



Original/*Nutrición enteral*

Microbiological quality of enteral feeding and infant formula produced in dietary units, according to the triad of Donabedian

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Abstract

Introduction and aims: Microbial contamination of enteral feeding and infant formulas can result in a risk of worsening of the clinical condition of the patients, who are already weakened and susceptible to pathogens. The objective was to evaluate aspects of the management of quality hygienic - sanitary of enteral feeding and infant formulas in hospitals, focusing on the structure, process and outcome.

Methods: An observational, descriptive, prospective, with quantitative and qualitative variables study was done. The survey was conducted for 12 months and 227 samples of enteral feeding and 176 of infant formula were collected in Nutrition and Dietetic Services of Health Secretary / Federal District. In evaluating the operating conditions, the Tool 2 was applied to: Enteral Nutrition Preparation. Data were analyzed from the unified Donabedian's triad for evaluation of health services.

Results: The results obtained with the Tool 2 demonstrated that the Storage Block complies with legal requirements. Moreover, Dressing Block is a risk factor for the contamination. From the 403 samples, 56% corresponded to samples of Enteral Nutrition and 44% to samples of Infant Formulas. The data indicate that from 227 samples of Enteral Nutrition, 6.2% were in disagreement with the legislation, while from 176 samples of Infant Formulas, 4.6% were also in disagreement with the legislation.

Conclusion: The ineffective implementation of the sanitary and hygienic requirements during the preparation results in a microbiologically unsafe product to patients in debilitated health state, and the count of mesophilic microorganisms can be a good indicator of microbiological safety.

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Key words: *Donabedian. Enteral nutrition. Infant formula. Microbiological quality.*

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CALIDAD MICROBIOLÓGICA DE DIETAS ENTERALES Y FÓRMULAS INFANTILES PRODUCIDAS EN UNIDADES DIETÉTICAS, DE ACUERDO CON LA TRIÁDA DE DONABEDIAN

Resumen

Introducción y objetivo: La contaminación microbiana de dietas enterales y fórmulas infantiles puede conducir a una situación de riesgo de agravación del cuadro clínico de pacientes, ya debilitados y susceptibles a los agentes patógenos. El objetivo fue evaluar aspectos de la gestión de calidad de condiciones sanitarias de dietas enterales y fórmulas infantiles en los hospitales, centrándose en estructura, proceso y resultado.

Métodos: Fue hecho un estudio observacional, descriptivo, prospectivo, con variables cuantitativas y cualitativas. La encuesta fue por 12 meses y se recogieron 227 muestras de dietas enterales y 176 de fórmulas infantiles en los Servicios de Nutrición y Dietética de la Secretaría de Estado de Salud del Distrito Federal. Los datos fueron analizados a partir de la Tríada de Donabedian para la evaluación de los servicios de salud por medio de un cuestionario.

Resultados: Los resultados obtenidos muestran que en Bloque Almacenamiento cumple con los requisitos legales. Por otro lado, el Bloque Vestuario es un factor de riesgo de contaminación. De las 403 muestras, 56% eran muestras de Nutrición Enteral y 44%, muestras de Fórmulas Infantiles. Los datos indican que de 227 muestras de Nutrición Enteral, un 6,2% estaban en desacuerdo con la ley, mientras que de las 176 muestras de las Fórmulas Infantiles, 4,6% también estaban en desacuerdo con la legislación.

Conclusión: La falta de aplicación efectiva de requisitos higiénicos sanitarios durante la preparación resulta en producto microbiológicamente inseguro para pacientes debilitados, y el recuento de mesófilos totales puede ser un buen indicador de la seguridad microbiológica.

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Palabras clave: *Donabedian. Nutrición enteral. Fórmula infantil. Calidad microbiológica.*

Introduction

Enteral nutrition (EN) and industrialized infant formulas (IF) enable greater guarantee of nutritional quality and safety of products intended for hospitalized patients or not, for those in intensive care, post-surgical phase, and premature infants. It is also known that the microbiological quality of EN and IF may be an aggravation of risk situation of patients and can bring undesirable results, such as infectious complications. The literature suggests that enteric bacteria, especially *Salmonella sp.* and *Escherichia coli*, *Bacillus sp.*, *Staphylococcus aureus*, strict aerobic facultative mesophilic microorganisms are some of these species which may contaminate food products^{1,2}.

