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Records of the indiscriminate prescription of infant formulas in a Baby-Friendly Hospital

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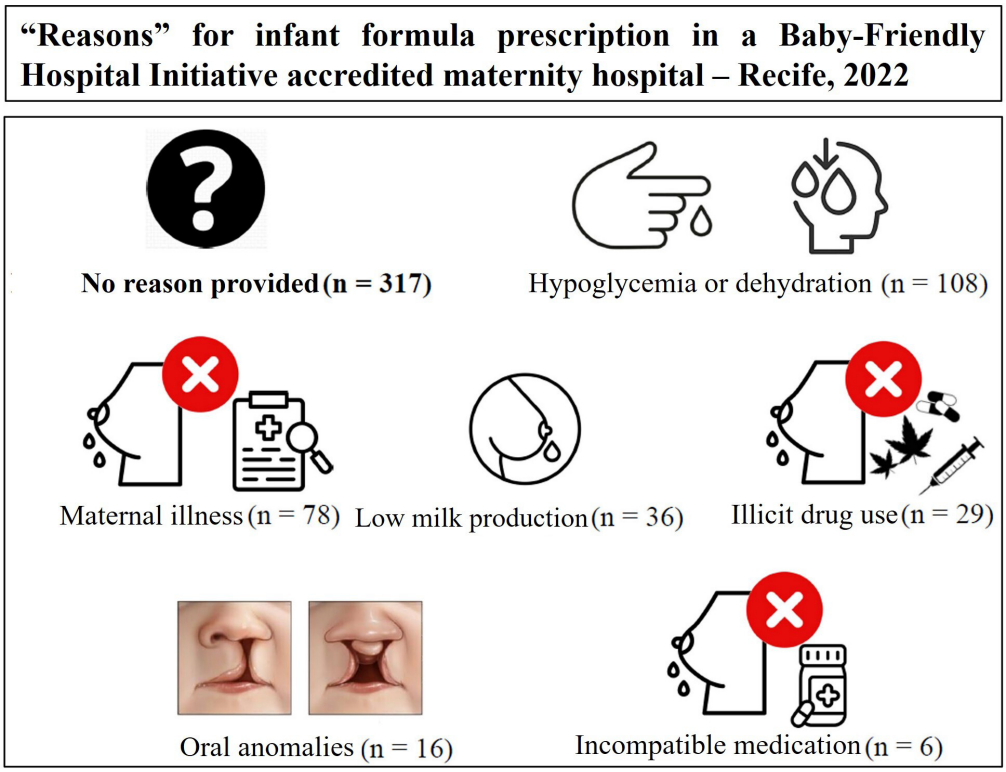
Graphical Abstract



Highlights

- *The procedure for prescribing infant formula violates the Baby-Friendly Hospital Initiative (BFHI) guidelines.*
- *42.2% of the prescriptions did not justify the indication of infant formula.*
- *Only 24.9% of prescriptions included the newborn's age.*
- *Only 7.1% of prescriptions identified the newborn's hospital bed.*
- *The low quality of prescriptions hinders care and indicator analysis.*

Abstract

Brazil mandates compliance with ten requirements of the Baby-Friendly Hospital Initiative (BFHI) to grant a hospital quality seal in both public and private sectors, certifying the commitment to ensuring the right to breastfeeding. This study aimed to evaluate the procedure for prescribing infant formula to newborns admitted to a Baby-Friendly Hospital in a capital city in Northeast Brazil. This is a retrospective documentary study based on a review of infant formula prescription records at a municipal maternity hospital accredited as a Baby-Friendly Hospital in Recife, Pernambuco, Brazil. A structured form—mirroring the institution's official infant formula prescription document—was used to assess recorded information on patient identification, medical reasons for prescription, formula characteristics, and prescriber information. A total of 662 prescriptions issued between August and November 2022 were analyzed. Medical record numbers were present in 71.9% of the prescriptions, but only 24.9% included the newborn's age. In 42.2% of the cases, no justification was given for the use of artificial formula, compromising the promotion of exclusive breastfeeding during the maternity stay. The prescription of artificial formulas for newborns was deemed to be of low quality due to the lack of adequate justification and improper patient identification, contravening the BFHI guidelines and potentially leading to early weaning. These findings raise concerns about child health outcomes and healthcare management practices within Brazil's Unified Health System (SUS).

