INFORMATION SOURCES AND PRACTICES – PREPARATION OF POWDERED INFANT FORMULA IN NEW ZEALAND - QUALITATIVE RESEARCH

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SUMMARY

A series of focus groups were run to examine aspects of the preparation of powdered infant formula. Participants in the focus groups were caregivers currently engaged in the preparation of infant formula. The three focus groups (two in Auckland, one in Christchurch) were made up of a total of 14 mothers, aged 20-41 years, with infants aged 1-11 months.

Focus groups were structure to gather information on:

- Current actual practices for the preparation, use and storage of powdered infant formula;
- Sources of information used to obtain information on preparation of powdered infant formula; and
- Knowledge of powdered infant formula, with particular attention to knowledge on the non-sterile nature of formula.

There appears to be a high level of compliance with information provided on the preparation of infant formula. Some deviations were identified. In most cases deviations were driven by cost considerations, pragmatism or an increasingly relaxed attitude with increased age of the infant. Cost considerations were a particular issue affecting decisions around discarding of unfinished feeds. Pragmatism and relaxation related deviations were more likely to exhibit in pre-preparation of night or away from home feeds and cessation of boiling of make up water.

While decisions to relax practices did not appear to be driven by conscious knowledge derived from guidance material, these decisions were often consistent with guidelines that include stricter hygiene measures during the first three months of life.

The information caregivers receive on preparation of infant formula is largely empirical ('do this, then do this') and the only **'indicator'** they have as to whether they are carrying out sterilisation, preparation, storage and discarding correctly, is **the health of their baby**. Their babies' responses to their feeding regimes initiated several kinds of behaviours, such as seeking advice or information from elsewhere (e.g. internet); re-reading available information; or most commonly, changing the formula.

Caregivers access a wide range of formal and informal sources of information. As most mothers approach birth with an intention of breastfeeding, information on preparation of infant formula is often not sought and generally not provided until the point in time when it is immediately needed.

Caregivers are typically information hungry and access to information on infant formula, in general, and preparation, in particular, was usually less than caregivers required. Information on infant formula tins was viewed as available, authoritative and trusted and was the major information source for most caregivers. Information from health professionals was valued and trusted, when it was provided, but in many cases the health professional available at the time were unwilling or unable to provide the necessary information. According to caregivers involved in the current study, a number of health professionals believed they were 'not allowed' to provide information on formula feeding.

Information from family, friends and other informal sources tends to be reviewed and accepted if it is found to be useful, although for some caregivers their family is **the** source of information.

A discussion of caregiver knowledge of facts related to powdered infant formula was designed to introduce information on the non-sterile nature of infant formula, without this topic dominating the whole focus group. In fact, the non-sterility of infant formula was discussed without concern in all focus groups.

Preparing formula with hot water was actively discussed in one focus group, with participants unanimously in agreement that this guideline was impractical and potentially dangerous, due to the risk of scalding. It should be noted that, after consultation, this practice has not been included in formula feeding guidelines for New Zealand.

1 INTRODUCTION

1.1 The International Environment

Internationally, there have been repeated affirmations that breast milk constitutes the best source of nutrition for infants. The International Code of Marketing of Breast-milk Substitutes, first codified under the auspices of the World Health Organization (WHO) in 1981 aims to:

- Contribute to the provision of safe and adequate nutrition for infants, by:
  - Protection and promotion of breastfeeding; and
  - Ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution

The Code can be accessed at:
http://www.who.int/nutrition/publications/code_english.pdf

The Code contains articles addressing:

- Aim;
- Scope;
- Definitions;
- Information and education;
- Health care systems;
- Health workers;
- Persons employed by manufacturers and distributors;
- Labelling;
- Quality; and
- Implementation and monitoring.

The principles of the Code have been endorsed by subsequent World Health Assemblies.

1.2 Implementation of the Code in New Zealand

The Code is given force by actions in individual countries, as appropriate to their social and legislative framework. In New Zealand, the Ministry of Health (MoH) have expressed their commitment to protecting, promoting and support breastfeeding and have produced a document outlining how the international Code will be implemented and monitored in New Zealand (Ministry of Health, 2007).

The international Code is implemented in New Zealand through four New Zealand specific codes:

- Code of Practice for Health Workers (Ministry of Health, 2007);
- New Zealand Infant Formula Marketers' Association (NZIFMA) Code of Practice for the Marketing of Infant Formula (http://www.ifanz-ibfan.org.nz/codes/nzifmacode.htm);
- Advertising Standards Authority Code for Advertising of Food (http://www.asa.co.nz/code_food.php); and

- Australia New Zealand Food Standards Code ("the Food Standards Code"; http://www.foodstandards.gov.au/thecode/).

With the exception of the Food Standards Code, these codes are voluntary and self-regulatory.

With particular reference to procedures for preparation of infant formula, the Health Workers Code states that:

"Only health workers should demonstrate to mothers or family members how to prepare and use formula. Family members who need to use formula require instruction and information on the preparation and safe storage of formula, feeding techniques and types of formula available."

The Health Workers Code directs health workers to the Ministry of Health's 'Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2): A Background Paper' (Ministry of Health, 2008) as a primary information source.

The NZIFMA Code includes similar provisions:

"It is agreed also that proper and suitable educational facilities be given to those mothers who do not breastfeed their infants. These educational facilities must be provided by the health care system with the co-operation, where appropriate, of the marketers of infant formula. It is essential that adequate instruction on the use of infant formula is given to mothers, both within the health care system, and in the educational literature and labelling provided by marketers. It is agreed that instructions provided should be simple and easy to comprehend."

