Methodology and indicators for NBCAL monitoring in stores and health services: a multicenter study (Multi-NBCAL)

Metodologia e indicadores para monitoramento da NBCAL em estabelecimentos comerciais e serviços de saúde: estudo multicêntrico (Multi-NBCAL)

Metodología e indicadores para el monitoreo de la NBCAL en establecimientos comerciales y servicios de salud: estudio multicéntrico (Multi-NBCAL)

Abstract

The Brazilian Code of Marketing of Infant and Toddlers Food, Nipples, Pacifiers and Baby Bottles (NBCAL), in force in Brazil since 1988, is still systematically violated, exposing mothers and family members to illegal marketing of products that compete with breastfeeding. This study aimed to describe a multicenter study methodology and propose standardized indicators for NBCAL monitoring. This is a Multicenter Study for NBCAL Compliance Assessment (Multi-NBCAL) conducted in seven Brazilian cities: Rio de Janeiro, São Paulo, Ouro Preto (Minas Gerais State), Florianópolis (Santa Catarina State), João Pessoa (Paraíba State), and Belém (Pará State). Assessment tools were adapted from NetCode/WHO and IBFAN Brazil (International Baby Food Action Network) to conduct two evaluations: (1) evaluation of NBCAL compliance in stores, and NBCAL knowledge and practices of store managers; (2) evaluation of the interaction between the baby food industry and health professionals and post-partum mothers in maternity hospitals. Five indicators were developed to assess NBCAL compliance in stores; seven indicators to assess the knowledge and practices of store managers; five indicators to assess the provision of incentives to maternity hospitals, health professionals, and mothers by sectors; and five indicators to assess NBCAL knowledge and practices of health professionals. The NBCAL assessment methodology with the proposal of standardized indicators allows comparability of studies about this theme. Using these indicators in periodic national or regional investigation can help monitor the level of NBCAL implementation in Brazil.

Breast Feeding; Marketing; Health Surveillance; Consumer Advocacy

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Introduction

Manufacturers and distributors of baby food, nipples, pacifiers and baby bottles are constantly designing marketing strategies that negatively affect the choices and decisions of mothers and family members about how to feed their babies. These practices prevent society from fully exploring the various benefits of breastfeeding and generate increasing sales margins and profits to companies worldwide. In this scenario, effective regulations for the marketing of foods and products that compete with breastfeeding have become a major priority for the World Health Organization (WHO). These regulations aim to provide an environment free from advertising influence to help increase breastfeeding rates and extend breastfeeding duration around the world.

The International Code of Marketing of Breast-Milk Substitutes (also known as the WHO Code), issued by the WHO in 1981, was developed to control the marketing of infant formulas and other products used as breast-milk substitutes. In 1988, the Brazilian Ministry of Health, based on the WHO Code, developed the Code for Commercialization of Food for Infants, which was later expanded and became the Brazilian Code of Marketing of Infant and Toddlers Food, Nipples, Pacifiers and Baby Bottles (NBCAL), adopted as an ordinance of the Brazilian Ministry of Health (Ordinance n. 2051 of 2001) and Resolutions RDC/ANVISA n. 221 and n. 222 of 2002, and then as Law n. 11,265 in 2006, regulated in 2015 and 2018. The acronym NBCAL is not described in official government regulations and ordinances, but it is widely adopted and accepted by civil society, government and academia.

The WHO Code and NBCAL have an interface and direct agreement with the universal human rights, the 2030 Agenda and its Sustainable Development Goals (SDGs). They also observe basic constitutional guarantees, which include food as a social right and support other national laws and policies, such as the Brazilian National Food and Nutrition Policy (PNAN) and the Brazilian National Policy for Integral Attention to Children’s Health (PNAISC).

However, despite the broad scope of the WHO Code and NBCAL supporting breastfeeding protection, and the International Baby Food Action Network (IBFAN Brazil) monitoring of NBCAL violations in several Brazilian States for over 40 years, conflicts of business interest in the country and the lack of systematic NBCAL enforcement have led to frequent violations of the Code. In addition, store managers, health professionals, and mothers have poor knowledge of NBCAL, which creates an environment that favors non-compliance with this Law and exposure of families to abusive marketing of these products and baby foods.

The Multicenter Study for NBCAL Compliance Assessment (Multi-NBCAL), conducted in seven cities in the five Brazilian macro-regions, used a combination of quantitative and qualitative methods to analyze NBCAL compliance by stores and health services in Brazil and assess the perception of mothers about the influence of marketing on their food choices for their young children, which will be analyzed in another publication.

This study aimed to discuss the quantitative aspect of the method used in the Multi-NBCAL study to assess NBCAL compliance of stores and maternity hospitals, providing research protocols, variables and standardized indicators.

Methods

Multicenter study Multi-NBCAL

This is a Multi-NBCAL conducted in seven Brazilian cities: Rio de Janeiro, São Paulo, Ouro Preto (Minas Gerais State), Florianópolis (Santa Catarina State), Brasília (Federal District), João Pessoa (Paraíba State), and Belém (Pará State), between November 2018 and November 2019, using two components: (1) assessment of stores; (2) assessment of maternity hospitals.
• **Selection of study centers**

Study centers were selected if covering at least one city from each of the five Brazilian macro-regions. The cities were chosen intentionally, according to the availability of institutions and researchers dedicated to the theme.

• **Fieldwork organization and questionnaire development**

Recurrent in-person and virtual meetings were held with the study centers to validate the questionnaire content and the interviewer’s manual, define strategies for fieldwork, data collection and analysis of results, and create a schedule comprising all research project stages. Content was validated by a panel of experts in a process involving collective reading of every question, followed by approval or alteration of questions, field testing, review and reapplication, until all questions (and skip patterns) were approved. Later, in each center, the questionnaires were analyzed by experts not belonging to the research group, and adjustments were made to the instrument.

Two questionnaires were developed for the evaluation of stores: (1) assessment of NBCAL compliance in drugstores and supermarkets; (2) assessment of NBCAL knowledge and practices of store managers. For the evaluation of maternity hospitals, an environment observation instrument and a questionnaire were developed to assess the influence of the infant food industry and products covered by NBCAL on maternity hospitals, health professionals, and postpartum women. In both stages, *Law n. 11,265/2006* was considered as the theoretical reference for the questionnaires, as it has legal precedence over decrees and technical regulations. Items not included in the Law, such as marketing of nipple protectors, but listed in *Resolution RDC/ANVISA 222/2002*, were included in the Multi-NBCAL study.