Keywords: Breastfeeding. Dietary Supplements. Infant Formula. Hospital Administration. Human Milk Banks.

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INTRODUCTION

Breast milk is essential for infant growth and development. It contains all the nutrients required for proper nutrition and provides a wide range of antibodies. During the maturation period of the child's immune and gastrointestinal systems, breast milk alone is sufficient, eliminating the need for other foods[1].

The World Health Organization recommends exclusive breastfeeding up to 6 months of age, followed by complementary feeding with appropriate foods up to 24 months or beyond. This practice benefits both the breastfeeding person and the infant, as increased breastfeeding rates are associated with reduced infant mortality and lower incidence of chronic diseases[1,2].

With the aim of strengthening exclusive breastfeeding practices and preventing early weaning while still in the hospital setting, the Baby-Friendly Hospital Initiative (BFHI) was launched in 1991 among United Nations member countries. It is based on hospital policy guidelines that promote breastfeeding through the implementation of the Ten Steps to Successful Breastfeeding, encouraging evidence-based clinical and managerial practices by trained professionals[3].

Brazil was among the 150 countries selected to initiate the BFHI after signing the Innocenti Declaration and is the only country that requires full implementation of all BFHI criteria to be granted the quality seal, which is based on the support, protection, and promotion of breastfeeding[3].

The BFHI has contributed to the reduction of infant mortality in Brazil, with data showing that births in Baby-Friendly Hospitals are associated with higher likelihood of breastfeeding in the first hour of life. Additionally, there has been a 3.5 to 4.2% reduction in infant deaths between 7 and 180 days of life among those born in Baby-Friendly Hospitals[4].

In Brazil, in addition to the BFHI, there are several other initiatives and public policies that promote, protect, and support breastfeeding, such as the "*Amamenta Alimenta Brasil*" Strategy; the Brazilian Code for the Marketing of Breastmilk Substitutes (NBCAL); the "*Empresa Cidadã*" Program; the National Policy for Comprehensive Child Health Care; the Kangaroo Method; and the Food Guide for Children Under Two Years[5]. These measures also recognize that there are situations in which breastfeeding is contraindicated for the infant.

The Brazilian Society of Pediatrics[6] recommends the use of breast milk substitutes only when breastfeeding is not possible or is contraindicated, especially during the first year of the infant's life. In such cases, Human Milk Banks can be accessed. These banks provide support for overcoming breastfeeding challenges and collect human milk, ensuring its safety and quality for donation to infants. These actions are effective ways to prevent early weaning[7]. The prescription of artificial substitutes should only occur after all possibilities of offering human milk have been exhausted[6].

Despite this, data from the National Survey on Infant Feeding and Nutrition, a Brazilian population-based survey, revealed that the Northeast has the highest prevalence of mixed feeding (26.8%) in infants under 6 months and the highest use of baby bottles (55.8%) in children under 2 years. While the national average prevalence of exclusive breastfeeding at 6 months was 45.8%, with a target of 70.0% proposed by the World Health Organization, only 39.0% of children in the Northeast reached 6 months of exclusive breastfeeding[8].

Studies assessing the reasons for prescribing substitute formulas have highlighted the lack of justification for such prescriptions, even within the context of the Baby-Friendly Hospital Initiative, despite its strict requirements[9,10]. When reasons are provided, the most frequently cited include hypogalactia due to psychological, sociocultural, biological, and medicinal factors; inadequate breastfeeding practices; and the absence of guidance and encouragement from health professionals—all of which contribute to early weaning and increased use of breast milk substitutes[9].

