



Understanding before incorporating: a portrait of milk allergy programs implemented in Brazil

Conhecer antes de incorporar: um retrato dos programas para alergia ao leite implementados no Brasil

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ABSTRACT

This paper aims to characterize the assistance offered to children with cow's milk allergy in public programs and challenges to their implementation, specifically assessing the pre-incorporation phase in the Brazilian Unified Health System of 3 formulas for infants with milk allergy. This exploratory, cross-sectional study with a quantitative approach assessed 21 programs/services from all regions of the country. The main motivation for the creation of these programs was judicialization (80.9%), and these special formulas were provided for children up to 2 years of age. The main challenges to creating and implementing these programs were a lack of human and financial resources, no counterpart federal program, no unified protocol for diagnosis (oral provocation test), and the selection of formula types. The most common strategy for reducing costs was updating norms and protocols (61.9%), which did not differ significantly between state and municipal programs. This study presents an unprecedented and detailed evaluation of the programs, raising discussion about decision-making, the rational use of public resources, better care for children, and means of strengthening of the national health system.

Keywords: Unified Health System, program evaluation, continuity of patient care, milk hypersensitivity, health manager.

Introduction

Allergic diseases are an important cause of morbidity worldwide and are a considerable burden to health systems in emerging and developed economies.¹ Cow's milk protein allergy (CMPA) is

RESUMO

Este trabalho objetiva caracterizar a assistência ofertada às crianças com alergia ao leite em programas públicos, e os desafios enfrentados na sua implantação, no contexto da pré-incorporação no Sistema Único de Saúde, de três fórmulas infantis para alergia ao leite. Estudo exploratório, transversal e abordagem quantitativa. Foram avaliados 21 programas/serviços de todas as regiões brasileiras. O principal indutor da criação destes programas foi a judicialização (80,9%), e o fornecimento destas fórmulas especiais foi realizado para crianças com até 2 anos de idade. Os principais desafios para a criação e execução destes programas foram a falta de recursos humanos e financeiros, a falta da contrapartida da União, protocolo unificado para o diagnóstico (Teste de Provocação Oral), e a escolha dos tipos das fórmulas. A estratégia mais adotada para redução dos custos foi a adequação das normas e protocolos (61,9%). Não houve diferença significativa entre os programas estaduais e municipais. Este estudo apresenta uma avaliação inédita e detalhada sobre os programas, trazendo discussões que corroboram a tomada de decisões, o uso racional de recursos públicos, a melhor assistência às crianças e o fortalecimento do sistema de saúde nacional.

Descritores: Sistema Único de Saúde, avaliação de programas e projetos de saúde, continuidade da assistência ao paciente, hipersensibilidade a leite, gestor de saúde.

an immune response to cow's milk protein fractions, especially α -lactalbumin, β -lactoglobulin, and casein.² This food allergy can compromise several organ systems, although the gastrointestinal, skin, and

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respiratory systems are most affected.³ CMPA is the most common food allergy in children, especially newborns.^{4,5} The severity of CMPA reduces over time in most children⁶, given that certain factors contribute to earlier cow's milk tolerance, such as CMPA not mediated by immunoglobulin E, and treatment with hydrolyzed casein + probiotics (strains of *Lactobacillus rhamnosus*). Factors such as cesarean delivery and breastfeeding < 3 days contribute to late tolerance.⁵ CMPA diagnosis is complex, based on several stages.⁷

For the mothers of children who have a reaction to breast milk proteins, the current Brazilian Consensus on Food Allergy⁶ recommends following an exclusion diet and monitoring the infant's symptoms. For formula-fed infants, the recommendation is to exclude CMP-based formulas, replacing them with extensively hydrolyzed formulas (EHF) based on cow's milk protein. If there is no clinical improvement after 2 weeks, these should be substituted with amino acid-based formulas (AAF).^{6,8,9} If the child shows improvement, an oral provocation test (OPT) must be performed. Positive OPT results indicate that the exclusion diet must be continued with the same formula for 6 to 12 months.⁶ In Brazil, no national level surveys have been conducted on the prevalence of CMPA.^{10,11}

According to Patton¹², "Systematic collection of information about the activities, characteristics and the results of these programs to pass judgment on them, improve its effectiveness and clarify decisions related to new software". This study was based on this definition; studies evaluating programs that provide special infant formulas are scarce, being generally related to the epidemiological and clinical characterization of patients¹³, histories of the creation of such programs¹⁴, or reports on interventions to encourage breastfeeding.¹⁵ This is the first nationwide study to describe and evaluate programs/services, reflecting their differences and specificities.

In 2012, discussion began about incorporating these special formulas for children with CMPA into the Brazilian Unified Health System (UHS) due to increased demand, the growing judicialization of states and municipalities and, a lack of initiatives at the federal level, proposals have been made to incorporate 3 types of formulas for children with CMPA: (1) soy-based (SBF), (2) EHF, and (3) AAF.¹⁰ In 2014, this measure was unanimously approved but not implemented until fiscal responsibility could be determined at federal, state, and municipal levels.

Since no conclusions were reached, the proposal was resubmitted in 2017, but was not implemented on a national level. The programs that currently exist are state and municipal initiatives.

According to the National Food and Nutrition Policy¹⁶, food and nutrition are basic conditions for health promotion and protection, allowing unrestricted growth and development with dignity and quality of life. However, this does not extend to special health conditions, such as food allergies. This underscores the need for discussion about improving care for children with food allergies and their families to guarantee health, citizenship, and quality of life.

Due to the relevance of the topic, the functioning, routines, and challenges directly involved in current programs and/or services that provide infant formula, as well as national-level programs still in the implementation phase, must be better understood before incorporating this new technology in the UHS to ensure greater equity and coverage.

Methods

This exploratory, quantitative, cross-sectional study identified municipalities and states with programs/services to assist children with CMPA, either through direct consultation with the Ministry of Health, the National Council of Health Departments, or the National Council of Municipal Health Departments (34 municipal and 5 state programs identified) or through an Internet search using the terms "program", "allergy" and "cow's milk" (16 municipal and 4 state programs identified).

After this step, the protocols and regulations of these programs were studied, and those that only provided formula due to court decision were excluded. Thus, a total of 35 programs were considered eligible (26 municipal and 9 state programs). Since the Sergipe State Department of Health and the Aracaju Municipal Health Department programs were formed through an agreement with the State Attorney General, we considered them to be a single program. The same occurred with the Vitória municipal program and the Espírito Santo state program. Thus, the total sample was 25 municipal and 9 state programs (Figures 1 and 2).

