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RESEARCH ARTICLE

Limiting axes in the strategy of fortification of wheat flour and cornmeal with iron and folic acid.

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Abstract

Objectives Food fortification consists of adding the essential nutrients that the population needs the most to processed foods or its ingredients during manufacturing to improve the nutritional quality of the product and benefit public health without jeopardizing health. Objective of the study was to assess the factors that limit success in the mandatory fortification of wheat flour and cornmeal with iron and folic acid.

Methods the sample consisted of official documents and the Interinstitutional Commission. Documents, official texts, and interviews were analyzed. The interviews were validated by semantic analysis and a group of expert judges. The model proposed by the Guidelines on Food Fortification with Micronutrients was used for analyzing the implementation. The software ALCESTE® version 2010 treated and analyzed the data.

Results The limiting axes of food fortification implementation were Regulatory Monitoring and participants' Integrated Commitment. The highest chi-squared values indicated concern with product quality control and monitoring. Monitoring and Assessment; and Communication, Social Marketing, and Advocacy were not properly planned. Technical and operational factors limited food fortification implementation.

Conclusions Also, managerial factors need to be agreed upon according to the Social Compromise to Fight Iron-Deficiency Anemia in Brazil.

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Introduction:-

Food fortification consists of adding the essential nutrients that the population needs the most to processed foods or its ingredients during manufacturing to improve the nutritional quality of the product and benefit public health without jeopardizing health (Allen, Benoist, Daryand Hurrell, 2006). Universal fortification aims to reduce nutritional deficiencies, especially in American countries that have fortification programs established politically (Hurrell, Ranum, de Pee, Biebing and Hukthen, 2010). In Brazil mandatory fortification of wheat flour and cornmeal with iron and folic acid was instituted in 1999 and 2001, respectively, to reduce anemia in children and women of childbearing age and the prevalence of neural tube defects (NTDs) (Brasil, 2002).

Folic acid was added later to wheat flour and cornmeal by request of the Association of Assistance to Disabled Children because of the prevalence of NTDs in Brazil: anencephaly in 0.862/1000 live births; and spina bifida in 1.139/1000 live births (Brasil, 2001).

The sustainability of a strategy, such as mandatory fortification, depends on many factors: preliminary assessment of micronutrient deficiencies and human resources; creation of technical and legal norms to standardize product identity and quality; implementation of a quality control and assurance system by the industry; inspection and regulatory monitoring; communication and social marketing plan; health impact assessment; debate of the theme with the public sector, social organizations, production sector, universities, and international organizations; and interinstitutional coordination at the federal level (PAHO, 2004; PAHO, 2008; Wirth, Laillou, Rohner, Northrop-Clewes, Macdonald and Moench Pfanner, 2012).

The model proposed by the Guidelines on Food Fortification with Micronutrients is an international reference for the planning and implementation of food fortification with micronutrients. It provides data on the benefits, limitations, conception, implementation, monitoring, assessment, cost-benefit relationship, and regulation, especially for developing countries (Allen, Benoist, Dary and Hurrell, 2006).

In face of the importance of food fortification to minimize health problems in more vulnerable groups and the inexistence of studies on the factors that affect food fortification implementation, this study aimed to assess the factors that limited success in the Brazilian wheat flour and cornmeal fortification with iron and folic acid from 1999 to 2012.

Methods:-

The sample consisted of fifteen official documents on mandatory food fortification in Brazil published on sites of the Ministry of Health and the National Sanitary Surveillance Agency.

All representatives of the agencies (n=12) involved in food fortification planning and coordination were invited to participate. These representatives composed an Inter institutional Commission, whose mission was to implement, follow, and monitor the fortification of wheat flour, cornmeal, and their byproducts (8). A busy schedule and little familiarity with the theme prevented representatives of two agencies to participate in the individual interviews, so ten subjects were included.

The documents were searched and selected at the sites of the Ministry of Health and National Sanitary Surveillance Agency using the keywords fortification, foods, prevention, nutritional deficiency, iron, and folic acid, and by contacting the institutions to obtain documents from the physical archives. After document classification, content analysis determined the relationship between linguistic context and its joint representation (May, 2004; Cellard, 2010; Bardin, 1977).

