



COI and FSA

Powdered Infant Formula

Qualitative Research

Final Report

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I Executive Summary

Project Approach

- The purpose of this research was to explore parents and health care professionals understanding of the term ‘non-sterile’, potential implications of ‘non-sterile’ in relation to powdered infant formula milk and attitudes towards information, labelling and advice needs regarding powdered infant formula milk.
- A qualitative approach was identified as the most effective methodology and this involved **10 group discussions with parents** with babies aged between 0 – 6 months old, including one group with mothers of pre-term and/or low birth weight babies. In addition, there was a further **group discussion and 5 depth interviews with Health Care Professionals (HCPs)**. The discussion groups with parents included those only using formula and those who mix formula feeding with breast feeding; a wide range of ages of parents; mothers and fathers; different social economic groups (SEG) and from a range of locations across the UK. The HCPs that we spoke to included a mix of health visitors, community and hospital midwives, a neonatal nurse and community practitioners. The research was conducted in March and April 2006.

Key Findings

- Differences in attitude towards use of powdered formula milk and the desire for information and advice were very evident in this research and were based on general **attitudinal differences** to food issues, covering 4 types: **Avoiders** who actively avoid issues in order not to have to change habits; **Pragmatists** who only change habits if they believe opinion is widespread; **Headline Reactives** who tend to display concern which is often short-lived, resulting in a fairly superficial impact, (N.B. Pragmatists and Headline Reactives display similar needs and were jointly termed **Mainstream** for the purposes of this research) and **Purists** who are more cautious and knowledgeable than the other segments so are more able to decide on what action to take as a result.

- Parents and Health Care Professionals agreed that **advice and information** given to parents about bottle feeding is extremely limited, even when parents state a preference for this method of feeding. Parents reported gaining advice and information by a variety of other means such as seeking advice from family and friends; on-pack advice was used by all when starting to formula feed, but use was fairly limited for most parents.
- The different sources of information and inconsistencies between these resulted in a diversity of knowledge and understanding about bottle feeding practices and, therefore a wide range of **current practices** in terms of preparation, storage and use of powdered infant formula milk, include inappropriate use. Interestingly, however, most caregivers believed they were following advice carefully and not taking any risks. Hence, there was little concern amongst parents about the use of powdered infant formula.
- In our small sample of healthcare professionals, there was limited awareness of powdered infant formula milk being **non-sterile**. Awareness was latent and not linked to reasons for parents to be more cautious, nor for HCPs to be more directive, about its preparation, storage and use.
- When the issue of sterility was discussed with parents, many assumed most canned or bottled food is sterile, at least until it is opened. Therefore, there was no awareness amongst parents that powdered infant formula milk is non-sterile.
- The term ‘non-sterile’ as a term was perceived very negatively and failed to communicate the nature and level of risk as most did not think it meant potentially harmful, but actually harmful. As a result, the news that powdered infant formula milk is non-sterile generated both concern and confusion. Although, parents’ reactions varied according to attitudinal type.

- Overall, as it poses a potential risk to babies, parents and healthcare professionals agreed that information about non-sterility and what it means should be **clearly communicated to parents**, so that they can make informed decisions and choices.
- Reactions to the **new guidelines** on the revised Bottle Feeding advice (Department of Health, 2005) indicated that the change of making up bottles fresh rather than in advance was deemed as very difficult to put into practice by the majority of parents who make them in advance. Other changes about water cooling time and out of home practice raised less concern but needed clarification about implementation.

Key Recommendations

- The research suggested that the most effective messages to communicate the issue to parents are those which help to **increase parental responsibility**.
- As information and advice is drawn from a wide range of sources across the attitudinal types, it will be important for this issue to be communicated via **all formal channels** in order to reach all parents, including HCPs, printed material (such as NHS booklets and other separate leaflets), and on-pack as well as internet sites and telephone care-lines.
- The discussion groups recommended a number of possible amendments that may help to improve the clarity of advice and guidance provided to parents by Government Departments, Health Care Professionals and on pack information.

II Introduction

A Background

Last year the World Health Assembly adopted a resolution that Member States should inform health care workers, parents and other caregivers about best practices for preparation and handling of powdered infant formula. This was due to international concern about the risk to infants from pathogenic microorganisms, because powdered infant formula milk is a non-sterile product.

Although infections caused by these microorganisms are rare, there have been 50-60 known cases in the last 40 years caused by powdered infant formula worldwide, they can be severe and the risk is considered to be greatest for pre-term, immuno-compromised and low birth weight infants.

In response, the Department of Health revised its leaflet on bottle feeding to advise parents on the new guidelines around preparation and storage of powdered infant formula milk. The advice covers best practice in using powdered formula milk, including using fresh tap water to fill the kettle, after the water has boiled to let the water cool for no more than half an hour, to make up fresh feeds each time and to use them immediately. If equipment is sterilised and powdered formula is prepared according to the guidelines, the risk of infection is greatly reduced.

The Food and Agricultural Organisation of the United Nations – World Health Organisation (FAO-WHO) recommended that the caregivers to infants should be informed that the powdered infant formula is not a sterile product and the European Food Safety Authority (EFSA) further recommended that guidelines for the preparation and storage of powdered infant formula should be prepared for use in the home and health care settings. Following discussions with industry about these recommendations, the Food Standards

Agency (FSA) wished to carry out research to explore understanding of the term non-sterile and attitudes towards labelling and advice on powdered infant formula amongst parents and healthcare professionals.

B Research Objectives

Overall: To explore understanding of the term ‘non-sterile’, potential implications of ‘non-sterile’ in relation to powdered infant formula milk and attitudes towards information, labelling and advice needs regarding powdered infant formula milk

Specifically the research needed to explore the following issues:

Amongst parents:

- Explore current understanding of the term ‘non-sterile’
 - what do people understand by this term generally e.g. associations, consequences
- Explore reaction to infant (and follow-on) formula being ‘non-sterile’ and impact on parents attitudes
 - awareness of formula being ‘non-sterile’
 - understanding of ‘non-sterile’ in relation to infant formula
 - attitudes towards ‘non-sterile’ infant formula
 - immediate concerns and levels of concern
 - impact, if any, this information has on feeding behaviour and the use of infant and follow-on formula
 - differences between infant and follow-on formula
- Examine information and advice needs from parents with regard to powdered infant formula
 - types of information and advice parents require e.g. best practice, potential risks etc
 - most appropriate ways to deliver the information e.g. print, web, face to face, back of pack, etc

- level of information and advice required (basic vs detailed)
- if and how infant formula should be labelled as 'non-sterile'
- who should provide the advice (e.g. FSA, health care professionals, other) and who do parents find most trustworthy
- impact of information to raise/reduce any concern with regard to 'non-sterile'

Amongst Health Care Professionals:

- Explore information requirements
- If/how targeted information should indicate that powdered infant formula is non-sterile
- Reaction towards labelling powdered infant formula as non-sterile

C Method and Sample

A qualitative approach was identified as the most effective methodology and this involved **11 group discussions and 5 depth interviews**, with parents of 0 – 6 month old babies and Health Care Professionals, structured as follows:

i. 9 groups with parents (7-8 respondents for 1 ½ hours)

<i>Group</i>	1	2	3	4	5
<i>Feed</i>	Formula	Formula	Formula	Formula	Formula
<i>Motivations</i>	Planned	Planned	Planned	Unplanned	Unplanned
<i>Lifestage</i>	1st time parent	1st time parent	Subsequent parent	1st time parent	Subsequent parent
<i>Age</i>	Younger	Younger	Older	Older	Younger
<i>Parent</i>	Dads	Mums	Mums	Mums	Mums
<i>SEG</i>	C2DE	C1C2	ABC1	C2DE	ABC1
<i>Location</i>	Scotland	London	North	Wales	Midlands

<i>Group</i>	6	7	8	9
<i>Feed</i>	Mix	Mix	Mix	Mix
<i>Motivations</i>	Planned	Planned	Unplanned	Unplanned
<i>Lifestage</i>	1st time parent	Subsequent parent	1st time parent	Subsequent parent
<i>Age</i>	Older	Younger	Younger	Older
<i>Parent</i>	Mums	Mums	Mums	Dads
<i>SEG</i>	ABC1	C2DE	C2DE	ABC1
<i>Location</i>	N. Ireland	Scotland	North	London

- All were parents of babies aged under 6 months old (including a spread of age from 0-6 months with at least half the group to be under 3 months)
- All feeding habits were based on how baby is currently fed
- 'Formula' were those only feeding formula
- 'Mix' were those feeding breast milk and formula (to include a spread of proportions of use)
- All were using powdered formula (vs. UHT-treated liquid formula) for majority of formula feeds
- All were involved in the feeding process on a regular basis (at least 3 times a week)
- All at least shared responsibility for products purchased (except fathers groups where at least half shared responsibility for products purchased)
- 'Planned' were those who had planned how to feed (breast or formula) and kept to that plan
- 'Unplanned' were those who had not planned to use formula but now do so (include spread of reasons for doing so)
- A spread of how long they have been using formula was ensured
- Younger parents were aged 18-30
- Older parents were aged 31-45
- First time parents were those who only had one child and subsequent parents were those who had 2 children or more
- A spread of age of other children for subsequent parent families was ensured
- At least 2-3 older parents were using/had used powdered follow on formula
- A spread of attitudes to sterilising was ensured
- Representative inclusion of ethnic minorities
- Those with 'at risk' (low birth weight, pre-term and immuno-compromised) babies were excluded from these groups

- Parents whose babies were on special prescription formulas for medical reasons (e.g. milk intolerant babies) were excluded

ii. **1 group with parents of ‘At Risk Babies’** (6 respondents for 1 ½ hours)

<i>Group</i>	10
<i>Feed</i>	Mix of formula only and formula/breast fed
<i>Motivations</i>	Mix of planned and unplanned
<i>Lifestage</i>	Mix of first time and subsequent parents
<i>Age</i>	25-45
<i>Parent</i>	Mums
<i>SEG</i>	(B)C1C2
<i>Location</i>	Midlands

- All were parents of ‘At risk’ babies i.e. pre-term and low birth weight babies (not clinically immuno-compromised)
- All were parents of babies aged under 6 months old (including a spread of age from 0-6 months)
- All feeding habits were based on how baby is currently fed
- All were using powdered formula (vs. UHT-treated liquid formula) for majority of formula feeds
- All were involved in the feeding process on a regular basis (at least 3 times a week)
- All were responsible for products purchased
- ‘Planned’ were those who had planned how to feed (breast or formula) and kept to that plan
- ‘Unplanned’ were those who had not planned to use formula but now do so (include spread of reasons for doing so)

- First time parents were those who only had one child and subsequent parents were those who had 2 children or more
- A spread of age of other children for subsequent parent families was ensured
- 2 parents with older children were using/had used powdered follow on formula
- Representative inclusion of ethnic minorities

- iii. **1 group with Health Care Professionals (HCP's)** (6 respondents for 1 ½ hours)

Group	11
<i>Profession</i>	Health Visitors Midwives (community and hospital) Community Practitioners
<i>Location</i>	London

- iv. **5 Health Care Professional face-to-face depth interviews** (for 1 hour)

Depth	1	2	3	4	5
<i>Profession</i>	Health Visitor	Community Midwife	Hospital Midwife	Neo-natal Nurse	Community practitioner
<i>Location</i>	South England	Scotland	Northern Ireland	Midlands	Wales

- All health care professionals were currently working full or part time for NHS
- All were involved with babies under 6 months old
- Spread of level of experience in role (include one newly qualified)
- Spread of age

All fieldwork took place around the UK, namely London, Hertfordshire, Birmingham, Sheffield, Edinburgh, Cardiff and Belfast between 20th March and 4th April 2006.

The research team comprised: Claire Vernon and Jill Swindells.

Copies of the recruitment questionnaires, discussion guides, self-completion sheet and stimulus material can be found in the Appendix.

III Detailed Findings

1. Attitudinal Types

Differences in attitude towards the use of powdered formula milk and the desire for information and advice were very evident in this research. These related to types identified in previous relevant projects for FSA which are based on general **attitudinal differences** to food issues, and have implications for levels of concern, behaviour and information needs. These types only vary slightly by demographics with a greater bias to higher socio-economic groups (SEGs) in the Purists segment and more females in the Purist and Headline Reactive segments, other than this there were little differences across the types, (including differences by location e.g. rural or urban).

In relation to powdered infant formula, distinctly different need sets emerged. While Purists had distinct requirements and Avoiders needed specific targeting to get the message across, Headline Reactives and Pragmatists demonstrated shared behaviour, level of concern and needs relating to both information and reassurance, such as *“I could do with knowing whether I need to worry or not”*

1.1 Avoiders

Avoiders prefer to be kept in the dark and actively avoid issues in order not to have to change habits, relating to both usage and purchasing. They represent a minority, a mix of both sex and age, who would *“Rather not know”*. They actively avoid issues as they do not want to think about or deal with them and, consequently, they may not watch or read the news, especially when it comes to specific, personally relevant or sensitive stories. As a coping mechanism they tend to make generic rationalisations, such as *“it isn’t a problem”* and seeing the media as *“hype and nonsense”*

If it's so rare it's not worth telling us...I'd rather not know
[Younger, 1st time Mums, C1C2, London]

My boys have all been fine on formula so I can't see it as a real problem
[Older, Dads, ABC1, London]

1.2 Pragmatists

Pragmatists feel “*life is too short*” and try to keep life simple by placing few restrictions on how they make decisions and choices. They try to keep issues in proportion using a variety of rationalisations to reduce perceptions of risk, such as an issue not yet being proven or prohibitive cost perceptions. They are only interested in ‘proven’ issues and they only change habits if they believe opinion is widespread. They might, however, follow some simple, easily accessible and less challenging advice. They choose not to take personal responsibility and put much trust in regulators, believing that ‘regulatory’ bodies should deal with issues on their behalf. They formed a larger portion of the sample and are found across all ages and both sexes. For the purposes of this research, we refer to this group along with Headline Reactives, below, as **Mainstream** as they display similar needs.

You can't blow these things out of proportion and get everyone worrying for no reason
[Older, Dads, ABC1, London]

If there are easy things you can do to reduce the risk then why not
[Younger, 1st time Mums, C1C2, London]

1.3 Headline Reactives

Headline Reactives are more likely to be female, but may be of any age. They are strongly influenced by the media and follow the latest issues and main media stories in both newspapers and mainstream TV. They like to be seen as fairly ‘*in the know*’.

