

APPENDIX 2.0

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

Appendix 2.1 Documentation required for implementation of focus groups: Parents and Day Nursery Nurses

Day Nursery Nurse Recruitment Questionnaire

Parent Recruitment Questionnaire

Parent and Day Nursery Nurse / Manager Information Sheet and Consent form

Invitation to Parent Focus Group

Invitation to Day Nursery Focus Group

Day Nursery Nurse Focus Group Discussion Guide

Parent Focus Group Discussion Guide

Appendix 2.2 Documentation required for implementation of focus groups: NHS Professionals (Health Visitors, Hospital Nurses, Hospital and Community Midwives

Flow chart indicating stages of obtaining NHS Ethical approval from MREC and local NHS Trust approval for FSA study.

MREC Approved Research Protocol

MREC Approval letter: Main Study

MREC Approval letter: Amendment 1 – Inclusion of Midwives in the study

Call to Action Letters – NHS department Managers


Call to Action – NHS healthcare professionals information sheet and invitation to participate in the study

Approved Recruitment Questionnaire: NHS Professionals [e.g. Health Visitor]

Approved Participant Information Sheet / Written Guidance: NHS Professionals

Approved focus group Discussion Guide: Health Care Professionals

Appendix 2.1 Documentation required for implementation of focus groups: Parents and Day Nursery Nurses

 <p>BEAUFORT RESEARCH 2 Museum Place, Cardiff, CF10 3BG</p>	<p>INFANT POWDERED FORMULA RECRUITMENT QUESTIONNAIRE PARENTS FINAL 2007 BQ2734</p>	FOR OFFICE USE ONLY
		<p>APPROACH PEOPLE AGED 18+</p>
<p>Hello, my name is of Beaufort Research. We are carrying out some research undertaken by U.W.I.C – the University of Wales Institute Cardiff – on behalf of the Food Standards Agency into feeding babies under 6 months old and would like your opinions. Could you spare just a few minutes to answer some questions? REASSURE IF NECESSARY: BEAUFORT RESEARCH IS AN INDEPENDENT CONSULTANCY & WE ARE NOT SELLING ANYTHING</p>		
<p>SHOW CARD 1</p>		
<p>Q.1 Have you or any member of your family ever been involved with or worked in the following areas?</p>	<p>Marketing 1 Market Research 2 Journalism 3 Broadcasting 4 Medical Profession 5 PR / Advertising 6 Government 7 Manufacturer or retailer of baby food / Milk / Formula 8</p>	<p>IF ANY CLOSE</p>
<p>Q.2 How old are you?</p>	<p>17 or under 18 – 30 31 - 45 46 or over</p>	<p>1 → CLOSE 2 → CONTINUE 3 → CONTINUE 4 → CLOSE</p>
<p>Q.3 How old is your baby?</p>	<p>0 – 3 months 4 – 6 months 7 months +</p>	<p>1 → CHECK QUOTAS & CONTINUE 2 → CHECK QUOTAS & CONTINUE 3 → CLOSE</p>

1

<p>Q.4 Do you have any other children?</p> <p>Yes No</p>	<p>1 → CHECK QUOTAS & CONTINUE 2 → CHECK QUOTAS & CONTINUE</p>
<p>SHOWCARD 2</p>	
<p>Q.5 How do you currently feed your baby?</p> <p>Breast Feeding Only Mix of powdered formula & breast milk Powdered Formula only</p>	<p>1 → CLOSE 2 → GO TO Q.6 3 → GO TO Q.7</p>
<p>Q.6 You say that you currently sometimes use powdered formula milk to feed your baby. Can you please tell me approximately how often you use powdered formula?</p> <p>At least once a day OTHER</p>	<p>1 → CONTINUE 2 → THANK & CLOSE</p>
<p>SHOWCARD 3</p>	
<p>Q.7 How often do you prepare powdered infant formula for your baby?</p> <p>All feeds At least once every day A few times a week Rarely / Never</p>	<p>1 → CONTINUE 2 → CONTINUE 3 → CLOSE 4 → CLOSE</p>
<p>Q.8 How involved are you in the sterilizing and preparation of bottles used for feeding formula?</p> <p>Very involved Shared involvement Little / No involvement</p>	<p>1 → CONTINUE 2 → CONTINUE 3 → CLOSE</p>
<p>Q.9 How long have you been using powdered formula feeds</p> <p>From birth In the last few weeks 2 - 3 months 3 - 4 months 5 - 6 months</p>	<p>1 → 2 → 3 → 4 → 5 →</p> <p>AIM FOR SPREAD & CONTINUE</p>

2

<p>SHOWCARD 4</p>	
<p>Q.10 Which of the following most closely describes how you decided to use powdered formula feeding?</p> <p>I/we had always planned to bottle feed exclusively I/we had always planned to do mixed feeding I/we had always planned to breast feed but now use/also use powdered formula</p>	<p>1 → PLANNED - CHECK QUOTAS & CONTINUE TO Q.12 2 → PLANNED - CHECK QUOTAS & CONTINUE TO Q.12 3 → UNPLANNED - ASK Q.13</p>
<p>SHOWCARD 5</p>	
<p>Q.11 You say that you had planned on breast-feeding. Could you tell me what prompted you to also use powdered formula or switch completely to powdered formula feeding?</p> <p>The baby was premature/low birth weight/another medical condition/immuno compromised and was unable to feed properly initially The baby did not take to breast feeding I was uncomfortable with breast feeding I wanted more freedom We wanted the father to get more involved in feeding I could not provide enough milk Other</p>	<p>1 → CLOSE. 2 3 4 5 6 7</p> <p>AIM FOR SPREAD & CONTINUE</p>
<p>Q.12 OCCUPATION OF CHIEF INCOME EARNER IN THE HOUSEHOLD</p>	
<p>Job Title: _____ ABC1</p> <p>Position/ Rank/Grade: _____ C2DE</p>	<p>1 → CHECK QUOTAS 2 → CHECK QUOTAS</p>
<p>Q.13 Have you ever been to a focus group before?</p> <p>Yes- within last 6 months Yes- longer ago No, never</p>	<p>→ ASK Q.15 → RECRUIT → RECRUIT</p>
<p>Q.14 What was the subject of the focus group discussion?</p> <p>_____</p>	<p>→ IF RELATED TO INFANT FEEDING / FORMULA, THANK & CLOSE. OTHERS CONTINUE</p>

3

<p>IF SUCCESSFULLY SCREENED INVITE RESPONDENT TO FOCUS GROUP: We are holding a focus group to discuss different aspects of feeding babies under 6 months old with powdered infant formula, and would like to invite you personally to attend. (READ OUT DATE) EXPLAIN FOCUS GROUP</p> <ul style="list-style-type: none"> • Informal, relaxed discussion • £30 "Thank-you" for attending • Will last about hour and a half <p>IF RESPONDENT WILLING TO ATTEND GROUP, HAND OUT INVITATION WITH RELEVANT DATE & TIME OF GROUP, THEN RECORD DETAILS BELOW</p>	
<p>RESPONDENT DETAILS:</p> <p>Name: _____ Address: _____ Postcode: _____ Telephone Number: _____</p>	
<p>RESPONDENT INFORMED CONSENT</p> <ul style="list-style-type: none"> • I have received written guidance on the nature and subject of the focus groups and have agreed to participate in the study. • I understand that all information gathered from the study will remain confidential and any contribution I make in the focus groups will be treated with anonymity. • I understand that participation in this study is voluntary; refusal to participate will involve no penalty. I am able to withdraw consent and discontinue participation in this project without prejudice. <p>Signature: _____ Date: _____</p>	
<p>INTERVIEWER DECLARATION</p> <p>I declare that I have conducted this interview in accordance with your instructions.</p> <p>Signature: _____ Date: _____</p>	

4

SHOWCARD 1

Marketing
Market Research
Journalism
Broadcasting
Medical Profession
PR / Advertising
Government
Manufacturer or retailer of baby
food / Milk / Formula

5

SHOWCARD 2

Breast Feeding Only
Mix of powdered formula
& breast milk
Powdered Formula only

6

SHOWCARD 3

All feeds
At least once every day
A few times a week
Rarely / Never

7

SHOWCARD 4

I / we had always planned
to bottle feed exclusively
I / we had always planned
to breast feed but now
use/also use powdered
formula
I / we had always planned
to do mixed feeding

8

SHOWCARD 5

The baby was premature/low
birth weight/another medical
condition/immuno compromised
and was unable to feed properly
initially
The baby did not take to breast
feeding
I was uncomfortable with breast
feeding
I wanted more freedom
We wanted the father to get
more involved in feeding
I could not provide enough milk

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**INFANT POWDERED FORMULA
RECRUITMENT QUESTIONNAIRE
DAY NURSERY NURSES
FINAL
AUGUST 2007
BQ2734**

FOR OFFICE USE ONLY

APPROACH PEOPLE AGED 18+

Hello, my name is of Beaufort Research. We are carrying out some research undertaken by U.W.I.C – the University of Wales Institute Cardiff – on behalf of the Food Standards Agency into feeding babies under 6 months old and would like your opinions. Could you spare just a few minutes to answer some questions?

