

Determining the Efficacy of Protocols Employed in Replacement /Artificial Feeding using Commercial Infant Formula in, Harare Zimbabwe

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ABSTRACT-*The study determined the efficacy of protocols employed in replacement/artificial feeding using commercial infant formula. The study was carried out in the different suburban locations of Harare, Zimbabwe. A sample size of 20 mothers/caregivers giving commercial infant formula to their babies at between 0-6 months was targeted; convenience and snowball sampling techniques were used to identify the participants. Interviews using a structured questionnaire were conducted and complemented by direct observation of the participants as they prepared the infant formula. The results were tallied against a checklist of recommended practices and label instructions. The results established that there were short falls in the preparation procedures as employed by the caregivers, mainly the mixing order of powder and water, temperature of the water for reconstitution and handling of left over formula after feed; 50 percent of caregivers were not adhering to the label instructions as given by the manufacturers and to recommendations proposed by World Health Organisation. Poor hand washing was indicative in 80 percent of cases, bottle feeding was predominant (n = 16) compared to cup feeding (n = 4) and the population practicing artificial feeding were mostly the young (90%), married (80%), educated (100%) and working group (90%). The researcher recommends that health providers strengthen efforts to ensure that adequate information /counselling and consistent advice of optimal benefit to the infant-mother pair be given and that the Ministry of Health and Child Welfare , Nutrition unit must strictly monitor the activities and the information given out by infant formula manufacturers as stipulated by the International Code of Marketing of Breastmilk Substitutes and also giving them the responsibility of following up on the appropriate use of their products.*

Keywords: commercial infant formula, infants, caregivers.

I. INTRODUCTION

Infant formula was developed in the 1920s to provide a medically acceptable alternative to breast milk for mothers who were not able to breastfeed their babies (Brown, 1973). According to the global strategy for infant and young child feeding of 2002, as a global public health recommendation, infants should be exclusively breastfed for the first six months of life to achieve optimal growth and development (WHO/UNICEF, 2003). However; some special or difficult circumstances may call for replacement feeding.

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Some mothers are unable to breastfeed, and others choose not to breastfeed, formula (Baby Friendly Hospital Initiative manual, or choose to combine breastfeeding with use of infant (2009). Use of infant formula has been cited for numerous increased health risks (FAO/WHO, 2006). It was noted that infants who consumed formula were at increased risk for acute otitis media, gastroenteritis, severe lower respiratory tract infections, atopic dermatitis, asthma, obesity, type 1 and 2 diabetes, sudden infant death syndrome (SIDS), eczema, necrotizing enterocolitis, autism, lowered I.Q and neuro developmental delays when compared to infants who were breastfed (Riodarn,1997). In underdeveloped countries, it is claimed that, these conditions are not available that is hygiene is lacking, sterilization procedures are not employed, and mothers lack the education to read written instructions (Li Ma et al, 2009).

II. THEORATICAL FRAMEWORK

Commercial infant formula

Infant formula is a manufactured food designed and marketed for feeding to babies and infants under 12 months of age, usually prepared for bottle-feeding or cup-feeding from powder (mixed with water) or liquid (with or without additional water). The U.S. Federal Food, Drug, and Cosmetic Act (FFDCA) defines infant formula as "a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk"(Food and Drug Administration (FDA), 1989). Powdered infant formula (PIF) is not a sterile product and may be intrinsically contaminated with pathogens that can cause serious illness in infants (i.e., children aged <1 year). Powdered infant formula (PIF) has been associated with serious illness and death in infants due to infections with *Enterobacter sakazakii* (WHO, 2007). During production, PIF can become contaminated with harmful bacteria, such as *Enterobacter sakazakii* and *Salmonella enterica* (Iversen et al, 2004).

Types/forms

- Products for Term Infants
- Products for Preterm Infants
- Products for Infants with Metabolic Disorders and Other Special Populations
- Products for Older Infants



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Reasons for using infant formula

- The mother's health
- The baby is unable to breastfeed
- Personal preferences and beliefs
- Absence of the mother
- Financial pressures
- Social pressures
- Lack of training/knowledge
- Lactation insufficiency

Associated risks of infant formula when compared to breastfeeding

- Diarrhea
- Malnutrition
- gastroenteritis
- severe lower respiratory tract infections
- atopic dermatitis
- asthma
- obesity
- type 1 and 2 diabetes
- lowered I.Q and neuro developmental delays

