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Implementation of a HACCP system for on-site hospital preparation of infant formula

R.C.C. Almeida [a,*], C.O. Matos [a,c], P.F. Almeida [b]

[a] *Escola de Nutricao, Rua Araujo Pinho, No. 32, Canela, CEP 41 100-000 Salvador, Bahia, Brazil*
[b] *Instituto de Ciências da Saúde, Rua Araujo Pinho, No. 32, Canela, CEP 41 100-000 Salvador, Bahia, Brazil*
[c] *Universidade Federal da Bahia, Salvador, Bahia, Brazil*

Abstract

Hazard Analysis and Critical Control Point (HACCP) system was introduced to infant formula preparation rooms in four hospitals in Salvador, Bahia, Brazil. The homogenization of powdered milk and ingredients, refrigeration and holding steps before service were identified as critical control points (CCPs). Utensils and workers' hands were identified as sources of cross contamination. Educational training courses emphasizing food safety and good preparation practices were introduced to the personnel of the rooms. Corrective actions were adopted at the CCPs that were found to be out-of-control. Implementation of HACCP system improved infant formula quality by reducing total aerobic microbial counts in the formula, and on utensils and workers' hands of approximately 4.0, 3.0 and 4.0 log cycles, respectively. *S. aureus* and fecal coliforms were no longer found.

Keywords: Infant formula; HACCP; Hospital

1. Introduction

Infant formulas are liquids or reconstituted powders fed to infants and young children. They serve as substitutes for human milk. Infant formulas have a special role to play in the diets of infants because they are often the only source of nutrients for infants. For this reason, the composition of commercial formulas is carefully controlled and FDA requires that these products meet very strict standards.

Prepared infant formula is primarily water and non-fat cow's milk. Among other ingredients, it may include sweeteners, such as lactose, corn syrup or other sugars and fats, such as coconut and soybean oils. Vitamin and mineral supplements are typically universal additions. A few brands contain mono-and diglycerides, emulsifiers that keep the liquid from separating.

Formula preparation rooms are special rooms within the hospitals used to prepare and distribute infant formula, hydration and replacement fluids to feed newborns and infant patients. Standard techniques of hygiene and nutrition are necessary to assure food safety.

The routine operations in these rooms must be continuously monitored due to the potential risk for the infant patients. The evidence presented in earlier investigations showed that these rooms were in need of special attention, because of the potential risks in the transmission of foodborne disease agents (Sessa & Furlanetto, 1990).

According to Pessoa (1978), almost all infections in nurseries and pediatric rooms investigated in São Paulo, Brazil, were caused by enteric bacteria, mainly *Salmonella* and *Escherichia coli.* These microorganisms were also isolated from infant formula. The presence of *E. coli* in general is of concern because it can indicate the possible presence of enteric pathogens, such as *Salmonella, Shigella, E. coli* O157:H7, and others.

While some preparation of infant formula does not include a microbial destruction kill step, it is imperative to control all possible avenues through which the product can be contaminated. There are several potential sources of pathogens that affect preparation of infant formulas. Powdered milk and ingredients, equipment and employees are the most common sources of pathogens; however, dust, insects, pests, and anything that might come in contact with the food or food

* Corresponding author. Tel.: +55-71-235-2416; fax: +55-71-245-0587; e-mail: pfa@e-net.com.br

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preparation surfaces must be considered possible pathogen sources.

The HACCP system is recognized as effective in preventing and minimizing the risks of food borne illness (Bryan, 1988). This concept is based on a systematic investigation to identify, evaluate and control the biological, physical and chemical hazards associated with steps in the manufacture of a product. Controls are established and systematically monitored to prevent creation of a hazard (Bobeng & David, 1978; Bauman, 1990).

The main goals of this study were to improve good manufacturing practices (GMPs) and sanitation standard operating procedures (SSOPs) and to implement a HACCP system in infant formula preparation rooms in hospitals.

