (%)	Sample who stated values 8-10. n (%)	Mean ranking (SD)	Don't know/no response n (%)
What do you consider to be the risk of illness to infant from drinking made-up powdered infant formula prepared by.....[insert each of the following caregivers]? (1= Very High Risk, 10= Very Low Risk)	...your nursery staff	9 (4)	175 (78)	8.8 (1.6)	20
	... parents	7 (3)	152 (68)	7.6 (2.1)	48
	... hospital staff	2 (<1)	134 (60)	9.4 (1.1)	76
How much control do you think ... [insert each of the following caregivers]..... have over hygiene and safety when preparing infant feeds? (1= No control ; 10=Full control)	...your nursery staff	4 (2)	183 (82)	8.9 (2.1)	18
	... parents	7 (3)	107 (48)	8.8 (1.9)	41
	... hospital staff	8 (3)	108 (48)	8.2 (1.5)	73
How much responsibility do you think ... [insert each of the following caregivers]..... have for the safety infant feeds? (1=No responsibility; 10=Full responsibility)	...your nursery staff	2 (<1)	201 (90)	9.5 (1.1)	14
	... parents	3 (1)	181 (81)	9.4 (1.4)	30
	... hospital staff	0	155 (69)	9.7 (1.1)	64
How conscious of hygiene do you think ... [insert each of the following caregivers].....are when preparing infant feeds? (1=Not at all conscious; 10=Very conscious)	...your nursery staff	2 (<1)	198 (88)	9.4 (1.1)	16
	... parents	4 (1)	115 (51)	8.1 (1.9)	57
	... hospital staff	0	130 (58)	9.1 (2.1)	84

### 4.3.12 Importance of implementation of key powdered infant formula preparation and handling behaviours

Data presented in Tables 4.34 and 4.35 illustrate day nursery nurses' and day nursery managers' perceptions of the importance of key, recommended PIF behaviours.

**Table 4.33 Importance for implementation of key powdered infant formula preparation and handling behaviours: day nursery nurses**

	Very important n (%)	Fairly important n (%)	Neither n (%)	Not very important n (%)	Not at all important n (%)
• Clean the preparation area every time a bottle of powdered formula milk feed is prepared (n=332)	308 (91)	22 (7)	2 (<1)	0	0
• Wash and dry hands every time a bottle of powdered formula milk feed is prepared (n=332)	317 (94)	13 (4)	2 (<1)	0	0
• Wash feeding bottles and components with detergent and hot water before sterilising (n=325)	275 (81)	36 (11)	9 (3)	3 (1)	1 (<1)
• Rinse washed feeding bottles and components with running water before sterilising (n=324)	264 (78)	45 (13)	11 (3)	2 (<1)	1 (<1)
• Sterilise feeding bottles and components before use (n=327)	297 (88)	14 (4)	9 (3)	4 (1)	3 (1)
• Use boiled water (fresh from the tap before boiling) to make up powdered infant formula (n=327)	186 (55)	75 (22)	36 (11)	18 (5)	5 (2)
• Ensure the temperature of boiled water has cooled, but is higher than 70°C when mixed with the milk powder (n=320)	313 (92)	8 (2)	6 (2)	0	0
• Mix milk powder with boiled water that has cooled for less than 30 minutes (n=318)	155 (46)	87 (26)	51 (15)	19 (6)	6 (2)
• Feed the made-up powdered formula <u>immediately</u> after preparation (once at a suitable temperature) (n=317)	188 (56)	55 (16)	49 (15)	30 (9)	4 (1)
• Prepare (i.e. add powder and water together) one feed at a time (n=317)	183 (54)	53 (16)	52 (15)	33 (10)	5 (2)

*NB: % may not add up to 100% due to non response*

**Table 4.35 Importance for implementation of key powdered infant formula preparation and handling behaviours: day nursery managers (n=224)**

	Very important n (%)	Fairly important n (%)	Neither n (%)	Not very important n (%)	Not at all important n (%)
• Clean the preparation area every time a bottle of powdered formula milk feed is prepared (n=219)	211 (94)	8 (4)	0	0	0
• Wash and dry hands every time a bottle of powdered formula milk feed is prepared (n=219)	216 (94)	3 (1)	0	0	0
• Wash feeding bottles and components with detergent and hot water before sterilising (n=217)	193 (86)	14 (6)	4 (2)	6 (3)	0
• Rinse washed feeding bottles and components with running water before sterilising (n=217)	182 (81)	20 (9)	7 (3)	5 (2)	3 (1)
• Sterilise feeding bottles and components before use (215)	216 (96)	1 (<1)	0	0	0
• Use boiled water (fresh from the tap before boiling) to make up powdered infant formula (n=215)	194 (87)	8 (4)	3 (1)	5 (2)	5 (2)
• Ensure the temperature of boiled water has cooled, but is higher than 70°C when mixed with the milk powder (n=213)	149 (67)	34 (15)	24 (11)	6 (3)	0
• Mix milk powder with boiled water that has cooled for less than 30 minutes (n=203)	107 (48)	41 (18)	41 (18)	12 (5)	2 (<1)
• Feed the made-up powdered formula <u>immediately</u> after preparation (once at a suitable temperature) (n=219)	116 (52)	51 (23)	23 (10)	25 (11)	2 (<1)
• Prepare (i.e. add powder and water together) one feed at a time (n=215)	114 (51)	39 (17)	32 (14)	29 (13)	1 (<1)

*NB: % may not add up to 100% due to non response*

Overall, responses between managers and day nursery nurses appeared consistent. However, 91% of day nursery managers, compared to 77% of day nursery nurses considered that using freshly boiled tap water to make up PIF was ‘very/fairly important’. More day nursery nurses (92%) than day nursery managers (67%) thought it was ‘very important’ to ensure that the temperature of boiled water had cooled, but is higher than 70°C when mixed with the PIF.

### 4.3.13 Day nursery policies and procedures

Sixty-four percent of managers reported that their day nursery had a policy containing procedures for preparing, handling and storage of PIF. The majority of these managers (41%) reported that their PIF policy was unique to their nursery. Seventeen percent of policies were reportedly devised for a chain of nurseries and 6% based on a national policy. Other sources that informed 'PIF policies' in nurseries included the following: food handling and hygiene policies, information from the Environmental Health Officer (EHO), Environmental Health and Hygiene Regulations and the FSA.

The majority (87%) of managers reported that the nursery manager/director/owner devised the PIF policies and procedures for use in the nursery. Other persons reported to devise this information included the nursery nurses (3%), a committee (<1%) and 'head office' (<1%).

Data presented in Table 4.36 indicates the frequency that PIF policies relating to procedures to ensure safe preparation, handling and storage are reviewed. Findings indicate that this occurs most commonly once a year (38%).

**Table 4.36 Reported frequency of powdered infant formula policy/procedures review (n=224)**

	Day nursery managers n (%)
More than once a month	0
Once a month	5 (2)
Every 6 months	30 (13)
Once a year	85 (38)
Less than once a year	5 (2)
Never	3 (1)

*NB: % may not add up to 100% due to non response*

Monitoring of correct procedures to ensure safe preparation and handling of PIF in nurseries (Table 4.37) was reportedly undertaken 'every day' by 26% of managers, 'more than once a week' or 'once a week' by 17% of managers and 'once a month' by a further 10%. Reported methods of monitoring included the following: observation and supervision, labelling of feeds, 'making staff aware of nursery policy and procedures' and in-house training (undertaken by the baby room supervisor).

**Table 4.37 Reported frequency of checking staff implementation of procedures required for safe preparation, handling and storage of powdered infant formula (n=224)**

	Day nursery managers n (%)
Every day	59 (26)
More than once a week	19 (8)
Once a week	19 (9)
Once a month	22 (10)
Every 6 months	13 (6)
Once a year	3 (1)
Less than once a year	2 (<1)
Never	3 (1)

*NB: % may not add up to 100% due to non response*

Fifty-eight percent of day nursery managers reported that the manager of the whole nursery usually implemented training about safe preparation, handling and storage of PIF for new staff; 30% reported training would be implemented by the baby unit manager. Other nursery staff reported that this training was implemented by senior nursery nurses and baby room leaders. Few (<1%) respondents indicated that external trainers would be providers of this information.

Methods of providing information about safe preparation, handling and storage of PIF are presented in Table 4.38. Data indicates provision of verbal instruction is the most common method employed (reported by 82% of managers) followed by an in-nursery demonstration of procedures (reported by 74% of managers).

**Table 4.38 Reported training for new staff caring for infants aged less than 6 months (n=224)**

	Day nursery managers n (%)
In nursery demonstration of safe procedures	165 (74)
Verbal instruction	183 (82)
Given written policy and procedures	111 (50)

*\*Respondents provided more than one response*

*Other responses: induction training (n=1); observe until supervisor is confident in abilities (n=1); poster in kitchen (n=1); updates and visits by the health visitor (n=1).*

Reported provision of training updates about PIF use is shown in Table 4.39. Findings indicate that 34% of managers reported provision of PIF training between every six months to one year. A large proportion of respondents indicated they would provide information ‘as and when required’ (no time scale).

**Table 4.39 Reported frequency of providing training updates about powdered infant formula use to nursery staff (n=224)**

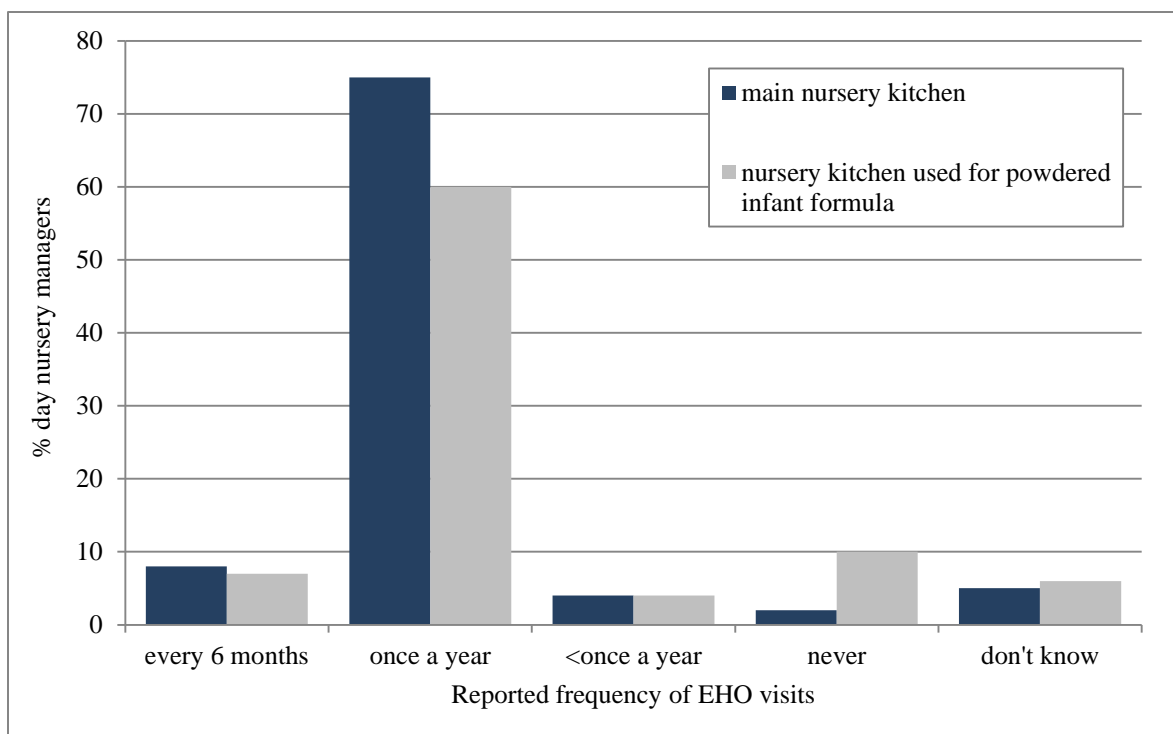
	Day nursery managers n (%)
More than once a month	7 (3)
Once a month	12 (5)
Every 6 months	38 (17)
Once a year	38 (17)
Less than once a year	14 (6)
Never	1 (<1)
Other	80 (36)

*NB: % may not add up to 100% due to non response*

Less than half (44%) of managers reported they had ever been contacted by an EHO about health and hygiene of the nursery. Data presented in Figure 4.4 shows the frequency of reported visits to the main nursery kitchen and kitchen used to prepare PIF. Findings illustrate that main nursery kitchens are reportedly visited by EHOs more often than nursery kitchens used for preparation of PIF. In addition 16% of managers reported the kitchen used for preparation of PIF was never visited or no recollection/knowledge of such visits.



**Figure 4.4 Frequency of EHO reported visits to the main nursery kitchen and kitchen used to prepare powdered infant formula (n=224)**



#### 4.3.14 Information sources and communication about safe preparation, handling and storage of powdered infant formula

The majority (48%) of day nursery managers reported never receiving information or updates about PIF preparation, handling and storage. Only 20% reported receiving such information at least once a year (see Table 4.40).

**Table 4.40 Reported frequency of receiving information, updates and recommendations about powdered infant formula preparation, handling and storage (n=224)**

	Day nursery managers n (%)
At least once a month	7 (3)
Every 6 months	17 (7)
Once a year	22 (10)
Less than once a year	39 (17)
Never	108 (48)
Don't know	23 (9)

*NB: % may not add up to 100% due to non response*

Seventy-five percent of managers reported always passing information, updates and recommendations about PIF onto nursery nurses, 7% ‘sometimes did’ and 9% never passed information on. Reported methods of communication can be seen in Table 4.41 – data indicates that information is most commonly communicated verbally in group meetings or one-to-one basis.

**Table 4.41 Reported methods of communication about powdered infant formula to nursery nurses (n=224)**

	Day nursery managers n (%)
Verbally – one to one	133 (59)
Verbally – in a group meeting	139 (62)
Original information source displayed on a notice board	97 (43)
Information is summarised and displayed on a notice board	35 (16)
Each nursery nurse is given written information to read and as a reference	79 (35)

*NB: % may not add up to 100% due to non response*

*Other methods of communication reported by managers include: read tins; written information is given to the unit; master copy of information is filed in the room for reference; during induction; staff/room meetings.*

Findings presented in Table 4.42 indicate that few (<19%) day nursery nurses or day nursery managers have been trained about the microbiological risks associated with PIF.

**Table 4.42 Reported receipt of training about the microbiological risks associated with powdered infant formula**

	Day nursery nurses (n=339) n (%)	Day nursery managers (n=224) n (%)
....ever?	46 (14)	42 (19)
....in the past 3 years?	45 (13)	31 (14)

Data shown in Table 4.43 indicates that a third (34%) of managers reported awareness/recalled seeing the FSA Guidance for Health Care professionals regarding use of PIF, and only 14% reported awareness/recall of the WHO information about PIF preparation, storage and feeding.

**Table 4.43 Reported awareness/recall of seeing WHO and FSA powdered infant formula information (n=224)**

Information source	Day nursery managers n (%)
FSA Guidance for Healthcare Professionals	77 (34)
WHO information about powdered infant formula preparation, storage and feeding	32 (14)

*NB: % may not add up to 100% due to non response*

Few day nursery managers (7%) reported previous communication with formula manufacturer reps.

Sixty four percent (144/224) of day nursery managers reported awareness of the change of PIF preparation, handling and storage recommendations in recent years.

The FSA was ranked as the organisation day nursery managers perceived to provide the most credible information about PIF.

#### **4.4 SUMMARY OF FINDINGS**

- Day nursery staff reportedly cared for varying numbers of infants aged less than 6 months at one time.
- Variable numbers of PIF feeds are brought to and made-up in day nurseries in the UK.
- Considerable variability was reported in methods used to manage and handle PIF in UK nurseries. Data indicate national and regional difference in reported methods. For example, in Wales, Scotland and Northern Ireland, use of PIF reconstituted by parents at home before nursery appears to be a more frequent practice.

##### **4.4.1 Powdered infant formula preparation, handling and storage behaviours**

- Day nursery nurses demonstrated inadequate knowledge regarding PIF handling, preparation and storage issues associated with formula safety.

- The majority of day nursery nurses believed that they knew all of the precautions necessary for safe preparation and storage of PIF; however, nearly half of day nursery nurses were not confident they knew all of the *up-to-date* recommendations.
- More than half of day nursery staff indicated that reconstituted PIF feeds are reportedly brought to the nursery, having been made-up at home beforehand, for storage and use throughout the period of infant care, which may for over 10 hours a day.
- The majority of parents (81%) who brought reconstituted PIF feeds to nurseries reportedly did so using methods that may encourage microbial growth.
- Nearly half of day nursery nurses and day nursery managers considered it acceptable for powdered formula to be made-up in advance of use and stored in the refrigerator all day. Furthermore up to 11% of day nursery staff considered it acceptable to store reconstituted PIF at room temperature for more than 2 hours.
- Another common method reported for managing powdered formula feeds in day nurseries was parent preparation of feeding bottle and boiled water and provision of powdered formula in a separate (sometimes measured out) container. The powdered formula feed was then reconstituted immediately before feeding, alleviating the need for storage of reconstituted feeds. However, use of this method meant that powdered formula is mixed with water <70°C before feeding, which is contrary to FSA/NHS UK recommendations and has implications for microbial safety.
- Large proportions of day nursery nurses and day nursery managers indicated negative attitudes towards the following practices:
  - the need to reconstitute PIF with boiled water
  - the need to cool boiled water for less than 30 minutes
  - feeding PIF formula immediately after preparation
  - preparation of one feed at a time.
- Many (93%) of day nursery nurses reported ‘checking’ the refrigerator temperature on a daily basis. However, more than 20% of nursery nurses did not know the correct refrigerator temperature or reported maximum temperatures that refrigerators should operate to ensure safety. Nearly half of made-up PIF feeds were reportedly stored in the refrigerator door.

- Nearly 40% of reconstituted feeds which felt warm or hot on arrival at the nursery were not refrigerated for between one and more than two hours after arrival at the nursery, whereas the majority of feeds that felt cold on arrival were refrigerated within 15 minutes.
- Three-quarters of day nursery nurses reported they prepared/made-up powdered formula feeds in their nursery. However, only 5% reported that one specific person in the nursery was responsible for making the infant feeds. In most cases, all nursery staff looking after infants prepared and reconstituted bottles of formula – whoever was available and/or staff caring for individual infants.
- PIF preparation and storage methods used in day nurseries were reported to be determined by parents' wishes. A fifth (18-20%) of day nursery staff reported parents have provided prepared feeding bottle(s) for feeding infants with powdered formula that staff considered to be unclean – but some (9-14%) also reported still using the unclean bottles to feed infants.
- Eighteen percent of nursery nurses reported they keep used feeding bottles containing unfed feeds to show and give the infants' parent(s) on collection of the infant. In some cases this feed is reportedly not refrigerated after the last feed, so has implications for safety if subsequently fed after leaving the nursery.

#### **4.4.2 Perception of microbial risks and nursery policy for powdered infant formula safety**

- The majority of day nursery staff (including managers) believed PIF is a sterile product before the tin is opened and most were unaware of the association with *E.sakazakii* and/or *Salmonella*.
- Although up to 72% of day nursery staff indicated the nursery where they work had a policy or systems in place for safe preparation, handling and storage of PIF, previous research (Redmond and Griffith, 2007) and Chapter 2 has suggested that reported 'policies' may be unstructured and limited.
- The majority of day nursery managers reported that policies associated with preparation, handling and storage of PIF were 'unique' to their nursery and most managers reported that a review of these policies was reportedly conducted once a year.

#### **4.4.3 Perceptions of risk, control, responsibility and hygiene consciousness**

- Day nursery nurses and managers demonstrated judgements of optimistic bias<sup>7</sup>, the illusion of control<sup>8</sup> and personal vulnerability<sup>9</sup> associated with PIF preparation. Day nursery nurses perceived themselves to be associated with lowest risk of illness after preparation of PIF feeds themselves, more control over safety, more conscious of hygiene and more responsible for the safety of infant feeds than other nursery nurses, infants' parents and hospital staff.
- Day nursery managers considered their nursery staff were associated with less risk, more control, more responsibility and more hygiene consciousness than infants' parents and hospital staff.

#### **4.4.4 Information sources and training**

- The majority of day nursery managers and day nursery nurses considered it was the responsibility of the manager to obtain and inform their staff of changes to PIF preparation and storage recommendations. However, data suggest that information about the new recommendations had not been sought or received by over a quarter of day nursery staff.
- Any training was reportedly usually implemented by day nursery managers. However, findings from this chapter have indicated that day nursery manager knowledge and positive attitudes towards key recommended practices are limited. Less than 20% of managers reported that they had been trained in the microbiological risks associated with PIF, and <15% of such training had been reportedly received since the new PIF recommendations had been released.
- Almost half of day nursery managers reported never receiving information updates and recommendations regarding safe PIF preparation, handling and storage. A further 9% of managers reported they did not know if they had received information and nearly 20% indicated they received information less than once a year.
- Only a third of day nursery managers reported awareness/recalled seeing the FSA Guidance for Healthcare Professionals.
- Day nursery managers ranked the FSA as the most credible provider of PIF information.

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<sup>7</sup> Optimistic bias relates to when individuals underestimate their personal probability of encountering negative events (Weinstein, 1980).

<sup>8</sup> The illusion of control is the tendency for individuals to overestimate their ability to control events (Thompson, 1999).

<sup>9</sup> Perceived vulnerability reflects an individual's belief about the likelihood of a health threat's occurrence or the likelihood of developing a health problem (Gerrard and Houlihan, 2008)

## CHAPTER 5

# NHS CAREGIVER ATTITUDES, SELF-REPORTED PRACTICES AND INFORMATION PROVISION RELATED TO POWDERED INFANT FORMULA PREPARATION, HANDLING AND STORAGE

### 5.1 INTRODUCTION

#### 5.1.1 Background

Hospitals are the reported location for most outbreaks of *E.sakazakii* (*Cronobacter* spp.) (Vasavada, 2005; Weir, 2002). Although the application of a HACCP based approach to preparation and use of PIF has been recommended (Almedia, *et al.* 1999) it is not commonly used. Practices in hospitals vary considerably, with some using ready to consume (UHT) products, whilst others have access to specialised formula preparation rooms, trained personnel and the latest microbiological information. Infection control policies, may stipulate maximum hang times, storage conditions, etc., and this part of the study will attempt to establish the variation in practices between different hospitals.

A health visitor is a qualified and registered nurse or midwife who has undertaken further training in order to be able to work as a member of the primary healthcare team. The role of the health visitor is about the promotion of health and the prevention of illness in all age groups. Health visitors have a vital role to play in supporting the important role of parents, including working with mothers of young babies - advising on such areas as feeding and safety. Research has shown that provision of a client centred health visitor service is very relevant and to the needs of mothers and is a service which is valued (Machen, 1996). Members of the public are less likely to have access to relevant information on hazards and risks associated with preparation and storage of PIF and how they can be controlled; in this context, the work of health visitors is crucial.

### **5.1.2 Aims and objectives**

The aim of this part of the study was to obtain quantitative data from 100 hospital nurses (who cared for infants aged less than 6 months in hospital) and 100 health visitors (who provide information to parents/care for infants aged less than 6 months) detailing NHS caregiver beliefs, attitudes, risk perceptions and self-reported practices/information provision related to PIF preparation, handling and storage.

Using postal questionnaires, the more specific objectives were to:

- Obtain formal NHS Ethical Approval, NHS Trust Approval and local management approval to undertake administer postal questionnaires to NHS staff.
- Quantify how PIF is prepared, handled and stored in UK hospitals.
- Investigate influencing factors as to why NHS caregivers may implement unsafe preparation, handling and storage behaviours when dealing with PIF in hospitals.
- Analyse NHS caregivers' perceptions of risk, control and responsibility for themselves and for others.
- Determine NHS caregivers' information sources and training about safe preparation and use of PIF.

Preliminary research and findings from focus groups (Chapter 2) indicated that hospital and community midwives are important caregivers providing information about infant feeding at antenatal and postnatal stages. Therefore, in addition to hospital nurses and health visitors, hospital and community midwives were also sent questionnaires (after required NHS approvals) for this component of the study.



## **5.2 METHODS**

For an overview of the plan of methods used for collection of quantitative data from NHS caregivers for this component of the study see Figure 5.1.

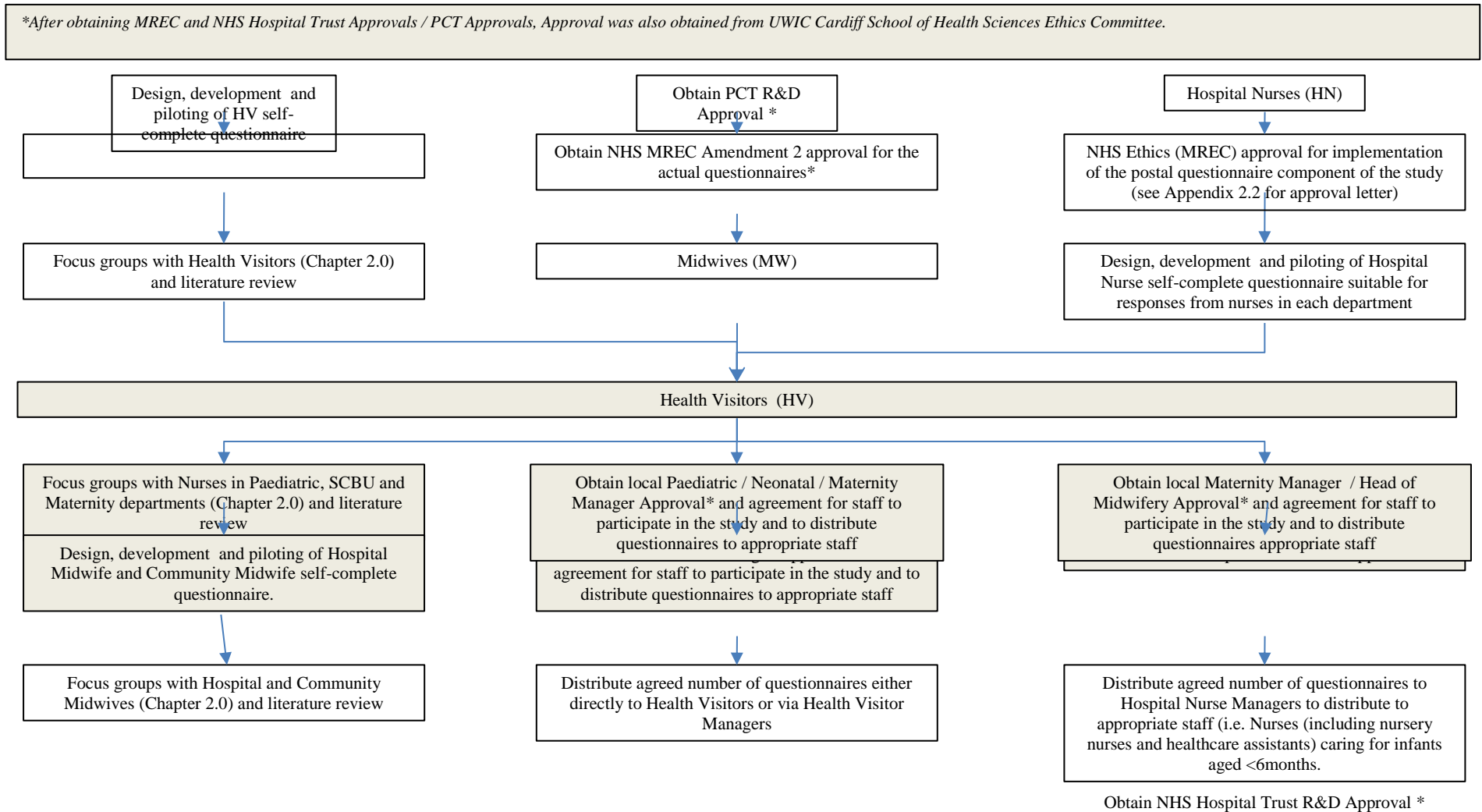
### **5.2.1 Development of the questionnaires for NHS caregivers**

Qualitative research with hospital nurses, hospital and community midwives and health visitors (Chapter 2) and a review of PIF microbiological data were used to prioritise important PIF safety handling and storage issues.

The self-complete questionnaire was designed to determine background information tailored for each caregiver group. Health visitor and community midwife questionnaires included longer sections about information provision and hospital nurses and midwives included larger sections detailing self-reported practices and use of formula in hospitals. All questionnaires assessed attitudes and perceptions towards use of PIF (and RTU/RTF formula) safety in hospitals, in the home and training about PIF that staff may have received. Each questionnaire was adapted according to national intervention differences e.g. in Scotland questionnaires referred to ‘Ready Steady Baby’ as opposed to ‘NHS Birth to Five’ books in England, Northern Ireland and Wales.

Attitudes and risk perceptions were assessed using five point Likert-type rating scales (strongly agree to strongly disagree) and a variation of a visual analogue scale (VAS) in the Likert-type style (Bowling, 2000). Attitude responses given on Likert-type rating scales provided ordinal data and no assumption of equal intervals was made. The variation of a VAS included a horizontal line and bound with adjectives at either end (e.g.) ‘Very low risk and very high risk’ (Bowling, 2000). A numerical scale was displayed at regular intervals along the line (from 1 to 10) to help respondents intuitively understand the scale (Bowling, 2000). This data was considered as ranked, ordinal data. Respondents were required to circle a number along each line to indicate how strongly they feel about the given statements.

**Figure 5.1 Plan of methods for the NHS caregiver postal questionnaire process**



### **5.2.2 NHS Approvals**

Before distributing any questionnaires to NHS staff, NHS approvals had to be obtained from MREC and local NHS Hospital Trusts and Primary Care Trusts (PCTs), as well as at a local management level in each department where hospital staff asked to participate in the study may work. A flow chart indicating stages of obtaining NHS approvals can be found in Appendix 2.2. For additional details regarding the NHS approvals process see Section 2.2.3

The initial MREC approval (Appendix 2.2) and Amendment 1 approval (see Appendix 2.2) granted permission for the NHS caregiver postal questionnaire component of the study to be implemented (including midwives), on condition of formal approval of the actual questionnaires (which had not been developed when the initial MREC application was submitted – before implementation of the focus groups). Therefore an amendment application was submitted and subsequently approved (see Appendix 5 for the approval letter).

Once MREC and NHS Trust approvals had been obtained, the Heads of Midwifery, Paediatrics and Neonatal departments, and Women and Child Services departments were telephoned in each hospital department to obtain local management approval to send questionnaires to relevant departments for distribution. Usually, such persons required all documentation to review before granting approval. (Usually this process took several weeks and required numerous follow up reminder calls).

Some hospital trusts required managers to give local management approval before submitting Trust application; however, managers were reluctant to do so without formal Trust approval. Other barriers to getting Trust approvals included not being registered on the Health Research Portfolio – therefore not a priority application; priority applications given to swine flu research studies. Frequently approval applications for this study would not be dealt with for ~4 weeks or more unless followed up to determine status. Refusals for local management approval have been obtained from several hospitals due to reasons indicated in Table 2.3.

In total, 47 NHS Trusts granted approval for questionnaire distribution to nurses in paediatrics, neonatal and SCBU, hospital midwives in maternity departments, community midwives and health visitors.

### **5.2.3 Data collection**

#### ***5.2.3.1 Pilot testing***

To aid development of the questionnaire, pilot testing occurred in two stages. Firstly, each of the NHS caregiver questionnaires were given to a small number of caregivers in each group. Direct feedback was obtained from respondents who completed the questionnaires, for example:

- understanding of instructions
- recorded length of completion time
- ease of respondent understanding terminologies and answering of questions/statements

Amendments were made to questionnaires in response to feedback. Pilot testing of the revised questionnaires (for each caregiver group) and postal methodology occurred using 5% of the total intended sample.

An initial analysis of data collected from the pilot study was undertaken using SPSS (Version 17.0) and Microsoft Excel (2007). Internal reliability/consistency was calculated for the piloted attitudinal data using Cronbachs Alpha; the attitude response scales for these questionnaires were considered to have acceptable internal consistency.

#### ***5.2.3.2 Sampling procedures***

The aim of this component of the study was to obtain 100 completed questionnaires from NHS health visitors and 100 hospital nurses. Previous UWIC research to healthcare and food safety professionals using a similar postal questionnaire method obtained 27-34% response rate (Redmond *et al.* 2005). To ensure the target number of questionnaires was returned (and airing on the side of caution), the number of NHS caregivers sampled was assuming 15% response rate.

Overall, applications for NHS Trust Approval were sent to 10% of all hospital trusts in the UK (n=47). A stratified, random sample was based upon an even geographical distribution (including rural and city locations), segmented the UK into geographic regions based on strategic health authority divisions (see Table 5.1 and Appendix 5). Twenty-four selected trusts were 'Baby Friendly' accredited and 23 were not accredited (but may have received a certificate of commitment).

**Table 5.1 Questionnaire distribution according to geographic location**

	Hospital nurses no. of NHS Trusts (hospitals; departments)	Hospital midwives no. of NHS Trusts (hospitals)	Community midwives no. of NHS Trusts (hospitals)	Health visitors no. of PCTs (sectors)
North England	5 (5;7)	4 (4)	4 (4)	9 (9)
Midlands/East England	4 (4;5)	4 (6)	3 (3)	2 (2)
South England	5 (5;8)	3 (5)	3 (3)	8 (10)
London	1 (1;1)	2 (2)	1 (1)	1 (1)
England	15 (15;21)	13 (17)	11 (11)	20 (22)
Scotland	7 (8;11)	8 (8)	8 (8)	6 (6)
Northern Ireland	2 (3;3)	2 (3)	2 (3)	1 (4)
Wales	1 (2;3)	1 (2)	1 (3)	2 (2)
<b>Total</b>	<b>25 (28;38)</b>	<b>24 (30)</b>	<b>22 (25)</b>	<b>29 (34)</b>

*For some Trusts approval was obtained/required from different sectors e.g. Northern, Southern Eastern and Western Sectors and/or obtained/required from different hospitals*

### **5.2.3.3 Main study data collection**

The final versions of the covering letters and postal questionnaires can be found in Appendix 5. Overall, NHS hospital trusts and PCTs were sent >1220 questionnaires. Distribution across the UK occurred between July 2009 and March/April 2010. All hospital nurse, hospital and community midwife questionnaires were sent to relevant managers in sealed envelopes for distribution. Each questionnaire had a prepaid envelope enclosed for return and these were placed in individually labelled A5 envelopes (see Appendix 5).

In some cases contact details of health visitors were obtained from publically available internet sources (GP surgeries etc) and also from some health visitor managers for the sole purpose of questionnaire distribution. This enabled direct distribution of the questionnaires and a subsequent two tiered follow up process to non-responses. However, the majority of health visitor questionnaires were sent to relevant managers in sealed envelopes for distribution.

The number of questionnaires sent to each hospital department/caregiver group was dependent upon size of the department and usually ranged from 20-50 questionnaires.

For occasions where managers were sent copies of the questionnaires for distribution and when no responses were obtained from departments after 3-4 weeks, follow up telephone calls were made. In all instances questionnaires had been reportedly received in the department, but not distributed. 'Promises' to distribute questionnaires were made, however, in some cases, no responses were obtained. Therefore, it is possible that up to 255 questionnaires sent to hospitals were not distributed to target staff.

#### **5.2.4 Data analysis**

Data was entered into a specially designed Microsoft Access (2007) database. An analysis of all postal questionnaire data was undertaken using SPSS (Version 15.0) and Microsoft Excel (2007).

### **5.3 RESULTS**

The need to obtain MREC and NHS approvals for administration of postal questionnaires to NHS caregivers (hospital nurses, hospital and community midwives and health visitors) around the UK caused a delay in the implementation of this part of the study. However, on completion, this part of the study exceeded FSA objectives by including additional quantitative data from hospital and community midwives (n=498) and exceeding required responses (n=100 for nurses and health visitors). In total, 426 responses were obtained from health visitors and 291 responses obtained from hospital nurses.

#### **5.3.1 Sample specification**

Overall, 26% health visitors, 23% community midwives, 18% hospital midwives/MHCAs and 15% paediatric nurses/HCAAs and 25% neonatal/SCBU nurses/HCAAs responded to the postal questionnaire, resulting in the return of 1215 questionnaires from NHS caregivers. Breakdown of responses according to geographic region/country is presented in Table 5.2.

**Table 5.2 Geographic breakdown of questionnaire responses (%) according to NHS caregiver group.**

Location	% Hospital nurses/HCAs (paediatric/SCBU /neonatal) n=291	% Hospital midwives/MHCAs n=266	% Community midwives n=232	% Health visitors n=426
England – London	6	4	8	<1
England – Midlands and East	16	12	2	5
England – North	17	11	7	24
England – South	17	29	22	24
England	56	56	61	57
Northern Ireland	12	12	11	4
Scotland	27	25	27	19
Wales	5	5	7	23
Total UK response rates per NHS caregiver group	21	18	23	26

### 5.3.2 Background

Data presented in Table 5.3 indicates that almost all NHS caregivers who responded to the questionnaires in this study reported they were in contact with infants fed using infant formula. Reported proportions of infants fed using formula in hospitals were greater in neonatal/SCBU and paediatric departments than in maternity departments. For example, findings indicated that 47% of paediatric departments fed >50% infants with powdered formula milk, whereas only 19% of maternity departments fed >50% infants with powdered formula milk. Infants requiring special care may be more likely to need feeding using specialist powdered formulas.

Health visitors reported larger proportions of their caseloads were fed using formula compared to community midwives. For example, 66% of health visitors reported that >50% of their caseload were fed using formula, whereas 42% of community midwives reported that >50% of their caseload were fed using formula.

The majority of health visitors reported that they usually make the first visit 10-14 days after the birth, however, some health visitors (1%) reported making the first visit up to 28-30 days after the birth. The number of visits was reported to be variable dependent upon client needs. However, 55%

of health visitors reported the minimum number of visits to be 1-2 visits and the maximum, approximately 4-6 visits (again, this was dependent upon circumstances and client need).

**Table 5.3 Approximate proportions of caseload/infants in hospital departments fed using infant formula (2009-2010)**

Location	Hospital nurses (paediatric/SCBU/neonatal)	Hospital midwives	Community midwives	Health visitors*
	n=291	n=266	n=232	n=426
	n (%)	n (%)	n (%)	n (%)
never	0	0	1 (<1)	1 (<1)
Up to 25%	27 (9)	33 (12)	68 (29)	38 (9)
25-50%	61 (21)	74 (28)	52 (22)	77 (18)
51-75%	70 (24)	41 (15)	47 (20)	155 (36)
76-100%	66 (23)	10 (4)	50 (22)	127 (30)
Don't know	5 (2)	18 (7)	12 (5)	17 (4)
No response	61 (21)	86 (32)	2 (1)	11 (3)

\* established by first home visit

### 5.3.3 Use of infant formula in UK hospitals

#### 5.3.3.1 Use of RTU/RTF infant formula

Ninety eight percent of hospital midwives/MHCAs and 99% of nurses/HcAs from paediatrics/SCBU/neonatal reported that RTU/RTF infant formula is used on maternity wards. The majority (96%) of hospital midwives/McAs indicated RTU/RTF formula was provided in glass bottles and only 3% indicated the formula was provided in cartons. Two percent of the same caregivers also indicated that parents/patients bring their own cartons of formula into the hospital to feed their infant. Less than 1% of caregivers reported formula was also provided in 'tins'.

Nearly all (99%) of hospital nurses/HcAs reported use of RTU/RTF infant formula from glass bottles; 27% also reported use of infant formula from cartons. Sixty-five percent of hospital midwives/MHCAs and 94% of nurses/HcAs from paediatrics/SCBU/neonatal reported that they decanted the RTU/RTF formula from the original container into different feeding bottles/cups/IV bags.



Data presented in Table 5.4 shows that hospital nurses/HCAs in neonatal/SCBU and paediatric departments reportedly store open and ‘in use’ containers of RTU/RTF infant formula for considerably longer than reported by hospital midwives/MHCAs in maternity departments. For example, 80% of hospital midwives/MHCAs reported use of formula within one hour of opening, whereas the majority of hospital nurses and HCAs reported use of the RTU/RTF formula for 4 hours. In addition, 3% of hospital midwives/MHCAs and 7% of hospital nurses/HCAs reported RTU/RTF formula could be opened and used for a period of up to 24 hours.

**Table 5.4 Reported lengths of time that containers of RTU/RTF infant formula are open and ‘in-use’**

	Hospital nurses/HCAs (paediatric/SCBU/neonatal) n=291 n (%)	Hospital midwives/MHCAs n=266 n (%)
0-59 minutes	16 (5)	21 (8)
60 minutes/1 hour	77 (26)	194 (72)
1-2 hours	1 (<1)	1 (<1)
120 minutes/2 hours	26 (10)	5 (2)
3 hours	13 (4)	2 (<1)
4 hours	108 (37)	5 (2)
5-8 hours	4 (1)	0
Up to 12 hours	2 (<1)	2 (<1)
Up to 24 hours/24 hours	19 (7)	8 (3)
No response	25 (9)	10 (3)

Data shown in Table 5.5 indicates that variability occurs between hospital departments as to who is responsible for monitoring the length of time that bottles of RTU/RTF formula are open and ‘in use’. From maternity departments, hospital midwives/MHCAs reported that in most cases (88%) individual mothers/parents were responsible for monitoring the length of time bottles of RTU/RTF formula were open and ‘in use’ for; whereas in neonatal/SCBU and paediatric departments hospital nurses/HCAs reported that in nearly all cases (95%) it was the responsibility of the nurse to monitor RTU/RTF formula opening and ‘in use’ times.

**Table 5.5 Reported person/persons responsible for monitoring the length of time that bottles of RTU/RTF infant formula are open and ‘in-use’**

	Hospital nurses/HcAs (paediatric/SCBU/neonatal) n=291 n (%)	Hospital midwives/MHCAs n=266 n (%)
Individual mothers/parents	110 (38)	231 (88)
Nurse	275 (95)	31 (12)
Midwife	65 (22)	137 (52)
Auxiliary workers	2 (<1)	8 (3)
Clinical support worker	2 (<1)	3 (1)
HCA <sup>■</sup> /MHCA*	2 (<1) <sup>■</sup>	32 (12)*
Nursery nurse	3 (1)	9 (3)
‘Everyone’	3 (1)	1 (<1)
Person providing care	8 (3)	0
Housekeeper	2 (<1)	0

*NB: Respondents provided more than one response*

Sixteen percent (43/266) of hospital midwives/MHCAs reported that RTU/RTF infant formula feeds were sometimes part used and used for later feeding – of these 56% (28/43) reported feeds would be stored in the refrigerator, 37% (16/43) reported the feeds would be stored on a work surface/cupboard (at ambient temperature).

Seventy percent (203/291) of nurses/HcAs (from paediatrics/SCBU/neonatal departments) reported that RTU/RTF infant formula feeds were sometimes part used and used for later feeding. Of these, 49% (143/291) reported feeds were reportedly stored in the refrigerator and 31% (90/291) stored on a work surface/cupboard (at ambient temperature).

### ***5.3.3.2 Use of powdered infant formula***

Fifteen percent of hospital midwives/MHCAs and 88% of nurses/HcAs from paediatrics/SCBU/neonatal departments reported use of specialist or/and non-specialist powdered infant formula. Thirteen percent of nurses/HcAs from neonatal/SCBU and paediatric departments and 3% of hospital midwives/MHCAs from maternity reported preparation of PIF feeds occurring in a central feeds unit (see Table 5.6).

**Table 5.6. Reported locations for preparation of powdered infant formula feeds**

	Hospital nurses/HcAs (paediatric/SCBU/neonatal) n=291 n (%)	Hospital midwives/MHCAs n=266 n (%)
Hospital Central Infant Feeds Unit	34 (13)	7 (3)
In a ward/department kitchen or/and on the ward	210 (72)	36 (14)
Other*	40 (14)	12 (5)

*NB: Respondents provided more than one response*

*\*Other: nursery area, milk trolley by bedside/trolley designed for making up milk feeds*

In hospitals where PIF feeds were prepared in a central unit (Table 5.6), 94% nurses and HCAs reported that paediatrics/SCBU/neonatal departments received a delivery once a day (<1% reported that they would receive a delivery ‘on demand’ and <1% reported 2 deliveries per day). Maternity departments reported rarely receiving deliveries of made-up PIF (3% hospital midwives/MCAs reported once a week). Few <1% respondents reported that even if there was a Central Unit for preparation of PIF, feeds were sometimes prepared in the department.

Eighty-two percent of nurses/HcAs reported that the maximum length of time infant feeds from the central unit could be used for was 24 hours; a further 6% reported 48 hours and 2% reported they didn’t know.

Data in Table 5.7 indicates that in the majority of cases, reconstituted PIF feeds are transported from central feed units to hospital wards/departments at ambient temperatures in cardboard/plastic boxes/plastic bags/on a trolley – all with no temperature control.

**Table 5.7 Reported methods of transporting reconstituted powdered infant formula feeds from the Central Unit to wards for use**

	Hospital nurses/HcAs (paediatric/SCBU/neonatal) n=34 n (%)	Hospital midwives/MHCAs n=7 n (%)
A temperature controlled container	2 (6)	0
Cool bags with freezer packs	2 (6)	0
Cardboard box or plastic container	12 (35)	1 (14)
Plastic Bag	5 (15)	0
Trolley	3 (8)	0

*NB: % may not add up to 100 due to non responses*

*Other reported methods for transporting feeds from the Central Unit to wards included use of a wire mesh container/crate.*

In total, up to 14% of all hospital midwives / MHCAs and 72% of all nurses / HCAs reported preparation of PIF feeds in the departments.

Hospital nurses/HcAs and midwives /MHCAs reported that when PIF was prepared in the department, this would most likely occur in a designated kitchen for formula preparation on the ward (see Table 5.8). However, 34% of hospital nurses/HcAs and 7% of hospital midwives/MHCAs reported that feeds were prepared at the patients' (infants') bedside.

**Table 5.8 Reported location for preparation of powdered infant formula feeds within hospital department**

	Hospital nurses/HcAs (paediatric/SCBU/neonatal) n=251 n (%)	Hospital midwives/MHCAs n=42 n (%)
General ward kitchen	28 (11)	3 (7)
Designated formula preparation ward kitchen	184 (73)	36 (85)
At the patients' bedside	41 (34)	3 (7)

*NB: Respondents provided more than one response*

Hospital nurses/HcAs and midwives /MHCAs reported that nursing staff/midwives were most often responsible for making up PIF feeds (71-81%) (see Table 5.9). Thirty percent of hospital nurses/HcAs reported that parents made-up PIF feeds in neonatal/SCBU and paediatric departments and 19% of hospital midwives/MHCAs reported parents were responsible for making up feeds in maternity departments. Few dieticians (3%) were cited as a responsible caregiver for preparation of infant feeds.

The reported frequency of making PIF feeds up in the hospital was variable (Table 5.10). Some (12%) hospital nurses/HcAs reported making such feeds up on a daily basis, whereas 25% reported making feeds up between 2-3 days a week and once a week or more and 36% reported doing so once a month or more. Similarly, 17% of hospital midwives/MHCAs reported they prepared PIF feeds on a daily basis, 31% reported making feeds up between 2-3 days a week and once a week or more and 26% reported doing so once a month or more.

**Table 5.9 Reported person(s) in hospitals responsible for making-up the powdered infant formula feeds**

	Hospital nurses/HcAs (paediatric/SCBU/neonatal) n=251 n (%)	Hospital midwives/MHCAs n=42 n (%)
Dieticians	7 (3)	0
Infant Feeds Specialist	22 (9)	2 (5)
Infants' parents	75 (30)	21 (19)
Nursing staff or midwives	204 (81)	30 (71)
Other*	38 (15)	13 (31)

*NB: Respondents provided more than one response*

*\*Other: Auxiliary (nursing) staff; clinical support workers; dietetic assistants; HCAs; housekeeper; healthcare support workers; nursery assistants; nursery nurses.*

**Table 5.10 Reported frequency for reconstitution of powdered infant formula feeds**

	Hospital nurses/HcAs (paediatric/SCBU/neonatal) n=251 n (%)	Hospital midwives/MHCAs n=42 n (%)
Every day	30 (12)	7 (17)
2-3 days a week	19 (8)	4 (10)
4-5 days a week	3 (1)	1 (2)
Once a week or more	10 (16)	8 (19)
Once a month or more	91 (36)	11 (26)
Never	45 (18)	11 (26)

*% may not add up to 100 due to non responses*

**Table 5.11 Time of day when powdered infant formula feeds are reportedly prepared**

	Hospital nurses/HcAs (paediatric/SCBU/neonatal) n=251 n (%)	Hospital midwives/MHCAs n=42 n (%)
All together at the beginning of the day	39 (6)	5 (12)
Made-up in batches throughout the day	28 (11)	6 (14)
Made-up one up a time, as required	161 (64)	28 (67)

*Other: nurses = all together at 1pm; in the afternoon; middle of the day*

*% may not add up to 100 due to non responses*

The majority of hospital nurses/HCAs and hospital midwives/MHCAs (64-67%) reported that when PIF feeds were made-up in the hospital (in the department) they were made-up one at a time as required (see Table 5.11). However, 17% of hospital nurses/HCAs and 26% of hospital midwives/MHCAs also reported feeds were made-up either in batches, throughout the day or all together at the beginning of the day, requiring storage until required for feeding.

### 5.3.3.3 Preparation of powdered infant formula in UK hospitals

PIF reconstituted for feeding in UK hospitals were reportedly made-up using bottles of sterile water (usually stored at ambient temperature) or boiled tap water (see Table 5.12). In maternity departments, on the limited numbers of occasions when PIF was prepared, 88% of hospital midwives/MHCAs indicated this would be done so using boiled tap water and 19% reported using bottles of sterile water. In neonatal/SCBU and paediatric departments PIF was reportedly reconstituted more frequently using bottles of sterile water (reported by 61% of hospital nurses/HCAs).

**Table 5.12 Reported use of water from different sources for reconstitution of powdered infant formula**

	Hospital nurses/HCAs (paediatric/SCBU/neonatal) n=251 n (%)	Hospital midwives/MHCAs n=42 n (%)
... boil the kettle, cool boiled water in the kettle and then pour into a feeding bottle	92 (37)	31 (74)
... boil the kettle and pour hot water into feeding bottle(s) straight away	23 (9)	6 (14)
... use bottle of sterile water	152 (61)	8 (19)
... use tap water (not boiled)	0	0
... use bottle of mineral water	0	0

*NB: Respondents provided more than one response*

For instances when boiled tap water was used to reconstitute powdered formula milk 9% of hospital midwives/MHCAs and 10% of hospital nurses/HCAs reported cooling the boiled water for more than 30 minutes before reconstitution (see Table 5.13).

**Table 5.13 Reported length of time boiled water in the kettle is allowed to cool**

	Hospital nurses/HcAs (paediatric/SCBU/neonatal) n=251 n (%)	Hospital midwives/MHCAs n=42 n (%)
Less than 15 minutes	21 (8)	7 (17)
Between 16-30 minutes	58 (23)	20 (48)
31 minutes – 1 hour	19 (8)	7 (7)
More than 1 hour	5 (2)	1 (2)

*% may not add up to 100 due to non responses*

Findings indicating subsequent use of *reconstituted* powdered formula milk in hospitals are presented in Table 5.14. Results suggest that hospital midwives/MHCAs are reportedly more likely to feed the formula to the infant straight away (or when cooled to a suitable temperature) – few (12%) reported storage of made-up PIF feeds for later feeding. A larger number of hospital nurses/HcAs however, reported that formula would be stored in the fridge until required (see Table 5.14).