III. METHODOLOGY

Qualitative research was used. Face-to-face interviews using a semi structured questionnaire and overt observation techniques were employed. A checklist was used to evaluate the infant formula usage patterns against the recommendations and to determine gaps in usage. Non probability sampling methods namely the snowball and convenience methods were used to identify participants as statistics on mothers/caregivers using replacement/artificial feeding were unknown. A sample size of 20 was used and the inclusion criteria centered on purchase/inquiry of the starter infant formula (pharmacy context), consent to participate and caregivers of infants fed on formula from 0-6months of age (with or without complementary food) from Harare, Zimbabwe. The tools focused on getting data on socio-economic demography, infant information, preparation and feeding practices, and hygiene and handling. A pilot testing of the questionnaire was done to test suitability of the tool and adjustments made accordingly. Data was collected and presented in narrative, descriptive and pictorial analysis.

RESULTS

Socio demography

The majority (75percent) of the mothers/caregivers giving commercial formula to their infants were between the ages of 20-30years. The lowest education status reached was secondary school with 90 percent having gone through tertiary education. The percentage of working mothers was 90; employed as either full time, part time or self-employed only 10 percent were unemployed. 80 percent of the mothers/caregivers were married and 20 percent were single. The mothers to whom the present infant was the first child was 50 percent while those who had previous children represented the other 50 percent of the whole sample. Table 1 below shows the socio-demographic characteristics of the participating mothers (n=20).

Table 1: Socio-demographic characteristics

Variable	n	%
Age: years		
20-25	13	65
26-30	5	25
31-35	2	10
36-40	0	0
Highest education obtained		
Primary	0	0
Secondary	2	10
Tertiary	18	90
Marital status		
Married	16	80
Single	4	20
Employment status		
Full time	8	40
Part-time	4	20
Self employed	6	30
Unemployed	2	10
Number of children		
One	10	50
Two	9	45
Three	1	5
Four plus	0	0

Infant Formula Preparation Procedures

Table 2: Recommended steps for making infant formula

Recommended Step		Yes		No	
		n	%	n	%
1	Clean and disinfect a surface on which to prepare the feed.	11	55	9	45
2	Wash hands with soap and water, and dry using a clean cloth or a single-use napkin.	20*	100	0	0
3	Boil a sufficient volume of safe water. If using an automatic kettle, wait until the kettle switches off; otherwise make sure that the water comes to a rolling boil.	17	85	3	15
4	Pour the appropriate amount of boiled water that has been allowed to cool to no less than 70 °C, into a cleaned and sterilized feeding cup or bottle.(water should be left for no more than 30 minutes after boiling)	11	55	9	45
5	To the water, add the exact amount of formula as instructed on the label.	10	50	10	50
a	If using bottles; Shake or swirl gently until the contents are mixed thoroughly,	16	80	4	20
b	If using feeding cups: mix thoroughly by stirring with a cleaned and sterilized spoon	4	20	16	80
6	Immediately after preparation, quickly cool feeds to feeding temperature by holding the bottle or feeding cup under running tap water, or by placing in a container of cold or iced water. Ensure that the level of the cooling water is below the top of the feeding cup or the lid of the bottle.	16	80	4	20
7	Dry the outside of the feeding cup or bottle with a clean or disposable cloth.	20	100	0	0
8	To ensure the formula has cooled appropriately, let a few drops fall out on your forearm. The baby formula should feel warm on your arm, but not hot	19	95	1	5
9	Discard any feed that has not been consumed within two hours.	10	50	10	50



*All care givers washed their hands but the majority (80%) did not use soap, just water.

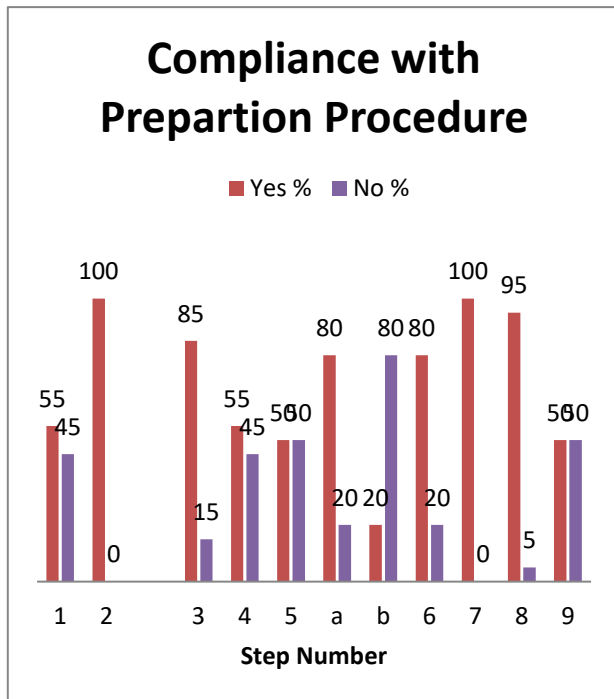


Figure 1: Compliance with the recommended infant formula preparation procedures

Handling and Hygiene during preparation of infant formula (step 1 and 2)