2. Materials and methods

2.1. Selection of infant formula preparation rooms

The infant formula preparation rooms were chosen among those that offered training to human nutrition undergraduate students in Salvador, Brazil. These facilities were designated A, B, C, and D producing 240, 420, 9, and 140 infant formulations per day, respectively.

2.2. Identification of critical control points

Infants formula-handling practices were evaluated for potential microbial cross contamination problems and infant formula-flow diagrams were drawn up and used to conduct hazard analysis. Potential physical, chemical, and microbiological hazards were identified for each preparation step. Microbiological criteria were used to develop a preliminary HACCP system and to provide reference values to evaluate the impact of the HACCP program after implementation.

The identification of hazards was carried out according to International Commission on Microbiological Specification for Foods (ICMSF, 1988), by examining the characteristics of the powdered milk and ingredients and evaluating the variables that could influence the safety of food. The CCPs were identified through application of the Decision Tree Approach (OMS, 1991) to unprepared and to ready made infant formula and to each step of the infant formula preparation.

2.3. Physical and chemical hazard evaluation

Prior to initiating processing operations, utensils and equipment were inspected visually for loose fittings. All sections of the facility were inspected by examining the sanitary conditions of the building, its communication with other rooms in the hospital, storage conditions of foods and material for cleanliness, presence of the foreign objects and the clothing of the employees (ICMSF, 1980). Infant formulas were inspected for chemical browning, caramelization or Maillard reaction. Time–temperature was checked during the process using an appropriate thermometer.

2.4. Microbial evaluation

Criteria were established using the parameters recommended for time–temperature in the cooking, refrigeration and holding of milk products. Microbiological standards to measure the presence of *Salmonella* spp., *Staphylococcus aureus*, *E. coli*, total and fecal coliform counts in powdered milk and dairy flour (Brasil, 1987), and in reconstituted dairy products to feed infants (Brasil, 1976) were used. International standard plate counts were used on utensils (Niskanen & Pohja, 1977; Solberg et al., 1990) and environmental air (Sveum, Moberg, Rude & Frank, 1992). All media and broth used for this research were obtained from Difco Laboratories (Detroit, MI).

The samples of foods, utensils, hands and environmental air were taken in triplicate 7, 5, 5 and 4 times in the formula preparation rooms A, B, C and D, respectively.

Foods. Triplicate aliquots of 100 g of unprepared and ready made infant formula were aseptically collected in the preparation rooms. They were transported to the laboratory in refrigerated containers and analyzed immediately. The samples were investigated using standard procedures for the presence of *Salmonella* spp. (Flowers, D'aoust, Andrews & Bailey, 1992), standard plate count (Swanson, Busta, Peterson & Johnson, 1992), fecal coliforms and *E. coli* (Hitchins, Hartman & Todd, 1992) and *S. aureus* counts (Lancette & Tatini, 1992).

Air sampling. Air samples of the facilities environment were analyzed using the sedimentation method described by Sveum et al. (1992).

Utensils. Samples of nursing bottles, cups, blender cups and sieves were collected prior to infant formula preparation using the polyurethane sponge method (Quevedo, Lasta & Dinelli, 1977). Standard plate counts were determined using the procedures described by Swanson et al. (1992).

Hands. The hands of the workers who handled the foods were evaluated before and after handling. Samples were collected using the polyurethane sponge method (Quevedo et al., 1977). Standard plate counts were determined as above. *S. aureus, Salmonella* spp and fecal coliform/*E. coli* were determined using the same procedure for foods, after homogenization of the sponges with 100 ml of peptone saline solution.

2.5. Educational training

Food safety, hygiene and good manufacturing practices (GMPs) were introduced using videotape, lectures and team work. The videotape "Food Without Fear" in its Portuguese version, i.e., "Alimentos sem medo", was used [1]. This tape emphasized the relationship between personal hygiene and microbial contamination of foods. The lectures deal with "Safe Food Processing" focusing on hygiene and microbiological principles. After the lectures, the staff was divided into small work groups. Discussion about major problems in the infant formula preparation room and suggestions for improvement were prompted.