Negative stories raise their levels of anxiety and concern and, consequently, they feel the need to move away from potential danger, but this concern is often short-lived, reducing significantly over time and, so, having a more superficial impact in the longer term. They

are only likely to change behaviour in the short term unless reminded regularly. They choose not to be very proactive so do not go in to issues in real depth, compared to the Purists, and so are more likely to use headline pack descriptors rather than go through all the detail. For the purposes of this research, we refer to this group along with Pragmatists, above, as **Mainstream** as they display similar needs.

You hear things can harm your baby and you start panicking
[Younger, 1st time Mums, C1C2, London]

The health visitor really worried me so I started doing it fresh but it was too difficult so I went back to making it and storing it
[Younger, Mums, ABC1, Midlands]

1.4 Purists

Purists are more discerning and cautious about food and take a real interest in nutrition and health. ‘Quality’ is more of an issue for this niche group compared to the others and this is combined with a strong distrust of manufacturers and trade. They display niche purchasing habits, choosing, for example, to buy organic and believing in taking personal responsibility for what you eat ... *‘I’m worried and I need to know more’*.

They are more likely to be female, (although only a small sample of men were included in this research), upmarket and in this sample included more parents with premature babies. They are much more knowledgeable and well informed compared to the other segments as they actively look into media stories in detail by, for example, seeking further information from the internet and journals. They also are more likely to check information in store on labels and packaging. They are able to process the information more fully than others as they are more confident in their knowledge and ability to decide on what action they should take as a result.

I try and read about things I hear about or find more information to decide what I should do about it
[Younger, Mums, ABC1, Midlands]

1.5 ‘At risk’ parents

The parents in the ‘at risk’ group tended to fall into the Purist segment as they displayed greater concern and anxiety about their premature/low birth weight baby given their more vulnerable status. Given the cautious attitude these parents had with their premature/low birth weight child they were more likely to be proactive about finding out about issues that may affect their baby and more likely to be cautious and safety conscious in terms of their behaviour. This group contained both first time and subsequent parents and it was evident that each of these types of parent displayed equal concern with subsequent parents being less likely to display resistance to changing their habits compared to other subsequent parents.

When you have a premature baby you want to do anything to minimise risks to their health and err on the side of caution

[Mums of ‘At risk’ babies, (B)C1C2, Midlands]

These mothers had been specifically encouraged to breast feed due to the potential benefits this could provide their more vulnerable baby. As a result most had breast fed their baby for at least the first month and when formula was introduced it tended to be used in conjunction with breast milk. Those who had given birth before 35 weeks and especially those who were first time mothers reported feeling under prepared as they had not yet attended antenatal classes, not read everything about post birth including feeding or purchased everything they needed. In contrast to other mothers, however, they reported receiving more help and advice from midwives.

I was told breast feeding would be better for him so I expressed milk when he was in the unit..it felt like the only thing I could do for him. I didn't breast feed my first one but I wanted to do it for him as he really needed it, it was the only way I could help him

[Mums of ‘At risk’ babies, (B)C1C2, Midlands]

I felt I missed a huge chunk of information because I had missed the classes and didn't have everything I needed yet but I did get quite a bit of advice from the midwives and nurses

[Mums of ‘At risk’ babies, (B)C1C2, Midlands]

2. Powdered Infant Formula Milk Current Practice

2.1 Overview of information sources informing current practice

A wide variety of spoken and written, formal and informal sources of information and advice on feeding babies, was discussed in the research, but most parents felt there was a distinct lack of formal advice on bottle feeding, especially compared to breast feeding. Health Care professionals agreed that this is the case, even when parents state a preference for this method of feeding. This lack of formal information related to discussion with parents as well as literature given out to parents.

This is especially evident with midwives, who were seen as the key HCP, as feeding options are normally communicated and/or decided during pregnancy. However, this was mostly due to midwives feeling unable to discuss or advise on bottle feeding as it is seen as ‘not allowed’, due to baby friendly initiatives. Health visitors were seen to be in a position to offer more advice, but this can come too late if feeding habits are already established.

Due to the relative lack of formal information available, parents gained advice and information by a variety of other means. The repertoire of particular sources used depended on their attitude, their propensity to actively search for information and their relative need, particularly if they were undecided about how to feed their babies. It also varied with time, requiring a different focus if it was before starting formula feeding (which may be during pregnancy, shortly after delivery or after variable lengths of time breast feeding), at the start of bottle feeding or once it had already started and habits were already established.

First time parents were much more proactive and used a range of sources and made more use of formal sources compared to subsequent parents, who tended to rely on old habits

with, at best, a brief check or catch up as a reminder. In addition, health care professionals may assume that subsequent mothers have all the knowledge they require and so offer less.

Mothers were much more likely than fathers to seek information. They then passed on their knowledge to the fathers as required, which may include doing ‘demos’ of mothers’ perceived best practice for them.

Purists were the most proactive in finding information, compared to Mainstream parents who tended to use the sources given to them, and Avoiders who were more likely to rely on advice from spoken informal sources, such as friends and family. This information was then filtered, based on perceptions of convenience, safety, reliability and “*what’s right for me and my baby*”. As a result there was a very broad range of current preparation, storage and use behaviour in evidence.

2.1.1 *Sources of information and advice prior to bottle feeding*

Whilst pregnant, first time mothers reported being information hungry and having plenty of time available to read and absorb the written information and advice available to them, such as the pregnancy booklet given at their booking visit - Bounty packs and Emma’s diary. This represents a window of opportunity to communicate with mothers because, in contrast, information given after the birth is not only more inconsistent but also has significantly less impact as mothers are both time and energy starved.

You have the time to read when you’re pregnant
[Older, Mums, ABC1, North]

Leaflets given in hospital were often lost, especially if they were not needed for a while after leaving hospital and specific bottle feeding information in the Birth to 5 booklet was often overlooked. Books, magazines and internet were used by Purists and some Mainstream parents, but the danger here was that they can be out of date, especially books.

Family, particularly mothers and sisters, as well as friends who already have a baby, were both useful and trusted sources of spoken information and advice on bottle feeding, especially in cases where there was a lack of formal options made available. In such cases, there was a real danger of over-reliance on such informal sources and an added risk of advice received in this way was that it is more likely to be out of date or inaccurate.

Midwives, Parent craft and antenatal classes were reported to vary enormously in the information and advice they provide for mothers to be, with the majority providing little, if any, on bottle feeding. There appeared to be more information, such as bottle feeding demonstrations, for more vulnerable mothers, including teenagers, those with learning difficulties and also mothers of babies ‘at risk’ i.e. premature or low birth weight. For others, demonstrations on good bottle feeding practice were rare and only occurred when specifically requested, although sometimes not even then.

Teenage girls’ antenatal specialist classes cover bottle feeding
[Community Midwife]

Bottle feeding is a taboo subject
[Hospital Midwife]

They leave hospital not knowing how to make-up feeds or sterilise
[Hospital Midwife]

2.1.2 Sources of information and advice when starting bottle feeding

When starting bottle feeding, on-pack ‘preparation instructions’ and ‘feeding guidelines’ were the most important written information sources used by parents. However, on pack information tended to be referred to just for the first few feeds and rarely referred to again, even for subsequent babies. It was noted that there is a lot of information ‘on pack’ and unless information and advice is highlighted in some way it can be overlooked. Boxes, grids, contrasting colours and bullets were all seen to be valuable in helping key information stand-out better.

You learn how to make up bottles by reading the tin

[Younger, 1st time Mums, C1C2, London]

Other 'on pack' information, such as 'important feeding information' was also read when first purchased and used, particularly by Purists, whilst Avoiders were unlikely to read such detail. 'Nutrition', 'ingredients', 'guarantees', etc., were only read by Purists, who were also more likely to check the details even when bottle feeding had been established. Again, it was noted that key points would stand out better if they were highlighted.

All printed bottle feeding information given out when pregnant or when leaving hospital, including the booklets and leaflets mentioned earlier, was often lost in the mass of 'other' information and emotional overload after the baby's arrival. They may, therefore, have little impact when actually starting bottle feeding, particularly if there is a significant delay between receiving the information and needing to refer to it, as is the case with those who breast feed for longer.

Family and friends were valuable sources of help and advice, when starting to bottle feed, as they were on hand and able to demonstrate as and when required. Depending on the stage the mother is at when starting bottle feeding, midwives, auxiliary and parent craft nurses or health visitors sometimes play a valuable role, but this appeared to be secondary to family and friends in most cases. Neonatal Nurses and Community Practitioners may only have contact with vulnerable mothers and mothers of preterm babies and their specialist advice was much more valued as it was not available through family and friends.

Advice comes from the babies grandparents but varies. Good and bad practices
[Hospital Midwife]

Advice received beforehand or when just starting to bottle feed was obviously of more value than that received after starting. Thus the timing is critical in order to have maximum impact. The standard of attention and care received seemed to vary greatly and this was further exacerbated by a lack of consistency in spoken communications provided by the range of health care professionals mothers have contact with.

According to the health care professionals we spoke to the opportunity to give more formal help and advice whilst in hospital seemed to be severely restricted by the baby friendly initiatives, resulting in hospital demonstrations being very rare, also the use of ready made bottles in hospital further restricted the learning opportunities for mothers in hospital.

Finally, the inconsistencies between and within all sources of information, up to and including starting bottle feeding, resulted in a lot of misinterpretation which led to a wide variation in current bottle feeding practices.

2.1.3 Sources of information and advice *when* bottle feeding

Once bottle feeding practices were established, there was little perceived need for further information and advice beyond a baby's changing needs as it gets older. This was provided by 'on-pack feeding guidelines'. Other on-pack information was very rarely used after bottle feeding started, unless very specific clarification or reassurance was required, prompted, for example, by a Purist after hearing a new piece of information from a friend.

Only really look back at the tin for number of scoops by age
[Younger, Mums, ABC1, Midlands]

Purists and some Mainstream parents sometimes accessed additional information from leaflets and booklets received in the past, as well as books and magazines for a specific need or just in passing.

Family and friends remained as a frequently used and trusted source, also providing the opportunity to share and discuss both knowledge and problems relating to bottle feeding.

After the baby is home you rely more on word of mouth from family and friends
[Older, Mums, ABC1, North]

The use of a health visitor, at the clinic or at a home visit, varied according to the relationship established and degree of trust built, so whilst highly valued by some, they were

actively avoided by others. The community practitioner remained in contact with ‘vulnerables’ and mothers of preterm babies for as long as required and were, more often than not, highly valued when problems arose.

In addition to the risk of misinformation from informal sources, an individual’s own interpretation of all the information and advice they receive, as well as inaccurate recall of their own knowledge base and practice was also seen to result in poor practice becoming reinforced and entrenched.

It’s not mentioned unless new mothers ask
[Community Midwife]

You do it how you want anyway ...
[Older, Mums, ABC1, North]

2.2 Sources of information and advice for health care professionals

Most health care professionals’ formal knowledge about bottle feeding practices appeared to be based on information they received during formal training some years ago. None of those included in our sample were aware of any significant changes to their knowledge base or reported any updating of information or new learning or advice in this area, either recently or in the distant past. Bottle feeding emerged as a very low priority issue, particularly when compared to breast feeding

I trained 10 years ago ... no changes in advice and no updates ...
[Community Midwife]

Any on going knowledge was drawn from a variety of ‘official’ sources including discussion with colleagues as well as reading the NHS leaflet, plus Pregnancy and Birth to 5 booklets. Whilst they felt there have been no major changes in advice, they did believe that the literature they use with parents had been updated, although not very recently.

There is an NHS bottle feeding leaflet it gets updated from time to time
[Health Visitor]

Information was also gleaned, on an on going basis, from their own experience as parents, discussions with the parents for whom they are responsible, as well as reading formula packaging. Some had also had contact with formula milk industry representatives when information needs focused on understanding new specialised formula rather than mainstream milks, but most health care professionals revealed that they were not allowed to see industry representatives under any circumstances.

I see reps to find out about new milks..they give out leaflets that can have useful information but you can't pass those onto parents
[Health Visitor]

In addition, although based on a sample of one, it would appear that neo-natal units have a written policy on the use of formula which covers how to prepare and store it safely. However this did not seem to incorporate the new advice.

We have a feeding policy folder that covers how to make up feeds
[Neo-natal nurse]

2.3 Current bottle feeding practice

Parents acknowledged the importance of correct preparation, storage and use of powdered infant formula milk and all strongly believed that they were carefully following the advice they received. Having said that, those with older or subsequent babies did admit to taking more care when their baby was younger, as it is noted that they are more vulnerable. It was evident that most care is taken for those under 3 months and those that are born premature, compared to those aged 3-6 months. The majority of subsequent parents admitted to becoming much less concerned after 6 months, although for a minority it is more like 1 year. In addition, the level of care taken was found to vary by attitudinal type, with Purists being most cautious and Avoiders the least so.

Having said that, there was evidence of a great variation in understanding of ideal and safe practices and this was due to inconsistencies, misinformation, misinterpretation and gaps in knowledge. This was exacerbated by limited formal communication to parents about safe bottle feeding practice, both written and spoken. This was both mirrored and acknowledged by health care professionals and, as a consequence, they were very aware that what might be believed to be good practice by a parent can be far from it in reality.

Advice conflicts – it would be easier if there was one set of rules, but lots of people say different things

[Older, 1st time Mums, ABC1, N. Ireland]

Bottle feeding problems might be arising as there isn't enough advice

[Community Midwife]

In addition, once practices were established, parents tended to become fixed in their behaviour and were increasingly unwilling to consider changes. As you would expect, Purists display the greatest willingness to change, given good reason, and Avoiders the least.

You're more cautious at first and do everything to the book, but after you follow your own instincts

[Older, Mums, ABC1, North]

There was no real concern currently amongst parents about using powdered formula milk. Current messages concerning parental responsibility to follow the preparation and use guidelines do not seem to be getting through as well as they might. The wide variation in practice confirmed that there is a strong need for clearer and more consistent communication of the guidelines.

2.3.1 Making in advance rather than as required

The vast majority of parents made up powdered formula milk in advance, according to 'on pack' instructions, or their interpretation of them and this was perceived by most to be the only advice 'on pack'. Making in advance was seen as a convenient approach and there was no awareness amongst those using this method that it was less safe than making formula up

as required. Most made up all their required bottles once a day for the following 24 hours, whilst some prepared feeds twice a day.

It's a lot easier to make them all in one go in the morning and it's quicker then to feed your baby when they're screaming for it
[Younger, Mums, ABC1, Midlands]

The majority of those preparing in advance stored prepared formula milk in the fridge for up to 24 hours and this was considered by all to be acceptable practice, although for those preparing twice a day storage time was, by chance, reduced to 12 hours. After preparation, a minority kept prepared bottles out of the fridge for up to 4 hours before use.