REASSURE IF NECESSARY: BEAUFORT RESEARCH IS AN INDEPENDENT CONSULTANCY & WE ARE NOT SELLING ANYTHING

Q.1	Are you a professionally trained nursery nurse? Yes No	1 → CONTINUE 2 → CLOSE
Q.2	What ages of babies do you work with nowadays? 0 – 6 months 6 – 12 months 12+ months	1 → CONTINUE 2 → CLOSE 3 → CLOSE
Q.3	Do you sometimes prepare powdered infant formula in the nursery? Yes No	1 → CHECK QUOTAS & CONTINUE 2 → CHECK QUOTAS & CONTINUE
Q.4	Have you ever been to a focus group before? Yes- within last 6 months Yes- longer ago No, never	→ ASK Q.5 → RECRUIT → RECRUIT
Q.5	What was the subject of the focus group discussion? _____	→ IF RELATED TO INFANT FEEDING / FORMULA, THANK & CLOSE. OTHERS CONTINUE

IF SUCCESSFULLY SCREENED INVITE RESPONDENT TO FOCUS GROUP:

We are holding a focus group to discuss different aspects of feeding babies under 6 months old with powdered infant formula and would like to invite you personally to attend. (READ OUT DATE)

EXPLAIN FOCUS GROUP

- Informal, relaxed discussion
- £40 "Thank-you" for attending

Will last about hour and a half

IF RESPONDENT WILLING TO ATTEND GROUP, HAND OUT INVITATION WITH RELEVANT DATE & TIME OF GROUP, THEN RECORD DETAILS BELOW

RESPONDENT DETAILS:

Name: _____

Address: _____

Postcode: _____

Telephone Number: _____

INTERVIEWER DECLARATION

I declare that I have conducted this interview in accordance with your instructions.

Signature: _____

Date: _____

ASK RESPONDENTS: Are you willing for us to pass on your details to UWIC so that they may contact you to take part in further research next year? The research will take the form of a self-completion which will be posted to you.

Yes, I am willing for my details to be passed on to UWIC

No, I am not willing for my details to be passed on to UWIC

Focus Group Invitation from.....



2 Museum Place, Cardiff, CF10 3BG
Tel: 029 2037 8565 Fax 029 2037 0600



PLEASE BRING THIS INVITATION WITH YOU.

Dear Sir/Madam
Thank you for agreeing to attend our Group Discussion. This Invitation is for you personally – please do not pass it on to anyone else.

The discussion will be held at:

Place: _____

Time: _____ Date: _____

You will receive _____ £30 _____ to cover your expenses
for attending the group discussion

If for any reason you cannot attend, kindly contact _____
telephone number _____ as soon as possible.

You have been asked to come along to talk with us because we are interested in your opinion as a [*Parent*]. We look forward to meeting you and may we assure you that in no way will you be asked to purchase anything. To help in the analysis of your views, the group will be recorded. The group will last 1 & a half hours.

Yours sincerely,

Lisa Williams
Version 1 (01/10/2007)

Focus Group Invitation from.....



2 Museum Place, Cardiff, CF10 3BG
Tel: 029 2037 8565 Fax 029 2037 0600

PLEASE BRING THIS INVITATION WITH YOU.

Dear Sir/Madam
Thank you for agreeing to attend our Group Discussion. This Invitation is for you personally – please do not pass it on to anyone else.

The discussion will be held at:

Place: _____

Time: _____ Date: _____

You will receive _____ £40 _____ to cover your expenses
for attending the group discussion

If for any reason you cannot attend, kindly contact _____
telephone number _____ as soon as possible.

You have been asked to come along to talk with us because we are interested in your opinion as a [*Day Nursery Nurse*]. We look forward to meeting you and may we assure you that in no way will you be asked to purchase anything. To help in the analysis of your views, the group will be recorded. The group will last one & half hours hours.

Yours sincerely,

Lisa Williams
Version 1 (01/10/2007)

FSA RESEARCH: POWDERED FORMULA MILK

MAIN STUDY Focus Group Discussion Guide: Day Nursery Nurses

1. INTRODUCTIONS (~5mins)

- Moderator to introduce self, explain the process of market research to respondents and the format of the discussion, reiterate the need for honesty to help with the research and reassure confidentiality.
- The topic of this discussion involves your role as nursery nurses looking after and feeding babies aged **0-6 months** in day nurseries. In particular, we are interested in what they think about feeding babies with **powdered formula milk** and related matters. (*need to*)
- Important to explain that the Food Standards Agency is not promoting bottle feeding, however it is keen to understand about aspects of preparation, feeding and storage of made up formula milks.
- Introductions: brief background details of respondents – first name, job title, name of nursery, length of time in job

2. ROLES, RESPONSIBILITIES & GENERAL NURSERY PRACTICES (~10 mins)

- How many babies aged **<6months** do you have in your nursery? (*go round table & ask all participants*)
- Ages of babies (<6months) in their care? (*in weeks or months*)
- Usually how long per day are such babies in their care?
Usually how many feeds per baby, per day.
- How many members of staff (*in total*) look after all the babies aged <6 months?
- How is the care and feeding organised – is it one nursery nurse responsible for one baby or could it be whoever is available when necessary?
- Just thinking about the babies aged <6months, what happens about formula feeding in your nursery – do you make it up in the nursery or do parents bring it to the nursery already made up? Or something else?
- Do the parents have a choice as to whether your nursery makes the formula up for their baby or whether they bring reconstituted formula in ready to feed?
Do you have a standard policy in your nursery re such issues?
- In your nursery, are there any codes of practice or official standard procedures that you have to adhere to when:
 - a) preparing powdered formula milk in the nursery
 - b) storing reconstituted (*made up*) formula in the nursery
 - c) sterilising bottles and utensils?
- If there are codes of practice etc, are they specific to your nursery or nationwide standards? **PROBE**
Find out what they are and details + what they think about them.

3a. SELF-REPORTED PRACTICES & ATTITUDES: PREPARATION & STORAGE (~25mins)

This section intends to determine reported accounts of how powdered formula milk is prepared and stored in day nurseries. Information detailing who is responsible for making feeds, where and when feeds are made up, the length of time powdered formula is made up before feeding and general organisation of preparation and storage will be determined.

Discuss different scenarios (re Showcard 1 section 2):

Only thinking about **making up feeds** from powdered formula milk in the nursery:

- Do you provide all of the **bottles and teats** etc for feeding babies in your nursery? Or do parents provide such items?
PROBE: investigate opinions / issues faced / preference re both options (talk about cleaning and sterilising in the next section)
- Do you provide the powdered formula for all feeds? (**PROBE:** are parents asked to bring in tins of formula that they use)
 - Once **tins of powdered formula** are opened in the nursery is the length of time they are opened monitored at all? (**PROBE** e.g. date of opening written on the lid of the formula tin)
 - Does your nursery have any policy re the length of time opened tins of formula are kept? (*If YES PROBE for details*)
 - In your nursery, how long can the tins of powdered formula be open for? Are they ever thrown away? After what period of time?
- **Who** is responsible for making the feeds up in your nursery?
 - Is it the same person every day – have they had any special / extra training to do so?
 - Or is it whoever is available at the time? (*confirm the respondents in the group do make up feeds*)
- **Where** are the feeds made up? (*Designated nursery kitchen?*)
Approximate size of kitchen? and available work surface space? Is it big enough?
Is the kitchen only ever used for formula preparation? If not, what else is kitchen used for? (**PROBE:** or food preparation for other children or staff – ever include raw chicken/meat or eggs, washing up etc)
What is in the kitchen? (**PROBE** – sink? Fridge? Freezer? microwave? Kettle? Cooker? Hob?)

- **Fridge:** Is there a fridge in the kitchen?
 - Whereabouts in the fridge are the bottles of made up formula stored?
 - Is the temperature of the fridge monitored?
 - How is the temperature measured? (*determine type of thermometer*) Is ever checked to see if its working properly?
 - Is the temperature ever written down and recorded?
 - Do you think recording such information is necessary?
 - (*IF TEMP NOT RECORDED...*) Would it be possible (e.g. every day)? Foresee any problems if you were asked to do this is in your nursery?
 - Do you know the temperature of the fridge in your nursery?
 - Do you know what temperature it should be?
 - Is the fridge only used for storing formulas (**PROBE:** *or e.g. other foods for older children / staff lunches / coffee milk etc*)? *If YES* – do you think this is ok?
 - How often is the fridge opened and closed throughout the day? (*all the time, once or twice etc*)
 - Is the fridge ever cleaned? (If YES) How is it cleaned? How often? Whose responsibility is it? What determines when it is cleaned?
- **When** are the feeds made up in your nursery? (**PROBE** separately or all at once; if all at once, what time of the day? in the morning – or make up immediately before required feeding?)
- **How many** bottles of formula are usually made up at one time?

We would like to talk through the **process** of how bottles of powdered formula milk are made up in your nursery *open question, and then probe the following:*

- Do you ever **clean** the work surface before you start making the formula up?
 - *If YES* – exactly how surface is cleaned – use what cleaning agents? Use of a cloth? (*if use of cloth ask if it's a new cloth or previously used*).
 - Ask if the described practice is done every single time. Ever times when this is not done? Why
 - *If NO* – why not? What stops them? How important do they think it is?
 - How can they tell when a work surface is 'clean'.
 - Is the cleanliness of the surface ever tested?
- Do you ever **wash and dry your hands** before making the formula up?
 - Do you think it's important to do this before preparing a feed? Why?
Use show cards to determine reported practice (SHOWCARDS 2-5).
 - Is this how you wash your hands before preparing a feed – sometimes – always?
Which of the descriptions you do think should be done –achievable all the time?

For the next bit go round the table to ask each participant / for each nursery

- Do you **make up all feeds** for babies aged <6months with water boiled in a kettle? (why?)
 - Is all of the water used always fresh from the tap? (why?)
 - After the water has boiled, what happens? (leave in the kettle or poured straight into the bottles?)
 - **How long** is it before you mix the boiled water with the powder?
 - How is this time before use judged? Is it ever timed?
 - Is the boiled water always poured into bottle first (i.e. before addition of powder?)
- Are all of the **utensils** (*e.g. measuring scoop / knife to level top*) used to measure powdered formula into bottles always sterilised? *If NO*, why not? *If YES:* find out sterilisation method used.
- When placing the teat and screw cap onto the bottle which part of the teat do you handle (*get participants to demonstrate using whole bottles*)
- Once powder has been added to the boiled water is it still too hot to feed to a baby? *Y/N*
 - How is the reconstituted formula **cooled** for immediate feeding? How often does this happen?
 - If reconstituted formula is prepared for later use where is it stored?
if response = fridge - How is the reconstituted formula cooled before storage in the fridge? (provide max & min times).
If placed in the fridge how long is it likely to be stored in the fridge for later feeding? (max & min times) How often does this happen?
if response = room temperature / on work surface etc – How long for? (provide max and min times)
- **Labelling:** How do you know which bottle / reconstituted feeds are for which baby? (**PROBE** *find out what labelling system is used – exactly what is written on the label every time a bottle is made up. Is it a new label for every new made up bottle???*)
- Do you have any **concerns** about making powdered formula feeds up in the nursery? If so what?
What about concerns about making feeds up for use throughout the day? If so what?

