



OBJN
Online Brazilian Journal of Nursing

ENGLISH

Universidade Federal Fluminense

v.11, n.1 (2012)
ISSN 1676-4285



ESCOLA DE ENFERMAGEM
AURORA DE AFONSO COSTA

Received: 14/08/2011
Approved: 09/04/2012



EVALUATION OF HUMAN MILK BANKS

PARANÁ- BR: A COMPARATIVE STUDY

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Abstract: Human milk banks (HMB) are designed to Provide quality natural food for newborns. **Objectives:** To Evaluate and compare the structure and processes of eight BLH from Paraná based on RDC-171/2006 and the Manual of Operation of BLH of ANVISA. **Method:** Survey of normative and comparative assessment, in which the benchmarking techniques were applied and the systematic observation techniques and questionnaire to eight coordinators of HMB in 2009. Result: There are best practices in different BLH, and Deficiencies Relating to personnel, training, physical structure, documentation, records, and availability of standard operating procedures (SOP). **Discussion:** There is a need to hire employees, According to statutory requirements,



ORIGINAL ARTICLES

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documentation updated and available management and technical training, and provision of material resources, development and delivery of POP and supervision. **Conclusion:** In general, HMB present Structural deficiencies that require management and investment management, taking reference to the current Regulations and best practices identified.

Keywords: Milk Banks; Health Evaluation; Benchmarking.

INTRODUCTION

The support and encouragement to breastfeeding have been prioritized by the Brazilian public health policies in the last Decades and has strengthened the importance of human milk banks (HMB) to society⁽¹⁾. These specialized services are responsible for promoting, protecting and supporting breastfeeding, as well as the implementation of activities to collect the excess of milk production in nursing mothers, through processing, quality control and distribution of human milk collected⁽²⁾.

The first HMB was implemented in Brazil in 1943, in the National Institute of Child Care, now called Institute Fernandes Figueira - IFF. Its purpose was to collect and distribute human milk to satisfy the special cases of prematurity and allergies to heterologous proteins. Raw milk was distributed, without any thermal treatment, just observing the rigorous care to manipulate since the milking until the consumption⁽²⁾.

In the 80s of the twentieth century there was an expansion of these units, associated with the development of the National Program of Incentive to Breastfeeding. The HMB now assumed a new role in the Brazilian public health scenario, getting transformed into strategic elements for actions related to breastfeeding⁽³⁾.

In 1998 the Ministry of Health, with the support from the National Institute of Nutrition (INAN) and the Oswaldo Cruz Foundation (FIOCRUZ), created the National Network of Human Milk Banks, with the objective of supplying maternal milk to preterms, to low weight and to infants admitted to hospitals, in order to perpetuate the practice of exclusive breastfeeding, and contribute to reducing child mortality⁽⁴⁾.

With the expansion of human milk banks it was evident the need for standardization and development of technologies to provide a quality product. As a result, the National Agency of Sanitary Surveillance (ANVISA) has approved the Technical Regulations, Entitled RDC No. 171/2006 laying down the requirements for the installation and operation of these banks, as well as Human Milk Collection Stations throughout the country⁽⁵⁾.

The RDC 171/2006 orientates HMB managers and technicians to make efforts as to enable the adaptation of such services to operating standards, in order to improve process to structural aspects, such as purchase of equipment, implementation of mandatory examinations, record of processing steps of human milk and strict control of the quality of the product⁽⁵⁾. The regulations refer to Aspects of structure and process⁽⁶⁾ and, when met, contribute to the achievement of results with the quality ideally desired. However, HMB that has problems and structural difficulties in the processes can reach undesirable results, impairing the quality of excellent production, such as volume of pasteurized human milk (PHM) insufficient to meet the demand and disposal of HM due to deficiency in the collection process.

In the health sector, quality is defined as a set of attributes that includes a qualified professional, efficient use of resources, minimum risk and high degree of customer satisfaction, based on essentially the existing social values⁽⁷⁾. The evaluation of work processes and outcomes is relevant to the diagnosis and monitoring of changes implemented and their results. In order to have a continuous quality improvement in health services, assessments are necessary to identify appropriate practices and non-compliance to the technological requirements of their production as well as the needs of their clientele.