In the hospital environment, microbial contamination of EN and IF has a multifactorial origin and it is mainly related to the conditions of manipulation. It is generally associated with addition of contaminated ingredients, with improper sanitization of equipment and utensils as well as personal sanitization^{3,4,5}.

Donabedian's triad is used worldwide as a benchmark to assess the quality of health services⁶. According to this triad, the information of Structure, Process and Results dimensions from previously established criteria are analyzed to measure the level of quality achieved. The use of proxy indicators of these three categories allows establishing the level of quality achieved, the problems and faults occurred⁷.

Considering the gap in the literature about the impact of Structure, Process and Results dimensions in the quality of products for enteral nutrition and feeding of infants, the objective of this research was to evaluate the microbiological quality of enteral nutrition and infant formulas according to Donabedian's triad.

Methods

This project was approved by the Ethics Committee on Human Research of the State Health Department of Federal District - ECHR / SHD / FD, as Protocol 127/2012.

Type of study

Observational, descriptive, prospective study with quantitative and qualitative variables held from two strategies: the first consisted of collecting Enteral Nutrition and Infant Formula samples and the second, of the application of checklist in the production process.

Sample

To evaluate the structure and the production process of enteral nutrition (EN) and infant formula (IF), the sample universe consisted of all Dietary Units (DU)

of public hospitals of the Federal District (n = 14), hereinafter termed H1, H2, H3, H4, H5, H6, H7, H8, H9, H10, H11, H12, H13 and H14. Of these, six units offer highly complex procedures: H1, H2, H3, H8, H9 and H10.

Industrial products for EN and IF were used for microbiological analyzes prepared in their respective hospitals DU.

Strategy for sampling

In this study, we analyzed all DU hospitals of the Federal District. In each DU (n = 14), was performed, at least, an audit for assessing operational conditions and sample collected monthly of EN and IF for a period of 12 months. The calculated number of samples to be collected monthly, for a level of statistical significance of 95%, with a sampling error of 2%, was at least 168 for EN and IF. However, the final sample was of 227 samples of EN and 176, IF, because in some units were collected over a monthly sample.

Samples were prepared and analyzed, monthly, as a set schedule and legal instructions for sample collection (RDC No. 275 of 21 October 2002⁸ and RCD No. 63 of 6 July 2000⁹. Each sample of EN and IF was composed of 200 ml of the formula selected by DU, calculated based on the standard indicated by the manufacturer, and bottled in specific bottles for each specific type of diet^{10,11}.

Evaluation of the Structure and Process of preparing enteral nutrition and infant formula

The evaluation of the Structure and Process was performed by applying the Tool 2, adapted for this study, and had as indicator appropriateness of these areas to the legislation¹². The adapted instrument had 72 checking items grouped in Blocks: Storage and Dressing (19 check items), Preparation, Cleaning, Sanitization, Conservation and Transportation (32 check items) and Quality Control and Quality Assurance (21 check items). So for the Donabedian's Triad proposed for this research, the Structure includes the Storage units and Dressing, while the Process covers the Blocks of Preparation, Cleaning, Sanitization, Conservation and Transportation and Quality Control and Quality Assurance.

The 5 points Likert Scale (1-5) was used to score each item of blocks, according to the level of agreement with the rules: 1 – Totally Disagree; 2 – Partially disagree; 3 - Indifferent; 4 – Partially agree; 5 - Totally agree. To estimate the attendance percentage of each Nutrition and Dietetics Service to these items, it was admitted the following criteria: response with values in Likert scale between 1 and 2 correspond to the non-compliance with current legislation; value of 3 corresponds to a lack of information; and values between 4 and 5 corresponded to compliance with current le-

gislation. It was considered that the Services complied with the legal requirements when achieved a level of agreement $\geq 75\%$ for the corresponding answers to the analyzed question¹². As Process indicator, the results of microbiological analyzes in the collected samples were still considered.

Microbiological analyzes

Analyzes were performed to Count of *strict aerobic facultative mesophilic microorganisms*, *Total coliforms*, *Salmonella sp.* and *Coagulase-positive staphylococci* (*S. aureus* as indicator).

The choice of *Coagulase positive staphylococci* analysis was due to the fact that the species *S. aureus* the most important in the genre *Staphylococci*, and responsible for the second highest number of infections in humans. This genre is divided into two large groups based on plasma clotting ability.