You can store them in the fridge for 24 hours – it tells you on the pack
[Older, Mums, ABC1, North]

A small minority, who were more likely to be Purists, were discovered to already make formula 'fresh', as and when required. Of these some were making from 'scratch', a few were using bottles of 'sterile' water stored in the fridge and a few others were keeping boiling water in a flask. The reason for making one bottle up each time was due to personal preference and based on perceptions of 'freshness' rather than specific safety concerns for the majority. Some had developed the technique themselves, whilst others had noted information 'on pack' and one had been told by an HCP that it was an option rather than a rule.

My NCT class said you need to make it fresh each time so I do that
[Mums of 'At risk' babies, (B)C1C2, Midlands]

I read in the other information on the tin that it is better if you make each bottle fresh each time
[Younger, Mums, ABC1, Midlands]

2.3.2 *Out of home preparation, storage and use*

Ready made cartons were rarely used due to their relatively high cost compared to powdered formula. However, they emerged as very popular and highly valued for

occasional use out of the home, primarily for reasons of convenience, and urgency in an emergency, rather than prompted by safety concerns. In relation to the use of ready made cartons, the more cautious were concerned about how long a sterilised bottle was safe for use, especially when taken out of the house and carried at room temperature.

Ready made is easier when you're out of home
[Younger, 1st time Mums, C1C2, London]

Bottles are not sterile for long when you've got them out of the steriliser
[Older, 1st time Mums, C2DE, Wales]

For use out of the home, whether for social reasons or taking the baby to a child minder, most parents took milk they had made-up earlier and kept it cool (from fridge) for up to 4 hours in a cool bag or a similar device. Others, however, did not keep the bottles cool, but at room temperature for up to 4 hours when they were out, just putting them in a bag or in the 'buggy'. A very small minority were making the milk up 'fresh', just before leaving the house, and keeping it warm in the 'cool' bag or similar.

I take a ready made bottle out with me and it seems to be ok for a few hours...he hasn't been ill with it
[Younger, 1st time Mums, C1C2, London]

I just leave it in the changing bag
[Older, Mums, ABC1, North]

Purists were the most likely to be making it 'fresh' using one of several methods, including taking cool water in a bottle from fridge (in cool bag or not), and taking boiling water in a bottle to cool before use. A few took hot water in a flask, whilst others tried to get boiling water when they were out. Powder was then added just before use and the bottle was cooled or warmed, as appropriate.

I take out powder in those containers where you measure out the scoops beforehand and then you can get boiling water when you're out or I take cold boiled water out in the cool bag and add the powder and then warm it up
[Younger, Mums, ABC1, Midlands]

For extended periods away from home, prepared bottles were stored in a fridge, when one was available, whether visiting friends and family or for use at nursery or a child minders. For longer periods away from home, all the necessary equipment had to travel too.

You want to make up your own bottles for nursery to know they have been done right... and they ask you to do that anyway and then they keep it in their fridge and warm them up when they're needed

[Younger, Mums, ABC1, Midlands]

2.3.3 *Temperature/cooling time before adding the powder*

The majority claimed to follow 'on pack' instructions and cooled the water in the kettle for 30-40 minutes. It was noted, however, that the times 'on pack' do vary from brand to brand.

A few revealed that they make up the formula with boiling water and others with very cool water, left to cool for 1-3 hours, and neither were aware of the implications of such practices.

I pour the water into the bottle straight after the kettle has boiled and then add the powder after that so there's no waiting about...to get it to the right temperature we just run it under the cold tap

[Older, Dads, ABC1, London]

Most cool water in the kettle, but a few admitted that they left it to cool in the bottles as it cooled faster. As far as cooling before putting in the fridge was concerned, most cooled the made up bottles quickly under running water from the cold tap, some cooled more slowly by leaving on the work surface for up to 2 hours and a few placed the bottles in the fridge immediately, with out cooling first.

Pour boiling water into the bottle and let it cool for about 15mins then add powder
[Younger, Mums, ABC1, Midlands]

Leave water to cool for about an hour in the kettle
[Mums of 'At risk' babies, (B)C1C2, Midlands]

In addition to a variety of cooling procedures, a range of warming methods were also discovered. The majority used hot water in a jug, a few used the microwave, despite ‘knowing’ that they shouldn’t, whilst others just left it out of the fridge for up to an hour to reach room temperature.

You know you're not supposed to use the microwave because of 'hot spots' but you just give it a really good shake
[Younger, 1st time Mums, C1C2, London]

2.3.4 *Throwing formula milk away*

This was not a new guideline issue, but as there seemed to be a lot of misunderstanding around the issue, it has been included in the interest of both information and safety needs.

Everyone seemed to be well aware of and claimed to adhere to the advice to throw formula away after 24 hours in the fridge. Most believed that what has been out of the fridge should be thrown away after 1 hour, but some admitted keeping it for longer, up to 4 hours. However, it was unclear to most whether this applies to milk after using, after warming or just if left out at room temperature.

I know people who leave it out for 4 hours at night
[Older, 1st time Mums, C2DE, Wales]

Leftover used milk was often thrown away straightaway, but some admitted stretching this, and keeping for it 30 – 60 minutes, especially when not a lot of milk has been taken. A few revealed that they had kept it for up to several hours before reusing left over milk on a regular basis.

I keep it for a few hours... I think I should throw it ... but I don't like to waste it
[Older, 1st time Mums, ABC1, N. Ireland]

2.4 Perceptions of risk if guidelines are not followed carefully

There was a good level of understanding across the sample that very young, premature and ill babies are at greatest risk but there was a wide variation in understanding and appreciation of both the risk factors and consequences for all babies.

Avoiders had a vague understanding of risks and consequences and their steadfast denial of any lax practices reinforced their more casual and sometimes unsafe approach.

What I do must be fine because my baby hasn't been at all ill ...
[Younger, Mums, C2DE, Scotland]

The Mainstream, as Avoiders, displayed an over-reliance on their established practices. Little experience or recognition of any problems associated with bottle feeding confirmed their belief that their own practices are entirely adequate. Unlike Avoiders, Mainstream parents had more knowledge, but this lacked real substance and focused on the importance of following 'on pack' advice to avoid illness or harm. Most did not consider the reasons and their 'safe' practices often slipped if there was no evidence of harm.

There are more risks than I thought
[Younger, 1st time Mums, C2DE, North]

Maybe puke[sick]... but I don't know if it's dangerous
[Older, 1st time Mums, ABC1, N. Ireland]

Purists emerged as much more knowledgeable about the risks and the consequences, being aware that lax practices can result in sickness, diarrhoea or gastroenteritis. A few were also aware that this is caused by a build up of bacteria when milk is left at inappropriate temperatures for too long, and the longer the time the greater the risk. As a consequence of greater awareness of the issues, they were more careful and some were more likely to make up 'fresh'.

I was told storing could give stomach ache or make them ill so I make them up fresh

[Older, 1st time Mums, ABC1, N. Ireland]

They can get ill if leave the milk out because bacteria starts to grow and I suppose this can even happen in the fridge which is why they say on the pack that it's better to make them up one at a time

[Younger, Mums, ABC1, Midlands]

3. Reactions to Powdered Formula Milk Being Non – Sterile

3.1 Overview of non-sterile issue

Currently there is no awareness amongst parents that powdered infant formula milk is non-sterile and the term non-sterile tended to generate a lot of concern. Amongst healthcare professionals, there was some awareness, but it was latent and not linked to reasons to be more cautious about preparation, storage and use. Overall there was little evidence in our sample to show that health care professionals were aware of any new information surrounding new guidelines and there was only minimal evidence that this information was being communicated to parents currently.

Although parents were initially shocked at the news that powdered infant formula milk is non-sterile, reactions varied significantly by attitude.

Overall, both parents and health care professionals agreed that any information of this kind, which carries a risk of harmful consequences to babies, must be clearly communicated to parents, so that they can make an informed choice about its use.

The level of detail and explanation required also varied by attitudinal type and a range of communication channels were likely to be needed to get the message across.

Ultimately the impact that this news will have on behaviour will vary dramatically by attitude type, with some unlikely to change their habits, whilst others will follow the new guidelines to the letter.

3.2 Health care professionals awareness and response to the non-sterile issue

Only a few health care professionals were aware that powdered formula milk is non-sterile but, even when known, it was not top of mind. The importance of safe practice was

strongly acknowledged, but this was not prompted by the non-sterile issue. In addition, there was no spontaneous connection with this fact and the need to change information given to parents beyond the current advice, despite a high awareness of lax practices. Current advice focused on the need to be careful with formula milk and to follow manufacturer's guidelines as it is important for the baby's health and safety.

I think I know... but you think it's sterile because it's sealed
[Hospital Midwife]

It can't be completely sterile because its freeze dried powder..I've know since I was a student but its not considered a big deal unless we started getting huge gastroenteritis problems
[Health Visitor]

There can't be an issue babies survive on it
[Health visitor]

It would be taken off the market of it contained bacteria
[Community Midwife]

No formal communication had been received to date by the health care professionals in our sample concerning either the non-sterile issue or a change in the guidelines. Only one health visitor had some awareness of the issue and this had been communicated via a colleague. She and her other colleagues were asked to tell parents of babies under 1 month to use cartons and not to store prepared formula in the fridge as '*powdered formula can have bacteria in it that causes gastroenteritis*'. Interestingly, she and her colleagues chose to ignore this advice as it had not come via a formal channel and was not backed up with any supporting evidence.

We got an email from our breast feeding councillor about it but we didn't take it very seriously as there was no evidence to back it up ...and we had no official communication about it ...and it seems a bit extreme to tell parents they have to buy only cartons for a month
[Health Visitor]

However, Birmingham seemed to be slightly ahead of the game, with some parents mentioning that health visitors had discussed not making formula in advance, but without much discussion of either risks or consequences. Whilst some parents admitted to ignoring the advice, others indicated that they had attempted to change but soon lapsed, leaving only one first time mother who was following the revised guidelines.

My health visitor said you have to make up bottles as you go now as keeping them in the fridge can make your baby ill
[Younger, Mums, ABC1, Midlands}

Health care professionals felt that they should be fully informed through formal channels, so that they can inform parents appropriately, as required, depending on individual needs. They recognised that care needs to be taken to avoid panic, an over-reaction or a boycott of powdered infant formula, to maximise parents understanding and the implications, to minimise contradictory information and advice as well as promote parental responsibility more strongly. As a result, it was clear that health care professionals have a valuable role to play in both communication and reassurance.

They need background information ... not just a change in advice
[Community Midwife]

It is our role to inform parents of what they should know
[Hospital Midwife]

3.3 Current parental understanding of the term non-sterile

It was very clear that the term non-sterile carries with it very strong negative associations and these included: dirty, unclean, contaminated, bacteria, germs, not sealed, infections, getting sick or ill, unsafe and 'likely to be' more than 'potentially' harmful.

Food and drink sterility was not an issue that was really considered by parents. The majority assumed that all food and drink, especially baby products, are sterile at least until opened. Most expected that all products for human consumption, particularly those targeted at babies, are produced and packed with care, sealed to maintain 'sterility' and need to be stored and used with care to reduce risks of causing illness and for some, more specifically, food poisoning.

I've never really thought about it before
[Older, 1st time Mums, C2DE, Wales]

I thought it would be sterile till opened ... like ready made cartons

[Younger, Mums, C2DE, Scotland]

If it's sealed you think it's sterile
[Hospital Midwife]

A small minority, mainly Purists, had a better understanding of the term and recognised that only 'long life', UHT and sterilised products are sterile and that this is only prior to opening, as with ready made formula cartons, plus tinned and jarred baby food. However, all, even these more knowledgeable parents, anticipated that powdered formula milk is similarly sterile.

UHT is definitely sterilised
[Younger, 1st time Mums, C2DE, North]

Hence, there was no current awareness or consciousness amongst parents of powdered formula milk being non-sterile and the automatic assumption was that it is sterile. Furthermore, the term non-sterile had very negative associations of 'real' harm rather than 'potential' harm and this led to immediate concerns and serious questioning in response to the non-sterile news.

Angry – because my baby is all the world to me and it puts him at risk
[Younger, 1st time Dads, C2DE, Scotland]

3.4 Parents response to non-sterile powdered formula milk

All parents displayed a shocked reaction to the new information that powdered formula milk is 'non-sterile'. In isolation, without supporting information and advice, it created an immediate panic response because of strong negative associations combined with a very limited understanding of the real issue and associated potential risks.

Concerns covered the following issues:

- it should be sterile
- parents should be told

- it puts my baby at risk
- it is a dangerous or harmful product
- it's the governments responsibility
- it should be taken off the market
- it would have been taken off the market
- I don't know what to think ...

And questions raised include:

- what are the risks? Is it a low risk?
- why do you sterilise bottles then?
- which brands are affected?
- is it a pro-breast feeding tactic?
- what do I do now?
- it must be safe enough to use?
- how can you make it safer?

You would think it would be clean given that they're making it for babies
[Older, 1st time Mums, ABC1, N. Ireland]

If it was unsafe there would be a public outcry
[Older, Mums, ABC1, North]

What's the point of sterilising everything?
[Younger, 1st time Mums, C2DE, North]

People need to be told ...or they can't make an informed choice
[Younger, 1st time Mums, C2DE, North]

You're told that all things should be sterile
[Older, 1st time Mums, C2DE, Wales]

Can I make it sterile by putting it in a different container?
[Younger, 1st time Mums, C1C2, London]

Is this why they're pushing breast feeding?
[Older, 1st time Mums, C2DE, Wales]

Once you add boiling water it must be sterile then?
[Older, Dads, ABC1, London]

3.5 Parents' levels of concern about non-sterile powdered formula milk

Levels of concern varied according to typology, but all acknowledged that concern will be greatest amongst new mothers and for newborns and younger babies as well as premature and ill babies. As a consequence of differing levels of concern, information requirements also varied, so care needs to be taken to cater appropriately for different needs.

Avoiders showed a lower level of concern compared to the other groups, usually rating initial concern at 2 or 3 out of 5. Their automatic response showed high levels of rationalisation, seeing the news as scaremongering, a possible pro-breast feeding tactic or that it can't be a real problem as babies would not have survived on it for so many years. Given that they've had no 'known' problems or negative formula experiences, they tended to be quite dismissive, but also relatively accepting of the news. Their response was more limited compared to other parents, having both fewer questions needing to be answered and limited information needs.