Multi-NBCAL was designed before the 2018 *Presidential Decree n. 9,597* which changes the definition of early childhood. *Law n. 11,265/2006* defines early childhood as the period from birth to three years old, while *Decree n. 9,579/2018* defines early childhood as the period from birth to six years old. Although the law prevails over a decree, future monitoring must consider these discrepancies until a norm defines the valid age.

The questionnaires for these stages were adapted from those used by IBFAN to monitor NBCAL compliance and the NetCode Toolkit (https://toolkits.knowledgesuccess.org/toolkits/breastfeeding-advocacy-toolkit/netcode) proposed by the WHO/UNICEF to monitor the WHO Code, as well as questions regarding the study objective with a proper structure for data collection through mobile application. Regarding NetCode questionnaires, the questions were adapted for NBCAL assessment. Foods and products considered in the questionnaire for the evaluation of stores observed the definitions contained in *Law n. 11,265/2006*, art. 2. Although dairy compounds are not mentioned in the Law, they were included in the Multi-NBCAL assessment because they are for children aged 1 year or older. The questionnaires had sections, which will be detailed under the Results.

In each study center, the questionnaires were pre-tested in districts or municipalities other than those selected for the study, and changes were made to the questionnaire structure, i.e., question inclusion or removal, and skip pattern rules were created in this stage; then the final questionnaire was provided to each center.

The questionnaires were developed using MAGPI application (https://www.magpi.com/), which has an intuitive interface for data entry, electronic cloud hosting, online monitoring of data collection, and data export to common statistical packages.

This study was approved by the Research Ethics Committee of the Escola Politécnica de Saúde Joaquim Venâncio, Oswaldo Cruz Foundation (Fiocruz), process n. 2,912,729 of September 24, 2018, in agreement with CNS Resolution n. 466/2012.
Results

Assessment of NBCAL compliance by stores and knowledge and practices of store managers

• Study design and sample

The first study was an epidemiological investigation assessing NBCAL compliance by stores and knowledge and practices of managers or pharmacists from such stores. The study analyzed drugstores and supermarkets that sold baby food and products within the scope of NBCAL through interviews conducted with the managers or pharmacists in charge of the stores. Compounding pharmacies were excluded.

The study defined a minimum number of 200 stores for each center in a purposive sample; this sample number was calculated to ensure comparability between centers, based on 50% estimated prevalence of NBCAL violation, a 3% margin of error, and a 95% confidence interval (95%CI).

In the city of Rio de Janeiro, all stores in the south zone were evaluated using the same methodology as Silva et al. 22, which allows the assessment of stores in neighborhoods of different socioeconomic levels and a comparison of these stores over time.

In Belém and Ouro Preto, all drugstores and supermarkets were mapped, since 200 or fewer stores were found in these locations. In João Pessoa, São Paulo, Brasilia, and Florianópolis, a region of contiguous districts was intentionally chosen to cover populations of different socioeconomic levels comprising at least 200 eligible stores. The selection of neighborhoods in these locations was discussed and planned in detail to ensure socioeconomic diversity. Prior mapping of stores in each center was conducted through internet search and knowledge of local researchers. Internet search was based on the standards of Silva et al. 22 using electronic search engine (http://www.google.com) and websites of main chains of stores in each center.

• Team training and data collection

The interviewers selected at each center had a 20-hour course about NBCAL compliance assessment, followed by data collection training at stores and maternity hospitals. The course and training were provided at each study center by a member of the central coordination, the coordinator of each center, and was supported by a member from local IBFAN, when available.

Data were collected by interviewers in drugstores, markets and supermarkets in selected districts, assessing all eligible stores in that location, previously listed or not.

For data collection, interviewers used smartphones, displaying an electronic questionnaire developed in MAGPI (https://www.magpi.com/) 25 application. The questionnaire had three sections: store identification; NBCAL compliance assessment; interview with store manager or pharmacist about their characteristics and knowledge about NBCAL and breastfeeding, visits from industry representatives, as well as questions about who organized products and foods on the shelves and their sales prices. Data collection was conducted in all centers between November and December 2018.

Assessment of stores

Compliance with NBCAL by stores was assessed considering items from Chapters I and II of Law n. 11,265/2006 11 related to sales and advertising of products covered by NBCAL at points of sale (Box 1).

The outcome of this study was NBCAL violation, characterized as non-compliance with one or more items related to the commercial promotion of products and foods within the scope of NBCAL in stores 9. Two main groups were considered: group 1 – foods and products of prohibited commercial promotion; and group 2 – foods of commercial promotion permitted with a warning phrase (Box 1). In group 1 products, the identification of any commercial promotion was considered an NBCAL violation. In group 2 products, commercial promotion was considered a violation without a warning phrase, as recommended by the Brazilian Ministry of Health 9 (Box 1).
Variables for Brazilian Code of Marketing of Infant and Toddlers Food, Nipples, Pacifiers and Baby Bottles (NBCAL) monitoring in stores (Multi-NBCAL, 2020).