The Advertising Code does not address this issue specifically, but the NZIFMA Code is endorsed by the Code for Advertising of Food as the appropriate industry code of ethics.

The Food Standards Code principally deals with issues of the labelling, composition and quality of infant formula. Standard 2.9.1 of the Code specifies the following labelling requirements with respect to infant formula preparation:

"**14 Required warnings, directions and statements**

(1) The label on a package of infant formula product must include the following warning statement -

> (a) in the case of infant formula product in powdered form - 'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder except on medical advice. Incorrect preparation can make your baby very ill'; and
> (b) in the case of concentrated infant formula product - 'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of concentrate except on medical advice. Incorrect preparation can make your baby very ill'; and
> (c) in the case of 'ready to drink' infant formula product - 'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not dilute or add

anything to this 'ready to drink' formula except on medical advice. Incorrect preparation can make your baby very ill'.

(2) The label on a package of infant formula product must include directions for the preparation and use of the infant formula product which include words and pictures instructing -

(a) that each bottle should be prepared individually; and

(b) that if a bottle of made up formula is to be stored prior to use, it must be refrigerated and used within 24 hours; and

(c) that potable, previously boiled water should be used; and

(d) where a package contains a measuring scoop, that only the enclosed scoop should be used; and

(e) that formula left in the bottle after a feed must be discarded.

(3) Subject to subclause (4), the label on a package of infant formula product must contain the following warning statement -

'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice.';

under a heading that states –

'Important Notice' or any word or words having the same or similar effect."

The Ministry of Health is responsible for monitoring the implementation of the Health Workers' and NZIFMA Codes in New Zealand, through receipt of complaints regarding potential breaches of these Codes (Ministry of Health, 2007). The Advertising Standards Complaints Board is responsible for monitoring compliance with the Code for Advertising of Food, while the New Zealand Food Safety Authority is responsible for administering and monitoring compliance with the Food Standards Code.

1.3 Microbiological Hazards Associated with Powdered Infant Formula

Powdered infant formula (PIF) is not a sterile product and intrinsic contamination of powdered infant formula with *Enterobacter sakazakii* and *Salmonella* has been a cause of infection and illness in formula-fed infants (JEMRA, 2004). In some cases disease has resulted in serious developmental sequelae and death.

An assessment of associated risks by the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA) concluded that the key factors contributing to microbiological risk of powdered infant formula were:

- The level of contamination in the powdered infant formula;
- The level of hygiene in the preparation and delivery of the reconstituted formula;
- Inclusion of bactericidal treatment at the time of preparation; and
- The duration of the feeding period and the temperature.

While the first of these is an industry issue, the latter three are dependent on the knowledge and behaviour of caregivers. A component of this knowledge is the information provided to caregivers by official sources and their interpretation of that information.

Relevant risk reduction practices outlined in the JEMRA report include:

- Use of temperatures in excess of 70˚C for reconstitution, either through a point-of-use pasteurisation step or use of hot water (70-90˚C) during reconstitution.

- Minimising growth potential following reconstitution and prior to consumption by rapid cooling and storage below 10˚C, if not for immediate use, and minimising the length of time between reconstitution and consumption.

1.4 Current Study

The current study was initiated to investigate:

- Actual practices used by New Zealand caregivers in preparation, use and storage of powdered infant formula, including identification of deviations from recommended practice;
- Source of information on the preparation of powder infant formula used by caregivers; and
- Caregiver knowledge concerning the non-sterile nature of powdered infant formula.

An initial study was carried out to summarise advice currently available and to review overseas studies on infant formula preparation practices and information sources (Cressey, 2007).

2 METHODS

The available information sources suggest three possible methods for determining the knowledge and beliefs of New Zealand caregivers, including information on where knowledge is accessed, and actual practices with respect to preparation of powdered infant formula:

- Structured questionnaires;
- Focus groups; or
- Observational studies.

Each of these approaches has strengths and weaknesses.

A meeting of the project steering committee was held on 13 December 2007, at which the following details of the survey design were agreed:

- The survey will be conducted using a focus group format.
- The target is to conduct three focus groups; two in the Auckland region and one in the Christchurch region.
- Focus groups will be of 6-8 participants
- An attempt will be made to recruit diverse participants to the focus groups, to include early and long-term formula feeders, as well as a mix of rural/urban, Maori/Pacific Island/Asian representatives.
- Participants are to be currently preparing powdered infant formula in the home environment.
- Infants to ideally be six months of age or less

2.1 Rationale for Choice of Focus Groups

Focus groups are a form of group interview (most often conducted with 6-10 participants) that utilise **group communication and interaction** to provide data and insights relating to specific topics of interest (Kitzinger, 1995; Morgan, 1988; Morgan and Krueger, 1993). Although these explore a predefined topic, they are designed to remain open and flexible, thus allowing a more intensive exploration of the focus topic. Subsequently, focus group data can provide additional insight into the motives and reasons for reported attitudes and behaviours. Additional advantages of using a focus group methodology include:

- *Their ability to provide learning about the gap between professionals and their target audience*. Interactions in focus groups provide a clear view of how others think and talk, therefore they can be a powerful means of exposing professionals to the reality of the customer, student or client.
- *Their ability to investigate complex behaviour and motivations.* Through comparing the different points of view that participants exchange during the interactions, researchers can examine motivation with a degree of complexity that is typically not available with other methods.
- *Their ability to enable more learning about the degree of consensus on a topic.* Interaction in a focus group can provide a basis for exploring the range of opinions or experiences that people have. While failure to disagree should not be mistaken for actual consensus, focus group researchers can gain insights into both the range of opinions there are and the sets of circumstances that lead to one response rather than another.