To evaluate the existing programs, the states and municipalities were contacted through official institutional channels (eg, website "Contact Us" links, telephone numbers, or social media channels). A

database was produced with this information to speed up communication. However, much of this information was out of date, which led to new searches and contact with other health departments in an effort to reach the relevant secretaries of health and locate the sectors responsible for the program.

Data were collected through a semi-structured interview by telephone and/or videoconference (Microsoft Teams or Google Meet) with the program coordinators appointed by the respective health departments. Data pending at the time of the interview were requested later via e-mail. The script of the interview was based on the program's protocols and a literature review, being divided into the following 5 sections (28 total questions):

- *Institutionalization*: program level (municipal or state), official program name, starting year, motivation, department responsible for managing the program administratively and financially, partnerships, and communication with other health departments;
- *Epidemiological data, formula types, and the direct costs of each program*: the number of children assisted and the cost of formula acquisition in the last five years (2015 to 2019), the provision of formula to children > 2 years of age, the most used formulas in children < and > 6 months of age;
- *Team and routines*: the professionals who directly assist children with CMPA, the minimum and maximum time from registration until the first formula is received, periodicity of monitoring by a professional, testing within the program, factors considered in CMPA diagnosis, oral provocation testing, and the conditions for performing OPT;
- *Breastfeeding*: guidance about the importance of breastfeeding, providing educational material about the exclusion diet, and institutions or initiatives to support breastfeeding in the city/state;
- *Managerial view*: the main difficulties in implementing and executing the program, suggestions for resolving reported difficulties, and cost reduction strategies.

The interviews were preceded by telephone and/or institutional e-mail contact. The provided services (diagnosis, access, and monitoring) were characterized using data officially available through the health departments. The interviews were conducted between June 2020 and June 2022.

The data were organized in tables and descriptive

statistical analysis was performed, including calculations of simple and relative frequencies for qualitative variables, and measures of central tendency and dispersion for quantitative variables. In the inferential analysis, the chi-square test of homogeneity was used to determine whether a random variable behaved similarly (homogeneously) in several categories of the same variable. The significance level was set at 5%, and IBM SPSS Statistics 20.0 and R 3.6.0 were used for the analyses.

The project was approved by the University of Brasília Faculty of Health Sciences Research Ethics Committee (29583520.4.0000.0030, opinion 3.984.775), the Curitiba Municipal Health Department Ethics Committee (29583520.4.3001.0101, opinion 4.852.974), the Belém Permanent Education Nucleus (authorized on April 28, 2021), the Espírito Santo Institute of Education, Research, and Innovation in Health's Research Sector (authorized on August 20, 2020), and the Maringá Permanent Commission for Process Evaluation (authorized on July 2, 2021).

Results

The study included 21 programs/services. The 15 municipal programs were in Afogados da Ingazeira (PE), Belém (PA), Belo Horizonte (MG), Blumenau (SC), Campos Altos (MG), Caruaru (PE), Contagem (MG), Curitiba (PR), Dourados (MS), Florianópolis (SC), Lucas do Rio Verde (MT), Maringá (PR), Rio Verde (GO), São José (SC), and Várzea de Palma (MG). The 6 state programs were in Ceará, the Federal District, Espírito Santo, Maranhão, Rio Grande do Norte, and Sergipe).

The municipal program coordinators in Almirante Tamandaré (PR), Camaçari (BA), Jaboatão dos Guararapes (PE), Jaguariúna (SP), Lupionópolis (PR), São Lourenço (MG), São Sebastião do Paraíso (MG), Sete Lagoas (MG) and Uruana (GO), and the state coordinators of São Paulo and Mato Grosso do Sul did not respond after numerous attempts via telephone and e-mail. The state coordinator of Rio Grande do Sul replied that it was not possible to participate in the study.

Most of these programs were embedded in other programs that provide enteral formulas and other special dietary products (state: the Federal District, Espírito Santo, and Sergipe; municipal: Campos Altos, Caruaru, Contagem, Blumenau, Curitiba, and Rio Verde), food allergy programs (Afogados da