**Table 5.14 Reported reconstitution of powdered infant formula**

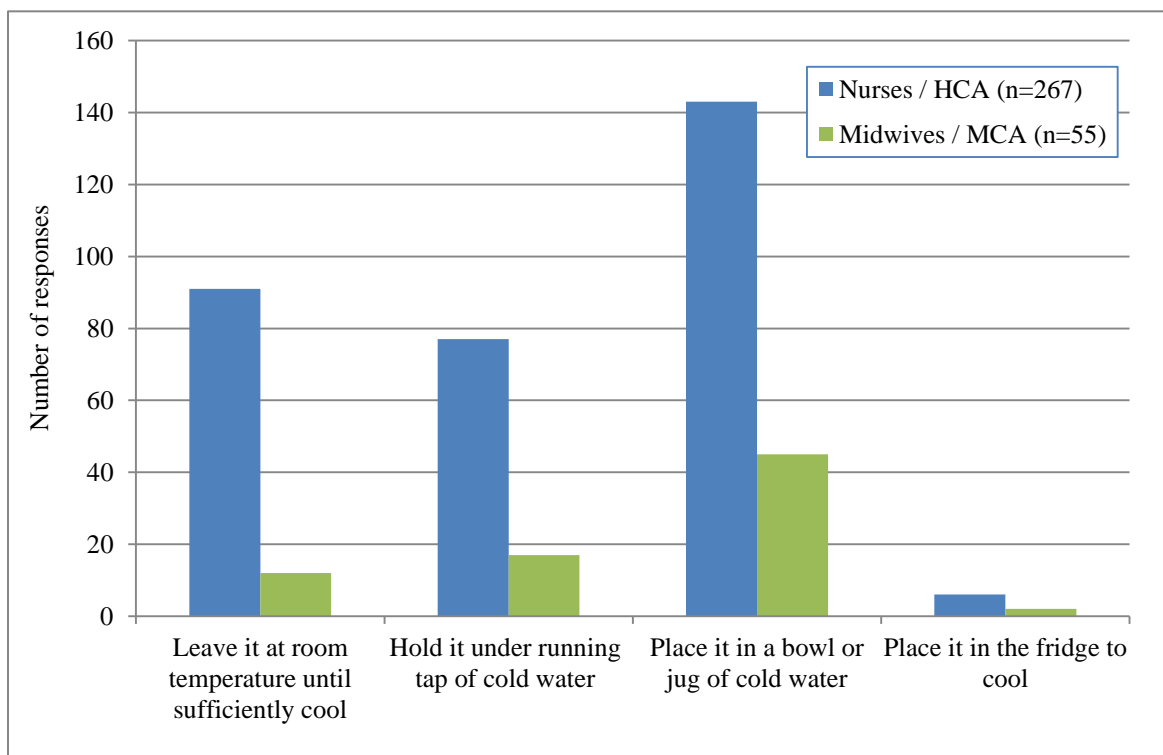
	Hospital nurses/HcAs (paediatric/SCBU/neonatal) n=251 n (%)	Hospital midwives/MHCAs n=42 n (%)
Feed the made-up formula to the infant immediately	91 (36)	10 (24)
Cool the made-up formula to a suitable temperature and feed to the baby immediately	71 (28)	24 (57)
Warm the made-up formula to a suitable temperature and feed to the baby immediately	70 (28)	10 (24)
Place the made-up formula in the fridge and store until required for feeding	93 (37)	4 (10)
Leave the made-up formula at room temperature until required for feeding	12 (5)	1 (2)
Other*	6 (2)	3 (7)

*NB: Respondents provided more than one response*

*\* Other: midwives/MHCAs – allow to cool at room temperature, then fridge when needed (n=2); nurse/HcA – cool at room temperature then fridge until needed (n=3).*

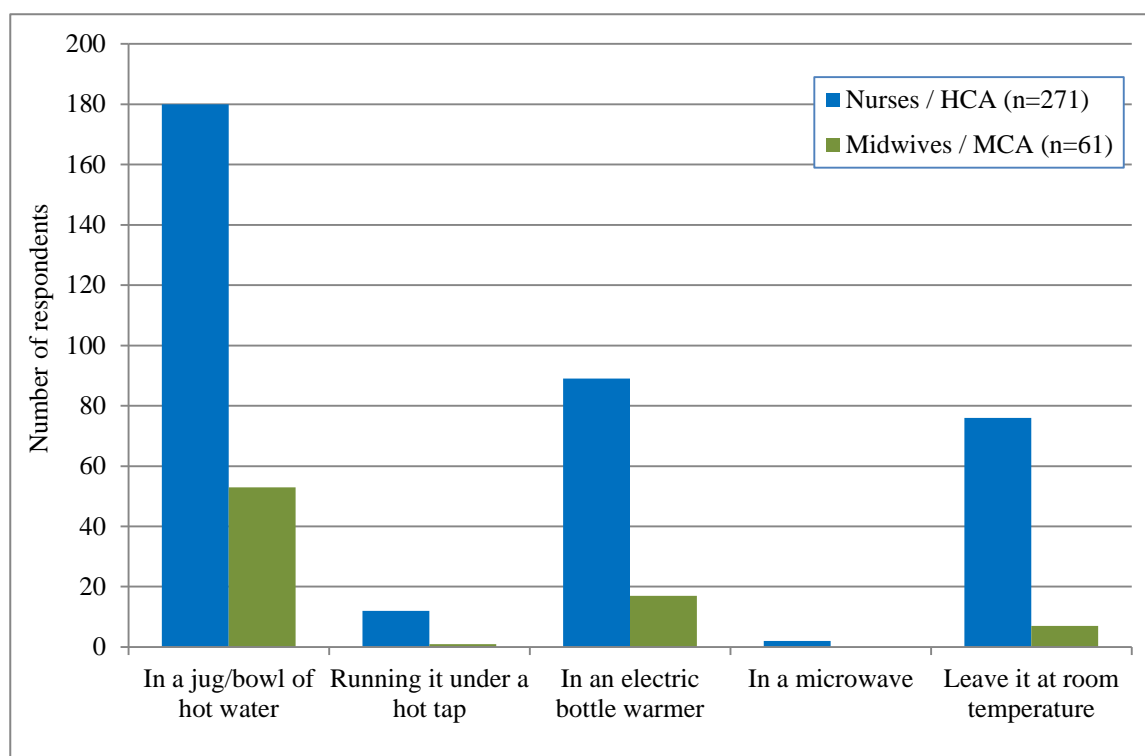
The most common method reportedly used by hospital midwives/MHCAs and hospital nurses/HCAs for cooling reconstituted powdered formula milk feeds was identified to be ‘placing the feed in a bowl or jug of cold water’ (see Figure 5.2). Similarly, the most common method reportedly used for reheating/warming powdered formula milk feeds was ‘placement in a jug or bowl of hot water until suitable temperature for feeding has been reached’ (see Figure 5.3).

**Figure 5.2 Reported practices used for cooling reconstituted powdered infant formula feeds before feeding**





**Figure 5.3 Reported practices used for reheating reconstituted powdered infant formula feeds before feeding**



Just over half of hospital midwives/MHCAs (55%) and hospital nurses/HCAs (57%) reported that when powdered formula milk feeds were made-up in advance of use, they were stored in a dedicated refrigerator for formula feeds; 6% of hospital nurses/HCAs and 10% of hospital midwives/MHCAs also reported storage of made-up feeds in a general use fridge (Table 5.15).

**Table 5.15 Reported locations for storage of made-up powdered infant formula feeds before feeding**

	Hospital nurses/HCAs (paediatric/SCBU/neonatal) n=251 n (%)	Hospital midwives/MHCAs n=42 n (%)
In a general use fridge	14 (6)	4 (10)
In a fridge for formula only	142 (57)	23 (55)
In the fridge door	6 (2)	1 (2)
Wherever there is room in the fridge	13 (5)	1 (2)
On a shelf near the back of the fridge	16 (6)	4 (10)
On a work surface	8 (3)	0

*NB: Respondents provided more than one response*

Eighty one percent of hospital midwives/MHCAs and 90% of hospital nurses/HcAs reported refrigerators used to store powdered formula milk were checked at least once a day. Of concern, 2% hospital nurses/HcAs and 4% of hospital midwives/MHCAs reported the fridge temperature to be checked once a month or never (Table 5.16).

**Table 5.16 Reported frequency of checking fridge temperature**

	Hospital nurses/HcAs (paediatric/SCBU/neonatal) n=251 n (%)	Hospital midwives/MHCAs n=42 n (%)
2 or more times a day	63 (25)	4 (10)
At least once a day	163 (65)	30 (71)
Once or twice a week	0	1 (2)
Once a week or more	4 (2)	1 (2)
Once a month or more	1 (<1)	1 (2)
Less than monthly	0	0
Never	3 (1)	1 (2)

*% may not add up to 100 due to non responses*

Data shown in Table 5.17 indicates that >22% of hospital nurses/HcAs and >31% of hospital midwives/MHCAs reported that they were unaware what the maximum temperature a refrigerator should run at to ensure food safety, or indicated the maximum temperature exceeded 6°C (Table 5.17). Fridge temperature was reportedly monitored using a variety of devices (Table 5.18).

**Table 5.17 Knowledge of the maximum temperature that their fridge should operate to ensure food safety**

	Hospital nurses/HcAs (paediatric/SCBU/neonatal) n=251 n (%)	Hospital midwives/MHCAs n=42 n (%)
<0°C	2 (<1)	0
1-5°C	127 (51)	20 (48)
>6°C	50 (20)	7 (17)
Don't know	5 (2)	6 (14)
No response	63 (25)	9 (21)

**Table 5.18 Reported method for monitoring refrigerator temperature**

	Hospital nurses/HcAs (paediatric/SCBU/neonatal) n=251 n (%)	Hospital midwives/MHCAs n=42 n (%)
Use of a plastic, traditional fridge thermometer	53 (21)	7 (17)
Use of a digital fridge thermometer	82 (33)	19 (45)
Built in thermometer	84 (34)	12 (29)

*% may not add up to 100 due to non responses*

Seventy-four percent (31/42) of midwives/MHCAs and 81% (202/251) nurses/HcAs reported that the refrigerator temperature was written down and recorded.

Eighty-two percent (26/42) of midwives/MHCAs reported that formula feeds were labelled when made-up. Information noted on the label included the patient's name/initials (60%), the date the formula was made-up (60%), the time the formula was made-up (55%), the batch number (2%), the brand of formula (43%) and when the formula must be used by (14%).

Eighty-six percent (216/251) of nurses/HcAs reported that feeds were labelled when made-up. Information noted on the label included the patient's name/initials (88%), the date the formula was made-up (88%), the time the formula was made-up (78%), the batch number (6%), the brand of formula (78%) and when the formula must be used by (30%).

Findings presented in Table 5.19 show that the reported frequency that parents brought made-up PIF feeds from home to feed in hospital, frequency of making up feeds in hospital and the frequency of parents bringing in empty prepared feeding bottles for use in hospital. Overall, data indicated that there were instances when parents brought in reconstituted powdered formula milk feeds into hospital from home for feeding in hospital. This occurred more often in neonatal/SCBU and paediatric departments (reported by 28% of hospital nurses/HcAs) than maternity departments (reported by 12% of hospital midwives/MHCAs).

**Table 5.19 Use/reconstitution of powdered infant formula/feeding items brought from parents' homes, for use in hospital**

		Hospital nurses/HcAs (paediatric/SCBU/neonatal) n=291 n (%)	Hospital midwives/McAs n=266 n (%)
Frequency parents bring in made-up powdered infant formula feeds from home for feeding in the hospital	Often	8 (3)	10 (4)
	Sometimes	23 (8)	9 (3)
	Rarely	48 (17)	15 (6)
	Never	192 (66)	41 (15)
	No response	20 (7)	191 (72)
Frequency parents make-up powdered infant formula feeds for their infant in hospital/using hospital facilities	Often	19 (7)	14 (5)
	Sometimes	60 (21)	7 (3)
	Rarely	90 (31)	13 (5)
	Never	99 (34)	44 (17)
	No response	23 (8)	188 (71)
Frequency parents bring in empty feeding bottles from home ready for infant feeding (i.e. cleaned and disinfected) with formula provided by the hospital	Often	89 (31)	11 (4)
	Sometimes	63 (22)	10 (4)
	Rarely	32 (11)	21 (8)
	Never	83 (29)	36 (14)
	No response	24 (8)	188 (71)

Similarly, parents' preparation of powdered formula milk feeds was reported by hospital nurses/HcAs in neonatal/SCBU and paediatric departments and hospital midwives/MHCAs in maternity departments. However, this practice was undertaken more frequently in neonatal/SCBU and paediatric departments (reported by 59% of hospital nurses/HcAs) than in maternity departments (reported by 13% hospital midwives/MHCAs).

Sixty-four percent of hospital nurses/HcAs and 16% of hospital midwives/MHCAs reported that parents bring in empty feeding bottles prepared at home for feeding in the hospital.

### 5.3.4 NHS Caregiver attitudes towards powdered infant formula, preparation and storage behaviours and information provision

Hospital midwives’/MHCAs’ and hospital nurses’/HCAs’ attitudes towards issues relating to preparation and storage of powdered formula milk are presented in Table 5.20.

Fifty percent of hospital midwives/MHCAs and 58% of hospital nurses/HCAs considered it difficult for individual infants’ feeds to be made-up one at a time in hospital. Similar proportions of hospital midwives/MHCAs (59%) and hospital nurses/HCAs (63%) also considered it difficult for parents to make up one feed at a time when required for feeding at home. Seventeen percent of hospital midwives/MHCAs and 25% of hospital nurses/HCAs believed that making up PIF feeds with cold or warm water is an acceptable practice – however, this is contrary to DoH and FSA PIF recommendations. Approximately half of hospital midwives/MHCAs (56%) and hospital nurses/HCAs (53%) believed it was difficult to judge the actual temperature of water when it is mixed with the formula powder. More hospital nurses/HCAs (35%) than hospital midwives/MHCAs (16%) believed that it is acceptable to make-up bottles of powdered formula milk in advance of use.

**Table 5.20 Hospital nurse and midwife attitudes towards powdered infant formula preparation and storage behaviours**

	Hospital midwife (MW)/MHCA			Hospital nurse (HN)/HCA		
	Strongly Agree/Agree n (%)	Neither n (%)	Strongly Disagree/Disagree n (%)	Strongly Agree/Agree n (%)	Neither n (%)	Strongly Disagree/Disagree n (%)
Making up one feed at a time is difficult to do for every infant, <u>all</u> of the time in the hospital. (MW=221; HN=287)	110 (50)	47 (21)	41 (19)	167 (58)	35 (12)	85 (30)
Making up powdered infant formula feeds with cold or warm water is acceptable practice. (MW=216; HN=283)	44 (17)	20 (8)	182 (70)	70 (25)	41 (14)	165 (59)
It is difficult to judge the actual temperature of water when it is mixed with the formula powder. (MW=258; HN=285)	120 (56)	50 (23)	53 (25)	150 (53)	55 (19)	73 (26)
It is acceptable to make up bottles of powdered formula milk in advance of use. (MW=256; HN=287)	40 (16)	19 (7)	196 (77)	101 (35)	32 (11)	153 (53)
Making up one feed at a time is difficult for parents to do <u>all</u> of the time. (MW=258; HN=289)	153 (59)	32 (12)	63 (24)	181 (63)	28 (10)	78 (27)

*% for some attitude statements may not add up to 100 due to non responses/don't know responses*

Data presented in Table 5.21 shows hospital midwives'/MHCAs' and hospital nurses'/HCAs' attitudes towards microbiological hazards associated with powdered formula milk. Overall, 60% of hospital midwives/MHCAs and 77% of hospital nurses/HCAs believed that before a tin of PIF has been opened, the formula is a sterile product. Likewise, 73% of hospital nurses/HCAs and 77% of hospital midwives/MHCAs did not know (were unaware or disagreed) that *E.sakazakii* could be present in powdered formula; 60% of hospital nurses/HCAs and 49% of hospital midwives/MHCAs also believed there was no association between powdered formula milk and *Salmonella*.

A larger proportion of hospital midwives/MHCAs (81%), compared to of hospital nurses/HCAs (69%), believed that making up one feed at a time (fresh), for immediate feeding is essential to reduce the chance of illness from PIF.

The majority of hospital midwives/MHCAs (88%) and hospital nurses/HCAs (91%) believed they knew all of the precautions necessary for safe preparation and storage of powdered formula milk, however, less than half (43% of hospital nurses/HCAs and 48% of hospital midwives/MHCAs) were confident they knew all of the up to date guidelines about minimising microbial risks associated with feeding with powdered formula milk.

Many hospital midwives/MHCAs (53%) and hospital nurses/HCAs (48%) believed the mothers they cared for did not know all of the safety practices necessary for safe preparation and feeding of powdered formula milk. In addition, 72% of hospital midwives/MHCAs and 51% of hospital nurses/HCAs indicated they were sometimes concerned about the safety of formula feeding practices when mothers and infants left hospital.

**Table 5.21 Hospital nurse and midwife attitudes towards powdered infant formula, perceived efficacy and other issues**

Attitude statement	Hospital midwife (MW)/MHCA			Hospital nurse (HN)/HCA		
	Strongly Agree/Agree n (%)	Neither n (%)	Strongly Disagree/Disagree n (%)	Strongly Agree/Agree n (%)	Neither n (%)	Strongly Disagree/Disagree n (%)
Before opening a tin of powdered formula milk, the powdered milk is a sterile product (i.e. is free from all germs and bacteria) (MW=251; HN=282)	151 (60)	35 (14)	49 (20)	217 (77)	22 (8)	36 (13)
<b>Microbial hazards</b> <i>Enterobacter sakazakii</i> can be found in powdered infant formula (MW=256; HN=281)	57 (22)	55 (21)	7 (3)	74 (27)	55 (20)	2 (<1)
There is no association between <i>Salmonella</i> and powdered formula (MW=258; HN=286)	23 (9)	37 (14)	132 (51)	28 (10)	70 (25)	112 (40)
Making up one feed at a time (fresh) for immediate feeding is <u>essential</u> to reduce the chance of illness from powdered infant formula. (MW=258; HN=286)	208 (81)	32 (12)	16 (6)	197 (69)	49 (17)	35 (12)
<b>Perceived efficacy</b> I know all of the precautions necessary for safe preparation and storage of powdered formula milk (MW=259; HN=287)	229 (88)	18 (7)	10 (4)	262 (91)	20 (7)	5 (2)
It is easy to implement all of the recommended safety practices for safe preparation of powdered infant formula (MW=255; HN=286)	143 (56)	52 (20)	55 (22)	181 (63)	56 (20)	47 (16)
I am confident that I know all of the up-to-date guidelines about minimising microbial risks associated with feeding with powdered formula milk (MW=260; HN=285)	113 (43)	67 (26)	67 (26)	138 (48)	80 (28)	54 (19)
<b>Other issues</b> I think that most of the mothers I care for in hospital know all of the safety practices necessary for safe preparation and feeding of formula milk. (MW=264; HN=289)	124 (47)	56 (21)	78 (30)	151 (52)	73 (25)	65 (23)
I am sometimes concerned about the safety of formula feeding practices when mothers and their infants leave hospital. (MW=265; HN=286)	190 (72)	33 (12)	38 (14)	145 (51)	73 (26)	65 (23)
Infants experiencing gastro-intestinal infections resulting from powdered infant formula are extremely rare. (MW=260; HN=287)	28 (1)	47 (18)	159 (61)	67 (23)	85 (30)	112 (39)

% for some attitude statements may not add up to 100 due to non responses/don't know responses

Community midwife and health visitor attitudes towards powdered formula milk preparation and storage behaviours were relatively comparable with each other (Table 5.22). The majority (82-84%) of community midwives and health visitors believed that the recommended practice of making-up one feed at a time was difficult for parents to implement all of the time at home. Although the majority of health visitors (86%) and community midwives (83%) believed making up powdered formula milk with cold or warm water was not an acceptable practice, 61% of community midwives and 64% of health visitors also believed that it was difficult to judge the actual temperature of the water when it is mixed with the powdered formula.

Twenty one percent of community midwives and 28% of health visitors believed that it was acceptable (or 'not unacceptable') to reconstitute PIF feeds in advance of use. Furthermore, 28-30% community midwives and health visitors also believed that it was acceptable for reconstituted bottles of powdered formula milk to be made-up at home and taken away from the home for feeding.

Data in Table 5.23 indicated that community midwives' and health visitors' attitudes towards microbial hazards associated with powdered formula milk. Fifty percent of community midwives and 56% of health visitors believed that powdered formula milk was a sterile product before the tin has been opened and a limited awareness of *E.sakazakii* and *Salmonella* contamination of powdered formula was identified (where 63% of community midwives and 60% of health visitors were unaware of PIF association with *E.sakazakii* and 54% of community midwives and 43% of health visitors were unaware of the association with *Salmonella*).

Nearly half of health visitors (43%) and community midwives (47%) reported they often have seen implementation of behaviours that are contrary to powdered formula milk preparation and handling recommendations. Only 43% of community midwives and 36% of health visitors believed that most of the parents they care for knew all of the safety practices required for safe preparation and feeding of powdered formula milk.



**Table 5.22 Community midwives' (n=232) and health visitors' (n=426) attitudes towards powdered infant formula preparation and storage behaviours**

	Community midwife (CM)			Health visitor (HV)		
	Strongly Agree/Agree n (%)	Neither n (%)	Strongly Disagree/Disagree n (%)	Strongly Agree/Agree n (%)	Neither n (%)	Strongly Disagree/Disagree n (%)
Making up one feed at a time is difficult to for all parents to do, all of the time (CM=228; HV=413)	186 (82)	16 (7)	30 (13)	346 (84)	34 (8)	32 (8)
Making up powdered infant formula feeds with cold or warm water is acceptable practice. (CM=224; HV=413)	14 (3)	9 (4)	193 (86)	34 (8)	31 (8)	341 (83)
It is difficult to judge the actual temperature of water when it is mixed with the formula powder. (CM=225; HV=409)	138 (61)	33 (15)	53 (24)	260 (64)	70 (17)	75 (18)
It is acceptable to make up bottles of powdered formula milk in advance of use. (CM=227; HV=408)	17 (7)	32 (14)	178 (78)	44 (11)	68 (17)	296 (72)
It is better to feed bottle fed infants with ready-to-use formula (in cartons) when away from the home. (CM=228; HV=411)	132 (58)	52 (23)	40 (18)	201 (49)	136 (33)	70 (17)
It is acceptable for parents to take reconstituted bottles of powdered infant formula with them when away from the home. (CM=225; HV=410)	26 (12)	37 (16)	159 (71)	43 (10)	82 (20)	282 (69)
Preparation of powdered infant formula with boiled water from a flask is a good way to make-up feeds when away from the home or during the night. (CM=226; HV=412)	105 (46)	41 (18)	78 (35)	196 (48)	77 (19)	132 (32)
For night feeds, it is safer to reconstitute powdered formula milk beforehand, rather than make it from scratch when needed in the middle of the night (CM=229; HV=414)	36 (16)	32 (14)	158 (69)	56 (14)	98 (24)	257 (62)
It is easy to implement all of the recommended safety practices for safe preparation of powdered infant formula (CM=226; HV=412)	121 (54)	31 (14)	74 (33)	169 (41)	69 (17)	172 (42)

*% for some attitude statements may not add up to 100 due to non responses/don't know responses*

**Table 5.23 Community midwives' (n=232) and health visitors' (n=426) attitudes towards powdered infant formula, perceived efficacy and other issues.**

Attitude statement	Community midwife (CM)			Health visitor (HV)		
	Strongly Agree/ Agree n (%)	Neither n (%)	Strongly Disagree/ Disagree n (%)	Strongly Agree/ Agree n (%)	Neither n (%)	Strongly Disagree/ Disagree n (%)
Before opening a tin of powdered formula milk, the powdered milk is a sterile product (i.e. is free from all germs and bacteria) (CM=226; HV=411)	113 (50)	20 (9)	87 (38)	186 (45)	46 (11)	175 (43)
<b>Microbial hazards</b> <i>Enterobacter sakazakii</i> can be found in powdered infant formula (CM=227; HV=408)	84 (37)	40 (18)	17 (7)	164 (40)	97 (24)	35 (9)
There is no association between <i>Salmonella</i> and powdered formula (CM=226; HV=409)	33 (15)	47 (21)	104 (46)	72 (18)	89 (22)	191 (47)
Making up one feed at a time (fresh) for immediate feeding is <u>essential</u> to reduce the chance of illness from powdered infant formula. (CM=228; HV=414)	165 (72)	35 (15)	26 (11)	273 (66)	83 (20)	47 (14)
I think that most of the parents/mothers I care for know all of the safety practices necessary for safe preparation and feeding of powdered formula milk (CM=228; HV=416)	97 (43)	43 (19)	88 (39)	149 (36)	16 (66)	196 (47)
<b>Other issues</b> I often see parents/mothers not implementing recommended behaviours needed to ensure powdered formula fed to their baby is safe. (CM=227; HV=413)	106 (47)	28 (12)	91 (40)	179 (43)	83 (20)	148 (36)
Ultimately, it is the parents/mothers responsibility to decide how they prepare powdered infant formula feeds (CM=227; HV=413)	96 (42)	32 (14)	98 (43)	193 (47)	62 (15)	156 (38)
A large proportion of my caseload feed infants aged less than 6 months with powdered formula milk (exclusively or partially). (CM=225; HV=416)	132 (59)	21 (9)	70 (31)	330 (79)	30 (7)	51 (12)
Infants experiencing gastro-intestinal infections resulting from powdered infant formula are extremely rare. (CM=228; HV=412)	34 (15)	34 (15)	143 (63)	87 (21)	85 (21)	122 (30)

*% for some attitude statements may not add up to 100 due to non responses/don't know responses*

### 5.3.5 Perceptions of risk, control, responsibility and hygiene consciousness during preparation of powdered infant formula: NHS caregivers

Data indicating perceptions of risk, control, responsibility and hygiene consciousness were determined for hospital midwives/MHCAs (see Table 5.24) and hospital nurses /HCAs (see Table 5.25). Both groups of NHS caregivers considered the risk of illness to an infant after drinking PIF made-up by themselves to be less than other hospital nurses and parents.

**Table 5.24 Hospital nurses’/HCAs’ perceptions of risk, control, responsibility and hygiene consciousness during preparation of powdered infant formula (n=291)**

Assessment of perceived risk, control and responsibility (key to ranking)	Caregivers	Sample who stated values 1-3 n (%)	Sample who stated values 8-10 n (%)	Mean ranking (SD)	Don't know/no response n (%)
What do you consider to be the risk of illness to an infant from drinking made-up powdered infant formula prepared by..... <i>[insert each of the following caregivers]</i> ? (1= Very High Risk, 10= Very Low Risk)	...you	2 (<1)	236 (81)	9.0 (1.2)	18 (6)
	...other hospital nurses	4 (1)	192 (66)	8.6 (1.6)	52 (18)
	...parents	3 (1)	135 (46)	7.7 (1.6)	46 (16)
How much control do you think ... <i>[insert each of the following caregivers]</i> ..... have over hygiene and safety when preparing infant feeds in your care? (1= No control ; 10=Full control)	...you	14 (5)	221 (76)	8.5 (2.2)	3 (1)
	...other hospital nurses	14 (5)	182 (63)	8.2 (2.3)	34 (12)
	...parents	22 (8)	170 (58)	7.8 (2.5)	16 (5)
How much responsibility do you think ... <i>[insert each of the following caregivers]</i> ..... have for the safety infant feeds? (1=No responsibility; 10=Full responsibility)	...you	2 (<1)	265 (91)	9.5 (1.1)	3 (1)
	...other hospital nurses	2 (<1)	246 (85)	9.5 (1.2)	22 (8)
	...parents	8 (2)	232 (80)	9.1 (1.8)	16 (5)
How conscious of hygiene do you think ... <i>[insert each of the following caregivers]</i> .....are when preparing infant feeds? (1=Not at all conscious; 10=Very conscious)	...you	0	269 (92)	9.5 (0.8)	2 (<1)
	...other hospital nurses	0	221 (76)	9.3 (1.1)	40 (4)
	...parents	1 (<1)	180 (62)	8.4 (1.5)	37 (13)

Similarly, hospital midwives/MHCAs and hospital nurses/HcAs considered that they had more control over hygiene and safety, and were more conscious of hygiene and safety than other hospital nurses, infants' parents and hospital staff.

**Table 5.25 Hospital midwives'/MHCAs' perceptions of risk, control, responsibility and hygiene consciousness during preparation of powdered infant formula (n=266)**

Assessment of perceived risk, control and responsibility (key to ranking)	Caregivers	Sample who stated values 1-3 n (%)	Sample who stated values 8-10 n (%)	Mean ranking (SD)	Don't know/no response n (%)
What do you consider to be the risk of illness to an infant from drinking made-up powdered infant formula prepared by..... <i>[insert each of the following caregivers]</i> ? (1= Very High Risk, 10= Very Low Risk)	...you	2 (<1)	159 (60)	8.8 (1.5)	38 (4)
	...other hospital nurses	2 (<1)	118 (44)	8.3 (1.7)	66 (25)
	...parents	8 (3)	65 (24)	6.8 (1.9)	60 (23)
How much control do you think ... <i>[insert each of the following caregivers]</i> ..... have over hygiene and safety when preparing infant feeds in your care? (1= No control ; 10=Full control)	...you	21 (8)	129 (48)	7.7 (2.8)	27 (10)
	...other hospital nurses	30 (11)	93 (35)	7.0 (3.1)	56 (21)
	...parents	20 (8)	135 (51)	7.8 (2.6)	30 (11)
How much responsibility do you think ... <i>[insert each of the following caregivers]</i> ..... have for the safety infant feeds? (1=No responsibility; 10=Full responsibility)	...you	7 (3)	181 (68)	9.0 (1.9)	18 (7)
	...other hospital nurses	5 (2)	166 (62)	9.0 (1.8)	37 (14)
	...parents	4 (2)	182 (68)	9.1 (1.6)	23 (9)
How conscious of hygiene do you think ... <i>[insert each of the following caregivers]</i> .....are when preparing infant feeds? (1=Not at all conscious; 10=Very conscious)	...you	0	199 (75)	9.6 (0.7)	20 (8)
	...other hospital nurses	1 (<1)	157 (59)	9.3 (1.1)	53 (20)
	...parents	4 (2)	102 (38)	7.6 (1.8)	47 (18)

### 5.3.6 The importance of the correct implementation of key powdered infant formula preparation and handling behaviours: NHS Caregivers

Findings presented in Table 5.26, 5.27, 5.28 and 5.29 illustrate how important NHS caregivers perceive recommended PIF preparation and handling behaviours. Data suggests that considerable proportions of each caregiver group do not perceive powdered formula milk preparation and handling behaviours recommended by the DoH and FSA for safety, to be important. For example, 18% of hospital nurses/HCAs and 14% of hospital midwives/MHCAs do not think that ensuring boiled water is  $>70^{\circ}\text{C}$  when mixed with the powdered formula is very or fairly important; 16-17% of hospital nurses/HCAs and 8-9% of hospital midwives/MHCAs do not think that making up one feed at a time or feeding formula immediately after preparation (once at a suitable temperature) are very or fairly important.

**Table 5.26 Perceived importance of the implementation of key powdered infant formula preparation and handling behaviours: hospital nurse/HCAs (n=291)**

	Very important n (%)	Fairly important n (%)	Neither n (%)	Not very important n (%)	Not at all important n (%)
• Clean the preparation area every time a bottle of powdered formula milk feed is prepared (n=285)	270 (93)	14 (5)	0	0	0
• Wash and dry hands every time a bottle of powdered formula milk feed is prepared (n=285)	283 (97)	2 (<1)	0	0	0
• Wash feeding bottles and components with detergent and hot water before sterilising (n=284)	276 (95)	6 (2)	1 (<1)	1 (<1)	0
• Rinse washed feeding bottles and components with running water before sterilising (n=280)	234 (80)	30 (10)	11 (4)	3 (1)	2 (<1)
• Sterilise feeding bottles and components before use (n=282)	275 (95)	5 (2)	2 (<1)	0	0
• Use boiled water (fresh from the tap before boiling) to make up powdered infant formula (n=276)	236 (81)	15 (5)	14 (5)	4 (1)	6 (2)
• Ensure the temperature of boiled water has cooled, but is higher than $70^{\circ}\text{C}$ when mixed with the milk powder (n=269)	163 (56)	52 (18)	44 (15)	8 (3)	2 (<1)
• Mix milk powder with boiled water that has cooled for less than 30 minutes (n=267)	162 (56)	59 (20)	37 (13)	6 (2)	2 (<1)
• Feed the made-up powdered formula <u>immediately</u> after preparation (once at a suitable temperature) (n=278)	187 (64)	49 (17)	27 (9)	14 (5)	1 (<1)
• Prepare (i.e. add powder and water together) one feed at a time (n=281)	179 (62)	54 (19)	25 (9)	20 (7)	3 (1)

*NB: % may not add up to 100% due to non response*

**Table 5.27 Perceived importance of the implementation of key powdered infant formula preparation and handling behaviours: hospital midwife/MHCAs (n=266)**

	Very important n (%)	Fairly important n (%)	Neither n (%)	Not very important n (%)	Not at all important n (%)
• Clean the preparation area every time a bottle of powdered formula milk feed is prepared (n=259)	241 (91)	17 (6)	1 (<1)	0	0
• Wash and dry hands every time a bottle of powdered formula milk feed is prepared (n=259)	254 (96)	5 (2)	0	0	0
• Wash feeding bottles and components with detergent and hot water before sterilising (n=259)	244 (92)	10 (4)	2 (<1)	1 (<1)	1 (<1)
• Rinse washed feeding bottles and components with running water before sterilising (n=259)	207 (78)	31 (12)	14 (5)	5 (2)	1 (<1)
• Sterilise feeding bottles and components before use (n=259)	254 (96)	4 (2)	1 (<1)	0	0
• Use boiled water (fresh from the tap before boiling) to make up powdered infant formula (n=259)	234 (88)	14 (5)	4 (2)	5 (2)	1 (<1)
• Ensure the temperature of boiled water has cooled, but is higher than 70°C when mixed with the milk powder (n=247)	160 (60)	49 (18)	23 (9)	12 (5)	3 (1)
• Mix milk powder with boiled water that has cooled for less than 30 minutes (n=251)	156 (59)	47 (18)	28 (11)	18 (7)	2 (<1)
• Feed the made-up powdered formula <u>immediately</u> after preparation (once at a suitable temperature) (n=256)	178 (67)	53 (20)	11 (4)	13 (5)	1 (<1)
• Prepare (i.e. add powder and water together) one feed at a time (n=258)	184 (69)	51 (19)	12 (5)	8 (3)	3 (1)

*NB: % may not add up to 100% due to non response*

**Table 5.28 Perceived importance of the implementation of key powdered infant formula preparation and handling behaviours: community midwives (n=232)**

	Very important n (%)	Fairly important n (%)	Neither n (%)	Not very important n (%)	Not at all important n (%)
• Clean the preparation area every time a bottle of powdered formula milk feed is prepared	197 (85)	32 (14)	2 (1)	0	0
• Wash and dry hands every time a bottle of powdered formula milk feed is prepared	225 (97)	7 (3)	0	0	0
• Wash feeding bottles and components with detergent and hot water before sterilising	219 (94)	12 (5)	0	0	0
• Rinse washed feeding bottles and components with running water before sterilising	173 (75)	41 (18)	9 (4)	5 (2)	4 (2)
• Sterilise feeding bottles and components before use	225 (97)	7 (3)	0	0	0
• Use boiled water (fresh from the tap before boiling) to make up powdered infant formula	172 (74)	30 (13)	8 (3)	3 (1)	11 (5)
• Ensure the temperature of boiled water has cooled, but is higher than 70°C when mixed with the milk powder	132 (57)	53 (23)	22 (10)	15 (7)	3 (1)
• Mix milk powder with boiled water that has cooled for less than 30 minutes	130 (56)	63 (27)	29 (13)	2 (1)	2 (1)
• Feed the made-up powdered formula <u>immediately</u> after preparation (once at a suitable temperature)	165 (71)	51 (22)	6 (2)	10 (4)	0
• Prepare (i.e. add powder and water together) one feed at a time	171 (74)	44 (19)	9 (4)	6 (3)	0

*NB: % may not add up to 100% due to non response*

**Table 5.29 Perceived importance of the implementation of key powdered infant formula preparation and handling behaviours: health visitors (n=426)**

	Very important n (%)	Fairly important n (%)	Neither n (%)	Not very important n (%)	Not at all important n (%)
• Clean the preparation area every time a bottle of powdered formula milk feed is prepared	363 (85)	59 (14)	1 (<1)	0	0
• Wash and dry hands every time a bottle of powdered formula milk feed is prepared	413 (97)	9 (2)	1 (<1)	0	0
• Wash feeding bottles and components with detergent and hot water before sterilising	401 (94)	18 (4)	2 (<1)	0	1 (<1)
• Rinse washed feeding bottles and components with running water before sterilising	309 (73)	83 (20)	19 (5)	9 (2)	2 (<1)
• Sterilise feeding bottles and components before use	416 (98)	5 (1)	1 (<1)	0	0
• Use boiled water (fresh from the tap before boiling) to make up powdered infant formula	320 (75)	33 (8)	17 (4)	4 (1)	22 (5)
• Ensure the temperature of boiled water has cooled, but is higher than 70°C when mixed with the milk powder	268 (63)	80 (19)	46 (11)	18 (4)	2 (<1)
• Mix milk powder with boiled water that has cooled for less than 30 minutes	241 (57)	107 (25)	52 (12)	15 (4)	0
• Feed the made-up powdered formula <u>immediately</u> after preparation (once at a suitable temperature)	266 (62)	130 (31)	13 (3)	8 (2)	0
• Prepare (i.e. add powder and water together) one feed at a time	291 (68)	105 (25)	18 (4)	7 (2)	0

*NB: % may not add up to 100% due to non response*



Overall, comparable proportions of NHS caregivers reported key behaviours, recommended for safety of PIF, to be ‘very important’ (see Table 5.30). Practices such as ensuring water temperature exceeds 70°C when mixed with powdered formula, making one feed up at a time and feeding the made-up powdered formula milk immediately after preparation were not considered to be ‘very important’ by large proportions of all NHS caregivers. Such perceptions may influence provision of advice about implementation of such practices.

**Table 5.30 The importance of the implementation of key powdered infant formula preparation and handling behaviours: a comparison of NHS caregivers’ perceptions considering behaviours to be ‘very important’**

	Hospital nurses/HCAs %	Hospital midwives/MHCAs %	Community midwives %	Health visitors %
• Clean the preparation area every time a bottle of powdered formula milk feed is prepared	93	91	85	85
• Wash and dry hands every time a bottle of powdered formula milk feed is prepared	97	96	97	97
• Wash feeding bottles and components with detergent and hot water before sterilising	95	92	94	94
• Rinse washed feeding bottles and components with running water before sterilising	80	78	75	73
• Sterilise feeding bottles and components before use	95	96	97	98
• Use boiled water (fresh from the tap before boiling) to make up powdered infant formula	81	88	74	75
• Ensure the temperature of boiled water has cooled, but is higher than 70°C when mixed with the milk powder	56	60	57	63
• Mix milk powder with boiled water that has cooled for less than 30 minutes	56	59	56	57
• Feed the made-up powdered formula <u>immediately</u> after preparation (once at a suitable temperature)	64	67	71	62
• Prepare (i.e. add powder and water together) one feed at a time	62	69	74	68

### 5.3.7 Sources of information and training

Data presented in Table 5.31 shows that less than a third of NHS caregivers working with infants aged less than 6 months reported receiving training about the microbiological risks associated with PIF. Less than a fifth of the same caregivers reported training of such issues in recent years.

**Table 5.31 Reported receipt of training about the microbiological risks associated with powdered infant formula**

	Hospital nurses/HcAs (paediatric/SCBU/neonatal) n=291 n (%)	Hospital midwives/MHCAs n=266 n (%)	Community midwives n=232 n (%)	Health visitors n=426 n (%)
....ever?	75 (26)	77 (29)	71 (31)	102 (24)
....in the past 3 years?	35 (12)	51 (19)	39 (17)	61 (14)

Reported awareness/recollection of FSA/DoH and WHO PIF guidance notes was limited (see Table 5.32). The lowest awareness was among hospital midwives and the more widespread awareness among health visitors.

**Table 5.32 Reported awareness/recall of seeing WHO and FSA powdered infant formula information**

Information source	Hospital nurses/HcAs (paediatric/SCBU/neonatal) n=291 n (%)	Hospital midwives/MHCAs n=266 n (%)	Community midwives n=232 n (%)	Health visitors n=426 n (%)
FSA/DoH Guidance for Healthcare Professionals on the safe preparation, storage and handling of powdered infant formula.	105 (36)	69 (26)	86 (37)	171 (40)
Guidance for making up special feeds for infants and children in hospital (produced by the British Dietetic Association and published by the FSA)	38 (13)	11 (4)		
WHO information about powdered infant formula preparation, storage and feeding	85 (29)	72 (27)	76 (33)	178 (42)

Twenty seven percent of hospital nurses/HCAs, 17% of midwives/MHCAs, 30% of community midwives and 65% of health visitors reported they have communicated with commercial PIF reps in the past for information about feeding infants with PIF. Findings presented in Table 5.33 illustrate that when commercial formula reps have been contacted for information about PIF, many NHS caregivers (up to 83%) reported obtaining useful information about PIF. For example, 53-71% of caregivers reported that formula reps gave them up-to-date information about PIF preparation, handling and storage of powdered formula milk and 42-58% reported that the reps provided them with information about the microbiological safety of formula. However, up to 65% of caregivers reported they are not officially permitted to talk to reps directly.

**Table 5.33 Health professionals reported contact with commercial powdered infant formula reps**

Information source		Hospital nurses/HCAs (paediatric/SCBU/neonatal) n=79 n (%)	Hospital midwives/MHCAs n=45 n (%)	Community midwives n=69 n (%)	Health visitors n=278 n (%)
Useful information about the effect of consumption of powdered formula upon infants' digestive systems		67 (85)	31 (69)	55 (80)	231 (83)
Promote any of their products to you		53 (67)	29 (64)	42 (61)	180 (65)
Provide information about the microbiological safety of powdered formula		33 (42)	24 (53)	40 (58)	143 (51)
Encourage you to promote any of their products to parents		14 (18)	8 (18)	25 (36)	60 (22)
Give you up-to-date information about powdered infant formula preparation and storage guidelines		42 (53)	34 (76)	45 (65)	196 (71)
Officially permitted to communicate with reps (MW=45; HN=79; CM=232; HV=196)	Yes	59 (20)	24 (9)	15 (7)	54 (13)
	No	101 (35)	142 (53)	119 (51)	276 (65)
	Don't know	114 (39)	85 (32)	31 (13)	34 (8)

*Other information obtained from formula reps:*

*Nurses: 'how long pre-prepared feeding bottles can be used when opened'*

*Community midwives: 'Excellent study days on infant formula feeds'; 'Range of soya free preparations'*

*health visitors (representative selection of responses): 'advice given regarding change of formula'; 'advice on which product is suitable for a baby with reflux/intolerance'; 'information on more specialist formula milks'; 'always exceptionally helpful and never promoted own milks'; 'composition of their formula'; 'gave excellent feeding advice and updates to professionals'; 'gave useful information relating to specialist formulas i.e. lactose free'; 'health visitor not recommended to see directly – infant feeding advisor to cascade information'.*

**Table 5.34 Reported ‘Baby Friendly’ accreditation and associated training/inclusion of information about safe powdered infant formula preparation, handling and storage**

	Hospital nurses/HcAs (paediatric/ SCBU/ neonatal) n=291 n (%)	Hospital midwives/ MHCAs n=266 n (%)	Community midwives n=232 n (%)	Health visitors n=426 n (%)
My workplace has Full Baby Friendly Accreditation	109 (38)	109 (41)	77 (33)	55 (13)
My workplace has a ‘Baby Friendly’ certificate of commitment	43 (15)	81 (31)	59 (25)	92 (22)
My workplace has no ‘Baby Friendly’ status, but we follow the ‘Baby Friendly rules’	44 (15)	47 (18)	34 (15)	127 (30)
My workplace has no association with the Baby Friendly Initiative	5 (2)	3 (1)	1 (<1)	26 (6)
Don’t know	63 (22)	11 (4)	4 (2)	57 (13)
Ever received training through BF initiative	139 (48)	182 (68)	172 (74)	239 (56)
Those who reported receiving training about powdered infant formula preparation and storage through the Baby Friendly Initiative (MW=139; HN=182; CM=172; HV=239).	16 (12)	29 (16)	29 (17)	31 (17)

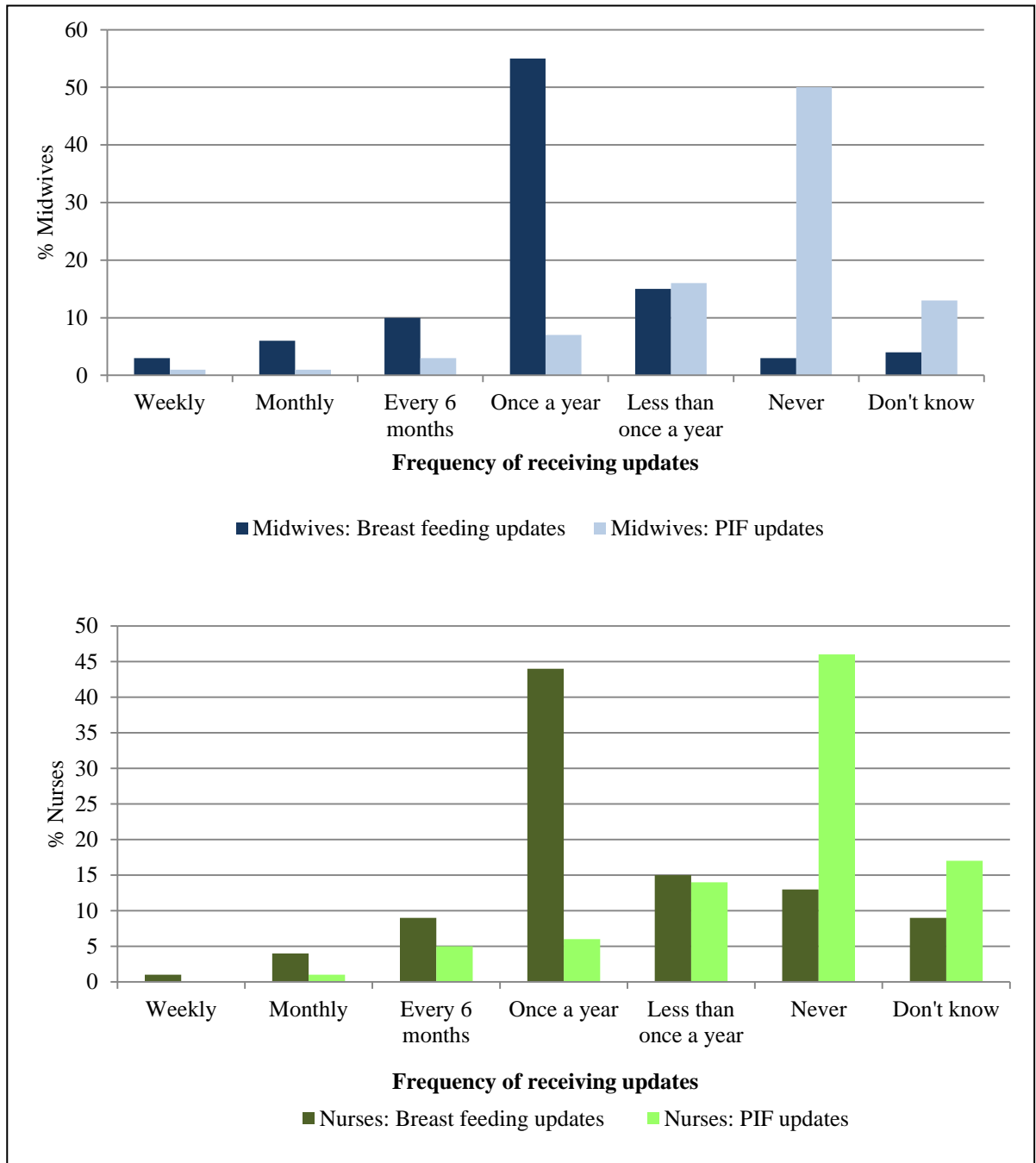
*NB: % may not add up to 100% due to non response*

Half of NHS Trusts where caregiver questionnaires for this study were sent were reported to be ‘Baby Friendly’ accredited; however, data in Table 5.34 shows that few NHS caregivers’ workplaces have no association with the Baby Friendly Initiative. In instances when accreditation or a certificate of commitment has not been achieved, many caregivers reported that their workplaces reportedly followed ‘Baby Friendly Rules’.

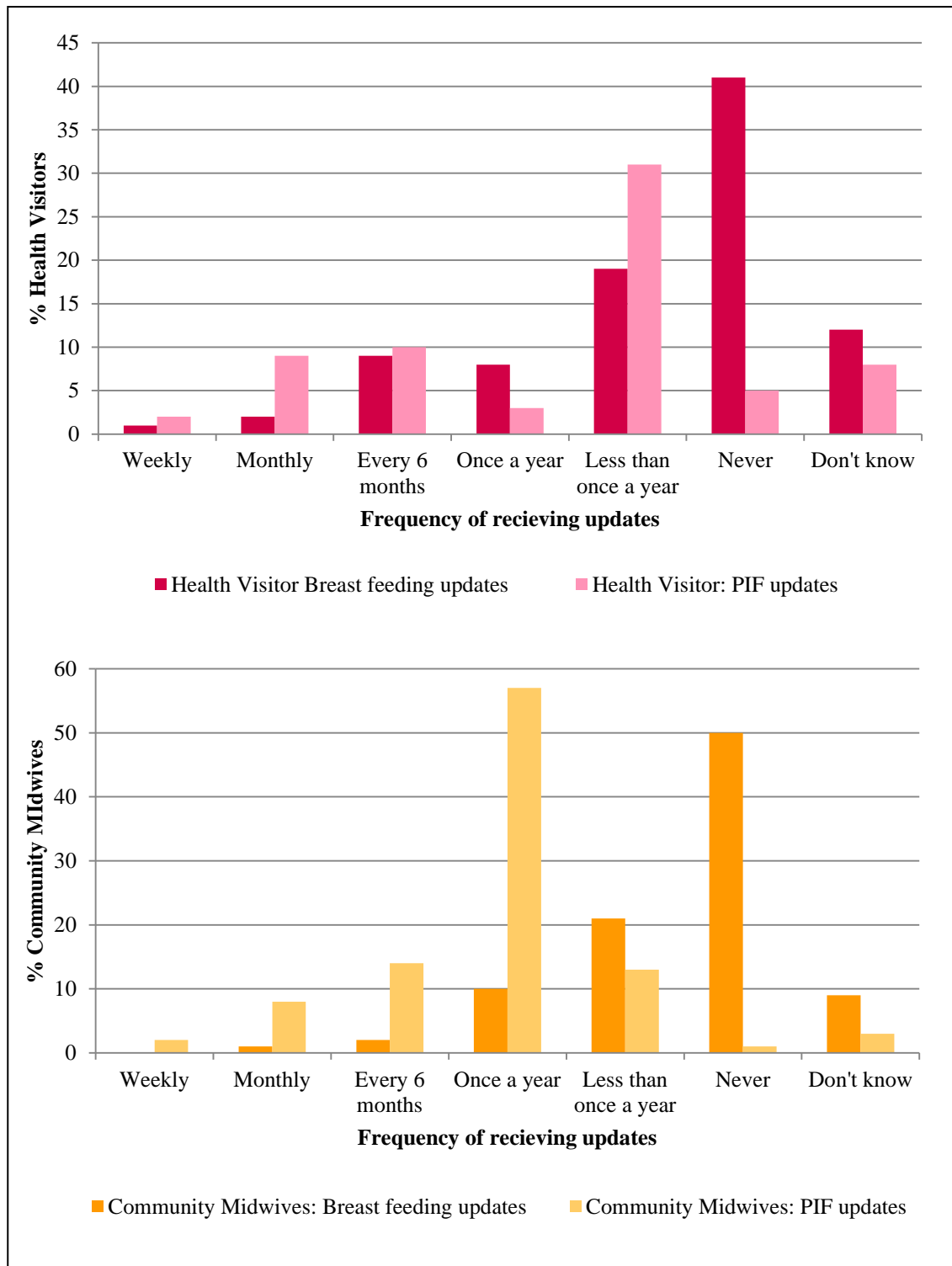
Large proportions, particularly of midwives (68-74%) reported receiving training about infant feeding through the Baby Friendly Initiative. However, only 12-17% reported inclusion about safe preparation, handling and storage of PIF in such training sessions.

Figure 5.4 and 5.5 illustrates that information about breastfeeding is updated more frequently for all caregiver groups in this study, than for PIF. Overall, ~50% of all caregivers reported never receiving updated information about powdered formula milk use and feeding.

**Figure 5.4 Bar charts indicating the frequency of receiving ‘updates’ about breastfeeding and safe preparation, handling and storage of powdered infant formula: hospital midwives and hospital nurses**



**Figure 5.5 Bar charts indicating the frequency of receiving ‘updates’ about breastfeeding and safe preparation, handling and storage of powdered infant formula: community midwives and health visitors**



31% (83/266) of midwives/MHCAs reported that their workplace did have an infant feeding policy that included PIF; 27% did not know and 34% indicated that their workplace did not have an infant feeding policy that included PIF.

47% (138/291) of nurses/HCAs reported that their workplace did have an infant feeding policy that included PIF; 27% did not know and 17% indicated that their workplace did not have an infant feeding policy that included PIF.

44% of community midwives reported that their workplace did have an infant feeding policy that included PIF; 25% did not know and 25% indicated that their workplace did not have an infant feeding policy that included PIF.

36% of health visitors reported that their workplace did have an infant feeding policy that included PIF; 31% did not know and 24% indicated that their workplace did not have an infant feeding policy that included PIF.

### **5.3.8 Information provision: hospital midwives and hospital nurses**

Variable (including many negative) attitudes were identified among NHS caregivers regarding provision of information to parents about PIF (see Table 5.35).

Only 30% of hospital midwives/MHCAs and hospital nurses/HCAs were aware that recommendations about safe preparation, handling and storage have changed in recent years and most believed that recommended practices were consistent between different sources. Most caregivers (62-76%) also reported that they would like to receive up to date information about PIF guidelines.

Forty percent of hospital midwives/MHCAs and hospital nurses/HCAs considered there was not enough information available about feeding infants with powdered formula milk and 51-61% believed bottle feeding mothers were not given as much information and support about infant feeding as breast feeding mothers.

Most hospital midwives/MHCAs and hospital nurses/HCAs believed that the information they give to parents about formula feeding is adequate for their needs, although 62% of hospital midwives/MHCAs indicated that 'midwives' were not a good source of PIF information.