Semi-structural interviews investigated the Inter institutional Commission's understanding of food fortification implementation. The script of the interviews was validated by semantic analysis and a group of expert judges (Pasquali, 1998). The variables were chosen from the following documents: Micronutrient Programs: What Works and What Needs More Work? And *Fortificación del azúcar con vitamina A en Centro América: experiencia y lecciones aprendidas* (Fortification of sugar with vitamin A in Central America: experience and lessons learned, MOST, The USAID Micronutrient and Child Blindness Project) (Klemm, Harvey, Wainwright, Faillace and Wasantwisut, 2009). Content analysis analyzed the relationship between linguistic content and the joint representation of the interviews (Bardin, 1977). Data were collected after the subjects signed a consent form and a term authorizing the use of voice recordings for study purposes.

Compliance with the 27 items of the five stages of the Guidelines on Food Fortification with Micronutrients was assessed to verify whether the official documents included the implementation stages required by the Guidelines: a) definition and establishment of nutritional goals based on documented information; b) monitoring and assessment; c) estimates of cost-effectiveness and cost-benefit; d) communication, social marketing, and advocacy; and e) national food legislation (Allen, Benoist, Dary and Hurrell, 2006).

The software *Analyse Lexicale par Contexte* d'um Ensemble de Segments de Texte – ALCESTE® Version 2010 quantified the frequency of words and segments of the official documents and interviews, and extracted lexical and thematic meanings of the text, which facilitate global interpretation by grouping semantic roots and the formation of classes and their relationships, always taking into account the function of a word in a given text and context. Thus, the classes were defined by occurrence, co-occurrence, and textual function of the words (Camargo, 2005). The elementary context units (ECUs) - elementary representation or minimum statement in a discourse – and the classes, constructed by grouping many ECUs – were defined as text fragments with equal size and homogeneous vocabulary (Nascimento and Menandro, 2006). The chi-square test measured the strength of association between words.

This study was approved by the Research Ethics Committee of the School of Health Sciences of the University of Brasilia under protocol number 127/12.

Results:-

The fifteen study documents were classified as primary and public. Their analysis contemplated five dimensions indicating that: they were created jointly by the government, production sector, universities, and civil society; they were created by the managers responsible for coordinating the action in situ; they had legal, technical, and scientific nature; they discussed iron and folic acid deficiencies in mother/child dyads, their negative impacts on children's cognitive development, and the associated gestational morbidity and mortality; and they claimed that the pillars of the wheat flour and cornmeal fortification strategy were the National Food and Nutrition Policy and the Social Commitment to Fight Iron-Deficiency Anemia in Brazil. Content analysis by ALCESTE® indicated use of 98.5% of the vocabulary, 1,159 ECUs, and six classes. These classes enabled the identification of two thematic axes: Monitoring and Assessment and Food and Nutrition (Table 1).

Table 1. List of radicals in the official documents that determined the axis Monitoring and Assessment (class 1 – Regulatory Monitoring, class 3 – Technological Process, and class 5 – Impact of fortification and the axis Food and Nutrition (class 2 – Management of food and nutrition actions, class 6 – Promotion of a healthy diet, and class 4 – Nutritional diseases).

Monitoring and Assessment									Food and Nutrition								
Class 1 – 21%			Class 5 – 8%			Class 3 – 14%			Class 2 – 17%			Class 6 – 29%			Class 4 – 4%		
Radical	X ²	f	Radical	X ²	f	Radical	X ²	f	Radical	X ²	f	Radical	X ²	f	Radical	X ²	f
Flour	103	108	Prevalence	161	26	Product	196	78	Policy	191	79	Nutrition	117	125	Malnutrition	147	22
Sample	87	44	Tube	141	13	Addition	147	35	State	99	30	Food	86	185	Weight	144	19
Wheat	75	78	Neural	141	13	Iron	146	113	Municipal	96	34	Foods	62	99	Obesity	137	20
Monitoring	69	59	Defect	117	11	Compound	146	35	Nutrition	94	83	Right	55	43	Child	134	32
Inspection	67	20	Anemia	921	27	Reduced	102	18	Guideline	74	25	Health	52	115	Etar	68	08

The axis Monitoring and Assessment (classes 1, 3, and 5) related the central ideas on the implementation of mandatory fortification identified by the highest chi-square values, and demonstrated concern with product quality control and follow-up.

Class 1 defined product quality control and monitoring, which aimed at sanitary inspection and oversight; technical audit; Good Manufacturing Practices manual; use of inspection guidelines; data recording for monitoring; sampling plan; easy-to-use quantitative methodology (Table 1).

Class 3 centralized and detailed aspects of production technology (Table 1). The text fragments with the highest chi-square values demonstrated concern with the technologies that disperse and homogenize the micronutrient mix, and the impact of different compounds on the characteristics of the final product, their physical and chemical stability, and ease of dispersion and homogenization. These aspects were also considered for fortifiable corn-based products: cornmeal with iron, products for fortification, grits, flour, snacks, micro aspersions, cornflakes, corn flour, and cream corn.