Too late to worry!
[Older, 1st time Mums, C2DE, Wales]

Babies need a few germs to boost their immune system
[Younger, 1st time Mums, C1C2, London]

Mainstream parents displayed a medium level of initial concern, at 3 or 4 out of 5. As Avoiders, they also tried to rationalise the news and also questioned the need to worry, preferring to see it as an over reaction to a low risk. Unlike Avoiders, they tended not to dismiss the news but felt the need for additional information before they decided how to respond.

If it's guaranteed to be safe, I'm not concerned
[Younger, 1st time Dads, C2DE, Scotland]

More important when they're younger
[Older, 1st time Mums, C2DE, Wales]

Purists revealed the highest levels of concern, with most rating 5 out of 5. For this group, the news not only raised levels of concern about the future, but also the past, which brought with it a feeling of guilt, in relation to non-sterility being the possible cause of any past sickness and diarrhoea problems. They felt very cautious about the way forward from here and wanted to know what they should do for the best. They showed the most willingness to respond proactively and had a strong need for more detailed information.

I'm concerned as he was so premature I should have been told about this. What can we do about it?

[Mums of 'At risk' babies, (B)C1C2, Midlands]

My baby has reflux and maybe this has been a contributory factor?

[Younger, Mums, C2DE, Scotland]

3.6 Communicating non-sterile risks and consequences

The term 'non-sterile' alone lacked useful meaning and was liable to cause a panic response, high levels of concern and confusion. So, successful communication will require careful explanation to reassure parents, maximise their understanding of the relative risks, explain how to reduce the risks by following new guidelines and the increased need for adult responsibility. It is anticipated that the latter can be achieved by using a more direct communication than is currently used, concerning the types of illnesses that might be caused as a consequence of not following the guidelines carefully.

You can't just say - non-sterile!

[Older, Mums, ABC1, North]

Don't say not sterile as it will cause panic

[Older, 1st time Mums, C2DE, Wales]

The longer you keep it the worse it gets

[Older, Mums, ABC1, North]

You need to know what the risks are so you understand why it's important

[Younger, 1st time Mums, C2DE, North]

However, whilst helpful to some (Purists), more detailed information about non-sterile facts may be counter-productive for others, who may benefit from a different focus. So, care needs to be taken to communicate at different levels through different channels, using each, as appropriate, to deliver varying information needs. This suggests that the best way forward would be to make information suitable to all freely available to parents, but to deliver, or make available, more sensitive information according to needs – such as through health care professionals and websites/carelines.

Too much information will scare people
[Younger, Mums, C2DE, Scotland]

Our data suggests that certain terms and words, in relation to communicating ‘non-sterile’ powdered formula milk, generate different reactions. For example, ‘scientific opinion’, ‘research shows’ and ‘experts agree’ type phrases were more likely to be believed and sometimes helped to reduce concern. Other phrases or words need to be used with caution as they could possibly have a negative impact on levels of concern and perceptions of importance around adult responsibility.

- i. Long, complex scientific names, such as ‘E.sakazaki’, and scientific concepts, such as ‘low numbers..’ do not normally lead to illness’ were found to **create confusion** as they are not understood by many. They require simplifying, more explanation or should not be used.

No big names!
[Older, Mums, ABC1, North]

Those scientific words are meaningless
[Older, Dads, ABC1, London]

- ii. **Concern** was found to be **exacerbated** by scary illnesses, such as ‘Salmonella’ and ‘Meningitis’, and by any reference to germs and bacteria, such as ‘Not free from germs’ and ‘Contains harmful bacteria’. Having said that, there is a trade off here, as whilst one does not wish to cause panic, enough concern needs to be created to prompt and maintain a behaviour change through adoption of the new guidelines. In

addition, such communications also run the risk of reducing some parents' ability to process the whole story effectively as they tend to focus on the most scary or least helpful words or expressions. This suggests that such words and terms are channel sensitive and are, therefore, not suitable for general use in freely available communications.

Not meningitis – that is scary – you think about death
[Younger, 1st time Mums, C1C2, London]

There's no need to say what harmful bacteria ... you don't need that detail
[Older, 1st time Mums, C2DE, Wales]

- iii. Reducing concern** can result in either a positive or a negative outcome. Communicating the rarity of cases, for example, as in '50 cases in 40 years' can reassure a Purist to continue using formula carefully, but confirm the risk as insignificant to an Avoider, who will then happily continue lax practices. Hence, this type of communication is also channel sensitive.
- iv. Increasing adult responsibility** is an extension of what current packaging tries to achieve though 'failure to...can be harmful/make baby ill', 'infants more at risk' and 'it is much safer ...if'. It would appear that these communications are not getting through strongly enough, so it was suggested that the addition of common illnesses are included as examples, such as 'sickness, diarrhea and gastroenteritis'. These words raised some concern, but not to panic levels, and prompted a better understanding of the need for increasing adult responsibility. Such communications seemed to be the most effective and are safe as baseline communications made freely available through all channels, without restriction.

You need to know what to do to reduce the risk then you won't worry so much
[Younger, Mums, ABC1, Midlands]

I don't like the idea I could do something to make my baby ill
[Younger, Mums, ABC1, Midlands]

Interestingly, ‘careful preparation’ and ‘following guidelines reduces risk’ achieved both a reduction of concern, as they showed what parents can do, as well as increasing adult responsibility. However, this type of communication was often overlooked or missed ‘on pack’ or in leaflets and this suggests that such communications should be given greater stand out wherever they appear.

As long as you follow the rules the chances are minimal
[Older, Dads, ABC1, London]

3.7 Parents reactions to change in guidelines

The new guidelines relating to minimising the risks posed by non-sterility focus on 3 key areas of information concerning preparation, storage and use:

- not making up feeds in advance and so not storing made up formula,
- water temperature/ kettle cooling time, and
- feeding out of the home/ later feeds.

However, as mentioned earlier, there seemed to be a lot of misunderstanding around how long formula can be kept / when to throw formula feeds away (when not stored in the fridge after making up), so it has also been included as a fourth area of information and safety needs.

Of the 4 information areas, the first two, ‘Not in advance’ and ‘Later feeds/out of home’ were perceived to be too difficult or challenging by many and led to requests for additional, easier to achieve, ‘safer’ practices to be included in the new guidelines:

3.7.1 *Not making up feeds in advance*

This guideline was perceived by the majority as the most difficult to execute, being seen as impractical and unrealistic as it was anticipated that each bottle would take about 45 minutes to prepare and be ready to use. It was seen as potentially very stressful for both the parent making the feed as well as the baby waiting for the feed.

It posed the biggest challenge to parents of newer and less predictable babies who were taking bottles more frequently and without a steady routine. The night feed and first feed in the morning were seen as the most challenging, as well as feeding out of the home. The small minority of parents who were already preparing bottles completely from ‘scratch’, were unsurprisingly the least concerned, followed by those who make bottles up from sterilised water or flask, as they would only need to make small changes in behaviour to adapt to and adopt this guidelines.

I need to have that bottle first thing!
[Older, 1st time Mums, C2DE, Wales]

As might be expected, the strongest resistance to this change in guideline came from Avoiders but, also, from subsequent parents who were generally more confident about their own judgment and abilities. In addition, it was seen as particularly difficult for parents using child care as not being responsible for the preparation of their babies bottles represents a loss of control as well as a worrying need to trust and rely on others to prepare their babies bottles.

Impossible !Nobody is going to do that!
[Older, Mums, ABC1, North]

New, especially first time mothers were more willing to follow the new guidelines as they are more concerned about careful preparation and first time mothers have no established practices to change. Having said that the danger here lies in the current lack of formal

communications and the resulting over-reliance on informal information and advice which can be out of date and, at worst, unsafe.

Not preparing bottles in advance created concerns about how to go about sterilising equipment as normally all bottles are sterilised and prepared together, also how to cool bottles quickly which is important for both speed and safety.

3.7.2 Feeding out of the home and later feeds

The current emphasis of this guideline is on flask use out of home rather than in home use. However, given that parents were hungry for help and advice to make any changes easier to achieve and so more likely to adopt, clearer communication about the **in home** use of flasks for storing hot water may help encourage adoption of the previous guideline. The use of a flask of hot water was perceived to reduce both time and effort and could, therefore, be positioned as a useful tip for making fresh bottles at home.

Conversely, there were real concerns about using a flask of water for making feeds up **out of home**, particularly for those taking prepared bottles from fridge. A flask, in this context, was seen as heavy and impractical. Others concerns relate to:

- bottle sterility (how long the empty bottles are safe for)
- transporting powder (how this can be done conveniently and safely)
- hand cleanliness (particularly in the absence of hand washing facilities)

Those already using ready made cartons out of the home were doing so for convenience or in an emergency rather than for safety. Hence, given resistance to flask use, there may be some value in communicating the safety benefits of cartons for out of home use, as well as for emergencies in home when there isn't time to prepare a bottle from 'scratch'.

Bottles aren't sterile for long after you've got them out of the steriliser
[Older, 1st time Mums, C2DE, Wales]

Reactions to the two guidelines below, water temperature and throwing formula feeds away, revealed that they are more likely to be adopted as they were seen as easier to achieve. They also demonstrate that there is a need for clearer communication which should be accompanied by the rationale behind changes as this will help parents understanding, overcome resistance and increase likelihood of maintaining changes:

3.7.3 Water temperature/ kettle cooling time

This was seen as the easiest of the three guideline changes to adopt but, as it was worded in the communications shown, it lacked clarity. ‘No more than 30 minutes’ can mean anything from 0-30 minutes and, so, runs the risk of water which is too hot being used. A time parameter would be ideal, for example, 20-30 minutes.

30 minutes is easy to change to
[Older, 1st time Mums, C2DE, Wales]

Why half an hour? Why not more or less?
[Older, 1st time Mums, C2DE, Wales]

Many liked the idea of a temperature guideline, such as 70 degrees, as this was seen as more precise than timing. However, it was recognised that it would necessitate the use of a thermometer which would also need to be sterilised, unless it could be applied to the outside of the bottle.

70 degrees would be ok if you were given a way to test the temperature
[Younger, Mums, ABC1, Midlands]

Some were unclear about the exact meaning of ‘fresh tap water’, and this could be clarified by including expressions such as ‘fill the kettle just before using it’ or ‘use water that has not ... been boiled already / been standing in the kettle’. In addition, the reference to ‘cooled boiled water’(being put in the bottles before the powder) was confusing for some

as it suggested to them that more cooling time is needed beyond the 30 minutes already recommended.

3.7.4 *Throwing prepared formula feeds away*

As already mentioned, this area of information was not a new guideline, but it was currently not clearly understood and open to gross misinterpretation. Thus, there is a clear need for clarification relating to the various different situations or scenarios when decisions about throwing milk away need to be made.

The rationale and the consequences behind the need to throw milk away needs to be more clearly communicated and this should include the implications of both time and temperature, such as ‘the longer it is kept/the higher the temperature the greater the risk’ and ‘like all milk products, formula milk can go off if not kept at the right temperature/not used straight away/soon’. It is important that this covers both made up powdered milk as well as opened cartons.

The longer it's kept out of the fridge the higher the risk
[Younger, 1st time Mums, C2DE, North]

The current message is simply to ‘throw away any left over milk’, but parents would appreciate knowing if this needs to be immediately or after how long, and under what circumstances, after making, warming or using.

Say how soon .. Like an hour
[Older, 1st time Mums, C2DE, Wales]

3.8 Likely impact of new guidelines on parents behaviour

Parental response to the new guidelines emerged as very variable and highly dependent on the attitudinal type discussed earlier. Having said that, it was more likely that new, first time mothers responded positively as their levels of concern, cautiousness and care were at a

peak, whilst mothers of babies older than 6 months and those using follow-on formula were less likely to claim that they would make any positive changes. Levels of concern were, more often than not, reduced when parents were given the information needed to reduce the risks, particularly the Purists, who claimed they would be more likely to adopt the new guidelines.

Avoiders showed the lowest levels of concern and were the least likely to say they would change their behaviour as they perceived the level of risk to be limited and their established practices as ‘good enough’.

Most want what's best, but some will think I can't be bothered and what they're doing is ok
[Community Midwife]

It's not practical to start making bottles up each time I won't do and people have been doing it like this for years anyway so it can't be that bad
[Younger, 1st time Mums, C1C2, London]

Pragmatic parents showed some concern and were likely to say they would make some easy changes, such as the kettle cooling time and guidelines on throwing milk away. Headline Reactives showed more concern and were more likely, therefore, to claim they would make changes in short term. However, they are highly likely to slacken off as the baby gets older, particularly if the messages are not reinforced well. For this group, cartons became more appealing for use out of the home, as occasional use is not seen as prohibitively expensive.

I'll make some changes to reduce the risks
[Older, 1st time Mums, C2DE, Wales]

I don't feel as bad now that I know how to prepare her bottles
[Older, 1st time Mums, ABC1, N. Ireland]

You're more relaxed as the baby gets older
[Younger, 1st time Mums, C2DE, North]

As already mentioned, Purists were the most concerned and showed the greatest willingness to follow all the new guidelines. Indeed, some Purists were already making up ‘fresh’ formula feeds. They had a very strong desire to minimise the risks and they saw the guidelines as allowing them to achieve their aim. They also emerged as information and advice hungry, so are likely to proactively seek out more depth and detail around this issue.

Many Purists are very likely as a result to use only readymade cartons out of the home, whilst the most cautious claimed that they would use them exclusively, in home too, for safety reasons.

I prefer to use cartons as they're sterile... as her immune system is low
[Mums of 'At risk' babies, (B)C1C2, Midlands]

I will no longer be buying powder
[Younger, Mums, C2DE, Scotland]

We won't make it in advance anymore
[Older, Dads, ABC1, London]

All had a strong desire to reduce the risks but, apart from the Purists this was without any or with minimum effort, and this was particularly the case with Avoiders. All but the Avoiders (and particularly the Purists) claimed that, had they known about the risks, they may have decided, or will decide, to breast feed for longer to avoid the risk when their baby is most vulnerable.

I may have tried to persuade my wife to breast feed for longer
[Younger, 1st time Dads, C2DE, Scotland]

3.9 Managing the change in guidelines

There was very strong evidence to suggest that some parents will not adopt new practices or maintain them in the longer term, whilst others may adapt them to suit their own perceptions of what is safe. Whilst clear and consistent best practice guidelines are important to communicate, these alone have a very real and dangerous potential to cause greater variation in practice. It is, therefore, important to also promote safer practices which are easier to achieve and less stressful to execute for those who are less willing to comply.