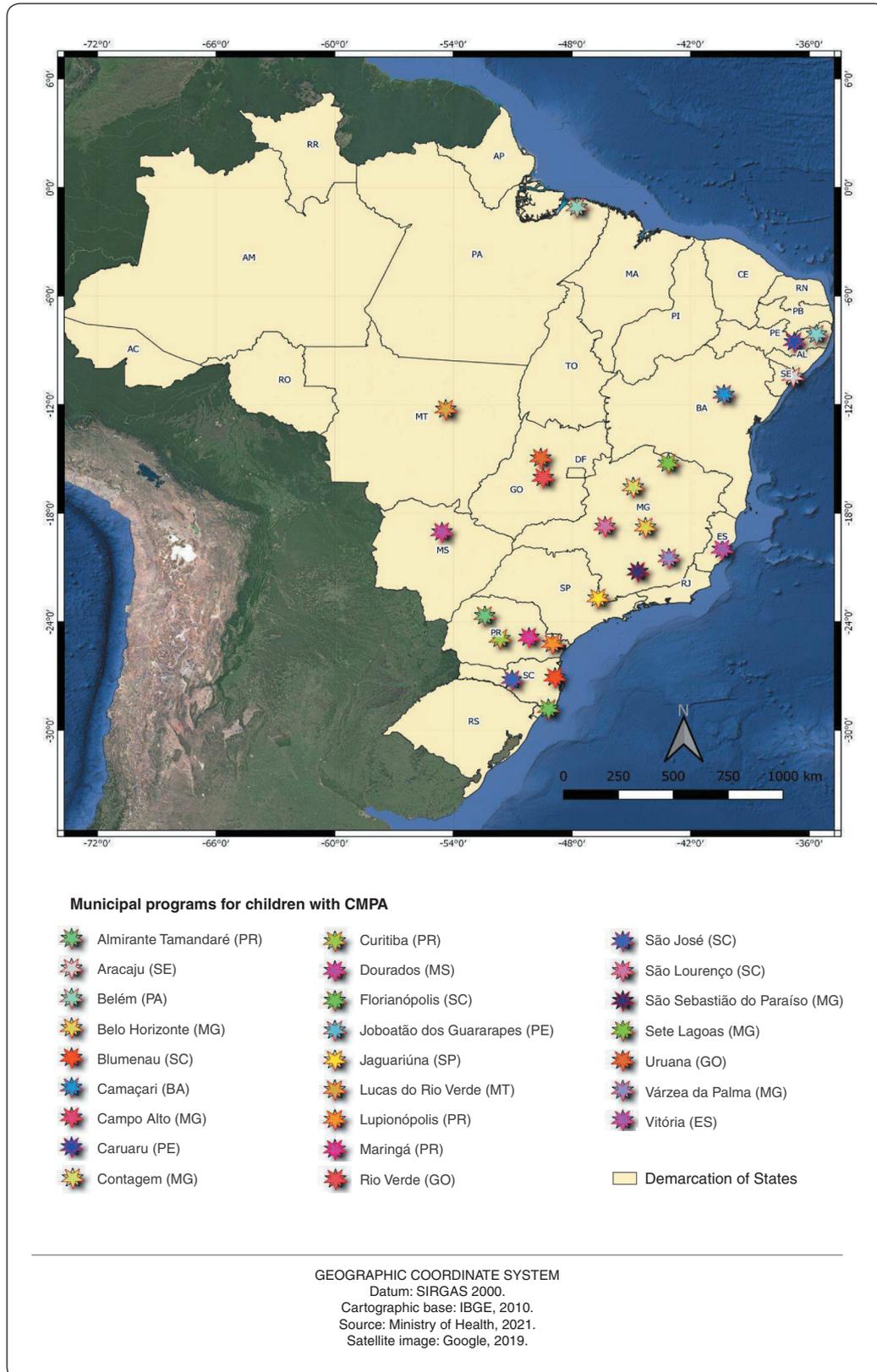


Figure 1
 Geographical distribution of Brazilian municipalities with programs that provide formula for children with cow's milk protein allergy (CMPA), Brazil, 2022

Ingazeira, Belém), or programs for special needs children (Dourados, Florianópolis, Maringá, São José, Várzea de Palma); programs exclusively for CMPA (state: Ceará, Maranhão, and Rio Grande do Norte; municipal: Belo Horizonte), or as a specialized

component of a municipal program (Lucas do Rio Verde).

Judicial action was the main motive behind the creation of these programs (80.9%) (Table 1). All programs were linked, administratively and financially,

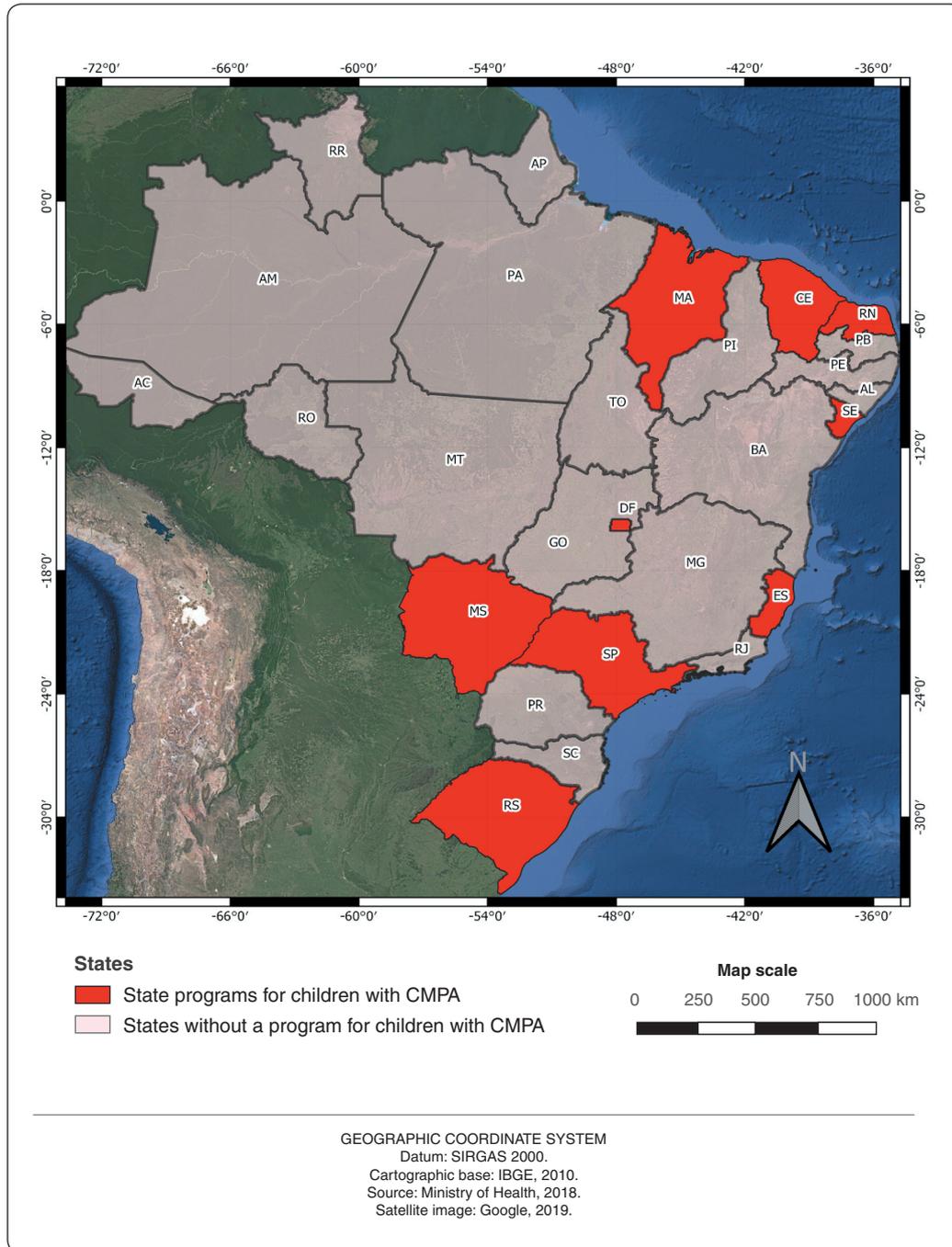


Figure 2
 Map layout of Brazilian states with programs that provide formula for children with cow's milk protein allergy (CMPA), Brazil, 2022

to municipal or state health departments, and 80.9% had no partnership or planned communication with other health departments.