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>DESCRIPTION/CATEGORIES</th>
<th>REMARKS</th>
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<tbody>
<tr>
<td>(1) Product</td>
<td>Smallest unit of analysis for NBCAL monitoring. Each product is distinguished from the others by the following characteristics described on the labels: type, name and manufacturer.</td>
<td>The product can be displayed for sale in one or more places of the store and may present different NBCAL violations in those places. For instance, off-price and special display.</td>
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<tr>
<td>(2) Groups and types of products</td>
<td>Product grouping according to Law n. 11,265/2006 as follows: I - Infant formulas (IF): (1) infant formulas for infants; (2) infant follow-up formulas for infants; (3) infant formulas for specific dietary needs. II - Formulas for young children (FYC): (4) infant follow-up formulas for young children. III - Nipples (NI): (5) baby bottles; (6) nipples; (7) pacifiers; and (8) nipple protectors. IV - Milks (MI): (9) fluid milk; (10) powdered milk; (11) modified milk and similar plant-based milk. V – Processed complementary foods (CF): (12) processed complementary foods and cereal-based foods suitable for infants or young children, as well as other milk-based foods or drinks or not, when marketed or otherwise presented as suitable for feeding infants and young children. VI - Dairy Compounds (DC): (13) dairy compounds are growing-up milks, they fit both the definition of “other milks-based foods or drinks” and the milk group.</td>
<td>1: Nutrient formulas, presented or recommended for high-risk newborns, cannot be marketed as only hospitals are allowed to use them, so they are not included in the list of product groups. Marketing of this group of products, when observed, must be registered separately, included as item 14). 2: Dairy compounds were grouped separately as the 6th group (VI), because they are frequently marketed, involving frequent infractions. These products, created after the enactment of Law n. 11,265/2006, although not mentioned by their names, are part of its scope as they are presented as suitable for feeding young children. They are regulated by MAPA Normative Instruction n. 28/2007.</td>
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<tr>
<td>(3) Types of commercial promotion</td>
<td>- Special display (SD): defined as “any product display that makes it stand out from the others in the store, such as a shop window, shelf edge, products arranged as a pyramid or island, product crates, shelf ornaments, and others”. - Off-price (OP): discounts, special offer, discount coupons, progressive discounts, and other forms of price reduction. - Gifts or samples (GI): products, accessories or toys offered by the store, associated with product purchase. - Others (OT): any other system that induces consumers to buy the product.</td>
<td>Commercial promotion is defined by NBCAL as “a number of information and persuasion activities from companies that manufacture, handle, distribute and market products aiming to induce the acquisition or sale of a certain product”. For each product, one or more categories of commercial promotion can be observed. That is, multiple responses can be observed for each product.</td>
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</table>

The unit of analysis was the product sold at stores and each product could or could not have one or more NBCAL violations. The total number of products with NBCAL violations in each store could range from zero (no violation) to the total distinct products sold at the store. The total number of products with NBCAL violations was continuously computed (counting). Then, violations were categorized in a binary manner, indicating whether the assessed store presented NBCAL violations or not (Box 2).
Box 1 (continued)

<table>
<thead>
<tr>
<th>VARIABLE</th>
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<th>REMARKS</th>
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<tbody>
<tr>
<td>(4) NBCAL violation</td>
<td>NBCAL violations can be divided into two major product groups: &lt;br&gt; - Products with prohibited commercial promotion: include IF and NI. &lt;br&gt; Any type of commercial promotion of products from these groups constitutes a NBCAL violation. &lt;br&gt; - Products with permitted commercial promotion with a warning phrase: include FYC, CF, MI and DC. &lt;br&gt; These products can have commercial promotion as long as they present a warning phrase from the Brazilian Ministry of Health. Absent or inadequate warning phrases constitute a NBCAL violation.</td>
<td>Calculation method: &lt;br&gt; (a) observe if the product has any type of commercial promotion. &lt;br&gt; (b) write down the product group, manufacturer name, product name, and type of violation(s). &lt;br&gt; (c) if the product belongs to the group that allows commercial promotion (FYC, CF, MI, and DC), check if it presents a warning phrase: “The Brazilian Ministry of Health informs: breastfeeding prevents infections and allergies and is recommended up to 2 years old or older” – for MI and FYC products, or “The Brazilian Ministry of Health informs: after 6 months of age, keep breastfeeding your child and offer new foods” – in the case of CF products. For DC, accept either phrase, as it is a product not regulated by ANVISA. &lt;br&gt; (d) then, if the product presents a warning phrase, observe whether it is highlighted, with auditory or visual evidence, whether it is legible, bold, framed, in a horizontal position, and close to the product being promoted. If these requirements are not met, the commercial promotion of the product violates NBCAL.</td>
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ANVISA: Brazilian Health Regulatory Agency; Multi-NBCAL: Multi-NBCAL: Multicenter Study for NBCAL Compliance Assessment.

- **Script for store assessment**

  First, information was collected about the characteristics of each store, including address, type of store (drugstore or market/supermarket); whether it belonged to a chain of stores (yes or no); its location (GPS marking, city, district, address); and size (small, midsize, large, hyperstore) – subjectively assessed by the interviewer.

  Then, all products sold at the stores covered by NBCAL were registered. Also, the assessment and identification of NBCAL violation type were performed (Box 1). As approved by the Research Ethics Committee, this stage of the study did not require an Informed Consent Form (ICF) to assess the public environment of stores in order to prevent the manager or pharmacist from modifying the environment when learning about the study objectives.

  When a product was identified with an NBCAL violation, the manufacturer name and the product name were registered. Then, the type of commercial promotion (off-price, special display, gifts or samples, and others) was registered, with multiple answers for each product. For products belonging to group 2, with commercial promotion allowed, the presence of a warning phrase and its adequacy (Box 1) were checked. NBCAL violations were registered product by product until all infractions were exhausted.

  After a complete assessment of the store environment, the interviewers introduced themselves to the manager or pharmacist in charge and applied the questionnaire after reading the informed consent form and obtaining a verbal consent. A copy of the ICF signed by the study coordinator was provided to the interviewees.
Box 2

Indicators for Brazilian Code of Marketing of Infant and Toddlers Food, Nipples, Pacifiers and Baby Bottles (NBCAL) monitoring in stores (Multi-NBCAL, 2020).