**Table 5.35 Hospital nurse and midwife attitudes towards recommendations and information provision/sources about safe preparation, handling and storage of powdered infant formula**

	Hospital midwife (MW)/MHCA			Hospital nurse (HN)/HCA		
	Strongly Agree/Agree n (%)	Neither n (%)	Strongly Disagree/Disagree n (%)	Strongly Agree/Agree n (%)	Neither n (%)	Strongly Disagree/Disagree n (%)
NHS health professionals provide a consistent source of information about preparation and storage of powdered infant formula. (MW=264; HN=288)	118 (45)	48 (8)	92 (35)	139 (48)	75 (26)	64 (22)
Recommendations for safe preparation and storage of powdered infant formula have changed in recent years. (MW=261; HN=284)	78 (30)	64 (25)	56 (31)	84 (30)	76 (27)	47 (17)
Recommendations about preparation and storage of powdered formula milk are consistent from different sources (e.g. NHS, FSA, NCT, supermarkets, formula manufacturers etc). (MW=251; HN=285)	226 (90)	20 (8)	4 (2)	244 (86)	16 (6)	5 (2)
Preparation and storage of powdered infant formula <u>should be included</u> in all antenatal/parentcraft classes. (MW=262; HN=288)	166 (63)	26 (10)	68 (26)	235 (82)	29 (10)	22 (8)
Midwives are a good source of information about powdered formula (MW=263; HN=285)	101 (38)	71 (27)	84 (32)	88 (31)	81 (28)	89 (31)
I do not have time to search and read information about infant feeding. (MW=261; HN=285)	64 (25)	80 (31)	113 (43)	47 (16)	88 (31)	149 (52)
I would like to receive up-to-date information about powdered infant formula preparation and storage guidelines (MW=263; HN=284)	163 (62)	53 (20)	42 (16)	217 (76)	43 (15)	23 (8)
Following preparation and storage instructions on tins of powdered formula is <u>not</u> essential. (MW=263; HN=287)	12 (5)	6 (2)	244 (93)	9 (3)	8 (3)	267 (93)
There is not enough information available to parents about feeding babies with powdered formula milk. (MW=263; HN=285)	104 (40)	47 (20)	109 (41)	117 (41)	62 (22)	97 (34)
Bottle feeding mothers are not given as much information or support about infant feeding as breast feeding mothers. (MW=262; HN=285)	159 (61)	26 (10)	74 (28)	145 (51)	46 (16)	81 (28)

*% for some attitude statements may not add up to 100 due to non responses/don't know responses*



**Table 5.35** (continued)

	Hospital midwife (MW)/MHCA			Hospital nurse (HN)/HCA		
	Strongly Agree/ Agree n (%)	Neither n (%)	Strongly Disagree/ Disagree n (%)	Strongly Agree/ Agree n (%)	Neither n (%)	Strongly Disagree/ Disagree n (%)
Mothers/parents often ask me about issues associated with safe preparation and storage of powdered infant formula (MW=259; HN=286)	112 (43)	55 (21)	91 (35)	114 (40)	65 (23)	105 (37)
In the department where I work, ALL mothers are provided with information about safe preparation and use of powdered infant formula (MW=264; HN=287)	155 (59)	27 (10)	77 (29)	168 (59)	38 (13)	77 (27)
Hospital nurses should give ALL mothers/parents advice about safe preparation and storage of powdered formula milk, <u>before</u> they leave hospital. (MW=264; HN=288)	196 (74)	20 (8)	44 (17)	240 (83)	23 (8)	28 (10)
I always discuss microbiological safety of powdered infant formula with bottle feeding parents (MW=260; HN=283)	124 (48)	55 (21)	79 (30)	135 (48)	67 (24)	75 (27)
I think that information that I give to mothers/parents about powdered formula feeding is adequate for their needs (MW=260; HN=287)	195 (75)	32 (12)	28 (11)	238 (83)	31 (11)	16 (6)
It is important to demonstrate recommended powdered infant formula practices to ALL parents before they leave hospital (MW=262; HN=288)	100 (38)	52 (20)	107 (41)	175 (61)	58 (20)	52 (18)
It is important to <u>demonstrate</u> recommended powdered infant formula practices to formula feeding mothers/parents before they leave hospital (MW=260; HN=285)	173 (67)	35 (13)	46 (18)	225 (61)	58 (20)	52 (18)
There is no need to discuss preparation and storage of powdered formula milk with mothers who are exclusively breastfeeding. (MW=263; HN=287)	92 (35)	41 (16)	129 (49)	41 (14)	34 (12)	210 (73)
I only provide information about preparation and storage of powdered infant formula if/when a parent asks. (MW=263; HN=285)	73 (28)	29 (11)	160 (61)	75 (26)	25 (9)	181 (64)
Parents are not given enough advice and support about how to safely prepare and store powdered formula feed (MW=259; HN=284)	104 (40)	52 (20)	97 (37)	84 (30)	79 (28)	110 (39)

*% for some attitude statements may not add up to 100 due to non responses/don't know responses*

**Table 5.35** (continued)

	Hospital midwife (MW)/MHCA			Hospital nurse (HN)/HCA		
	Strongly Agree/ Agree n (%)	Neither n (%)	Strongly Disagree/ Disagree n (%)	Strongly Agree/ Agree n (%)	Neither n (%)	Strongly Disagree/ Disagree n (%)
I am happy to give branded information (from formula manufacturers) to parents about powdered formula milk. (MW=264; HN=288)	53 (20)	45 (17)	160 (61)	93 (33)	80 (28)	100 (35)
The NHS Birth to Five book adequately covers the microbiological safety of formula milk preparation and storage. (MW=264; HN=288)	64 (25)	57 (22)	7 (3)	57 (20)	69 (24)	11 (4)
Placement of leaflets/posters detailing safe preparation and use of formula milk in hospital wards may increase formula feeding. (MW=264; HN=288)	107 (40)	54 (20)	101 (38)	83 (29)	85 (30)	112 (39)
The Baby Friendly Initiative provides support to bottle feeding mothers. (MW=264; HN=288)	44 (17)	44 (17)	154 (59)	29 (10)	63 (22)	143 (50)
Achieving 'Baby Friendly' Accreditation is associated with a positive Trust/departmental status. (MW=264; HN=288)	208 (78)	37 (14)	15 (6)	186 (71)	53 (19)	12 (4)
Implementation of the Baby Friendly Initiative provides a framework to give ALL mothers the best infant feeding advice. (MW=264; HN=288)	129 (49)	52 (20)	72 (27)	124 (44)	60 (21)	64 (23)
I am not allowed to discuss formula feeding with parents unless formula feeding is medically advised. (MW=264; HN=288)	59 (22)	51 (19)	146 (56)	57 (20)	56 (20)	160 (56)

*% for some attitude statements may not add up to 100 due to non responses/don't know responses*

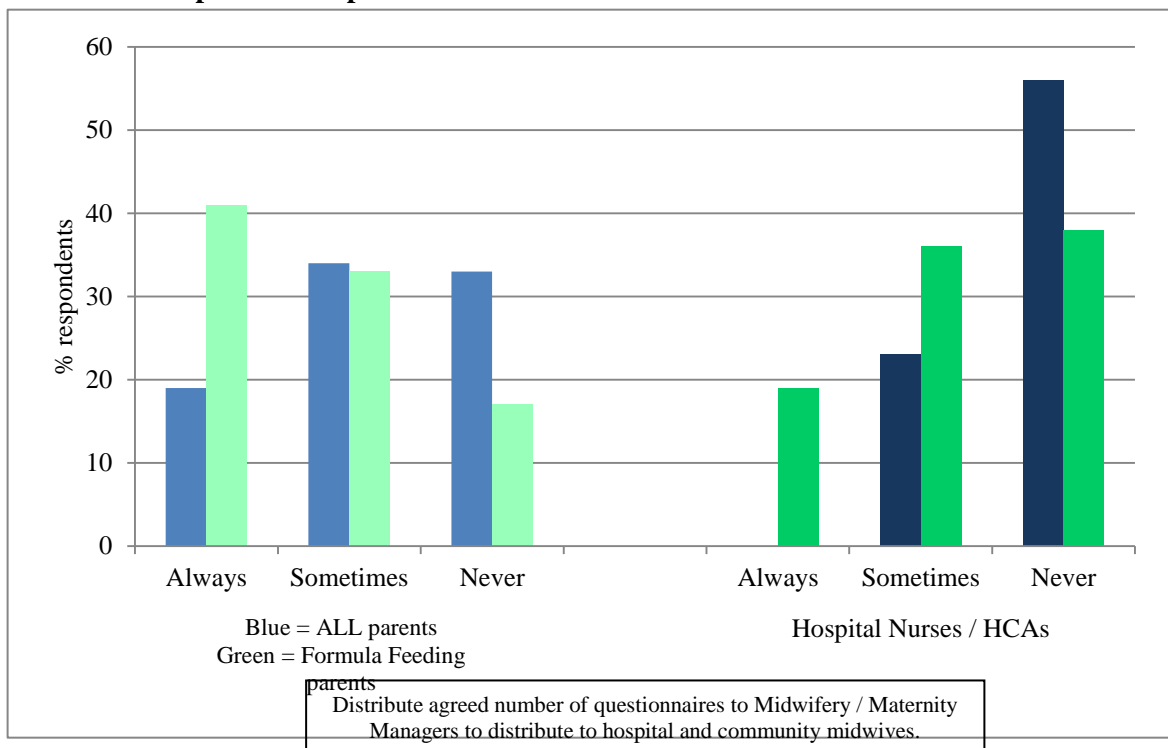
More hospital nurses/HCA's (61%) reported they believed it is important to demonstrate recommended PIF practices to all parents before they leave hospital, compared to 38% of hospital midwives/MHCA's.

Approximately a third (35%) of hospital midwives/MHCA's believed that there is no need to discuss preparation, handling and storage of PIF with mothers who are exclusively breastfeeding.



More than half (50-59%) of hospital nurses/HCAs and hospital midwives/MHCAs believed that the Baby Friendly Initiative does not support bottle feeding mothers and 23-27% also believed that implementation of the initiative does not provide a framework to give all mothers the best infant feeding advice. Between 20-22% of hospital nurses/HCAs and hospital midwives/MHCAs reported that they are not allowed to discuss formula feeding with parents unless formula feeding is medically advised.

The bar chart in Figure 5.6 illustrates that hospital nurses/HCAs more frequently provide demonstrations of recommended/safe PIF practices to parents and more than 55% of hospital midwives/MHCAs reported that they never give demonstrations.

**Figure 5.6 Reported frequency of giving demonstrations of recommended/safe powdered infant formula practices to parents/mothers**



**Table 5.36 Awareness and reported availability and provision of powdered infant formula information: hospital midwives/nurses**

Information Sources	Hospital midwives/MHCAs				Hospital nurses/HCAs				
	n (%) respondents who have seen information sources (see left)	Of the respondents who reported seeing the sources: n (%) respondents reported availability of the source to give to parents at all times	Of the respondents who reported seeing the sources: n (%) respondents who give this source to all new/prospective parents	Of the respondents who reported seeing the sources: n (%) respondents who give this source to formula feeding parents	n (%) respondents who have seen information sources (see left)	Of the respondents who reported seeing the sources: n (%) respondents reported availability of the source to give to parents at all times	Of the respondents who reported seeing the sources: n (%) respondents who give this source to all new/prospective parents	Of the respondents who reported seeing the sources: n (%) respondents who give this source to formula feeding parents	
 <p>England, Wales, NI data only</p>	England MW=150; HN=166	106 (71)	73/106 (69)	13/106 (12)	93/106 (88)	87 (52)	67/87 (77)	36/87 (41)	72/87 (83)
	Wales MW=14; HN=13	5 (87)	3/8 (38)	1/8 (13)	3/8 (38)	6 (46)	4/6 (67)	2/6 (33)	6/6 (100)
	NI MW=33; HN=32	14 (42)	11/14 (79)	3/14 (21)	13/14 (93)	11 (34)	7/11 (64)	2/11 (18)	9/11 (82)
 <p>England,</p>									
<p>Welsh Government (for Wales) and the Health Protection</p>					160 (55)	100/160 (63)	48/160 (30)	106/160 (66)	

Awareness and reported availability of PIF information sources is presented in Table 5.36. Data indicates that more hospital midwives/MHCAs are aware of NHS/WAG/HPA Bottlefeeding leaflets and UNICEF A4 information sheets than hospital nurses/HCAs, particularly in England and Wales.

Reported availability of the leaflets among Welsh hospital midwives/MHCAs was reportedly more limited (38%) than in England (69%) and Northern Ireland (79%). Although awareness of the HPA NI Bottle Feeding leaflet was less widespread, hospital midwives/MHCAs who were aware of it reported increased availability and provision of the leaflet to parents.

Less than 21% of hospital midwives/MHCAs in England, Wales and Northern Ireland reported giving the leaflet to all prospective/new parents and only 38% of Welsh hospital midwives/MHCAs reported giving it to formula feeding parents, compared to 88-93% of hospital midwives/MHCAs from England and Northern Ireland.

Almost all hospital midwives/MHCAs (90%) were aware of the UNICEF ‘Baby Friendly’ bottle preparation/formula feeding information sheet – 64% reported availability to give parents at all times and 66% reported giving this source to formula feeding parents.

As previously noted, limited awareness of PIF leaflets and information sheets was reported by hospital nurses/HCAs. However, provision of such information sources, when available, to all parents and formula feeding parents was reportedly more frequent, particularly in England and Wales.

### **5.3.9 Information provision: community midwives and health visitors**

#### ***5.3.9.1 Communication/contact with parents***

All community midwives reported that they have antenatal contact with prospective mothers, mostly when they attend clinics/surgery or antenatal/parentcraft classes; whereas 70% of health visitors reported antenatal contact. Reported methods of antenatal contact are presented in Table 5.37.

**Table 5.37 Reported method of antenatal contact used with prospective parents**

	Community midwives n=232 n (%)	Health visitors n=426 n (%)
Written communication (letter/email)	96 (41)	94 (22)
Telephone	165 (71)	102 (24)
Home Visit	178 (77)	220 (52)
When prospective mother attends a clinic/surgery	223 (96)	109 (26)
Antenatal/parentcraft class	192 (83)	92 (22)

*Other reported methods of contact:*

*Community midwives: aqua-natal exercise classes; breastfeeding workshops*

*Health visitors: breastfeeding workshops; if identified as cause for concern/vulnerable adults; when visiting another sibling; opportunistic contacts unless known concerns; regular liaison with midwife; drop in sessions.*

Frequency of community midwife and health visitor provision about preparation, handling and storage of powdered formula milk to breastfeeding and formula feeding parents is found in Table 5.38. In most instances, antenatally and postnatally, information about PIF is reportedly not often provided to breastfeeding mothers. Sixteen percent of community midwives and 35% of health visitors reported they never give antenatal advice about PIF preparation, handling and storage to prospective mothers who plan to bottle feed.

**Table 5.38 Frequency of information provision about preparation, handling and storage of powdered infant formula to breastfeeding and formula feeding mothers/parents**

	Community midwives n=232 n (%)			Health visitors n=426 n (%)		
	Always	Sometimes	Never	Always	Sometimes	Never
	I give <u>antenatal</u> advice about powdered infant formula preparation and storage to prospective mothers who plan to breast feed.	7 (3)	63 (27)	162 (70)	24 (6)	117 (28)
I give <u>antenatal</u> advice to parents about powdered infant formula preparation and storage to prospective mothers who plan to bottle feed.	88 (38)	107 (46)	36 (16)	106 (25)	154 (36)	149 (35)
I give <u>postnatal</u> advice to breastfeeding mothers about powdered infant formula preparation and storage.	14 (6)	113 (49)	103 (44)	54 (13)	262 (62)	102 (24)
I give <u>postnatal</u> advice to bottle feeding mothers about powdered infant formula preparation and storage.	196 (85)	35 (15)	1 (<1)	298 (70)	119 (28)	3 (<1)
I give written information about preparation and storage of powdered infant formula feeds to breast feeding mothers.	11 (5)	52 (22)	169 (73)	73 (17)	169 (40)	178 (42)
I give verbal advice about preparation and storage of powdered infant formula feeds to breast feeding mothers.	25 (11)	115 (50)	90 (39)	75 (18)	265 (62)	77 (18)
I demonstrate preparation behaviours required for reconstitution of powdered infant formula feeds to breast feeding mothers.	2 (1)	48 (21)	181 (78)	4 (1)	82 (19)	332 (78)
I give written information about preparation and storage of powdered infant formula feeds to bottle feeding mothers.	118 (51)	85 (37)	24 (10)	171 (40)	185 (43)	63 (15)
I give verbal advice about preparation and storage of powdered infant formula feeds to bottle feeding mothers.	181 (78)	42 (18)	7 (3)	272 (64)	141 (33)	8 (2)
I demonstrate preparation behaviours required for reconstitution of powdered infant formula feeds to bottle feeding mothers.	47 (20)	134 (58)	49 (21)	24 (6)	246 (58)	151 (35)

Data presented in Tables 5.39 and 5.40 indicate health visitors' and community midwives' perceptions of the importance of different methods for communicating PIF information at different stages of pregnancy/after the birth. Almost all community midwives and health visitors indicated they considered undertaking at least one postnatal home visit to be 'very' or 'fairly' important; similarly, almost all community midwives and health visitors indicated that provision of PIF preparation, handling and storage information to parents when they change from breastfeeding to bottle feeding to also be 'very' or 'fairly' important.

Concurring with other findings in this study, fewer health visitors and community midwives reported the need to give breastfeeding parents information and demonstrations about safe preparation, handling and storage of PIF. However, more health visitors (than community midwives) indicated it was 'very' or 'fairly important' to discuss or provide information about safe practices as well as demonstrate recommended practices.

**Table 5.39 Importance for information provision about powdered infant formula: Health visitors (n=426)**

<b>How important do you think that it is .....</b>	<b>Very important n (%)</b>	<b>Fairly important n (%)</b>	<b>Neither n (%)</b>	<b>Not very important n (%)</b>	<b>Not at all important n (%)</b>
...to give all prospective parents information about preparation and storage of powdered infant formula ( <u>antenatally</u> )	180 (40)	142 (33)	50 (12)	25 (6)	7 (2)
...to give all new parents information about preparation and storage of powdered infant formula <u>before leaving hospital</u>	241 (57)	115 (27)	30 (7)	13 (3)	5 (1)
...to do at least one antenatal home visit to all parents	162 (38)	162 (38)	56 (13)	23 (5)	4 (1)
...to do at least one postnatal home visit to all parents	404 (95)	7 (2)	0	0	0
...to discuss and demonstrate powdered infant formula preparation and storage in antenatal/parentcraft classes	186 (44)	142 (33)	52 (12)	20 (5)	8 (2)
...demonstrate recommended powdered infant formula preparation practices to all parents	123 (29)	134 (32)	96 (23)	40 (9)	13 (3)
...demonstrate recommended powdered infant formula preparation practices to all formula feeding parents	227 (53)	119 (28)	45 (11)	16 (4)	3 (<1)
...give powdered infant formula preparation and storage information when parents change from breast feeding to bottle feeding	307 (72)	92 (22)	9 (2)	3 (<1)	0



NB: % may not add up to 100% due to non response

**Table 5.40 Importance for information provision about powdered infant formula: community midwives (n=232)**

How important do you think that it is .....	Very important n (%)	Fairly important n (%)	Neither n (%)	Not very important n (%)	Not at all important n (%)
...to give all prospective parents information about preparation and storage of powdered infant formula ( <u>antenatally</u> )	60 (26)	74 (32)	33 (14)	45 (19)	18 (8)
...to give all new parents information about preparation and storage of powdered infant formula <u>before leaving hospital</u>	98 (42)	54 (23)	29 (13)	31 (13)	13 (6)
...to do at least one antenatal home visit to all parents	80 (35)	56 (24)	24 (10)	53 (23)	15 (7)
...to do at least one postnatal home visit to all parents	210 (91)	18 (8)	1 (<1)	0	0
...to discuss and demonstrate powdered infant formula preparation and storage in antenatal/parentcraft classes	50 (22)	68 (29)	34 (15)	47 (20)	30 (13)
...demonstrate recommended powdered infant formula preparation practices to all parents	34 (15)	68 (29)	58 (25)	42 (18)	28 (12)
...demonstrate recommended powdered infant formula preparation practices to all formula feeding parents	119 (51)	78 (34)	18 (8)	8 (3)	6 (3)
...give powdered infant formula preparation and storage information when parents change from breast feeding to bottle feeding	178 (77)	45 (19)	4 (2)	2 (1)	2 (1)

NB: % may not add up to 100% due to non response

Findings indicating community midwives' (n=232) and health visitors' (n=426) attitudes towards recommendations and information provision/sources about safe preparation, handling and storage of PIF can be found in Table 5.41.

More community midwives (62%) were confident that they knew all of the up-to-date guidelines about minimising microbial risks associated with feeding with powdered formula milk than health visitors (53%). Almost all (97-99%) of health visitors and community midwives were aware that recommendations had changed in recent years and only 22% believed recommendations from different sources were consistent.

**Table 5.41 Community midwives' (n=232) and health visitors' (n=426) attitudes towards recommendations and information provision/sources about the safe preparation, handling and storage of powdered infant formula**

	Community midwife (CM)			Health visitor (HV)		
	Strongly Agree/ Agree n (%)	Neither n (%)	Strongly Disagree/ Disagree n (%)	Strongly Agree/ Agree n (%)	Neither n (%)	Strongly Disagree/ Disagree n (%)
I am confident that I know about all of the up-to-date guidelines to minimise microbial risks associated with feeding with powdered formula milk. (CM=227; HV=412)	140 (62)	40 (18)	42 (19)	217 (53)	95 (23)	93 (23)
NHS health professionals provide a consistent source of information about preparation and storage of powdered infant formula. (CM=228; HV=413)	100 (44)	40 (18)	80 (35)	153 (37)	83 (20)	153 (37)
Recommendations for safe preparation and storage of powdered infant formula have changed in recent years. (CM=232; HV=422)	226 (97)	2 (<1)	1 (<1)	416 (99)	4 (<1)	1 (<1)
Recommendations about preparation and storage of powdered formula milk are consistent from different sources (e.g. NHS, FSA, NCT, supermarkets, formula manufacturers etc). (CM=228; HV=412)	50 (22)	54 (24)	70 (31)	91 (22)	104 (25)	148 (36)
Preparation and storage of powdered infant formula <u>should be included</u> in all antenatal/parentcraft classes. (CM=226; HV=412)	123 (54)	20 (9)	79 (35)	350 (85)	30 (7)	31 (8)
Midwives are a good source of information about powdered formula (CM=228; HV=413)	120 (53)	49 (21)	57 (25)	84 (20)	133 (32)	176 (43)
I do not have time to search and read information about infant feeding. (CM=232; HV=422)	72 (31)	63 (27)	97 (42)	150 (36)	107 (25)	164 (39)
I would like to receive up-to-date information about powdered infant formula preparation and storage guidelines. (CM=232; HV=420)	185 (80)	29 (13)	17 (7)	366 (87)	32 (8)	22 (5)
Following preparation and storage instructions on tins of powdered formula is <u>not</u> essential. (CM=227; HV=413)	6 (3)	11 (5)	206 (91)	9 (2)	24 (6)	376 (91)
There is not enough information available to parents about feeding babies with powdered formula milk. (CM=227; HV=413)	127 (56)	27 (12)	73 (32)	213 (52)	72 (17)	127 (31)
Bottle feeding mothers are not given as much information or support about infant feeding as breast feeding mothers. (CM=228; HV=413)	135 (59)	19 (8)	74 (32)	254 (62)	37 (9)	121 (29)

*% for some attitude statements may not add up to 100 due to non responses/don't know responses*

**Table 5.41** (continued)

	Community midwife (CM)			Health visitor (HV)		
	Strongly Agree/ Agree n (%)	Neither n (%)	Strongly Disagree/ Disagree n (%)	Strongly Agree/ Agree n (%)	Neither n (%)	Strongly Disagree/ Disagree n (%)
Mothers/parents often ask me about issues associated with safe preparation and storage of powdered infant formula. (CM=229; HV=416)	134 (59)	26 (11)	69 (30)	209 (50)	74 (18)	131 (31)
Health visitors should give ALL mothers/parents advice about safe preparation and storage of powdered formula milk, <u>before</u> they leave hospital. (CM=228; HV=414)	141 (62)	15 (7)	72 (32)	292 (71)	48 (12)	74 (18)
I always discuss microbiological safety of powdered infant formula with bottle feeding parents. (CM=228; HV=414)	155 (68)	35 (15)	38 (17)	246 (59)	81 (20)	87 (21)
I think that information that I give to mothers/parents about powdered formula feeding is adequate for their needs. (CM=228; HV=413)	191 (84)	16 (7)	19 (8)	231 (56)	45 (11)	43 (10)
There is no need to discuss preparation and storage of powdered formula milk with mothers who are exclusively breastfeeding. (CM=228; HV=412)	96 (42)	33 (14)	99 (43)	107 (26)	65 (16)	239 (58)
I only provide information about preparation and storage of powdered infant formula if/when a parent asks. (CM=228; HV=412)	46 (20)	14 (6)	168 (74)	90 (22)	38 (9)	284 (69)
Parents are not given enough advice and support about how to safely prepare and store powdered formula feed. (CM=226; HV=413)	117 (52)	30 (13)	79 (35)	233 (56)	76 (18)	103 (25)
I am happy to give branded information (from formula manufacturers) to parents about powdered formula milk. (CM=232; HV=420)	28 (12)	31 (13)	172 (74)	79 (19)	81 (19)	259 (62)
The NHS Birth to Five book adequately covers the microbiological safety of formula milk preparation and storage. (CM=230; HV=411)	73 (32)	43 (19)	12 (5)	224 (55)	92 (22)	61 (15)
The Baby Friendly Initiative provides support to bottle feeding mothers. (CM=230; HV=418)	33 (14)	37 (16)	139 (60)	50 (12)	76 (18)	261 (62)
Achieving 'Baby Friendly' Accreditation is associated with a positive Trust/departmental status. (CM=231; HV=420)	168 (73)	31 (13)	22 (10)	278 (66)	85 (20)	38 (9)
I am not allowed to discuss formula feeding with parents unless formula feeding is medically advised. (CM=231; HV=414)	64 (28)	41 (18)	126 (55)	38 (9)	40 (10)	334 (81)

*% for some attitude statements may not add up to 100 due to non responses/don't know responses*

Considerably more health visitors (85%) (compared with 54% community midwives) believed that information about preparation, handling and storage of powdered formula milk should be included in all antenatal/parentcraft classes.

Only 20% of health visitors believed that midwives are a good source of PIF information.

Community midwives (80%) and health visitors (87%) indicated they would like to receive up-to-date information about PIF preparation, handling and storage guidelines. More than half the health visitors (52%) and community midwives (56%) believed there was insufficient information available to parents about feeding infants with powdered formula milk. Many community midwives (59%) and health visitors (62%) believed bottle feeding mothers were not given as much information or support about infant feeding compared to breastfeeding mothers.

More than half of community midwives (59%) and health visitors (50%) indicated that parents often asked them about issues associated with safe preparation, handling and storage of PIF.

More community midwives (84%) than health visitors (56%) believed the information they gave mothers/parents about infant feeding was adequate for their needs.

Forty two percent of community midwives agreed there was no need to discuss preparation, handling and storage of powdered formula milk with mothers who were breastfeeding, however, 58% of health visitors disagreed with this statement suggesting they believed there was a need to discuss safe preparation, handling and storage of powdered formula milk with breast feeding mothers.

Between 60-62% community midwives and health visitors believed that the Baby Friendly Initiative did not provide support to bottle feeding mothers. Achieving 'Baby Friendly' accreditation was perceived to be associated with positive trust status by 73% of community midwives and 66% of health visitors.



Data presented in Table 5.42 indicates that similar proportions of community midwives (60-77%) and health visitors (64-74%) in England and Wales are aware of DoH and WAG bottle feeding leaflets, but fewer community midwives and more health visitors in Northern Ireland are aware of the HPA bottle feeding leaflet.

Data indicates variability regarding availability of such leaflets – which appeared to be particularly lower in Wales – and also variability in giving these leaflets, as a source of up-to-date information about preparation, handling and storage of PIF to all parents. When provision of these information sources was reported, it is more often given to exclusively formula feeding parents.

Community midwives reported widespread awareness (80%) of the UNICEF ‘Baby Friendly’ A4 information sheet about formula use; however, limited provision was reported to parents. Awareness of this source was lower for health visitors (42%) with low reported availability and provision to parents.

## **5.4 SUMMARY OF FINDINGS**

- Almost all NHS hospital midwives/MHCAs, hospital nurses/HCAs, health visitors and community midwives reported that they were in contact with infants being fed using infant formula.

### **5.4.1 Powdered infant formula preparation, handling and storage behaviours**

- RTU/RTF formulas (in glass bottles) were predominately used as the type of formula/artificial feed in maternity departments, but also in neonatal/SCBU and paediatric departments. Specialist and non-specialist PIF feeds were more frequently prepared/used for feeding in neonatal, SCBU and paediatrics departments.
- In maternity departments and neonatal/SCBU and paediatrics, midwives and nursing staff reported the need to sometimes decant/transfer RTU/RTF formula into other containers/bags for feeding.
- Hospital nurses/HCAs in neonatal/SCBU and paediatrics reported longer lengths of time that they considered RTU/RTF formula can be open and in use for feeding than hospital midwives/MHCAs in maternity departments. Reported responsibility for monitoring the time

RTU/RTF formula bottles were in use was variable between departments – in maternity, 88% of midwives reported parents/mothers to be primarily responsible (88%), whereas in neonatal/SCBU and paediatrics, 95% of nurses reported nursing staff to be responsible.

- The location for preparation of PIF feeds was variable between hospitals. In hospitals all feeds were prepared in ward/department kitchens or at the patient/infants bedside, however, in some hospitals the majority of feeds were prepared in Central Feeds Units.
- Powdered formula milk feeds prepared in Central Feeds Units were reportedly delivered once a day, therefore reconstituted powdered feeds required refrigerated storage for up to (and possibly more than) 24 hours; transport of such feeds between the Central Unit and departments/wards occurred frequently using a container that was not temperature controlled.
- In total, 14% of all hospital midwives/MHCAs and 72% of all nurses/HCAs reported preparation of PIF feeds in the department. When PIF feeds required preparation in the department, this was undertaken by midwives and nursing staff (no midwives or nurses reported a designated person being responsible for making up all infant feeds).
- In neonatal/SCBU and paediatric departments and in Central Infant Feed Units, PIF (specialist and non-specialist) was reportedly reconstituted using bottles of sterile water (at ambient temperature).
- In maternity departments preparation of PIF was reportedly uncommon; however, if it was required it was reportedly prepared using cooled boiled water from a kettle.
- Hospital midwives/MHCAs and hospital nurses/HCAs reported that there are instances when parents bring formula milk powder, reconstituted feeds and prepared (cleaned and sterilised) empty feeding bottles in from home for feeding in hospital. Furthermore it was reported that parents do sometimes prepare their infants' feeds in hospital. Such practices were reportedly more common in neonatal/SCBU and paediatric departments.

#### **5.4.2 Microbial risks**

- All NHS caregivers demonstrated inadequate knowledge of microbiological hazards associated with PIF; many (60% hospital midwives/MHCAs, 77% hospital nurses/HCAs, 50% community

midwives and 45% health visitors) believed that before tins are opened, the powdered formula is a sterile product.

- Many hospital nurses/HCAs (51%) and hospital midwives/MHCAs (71%) were concerned about the safety of formula feeding when parents left hospital; many nurses (53%) and midwives (47%) also reported that they did not think most of the parents/mothers they cared for in hospital knew all of the safety practices necessary for safe preparation and feeding of formula. In addition, 47% of health visitors and 43% of community midwives reported they often see parents/mothers not implementing recommended behaviours needed to ensure the powdered formula fed to their infant is safe.

#### **5.4.3 Perceptions of risk, control, responsibility and hygiene consciousness**

- Hospital midwives/MHCAs and hospital nurses/HCAs considered the risk of illness to an infant after drinking PIF made-up by themselves to be less than other hospital nurses and parents, similarly, hospital midwives/MHCAs and hospital nurses/HCAs considered they had more control over hygiene and safety and were more conscious of hygiene and safety than other hospital nurses, infants' parents and hospital staff.
- Although cumulatively, the majority of NHS caregivers perceived recommended practices to reduce the risk of illness from feeding with powdered formula milk to be important, practices associated with preparing one feed at a time, feeding reconstituted feeds immediately after preparation and reconstitution using boiled water cooled for <30 minutes/at >70°C were not considered to be 'very' or 'fairly' important by up to 18% of NHS caregivers.
- The majority of community midwives and health visitors believed preparation of one feed at a time and judgement of water temperature (>70°C) were difficult for parents to implement. Negative attitudes identified towards recommended behaviours may influence information given about them.

#### **5.4.4 Information provision**

- NHS caregivers indicated variable attitudes towards provision of information and advice about PIF to parents.



- Half of hospital nurses/HCAs (52%) and hospital midwives/MHCAs (57%) and 38% of community midwives and 47% of health visitors were unsure or not confident that they knew all of the up-to-date guidelines about safe preparation, handling and storage of PIF.
- A significant difference in awareness of the change to PIF recommendations was determined between NHS hospital caregivers (i.e. hospital midwives/MHCAs and hospital nurses/HCAs) and NHS caregivers working in the community (i.e. community midwives and health visitors). Only 30% of hospital midwives/MHCAs and hospital nurses/HCAs were aware recommended practices had changed in recent years compared to 97% of community midwives and 99% of health visitors.
- Almost all of hospital midwives/MHCAs (90%) and hospital nurses/HCAs (86%), but only 22% of community midwives and health visitors reported they believed recommended practices for safe preparation, handling and storage of PIF were consistent between sources (NHS, FSA, NCT, supermarkets, formula manufacturers etc).
- Forty-eight percent of hospital midwives/MHCAs and hospital nurses/HCAs and 68% of community midwives and 59% of health visitors reported that they always discuss microbiological safety of powdered formula with bottle feeding parents. However, less than a third of all NHS caregivers reported they had ‘ever’ had training about microbiological risks associated with PIF and <20% reported they had received any such training in the past three years.
- Data indicated that more information was given and demonstrations undertaken by hospital nurses/HCAs in neonatal/SCBU and paediatric departments to show how to safely prepare, handle and store PIF to parents.
- Many hospital midwives/MHCAs and hospital nurses/HCAs (59%), community midwives (62%) and health visitors (71%) reported they thought all mothers should be given information about safe preparation, handling and storage of PIF.
- Almost all health visitors (94%) and community midwives (99%) indicated it was very/fairly important to give PIF preparation, handling and storage information to parents when changing from breastfeeding to formula feeding.

- Large proportions of NHS caregivers (75% hospital midwives/MHCAs, 83% hospital nurses/HCAs, 84% community midwives and 56% of health visitors) indicated that they believed that the information they give to parents/mothers about PIF is adequate for their needs.
- Awareness, availability and provision of bottle feeding leaflets were reportedly variable between NHS caregivers and between England, Wales and Northern Ireland. For example, the availability of the leaflets among Welsh hospital midwives/MHCAs was reportedly more limited (38%) than in England (69%) and Northern Ireland (79%). When leaflets were available to NHS caregivers, they were reportedly infrequently given to mothers/parents who were not formula feeding.

#### **5.4.5 Information sources/training/policy**

- Reported awareness/recollection of FSA/DoH and WHO PIF guidance notes was limited among all NHS caregivers and lowest among hospital midwives and more widespread among health visitors.
- Less than a third of all NHS caregivers reported they had ‘ever’ had training about microbiological risks associated with PIF and <20% reported they had received any such training in the past 3 years.
- Large proportions, particularly of midwives (68-74%) reported receiving training about infant feeding through the Baby Friendly Initiative. However, only 12-17% reported inclusion about safe preparation, handling and storage of PIF.
- All caregiver groups reported that information about breastfeeding was updated more frequently than PIF. Overall, ~50% of all caregivers reported never receiving updated information about powdered formula milk use and feeding.
- Many (42-71%) NHS caregivers reported in the past, formula reps have provided them with up-to-date information about PIF microbiological safety and preparation, handling and storage guidelines. However, up to 65% of NHS caregivers now report they are not officially allowed to speak to such reps directly.

- NHS caregivers reported regularly receiving updates about breastfeeding, however, most reported never or very rarely receiving information about preparation, handling and storage of PIF.
- Less than half of each caregiver group reported that their workplace had an infant feeding policy that included preparation, handling and storage of PIF.
- Although not all NHS caregiver respondents worked for ‘Baby Friendly’ accredited hospitals/workplaces, the majority reported that their workplace (if not fully accredited yet) either had obtained a certificate of commitment or followed ‘Baby Friendly rules’.
- More than half (50-59%) of hospital nurses/HCAs and hospital midwives/MHCAs believed that the Baby Friendly Initiative does not support bottle feeding mothers and 23-27% also believed that implementation of the initiative does not provide a framework to give all mothers the best infant feeding advice.

## CHAPTER 6

# PARENT HANDLING, PREPARATION AND STORAGE OF POWDERED INFANT FORMULA FEEDS: OBSERVATION AND MICROBIOLOGICAL ANALYSIS

### 6.1 INTRODUCTION

#### 6.1.1 Background

Understanding parents' PIF preparation and storage behaviours is important for informing risk communication strategies. Data presented in Chapters 2 and 3 of this study has determined parents' self-reported PIF practices, knowledge and awareness of guidelines and parents' attitudes and perceptions towards preparation, handling and storage behaviours and recommendations. Such findings provide valuable information for understanding why behaviours are practised and informing the development of health education strategies to improve the safety of PIF handling and feeding inside and outside of the home. However, discrepancies between what people reportedly know, say they do and actually do have previously been reported (Redmond and Griffith, 2003; Redmond, 2002, Griffith *et al.* 1998; Jay *et al.* 1999); therefore there is a need for more analysis of observed behaviours.

The observation technique is a method of data collection used for understanding complex behavioural situations more accurately (Bowling, 2000). Observation does not depend on second hand reported accounts of behaviour from respondents who may have put their own interpretation on events (Saunders, 2000) and therefore, the direct observation of human and animal behaviour is considered by social scientists to be superior to other methods of data collection.

Observation methodologies may be structured or unstructured, direct or indirect, recorded or unrecorded. Structured observation is systematic, quantitative and is limited to defined, measurable and observable behavioural variables, which are determined before the actual observation is carried out (Sven and Ary, 1989). Data denoting observed actions from structured observations is usually collected and recorded using a predetermined standardised and validated 'observational checklist'. Development of a unique observational checklist with clearly defined categories (Hutt and Hutt, 1970) has to meet a variety of criteria to ensure an accurate measurement of behaviour is obtained.

Control can be exercised not only of the structure of recorded data, but also over the environment in which the observations take place (Coolican, 1999). Observational study settings may occur in natural (uncontrolled) or laboratory (controlled) environments. There are advantages and disadvantages when carrying out observational research in both environments. It has been reported that observations carried out in the natural environment are more realistic than in a laboratory, which may provide a highly artificial, possibly inhibiting atmosphere. In a natural environment, *if* there is no reactivity bias, observed behaviours have been considered to be entirely genuine (Coolican, 1999). However, extraneous variables are poorly controlled in the natural environment, and pose a greater threat to validity than in the laboratory, this may result in a greater ambiguity of observable actions and therefore an increased potential for observer and reactivity bias. In addition to this, replication of collected data is more difficult (Coolican, 1999). Direct comparisons of recorded behaviours between subjects in different environments may not necessarily be viable or possible.

When undertaking observational studies there is a need to consider a potential for bias from the 'Hawthorne effect'. This is thought to occur when people observed during a research study temporarily change or distort their behaviour or performance in some way, simply as a result of being studied (Bowling, 2000; Coolican, 1999). Research conducted in the UK has addressed this potential for observation bias and determined the consistency of observations of consumer hygiene behaviours recorded in a model domestic kitchen and in consumers' home kitchens (Redmond, 2002). Using data based on a risk based observational checklist and scoring system findings showed no significant difference between behaviours observed in repeated meal preparations undertaken in the model domestic kitchen and consumer home kitchens. Thus indicating that key hygiene malpractices may be habitual and reproducible between different environments. Overall, observations of consumer hygiene malpractices in the model kitchen are representative of practices implemented in the home. An evaluation of repeatability and reproducibility of consumers' hygiene behaviours found that specific hygiene malpractices were consistent during repeated meal preparations and between preparation of different meals (Redmond *et al.*, 2000; Redmond, 2002). Observation provides information on what parents do, but does not provide information on the risk associated with those practices. This type of information is needed, and coupled with the observation, provides a powerful tool in the development of risk-based advice for consumers.

To date, no observational studies have evaluated parents' PIF preparation, handling and storage behaviours. Furthermore, no studies have equated observed data (i.e. handling practices) with microbiological contamination of PIF feeds and kitchen surfaces, post-feed/food preparation.

### **6.1.2 Aims and objectives**

The aim of this part of the study was to observe parents' hygiene practices and analyse the microbiological quality of 100 prepared PIF feeds and environmental kitchen surfaces, post feed preparation. The more specific objectives were to:

- Develop an observational checklist to facilitate assessment of parents' preparation, handling and storage behaviours.
- Recruit parents with infants aged less than 12 months, feeding at least once a day, to attend a PIF preparation session in UWIC model kitchen.
- Observe parents' hygiene behaviours and practices related to the microbiological safety of PIF.
- Sample 100 reconstituted PIF feeds and selected sites on prepared infant feeding bottles and in the model kitchen for residual infant formula (organic debris) aerobic colony counts, *Enterobacteriaceae* and *Staphylococcus aureus* contamination.
- Compare observed parents' PIF practices with DoH/FSA recommendations.

## **6.2 METHODS**

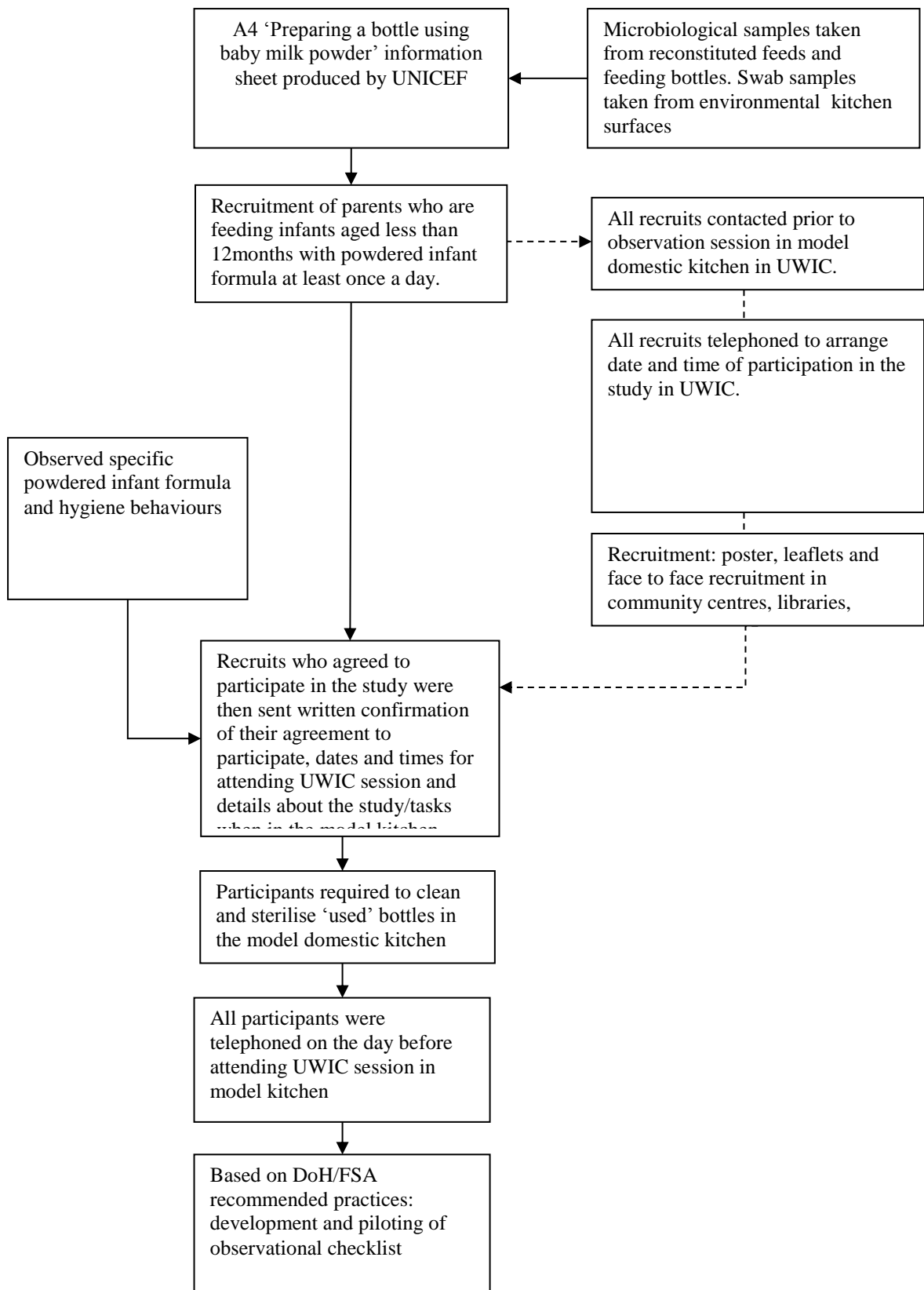
For a plan of methods see Figure 6.1.

### **6.2.1 Organisation of model kitchen for observation of meal preparations**

#### ***6.2.1.1 Design of model kitchen/kitchen facilities***

The UWIC model domestic kitchen where PIF preparations were carried out was of a modern design that had been recently installed (see Figure 6.2). The design was considered to be typical of many domestic home kitchens. There were four distinct work surfaces available for use as well as a wide range of equipment, utensils, crockery and kitchenware. More equipment than was needed for meal preparation was provided in the model kitchen, thus allowing scope for participant selection. General kitchen equipment choice included a number and choice of (constructional) types of chopping boards (e.g. wood, plastic, glass), knives (of all sizes), saucepans (of all sizes) and a variety of mixing bowls, serving dishes and general use utensils etc. In addition, a full range of cleaning facilities and chemicals were also provided including soaps (ordinary/anti-bacterial), creams, detergents, sanitisers, cotton cloths and disposable paper towels.

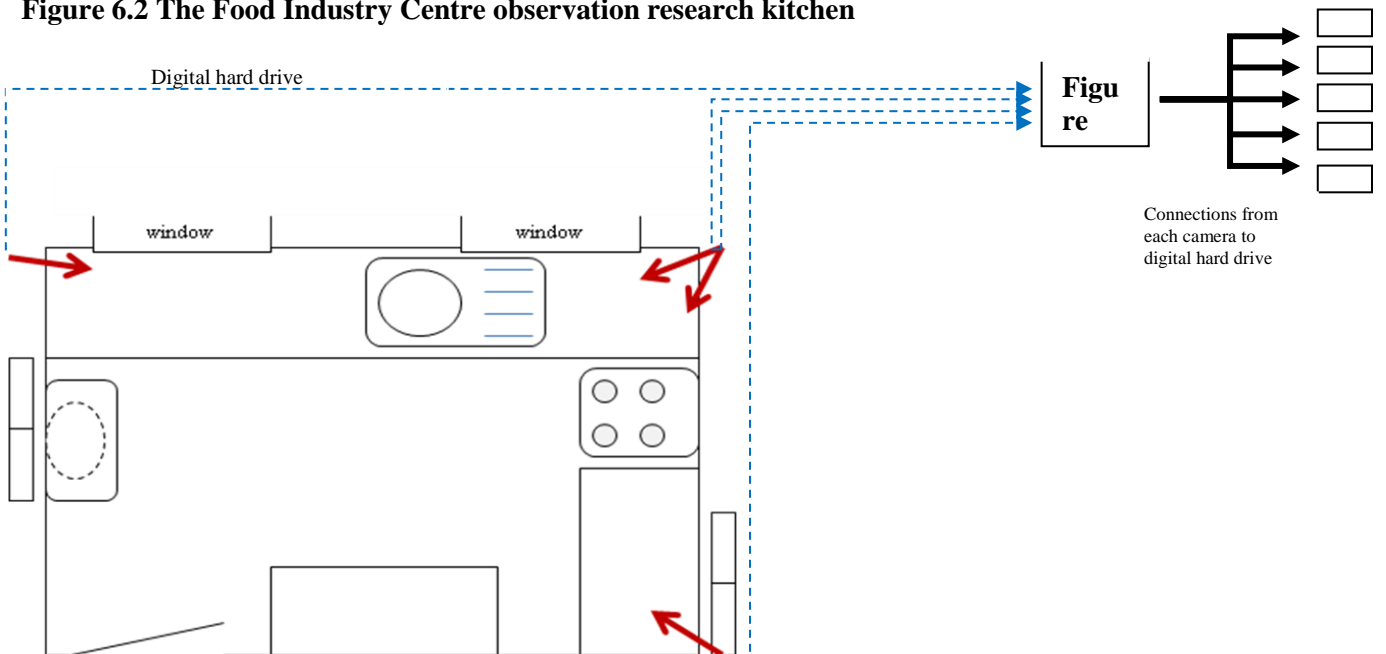
**Figure 6.1 Plan of methods for observation study**



Recorded behaviours in standardised and piloted observation checklists.  
(malpractices recorded)



**Figure 6.2 The Food Industry Centre observation research kitchen**





All equipment and utensils were considered of a typical standard for consumer usage. Placement of equipment and utensils in the model kitchen occurred in a logical manner and it was ensured that everything needed was easily accessible. To facilitate convenient usage of the kitchen, signs were placed on the doors of cupboards and drawers to inform participants of the contents. For equipment/utensils provided specifically for PIF preparation sessions, see section 6.2.2.

## **6.2.2 Participation and provision of equipment**

Parent participation in the study involved preparation of six ‘used’ feeding bottles and a simple chicken salad.

For all sessions, each parent was provided with all food ingredients for the chicken salad and six feeding bottles (Tommee Tippee 260ml) with residues of reconstituted powdered formula milk. Feeding bottles with 260ml made-up SMA powdered formula milk were prepared according to DoH/FSA recommendations and then stored in a refrigerator (<5°C) for 12-24 hours before the session in the model kitchen. The feed was poured out of the feeding bottle before the preparation session, leaving a residue – simulating a ‘used’ feeding bottle. Each participant was asked to prepare feeding bottles to demonstrate preparation and handling inside and outside of the home – for more details and instructions, see section 6.2.4.

The rationale for including preparation of six feeding bottles was based upon quantitative data from Chapter 3 of this study and research needs. Firstly, one feeding bottle was left empty, post-cleaning/sterilisation (to be sampled post preparation session to assess microbiological contamination of bottles before addition of PIF feeds). Secondly, parents were asked to reconstitute one bottle of reconstituted powdered formula milk for ‘immediate feeding’ - unless more than one infant was present in a household it would be unrealistic to ask parents to prepare more than one feed ‘ready for immediate feeding’; preparation of one PIF feed at a time was reportedly implemented by 60% of parents interviewed in Chapter 3. Interview data (Chapter 3) also indicated that ~30% of parents reported preparing up to four feeds at one time therefore, if parents prepare more than one feed at a time, asking them to prepare an additional three feeds for feeding later in the day was considered to be realistic; participants who reported never reconstituting PIF feeds in advance of use were asked to prepare the feeding bottles as they would normally do at home for feeding at home – this included leaving cleaned and sterilised bottles empty ready for use and pouring boiled water into cleaned and sterilised bottles (for storage until required, ready for addition of the powdered formula. Using the final (sixth bottle), parents were asked to demonstrate how they dealt with PIF feeding away from the home.

All participants were asked to prepare feeding bottles in the model kitchen using SMA formula milk. Prior to participation in the preparation session in UWIC, each parent was asked what type

of sterilising equipment (if any) they currently used for preparing feeding bottle. The type of steriliser they reported (an electric steam steriliser, a microwave steam steriliser, cold water steriliser or other) was provided in the model kitchen for their use (with manufacturer's instructions) during the session. Other equipment required for bottle and infant feed preparation was provided in the model kitchen if required - including bottle brushes, Pyrex jugs of variable sizes etc. As participants were asked to demonstrate how they dealt with powdered infant feeding away from the home a variety of bags, freezer packs, powder storage containers, flask and ready to use cartons were provided for use if necessary (see Figure 6.4).

**Figure 6.4 Equipment and items provided for powdered formula preparation sessions**



Inclusion of food preparation in observation sessions represented a more realistic 'in use' kitchen setting. Preparation of a simple chicken salad using raw foods made the scenario more like a 'real kitchen' with real risks and provided *additional* opportunities to observe parents' hygiene practices. The meal selection was based upon a review of literature detailing foods commonly reported as vehicles of food poisoning, a review of reported contributory factors associated with incidents of food poisoning, and recent trends of meal consumption and food preparation habits. Preparation of the chicken salad required handling raw chicken and other ready to eat foods (salad ingredients and cooked ham) and thus involved opportunities for implementing cross contamination behaviours.