2.6. HACCP implementation

After the introduction of GMPs, HACCP was implemented in formula preparation rooms. The steps of the preparation of infant formula, such as homogenization, refrigeration and holding, were identified as critical control points (CCPs), since written sanitation standard operating procedures had not been developed at these facilities. Nursing bottles, cups, blender cups, sieves and employees' hands were sources of microbial cross contamination of foods. Corrective actions were adopted at the CCPs out-of-control; controls were established and systematically monitored to prevent the creation of a hazard.

2.7. Cleaning and sanitizing

These steps were monitored by visually inspecting for organic material after cleaning and sanitizing utensils. The cleaning was conducted by a system of three sinks (ICMSF, 1980). The sanitizing was carried out by immersion in sodium hypochlorite solution with 250 ppm of the available chlorine, soaked per 30 min, and dried by air in a clean place (Almeida, Kuaye, Serrano & Almeida, 1995b; Brasil, 1994).

Floors and work surfaces were cleaned and sanitized at least once a day and walls once a week. In these places sanitation was carried out with sodium hypochlorite solution with 500 ppm of available chlorine (Brasil, 1994). The total available chlorine concentration was determined by Richardson's method (Richardson, 1985).

Verification procedures relied on total plate counts for sponge sampling of utensil surfaces, and on plate technique sampling of environmental air.

2.8. Personal hygiene

Sanitation supplies and equipment, including foot-operated hand-washing sinks, trash cans with lids, sterile aprons and special shoes, disposable gloves, disposable masks and sanitation agents, were obtained and introduced in rooms. Antisepsis of the hands of the employees were carried out with an iodophor solution with 100 ppm of available iodine, according to the procedures described by Almeida, Kuaye, Serrano & Almeida (1995a) and Sheena and Stiles (1982). The total available iodine concentration was determined by Richardson's method (Richardson, 1985). In some facilities germicidal hand wash products [2,3] were used.

Verification procedures relied on sponge sampling of hand surfaces for total plate counts, *Salmonella* spp., *Staphylococcus aureus*, fecal coliforms/*E. coli*.

2.9. Monitoring time and temperature

The time and temperature used in the preparation of infant formulas were monitored by immersing a thermometer into infant formulas during the steps of homogenization, refrigeration, re-heating and holding. The time and temperature were monitored at least twice during the process. The ingredients of the infant formulas were homogenized with hot water (80–90°C) for 2 min and distributed in nursing bottles. The nursing bottles contained the formula were held at room temperature for 30 min before service, or chilled into current water and refrigerated (2.0–4.0°C) for 4 h. Reheating was conducted until the formula reached 71°C. In room B, the step of the terminal sterilization was eliminated to avoid caramelization or Maillard reaction in infant formula.

Samples of the unprepared and ready made infant formula were taken and analyzed using the same procedures as before the adoption of the corrective actions. Samples of water used in the hydration of the powdered milk and ingredients were taken and analyzed for total plate counts and fecal coliform by the multiple tube technique according to American Public Health Association (APHA, 1980).

The effectiveness of the installation of sanitation equipment, food-safety training sessions and implementation of the HACCP systems was evaluated by decimal reductions obtained from the microbiological counts.

[1] Diversey–Lever Laboratories, Av. De Pinedo, 401, Socorro, São Paulo, SP, Brasil.

[2] Bac Stop, Diversey–Lever laboratories, Av. De Pinedo, 401, Socorro, São Paulo, SP, Brasil.

[3] Microsshild, Johnson–Johnson laboratories, Rod. Pres. Dutra Km 154, s/n, Jardim das Indústrias, São José dos Campos, São Paulo, Brasil.

3. Results and discussion

3.1. Evaluation prior to implementation of HACCP

Infant formula preparation room A used the following formulations: whole powdered milk, corn starch, water and sugar; whole powdered milk, cereal, sugar and water; partially skim powdered milk, whey, soybean milk, corn starch, medium chart triglycerides, sweeteners and water. In room B, whole powdered milk, corn starch, rice flour, sugar and water or whole powdered milk, sugar and water were used. In room C, partially skim powdered milk, whey, and water were used and in room D whole powdered milk, cereal and water.