It is suggested that these should embrace the full range of issues, including:

- clearer communication of the use of a flask in home,
- the potential for reheating sterilised bottled water from the fridge,
- the possibility of storing prepared formula in fridge up to 6 hours,
- how to cool and warm bottles quickly,
- how to keep prepared bottles very cool for an hour or more out of home, and
- the possibility of throwing away any leftover/unfinished feed after 1 hour, rather than immediately.

I won't be doing as many in advance now I'm more aware of why I shouldn't ... so I know how to do things more safely

[Younger, 1st time Mums, C2DE, North]

This is the best way ... but if you can't you can do it this way – within safe limits

[Older, 1st time Mums, C2DE, Wales]

You need more information on what to do and what not to do

[Older, 1st time Mums, C2DE, Wales]

Clear and concise instructions on how to prepare the feed and how to store it... if at all

[Younger, 1st time Dads, C2DE, Scotland]

4. Communication of the Non-Sterile Issue and the Change in Guidelines

4.1 Communication Overview

As information and advice is drawn from a range of sources, it is important that the messages are communicated via all formal channels, including health care professionals, all print, internet, care/information lines and ‘on pack’, with varying degrees of appropriate depth. Communications need to ensure consistency across all channels and also easy access to more detailed information, if desired as is likely with Purists.

It's confusing when they say different things
[Older, Mums, ABC1, North]

Printed sources of information, such as booklets and leaflets, and **‘on pack’** are both suitable for providing all base line information which is freely available to all parents. They should all provide clear and concise information and advice, ideally in a step by step or bullet point style along with visuals, wherever possible, in addition to where to get more information for those who require it.

Health care professionals, on the other hand, have a more flexible role to play. They should ideally provide all the base line information to all parents via the formal printed sources mentioned above, and back this up, where required and as appropriate, with direct contact through conversations with parents. Health care professionals can play a valuable role in adapting information and advice to needs, through speaking to parents, passing on additional printed information giving more detail or referring parents on to websites and information/care lines. This is likely to involve emphasising the importance of making changes to Avoiders, encouraging the Mainstream and reassuring the Purists.

Internet and information/care lines are an important part of the communication mix as they can provide the depth and detail required by the minority. These would be mainly

Purists who could access further information and advice online, via a helpline and/or through mailing out printed information. Ideally, they should also encourage the use of and refer parents back to their relevant HCP, who will be able to provide the more personal approach.

Successful communication of non-sterility and the new guidelines across all of the communication channels will require the following to be achieved and with the appropriate depth and detail for each channel:

- i. Drawing **attention to the change** in guidelines, which indirectly implies that it supersedes other advice, as appropriate for each channel
- ii. Explaining the **new best practice guidelines** clearly and avoiding any ambiguity
- iii. Explaining the **relative risks, consequences and rationale** behind the recommendations to increase concern and prompt behavioural change without causing panic – done best by stronger parental responsibility messages
- iv. Advice, help and tips on managing and maintaining changes
- v. Communicating **non-sterile fact** subtly and within context, and
- vi. Offering ‘safer’ practice suggestions as a safety net

You can't just say how to prepare ... you need to know why?
[Older, Mums, ABC1, North]

I know it's up to me which I'm comfortable with
[Older, 1st time Mums, ABC1, N. Ireland]

Will you have to sterilise everything all the time?
[Older, Mums, ABC1, North]

There are risks of infection if the new procedures are 'not followed'
[Younger, 1st time Dads, C2DE, Scotland]

The risk is very small and it is about how you make up the bottles ... that is really important
[Younger, Mums, C2DE, Scotland]

4.2 Informing health care professionals of the non-sterile issue and the change in guidelines

The full story with all the details needs to be communicated directly to all health care professionals, who have yet to be informed. This includes all maternity, paediatric and neonatal staff, parent craft and antenatal sisters, GPs and health visitors, community midwives and practitioners. For note and action to be taken, this communication needs to go through formal channels, such as professional journals, study days, trade shows, emails, protocol bulletins and practice boards.

However, due to the baby friendly status of health care trusts or the pro-breast lobby, there were real concerns amongst health care professionals about what they, especially hospital midwives, will be allowed to say, despite a clear need for their involvement. They represent the only formal spoken channel of communication, the only ones able to adapt information and advice to needs and offer the opportunity for direct parental persuasion, encouragement or reassurance, as required.

Midwives are just involved in delivery and push breast feeding
[Older, 1st time Mums, ABC1, N. Ireland]

As midwives we reactively discouraged bottle feeding
[Community Midwife]

Hence, in this context, optimising the health care professionals' role may necessitate a change in protocol concerning what they are allowed to say about bottle feeding to parents. This may arouse concerns about a negative impact on breast feeding, but in reality it may have the potential for careful pro breast leverage.

The content of the Department of Health/FSA statement dated 13/02/06 was appreciated, being seen as a useful introduction to the issue. However, most health care professionals

felt that a more thorough communication was needed, so further development was suggested to ensure coverage of the following:

- clearer communication about the non-sterile issue,
- all relevant details and research about the full risks and consequences,
- full details about the new guidelines,
- avoiding any ambiguity, such as under 30 minutes,
- clear rationale behind changes and the advice, and
- any other implications for the use of powdered formula in the future.

Ideally, communications with health care professionals would also include:

- 'safer' practice suggestions
- hints for managing and maintaining changes, and
- a clear understanding of all delivery channels addressing parents' needs, to enable them to use them all appropriately and according to needs.

To ensure that health care professionals deliver a clear and consistent message directly to parents, they will require, as a minimum, supplies of updated leaflets and booklets to pass on to parents. In addition, the use of posters in clinics and other key locations would help raise awareness of the need for parents to review and update their practices, whilst a video demonstration of good bottle feeding practice would be beneficial for use in antenatal classes and baby clinics. The use of a good range of support material, all communicating the same strong messages, should help avoid mixed messages reaching parents.

I think they should do posters in the doctor's surgery so you see it when you go to see the midwife or the health visitor
[Younger, 1st time Mums, C2DE, North]

4.3 Communicating via printed information

“The Pregnancy Book” and “Birth to Five” were valued sources of information about bottle feeding, but this information can easily be overlooked in the mass of information and advice they both contain. This was particularly the case with the latter publication as it is given out after delivery, when new mothers are both overwhelmed and exhausted. A stand alone booklet is the ideal approach as it is more accessible, focused and can be more easily kept and used where and when required. However, as with other publications, it relies heavily on being disseminated to parents by Health care professionals, but there was evidence to suggest this is not happening currently with the stand alone booklet.

The “NHS Bottle Feeding” booklet was examined in depth with the groups and it was evident that it would benefit from further development, as would the other printed communications viewed. As already mentioned, it is important that all information and advice is consistent, so the suggestions below are relevant across the board.

All of the printed information shown currently lacks the emphasis required to draw attention to a change in guidelines and to communicate the key changes. It is, therefore, unlikely that those already bottle feeding, particularly second timers, will notice the change. In addition, scan reading by others may result in key information and advice being missed, as the key points do not currently stand out enough.

I wouldn't look at that it doesn't tell me there's anything new
[Older, Dads, ABC1, London]

A stand alone publication is likely to have a higher impact on parents. A ‘step by step’ approach with visuals, encouraging good baseline practice, was much preferred as it is easier to follow. As it is, the stand alone booklet contains some clear information as well as some risks and consequences, but there was room for improvement.

Step by step and photos make it very clear
[Older, 1st time Mums, ABC1, N. Ireland]

It's got the right amount of detail, how to do it, and some reasons why you need to be careful
[Older, Dads, ABC1, London]

It's important that you have the information before the baby is born so you know from the very beginning
[Older, 1st time Mums, C2DE, Wales]

We could keep a little thing like that next to the kettle along with all the other bottle feeding equipment
[Younger, 1st time Dads, C2DE, Scotland]

It is important to flag-up, on the front, that new advice can be found inside. The 'ideal' key points would benefit from stronger stand-out and an overview of the risks and consequences would help emphasise the need for greater adult responsibility. Ambiguity should be avoided in the guidelines, such as under 30 minutes, so nothing is left open to interpretation. It was also suggested that any age specific recommendations are included for this reason.

New advice in a different colour so it stands out more
[Younger, 1st time Mums, C2DE, North]

Separate sections for 'out of home' use and 'safer' practices would help parents access information with the minimum of effort. Tips and hints on making and managing the changes will help encourage adoption and commitment in the longer term. Stronger Department of Health endorsement would provide greater credibility and weight to the communications.

The stand alone booklet currently has a very dated feel, in terms of design, layout and visuals and would, therefore, benefit greatly from a redesign. This would also help reduce the current dissonance between the design and the new 'up to date' information and advice it contains.

1970's leaflet – look at the kettle, you wouldn't think that was recent advice!
[Older, 1st time Mums, C2DE, Wales]

4.4 Communicating via websites

The internet, as well as information/care lines, were most likely to be accessed, by Purists, in response to a need for more detailed information and reassurance which is not satisfied by other formal communications. However, it is important that they provide all the information available elsewhere, with easy to follow links on the web and additional leaflets for care lines to provide the greater detail required by a minority, so they cover the ‘full story’, as well as refer parents back to their Health care professionals.

You want to go online to find out everything, read the research
[Mums of ‘At risk’ babies, (B)C1C2, Midlands]

The Eat Well page grab was quite liked, but emerged as not detailed enough as a stand alone communication and was felt to be lacking in terms of basic information, as well as the further detail required by some. It was seen as short and concise – a useful reminder of some points and containing some new points and advice not found elsewhere. However, it was seen to lack the depth and breadth of other sources and some points were felt not to be clear enough. There was a clear need for risks and consequences to be included, as well as further tips and advice. A bullet point approach was preferred, as were visuals to aid communication. Department of Health endorsement would also improve the communication.

Step by step information is clearer
[Older, 1st time Mums, C2DE, Wales]

4.5 Communicating information ‘on-pack’

Requirements for information and advice ‘on pack’ were very consistent across all parents and Health care professionals. Overall, these focused on 8 key points:

- i. **Drawing attention** to the change in guidelines and the new advice was important to help reach already established users, as use of ‘on-pack’ information tended to be

limited to first time parents on first purchase. This should ideally be backed up with in store shelf edge information and leaflets. This could be achieved by using a sticker on the lid or having a call-out on the front of the pack, which is visible at the point of sale, along the lines of:

“Attention – instructions for use - important changes”

Draw attention on the front to the change in advice so you read it
[Older, 1st time Mums, C2DE, Wales]

New mums will read it but others might not notice the change
[Older, Mums, ABC1, North]

The front of the product should alert you to new preparation procedures
[Younger, 1st time Dads, C2DE, Scotland]

- ii. **Reinforcing the importance** of following the guidelines and, in doing so, reminding parents of their parental responsibility through the risks and consequences. This needs to be done more strongly than it is done currently, but should focus on the potential harm. This could be achieved using a contrasting colour, bold type and/or a box above the ‘Preparing the Feed’ section on pack and ideally below the ‘Feeding Guidelines’ where layout allows:

“Failure to follow these instructions may be harmful to your babies health and make them ill e.g. sickness, diarrhoea, gastroenteritis”

As long as you stick to the guidelines there’s no cause for concern
[Older, 1st time Mums, ABC1, N. Ireland]

Big letters at the beginning of preparation
[Younger, 1st time Mums, C2DE, North]

We need to be told more clearly that there are consequences if we don’t do it properly
[Mums of ‘At risk’ babies, (B)C1C2, Midlands]

- iii. **Highlighting and justifying the new feeding guidelines** will help develop an understanding that this supersedes earlier practices and all other advice. Bold type in contrasting colour is suggested at the start of ‘Preparing the Feed’.

*Research, carried out in 200?, has shown that it is much safer for babies if milk feeds are freshly made, as required, and **not** made in advance and stored”*

Bold doesn't stand out as much as a different colour ...
[Community Midwife]

New research has shown that ...stands out and makes you read it
[Older, 1st time Mums, C2DE, Wales]

- iv. **Preparation instructions** in which the changes and key points are highlighted. This was seen as easier to follow if it is in a step-by-step approach with corresponding visuals, ideally in bold type for the new key points. The instructions should be clear and unambiguous, such as 20-30 minutes cooling in the kettle and 70° if a method of achieving this is suggested and is readily available, such as a thermometer like those used for a babies bath. This should include advice, suggestions, tips and a rationale for making and managing the changes.

You need to explain why 70 degrees is important ...
[Community Midwife]

It would be good to be able to measure the temperature
[Younger, Mums, C2DE, Scotland]

Proper wording on the side of packs would help
[Older, 1st time Mums, ABC1, N. Ireland]

- v. An additional point with visuals, in the preparation instructions, to explain **safe guidelines for ‘out of home’ use**. Ideally this would be in bold type for the key points, clear and unambiguous and suggesting that all other advice should be followed, such as the water first. In additions, suggestions for maximising sterility of both the flask and bottle would be appreciated, as well as how to transport the powder conveniently and safely. It may be of some value to suggest the use of ready made cartons, if in any doubt.

You can buy something to put powder in for when you're out
[Younger, 1st time Mums, C2DE, North]

You could suggest cartons for safer travel and say that they're sterile till opened ... as well as safe practice for carrying powder when you're on the move ...
[Older, 1st time Mums, C2DE, Wales]

- vi. Highlighting new key points in the feeding information about **'safer' preparation, use and storage practices if formula is made in advance, as well as advice for throwing milk away** – unused, warmed and used.. This could appear after 'Preparing the Feed' or highlighted in the 'Important Feeding Information' and needs to be clear and unambiguous. Better stand out would be achieved if bold type was used for key points, alternatives would be bullet points, such as ✓/X or the use of icons, for example:

Kettle	Fridge	Fridge	Bottle
Visual	Visual	Visual	emptying
20-30	X	6hrs	Visual
mins		max	1hr max

Writing bigger and bolder so it stands out and more people take notice
[Older, Mums, ABC1, North]

Do's and don'ts makes information more accessible
[Older, 1st time Mums, ABC1, N. Ireland]

- vii. Subtle communication of the **non-sterile issue** communicated in context and linked to increasing parental responsibility, in the standard copy as an additional point in 'Important Feeding Information'.

*"Experts agree that, because powdered formula milk is **non-sterile**, great care should be*

Subtle is ok because the risk is low
[Community midwife]

Followed by ...

viii. Where to find further information and advice... at end of 'Important Feeding Information'.

For more information and advice speak to your midwife or health visitor or contact DH web and telephone no."