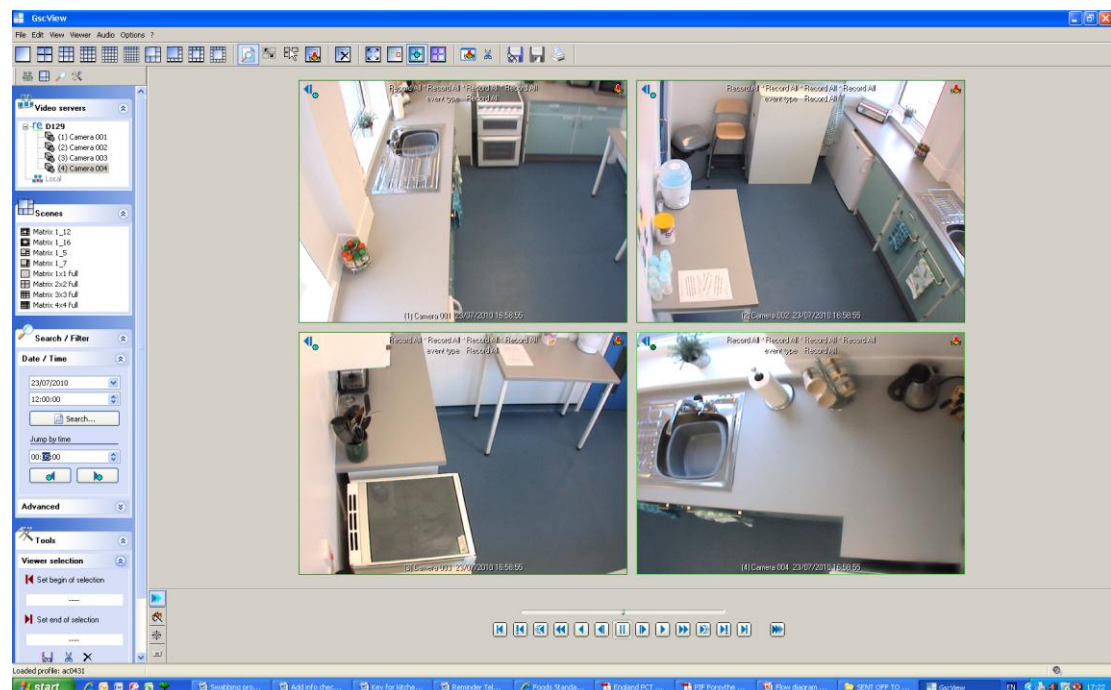
### 6.2.3 Observation of parents' powdered infant formula and hygiene practices

Extensive observation research has been undertaken in the UWIC model domestic kitchen with CCTV (Griffith *et al.* 1999a; Griffith *et al.* 1999b; Redmond, 2002; Redmond *et al.* 2001; Redmond *et al.* 2004; Clayton *et al.* 2003). As noted in section 6.1, previous research has found that key hygiene malpractices may be habitual, consistent and reproducible between different environments and overall, observations of consumer hygiene malpractices in the model kitchen are representative of practices implemented in the home. In addition, an evaluation of repeatability and reproducibility of consumers' food safety behaviours found that specific hygiene malpractices observed in the model kitchen were consistent during repeated meal preparations and between preparation of different meals (Redmond *et al.*, 2000; Redmond, 2002).

#### 6.2.3.1 Digital recording of powdered infant formula/food preparation sessions

The 'model' kitchen was equipped with four ceiling mounted digital video cameras (Sony Camera Model: CS11) (see Figure 6.3) which encompassed wide fields of view of all preparation areas (see Figure 6.5). The four digital cameras were connected via the network to a single digital data recorder (Geutebruck re\_reporter – 4), recording 25 frames per second. Images were viewed and reviewed using 'GSCview: GeviScope media and database viewer' software, which monitored and recorded from the four cameras simultaneously. The software was used for trimming and reviewing recordings before capturing them for analysis. For issues related to ethics see section 6.2.4.

Figure 6.5 'GSCview' fields of view of Food Industry Centre model kitchen



### ***6.2.3.2 Design and development of observational checklist***

Design and development of the observational checklist resulted from a thorough review of PIF literature. Observed malpractices were recorded with failure to implement control measures recommended for safe preparation of PIF in the UK by the DoH and FSA (FSA, 2006/DoH, 2008). For a copy of the observational checklist used in this study see Appendix 6.

## **6.2.4 Organisation of participants and observation study**

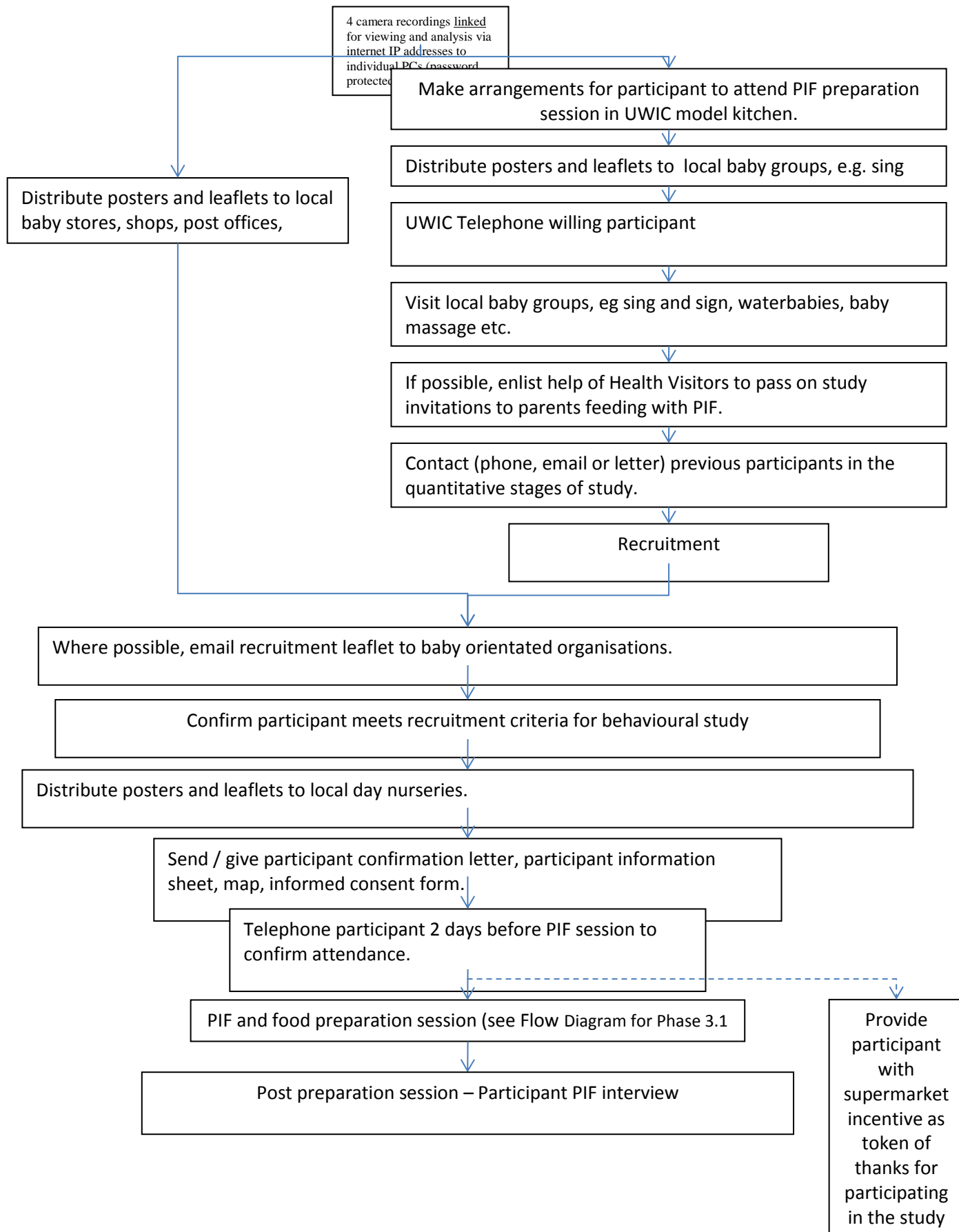
### ***6.2.4.1 Recruitment of parents***

Recruitment of parents to take part in the observation study occurred using a variety of staggered methods in South Wales (predominately Cardiff), largely including face-to-face recruitment and displaying posters and leaflets in community venues and locations likely to be frequented by mothers/fathers of young infants. A recruitment plan can be seen in Figure 6.6 and a summary of recruitment methods, approaches and locations used can be found in Table 6.1. Copies of posters, leaflets, adverts and other recruitment documentation used can be found in Appendix 6.

All participants were recruited according to a predefined recruitment questionnaire (Appendix 6). Recruitment criteria included: being a parent to an infant aged less than 12 months and feeding using PIF at least once a day.

After recruitment participants were sent a covering letter confirming arrangements, a participant information sheet, instructions for PIF and food preparation in the model kitchen and a map of the UWIC Llandaff campus (see Appendix 6).

**Figure 6.6 Plan for recruitment of parents for observation study**



**Table 6.1 Recruitment locations and methods used for observation study**

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Observation study recruitment methods/locations

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- Face to face recruitment at over 20 mother and baby/parent and toddler groups in community and learning centres including: Rhyme Times in Cardiff libraries, Books and Babies, Waterbabies, Baby Massage, Busy Bees local community playgroups, Baby signing groups, Gymbabes, Tumbletots, Sing and Sign etc.
  - More than 350 A4 and A5 posters and leaflets were distributed and displayed in local shops, community shopping centres, post offices around Cardiff.
  - Adverts in local community directories e.g. the Marshfield Mail, My Valleys magazine, Caerphilly Local View, North Community Times and East Cardiff Community Times (see Appendix 6).
  - Leaflets and posters were displayed in all Cardiff libraries (n=20) and in more than 10 community centres/community centre crèches.
  - Chapter Arts Centre - special cinema screenings for people with infants for less than 12 months 'Carry on Screaming'.
  - Letters, leaflets and posters sent to local day nurseries that care for infants aged less than 12 months.
  - Attempts made to leave leaflets in Mothercare, Toys-r-us/Babies-r-us, Boots, Pharmacies, other toy shops and baby clothes shops, Marks and Spencers etc. Some stores refused, while others agreed to place the leaflets in their stores.
  - Postcard advertisements were placed in all main supermarkets and in 12 newsagents for periods of 6-8 weeks.
  - Leaflets and posters placed in baby friendly coffee shops e.g. Fino Lounge, Whitchurch; Cafe Junior, Cathays and Bambeans, Canton.
  - Leaflets were given to parents with infants aged less than 12 months, feeding with PIF in the Flying Start Clinic, Ely (c/o health visitors, arranged through Susan Sky).
  - Exhibition stand at Mauds Baby Show (4<sup>th</sup> –5<sup>th</sup> September, 2010), Talybont Sports Centre, Cardiff (+1000parents attended); study leaflets placed in 100 'goody bags'; face to face recruitment at the exhibition stand; leaflets and information about the study available to parents interested in participating in the study (see Appendix 6).
-

#### **6.2.4.2 Protocol for powdered infant formula/food preparation sessions**

Observation sessions occurred in the model kitchen according to a protocol (see Appendix 6). Once participants had arrived in UWIC they were met by the researcher and taken to the FIC model kitchen. A full explanation of where equipment/utensils/kitchenware and food/PIF were stored was given to each participant.

In no particular order, participants were instructed to undertake the following:

- Prepare one empty bottle – prepared ready for addition of PIF and/water
- Prepare one bottle of reconstituted PIF ready for immediate feeding (suitable temperature etc)
- Prepare three bottles of PIF at least 2 hours(or more) in advance of feeding
- Using the one remaining bottle demonstrate how they usually deal with feeding their infant with formula when away from the home (the kitchen has cartons of ready-to-use feeds, small containers for powder, flasks, cool/thermo bags, cool packs etc available for use).
- Prepare a chicken salad (including raw chicken, RTE ham and salad vegetables)

PIF instruction cards (Appendix 6) and a recipe card detailing instructions for preparing the chicken salad (Appendix 6) were provided and participants were requested to prepare the feeding bottles/PIF feeds and chicken salad ‘as they would in their home’. Participants were also instructed to ‘leave the kitchen as they would leave it in their own home using any cleaning agents/materials or procedures that they would normally carry out.

Participants were left to prepare the meal in the kitchen on their own and the researcher checked their progress at 20 minute intervals or when required.

#### **6.2.4.3 Ethics and digital recording of activities in UWIC, FIC model domestic kitchen.**

All participants were informed that activities in the model kitchen would be digitally recorded and analysed by the researcher at a later date. Before preparation sessions started all participants were asked to sign and give consent for participation in this part of the study. For a copy of the consent form and supporting documentation see Appendix 6. All methods and documentation used for this component of the study were reviewed and approved by the UWIC Ethics Committee (Reference 2245).

#### **6.2.4.4 Implementation of the main observation study**

Prior to the main study, a pilot study was undertaken to ensure the recruitment process, practical sessions, documentation, instructions, observational checklist and microbiological sampling protocol were effective. Amendments were made where required.

#### **6.2.5 Microbiological methods for swab, rinse and powdered infant formula samples**

##### **6.2.5.1 Preparation of pathogen free surfaces before observation sessions in model kitchen**

Before each observation session, the FIC model kitchen was deep-cleaned using a validated protocol (Griffith *et al.* 1999) to ensure kitchen surfaces had ATP (adenosine triphosphate) values <100 relative light units (RLU) and <1cfu per cm<sup>2</sup>. The effectiveness of the deep-cleaning protocol was routinely monitored.

##### **6.2.5.2 Sample collection and microbiological methods used post- observation session**

Subsequent to the completion of the PIF and food handling session in the model kitchen, the microbiological quality of the end products (prepared PIF feeds) and microbiological contamination of prepared (cleaned/sterilised) feeding bottles and environmental kitchen surfaces were assessed for cleanliness using 3M<sup>TM</sup> ATP Bioluminescence (3M<sup>TM</sup> Cleantrace and 3M<sup>TM</sup> Aquatrace swabs) and microbiological contamination using 3M<sup>TM</sup> Petrifilm to determine Aerobic Colony Counts (ACCs) (Ref 06406) and *Enterobacteriaceae* (Ref 06421) and *Staphylococcus aureus* (Ref 06491/06493) counts. A complete list of all sampled surfaces with ATP/microbiological tests can be found in Appendix 6.0.

Using hydrated ACC, *Enterobacteriaceae* and *S.aureus* petrifilms, kitchen work surfaces, dishcloths (and other cleaning materials); tea towels and hand towels were sampled using a direct contact method (3M<sup>TM</sup> Environmental Monitoring Procedures, 2003). Sampled feeding bottle locations included the outer rim, inner screwcap, inner teat and rinse of the inside surface of the bottle. Methods for sampling are outlined in Redmond and Griffith, (2009a). All other kitchen surfaces were sampled using cotton-tipped swabs, moistened with maximum recovery diluent (MRD) (Oxoid CM0361). A maximum of 25 samples were analysed for each preparation session.

All microbiological methods associated with petrifilm use were according to manufacturer's instructions: 3M<sup>TM</sup> Petrifilm<sup>TM</sup> Aerobic Count Plates, 2005; 3M<sup>TM</sup> Petrifilm<sup>TM</sup> *Enterobacteriaceae* Count Plates, 2000; and 3M<sup>TM</sup> Petrifilm<sup>TM</sup> Staph Express Count Plates, 2009, with 3M<sup>TM</sup> Petrifilm<sup>TM</sup> Staph Express Disks, 2009.



### 6.2.5.3. Analysis of ATP and microbiological data: classification of ‘satisfactory’ and ‘unsatisfactory’ measures of bottle and environmental surface cleanliness and microbiological contamination

Standards of satisfactory and unsatisfactory microbiological and ATP levels were required to classify findings. The manufacturers of the ATP system (3M™) recommended that users determine their own standards for clean, although suggest for different sites and conditions values between 200 and 1000 RLUs can be used. Research has established that most surfaces after routine cleaning (but not necessarily disinfected) can have an ATP level less than 500RLUs (Griffith, 2005). Previous PIF and feeding bottle/component work has indicated that with good cleaning techniques and disinfection/sterilisation equipment, a value less than 200 RLUs could routinely be attained (Redmond and Griffith, 2009b). This value was therefore used throughout as a benchmark RLU value for satisfactory residual organic soil levels on infant feeding bottles considered to be ‘clean’. Previous work has demonstrated that, for surfaces in good condition, microbial levels <1cfu ACC/area sampled was routinely attainable when following UK DoH cleaning recommendations (DoH, 2008) and manufacturers guidelines (Redmond and Griffith, 2009a). This was used as a benchmark value or ‘standard’ for a ‘satisfactory’ clean bottle surface. These microbiological levels for ‘satisfactory clean’ are more stringent than previously used older standards (Creagh *et al.* 1978). However, the levels used in this study can be justified when considering the vulnerability of young infants who will consume the reconstituted formula from the bottles, particularly when coupled with potential risks of temperature abuse and microbial growth within the formula during storage prior to consumption.

To enable classification of realistic consumer surface cleaning procedures (Beumer *et al.* 2008; WHO, 2007) validation studies were carried out in the model domestic kitchen. ATP levels of <100RLU, with aerobic colony counts (ACCs) <1cfu/10cm<sup>2</sup> and absence of *Enterobacteriaceae* and *S.aureus* were routinely achievable and used as a benchmark value or ‘standard’ for a ‘satisfactory’ clean kitchen surface.

**Table 6.2 Satisfactory/realistically clean standards for organic debris and microbiological contamination**

	ATP (RLUs)	ACC	<i>Enterobacter</i> <i>-iaceae</i>	<i>S.aureus</i>
Cleaned and sterilised/disinfected empty feeding bottles <sup>1</sup> (screw cap, inner teat, rinse and outer rim) (Redmond and Griffith, 2009b)	<200/area sampled	<1cfu/area sampled	Absent/ area sampled	Absent/ area sampled
Standards for ‘cleaned and sanitised’ kitchen surfaces (including preparation surfaces, tap, kettle and fridge handles, tea towels, hand towels and dishcloths) (validation data see Appendix 6)	<100/10cm <sup>2</sup>	<1cfu/10cm <sup>2</sup>	Absent/10cm <sup>2</sup>	Absent/10cm <sup>2</sup>

<sup>1</sup>using four types of sterilising equipment (electric steam, microwave steam, cold water and boiling) (Redmond and Griffith, 2009b)

## 6.3 RESULTS

### 6.3.1 Profile of recruited parents

Overall, 92% of the participant sample was female, and 8% was male; the majority (64%) were aged 25-34 years. Six percent were aged 16-24 years and 30% were aged 35-45 years. Data in Table 6.3 indicates the demographic breakdown of the participant sample according to age and SEG.

Thirty-eight percent of parents who participated in the study reportedly fed an infant aged less than 6 months with PIF (Table 6.4). The majority (52%) of parents reported they were employed part-time (Table 6.5).

**Table 6.3 Demographic breakdown of the respondent sample (n=50)**

Demographic	Socio-economic group n (%)				Total (%)
	AB	C1	C2	DE	
Age 16-24 years	0	1 (2)	0	2 (4)	3 (6)
25-34 years	4 (8)	17 (34)	5 (10)	5 (10)	32 (64)
35-45 years	2 (4)	7 (14)	5 (10)	1 (2)	15 (30)
Total	6 (12)	25 (50)	10 (20)	8 (16)	

**Table 6.4 Age of infant fed by parent respondent (n=50)**

Age of infant	% of participant sample n (%)
1-2 months	4 (8)
3-4 months	7 (14)
5-6 months	8 (16)
7-8 months	11 (22)
9-10 months	15 (30)
11-12 months	5 (10)

**Table 6.5 Parental employment status (n=50)**

	Male (n=4) n (%)	Female (n=46) n (%)	Total (n=50) n (%)
Unemployed	1 (2)	4 (8)	5 (10)
Employed full time (30 hours a week or more)	1 (2)	7 (14)	8 (16)
Employed part time (less than 30 hours)	0	26 (52)	26 (52)
Full time housewife	0	4 (8)	4 (8)
Part time housewife	0	0	0
Full time student	0	0	0
Part time student	0	0	0
Refused	2 (4)	5 (10)	7 (14)

Data in Table 6.6 shows that the majority of parents who took part in the study were feeding their infant with PIF exclusively; 10% were formula feeding in conjunction with breast feeding. Half of the sample (50%) had no other children, whereas 28% of the sample had children aged more than 5 years old (Table 6.7).

**Table 6.6 Reported current feeding method, feeding method when infant was first born (within first two weeks and planned feeding method) (n=50)**

	Current practices n=50 n (%)	Practices when infant was first born (within first two weeks) n=50 n (%)	Planned feeding practice n=50 n (%)
Exclusive formula feeding	45 (90)	15 (30)	11 (22)
Mostly formula feeding, partly breastfeeding	1 (2)	3 (6)	
Equal formula feeding and breastfeeding	3 (6)	5 (10)	8 (16)
Mostly breastfeeding, partly formula feeding	1 (2)	6 (12)	
Exclusive breast feeding		21 (42)	31 (62)

**Table 6.7 Reported age of respondents' eldest child (n=50)**

	Number of participants n (%)
Not applicable – only have one child	25 (50)
1-2 years	4 (8)
3-4	7 (14)
5-6	2 (4)
6+ years	12 (24)

### 6.3.2 Observation results

Observation of consumer hygiene practices in the model kitchen has been validated in previous research projects (Griffith *et al.* 1999a; Redmond, 2002; Redmond *et al.* 2000).

Cumulatively, PIF/food preparation sessions resulted in >80 hours of observable practices. These included observations of the preparation and handling of 296 infant feeding bottles (see Table 6.8); 118 were reconstituted feeds, 50 prepared for ‘immediate feeding’, 58 prepared for feeding >2 hours in advance and 10 prepared to be taken away from the home. Fifty bottles were left empty for assessment of cleaning efficacy and a further 33 bottles were left empty for ‘later use’ inside and outside of the home. Ninety-five bottles were prepared with boiled water for storage and later mixed with PIF when required for feeding (inside and away from the home).

**Table 6.8 Summary of PIF and food preparation sessions – number of bottles**

	No. of bottles	
Empty feeding bottles assessed for cleaning efficacy	50	
Reconstituted feeds for immediate feeding	50	
Reconstituted feeds for feeding later in the home	58	*118
Reconstituted feeds taken away from the home	10	
Empty feeding bottles prepared ‘ready-for-use’ (i.e. cleaned and sterilised) for later use at home	19	
Empty feeding bottles prepared ‘ready-for-use’ (i.e. cleaned and sterilised) for use away from the home	14	
Feeding bottles with boiled water prepared ready for addition of powdered formula for feeding at home	67	
Feeding bottles with boiled water prepared ready for addition of powdered formula for feeding away from the home	28	
<b>Total number of feeding bottles/feeds prepared for the study</b>	<b>296</b>	

\*total number of reconstituted feeds

As described in section 6.2.4.2, parents were asked to prepare infant feeds as would be their usual practice – for feeding inside and away from the home. Data presented in Table 6.9 indicates that the majority (46-54%) of parents prepared feeding bottles with boiled water in advance, ready for addition of the powdered formula when required for feeding. Forty percent of parents reconstituted feeds for storage and feeding in the home (>2 hours time) and 20% prepared reconstituted feeds for feeding away from the home.

**Table 6.9 Powdered infant formula preparation and storage behaviours implemented in the model kitchen**

	No. of participants (n=50) n (%)
Reconstituted feeds for feeding later in the home	20 (40)
Reconstituted feeds taken <u>away</u> from the home	10 (20)
Empty feeding bottles prepared ‘ready-for-use’ (i.e. cleaned and sterilised) for later use at home	7 (14)
Empty feeding bottles prepared ‘ready-for-use’ (i.e. cleaned and sterilised) for use <u>away</u> from the home	13 (26)
Feeding bottles with boiled water prepared ready for addition of powdered formula for feeding at home	23 (46)
Feeding bottles with boiled water prepared ready for addition of powdered formula for feeding <u>away</u> from the home	27 (54)

Although 70% of parents failed to wash their hands before cleaning and sterilising ‘used’ feeding bottles (see Table 6.10), the majority immersed their hands in bowls of hot water with detergent while cleaning/rinsing the items, as the first task in the model kitchen.

**Table 6.10 Implementation of recommended feeding bottle/component cleaning practices (according to FSA Guidance, 2006/DoH, 2011)**

	% parents	
Wash hands thoroughly before cleaning and sterilising feeding equipment	Adequate handwashing and drying	10%
	Inadequate handwashing and drying	20%
	No attempt handwashing and drying	70%
Immerse and wash feeding and preparation equipment in hot soapy water	All bottles & components	100%
	Some bottles & components	0
	No bottles & components	0
Use of a clean bottle/teat brush	Used for all bottles & components	90%
	Used for some bottles & components	0
	Not used for any bottles & components	10%
After washing feeding equipment rinse it thoroughly under the tap (clean, running water)	All bottles & components	60%
	Some bottles & components	30%
	No bottles & components	10%

Overall, 20% of parents failed to separate the teat from screwcap for cleaning/rinsing and most (but not all) of such parents continued to sterilise/disinfect the teat and screwcap without separating. All parents used a bowl of fresh, hot water with detergent for cleaning of the used bottles and components. Sixty-seven percent of parents rinsed PIF residues from the bottles (more frequently) and/or components before immersing in hot water with detergent for cleaning. The majority of parents scrubbed bottles and components using a bottle brush, <5% of the sample only dipped the bottles and components into the water and swilled them around with no scrubbing motion. Observations of cleaning efficacy of bottle component parts can be seen in Table 6.11. Almost all parents scrubbed the inner surfaces of feeding bottles and teats, however, fewer parents (30-40%) scrubbed the outside rim/thread of the bottle or outside surface of teats. Similarly, the screwcap was less frequently scrubbed clean by parents. Rinsing practices were observed and 89% of parents rinsed bottles and teats with fresh water after cleaning and 78% rinsed screwcaps.

**Table 6.11 Implementation of recommended feeding bottle/component cleaning practices**

Scrub components to ensure that all remaining feed is removed:	Implementation of adequate cleaning for ALL bottles/ components % parents	Implementation of adequate cleaning for SOME bottles/ components % parents	Implementation of adequate cleaning for NO bottles/ components % parents
- inside of bottles	90%	0	10%
- outside of bottles	0	0	100%
- outside rim of bottle	40%	10%	50%
- inside of teats	80%	10%	10%
- outside of teats	30%	0	70%
- inside of screwcap	60%	0	40%
- outside of screwcap	10%	0	90%

After washing and rinsing, a third of parents placed bottles/components directly into the sterilising unit, a third placed items onto the work surface (no prior cleaning implemented), 20% placed items into an empty washing up bowl and the majority (70%) placed items onto the washing up rack/sink draining board. (a number of parents placed items onto multiple surfaces before sterilisation/disinfection).

**Table 6.12 Use of steriliser/disinfection equipment during powdered infant formula/food preparation sessions in model kitchen**

Steriliser/disinfection equipment	% parents
Electric Steam Steriliser	50%
Microwave Steam Steriliser	22%
Cold water steriliser	16%
No sterilisation*	12%

\* 33% infants aged 5-6 months, 33% aged 7-8 months and 33% aged 11-12 months

Parents were provided with the type of steriliser that they reportedly used at home (if used at all). Data in Table 6.12 shows that half of the participants used an electric steam steriliser, 22% a microwave steriliser and 16% a cold water steriliser. Twelve percent of parents did not sterilise/disinfect feeding bottles at all (only cleaned before re-use).

Data in Table 6.13 shows that where commercial sterilisers were used, 75% of parents only partly followed instructions. Key sterilisation/disinfection malpractices observed included failure to allow for required 'cooling time' before opening microwave and electric steam sterilisers, placement of items in the steriliser contrary to manufacturer instructions and sterilising/disinfecting teats attached to screwcaps. Only 38% of parents attempted to wash their hands before removal of items from the steriliser and 62% implemented cleaning methods that are considered to be inadequate (a further 38% failed to clean surfaces at all). Inadequate cleaning practices observed included use of potentially contaminated dishcloth /scourer to wipe surfaces, removal of debris from surface using surface spray/antibacterial spray and paper towel, use of hand towel/tea towels to wipe surfaces etc. Only a quarter of parents assembled feeding bottles immediately after removal from sterilisers – many placed them on paper towels until ready for reconstituting the feed/filling with boiled water for later use.

**Table 6.13 Implementation of recommended feeding bottle/component sterilisation/disinfection practices (according to FSA Guidance, 2006/DoH, 2011)**

Sterilisation/disinfection practices		% parents
If using a commercial steriliser follow manufacturer's instructions	All instructions followed	25%
	Instructions partly followed	75%
	Instructions not followed at all	0
Wash hands thoroughly before removing equipment from steriliser	Adequate handwashing and drying	0
	Inadequate handwashing and drying	38%
	No attempt handwashing and drying	62%
Clean the surface around the steriliser before removing equipment	Adequate cleaning	0
	Inadequate cleaning	62%
	No attempt at cleaning	38%
Use/assemble bottles immediately after they are removed from the steriliser	All bottles are assembled immediately after removal from steriliser	25%
	Some (not all) bottles are assembled immediately after removal from steriliser	50%
	No bottles are assembled immediately after removal from steriliser	25%

Data in Table 6.14 indicates a considerable lack of handwashing/drying and cleaning of surfaces immediately before reconstitution of PIF feeds.

**Table 6.14 Implementation of recommended PIF preparation practices in the home (A) (according to FSA Guidance, 2006/DoH, 2011)**

Powdered infant formula preparation practices		% parents
Clean the surface thoroughly on which to prepare the feed	Adequate cleaning	0
	Inadequate cleaning	40%
	No attempt at cleaning	60%
Wash hands with soap and water and then dry before powdered infant formula preparation	Adequate handwashing and drying	0
	Inadequate handwashing and drying	0
	No attempt handwashing and drying	100%



All parents prepared powdered formula feeds using fresh, boiled tap water (see Table 6.15). Although a large proportion of parents reconstituted PIF feeds (for immediate feeding) within 30 minutes of the kettle boiling, more than half of parents used methods to cool the boiled water *before* addition of the powdered formula – suggesting that feeds may be prepared with water <70°C even though within the recommended 30 minutes from end of boiling time. In addition, nearly half (46%) of parents reported they usually prepared PIF feeds for ‘immediate feeding’ using boiled water stored in prepared feeding bottles for >2 hours for reconstitution, which would be <70°C.

**Table 6.15 Implementation of recommended PIF preparation practices in the home (B) (according to FSA Guidance, 2006/DoH, 2011)**

PIF preparation practices	% parents
Boil fresh tap water in a kettle	100%
Allow the boiled water to cool to no less than 70°C (this means using water that has been left covered, for <30 minutes after boiling):	70%
Water covered	90%
Cool in kettle	100%
Cool in bottle	60%
Use of methods to cool water faster before addition of powdered infant formula	60%
>30 minutes	70%
Cool reconstituted feed quickly by holding under a running tap	20%
Cool reconstituted feed quickly by placing in a container of cold water	60%
Check the temperature by shaking a few drops onto the inside of the wrist – it should feel luke warm.	40%

In the model kitchen, time between end of kettle boiling and reconstitution with PIF ranged from <5 minutes to 51 minutes (for feeds to be fed immediately and stored for later feeding). In addition to allowing the boiled water to cool in the kettle for short periods of time, parents added cold tap water (unboiled) to the boiled tap water (to cool it down) before addition of the formula, poured boiled water into feeding bottles which were immediately cooled in jugs/bowls and washing up bowls of cold water for between 5-9 minutes (with up to two cold water changes to speed cooling) and/or holding the feeding bottle containing boiled water under a running tap for short periods of time (1-2 minutes). After reconstitution, 70% of parents cooled feeds using cold running water and/or immersed in jugs/bowls/washing up bowl of cold water to achieve a suitable temperature for feeding. Feeds immersed in containers of cold water for 5-11 minutes and feeds were held under cold running water for 1-3.5 minutes. As noted in Table 6.14, only 40% of parents checked the temperature of feeds to determine suitability for feeding by shaking a few drops of the feed on the inside of the wrist; other parents felt the outside of the

bottle or tasted the feed or held the feeding bottle against the side of their face to determine suitability of temperature.

Overall, 40% of parents who participated in this component of the study demonstrated preparation and storage of reconstituted PIF for feeding in the home, <2 hours after preparation. The majority reported that they would leave the made-up feeds at room temperature (usually <1 hour) before refrigeration; a small number of parents cooled the feeds in cold water for 5-11 minutes before refrigeration. Of those who placed made-up feeds in the fridge, half placed the feeds in the door and the remaining stored the feeds on the middle shelf near the back of the fridge.

Fourteen percent of parents prepared empty feeding bottles 'ready-for-later-use' in the home – all of these were stored, reassembled at room temperature until required. The majority of parents (46%) prepared feeding bottles with boiled water (ready-for-use) for use later in the home – most of whom stored such bottles with water at room temperature (although two parents stored the bottles in the fridge). Reasons given for storage of the boiled water at room temperature included easier reconstitution/dissolving of powdered formula in warmer water and avoiding the need to re-warm the made-up feed for a desired temperature for feeding.

All parents demonstrated methods used for managing PIF feeding away from the home. Twenty percent demonstrated storage of reconstituted feeds away from the home; only one parent cooled the reconstituted feed using ice and cold water and stored the cooled feed in a cool-bag with freezer packs. A few parents carried made-up feeds in a 'normal' bag – i.e. no cooler packs/insulation and other parents aimed to keep the made-up feed 'warm' until ready for feeding – using bottle thermal bags. Some parents reported taking a flask filled with boiled water and a separate container away from the home with them, for warming feeds immediately before feeding.

A quarter (26%) of parents prepared empty bottles 'ready-for-use', to be taken away from the home and 52% prepared bottles with boiled water ready for addition of PIF away from the home. The majority demonstrated measurements of powdered formula in segmented containers – some containers were sealed and could be fitted into the top of the bottles (with/without water) until ready for use. Less than 3% of parents attempted to clean or sterilise the powder containers before use. The majority of parents demonstrated storage of bottles with boiled water in insulated containers – with the intention of keeping the boiled water warm until feeding time.

In addition to preparation of infant feeding bottles and powdered formula feeds, parents were also asked to prepare a simple chicken salad requiring handling of raw chicken, salad vegetables and RTE ham. This provided an opportunity to observe food safety behaviours and the potential for cross contamination between food products and feeding bottles/feeds. Findings in Table 6.16 show that 63-80% of parents handled the raw chicken before removal of feeding bottles from the steriliser and/or preparation of infant feeds. Between 67-83% of parents prepared the RTE foods after handling raw chicken and/or used the same work surface for preparation of RTE foods and raw chicken. However, no parents prepared infant feeding bottles or reconstituted feeds on the same work surface as the raw chicken.

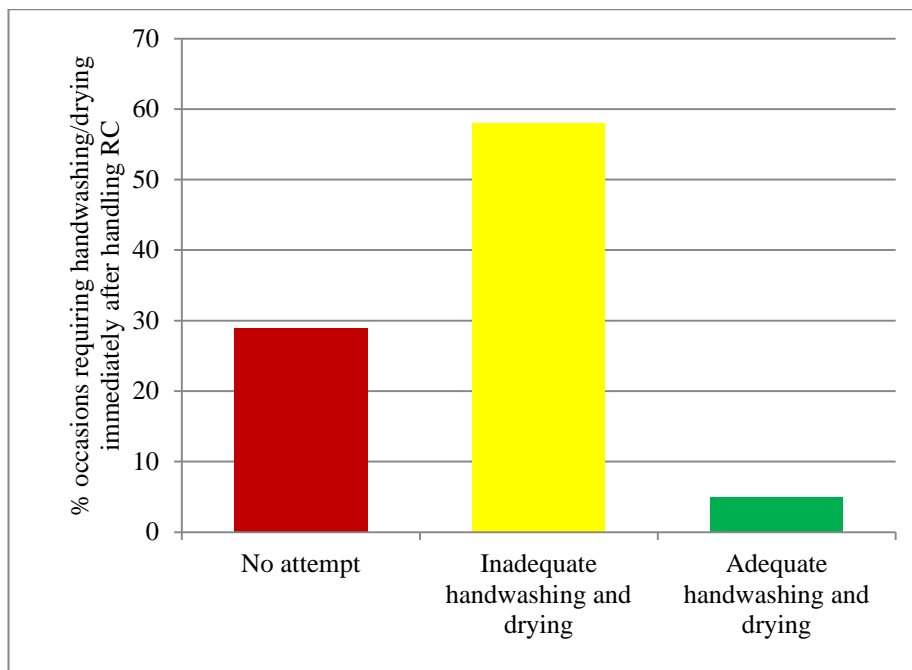
**Table 6.16 Preparation of raw chicken (RC), feeding bottles and powdered infant formula – order of preparation/use of same/separate preparation surfaces**

Observed behaviour	% parents
Preparation of ANY RC before bottle cleaning	13
Preparation of ANY RC before disinfection/sterilisation	13
Preparation of ANY RC before removal from disinfection/sterilisation	63
Preparation of ANY RC before powdered infant formula feed reconstitution	63
Preparation of RC and RTE foods (salad/ham) on same surface as powdered infant formula	83
Bottle preparation on same surface as RC	0
Reconstitution of powdered infant formula on same surface as RC	0
Bottle cleaning after RC handled	0
Removal of items from steriliser after RC handled	80
Powdered infant formula reconstitution after RC handled	57
Preparation of RTE foods (salad/ham) after RC handled	67
Attends to infant during food preparation	75
Attends to infant during bottle preparation	75
Attends to infant during powdered infant formula preparation	25

Of the parents who brought their infants with them to the model kitchen, the majority (75%) attended to their infant during bottle and food preparations. This included one nappy change which was followed by only rinsing of hands before reconstitution of PIF feeds.

Data in Figure 6.7 indicates the frequency of handwashing and drying efficacy immediately after handling raw chicken. Handwashing/drying attempts were made on >55% occasions. The most common reason for ‘inadequate’ handwashing was potential contamination of tap handles before and after washing and/or failure to rinse hands after washing. Hand drying behaviours were implemented more frequently; malpractices observed when potentially contaminated hand towels were re-used for drying freshly washed hands. After 30% of occasions, no attempt was made to wash or dry hands, thus indirectly cross contaminating other hand contact surfaces in the kitchen with raw chicken. Parents touched between 0 and 4 items with potentially contaminated hands after handling raw chicken, and 60% retouched such kitchen surfaces after attempting handwashing/drying, surfaces included hot tap handle, frying plan handle, utensil handles, kettle handle, hob controls, bin lid, cupboard handles and gas lighter.

**Figure 6.7 Frequency of handwashing/drying immediately after handling raw chicken**



Additional observed preparation/cleaning behaviours related to PIF and food preparation are recorded in Table 6.17 and screen caps of a selection of positive and negative practices are found in Figure 6.8.

**Table 6.17 Additional observed practices related to powdered infant formula and food preparation/handling**

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- Feeding bottles dried using ‘used’ hand towels and tea towels, post-sterilisation/disinfection.
  - Powdered infant formula scoop ‘washed’/dipped into washing up water before measuring powder for feeds.
  - Use of same dishcloth for washing up chopping board used for raw chicken and wiping kitchen surfaces before emptying sterilising unit and reconstitution of powdered infant formula.
  - Addition of powdered infant formula powder to an empty (prepared) bottle and measures boiled water in a second (prepared) bottle and then pours measured water in with the powder to mix.
  - Touched tap handle (which was touched <20 minutes beforehand with unwashed hands after handling raw chicken), then touched end of infant’s dummy before placed dummy in infant’s mouth.
  - Held bottle of reconstituted powdered infant formula against face to judge temperature suitability for feeding; tasted feed to ensure suitable temperature.
  - Use of hand towels and tea towels to wipe work surfaces, dry washed up items and dry outside of feeding bottles when removed from steriliser/disinfection.
  - Use of same (unwashed) knife to open raw chicken packaging and cut cooked piece of chicken to ensure cooking efficacy.
  - Indirect cross contamination between inadequately washed hands and RTE ham and salad vegetables.
  - Poured boiled water (9mins after boiling) over cleaned and sterilised/disinfected teat and screwcap and rinsed out feeding bottle before reassembling bottle (use of steam steriliser).
  - Held prepared (cleaned and sterilised/disinfected) bottle with fingers on the inside rim of the bottle and also touched outside rim.
  - Dropped bottle components onto the floor after cleaning and before sterilisation/disinfection.
  - Failed to adequately wash and dry hands after changing infants’ nappy – only rinsed under running water before preparing infant feed.
  - In an attempt to adhere to DoH/NHS/FSA guidance related to ‘preparation of powdered infant formula feeds immediately before feeding every time an infant is fed using powdered formula’, one parent prepared feeding bottles of (measured) boiled water, cooled and stored in the refrigerator – then when an immediate feed was needed, used boiled water (<30 minutes cooling) to mix with the powder and then added the cold boiled water to make up the required volume. The parent reported the feed was then at an appropriate temperature for immediate feeding.
  - To ‘clean’ powdered infant formula segmented storage container –boiling water was poured over the contained which was then dipped into used washing-up water and then dried using a paper towel.
-

**Figure 6.8 Examples of observed practices (positive and negative) during cleaning, sterilisation/disinfection and preparation of powdered infant formula feeds**

(C) Use of hands to pull teat through screwcap, post cleaning and sterilisation; removal of items from steriliser in advance of use – storage on paper towel.



(A) Placement of sterilised screwcaps and teats on paper towel; incorrect placement of items in microwave steriliser including failure to remove teats from screwcaps.



*Post observation session – Micro-sampling*



(E) Cooling of reconstituted feeds in washing-up bowl.



(F) Use of bottle brush to clean inside of teat.



(B) Placement of the base of feeding bottle screwcaps on uncleaned surface.



### **6.3.3 ATP and microbiological results**

Cumulatively, ATP levels were determined for 275 infant feeding bottle surfaces (See Table 6.18). Findings show that bottle locations associated with higher ATP levels included screwcaps and outer rims of bottles, with 16-22% of such surfaces exceeding satisfactory levels of organic soiling. Indeed, highest ATP levels (up to 5179RLUs) were determined for screwcap surfaces. Although the majority of outer rims of feeding bottles prepared with boiled water for later use (93%) or left empty for later use (91%) were considered satisfactorily clean, it is of note that 7-9% had unsatisfactory clean ATP levels.

Outer rim surfaces sampled from bottles containing reconstituted powdered formula were found to have higher ATP levels than empty prepared bottles. This may be due to the presence of drops of reconstituted PIF containing proteins and other organic matter, thus providing increased levels of ATP. For this reason, fewer bottles (10-26%) resulted in satisfactorily clean standards.

**Table 6.18 Organic soiling (ATP) detected from infant feeding bottle surfaces prepared ready for use**

Sample location		% bottles achieved realistically clean standard (<200RLUs)	Mean (RLUs)	SD (RLUs)	Range (RLUs)
Empty feeding bottle (n=50)	Screwcap	78%	335	814	17-5179
	Inner Teat	92%	93	227	10-1321
	Outer rim	84%	176	275	16-1304
	Rinse	100%	30	13	14-102
Reconstituted feed for immediate feeding (n=50)	Outer rim	24%	497	461	27-2826
Reconstituted feed prepared in advance for feeding at home (n=58)	Outer rim	26%	484	358	47-1412
Reconstituted feed prepared in advance for feeding away from the home (n=10)	Outer rim	10%	630	447	130-1562
<b>CUMULATIVE DATA:</b> Reconstituted feeds (n=118)	Outer rim	24%	502	410	27-2826
Feeding bottle prepared with boiled water in advance for feeding at home (n=52)	Outer rim	92%	48	52	8-303
	Boiled water	92%	64	51	10-275
Feeding bottle prepared with boiled water in advance for feeding away from the home (n=23)	Outer rim	96%	66	51	16-224
	Boiled water	100%	49	42	13-193
<b>CUMULATIVE DATA:</b> Feeding bottles prepared with boiled water (n=75)	Outer rim	93%	64	51	10-275
	Boiled water	95%	48	50	8-303
Empty feeding bottle prepared in advance of use in the home (n=20)	Outer rim	90%	143	251	29-1174
	Rinse	100%	30	8	20-53
Empty feeding bottle prepared in advance of use away from the home (n=12)	Outer rim	92%	76	72	20-290
	Rinse	100%	24	8	9-39
<b>CUMULATIVE DATA:</b> Empty feeding bottles prepared for use(n=32)	Outer rim	91%	118	204	20-1174
	Rinse	100%	28	9	9-53



Overall, ATP samples were taken from 452 surfaces in the model kitchen (see Table 6.19). Results indicated that only a small proportion of surfaces (0-20%) achieved a standard for a ‘cleaned and sanitised’ surface. This is not surprising given that observation results showed that few parents implemented adequate cleaning practices.

Surfaces where PIF was prepared were found to have higher levels of organic soiling than surfaces where raw chicken had been prepared; this may be due to the fact that powdered formula was frequently spilt onto surfaces where reconstituted feeds were prepared and few parents directly contaminated work surfaces with raw chicken.

Tap handles and the fridge handle were also associated with increased levels of ATP, as were dishcloths and scourers.

**Table 6.19 Detection of ATP from model kitchen surfaces, post powdered infant formula/food preparation**

Sample location	% achieve standard for cleaned and sanitised surface (<100RLUs)	% achieve standard for cleaned surface (<500RLUs)	Mean (RLUs)	SD (RLUs)	Range (RLUs)
Preparation surfaces used for powdered infant formula preparation (n=41)	14%	68%	2705	4197	48-19442
Preparation surface used for raw chicken preparation (n=41)	12%	39%	487	562	30-2683
Hot tap handle (n=50)	8%	32%	3329	6478	37-26863
Cold Tap handle (n=49)	0	16%	9938	26999	141-138782
Kettle Handle (n=50)	0	24%	2046	2542	119-14910
Fridge handle (n=50)	20%	48%	5296	25840	15-183200
Tea towel (n=50)	8%	62%	884	1336	54-7807
Hand towel(n=50)	4%	40%	888	878	56-3765
Dishcloth (n=39)	3%	23%	5607	16544	47-104095
Scourer (n=32)	6%	13%	14794	25203	46-97311

**Table 6.20 ACC contamination of infant feeding bottle surfaces prepared ready for use/storage**

Sample location		% achieve realistically clean standard	Mean (cfu/area sampled)	Range (cfu/area sampled)
Empty feeding bottle (n=50)	Screwcap	56%	4.4x10 <sup>2</sup>	0 - 2.0x10 <sup>4</sup>
	Inner Teat	80%	5.4x00	0 - 7.5x10
	Outer rim	68%	6.8x10	0 - 2.9x10 <sup>3</sup>
	Rinse	78%	0.9x00	0 - 1.7x10
Reconstituted feed for immediate feeding (n=50)	Outer rim	54%	4.0x10	0 - 1.1x10 <sup>3</sup>
	Feed	6%	9.0x00	0 - 6.5x10
Reconstituted feed prepared in advance for feeding at home (n=58)	Outer rim	60%	2.7x10	0 - 5.4x10 <sup>2</sup>
	Feed	14%	5.8x00	0 - 7.5x10
Reconstituted feed prepared in advance for feeding away from the home (n=10)	Outer rim	30%	1.0x10 <sup>2</sup>	0 - 3.6x10 <sup>2</sup>
	Feed	0	5.2x00	0 - 1.2x10
CUMULATIVE DATA: reconstituted feeds (n=118)	Outer rim	55%	3.9x10 <sup>1</sup>	0 - 1.1x10 <sup>3</sup>
	Feed	9%	7.2x00	0 - 7.5x10
Feeding bottle prepared with boiled water in advance for feeding at home (n=52)	Outer rim	90%	0.8x00	0 - 1.5x10
	Boiled water	96%	0.2x00	0 - 5.0x00
Feeding bottle prepared with boiled water in advance for feeding away from the home (n=23)	Outer rim	91%	2.8x00	0 - 5.0x10
	Boiled water	100%	0	0
CUMULATIVE DATA: Feeding bottle prepared with boiled water (n=75)	Outer rim	91%	1.4x00	0 - 5.0x10
	Boiled water	97%	0.1x00	0 - 5.0x00
Empty feeding bottle prepared in advance of use in the home (n=20)	Outer rim	100%	3.3x00	0 - 2.5x10
	Rinse	95%	5.5x00	0 - 7.8x10
Empty feeding bottle prepared in advance of use away from the home (n=12)	Outer rim	75%	3.7x10	0 - 3.9x10 <sup>2</sup>
	Rinse	75%	6.8x00	0 - 7.8x10
CUMULATIVE DATA: Empty feeding bottle prepared in advance of use away from the home (n=32)	Outer rim	91%	1.6x10	0 - 3.9x10 <sup>2</sup>
	Rinse	88%	5.9x00	0 - 7.8x10

Overall, low levels of microbial contamination were detected from most feeding bottle surfaces; however, data suggests inadequate cleaning/sterilisation/disinfection for some bottle locations (up to  $10^4$  cfu/area sampled) and the potential for microbial growth if such bottles containing PIF feeds were stored at an inappropriate temperature for extended periods of time.

Microbiological results indicating viable bacterial counts of infant feeding bottle surfaces prepared by parents ready for use/storage are found in Table 6.20. Findings indicate that 45% of outer rim surfaces from bottles containing reconstituted feeds had unsatisfactory microbial levels exceeding 1cfu/area sampled. However, only between 0-14% of reconstituted feeds had unacceptable microbial levels, suggesting the higher proportion of outer rim surfaces contaminated may be due to inadequate cleaning and/or handling of the outer rim of the bottle during preparation.

Overall, 9% of outer rims of empty feeding bottles/feeding bottles containing boiled water for later use had microbial levels exceeding a realistic clean standards (1cfu/area sampled).

**Table 6.21 ACC contamination of model kitchen surfaces, post powdered infant formula/food preparation**

Sample location	% achieve realistically clean standard for cleaned and sanitised surfaces	Mean (cfu/10cm <sup>2</sup> )	Range (cfu/10cm <sup>2</sup> )
Preparation surfaces used for powdered infant formula preparation (n=41)	5%	1.3x10	0 – 1.1x10 <sup>2</sup>
Preparation surface used for raw chicken preparation (n=41)	15%	6.1x00	0 – 4.9x10
Hot tap handle (n=50)	78%	5.8x00	0 – 9.5x10
Cold Tap handle (n=49)	68%	6.8x00	0 – 7.5x10
Kettle Handle (n=50)	86%	1.4x00	0 – 2.0x10
Fridge handle (n=50)	58%	9.6x00	0 – 1.3x10 <sup>2</sup>
Tea towel (n=50)	4%	7.8x10	0 – 9.5x10 <sup>2</sup>
Hand towel(n=50)	4%	8.5x10	0 – 5.7x10 <sup>2</sup>
Dishcloth (n=39)	0	3.1x10 <sup>2</sup>	0 – 1.1x10 <sup>3</sup>
Scourer (n=32)	0	3.0x10 <sup>2</sup>	0 – 1.8x10 <sup>3</sup>

Findings shown in Table 6.21 show that new dishcloths and scourers used during the preparation sessions had higher bacterial counts than other surfaces sampled in the model kitchen. No dishcloths/scourers were of a microbiologically acceptable 'clean' standard, post-preparation. Similarly, few (41%) tea towels and hand towels sampled were not considered to be acceptably clean post preparation, nor were 95% of work surfaces used for preparation of PIF. Surfaces associated with lower levels/frequency of contamination included the hot tap handle and kettle handle.

Data in Table 6.22 illustrates that *S.aureus* was isolated in 8% of reconstituted powdered feeds and outer rims of bottles containing made-up feeds. Between 2-12% of outer rims and inner screwcaps of empty feeding bottles/bottles containing boiled water for later use were also contaminated with *S.aureus*.

*Enterobacteriaceae* were detected in few (2%) empty feeding bottle surfaces and overall in <1% of reconstituted PIF feeds.

**Table 6.22 *Enterobacteriaceae* and *S.aureus* contamination of infant feeding bottle surfaces prepared ready for use/storage**

Sample location		<i>Enterobacteriaceae</i>		<i>S.aureus</i>	
		% bottles contaminated	Maximum level of contamination	% bottles contaminated	Maximum level of contamination
Empty feeding bottle (n=50)	Screwcap	2%	3.5x10	6%	4.4x10 <sup>2</sup>
	Inner Teat	2%	6.0x10	2%	2.0x10
	Outer rim	2%	2.5x10	12%	5.0x10
	Rinse	0	0	2%	9.5x00
<hr/>					
Reconstituted feed for immediate feeding (n=50)	Outer rim	0	0	6%	7.0x10 <sup>2</sup>
	Feed	2%	5.0x10	12%	8.5x10
Reconstituted feed prepared in advance for feeding at home (n=58)	Outer rim	2%	5.0x00	7%	9.5x10
	Feed	2%	1.0x00	3%	4.0x10
Reconstituted feed prepared in advance for feeding away from the home (n=10)	Outer rim	0	0	30%	2.9x10 <sup>2</sup>
	Feed	0	0	20%	5.0x00
CUMULATIVE DATA: reconstituted feeds (n=118)	Outer rim	<1%	5.0x00	8%	2.9x10 <sup>2</sup>
	Feed	<1%	5.0x10	8%	4.0x10
<hr/>					
Feeding bottle prepared with boiled water in advance for feeding at home (n=52)	Outer rim	0	0	2%	5.0x00
	Boiled water	0	0	0	0
Feeding bottle prepared with boiled water in advance for feeding away from the home (n=23)	Outer rim	0	0	4%	4.5x10
	Boiled water	0	0	0	0
CUMULATIVE DATA: Feeding bottle prepared with boiled water (n=75)	Outer rim	0	0	3%	4.5x10
	Boiled water	0	0	0	0
<hr/>					
Empty feeding bottle prepared in advance of use in the home (n=20)	Outer rim	0	0	5%	3.5x00
	Rinse	0	0	0	0
Empty feeding bottle prepared in advance of use away from the home (n=12)	Outer rim	0	0	0	0
	Rinse	0	0	0	0
CUMULATIVE DATA: Empty feeding bottle prepared in advance of use away from the home (n=32)	Outer rim	0	0	6	0
	Rinse	0	0	0	0

**Table 6.23 *Enterobacteriaceae* and *S.aureus* contamination of model kitchen surfaces post powdered infant formula/food preparation**

Sample location	<i>Enterobacteriaceae</i>		<i>S.aureus</i>	
	% surfaces contaminated	Maximum level of contamination	% surfaces contaminated	Maximum level of contamination
Preparation surfaces used for powdered infant formula preparation (n=41)	0	0	0	0
Preparation surface used for raw chicken preparation (n=41)	5%	2.5x00	0	0
Hot tap handle (n=50)	2%	1.5x10	2%	5.0x00
Cold Tap handle (n=49)	8%	2.5x10	4%	4.5x10
Kettle Handle (n=50)	0	0	2%	1.0x10
Fridge handle (n=50)	6%	2.0x10	4%	5.0x00
Tea towel (n=50)	24%	3.6x10 <sup>2</sup>	22%	5.4x10
Hand towel(n=50)	36%	2.6x10	24%	1.7x10 <sup>2</sup>
Dishcloth (n=39)	79%	1.4x10 <sup>3</sup>	31%	3.8x10 <sup>2</sup>
Scourer (n=32)	78%	1.3x10 <sup>3</sup>	25%	1.5x10 <sup>2</sup>

*Enterobacteriaceae* was isolated from 24-36% hand towels and tea towels and 78-79% of dishcloths and scourers; similarly *S.aureus* was isolated from 22-24% of hand towels and tea towels, yet fewer (25-31%) dishcloths and scourers.