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<tr>
<th>INDICATOR</th>
<th>DEFINITION</th>
<th>CALCULATION METHOD</th>
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<tbody>
<tr>
<td>(1) Number of products with NBCAL violation by store</td>
<td>Total number of distinct products with NBCAL violation in each store.</td>
<td>- Each product for sale in the store may have one or more NBCAL violations (see section: Type of commercial promotion).</td>
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<td></td>
<td>- Regardless of the variety of violations attributed to each product, this product will receive the “violation” attribute when one or more product-related violations are observed, constituting a binary variable (yes/no).</td>
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<td></td>
<td>- Each product with one or more NBCAL violations will be counted and the total number of products with infractions in each store establishment will be summed up, ranging from zero (store with no violation) to the total number of distinct products the store sells.</td>
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<td></td>
<td></td>
<td>- Each store now receives a value for this variable.</td>
</tr>
<tr>
<td>(2) Number of stores with NBCAL violation</td>
<td>Indicates the store has NBCAL violation.</td>
<td>To obtain this indicator, a binary variable (yes/no) will be built, based on the “total NBCAL violations by store” in which yes refers to the store where at least one NBCAL violation has been observed in at least one product.</td>
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<tr>
<td></td>
<td>Presence or not of NBCAL violation in each store.</td>
<td>Then, the number of stores with at least one NBCAL violation is summed up.</td>
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<tr>
<td>(3) Average number of products with NBCAL violation of by store</td>
<td>Average number of products with at least one NBCAL violation in each store.</td>
<td>Numerator: sum of the number of products marketed that present an NBCAL violation. Denominator: sum of stores that sell products covered by NBCAL. Note: this indicator can be stratified by product groups: IF, FYC, NI, MI, CF, and DC. In this case, the denominator varies according to the presence or not of products from that group in the store.</td>
</tr>
<tr>
<td>(4) Proportion of stores with NBCAL violation</td>
<td>Proportion of stores with at least one NBCAL violation.</td>
<td>Numerator: number of stores with NBCAL violations. Denominator: number of stores that sell products covered by NBCAL. Multiply the result by 100. Note: this indicator can be stratified by product groups: IF, FYC, NI, MI, CF, and DC. Then, the denominator will be the number of stores that sell each type of product.</td>
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<td></td>
<td>It can also be stratified by companies that produce infant formula, nipples, pacifiers and bottles (products with prohibited promotion). The denominator, in this case, must only include the stores that sell products from a specific company.</td>
</tr>
<tr>
<td>(5) Proportion of each type of commercial promotion with NBCAL violation</td>
<td>Percentage of each type of commercial promotion with NBCAL violation: (off-price/ special display/ gifts and samples/ others) by product category in the store.</td>
<td>Numerator: total number of each type of commercial promotion with NBCAL violation (SD, OP, GI). Denominator: total number of stores with NBCAL violation. Multiply the result by 100. Note: this indicator can be presented in two different ways:</td>
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<td>- Frequency stratified by type of commercial promotion, where each type of promotion will present its frequency percentage. The sum of these frequencies may be higher than 100%, as one product may present more than one type of commercial promotion in disagreement with NBCAL.</td>
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<tr>
<td></td>
<td></td>
<td>- Combined frequency of types of commercial promotion: SD, OP, GI, SD+OP, SD+GI, OP+GI, SD+OP+GI. The sum of the percentages for this indicator will be equal to 100%. This indicator can be stratified by product.</td>
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</tbody>
</table>

CF: processed complementary foods; DC: dairy compounds; FYC: formulas for young children; GI: gifts or samples; IF: infant formulas; MI: milks; NI: nipples; OP: off-price; SD: special display; Multi-NBCAL: Multicenter Study for NBCAL Compliance Assessment.

Note: these indicators must have time (month/year) and space (neighborhood/region/administrative district/city/state/ macro-region/country) identification.
The interview also analyzed the knowledge of managers or pharmacists of Law n. 11,265/2006, the name of the companies that visited the store, the frequency of these visits, whether they provided guidance to customers about infant food, as well as commercial practices influenced by this industry such as bonus offered for better product display and incremental sales (Box 3).

Once the store assessment ended, the electronic questionnaire was sent over the internet and stored as an electronic file. Collected variables were then categorized (Box 1) and the indicators were calculated (Boxes 2 and 3). Multi-NBCAL developed five indicators to assess NBCAL compliance in stores and six indicators to assess the knowledge and practices of managers or pharmacists in charge of the store.

Assessment of marketing practices of manufacturers of products covered by NBCAL with health professionals, institutions and post-partum women

- Study design and sample

The second Multi-NBCAL study was an epidemiological investigation conducted in maternity hospitals in six Brazilian cities: Rio de Janeiro, São Paulo, Ouro Preto, Florianópolis, Brasília, and João Pessoa, where aspects related to Chapters I, II, and IV of NBCAL were evaluated, regarding financial or material sponsorship by the food industry and products within the scope of NBCAL, and about education and public information, such as educational materials.

In each city, all hospitals/maternity hospitals that performed more than 500 births a year were mapped via search on the National Registry of Health Centers (CNES, http://www.cnes.datasus.gov.br). Then, the hospitals were sorted by funding source as public, public accredited by the Baby-Friendly Hospital Initiative (BFHI), and private. The sample aimed to include two hospitals from each stratum in each city. However, Florianópolis and Outro Preto had only four and one maternity hospitals, respectively. In Rio de Janeiro and São Paulo, three private maternity hospitals refused to participate in the study, and obstacles to obtain Institutional Acceptance Terms (IAT) prevented to reach the previously planned sample.

- Data collection

At each maternity hospital, the interview with health professionals took place on a single day and included up to 10 professionals, including pediatricians, nutritionists, and speech therapists. These professionals were selected either because they are included in Law n. 11,265/2006 (nutritionists and pediatricians), or because they use children’s products covered by NBCAL in their professional practice, such as speech therapists. For maternity hospitals with less than 10 professionals present on the interview day, all of them were interviewed. When more than 10 professionals were present, a list of pediatricians, nutritionists and speech therapists present on the interview day was requested, and up to 10 professionals were randomly selected per maternity hospital. In addition, the director of each maternity hospital was interviewed. The physical environment of the maternity was also observed, including the areas of patient circulation and the areas for pediatricians, nutritionists and speech therapists. All interviews were conducted with ICF signing.

The interviewers and fieldwork supervisors were the same as those from the store assessment stage. Data collection took place between November 2018 and November 2019.

Data were collected in 25 hospitals with maternity hospitals: 6 (1 private, 3 public, and 2 public BFHI hospitals) in Rio de Janeiro; 4 (1 private, 2 public, and 1 public BFHI hospitals) in São Paulo; 4 (2 private, 2 public BFHI hospitals) in Florianópolis; all 6 maternity hospitals (2 private and 4 public BFHI hospitals) in João Pessoa; 4 (2 private, 1 public, and 1 public BFHI hospitals) in Brasília; and the only public BFHI maternity hospital in Ouro Preto. In these maternity hospitals, 217 health professionals were interviewed: 14 directors, 31 heads of services or departments, 170 health care professionals, and 2 university professors.
### Box 3

Indicators to assess knowledge and practices of managers or pharmacists in charge of stores (Multi-NBCAL, 2020).