The most important extracellular enzyme is the coagulase. The production of coagulase is part of the *Staphylococcus aureus*. Thus, the presence of *Coagulase Positive Staphylococci* suggests the presence of *S. aureus*. The coagulase test is considered the most simple to differentiate potentially pathogenic organisms, but not all coagulase positive strains produce toxins, besides the fact that coagulase-negative strains have already been implicated in outbreaks¹³.

In FI samples were performed analyzes to detect *Salmonella sp.*, Thermotolerant and Overall *Coliforms*, *Bacillus cereus* and *Staphylococcus coagulase positiva*¹⁴. In this study, the indicator for result was the absence of biological risk.

Analysis of proposed corrective actions based on the results of the microbiological analyzes

The analysis of proposed corrective actions to minimize the presence of biological hazards was performed using control records prepared by the team responsible for producing the EN and IF in each Nutrition and Dietetics Service, during the survey period. The indicator for the confirmation of adoption of corrective actions was the absence of biological risk.

Processing of data

Data were analyzed using Microsoft Excel (version 2007) and the IBM SPSS Statistics 20.0 software and the variables were treated from descriptive statistics.

Results

Regarding the Structure, the data indicated that Block 2 - Products Storage for EN and IF, complied

with the legal requirements in 92.95% (n = 13) of respondents Services. Even so, it was observed that there were units that did not have SSOP for adequate products storage.

For Block 5 - Dressing (anteroom), it was found that only 57.14% (n = 8) had agreement levels $<75\%$ (Table I). These results were due to the fact that most of the surveyed hospitals have no exclusive dressing in the area for the Service. In addition, procedures for scrub and hand sanitization were not available or visible in most of these dressing units.

For Process, Block 3 - Preparation of EN and IF (17 items) - there was an agreement level $\geq 75\%$ in 78.57% (n = 11) of respondents Services. However, it should be emphasized that 7.15% (n = 1) of these were in agreement level equal to 56%, due to non-compliance and the absence of SSOP for cleaning the area of handling and packaging products, in addition to the omission of information on storage temperature of products handled, responsible technician's name answerable for processing as well as data about date, manipulation time, expiry date, preparations map, formulas dilution, use of equipment, among others. It was still identified the lack of input and output control records of staff and inadequate isolation of the handling room.

For Block 4 - Sanitization (8 items) -it was found that only 7.15% (n = 1) of the Services had agreement level equal to 100%; 35.75% (n = 5) had their agreement level equal to 75%; 35.75% (n = 5), agreement level $\geq 75\%$; while 21.45% (n = 3) had agreement levels of 63%. The main problems were the unavailability of documents to achieve the SSOP for sanitization, suggesting some possibility of errors in performing the activity, especially hand sanitization, as well as the absence of records of their activities, not performing visual inspection after the sanitization of materials in all surveyed Services. In addition, in one of these Services, the site for the sanitization was not attached to the handling room.

Regarding Block 6 - Storage and transport (7 items), it was found that only 21.45% (n = 3) had level of agreement $\geq 75\%$ for EN temporary storage already labeled. It was found that the prepared products were kept in refrigeration, if not immediately used and discarded within 24 hours; However, no service made the temperature conference of the products stored immediately before administration to patients. The SSOP for the storage and transport of EN and IF were not available, and the SSOP did not exist for the temporary storage of EN and IF already labeled.

As the result, it was found for Blocks 7 and 8 - Quality Control and Quality Assurance, respectively, 85.80% (n = 12) of the Services had levels of agreement $\geq 75\%$; while 57.15% (n = 8) had level of agreement $\geq 75\%$ for Quality Assurance. The non-conformities were related to unavailability of SSOP, to not conducting periodic microbiological analyzes in EN / IF prepared with a statistically significant sample, the lack of SSOP to collect rebuttal in some units, the lack

Table I
Average of the grades obtained in the blocks for the dimensions Structure and Process, according to the triad' proposed by Donabedian