- *Their ability to provide a friendly research method that is respectful and not condescending to the target audience.* This is done through creating and sustaining an atmosphere that promotes meaningful interaction, sensitivity and a willingness to listen without being judgmental (Morgan and Krueger, 1993).

2.2 Method Details

Participants were identified through local co-ordinators. The local co-ordinators for this study were childbirth educators, who had conducted ante-natal classes and subsequently retained contact with a large number of caregivers during the post-natal period.

The Auckland focus groups (Birkenhead and Botany Downs) were held during the day and participants were informed that they were welcome to bring their babies with them. They were held in community-based settings that were relatively easy to access. The Christchurch focus group was held at ESR which meant the meeting had to be held in the evening.

At all venues participants were offered refreshments and the meeting began with introductions and an explanation of the project.

The focus group discussions were audio-taped and field-notes were also taken. The tapes were transcribed verbatim and the field notes were added at the end of the transcript.

Analysis of the combined data (all focus groups and field-notes) was carried out by using different coloured highlighting for sections of text related to different questions. These sections of text were then analysed in terms of consensus of behaviours, practices and beliefs within the group as well as the range between participants. The findings – in relation to each question - are illustrated through using direct quotes from the transcripts.

3 RESULTS AND DISCUSSION

3.1 Characteristics of Focus Groups

Table 1 summarises key characteristics of the three focus group cohorts involved in the current study. While six participants were identified for each focus group, on-day issues for caregivers recruited to the Botany Downs group meant that only two participants were present. Recruitment of the Christchurch focus group was carried out over an extended timeframe, resulting in two infants being older than six months on the day of the focus group (target age range for infants was 0-6 months). A late defection from the Christchurch focus group was also replaced by a caregiver whose infant was no longer in the target age range, but met all other entry criteria.

In comparison to the total New Zealand population; the overall median age of the participants (31.5 years) was slightly higher than the most recent New Zealand median age of women giving birth (30 years) (Statistics New Zealand, 2008).

The focus groups included a higher proportion of New Zealand Europeans and Māori (86% and 21% respectively) than the New Zealand population, as determined at the 2006 census (68% and 15% respectively) (Statistics New Zealand, 2007). Asian ethnic groups, who make up 9% of the New Zealand population, were not represented in the focus groups.

Table 1: Characteristics of focus groups, powdered infant formula project

Characteristic	Group 1	Group 2	Group 3	Total
Number of participants	6	2	6	14
Gender (F/M)	6/0	2/0	6/0	14/0
Average age of participant (range) (years)	32.7 (28-41)	20.5 (20-21)	31.7 (28-35)	30.5 (20-41)
Ethic group of participant	NZ European - 6	Māori - 1 Cook Island Māori - 1	NZ European - 4 NZ European/ Māori - 2	NZ European - 10 NZ European/ Māori - 2 Māori - 1 Cook Island Māori - 1
Average infant age (range) (months)	3.7 (1-6)	5 (4-6)	6.7 (3-11)	5.1 (1-11)
Other children (No/Yes)	6/0	2/0	3/3	11/3
Current infant feeding	Formula only – 5 Mix formula/breastmilk - 1	Formula only – 2	Formula only – 6	Formula only – 6 Mix formula/breastmilk - 1
Formula type	Powdered – 5 Special prescription – 1	Powdered – 2	Powdered – 5 Special prescription - 1	Powdered – 12 Special prescription - 2
Who chooses formula?	Self – 2 Partner – 1 Self and Partner – 2 Self and specialist – 1	Self – 2	Self – 2 Self and Partner – 3 Paediatrician - 1	Self – 6 Self and Partner – 5 Partner – 1 Self and specialist – 1 Paediatrician - 1
How often does participant personally feed formula?	Most feeds – 6	Most feeds – 2	Most feeds – 6	Most feeds - 14
How involved is the participant in sterilising equipment?	Very involved – 6	Very involved – 2	Very involved – 4 Shared involvement - 2	Very involved – 12 Shared involvement - 2
How long has the infant been fed formula?	From birth – 4 Last few weeks – 1 3-4 months - 1	From birth – 1 2-3 months – 1	From birth – 5 5-6 months - 1	From birth – 10 Last few weeks – 1 2-3 months – 1 3-4 months – 1

Characteristic	Group 1	Group 2	Group 3	Total
				5-6 months - 1
Formula feeding decision				
- always planned exclusive formula feeding	1		0	2
- always planned breast feeding, now use formula	3	1	5	9
- always planned mixed feeding	2	1	1	3

3.2 Infant Formula Preparation

Participants were asked to describe in detail their usual procedures for the preparation of powdered infant formula. In general, participants demonstrated a good appreciation of the importance of correct preparation. However, in most cases they did not know why particular preparation practices were important.

3.2.1 Hygiene

Hand hygiene and cleanliness of the preparation environment was considered by most participants to be so obvious that it often wasn't mentioned, until prompted.

"*You take it for granted you wash your hands"*

However, as with a number of aspects of formula preparation, attitudes and practices tended to be more pragmatic with second or later children.

"*I think you get more relaxed with your second one after the first. When we first had [first child name] I was very particular about washing hands and making sure [partner name] washed his hands – tried to be perfect. And now with [second child name], I don't so much*"

3.2.2 Sterilising equipment

A range of practices for sterilising equipment, particularly bottles, were reported, including:

- Chemical sterilisation (sterilising tablets)
- Boiling in water
- Adding boiling water to overflow
- Microwave sterilisation

Commercial microwave sterilisers appeared to be very popular, particularly as they provide a simple, time-saving option.