<table>
<thead>
<tr>
<th>INDICATOR</th>
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<th>CALCULATION METHOD</th>
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<tbody>
<tr>
<td>(1) Proportion of managers or pharmacists with knowledge of NBCAL</td>
<td>Percentage of managers or pharmacists who know NBCAL. This question allowed 3 categories of answers: yes, more or less, no.</td>
<td>Numerator: number of managers or pharmacists interviewed who said they knew NBCAL. Denominator: total number of managers or pharmacists interviewed. Multiply the result by 100.</td>
</tr>
<tr>
<td>(2) Proportion of managers or pharmacists that can name products covered by NBCAL</td>
<td>Percentage of managers or pharmacists that can name products covered by NBCAL.</td>
<td>Numerator: number of managers or pharmacists interviewed who were able to name at least 3 products covered by NBCAL. Denominator: total number of managers or pharmacists interviewed. Multiply the result by 100.</td>
</tr>
<tr>
<td>(4) Proportion of managers or pharmacists with NBCAL training</td>
<td>Percentage of managers or pharmacists with NBCAL training.</td>
<td>Numerator: number of managers or pharmacists interviewed who reported NBCAL training or class. Denominator: total number of managers or pharmacists interviewed. Multiply the result by 100.</td>
</tr>
<tr>
<td>(3) Proportion of managers or pharmacists with breastfeeding or infant food training</td>
<td>Percentage of managers or pharmacists with breastfeeding or infant food training.</td>
<td>Numerator: number of managers or pharmacists interviewed who reported breastfeeding or infant food training. Denominator: total number of managers or pharmacists interviewed. Multiply the result by 100.</td>
</tr>
<tr>
<td>(5) Proportion of managers or pharmacists who advise mothers on infant food</td>
<td>Percentage of managers or pharmacists who improperly advise mothers on infant food.</td>
<td>Numerator: number of managers or pharmacists interviewed who reported providing infant food guidance to mothers. Denominator: total number of managers or pharmacists interviewed. Multiply the result by 100.</td>
</tr>
<tr>
<td>(6) Proportion of managers or pharmacists who receive visits of representatives from companies of infant foods, nipples, baby bottles, and pacifiers</td>
<td>Percentage of managers or pharmacists who receive visits of representatives from companies of infant foods, nipples, baby bottles, and pacifiers.</td>
<td>Numerator: number of managers or pharmacists interviewed who reported visits of representatives from companies of infant foods and products. Denominator: total number of managers or pharmacists interviewed. Multiply the result by 100.</td>
</tr>
<tr>
<td>(7) Proportion of stores that receive visits of representatives from companies of infant foods, nipples, baby bottles, and pacifiers</td>
<td>Percentage of managers or pharmacists who receive daily, weekly, monthly or sporadic visits of representatives from companies of infant foods and products.</td>
<td>Numerator: number of managers or pharmacists interviewed who reported daily visits of representatives from companies of infant foods and products. Denominator: total number of managers or pharmacists who receive visits of representatives from companies of infant foods and products. Multiply the result by 100. Note: repeat the operation to calculate the percentage of weekly, monthly, and sporadic visits.</td>
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</table>

Multi-NBCAL: Multicenter Study for NBCAL Compliance Assessment; NBCAL: Brazilian Code of Marketing of Infant and Toddlers Food, Nipples, Pacifiers and Baby Bottles.
Assessment of maternity hospitals

For the assessment of maternity hospitals, the study was conducted in three modules:

1. Module I – environment: presence of educational and technical-scientific materials produced by manufacturers in environments restricted to health professionals and patients; presence of equipment, gifts or free samples provided by companies related to NBCAL in these environments.
2. Module I – characterization of maternity hospitals and assessment of incentives offered by manufacturers to: (a) maternity hospitals; (b) health professionals; and (c) post-partum women.
3. Module – characterization of health professionals, including age, sex, race/skin color, profession, time since graduation, and place of work in the maternity hospital. The interviews with the professionals also addressed their knowledge about NBCAL and their participation in a class or course about NBCAL. Finally, they were asked about their participation in courses and congresses about breastfeeding or infant food in the last two years, whether these events were sponsored by manufacturers, and whether they received personal incentive, such as congress registration, meal during the congress or another incentive.

The outcome of this study was NBCAL violation by manufacturers, characterized as non-compliance with articles 6, 8, and 18 of Law n. 11,265/2006, through the provision of incentives to health professionals, maternity hospitals, and post-partum women. Article 6 prohibits actions of commercial representatives in health facilities, except for the communication of technical and scientific aspects of products to pediatricians and nutritionists. Article 8 stipulates that manufacturers of products covered by Law n. 11,265/2006 are allowed to grant financial sponsorships only to scientific educational and research entities or nationally recognized pediatric and nutritionist associations, and any sponsorship to individuals is prohibited. Article 18 prohibits the production of educational materials for consumers addressing infant food by manufacturers or distributors of products covered by NBCAL.

Box 4 shows the indicators whose unit of analysis is maternity hospitals: one indicator measures the industry approach to maternity hospitals and three indicators assess industry infractions by offering incentives to maternity hospitals, health professionals who work in maternity hospitals, and assisted post-partum women. Box 5 shows indicators whose unit of analysis is health professionals, which measure their knowledge and training about NBCAL, their participation in scientific congresses or events sponsored by the food and infant product industry, and NBCAL violation by health professionals as they received personal incentive at these events.

Discussion

The Multi-NBCAL innovates by developing and systematizing a methodology for compliance assessment, with the standardization of questionnaires and indicators for the assessment of stores and maternity hospitals. The methodology and the indicators were applied in cities in the five Brazilian macro-regions and constitute an essential tool for the assessment of the magnitude and number of Law n. 11,265/2006 violations to monitor the temporal evolution of law compliance, revealing different promotion strategies in different regions.

The Multi-NBCAL methodology is in line with the food and nutrition surveillance and food control guidelines of the PNAN 17, and axis 2 of the PNAISC, as it protects breastfeeding 18, helping mothers and family members make informed decisions about the best foods for their children, free from marketing influence and corporate practices for products covered by NBCAL.

Studies addressing NBCAL compliance in stores have been conducted in different areas in Brazil. Some have reported discounts, special displays, gifts, and different presentation of baby bottles, nipples and pacifiers in drugstores and supermarkets, including an investigation conducted in Piracicaba (São Paulo State) in 2012 27. Other studies have found violations in the commercialization of infant formulas, as observed in a chain of supermarkets in Teresina (Piauí State), in 2009 28. Irregular promotion of these two types of products were also observed in 2016 in a study conducted in 54.3% of all supermarkets in Mossoró (Rio Grande do Norte State) 29. But what is the magnitude of violations reported in these scenarios? What parameters were used to measure them? How to respond to these issues without standard indicators developed for this purpose?