The levels of contamination of the unprepared infant formula were low, according to the microbiological standards for powdered milk and dairy flour (Brasil, 1987). Therefore these foods were considered safe. The samples of ready made infant formula from room A and D, respectively, show that 14% and 25% had aerobic plate counts higher than those suggested for reconstituted dairy products to feed infants, 5.0×10^4 CFU per ml (Brasil, 1976). The fecal coliform counts were higher than the microbiological standards, 10 per gram, in 28% of the samples from room A ($>2.4\times10^4$ MPN/g) and positive for *E. coli*. In room D, 25% of the samples had fecal coliform counts about 2.1×10^2 MPN/g and *S. aureus* counts about 2.0×10^2 CFU/g. *Salmonella* spp. were not isolated from samples in those rooms.

On investigation of utensils, the sieves had the highest total aerobic counts, 2.9×10^5 CFU/cm^2 in room A; nursing bottles, 4.5×10^4 CFU/cm^2 and 5.6×10^4 CFU/cm^2 in room B and C, respectively, and blender cups, 1.3×10^2 CFU/cm^2 in room D. According to Solberg et al. (1990) and Niskanen and Pohja (1977), 83% of utensils from room A; 77% from room B; 40% from room C and 33% from room D were not safe for contact with foods.

In general, microbial samples collected from workers' hands, during preparation operations presented high aerobic plate counts mean, 1.8×10^6; 3.7×10^5 and 3.1×10^5 CFU/hand, in rooms A, B and C, respectively. In room D, the gloves used by employees showed 4.2×10^3 CFU/glove. High counts of fecal coliforms were found on the hands of employees in rooms A, $>2.4\times10^4$ CFU/hand and B, 1.5×10^3 CFU/hand. *E. coli* was isolated from samples in room A and *S. aureus* were isolated in rooms A, B and C (2.0×10^4, 7.0×10^3 and 1.1×10^4 CFU/hand, respectively).

The samples from environmental air in rooms A, B, C and D had higher aerobic plate counts than that suggested by Sveum et al. (1992), 3.0×10^1 CFU/cm^2/week. However, samples from laminar flow hood were satisfactory.

3.2. Evaluation after implementation of HACCP system

Total aerobic counts from unprepared infant formula had been satisfactory. However, the introduction of HACCP system reduced these counts (Table 1) and the ready made infant formula also showed decreased aerobic plate count, probably due to time-temperature control and the introduction of GMPs (Table 2). This reduction was about 3, 1, 2 and 2 log cycles for rooms A, B, C and D, respectively. Pathogenic microorganisms such as *E. coli* and *S. aureus* were not isolated from the samples. The samples of water were not contaminated by fecal coliforms.

Aerobic plate counts obtained from utensils, after cleaning and sanitation with sodium hypochlorite solution at 250 ppm, were reduced to <10 CFU/cm^2 and they were classified as acceptable or good for food preparation (Table 3).

By training personnel to wash their hands with liquid soap and antiseptic (iodophor), the aerobic plate counts were reduced after the implementation of HACCP system by 3 log cycles in three rooms investigated, A, B and C (Table 4). The workers from room D cleaned their hands with germicidal hand wash products. This procedure did not result in a similar reduction, but the microbial level on the hands was satisfactory. Pathogenic microorganisms investigated, *E. coli* and *S. aureus*, were not found on the hands after implementation of the HACCP system.

The procedure of the sanitizing of floor, walls and work surfaces and the control of the flow of people through the rooms improved the quality of the environmental air, and the samples analyzed had lower

Table 1
Mean aerobic plate counts in the unprepared infant formula, before and after implementation of HACCP system

Preparation room	Before		After	
	No. samples	Mean (CFU/g)	No. samples	Mean (CFU/g)
A	7	5.0×10^2	5	4.9×10^1
B	5	3.2×10^2	5	1.2×10^2
C	5	5.5×10^1	5	3.7×10^{1a}
D	4	1.0×10^3	3	1.3×10^2

[a] Two samples had counts <10 CFU/g, CFU/g-colony forming units per gram.