Although all participants washed their hands as indicated in table 2 only 20 percent managed to follow the full procedure of using soap every time they washed their hands hence the score of average for 80 percent of the participants who only used water to wash their hands as indicated in figure 2 below. As can be seen in figure 1 above, 55 percent of the participants wiped the preparation surface with a wet (50%) or dry (5%) cloth before starting the preparation process. However on observation 45 percent just went straight to preparation without wiping the surface.

Temperature of water for reconstitution (Steps 3 and 4)

85 percent of participants got step three correct as indicated in table 2 and figure 1 and 15 percent (n=3) failed to follow the boiling procedure, two of these were using the electric kettle and did not wait for it to turn off by itself instead they removed it when it started to boil and the one using the stove removed the water when it started to show bubbles instead of the rolling boil. As for step 4 depicted in figure 1, fifty five (55) percent got the procedure correct by waiting for not more than 30 minutes for the boiled water to cool and 45 percent used the water while boiling thus did not wait for it to cool.

Equipment used for formula feeding (bottle vs. cup)

80 percent of the participants used bottles with teats for feeding the commercial infant formula and 20 percent used the cup as shown in table 2.

Use and storage of infant formula (steps 6-9)

In the study 80 percent of the mothers managed to follow the procedure of quickly cooling the formula after the addition of the hot water by placing in a dish full of cold water while 20 percent left the bottle to cool at room temperature. All participants as can be seen in table 2 dried the cup and bottle on the outside with a dish towel. 75 percent (signifying the total participants giving formula while warm) tested the temperature on their palms while 25 percent did not test the temperature as they fed the formula at room temperature.

Dilution of infant formula

Nan 1, Lactogen 1 and S26 commercial infant formulas instruct that water must be measured first, then an exact amount of powder (as indicated on the tin and measured by the scoop provided with the tin) be added to the water before mixing. In this study 50 percent of participants' added powder to water and the other 50 percent added water to powder. Five percent of the mothers (n=1) used an electric balance to measure the powder and 10 percent of the mothers (n=2) used a rounded scoop measure instead of the level. Water measurements were done using the measuring jug (n=9), the feeding bottle (n=10) and a tea cup (n=1).

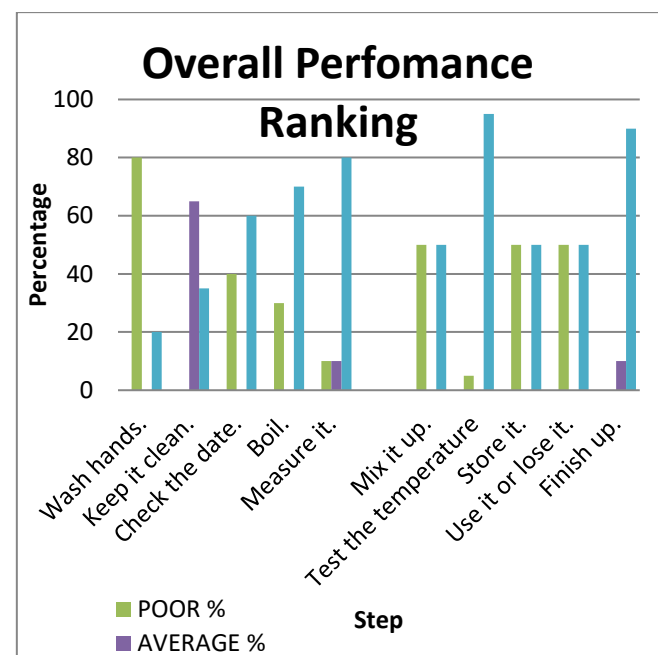


Figure 2: Overall performance ranking of formula preparation procedures

Water and Sanitation

Cleaning and sterilizing feeding and preparation equipment

30 percent washed their hands before cleaning equipment and 70 percent did not wash their hands as they did not see the rationale behind the procedure, the assumption was that their hands would be cleaned in the process of washing and sterilization of the equipment thus it was perceived as an unnecessary step.