"*The information I got from the lactation expert was to wash the bottles, rinse them and sterilise them in a pot of boiling water, and that took me ages, and then my sister who came to stay bought me a microwave steriliser so that's how I sterilise them now*"

There was a reasonable level of understanding that sterilisation was most important during the first 3 months, although most mothers expressed a tendency to err on the side of caution.

"*I do my sterilising thing at night – yesterday at Plunket I heard that you have to sterilise the bottles until they're 6 months old – it used to be that you had to do it until they're 3 months old. But it's coming up winter and there's enough germs up here*"

3.2.3 Preparing water

Preparation of make-up water for infant formula preparation was usually reported to be carried out in a satisfactory manner and was generally carried out for a longer period than the three month period specified in many guidelines.

"*My midwife said you don't use boiled after three months. I'll continue to do that until 6 months*"

Common practices included putting boiled water into a number of bottles, so they were 'ready to go', or placing the boiled water into a jug or similar container and storing for future use, either on the bench or in the refrigerator. Participants were approximately equally divided between these two practices. Boiling water for each individual feed did not appear to be a common practice.

Cultural issues associated with water were raised by one participant, resulting in the use of bottled water for preparing formula.

"*I use bottled water – usually boil it. Don't want to use water from the Waikato – people have died in it, the bottled water is like from a spring*"

Cessation of boiling water for making up formula was usually either driven by a benchmark age (e.g. six months) or by reasoned pragmatism.

"*Sometimes I use the jug, sometimes I just use cold water and microwave it. When [child's name] was very, very young we always used boiled water and sterilised the bottles but now that she's chewing on toys and eating solids I don't feel the need to sterilise any more*"

3.2.4 Adding formula

While there was generally a high level of reported compliance with manufacturers' instructions with respect to adding formula to bottles, some deviations were reported. One participant reported adding water to formula, rather than formula to water, while another reported use of non-levelled scoopfuls by their partner.

"*My husband was quite generous with the scoops, and I had to put a stop to that. I mean you can help them gain weight but*…"

3.2.5 Reheating

Reheating in the microwave was widespread amongst participants. The issue of uneven heating and the need to shake microwave heated formula before feeding was generally understood, although this detail was raised by only one participant. Upon prompting, this appeared to be generally known.

"*But if I make one up from fresh, I actually put it in the microwave otherwise it takes too long and it mixes more easily when water's hot – as long as you mix it really well and test it on your arm*"

"*They say it can heat unevenly so I usually give it a mighty good shake*"

Approximately one-quarter of the participants did not bring the formula to body temperature, either feeding formula hot or cold. The common rationale for this deviation was that the baby preferred formula hot/cold to warm.

3.2.6 Unfinished feeds

There were generally high rates of compliance with guidelines for unfinished feeds (discard if not consumed within two hours, do not reheat).

"*If she hasn't taken it, I might give her a little break – not for long though – and if she doesn't want it I throw it out*"

However, two participants reported that if the infant wouldn't feed the prepared bottle would be returned to the refrigerator and reheated at a later stage.

"*If there's quite a bit left over I actually put it in the fridge*"

"*When he was a bit younger, and he didn't take it I would actually put it in the fridge then re-heat it again*"

One participant reported that they would reheat the formula if the feeding process became sufficiently drawn out.

"*If he'd left quite a lot and I'd think this was a bit unusual, and I'd probably try him again in about ten minutes – I'd probably just leave it on the bench and may have to reheat it a little if it was too cool, but if it was just a little bit left and I'd reheated and tried him and he didn't want it I'd throw it out*"

The cost of formula, particularly for those using expensive, specialised formula, was a major driver for participants deviating from best practice. Discarding unused feeds obviously involved a complex cost-benefit decision in these cases.

3.2.7 Night-time/away from home feeds

Both of these situations can be problematic. Away from home feeds are sometimes in situations where the caregiver doesn't have access to their usual resources, while night feeds are often carried out against a background of time pressure – the infants wants to be fed as soon as possible and the caregiver wants to return to bed as soon as possible.

Reported behaviours covered a wide range of approaches. Most caregivers adopted a very correct approach.

"*I put the water in the bottle and have the formula on the bench beside it. [And how do you heat it?]. I put it in the microwave*"

"*And if we're going out, yeah, take the formula with us in one of those Tommy-Tippee things, have the water there and find some way to heat it up or take a thermos of hot water and mix it. That's for long road trips – you can't always guarantee you're going to be near a microwave or – you can pretty much get it to the right temperature*"

Other caregivers adopted a mixed approach to these feeding situations, to accommodate the urgency of the situation.

"*Sometimes I usually have a bottle made up in case he wakes in the night, and if he's hungry, he needs it now! But if I go out I never take a made up bottle, I take the boiled water and the formula and make it up when I need it*"

There was a reasonable level of awareness that prepared feeds could be stored in the refrigerator. Manufacturers instructions can differ on this point with some stating prepared formula can be stored in the refrigerator for 12 hours, while others state that it can be stored for up to 24 hours (Cressey, 2007). Pre-preparation and refrigeration was used in some cases for night feeds.

"*I make up five bottles – I work full-time, so during the weekends and at night I make up 5 bottles – if the jug had been boiled I'd use that but if not, the cold tap. I'd make up the five bottles and put them in the fridge and if she hadn't drunk them – I don't really reheat them, or put it back in the fridge and give to her later*"

"*We do waste lots as well, but it does say you can keep it in the fridge for up to 12 hours*"

3.2.8 Powdered infant formula preparation – conclusions

There appears to be a high level of compliance with information provided on the preparation of infant formula. Some deviations were identified. In most cases deviations were driven by cost considerations, pragmatism or an increasingly relaxed attitude with increased age of the infant. Cost considerations were a particular issue affecting decisions around discarding of unfinished feeds. Pragmatism and relaxation related deviations were more likely to exhibit in pre-preparation of night or away from home feeds and cessation of boiling of make up water.