Between 2-4% of hot taps, cold taps, fridge and kettle handles were associated with low levels of *S. aureus* contamination and low levels of *Enterobacteriaceae* were isolated from 0-8% of the same surfaces. No *Enterobacteriaceae* or *S.aureus* were detected on work surfaces where PIF feeds were prepared, however, *Enterobacteriaceae* was isolated on 5% surfaces where raw chicken was prepared.

## 6.4 SUMMARY OF FINDINGS

### 6.4.1 Observation of powdered infant formula/food preparation sessions

- Observational findings showed that the methods used by parents for cleaning, sterilisation/disinfection of feeding bottles and preparation of PIF feeds are variable and frequently contravene FSA/DoH guidance/recommended practice.
- The most common parental practices observed for managing powdered formula milk feeds in the home included reconstitution of powdered formula milk feeds (40%) and preparation of feeding bottles containing boiled water (46%).
- Observed practices suggest that the majority of parents (60%) do not routinely store reconstituted powdered formula milk feeds for >2 hours, but do reconstitute feeds using boiled water at ambient or refrigerated temperatures which is <70°C as recommended by the FSA/DoH.
- All participants implemented pre and post disinfection/ sterilisation related behaviours that are contrary to FSA/DoH guidance.
- The most common *cleaning* malpractices implemented included failure to rinse all bottles and particularly components after washing in hot water and detergent. In addition, large numbers of participants (up to 90%) failed to clean the inside and outside of the screwcap, outside of teats and around the outer rim of the feeding bottle. The screwcap and outer rim threads are key bottle locations known to harbour food residues and micro-organisms if inadequately cleaned. Furthermore, 20% of participants failed to separate the teat and screwcap for cleaning/rinsing and most continued to sterilise/disinfect such items without separating.
- Common *disinfection/sterilisation* malpractices implemented included failure to follow all manufacturers instructions for disinfection/sterilisation equipment, particularly failing to load the disinfection/steriliser unit according to instructions and failure to allow for ‘cooling time’ after completion of disinfection/sterilisation cycles and before removal of items from units.
- All participants’ prepared powdered formula feeds using fresh, boiled tap water. Although a large proportion of parents reconstituted PIF feeds (for immediate feeding) within 30 minutes of the kettle boiling, >50% parents used methods to cool the boiled water *before*

addition of the powdered formula – suggesting that feeds may be prepared with water <70°C even though within the recommended 30 minutes from end of boiling time.

- Nearly half (46%) of parents reported they usually prepared PIF feeds for ‘immediate feeding’ using boiled water stored in prepared feeding bottles for >2 hours for reconstitution, which would be <70°C.
- The majority of participants did not wash and dry their hands adequately at key PIF preparation steps as recommended by the FSA/DoH, for example, before commencing bottle preparation (cleaning), immediately before removal of bottles and components from sterilisation/disinfection and immediately before reconstitution of PIF feeds.
- Failure to attempt or implement adequate handwashing/drying during kitchen practices ongoing at the time of formula preparation (in this case after touching raw chicken) was observed on 87% of occasions.
- Post disinfection handling of bottle components, which could lead to cross contamination, particularly of inner and outer surfaces of teats, was carried out by a large number of participants.
- Other cross contamination actions were observed during all food and PIF preparation sessions.
- Recontamination of washed/dried hands was observed leading to potential contamination of infant feeding bottles.
- Almost all participants failed to clean surfaces adequately before removal of bottles and components from disinfection/sterilisation and also before preparation of powdered formula milk feeds. Most participants attempted to clean surfaces after food and PIF preparation, in most cases this consisted of wiping the work surface(s) with a used/damp cloth or paper towel and spraying with a multi-surface/antibacterial spray.



#### 6.4.2 Microbiological analysis of infant feeds, feeding bottles and kitchen surfaces

- Organic soiling detected on bottle and kitchen surfaces indicated inadequate cleaning efficacy – a finding that corresponds with observational results.
- Bottle locations associated with increased organic soiling (ATP) and microbiological contamination (including *Enterobacteriaceae* and *S.aureus*) included screwcaps and bottle outer rims. Observational findings indicated that such surfaces were frequently inadequately scrubbed clean and rinsed by parents prior to disinfection/sterilisation procedures.
- Findings indicate the presence of ATP on ‘ready-to-use’ feeding bottle surfaces and the potential for survival of bacteria on bottle/component surfaces between infant feeds.
- Nine percent of reconstituted feeds prepared in the model kitchen were found to have >1cfu/ml ACC, <1% >1cfu/ml *Enterobacteriaceae* and 8% >1cfu/ml *S.aureus*. Although data indicated low levels of microbial contamination, reconstituted powdered formula milk is known to be an ideal medium for microbial growth and survival; thus, if made-up feeds were stored at an inappropriate temperature for extended periods of time (as demonstrated by some parents in this component of the study) bacterial counts are likely to be considerably higher, increasing the potential risk of illness.
- Kitchen surfaces associated with a increased microbial contamination (up to  $10^3$  ACC and *Enterobacteriaceae* and  $10^2$  *S.aureus*) include dishcloths, scourers, hand towels and tea towels. Use of such items within the kitchen may result in cross contamination/recontamination of cleaned surfaces.

## CHAPTER 7

### TIME TEMPERATURE PROFILING OF RECONSTITUTED POWDERED INFANT FORMULA FEEDS PREPARED AND FED IN DAY NURSERIES AND INSIDE/OUTSIDE OF PARENT HOMES

#### 7.1 INTRODUCTION

##### 7.1.1 Background

Reconstituted PIF provides ideal conditions for growth of bacteria (WHO, 2007) and in the UK it is recommended that feeds are not prepared in advance of use (FSA, 2007; NHS, 2007). However, data (Chapter 2) suggests that parents often prepare PIF feeds in advance of feeding. Furthermore, data (Chapter 6) also indicates that many day nurseries either (a) require reconstituted PIF feeds to be brought to the nursery for use throughout the day or (b) prepare PIF feeds in the nursery in the morning or in batches, for use throughout the day. In such instances temperature control of refrigerated feeds is of paramount importance to maximise safety. Use of time temperature data from in-use PIF feeds stored inside and outside parents' homes and in day nurseries will provide data which can be used to determine the actual risk associated with reconstituted PIF storage.

##### 7.1.2 Aims and objectives

The overall aim of this part of the project was to obtain time-temperature data from 'in-use' reconstituted powdered formula feeds prepared in advance of feeding, inside and outside of the home. The data would then be used to model growth of *Cronobacter* spp. based on 'in-use' practices (see Chapter 8).

The more specific objectives were to:

- Validate the use of dataloggers for temperature monitoring of infant formula feeds (internal (milk) vs. external (bottle) temperatures).
- Track the time temperature profile of 25 feeds served in nurseries, prepared by parents or the nurseries themselves (*55 profiles were tracked*).
- Track the time temperature profile of 100 feeds prepared for consumption inside and outside the home (*143 profiles were tracked*).

## 7.2 METHODS

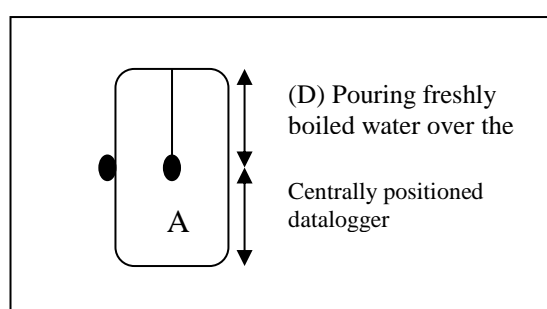
For all time temperature profiling Signatrol SL52T and SL53T dataloggers were used. These recently calibrated, single channel, self-contained temperature data logging buttons recorded temperatures over the range of  $-40^{\circ}\text{C}$  to  $+85^{\circ}\text{C}$  (for SL52T) and  $0^{\circ}\text{C}$  to  $+125^{\circ}\text{C}$  (for SL53T) (recording duration based upon sampling rate). Manufacturers reported the accuracy of the SL52T to be  $\pm 0.5^{\circ}\text{C}$  from  $-10^{\circ}\text{C}$  to  $+65^{\circ}\text{C}$  and  $\pm 1.0^{\circ}\text{C}$  outside of this range; accuracy for the SL53T dataloggers is reported to be  $\pm 0.5^{\circ}\text{C}$  from  $+20^{\circ}\text{C}$  to  $+75^{\circ}\text{C}$  and  $\pm 1.0^{\circ}\text{C}$  from  $0^{\circ}\text{C}$  to  $+20^{\circ}\text{C}$  and  $+75^{\circ}\text{C}$  to  $+115^{\circ}\text{C}$  (<http://www.signatrol.com/>). Manufacturers of the dataloggers indicated that the loggers take up to 270 seconds (4½ minutes) to achieve 95% temperature in air or 63% change in 90 seconds in circulating air/up to 90% change in 180 seconds in circulating air (Signatrol, 2009). This was accounted for in the analysis.

For determination of internal temperatures of bottles of reconstituted PIF (validation experiments only) dataloggers were protected in a silicone rubber waterproof casing (SL-ACC06). SL52 and SL53 dataloggers within this two part enclosure (measuring 22.5mm diameter and 25mm length) were reported to have a 63% response time in water within 90 seconds and up to 90% step change within 243 seconds (Signatrol 2009).

The button dataloggers used were very small (measuring 17mm diameter x 6mm height - about the same size as a watch battery) in a stainless steel casing. For all validation studies, day nursery and parent feed profiling loggers were programmed to record temperatures in  $^{\circ}\text{C}$ , at a sampling rate of one minute and where required, programmed to start logging at a delayed time. Recorded data was downloaded using SL50-USB cable interface into in TempIT Pro Analysis & Configuration Software. Logger data was subsequently exported into Microsoft Excel 1997 as a CSV file for analysis, further analysis was undertaken using SPSS for Windows (Version 15).

For all validation studies dataloggers were suspended/secured inside and outside of infant feeding bottles respectively (see Figure 7.1). Datalogger B being encased in the waterproof silicone capsule and suspended in the centre using cotton at a central distance between top and bottom of the bottle.

**Figure 7.1 Diagram illustrating dataloggers positioned inside and outside infant feeding bottles for validation profiling**



Ethical approval was obtained from the Cardiff School of Health Sciences Ethics Committee (UWIC) to implement this component of the study.

### **7.2.1 In-use validation of dataloggers**

Powdered formula feeds (260ml) were reconstituted ready for infant feeding (in Tommee Tippee Closer to Nature bottles), inside and outside a parent's home. For each powdered formula feed actually fed to the infant (aged 11 months), a replicate feed (treated in exactly the same way) was also prepared with one datalogger secured on the outside of the bottle and a second datalogger (in waterproof casing) suspended in the centre of the feed at a central distance between the top and bottom of the bottle. Feeds containing the suspended datalogger were not fed to the infant. The parent was provided with a participant information form, instructions and a short form to complete to record length of time between kettle boiling and addition to the feeding bottle, time of reconstitution, placement in location of storage and time of feeding. Signed consent for participation in this part of the study was obtained.

Replicate reconstituted powdered formula feeds (n=8) were stored in the same way as would normally be stored. An overnight feed was prepared using boiled water (cooled for 30-40 minutes in a stainless steel kettle) during the evenings and stored upright in the home overnight at ambient temperature in the infant's nursery until required for morning feeding. The ambient temperature recorded next to stored feeds in the nursery was also recorded. Similarly, reconstituted feeds prepared during the day for feeding away from the home were also profiled. As before, the parent implemented her usual practice to prepare the PIF with boiled water (cooled for 30-40 minutes in a stainless steel kettle) which was then immediately placed into the insulated bottle compartment of a baby bag until required for feeding.

### **7.2.2 In-vitro validation of dataloggers**

Internal and external time-temperature profiles of replicate single strength PIF were determined in-vitro using 125ml (n=3) and 260ml (n=3) bottles. Initial temperatures of infant feeds ranged from <5°C, ~20°C and 70°C. All time temperature profiles were recorded during storage at ambient temperature for up to 12 hours.

### **7.2.3 Determination of time temperature profiles of reconstituted powdered formula feeds served in day nurseries**

Fifteen day nurseries in Cardiff were contacted to request participation in this part of the study. Before participation, day nurseries were provided with a participant information sheet, and signed consent was obtained from nursery/baby unit managers (see Appendix 7.1). Nurseries were provided with supermarket vouchers as a token of thanks for participation.

Demonstrations and written instructions detailing the positioning and method of attaching the datalogger to bottles of infant feeds were provided to nurseries. Nursery staff were asked to attach dataloggers to feeding bottles as soon as infant feeds were made/brought to the nursery. Day nurseries were provided with the dataloggers, masking tape and digital clock. In addition, for each time-temperature profile recorded a short information sheet was completed by nursery staff to obtain background information.

- For feeds made-up and brought into the nursery the following background information was collected (see Appendix 7.1):
  - times of arrival in the nursery
  - time of attachment of the datalogger to infant feed bottle
  - size of the bottle
  - volume of feed
  - feel of the bottle of reconstituted feed on arrival at the nursery (cold, ambient or very warm)
  - information from the parents regarding when the feed had been made-up (previous day, previous evening or morning before nursery)
  - record how the feed had been brought to the nursery (e.g. cool bag, carrier bag etc)
  - additional notes including time placed into the refrigerator, positioning in the refrigerator
  - time of feeding
  - time of removal of datalogger from bottle.
- For feeds made-up in the nursery the following information was collected (Appendix 7.1):
  - time when infant feed was made-up in the nursery
  - time datalogger attached to the infant feed
  - size of the bottle
  - volume of feed
  - method of reconstitution
  - feel of the bottle of reconstituted feed after it had been made-up
  - where made-up feed is stored immediately after reconstitution
  - time when made-up formula is placed in the refrigerator
  - additional notes including time placed into the refrigerator
  - positioning in the refrigerator
  - time of feeding
  - time of removal of datalogger from bottle.

Dataloggers from all feeds were removed from bottles on removal from the refrigerator immediately prior to reheating and feeding. Nursery staff reported that the majority of feeds were warmed in a bottle warmer or in jug of hot water for feeding – time temperature profiles of

such practices could not be recorded. In addition, due to health and safety issues, it was not possible to record time temperature profiles of feeds until the end of the feed had been given, no data could be obtained regarding the length of feeding times in the nursery. In addition to time temperature profiles of reconstituted infant feeds, nursery refrigerator and kitchen ambient temperature profiles were determined for both day nurseries.

Recorded data was downloaded into in TempIT Pro Analysis Software and subsequently analysed in Microsoft Excel 1997 and SPSS for Windows (Version 15). Excel spreadsheets of the data were sent to Dr Martine Reij at the University of Wageningen, The Netherlands for Risk Modelling (see Chapter 8).

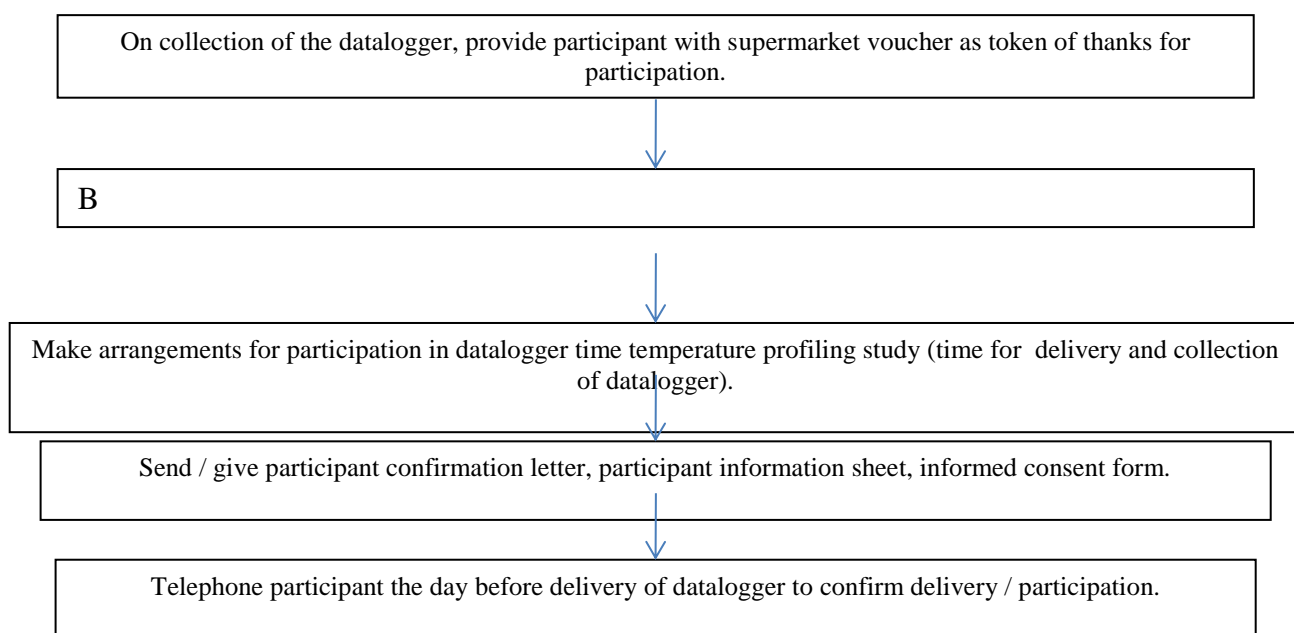
#### **7.2.4 Time temperature profiles of feeds prepared and served by parents inside and outside of the home**

Recruitment of consumers for this part of the study is outlined in Figure 7.2. For specific recruitment approaches see details noted in Chapter 6. Recruitment criteria included the following (for recruitment questionnaire, see Appendix 7.2):

- Parents of infants aged <12 months who prepare and feed their infant(s) at least once a day using PIF.
- Parents who prepare PIF feeds at least 2 hours in advance of feeding.
- Participants must be aged >18 years. No maximum age limit for participation or quotas for male/female participation.
- Participants must be able to read and understand English to an adequate level to take part in the study.

Parents were provided with dataloggers to attach to the outside of infant feeding bottles containing reconstituted feeds prepared in advance of feeding. In addition, parents were also provided with dataloggers to leave at room temperature/place in the refrigerator where corresponding feeds were stored. Before participation in the study, recruited parents were provided with a participant information sheet and signed consent was obtained (Appendix 2.8). Parents were allowed to attach dataloggers to more than one feed at a time. Supermarket vouchers were provided to parents who participated in the study as a token of thanks for participation.

**Figure 7.2 Plan for implementation of time temperature profiling study with parents**



Demonstrations with written instructions detailing positioning and method of attaching the datalogger to bottles of infant feeds, individually Time Temperature Profiling: In their own homes. participants will be provided with a Signatrol were

provided to all parents taking part in the study. Parents were asked to attach dataloggers to feeding bottles before addition of boiled water; all were provided with the dataloggers, masking tape and digital clock. In addition, for each time-temperature profile parents were required to complete an information sheet to obtain background information and times of datalogger attachment and removal etc. (Appendix 7.2).

Supportive information required in the information sheet (see Appendix 7.2) included age of infant, indication of where the feed was prepared, brand, type and size of feeding bottle and volume of feed prepared. Other data required included time when water was added to the bottle, time of reconstitution with PIF, time when made-up PIF was placed in the refrigerator/cool bag (as appropriate) and time of start and end of feeding. In addition, details related to treatment of boiled water were also recorded as well as details and times of reheating feeds before feeding.

Recorded data was downloaded into in TempIT Pro Analysis Software and subsequently analysed in Microsoft Excel 1997 and SPSS for Windows (Version 15). Excel spreadsheets of the data were sent to Dr Martine Reij at the University of Wageningen, The Netherlands for Risk Modelling (see Chapter 8.0).

### **7.3 RESULTS**

### 7.3.1 In-use validation of dataloggers

#### 7.3.1.1 Powdered infant formula feeds reconstituted in advance for feeding in the home

Reconstituted PIF feeds prepared and fed within the home were stored for between 8 hours and 49 minutes – 9 hours and 41 minutes at ambient temperature (21-25°C). Internal temperatures of feeds 5mins after reconstitution (accounting for datalogger lag) ranged from 55.56 – 71.38°C. After three hours of storage, data in Table 7.1 and Figure 7.3 indicate that temperature difference was <1°C.

**Table 7.1 Difference in temperature between internal and external dataloggers in reconstituted powdered infant formula feeds stored at ambient temperature for 529 minutes**

Time	Temperature difference between internal and external dataloggers (°C)				Mean (°C)	SD
	N1	N2	N3	N4		
0	9.78	10.93	6.47	4.89	8.02	2.81
60 (1 hour)	3.45	5.00	3.01	2.91	3.59	0.97
120 (2 hours)	1.47	2.01	1.52	0.41	1.35	0.67
180 (3 hours)	0.97	1.52	1.02	0.41	0.98	0.45
240 (4 hours)	0.47	1.02	-0.48	-0.09	0.23	0.66
300 (5 hours)	0.47	0.52	-0.48	-0.09	0.11	0.48
360 (6 hours)	0.47	0.02	-0.48	-0.09	-0.02	0.39
420 (7 hours)	1.02	0.02	0.02	-0.09	0.24	0.52
480 (8 hours)	0.47	0.52	0.02	0.41	0.36	0.23
529 (8 hours 49mins*)	-0.03	0.02	0.47	-0.09	0.09	0.26

*Table 7.1 notes: N1-N4= replicate feed codes*

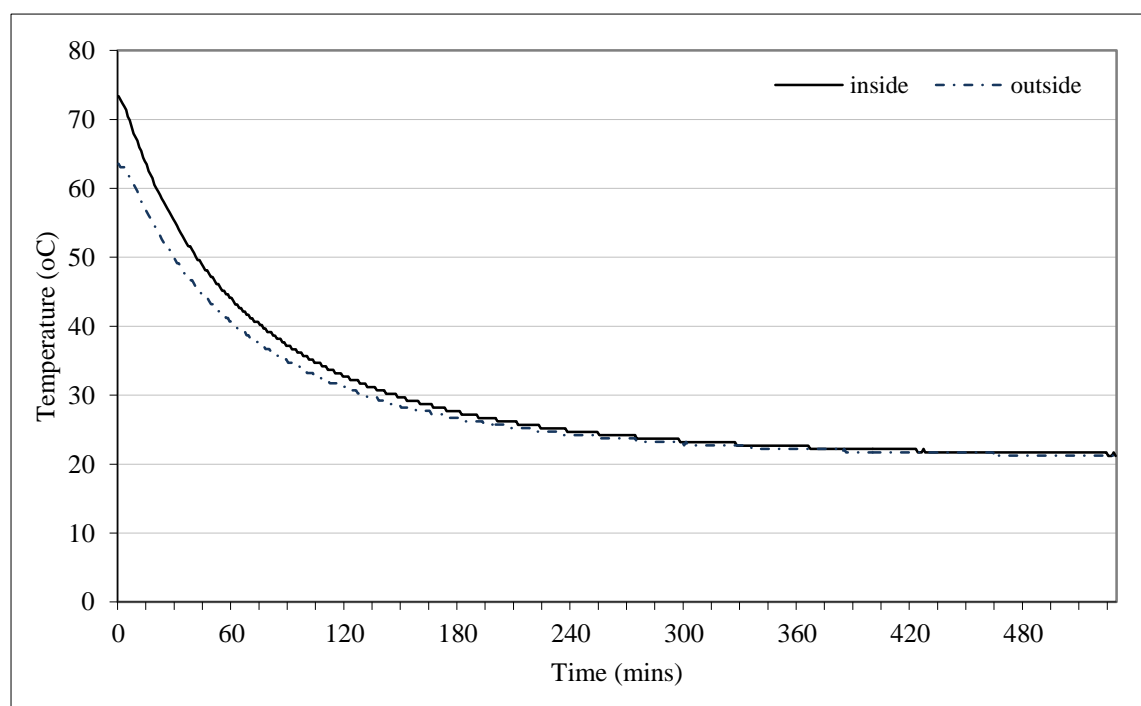
*\*shortest time feed stored – therefore comparable between 4 feeds*

*Time 0 = when logging started (data presented is before 4.5 minutes logging lag of datalogger)*

*A minus difference between internal and external temperatures is due to the internal datalogger being colder than the external logger.*



**Figure 7.3 Example of in-use comparison of internal and external reconstituted powdered infant formula feed (N1) (260ml) temperatures stored at ambient temperature (21-25°C) for 8 hours, 49mins) overnight**



### 7.3.1.2 Powdered infant formula reconstituted in advance for feeding outside of the home

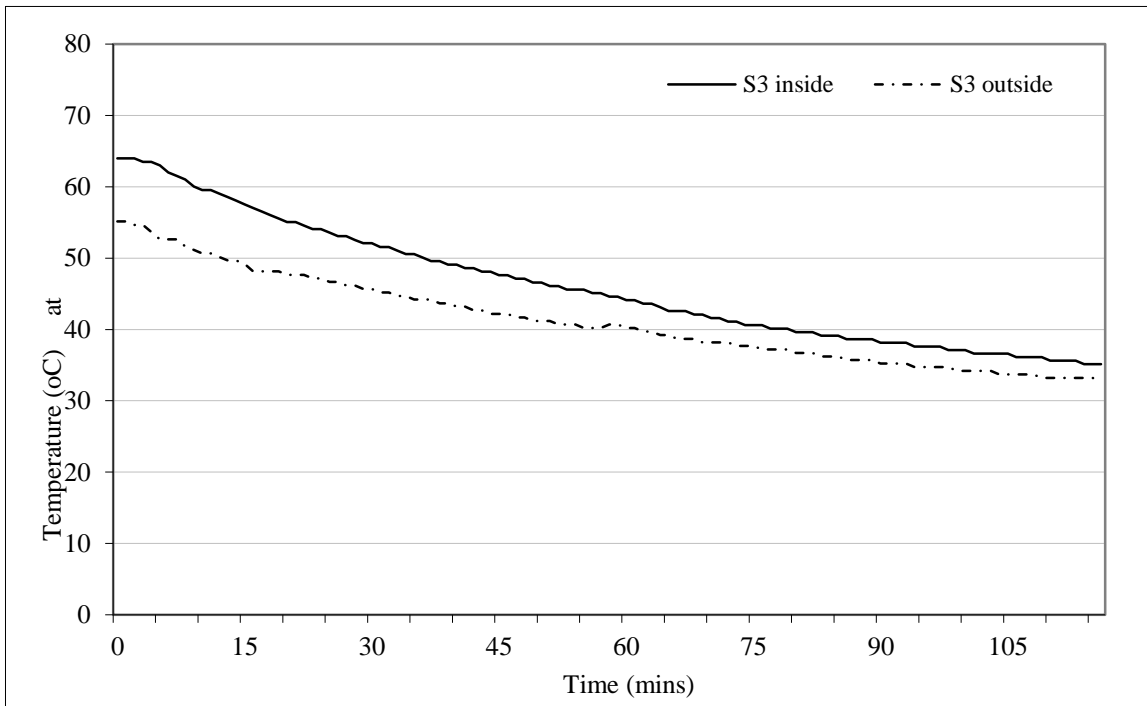
Reconstituted PIF feeds prepared at home for feeding away from the home were stored in an insulated bottle compartment of a baby bag [to be kept warm until feeding] for between 1 hour 14mins – 2 hours 6mins. Feeds were placed in the insulated compartment (no freezer packs) within 6-15 minutes of reconstitution and stored in an upright position. Data in Table 8.2 and Figure 8.4 indicate that after 30 minutes of storage, the internal temperature of the feed was 4°C warmer than the external datalogger, however, after 60 minutes, this difference had reduced to 2°C.

**Table 7.2 Difference in temperature between internal and external dataloggers in reconstituted powdered infant formula feeds stored in an insulated compartment of a baby bag for 0-90 minutes**

Time	Temperature difference between internal and external dataloggers (°C)				Mean (°C)	SD
	S1	S2	S3	S4		
0	7.98	5.49	8.87	5.52	6.97	1.72
30 minutes	2.50	4.49	6.39	4.01	4.35	1.60
60 minutes	0.90	3.00	3.90	3.01	2.70	1.27
90 minutes	/	2.50	2.91	/	2.71	0.29

Table 7.2 notes: S1-S4= replicate feed codes; Time 0 = when logging started (data presented is before 4.5 minutes logging lag of datalogger)

**Figure 7.4 Example of in-use comparison of internal and external reconstituted powdered infant formula feed (S3) (260ml) temperatures stored in an insulated bottle compartment of a baby bag (26°C) for 2 hours and 6 minutes when away from the home**

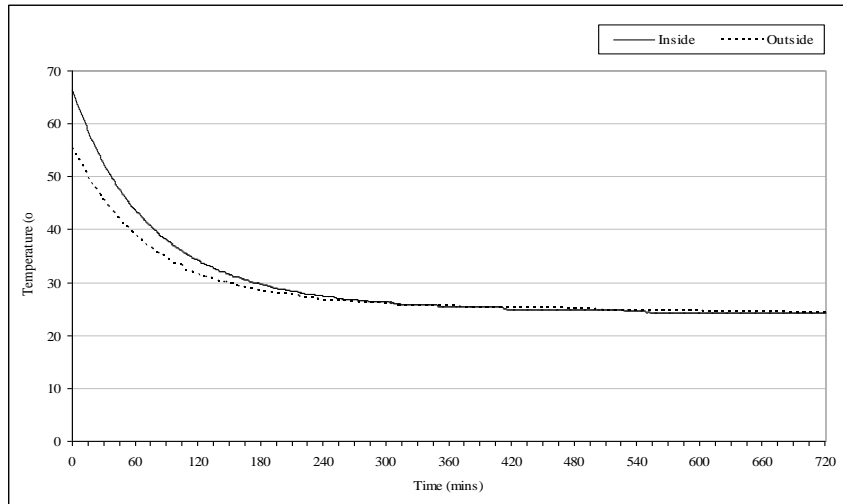


All in-situ temperature profiles indicated temperature differences between internal and external datalogger records. Internal temperatures (6.97–8.02°C mean values) were greater than external temperatures at time zero. In both scenarios (feeds stored at ambient temperature overnight and in an insulated part of a baby bag – no freezer packs) the temperature difference reduced to 2.70–3.59°C (mean values) after 60 minutes. For feeds stored in excess of 90 minutes, the temperature difference observed decreased to <1°C after three hours (180 minutes).

### 7.3.2 In-vitro validation of datalogger use

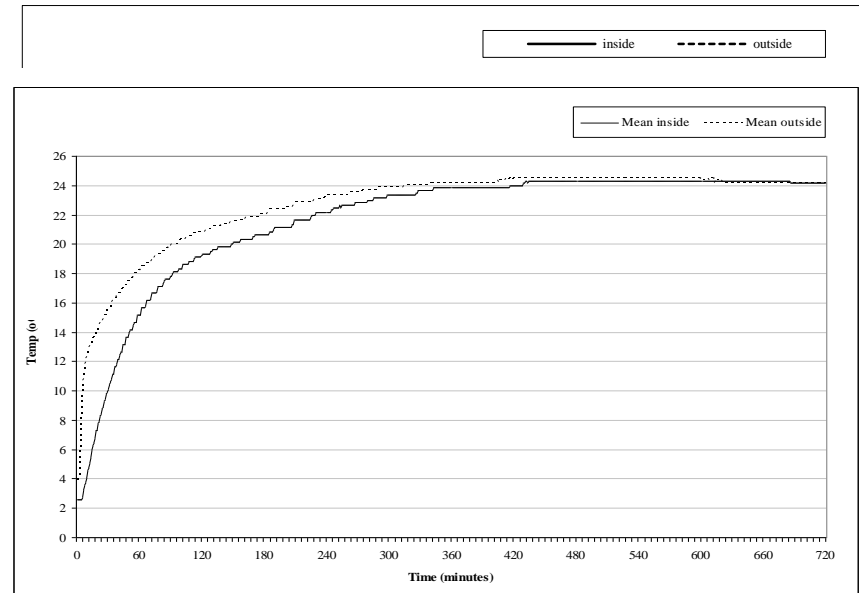
Data presented in Figures 7.5–7.10 demonstrate time temperature profiles from internal and external dataloggers attached to feeding bottles containing reconstituted PIF with a starting temperature of >70°C. Dataloggers attached to feeds with a greater starting temperature (70°C) showed that internal temperatures were up to 13.71°C hotter (125ml) and 10.75°C (260ml) at time zero. As shown in the in-situ experiments, temperature differences decreased over time within 2-3 hours to <1°C. For feeds with a lower starting temperature (<5°C), data indicates (Table 7.3) that external data logger recordings were lower than internal temperatures.

**Figure 7.6. In-vitro time temperature profiles of 125ml powdered infant formula (~70°C initial temp) stored at ambient temperature (23-25°C) for 12hours**

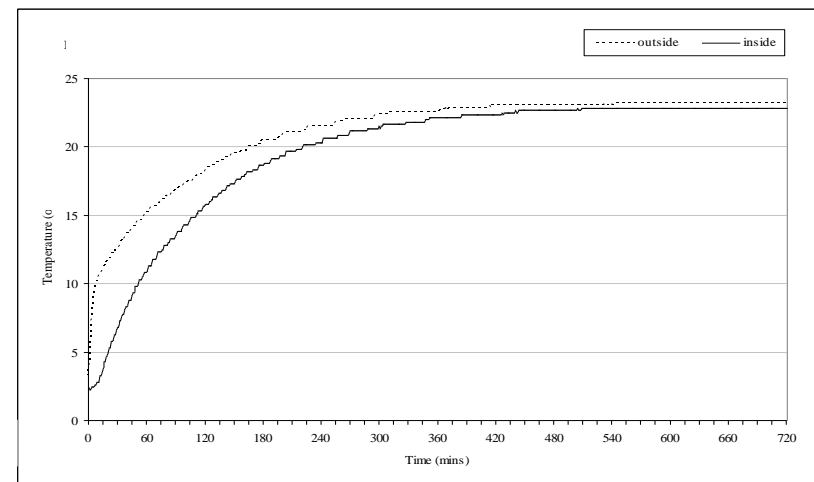


**Figure 7.8. In-vitro time temperature profiles of 260 powdered infant formula (~4°C initial temp) stored at ambient temperature (mean 23°C) for 12hours**

Via telephone / at baby group meeting confirm participant meets recruitment criteria (specifically that PIF feeds are made >2hours in advance of use).

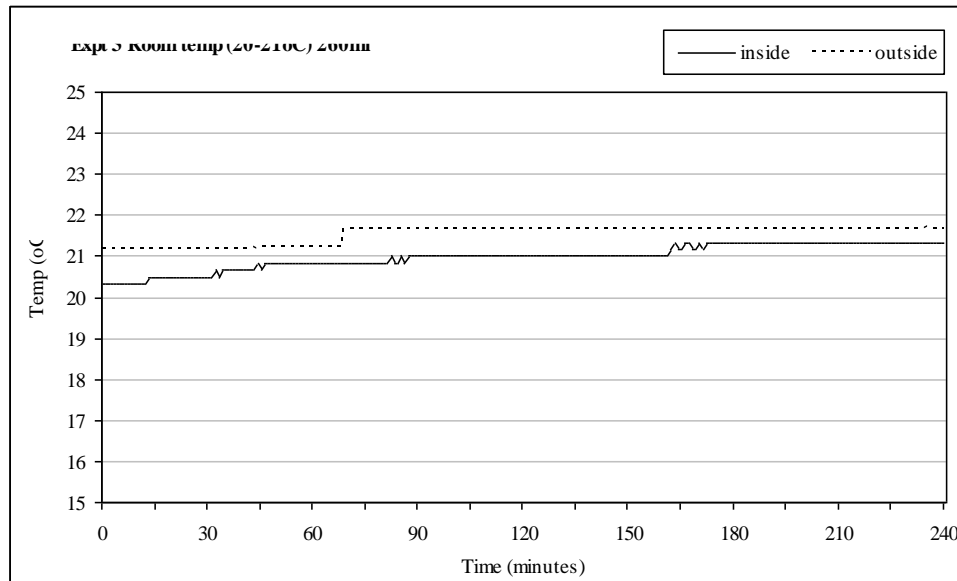


**Figure 7.7. In-vitro time temperature profiles of 125ml powdered infant formula (~4°C initial temp) stored at ambient (mean 23°C) temperature for**

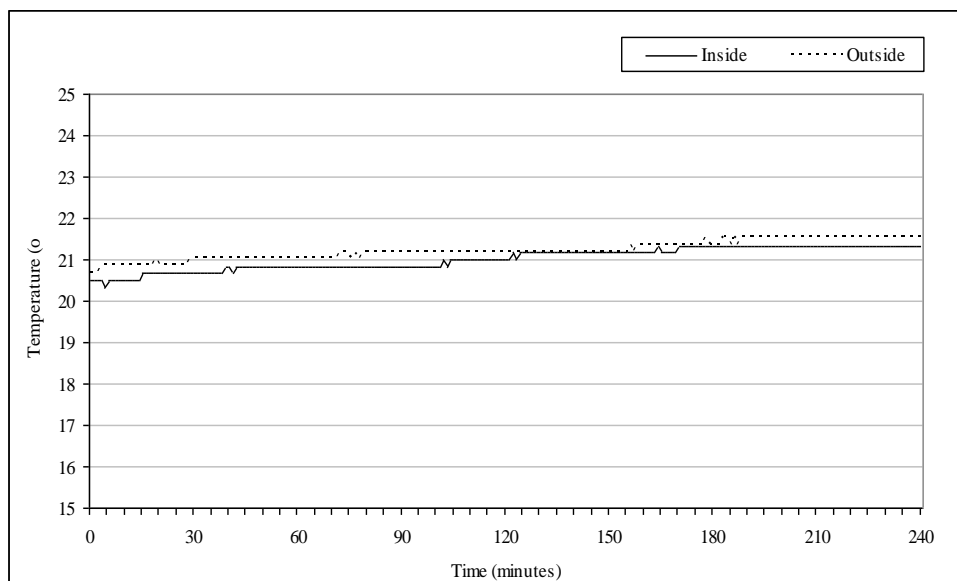


Differences appeared to be  $<1.5^{\circ}\text{C}$ , this difference increased to  $3\text{-}4^{\circ}\text{C}$  as the feeds were stored at ambient temperature, however after 3-4 hours the temperature difference was found to be  $<1\text{-}2^{\circ}\text{C}$ . For feeds with a starting temperature of  $\sim 20^{\circ}\text{C}$  (Figures 7.9 and 7.10), the internal and external temperatures were found to be within  $1^{\circ}\text{C}$  of each other from the start.

**Figure 7.9. In-vitro time temperature profiles of 260ml powdered infant formula ( $\sim 20^{\circ}\text{C}$  initial temperature) stored at ambient temperature for 4 hours**



**Figure 7.10. In-vitro time temperature profiles of 125ml powdered infant formula ( $\sim 20^{\circ}\text{C}$  initial temperature) stored at ambient temperature for 4 hours**



**Table 7.3 In-vitro determination of time temperature difference between dataloggers positioned on the outside and inside of a bottle of reconstituted powdered infant formula**

Time (mins)		Ambient storage from formula starting at refrigeration temperature		Ambient storage from formula starting at ambient temperature		Ambient storage from formula starting at recommended reconstitution temperature	
		<5°C 125ml Mean temp (SD)	<5°C 260ml Mean temp (SD)	~20°C 125ml Mean temp (SD)	~20°C 260ml Mean temp (SD)	~70°C 125ml Mean temp (SD)	~70°C 260ml Mean temp (SD)
	Room temperature	24-25°C	23°C	20-21°C	20-21°C	23-25°C	24-25°C
0	Outside bottle	3.96 (0.73)	3.29 (0.27)	20.69 (0.03)	21.17 (0.28)	53.74 (2.75)	55.55 (0.80)
	Inside bottle	2.61 (0.51)	2.44 (0.31)	20.50 (0.32)	20.33 (0.31)	67.45 (0.84)	66.30 (0.56)
	<b>Temperature difference (inside/outside)</b>	<b>1.30</b>	<b>0.85</b>	<b>0.19</b>	<b>0.84</b>	<b>13.71</b>	<b>10.75</b>
60	Outside bottle	18.18 (0.48)	15.17 (0.48)	21.02 (0.26)	21.33 (0.03)	35.17 (1.03)	38.99 (0.25)
	Inside bottle	15.15 (0.53)	10.97 (0.28)	20.83 (0.31)	20.83 (0.31)	39.48 (1.06)	43.62 (0.51)
	<b>Temperature difference (inside/outside)</b>	<b>3.03</b>	<b>4.20</b>	<b>0.19</b>	<b>0.50</b>	<b>4.31</b>	<b>4.63</b>
120	Outside bottle	20.85 (0.28)	18.18 (0.48)	21.19 (0.03)	21.67 (0.28)	29.19 (0.53)	31.68 (0.03)
	Inside bottle	19.32 (0.31)	15.82 (0.31)	21.00 (0.32)	21.00 (0.28)	30.66 (0.88)	24.15 (0.51)
	<b>Temperature difference (inside/outside)</b>	<b>1.53</b>	<b>2.36</b>	<b>0.19</b>	<b>0.67</b>	<b>1.47</b>	<b>2.47</b>
240	Outside bottle	23.19 (0.03)	21.52 (0.26)	21.52 (0.26)	21.67 (0.26)	25.19 (0.03)	26.69 (0.03)
	Inside bottle	22.16 (0.53)	20.33 (0.31)	21.83 (0.31)	21.33 (0.31)	25.50 (0.60)	34.15 (0.51)
	<b>Temperature difference (inside/outside)</b>	<b>1.03</b>	<b>1.19</b>	<b>0.19</b>	<b>0.34</b>	<b>0.31</b>	<b>0.64</b>
480	Outside bottle	24.52 (0.26)	23.02 (0.26)			23.69 (0.03)	25.02 (0.26)
	Inside bottle	24.33 (0.31)	22.66 (0.03)			23.83 (0.31)	27.33 (0.31)
	<b>Temperature difference (inside/outside)</b>	<b>0.19</b>	<b>0.36</b>			<b>0.14</b>	<b>0.19</b>
720	Outside bottle	24.16 (0.03)	23.19 (0.03)			23.19 (0.03)	24.19 (0.03)
	Inside bottle	24.19 (0.03)	22.83 (0.31)			23.00 (0.19)	24.16 (0.03)
	<b>Temperature difference (inside/outside)</b>	<b>0.03</b>	<b>0.36</b>			<b>0.19</b>	<b>0.03</b>

**Table 7.4. In vitro data indicating temperature differences (°C) at time points 0-12 hours (when datalogger is secured to the outside of feeding bottle)**

		0	1	2	4	8	12
	<5°C	-1.5	-3	-1.5	-1	-<0.5	±<0.5
125ml	ambient	±<0.5	±<0.5	±<0.5	±<0.5	-	
	>70°C	+14	+4.5	+1.5	+0.5	+<0.5	±<0.5
	<5°C	-1	-4	-2.5	-<0.5	-0.5	±<0.5
260ml	ambient	±1	±0.5	±1	±0.5	-	
	>70°C	+11	+5	+2.5	+0.5	+<0.5	±<0.5

*All figures rounded to nearest 0.5°C*

Cumulatively, in-vitro and in-situ validation data were compared and data was consistent, with 88% of end-point temperatures (immediately before feeding) were within 1°C of each other.

Interpretation of in-situ time temperature profiles of infant feeds provided by parents and day nurseries (using a datalogger attached to the outside of feeding bottle) will account for the datalogger lag and be in accordance to validation data presented in section 7.4.1.

### **7.3.3 Time temperature profiles of feeds served in day nurseries**

Cumulatively, 13% (n=2) of nurseries approached to participate in this part of the study agreed to take part. Both nurseries dealt with PIF feeds for infants in their care in different ways. Having conducted the focus groups (Chapter 2), postal questionnaires (Chapter 4) and undertaken preliminary observations of cleaning, sterilisation, preparation, handling and storage practices in day nurseries in this and other research studies (Redmond and Griffith, 2007) it was considered that the practices implemented in the nurseries that participated in this part of the study were not atypical.

- Nursery A provided the study with profiled data for 10 reconstituted PIF feeds, each of which were prepared in the morning on the nursery premises by nursery nurses. Dataloggers were attached to feeding bottles immediately before water was added to the feeding bottle (i.e. before reconstitution).
- Nursery B provided the study with profiled data for 45 reconstituted PIF feeds brought to the nursery, reportedly prepared by parents; such feeds were of varying temperatures on arrival at the nursery.

**7.3.3.1 Descriptive analysis of infant feeds made-up in day nursery A in the morning for use throughout the day (n=10) (Data collected May, 2009)**

All PIF feeds in the nursery were prepared using boiled tap water, which had been cooled for more than 30 minutes in the kettle. All feeds were prepared in 260ml bottles and volume of feed ranged from 4-6fl oz<sup>10</sup>. All feeds were cooled at ambient temperature for durations ranging from 32 minutes to 1 hour before being stored in a refrigerator for between 55 minutes and 5 hours, 30 minutes.

Data in Table 7.5 indicates that the mean end temperatures for feeds stored in excess of 100 minutes was 4.1°C, whereas the mean end temperature of feed stored for <100 minutes was 21°C.

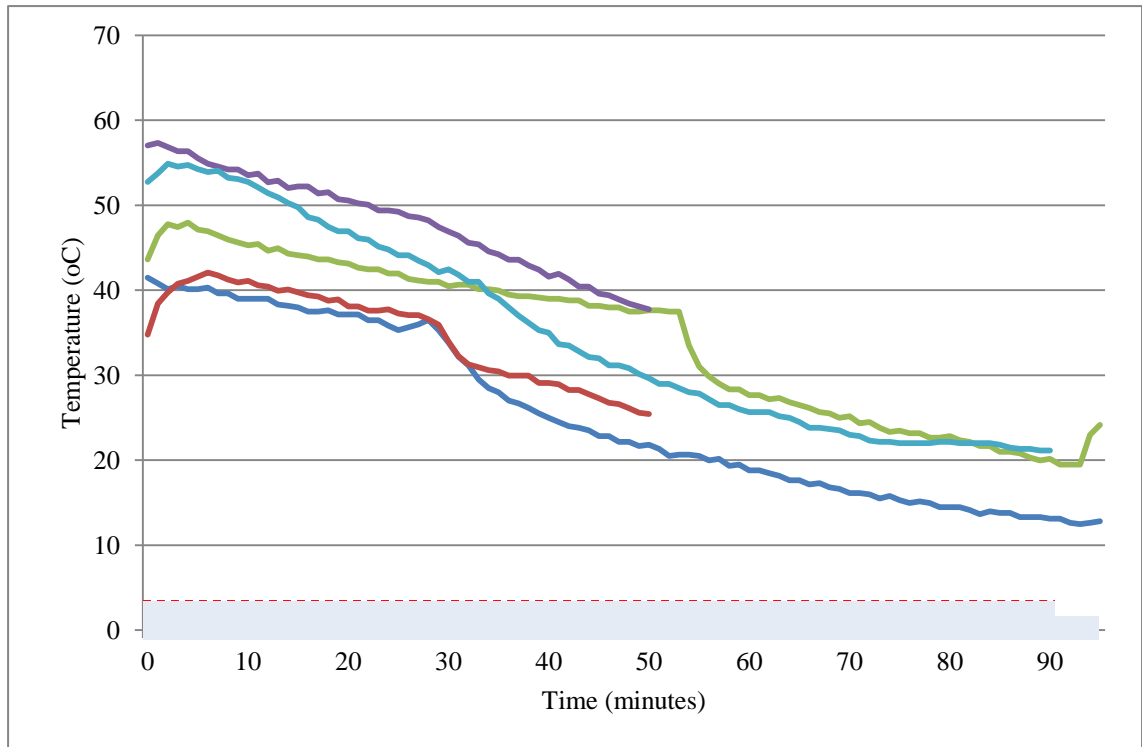
**Table 7.5 Summary of time temperature data from powdered infant formula feeds made-up and stored in a day nursery (n=10) (NB values are a direct temperature from the datalogger attached to the outside of the bottle)**

	Starting temperature				End temp			
	Mean	SD	Min	max	Mean	SD	Min	max
Storage <100 minutes	43.4	5.2	37.2	49.1	21.1	8.4	11.2	33.6
Storage >100 minutes	43.2	5.8	35.7	50.1	4.1	2.4	1.1	6.6
<b>ALL FEEDS</b>	<b>43.3</b>	<b>5.2</b>	<b>35.7</b>	<b>50.1</b>	<b>12.6</b>	<b>10.7</b>	<b>1.1</b>	<b>33.6</b>

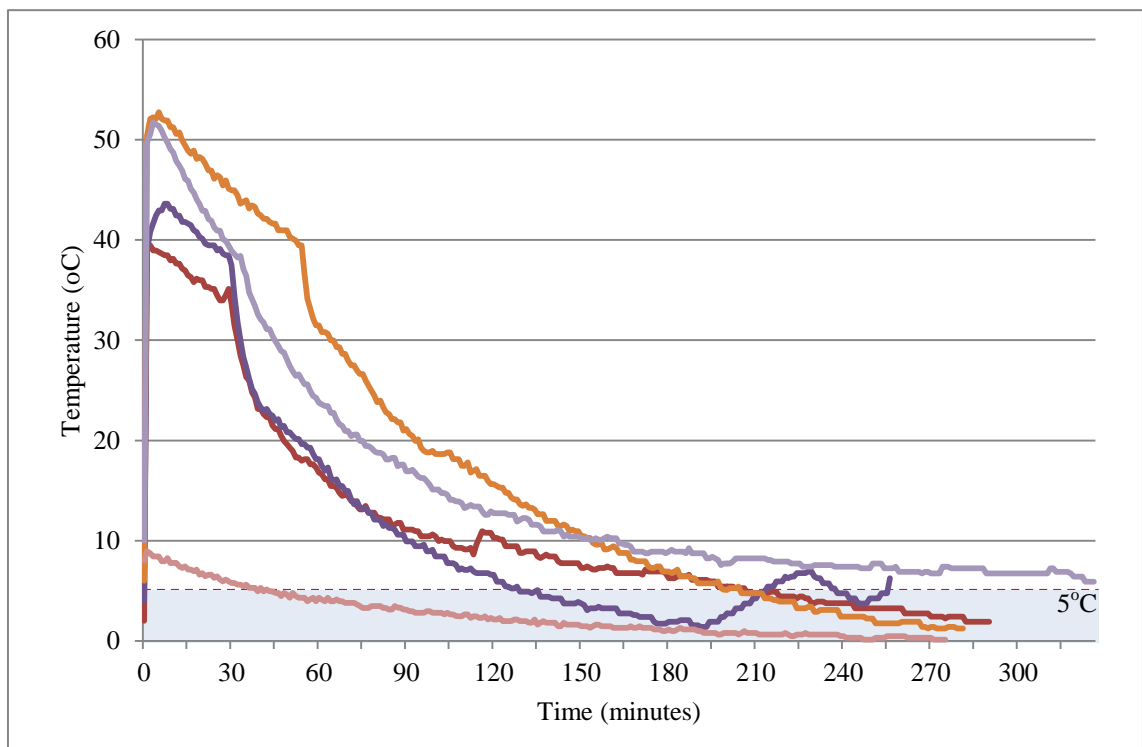
Figures 7.11 and 7.12 illustrate time- temperature profiles of reconstituted PIF feeds stored in day nursery A. It can be seen that some, although not all, feeds reached temperatures <5°C.