In the sterilization step ,25 percent of the mother/caregivers (n=5) used chemical sterilizer,25 percent immersed the equipment in boiling water for a few minutes and another 25 percent boiled the equipment in a large pan full of water and the remainder just followed the normal washing procedure using dish washing liquid. 90 percent of the caregivers removed and dried the utensils soon after the sterilization process to put away in the cabinet instead of keeping them in the sterilization equipment until required for the next feed. 35 percent remembered to wash their hands before removing the equipment from the cabinet in preparation of the next feed and the rest did not wash their hands then.

Water sources and safety measures

In the study caregivers were asked to rank the availability of water and sanitation within their households, 20 percent ranked it as poor, 50 percent as average and 30 percent ranked it as good. The availability of adequate water and sanitation is one of the prerequisites in meeting the Affordable, Feasible, Acceptable, Safe and Sustainable (AFASS) criteria as a condition for initiating successful replacement feeding using commercial infant formula (UNICEF, 2010).80 percent of the participants used boiling as a safety measure, 10 percent used aqua tabs/water gaurd and the remainder did not perform any measure to ensure water safety.

Feeding practices

Adequacy and frequency of feeds

40 percent of the infants (0-6months) were being given both breastmilk and commercial formula; the other 40 percent were on breastmilk and commercial infant formula as well as complementary foods with the remainder (20 percent) on exclusive commercial formula. As such adequacy could only be determined for the percentage on exclusive replacement feeding as the amount of breastmilk and complementary foods given was out of the scope of this study. Twenty five percent of infants (n=1) on exclusive replacement feeding received the adequate amount of formula per day, 50 percent (n=2) received and inadequate amount of formula and the remaining 25 percent were getting an excess amount of formula per day.

Active /responsive feeding

In the study the mother of the infant, the maid and close relatives (sisters and aunts) fed the infants. The mothers only fed their babies when they were at home and the maids and relatives took up the responsibility in the absence of the mother. It was established that adequacy at each feed was deduced by refusal to continue feeding, spitting or vomiting.

Label Instructions

Reading and following instructions

Half of the participants got the mixing of powder and water procedure wrong. As per instruction water is measured first then the measured powder placed into the water and mixed thoroughly for homogeneity. As for the temperature of water for reconstitution the instruction is to leave the boiled water to cool for no more than 30 minutes or to prepare the water approximately 30 minutes before reconstitution. However 45 percent mixed the water soon after boiling the reason

being that it made the mixing easier as the powder quickly dissolved.

IV. CONCLUSIONS

The study found that there were short falls in the preparation procedures as employed by the caregivers, mainly the mixing order of powder and water, temperature of the water for reconstitution and handling of left over formula after feed procedures. This showed that caregivers were not adhering to the instructions as given by the manufacturers. This compromises the safety and nutritional adequacy of a formula feed making the infant more susceptible to diarrheal diseases and malnutrition. Poor hand washing procedures were identified prior to preparation of the infant formula and during the cleaning and sterilization of feeding equipment. Hand washing using the correct procedure is very crucial at every stage considering that at this stage there is a lot of dirty nappy handling and the chances of cross contamination are very high, thus increasing the vulnerability of the infant to infection. The majority of the caregivers used bottles with teats for feeding as opposed to cups, sighting the reasons that it was easier to feed with a bottle than a cup and that cup feeding was tedious and messy. Cup feeding is recommended for hygienic reasons, it is easy to clean and impossible to keep left over formula for a prolonged duration unlike bottles which are difficult to clean on the crevices and encourage the keeping of left over formula for a greater duration, thus spoilage.

The majority of the mothers giving infant formula were educated working mothers, with tertiary education thus indicative of having good jobs and a good income which might have influenced the decision to give infant formula. Young mothers of one child composed half of the total sample size thus being a first time mother might be attributed to lack of knowledge on the benefits of breastfeeding, lack of support on breastfeeding making replacement feeding the easier option or modernization where giving formula is perceived as affluent. The main conclusion of this study is that there are some identifiable gaps between the protocols being employed by caregivers/mothers in the preparation of formula and those recommended by both the manufacturer and WHO which pose a risk to the health and development of infants on replacement/artificial feeding using commercial infant formula.

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