Only thinking about when parents bring made-up powdered formula milk into the nursery:

(determine responses for each nursery)

- Do parents ever bring formula milk to your nursery that they have made up at home for use during the rest of the day?

IF NO, GO TO SECTION 3B, IF YES, CONTINUE

- How often does this happen (**PROBE** on a daily basis? – determine relative frequency...)
- If made up formula is brought to the nursery, how are the bottles usually brought to the nursery? (**PROBE** e.g. in a carrier bag, rucksack, handbag, in cool bag, thermal bag, other?)
- When the feeds arrive at the nursery are they usually very warm (having recently been made up)? or cold (already been refrigerated)?, or just room temperature? Varies??
- How are the made up feeds stored in the nursery before use? (*probably responses will be in the fridge*)
- Are all bottles given to the nursery placed in the fridge immediately? (*probably response will be yes*)
 - What about feeds that are still very warm?
 - Are there ever circumstances when you might be really busy with lots of children and babies arriving at once and bottles might not reach the fridge immediately?
 - What would you estimate is the maximum length of time a prepared feed might be left out of the fridge for?
- How many bottles are usually brought in and stored in the nursery each day?
- What do you think about parents making powdered formula feeds up for use throughout the day in the nursery? Any concerns?

(FOR ALL PARTICIPANTS)

- Do you ever take made up powdered formula milk outside of the nursery e.g. if taking the baby for a walk?
 - Determine how the made up feed is stored and for approximately what length of time.
- Do you ever have to heat made-up feeds up before feeding? (*i.e. if been in the fridge*)
 - How do you do this? How long does it take to warm a bottle to the right temperature if its been in the fridge?
- Do babies sometimes prefer / have feeds that are at room temperature?
 - Do parents ever request this?
 - Are these feeds left out on the surface to get to the right temperature? For how long?

4. POWDERED FORMULA MILK (~15mins)

The aim of this section is to determine attitudes of day nursery nurses towards general and specific microbiological risks associated with stages of preparation, use and storage of powdered formula milk.

- Do you have any **concerns** about feeding babies aged <6months with powdered formula milk in your nursery? WHAT CONCERNS? WHY etc. (*concerns may be nutrition orientated – need to probe re concerns re safety and hygiene*)
- Do you think that powdered formula milk is a **sterile** product? (**PROBE WHY** to responses) (*if non-sterile product find out WHY they think so & implications of it being not sterile*)
- What do you consider the **most important actions** are to ensure that made up powdered formula milk is safe to feed? (*open question*)

Obtain an understanding of microbiological hazards associated with feeding babies aged <6months with powdered formula milk.

- Do you think there are there **microbiological hazards** associated with feeding babies aged <6months with powdered formula milk? Give examples of such hazards.
- Do you think it is safe to make up powdered formula milk **in advance** of use? **PROBE extensively why to yes or no responses**
 - How long in advance do you consider it to be safe?
 - If formula is prepared in advance do you think there any storage requirements necessary? If so what?
- Have you ever heard of *Enterobacter sakazakii* (*SHOWCARD 8*)
 - what do they know about it? Where from?
- Are you aware of any other bacterial hazards associated with powdered formula milk? – what do they know about it? Where from? What about Salmonella?

Determine understanding of risks of microbial cross contamination from unclean hands or unclean surfaces / utensils during preparation of powdered formula milk.

- Are you aware of **cross contamination** issues during preparation of a powdered formula feed?
 - If YES:* give examples. (*if not mentioned, PROBE unwashed hands and unclean surfaces / utensils*)
 - If NO:* show *SHOWCARD 9*: cross contamination is transferring bacteria from one surface to another (*then PROBE unwashed / unclean hands and unclean surfaces / utensils*)
- What difficulties do you think parents have when feeding babies **away** from the home (*obtain separate responses for the following examples PROBE e.g. shopping trip / holiday*)?
 - If a baby is fed away from the home do you think it is better to make the feed up at home before leaving or make up on the spot when required? **PROBE** Why?

5. TRAINING / INFORMATION SOURCES (~5mins)

This section aims to establish whether nursery nurses working in day nurseries are educated specifically about the microbiological risks associated with preparation and storage of powdered infant formula, as well as cleaning and sterilisation of bottles used for feeding with powdered infant formula. Ascertain source of education.

- Have you ever been formally educated about the microbiological risks of preparation and storage of powdered formula milk?
Cleaning and disinfection of bottles and components?
Expand on when, where, taught what – theory? practice?
Formal training? On the job training?
Information from colleagues?
- What did they teach you about preparation and feeding with formula in college?
- Do you ever receive / attend training updates – structured / unstructured? Frequency etc.
- Has anyone ever been on a hygiene course?
- Do you ever formally or informally talk to parents about safe methods of preparation, use or storage of powdered formula milk or cleaning and sterilisation methods? Do they ever ask your advice?
- Do you ever tell parents about microbiological risks associated with feeding powdered formula milk?
- Do you think it is part of your role as a nursery nurse to tell parents about safe preparation and feeding methods?

5. INFORMATION SOURCES (~15mins)

- Are you given any advice / information about using powdered formula milk in your nursery?
 - *IF YES*, where from? (*any official sources?*)
 - Is information and advice updated?
 - Frequency of updates?
 - *IF NO*, would you like information? Why?
 - Do you feel that information SHOULD BE available to you or other people like you working in nurseries?
 - Do you think the information is NEEDED?

Trust of sources of bottle feeding information (SHOWCARD 10)

- Which sources would you **most trust** as providers of credible information for yourselves and people like you WORKING IN DAY NURSERIES with young babies? **Least trust? WHY?**
- What sources do you think should provide bottle feeding information to nursery nurses like yourselves? Why?
- Have you ever contacted / asked any of these sources for bottle feeding advice in the past? Which? Why?
- Which if any would you contact in future? Why?

- What do you think about using the INTERNET as a source for formula feeding information?
- Have you ever searched for any information about formula feeding on the internet before?

IF YES: What information did you look for? What made you think about looking for it? Did you find anything of use? What? (*if possible determine sources*)

IF NO: Is it something you have ever thought of doing in the past? Might think about doing in the future?

- Are you aware of any changes to recommendations re preparation / storage of powdered formula milk in recent years?

IF YES: Do you know why such changes have made?

Are they achievable in your nursery?

Good or bad thing? why?

Have these changes in the recommendations caused any changes in practices in your nursery? What?

IF NO – see next question

SHOWCARD 11 – GIVE ALL PARTICIPANTS THE FSA GUIDELINES – get them to have a look

- Anyone ever seen these recommendations before? When? Where from etc?

Go through the following key points and ascertain whether nursery nurses agree with components of the recommendations – are they achievable in the nursery or not and why.

- KEY POINTS:
 - a. It is best to make up formula 'fresh for each feed' / make one feed at a time – Is this possible in your nursery? Why is it necessary? What do you think about it?
 - b. Use boiled water to cool to no less than 70°C – Is this possible in your nursery? Why is it necessary? What do you think about it?
 - c. Discard any feed that has not been used within 2 hours. – Is this possible in your nursery? Why is it necessary? What do you think about it?
- How achievable do you consider these recommendations to be in your nursery?
- Any other comments about the recommendations?

- Have you ever seen any formula guidelines such as shown on **SHOWCARD 12** (show at the same time – as WHO booklets) from the World Health Organisation? When? Where from?
- Would you like to have this information available in your nursery?

FSA RESEARCH: POWDERED FORMULA MILK
Main Study Focus Group Discussion Guide: Parents

1. INTRODUCTIONS (~5mins)

- Moderator to introduce self, explain the process of market research to respondents and the format of the discussion, reiterate the need for honesty to help with the research and reassure confidentiality.
- Explain topic of discussion is parental experience of feeding babies of 0-6 months and in particular what they know and how they use **powdered formula milk**.
- Introductions: brief background details of respondents – first name, name and age of baby, family composition –first/subsequent children, length of time using powdered formula milk.

2. WARM UP (~<5 mins)

Powdered formula milk..... word association exercise –

- What comes in to your mind when you think of powdered formula milk?
- What feelings and emotions come to mind?

3a. SRP & ATTITUDES: PREPARATION & STORAGE (<25mins)

This section intends to determine self reported practices (SRP) and accounts of how powdered formula milk is prepared and stored inside and outside of the home. Information detailing who is responsible for making feeds, where and when feeds are made up, the length of time powdered formula is made up before feeding and general organisation of preparation and storage will be determined.

- Usually how many powdered formula feeds (i.e. made up bottles) does your baby have within 24 hours? How many in the day? How many in the night? (*go round the table to ask each participant*)
- In your household **who is responsible** for: preparing the formula? (*confirm they prep formula & bottles*) cleaning and sterilising bottles?
- **Where** are the feeds made up? (*presumably in the kitchen? aim is to determine that the same work surfaces where formula is made up is also used for preparation of other foods such as raw meat and chicken etc*)
- Is formula made up in the same area / same work surface where you or anyone else prepares foods for yourself /family?

We'll talk about how you make the feeds up in a few minutes, but first of all can you tell me: (*go round the table to ask each participant*)

- When you make formula up (*i.e. add the powder & the water together*), is it for **individual feeds** or for **the whole day**? What about for **night** feeds?
- **How many bottles** are made up at a time?