<sup>10</sup> Approximate ml/fl oz conversion for preparation of single feeds= 3fl oz = 90ml (according to SMA formula tin)

**Figure 7.11** Time temperature profiles of reconstituted powdered infant formula feeds prepared in day nursery A for feeding within <100 minutes of preparation (n=5). (Nb Data adapted according to validation findings)



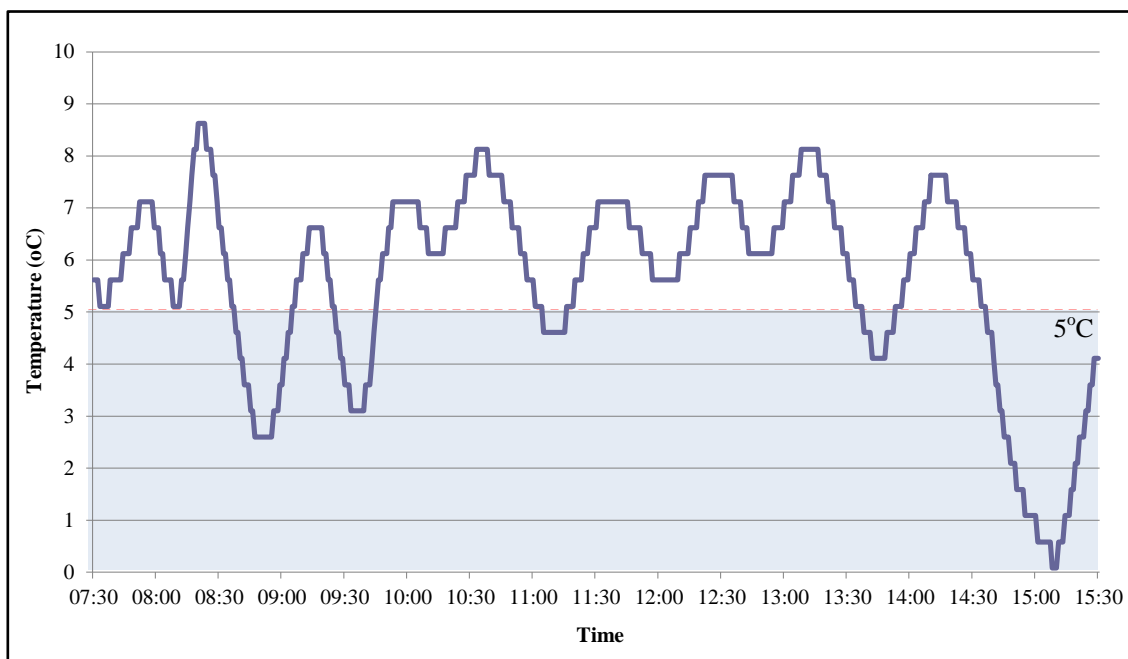
**Figure 7.12** Time temperature profiles of reconstituted powdered infant formula feeds prepared in day nursery A for feeding within >100 minutes of preparation (n=5). (Nb Data adapted according to validation findings)





The temperature profile of the refrigerator used to store 4 x 260ml bottles of reconstituted PIF in nursery A (between 0730 -1530) is presented in Figure 7.13. It can be seen that the refrigerated formula only achieves <math> < 5^{\circ}\text{C}</math> for <math> < 50\%</math> of the time throughout the day.

**Figure 7.13 Time-temperature profile of the refrigerator used to store reconstituted infant feeds in day nursery A over a period of one day (0730-1530)**



Data shown in Table 7.6 indicates that the maximum temperature reached was  $8.6^{\circ}\text{C}$  and the minimum temperature was  $0.6^{\circ}\text{C}$ .

**Table 7.6. Summary of temperature data recorded over 6 hours in the refrigerator used to store infant formula feeds in day nursery A (n=5)**

	Refrigerator temperature				Kitchen temperature
	Mean temperature (°C)	Maximum temperature (time 24hrs)	Minimum temperature (time 24hrs)	Temperature change (°C) after freshly made feeds placed in fridge	Mean temperature recorded during 0800-1030 (max daily temp)
0730-1530	5.6	8.6 °C (0820)	0.6°C (1508)	5.1-8.6	24.6 (25.7)

**7.3.3.2 Descriptive analysis of infant feeds prepared by parents and brought to day nursery B for use throughout the day (n=45) (Data collected May-June, 2009)**

All reconstituted infant feeds were brought to the nursery B between 0800-1000 (84% arrived between 0800-0900). Thirty six percent of feeds (n=16) had been reportedly made-up by parents the previous evening; the remaining 64% of feeds (n=29) had been reportedly made-up the morning before nursery. All feeds were reportedly brought to the nursery in a carrier bag/general bag/child’s bag where no use of cool bags or frozen cool packs was observed. Time of feeding the made-up PIF feeds monitored for profiling during the study ranged from 0950 to 1630 with the majority of feeds being fed between 1300 and 1400. In total, 15.5% feeds brought to the nursery were 3-4fl oz (85-113ml); 44.5% were 5-6fl oz (142-170ml) and 40.8% were 7-8fl oz 198-227ml). No significant difference in the end temperature of feeds of different volumes was determined (p=0.63) (Anova).

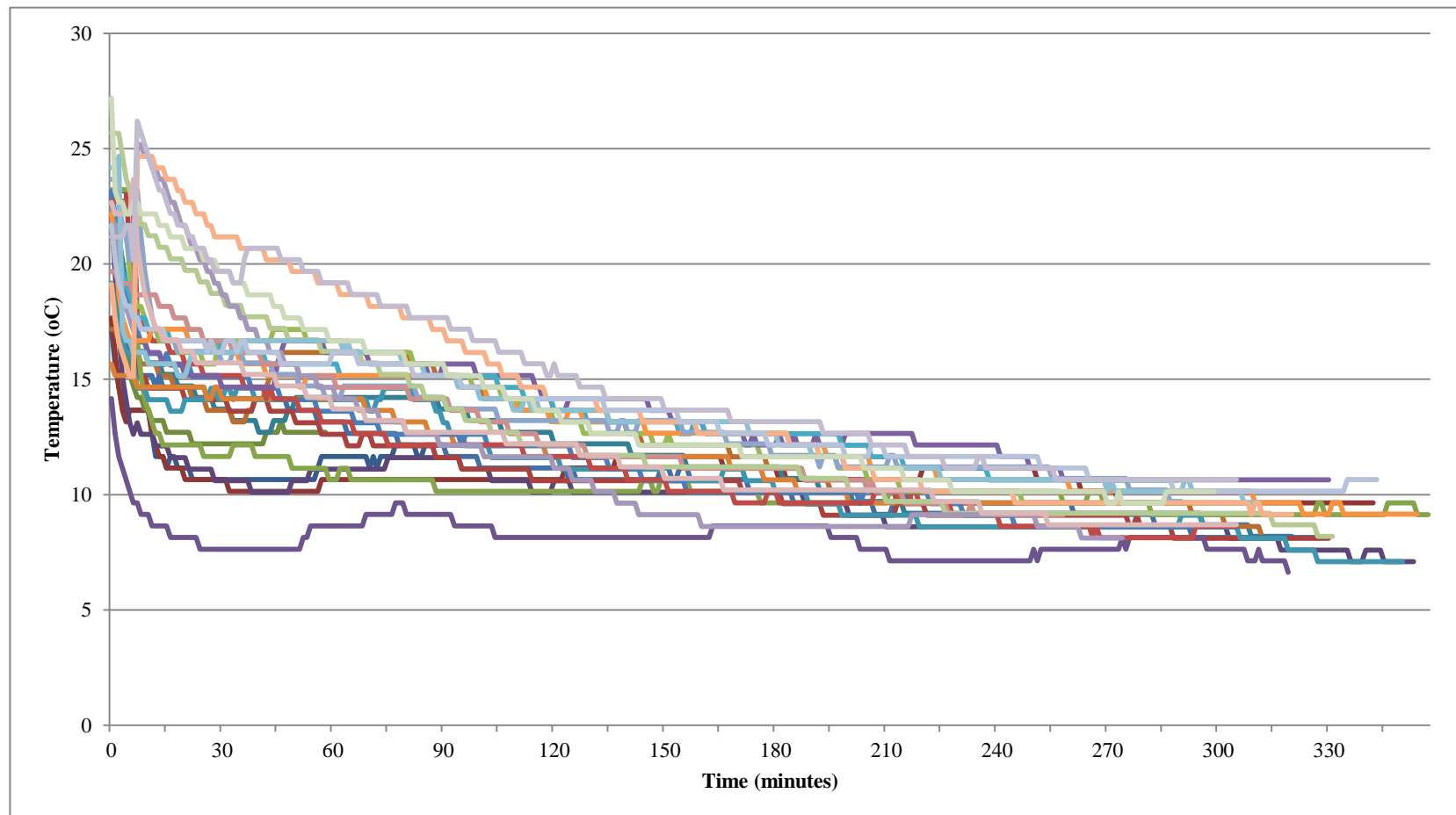
On arrival at the nursery, staff were asked to record their perceived sense and description of bottle temperature (recorded as ‘cold, room temperature or very warm’). This information may be subjective and will have been noted by more than one member of the nursery staff. However, all feeds described as ‘cold and room temperature’ ranged from 14.6 – 27.19°C and feeds considered ‘very warm’ ranged from 37.2-52.1°C. Although significant difference (p<0.01) in temperatures was identified between groups of feeds (according to the reported ‘feel’ at the start of datalogging), no significant difference (p=0.36) of temperatures between groups of feeds was determined at the end of datalogging (Anova).

Time-temperature profiles of all feeds (according to initial feed temperature) are presented in Figures 7.14 and 7.15. Findings illustrate that the external temperature of reconstituted feeds was variable, ranging from 14.2 to 52.1°C. In addition, it is of importance to note that even when accounting for the validation external vs. internal data, 98% of reconstituted PIF feeds stored in day nursery B did not achieve temperatures of <5°C during storage (see Table 7.7).

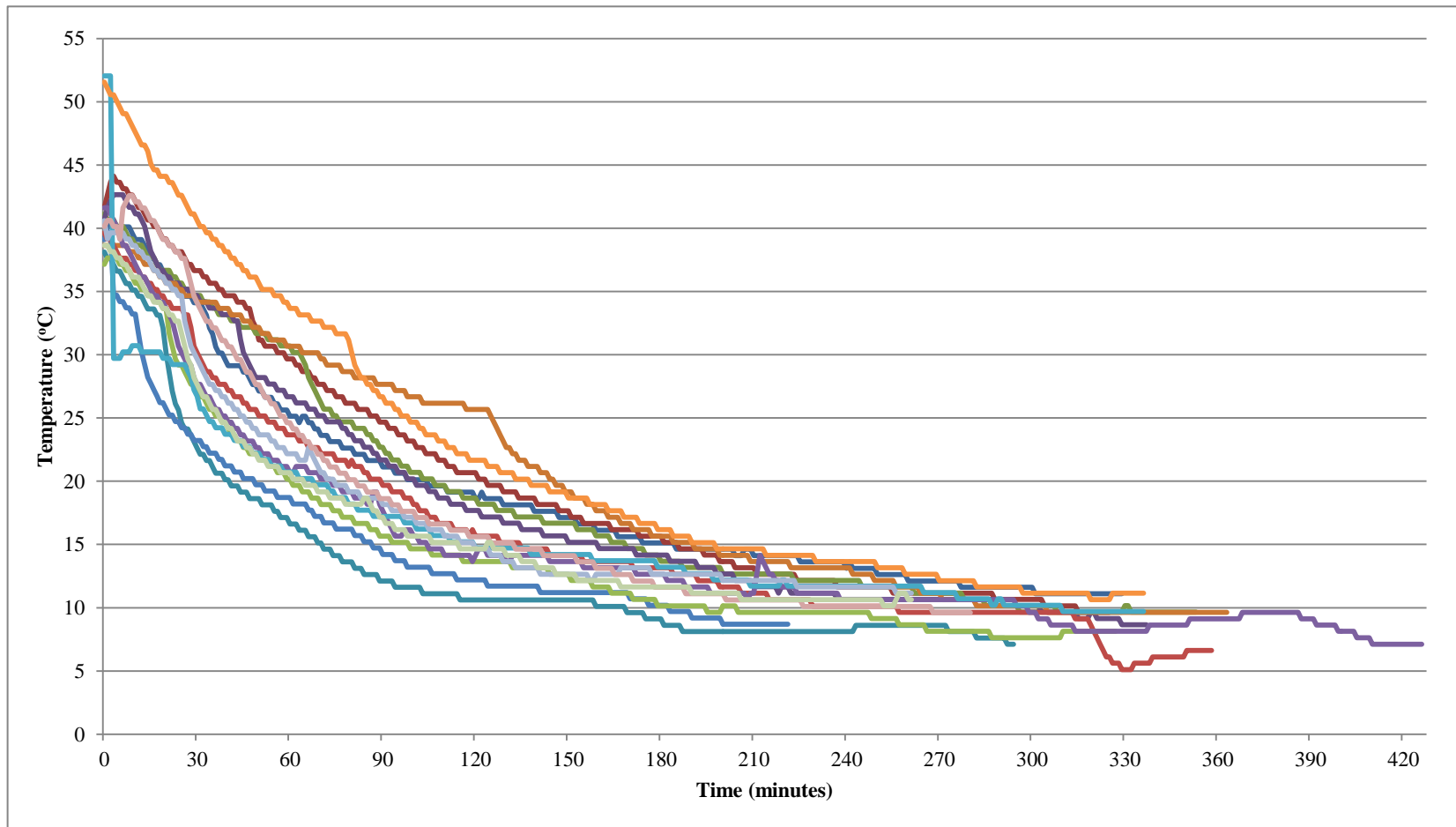
**Table 7.7. Summary of time temperature data from powdered infant formula feeds brought into and stored in a day nursery (n=45)**

Reported ‘feel’ of bottles of made-up feeds on arrival at the nursery	Starting temperature				End temp			
	Mean	SD	Min	max	Mean	SD	Min	max
Cold	20.3	3.1	14.16	23.22	8.9	1.8	6.6	12.7
Ambient	22.6	2.1	19.1	27.2	9.6	0.9	8.1	10.7
Very Warm	41.3	4.4	37.2	52.1	9.3	1.2	6.6	11.2
<b>ALL BOTTLES</b>	<b>28.1</b>	<b>10.1</b>	<b>14.2</b>	<b>52.1</b>	<b>9.3</b>	<b>1.4</b>	<b>6.6</b>	<b>12.7</b>

**Figure 7.14. Time - temperature profiles of reconstituted infant feeds stored in day nursery B for up to 360 minutes: temperature ‘feel’ on arrival at the nursery = ‘cold/ambient’ whereby, initial temperatures ranged from 14.16 – 27.19°C (n=30) (nb values plotted are actual datalogger temperatures from the outside of the bottle)**



**Figure 7.15. Temperature profiles of reconstituted infant feeds stored in day nursery B for up to 360 minutes: temperature ‘feel’ on arrival at the nursery = ‘very warm’ whereby, initial temperatures ranged from 37.15 – 52.15°C (n=15) (nb values plotted are actual datalogger temperatures from the outside of the bottle)**



Reconstituted PIF feeds were stored in nursery B for up to 7 hours 20 minutes before feeding (see Table 7.8). The majority of feeds (85%) were stored for 5-7 hours in the nursery before feeding. Time between arrival of feed in the nursery and placement in the refrigerator were recorded and, although some feeds were placed in the fridge straight away (3%), others remained at ambient temperature for up to 135 minutes (2 hours and 15 minutes). Data presented in Table 7.10 shows that only 15% of feeds were refrigerated within 10 minutes of arrival at the nursery, whereas 45% were refrigerated between 31 - 60 minutes. Sixteen percent were refrigerated over an hour after arrival at the nursery.

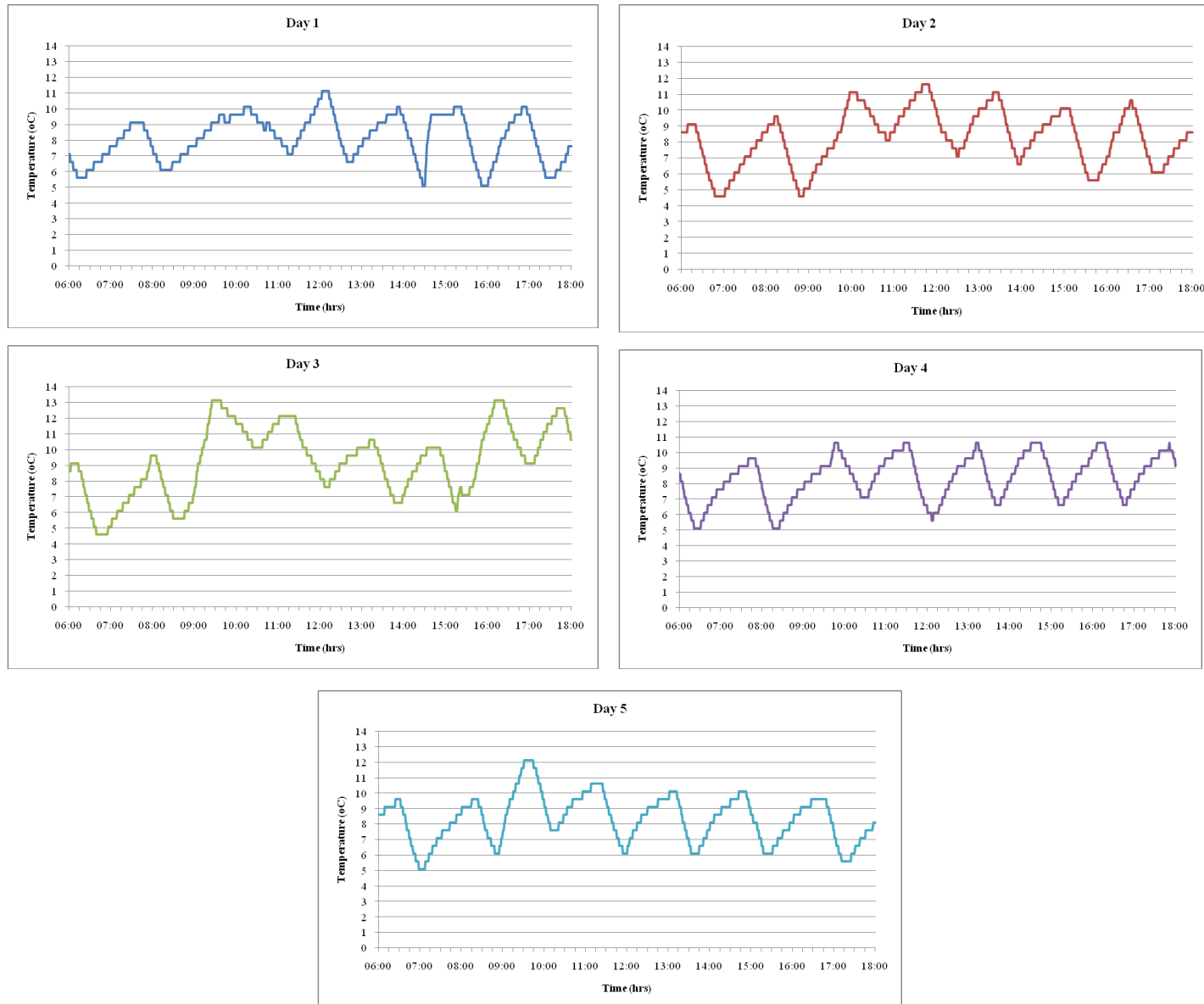
**Table 7.8. Storage of reconstituted powdered infant formula feeds in day nursery B (n=45 feeds)**

	Mean	SD	Min	Max
Time between arrival at the nursery and placement of feed in the fridge	39 minutes	26 minutes	0 minutes	135 minutes
Length of time feed stored in nursery before feeding	5 hours, 4 minutes	7 hours, 20 minutes	1 hour, 30 minutes	7 hours, 20 minutes

**Table 7.9 Reported length of storage time of powdered infant formula feeds monitored for time-temperature profiling in this study (n=45)**

Storage time	n (%) made-up powdered infant formula feeds
<59 minutes	0
01:00hr -01:59 hrs	2 (4)
02:00hr -02:59 hrs	0
03:00hr -03:59 hrs	0
04:00hr -04:59 hrs	4 (9)
05:00hr -05:59 hrs	20 (44)
06:00hr -06:59 hrs	18 (41)
07:00hr -07:59 hrs	1 (2)

**Figure 7.16 Time-temperature profiles of the refrigerator used to store reconstituted infant feeds in nursery B over a period of 5 days**



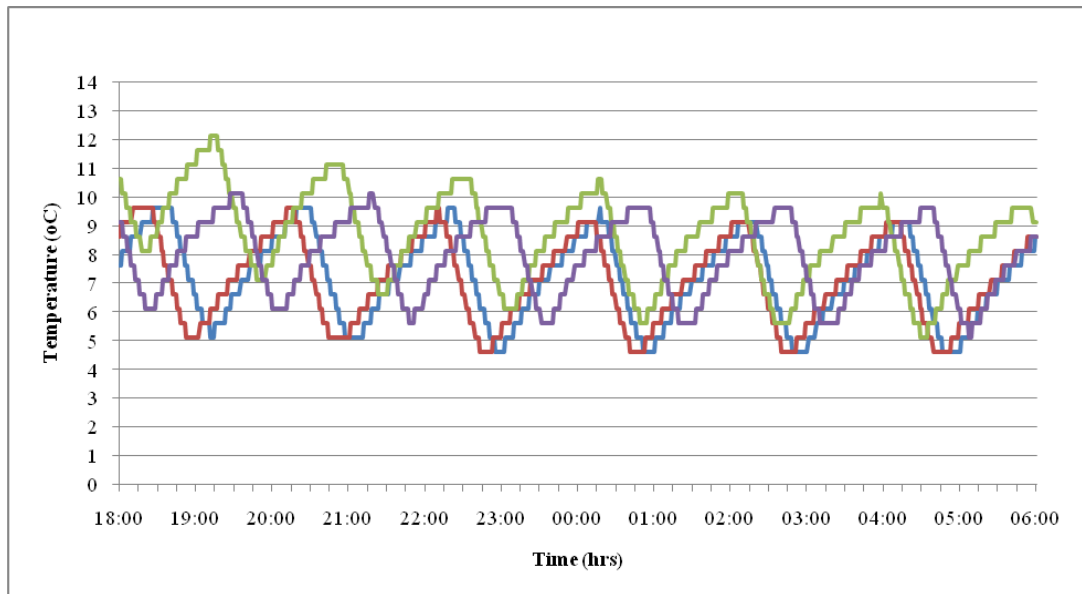
**Table 7.10. Reported time between arrival of feed in the day nursery & refrigerated storage (n=45)**

Minutes	n (%) made-up powdered infant formula feeds
0	1 (2)
1-10	6 (13)
11-20	8 (17)
21-30	3 (7)
31-40	11 (24)
41-50	5 (11)
51-60	4 (10)
61-70	4 (10)
71-80	1 (2)
81-90	1 (2)
91 or more*	1 (2)

\* = 135 minutes

During the course of datalogging during an individual day, approximately 15 made-up feeds were stored in the refrigerator, this was reported to be typical by nursery staff, although it was also reported that, depending on the number of infants during day care, the number of bottles stored could be more. It was reported that the majority of feeds were stored on the top shelf of the refrigerator. Time temperature profiles of the refrigerator used to store such feeds in nursery B are presented in Figures 7.16 and 7.17. The maximum temperature recorded for the refrigerator in nursery B was 13.2°C (see Table 7.11). When nursery B was closed (1800-0800) time temperature data for the refrigerator indicated fluctuations in temperature of 5-6°C. However, increased fluctuations in temperature between 0800-1030 can also be observed each day – this is the time when reconstituted feeds made-up by infants parents are brought to the nursery and likely to be placed into the refrigerator for storage.

**Figure 7.7 Time-temperature profile of the refrigerator used to store reconstituted infant feeds in nursery B over a period of four nights**



**Table 7.11. Summary of temperature data recorded over 120 hours in the refrigerator used to store infant formula feeds in nursery B**

	Refrigerator temperature			Temperature change (°C) between ~0800 and ~1030	Kitchen temperature
	Mean temperature (°C) 0600-1800	Maximum temperature (time 24 hours)	Minimum temperature (time 24 hours)		Mean temperature recorded during 0800-1030 (max daily temp)
Day 1	6.1	11.1°C (1203)	5.1°C (1427)	6.0-10	24.6 (25.7)
Day 2	7.2	11.6°C (1139)	4.6°C (0846)	4.6-11.1	25.3 (26.7)
Day 3	8.5	13.2°C (0925)	4.6°C (0646)	5.6-13.2	24.7 (26.2)
Day 4	8.3	10.6°C (0945)	5.1 °C (0815)	5.1-10.6	23.7 (25.7)
Day 5	8.3	12.1°C (0931)	5.1 °C (0700)	6.1-12.14	24.7 (24.7)



### **7.3.4 Time temperature profiles of feeds prepared in advance and served inside and outside of the home** (*Data collected July-October, 2010*)

In total, 143 time temperature profiles of reconstituted PIF feeds were obtained. Storage times of profiled made-up feeds ranged from 1 hour 56 minutes to 24 hours, 26 minutes. Variable storage practices implemented by parents were represented when managing reconstituted PIF feeds inside and outside of the home.

Time-temperature profiles included feeds subject to the following ‘real-life’ storage practices:

- Reconstituted feeds only stored at ambient temperature from preparation to feeding (n=48) for periods of time up to 21 hours, 15 minutes.
- Reconstituted feeds stored at ambient temperature (up to 11 hours, 19 minutes) followed by refrigeration (n=80) (for cumulative storage time of up to 24 hours 26 minutes).
- Reconstituted feeds stored at ambient temperature followed by storage in the refrigerator and then in a cool bag with ice/freezer packs (n=6) for periods of time from 41 minutes up to 8 hours 34 minutes in the cool bag (after between 11-18 hours in the refrigerator).
- Reconstituted feeds stored at ambient temperature followed by storage in the refrigerator and then in a cool bag with no ice/freezer packs (n=3).
- Reconstituted feeds stored at ambient temperature followed by ambient storage in a baby bag (no cool or insulated compartment and no ice/freezer packs) (n=6).

Scenarios noted above included variations in volume, reconstitution temperatures, length of time stored at ambient/refrigeration temperature and variable corresponding ambient and refrigeration temperatures.

Background information indicated that 10% of feeds were prepared for infants aged 3-4 months; 25% for infants aged 5-6 months; 25% aged 7-8 months; 2% aged 9-10 months and 20% for infants aged 11-12 months.

Ten percent of feeds were 240ml<sup>11</sup>, 71% were 260ml and 19.1% were 300ml. Size of feeding bottles reported were 260ml and 300ml (no smaller than 125ml feeding bottles were profiled).

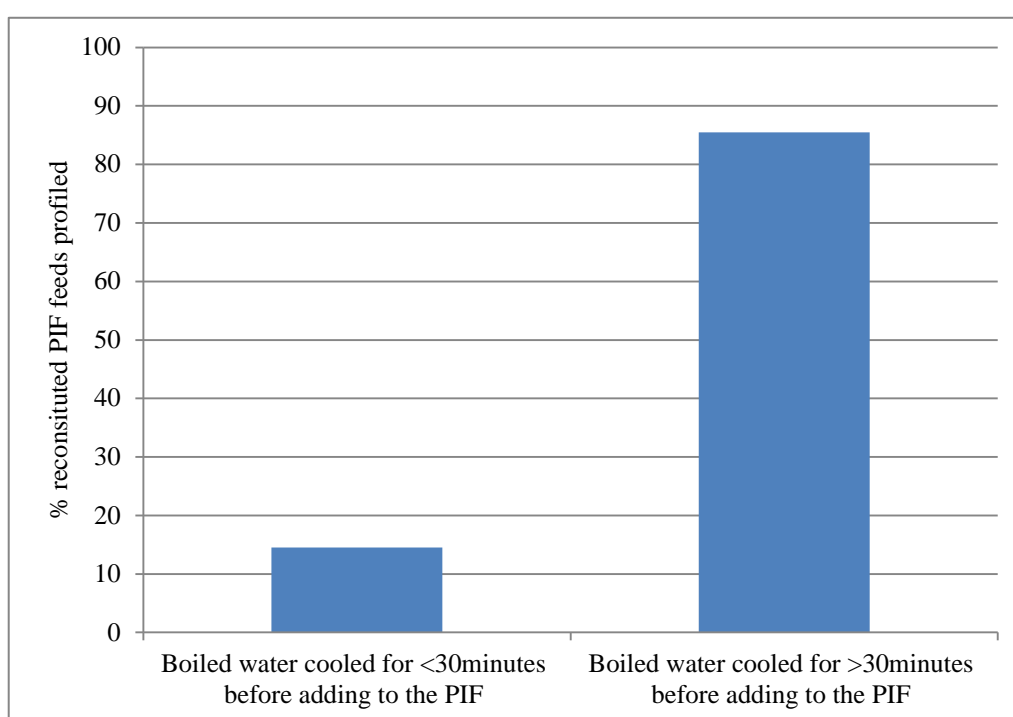
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<sup>11</sup> Approximate ml/fl oz conversion for preparation of single feeds= 3fl oz = 90ml (according to SMA formula tin)

### 7.3.4.1. Preparation of powdered infant formula feeds

Length of time between end of kettle boiling and reconstitution with PIF was provided with 117 profiles recorded; of these, only 15% of feeds were prepared with boiled water cooled for less than the recommended 30 minutes. Eight-five percent of feeds were reconstituted using boiled water cooled for more than 30 minutes (see Table 7.18). On average, feeds were prepared with water cooled for 52 minutes (minimum boiled water cooling time=14 minutes, maximum 194 minutes, standard deviation (SD) 35 minutes (n=117)).

**Figure 7.18 Proportions of profiled reconstituted feeds prepared with boiled water cooled for more than and less than 30 minutes (n=117 profiles)**



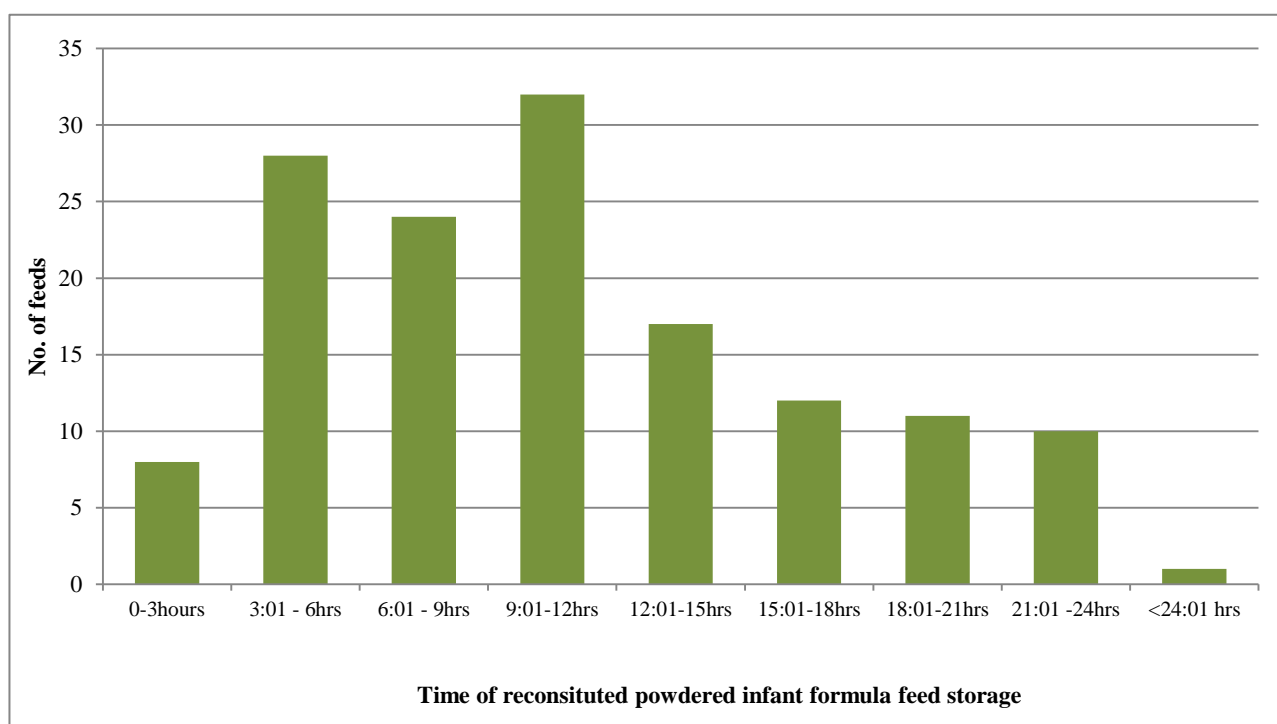
It was reported that 87% of feeds were prepared using boiled water considered to be hot/warm from the kettle, whereas 7% of feeds were reportedly prepared using water cooled to 'room temperature' in the feeding bottle and 6% cooled to 'room temperature' in the kettle.

However once boiled water had been poured into the prepared feeding bottle, PIF was added within 5 minutes for 88% feeds (range <1 minute – 98 minutes).

### 7.3.4.2. Length of storage of reconstituted powdered infant formula feeds

Findings detailing length of reconstituted PIF storage times can be found in Figure 7.19 and Table 7.12. The maximum length of time a reconstituted PIF feed was stored and profiled was 1466 minutes. Twenty two percent of feeds were stored and fed after 9-12 hours, 17% for 6-9 hours and 20% for 3-6 hours. All storage practices, where time temperature profile data was obtained, were reported to be typical of 'in-use' practices by parents taking part in the study.

**Figure 7.19 Storage times of profiled reconstituted powdered infant formula feeds (n=143)**



Data presented in Table 7.12 indicates that parents stored reconstituted PIF feeds for up to 21 hours 15 minutes at ambient temperature<sup>12</sup>. Findings also showed that feeds which were not stored in the fridge were stored at ambient temperature for periods ranging from 2 hours 17 minutes to 19 hours 44 minutes. Made-up feeds stored away from the home were stored in bags with no insulation or freezer packs for up to 8½ hours. Feeds were also stored in insulated bags with freezer packs for 8 hours and 34 minutes and without freezer packs for up to 3 hours and 5 minutes.

<sup>12</sup>The main reason given as to why the parent who stored reconstituted powdered infant formula feeds for long periods of time at ambient temperature did so, was because she had been [reportedly] told (by a friend) that the recommendations for preparing and storing feeds had changed (she had previously made-up feeds and stored them in the fridge for her previous three infants). She had been told that made-up feeds should now not be stored in the fridge, so she believed she was implementing the 'new' recommendations by *not* storing them in the fridge, but at room temperature instead.

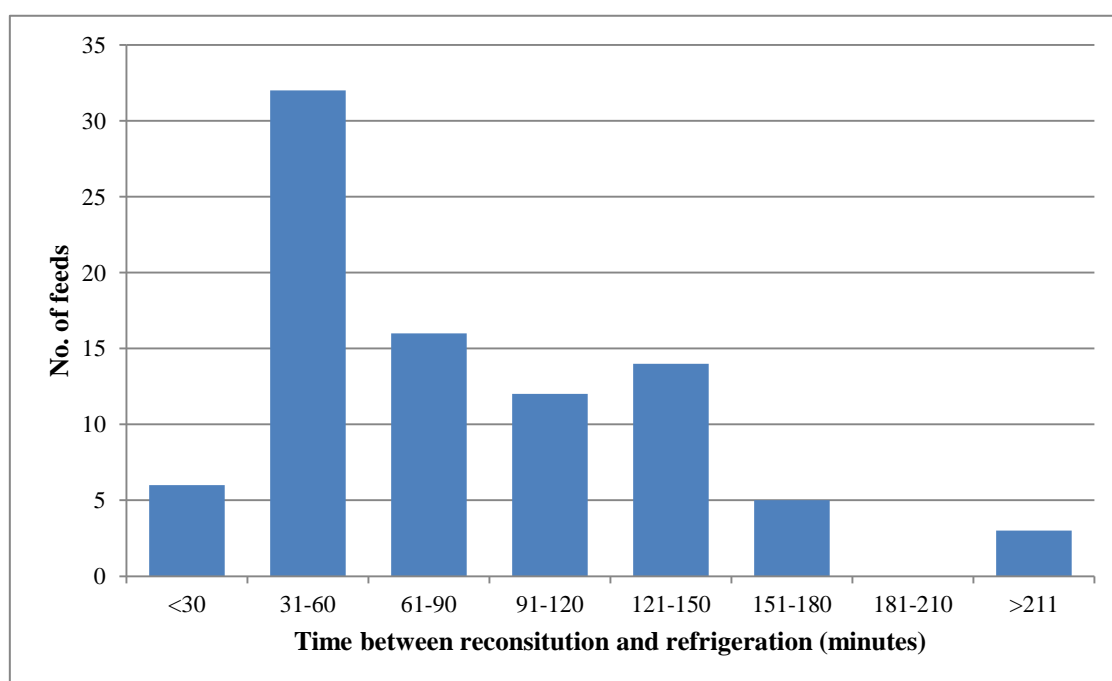
**Table 7.12 Lengths of time profiled reconstituted powdered infant formula were stored at ambient and refrigeration temperatures**

Scenario	n	Total Minimum storage time (minutes)	Total Maximum storage time	Range of storage times at ambient temperature	Range of storage times refrigeration	Storage time cool bag
• Reconstituted feeds only stored at ambient temperature from preparation to feeding	48	1hr 56mins	21hrs 15mins	1hr 56mins-21hrs 15mins	NA	NA
• Reconstituted feeds stored at ambient temperature followed by refrigeration	80	2hrs 59mins	24hrs 26mins	26mins-11hrs 19mins	2hrs 17mins-20hrs 35mins	NA
• Reconstituted feeds stored at ambient temperature followed by storage in the refrigerator and then in a cool bag with ice/freezer packs	6	13hrs 45mins	20hrs 50mins	26mins-48mins	11hrs 24mins-18hrs 35mins	1hr 16mins-8hrs 34mins
• Reconstituted feeds stored at ambient temperature followed by storage in the refrigerator and then in a cool bag with NO ice/freezer packs	3	15hrs 45mins	22hrs 51mins	48mins-3hrs 45mins	9hrs 37mins-19hrs 44mins	2hrs 7mins-3hrs 5mins
• Reconstituted feeds stored at ambient temperature followed by ambient storage in a baby bag (no cool or insulated compartment and no ice/freezer packs)	6	4hrs 2mins	9hrs 47mins	31mins -4hrs 28mins <i>(before placement in the baby bags)</i>	NA	1hr 46mins-8hrs 30mins
All profiled feeds	143	1hr 56mins	24hrs 26mins	26mins-21hrs 15mins	2hrs 17mins-19hrs 44mins	1hr 16mins-8hrs 34mins

### 7.3.4.3. Refrigerated and ambient storage of reconstituted powdered infant formula feeds

Eighty nine (62%) reconstituted profiled PIF feeds were stored in the refrigerator at some stage during storage. The time between PIF feed reconstitution and placement in the refrigerator was calculated and results are presented in Figure 7.20. Data indicated that time between reconstitution and refrigeration ranges from 26-679 minutes (average = 90.90 minutes, SD=779.41 minutes). Six feeds were refrigerated within 30 minutes of reconstitution, whereas a further 32% were refrigerated after 31-60 minutes ambient storage; 22% were stored at room temperature for more than 2 hours before refrigeration.

**Figure 7.20 Length of time between powdered infant formula feed reconstitution and placement in the refrigerator (n=89)**



Position profiled feeds stored in the refrigerator – data provided for 89 profiled events

- 32 (36%) feeds were stored ‘on the middle shelf’ of the fridge
- 27 (30%) feeds were stored at the ‘bottom and back of the fridge’
- 15 (17%) feeds were stored ‘in the door’ of the fridge
- 15 (17%) feeds were stored ‘in the door and on the middle shelf of the fridge’

Ambient temperatures where reconstituted feeds were stored ranged from 18.72-28.17°C (see Table 7.13), typically increasing in temperature during the day and cooler at night.

**Table 7.13 Summary of ambient temperature profiles (5-7 day periods) recorded where reconstituted powdered infant formula was being stored for variable lengths of time**

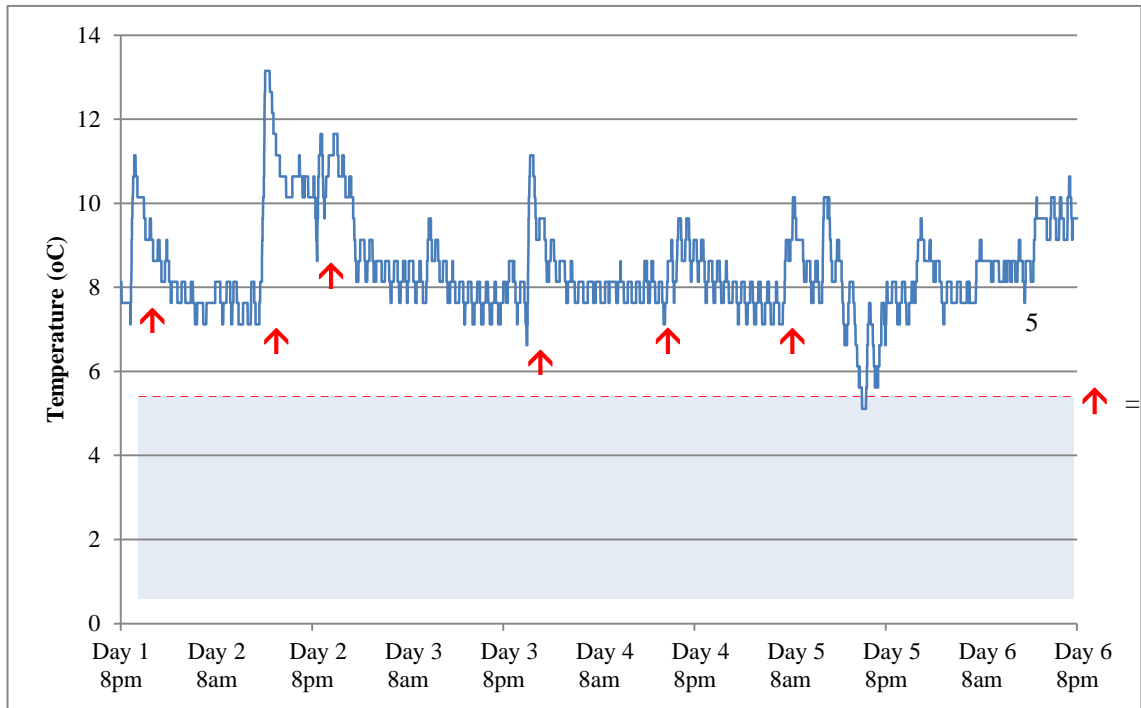
Date	Participant	Minimum temperature	Maximum temperature	Mean temperature	Standard Deviation
August, 2010	007	20.13	26.63	22.09	0.73
August, 2010	016	18.72	25.72	20.65	0.86
August, 2010	019	20.67	28.17	23.14	1.03
October, 2010	036	20.72	26.72	23.64	1.42

Figure 7.21 illustrates two time temperature profiles of parent fridges where PIF feeds were stored.

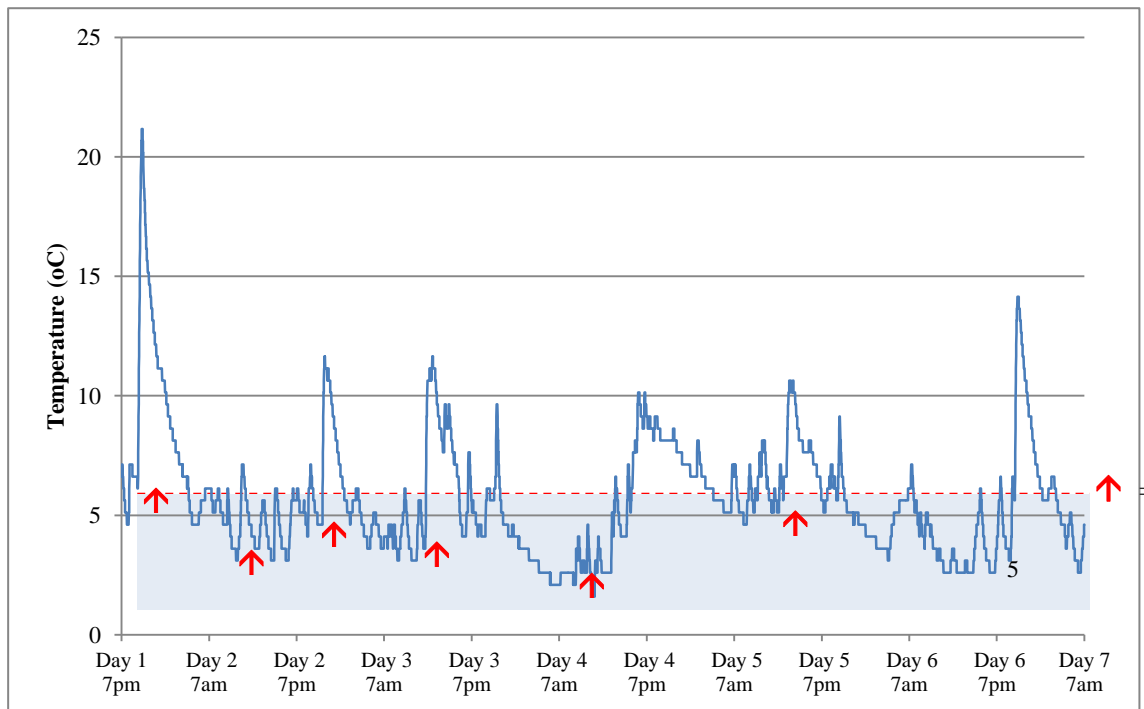
- Participant 016 (top graph profile) allowed between 64-227 minutes at room temperature between reconstitution and placement of two to four feeds the refrigerator. Made-up feeds were stored in this refrigerator for period of up to 15 hours and 58 minutes. For this fridge, it can be seen that temperatures exceed  $<5^{\circ}\text{C}$  for  $>99\%$  of minutes during the five and a half day profiling period.
- Participant 036 (bottom graph profile) allowed between 40-679 minutes at room temperature between reconstitution and placement of one to three made-up feeds into the refrigerator. Subsequently, these feeds were stored in the refrigerator for up to 12 hours, 11 minutes. For this fridge, it can be seen that temperatures exceed  $<5^{\circ}\text{C}$  for 41.3% of minutes during the six and a half day profiling period.

For both fridge temperature profiles illustrated in Figure 7.21, temperature increases in the refrigerator can be observed when made-up feeds (which may be still warm/ambient temperature) are placed into the refrigerator.

**Figure 7.21 Time temperature profiles of fridges where reconstituted powdered infant formula feeds were stored**



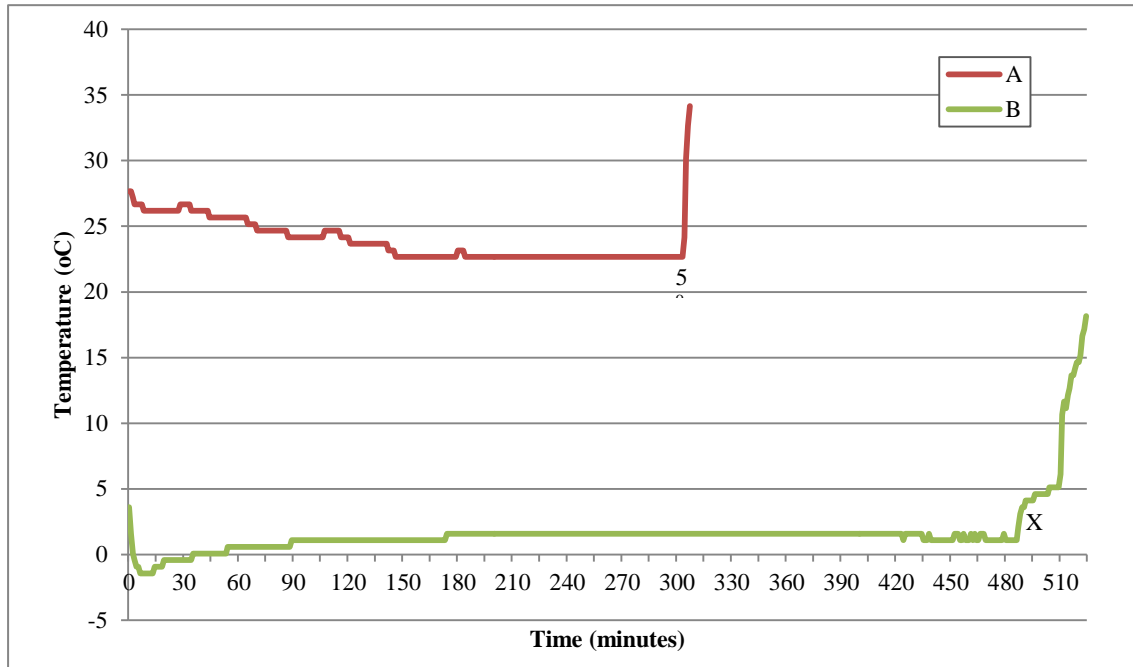
*Participant 016, August, 2010*



*Participant 036, October, 2010*

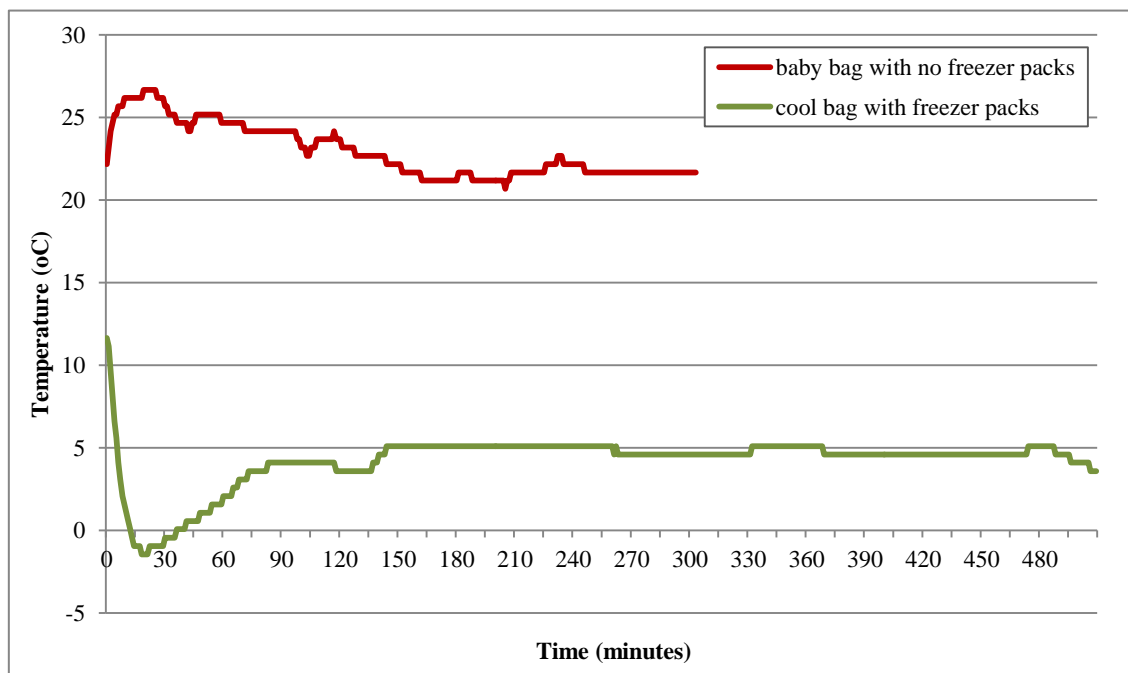
7.3.4.4. Storage of reconstituted powdered infant formula feeds away from the home.

**Figure 7.22** Example of two time temperature profiles of reconstituted powdered infant formula feed stored away from the home, in a normal compartment of a baby bag (A) and in a cool bag with freezer packs (B)



X=reheating feed & start of feeding temperatures  
 (nb values plotted are actual datalogger temperatures from the outside of the bottle)

**Figure 7.23** Corresponding air temperature profiles for reconstituted powdered infant formula feeds stored in a cool bag with freezer packs and normal compartment of baby bag (no freezer packs)



(nb values plotted are actual datalogger temperatures from the outside of the bottle)



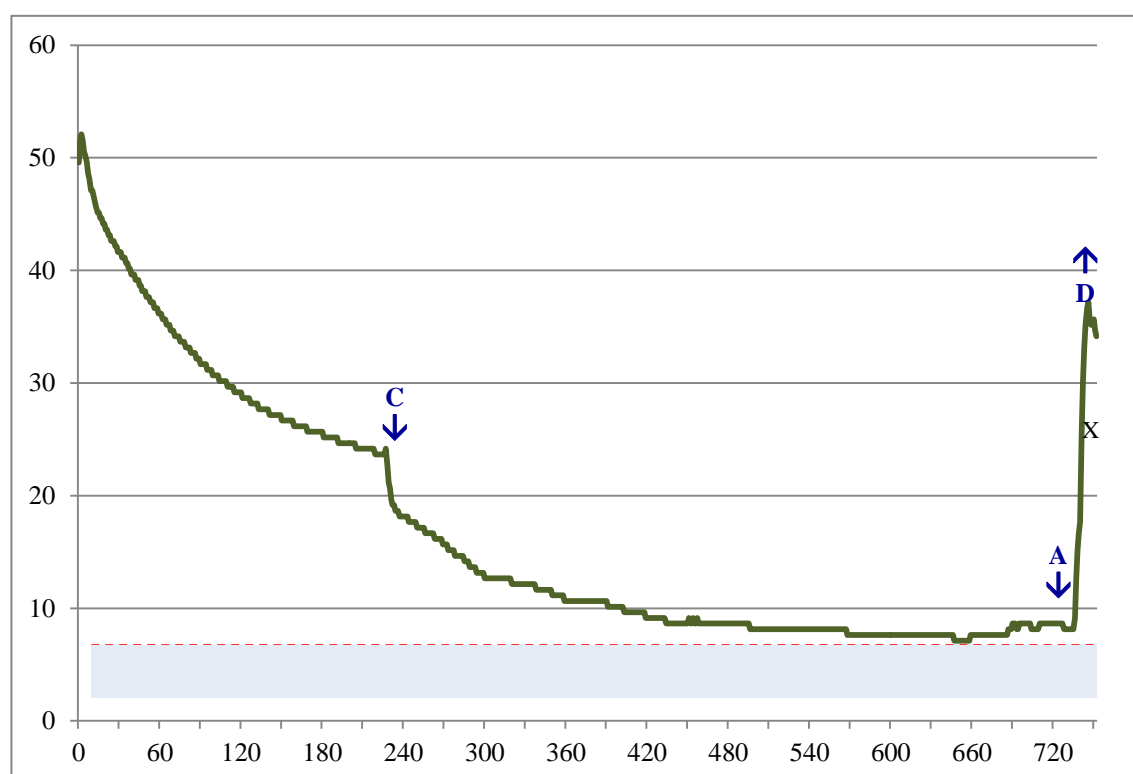
Overall dataloggers were attached to 10% (15/143) reconstituted PIF feeds taken and fed away from the home and this required alternative storage practices. Six percent of feeds were stored in an insulated cool bag/compartment of a baby bag, of which 3% were stored alongside two to three freezer packs. Time temperature profiles of examples of feeds stored away from the home are presented in Figure 7.22. Corresponding air temperatures in the same point of the cool bag/baby bag are presented in Figure 7.23. It is clear that reconstituted infant feed temperatures are kept colder when using the freezer packs in an insulated cool bag than in a normal insulated point of a baby bag. This data also suggests that it is possible to store made-up feeds at <math><5^{\circ}\text{C}</math> when away from the home.