Table 2
Mean aerobic plate counts in the ready made infant formula, before and after implementation of HACCP system

Preparation room	Before		After	
	No. samples	Mean (CFU/g)	No. samples	Mean (CFU/g)
A	7	9.2×10^4	6	2.7×10^1
B	5	8.5×10^2	5	8.5×10^{1a}
C	5	3.2×10^3	5	3.4×10^{1b}
D	4	2.5×10^4	4	2.2×10^2

[a] One sample had count<10 CFU/g.
[b] Three samples had counts<10 CFU/g.

Table 3
Classification of utensils used to prepare the infant formula, in accordance with microbiological standards

Utensils	Before				After	
	No. of samples	Acceptable or good [a] (%)	Satisfactory or normal [b] (%)	Dangerous or not satisfactory [c] (%)	No. of samples	Acceptable or good [*] (%)
Room A						
Bottles	7	14	14	72	5	100
Sieves	5	–	–	100	3	100
Cups	6	17	–	83	3	100
Total	18	11	6	83	11	100
Room B						100
Bottles	5	20	–	80	4	100
Sieves	4	25	–	75	5	100
Cups	4	25	–	75	5	100
Total	13	23	–	77	14	100
Room C						
Bottles	5	–	20	80	4	100
Cups	5	40	20	40	5	100
Sieves	5	100	–	–	4	100
Total	15	47	13	40	13	100
Room D						
Bottles	4	50	25	25	4	100
Blender cups	5	60	–	40	4	100
Total	9	56	11	33	8	100

[a] <10 CFU/cm^2.
[b] 10–20 CFU/cm^2.
[c] >20 CFU/cm^2.

aerobic plate counts than before. However, these reductions were more significant when the laminar flow hood in room D was used (Table 5).

The presence of *S. aureus* and fecal coliforms in 25% of the samples from room D and fecal coliforms in 28% of the samples from room A in the ready made infant formula, before implementation of the HACCP, indicated that hospital staff needed to improve personal hygiene practices. Educational programs should be established to continually reinforce food-safety principles.

Given the special nature of the consumers of this product, infant patients, this food should be prepared in laminar flow hoods in an effort to minimize cross-contamination.

The implementation of HACCP system and GMPs improved infant formula quality by reducing microbial contamination in the formula, on the surfaces of utensils and on the workers' hands. For the HACCP system to be successfully implemented, all personnel should undergo food-safety training and get involved in the program.

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Table 4
Lowest, highest and mean microbial counts on workers' hands after implementation of HACCP system[a]

Preparation room	Counts	APC (CFU/hand)	*S. aureus* (CFU/hand)	Fecal coliform (MPN/hand)
A	Lowest	3.5×10^2	$<10^2$	<3
	Highest	7.9×10^3	$<10^2$	<3
	Mean	3.1×10^3	na	na
B	Lowest	$<1.0\times10^2$	$<10^2$	<3
	Highest	1.0×10^3	$<10^2$	<3
	Mean	2.8×10^2	na	na
C	Lowest	$<1.0\times10^2$	$<10^2$	<3
	Highest	4.3×10^3	$<10^2$	<3
	Mean	9.7×10^2	na	na
D	Lowest	1.9×10^3	$<10^2$	<3
	Highest	1.9×10^4	$<10^2$	<3
	Mean	5.3×10^3	na	na

[a] MPN/hand – most probable number per hand, na-not applicable.

Table 5
Mean aerobic plate counts from environmental air, before and after implementation of HACCP system

Preparation room	Before		After	
	No. samples	Mean CFU/cm^2/week	No. samples	Mean CFU/cm^2/week
A	7	1.9×10^2	2	2.1×10^1
B	5	2.0×10^2	3	1.1×10^2
C	3	1.7×10^2	2	6.8×10^1
D	2	1.1×10^2	1	3.0×10^1
D[a]	2	$6.7\times10^{\circ}$	2	1.4×10^1

[a] Samples collected on the laminar flow hood.

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