3a. SELF-REPORTED PRACTICES & ATTITUDES: PREPARATION & STORAGE (~25mins)

This section intends to determine reported accounts of how powdered formula milk is prepared and stored in day nurseries. Information detailing who is responsible for making feeds, where and when feeds are made up, the length of time powdered formula is made up before feeding and general organisation of preparation and storage will be determined.

Discuss different scenarios (re Showcard 1 section 2):

Only thinking about making up feeds from powdered formula milk in the nursery:

- Do you provide all of the **bottles and teats** etc for feeding babies in your nursery? Or do parents provide such items?
PROBE: investigate opinions / issues faced / preference re both options (talk about cleaning and sterilising in the next section)
- Do you provide the powdered formula for all feeds? (**PROBE:** are parents asked to bring in tins of formula that they use)
 - Once **tins of powdered formula** are opened in the nursery is the length of time they are opened monitored at all? (**PROBE** e.g. date of opening written on the lid of the formula tin)
 - Does your nursery have any policy re the length of time opened tins of formula are kept? (*If YES PROBE for details*)
 - In your nursery, how long can the tins of powdered formula be open for? Are they ever thrown away? After what period of time?
- **Who** is responsible for making the feeds up in your nursery?
 - Is it the same person every day – have they had any special / extra training to do so?
 - Or is it whoever is available at the time? (*confirm the respondents in the group do make up feeds*)
- **Where** are the feeds made up? (*Designated nursery kitchen?*)
Approximate size of kitchen? and available work surface space? Is it big enough?
Is the kitchen only ever used for formula preparation? If not, what else is kitchen used for? (**PROBE:** or food preparation for other children or staff – ever include raw chicken/meat or eggs, washing up etc)
What is in the kitchen? (**PROBE** – sink? Fridge? Freezer? microwave? Kettle? Cooker? Hob?)

- **Fridge:** Is there a fridge in the kitchen?
 - Whereabouts in the fridge are the bottles of made up formula stored?
 - Is the temperature of the fridge monitored?
 - How is the temperature measured? (*determine type of thermometer*) Is ever checked to see if its working properly?
 - Is the temperature ever written down and recorded?
 - Do you think recording such information is necessary?
 - (*IF TEMP NOT RECORDED...*) Would it be possible (e.g. every day)? Foresee any problems if you were asked to do this in your nursery?
 - Do you know the temperature of the fridge in your nursery?
 - Do you know what temperature it should be?
 - Is the fridge only used for storing formulas (**PROBE**; or e.g. other foods for older children / staff lunches / coffee milk etc)? *If YES* – do you think this is ok?
 - How often is the fridge opened and closed throughout the day? (*all the time, once or twice etc*)
 - Is the fridge ever cleaned? (If YES) How is it cleaned? How often? Whose responsibility is it? What determines when it is cleaned?
- **When** are the feeds made up in your nursery? (**PROBE** separately or all at once; if all at once, what time of the day? in the morning – or make up immediately before required feeding?)
- **How many** bottles of formula are usually made up at one time?

We would like to talk through the **process** of how bottles of powdered formula milk are made up in your nursery open question, and then probe the following:

- Do you ever **clean** the work surface before you start making the formula up?
 - *If YES* – exactly how surface is cleaned – use what cleaning agents? Use of a cloth? (*if use of cloth ask if it's a new cloth or previously used*).
 - Ask if the described practice is done every single time. Ever times when this is not done? Why
 - *If NO* – why not? What stops them? How important do they think it is?
 - How can they tell when a work surface is 'clean'.
 - Is the cleanliness of the surface ever tested?
- Do you ever **wash and dry your hands** before making the formula up?
 - Do you think it's important to do this before preparing a feed? Why?
 - Use show cards to determine reported practice (SHOWCARDS 2-5),*
 - Is this how you wash your hands before preparing a feed – sometimes – always?
 - Which of the descriptions you do think should be done – achievable all the time?*

4. POWDERED FORMULA MILK (~15mins)

The aim of this section is to determine attitudes of parents towards general and specific microbiological hazards associated with stages of preparation, use and storage of powdered formula milk.

- Do you have any **concerns** about feeding babies aged <6months with powdered formula milk? What, why etc. (*concerns may be nutrition orientated – need to probe re concerns re safety and hygiene*)

Determine awareness amongst parents that powdered formula milk is a non-sterile product.

- Do you think that powdered formula milk is a **sterile** product? (**PROBE WHY** to responses) (*if non-sterile product find out WHY they think so & implications of it being not sterile*)
- What do you consider the **most important actions** are to ensure that reconstituted powdered formula milk is safe to feed? (*open question*)

Determine understanding of risks of microbial cross contamination from unclean hands or unclean surfaces / utensils during preparation of powdered formula milk.

Are you aware of **cross contamination** issues during preparation of a powdered formula feed?

If YES: give examples. (*if not mentioned, PROBE unwashed hands and unclean surfaces / utensils*)

If NO: show **SHOWCARD 8**: cross contamination is transferring bacteria from one surface to another (*then PROBE unwashed / unclean hands and unclean surfaces / utensils*)

Obtain an understanding of microbiological hazards associated with feeding babies aged <6months with powdered formula milk.

- Do you think there are there **microbiological hazards** associated with feeding babies aged <6months with powdered formula milk? Give examples of such hazards.
- Have you ever heard of **Enterobacter sakazakii** (**SHOWCARD 7**)
 - what do they know about it? Where from?
- Are you aware of any other bacterial hazards associated with powdered formula milk? – what do they know about it? Where from?

5. INFORMATION SOURCES + EVALUATION (~25mins)

- **Where does your knowledge** about feeding your baby come from – **where do you get information** and advice about feeding your baby? (*open question re all sources, then specifically probe SHOWCARDS 9-13 – do all showcards at once (place on the table)*)

Showcard 9: Health care professionals = GPs, midwives (which ones community/hospital?), health visitors?

Showcard 10: Books, magazines, booklets, leaflets, internet, posters – what?

- How likely are you to access information re bottle feeding from the internet?
- Ever use internet forums? What do you think of the info from the forums? Trust it? Accurate?

Showcard 11: Family and friends? who?

Showcard 12: Organisations, clubs, groups – which?

Showcard 13: On pack information, product labels / leaflets which?

- What is your preferred source of information? (*could be combination?*)

Information sources & what you've been told about feeding at different stages of pregnancy / after birth of baby (SHOWCARDS 14-16). Use each showcard to focus discussion re each stage.

- **Before your baby was born**

- Did you want / feel that you needed information about feeding with powdered infant formula before your baby was born?
- Who provided you with the information?
- What did they tell you?
- Did you feel you'd been given enough information?

- **In hospital**

- At this stage what information did you want / feel that you needed about feeding with formula?
- Who provided you with the information?
- What did they tell you?
- Did you feel you'd been given enough information?

- **Once you and your baby have left hospital & are at home**

- At this stage what information did you want / feel that you needed about feeding with formula?
- Who provided you with the information?
- What did they tell you?
- Did you feel you'd been given enough information?

- Overall, do you feel that you have been given **enough information** and advice about feeding your baby with powdered formula? Would you like to have been given more advice? from whom? when?

- Has a health professional (e.g. health visitor, midwife or nurse) ever **shown** you how to prepare formula safely? or how to sterilise bottles etc?

If YES – PROBE WHO?

WHERE (in hospital, clinic in home)?

WHEN (at what stage of babyhood?)

GROUP? ONE TO ONE?

If NO – would you like someone to have demonstrated 'best practice' to you? Who and why? What stage?

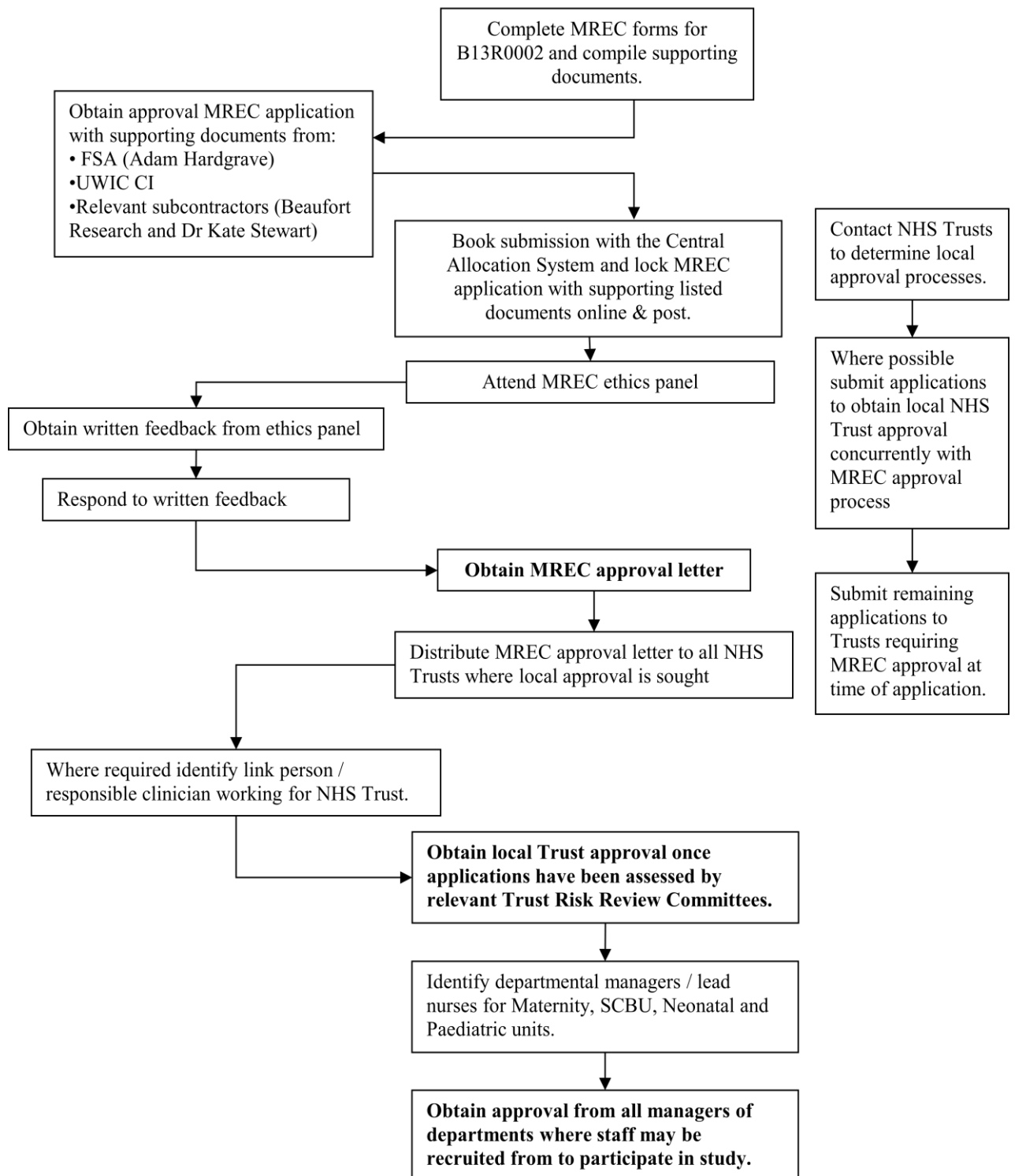
- What do you think new Mums should be told about safe preparation of formula and sterilising? When should they be told this? By whom?