Regarding the evaluation process in the health sector, it is about investigating the extent in which the services perform them properly to achieve the desired results⁽⁶⁾. From this perspective, the process in health relates to all activities referring to care provided in health care, diagnosis, treatment, rehabilitation and patient education, also including administrative routines and procedures⁽⁷⁾.

In the case of process evaluation in human milk bank, It should focus on processes such as registration of donors, milking, transport, storage and pre-storage (storage in the cold chain), selection of human milk (HM), comprising creatocrit and Dornic acidity tests, processing or pasteurization, storage,

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equipment maintenance, general records, microbiological control of pasteurized HM, as well as the health care to the worker and hospital infection control. This assessment may occur by comparing the "services offered by the program or intervention with predetermined criteria and standards according to the desired results"^(7:36).

However, healthcare organizations can consult others that are public or private, national or not, but that perform one or more similar processes in order to compare the performance and improve the quality of their own processes⁽¹⁾. This is possible through benchmarking, defined as "[...] a continuous and systematic process to evaluate products and work processes of organizations that are recognized for representing the best practices for the purpose of organizational improvement"^(8:10). Its purpose is to determine, through performance comparisons and best practices, with the intention of improving the work developed in an organization⁽⁹⁾.

This research aimed to evaluate the structure and processes of the HMBs from Paraná based on RDC-171/2006 and the manual of ANVISA⁽²⁾ on their operations. We used the technique of benchmarking with HMB, with to justify that the best practices in accordance with these regulations, identified among them, would work as benchmarks for improvements of the other ones.

METHOD

The survey was preceded by the approval of the Ethics in Research of the Department of Health, Federal University of Paraná, under registration CEP / SD: 700.035.09.05; 0013.0.091.000-09 CAAE. The HMB were included in the study after approval of the managers of each institution and the individuals took part in it after they signed an informed consent.

It is about a comparative study in which was performed a normative evaluation⁽⁶⁾, of quantitative approach, under the managing perspective. Data collection was conducted from May to October 2009 in HMB Paraná, by applying the techniques of systematic non-participant observation and questionnaire. The evaluated units were eight HMB of paraná encoded randomly in the numbering 1-8. The subjects were the coordinators of HMB or authorized representatives of the institution.

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It was used as a method of benchmarking procedure, applying its early stages, planning and analysis(9). The type of benchmarking used was functional(8), since the for HMB of state of Paraná were evaluated and compared.

The data collected provided a database in a spreadsheet. For each BMH were analyzed separately the data on the dimensions of structure and process, and was identified to what extent they meet the items laid out in regulations.

RESULTS

The percentage of compliance to the standards ranged from 72.63% to 85.79% among the banks of Paraná. As non-compliance to the standards, assessments were considered 'no' and 'in part' for each item evaluated. The percentage of non-compliance ranged from 14.21% to 27.37% among banks. The average occurrence of non-conformities between the HMB was 21, 05%.

Regarding the legal aspects, none of the health institutions showed Sanitary License updated, documentation of agreements with institutions that provides or receives HM milked in the HMB evaluated, nor a copy of the Waste Management Plan approved by the Health Surveillance.

In none of the HMB of Paraná the technical officer is graduated in food technology, as shown by the RDC No. 171/2006(5). The ones who really take responsibility for the processes are the professionals with higher education encharged in the HMB. In HMB 5 the technician responsible for the service of Health Surveillance is a physician who is also the clinical director of the institution. In the others, the technicians responsible are nutritionists (HMB 1, 3, 6) or nurse (HMB 2, 4, 7, and 8).

Nurses, technicians and/or nursing assistants working in 100% of HMB, with the first ones account for the coordination of HMB in 62.5% of them (HMB 2, 4, 5, 7 and 8). Only two banks (HMB 5, 7) there are no nutritionists in service, taking charge for the processing of human milk, including selection, classification and pasteurization. In the unavailability of these professionals, nurses take responsibility for these processes. Regarding the biochemical pharmaceutical professional, in HMB 5 there is one that works exclusively on their facilities, in which he conducts examinations concerning the selection of the

HM. In the others, these tests are done by professionals that perform pasteurization, such as nursing assistants and technicians, dietitians, nurses and nutrition assistants.

It is observed that in certain HMB (3, 6 and 8), the lack of professionals is It is observed completed by mid-level trainees, undergraduate or already graduated, and also by volunteers. They have no employment contract and work temporarily in the service.