The milling industry mobilized itself to minimize technology-related problems, pledging to establish partnerships with sponsor agencies and research institutes that encourage the search of a simple and viable technology that enables micro- and small milling enterprises to add iron compounds to their products.

Class 5 ratified the positive impact of folic acid fortification on the prevalence of congenital malformations, considering this the main tool for the primary prevention of congenital malformations (Table 1).

The Food and Nutrition axis (classes 2, 4, and 6) demonstrated that actions that promote a healthy diet are determinants in the agendas of nutritional deficiencies and mandatory fortification (Table 1).

Class 2 related to the financing, structuring, and planning of nutrition actions that aim to compose the tripartite financing of these actions in the state health care network and to provide technical assistance and institutional support to the management of food and nutrition programs and actions.

Class 4 identified nutrition-related diseases stemming from individual eating behavior or from inappropriate qualitative and/or quantitative eating habits.

Class 6 was associated with nutritional value and the concept of food security. The following ideas were also identified: appropriate and healthy diet themes; respect to cultural diversity; determinants of food and nutrition situation; access to healthy foods; sanitary responsibility and the right to information and proper food choice.

Content analysis of the interviews indicated that the corpus used approximately 98.5% of the vocabulary, analyzed 833 ECUs, and formed five classes that identified two thematic axes: Regulatory Monitoring and Integrated Commitment (Table 2).

Table 2 List of radicals in the interviews that determined the axis Regulatory Monitoring (class 1 – Quality Control and Assurance and class 3 – Sanitary Inspection) and the axis Integrated Commitment (class 2 – Advocacy, class 4 – Responsibility and Competence, and class 5 – Professional Qualification).

Regulatory Monitoring						Integrated Commitment								
Class 1 – 41%			Class 3 – 13%			Class 2 – 22%			Class 4 – 12%			Class 5 – 12%		
Radical	X^2	f	Radical	X^2	f	Radical	X^2	f	Radical	X^2	f	Radical	X^2	f
company	36	42	people	57	54	fortification	53	32	ministry	66	24	sanitary	72	33
wheat	28	25	analysis	54	28	evidence	46	23	commission	63	32	surveillance	65	22
corn	20	19	mandatory	45	11	communication	34	13	surg	50	11	masters	58	09
mill	20	20	inspection	40	11	is not	32	83	assume	36	08	nutrition	50	11
vitamin	19	26	make	33	28	of the	31	28	implementation	36	18	foods	44	14

Axis 1 (classes 1 and 3) focused on the internal (quality control and assurance by the industry) and external monitoring (sanitary inspection in situ) of mandatory fortification, which focused on quality control and assurance standards and legal norms for the inspection of fortified foods.

Class 1 expressed the importance of using appropriate doers to add the micronutrient mix to the products and proper homogenization because addition alone does not ensure equal distribution of the mix.

Class 3 identified the importance of controlling the amount of nutrients added to the flours, especially folic acid, and monitoring by the sanitary surveillance agency given the limited physical and operational conditions.

Axis 2 related to the commitment and involvement of decision makers to defend food fortification implementation. Class 2 expressed the need of political prioritization of the monitoring stage by disseminating and communicating its positive impact on the incidence of neural tube defects to the managers who make the decisions and the organized sectors of society. It equally emphasized the importance of social participation in the creation of a public health strategy and the need of reinforcing social participation by providing more incisive and ample communication.

Class 4 identified the need of the institutions that signed the Social Commitment to Fight Iron-Deficiency Anemia in Brazil to commit to and assume their responsibilities in order to allow a legitimate course for the Commission's actions.

Class 5 identified the professional multidisciplinary of the Commission, the high level of professional qualification and experience, ensuring technical and scientific credibility for food fortification implementation.

To verify whether the implementation complied with the 27 items of the five stages proposed by the Guidelines on Food Fortification with Micronutrients, the frequency of all the stages and their determinants were quantified. The

results demonstrated that all stages had been recorded in the official documents, but only 19 (70.4%) of their items were documented. The stages with the highest percent of data were the Definition and Establishment of Nutritional Goals (n=8; 75%) and National Food Legislation (n=9; 88.9%). The stage with the lowest percentage was Estimate of Food Fortification Cost-Effectiveness and Cost-Benefit (n=3; 33.3%)

However, the text fragments obtained in the interviews revealed that the Internal monitoring (quality control/quality assurance), the impact of the evaluation and the advocacy were the items that have a negative impact on evaluation of respondents (Table3).