- Have you ever seen any formula guidelines such as from the UK Food Standards Agency, NHS or World Health Organisation?

- Would you like to have been given this information? At what stage?

Appendix 2.2.Documentation required for implementation of focus groups: NHS Professionals (Health Visitors, Hospital Nurses, Hospital and Community Midwives).

Flow chart indicating stages of obtaining NHS Ethical approval from MREC and local NHS Trust approval for FSA Study B13R0002



MREC Approved Research Protocol



RESEARCH PROTOCOL



TITLE OF RESEARCH PROJECT

An Investigation into the Attitudes and Behaviours of Consumers and Caregivers in the Preparation, Handling, Storage and Feeding of Powdered Infant Formula Inside and Outside the Home

BACKGROUND

Reconstituted powdered infant formulas are considered to be a food class of high risk because of the susceptibility of the infant population to enteric bacterial pathogens, severe response to enterotoxins and increased mortality (Rowen and Anderson, 1998). Powdered milk formula is not a sterile product and provides an ideal growth medium for spoilage and pathogenic bacteria. In recent years there has been international concern about the risk of infection from *Salmonella* and *Enterobacter sakazakii* if such organisms are present in these powders. Although these infections are rare they can be severe (INFOSAN, 2005; Himehright *et al.* 2002) and the risk is considered to be greatest for pre terms, immuno compromised and low birth weight infants (Food and Agriculture Organisation / World Health Organisation, 2004). Prevention of infection by *Enterobacter sakazakii* and other organisms requires care in the production / manufacturing of the formula product as well as how it is re-constituted and subsequently handled prior to feeding. The European Food Standards Agency (2005) have indicated that the presence of such organisms in powdered milk formula constitutes a considerable risk if conditions after reconstitution permit multiplication. Organisms can grow in the reconstituted product if stored above 5°C for a sufficient time and multiply very rapidly at room temperature. It is considered that good hygiene practices at reconstitution, storage and feeding are essential to avoid recontamination and or multiplication of pathogens in reconstituted formula (INFOSAN, 2005; FAO/WHO, 2004). Relatively little is known about how parents or caregivers, manage the safety aspects of powdered infant formula preparation and storage. The proposed project seeks to address this lack of information and to inform the development of guidelines and informed, targeted risk communication materials for use in the home and in hospitals.

AIMS AND OBJECTIVES

Methods used to reconstitute and store powdered milk formula have important microbiological implications for the safety; this is of particular importance given that young infants who consume the reconstituted product may have increased susceptibility to infection. There is a need to reduce the risk and potential for infection that can be caused by implementation of malpractices during reconstitution and storage of powdered infant formula in the home and health care settings. This may be achieved by parents and caregivers being equipped with adequate and correct knowledge, positive attitudes and motivation to implement desired behaviours that can minimise microbial risks. Therefore there is a need to determine parent and caregiver behaviours as well as attitudes and perceptions towards current and recommended procedures. Furthermore, there is a need to determine sources of information about powdered infant formula as well as perceptions of sources in terms of trust, content, method and time of delivery of such advice. Cumulatively, this study will help to inform the development of informed, targeted information sources that address microbial risks of preparation and storage of powdered infant formula.

Aims and objectives relevant to the component of study involving NHS Health Visitors and Hospital Nurses.

Health visitors and hospital nurses are key health professionals that provide support to parents about appropriate feeding practices for new infants. Through a series of focus group discussions with such healthcare professionals this component of the study aims to:

- Understand beliefs, attitudes, practices and information provision relating to infant feeding with powdered milk formula.
- Determine information content and availability for health professionals and also for parents.
- Support and inform the development of a postal questionnaire which will aim to identify issues that health visitors and hospital nurses feel are important for safe preparation of powdered formula milk and effective communication.

METHODS FOR DATA COLLECTION

- Target population:

NHS Health Visitors and NHS Hospital Nurses from Special Care Baby Units (SCBU), maternity departments and paediatric departments.

- Methodology for Stage 1 of the study:

Qualitative focus group discussions with health visitors and hospital nurses will be conducted to explore attitudes and important procedures related to preparation and storage of powdered formula milk as well as identify and explore formula feeding information sources. Qualitative findings will be used to provide a rationale for the design and development of postal questionnaires.

A focus group is a group discussion on a given topic organised for research purposes. It is guided, monitored and recorded by a trained researcher. In this study focus groups will explore the roles and responsibilities of health visitors and nursery nurses as important information providers of information and advice at different 'baby stages'. Similarly, groups will be used to obtain an understanding of the preparation and storage practices hospital nurses implement while involved in the feeding process of babies while in hospital. In addition reasons why such practices are implemented will be discussed as well as attitudes towards current behaviours and recommended procedures.

- Methodology for Stage 2 of the study:

Postal questionnaires administered to health visitors and hospital nurses across the UK will explore attitudes towards specific procedures related to preparation and storage of powdered formula milk determined in stage 1 of the study.

A questionnaire is a data-gathering device that elicits information from respondents' answers or reactions to printed (pre-arranged) questions presented in a specific order; the postal questionnaire is a typical form of self-administered study. This standard method for data collection through the post involves the transmission of a questionnaire to a respondent, accompanied by a letter of explanation and a return envelope; the respondent completes the questionnaire and returns it to the researcher through the mail.

In this study postal questionnaires will be sent to health visitors and hospital nurses. Use of this research method will facilitate obtaining information from such care givers all across the UK at a relatively low cost.

- Sample:

A non-probability purposive sampling strategy will ensure the samples include an appropriate geographical spread according to the research population.

- *Stage 1 Focus groups:* 3 health visitor focus groups (each involving 8-10 participants) and 3 hospital nurse focus groups (each involving 8-10 participants) will be conducted private hotel function rooms in five geographical locations of the UK.
- *Stage 2 Postal questionnaires:* Administration of postal questionnaires to Health Visitors across the UK and questionnaires to Hospital Nurses in SCBUs, maternity departments and paediatric departments across the UK.

- Research participants

Stage 1: Focus group participants will be recruited by a trained field researcher from Beaufort Research Ltd, (Cardiff). All recruitment and fieldwork will be in accordance with BS7911 which is a widely recognised fieldwork standard IQCS (Interviewer Quality Control Scheme) which sets out best practice in this area.

- *Recruitment process for Health Visitors*
 - Clinics and GP surgeries will initially be telephoned to establish whether suitable persons may be available to participate in the study. Call to action invitations and information sheets will be distributed to managers to distribute to appropriate hospital staff.
 - Potential participants will be contacted directly to complete the recruitment questionnaire, obtain informed consent and be given an official invitation to the focus group from Beaufort Research and also be given written guidance about the study.
 - Completion of the recruitment questionnaire (5minutes) will take place at least 5 days before the focus group is undertaken.
 - No more than 2 health visitors will be recruited from an individual clinic / surgery.

- Recruitment process for Hospital Nurses
 - Persons managing *SCEUs*, maternity departments and Paediatric departments will initially be telephoned to establish whether suitable nurses in such departments may be available to participate in the study. Call to action invitations and information sheets will be distributed to managers to distribute to appropriate hospital staff.
 - Potential participants will be contacted directly to complete the recruitment questionnaire, obtain informed consent and be given an official invitation to the focus group from Besufort Research and also be given written guidance about the study.
 - Completion of the recruitment questionnaire (5 minutes) will take place at least 5 days before the focus group is undertaken.
 - No more than 1 nurse will be recruited from an individual department.
- All individuals who agree to participate in the study will be provided written guidance for participation and an official invitation from Besufort Research outlining contact details, date, time and venue for the focus group.
- Between 8-10 participants will be recruited for each focus group.
- Each group discussion which will follow a specified discussion guide is expected to last no longer than 90 minutes
- Focus groups will be held in private function rooms of local hotels and will be conducted outside of working hours

Stage 2: Gatekeeper contacts e.g. Department Managers in relevant institutions and departments will be identified and contacted to request participation in the study. Postal questionnaires will either be distributed to such gatekeepers to distribute questionnaires to relevant persons (i.e. nurses / health visitors) in their department / institution. Alternatively where specific participant names are made available, the postal questionnaire will be posted directly to the research participant. Each questionnaire will take ~15 minutes to complete. A prepaid envelope will be provided for the return of completed questionnaires.