You can find out more from your health visitor
[Younger, Mums, C2DE, Scotland]

Definitely the Department of Health as this is about your babies health
[Older, 1st time Mums, C2DE, Wales]

5. Conclusions and Recommendations

1. Differences in attitude towards use of powdered formula milk and the desire for information and advice were very evident in this research. These related to types identified in previous projects for FSA which are based on general **attitudinal differences** to food issues, and have implications for levels of concern, behaviour and information needs:

- (i) **Avoiders** prefer to be kept in the dark and actively avoid issues in order not to have to change habits,
- (ii) **Pragmatists** feel life is too short, try to keep issues in proportion using a variety of rationalisations to reduce perceptions of risk; are only interested in 'proven' issues and they only change habits if they believe opinion is widespread,
- (iii) **Headline Reactives** tend to display concern about issues and react strongly to media stories, but this concern is often short-lived, resulting in a fairly superficial impact

N.B. Pragmatists and Headline Reactives display similar needs and make up the largest proportion of the sample and are, therefore, jointly termed **Mainstream** for the purposes of this research.

- (iv) **Purists** are more discerning about food generally and believe in personal responsibility, so emerge as more cautious than the other segments. They are much more knowledgeable as they actively seek information, and are able to process the information and so are more able to decide on what action to take as a result.

In relation to powdered infant formula, distinctly different need sets emerged. While Purists had distinct requirements and Avoiders needed specific targeting to get the message across, Headline Reactives and Pragmatists demonstrated shared behaviour, level of concern and needs relating to both information and reassurance.

2. Parents and Health Care Professionals (HCPs) agreed that **advice and information** given to parents about bottle feeding is extremely limited, even when parents state a preference for this method of feeding. This lack of information relates to both discussion with parents and literature given out to parents.

This is especially evident with midwives, who were seen as the key HCP, as feeding options are normally learnt about and or decided during pregnancy. This lack of information is mostly due to midwives feeling unable to discuss or advise on bottle feeding as it is seen as ‘not allowed’, due to baby friendly initiatives. Health visitors were seen to be in a position to offer more advice, but this can come too late if feeding habits are already established.

3. Due to the relative lack of **formal information** available, parents reported gaining advice and information by a variety of other means. The repertoire of particular sources used depended on their attitude, their propensity to actively search for information and their relative need, particularly if they were undecided about how to feed their babies. It also varied with time, requiring a different focus if it is before starting formula feeding, at the start or once it is already established.

Some mothers, especially in first pregnancies, made use of a mix of formal literature, such as the Pregnancy Booklet, other books and magazines as well as seeking advice from family and friends. Whilst others, particularly Avoiders, were less likely to use formal sources, but instead rely on **informal sources**, especially family and friends.

4. **On-pack advice** was used by all when starting to formula feed, but use was fairly limited or restricted to first time use for most parents. All read ‘preparing the feed’ for the first few times they prepared the feed, but it then declined significantly. Most claimed to read ‘important feeding information’ on first use, but retention of this information varied enormously. In addition, most also claimed to read all about the product and other related products on first use. The ‘Feeding table’ guidelines were one element that was accessed a number of times as the baby grows and its formula needs change. Other information areas, e.g. ‘nutrition’, ‘ingredients’, ‘guarantees’ etc., appeared to only be read by Purists, who were also more likely to refer back to pack to check on details.
5. The wide variation in use of different sources of information, plus inconsistencies between and within all sources resulted in a diversity of knowledge and understanding about bottle feeding practice, with many misconceptions and gaps in knowledge evident. This not surprisingly generated a wide range of **current practices in terms of preparation, storage and use of powdered infant formula milk**. In addition, once practices were established, there was little reported change in behaviour and parents tended to become very fixed into their ways of behaving. As a result, we saw parents, even before the planned change in guidelines, using powdered infant formula inappropriately. Interestingly, however, most believed they were following advice carefully and not taking any risks. This indicates there were already issues with the communication of safe practice and guidelines for the use of powdered infant formula milk.

In reality, there are:

- (i) **Avoiders** with fairly lax practices
- (ii) **Mainstream** parents who follow key guidelines, but may deviate from this once the baby is older or if there is no evidence of ill effect, and
- (iii) **Purists** in a minority, who are following the guidelines most cautiously

6. Over reliance on established practices combined with little experience or recognition of any problems associated with parents own current practice confirmed the belief that their own practices are entirely adequate. Hence, there was little concern amongst parents about the use of powdered infant formula. This was exacerbated by the fact that current messages to increase parental responsibility are not cutting through strongly nor consistently. This seemed to be due to other advice diluting the message and lack of prominence of certain key points of information e.g. 'important feeding information' 'on pack'.
7. In our small sample of healthcare professionals, there was limited awareness of powdered infant formula milk being **non-sterile**. Awareness was latent and not linked to reasons for parents to be more cautious, nor for HCPs to be more directive, about its preparation, storage and use. There was only one case of new information about risks and new guidelines being known by a HCP and even in this case the information was not being communicated to parents.
8. When the issue of sterility was discussed with parents, it was clear the majority did not consider food and sterility hand-in-hand and many assumed most canned or bottled food is sterile, at least until it is opened. In particular, when considering anything that is intended for babies, including jars of food or formula, the assumption was certainly that it is sterile. Therefore, there was no awareness amongst parents that powdered infant formula milk is non-sterile.
9. Non-sterile as a term was perceived very negatively by the majority and it emerged as meaning dirty, containing germs or bacteria which would make food unsafe, creating illness or infection. This term failed to communicate the nature and level of risk as most did not think it meant potentially harmful, but **actually harmful**. As a result, the news that powdered infant formula milk is non-sterile generated both concern and confusion. Having said that, reactions of parents did vary significantly by attitudinal type:

- (i) **Avoiders** displayed least concern as they rationalised, for example, that it can't be a huge problem or else babies wouldn't have survived on it for years, etc
- (ii) **Mainstream** parents displayed some concern and wanted more information about relative risks and help to enable them to decide what to do as a result, and
- (iii) **Purists** displayed most concern and required most detail about risks, consequences and outcomes.

10. Overall, as it poses a potential risk to babies, parents and healthcare professionals agreed that information about non – sterility and what it means should be **clearly communicated to parents**, so that they can make informed decisions and choices.

11. The research suggested that the most effective messages to communicate the issue to parents are those which help to **increase parental responsibility**. These include simple messages that provide a balanced view and clearly communicate what can be done to reduce the risk of harmful consequences. For example, *careful preparation by following new guidelines reduces the risk of your baby becoming ill ... with sickness, diarrhoea, gastroenteritis*. This is more than is communicated currently as it gives examples of possible illnesses.

12. Other information should be used with caution. **Exacerbating concern** facts, such as mentioning serious illnesses like Meningitis or referring to 'harmful bacteria', can be unhelpful in that they fuel a panic reaction and reduce many parents ability to process the whole story effectively. However, they could be useful in making parents understand the need to change behaviour. **Reducing concern** facts, such as mentioning the rarity of cases i.e. '50 cases in 40 years', run the risk of being focused on by some (mostly Avoiders and some Pragmatists) to dismiss the issue outright.

These facts, therefore, are highly **channel sensitive** and are best avoided on those which are unsuitable for communicating significant depth or detail, e.g. on-pack and some print. They are more appropriate for use in channels which either tailor information to needs, as with health care professionals, or in written communications when the full depth and detail can be provided (e.g. websites), which are likely to only be accessed by a minority (Purists).

13. Reactions to the **new guidelines** indicated that some of the changes were deemed as very difficult to put into practice by the majority of parents:

- (i) **Making up bottles fresh** rather than making them in advance was seen, in particular, as extremely impractical by the majority who make them up in advance. It could prove more difficult to get parents with established habits to change, compared to new first timer parents.
- (ii) **Out of home practice using a flask** raised other concerns such as portability of the flask and sterility of the bottle for some.
- (iii) **Water temperature/cooling time** to under 30 minutes emerged as less of a problematic shift, but clarity is needed in exactly what this means and how to implement it.
- (iv) **Throwing away milk after use**, in terms of what and when, also requires greater clarity.

Ultimately, it is very likely that the impact of the new guidelines on behaviour will vary dramatically by attitude types:

- (i) with some, mostly Avoiders, unlikely to change their habits
- (ii) others, predominantly Mainstream, making some easier changes, but with the potential to lapse back to previous habits over time, especially if the risks are not reinforced, whilst
- (iii) others, mostly Purists, will follow new guidelines to the letter.

14. **Successful communication** of non-sterile and the new guidelines will require the following:

- (i) Drawing **attention to the change** in guidelines, which indirectly implies that it supersedes other advice, as appropriate for each channel
- (ii) Explaining the **new ‘ideal’ guidelines** clearly and avoiding any ambiguity
- (iii) Explaining the **relative risks, consequences and rationale** behind the recommendations to increase concern and prompt behavioural change without causing panic. As already mentioned this is best done by stronger parental responsibility messages
- (iv) **Advice, help and tips** on managing and maintaining changes
- (v) Communicating the **non-sterile fact** subtly and within context
- (vi) **Offering ‘safer’ practice suggestions as a safety net**

15. As information and advice is drawn from a wide range of sources across the attitudinal types, it will be important for this issue to be communicated via **all formal channels** in order to reach all parents, including HCPs, printed material (such as NHS booklets and other separate leaflets), and on-pack as well as internet sites and telephone care-lines.

16. **Health care professionals** are a critical channel in the communication mix as they have the potential to reach all parents and are also in a unique position of being able to tailor the information they provide to individual needs in order to gain parental responsibility and encourage adherence to the new guidelines.

Despite the issue of revised guidance on the preparation and storage of powdered infant formula by the Department of Health and FSA, the majority of health care professionals consulted in this research were not aware that powdered infant formula milk is non-sterile or the possible impact and implications of this, so it is critical that this audience are officially informed via **established formal channels of communication**. In

addition, given the impact of the current **baby friendly initiative**, there was evidence that suggested that this information may not be passed on. Hence, some encouragement is needed for health care professionals, especially midwives, to feel that it is acceptable for them to embrace the communication of good bottle feeding practice with parents.

17. Separate printed advice such as the **NHS bottle feeding leaflet** is also important, not only to encourage adoption of the new guidelines, but also to encourage better baseline practice. As a stand alone communication this will have more impact when given to parents, especially first timers. However, it will rely on being disseminated to parents by health care professionals and there was evidence to suggest this is not happening currently. In addition, this research suggested the leaflet would benefit from a **redesign to better highlight changes and new advice** in order that key information stands out more clearly and alerts subsequent parents of the need to read it, rather than pass it by.

18. **‘On pack’ information** is also a critical channel in the information mix as it is always examined thoroughly by all first time users and, if designed appropriately, the key messages should also reach the majority of users. The following approach is recommended for communicating ‘on pack’:
 - (i) **Attention needs to be drawn to the change in guidelines** in order that all parents are alerted to the new information and advice
 - (ii) **Parental responsibility** should be reinforced in the ‘preparing the feed’ section, to encourage adherence and provide justification, via messages that indicate the potential harm to the baby if the instructions and advice are not followed
 - (iii) The new guideline of **not preparing in advance** needs to particularly stand out as well as justification as it is seen as a difficult practice for many to adopt. So, it is recommended that this should be highlighted at the start of

the ‘preparing the feed’ section and backed up by *‘expert opinion/research shows it is much safer if...’*

- (iv) **All new guidelines**, including out of home practice, need to be highlighted within the step-by-step ‘preparing the feed’ section to clearly stand out as something new as well as ensuring that clear explanations are provided to avoid ambiguity
- (v) Given that some parents are unlikely to make each bottle freshly, as required, on-pack information would also benefit from additional instructions about **safer use if making in advance**, best placed in the section following on from ‘preparing the feed’ or under ‘important feeding information’
- (vi) **Non-sterile** is seen as important to communicate ‘on pack’, but best done subtly and in context, in the ‘important feeding information’ section, where it is linked again to increasing parental responsibility
- (vii) Finally, at the end of the ‘important feeding information’ section we recommend that there should be details of where to find **further information and advice** that is endorsed by The Department Health, e.g. website or careline number

APPENDICES

APPENDIX 1 - Recruitment Questionnaires

Job Name: FSA Formula

AJS 600

Interviewer: _____

Respondent _____

Address: _____

_____ Post Code: _____

Tel. _____ (Hm) _____ (Wk) _____ (Mobile)

Please note method of recruitment: (tel/f2f/snowballing/list)

What is the occupation of the head of your household?

.....

A B C1 C2 D E **CHECK QUOTAS**

Q1. Do you or do any of your close friends or relatives work in the following occupations?

Journalism	1	Close	Design	2	Close
Television	3	Close	Public Relations/media/advertising	4	Close
Medical profession	5	Close	Manufacturer or retailer of baby food/milk/formula	6	Close
Marketing/market research	7	Close	Government	8	Close

MALE 1 FEMALE 2 **CHECK QUOTAS**

Q2. How old are you?

17 or under	1	CLOSE
18 – 30	2	YOUNGER
31 – 45	3	OLDER

Q3. How old is your baby?

0 – 3 months	1	AT LEAST HALF IN EACH GROUP
4 – 6 months	2	
7 months+	3	CLOSE

Q4. Do you have any other children?

Yes	1	OTHER CHILDREN - OLDER -> Q5 YOUNGER -> Q6
No	2	1st TIME PARENT -> Q6

Q5. What ages are your other children?

1 – 3 years	1	AIM FOR SPREAD OF AGES FOR 'OLDER PARENTS OTHER CHILDREN' GROUPS
4 – 6 years	2	
7 – 9 years	3	
10+ years	4	

Thinking about your youngest only unless otherwise mentioned

Q6. How do you currently feed your baby? (**READ OUT**)

Breast feeding only	1	CLOSE	}	CHECK QUOTA
Formula only	2	-> Q8		
Mix of Formula and breast milk	3	-> Q7		

Q7. You say that you currently sometimes use formula milk to feed your baby. Can you please tell me approximately how often you use formula milk? (**READ OUT**)

Occasionally	1	CLOSE	}	SPREAD OF USAGE IN EACH MIXED GROUP
For a few feeds	2			
For about half the feeds	3			
For most of the feeds	4			

Q8. What type of formulas do you use with your under 6 month old baby most frequently nowadays?

Powdered formula	1	CONTINUE
UHT treated liquid formula	2	CLOSE
Special prescription formula	3	CLOSE

FOR OTHER CHILDREN PARENTS ONLY

Q8b Have you used/or do you use follow-on powdered formula with any of your other children?

Yes	1	AT LEAST 2-3 OLDER PARENTS TO CODE FOR OLDER CHILDREN USING NOW OR PREVIOUSLY
No	2	

Q9. Who has responsibility for choosing the formula that you currently use?