#### ***7.3.4..5. Reheating of reconstituted powdered infant formula feeds before feeding.***

Data regarding feed reheating before feeding was obtained for 120 (84%) of profiled feeds. Of these, 73% of feeds were reheated before feeding, the remaining were not reheated. In 90% of cases, reheating was performed by microwaving bottles of made-up feed for between 20–75 seconds in microwaves with wattage ranging from 800-900watts. Other methods reportedly used for reheating included use of an electric bottle warmer for between 70 seconds – 5 minutes or immersion of the feed into a jug of boiled water for 10 minutes. Time temperature profiling of feeds during reheating was not possible as dataloggers were not water/microwave proof – however, some participants reattached the dataloggers to the feeding bottles after reheating, so give an indication of profiles during feeding.

Figure 7.24 illustrates a time temperature profile of the external temperature of a feed from reconstitution to refrigeration and after reheating during feeding, highlighting the variable temperatures a feed may be subject to over long periods of time.

**Figure 7.24 Example of time temperature profile of reconstituted powdered infant formula feed stored at room temperature, in the fridge and reheated for feeding**



A= Placement of feed in refrigerator; B=removal of datalogger for reheating (microwave 850W 50 seconds on High); C=reattachment of datalogger after reheating for feeding; D=end of feeding time/profiling.

(nb values plotted are actual datalogger temperatures from the outside of the bottle)

#### **7.3.4.6. Length of feeding of reconstituted powdered infant formula feeds**

Overall, time temperature profiles and corresponding data were obtained for the duration of feeding for 86% of reconstituted feeds. Table 7.14 illustrates the variation in length of feeding time observed. Data indicates that the majority of feeds were fed within 6-15 minutes. The maximum length of feeding time was 45 minutes.

**Table 7.14 Length of feeding time**

	No. of feeds (%)
0-5 minutes	11 (9)
6-10 minutes	46 (37)
11-15 minutes	34 (28)
16-20 minutes	11 (9)
21-25 minutes	13 (11)
26-30 minutes	4 (3)
31+ minutes	4 (3)

## 7.4 SUMMARY OF FINDINGS

- There was considerable variation in the time temperature history of reconstituted infant feeds stored in day nurseries and inside/outside of parents' homes. The time temperature profiles of some reconstituted feeds could have allowed microbial proliferation.

### 7.4.1 Day nurseries

- Temperatures of feeds soon after arrival at the day nursery ranged from 14.2-52.1°C.
- No reconstituted feeds brought to the day nursery for use during the day achieved <5°C.
- Refrigerators used to store reconstituted feeds in day nurseries for up to 7 hours and 20 minutes (in the current study) did not consistently run at <5°C as recommended by the FSA Guidance for use of PIF in care settings.
- Reconstituted feeds were not transferred from parents' homes to the day nursery using cool bags or freezer packs – it was reported that all feeds were transported in rucksacks, carrier bags, infants' bag, by hand etc.
- Nursery staff reported being too busy when infants and children arrived at the nursery and frequently did not store made-up feeds in the refrigerator immediately.
- Reported time between arrival at the nursery and storage of reconstituted feeds in the refrigerator ranged from 0-135 minutes (average 39 minutes). 45% of reconstituted feeds were stored at room temperature for 31-60 minutes before refrigeration and 16% for more than 61 minutes. Data indicated that the warmer the feed 'felt' on arrival at nursery, the longer it would remain at room temperature before refrigerated storage.
- Feeds that were too hot to be refrigerated immediately on arrival at the nursery were left at room temperature until suitably cooled or the nursery employee had time to place it in the refrigerator.

### 7.4.2 Parents

- Profiled reconstituted PIF feeds prepared by parents and reportedly fed to infants were stored for 2->24 hours. Parents implemented variable storage practices including at ambient temperature for >21 hours, ambient temperature (for >11 hours) followed by refrigeration (for >24 hours), in cool bags/normal bags with and without cool packs for variable lengths of time.
- Only 15% of feeds were reconstituted with boiled tap water cooled for less than 30 minutes – on average, feeds were reconstituted with boiled water cooled for 52 minutes.

- Made-up feeds were stored away from the home in bags with no insulation or freezer packs for up to 8½ hours before reported feeding.
- Storage of reconstituted feeds in a cool bag with freezer packs maintained a temperature of <5°C to be achieved over a period of 480 minutes.
- Feeding duration for 74% of feeds was <15 minutes; maximum feeding time reported was 45 minutes.

## CHAPTER 8

### PREDICTION OF THE GROWTH OF *CRONOBACTER* SPP. IN RECONSTITUTED POWDERED INFANT FORMULA FEEDS STORED IN DAY NURSERIES AND INSIDE/OUTSIDE PARENTS' HOMES.

#### 8.1 INTRODUCTION

Caregivers are currently advised by the UK FSA to reconstitute PIF with water that has been boiled and left no longer than 30 minutes at room temperature (FSA, 2006) using water  $>70^{\circ}\text{C}$ . Although not advised, data suggests that some caregivers prepare one or more bottles of reconstituted powdered feeds in advance and store them in the refrigerator. However, even if the temperature of the refrigerator is controlled, the temperature of the reconstituted formula itself is not yet controlled. The liquid formula needs time to cool down in the refrigerator and bacteria present in the powder infant formula, or any bacteria present in the bottle or utensils, may start growing during this cooling process. Of particular concern is *E.sakazakii* (*Cronobacter*), a genus in the family of *Enterobacteriaceae*. This bacterium has been shown to be present in very low concentrations in PIF and has been responsible for rare but very severe infections in infants, specifically in neonates ( $< 28$  days) and premature infants (FAO/WHO, 2006).

The cooling rate of the liquid in a baby's bottle depends on the surrounding air temperature, the filling rate, and the air velocities in the refrigerator and the geometry of the food container, the thermal properties of food and bottle, and the volume of the container to be cooled. In household refrigerators, also referred to as static refrigerators, heat transfer at the container surface is principally due to natural convection by a very limited airflow caused by variations in air density. These variations are mainly related to differences in temperature, filling of the fridge, and humidity gradients. In air-ventilated refrigerators, mechanic ventilation forces air convection, which improves heat transfer. Air-ventilated refrigerators are often, but not always, used in hospitals and hospital wards, but have not been included in this study.

##### 8.1.1 Aims and objectives

The overall aim of this part of the project was to model time-temperature profile data to project growth of *Cronobacter* spp. in reconstituted PIF feeds prepared, stored and fed to infants (aged less than 12 months) in day nurseries and inside/outside of parent homes (see Chapter 7).

The more specific objectives were to:

- Relate temperature as measured on the outside of bottles to the temperature in the centre of the bottle filled with infant formula.
- Determine heat transfer coefficients and reconstitution temperatures.
- Project potential growth of *E.sakazakii* (*Cronobacter*) using the risk assessment model for *Enterobacter sakazakii* in PIF by Paoli and Hartnett (2006).

## 8.2 METHODS

Temperatures profiles were measured by sensors placed on the outside of bottles as shown in Figure 8.1B. The inner temperature of the bottle, however, as shown in Figure 8.1A, may differ from the temperature as measured at the outside, specifically in cases in which the temperature difference between formula temperature and air temperature is large. Any heat transfer is driven by the temperature difference between one location and the other, as in equation 1:

$$F_{i\_to\_j} = \alpha \cdot A \cdot (T_i - T_j) \quad \text{Eq. 1}$$

Where  $F$  is the heat flux [W],  $\alpha$  is the heat transfer coefficient [ $\text{W m}^{-2} \text{°C}^{-1}$ ],  $A$  is the area over which heat is transferred, and  $T_i$  and  $T_j$  are the temperatures of locations  $i$  and  $j$  respectively. The temperature difference  $T_i - T_j$  is called the ‘driving force’ for heat transfer. When this equation is applied to the bottles as shown in figures Figure 8.1A and Figure 8.1B, it can be deduced that:

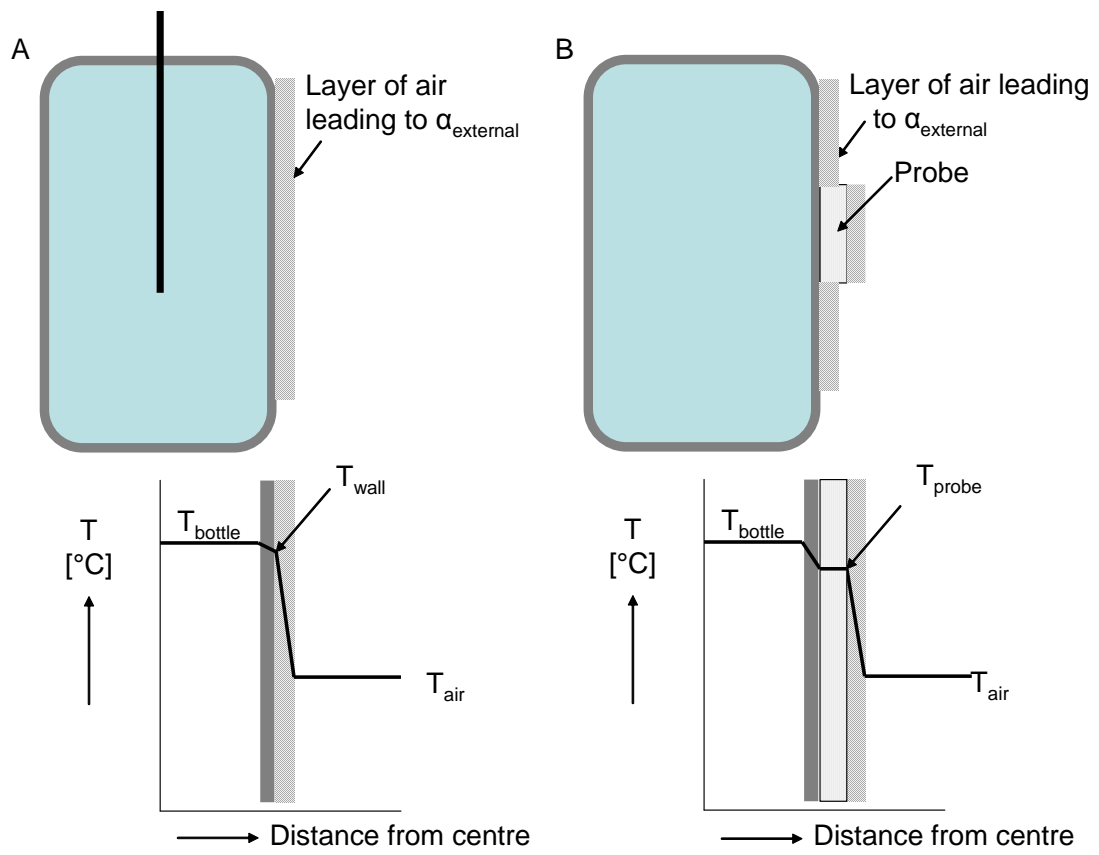
$$F_{bottle\_to\_air} = \alpha_1 \cdot A \cdot (T_{bottle, internal} - T_{air}) = \alpha_2 \cdot A \cdot (T_{probe\_external} - T_{air}) \quad \text{Eq.2}$$

The internal temperature can thus be calculated from the temperature of the external probe using Equation 3:

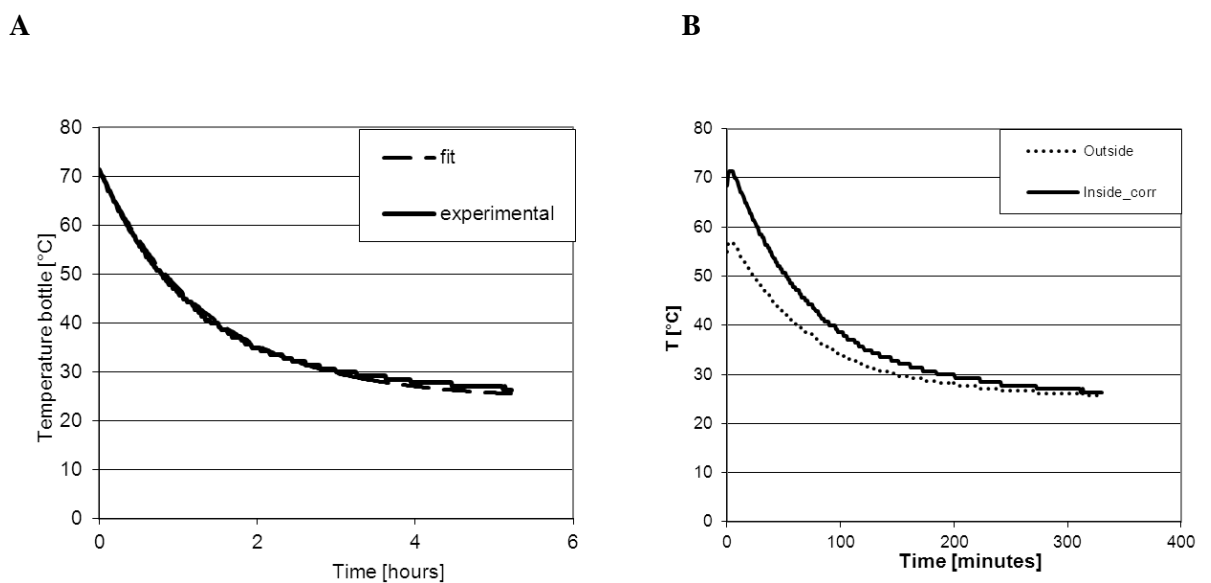
$$T_{bottle, internal} = \frac{\alpha_2}{\alpha_1} \cdot (T_{probe\_external} - T_{air}) + T_{air} \quad \text{Eq. 3}$$

Temperature profiles during cooling were fitted using the solver function in Microsoft Office Excel 2003 by minimizing the residual sum of squares to estimate the overall heat transfer coefficient ( $\alpha$ ) and the air temperature as in Kandhai *et al.* (2009). After fitting the reconstitution temperature was read manually from each individual graph.

**Figure 8.1 Schematic representation of heat transfer with (A) internal probe and (B) external temperature probe**



**Figure 8.2 Results of (A) fitting the heat transfer coefficient ( $\alpha$ ) and air temperature to the measured profiles and (B) comparison of external (dotted) and internal (solid) temperatures. The striped line (A only) shows the fitted profile from which  $\alpha$  is read**



Characteristics of the temperature profiles were used to simulate risk using the risk assessment model for *Enterobacter sakazakii* in PIF by Paoli to obtain the relative risk (Paoli and Hartnett, 2006). All data were gathered and processed in Excel for Windows 2003.

## 8.3 RESULTS

### 8.3.1 Temperature profiles

#### 8.3.1.1 Transforming external temperature to temperature inside bottle

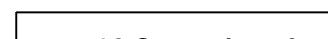
Validation experiments were performed (see Chapter 7) in which both temperature of the external probe and the internal bottle temperatures were measured. Analysis of the validation experiments showed that the temperature measured at the outside of a bottle may differ up to 20°C from the actual temperature inside the bottle. The simplest way of correcting the temperature would be to correct the initial temperature at the start of the experiment by a fixed correction factor. The validation data have been analyzed for linearity as shown in figure 8.3.

**Figure 8.3: The relation between the true temperature difference ( $T_{\text{bottle}} - T_{\text{air}}$ ) at the start of the experiment (y-axis) as a function of the temperature difference measured at the outside of the bottle (x-axis) for (A) two types of bottles and (B) both bottle types combined**

**B**



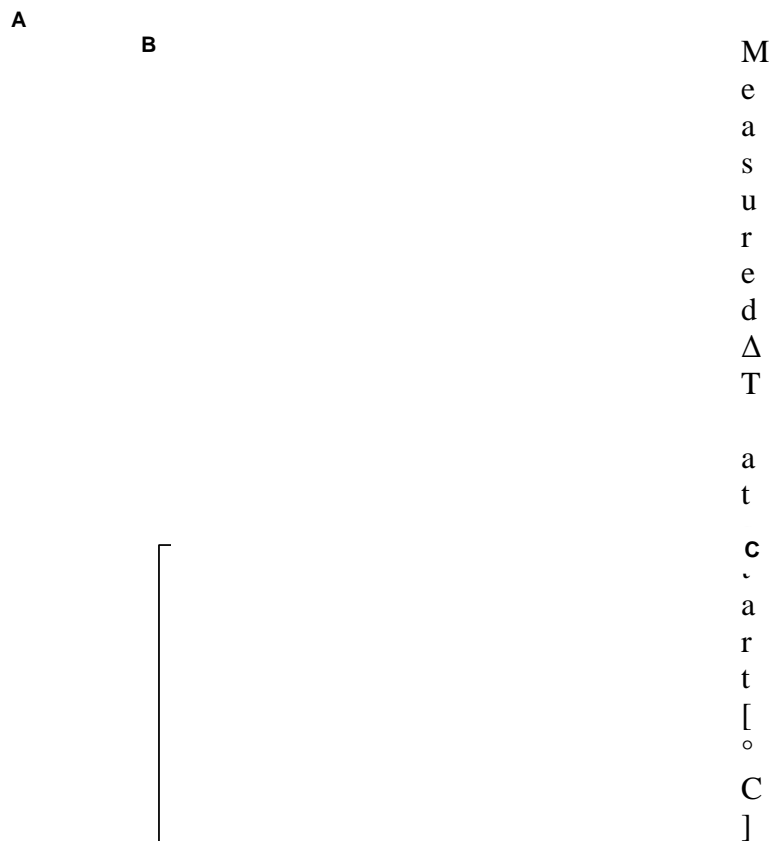
Measured  $\Delta T$  at start



Temperature difference at the start of the experiment is not a linear function of the measured temperature difference. Therefore the temperature of the bottle content at the start of the experiment cannot be deducted from the temperature measured at the outside.



**Figure 8.4 A-D: The driving force, which is the temperature difference between the bottle and the air at the outside ( $T_{\text{bottle}} - T_{\text{air}}$ ). The x-axes show the values as measured at the outside of the bottle, while on the y- axis the actual data as measured in the bottle are shown**



Figures 8.4 A-D show an overview of 12 experiments, representing 125ml and 260ml bottles reconstituted either at 40°C or 70°C. Throughout the experiments the driving force as measured internally ( $T_{\text{probe, internal}} - T_{\text{air}}$ ), has a linear relationship with the driving force as measured outside of the bottle ( $T_{\text{probe, external}} - T_{\text{air}}$ ) except for some points at the top of the lines, which represent the first 5 to 8 minutes of the experiment, during which the temperature probe had to adapt to the temperature of the bottle wall. The slope of the line, representing  $\alpha_2/\alpha_1$  as in Equation 8.1, is on average 1.437 (SD 0.091). No relation between slope and bottle size or reconstitution temperature was found. As a consequence the driving force as measured outside of the bottle should be multiplied by the average slope of the line (1.437) to get the true driving force. This means that the temperature difference between bottle and air is in fact 44% more than the difference as measured at the outside of the bottle.

All temperature profiles as measured using the external temperature sensors were recalculated according to Equation 3 before further data analysis.

### 8.3.1.2 Determining the overall heat transfer coefficient ( $\alpha$ )

The heat transfer coefficient  $\alpha$  was determined by fitting each individual temperature profile and averages and standards deviation of in total 45 profiles are displayed in Table 8.1.

**Table 8.1 Overview of average heat transfer coefficients for reconstituted feeds (n=45) stored using different scenarios/locations in refrigerators**

Storage scenario	Heat transfer coefficient ( $\alpha$ ) (W m <sup>-2</sup> s <sup>-1</sup> )	
	mean	st dev
Nursery A	10.04	3.61
Nursery B	12.67	5.79
Consumer: bench (not put in fridge)	10.17	1.52
Consumer: middle shelf	7.65	1.39
Consumer: door & middle shelf	7.84	0.97
Consumer: bottom & back	7.05	1.30
Consumer: door & middle shelf	6.70	2.53

In a study by Kandhai *et al.* (2009) the 95% confidence intervals for the overall heat transfer coefficient ranged from 4.4 – 13.3 W m<sup>-2</sup> °C<sup>-1</sup> with an average of 7.7 W m<sup>-2</sup> °C<sup>-1</sup> for one type of bottle and 10 W m<sup>-2</sup> °C<sup>-1</sup> for the other type, which is in line with the ranges observed in this study. The cooling characteristics of the nursery refrigerators are better than those of households, but due to the high variability, the differences are not statistically significant. On the bench the heat transfer properties are slightly better than in the household refrigerators, indicating that drafts of air on the bench cool down the bottle. As the temperature on the bench, however, is higher than in the household refrigerators, the overall performance of the cooling is not better than in the refrigerator, and a safe refrigeration temperature can not be reached.

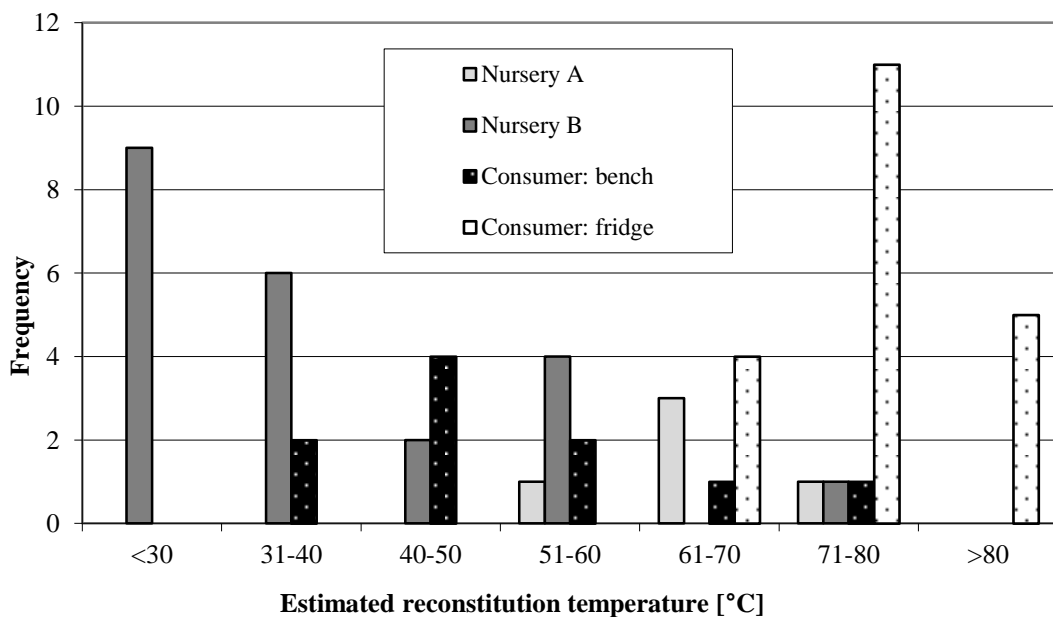
### 8.3.1.3 Determining reconstitution temperatures

An overview of the reconstitution temperatures is given in Figure 8.5. In nursery A as shown by the dark blue bars, all bottles were prepared on site with water of 70°C or more, except for one bottle with an apparent reconstitution temperature of 54°. The temperature profile of this bottle, however, was quite variable and incoherent. As the bottle was prepared at the same time as another bottle, which was initially more than 70°C, the explanation for this aberration may have been the fact that the temperature sensor had not been attached properly to this bottle.

In nursery B bottles are brought in by the parents, and as a consequence the initial temperature as measured in this study, does not reflect the true reconstitution temperature. Bottles arriving hot at the nursery were probably prepared just before arrival, but bottles arriving cold or lukewarm, may have been prepared either the night before or shortly before arrival. A mixture of practices is reflected by the large variety in apparent reconstitution temperatures as shown by the purple bars in Figure 8.5.

At home most caregivers use water of 70°C or more to reconstitute PIF as shown by the blue bars. One specific caregiver, however, as indicated by the yellow bars, used water of variable temperatures between 31 and 76°C to reconstitute the formula. After such reconstitution bottles were stored on the bench for a variable amount of time, instead of in a refrigerator.

**Figure 8.5 Overview of the initial temperature of the reconstituted infant formula as prepared at different locations. See figure legend to illustrate that light grey represents nursery A; dark grey, nursery B; black, storage on bench; dotted bars, storage in household fridges**



## 8.3.2 Predictions

### 8.3.2.1 Selection of scenarios and baseline

The following scenarios in day nurseries and parents' homes were selected to project the potential growth of *E.sakazakii* (*Cronobacter*) during handling and storage. Day nursery scenarios are shown in Table 8.2. In nursery A formula was reconstituted with hot water and stored for 5 hours in the refrigerator, reheated to 37°C within 30 minutes and consequently consumed within 30 minutes. In nursery B infant formula was brought in by the parents in the morning. Two scenarios were considered: reconstitution at the parents' home in the evening before arrival at the nursery, and reconstitution in the morning at the parents' home within 2-3 hours before arrival at nursery. For both scenarios the formula was subsequently stored for 7 hours in the nursery's refrigerator before reheating and consumption.

For comparison two scenarios were added: The UK standard 'best practice' scenarios as recommended by the FSA (FSA, 2006) which consisted of reconstitution of the PIF at 70°C on the bench at 20°C, rapid cooling to 37°C in 15 minutes followed by immediate consumption. The baseline scenario was chosen to be reconstitution of PIF with lukewarm water (37°C), followed by immediate consumption.

Table 8.3 shows the selected scenarios that were observed in parents' homes.

Parent 1 prepared feed with boiled water that had cooled for more than 30 minutes in the feeding bottle. The prepared feed was consequently stored on the bench at ambient conditions for more than 11 hours until feeding.

Parent 2 prepared the feed using boiled water that had cooled for 42 minutes in the kettle (which is more than the recommended 30 minutes). Subsequently, the reconstituted feed was stored for 75 minutes on the bench at ambient temperature followed by prolonged storage in the fridge, reheating and 10 minutes feeding time.

Parent 3 prepared feed with boiled water that had cooled for 21 minutes (less than the recommended 30 minutes). The bottle was then stored at ambient temperature for one hour, refrigerated in the door of the fridge for half a day, followed by reheating and consumption.

**Table 8.2 Typical preparation and storage scenarios as applied in day nurseries**

Scenario	Reconstitution temp. (°C)	Preparation stage	Air temp. (°C)	Time (hours)	Holding conditions
Nursery A (PIF feeds reconstituted on site)	40*, 50*, 60*, 70, 80	Preparation of formula	25	0.5	Still air and Bottle
		Holding/Cooling	5.64	4.55	Still air and Bottle
		Active re-warming/ rapid cooling	37	0.5	N/A
		Feeding Period	25	0.5	Still air and Bottle
Nursery B (PIF feeds reconstituted in evening)	40, 50, 60, 70, 80	Preparation of formula	20	0.5	Still air and Bottle
		Holding/Cooling	7.68	5.5	Still air and Bottle
		Active re-warming /rapid cooling	37	0.5	N/A
		Feeding Period	25	0.5	Still air and Bottle
Nursery B (rec in morning)	40, 50, 60, 70, 80	Preparation of formula	20	0.5	Still air and Bottle
		Holding/Cooling	7.68	7.1	Still air and Bottle
		Active re-warming /rapid cooling	37	0.5	N/A
		Feeding Period	25	0.5	Still air and Bottle
Baseline: luke warm	37	Preparation of formula	20	0.5	Still air and Bottle
		Holding/Cooling	20	0.25	Still air and Bottle
		Active re-warming/ rapid cooling	37	0	N/A
		Feeding Period	25	0.5	Still air and Bottle
Best practice as in guideline	70	Preparation of formula	20	0.5	Still air and Bottle
		Holding/Cooling	37	0.25	Rapid cooling
		Active re-warming/ rapid cooling	37	0	N/A
		Feeding Period	25	0.5	Still air and Bottle

\* These temperatures were simulated, but not observed in practice.

**Table 8.3 Typical preparation and storage scenarios as observed in parents' homes**

Scenario	Reconstitution temp. (°C)	Preparation stage	Air temp. (°C)	Time (hours)	Holding conditions
Parent 1	25	Preparation of formula	20	0.75	Still air and Bottle
		Holding/Cooling	20	11.35	Still air and Bottle
		Active re-warming/ rapid cooling	20	0	N/A
		Feeding Period	20	0.5	Still air and Bottle
Parent 2	69	Preparation of formula	20	1.25	Still air and Bottle
		Holding/Cooling	6.18	15.88	Still air and Bottle
		Active re-warming/ rapid cooling	35	0.5	N/A
		Feeding Period	20	0.167	Still air and Bottle
Parent 3	85	Preparation of formula	20	0.98	Still air and Bottle
		Holding/Cooling	5	21.83	Still air and Bottle
		Active re-warming/ rapid cooling	37	0.5	N/A
		Feeding Period	20	0.5	Still air and Bottle
Baseline: luke warm	37	Preparation of formula	20	0.5	Still air and Bottle
		Holding/Cooling	20	0.25	Still air and Bottle
		Active re-warming/ rapid cooling	37	0	N/A
		Feeding Period	25	0.5	Still air and Bottle
Best practice as in guidelines	70	Preparation of formula	20	0.5	Still air and Bottle
		Holding/Cooling	37	0.25	Rapid cooling
		Active re-warming/ rapid cooling	37	0	N/A
		Feeding Period	25	0.5	Still air and Bottle

### 8.3.2.2 Growth predictions

The probability that *E.sakazakii* (*Cronobacter*) grows in the reconstituted PIF and the levels that may be reached in a bottle were predicted using the risk assessment model for *Enterobacter sakazakii* in PIF by Paoli and Hartnett (2006). Table 8.4 shows the relative risk reduction as compared to the baseline model consisting of reconstitution of PIF with lukewarm water (37°C), followed by immediate consumption for 30 minutes. A high relative risk reduction means that *E.sakazakii* (*Cronobacter*) is inactivated and/or will not be able to grow. A scenario with a high score thus can be considered to be safe with respect to *E.sakazakii* (*Cronobacter*). Numbers below one implicate that such scenario allows *E.sakazakii* (*Cronobacter*) to grow in the reconstituted PIF.

The scenario with lukewarm water, and not the UK standard 'best practice' scenario, was chosen to serve as a baseline, as this allows comparison between both scenarios with elevated risk and scenarios with increased risk. Had the 'best practice' scenario been chosen, then all bottles reconstituted below approximately 65°C would get the same relative risk reduction of  $<1.0 \times 10^{-5}$ , and no comparison between various relevant scenarios would be possible.

Table 8.4 shows the predicted relative risk reduction for practices observed and plausible in day nurseries. It can be seen that in nursery A, where bottles are prepared on-site the relative risk is comparable with the 'best practices' scenario as in the guideline, and very low. If the bottles have been prepared at lower temperatures which were not observed, the relative risk may increase up to maximally 21-fold the baseline risk if the bottle would be prepared at 50°C. For nursery B the relative risk cannot be established with certainty, as the bottles were brought in by the parents at an unknown time after reconstitution at an unknown temperature. Again, if the bottle were prepared at 70°C or higher, the risk is equally low as in the 'best practice' scenario, irrespective of the duration of cold storage in nursery B's refrigerator. It should be noted, however, that holding of the bottles before arrival at the nursery was not recorded in this study, and consequently not included in this prediction.

As can be seen in table 8.4 all scenarios of reconstitution at 40°C and 60°C lead to a relative risk that is in the same order of magnitude as the baseline scenarios (1.0). Storage in the nurseries' refrigerator does not have a large effect on the relative risk, as compared to fresh preparation of each bottle with lukewarm water. Reconstitution at 50°C, however, is predicted to increase the risk by a factor of 20-25.

**Table 8.4 Predicted relative risk reduction as compared to the baseline scenario for practices observed in day nurseries**

Scenario: Preparation method	Reconstitution temperature (°C)	Relative risk reduction
Nursery A (feeds reconstituted on site)	40*	0.34
	50*	0.0482
	60*	1.55
	70	>1.00 x 10 <sup>5</sup>
	80	>1.00 x 10 <sup>5</sup>
Nursery B (feeds reconstituted in evening)	40	0.34
	50	0.0446
	60	0.57
	70	>1.00 x 10 <sup>5</sup>
	80	>1.00 x 10 <sup>5</sup>
Nursery B (feeds reconstituted in morning)	40	0.27
	50	0.0389
	60	0.54
	70	>1.00 x 10 <sup>5</sup>
	80	>1.00 x 10 <sup>5</sup>
Baseline scenario: luke warm reconstitution and no storage	37	1.00
Best practice as in guideline	70	>1.00 x 10 <sup>5</sup>

\* Temperatures indicated with \* were simulated, but not observed in practice.

Table 8.5 shows that the scenario as observed at Parent 1 had a relative risk reduction of 0.00819, implicating that the risk is 122 fold higher than the baseline scenario of lukewarm reconstitution and immediate consumption. This is more than 10 million times more risky with regard to *Cronobacter* proliferation than the recommended best practice. The scenarios at Parent 2 and Parent 3, which both used storage of bottles after hot reconstitution, have the same level of safety as the ‘best practices’ scenario.

**Table 8.5 Predicted relative risk reduction as compared to the baseline scenario for selected practices observed in home settings**

Scenario: Preparation method	Reconstitution temperature (°C)	Relative risk reduction
Parent 1	25	0.00819
Parent 2	69	>1.00 x10 <sup>5</sup>
Parent 3	85	>1.00 x10 <sup>5</sup>
Baseline scenario: luke warm reconstitution and no storage	37	1.00
Best practice as in guideline	70	>1.00 x10 <sup>5</sup>



## 8.5 SUMMARY OF FINDINGS

- Temperature profiles were corrected to be able to deduct heat transfer coefficients and reconstitution temperatures inside the bottles.
- The overall heat transfer coefficients ( $\alpha$ ) were determined and were shown to have a large variability in both household refrigerators and nursery refrigerators. The transfer rates, however, were in the same range as in previous studies, and were in line with the assumptions made in the predictive model used.
- The nursery that prepared the bottles on-site and the majority of parents in their home, reconstituted infant formula using water that has a temperature of 70°C or higher.
- The risk assessment model predicts that for all bottles reconstituted at 69°C or more, the risk for *E.sakazakii* (*Cronobacter*) was predicted to be equally low as in bottles prepared exactly according to the UK best practices guidelines. Subsequent storage on the bench for up to 75 minutes and/or storage in the refrigerator for up to 22 hours, was predicted not to affect the risk.
- From the range of reconstitution temperatures (40, 50, 60, 70, and 80 °C), 50°C was found to have the highest relative risk for *E.sakazakii* (*Cronobacter*), while 70°C and 80°C had a significantly reduced risk for proliferation of *E.sakazakii* (*Cronobacter*). It should be noted, however, that other risks, such as risk for the growth of bacterial spores, the risks of scalding, and the risks of thermal inactivation of essential nutrients in PIF were not considered in this study.
- Luke warm or ambient reconstitution, followed by holding on the bench for 11 hours is associated with a more than 100-fold increase in risk as compared to the baseline scenario, and a more than 10<sup>7</sup>- fold increase as compared to the ‘best practice’ scenario.

### Overall conclusions

- Temperature profiles measured with an external probe need to be recalculated into internal temperature profiles using the method in chapter 8.2, before they can be interpreted or be used for growth prediction.
- With regard to the growth of *E.sakazakii* (*Cronobacter*), bottles which have been reconstituted at 70°C or more, can safely be stored in the refrigerator provided they are refrigerated promptly.
- From a risk-based perspective, the most relevant scenario for growth of *E.sakazakii* (*Cronobacter*) observed in this study, is prolonged storage of bottles on the bench, after reconstitution with water of ambient temperature.

## CHAPTER 9

### CUMULATIVE FINDINGS, FINAL SUMMARY, RECOMMENDATIONS AND FURTHER RESEARCH

#### 9.1 CUMULATIVE FINDINGS: PARENTS

##### 9.1.1 Powdered infant formula preparation, handling and storage behaviours

- Overall, UK parents reported carrying out **variable methods** used to prepare, handle and store PIF inside and outside the home. Although all feeds were reportedly prepared with boiled water, many reported methods/practices are not in accordance with current UK DoH and FSA PIF preparation and handling recommendations.
- Overall, most common methods reported by parents (Chapters 2 and 3) and observed (Chapters 6 and 7) for preparation of powdered formula milk feeds inside and outside the home included storage of feeding bottles with cooled boiled water (for up to 24 hours) at ambient or refrigerated temperatures and addition of the powdered formula to the water when required for immediate feeding and reconstitution of feeds in advance of use.
- Parents expressed variable and negative attitudes towards practices associated with cooling of boiled water to  $>70^{\circ}\text{C}$  and judgement of water temperature for PIF reconstitution which could contribute to non-compliance and have implications for microbial safety. Indeed, self-reported practice data suggests that many parents frequently cool boiled water to temperatures  $<70^{\circ}\text{C}$  for reconstitution and only 15% of time-temperature profiled reconstituted feeds were made-up using boiled tap water cooled for less than 30 minutes – on average, feeds were reconstituted with boiled water cooled for 52 minutes.
- For feeding with powdered formula milk away from the home, variable practices were reported and observed (Chapters 2, 3, 6 and 7). Some parents reported taking a measured quantity of boiled water in a prepared bottle, powder in a separate container (sometimes upturned in the formula bottle with water); others reported taking an empty sterilised bottle, powder in a separate container and obtain boiled water when out and others reported taking sterilised bottles and cartons of RTU formula. Some parents reported reconstituting the feed before leaving the home and taking it with them (sometimes in a cool bag with cool packs, other times in an insulated bag to keep the feed warm and at other times in a normal bag (i.e. no cool/warm insulation). Quantitative data (Chapter 3) showed that larger proportions of parents from SEG C2DE were more likely to take reconstituted PIF away from the home for feeding than parents from SEG ABC1. Time temperature profiling data (Chapter 7) showed that made-up feeds were stored away from the home in bags with no insulation or freezer packs for up to 8½ hours before reported feeding. Storage of reconstituted feeds in a cool bag with freezer packs maintained a temperature of  $<5^{\circ}\text{C}$  to be achieved over a period of 480 minutes.

- Qualitative and quantitative data (Chapters 2 and 3) concurred indicating that most parents reported ‘*doing everything by the book*’ for the first few weeks of preparing PIF feeds – but found recommended practices too difficult, impractical and time consuming, resulting in ‘*corners being cut*’. Indeed, 43% of parents reported that they were more careful when they first prepared infant feeds.
- Mothers who had more than one child reported they usually implemented the same infant feeding practices (if using formula) as they had for their first baby, particularly if they encountered no problems; this was particularly the case for preparation of feeds 12-24 hours in advance.
- A large proportion (58%) of parents considered it to be acceptable for PIF to be prepared and stored in advance of use. Attitudinal data concurred with self-reported and time-temperature profiling data (Chapter 7) which indicated parents do still reconstitute PIF in advance of use for periods of time 12->24 hours, in some cases storage was observed at ambient temperature. Predictive modelling of such time – temperature profiles indicated high levels of risk for growth of *E.sakazakii* (*Cronobacter*) (Chapter 8).
- Fewer parents from SEG DE who used PIF for feeding in conjunction with breastfeeding found implementation of all recommended practices ‘easy’, compared to exclusively formula feeding parents from SEG AB; however, parents using a combination of feeding methods were more confident that the formula they prepare is safe.
- Older parents (aged 35-45 years) were significantly associated with negative attitudes towards PIF safety and recommended practices.

### **9.1.2 Knowledge of microbiological hazards associated with powdered infant formula and powdered formula milk safety**

- Qualitative and quantitative data (Chapters 2 and 3) both revealed a widespread lack of knowledge and negative attitudes expressed towards microbiological risks associated with PIF. No parents had heard of *E.sakazakii* and few (17%) were aware of the association of *Salmonella*. Nearly three-quarters of parents believed that PIF is a sterile product before the tin is opened – this included a large proportion of parents from SEG DE and age group 35-45 years.
- Qualitative and quantitative data (Chapters 2 and 3) revealed misconceptions regarding storage of opened cartons of RTU UHT formula (with instructions indicating storage for 24 hours in a refrigerator) and reconstituted PIF (recommendation indicating no storage and immediate feeding after reconstitution). Parents perceived these instructions to be contradictory and caused confusion as the RTU formula and the reconstituted PIF were regarded by many parents to be the ‘same’.

### 9.1.3 Perceptions of risk, control, responsibility and hygiene consciousness

- Judgements of optimistic bias, the illusion of control and personal invulnerability associated with PIF preparation have been identified.
- The majority (70%) of parents considered that ultimately the safety of PIF was the responsibility of manufacturers. Failure to recognise personal responsibility for the safety of PIF feeds may not only impede upon intervention efforts, but also result in a negative assumption that ‘others’ have ensured complete safety of powdered formula milk feeds. Thus, necessary safety control measures that are required during formula preparation may not be implemented, which subsequently increases the risk of illness.

### 9.1.4 Powdered formula milk advice and information sources

- Cumulatively qualitative and quantitative data suggested that overall, the majority of mothers reported a lack of information provision from NHS professionals about preparation, handling and storage of PIF; all reported a huge amount of information being available and given to them from midwives and health visitors about breastfeeding.
- Mothers perceived midwives and health visitors to be key information providers about infant health etc; however, a **substantial variability** in provision of information to parents about PIF feeding, preparation, handling and storage from these providers was observed by the variability in parent attitudes and beliefs regarding the adequacy of information about PIF that they received.
- Considerable numbers of parents (particularly first time parents) reported they felt that insufficient information regarding preparation and handling of PIF was available, they would have liked more information and felt they needed more information.
- Almost all mothers (excluding those of at-risk babies) reported being given no information about PIF preparation, handling and storage during their stay in hospital for the birth of their infant. In hospital, mothers reported that midwives were more interested in encouraging breastfeeding.
- Qualitative data (Chapter 2) indicated that for parents, the main source of information was the instructions on the PIF milk tin, and quantitative findings (Chapter 3) indicated that 71% of parents felt that following the instructions was essential. In addition, parents’ mothers and friends were also important and influential sources of information.
- The majority of parents suggested they would have liked more information and advice from the midwives and health visitors about preparation, handling and storage of PIF.
- Almost all (94-99%) health visitors and community midwives reported that it was very/fairly important to give PIF information to mothers when changing from breastfeeding to formula feeding. However, qualitative findings showed that many mothers were not given any information/advice about PIF safety from the midwife or health visitor.

- Mothers of ‘at-risk’ infants (all who had been in SCBU/neonatal or paediatric departments) reported being given information, advice and one-to-one demonstrations from paediatric/neonatal/SCBU staff regarding cleaning, sterilisation of feeding equipment and preparation of PIF feeds before their infant was discharged from hospital. Parents reported this provision of information with a positive attitude.
- Many parents believed that information and recommended PIF practices were always changing – which undermined the content and credibility of the information.
- Parents with other infants/older children believed they did not need more information about safe preparation and handling of PIF – however, such information may be needed if recommendations have changed between the birth of their first and subsequent infants.
- The majority of parents recalled being given/seeing at least one of the NHS Pregnancy/Birth to Five books. However, limited recollection was reported for bottle feeding leaflets- where in Wales only 12% of formula feeding parents recalled seeing/receiving this information source.

## **9.2 CUMULATIVE FINDINGS: UK DAY NURSERIES**

- Day nursery staff care for varying numbers of infants aged less than 6 months at one time. Variable numbers of PIF feeds are brought to, and made-up in, day nurseries in the UK.
- Considerable variability was reported in methods used to manage and handle PIF in UK nurseries. Data indicate national and regional differences in reported methods. For example, in Wales, Scotland and Northern Ireland, use of PIF reconstituted by parents at home before nursery appears to be a more frequent practice.

### **9.2.1 Powdered infant formula preparation, handling and storage behaviours**

- Variable methods of preparation, storage and feeding the PIF were reported between and within nurseries.
- More than half of day nursery staff indicated that reconstituted PIF feeds (made-up at home) are frequently brought to nurseries, for storage and use throughout the period of infant care, which may be for over 10 hours a day. Data from Chapter 7 indicated that refrigerators used to store reconstituted feeds in day nurseries did not consistently run at <5°C as recommended by the FSA guidance for use of PIF in care settings.
- Quantitative data (Chapter 4) indicated that the majority of parents (81%) who brought reconstituted PIF feeds to nurseries reportedly did so using methods that may encourage microbial growth. These findings compared with qualitative data obtained from Chapter 7, where nursery staff reported that reconstituted feeds were not transferred from parents’ homes to the day nursery using cool bags or freezer packs. It was reported that all feeds were transported in rucksacks, carrier bags, infants’ bags, by hand etc.

- Nearly half of day nursery nurses and day nursery managers considered it acceptable for powdered formula to be made-up in advance of use and stored in the refrigerator all day before feeding. However, in the time temperature profiling study (Chapter 7) no reconstituted feeds brought to the day nursery for use during the day achieved  $<5^{\circ}\text{C}$  which has microbiological implications for safety.
- Another common method reported for managing powdered formula feeds in day nurseries was parent preparation of feeding bottle and boiled water (at home) and provision of powdered formula in a separate (sometimes measured out) container. The powdered formula feeds are then reconstituted immediately before feeding, removing the need for storage of reconstituted feeds. However, use of this method means that powdered formula is mixed with water  $<70^{\circ}\text{C}$  before feeding, which is contrary to FSA/NHS UK recommendations and has implications for microbial safety.
- Large proportions of day nursery nurses and day nursery managers indicated negative attitudes towards the following practices:
  - the need to reconstitute PIF with boiled water, cooled for less than 30 minutes,
  - feeding PIF immediately after preparation and preparation of one feed at a time.
 Such attitudes may suggest non-compliance with such practices.
- Many (93%) day nursery nurses reported ‘checking’ the refrigerator temperature on a daily basis. However, more than 20% of nursery nurses did not know the correct refrigerator temperature or reported maximum temperatures that refrigerators should operate to ensure safety. Nearly half of made-up PIF feeds were reportedly stored in the refrigerator door.
- Nursery staff (Chapter 7) reported being too busy to store made-up feeds in the refrigerator immediately - indeed for the time temperature profiling component of the study, the reported time between arrival at the nursery and storage of reconstituted feeds in the refrigerator ranged from 0-135 minutes (average 39 minutes). Nearly half (45%) of reconstituted feeds were stored at room temperature for 31-60 minutes before refrigeration and 16% for more than 61 minutes. Data indicated that the warmer the feed ‘felt’ on arrival at nursery, the longer it would remain at room temperature before refrigerated storage. This data corresponds with quantitative self-reported findings (Chapter 4) which indicated that nearly 40% of reconstituted feeds that felt warm/hot on arrival at the nursery were not refrigerated for 1->2 hours after arrival at the nursery.
- Three-quarters of day nursery nurses reported that they prepared/made-up powdered formula feeds in their nursery. However, only 5% reported one specific person in the nursery was responsible for making infant feeds – in most cases all nursery staff looking after infants would be making up bottles of formula – whoever was available and/or staff caring for individual infants.
- Qualitative findings indicated that methods implemented for preparation, storage and feeding of PIF were frequently led and instructed by parents, even if the nursery nurses did not believe such practices to be appropriate. This finding concurred with quantitative data (Chapter 4) where 76-82% of nursery nurses/managers reporting the same practice. As a

consequence of parent instructions some day nursery staff (18-20%) reported parents have provided prepared feeding bottle(s) for feeding infants with powdered formula nursery that staff considered to be unclean – but some (9-14%) also reported still using the unclean bottles to feed infants.

- Eighteen percent of nursery nurses reported they keep used feeding bottles containing unfed feeds to show and give the infants' parent(s) on collection of the infant. In some cases this feed is reportedly not refrigerated after the last feed, so has implications for safety if subsequently fed after leaving the nursery.
- From a risk-based perspective, the most relevant scenario for growth of *E.sakazakii* (*Cronobacter*) observed in this study, is prolonged storage of bottles on the bench, after reconstitution with water of ambient temperature.

### **9.2.2 Knowledge of microbiological hazards associated with powdered infant formula and powdered formula milk safety**

- The majority of day nursery nurses believed that they knew all of the precautions necessary for safe preparation and storage of PIF. However, few nursery nurses demonstrated knowledge of recommended handling, preparation and storage behaviours and almost all were unaware of the current guidelines.
- Most nursery nurses reported that they were confident with the safety of their current practices and did not perceive a need for change; however, nearly half of day nursery nurses were not confident they knew all of the *up-to-date* recommendations.
- Qualitative (Chapter 2) and quantitative (Chapter 4) data both indicated that the majority of day nursery staff (including managers) believed PIF is a sterile product before the tin is opened and most were unaware of the association with *E.sakazakii* and/or *Salmonella*.
- All day nursery nurses were responsible for safe handling, reconstitution, storage and feeding of PIF to infants aged less than 6 months. Many reported misconceptions of safe storage of reconstituted powdered feeds and lacked knowledge and awareness of microbiological issues.

### **9.2.3 Perceptions of risk, control, responsibility and hygiene consciousness**

- Day nursery nurses and day nursery managers demonstrated judgements of optimistic bias, the illusion of control and personal invulnerability associated with PIF preparation. Day nursery nurses perceived themselves to be associated with lowest risk of illness after preparation of powdered formula feeds themselves, more control over safety, more conscious of hygiene and more responsible for the safety of infant feeds than other nursery nurses, infants' parents and hospital staff.

- Day nursery managers considered their nursery staff were associated with less risk, more control, more responsibility and more hygiene consciousness than infants' parents and hospital staff.

#### **9.2.4 Information sources, training powdered infant formula policy**

- Almost half of day nursery managers reported never receiving information updates and recommendations regarding safe PIF preparation, handling and storage. A further 9% of managers reported they did not know if they had received information and nearly 20% indicated they received information less than once a year.
- Only a third of day nursery managers reported awareness/recalled seeing the FSA Guidance for Healthcare Professionals.
- The majority of day nursery managers and day nursery nurses considered it was the responsibility of the manager to obtain and inform their staff of changes to PIF preparation and storage recommendations. However, data suggest that information about the new recommendations had not been sought or received by over a quarter of day nursery staff.
- Any training was reportedly usually implemented by day nursery managers. However, findings from this chapter have indicated that day nursery manager knowledge and positive attitudes towards key recommended practices are limited. Less than 20% of managers reportedly that they had themselves been trained in the microbiological risks associated with PIF, and <15% of such training had been reportedly received since the new PIF recommendations had been released.
- Day nursery managers ranked the FSA as the most credible provider of PIF information.
- Although day nursery nurses reported wanting to receive information/updates about safe handling, preparation, storage and feeding of PIF, the majority perceived that recommendations were constantly changing and difficult to keep up to date with.
- Although 65-72% of day nursery staff indicated the nursery where they work had a policy or systems in place for safe preparation, handling and storage of PIF, previous research (Redmond and Griffith, 2007) and Chapter 2 has suggested that reported 'policies' may be unstructured and limited.
- The majority of day nursery managers reported that policies associated with preparation, handling and storage of PIF were 'unique' to their nursery and most managers reported that a review of these policies was reportedly conducted once a year.



### 9.3 CUMULATIVE FINDINGS: NHS CAREGIVERS

- Almost all NHS hospital midwives/MHCAs, hospital nurses/HCAs, health visitors and community midwives reported they are in contact with infants being fed using infant formula.
- Considerable differences in the use, perceived acceptability and preparation of PIF were determined in qualitative (Chapter 2) and quantitative (Chapter 5) findings between maternity departments, neonatal/SCBU and paediatric departments.
- Cumulatively, in all departments (particularly maternity), breast feeding is reported to be a priority and ‘encouraged’ before and as soon as infants are born.

#### 9.3.1 Preparation, handling and storage of powdered infant formula in UK hospitals

- Overall, formula use in neonatal/SCBU and paediatric departments was perceived by nurses as acceptable and in many cases necessary. All nurses from these departments who contributed to the study recognised that breast feeding is best for infants, however did not enforce and ‘push’ this on parents. The same nurses believed that breastfeeding was ‘pushed’ onto parents in maternity departments.

##### *Maternity departments*

- Qualitative data (Chapter 2) indicated that no powdered infant formula is allowed on maternity wards (unless for reasons such as religion) and so midwives are never involved in preparation and handling of powdered infant formula. However, in the quantitative component of the study (Chapter 5) 14% of hospital midwives/MHCAs reported preparation of PIF feeds in the maternity department (reportedly undertaken by midwives and nursing staff (no midwives or nurses reported a designated person being responsible for making up all infant feeds).
- In the majority of cases in maternity departments, mothers who formula feed usually only use the RTU/RTF formula (in small glass bottles).
- Qualitative (Chapter 2) and quantitative data (Chapter 5) compare and indicate that in maternity departments, monitoring of the length of time feeds are opened is usually the responsibility of the mother and not NHS caregiver. However, it is the responsibility of the caregiver to inform the mother of maximum periods of time the formula may be open, ‘in-use’ and safe to feed the infant.
- Midwives/MHCAs reported the need to sometimes decant/transfer RTU/RTF formula on the ward into other containers/bags for feeding.
- Nurses working on maternity wards reported they do not have the facilities for cleaning and sterilising infant feed equipment, or reconstitution of powdered milk formula feeds.