-Analysis

- Stage 1: All focus group discussions will be digitally recorded, fully transcribed and analysed using appropriate software analysis software such as Nvivo 7.
- Stage 2: All postal questionnaire responses will be analysed using Microsoft Excel and SPSS. Descriptive statistics will be used to quantify overall findings.

DATA CONFIDENTIALITY

Stage 1: Focus groups

- All focus group participants will be provided with written guidance about participation in the study.
- All participants will be required to complete and sign a consent form at the time of recruitment. The consent form will specifically ask for permission for the discussion to be digitally recorded.
- All focus group discussion recordings will be anonymously transcribed for analysis purposes. Any quotations will be non identifiable to any research participants or specific institutions / departments.
- Contributions of individual members of the focus groups will be treated with confidentiality and the identity of participants will not be disclosed at any stage in the dissemination of the research.
- Data resulting from the focus group discussions such as digital audio files, documents or contact details will be stored in a secure place to guarantee anonymity of participants.
- There will be no deductive disclosure of quotations in any reporting of findings from this study.

Stage 2: Postal questionnaires

- Contact details of where postal questionnaires will have been administered to will be stored in paper form in a locked filing cabinet in a research office in UWIC.
- All responses to postal questionnaires will be anonymous.
- Returned questionnaires will be stored in a secure place.
- Questionnaire data will be reported at an aggregate level and there will be no deductive disclosure of data from individual sources / institutions / departments or Trusts.

CONTACT DETAILS:

Dr Elizabeth Redmond, Researcher, Food Research and Consultancy Unit, University of Wales Institute, Cardiff, CF52YB.
 Telephone: 02920 416452
 Email: eredmond@uwic.ac.uk

MREC Approval letter: Main Study

07/MRE09/73

Page 1

**Multi-Centre Research
Ethics Committee for
Wales**

**Chairman/Cardeirydd :
Dr Gordon Taylor**

**MREC
for
WALES**

**Pwyllgor
Ymchwil Ethegau
Aml-Ganolfan
yng Nghymru**

**Administrator/Gweinyddes:
Dr. Corinne Scott**

**Churchill House, Fourth Floor, 17 Churchill Way, Cardiff, CF10 2TW
Ty Churchill, 17 Ffordd Churchill, Caerdydd, CF10 2TW**

WHIS 0 1809

Telephone enquiries to: 02920 376 829

Fax No. 02920 376 824

**MREC website: <http://www.mrecspsa.nhs.uk>
e-mail: mrec@hsc.wales.nhs.uk**

**Professor Chris J Griffith
Head of Food Research and Consultancy Unit, UWIC
University of Wales Institute, Cardiff
Western Avenue,
Cardiff,
CF52YB**

19 December 2007

Dear Professor Griffith

**Full title of study: An Investigation into the Attitudes and Behaviours of
Consumers and Caregivers in the Preparation, Handling,
Storage and Feeding of Powdered Infant Formula Inside
and Outside the Home**

REC reference number: 07/MRE09/73

Thank you for your letter of 14 December 2007, responding to the Committee's request for further information on the above research.

The further information was considered by the Chairman.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). There is no requirement for [other] Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Application		16 November 2007
Investigator CV		16 November 2007
Protocol	1	16 November 2007
Covering Letter	signed Dr Elizabeth Redmond	16 November 2007
Summary/Synopsis	(1) Flow chart to illustrate key stages in stage 1 of this study : focus groups (2) Flow chart to illustrate key stages in stage 2 of this study : postal questionnaire; both version 1	16 November 2007
Letter from Sponsor	signed Professor Adrain Peters, Director of Research, UWIC; dated October 2007.	
Compensation Arrangements	(1) UM Association certificate of insurance : University of Wales, Institute Cardiff; expires 31 July 2008 (2) Hiscox endorsement; effective date 18 August 2005	
Interview Schedules/Topic Guides	Focus group discussuin guide : health professionals, version 1	16 November 2007
Letter of invitation to participant	Focus Group Invitation, version 1	01 October 2007
Participant Information Sheet: Front page of postal questionnaire - Health visitors	1	05 November 2007
Participant Information Sheet: Front page of postal questionnaire - Hospital nursery nurses	1	08 November 2007
Powdered formula milk study @ focus groups guidance for health care professionals	1	26 October 2007
Focus groups : recruitment questionnaire and consent form for Health Visitors	1, BQ2734	01 October 2007
Focus groups : recruitment questionnaire and consent form for Hospital Nursery Nurses	1, BQ2734	01 October 2007
Letter from funder	Food Standards Agency	
References document	1	16 November 2007
Postal questionnaire gatekeeper letter	1	16 November 2007
Postal questionnaire respondent letter	1	06 November 2007
Letter signed by Dr Elizabeth Redmond		14 December 2007

R&D approval

All researchers and research collaborators who will be participating in the research at NHS sites should apply for R&D approval from the relevant care organisation, if they have not yet done so. R&D approval is required, whether or not the study is exempt from SSA. You should advise researchers and local collaborators accordingly.

Guidance on applying for R&D approval is available from <http://www.rdforum.nhs.uk/rdform.htm>.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

Here you will find links to the following

- a) Providing feedback. You are invited to give your view of the service that you have received from the National Research Ethics Service on the application procedure. If you wish to make your views known please use the feedback form available on the website.
- b) Progress Reports. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
- c) Safety Reports. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
- d) Amendments. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
- e) End of Study/Project. Please refer to the attached Standard conditions of approval by Research Ethics Committees.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nationalres.org.uk.

07/MRE09/73**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely



**Dr Gordon Taylor
Chair**

Email: mrec@bsc.wales.nhs.uk

Enclosures: *Standard approval conditions*

Copy to: R&D office

MREC Approval letter: Amendment 1 – Inclusion of Midwives in the study

Research Ethics
Committee for Wales

Chairman/Cardeirydd :
Dr Gordon Taylor



Ymchwili Ethegau
Aml-Ganolfan
yng Nghymru

Administrator/Gweinyddes:
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Website: <http://www.nres.npsa.nhs.uk>
e-mail: corinne.scott@tec.wales.nhs.uk

Fax No. 029 2037 6824

07 August 2008

Professor Chris J Griffith
Head of Food Research and Consultancy Unit, UWIC
Western Avenue,
Cardiff, CF5 2YB

Dear Professor Griffith

Study title: An Investigation into the Attitudes and Behaviours of Consumers and Caregivers in the Preparation, Handling, Storage and Feeding of Powdered Infant Formula Inside and Outside the Home

REC reference: 07/MRE09/73
Amendment number: Amendment 1
Amendment date: 08 July 2008

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 01 August 2008.

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Questionnaire	Focus groups : recruitment questionnaire and consent form for midwives, version 1	06 July 2006
Protocol	2	06 July 2006
Notice of Substantial Amendment (non-GTIMPs)	Amendment 1	06 July 2006
Letter of invitation to participant	Focus group invitation, version 2	06 July 2006
Interview Schedules/Topic Guides	Focus group discussion guide : health professionals, version 2	06 July 2006
Covering Letter	signed Dr Redmond	06 July 2006

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

07/MRE09/73:	Please quote this number on all correspondence
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Yours sincerely

Dr. Gordon Taylor
Chairman

E-mail: corinne.scott@bsc.wales.nhs.uk

Enclosures List of names and professions of members who were present at the meeting
and those who submitted written comments

REC for Wales

Attendance at Sub-Committee of the REC meeting on 01 August 2008

Name	Profession	Capacity
Dr Maurice Buchalter	Alternate Vice Chairman / Hospital Consultant (Cardiologist)	Expert
Dr Gordon Taylor	Chairman / Statistician	Expert
Dr Pete Wall	Vice Chairman / Clinical Physiologist	Expert

Call to Action Letters – NHS department Managers

25th April 2008

Dear [REDACTED]

University of Wales Institute Cardiff / UK Food Standards Agency Research Study 2007-2009: An Investigation into the Attitudes and Behaviours of Consumers and Caregivers in the Preparation, Handling, Storage and Feeding of Infant Formula Inside and Outside the Home.

Approved by MREC (reference 07/MRE09/73)

Approved by Gateshead Health NHS Foundation Trust (reference 587/07)

Further to our recent telephone conversation I am writing to you in the capacity as the Assistant Division Manager for Women and Child Services in The Queen Elizabeth Hospital in Gateshead to provide you with some information regarding the research study that the Food Research and Consultancy Unit in The University of Wales Institute, Cardiff (UWIC) has recently been commissioned to undertake. The study may involve staff from Maternity, SCBU/Neonatal and Paediatric departments within your hospital.

It is acknowledged that breast milk is the best form of nutrition for infants, however, this research, funded by the UK Food Standards Agency, aims to investigate attitudes and perceptions related to preparation behaviours important during reconstitution and storage of formula milk inside and outside of the home. In addition, the study aims to identify sources of information about formula milk. Hospital staff are considered to be key health professionals that provide support to parents about appropriate feeding practices for new infants and therefore part of the study includes conducting focus groups all around the UK to determine beliefs, attitudes, practices and information provision relating to infant feeding with milk formula.

This study has been formally approved by MREC (reference 07/MRE09/73) and formally approved by Gateshead Health NHS Foundation Trust (reference 587/07). Please be assured that the study has no links or involvement with formula companies and at no stage will the use of formula be advocated nor will information provision regarding formula use be encouraged. In addition, staff participation in the study will not affect UNICEF Baby Friendly status.