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Box 4

Indicators to assess the provision of incentive to maternity hospitals, health professionals and post-partum women from companies of infant foods and products (Multi-NBCAL, 2020).

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<thead>
<tr>
<th>INDICATOR</th>
<th>DEFINITION</th>
<th>CALCULATION METHOD</th>
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</table>
| (1) Proportion of maternity hospitals that received visits of representatives from companies of infant foods, nipples, baby bottles, and pacifiers | Percentage of maternity hospitals that received visits of representatives from companies of infant foods, nipples, baby bottles, and pacifiers. | Information provided by the health professional, but the unit of analysis is maternity hospital. The following steps were considered to build the indicator:

(a) Each maternity hospital will receive ‘yes’ if at least one professional reports that one or more companies (or distributors) of infant food or products visited one or more health professionals in person in the maternity hospital.

(b) Calculate the indicator: numerator = number of maternity hospitals that received in-person contact from companies; denominator = total number of maternity hospitals evaluated.

Multiply the result by 100.

The analysis of this indicator can be stratified by company. For ex.: companies X, Y, and Z visited #%, #% and #% of evaluated maternity hospitals that received an in-person visit of representatives from companies of infant foods or products.

To qualify the indicator, stratify the visit frequency at least once a month and bimonthly or more, calculating the frequency percentage of the indicator for each of these two categories.

Note: the questions related to this variable refer to the last 12 months. |
| (2) Proportion of maternity hospitals where health professionals receive visits of representatives from companies of infant foods, nipples, baby bottles, and pacifiers | Percentage of maternity hospitals where health professionals receive daily (weekly, monthly, sporadic) visits of representatives from companies of infant foods, nipples, baby bottles, and pacifiers. | Numerator: number of maternity hospitals where one or more health professionals reported receiving daily (weekly, monthly, sporadic) visits of representatives from companies of infant foods, nipples, baby bottles, and pacifiers.

Denominator: total number of maternity hospitals where one or more health professionals reported receiving visits of representatives from companies of infant foods, nipples, baby bottles, and pacifiers.

Multiply the result by 100.

Note: repeat the operation to calculate the percentage of weekly, monthly, and sporadic visits.

This indicator can be stratified by visiting company. For ex.: company X visits #% of maternity hospitals and company Y visits #% of maternity hospitals. |
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<th>INDICATOR</th>
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<th>CALCULATION METHOD</th>
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<tbody>
<tr>
<td><strong>(3) Proportion of maternity hospitals where companies of infant foods, nipples, bottles and pacifiers commit NBCAL violation by offering incentives to health professionals</strong></td>
<td>Percentage of maternity hospitals where companies of infant foods, nipples, bottles and pacifiers commit NBCAL violation by offering incentives to health professionals. Offering incentives constitutes NBCAL violation; it was identified through 5 questions: (a) offering informational or educational materials to be distributed to mothers; (b) offering gifts or giveaways (pens, notepads, USB sticks or other gifts); (c) offering sponsorship for activities or events outside the institution; (d) offering invitations to social events; (e) offering discounts at product purchase. Offering other materials must also be registered to be analyzed whether it constitutes an NBCAL violation.</td>
<td>Firstly, the proportion of maternity hospitals where one or more companies of infant foods, nipples, bottles and pacifiers offer incentives to health professionals is analyzed, which characterizes illegal contact from these companies with health professionals: (a) Each maternity hospital receives an attribute (yes/no) if one or more health professionals report the offer of incentive from companies of infant foods, nipples, bottles and pacifiers through their representatives. (b) Calculate the indicator: numerator = number of maternity hospitals where one or more health professionals reported the offer of one or more incentives by a company; denominator = total number of maternity hospitals. Multiply the result by 100. Note: this indicator can be stratified by company: numerator = number of maternity hospitals reporting incentive from company X; denominator = total number of maternity hospitals reporting incentive from companies of infant foods and products. Multiply the result by 100. Example: companies X, Y, and Z offered incentives to health professionals in #%, #%, and #% of all maternity hospitals evaluated, respectively.</td>
</tr>
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</table>

| **(4) Proportion of maternity hospitals where companies of infant foods, nipples, bottles and pacifiers commit NBCAL violation by offering incentives to maternity hospitals** | Percentage of maternity hospitals where companies commit NBCAL violation by offering incentives to maternity hospitals. Identification of product offer, where a product is offered free of charge or at a reduced price to the maternity hospital, of the following incentives from a company or distributor: (a) free supplies of infant formula or other baby food products; (b) nipples, pacifiers, bottles or nipple protectors; (c) breast pumps; (d) equipment or devices; (e) event sponsorship; (f) courses or workshops held at the maternity hospital; (g) office supplies; (h) area renovations or improvements; (i) educational and informational materials; (j) discounts or subsidies for product purchases; (l) offering other materials not listed above. | The categories in this item are attributed to maternity hospitals where a listed incentive was offered to one or more health professionals by a company or distributor to the institution where they work, constituting a positive response (binary, yes/no answer) for each category of this indicator. (a) Each maternity hospital receives an attribute (yes/no) if one or more health professionals report the offer of incentives from companies to the maternity hospital. (b) Calculate the indicator. Numerator = number of maternity hospitals where one or more health professionals reported the offer of one or more incentives to the maternity hospital by a company; Denominator = total number of maternity hospitals. Multiply the result by 100. Note: the offer of each incentive is related to a specific company or distributor. The results of offering one or more incentives can be described by company or distributor. For ex.: company X offered one or more incentives to healthcare professionals in #% (n = #) of the maternity hospitals that received incentives from the companies of infant foods, nipples, pacifiers and bottles. Note: the questions related to this variable refer to the last 12 months. |
### Box 4 (continued)