Table 3 Mandatory fortification stages and determinants identified from text fragments classified during the food fortification stages according to the model by Allen *et al.*, 2006.

Stages	Determinants	Text fragments (> X ² /Class and Thematic axis)	X ² /Class/Thematic axis
Documented Definition and Nutritional Goals	Biochemical evidence	"prevalence (one) (picture) of morbidity and mortality, dominated by the binomial (malnutrition)/(infection), that (affects), mainly, (poor) (children) (in) (regions) with social and (economic) delays" "the predominant group of (overweight) and (obesity), (diabetes) mellitus, cardiovascular (diseases) and some neoplasms, having (as) elective host the segment of (adults) and people of (more) (advanced) (age)"	100
Monitoring and Assessment	Internal monitoring (quality control / quality assurance)	"(technologies) (used) for (dispersing) and (homogenizing) the micronutrient (mix)"	93
		"impact of (using) different (compounds) on the (characteristics) of the (final) (product), physical and (chemical) (stability)"	39
	Impact assessment	"(group) (elaborated) (a) (theoretical) (list) (to verify) (good) manufacturing practices (for) the (companies) that (manufacture) (wheat) (flour) and used (this) instrument to (validate) the collected (data)"	76
Communication, Social Marketing, and Advocacy	Communication and Education	"(create) e-mail (group) (to) improve (communication) of the (commission) (to) (disseminate) (reports)"	42
	Advocacy	"we understand that (adequate) (and) (healthy) (diet) (is) (a) (dietary) (practice) (appropriate) (to) (the) (biological) (and) sociocultural (aspects) (of) (individuals) "	48
		"(allocate) (state) (resources) to compose (the) (tripartite) (sponsoring) of the food and (nutrition) (actions) in the (health) care (network) (at) (the) (state) (level) " "(provide) technical (assistance) and institutional (support) to the (municipalities) and (regional) (health) (units) (in) (the) (management), (planning), (execution), monitoring, and (assessment) (processes) of food and nutrition (programs) and (actions)"	58

Discussion:-

The originality of this study lies in the identification of the thematic axes that limited the success of mandatory wheat flour and cornmeal fortification with iron and folic acid in Brazil. Such technical, operational, and managerial limitations were related to Monitoring and Integrated Commitment.

Although the development of universal fortification was grounded in the guidelines of the National Food and Nutrition Policy (Brasil, 1999a; Brasil, 2011) and the Social Commitment to Fight Iron-Deficiency Anemia in Brazil (Brasil, 1999a), joint analysis of official documents and interviews, and chi-square values showed that monitoring is a challenge and limits product quality control and follow-up.

Especially in this context, adequate addition and homogenization of the micronutrient mix is important as it is associated with official quality control (Brasil, 1999a; Brasil, 1999b; Brasil, 2011). These pieces of evidence may justify the findings of some studies on the impact of fortification, that is, that the iron status of the population did not change significantly in response to the type of compound used for food fortification and its bioavailability.

The positive impact of flour fortified with iron is probably related to the standardization of fortification technologies that guarantee the quality of the final product and to a rigorous inspection of the manufacturing processes (Assunção, Santos, Barros, Gigante and Victora, 2012; Assunção, Santos, Barros, Gigante and Victora, 2007; Latorre, 2005; Latorre and Colli, 2008).

Although Brazil has local surveillance systems with established structures, most of the states have serious problems with infrastructure and human resources. Traditional management and political interests prevent proper function execution, limiting any plan of monitoring a public health action or program (Lucchese, De Seta, Pepe and Oliveira, 2006).

Integrated commitment was another limiting factor for food fortification, and the results indicate that institutions need to recognize, assume, and conduct the responsibilities listed in the Social Commitment and defend universal fortification. The term Advocacy, expressed in one of the classes, excluded the need of disseminating and communicating the positive impact of folic acid fortification on the incidence of NTDs to the managers and population.

The government's agenda does not currently include the theme "nutritional deficiencies," even though interventions that prevent and control these deficiencies are inexpensive and have great impact on the health of the mother/child dyad. Some authors believe that this challenge depends on strategic advocacy actions that reach beyond the health sector (Mannar, 2006; Stoltzfus, 2011).

Advocacy done by effective leadership and communication among actors are determinants in the implementation of large scale micronutrient programs, such as universal fortification (Klemm, Harvey, Wainwright, Faillace and Wasantwisut, 2009). Brazil has documented the production of technical training materials for professionals of the regulated sector but not activities that communicated and disseminated the importance of food fortification for improving nutritional status and reducing folic acid-associated diseases (Germani, 2001).