Despite the initiative's undeniable positive effects, systematic monitoring is needed to identify hospital practices that jeopardize the right to breastfeeding—especially in regions such as the Northeast, which has historically shown fragile nutritional indicators compared to other areas.

This study aimed to assess the procedure of infant formula prescription for newborns admitted to a Baby-Friendly Hospital in a capital city of Brazil's Northeast region.

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METHODS

This was a retrospective documentary study conducted through a review of infant formula prescription records at a municipal maternity hospital accredited as a Baby-Friendly Hospital in Recife, Pernambuco, Brazil. The unit serves low-risk patients, admitting cases both via walk-in care and referrals from the Health Department of Pernambuco's Regulation Center, performing an average of 300 deliveries per month.

The study assessed the completion pattern of the prescriptions (mother's name, medical record number, newborn's age, ward identification, and bed identification), justification for the formula prescription (medical reason), information about the prescribed formula (dilution, volume, feeding schedule, route of administration), and prescriber details.

The institution's official form included nine acceptable medical reasons for prescribing infant formula, according to BFHI3, namely: newborn under 32 weeks of gestational age and/or very low birth weight (<1500g) (when no human milk is available in the Human Milk Bank); newborn with severe suction difficulty or oral abnormalities; newborn with hypoglycemia or dehydration not improving with breastfeeding or expressed human milk; infant with rare metabolic disease preventing breastfeeding; maternal illness that prevents the mother from caring for the newborn or contraindicates breastfeeding; mother using medications incompatible with breastfeeding (temporarily or permanently); mother using illicit drugs (subject to health team evaluation); breast reduction surgery when maternal milk production does not support adequate newborn weight gain; and other reasons only after assessment by the Human Milk Bank. The data collection instrument retained these nine options and also recorded any additional reasons, even if not listed.

Data collection took place in November and December 2022, using the semester's physical archives available in the Human Milk Bank sector of the maternity unit. A structured form was developed to mirror the institution's infant formula prescription document and was reviewed by experts.

A total of 674 prescriptions issued between August and November 2022 were reviewed, representing all prescriptions from that semester. During the data consistency check phase, 12 prescriptions were excluded for lacking any identifying information (name and/or record number) of the mother and/or newborn. For analytical purposes, identification variables were recorded as dichotomous categorical variables (present/absent), ensuring anonymization of the forms.

Data were collected using an electronic form that automatically directed responses to a Microsoft Excel 2013 spreadsheet, where the analyses were performed. The prescription completion pattern, justification, and identification were analyzed descriptively using absolute and relative frequencies for qualitative variables.

The research was approved by the Research Ethics Committee of Faculdade Frassinetti do Recife (CAAE 61450722.6.0000.5586, ruling 5.631.702), in accordance with Resolutions 466/12 and 510/2016 of the Brazilian National Health Council. The requirement for informed consent was waived.

RESULTS

A total of 662 infant formula prescriptions issued by the maternity hospital were analyzed. Among these, 71.9% included the medical record number, while only 24.9% contained the age of the newborns who were to receive the artificial formula. Regarding header information that guides the delivery of the prescribed formula, Table 1 shows that ward identification was incomplete, and bed identification was even rarer, appearing in only 7.1% of cases in the shared ward where the newborn was hospitalized.

The medical justification for prescribing a breast milk substitute was absent in 42.2% of the analyzed forms. Other essential information for the preparation and administration of infant formulas was infrequent in the documentary records, such as instructions for product dilution (37.0%) and the specified feeding route (21.1%). On the other hand, the indication of a preferred brand, unrelated to the product's composition or the patient's clinical condition, was found in 19.5% of the prescriptions (Table 1). It is important to highlight that, of the

129 times prescribers suggested a specific infant formula brand, the recommendations referred exclusively to three products from two multinational brands that were not available in the hospital unit. Furthermore, the institutional form did not include a specific field for recording this information.