Cumulatively, it is planned that 8-10 nursery nurses, healthcare assistants and paediatric nurses from Maternity, SCBU/Neonatal and Paediatric departments in hospitals in Gateshead and Newcastle will be recruited and voluntarily participate in one focus group to discuss issues related to formula preparation and storage and information provision to parents. This focus group is scheduled to take place on 5th June, 2008. Recruitment of hospital nurses for the focus group will take place in two stages and your involvement is key to the success of the study by facilitating access to your staff. As we discussed, I would be very grateful if you would distribute the enclosed information envelopes to nursery nurses, and healthcare assistants in Maternity, SCBU/Neonatal and Paediatric departments in the Queen Elizabeth Hospital. The envelopes include guidance about participation in the focus group and a telephone number which potential participants may call to register interest in the study. Secondly, before the focus group a field researcher from Beaufort Research may telephone your department to speak to nurses involved with feeding infants to potentially recruit interested participants.

In addition to the information envelopes, I have enclosed a copy of the MREC approval letter, local Trust approval letter and research protocol for your information. I hope this will be sufficient information to facilitate progress of the study. If you have any queries or require further information, please do not hesitate to contact me via email redmond@uwic.ac.uk or telephone: Cardiff (029) 20416452.

Yours Sincerely,

Dr. Elizabeth Redmond
Researcher



Invitation to Participate in a Focus Group to Discuss Infant Feeding.

'Determination of consumer and caregiver attitudes and behaviours related to the preparation, handling, storage and feeding of infant formula inside & outside of the home'.

The University of Wales Institute Cardiff (UWIC) and Beaufort Research Ltd (Cardiff) have been requested to undertake an important research study for the Food Standards Agency to determine the attitudes and behaviours of consumers (with infants aged <6months old) and caregivers regarding the preparation, handling, storage and feeding of infant formula inside and outside the home.

It is acknowledged that breast milk is the best form of nutrition for infants; however, the aim of this important study is to maximise the safety of formula milk. Please be assured that the study has no links or involvement with formula companies and at no stage will the use of formula be advocated nor will information provision regarding formula use be encouraged. In addition, staff participation in the study will not affect UNICEF Baby Friendly status. Information obtained from the study aims to reduce the risk of infection from organisms such as *Escherichia sakazakii* from formula milk. Findings will be used by the UK FSA to inform the development of guidelines and targeted risk communication materials for use in the home and in hospitals.

Nurses who work in Paediatric, Special Care Baby Units (SCBU) Neonatal and Maternity departments who are involved in the feeding of infants aged <6months will form an important part of the study. Through a series of focus group discussions this component of the study aims to understand beliefs, attitudes, practices and information provision relating to infant feeding.

Participation in this study:

- Attendance to a 90 minute discussion group in Gateshead to discuss aspects of infant feeding regarding infants aged <6 months. The discussion will include issues related to recommended practices and information provision to parents.
- You will be provided with free refreshments and £40 to cover expenses for attendance.
- The group will include 8-10 nurses from Paediatric, SCBU/Neonatal and Maternity departments
- The discussion will be held in a private function room of a local hotel in non-working hours
- The date and time of the discussion will be: *7pm, Thursday, 5th June, 2008*
- Staff participation in this study is entirely voluntary
- Please be assured that formal NHS ethical approval (ref 07/MRE09/73) and local NHS Trust approval (Gateshead Health NHS Foundation Trust Ref 587/07) has been granted for this study.

***To register your interest in participating in this study, please contact:
ANNETTE LITTLECHILD, Field Manager, Beaufort Research, Cardiff***

Telephone: 029 20378565

If you are unable to call during normal office hours please leave an answer phone message with your name and telephone number and you will be contacted by a field researcher to discuss participation.

Once you have registered your interest in attending the focus group you will be asked 1-2 recruitment questions to ensure you are eligible to participate.

Call to Action – NHS healthcare professionals information sheet and invitation to participate in the study (page 2)

INFANT FEEDING STUDY: FOCUS GROUPS
GUIDANCE FOR HEALTH CARE PROFESSIONALS

Title of Research: Preparation, Handling and Storage of Infant Formula

Research Team: Beaufort Research Ltd., Cardiff
University of Wales Institute Cardiff, Cardiff
The Food Standards Agency, London

Explanation of Procedures

You are being asked to participate in the research project to investigate the attitudes and perceptions of parents and caregivers towards the use of infant formula. The approach of the research is exploratory focus groups. A focus group is a small group of people (about 8-10) who meet together and discuss a chosen topic and answer some questions asked by a group leader (from Beaufort Research). You will be asked some questions about formula milk reconstitution and storage procedures and about what advice / information you provide to parents about feeding infants with such formula. In addition you will be asked your opinions about examples of current advice about infant formula. Details of the date and location of the focus group are found on your invitation. The focus group will last approximately 1-1 ½ hours. For analysis purposes the discussion will be digitally recorded and transcribed.

Risks and Discomforts

You will not be at physical or psychological risk and should experience no discomfort resulting from the research procedures.

Benefits

As a token of thanks for participating in the research you will receive £40 expenses and complimentary refreshments will be available to you during the time at the focus group. This research is expected to provide useful information to the UK Food Standards Agency about how parents and caregivers prepare infant formula for babies aged 0-6months and what they think about methods of preparation and current information about recommended methods. It is hoped that information collected during the course of study will be used to inform the development of revised educational materials.

Alternative Procedures

If a person chooses not to participate, an alternative procedure is not necessary.

Withdrawal Without Prejudice

Participation in this study is voluntary; refusal to participate will involve no penalty. Each participant is free to withdraw consent and discontinue participation in this project at any time without prejudice from this institution.

Confidentiality

All information gathered from the study will remain confidential. Your identity as a participant will not be disclosed to any unauthorised persons; only the researchers at Beaufort Research will have access to the your contact details, which will be kept in a locked filing cabinet until the end of the study.

Anonymous quotes from transcriptions may be used in reports and presentations but these quotes are never attributed to any one individual or specific organisation; all reporting is on an aggregate level. Any references to your identity that would compromise your anonymity will be removed or disguised prior to the preparation of the research reports and publications. Digital audio files will be erased at the end of this study.

Ethical and Local Trust Approval

Formal NHS ethical approval (ref 07/MRE09/73) and local NHS Trust approval (Gateshead Health NHS Foundation Trust Ref 587/07) has been granted for this study.

If you have any additional questions about participation in the focus group please contact:
Annette Littlechild, Field Manager, Beaufort Research Ltd., 2 Museum Place, Cardiff CF103BG

Telephone 02920 378565

UWIC


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AGENCY**

Email circulated to Health Visitors prior to focus group recruitment

April, 2008

For the attention of Health Visitors in Cardiff and the Vale NHS Trust

Research Study: An Investigation into the Attitudes and Behaviours of Consumers and Caregivers in the Preparation, Handling, Storage and Feeding of Powdered Infant Formula Inside and Outside the Home.

The University of Wales Institute Cardiff has been commissioned by the UK Food Standards Agency to undertake a 24 month research study concerning feeding infants with powdered infant formula. The study will involve parents, day nursery nurses, hospital nurses and health visitors from across the UK. Information will be obtained to identify and manage risks associated with preparation and storage of formula and identify when parents receive advice about such issues, from whom, type and content of information etc. The overall aim of the study is to maximise the safety of powdered infant formula preparation and storage.

This letter is to inform you that in April-May, 2008 one focus group is planned with Health Visitors from xxxxxxxxxxxxxxxxxxx NHS Trust in Cardiff. A focus group is a small group of people (about 8-10) who meet together and discuss a chosen topic and answer some questions asked by a group leader (~90minutes). Please be assured that National Ethical Approval has been obtained for this study (MREC No. 07/MRE09/73) and Local NHS Approval has also been obtained from xxxxxxxx Trust (Project ID: xxxxxxxx). Furthermore, Health Visitor Managers [name(s)] within the area of xxxxxxxx have also been made aware of this study.

To participate in the focus group, a trained researcher from Beaufort Research will telephone Health Visitors (randomly selected) in your area to ask for interest in participating in the study. Participation in the discussion group is completely voluntary and interested persons who satisfy recruitment criteria will be provided with additional information about the study for their reference. The discussion group will be held out of normal working hours in a private function room of a local hotel and all participants will be given £40 expenses to cover time and transport costs.

All information collected during the course of study will remain strictly confidential at all times.

Yours Sincerely,

Dr Elizabeth Redmond
Principal Investigator for the study.
Senior Researcher, Food Research and Consultancy Unit,
University of Wales Institute, Cardiff, CF149JJ
eredmond@uwic.ac.uk

Approved Recruitment Questionnaire: NHS Professionals [e.g. Health Visitor]

FOR OFFICE USE ONLY

**INFANT POWDERED FORMULA
RECRUITMENT QUESTIONNAIRE
HEALTH VISITORS
FINAL
OCTOBER 2007
BOZ734**

APPROACH PEOPLE AGED 18+

BEAUFORT RESEARCH
2 Museum Place, Cardiff, CF10 3BG

FOR OFFICE USE ONLY

APPROACH PEOPLE AGED 18+

Hello, my name is of Beaufort Research. We are carrying out some research undertaken by U.W.I.C—the University of Wales Institute Cardiff—on behalf of the Food Standards Agency into feeding babies under 6 months old and would like your opinions. Could you spare just a few minutes to answer some questions?
REASSURE IF NECESSARY: BEAUFORT RESEARCH IS AN INDEPENDENT CONSULTANCY & WE ARE NOT SELLING ANYTHING

IF RESPONDENT WILLING TO ATTEND GROUP, HAND OUT INVITATION WITH RELEVANT DATE & TIME OF GROUP, THEN RECORD DETAILS BELOW

RESPONDENT DETAILS:

Name: _____

Address: _____

Postcode: _____

Telephone Number: _____

INTERVIEWER DECLARATION

I declare that I have conducted this interview in accordance with your instructions.

