AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D. C. 20523

BIBLIOGRAPHIC INPUT SHEET

FOR AID USE ONLY
BATCH 42

1. SUBJECT CLASSIFICATION

A. PRIMARY: Food production and nutrition — AS10-0120-0000

B. SECONDARY: Food composition--Cereals--Maize

2. TITLE AND SUBTITLE

A model for maize fortification with soy bean flour, lysine, and other nutrients in a low socioeconomic rural community

3. AUTHOR(S)

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4. DOCUMENT DATE	5. NUMBER OF PAGES	6. ARC NUMBER
1973	15p.	ARC

7. REFERENCE ORGANIZATION NAME AND ADDRESS

PAHO

8. SUPPLEMENTARY NOTES *(Sponsoring Organization, Publishers, Availability)*

(In Nutritional improvement of maize,ed.by R.Bressani,J.E.Brahma,M.Behar,1973,p.273-287)
(In English and Spanish; Spanish,17p.:PN-AAA-169)

9. ABSTRACT

10. CONTROL NUMBER	11. PRICE OF DOCUMENT
PN-AAC-781	

12. DESCRIPTORS

Enrichment
Lysine
Maize
Rural areas
Soybean

13. PROJECT NUMBER

14. CONTRACT NUMBER
CSD-3357 Res.

15. TYPE OF DOCUMENT

AID 590-1 (4-74)

CSD-3357 Res.
PN-AAC-781

Reprinted from: Nutritional Improvement of Maize, Institute of Nutrition of Central America and Panama (INCAP), Bressani, R., J.E. Braham and M. Béhar (editors), 1973

A MODEL FOR MAIZE FORTIFICATION WITH SOY BEAN FLOUR, LYSINE AND OTHER NUTRIENTS IN A LOW SOCIOECONOMIC RURAL COMMUNITY

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Introduction

The deficiency of proteins and calories is a serious problem in the Central American countries. This situation is due to the low biological value of dietary proteins, and to the greater nitrogen demands and losses of the population resulting from frequent infectious diseases. Studies of the Institute of Nutrition of Central America and Panama (INCAP) have revealed that although the total protein intake is often adequate in quantity, its quality is low due to the fact that it is derived from cereals. In Guatemala more than 70% of the proteins and calories consumed in rural areas come from maize, and only a small proportion from animal sources.

An apparent solution to this problem could be to increase production and consumption of animal protein, but this is difficult to accomplish because of the socioeconomic conditions prevailing in the countries of the Central American area. An alternative that offers a favorable perspective is fortification (enrichment) of low quality protein, implemented in large sectors of the population. Such solution becomes of greater significance if its practice does not introduce changes in the usual diet or any substantial modification of the infrastructure and operational capacity of the countries. Before launching a nutritional recommendation such as this, it is important to demonstrate its effectiveness in the field. For such demonstration it is necessary to have a rural community with the nutritional problem, and where conditions to measure possible effects of the intervention are present.

The circumstances required to carry out such demonstration exist in a village intensively studied by INCAP since 1963 (1, 2). The population, Santa María Cauqué, of the Maya-Cakchiquel culture, is located in the Guatemalan highlands, and has socioeconomic characteristics typical of the majority of rural populations of Guatemala and other Central American countries.

The present paper summarizes the main public health problems in the community, and describes several scientific and operational considerations taken into account in the implementation of a model for maize fortification.

The Problem

The health problem in Santa María Cauqué, as in the majority of the Central American communities, is complex. It can be stated that the poor diets and the high incidence of infections are the main factors responsible for malnutrition and growth retardation in childhood.

Diet

Table 1 shows the characteristics of the usual diet of pregnant women. In general there is a deficiency in intake, of calories, protein, vitamin A and riboflavin (2) when compared with the recommendations for the gestational period (3), when it is considered that animal protein represents only 14% of the total protein intake in the first trimester, and from 10 to 11% in the second and third trimesters of pregnancy; the rest is provided mainly by maize, which has a low biological value. Iron is also deficient because it is derived fundamentally from legumes (beans: *(Phaseolus vulgaris)* and therefore of limited utilization. There is no doubt that deficient diets contribute to the poor nutritional status of women affecting fetal nutrition and growth of the breast-fed infant.

TABLE 1

Average daily intake of 33 pregnant women, Santa María Cauqué

	Trimester			Recommended allowance[1]
	1	2	3	
Calories	1755 ± 977	2218 ± 634	2082 ± 503	2200
Total protein, g	56 ± 32	65 ± 17	64 ± 18	75
Animal protein, g	8 ± 4	7 ± 6	7 ± 6	
Iron, mg**	22 ± 13	23 ± 11	21 ± 8	18
Vitamin A, mg	0,9 ± 0,5	0,8 ± 0,7	0,9 ± 0,7	1,6
Riboflavin, mg	0,6 ± 0,3	0,7 ± 0,3	0,7 ± 0,2	1,2

1 INCAP (3).
* 80% or more from maize.
** Mainly from vegetable (pulse) origin.

Regarding food intake of children, all receive maternal milk exclusively during the first three to six months of life; breast-feeding is prolongued from one to three years or more, concomitantly with supplementary feeding (1, 2). The quality and quantity of maternal milk in Santa María Cauqué has not been determined. Maternal milk becomes deficient after two or three months of lactation in similar communities (4). The nutritional value of the supplement to breast milk, or of the total diets of fully weaned children is deficient in calories and proteins, as shown in Table 2 (5); most of the values do not reach the recommendations established for those ages (3).

In short, the diet of the child is deficient from early life: in the first few months it consists exclusively of milk often from malnourished women; later, when weaning begins, the diet becomes markedly deficient consisting fundamentally of maize, and lacking proteins of animal origin.