		MUMS	DADS
Self	1	ALL TO CODE EITHER 1 OR 3	AT LEAST 4 TO CODE EITHER 1 OR 3
Partner	2		
Self and Partner equally	3		

Q10. How often do you personally feed your baby each week?

Most feeds	1	
At least 3 times per week	2	
Less than 2 times per week	3	CLOSE
Rarely/Never	4	CLOSE

Q11. How involved are you in the sterilizing and preparation of formula bottles?

Very involved	1	
Shared involvement	2	
Little/No involvement	3	CLOSE

Q12. How long have you been using formula feeds?

- | | | |
|-----------------------|---|-------------------------|
| From birth | 1 | } AIM FOR SPREAD |
| In the last few weeks | 2 | |
| 2 – 3 months | 3 | |
| 3 - 4 months | 4 | |
| 5 - 6 months | 5 | |

Q13. Which of the following most closely describes how you decided to use formula feeding?

- | | | |
|---|---|---|
| I/we had always planned to bottle feed exclusively | 1 | PLANNED (If full formula feeder) |
| I/we had always planned to breast feed but now use/also use formula | 2 | -> Q14 |
| I had always planned to do mixed feeding | 3 | PLANNED (If mixed feeder) |

Q14. You say that you had planned on breast-feeding. Could you tell me what prompted you to also use formula or switch completely to formula feeding?

The baby was premature/low birth weight/another medical condition/immuno compromised and was unable to feed properly initially	1	GO THROUGH 'AT RISK' QUESTIONNAIRE CLOSE FOR THESE GROUPS
The baby did not take to breast feeding	2	
I was uncomfortable with breast feeding	3	AIM FOR SPREAD OF REASONS FOR CHANGE -> Q15
I wanted more freedom	4	
We wanted the father to get more involved in feeding	5	
I could not provide enough milk	6	
Other *.....	7	

Q15. Which of the following statements, if any, most closely matches your attitude to sterilising?

I am concerned about hygiene and feel sterilizing all feeding equipment for the baby is really important until they are one year old	1	AIM FOR SPREAD OF ATTITUDES
I am fairly concerned about hygiene and sterilizing but only really think its worth sterilising bottles/teats	2	
I am less concerned about hygiene and sterilizing once your baby is moving around and putting things in their mouth (from about 6 -9 months)	3	
I think you can get too worried about hygiene and sterilizing, babies need a few germs to build up their immunity once they are over 5-6 months	4	

PLEASE AIM FOR SOME ETHNIC MINORITIES WHERE POSSIBLE IN YOUR AREA

APPENDIX 1 - Recruitment Questionnaires (cont.)

Job Name: FSA Formula At Risk Babies

AJS 600

Interviewer: _____

Respondent _____

Address: _____

_____ Post Code: _____

Tel. _____ (Hm) _____ (Wk) _____ (Mobile)

Please note method of recruitment: (tel/f2f/snowballing/list)

What is the occupation of the head of your household?
.....

~~A~~ B C1 C2 ~~D~~ ————— ~~E~~

Qa) We would like to speak to parents of babies who were born pre-term or had a low birth weight and may have spent some time in a special care baby unit in hospital. Can you tell me which of the following, if any, were applicable to your baby?

Pre-term – born between 30 and 37 weeks (ensure a range)	1	MUST CODE 1 OR 2 OR BOTH TO CONTINUE
Low birth weight – below 2.5 kilos (5lbs 8ozs)	2	

Q1. Do you or do any of your close friends or relatives work in the following occupations?

- | | | | | | |
|---------------------------|---|-------|--|---|-------|
| Journalism | 1 | Close | Design | 2 | Close |
| Television | 3 | Close | Public Relations/media/advertising | 4 | Close |
| Medical profession | 5 | Close | Manufacturer or retailer of baby food/milk/formula | 6 | Close |
| Marketing/market research | 7 | Close | Government | 8 | Close |

MALE 1 - **CLOSE** FEMALE 2

Q2. How old are you?

- | | | |
|-------------|---|--------------|
| 24 or under | 1 | CLOSE |
| 25 – 45 | 2 | Q3 |
| 46+ | 3 | CLOSE |

Q3. How old is your baby?

- | | | |
|--------------|---|---------------------------------------|
| 0 – 3 months | 1 | } AIM FOR SPREAD OF AGES CLOSE |
| 4 – 6 months | 2 | |
| 7 months+ | 3 | |

Q4. Do you have any other children?

- | | | |
|-----|---|--|
| Yes | 1 | Q5 (OTHER CHILDREN – at least 3 |
| No | 2 | Q6 (1st TIME PARENT – at least 3 |

Q5. What ages are your other children?

1 – 3 years	1	AIM FOR SPREAD OF AGES
4 – 6 years	2	
7 – 9 years	3	
10+ years	4	

Q6. How do you currently feed your baby? (**READ OUT**)

Breast feeding only	1	CLOSE	}	CHECK QUOTA
Formula only	2	-> Q8		
Mix of Formula and breast milk	3	-> Q7		

Q7. You say that you currently sometimes use formula milk to feed your baby. Can you please tell me approximately how often you use formula milk? (**READ OUT**)

Occasionally	1	CLOSE	}	SPREAD OF USAGE IN EACH MIXED GROUP
For a few feeds	2			
For about half the feeds	3			
For most of the feeds	4			

Q8. What type of formulas do you use with your baby most frequently nowadays?

Powdered formula	1	CONTINUE
UHT treated liquid formula	2	CLOSE
Special prescription formula	3	CLOSE

Q9. Who has responsibility for choosing the formula that you currently use?

Self	1	ALL TO CODE EITHER 1 OR 3
Partner	2	
Self and Partner equally	3	

Q10. How often do **you personally** feed your baby each week?

Most feeds	1	
At least 3 times per week	2	
Less than 2 times per week	3	CLOSE
Rarely/Never	4	CLOSE

Q11. How involved are you in the sterilizing and preparation of formula bottles?

Very involved	1	
Shared involvement	2	
Little/No involvement	3	CLOSE

Q12. Which of the following most closely describes how you decided to use formula feeding?

I/we had always planned to bottle feed	1	PLANNED (If full formula feeder)
I/we had always planned to breast feed but now use/also use formula	2	-> Q13
I had always planned to do mixed feeding	3	PLANNED (If mixed feeder)

Q13. You say that you had planned on breast-feeding. Could you tell me what prompted you to also use formula or switch completely to formula feeding?

I was unable to feed my baby as they were placed in a special care baby unit	1	AIM FOR SPREAD OF REASONS FOR CHANGE
The baby did not take to breast feeding	2	
I was uncomfortable with breast feeding	3	
I wanted more freedom	4	
We wanted the father to get more involved in feeding	5	
I could not provide enough milk	6	
Other *.....	7	

APPENDIX 1 - Recruitment Questionnaires (cont.)

Job Name: FSA Formula – Health Care Professionals

AJS 600

Interviewer: _____

Respondent _____

Address: _____

_____ Post Code: _____

Tel. _____ (Hm) _____ (Wk) _____ (Mobile)

Please note method of recruitment: (tel/f2f/snowballing/list)

MALE 1 FEMALE 2 **GOOD SPREAD PLEASE**

AGEWRITE IN **GOOD SPREAD PLEASE**

Q1. What is your current working status?

Fulltime for the NHS	1
Fulltime for a private hospital	2 – CLOSE
Part time for the NHS	3
Part time for a private hospital	4 – CLOSE

Q2. Which of these best describes your current job?

Health Visitor	1	} AIM FOR A SPREAD
Community Midwife	2	
Hospital Midwife	3	
Community Practitioner	4	
Neo natal nurse	5	
None of these.....	6 – CLOSE	

NB Ensure 1 hospital midwife depth and 1 hospital midwife in the group work in a neo-natal special care baby unit (if not hospital midwife then recruit neo-natal nurse)

HOSPITAL MIDWIVES/NEO-NATAL NURSES ONLY

Q3. Do you spend more than half of your time at work caring for pre-term/low birth weight/immuno-compromised babies?

Yes 1 > **Q6** No 2 – **CLOSE**

Q4. What ages of babies, if any, do you work with nowadays?

0-6 months	1 – MUST CODE
6-12 months	2
12+ months	3

Q5. What level of experience do you have in your current role?

- Newly qualified – less than 1 year
- 1-4 years experience
- 5 10 years experience
- 10+ years experience

- 1
- 2
- 3
- 4

**INCLUDE 1 NEWLY QUALIFIED RESPONDENT
AIM FOR A SPREAD**

Q6. Which PCT are you currently employed by?

..... **AIM FOR A SPREAD IN GROUPS and DEPTHS_**

APPENDIX 2 – Discussion Guides

DISCUSSION GUIDE: FSA Powdered Infant Formula

Parents Group Discussions

N.B. This Guide indicates the areas to be explored in the discussion, the likely order in which topics will be covered and the kinds of questions and techniques which may be used. However, as this is qualitative research, the approach will be flexible depending on the dynamics of each group.

INTRODUCTIONS

- Moderator to introduce self, explain the process of market research to respondents and the format of the discussion (some topics for discussion and occasional exercise for them to do), reiterate need for honesty to help with research and **reassure on confidentiality**.
- Explain topic of discussion is their experience of feeding young babies of 0 – 6months and in particular what they know and how they use **powdered formula milk**.
- Introductions: brief background details of respondents (first name, family composition – first/subsequent children - ages, how you feel about feeding babies, etc)

WARM UP

Spontaneous associations and feelings are best captured through free association.

Powdered formula milk - word association exercise ...

- What comes in to your mind when you think of?
- What feelings and emotions come to mind?
- Think back to the early days of feeding your baby and think about now ...

CURRENT KNOWLEDGE

Advice/Sources of Information

Where does your **knowledge** about feeding your baby come from – where do you get **information and advice** about feeding your baby? Has this changed over time at all or as your baby has got older/for subsequent children? What about for formula feeding specifically?

PROBE: for all sources including ...

- All health care professionals – GP's, midwives (which?) health visitors, etc.
- Books/magazines/booklets/leaflets, internet, posters – what?
- WOM/family and friends – who?
- Organisations/clubs/groups – which?
- On Pack information, product labels/leaflets – which?

FOR EACH SOURCE ...

- Which are most/least useful/valued and when?
- For what sorts of advice/information about feeding your baby?
PROBE: preparation, storage and use of powdered formula milk
- What are their strengths and weaknesses/your likes and dislikes?

An understanding of where current information and advice comes from now and how it is perceived will help us identify the best routes for non-sterile messages and advice in the future.

CURRENT PREPARATION, STORAGE AND USE BEHAVIOUR vs ADVICE

It's important to understand the rationale for current behaviour and how this compares to the information and advice they've been given. This will help us gauge how best to communicate the new advice in order to ensure it is heard and acted upon – message, tone, impact, rationale.

Current Behaviour

How do you usually **prepare, store and use** powdered formula milk? Why do you do it this way?

PROBE:

- When made up and how many bottles at a time – why?
- How do you make it up – kettle, time, equipment used, etc. – why?
- Where stored till used when at home/out of home – why?
- What's the longest you'd keep bottles you've made up, at home/out of home – why?
- How has this changed as your baby has got older/for subsequent children – why?

If you sometimes **breast feed or use expressed breast milk in a bottle or use ready made liquid formula from a carton** ...when do you do this and for what reasons?

PROBE: convenience/speed/hygiene/safety/other rationale

Is what you actually do any **different from the information and advice** you've received?

- In what ways? Why do you do things differently?

Perceived Ideal Behaviour

If you were going to follow information and advice about powdered formula milk **exactly** ... what would this be ... what are **the golden rules as you understand them now**?

- Does this change as a baby gets older – if so, how and why?
- Where does this information and advice come from mainly? And where else?
- Which sources of information and advice to you take most notice of? When and why?
- What are the perceived risks of not following advice exactly?

Usage of Pack/ Labelling

SHOW A RANGE OF POWDERED FORMULA MILK PRODUCTS – including some packs with sterile messages without drawing attention to it

- What, if anything, do you look at on packs/labels? Why/why not?
- When did you last **look carefully** at the information and advice written on the powdered formula milk product(s) you buy? Why/what prompted you?
- Do you read everything or only part of the information and advice written on the pack, and if so which parts?

Allow a few minutes for the products to be passed around the group

- Discuss what noted spontaneously.
- Do any of these products give any **new/different information and advice** or recommend any different practices compared to our golden rules/what you believed to be recommended practice?
- What and how do you feel about this? Explore the perceived rationale/implications of any new information/advice

This will help us understand how accessible/impactful current on pack information and advice is – although in reality it's anticipated that only first time users of a brand check/read the on pack information – unless it has good stand out/impact.

KNOWLEDGE ABOUT FORMULA MILK AND STERILITY ISSUE

In order to get a relative understanding of responses to non-sterility we suggest presenting this fact along with other facts about formula to see if there are any immediate concerns and impact on likely behaviour

SHOW FORMULA MILK FACTS BOARD – rotate order as appropriate

Gauge spontaneous reactions to these facts before probing (i.e. see if non-sterile is noted as important vs other facts and why/why not)

Which of these facts are well known, known by some and which are not generally known?

- Check current knowledge, level of understanding, relative importance
- PROBE: perceived pros and cons/reassurances and concerns
- What implications does/might it have on perceptions and use of powdered formula milk
- Perceptions of significance depending on age of baby/other influencing factors e.g. 'at risk'

Ask each respondent individually to write down initial reactions to non-sterile and note level of concern on a 5 point scale. (They will be given a piece of paper and asked to write down their responses to the following questions)

- *My thoughts about powdered infant formula being non-sterile are....*
- *I would rate my level of concern about this issue as (5 point scale where 0 = not at all concerned and 5 = extremely concerned)*

Sterile/non-sterile - word association exercise ... EACH IN TURN

- What comes in to your mind when you think of **sterile/non-sterile**?
- What does sterile/non-sterile **mean** to you?
- PROBE: positive and negative associations with each
- What other things come to mind?
- What other products? Food, drink, baby products, non-baby products?

When and why is sterile **important/not important**?

PROBE: How does/might it influence choice, purchase, storage and use?

Sorting Exercise

SHOW RANGE OF STERILE AND NON-STERILE FOOD AND DRINK, INCLUDING POWDERED AND READY MADE FORMULA MILKS

Allow a few minutes for the products to be passed around the group and ask for them to be sorted in to groups of sterile and non-sterile products (fairly quick not examining packs in detail)

How do you know/assess whether products are sterile or non-sterile?

- Where does your **information** come from? What are the clues?
- What difference does **sterility** make to how ...
 - you **feel** about the products? Reassured/concerned?
 - you might **choose, store and use** for feeding at home/away from home?
 - you perceive its **suitability/safety** for babies of different ages?