The highest percentage of professionals trained by the Course 'Processing and Quality Control of human milk' was 83.3%, observed in HMB 3. In HMB 1, 2, 7 and 8 there is, respectively, only one worker qualified in this course. In turn, although the course 'Promotion, Protection and Support of Breastfeeding in HMB with the participation of the entire staff of four HMB (4, 5, 6, 7), in one of the banks of Paraná (HMB 2) no employee was qualified.

Among the non-compliances observed in the elements of physical structure are: lack of locker room adjacent to the milking parlor and collecting for donors (HMB 2 and 3); room storage of expressed raw human milk and pasteurized human milk (HMB 2 and 7), and of a reception room for external collection (in all HMB).

In relation to proceedings in all HMB there are no doctors to perform the selection of donors. This selection is performed by nurses or nutritionists. In turn, donors records are incomplete in HMB 6 and 8.

The HMB1 does not perform a temperature control of cool boxes nor supplies it with ice packs in sufficient quantity. The remaining HMB perform such control, but not in accordance with the standards. In all HMB it is not required from suppliers certificates of analysis of materials and reagents purchased for use in exams.

It was found that only two HMB (3 and 4) there are standard operating procedures (SOP) for employee orientation. It was observed in the others (75%) the absence of SOP on the distribution of HM (HMB 1 and 7), portioning of HM milked pasteurized (HMB 1, 2 and 6), cleaning and disinfection of furnishings (HMB 8) and thawing of LHOP for consumption (HMB 5 and 6).

However, the best practices, which go beyond what is determined by regulations, were found in different human milk banks in Paraná. We highlight HMB 5, where there are more nursing

professionals, consisting of two nurses, six assistants, a professional for administrative support with a degree in administration, responsible for administrative routines, and a pharmacist who work exclusively in its premises . In HMB 3 and 6 there are nutritionists who work exclusively in the service. The HMB 1 has a computerized system that records data on the drive. The HMB 4 participates in the Quality Control of BMH Network. In HMB 6 and 7 internal or external audits of quality control are carried out. The HMB 3 conducts once a week weekly visits to donor with difficulties or who are starting the donation as a strategy to attract donors and encouraging the continuation of the donation.

DISCUSSION

Based on the RDC-171/2006⁽⁵⁾ and Operating Manual for HMB⁽²⁾ of ANVISA, we analyzed the structural aspects: the physical, material, and human resources and the forms of organization and operation; the process: records of donors; milking, transportation, storage and pre-storage (conservation in the cold chain); selection of HM (creamatorcrit and Dornic acidity), processing (pasteurization) storage, maintenance of equipment; records, worker's health care; microbiological control of the PHM, and hospital infection control.

On average, we found the occurrence of 21.05% of non-conformities between the HMB. Regarding the structure, all institutions (100%) have their health licenses past due; they do not perform agreements or contracts between institutions suppliers of HM milked raw and receptors of pasteurized HM; they totally disregard the requirement to maintain a copy of the Waste Management Plan approved by the Sanitary Surveillance, they do not have 100% of qualified employees in the course of Processing and Quality Control in HMB.

The existence of sanitary license is related to the conditions of the institutions in which HMB are inserted, since this document authorizes the operation of the hospital and all its sectors and proves that the establishment has been inspected and met the requirements of standards of good practice established and controlled by ANVISA Health Surveillance services (VISA) corresponding⁽⁵⁾.

Contracts are legal instruments that could regulate the relations of partnership between the HMB and institutions suppliers of HM milked raw and receptors of pasteurized HM. Once established, they would define the services to be performed and their respective officers, in order to contribute to the effectiveness of common goals.

As for the waste management plan, all HMB should keep it available for presentation to the authorities, as well as all other documents⁽⁵⁾.

There was diversity among the staffs of HMB Paraná, predominantly nurses, technicians and/or nursing assistants in all of them. The presence of the nurse professional is guaranteed by law⁽¹¹⁾ in which Article 15 ensures that professional the supervision and guidance of activities of the professionals and nursing assistants, when undertaken in health institutions, public and private, and health programs . In the HMB the nursing team works, in every individual assistance, to pregnant and lactating women in nursing consultations, and also in the processing of HM.