While decisions to relax practices did not appear to be driven by conscious knowledge derived from guidance material, these decisions were often consistent with guidelines that include stricter hygiene measures during the first three months of life.

The information caregivers receive on preparation of infant formula is largely empirical ('do this, then do this') and the only **'indicator'** they have as to whether they are carrying out sterilisation, preparation, storage and discarding correctly, is **the health of their baby**. Their babies' responses to their feeding regimes initiated several kinds of behaviours, such as seeking advice or information from elsewhere (e.g. internet); re-reading available information; or most commonly, changing the formula.

"I'm still sterilising because he had diarrhoea and vomiting and I had stopped sterilising – it could have been coincidence but I've gone back to washing, rinsing, sterilising and I do several things – sometimes tip out a bit of the water and top it up with water from out of the jug to heat it up and that's a quick way; sometimes we use the microwave and my husband

uses the jug. And now, when he's had enough - he won't take any more - I tip the left-over out. When he was a bit younger, and he didn't take it I would actually put it in the fridge then re-heat it again. Yeah, I think we do things a lot more simply now."

3.3 Sources of Information on Preparing Powdered Infant Formula

Participants were asked where they had obtained information on the preparation of powdered infant formula. They were then asked about the level of trust they had in each of the sources they had used.

3.3.1 The formula tin

All participants get information that they know is relevant and useful from the formula tin. The first thing they want to know is whether the formula is the right formula for the age of their baby. The next two interrelated pieces of information they seek are (i) how to make up the bottles and (ii) how much they need to give their baby.

A number of participants also read the contents section of the tin – what is in the formula.

"*We went to the supermarket and read every single brand – the ingredients and the difference between them"*

"*I scan the main headings really because I want to make sure this is the right one to buy - the from birth kind of thing, and then I would look at the chart – the feeding guide to know how much to give him. Although when I changed the formula, before I gave it to him I read everything*."

Paradoxically, another participant, in relation to the contents-related information on the tins, stated that; "*I think sometimes what you need is assurance – a lot of the information I don't look at because I actually don't want to know – that's why I generally don't look at anything other than the feeding guide. Somebody decided there was good stuff in it, and having a range actually requires you to make a decision."*

Most also knew there was an expiry date on the tin.

One participant stated that she reads the 'safety' information.

"*And the safety information – like discard after 4 weeks and discard unused milk after a feed. Yeah, things to do with safety…"*

A self-confessed 'label reader' stated "*Probably the only thing I take in first is how many feeds, how much they should be taking*." Another participant who also "read everything" stated that for her the key messages were "*hygiene and what formula to get for age of baby."* This participant also said that once she'd read the tin she didn't read it again.

Participants also talked about information from (a) a pamphlet that came with the formula:

"My formula had a little thing under the lid and if you wanted more information you could send away, so I did, and they sent me this really cute book as a present and little sensor and a

whole lot of information about their formula , and about putting formula with solids and - it was full of information and I thought every brand should have that- it was really good information; it had recipes to use, like when he goes on solids. So that was really cool."

And (b) websites that they got off the tin:

"I got the website from the tin."

3.3.1.1 Degree of trust- formula tin

There was a high degree of trust from all participants in the information provided on the tin. Some of the statements that indicated trust included:

"*This is a 'legal document' written by experts - I'm really worried if I'm not doing what the tin says.*"

"*The tins don't lie*"

"So I really trusted what was on the tin and the guidelines."

Participants also trusted the information from websites they accessed from the tin. These websites were differentiated from other kinds of information available via the internet.

"*What I take for gospel is manufacturers' websites*"

"Proper websites – not blogs."

3.3.2 Family and friends

Most participants stated that they got information and/or advice from family and friends. For one of the caregivers, her mother was the most important provider of information about how to make up the formula, followed by other relatives, especially those who had children.

"I do what Mum says – and I think it's right. She's the one that taught me how to make it up, and I trust her, she's my mother."

Others also talked about family – sisters, sister-in-laws – and/or friends who had children and/or babies around the same age.

[I get information] *"from my sister - she was a year older than me. From friends as well - a friend of mine had a baby."*

"And I think probably my sister-in-law – she had feeding issues around that time and she was 4 months ahead, I talked to her about that and she was the one that let me in on some tips for - how to be mobile with bottles and all that."

"There was also – a lot of our friends had children so they gave advice."

"I had a friend who's had a couple of children and I used to watch her …"

3.3.2.1 Level of trust – family and friends

Apart from the young mother quoted at the beginning of this section who trusted her mother absolutely, most of the other participants saw information and/or advice offered by family and friends as something they could choose to use or not, depending on their evaluation of its relevance to them. The trust in this information/advice was also influenced by the manner in which it was offered; participants did not appear to respond to being *told* what they should do, whether the information/advice came from family members or friends.

"I've got friends who don't like to tell you what to do so you didn't get that – it was advice but it wasn't advice."

"I take the advice that I think suits us best. I take from what people say – well what we need."

"*We say thanks for the advice and we either ignore it, or try it and see what happens*; *I don't take any of my mother's advice – we have more information*"

"*My friends know they have to turn any advice into something funny to get me to change something they might think is a problem*."