A successful universal fortification program requires investment in communication activities to raise the population's awareness of the benefits of the intervention. These interventions aim to change individual or population behaviour and obtain the commitment of government, regulated sector, social representations, and other associated institutions (Allen, Benoist, Dary and Hurrell, 2006; Griffiths, 2003).

The theme "Responsibilities and Competences," attributed to the institutions that signed the Social Commitment to Fight Iron-Deficiency Anemia in Brazil, contained a warning for all actors to assume and perform their responsibilities as partner institutions. This calling is justified because the said Commitment lists individual and shared responsibilities for the normalization of wheat flour and cornmeal fortification, and for the joint management of food fortification implementation and coordination with state and municipal managers to promote educational actions about fortified products (Brasil, 1999b). Collaborative work and multisector coalitions are critical for the implementation of mass fortification (Hurrell, Ranum, de Pee, Biebinger, Hulthen, Johnson, et al, 2010).

Comparison of universal fortification of wheat flour and cornmeal with iron and folic acid in Brazil in 2002 with the model proposed by Allen et al. (Allen, Benoist, Dary and Hurrell, 2006, Griffiths, 2003) has shown that there has been enough technical investigation based on scientific evidence to define the nutritional objectives and that fortification normalization regulated the process of implementation. However, the list of iron compounds used in food fortification listed in the Brazilian legislation needs to be reviewed and updated to allow selection of the compounds with the best bioavailability and cost (Brasil, 2002).

A mean micronutrient content and upper limit in fortified foods need to be defined for nutrient content standardization and control. Currently only the minimum content is defined, despite the mention of this need in the referrals of the regular meetings of the Inter institutional Commission (Brasil, 2009).

Regulation contributes substantially to the implementation of public health actions (1). Some authors believe that a food fortification program is not very likely to have significant impact in the absence of a national law establishing quality parameters, and emphasize that the legal environment may facilitate or delay the implementation process (PAHO, 2008; Fiedler and Macdonald, 2009).

There is a lack of documented information about the cost-effectiveness and cost-benefit of implementing food fortification, except in a document that estimated the cost of the fortification compound, equipment, and laboratory infrastructure (Brasil, 1999c). The documents did not mention the cost of an impact study, social marketing, quality control performed by the manufacturers, and monitoring and assessment conducted by the government.

The few cost data available possibly limited estimating the required investment and failed to sensitize decision makers regarding the inclusion of the theme in the government's agenda. A national fortification program needs to reassess the challenges related to the legislation, quality assurance, control systems, social marketing, and impact follow-up and assessment to make changes that improve program implementation (Wirth, Laillou, Rohner, Northrop-Clewes, Macdonald and Moench-Pfanner, 2012).

Ineffective communication among the institutions involved, the fragile structure of the monitoring and assessment programs, the limited financial resources to conduct studies, and the somewhat ineffective leadership in the coordination of the actions and creation of priority scenarios prevent the total implementation of food fortification programs (Klemm, Harvey, Wainwright, Faillace and Wasantwisut 2009).

The World Health Organization (WHO) suggests that the countries that intend to implement universal fortification should conduct monitoring and assessment by continuously collecting data in critical points of the process to obtain the information required to identify inefficiency, take corrective measures, and redirect the program if necessary. Impact assessment, which will certify performance quality and the fulfilment of nutritional objectives, should only occur after satisfactory program implementation. If implementation is partial, it is not possible to measure fortification effectiveness (Allen, Benoist, Dary and Hurrell, 2006, Griffiths, 2003).

Analysis of documents and subject discourses and comparison with the adopted model confer reliability and complementarity to the study data. Since analysis of subject discourse was consonant with the official documents and presented situations intrinsic to the work of both the Inter institutional Commission and affiliated institutions, it was possible to identify in the individual discourses the Commission's understanding of food fortification and the specific problems that limited implementation.

The study limitation is the non-inclusion of questions in the instrument that would identify the solutions suggested by the Inter institutional Commission.

Conclusions:-

Food fortification needs to be reintroduced in the agenda of micronutrient deficiencies to achieve a new agreement between signatories of the Social Commitment to Fight Iron-Deficiency Anemia in Brazil and to identify new advocacy partners that use ample communication strategy, and consider the various sectors involved and the population.

Author Karla Lisboa Ramos declares that has no conflict of interest.

Author Wilma M. C. Araújo declares that has no conflict of interest.

Author Rita Akutsu declares that has no conflict of interest.

Ethical approval: Informed consent was obtained from all individual participants included in the study.

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