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<tr>
<td>(5) Proportion of maternity hospitals where post-partum mothers had contact with representatives from companies of infant foods, nipples, pacifiers and bottles in the maternity hospital</td>
<td>Percentage of maternity hospitals where post-partum mothers had contact with representatives from companies of infant foods, nipples, pacifiers and bottles in the maternity hospital. Identification of contact from commercial representatives of a company or distributor with post-partum women in a maternity hospital. Subcategories of this variable: the name of the company that made such contact, type of contact and frequency of contact in the evaluated maternity hospital.</td>
<td>One or more positive answers to this question characterize the contact of commercial representatives of a company or distributor with post-partum women in the evaluated maternity hospital. (a) Each maternity hospital receives an attribute (yes/no) if one or more health professionals report a company’s contact with post-partum women in the maternity hospital. (b) Calculate the indicator: numerator = number of maternity hospitals in which one or more health professionals reported contact of a company’s representative with post-partum women in the maternity hospital; denominator = total number of maternity hospitals. Multiply the result by 100. Note 1: the companies or distributors that had contact with post-partum women in the maternity hospitals can be described. Note 2: the questions related to this variable refer to the last 12 months. Note 3: in case of direct contact of representatives from companies or distributors with post-partum women in the maternity hospitals, analyze the types of benefits offered: (a) promotional materials for specific products; (b) informational or educational materials; (c) samples of milk or other baby food products; (d) gifts or giveaways; (e) coupons; (f) other benefits not listed above.</td>
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Box 5

Indicators to assess the knowledge of health professionals about Brazilian Code of Marketing of Infant Toddlers Food, Nipples, Pacifiers and Baby Bottles (NBCAL) and NBCAL violations related to receiving personal incentives from companies of infant foods or products for congresses or events sponsored by such organizations (Multi-NBCAL, 2020).

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<tr>
<th>INDICATOR</th>
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<th>CALCULATION METHOD</th>
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<tr>
<td>(1) Knowledge of health professionals about NBCAL</td>
<td>Proportion of health professionals who know NBCAL. The question allowed 3 categories of answer: yes, more or less, no.</td>
<td>Numerator: number of health professionals who reported they knew NBCAL (here only the answer “Yes, I know NBCAL” was considered – “More or Less” was not considered). Denominator: total number of health professionals interviewed. Multiply the result by 100.</td>
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<tr>
<td>(2) Ability of health professionals to name products covered by NBCAL</td>
<td>Proportion of health professionals that can name products covered by NBCAL.</td>
<td>Numerator: number of health professionals who could name at least 3 products covered by NBCAL. Denominator: total number of health professionals interviewed. Multiply the result by 100.</td>
</tr>
<tr>
<td>(3) NBCAL training of health professionals</td>
<td>Proportion of health professionals with NBCAL training.</td>
<td>Numerator: number of health professionals who reported participation in course, training or class about NBCAL. Denominator: total number of health professionals interviewed. Multiply the result by 100.</td>
</tr>
<tr>
<td>(4) Participation of health professionals in a congress or event sponsored by a company of infant foods or products</td>
<td>Proportion of health professionals who participated in a conference sponsored by a company of infant foods or products.</td>
<td>Numerator: number of health professionals who reported participation in a congress sponsored by a company of infant foods and products. Denominator: total number of health professionals interviewed. Multiply the result by 100.</td>
</tr>
<tr>
<td>(5) NBCAL violation due to personal incentive accepted by health professionals for the participation in congresses or events sponsored by a company of infant foods or products</td>
<td>Proportion of health professionals who received any of the personal incentives below at a conference or event sponsored by a company of infant foods or products: (a) congress registration; (b) ticket or transportation to the congress; (c) meal or party during the congress; (d) office supplies (pens, notepads, etc.); (e) gifts.</td>
<td>Numerator: number of health professionals who received a personal incentive for a congress sponsored by a company of infant foods or products. Denominator: total number of health professionals who participated in a congress sponsored by a company of infant foods or products. Multiply the result by 100.</td>
</tr>
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</table>

Multi-NBCAL: Multicenter Study for NBCAL Compliance Assessment.

Regarding the sampling process, both NetCode and Multi-NBCAL use a purposive sample. In NetCode, a health unit (maternity hospital or outpatient clinic) is the starting point, and from then, a number of surrounding stores is mapped. In Multi-NBCAL, the sample of stores is mapped in an area with different social strata, with all stores selected in this area, ensuring sample representativeness. Likewise, the sample of maternity hospitals ensures representativeness by including the public and private sectors, with and without adherence to the BFHI.

IBFAN has performed an annual monitoring of NBCAL for over 40 years, identifying different NBCAL violations. However, it does not aim to offer a systematic analysis to identify the proportion of stores and hospitals that fail to comply with NBCAL. This aspect was developed in Multi-NBCAL, which enables to identify the magnitude and frequency of NBCAL infractions in a certain territory.
Lessons learned

The Multi-NBCAL methodology construction is part of a collective construction process, in which a dialogue between academia and organized civil society (in this case IBFAN) took place in an intense and productive manner. This research project involved different challenges. For instance, structuring a questionnaire that allowed a continuous flow of registration of NBCAL violations in stores and a questionnaire to assess maternity hospitals and health professionals, associated with the absence of national indicators for NBCAL monitoring, were intensely debated issues. These questionnaires were pre-tested in training sessions until they could be used in different scenarios.

For operational reasons, other aspects of NBCAL were not considered in the study scope, for instance, assessment of product labeling of the items covered by NBCAL, marketing in social media channels, content of educational materials, and adequacy of free sample delivery practices. Future studies may standardize specific methodologies and indicators to address these aspects.

Ethical issues constituted another challenging aspect. Although the project was approved by the Research Ethics Committee of the study institution and centers, some maternity hospitals did not authorize study participation and had to be replaced with others, delaying the study start by 8 months. Despite these issues, the multicenter configuration of Multi-NBCAL ensured autonomy of center coordinators, who managed their activities and use of data collected in their respective centers.

The use of smartphones with an application that contained all questionnaires allowed store assessment without attracting the attention of store managers. In a study conducted by Oliveira et al., tablets and printed forms were used to assess compliance with NBCAL in stores, which occasionally generated curiosity of store managers at the assessment moment and an attempt to change the environment by removing commercial promotions that violated NBCAL (unpublished data). The smartphone application also allowed real-time virtual monitoring of data collection.

One of the effects of this study was the development by Fiocruz of a free NBCAL monitoring system that uses the Multi-NBCAL methodology, in addition to training courses for human resource with a focus on health and the engagement of undergraduate students, PIBIC scholarship holders and graduate students in Multi-NBCAL.

Study limitations refer to differences in store sampling between the centers. Purposive samples were used in most cities, choosing areas with different population segments, except in Ouro Preto and Belém, where censuses were performed due to the impossibility of obtaining an accurate list of all stores, either over the Internet or from government agencies, which did not allow a random selection.