3.3.3 Other informal groups and/or other organisation-based sources of information.

Some participants had attended (or were attending) "coffee groups" that usually originated from attending antenatal classes, or mothers' groups set up through Plunket. Other women in these groups who were formula feeding were also seen as sources of information or advice, but these were in the minority and those women who were formula feeding did not feel as though they fitted into these groups, where most mothers were breastfeeding.

"And in our group most of them were breast feeding but there was one other who was bottle feeding and we could talk together about …"

"In my coffee group there was this one girl I didn't get on with and I get on with most people – but we didn't gel and all of a sudden she said to me - "I wouldn't say it out loud but I was always anti bottle feeding", but then she got mastitis and had to, and now those who are formula feeding in our group come to me for advice because they've got no-one else to go to."

"Out of the 15 women there were 2 of us who were bottle feeding and I'd try and hide in the corner with my thickened formula and that was - that was really hard, but now most of them are about 6 months and most of them are formula feeding anyway, so…"

Other organisation-based sources of information and/or advice included parents' centre and early childhood centres where one of the participants worked.

"I am also in the early childhood industry so I asked a number of people. I think being around – making up bottles and being around parents and stuff, I just asked. I didn't have

many friends who had had children, so it was mainly staff at my centre and other parents, and just reading the tins as well."

3.3.3.1 Level of trust – other informal groups

Information from coffee groups, etc. appears to be treated in a similar manner to information from family and friends – it will be reviewed as to usefulness and trialled if it appears useful.

3.3.4 Health professionals

The majority of participants had quite a lot to say about information and/or advice provided by health professionals. Health professionals that provided information/advice to participants included midwives, Plunket nurses, general practitioners (GPs) and specialists. While some participants had positive experiences when seeking information or advice, these experiences were relatively few; most talked about the unwillingness of health professionals to provide either information or advice on formula feeding because they saw this as compromising the message that breast-feeding is better, and/or they could not be seen as providing brand-related advice.

"My midwife certainly wasn't encouraging the whole formula thing the first time round."

"I got information from the midwife – but she prefers you to breastfeed."

"The stigma attached to it [formula feeding] – and I think that's what I'm really annoyed at."

"*The only time I felt guilty was when I was in hospital and I had* [a medical condition] *and I was so stressed that I didn't make milk and they didn't give me formula. I tried expressing and nothing was coming out, so - forget it, but they didn't like getting it* [formula] *for me*."

"*Well one of the dads in our group – they just wanted to know about sterilising. I mean even though I assumed I would be breast feeding I assumed I would also express so my husband could feed him now and then, but she wasn't even allowed to say anything about that. And he said – oh but my wife's going to breast feed, I'm only going to feed him now and then and she said – I can't really say anything about sterilising bottles*"

It appears that participants did not think there was a lack of available information or advice, but that health professionals did not provide it willingly. This appeared to significantly impact on first-time mothers who formula fed their babies from birth.

"The thing though with Plunket, the unfortunate thing is that you don't go until the baby is six weeks and six weeks is a long time to go without advice if you don't really know what you're doing."

A number of participants who started off breast-feeding then had changed to formula feeding were, by then, seeing the Plunket nurse, or belonged to coffee-groups that were set up through ante-natal classes, or had family or friends with babies as a resource for accessing information or advice. However, for those participants without these latter non-health professional resources, information and/or advice from health professionals (and the

information on the tin) appeared to be very important in order to reduce anxiety and provide reassurance.

"I think the first time round I really trusted the Plunket nurse because I think, that's their job so they must know what they're talking about, so – I was taking their advice because that was their profession and I didn't really have any friends or family that had children so I didn't have a lot of people. I think definitely because it was the profession that I trusted."

"I went to the Plunket nurse down here and she was really good because I was struggling big time, and she said at the end of the day we have to do this right."

"… and at 6 weeks my GP said I think you're getting post-natal depression and you need to stop breast-feeding and since [infants name] been on formula everything's not entirely better but I think I've changed my views a lot, and if I have another child I'm not going to feed."

One of the major issues related to **when** mothers could access professional help. Participants who bottle-fed from birth wanted professionally-given information or advice from birth, and this appeared to be lacking. Those mothers who commenced bottle-feeding after a relatively short time of breast-feeding (up the baby was three months of age) also valued advice from professionals, but these mothers were usually attending Plunket or had visited their GPs and received information or advice that was useful in the transition from breast feeding to formula feeding.

3.3.4.1 Level of trust – health professionals

There was a high degree of trust in information/advice from health professionals (midwives, plunket nurses, general practitioners or specialists) **when information/advice was provided.**

"Endorsement from health care professionals is what I'll listen to."

"We got a reasonable amount of information from the hospital midwife who let us know what brand of formula they used and we just continued with that."

"… it was my Plunket nurse that suggested the thickened formula which actually did work. We had a good Plunket nurse …"

"I think I was really lucky to have that Plunket nurse. My midwife certainly wasn't encouraging the whole formula thing the first time round. It was my Plunket nurse – she was great".

"I really trusted my GP - they made it feel as though bottle feeding was as normal as breast-feeding."

Only one participant stated that her midwife did not have the information to provide.

"*The midwife just had no idea; she didn't even know how much formula she should have*."