Another finding was the mention of expressed or pasteurized human milk in the prescriptions. Only 4.8% of prescriptions included expressed or pasteurized breast milk as an alternative for infant feeding. Among these, 6.3% requested dilution of human milk at the same standard concentration as the formula adopted by the hospital unit, fifteen percent. In addition, some cases showed the absence or incompleteness of the mandatory identification of the prescribing professional. When the prescriber's professional category was identified, pediatricians (37.5%) and neonatologists (36.6%) predominated, followed by general practitioners (22.7%) (Table 1).

Table 1 - Completion profile of infant formula prescription forms in a Baby-Friendly Hospital in Recife. Pernambuco, Brazil, 2022 (n = 662).

Variables	N (%)
Header information	
Mother's name	662 (100)
Medical record number	476 (71.9)
Newborn's age	165 (24.9)
Ward identification	517 (78.1)
Bed identification	47 (7.1)
Medical reasons for infant formula prescription	
Medical indication provided	383 (57.8)
Information on prescribed infant formula	
Dilution	245 (37.0)
Volume	661 (99.8)
Feeding schedule	636 (96.1)
Feeding route	140 (21.1)
Brand	129 (19.5)
Prescriber information	
Name	655 (98.9)
Professional category	655 (98.9)
Professional registration number	655 (98.9)
Stamp	650 (98.2)
Signature	656 (99.1)

Of the justifications that met the accepted criteria for prescribing infant formula, according to the Baby-Friendly Hospital Initiative and listed in the institutional form, 220 prescriptions mentioned valid reasons. Among these, the clinical condition of hypoglycemia or dehydration was the most common reason for replacing breast milk with infant formula, accounting for 27.7% of the prescriptions (Table 2). There were no mentions of cases involving very low birth weight newborns, rare metabolic diseases, or postpartum women with mammoplasty resulting in reduced milk production.

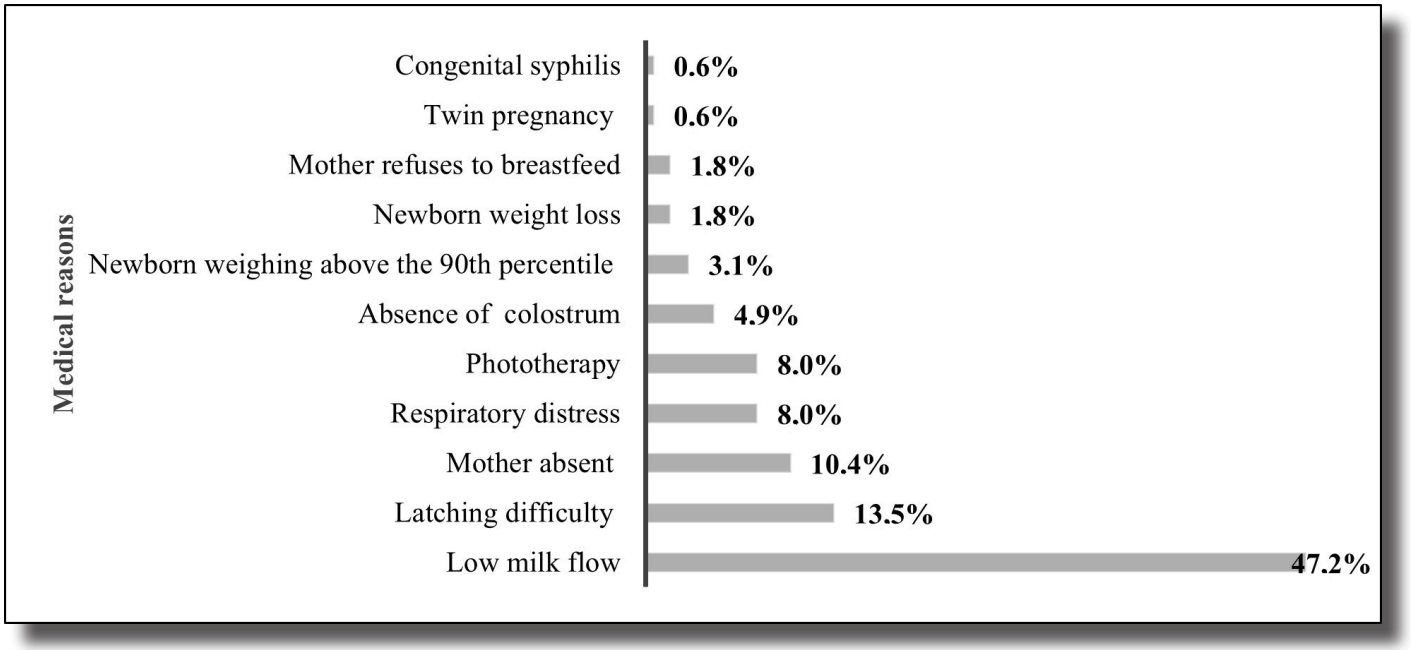
For 219 prescriptions, no justification was indicated. In another 100, the option "other reasons only after evaluation by the Human Milk Bank" was selected, which refers to reasons not included in the list of criteria accepted by the Baby-Friendly Hospital Initiative and requires a detailed description. However, in 60.0% of the prescriptions that selected this option, the prescriber did not provide any description of the reason for prescribing infant formula (Table 2).