The programs in Blumenau, Curitiba, and São José communicate with the departments of education and social service, the department food and nutrition security (only Curitiba), and the municipal social service department (Campos Altos)(Table 1). Partnership, in this context, refers to pre-established formal relationships within the program, in addition to informal communication not established in the program regulations.

The secretary of education was contacted regarding assisted children enrolled in municipal daycare centers to guarantee safe meals without allergens and an adequate supply of formula according to the time spent in daycare. The department of social service was contacted to verify sufficient environmental hygiene to safely prepare the formula, the family's social conditions, and the social reception of the program, including guidance about other programs. The Curitiba program reported communication with the municipal Food and Nutritional Security Department, which instructs families in vulnerable situations to register with the "Family Warehouse" Program to gain access to basic products below market prices.

In most programs (Table 2) special formulas are provided until the children reach 2 years of age, although 9 programs (state: Maranhão, Rio Grande do Norte, and Sergipe; municipal: Afogados da Ingazeira, Belém, Curitiba, Florianópolis, Lucas do Rio Verde, and Maringá) allow extensions based on evaluation by specialists and/or the program's internal committees. The most widely available formulas for children < and > 6 months of age were lactose-free EHF and AAF; SBF was also widely used for children > 6 months of age (Table 2).

Table 3 shows the number of children assisted by each program in the last 5 years (2015 - 2019) and the direct costs of special formulas. However, inferences could not be made about the relationship between follow-up routines, program format, and cost per child, since most of the programs did not keep such data. However, if only the programs with complete data are considered (Espírito Santo, Maranhão, Blumenau, and Curitiba), the average annual cost per child varied from BRL 1663.00 (Curitiba) to BRL 2081.00 (Espírito Santo), which is close to the expected value. The cost in Blumenau (BRL 6400.00) was 3 times that of Espírito Santo, while that of Maranhão (BRL

17,640.60) was 8 times that of Espírito Santo. Thus, the second major question arose: what is the cause of the large variations?

Some factors that might explain the cost discrepancy between Maranhão's Special Milk Program and the other programs include providing formula for children up to 36 months of age, inconsistencies regarding the use of soy-based formula (SBF) in children < 1 year of age (SBF and rice-based infant formula are not recommended for children < 1 year of age), the lack of an allergologist or pediatric allergist on the program's evaluation committee, in addition to logistics and transportation costs. The children are monitored by pediatric gastroenterologists and nutritionists linked to the UHS, and OPT is performed every 6 months at home; however, in cases of immunoglobulin E-mediated CMPA, milk must be reintroduced in conjunction with OPT in a controlled environment. The number of cans provided per month is limited according to age: 8 per month for children ≤ 12 months old, 6 per month for children ≤ 24 months old, and 4 per month for children ≤ 36 months of age (Government of Maranhão, n.d.) .

SBF is a viable alternative due to its lower cost and the fact that it can be given to children with immunoglobulin E-mediated CMPA beginning at 6 months of age.⁶ The specialized municipal program in Lucas do Rio Verde does not provide formula for children < 6 months of age, while for those > 6 months of age it only provides only SBF, which can explain the program's low annual cost (BRL 204.17) per child. However, the Ceará program does not provide SBF, reasoning that it would lead to greater permanence in the program, which would increase costs, given that there are similar products that could be incorporated in the program due to new court decisions.

The Maringá program was the only one to mention, in addition to the standard formulas for CMPA (AAF, EHF and SBF), a rice-based formula, whose use has not been approved by National Commission for Incorporating Technologies in the Unified Health System. Since only one manufacturer produces this formula, competition is impossible, which could increase program costs. However, because this type of formula was only released in 2021, its effects have not yet been observed.

The programs in the states of Ceará, Espírito Santo, Maranhão and in the city of Belém (PA) also provide AAF to children > 1 year of age (1 to 10 years) as an additional alternative. This, too, is also produced by a single manufacturer, with no equivalent product

available on the market.

Programs that provide more AAF have higher costs than those that provide more EHF and SBF, although all 3 alternatives are necessary. Factors such as distribution logistics and administrative purchasing processes also contribute to these differences. In 2022, the National Commission for Incorporating

Technologies in the Unified Health System¹¹ reported that the lowest price for each product was BRL 15.12 for SBF, BRL 20.33 for EHF, and BRL 36.37 for AAF, although these values are now out of date. Since the programs did not keep records on the amounts spent on each type of formula during this period, the totals cannot be estimated.

Most programs provide guidance on the importance

Table 1

Programs and services that provide formula for children with cow's milk protein allergy (CMPA), Brazil, 2022

	N°	%
Program level		
State	6	28.6
Municipal	15	71.4
Program start date		
< 2000	1	4.8
2001-2010	8	38.1
2011-2020	12	57.1
Justifications for creating the programa		
Increased demand	8	38.1
Absence of similar initiatives at the federal and state levels	2	9.5
Suppressed demand	2	9.5
Lack of patient follow-up	4	19
Judicialization or other legal issues	17	80.9
To organize the flow of formula provision	2	9.5
Rational use of public resources	5	23.8
Department to which the program and/or service is linked		
Health	21	100
Partnerships and/or communication with other departments		
No	17	80.9
Yes	4	19.1
Social assistance	4	
Education	3	
Food and nutrition security	1	

^a Food and nutrition security: p-value < 0.001.

of breastfeeding and an exclusion diet (Table 2), which should include instructions about restricting milk and milk derivatives, guidance about reading labels, technical terms indicating the presence of milk and its protein fractions, as well as about foods that the mother can consume to avoid unnecessary restrictions. A total of 71.4% of the programs reported providing educational materials about the exclusion

diet. Most program managers (76.2%) mentioned initiatives to promote and protect breastfeeding in their territories.