### *Neonatal/SCBU and paediatric departments*

- Although RTU/RTF formula (in glass bottles) is predominately the type of formula used as an artificial feed in maternity departments, it is also used in neonatal/SCBU and paediatric departments. In addition, specialist and non-specialist PIF feeds are more frequently prepared/used for feeding in neonatal, SCBU and paediatrics departments.
- In addition to the standard RTU/RTF glass bottles of formula, a wide variety of specialist PIF powders are used for feeding by hospital nurses/HCAs in neonatal/SCBU and paediatric departments.
- Hospital nurses/HCAs in neonatal/SCBU and paediatrics reported longer lengths of time that they considered RTU/RTF formula can be open and in use for feeding than hospital midwives/MHCAs in maternity departments. Reported responsibility for monitoring the time RTU/RTF formula bottles were in use was variable between departments – in maternity, 88% of midwives reported parents/mothers to be primarily responsible (88%), whereas in neonatal/SCBU and paediatrics, 95% of nurses reported nursing staff to be responsible.
- Location for preparation of PIF feeds was variable between hospitals. In the majority of hospitals, all feeds are prepared in ward/department kitchens or at the patient/infant's bedside; however, in some hospitals feeds are prepared in Central Feeds Units.
- Powdered formula milk feeds prepared in Central Feeds Units were reportedly prepared by a designated person and usually delivered to wards/departments once a day. Transport of such feeds between Central Units and departments/wards/hospital sites usually did not occur using a temperature controlled container. After delivery to wards, reconstituted powdered feeds required refrigerated storage for up to (and possibly more than) 24 hours.
- Other hospitals have (in some cases in addition to the central feeds unit) kitchens on the wards where feeds are made-up by ward staff. In some cases these kitchens are designated for preparation and storing specialist powdered feeds, in other cases the kitchens may also be used for preparation of simple meals, storage of staff lunches, making staff coffees etc.
- Refrigerators for storage of reconstituted infant feeds in neonatal/SCBU and paediatric departments were reported by some nurses as being specifically for such feeds; others stored other foods and even staff lunches. Some nurses reported monitoring and recording refrigerator temperatures.
- As in maternity departments, qualitative (Chapter 2) and quantitative (Chapter 5) findings from neonatal/SCBU and paediatrics departments concurred, indicating that hospital nurses/HCAs sometimes decanted/transferred RTU/RTF formula into other smaller bottles or plastic cups for feeding or into enteral feeding bags etc.
- In neonatal/SCBU and paediatric departments and in Central Infant Feed Units, PIF (specialist and non-specialist) was reportedly reconstituted using bottles of sterile water (at ambient temperature).

- In paediatric wards, some hospitals allow parents to bring the PIF used to feed the infant at home, into the hospital. In some cases such feeds are made-up in the room where the infant is ill, on other occasions the hospital requires a new, sealed tin of feed to be brought into the ward and feeds to be reconstituted in a ward kitchen by ward staff (usually nursery nurses or HCAs).
- Qualitative (Chapter 2) and quantitative (Chapter 5) findings indicated that NHS hospital caregivers reported that there are instances when parents bring formula milk powder, reconstituted feeds and prepared (cleaned and sterilised) empty feeding bottles in from home for feeding in hospital. Furthermore it was reported that parents do sometimes prepare their infants' feeds in hospital. Such practices were reportedly more common in neonatal/SCBU and paediatric departments.

### **9.3.2 Perceptions of behaviours used and/or recommended for preparation, handling and storage of powdered infant formula**

- Although cumulatively, the majority of NHS caregivers perceived recommended practices to reduce the risk of illness from feeding with powdered formula milk to be important, practices associated with preparing one feed at a time, feeding reconstituted feeds immediately after preparation and reconstitution using boiled water cooled for <30 minutes/at >70°C were not considered to be 'very' or 'fairly' important by up to 18% of NHS caregivers.
- The majority of community midwives and health visitors believed preparation of one feed at a time and judgement of water temperature (>70°C) were difficult for parents to implement. Negative attitudes towards recommended behaviours may influence information given about them.

### **9.3.3 Perceptions of risk, control, responsibility and hygiene consciousness**

- Hospital midwives/MHCAs and hospital nurses/HCAs considered the risk of illness to an infant after drinking PIF made-up by themselves to be less than other hospital nurses and parents. Similarly, hospital midwives/MHCAs and hospital nurses/HCAs considered they had more control over hygiene and safety and were more conscious of hygiene and safety than other hospital nurses, infants' parents and hospital staff.

### **9.3.4 Awareness of microbiological risks associated with powdered infant formula**

- All NHS caregivers demonstrated inadequate knowledge of microbiological hazards associated with PIF; many (60% hospital midwives/MHCAs, 77% hospital nurses/HCAs, 50% community midwives and 45% health visitors) believed that before tins are opened, the powdered formula is a sterile product.
- Many hospital nurses/HCAs (51%) and hospital midwives/MHCAs (71%) were concerned about the safety of formula feeding when parents left hospital; many (47-53%) of nurses and midwives also reported that they did not think most of the parents/mothers they cared for in hospital knew all of the safety practices necessary for safe preparation and feeding of formula. In addition, 43-47% health visitors and community midwives reported they often see parents/mothers not implementing recommended behaviours needed to ensure the powdered formula fed to their infant is safe.
- Health visitors reported that they encountered considerable confusion amongst parents regarding correct practice in the preparation of PIF feeds – particularly regarding the temperature of the boiled water. Confusion and misunderstandings were reported to have become prevalent in recent years since advice had been changed and revised. This particularly related to the recommendation to prepare one feed at a time and the desirable temperature of the boiled water when mixed with the powder at the time of mixing.

### **9.3.5 NHS caregiver information provision to parents**

- NHS caregivers indicated variable attitudes towards provision of information and advice about PIF to parents.
- First contact with the community midwife is usually in the 8-10<sup>th</sup> week of pregnancy and they usually meet with first time mothers about 10 times and other mothers 6-7 times before the birth. Usually the first visit (during pregnancy) is in the mother's home and subsequent contact may be in the home or in clinics or parentcraft classes. After the birth the first home visit is within 24 hours of discharge.
- The majority of health visitors make the first home visit within 10-14 days of the birth. Many health visitors reported that by the time they make the first home visit, feeding practices are already established. Some health visitors reported observing malpractices regarding formula feeding which had not been noticed or advised upon by previous healthcare professionals.
- Frequency of health visitors' contact, home visits and provision of advice to clients was commonly based on an ongoing individual assessment of need. Although standards and best practice regarding frequency and duration of visits are present for some areas/Trusts, all health visitors reported their heavy caseload restricted their role.
- Nurses believed health visitors and midwives are the most influential persons providing information to parents about infant feeding. All hospital and community midwives in the

focus groups perceived themselves to be the main and most influential health professionals that have contact with prospective mothers during pregnancy and in the first weeks after the birth. Many health visitors reported they believed their role was to inform prospective mothers of the recommended guidelines based on up to date research findings – whether this be regarding breast feeding or artificial feeding. The infant feeding priority for many health visitors was to advise and encourage about breast feeding.

- Half of hospital nurses/HCAs and hospital midwives/MHCAs (52-57%) and 38- 47% of community midwives and health visitors were unsure or not confident that they knew all of the up-to-date guidelines about safe preparation, handling and storage of PIF.
- A significant difference in awareness of the change to PIF recommendations was determined between NHS hospital caregivers (i.e. hospital midwives/MHCAs and hospital nurses/HCAs) and NHS caregivers working in the community (i.e community midwives and health visitors). Only 30% of hospital midwives/MHCAs and hospital nurses/HCAs were aware recommended practices had changed in recent years compared to 97% of community midwives and 99% of health visitors.
- Qualitative results indicated that hospital nurses/HCAs from paediatric and neonatal departments in some hospitals, reported giving all formula feeding mothers demonstrations regarding formula preparation and sterilisation before leaving hospital. Similarly, quantitative findings indicate that more information is given and demonstrations undertaken by hospital nurses/HCAs in neonatal/SCBU and paediatric departments to show how to safely prepare, handle and store PIF to parents.
- Usually no information is reportedly given to mothers about PIF during pregnancy from community midwives, unless the prospective mother asks for information.
- Health visitors from all focus groups reported that information about PIF preparation, handling and storage is not provided to parents in antenatal/parentcraft classes.
- Many hospital midwives/MHCAs and hospital nurses/HCAs (59%), community midwives (62%) and health visitors (71%) reported they thought all mothers should be given information about safe preparation, handling and storage of PIF.
- When mothers and their infants are discharged from maternity departments/hospital the breast feeding mothers are reportedly not given any information about PIF; bottle feeding mothers are reportedly given a bottle feeding leaflet (if available) and UNICEF photocopied sheets instructing how to prepare a feed and sterilise bottles.
- Many midwives reported that they believed many mothers were afraid to talk to them about feeding their infant with PIF due to the focus on breast feeding.
- During the birth, hospital midwives reported they are not allowed to ask how the mother is going to feed the infant, they (the midwives) have to assume the mother will breast feed. Even when mothers have indicated they intend to bottle feed using formula, hospital midwives reported they will still encourage breastfeeding.

- Some health visitors indicated that they do not discuss PIF at all unless a parent asks them about it.
- Large proportions of NHS caregivers (75% hospital midwives/MHCAs, 83% hospital nurses/HCAs, 84% community midwives and 56% of health visitors) indicated they believed that the information they give to mothers about PIF is adequate for their needs.
- Some midwives considered it to be unfair that bottle feeding mothers are not given the same time/support and information as breast feeding mothers.
- A common belief indicated in qualitative findings (Chapter 2.0) among health visitors was that there is a lot of inconsistent information and advice provided about recommended practices for handling, preparation, storage and feeding of PIF from different organisations. This finding concurred with quantitative results indicating only 78% of health visitors (and community midwives) believed recommended practices for safe preparation, handling and storage of PIF were not consistent between sources (NHS, FSA, NCT, supermarkets, formula manufacturers etc). However, results also showed that almost all of hospital midwives/MHCAs (90%) and hospital nurses/HCAs (86%), believed that recommended practices for safe preparation, handling and storage of PIF were consistent between sources.
- Health visitors reported that inconsistent information sources resulted in them finding it confusing themselves, and difficult to know the right way of preparing and handling formula, and thus advising best practice.
- Forty-eight percent of hospital midwives/MHCAs and hospital nurses/HCAs and 68% of community midwives and 59% of health visitors reported they always discuss microbiological safety of powdered formula with bottle feeding parents. However, less than a third of all NHS caregivers reported they had ‘ever’ had training about microbiological risks associated with PIF and <20% reported they had received any such training in the past 3 years.
- Almost all health visitors (94%) and community midwives (99%) indicated it was very/fairly important to give PIF preparation, handling and storage information to parents when changing from breastfeeding to formula feeding.
- Health visitors from all focus groups reported that they experience problems with providing accurate information to non-English speaking clients. Interpreting (sometimes unofficial – usually by other family members, other times by use of an official interpreter) was considered to be time consuming and they reported they were not sure if information being advised is actually translated. Other health visitors reported problems in providing written information for non-English speaking clients. Some health visitors indicated that the problem of language barriers could be overcome with the DoH Bottle Feeding leaflets which include big pictures. However, then the health visitors encountered the problem of limited resources and did not always have such leaflets readily available.
- Awareness, availability and provision of bottle feeding leaflets were reportedly variable between NHS caregivers and between England, Wales and Northern Ireland. For example,

reported availability of the leaflets among Welsh hospital midwives/MHCAs was reportedly more limited (38%) than in England (69%) and Northern Ireland (79%). When available leaflets were available to NHS caregivers, they were reportedly infrequently given to mothers/parents who were not formula feeding.

### **9.3.6 NHS caregiver powdered infant formula training, policies including influence of The Baby Friendly Initiative in hospital departments**

- All midwives reported they rarely, if ever, received information or updates regarding PIF preparation, handling and storage. However, they reported frequently receiving updated information about breast feeding and other health issues. They all reported they would like to be updated about PIF and importantly would like the freedom to be able to act upon it.
- Sources of up-to-date information for health visitors regarding the microbiological safety of PIF preparation were reported to be non-existent or limited. In many cases health visitors reported having to contact formula reps (even though they are officially not allowed) to get correct, current and required information to be able to answer client questions and also provide accurate, up-to-date advice.
- Reported awareness/recollection of FSA/DoH and WHO PIF guidance notes was limited among all NHS caregivers and lowest among hospital midwives and more widespread among health visitors.
- Less than a third of all NHS caregivers reported they had ‘ever’ had training about microbiological risks associated with PIF and <20% reported they had received any such training in the past 3 years (since 2006/2007).
- Information about breastfeeding was reportedly updated more frequently to all caregiver groups, than PIF information. Overall, ~50% of all caregivers reported never receiving updated information about powdered formula milk use and feeding.
- Many (42-71%) NHS caregivers reported in the past, formula reps have provided them with up-to-date information about PIF microbiological safety and preparation, handling and storage guidelines. However, up to 65% of NHS caregivers now report they are not officially allowed to speak to such reps directly.
- NHS caregivers reported regularly receiving updates about breastfeeding, however, most reported never or very rarely receiving information about preparation, handling and storage of PIF.
- Less than half of each caregiver group reported their workplace had an infant feeding policy that included preparation, handling and storage of PIF.
- Breastfeeding coordinators/infant feeding coordinators (reportedly often responsible for implementation of The Baby Friendly Initiative within hospitals) were cited by all NHS caregiver groups as gatekeepers to PIF information.

- Large proportions, particularly of midwives (68-74%) reported receiving training about infant feeding through the Baby Friendly Initiative. However, only 12-17% reported inclusion about safe preparation, handling and storage of PIF.
- None of the nurses in focus groups reported an infant feeding policy for their ward/hospital with regards to feeding or preparation and storage with infant formula, policies were only in place for breast feeding.
- Policies for breast feeding are present in many hospitals and reported to be based upon the UNICEF Baby Friendly Initiative. This policy primarily affects staff that have contact with breast feeding women: midwives, healthcare assistants and health visitors, paediatric and neonatal nurses and all medical staff.
- Not all NHS caregivers who participated in the study worked for 'Baby Friendly' accredited hospitals/workplaces, however the majority reported that their workplace (if not yet fully accredited) either had obtained a certificate of commitment or followed 'Baby Friendly rules'.
- Nurses in all focus groups from all hospitals reported variable opinions and attitudes towards the implementation and conformance to the Baby Friendly Initiative.
- The majority of nurses, who were supportive of the need for breast feeding, believed the Baby Friendly Initiative was '*too extreme*' and '*detrimental*' to bottle feeders.
- All nurses reported that a result of the Baby Friendly Initiative is that they now '*promote breast feeding more than they used to*'. Formula feeds are only allowed to be offered in hospital, according to the Initiative, if medically advised.
- Maternity ward nurses were considerably more supportive of the Baby Friendly Initiative and implemented policies and 'rules' reportedly without exception. All maternity nurses reported that they are not allowed to discuss, suggest or encourage formula feeding with mothers.
- Midwives reported that the Baby Friendly Initiative has a substantial impact upon their role, in some cases reportedly undermining professional judgement about giving PIF advice. Implementation of the Initiative relies on them following a set of rules and influences what they can tell or talk to parents/mothers about (e.g. they do not ask a mother how she intends to feed her infant or even mention PIF feeding/preparation etc). Midwives reported they are under pressure to increase breast feeding rates.
- All health visitors were aware of the UNICEF Baby Friendly Initiative which was reported to impact upon their role as a provider of health information to prospective mothers. Attitudes towards the initiative were variable. Some health visitors were very much in support of the initiative, whereas others considered it an impediment to provision of important feeding information to mothers.
- More than half (50-59%) of hospital nurses/HCAs and hospital midwives/MHCAs believed that the Baby Friendly Initiative does not support bottle feeding mothers and 23-27% also



believed that implementation of the initiative does not provide a framework to give all mothers the best infant feeding advice.

- Parentcraft classes were reportedly offered to all prospective parents; however it was reported that no information about PIF is included—due to the Baby Friendly Initiative as well as Health and Safety issues. Demonstration of preparation of PIF feeds was reportedly ‘seen’ to be promoting bottle feeding and therefore not allowed.
- In some areas/trusts health visitors reported that they and other health professionals (e.g. midwives) are not ‘allowed’ to discuss artificial feeding to prospective parents. This was perceived by health visitors to be problematic, and unrealistic as a large percentage of their client base bottle fed with PIF.

## **9.4 FINAL KEY FINDINGS WITH RECOMMENDATIONS**

### **9.4.1 Powdered infant formula preparation, handling and storage behaviours inside and outside the home**

- Overall, UK parents reported and demonstrated using a variety of methods to prepare, handle and store PIF inside and outside the home. Although all feeds were observed and reportedly prepared with boiled water, many reported methods/practices are not in accordance with current UK DoH and FSA advice.
- All parents expressed positive attitudes towards preparation of safe PIF for their infant(s). However, negative attitudes towards some practices and methods required to achieve this were identified which could contribute to non-compliance and have implications for microbial safety.
- Reconstitution of powdered formula milk feeds in-advance of feeding remains common practice inside and outside of the home (35-40% parents) and modelling of the time temperature data from reconstituted feeds stored for 12-24 hours indicated high levels of predicted growth of *E.sakazakii* (*Cronobacter*) in made-up feeds stored at ambient temperature.
- Many parents also reported awareness of the new recommendation to prepare one feed at a time for immediate feeding. Almost all parents and NHS caregivers considered this to be difficult and impractical to implement. In addition, there was a widespread lack of understanding *why* preparation of individual feeds was now recommended, when making feeds up in-advance in the past was considered acceptable, more practical to implement and perceived to be non-problematic.
- The majority of parents and NHS caregivers considered the judgement of cooling boiled water temperature to  $>70^{\circ}\text{C}$  to be difficult. Cooling boiled water for longer than 30 minutes was frequently reported and observed in the model kitchen and during time-temperature studies. Many parents believed the recommendation was intended to prevent scalding infants with feeds that were too hot as opposed to reasons for microbiological safety.

- A common practice reported and observed for preparation of PIF feeds involved preparation of boiled tap water in cleaned and sterilised/disinfected bottles (stored at refrigerated or at room temperatures) with the addition of powdered formula when ready for immediate feeding. The majority of parents reported they believed that implementation of this practice was following guidelines by making ‘one feed at a time’. Similarly this practice was reportedly advocated by many community midwives and health visitors and day nursery staff. However, use of this method means that powdered formula is mixed with water <70°C before feeding, which is contrary to FSA/NHS UK recommendations and has implications for microbial safety.
- Findings have illustrated the diversity of attitudes and perceptions that parents have towards specific handling, preparation and storage behaviours and microbial safety of PIF use inside and outside of the home.
- Results indicate that parents ‘cut corners’ with required preparation practices, especially as the infants’ age increases. Indeed, 43% of parents reported that they were more careful with how they prepared their infants’ feeds when they first started preparing powdered formula.
- The most commonly observed cleaning malpractices implemented by parents included failure to rinse all bottles and components after washing in hot water and detergent. In addition, almost all (90%) of parents failed to clean the inside and outside of the screwcap, outside of teats and around the outer rim of the feeding bottle. The screwcap and outer rim threads are key bottle locations known to harbour food residues and micro-organisms if inadequately cleaned.
- Common disinfection/sterilisation malpractices included failure to follow all manufacturers instructions for disinfection/sterilisation of the equipment, particularly failing to load the disinfection/steriliser unit according to instructions and failure to allow for ‘cooling time’ after completion of disinfection/sterilisation cycles and before removal of items from units.
- The majority of participants did not wash and dry their hands adequately at key PIF preparation steps as recommended by the FSA/DoH and they also handled bottle components after disinfection/sterilisation, which could lead to cross contamination.

***Recommendation 1: Develop a PIF safety strategy to improve parents’ powdered formula preparation and hygiene behaviours and eliminate widespread misunderstandings and misinterpretation of current guidelines. Strategy formation should be based on results from this and other studies. Use of social marketing principles (Andreason, 1995) will facilitate the development of highly focused messages for targeted groups/clusters of parents with tailored intervention materials.***

***Recommendation 2: Target specific key PIF preparation malpractices associated with negative attitudes and/or frequently implemented by parents (e.g.) reconstitution of powdered formula using water >70°C. Advice detailing implementation needs to be supported with clear reasons WHY safety measures are required.***

*Recommendation 3: Determine practical and realistically achievable methods to enable parents to implement all recommended DoH/FSA PIF preparation guidelines and inform parents HOW to realistically implement current recommendations using scenario specific examples. It is suggested that messages are communicated to parents from trusted and credible sources using multiple channels and a combination of written, verbal and demonstrated methods.*

*Recommendation 4: Produce powdered formula milk advice for targeted groups of parents, for example first time parents using formula, those changing from breast feeding to formula feeding and parents with older children.*

*Recommendation 5: Work with UK manufacturers to develop equipment to make easier for parents to determine the temperature of the water used for reconstitution of formula.*

*Recommendation 6: Inclusion and reinforcement of the importance of how and when adequate handwashing/drying and surface cleaning is necessary in intervention materials. Consumer perceptions of ‘adequate handwashing/drying and surface cleaning’ are often less thorough than practices required for microbiological safety.*

#### **9.4.2 Powdered infant formula preparation, handling and storage behaviours in UK hospitals**

- RTU/RTF formula (in glass bottles) is predominately the type of formula used as an artificial feed in maternity departments, but also in neonatal/SCBU and paediatric departments. Specialist and non-specialist PIF feeds are more frequently prepared/used for feeding in neonatal, SCBU and paediatrics departments.
- Hospital nurses in neonatal/SCBU and paediatric departments considered RTU/RTF formula to be safe, if opened and in-use for feeding for longer periods of time (>4 hours) than hospital midwives in maternity departments who considered RTU/RTF formula to be safe, if opened and in-use for feeding for ~1 hour.
- Reported responsibility for monitoring the time RTU/RTF formula bottles were in use was variable between departments. For example, in maternity departments, 88% hospital midwives/MHCAs reported it was the parents’ responsibility to monitor the length of time the RTU/RTF formula was open and ‘in-use’; whereas 95% of hospital nurses in neonatal/SCBU and paediatric departments/HCAs reported that it was the responsibility of the nurse to monitor RTU/RTF formula opening and ‘in use’ times.
- The location for preparation of PIF feeds was variable between hospitals. In the majority of hospitals, all feeds are prepared in ward/department kitchens or at the patient/infants bedside; however, in some hospitals feeds are prepared in Central Feeds Units.
- In neonatal/SCBU and paediatric departments and in Central Infant Feed Units, PIF (specialist and non-specialist) is reportedly reconstituted using bottles of sterile water (at ambient temperature).
- Hospital caregivers reported that there are instances when parents bring formula milk powder, reconstituted feeds and prepared (cleaned and sterilised) empty feeding bottles in

from home for feeding in hospital. Furthermore it was reported that parents do sometimes prepare their infants' feeds in hospital. Such practices were reportedly more common in neonatal/SCBU and paediatric departments than in maternity.

- Cumulatively, the majority of NHS caregivers perceived recommended practices to reduce the risk of illness from feeding with powdered formula milk to be important. However, practices associated with preparing one feed at a time, feeding reconstituted feeds immediately after preparation and reconstitution using boiled water cooled for <30 minutes/at >70°C were not considered to be important by up to 18% of NHS caregivers.
- Less than half of all NHS caregivers surveyed were aware of infection control policies that included PIF. 'Policies' that were cited were associated with the Baby Friendly Initiative and/or general hygiene.

***Recommendation 7: Provision of information to parents using RTU formula in hospital to clarify the maximum length of time bottles of RTU formula, once opened can be in use for.***

***Recommendation 8: NHS nursing and midwifery staff in neonatal, paediatrics and maternity departments require clarification on the maximum length of time bottles of RTU/RTF formula, once opened, can be in use for.***

***Recommendation 9: Evaluate the microbiological safety of PIF preparation in 'Central Infant Feeds Units' and in 'ward kitchens' in UK hospitals and assess milk kitchen staff management, training, knowledge, attitudes and risk perceptions associated with important PIF behaviours and guidelines.***

***Recommendation 10: Evaluate applicable infection control procedures in ward milk kitchens and Central Infant Feeds Units, including preparation area cleaning.***

***Recommendation 11: Design, develop and provide maternity, neonatal/SCBU and paediatrics departments with safety/infection prevention management advice/systems on the preparation of PIF, based on a HACCP approach.***

#### **9.4.3 Powdered infant formula preparation, handling and storage behaviours in UK day nurseries**

- Considerable variability was reported in methods used to manage and handle PIF between and within UK day nurseries, for example, 55-61% day nursery staff reported that made-up bottles of powdered formula are brought to nurseries, 34-41% reported that empty bottles, (ready for use) are bought to nurseries and 35-47% reported that prepared ready for use bottles are bought to nurseries with boiled water, ready for addition of the formula. Data indicate national and regional differences in reported methods. For example, in Wales, Scotland and Northern Ireland, reconstitution of PIF at home before nursery appears to be a more frequent practice.
- More than half of day nursery staff indicated that reconstituted PIF feeds (made-up at home) are frequently brought to nurseries, for storage and use throughout the period of

infant care, which may last for >10 hours. Methods used for carrying reconstituted PIF feeds to nurseries may encourage microbial growth.

- Nearly half of day nursery staff considered it acceptable for powdered formula to be made-up in advance and stored in the refrigerator all day before feeding, however, time temperature profiling of reconstituted feeds showed that no feeds achieved <5°C during storage, which has microbiological implications for safety.
- Another common method reported for managing powdered formula feeds in day nurseries was parent preparation of feeding bottle and boiled water (at home) and provision of powdered formula in a separate (sometimes measured out) container. The powdered formula feeds are then reconstituted immediately before feeding, removing the need for storage of reconstituted feeds. However, use of this method means that powdered formula is mixed with water <70°C before feeding, which is contrary to FSA/NHS UK recommendations and has implications for microbial safety.
- More than 20% of day nursery nurses lacked knowledge of correct refrigeration temperatures.
- The majority of day nursery nurses believed that they knew all of the precautions necessary for safe preparation and storage of PIF. However, few nursery nurses demonstrated knowledge of recommended handling, preparation and storage behaviours and almost all were unaware of the current guidelines.
- The majority of day nursery staff (including managers) believed PIF is a sterile product before the tin is opened and most were unaware of the association with *Cronobacter* spp. (*E.sakazakii*) and/or *Salmonella*.
- Large proportions of day nursery staff reported never receiving up-to-date information about PIF guidelines and only a third of day nursery managers reported awareness/recalled seeing the FSA Guidance for Healthcare Professionals.
- Although 65-72% of day nursery staff reported their nursery had a policy in place covering safe preparation, handling and storage of PIF; other study findings have indicated that such reported 'policies' may be unstructured and limited.
- Training about PIF use in day nurseries was reportedly scarce and usually conducted by day nursery managers who reported rarely receiving information/updates about safe preparation, handling and storage of PIF. Day nursery managers (as well as nursery nurses) reported negative attitudes towards recommended practices and were unaware of microbial risks associated with powdered formula.

***Recommendation 12: Development and implementation of training courses/resources concerning the microbiological risks and recommended guidance for safe preparation, handling and storage of powdered formula milk is required for day nursery staff (managers and nursery nurses). This needs to be followed up with regular updates.***

***Recommendation 13: Further education courses for those wanting to train to become childminders/carers need to be developed to include training about the microbiological risks associated with PIF use and how to minimize these risks.***

***Recommendation 14: There is a requirement for a standard, PIF safety management policy to be implemented in all UK day nurseries caring for infants aged <12 months.***

***Recommendation 15: Design, develop and provide UK day nurseries with safety infection prevention management advice/systems on the preparation, handling and storage of PIF based on HACCP. Advice and systems should incorporate the design and development of a standard checklist and self-assessment mechanism for day nurseries to determine, monitor and record levels of compliance with PIF management safety policies to ensure microbiological risks are reduced and controlled.***

***Recommendation 16: Designate individuals in UK day nurseries who care for infants aged <12 months, specific responsibility for PIF safety.***

#### **9.4.4 Parent and caregiver awareness of microbiological hazards associated with powdered infant formula**

- A lack of knowledge and negative attitudes towards microbiological hazards associated with PIF was determined among parents, day nursery staff and to a slightly lesser extent, NHS caregivers. Nearly three-quarters of parents and 45-77% of NHS caregivers believed that PIF is a sterile product before the tin has been opened.
- Parents' confusion and misconceptions have been identified about the length of storage time of opened cartons of RTU UHT formula and reconstituted PIF.
- Judgements of optimistic bias, the illusion of control, personal invulnerability and confidence in current practices associated with PIF preparation have been identified among all caregiver groups. Such judgements may impede intervention effectiveness and need to be considered in the design of risk communication strategies.

***Recommendation 17: All caregiver groups studied require information to increase awareness of the microbiological risks associated with PIF including information indicating that powdered formula is not a sterile product. This is particularly important for NHS caregivers who not only frequently handle formula milk for infant feeding, but also are information providers to parents.***

***Recommendation 18: Increase the potential effectiveness of PIF strategies by making intervention materials personally relevant to different caregiver groups and by reducing the perception of personal invulnerability. Aspects of perceived risk and control, related to preparation of powdered formula milk related to risk of illness need to be addressed during the development of future strategies to inform parents about PIF risks.***

#### 9.4.5 Information provision to parents about the safe preparation and handling of powdered infant formula

- A *substantial variability* in provision of information to parents about PIF feeding, preparation, handling and storage was determined among NHS caregivers.
- Almost all NHS hospital midwives, hospital nurses, health visitors and community midwives reported they are in contact with infants being fed using infant formula. However, NHS caregivers indicated variable (and often negative) attitudes towards provision of information and advice about PIF to parents.
- The majority of mothers reported a lack of adequate information provision from NHS professionals about preparation, handling and storage of PIF. All reported a huge amount of information about breastfeeding being available and given to them from midwives and health visitors.
- Many NHS caregivers (up to 71%), in each caregiver group, reported that bottle feeding mothers/parents were not given as much time or support and information as breast feeding mothers.
- Substantial discrepancies were identified between parents' perceived need for information about PIF and NHS caregivers' provision of adequate information for needs. Most NHS caregivers believed they provided adequate information to meet parents' needs, but most parents reported they needed more support and advice about how to manage the safety of powdered formula milk feeds.
- Parents who were aware of the new recommendations reported that they required additional support and advice about *how* to implement them in realistic scenarios. Parents also wanted to know *why* recommended practices should be implemented.
- Although almost all (94-99%) health visitors and community midwives reported that it was important to give PIF information to mothers when changing from breastfeeding to formula feeding, many mothers reported that when they changed such feeding practices no information/advice was given.
- Health visitors reported that they encountered considerable confusion amongst parents regarding correct practice in the preparation of PIF feeds; this confusion was compounded by the belief amongst health visitors, community midwives and parents that recommended practices are not consistent between sources (NHS, FSA, NCT, supermarkets, formula manufacturers etc).
- NHS caregivers working in the community (particularly health visitors) reported experiencing difficulties providing accurate information to non-English speaking clients due to time constraints, lack of availability of interpreters and lack of availability of pictorial interventions.
- Few parents recalled being given DoH/NHS bottle feeding leaflets and large proportions of NHS caregivers reported lack of availability which was variable between countries and regions.

*Recommendation 19: Increase provision, and consistency of provision of information about safe preparation, handling and storage of powdered formula milk to parents from hospital nurses, health visitors and midwives.*

*Recommendation 20: Increase availability of printed DoH/NHS 'Bottle Feeding' leaflets for NHS caregiver (particularly community midwives and health visitors) to give to mothers/parents feeding their infant with formula.*

*Recommendation 21: Increase support and information provision (verbal, demonstrations and written) to mothers/parents who feed their infant using RTU/powdered formula when in hospital and when in the home.*

*Recommendation 22: Develop pictorial information sources and/or translated written material to aid NHS caregivers to communicate safe, recommended powdered formula preparation, handling and storage to non-English speaking parents.*

*Recommendation 23: Although many NHS caregivers were reluctant to discuss PIF use, the majority recognised the importance and need for preparation and handling safety. It is therefore suggested that the FSA work with the DoH/NHS to provide information about preparation, handling and storage of powdered formula milk solely on implementing risk-reducing behaviours and overcoming the microbiological risks, without adversely affecting breast feeding initiatives.*

*Recommendation 24: To overcome inconsistent sources of PIF advice and remove confusion among NHS caregivers and parents about 'best/safe practice', it is recommended that the FSA collaborates with sterilisation/disinfection manufacturers and other infant feeding organisations to produce consistent and reliable information for healthcare professionals and parents.*

#### **9.4.6 Training and sources of powdered infant formula information reported by NHS caregivers**

- Few (<31%) NHS caregivers reported they had 'ever' had training about microbiological risks associated with PIF and <20% reported they had received any such training in the past 3 years (since 2006/2007).
- Information about breastfeeding was reportedly updated more frequently to all caregiver groups, than PIF. Overall, ~50% of all caregivers reported never receiving updated information about powdered formula milk use and feeding.
- Reported awareness/recollection of FSA/DoH and WHO PIF guidance notes was limited among all NHS caregivers (26-40%) and lowest among hospital midwives (26%) and more widespread among health visitors.
- Formula reps were considered by some NHS caregivers (particularly in the community) to provide information that was useful, important and needed by caregivers. This information was reportedly needed to inform parents about up-to-date PIF guidelines, microbiological risks associated with formula and effect of consumption on the digestive system. However



the majority of caregivers reported they are now not allowed to contact such reps directly for information.

- Breastfeeding coordinators/infant feeding coordinators (reportedly often responsible for implementation of the Baby Friendly Initiative within hospitals) were cited by many NHS caregiver groups as gatekeepers to PIF information.

***Recommendation 25: Increase awareness and distribution of the documents ‘Guidance for making up Special Feeds for Infants and Children in Hospital (BDA/FSA) and ‘Guidance for Healthcare Professionals on the Safe Preparation, Storage and Handling of Powdered Infant Formula’ (FSA) directly to neonatal, paediatrics and maternity departments.***

***Recommendation 26: It is recommended that the FSA identifies how communication of key messages concerning preparation and handling of powdered formula milk can be delivered to health professionals and other carers for their own use and dissemination to parents.***

#### **9.4.7 Infant feeding policies and the Baby Friendly Initiative**

- Policies for infant feeding are present in many hospitals and reported to be based upon the UNICEF Baby Friendly Initiative and focus on breastfeeding.
- Almost all NHS caregivers reported the influence of the Baby Friendly Initiative – caregivers who did not work for an accredited hospital/workplace either had obtained a certificate of commitment or informally followed ‘Baby Friendly rules’.
- The majority of NHS caregivers reported that they promote breastfeeding ‘more than they used to’ and that the influence of the UNICEF Baby Friendly Initiative has a substantial impact upon their roles.
- NHS caregivers reported variable opinions and attitudes towards the implementation and conformance to the Baby Friendly Initiative. For example, the majority of hospital nurses who were supportive of the need and importance for breastfeeding, believed the Baby Friendly Initiative was ‘*too extreme*’ and ‘*detrimental*’ to bottle feeders. Other NHS caregivers, particularly community midwives and health visitors reported restricted provision of information to parents about PIF; others reported they believed adhering to ‘Baby Friendly rules’ undermined professional judgement.
- Less than half of respondents in each NHS caregiver group reported awareness that their workplace has an infant feeding policy that included PIF.

***Recommendation 27: Investigate how the FSA can link with other infant feeding and breast feeding initiatives (such as the Baby Friendly Initiative) to facilitate provision of effective information for parents about the microbiological safety of PIF preparation, handling and storage in a way that does not appear to contradict breastfeeding initiatives/advice.***

***Recommendation 28: Recognising the importance of breastfeeding and the constraints imposed on health professionals to advocate breast feeding, investigate means to overcome barriers to information provision about the microbiological safety of powdered formula milk preparation and handling.***

## 9.5 FURTHER RESEARCH

It is recommended that the FSA undertake further research on the preparation and handling of infant formula. The information collected will provide additional information which could be used for the design and delivery of risk communication initiatives leading to both greater awareness of key safety issues and behavioural change within a range of caregivers who prepare and handle powdered formula milk.

- Use social marketing (Andreason, 1995) and a consumer orientated approach as a framework to research a PIF strategy to improve specific risk based behaviours. Design interventions using formative research that are tailored for the needs of specific groups of parents who are formula feeding their infant(s). Evaluate the effectiveness of interventions on different groups of parents (targeted and segmented) by evaluating behavioural change using direct observation and assessment of targeted behaviours.
- Investigate the use of different methods for segmentation of target audiences, for example, use of other social cognition models, perceptions of risk of illness, risks of outcome expectations.
- Identify PIF practices that are most likely to be improved as a result of intervention and establish why these practices are more likely to be improved than others.
- Investigate practical and realistically achievable methods to enable parents to implement all recommended DoH/FSA PIF preparation guidelines.
- Evaluate PIF information available to parents, caregivers, NHS healthcare professionals and day nursery staff in terms of content, availability, understandability and credibility.
- Determine parents' awareness, attitudes, perceptions and receipt of information and advice about PIF preparation, handling and storage. Ascertain sources of information and spokespersons perceived to provide credible information.
- Identify channels to optimise message delivery and gatekeepers as a means for delivery of PIF safety messages to a variety of targeted groups of parents with infants aged less than 12 months.
- Collect qualitative and quantitative information detailing how consumers prefer to receive food safety information and from whom.
- Collect information on consumer perceptions of different intervention delivery methods, types and formats.
- Investigate how the FSA can link with other infant feeding and breast feeding initiatives to facilitate provision of effective information about the microbiological safety of PIF preparation, handling and storage to parents who are, or intend to, formula feed.
- Obtain information regarding psychological profiles of targeted groups/clusters of caregivers (including parents, childminders, grandparents, day nursery staff and NHS healthcare professionals). These groups share a particular set or combination of attitudes

towards different aspects of powdered formula milk use and/or towards specific PIF preparation and storage behaviours that are frequently implemented and pose significant risk potential to health.

- Re-enact observed parents' PIF preparation, handling and storage behaviours in the laboratory to further clarify the potential for pathogen growth and survival and associated microbial risks to improve the scientific/risk basis of advice provided.
- Development of a checklist with risk-based scoring system tailored for use by parents and/or day nursery staff to quantitatively assess PIF risks before starting to prepare/handle PIF for the first time.
- Obtain information from different target audiences concerning the content, format and source of PIF information preferred.
- Determine how key messages concerning the preparation and handling of powdered formula milk can be delivered to health professionals and other carers for their own use and dissemination to parents.
- Recognise the importance of breastfeeding and the constraints imposed on health professionals to advocate breast feeding, investigate barriers to information provision about the microbiological safety of powdered formula milk preparation and handling.
- Evaluate the safety of PIF preparation in 'milk kitchens' in UK hospitals.
- Assess milk kitchen staff management, training, knowledge, attitudes and risk perceptions associated with important PIF behaviours and guidelines.
- Evaluate applicable infection control procedures including preparation area cleaning.
- Observe powdered formula preparation behaviours and delivery of feeds to hospital wards; monitor time temperature of feeds from preparation until feeding and conduct microbiological analysis of prepared feeds and preparation surfaces of milk kitchen. Risk assess data collected.
- Evaluate and analyse the PIF management systems used in a range of premises (e.g. nurseries, hospitals etc) to determine efficacy and adequacy.
- Undertake studies to assess the levels of compliance with PIF safety management systems across a range of premises and link this to the prevailing organisational culture within those premises.
- Conduct a microbiological analysis of day nursery kitchens and environments where PIF is prepared and stored; observe preparation, storage and handling behaviours of day nursery staff and link to management systems and culture and the knowledge, attitude and risk perception and previous training of the staff.

## 10. PUBLICATIONS/PRESENTATIONS

### 10.1 Publications in preparation

*(nb this list is not exhaustive)*

1. Health visitor and community midwife attitudes and perceptions towards powdered infant formula preparation and storage behaviours and information provision: a qualitative study.
2. Powdered infant formula use and information provision in UK hospitals: a qualitative study.
3. A qualitative study of UK parents' powdered formula milk behaviours.
4. Powdered formula milk preparation and storage of powdered infant formula milk in UK day nurseries: a qualitative study.
5. A qualitative comparison of NHS caregiver perceptions about preparation and storage of reconstituted powdered milk formula: implications for microbiological safety and education.
6. A quantitative analysis of parents' attitudes, and perceptions towards powdered infant formula preparation and handling behaviours, microbial safety and information provision.
7. Consumer and caregiver perceptions of hygiene and safety associated with powdered infant formula risk, control and responsibility.
8. Parents' self-reported powdered infant formula preparation, handling and storage of powdered infant formula inside and outside of the home.
9. Reported powdered infant formula preparation, handling and storage in UK day nurseries.
10. Day nursery staff attitudes and perceptions towards powdered infant formula preparation and handling behaviours and microbial safety.
11. Time temperature profiling of reconstituted powdered infant formula feeds stored in UK day nurseries: implications for microbiological safety.
12. A quantitative study of NHS caregivers' attitudes and perceptions towards powdered infant formula preparation and storage behaviours and microbiological safety.
13. Antenatal and postnatal powdered infant formula information provided to parents with young infants.
14. Microbiological and observational analysis of parents' preparation and handling of powdered infant formula feeds.
15. Time temperature profiling of reconstituted powdered infant formula feeds prepared by parents and stored inside and outside of the home before feeding: implications for microbiological safety.
16. Prediction of the growth of *Cronobacter* spp. in reconstituted powdered infant formula feeds stored in day nurseries and inside/outside parents' homes.

## 10.2 Conference presentations

Redmond, E. C. and Griffith, C. J. (2010) Caregiver perceptions about preparation and storage of reconstituted powdered milk formula: implications for microbiological safety and education. 3<sup>rd</sup> European Public Health Association Conference (EUPHA), Amsterdam. The Netherlands; 10<sup>th</sup> -13<sup>th</sup> November, 2010 Poster presentation.

Redmond, E. C. and Griffith, C. J. (2010) Storage and Temperature Control of Reconstituted Powdered Infant Formula Feeds in Day Nurseries. The 97<sup>th</sup> International Association for Food Protection Conference Anaheim Convention Center, Anaheim, CA, USA; 1-4<sup>th</sup> August, 2010. Poster presentation.

Redmond, E. C. and Griffith, C. J. (2009) Use of Powdered Infant Formula in UK Day Nurseries: Implications for Microbial Safety. IAFP European Symposium, Estrel Convention Center, Berlin, Germany; 7-9<sup>th</sup> October, 2009. Poster presentation.

Redmond, E. C. and Griffith, C. J. (2009) Time-Temperature Profiling Associated with Preparation and Storage of Powdered Infant Formula: Implications for Microbial Safety. IAFP European Symposium, Estrel Convention Center, Berlin, Germany; 7-9<sup>th</sup> October, 2009. Poster presentation.

Redmond, E. C. and Griffith, C. J. (2009) Time-Temperature Profiling Associated with Preparation and Storage of Powdered Infant Formula: Implications for Microbial Safety. International Association for Food Protection Conference, 96<sup>th</sup> Annual Meeting, Grapevine, Texas, USA. Poster presentation.

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### 10.3 Conference abstracts/information

*3<sup>rd</sup> European Public Health Association Conference (EUPHA)*

*Amsterdam, The Netherlands*

*10<sup>th</sup> -13<sup>th</sup> November, 2010*

#### **Caregiver perceptions about preparation and storage of reconstituted powdered milk formula: implications for microbiological safety and education.**

**Elizabeth C. Redmond and Christopher Griffith**

*Background:* Methods used to prepare and store reconstituted powdered milk formula have important microbiological implications for safety and public health. Recommended procedures in the home and healthcare settings may be achieved by parents and caregivers being equipped with adequate/correct knowledge, positive attitudes and motivation to implement desired behaviours that can minimise microbial risks. This study aims to understand parent and caregiver beliefs, attitudes, practices and information provision relating to infant feeding with powdered milk formula.

*Methods:* Sixteen focus groups were conducted in seven locations across the UK and included homogenous groups of parents, day nursery nurses, hospital nurses and health visitors. Respondents were recruited according to employment responsibilities, frequency of formula preparation and demographics. Each group discussion followed a structured guide and included evaluation of educational materials.

*Results:* The majority of respondents were unaware of specific microbiological risks associated with formula and considered current practices to be 'safe'. Some parents reported storage of reconstituted formula at ambient temperature when away from the home; others reported to 'take water and powder separately' and reconstitute immediately before use. Common sources of formula information for parents included family, friends, midwives and health-visitors. A frequent barrier for obtaining information from professional sources was an attitude being 'dead against formula'. Hospital nurses, midwives and health-visitors reported having limited information to distribute regarding formula feeding and cited 'lack of time' and conformity to the UNICEF Baby Friendly Initiative as reasons for not providing formula based advice or bottle demonstrations. Further discrepancies between caregiver groups will be discussed, particularly regarding information provision.

*Conclusions:* Information sources for parents and healthcare professionals are lacking and messages are perceived to be inconsistent and reportedly cause confusion at a parent and professional level. Findings from this study will help to inform the development of informed, targeted information sources that address microbial risks of preparation and storage of powdered formula milk and improve public health.

**Storage and temperature control of reconstituted powdered  
infant formula feeds in day nurseries.**

**Elizabeth C. Redmond and Christopher Griffith**

*Introduction:* The use of day nurseries for infant care has increased in recent years and the majority store bottles of reconstituted powdered infant formula (PIF) feeds. PIF can become contaminated with micro-organisms, including pathogens, during production, handling and preparation. Inadequate temperature control may increase risk of microbial growth. Relatively little is known about how day nursery staff (DNS) manage the safety of reconstituted PIF storage.

*Purpose:* The aims of this study were to determine behavioural influences of PIF storage practices implemented by DNS and to track time-temperature profiles of reconstituted PIF stored in nurseries.

*Methods:* DNS knowledge, attitudes and beliefs were determined using a postal questionnaire, administered to 10% (n=830) of UK nurseries with infants aged less than 6 months. Time-temperature profiling of PIF feeds (n=55) occurred using a miniature datalogger (accuracy $\pm$ 0.5°C) and validated methods. Temperature tracking commenced from PIF reconstitution in nurseries or arrival at nursery, until feeding.

*Results:* On arrival at nurseries, temperatures of PIF feeds were 14-51°C( $\pm$ 1°C) and the length of time between arrival at nursery and refrigeration ranged from 0-135 minutes (mean 39 minutes) with the storage duration lasting for >7 hours. No reconstituted PIF brought to nursery achieved <5°C during storage prior to feeding. Warm/hot feeds were initially stored in nursery kitchens (23-25°C) for >2 hours before refrigeration. PIF made-up in nurseries were stored for less than 6 hours; such feeds stored for >60 minutes achieved <5°C. The majority (63%) of DNS were unaware of specific microbiological risks associated with PIF and 76% believed PIF is a sterile product. Knowledge of correct refrigeration temperatures was lacking and 87% reported never being trained regarding microbiological risks associated with PIF.

*Significance:* Findings indicate time-temperature abuse of reconstituted PIF prepared by parents and stored in day nurseries. This could have a major impact on PIF quality. Cumulatively, data will help development of targeted training and national policies that address the microbial risks of storage of PIF in day nurseries.

**2009 IAFP European Symposium**  
**Estrel Convention Center, Berlin, Germany**  
**7-9<sup>th</sup> October, 2009**

**Use of powdered infant formula in UK day nurseries: implications for microbial safety.**

**Elizabeth C. Redmond and Christopher Griffith**

Over the past few decades the need for non-maternal childcare has risen as increasing numbers of mothers with infants aged <12 months return to employment. Implementation of recommended procedures for preparation, storage and feeding of reconstituted powdered infant formula (PIF) have important microbiological implications for safety and are required to minimise microbial risks. Relatively little is known about how day nursery staff manage the safety aspects of PIF preparation and storage.

This study aimed to understand day nursery nurses' (DNN) knowledge, attitudes and behaviours relating to infant feeding with PIF in UK day nurseries. Data from DNN was obtained using focus group discussions across the UK (n=4) and self-complete postal questionnaires, administered to 10% of UK nurseries with infants aged less than 6 months (n=830).

Findings indicated that methods DNN (n=334) reportedly use to handle, prepare and feed PIF are variable within and between day nurseries. Ninety-five percent of DNN reported feeding PIF according to parent instructions, even if such practices were believed to be inappropriate. Common practices included (44%) feeding PIF reconstituted by parents and brought to the nursery for use throughout the day (up to 10 hours) and (53%) prepared feeds in the nursery using measured PIF, bottle with measured, pre-boiled water provided by the parents. Both practices are contrary to current safety recommendations which indicate it is best to make-up PIF fresh for each feed, using boiled water >70°C. Many DNN believed PIF is a sterile product '*I think it is sterile*' and up to 95% DNN lacked knowledge and awareness of microbiological issues, such as the association between *E.sakazakii*/*Salmonella* and PIF. The majority of DNN reported they had never received training about the microbiological risks associated with PIF.

Findings from this study will help the development of targeted information and national policies that address the microbial risks of preparation and storage of PIF in day nurseries.



*2009 IAFP European Symposium*  
*Estrel Convention Center, Berlin, Germany*  
*7-9<sup>th</sup> October, 2009*

**Consumer attitudes and risk perceptions associated with preparation and storage of powdered formula milk in the home: implications for microbiological safety and education.**

**Elizabeth C. Redmond and Christopher Griffith**

The risk to infants from powdered infant formula (PIF) milk has received increased attention in recent years due to possible contamination with pathogens such as *Enterobacter sakazakii* and *Salmonella*. Recommended procedures to safely prepare and use PIF in the home are available to parents; however implementation may be influenced by parental attitudes and risk-related perceptions. For health communication strategies to be effective it is important for them to be relevant. Related psychological constructs need to be identified and addressed. This study determines parents' attitudes and perceptions of risk, control and responsibility associated with preparation and storage of PIF in the home.

Structured face-to-face interviews with 200 parents were undertaken in hall-tests in England and Wales using a Computer-Assisted-Personal-Interviewing technique. Quota controls on age groups and socioeconomic-grading were applied and the sample was representative of parents who feed their infant(s) with PIF at least once a day.

Results indicated attitudes and risk perceptions that may impede implementation of safe preparation and storage behaviours. Sixty-nine percent of parents believed PIF was sterile and the majority were unaware of the association of PIF with *E.sakazakii* and/or *Salmonella* (83%). Ninety-percent of parents believed there was a very low risk of infant illness after feeding reconstituted PIF they had prepared; risk of illness was perceived to be greater if feeds were made-up by 'other parents', day nursery staff and hospital staff. The majority (97%) of parents believed they had full responsibility and full control of hygiene and safety when preparing PIF for their infant; smaller proportions of parents (44-73%) believed that 'other parents', day-nursery staff and hospital staff had the same level of responsibility (63-82%) and control (44-73%).

Findings suggest consumer judgements of 'optimistic bias' and the 'illusion of control' could be a factor in the adoption of appropriate hygiene practices. Data collected will help the development of targeted information and messages that address microbial risks of domestic preparation and storage of PIF.

*The 96<sup>th</sup> International Association for Food Protection Conference,  
Grapevine, Texas, USA.  
12<sup>th</sup>-15<sup>th</sup> July, 2009*

**Time-temperature profiling associated with preparation and storage of powdered infant formula: implications for microbial safety.**

**Elizabeth C. Redmond and Christopher Griffith**

*Introduction:* Powdered infant formula (PIF) is not sterile and UK recommendations are that powdered infant feeds are reconstituted using boiled water >70°C (cooled for 30 minutes). If not possible to reconstitute feeds immediately before use, made-up feeds should be refrigerated and transported in a cool bag for <4 hours. Research indicates frequent non-compliance with this advice.

*Purpose:* This study determines the time-temperature profiles and microbial counts of PIF reconstituted using water at different temperatures and subsequent storage.

*Methods:* Time-temperature profiles of three volumes of water (1.5litre, 1litre, 500ml) were determined for 30 minutes after boiling in domestic kettles (n=25) using a datalogger (accuracy ±0.5°C). Then 260ml aliquots of the cooled, boiled water was used to reconstitute PIF in cleaned/sterilized feeding bottles and sampled for Aerobic Colony Counts (ACC) and *Enterobacteriaceae*. In separate experiments, internal time-temperature profiles of replicate (n=5) reconstituted PIF feeds stored at ambient temperature and in cool-bags for >4 hours were recorded using miniature dataloggers (accuracy ±0.5°C). Initial temperatures of feeds ranged from <5°C, ~20°C and 70°C in 125ml/260ml bottles. ACC, *Enterobacteriaceae* and *Staphylococcus aureus* counts were determined immediately after reconstitution and before potential feeding.

*Results:* After 30 minutes of cooling temperatures of 1.5l boiled water were >70°C. Microbial counts of feeds reconstituted with this water were <1.0x10<sup>1</sup>ACC and no *Enterobacteriaceae* were isolated. However, temperatures of 1litre and 500ml boiled water, after 30 minutes were below 70°C and resultant ACC counts were up to 3.4x10<sup>3</sup>. The temperature of all feeds stored at ambient temperature and in cool-bags for >4 hours was conducive for microbial growth. No *Enterobacteriaceae* or *S.aureus* were isolated.

*Significance:* Cooling larger quantities of boiled water resulted in temperature remaining >70°C which has an effect on the microbial quality of the product. Microbial counts increased significantly within 4 hours when reconstituted feeds are stored >5°C. Studies have shown time-temperature abuse by consumers of over 18 hours and this could have a major impact on PIF quality.

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