Table 2 - Medical reasons indicated on structured forms for the prescription of infant formula in a Baby-Friendly Hospital in Recife. Pernambuco, Brazil, 2022 (n = 383).

Medical reasons for prescribing infant formula	N (%)
Newborn with severe sucking difficulty or oral abnormalities	11 (2.9)
Newborn with hypoglycemia or dehydration not improved by breastfeeding or expressed human milk	106 (27.7)
Maternal illness preventing care of the newborn or contraindicating breastfeeding	71 (18.5)
Mother using medication incompatible with breastfeeding, temporarily or permanently	5 (1.3)
Mother using illicit drugs	27 (7.0)
Other reasons only after evaluation by the Human Milk Bank	40 (10.4)
Other reasons not mentioning the Human Milk Bank	123 (32.1)

When detailing the "other reasons" option, it was observed that in 47.2% of the prescriptions, the justification for prescribing artificial milk was low milk flow. This was followed by latching difficulties, which accounted for 13.5%. Both reasons are fully manageable through interventions by the Human Milk Bank and the care team trained in corrective and educational practices. Other reasons included the need to restore respiratory function and cases of neonatal jaundice. Additionally, in isolated cases (<1.0%), infant formula was prescribed exclusively due to situations of twin births and congenital syphilis, conditions that, in fact, do not contraindicate breastfeeding (Figure 1).

Figure 1 - Prevalence of medical reasons not listed among the acceptable criteria established by the Baby-Friendly Hospital Initiative for the prescription of infant formula in a Baby-Friendly accredited maternity hospital in Recife. Pernambuco, Brazil, 2022 (n = 163).



DISCUSSION

The poor quality of information recorded by infant formula prescribers compromises the care provided to newborns and the generation of indicators related to such care. This is particularly concerning, as newborns require rigorous care to reduce morbidity and mortality rates and to promote healthy growth and development.

The absence of medical record numbers in the prescriptions analyzed hindered the cross-referencing of information related to hospitalization and the care provided to the mother-baby dyad. A similar study conducted in another city in northeastern Brazil indicated that in nearly half of the medical records, the reasons for the prescription were not documented, and the prescription itself was also often missing[9]. These documentation failures reveal that the lack of patient identification, although risky, is a common practice.

Furthermore, there was a frequent absence of information regarding the hospital ward and bed, critical data to ensure accurate patient location and correct delivery of the prescribed formula, preventing its administration to the wrong patient. Accurate patient identification in health records, whether manual or electronic, is essential to patient safety. In addition to names, it is recommended to use other identifiers to ensure effective identification[11].