HOSPITAL	BL2	BL 3	BL 4	BL 5	BL 6	BL 7	BL 8
	M	M	M	M	M	M	M
H1	3,73	3,63	4,00	2,30	3,43	3,20	3,37
H2	4,00	3,22	3,00	1,30	3,00	3,60	3,79
H3	3,80	3,50	3,00	4,00	2,86	3,20	3,79
H4	3,47	2,66	3,00	0	2,86	3,60	2,86
H5	3,73	3,63	4,00	3,50	3,43	3,80	3,16
H6	4,00	3,53	4,00	4,00	3,14	3,30	3,53
H7	3,33	3,25	3,00	2,50	3,00	3,20	3,05
H8	4,00	4,00	4,00	3,00	4,00	4,00	4,00
H9	3,60	2,63	3,00	3,00	3,14	3,10	2,16
H10	4,00	3,47	3,10	4,00	2,86	3,60	3,47
H11	3,53	3,41	3,50	2,00	2,86	3,80	3,47
H12	4,00	3,22	3,90	2,00	2,00	3,80	2,79
H13	3,87	3,25	3,50	3,50	3,43	3,20	2,4
H14	3,73	3,53	3,90	3,30	2,86	4,00	3,16
TOTAL	3,77	3,35	3,49	2,74	3,06	3,52	3,25

M = mean values obtained in each block.

of information about the documentation filing period of the NE / FI. In addition, the staff did not know that the documentation enabled the efficient screening for investigation of any suspected quality deviation in the production of formulas. For each item SSOP (acquisition of EN / IF inputs, utensils and environment sanitization, prescriptions receiving, formulas dilution, use of equipment, labeling, storage of EN / IF and transport of EN / IF), involving critical operations of this process, only one unit had standardization for all items.

About the existence and availability of records maps of activities, to monitor the process, we found that only 36% (n = 5) of the Services held environmental and refrigerators temperature controls and environmental humidity control, release products in stock control, internal audits control, complaints regarding quality deviations in processed formulas control.

About the "Result", 403 samples were analyzed of which 56% (n = 227) correspond to EN samples and 44% (n = 176) of IF samples. The data indicated that of 227 EN samples, 6.2% (n = 14) were at odds with the law, while 4.6% (n = 8/176) of FI samples also were at odds with the law (Table I).

Among the 14 EN samples at odds with the law, four were contaminated by *strict aerobic facultative mesophilic microorganisms* and Total coliforms, simultaneously or not, in this period. Regarding the presence of Total coliforms, it was found that about this sample

universe, 10 samples did not comply with the legal standards. There was no contamination by *Coagulase positive staphylococci (Staphylococcus aureus)* or *Salmonella sp.* in the samples.

For the eight IF samples at odds with the law, there was a contamination by *Salmonella sp.*, six contaminations by Total coliform and Thermotolerant coliform, simultaneously or not, and only one sample contaminated by Thermotolerant coliform

Regarding the presence of *Coagulase Positive Staphylococci* and *Bacillus cereus*, it was observed that there was no contamination in the IF samples analyzed FI in no Service during this period.

About the team responsible intervention for the Process of EN and IF, it was found that the proposed corrective actions were based on monthly reports of the microbiological analysis. For each result in disagreement, the team developed an Action Plan to reduce the non-compliances identified. Maintenance problems were also appointed in the physical structure, in the renewal of occupational health certificates, issues which in a certain way may influence the quality assurance of finished products (Table III).

Discussion

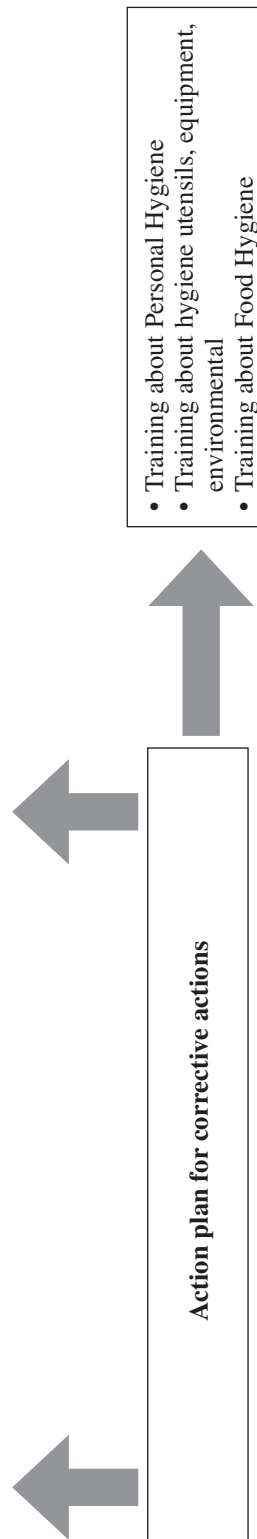
This research was conducted to evaluate the existence of biological risk in enteral nutrition samples (EN)

Table II

Percentage Assessment compliance with current legislation according to the level of agreement $\geq 75\%$ and results of the microbiological analysis of samples of enteral nutrition (EN) and infant formulas (IF) processed in Dietary units surveyed.