The most common type of professional involved in the follow-up of children with CMPA was nutritionists (85.7% of the programs; n = 18) (Table 4), except in Espírito Santo, where mandatory follow-up was only performed by professional assistants, Florianópolis,

Table 2

Formula types and maternal nutrition materials provided in programs for children with cow's milk protein allergy (CMPA), Brazil, 2022

	N°	%
Formula provided for children > 2 years of age?		
Yes	3	14.3
No	18	85.7
Formulas provided to children < 6 months of age		
AAF	18	85.7
RBF	1	4.8
EHF with lactose	14	66.7
EHF without lactose	19	90.5
FSO	1	4.8
Unavailable	1	4.8
Formula for children > 6 months of age		
AAF	19	90.5
AAF for children ≥ 1 year of age	4	19.1
RBF	1	4.8
EHF with lactose	14	66.7
EHF without lactose	19	90.5
SBF	18	85.7
Guidance on the importance of breastfeeding in CMPA and exclusion diet		
Yes	17	80.9
No	4	19.1
Receipt of educational material on diet of exclusion		
Yes	15	71.4
No	6	28.6
Presence of institutions/initiatives/incentive projects for breastfeeding		
Yes	16	76.2
No	5	23.8

Table 3
Number of children and direct costs for programs that provide formulas for children with cow's milk protein allergies in the last 5 years, Brazil - 2022

Variables	Home Enteral Nutritional Therapy Program (DF)	State Food Allergy Program (SE)	Decree 054R Apr 28, 2010 (ES)	Municipal Program for Dispensing Special Infant Formulas, Florianópolis (SC)	Special Food Program, Blumenau (SC)	Nutritional Care Program for People with Special Food Needs, Curitiba (PR)	Food Allergy Program, Belém (PA)	Special Infant Formula Program, Nutritional Care Program, Rio Verde (GO)	Special formula program for patients with CMPA (RN)	Nutrir Program, Dourados (MS)	Infant Formula Program, Maringá – (PR)
2015	Nº of children	395	1211	NI	33	617	NI	291 ^d	NI	NI	NI
BRL		2,450,376.44	2,450,376.44	NI	201,834.68	1,009,657.22	NI	NI	NI	NI	NI
BRL/child		-	2,023.43	-	6,116.20	1,636.4	-	-	-	-	-
2016	Nº of children	427	1,636	NI	38	629	385	266 ^d	NI	NI	NI
BRL		3,683,029.46	3,683,029.46	NI	215,811.12	884,428.9	NI	NI	NI	NI	NI
BRL/child		-	2,251.24	-	5,679.24	1,406.09	-	-	-	-	-
2017	Nº of children	280	1,830	NI	36	664	329	227	NI	NI	NI
BRL		2,172,222.48	4,159,091.60	NI	204,753.54	1,389,074.04	NI	NI	NI	NI	NI
BRL/child		-	2,272.73	-	5,687.60	2,091.98	-	-	-	-	-
2018	Nº of children	362	1,958	NI	33	812	352	223	NI	NI	NI
BRL		NI	4,287,135.05	NI	223,792.80	1,200,436.74	3,784,000.00	NI	NI	NI	NI
BRL/child		-	2,189.55	-	6,781.60	1,478.37	10,750.00	-	-	-	-
2019	Nº of children	395	1,791	1407	43	773	398	150	NI	NI	175
BRL		3,689,853.44	2,958,933.64	1,557,451.83	340,923.84	1,330,234.99	4,207,000.00	NI	NI	NI	931,866.00
BRL/child		9,341.4	1,652.11	1,106.93	7,928.46	1,720.87	10,570.35	-	-	-	5,324.91
Total	Nº of children	675 ^a	8,426	1,407 ^b	183	3,495	750 ^c	1,157 ^d	NI	NI	175 ^e
BRL		5,862,075.92 ^a	17,538,566.19	1,557,451.83 ^b	1,187,115.98	5,813,831.89	7,991,000.00 ^c	NI	NI	NI	931,866.00 ^e
BRL/child		8,684.56 ^a	2,081.48	1,106.93 ^b	6,486.97	1,663.47	10,654.67 ^c	-	-	-	5,324.91 ^e

BRL = Brazilian Reals; CMPA: cow's milk protein allergy; NI = Not informed.

^a Considering the total number of children assisted by Home Enteral Nutritional Therapy Program and the costs in 2017 and 2019 (complete data); not all of the children had CMPA, but according to the manager, they were the majority.

^b Considering the total number of children assisted by the Municipal Program to Provide Special Infant Formulas (Florianópolis, SC) and the 2019 costs (complete data).

^c Considering the total number of children assisted by State Food Allergy Program (PA) and costs in 2018 and 2019 (complete data).

^d In 2015 and 2016 Rio Verde (GO) program provided formula to children with CMPA up to 3 years of age; as of 2017 the limit was reduced to 2 years of age.

^e Considering the total number of children assisted by the Maringá Special Infant Formula Program and costs in 2019 (complete data).

^f Considering the total number of children assisted by the specialized municipal program of Lucas do Rio Verde (MT) and the costs for 2017 and 2018 (complete data).

^g The CMPA clinics in Belo Horizonte (MG) provided formulas to children at least 1 year of age.

^h Considering the total number of children assisted at the CMAP clinic in Belo Horizonte (MG) and the costs for 2017, 2018 and 2019 (complete data).

Table 3 (continued)
Number of children and direct costs of programs that provide formula to children with cow's milk protein allergy in the last 5 years, Brazil, 2022

Variable	Milk Formula Program for Intolerant and Sensitive People, Alogados da Ingazeira (PE)	Municipal protocol for dispensing special industrialized nutritional formulas, Várzea de Palma (MG)	Protocol for Dispensing Food Formulas, Contagem (MG)	Enteral diet protocol of the municipal health system of Caruaru (PE)	Municipal Infant Formula Distribution Program, Campos Altos (MG)	Specialized municipal component, Lucas do Rio Verde (MT)	Program for underprivileged children with food intolerance and/or allergy – Special Milk Program (IMA)	São José children's program, São José (SC)	CMPA/ Specialized Medical Assistance Service (CE)	Municipal CMPA clinic, Belo Horizonte (MG)
2015	Nº of children	NI	NI	NI	NI	NI	451	132	NI	16 ^g
BRL	NI	NI	NI	NI	NI	NI	6,782,202.27	NI	NI	NI
BRL/child	-	-	-	-	-	-	15,038.14	-	-	-
2016	Nº of children	NI	NI	NI	10	NI	474	99	NI	80 ^g
BRL	NI	NI	NI	NI	NI	1,198.80	7,094,429.16	NI	NI	NI
BRL/child	-	-	-	-	-	-	14,967.15	-	-	-
2017	Nº of children	NI	NI	NI	12	6	608	100	NI	153 ^g
BRL	NI	NI	NI	NI	NI	959.00	9,719,704.98	NI	NI	682,800.94
BRL/child	-	-	-	-	-	159.83	15,986.36	-	-	4,462.75
2018	Nº of children	NI	NI	NI	14	9	815	94	NI	226 ^g
BRL	NI	NI	NI	NI	NI	2,103.53	15,389,690.54	NI	NI	579,896.64
BRL/child	-	-	-	-	-	233.73	18,883.06	-	-	2,565.91
2019	Nº of children	NI	NI	NI	NI	3	750	107	NI	230 ^g
BRL	NI	NI	NI	NI	NI	NI	15,664,564.07	NI	NI	499,282.56
BRL/child	-	-	-	-	-	-	20,886.09	-	-	2,170.79
Total	Nº of children	NI	NI	NI	NI	15 ^f	3,098	532	NI	609 ^h
BRL	NI	NI	NI	NI	NI	3,062.53 ^f	54,650,591.02	NI	NI	1,761,980.14 ^h
BRL/child	-	-	-	-	-	204.17 ^f	17,640.60	-	-	2,893.24 ^h

BRL = Brazilian Reais; CMPA: cow's milk protein allergy; NI = Not informed.