There is the inconvenience of employing trainees to supply deficiencies of its own employees in the service. As the RDC 171/2006 states in section 5.2.1, the HMB and the collection points of human milk require organizational structure in which are well-defined the roles and functions of personnel, as well as their qualifications and responsibilities ⁽⁵⁾. The presence of interns and volunteers working in the absence of professional effectively hired refers to questions about their commitment to the work and the institution and capacity building for a qualified service.

On the other hand, with the lack of human resources, volunteers collaborate on daily activities, fact that reduces temporarily the workload of staff.

Concerning the selection of donors, the RDC 171/2006 recommends that the "[...] responsibility of the physician responsible for medical-assistance activities of the HMB"(5). In BMH of Paraná this process is performed by nurses or nutritionists.

All employees working in a HMB should be trained to work in the processing of HM. Consequently, these services shall maintain available records of training and qualifications of its professionals, as well as promote continuing education for their professionals, properly documented(5). The minimum training required for performance in the activities of processing and quality control in HMB requires

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proof of completion of courses in 'Processing and Quality Control of human milk' and 'Quality Management in HMB' by the employees. For assistance activities, it is required the Course "Promotion, Protection and Support of Breastfeeding in HMB ", which should be promoted by the State Reference Centers(2). It is noteworthy that this course prepares professionals to stimulate and guide mothers to breastfeed their children and to become donors, in order to provide the HMB with a continuous and increasing HM. So the bank can meet the needs of human milk of newborns in its own supporting institution, as well as store it and distribute it to other institutions(12).

The training of staff for handling food is critical for the control of undesirable microorganisms in the raw materials used in the human diet. This is particularly important with regard to HM, for it has no physical protection to prevent access to the microbiota of their nutrients, microorganisms such as those coming from secondary contaminants coming from the environment, utensils, donors and practitioners of HMB(2). Thus, the breast milk may be a source of transmission of pathogenic microorganisms if not handled under appropriate conditions.

There is the need of coordinators supervise the temperature control of the isotherms boxes according to the standards(5), oversee the records of donors to ensure they are complete, and obtain from suppliers the certificates of analysis of materials and reagents purchased for use in examinations, to ensure the quality of the productive processes involved.

CONCLUSION

We identified weaknesses and strengths in the practices of all eight HMB of Paraná. It was not identified non-compliances in relation to the processes of milking, storage, selection of HM (crematocrit and Dornic acidity), processing (pasteurization), maintenance of equipment, workers' health care, microbiological control of the PHM, and control of hospital infection.

There is a need for supervision of the temperature record of cool boxes containing ice packs used in the transportation of milk, for maintaining the cold chain.

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Nonconformities point out to the need of their current managers to maintain updated and available the legal documentation for the operation of HMB, supply them with materials, equipment and essential elements of the physical plant and with employed professionals who are qualified according to the legal requirements; to invest in management and technical training, and preparation of standard operating procedures and oversight of records and compliance with regulations.

Thus, all HMB should increase efforts to raise the percentage of compliance with the provisions of RDC 171/2006(5) and the guidelines of the technical manual for operation of HMB(2).

The investment in hiring and training of personnel is indispensable in many HMB of Paraná, because these units are still operating with minimal staff, which means extra work and activities related to related to HMB, like less involvement in activities of protection, promotion and support to breastfeeding.

In view of the various regulations that guide the HMB to how they should design and develop their processes in order to obtain as a result the production and distribution of human milk of quality to its customers; it is inferred that monitoring and evaluating are needed to lead them to their continuous improvement. It is suggested that periodic internal audits are made to enable the analysis of processes.

It is noteworthy that nurses are responsible for the Coordination of HMB in most banks of Parana. For efficient management of milk production and care of donors and nursing mothers, with quality and safety, it is necessary that they develop skills for conducting systematic, periodic and innovative evaluation processes. Normative and comparative evaluations of human milk banks, developed on a regular basis, make possible the identification of better practices and suggest strategies to improve their performance.

The best practices identified in this study highlight the commitment of HMB in seeking creative and innovative alternatives to improve its structure and processes, which exceed the current regulations.

The results were presented to the coordinators of HMB in the State Commission in 2011. They provided to the management information of the position of HMB in relation to the best practices in banks of Paraná regarding aspects of the structure and process. They pointed out how their practices could be

improved with a view to continuous improvement of service quality, and consequently, with a safe service for the customer, with benefits for their health. It also provided relevant information to state public policy in the breastfeeding area, especially in terms of investment and encouragement.

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