Operating Conditions		Result	Triad of Donabedian (1990), adapted
Structure	Process	Control and Assurance quality	Reports of microbiological analysis
Block 2 - Storage products for EN and IF (15 items) with level of agreement $\geq 75\%$	Block 3 – Preparation of EN and IF (17 items) with level of agreement $\geq 75\%$	Block 7 – Quality Control (10 items) 85,80% (n = 12) with level of agreement $\geq 75\%$	Enteral Nutrition (EN) 4 samples contaminated by <i>strict aerobic facultative mesophilic microorganisms</i> and Total coliforms, simultaneously or not 10 samples contaminated by Total coliforms There was no contamination by <i>Coagulase positive staphylococci (Staphylococcus aureus)</i> or <i>Salmonella sp.</i>
Block 5 – Dressing (Anteroom) (4 items) with level of agreement $\geq 75\%$	Block 4 – Cleaning and sanitization (8 items) with level of agreement = 100% 35,75% (n = 5) with level of agreement $\geq 75\%$.	Block 8 – Quality Assurance (11 items) 57,15% (n = 8) with level of agreement $\geq 75\%$	Infant Formula (IF) There was 1 contamination by <i>Salmonella sp</i> Six contaminations by Total coliform and Fecal coliform, simultaneously or not, 1 amostra contaminada por coliformes termotolerantes There was no contamination by <i>Coagulase Positive Staphylococci</i> and <i>Bacillus cereus</i>

BIOLOGICAL RISK



- Training about Personal Hygiene
- Training about hygiene utensils, equipment, environmental
- Training about Food Hygiene

Table III

Relationship between the type of contamination in enteral nutrition and infant formula samples and check items in disagreement with current legislation in the Dietary units surveyed.

<i>Hospital Unit</i>	<i>Type of contamination</i>	<i>Contamination frequency (times)</i>	<i>Block 2 check items - with agreement level ≤ 75%</i>
H2	Total Coliforms	8	Lack of information about the secure sharing of manipulation of the EN room.
	Mesophilic	1	Inappropriate Isolation of handling room (<i>pass-through</i> window with double doors for product input and output).
	Thermotolerant Coliforms	1	
H3	Total Coliforms	4	Lack of information about the secure sharing of manipulation of the EN room.
	Mesophilic	1	Lack of SSOP for all operations related to the Process.
H9	Total Coliforms	3	The labels did not contain the information required for conservation temperature.
	Mesophilic	2	
	<i>Salmonella sp.</i>	1	
H12	Total Coliforms	1	Lack of information about the secure sharing of manipulation of the EN room. Inappropriate Isolation of handling room (<i>pass-through</i> window with double doors for product input and output). Lack of SSOP for all operations related to the Process. The labels did not contain the information required for conservation temperature.

and infant formula (IF), produced in dietary units of hospitals in the public network of the Federal District, Brazil, using the quality assessment triad of dietary units proposed by Donabedian (1990)¹⁵.

The results are unpublished since there are no studies in literature evaluating the relationship between the non-compliance of the Structure and Process in the Results, expressed in the existence of biological risk.

Our data are consistent with the literature; Several studies have already shown EN and IF contamination by *Bacillus spp.*, *Pseudomonas aeruginosa*, *Enterobacter cloacae*, *Streptococcus spp.*, among other indicator micro-organisms of biological risk, in EN samples prepared in dietary units. The authors recommended corrective measures for hand sanitization, product handling, and storage of ready products at refrigerator temperature, between 0 ° C and 8 ° C. The manipulation may be an important turning point^{16,17}.