^a Considering the total number of children assisted by Home Enteral Nutritional Therapy Program and the costs in 2017 and 2019 (complete data); not all of the children had CMPA, but according to the manager, they were the majority.

^b Considering the total number of children assisted by the Municipal Program to Provide Special Infant Formulas (Florianópolis, SC) and the 2019 costs (complete data).

^c Considering the total number of children assisted by State Food Allergy Program (PA) and costs in 2018 and 2019 (complete data).

^d In 2015 and 2016 Rio Verde (GO) program provided formula to children with CMPA up to 3 years of age; as of 2017 the limit was reduced to 2 years of age.

^e Considering the total number of children assisted by the Maringá Special Infant Formula Program and costs in 2019 (complete data).

^f Considering the total number of children assisted by the specialized municipal program of Lucas do Rio Verde (MT) and the costs for 2017 and 2018 (complete data).

^g The CMPA clinics in Belo Horizonte (MG) provided formulas to children at least 1 year of age.

^h Considering the total number of children assisted at the CMAP clinic in Belo Horizonte (MG) and the costs for 2017, 2018 and 2019 (complete data).

where mandatory follow-up is performed by dietitians, and in Campos Altos, followed up is performed by pediatricians.

Although nutritionists are not part of mandatory follow-up, in Florianópolis they are a fundamental part of the multidisciplinary commission that evaluates cases which do not fit program criteria; they are also part of the Expanded Family Health Center team, which supports cases assisted in primary health care. In Espírito Santo, nutritionists are part of the technical expert group, and they are present in 95.2% of the evaluated programs in either assistance or management positions.

Specialist physicians (pediatric allergy specialists and pediatric gastroenterologists), pediatricians, and social workers were also well represented in follow-up routines. Follow-up periodicity varied according to specialty, averaging up to 3 months.

The clinical history (anamnesis) and evaluation of signs and symptoms were the main diagnostic methods for CMPA, followed by OPT (57.1%, $n = 12$) (Table 4). Program managers most often reported that the hospital was the best environment for performing OPT, with 80% considering it an adequate location if serious reactions (anaphylaxis) occur.

Program managers reported that the lack of human resources, especially professionals trained to organize work flows and routines, create protocols, and assist patients, was the main obstacle to implementing and executing these programs (Table 5). The lack of financial resources was also important, since no federal and few state initiatives exist to help these children, ie, municipalities were generally required to mobilize their own resources to maintain the programs.

Federal and state financial contributions, continuing education initiatives for health professionals, and the hiring of health professionals, mainly specialists, were cited as relevant actions for improving the management and scope of these programs (Table 5).

Developing and updating of standardized management protocols for CMPA patient care was reported as the most relevant way to reduce the financial costs of the programs (Table 5). Such protocols allow organized routines for patient care, identifying those who truly need formula, preventing inadequate preparation (errors in handling, dilution, and preparation [eg, with contaminated water]) and preventing fraud regarding these expensive formulas (eg, sale or distribution to third parties).

Discussion

Defining age limits is the *first challenge* of programs for children with CMPA, since, food source restrictions, especially situations beyond parental control, such as restaurants and day care centers, make introducing foods an even greater challenge. Children should be encouraged to shift from liquid to pasty foods and thus reduce formula intake, the previous main source of nutrition. This transition from a “safe” state, in which parents can safely prepare allergen-free food, to a new and more challenging scenario can lead to insecurity about the child’s growth, development, and health. Close continuous multidisciplinary follow-up helps reinforce the importance of a healthy, varied, and allergen-free diet, following national recommendations.¹⁷

A *second challenge* is determining which formulas to provide. The most common types provided to children < and > than 6 months of age are in line with the most current food allergy recommendations.⁶ Aguiar et al.¹³ evaluated 214 children assisted by Rio Grande do Norte’s Program for Evaluating, Indicating, and Using Special Infant Formulas for Children with Cow’s Milk Protein Allergy, finding that EHF and SBF were the most common types provided to children < and > 6 months of age, respectively. It should be pointed out that the programs provide EHF with and without lactose, about which no specifications have been made in the current food allergy consensus⁶ or the Ministry of Health’s CMPA Protocol.¹⁰ In clinical practice, managers reported that when physicians choose lactose-free formula it is mainly due to gastrointestinal impairment, since lactose intolerance can occur concomitantly with CMPA. Effective selection of the appropriate formula type can lower costs, an extremely important parameter for the UHS.

CMPA is difficult to diagnose since no single parameter can conclusively determine whether the child has this condition. Accurate diagnosis must follow these steps: (I) anamnesis and physical examination, observing signs, symptoms (frequency and reproducibility), and reports from parents and caregivers; (II) a restricted maternal diet for breastfed children; (III) immunoglobulin E tests, although this is more suitable for children with type I (immunoglobulin E-mediated) and mixed reactions, and should not be the only test performed; and (IV) periodic OPT based on medical follow-up to verify oral tolerance, provided that testing is performed under medical supervision in an appropriate environment with support in case of severe reactions.⁷

Table 4

Composition and routines two programs and services that dispense infant formulas for children with cow's milk protein allergy (CMPA), Brazil, 2022

	N°	%
Professionals who directly assist children with CMPA		
Allergopediatrician	6	28.6
Social worker	8	38.1
Nurse	5	23.8
Pharmacist	1	4.8
Gastropediatrician	11	52.4
General practitioner	4	19.1
Nutritionist	18	85.7
Nutrologist	2	9.5
Pediatrician	6	28.6
Psychologist	1	4.8
Nursing technician	1	4.8
None	1	4.8
Follow-up interval		
Social worker		
Registration	5	62.5
Trimestral	1	12.5
Semestral	1	12.5
Annual	1	12.5
Nurse		
Registration	2	40
Monthly	1	20
Bimonthly	1	20
Trimestral	1	20
Pharmacist		
Monthly	1	100
General practitioner		
Trimestral	2	50
Semestral	2	50
Specialist physician (pediatric allergist or gastropediatrician)		
Bimonthly	4	25
Trimestral	10	62.5
Semestral	2	12.5
Nutritionist		
Registration	1	5.5
Monthly	3	16.7
Trimestral	10	55.6
Semestral	4	22.2
Nutrologist		
Bimonthly	2	100

^a Homogeneity test: p-value = 0.002.