Signature: _____

Date: _____

2

BEAUFORT RESEARCH
2 Museum Place, Cardiff, CF10 3BG

APPROACH PEOPLE AGED 18+

FOR OFFICE USE ONLY

**INFANT POWDERED FORMULA
RECRUITMENT QUESTIONNAIRE
HEALTH VISITORS
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APPROACH PEOPLE AGED 18+

Hello, my name is of Beaufort Research. We are carrying out some research undertaken by U.W.I.C—the University of Wales Institute Cardiff—on behalf of the Food Standards Agency into feeding babies under 6 months old and would like your opinions. Could you spare just a few minutes to answer some questions?
REASSURE IF NECESSARY: BEAUFORT RESEARCH IS AN INDEPENDENT CONSULTANCY & WE ARE NOT SELLING ANYTHING

IF SUCCESSFULLY SCREENED INVITE RESPONDENT TO FOCUS GROUP:
We are holding a focus group to discuss different aspects of feeding babies with powdered infant formula under 6 months old and would like to invite you personally to attend.
(READ OUT DATE)
EXPLAIN FOCUS GROUP

- Informal, relaxed discussion
- Reimbursement of expenses
- Will last about hour and a half

Q.1 What ages of babies do you work with nowadays?

0 – 6 months 1 → CONTINUE
6 – 12 months 2 → CLOSE
12+ months 3 → CLOSE

Q.2 Have you ever been to a focus group before?

Yes- within last 6 months → ASK Q.3
Yes- longer ago → RECRUIT
No, never → RECRUIT

Q.3 What was the subject of the focus group discussion?

→ IF RELATED TO INFANT FEEDING / FORMULA, THANK & CLOSE—ASK APPENDED QUESTION. OTHERS CONTINUE

1

Approved Participant Information Sheet / Written Guidance: NHS Professionals

Version 1. 20th October, 2007

POWDERED FORMULA MILK STUDY: GUIDANCE FOR HEALTH CARE PROFESSIONALS

Title of Research: Preparation, Handling and Storage of Powdered Infant Formula

Research Team: Beaufort Research Ltd., Cardiff
University of Wales Institute Cardiff, Cardiff
The Food Standards Agency, London

Explanation of Procedures

You are being asked to participate in the research project to investigate the attitudes and perceptions of parents and caregivers towards the use of powdered infant formula. The approach of the research is exploratory focus groups. A focus group is a small group of people (about 8) who meet together and discuss a chosen topic and answer some questions asked by a group leader (from Beaufort Research). You will be asked some questions about powdered formula milk reconstitution and storage procedures and about what advice / information you provide to parents about feeding infants with such formula. In addition you will be asked your opinions about examples of current advice about powdered infant formula. Details of the date and location of the focus group are found on your invitation. The focus group will last approximately 1-1 ½ hours. For analysis purposes the discussion will be digitally recorded and transcribed.

Risks and Discomforts

You will not be at physical or psychological risk and should experience no discomfort resulting from the research procedures.

Benefits

As a token of thanks for participating in the research you will receive expenses and complimentary refreshments will be available to you during the time at the focus group. This research is expected to provide useful information to the UK Food Standards Agency about how parents and caregivers prepare powdered infant formula for babies aged 0-6 months and what they think about methods of preparation and current information about recommended methods. It is hoped that information collected during the course of study will be used to inform the development of revised educational materials.

Alternative Procedures

If a person chooses not to participate, an alternative procedure is not necessary.

Withdrawal Without Prejudice

Participation in this study is voluntary; refusal to participate will involve no penalty. Each participant is free to withdraw consent and discontinue participation in this project at any time without prejudice from this institution.

Confidentiality

All information gathered from the study will remain confidential. Your identity as a participant will not be disclosed to any unauthorised persons; only the researchers at Beaufort Research will have access to the your contact details, which will be kept in a locked filing cabinet until the end of the study.

Anonymous quotes from transcriptions may be used in reports and presentations but these quotes are never attributed to any one individual or specific organisation; all reporting is on an aggregate level. Any references to your identity that would compromise your anonymity will be removed or disguised prior to the preparation of the research reports and publications. Digital audio files will be erased at the end of this study.

If you have any additional questions about participation in the focus group please contact:
Lisa Williams, Senior Research Executive, Beaufort Research Ltd., 2 Museum Place, Cardiff CF103BG
Telephone 02920 20378565

UWIC


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Approved Typical Consent Form: NHS Professionals



CONSENT FORM

Title of the project: Preparation, Handling and Storage of Powdered Infant Formula

Name of Researcher: Lisa Williams, Senior Research Executive, Beaufort Research Ltd.

Please
initial box

1. I confirm that I have received the information guidance sheet dated 26th October, 2007 (version 1) for participation in a focus group the above study. I understand I have the opportunity to consider the information before the focus group takes place and may contact the Researcher responsible for this study to answer any questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.

3. I understand that all information gathered from the study will remain confidential and any contribution I make to the focus groups will be treated with anonymity.

4. I agree to take part in the above study.

.....
Name of participant

.....
Date

.....
Signature

.....
Name of person taking
consent

.....
Date

.....
Signature

When completed, the 1 original copy will be stored in paper form at Beaufort Research for 12 months.

Approved focus group Discussion Guide : Health Care Professionals

UWIC/FSA RESEARCH: POWDERED FORMULA MILK

Focus Group Discussion Guide: Health Professionals

1. INTRODUCTIONS

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

2. ROLES AND RESPONSIBILITIES

This section aims to get a good understanding of the roles and responsibilities of health professionals regarding health care and feeding of babies aged 0-6 months.

Explain that we would like to understand the roles and responsibilities health professionals have in relation to advising parents about feeding their babies.... particularly with powdered formula milk.

- Ask the health professionals to explain their roles and responsibilities in this context:
When and where do you have **first** and subsequent contact with parents?
(HEALTH VISITORS ONLY) Frequency of visits? Approx length of visits? Do they hold clinics?
Do you consider it is part of your role as a health professional to inform parents about safe preparation of powdered formula milk and storage of reconstituted formula milk?
- Which health care professionals do you think have the biggest influence on advising parents on feeding their babies – particularly re powdered infant formula in terms of preparation, storage and use?

3. POWDERED FORMULA MILK

The aim of this section is to determine attitudes towards general & specific microbial risks associated with stages of preparation, use & storage of powdered formula milk inside & outside of the home.

- Do you have any concerns for parents feeding a baby <6months with powdered formula milk? If yes – probe what concerns? & why?
- Do you think that powdered formula milk is a sterile product?
- What do you consider the most important actions are to make sure that reconstituted powdered formula milk is safe to feed?
- Do you think there are there microbiological hazards associated with feeding babies aged <6months with powdered formula milk? Probe for awareness of *Enterobacter sakazakii*.
- Probe for awareness of cross contamination issues during preparation / making up of a powdered formula feed?
- Do you think it is safe to make up powdered formula milk in advance of use? If formula is prepared in advance what storage requirements do you consider to be important?

- If a baby is fed away from the home do you think it is better to make the feed up at home before leaving or make up on the spot when required? What do you recommend in such circumstances?

HOSPITAL NURSERY NURSES ONLY:

- What powdered formula feeds (including special feeds) do you use in your department? Do you provide all of the powdered formula for all feeds? Do parents ever bring powdered formula into the hospital to feed their baby?
- Once tins of powdered formula are opened in the department is the length of time they are opened monitored at all? Is there a policy re the length of time opened tins of formula are kept?
- Who is responsible for making the feeds up in your department? Is it the same person every day – have they had any special / extra training to do so?
- Where are the feeds made up? If made up in a kitchen, describe size, equipment present and any other uses of the kitchen.
- Fridge: Is there a fridge in the kitchen? Is the temperature of the fridge monitored? Is the temperature ever written down and recorded?
- Discuss the process of how powdered formula milk feeds are made up in your department.
- Labelling: How do you know which bottle / reconstituted feeds are for which baby?

4. INFORMATION PROVISION

This section should determine what information and advice is being communicated from health professionals to parents at different stages of pregnancy and babyhood. Attitudes and perceptions towards the content, availability and suitability of information and key recommendations will be ascertained. Sources of information for health professionals will also be determined.

- It is acknowledged that breast milk is the best form of nutrition for infants and that exclusive breast feeding is recommended for the first 6 months of an infant's life. However, thinking about any circumstances when you may be asked to provide information on bottle feeding:

Is there standard advice that health visitors/ nursery nurses such as yourselves give to parents re this subject?

What are the key messages you are currently giving to parents about powdered formula milk?

Any differences in information provided between ages / stages of baby / pregnancy

At what stage do you think that parents need most information about feeding.

- If a mother intends to breast feed or is breast feeding do you ever give her / tell her information about feeding with powdered formula milk?
- *Determine format of information and advice (& sources) given to parents by health professionals?*
 - What types of information e.g literature etc do you give to parents?
 - How does the different literature / information sources / aids compare?
 - What do you think are the strengths and weaknesses of each type?
- **HEALTH VISITOR GROUP ONLY:** Clinics: What clinics are organised and run by health visitors – what stage of pregnancy / age of baby? Where are clinics held? How many clinics can mums to be / new parents attend? What information re preparation and storage of powdered formula milk and sterilization of bottles / components / utensils is included; Who determines the content of clinics?
- Where else do you think that parents may get information and advice about preparation, storage and use of powdered formula milk?
- Which sources of information about bottle feeding do you think have biggest influence on parents subsequent choice and behaviour? Why?
- **HEALTH VISITOR GROUP ONLY:** Do you think there is enough information and advice about powdered formula milk available to parents in your area? What ages / 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?

- *HEALTH VISITOR GROUP ONLY:* Do you ever observe preparation of powdered formula in parents homes. If yes – examples of problems encountered and how issues have been addressed by the health visitor. If not, why not.
- *Determine awareness of 'new' preparation / storage recommendations from NHS and FSA:*

S. INFORMATION SOURCES FOR HEALTH PROFESSIONALS

Where do you get your information about powdered formula milk from (to give to parents) / what do you base your advice on? What sources? Is information and advice updated? Frequency of updates? When did you last make changes to the information / advice you provide - what and why?