What **questions** do you/will parents have? What will they **want to know**?

PROBE: facts, advice, levels of risk, consequences,

relevance to first/subsequent babies/ages of babies/babies at risk

What are the **best ways** of getting this sort of information and advice across to parents?

PROBE: what to say and how to say it?

most suitable sources of information and advice?

Specifically – What is needed on pack? Need to label as non-sterile or similar wording or not? Why/why not?

This aims to understand what the non-sterile fact really means to parents and what issues it raises for them which the FSA messages will need to address.

COMMUNICATING NON-STERILE

Explain that whilst liquid infant formula is sterile that powdered formula milk has always been non-sterile, but it has not been clearly labelled on packs to date. Due to a few recent incidents where illness has been caused as a consequence of incorrect preparation, storage and use, it has been decided that this fact and related information should be brought to people's attention in order that they understand the risks and how to minimise them ...

Messages/facts about non-sterile

SHOW FSA STATEMENTS ABOUT NON-STERILE ISSUE – (explaining risks, relative risks and how to minimise risks) rotate order as appropriate

Explore each in turn:

- Awareness and source of information
- Understanding of statement and anticipated response
PROBE: more care/product switching/etc.
- Perceived risk and levels of concerns
PROBE: for different usage scenarios/parents/baby age/at risk
- Additional information/reassurances required
- Ideal source(s) and location for this information,
PROBE: health care advice/leaflets/websites/on pack
if on pack information – **what and where** –
leaflets/front/back/highlighted/beginning or end of the text?
revisit packs already with non/sterile information – is this good enough?
- Suggestions for how to improve the communication to get across message, achieve changes in behaviour (and avoid panic)

Reassure that if advice is followed that the risk is minimal ... so it's recognised that clearer instructions and advice are needed on packaging from now ... as well as updating other sources of information and advice.

Sources of Advice

This section aims to assess the ideal messages to use to explain non-sterile as well as the best mix of sources for the information and advice.

What **suggestions** do you have for getting the **advice** across on how to minimise the risks?

- What should be said and where should it come from for **maximum impact**?
- Does the non-sterile fact **need to be included**? Is a change in advice enough?

Explore **the pros and cons** of all the options:

- All health care professionals – GP's, midwives (which?) health visitors, etc.
- Print - Books/magazines/booklets/leaflets/internet
- Organisations/clubs/groups
- On Pack information – labelling/product packaging/stickers/leaflets

Which are taken **most seriously/ most noticed**? What is the **ideal mix** of sources?

Print

Explain that a variety of print sources are available e.g. leaflet from DH, website info from DH, FSA and NHS Birth to Five book guidelines etc [Explain they are welcome to keep a leaflet for their information and future reference]

SHOW CURRENT PRINT SOURCES – rotate order

Explore perceptions and anticipated response ...

- Have you seen this before?
- Is this what you were expecting?
- Easy/difficult to understand? Is it reassuring/alarming?
- What are the key/most important points?
- Suggestions for improvements and what else is needed to get the message across?
- Which of these are most/least useful? Why?

On Pack/Labeling

Explore perceptions and expected advice/warnings on pack:

- What would you expect to see written about this on formula labels?
- Should powdered infant formula packs be **labelled as non – sterile, i.e. non-sterile, may contain bacteria/microorganisms etc?** Why/not? If so, how should this be done?
 - What should be written? – (explore exact wording)
 - Where should it be placed on pack/positioned on the label? - front, back, (top, side, bottom etc), on/under lid, accompanying leaflet
 - How should it be presented? - subtle copy/highlighted/warning strip/specific messages (e.g. ‘your child is in danger if you do not following the instructions exactly’)
- And how should any **change in preparation**/use be communicated on pack?
 - in usual place only/somewhere else more noticeable?
 - subtle copy/highlighted/warning strip
- What are the key/most important points to cover on pack?

Endorsement

Will **official source backing/endorsement** help parents take notice and act on the advice? Spontaneous suggestions ...

SHOW LIST OF ENDORSEMENT SOURCES (e.g. DH, FSA, National College Midwives, Formula Brands etc) Which are parents most likely to **trust and take note of?** Why?

OVERVIEW

Ask each respondent individually to write down perceptions now of formula being non-sterile and note level of concern on a 5 point scale (same questions as before)

- What is the **best combination** of messages, information and advice
- What information/advice has **reassured** you the most?
- What should be avoided because it might cause too much **concern?**
- What **methods** should be used to communicate to parents?

How do you feel now about powdered formula milk being non-sterile NOW?

- Do you have any other questions/concerns we’ve not yet answered/reassured you about?

APPENDIX 2 – Discussion Guides (cont.)

DISCUSSION GUIDE: FSA Powdered Infant Formula HCP Depth Interviews/Group Discussions

N.B. This Guide indicates the areas to be explored in the discussion, the likely order in which topics will be covered and the kinds of questions and techniques which may be used. However, as this is qualitative research, the approach will be flexible depending on the dynamics of each interview/group.

INTRODUCTIONS

- Moderator to introduce self, explain the process of market research to respondent and the format of the discussion, reiterate need for honesty to help with research and **reassure on confidentiality**.
- Explain topic of discussion is their role as a health care professional in advising parents about feeding young babies of 0 – 6 months and in particular what they know and how they advise on the preparation, storage and use of **powdered formula milk**.
- **Important to explain that the Food Standards Agency is not promoting bottle feeding however it is keen to understand what information is provided to parents when bottle feeding and using powdered infant formula.**
- Introductions: brief background details of respondent(s) - first name, job title, length of time in job?

ROLES AND RESPONSIBILITIES

This section aims to get a good understanding of the roles and responsibilities of our respondents and the variation across different professional roles, various locations and where the HCP is based. This will help clarify which of the HCP has the most significant impact on parents feeding decisions and behaviour at different stages..

Explain that we'd like to understand the role and responsibilities they have in relation to advising parents about feeding their babies ... particularly powdered formula milk.

Ask participant(s) to explain **their role and responsibilities** in this context ...

PROBE:

- When and where do **you** have contact with parents?

- what age/stage of babyhood/pregnancy
- How does what you do **compare/fit in** with other HCP's? Explain the role of each.
 - Health visitor/community and hospital midwives/community practitioners/others?
- Is this different in different locations/areas? If so, how?
 - Around the UK
 - City, urban, rural
 - GP, hospital, community based
 - [Explore if differences depending on whether the health care trust is 'baby friendly' i.e. breast feeding friendly]
- Which HCP do you feel has the **biggest influence** on advising parents on feeding their babies, particularly powdered formula milk in terms of preparation, storage and use
 - Pre delivery
 - Post delivery
 - On returning home – the first few weeks
 - As the baby gets older – first few months, 6 months, over 6 months
 - And overall ... who has the biggest influence on this?
 - Identify which HCP or another influence?
 - PROBE: family, friends, books, leaflets, antenatal classes, etc

FEEDING ADVICE

This should establish what information and advice is being communicated by HCP's now, at different ages, stages and circumstances, as well as how responsive they are/might be to a call for change.

What information and advice are **you currently giving** to the parents you have contact with?

PROBE:

- Feeding options? - The pros and cons of powdered formula milk
- Types of formula milk – Powdered, Ready prepared, special medical purposes?
- Preparation, storage and use of powdered formula milk?
- Any differences between ages/stages of baby/pregnancy?

Where do you get your **information from** /what do you base your advice on?

PROBE:

- All the various sources
- Frequency of reviewing/updating information and advice.
- When did you last make any changes to the info./advice you provide? What and why?

What **literature/other aids/information sources** do you pass on to parents?

IN DEPTHS ASK TO SEE AND RETAIN IF POSSIBLE

PROBE FOR EACH:

- How do they compare?
- What are their strengths and weaknesses?

Where else do parents get information and advice about the preparation, storage and use of powdered formula milk? PROBE AS ABOVE

Which of all these sources has the **biggest influence on parents'** subsequent choice and behaviour? Is that good/bad? Why?

Is there **enough information and advice** available to parents in your area?

PROBE:

- What ages and stages/circumstances are **well catered for**?
- Which are **less well catered for**? And what should be done about this?
- Where are the gaps and how can they be filled?

POWDERED FORMULA MILK

This section asks the HCPs to focus on the detail of the messages they are giving to parents about powdered formula milk and whether they are aware of the non-sterile issue, amongst other facts.

It is acknowledged that breast milk is the best form of nutrition for infants and that exclusive breastfeeding is recommended for the first 6 months of an infant's life. However thinking about any circumstances where you may be asked to provide information on bottle feeding, what are the **key messages** you are currently giving about powdered formula milk. Explore how points are explained to parents – words/language used in relation to:

- Advantages and disadvantages/strengths and weaknesses
- How **powdered** compares to **ready made** formula
- How to **prepare, store and use** – PROBE FOR DETAIL
 - Length of time kettle stands before use?
 - How many to make up at a time?
 - Where and how long to store before unsafe to use?
 - What to do when out of home?
- **Allaying any concerns** – if so, what is the nature of concerns?

SHOW MILK FACTS CARDS

FOR EACH IN TURN:

- Are you aware of this fact? What does it mean to you?
- And are parents? What does/might it mean to parents?

NON-STERILE ISSUE

This section aims to explore the non-sterile issue in more depth in order to get a full understanding of the issue, its likely impact and implication as well as how best this can be communicated to parents.

Use FSA statements about non-sterile as appropriate – where knowledge low/unclear

If already aware of non-sterile issue,

- When did you first become aware of the fact?
- Where did this information come from? PROBE: all sources
- What was your reaction? What were your immediate thought and feelings? And now?
- What difference does this make in a hospital setting vs home setting? Why?
- Is it something you've discussed with parents? Any in particular and why?
- Has it influenced what you tell/give to parents at all? If so, how?
- What has been their response?
- What, if any, are their concerns and how do you reassure them?

If NOT already aware of non-sterile issue,

- What is your reaction? What are your immediate thoughts and feelings?
- How do you expect to be informed about this? (Explore all sources/levels of information)
- What difference does this make in a hospital setting vs home setting? Why?
- Will it influence what you tell/give to parents at all? If so, how?
- What do you anticipate will be their response?
- What do you think their concerns will be and how will you reassure them?

Did/does it **make any difference** to how you feel about powdered formula milk and the advice you give/will give to parents about choice, preparation etc.? What and why?

Whose **role** is it to **inform parents** about this issue and why? (Explore HCP, DH, FSA, manufacturers, retailers and trade associations etc)

What other sources of information and advice are/will be **important** in communicating this to parents? PROBE: all sources mentioned earlier

FOR EACH:

- What needs to be communicated to parents?
- Is it important to communicate the non-sterile fact? Where and how?
- Or is it enough to just change the usage advice? Where and how?

On pack

Should powdered infant formula packs be **labelled as non – sterile or a related term, i.e. may contain bacteria, etc?** Why/not?

If so, how should this be done?

- front, back, on/under lid, accompanying leaflet
- subtle copy/highlighted/warning strip

And how should any **change in preparation**/use be communicated on pack?

- in usual place only/somewhere else more noticeable?
- subtle copy/highlighted/warning strip
- before or after the nutritional information

Print

SHOW LABELLED PRODUCT, PAGE GRAB, WEB STATEMENT, DH LEAFLET etc

Allow time for each of them to be examined

FOR EACH IN TURN

- What do you think/feel about this?
- What do you like/dislike about it?
- How could it be improved? For HCPs? For parents?
- Are these alone enough? If not, why?
- And what else should be done to get the message across to all parents?

Overall ...

Will these suggestions ensure that the information and advice will be **heard and acted upon by all parents, without causing panic?**

- Age and stage of baby, first and subsequent parents, different locations and circumstances?
- If not, what else needs to be done?

Do you have any other suggestions?

BEFORE THANKS AND CLOSING

Seek permission to pass on details for further consultation direct with FSA.
If willing ask for completion of contact information and consent form

APPENDIX 3 – Self completion sheet for parents

1. My thoughts about powdered formula milk not being sterile are.....

2. How would you rate your level of concern about this issue? (Please circle relevant number)

Not at all concerned

Extremely concerned

1

2

3

4

5

Why do you say this?

3. My thoughts now about powdered formula milk not being sterile are.....

4. How would you rate your level of concern about this issue now? (Please circle relevant number)

Not at all concerned

Extremely concerned

1

2

3

4

5

Why do you say this?

APPENDIX 4 – Stimulus material

Facts About Formula

1. Infant formula milk is intended to replace breast milk when mothers cannot or choose not to breastfeed
2. Infant formula milk is formulated to be as close to breast milk as possible
3. Infant formula milk contains the correct mix of vitamins and minerals
4. Powdered infant formula milk is non-sterile
5. Powdered infant formula milk is not free from germs/bacteria
6. Most infant formula milks are based on cows' milk
7. Infant formula feeds should be used within one hour and any leftover milk should be discarded following feeding
8. Failure to follow preparation instructions carefully can be harmful to your baby's health
9. Before preparing your baby's feed wash your hands, clean the surfaces and sterilise all utensils
10. Prepare infant formula feeds as you need them and not in advance

APPENDIX 4 – Stimulus material (cont.)

FSA Statement

Infants and young children are more likely to suffer from foodborne infections

There is concern that reconstituted powdered formula milks may contain harmful bacteria (ie non-sterile)

And may be a source of illness for babies and young children especially if the feeds are prepared in advance

Illness from powdered formula milks containing harmful bacteria i.e. Salmonella and Enterobacter sakazakii are rare - approximately 50 cases of Enterobacter sakazakii reported worldwide in the last 40 years

Although Enterobacter sakazakii may result in severe food poisoning or meningitis

The risk of illness is considered greatest for premature babies

Scientific opinion is that healthy infants and children eating low numbers of Enterobacter sakazakii does not normally lead to illness

It is much safer for babies if milk feeds are made as you need them using freshly boiled water that has been left to cool for no more than 30 minutes

Formula feeds should not be stored and any leftover infant milk should be thrown away

APPENDIX 5 – References

Opinion of the Scientific Panel on Biological Hazards on a request from the Commission related to the microbiological risks in infant formulae and follow-on formulae. The EFSA Journal (2004) 113, 1-35

Department of Health Bottle Feeding leaflet, Crown copyright 2003 revised November 2005 (267816) www.dh.gov.uk/publications

Fifty-Eighth World Health Assembly, WHA58.32 Agenda item 13.11 Infant and young-child nutrition, 25 May 2005

Guidance on preparing infant formula
<http://www.food.gov.uk/news/newsarchive/2005/nov/infantformulastatementnov05>