^b Homogeneity test: p-value = 0.004.

IgE = immunoglobulin E dosage, OPT = oral provocation test.

Table 4 (continued)

Composition and routines two programs and services that dispense infant formulas for children with cow's milk protein allergy (CMPA), Brazil, 2022

	Nº	%
Pediatrician		
Monthly	1	16.7
Trimestral	3	50
Semestral	2	33.3
Nursing technician		
Monthly	1	100
Tests offered in the municipality/state (depending on the program level) ^a		
Diagnostic endoscopy	1	4.8
IgE (total and specific)	13	61.9
Skin test	6	28.6
OPT	10	47.6
None	4	19.1
Aspects considered in the diagnosis of CMPA ^b		
Exclusion diet	1	4.8
Diagnostic endoscopy	1	4.8
Laboratory tests (total IgE, fecal occult blood, etc.)	7	33.3
Clinical history	21	100
Signs and symptoms	21	100
OPT	12	57.1
OPT performed		
No	6	28.6
Yes	15	71.4
OPT obligatory		
No	11	52.4
Yes	10	47.6
Location of OPT (n = 15)		
Clinic	5	33.3
Specialty center (secondary care)	3	20
Residence	4	26.7
Hospital	8	53.3
Basic Health Unit (primary care)	2	13.3
Not informed	1	6.7
Conditions for performing the OPT (n = 15)		
Adequate	12	80.0
Inadequate	2	13.3
Not informed	1	6.7

^a Homogeneity test: p-value = 0.002.

^b Homogeneity test: p-value = 0.004.

IgE = immunoglobulin E dosage, OPT = oral provocation test.

Table 5

Challenges, suggestions and strategies pointed out by managers of programs that provide formula for children with cow's milk protein allergy, Brazil, 2022

	Nº	%
Difficulties in implementing and executing the program		
Lack of standardized protocols	4	19.1
Ineffective communication with the judicial system and parents of children with CMPA	3	14.3
Lack of patient follow-up	4	19.1
Lack of structure (storage, distribution, etc.)	8	38.1
Lack of guidance on breastfeeding in CMPA and exclusion diets	3	14.3
Lack of financial resources	13	61.9
Lack of human resources	15	71.4
Lack of tests (laboratory, OPT, endoscopy, etc.)	4	19.1
High rate of misdiagnosis	2	9.5
Sensitizing managers about the need for the program	2	9.5
Other	3	14.3
Suggestions for resolving the difficulties		
Program approval by municipal or state health councils	1	4.8
Increasing the number of tests	2	9.5
Development of indicators to evaluate the program	1	4.8
Counterpart funding from the Federal Government and States	12	57.1
Hiring of health professionals	8	38.1
Creation of reference centers	2	9.5
Creation of multidisciplinary technical commissions to communicate with the judicial system	1	4.8
Bimonthly distribution of formulas	1	4.8
Continuing education for health professionals	11	52.4
Preparation of reports to managers	3	14.3
Development and updating of standardized protocols	1	4.8
Improvement of the communication with the judicial system and parents of children with CMPA	2	9.5
Improvement of the physical structure and formula distribution logistics	6	28.6
Guidance on breastfeeding in CMPA and exclusion diets	3	14.3
Performing OPT	2	9.5
Dispensing special formulas and standard formulas separately	1	4.8
Cost reduction strategies		
Monitoring of bids	2	9.5
Increased use of soy-based formula	1	4.8
Hiring of health professionals	5	23.8
Ongoing dialogue with managers about indicators and the importance of the program	2	9.5
Continuing education for health professionals	2	9.5
Development and updating of standardized protocols	13	61.9
Establishment of partnerships with breastfeeding support networks	3	14.3
Creation of multidisciplinary teams to monitor children with CMPA	5	23.8
Provision proportional to social assessment/vulnerability	4	19.1
Inclusion of OPT	2	9.5
Organization of workflows and health networks	8	38.1
Auditing the processes	1	4.8
Reduction of the age to receive formula	2	9.5

In OPT, the child is exposed to the allergen under controlled conditions and medical supervision. Parents must be instructed about the risks and procedures to be performed, and the environment must be prepared for systemic reactions. However, 2 of the managers reported that OPTs are performed without the appropriate conditions, which can involve serious risks for the patient. There is no consensus among experts about OPT, since formulas with lactose can cause gastrointestinal intolerance that can be confused with CMPA. The clinical protocol for OPT in children with CMPA involves cow's milk or standard formulas, either without (preferably) or with low amounts of lactose to avoid lactose intolerance symptoms, which could be confused with CMPA. However, experts disagree about excluding lactose. This implies a *third challenge* to implementing these programs, since specialists are unsure about which type of protocol (low or no lactose) to use for the diagnostic test.

Continued breastfeeding is the first procedure, which is to determine if the child is reacting to breast milk⁶ and, if necessary, a maternal exclusion diet should be prescribed as a diagnostic and/or treatment tool. Expanding breastfeeding support strategies is essential, both to guide the exclusion diet and to positively reinforce breastfeeding for the mother-child dyad, resulting in lower demand for formula. Brazil is recognized worldwide for its programs to encourage breastfeeding, including a human milk bank network with 224 centers and 212 collection points nationwide.¹⁸ Such expertise must be accompanied by discussion, such as the present study, to protect infants from the unnecessary use of formulas and avoid early weaning as a result of erroneous guidance about exclusion diets and other problems.