In this study, the lack of records regarding the newborn's age prevented analysis of how early the formula was introduced, the duration of its use, and its relation to the reason for prescription. Other studies point out that the use of infant formula during postpartum hospitalization is one of the causes of early weaning, potentially leading mothers to offer other types of milk after discharge[10,12]. It is therefore necessary to systematically monitor the proportion of prescriptions for breastmilk substitutes and implement corrective measures.

The direct actions and omissions of the prescribing professional can determine the outcome of breastfeeding initiated in the maternity hospital. A study conducted in the United States revealed a higher frequency of artificial supplementation during the first 12 hours of life for babies born between 10 p.m. and 9 a.m.[13]. Another study in Canada, with first-time mothers who expressed the intention to breastfeed, found that the use of infant formula within the first 72 hours of life was associated with twice the likelihood of weaning between 30 and 60 days, and three times the likelihood of weaning after 60 days postpartum[14].

Breast milk is considered the primary natural source of antibodies[15]. It reduces the risk of infections, allergies, and metabolic diseases, while also providing protective effects for mothers against breast cancer and obesity[16,17]. Unless there are medically justified reasons for the use of infant formula, prescribing artificial substitutes to babies without specific need is considered inappropriate[18]. Therefore, proper documentation of medical reasons is essential for monitoring care quality indicators and for identifying the need for interventions that promote and protect exclusive breastfeeding through intersectoral and multiprofessional efforts.

It is alarming that a significant portion of the prescriptions analyzed lacked justification for the prescription of artificial formula to newborns. This practice increases the risk of weaning shortly after birth[19]. Furthermore, the absence of clear criteria for prescription raises concerns about whether proper clinical assessment was conducted and about the prescriber's qualifications. Infant formula should be prescribed judiciously, as its introduction during maternity hospitalization may encourage mothers to continue the practice at home[19,20].

A study conducted at a university hospital in Rio Grande do Norte revealed that 93.8% of infant formula prescriptions lacked justification. This occurred at another Baby-Friendly Hospital, where stricter criteria for formula authorization were expected9. Compared to that study, the assessment conducted at the maternity hospital in Recife showed a lower prevalence of unjustified prescriptions.

Moreover, according to estimates[18], the cost of maintaining an infant on artificial feeding is high for the public health system and increases over time as the baby grows. In contrast, breastfeeding does not burden the socioeconomic status of the patient and their family. Therefore, the responsible use of public resources through appropriate infant formula prescriptions is a matter of accountability and ensures that limited resources are directed to those who truly need them.

Medically acceptable indications for partial or complete replacement of breast milk are rare and may involve either the newborn or the mother[16]. For example, maternal seropositivity for Human Immunodeficiency Virus (HIV) or Human T-cell Lymphotropic Virus type 1 (HTLV-1) should be known prior to childbirth due to the 7% to 22% transmission risk[19]. Other factors that justify temporary or permanent breastfeeding suspension are related to the use of medications or psychoactive substances by the lactating individual. In the case of antineo-

plastics and radiopharmaceuticals, breastfeeding is contraindicated. Suspension is also recommended during the use of illicit drugs, barbiturates, opioids, and amphetamines[16].

Regarding newborns, glycemic control was a relevant reason for prescribing infant formula at the hospital under study. Formula feeding is recommended in cases of asymptomatic hypoglycemia confirmed by laboratory testing, whereas in symptomatic hypoglycemia, intravenous glucose should be administered[21]. Hypoglycemia may be associated with insufficient intake of breast milk, often resulting from poor latch technique[22]. Improper latching can hinder effective suction and breast emptying, which compromises milk production and often leads to the early introduction of infant formula[23].

Low milk flow and other breastfeeding-related difficulties were frequent reasons for the prescription of infant formula in the analyzed facility. Low milk production is reported as the most common difficulty during breastfeeding, especially prior to the onset of mature milk (lactogenesis II)[24]. Hypogalactia is identified as the main factor for early weaning in 33% to 71.7% of cases[9,25]. More recently, its incidence has been significantly lower (3.57%)[17], suggesting the effects of changes in breastfeeding practices or in the way difficulties have been managed over time.