It appears that participants trusted the information and/or advice even when they were aware that the health professional they approached promoted breast-feeding. However, knowing that health professionals are likely to – and do - actively promote breast-feeding seems to be a barrier for those mothers who are either formula feeding from birth or who change to formula feeding before the baby is three months old. The trust exhibited by the latter group of mothers may, in part, be due to the support received, rather than the quality of information or advice per se, as indicated by the narrative below:

"I think I had pretty rough time since he was born, and I think what happened was that he was breech and I had an elective caesarean, and I think, I just thought I could breast feed from my friends who had had babies and from my ante-natal classes and from my midwife. And then I realised I had real issues with breastfeeding and I'd been to a breastfeeding 'course' and I'd read so many books and I went to a lactation consultant in the first couple of weeks and everyone was telling me you're doing it right, everything's perfect, but I had this immense pain. It was never diagnosed but it's some sort of pain and I saw a naturopath and saw my GP and at 6 weeks my GP said I think you're getting post-natal depression and you need to stop breast-feeding. And since [*infant's name*] *been on formula everything's not entirely better but I think I've changed my views a lot, and if I have another child I'm not going to feed*."

The reluctance of mothers to approach health professionals who they know are going to give them the breast-feeding message, means that the information on the tin – as a source of trusted information is important.

3.3.5 Other internet and written advice

Some participants accessed information from internet sources other than those provided on the tin. One participant used Google and entered 'baby formula' because she stated that she was "*dubious about everything that is pro or anti different kinds of feeding*."

Other written information was accessed via written material such as books and pamphlets.

3.3.5.1 Level of trust – other internet and written advice

These sources of information were used in a similar way to information or advice provided from family and friends – if participants thought it might be useful they would trial the advice, and then evaluate its effectiveness for their situation.

3.3.6 Information sources – caregiver's ideal

The following section lists **what** participants would like to know, and **from where** they would like to access information and advice.

What participants would like to know

- If there are formulas that are better for babies with particular problems – e.g. constantly spilling or vomiting, allergies, particularly hungry.
- How to sterilise bottles and other feeding equipment (also relevant for breast-feeding mothers who express to enable someone else to feed the baby).

- Why there are differences between formula (for same age of baby) – content, instructions regarding preparation and storage.
- Where they can get information on bottle-feeding.
- Why health professionals say they cannot give new mothers advice about formula feeding.

Where they would **like** to get **early** information

- Health professionals including hospital and independent midwives, GPs, Plunket, parents' centres and/or other organised groups focusing on parenting and childcare.
- In pamphlet form – in the pack mothers get when they have the baby; in medical and from other organisational centres, such as Plunket, parents centre, early childhood and day care centres.

3.3.7 Information sources – conclusions

Caregivers access a wide range of formal and informal sources of information. As most mothers approach birth with an intention of breastfeeding, information on preparation of infant formula is often not sought and generally not provided until the point in time when it is immediately needed.

Caregivers are typically information hungry and access to information on infant formula, in general, and preparation, in particular, was usually less than caregivers required. Information on infant formula tins was viewed as available, authoritative and trusted and was the major information source for most caregivers. Information from health professionals was valued and trusted, when it was provided, but in many cases the health professional available at the time was unwilling or unable to provide the necessary information. According to caregivers involved in the current study, a number of health professionals believed they were 'not allowed' to provide information on formula feeding.

Information from family, friends and other informal sources tends to be reviewed and accepted if it is found to be useful, although for some caregivers their family is **the** source of information.

3.4 Facts About Infant Formula

Participants were presented with a fact board, listing ten facts related to powdered infant formula (see Appendix 2). The primary intent of the fact board was to test the participants' knowledge of and concern about the non-sterile nature of powdered infant formula. Two of the ten facts (4 and 5) describe non-sterility using different wordings.

This section of the focus group was generally surprising for the lack of surprise or concern about the non-sterile nature of powdered infant formula.

"*No – it's* [statement of non-sterility] *on the tin*"

"*I knew as soon as it was open it's not sterile*"

"*No, it's come through a factory – it's not come from us"*

"*I assume it's not sterile to start with so as soon as you open it, that's the worst it's going to get*"

Two participants commented on fact 6, which states that most infant formula is made from cows' milk powder. Confusion on this point appears to relate to good knowledge on when cows' milk should be introduced into the infant diet as a food (>1 year).

"*Made from cows' milk powder – they say not to give infants normal cow's milk because they could be allergic –I assumed that infant formulas weren't – don't know what they were*"

A further fact (7) was included to gauge responses to a further risk management step that has been included in WHO guidelines (World Health Organization, 2007). This step (preparation of formula with water at greater than 70ºC) was also included in the first draft of the recent revision of the Ministry of Health's Food and Nutrition Guidelines for 0-2 year olds, but was excluded from the final guidelines (Ministry of Health, 2008).

Fact 7, relating to making up infant formula with water at greater than 70ºC, created considerable discussion in one focus group. Participants felt that this practice would be impractical, particularly for night feeds and feeds given away from home. They also commented that this would require water to be boiled for every feed, rather than the most common practice of boiling water once per day and storing in bottles or a sterile container.

3.4.1 Infant formula facts – conclusions

This exercise was designed to introduce discussion on the non-sterile nature of infant formula, without this topic dominating the whole focus group. In fact, the non-sterility of infant formula was virtually a non-issue with all focus groups.

Preparing formula with hot water was actively discussed in one focus group, with participants unanimously in agreement that this guideline was impractical and potentially dangerous, due to the risk of scalding. It should be noted that, after consultation, this practice has not been included in formula feeding guidelines for New Zealand.

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APPENDIX 1: DETAILED DISCUSSION GUIDE

DISCUSSION GUIDE: NZFSA Powdered Infant Formula

Caregiver Group Discussions

This Guide indicates the topics to be explored in the discussion, the suggested order in which topics will be covered and example questions and techniques which may be used. However, the focus group approach requires maintenance of flexibility and the actual format will depend on the particular characteristics of each group.