Another limitation was the selection of maternity hospitals, with lower representativeness of private maternity hospitals due to their refusal to participate in Rio de Janeiro and São Paulo, which may have generated a selection bias. Due to a delayed processing in the Research Ethics Committee, maternity hospitals could not be assessed in Belém, thus not representing all five macro-regions in Brazil.

Conclusions

Although it is difficult to estimate the extent to which NBCAL compliance has contributed to increases in breastfeeding rates and indicators, NBCAL is considered one of the critical pillars for the breastfeeding policy as it supports effective breastfeeding actions. In this sense, monitoring actions that guarantee visibility of what is happening in territories, cities, and federated units, showing the extent of such issues, can be the first step of social awareness in order to enforce this important law.

Multi-NBCAL contributes to law monitoring by providing compliance indicators in stores and maternity hospitals. The application of this methodology can provide information to support actions from government sectors in charge of inspection and compliance with Law n. 11,265/2006.

Using this methodology in different scenarios will help support public policies to ensure NBCAL compliance, with broad dissemination of results to raise awareness of citizens to ensure infant food choices free from the influence of marketing actions from manufacturers of products and foods that compete with breastfeeding.

Finally, further studies seeking to expand the scope of the methodology, including monitoring of virtual environments, scientific events, labeling, and professional training aiming to standardize
data collection practices and development of indicators, are essential for the creation of a continuous monitoring system that allows noncompliant cases reported by civil society and NBCAL enforcement by government agencies.

Contributors

C. S. Boccolini coordinated the study, contributed to study concept and planning, data analysis and interpretation, bibliographic review, discussion of results, and manuscript writing. M. I. C. Oliveira, P. L. P. Peres and E. K. A. Santos contributed to study planning, data analysis and interpretation, bibliographic review, discussion of results, and manuscript writing. T. S. Toma contributed to fieldwork coordination, development of indicators, and manuscript revision. M. C. Passos and M. B. Gubert contributed to fieldwork coordination, data analysis and interpretation, bibliographic review, discussion of results, and manuscript writing. N. N. B. Sá, D. L. Gomes and T. M. A. L. Silva contributed to the construction of indicators and critical review of the manuscript. R. P. T. Vianna contributed to study planning, fieldwork coordination, data analysis and interpretation, bibliographic review, and manuscript writing. E. O. F. Sally contributed to study planning, data analysis and interpretation, bibliographic review, and manuscript writing. M. F. Rea contributed to bibliographic review and manuscript writing. All authors approved the final version for publication.

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References


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Resumo

A Norma Brasileira de Comercialização de Alimentos para Lactentes e Crianças de Primeira Infância, Bicos, Chupetas e Mamadeiras (NBCAL), vigente no Brasil desde 1988, ainda é sistematicamente infringida, expondo mães e familiares ao marketing ilegal de produtos que competem com o aleitamento materno. O objetivo foi descrever metodologia de estudo multicêntrico e propor indicadores padronizados para monitoramento da NBCAL.

Estudo Multicêntrico para Monitoramento da NBCAL (Multi-NBCAL) conduzido em sete cidades brasileiras: Rio de Janeiro; São Paulo; Ouro Preto (Minas Gerais); Florianópolis (Santa Catarina); Brasília (Distrito Federal); João Pessoa (Paraíba) e Belém (Pará). Instrumentos de avaliação foram adaptados do NetCode/WHO e da IBFAN Brasil (Rede Internacional em Defesa do Direito de Amamentar) para condução de dois inquéritos: (1) avaliação do cumprimento da NBCAL em estabelecimentos comerciais e das práticas e conhecimento dos seus gerentes sobre a NBCAL; (2) avaliação em maternidades da interação da indústria de alimentos infantis com profissionais de saúde e mães. Foram elaborados cinco indicadores para avaliação do cumprimento da NBCAL em estabelecimentos comerciais; sete indicadores para avaliar conhecimentos e práticas dos seus responsáveis; cinco indicadores para avaliar a oferta de incentivos a maternidades, profissionais de saúde e mães pelas indústrias e cinco indicadores para avaliar conhecimento e práticas de profissionais de saúde quanto à NBCAL. A metodologia de avaliação da NBCAL, com a proposta de indicadores padronizados, permite a comparabilidade de estudos sobre o tema. A utilização desses indicadores em inquéritos periódicos, nacionais ou regionais, pode contribuir para monitorar o grau de implementação da NBCAL no Brasil.

Aleitamento Materno; Marketing; Vigilância Sanitária; Defesa do Consumidor

Resumen

La Norma Brasileña de Comercialización de Alimentos para Lactantes y Niños en la Primera Infancia, Tetillas, Chupetes y Biberones (NBCAL), vigente en Brasil desde 1988, todavía es sistemáticamente infringida, exponiendo a madres y familiares al marketing ilegal de productos que compiten con la lactancia materna. El objetivo fue describir la metodología de estudio multicéntrico y proponer indicadores estandarizados para el monitoreo de la NBCAL.

Estudio Multicéntrico para Monitoreo de la NBCAL (Multi-NBCAL) llevado a cabo en siete ciudades brasileñas: Río de Janeiro; São Paulo; Ouro Preto (Minas Gerais); Florianópolis (Santa Catarina); Brasilia (Distrito Federal); João Pessoa (Paraíba) y Belém (Pará). Se adaptaron instrumentos de evaluación del NetCode/OMS y de la IBFAN Brasil (Red Internacional de Acción por la Alimentación Infantil) para la realización de dos encuestas: (1) evaluación del cumplimiento de la NBCAL en establecimientos comerciales y de las prácticas y conocimiento de sus gerentes sobre la NBCAL; (2) evaluación en maternidades de la interacción de la industria de alimentos infantiles con profesionales de salud y madres. Se elaboraron cinco indicadores para la evaluación del cumplimiento de la NBCAL en establecimientos comerciales; siete indicadores para evaluar conocimientos y prácticas de sus responsables; cinco indicadores para evaluar la oferta de incentivos a maternidades, profesionales de salud y madres por las industrias y cinco indicadores para evaluar el conocimiento y prácticas de profesionales de salud respecto a la NBCAL. La metodología de evaluación de la NBCAL, con la propuesta de indicadores estandarizados, permite la comparabilidad de estudios sobre el tema. La utilización de estos indicadores en encuestas periódicas, nacionales o regionales, puede contribuir a monitorear el grado de implementación de la NBCAL en Brasil.

Lactancia; Marketing; Vigilancia Sanitaria; Defensa del Consumidor

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