At the hospital level, Human Milk Banks play an important role in supporting breastfeeding individuals, providing follow-up and guidance regarding breastfeeding challenges. However, only a quarter of mothers are referred by the attending physician[7]. There appears to be a lack of multidisciplinary commitment to promoting the benefits of breastfeeding and to utilizing this service as a place of support and learning. Many factors that compromise exclusive breastfeeding can be mitigated through integrated action between Human Milk Banks and healthcare teams. These actions include ensuring proper latch-on during hospitalization, providing discharge instructions, and supporting the planning of a home routine conducive to breastfeeding[18,26].

Although the aim of the BFHI is to contribute to the reduction of infant mortality by increasing breastfeeding rates[3], its effectiveness depends on full compliance with the *Ten Steps to Successful Breastfeeding*, which form the foundation of the initiative[4]. The tenth step, which involves referring mothers to support groups within primary care, protects long-term breastfeeding by reinforcing support and promotion efforts starting in prenatal care[27,28]. Thus, actions properly initiated during the immediate postpartum hospitalization can be strengthened through public policies at the level of Primary Healthcare.

The lack of support and availability from healthcare teams contributes to the weakening of breastfeeding, leaving postpartum women without proper guidance and subject to the indiscriminate prescription of infant formula. After hospital discharge, even when formula use is indicated, families and infants are left with only the information provided on the labels of artificial infant nutrition products[29]. Despite progress in breastfeeding and exclusive breastfeeding indicators in Brazil over the past three decades[30], systematic evaluation of institutional policies is still necessary in healthcare facilities that promote the prescription and distribution of infant formula in disagreement with national guidelines for the promotion and protection of breastfeeding.

It is important to note that this study has limitations. One of them relates to the fact that the last two months of data collection coincided with the period during which the maternity hospital was being prepared for the renewal of its Baby-Friendly Hospital Initiative accreditation. Therefore, the results may have been positively influenced by a greater institutional focus on breastfeeding support and promotion practices during that time. In this context, we encourage a follow-up study using prescription data from the period after the recertification.

Finally, we acknowledge that this study reflects the reality of a single institution and we do not propose generalizing the results. Although the study met its initial objective, replicating the methodology in multiple centers and incorporating a qualitative approach involving prescribers could enhance representativeness and provide a broader understanding of the BFHI implementation in Brazil.

CONCLUSION

The prescription of artificial formula for newborns was assessed as being of low quality due to the lack of adequate justification and incorrect patient identification. This practice is inconsistent with the guidelines of the Baby-Friendly Hospital Initiative and may contribute to early weaning. The absence of proper justification for prescribing formula instead of human milk reflects a lack of commitment by healthcare professionals and institutions to the

promotion of exclusive breastfeeding. The negative interference of professionals in protecting breastfeeding should be interpreted as a denial of the right to health for both the breastfeeding person and the baby. As corrective and preventive institutional measures, it is recommended to enforce the mandatory completion of essential prescription fields, implement internal monitoring of BFHI indicators, and promote the continued training of professionals to ensure alignment of care practices with current scientific recommendations and public health policies in the country.

CRediT author statement

Conceptualization: Barbosa, LCS; Clark, SGF. Methodology: Barbosa, LCS; Clark, SGF. Validation: Clark, SGF. Statistical analysis: Clark, SGF. Formal analysis: Clark, SGF. Investigation: Barbosa, LCS. Resources: Barbosa, LCS. Writing – original draft preparation: Barbosa, LCS. Writing – review and editing: Barbosa, LCS; Clark, SGF. Visualization: Clark, SGF. Supervision: Clark, SGF. Project administration: Barbosa, LCS.

All authors have read and agreed to the published version of the manuscript.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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