The physical facilities comprise the Structure and, in this study, it was observed that the handler dressing, item which makes up the Structure in the proposed triad for this study, constitutes a source of contamination from the environment. In audits, it was found that the lack of essential items, such as sinks with pedal and toilets in place, most favored input and output flow of manipulators in dietary unit. It was also identified that the layout of the area for the handling of EN and IF did not favor the continuous flow to production and release of products.

The physical space of Enteral Nutrition Unit is the basic element of functional planning. In the area for

each use, the conditions of skill and functionality must be followed. The planned design and its features depend on the planned management of internal and circulation flows; Desirable qualities of the environment; the basic function is to deal with a highly technical and specific area¹⁸, and, as seen in the results of this study, compromises the quality of EN and IF.

Other studies also showed non-compliance in the physical facilities of food handling units, mainly for the toilets and dressing handlers. Unsatisfactory conditions of building may compromise the performance of the unit for implementation of the SSOP¹⁹.

Regarding the Process, it is possible to consider that not monitoring the temperature of the products in its supply chain and also inadequate personal sanitization, equipment and utensils sanitization favored the development of micro-organisms, affecting their quality now under the aspect of waste, sometimes in the aspect of public health. The hands, worn or disposable gloves, are the main source of contamination.

When the EN and / or IF are handled in advance, they must be prepared in provided daily quantity and kept at 4° C temperature for a period of up to 30 hours, for the prevention or retarding microbial decomposition is based on the inhibition of micro-organisms development and their activity and / or destruction of microorganisms²⁰.

In the surveyed dietary units there were no records about the conditions of storage and transport of products, despite the law provides that such operations should occur in ≤4°C temperature and during handling the time of exposure to risk of temperature (between

10°C and 60°C) should be no more than 30 minutes and the smaller storage time less than 12 hours²¹. In addition it is necessary to standardize the binomial time and temperature for the heating step before distribution, because this step is also a critical point of control that may especially favor the development of aerobic mesophilic micro-organisms.

The equipment and utensils sanitization is an important operation in the post-processing contamination, and therefore they should have their standard and well-defined operating procedures²². The existence of Standard Operating Procedures (SSOP), described and visible, as well as records of activities performance, possible to evaluate and identify possible errors that may occur compromising the health quality of products. Appropriate sanitization practices provide a good microbiological quality in IF prepared in dietary units. The microbiological monitoring of products and handling surfaces is an important aspect of quality assurance policy, allowing to take corrective action when an unsatisfactory result is found¹⁶.

As the Result, the data of microbiological analyzes for Total coliforms, Thermoyolerant coliforms confirmed significant flaws in food handling and signaled deficiencies in sanitization, also identified in the audits. For Block 4 - Sanitization, only one unit had dietary level of agreement of 100% and 5 units had level of agreement $\geq 75\%$ to items according to the legislation.

The presence of these indicators also suggests inefficient heat treatment failures in storage temperature of products in storage and distribution and / or post-sanitizing or post-processing contamination²³. These results were expected because regarding the preservation of transport of the products, only 3 units had level of agreement $\geq 75\%$.

Despite the analyzed samples had not presented contamination by *Coagulase Positive Staphylococcus* and *Bacillus cereus*, the above results determine the need to pay attention to the microbiological quality of handled products in these units. In addition, *Coagulase Negative Staphylococci* species are considered opportunistic micro-organisms and are usually isolated from hospital infections^{24,25}.

Study to evaluate the microbiological quality of IF identified that 54% (n = 156) of the sample universe was contaminated by *Bacillus sp.*; among these samples 54% were IF for premature; the authors also found that some points of the surfaces of manipulation were contaminated by *Enterobacter cloacae*, *Pseudomonas fluorescens*, *Burkholderia cepacia*, *Staphylococcus*¹⁶.

Microbial contamination of EN and IF has a multifactorial origin and is related to the conditions of manipulation. It is generally associated with adding contaminated ingredients, to improper equipment and utensils sanitization as well as to personal sanitization³.

In this research, it is possible to consider that the inadequacies observed in the Structure and in the Process may have favored the contamination by *Esche-*

richia Coli, indicating fecal contamination; *Staphylococcus aureus*, which indicates the presence of nasal area; *Bacillus cereus*, environmental contamination and *Pseudomonas aeruginosa*, which indicates the improper use of antiseptic products^{5,26}.

The level of compliance of legal compliance for Sanitization Blocks, Storage and transport, especially express the importance of compliance to production of EN and IF in dietary units.