INTRODUCTIONS

- Facilitator to introduce self, explain the process for the session to respondents and the format of the discussion. The need for honesty to help with research and reassurance of confidentiality to be reiterated.
- Explain topic of discussion is their experience of formula feeding young babies of 0 – 6 months and in particular what **they know** and **how they use** powdered infant formula (PIF).
- Introductions: brief background details of participants (first name, family composition – first/subsequent children - ages, how they feel about infant feeding, etc)

WARM UP

Spontaneous associations and feelings are best captured through free association.

Powdered infant formula - word association exercise:

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

CURRENT PREPARATION, STORAGE AND USE BEHAVIOUR

It's important to understand the rationale for current behaviour and how this compares to the information and advice available. This will help formulation of communication strategies for new advice in order to ensure its accessibility and relevance.

Current Behaviour

How do you **usually** prepare, store and use powdered formula? Why do you do it this way? Under what circumstances do you do it differently?

PROBE:

- When are bottle made up (as needed/in advance/day of feeding/previous day) and how many bottles at a time – why?
- Is feeding equipment sterilised? Every time or only some times? Boiling (how long) or sterilising solution (kept for how long)?
- Do you wash hands before preparing formula (always/sometimes, how long)?
- Do you refer to and keep to manufacturers instructions on can (always/first time/occasionally)? Explore issues for non-English speakers.
- Do you use the manufacturers scoop to measure out formula? How do you measure a scoop full (mounded/levelled/packed)? How do you level and/or pack the scoop?
- Do you boil the water to make the formula? How long do you boil it for? How cool do you let it get before preparing formula?
- Do you add the formula to the water or the water to the formula?
- How do you bring the prepared formula to feeding temperature (hold under running water/ place in hot water/microwave)? How do you test the temperature?
- How long before feeding do you prepare formula?
- 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? Where/how do you store prepared formula?
- 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? Do you use the same technique for breastmilk as you would for formula (i.e. cleaning equipment, heating and cooling the milk)?
- Do you add anything other than formula and water to your baby's bottle?

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?

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: Specifically for formula feeding, for all sources including:

- All health care professionals – GP's, midwives, Plunket/well child providers, etc.
- Books/magazines/booklets/leaflets, internet, posters – what?
- 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 infant formula

- What are their strengths and weaknesses/your likes and dislikes of different sources of information?

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

Perceived Ideal Behaviour and Information Sources

If you were going to follow information and advice about powdered formula exactly, what would this be? What are the most important behaviours 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 do 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

- What, if anything, do you look at on cans/labels? Why/why not?
- When did you last look carefully at the information and advice written on the powdered infant formula 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?
- Do you pay attention to 'use by'? Would you use formula beypnd its 'use by' date?

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

- Discuss what is noted first/spontaneously

PROBE: key messsages
- What are the key messages?
- What makes them key for you?
- What makes the key messages more or less visible?

This will help us understand how accessible (and what the impacts are) on current information and advice – 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 INFANT FORMULA FACTS BOARD

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 infant formula

PROBE: perceptions of significance depending on age of baby/other influencing factors

Explain that whilst liquid infant formula is sterile that powdered formula 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.

Explain that powdered formula may be contaminated with bacteria during the manufacturing process or after opening in the home.

- Does this later the way you view powdered formula? Would this encourage you to take more care with handling, use and storage of powdered formula?
- Do you think that breastmilk is sterile or non-sterile?

Reassure that if advice is followed that the risk is minimal, so it's recognised that clearer information and advice is required.

Sterile/non-sterile - word association exercise

- 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?

Communicating Non-Sterile

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, well child providers, 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?

APPENDIX 2: WORKING FOCUS GROUP PLAN

Infant Formula Project: plan for focus group meetings

	What we will do	Approx timing
1	**Introduction** **Introduce team and our various roles** **Purpose**: Inform development of useful information about preparation and handling of powdered infant formula **How we're going to do this**: Their experiences of formula feeding their babies so really value their input **Tape and confidentiality** **How long we will take** **Housekeeping**: toilets, breaks etc. **Round robin introduction**: name, children/babies and baby's age	15-20 mins
2	**Quick warm-up exercise (everyone in group)** Thinking about feeding baby – what is the first thing that comes to mind?	10 mins
3 **Activity**	**Moving on to experiences**: **What you usually do** - how you prepare, store and handle PIF, what sorts of changes occur (and why) **Why you do it this way** – advice, information (Where, who, how) **What sources do you trust the most? And why?** **List sources of advice/info** For each recurrent source record this (stars) Beginning with the source that has the most stars ask what degree of trust they place in that source.	 30 mins 15-20 mins 10 mins 15 mins
4	**Labels** (hand out tins) **How do you read what's written on the can?** Scan/headings/ in stages? **What kinds of messages do you remember?** The how to, the why, what the formula contains?	 15 mins
5	**Facts board** Do any of these statements surprise you?	 15- 20 mins

	Why? (Pick up on anyone talking about sterility and follow-up with the group)	
6	**Wrap up and thanks** • Did they learn anything new from participating in focus group?	10 mins

APPENDIX 3: INFANT FORMULA FACTS BOARD

1. Powdered infant formula is intended to replace breast milk when mothers cannot or choose not to breastfeed

2. Powdered infant formula is formulated to provide adequate nutrition for babies fully or partially formula fed

3. The composition of powdered infant formula is specified in the Australia New Zealand Food Standards Code

4. Powdered infant formula is not sterile

5. Powdered infant formula is not free from bacteria (germs)

6. Most powdered infant formulas are made from cows' milk powder

7. Powdered infant formula should be made up with water that is not less than 70ºC – that is, water left no more than 30 minutes after boiling

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 as close as possible to feeding time