The main challenges reported by program managers were the lack of human and financial resources. The professionals most capable of diagnosing and following up these children are allergists/allergologists, pediatricians, and gastroenterologists. According to the Federal Council of Medicine's national registry of physicians, there are 1648 allergists (of whom 134 are pediatric allergists), 37,736 pediatricians, and 4949 gastroenterologists (of whom 6 are pediatric gastroenterologists) in Brazil (CFM, 2022), the majority of whom are concentrated in the southeast region.¹⁹ However, there may be more, since this list includes only professionals who registered their specialty in a Regional Council of Medicine in order to legally advertise it.

Vieira et al. found low adherence to food allergy management guidelines among Brazilian pediatricians, which is important since most children with suspected CMPA and other food allergies will be diagnosed and treated by them, without the benefit of OPT.²⁰ Nutritionists are responsible for monitoring the nutritional status of these children and, according to the Federal Council of Nutrition, there are 187,532 active nutritionists in Brazil, of whom 89,057 (47.49%) are concentrated in the southeast region.²¹ Multidisciplinary teams can provide more conclusive diagnoses and better care for children with CMPA and their parents. Hiring specialists, as well as providing continuing education for those who directly assist these children, would facilitate the diagnostic process, excluding other health conditions that could be confused with CMPA, and provide guidance about changes common to children according to age group, as well as about clinical and laboratory tests as diagnostic support tools.

The program managers reported that a lack of federal and state funding and continuing education initiatives were the most common challenges, which shows the importance of defining competencies between agencies, hiring needs, and continuing education initiatives, which can result in better care for users and the rational use of resources.

With the emergence of the COVID-19 pandemic and social distancing practices, educational processes have undergone a number of changes, including a greater number of distance learning courses and the expansion of telemedicine and digital health initiatives. Proper implementation of these tools in the post-pandemic phase can expand and complement health professional training, allowing better care for children with CMPA. This is a further challenge to improving such programs in this country.

Other suggestions, such as increasing the number of tests, performing OPT, creating reference centers, and providing guidance about breastfeeding and exclusion diets, can contribute to more accurate diagnosis. These programs can also be strengthened by the creation of multidisciplinary technical commissions to communicate with the judicial system (and consequently reduce judicialization and include formulas not yet incorporated in the UHS), the development of indicators (time in the program, costs, etc.) and reporting objectives for managers, and program approval by municipal or state health councils.

To provide an international perspective, the government websites of the USA²², Canada²³, England²⁴ and Germany²⁵, in addition to the PubMed and SciELO databases, were searched using the keywords “milk hypersensitivity”, “cow’s milk allergy”, “program evaluation”, “infant formula”, “health service accessibility” and “allergy program”. We could find no other national programs that provided special formulas for children with CMPA.

Health Canada's Food Allergen Research Program²⁶ was created in the 1990s to improve allergen labeling regulations and support research on the prevalence of food allergies, intolerance, and celiac disease. A partnership between the Australasian Society of Clinical Immunology and Allergy and Allergy & Anaphylaxis Australia, together with patient associations and other organizations, resulted in the launch of the Australian National Allergy Strategy, which aims to “improve the health and quality of lives of Australians with allergic diseases and minimize the burden of allergic diseases on individuals, their caregivers, health services, and the community”. This is the first such initiative of medical and patient associations that has managed to attract significant federal fundin.^{27,28}

The U.S. Women, Infants, and Children Nutrition Program²⁹ provides standard foods and infant formula for vulnerable and pregnant women and children ≤ 5 years of age, although no mention is made of providing special formulas for children with CMPA.

The Finnish Allergy Program^{30,31} (2008-2018), which was developed to prevent allergies and asthma, led initiatives to improve health professional training programs, performed public information campaigns through social media, and established contact with patients and the program network. After 10 years, the program resulted in a 30% reduction in direct allergy costs, 50% fewer special diets for food allergies among preschoolers, and a 45% reduction in the incidence of occupational allergies. Compared to the results of our study, 3 points stand out. The first is the Finnish program’s standardization of diagnostic tests, ie, approximately 90% of the tests were performed in standardized, certified, and audited laboratories, providing greater reliability and lower cost. Similar initiatives are crucial for better organization in the UHS, which will diagnose and monitor CMPA and dispense these special formulas. Second, this program had goals, with tools and methods for measuring specific results, allowing better monitoring and evaluation. And, finally, the involvement of patients and organized civil society,

as well as providing promotional materials for professionals and the general public, allowed more effective communication.

In Finland, most of the health system is public, with a complementary private sector, which is similar to the situation in Brazil, but for a significantly smaller population (5.5 million³⁰ vs 215 million³²). There are also other differences, such as partial reimbursement for formulas and other hypoallergenic products. As of 2006, the Finnish Government began a partial reimbursement protocol only for children whose diagnosis was confirmed through OPT in a pediatric outpatient clinic, which resulted in a 70% cost reduction³⁰. Brazilian CMPA protocols¹¹ already include this condition, but nor reimbursement for OPT.

Data collection for the present report began in June 2020, but the methods were adapted due to COVID-19 emergency measures, ie, personal interviews and on-site visits were replaced with virtual meetings. Some health departments also requested that the project undergo review by their ethics committees or research foundations. However, due to the pandemic, the evaluations were delayed, since studies related to COVID-19 were prioritized. Notwithstanding, these limitations did not reduce data collection quality or the sample size.

Conclusions

The process of incorporating 3 formulas for children with CMPA into the UHS began in 2012, however, 10 years later, it has still not been completed. Thus, due to growing litigation, some states and municipalities have decided to create programs to provide AAF, EHF and SBF. The lack of state or federal funding or a specific budget in the UHS for these formulas, in addition to the vague definition of administrative responsibilities, have led program managers to use cost reduction strategies, since they are funded by local health departments. This is the first study of this type to be conducted on a national level. Understanding the experiences of programs that already provide these formulas is essential for determining their structures and the assistance they provide.

Setting the maximum age at 2 years to receive formula, promoting multidisciplinary monitoring of these children, discussion between professionals and managers about which formulas are to be included, and developing protocols for more accurate diagnosis must all be addressed to make incorporation of

these formulas more cost-effective and beneficial to users.

Although planned for all allergies and asthma, the Finnish Allergy Program has important lessons for Brazil's context, such as: defining goals and developing assessment and monitoring tools, a careful examination of the diagnostic process (ie, standardizing diagnostic tests and certifying the places where they will be carried out), continuing education for health professionals, developing educational campaigns for the public, involving patients and associations in planning discussions, and, finally, long-term planning, since these programs have a great social impact. Such strategies could be used in Brazil to improve and advance incorporation of these formulas into the UHS.

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