The contamination by Total coliforms is not, necessarily, indicator of fecal contamination or presence of pathogens, but a large number of these micro-organisms indicates unsatisfactory sanitary conditions^{27,28}.

In this study, the presence of mesophilic microorganisms possibly due to flaws in the temperature control during the preparation, storage and distribution of²⁹ (Table I). Or because there was no units surveyed in a safe flow to production and release of NE and FI, which probably may favor the contamination after processing, as well as the lack of SSOP for sanitization and use of equipment (Tables I and II) .

The research found that IF produced in dietary units with products with higher handling time had higher aerobic mesophilic bacteria contamination, and that after 24 hours of cooling, there was an increase in the count of these bacteria, including in the IF that were submitted into heat-treated terminal (autoclave at 105°C for 3 minutes)²⁶.

As indicators, strict aerobic facultative mesophilic microorganisms do not suggest direct risk to consumer health, however identify that the sanitization and / or transport and / or storage were performed improperly^{5,23,30}. According to some studies, environmental sanitization, equipment and utensils sanitization may contribute to the detection of heterotrophic bacteria mesophilic^{31,3}. The mesophilic microorganisms count may be used to track changes in process conditions and monitoring of hygienic conditions^{32,27}.

The contamination by *Salmonella sp* was probably due to inadequate practice of personal sanitization mainly from handlers with salmonellosis (Table I). *Salmonella* species are considered infectious micro-organisms and their presence features product potentially capable of causing food infection⁹. It is possible to consider that the problems identified for the Dressing Block has contributed to this result, as well as the isolation of handling room and the lack of SSOP for all activities, especially personal sanitization (Tables I and II). Research conducted to evaluate the EN microbiological quality did not show the presence of *Salmonella* in samples²⁷.

To correct the flaws during NE and FI production, Action Plans were prepared by the staff. These plans contemplated actions that would minimize and / or nullify the contamination of samples through the adoption of SSOP, especially for personal and products sanitization, inputs, equipment, utensils, environment. Training was also recommended for handlers about the importance of sanitization in product quality. Howe-

ver, when comparing the corrective actions foreseen in the Action Plan with the microbiological results, it was identified that there were no major changes in the handling of food according to the lessons transmitted in training.

The handler plays an important role in controlling infection rates as one of the main responsible for the transmission of micro-organisms. He/she should periodically undergo evaluations of health conditions, and must attend training on Good Hygienic Practices in Food Handling^{31,33}. However, there is no consensus in the literature about the effectiveness of training, although some studies show positive results in reducing the contamination rate in acceptable level, of EN and IF¹⁶.

Criteria that may be used to evaluate the effectiveness of a training program include reaction to training, acquisition of knowledge, changes in work related to behavior and performance and improvements in organizational level results. However, other factors outside the environment training may influence the effectiveness of any program. The knowledge by itself does not bring changes in food handling practices³⁴.

Microbiological data obtained in this study show that, despite the training conducted in the period of samples collection, there was no effectiveness as the products quality made in the dietary units. Work published about the effectiveness of quality systems in the production of EN and IF showed that microbial contamination was significantly reduced to values around 10¹ CFU / mL after the implementation of Hazard analysis and critical system control points (HACCP)²⁰.

About the Quality control of the production of EN and IF, there was an agreement level $\geq 75\%$ to 85.50% (n = 12) of the surveyed dietary units, while for Quality Assurance only 57.15% (n = 8) of the units had the level of agreement $\geq 75\%$. It is possible to consider, before these results, the instrument used in this study is an important tool for monitoring production quality of EN and IF in hospital environment¹².

To Donabedian (1992)³⁵, the item **Result** is the indicator for the indirect evaluation of quality and is relevant because it is responsible for intervening in other components and operate objective changes in the system.

The purpose of quality evaluation is to determine the degree of success of procedures to prevent the occurrence of risks, while the goal of quality control is to exercise constant vigilance, so that the standard deviations may be early detected and corrected.

This research showed that permanent audits help to identify risk situations and thus minimize problems arising from food contamination.

The authors consider that the adoption of continuous audits may minimize the costs of production since the microbiological analyzes may be restricted to sporadic situations, despite the limitation of this study being the small number of surveyed dietary units, it still counts with the lack of a sampling plan that enables offer accuracy of information about quality of processed products there in place.

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Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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