TABLE 2

Average daily intake of 45 children studied from birth to age three years, Santa María Cauqué, 1964-1970

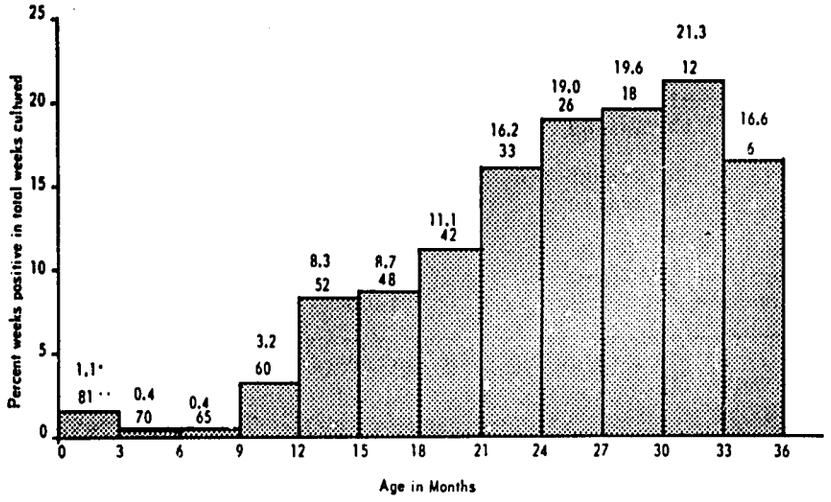
Age, months	Number	Calories	Total Protein*, g	Vitamin A Activity, mg
12	45, breast-fed	225	4,6	0.036
24	33, breast-fed	520	13,6	0.125
	12, weaned	614	17,2	0.164
36	11, breast-fed	830	23,7	0.141
	31, weaned	927	25,3	0.272
Recommended allowance**	1o.	1100	20.0	0.600
	2o.	1200	25,0	
	3o.	1400	27,0	

* 35 to 50% from maize. Not corrected for biological value.
** INCAP (3).

Infection

There is evidence indicating that intrauterine and postnatal infections are significantly more frequent in developing areas than in industrialized countries (6). Infections increase progressively with age to reach maximum values during the second and third year of life (1, 2). The magnitude of infection as illustrated with an example in Graph 1, making reference to enteropathogenic bacteria with invasive capacity of the intestinal mucosa (*Shigella*). *Shigella* infections are rare during the period of intensive breast-feeding as a result of mechanisms associated with human milk (7). As the child is weaned, infections become more frequent; 15 to 20% of the children from two to three years of age excrete bacilli at any time (8). The high prevalence reflects not only a high incidence, but a greater duration of infections as illustrated in Table 3. Infections, lasting classically one to three weeks, are chronic in a good proportion of cases; in 9% of the children infection persisted from 9 to 12 weeks, and in another 10% from 30 to 38 weeks (8). Other infectious agents show a similar situation to that of *Shigella* (6).

There is no doubt that the total problem of infection is reflected in high morbidity rates, particularly from enteric and respiratory infections, and in high mortality during the first years of life. The great duration and severity of many infectious processes in children of communities such as Santa María Cauqué, is due to the incapacity of the malnourished host to control infection (9). At any rate, infections, clinical or asymptomatic, induce physiologic and metabolic alterations of various kinds, resulting in nitrogen losses. They vary in magnitud according to the nature and frequency of the process (6).



* Figures with decimal point express percentage of positive Shigella cultures.

** Round figures correspond to number of children studied in period indicated.

GRAPH 1

Shigella excretion in feces of children cultured weekly from birth to three years of age, Santa María Cauqué, 1964-1967 (8)

TABLE 3

Duration of *Shigella* infections in children studied from birth to age three years, Santa María Cauqué, 1964-1967*

Shigella	No. of infections	Duration (weeks)					
		1	2-4	5-8	9-12	13-16	17-38
dysenteriae	29	7	10	4	3	2	3
flexneri	75	18	21	18	9	5	4
boydii	21	14	6	1			
sonnei	7	7					
Total	132	46 (35)**	37 (28)	23 (17)	12 (9)	7 (5)	7 (5)

* From Mata *et al.* (8).

** Figures in parentheses are percentages.

Growth

It seems logic that deficient diets and frequent infections affect growth at all stages of development. Table 4 shows data on gestational age and birth weight for the study village, corresponding to a considerable period in which more than 95% of all neonates were studied. Forty percent of all live newborns showed weight deficit (less than 2500 g) distributed as follows: a fourth were premature by gestational age (less than 37 weeks of gestation) and three fourths were born at term, with less than 2500 g, that is, with evidence of fetal growth retardation (10). These results are of interest because they show not only evidence of frequent fetal malnutrition, but also the interrelation of fetal growth retardation and infant mortality. In this regard, birth weight was found to be directly correlated with survival of the child as indicated in Table 5. Half of the children whose birth weight was below the average minus 1 standard deviation (that is, less than 2100 g) died during the first year. Infant mortality was 7 to 8% when the birth weight was between 2100 and 2899 g (within the average ± 1 standard deviation). None of the infants born with a weight of 2900 g or more died in the first year (10, 11).

TABLE 4

Fetal growth in 367 live borns, Santa María Cauqué, 1964-1971*

Gestation time, weeks	Classification	Number and relative %	Birth weight, g**
< 37	Premature	33 (9.0)	1,713 ± 368
≥ 37	Retarded	116 (31.6)	2,272 ± 248
≥ 37	Non retarded	218 (59.4)	2,789 ± 218

* From Mata *et al.* (6).
** Average ± standard deviation.

TABLE 5

Infant mortality according to birth weight, Santa María Cauqué, 1964-1971*

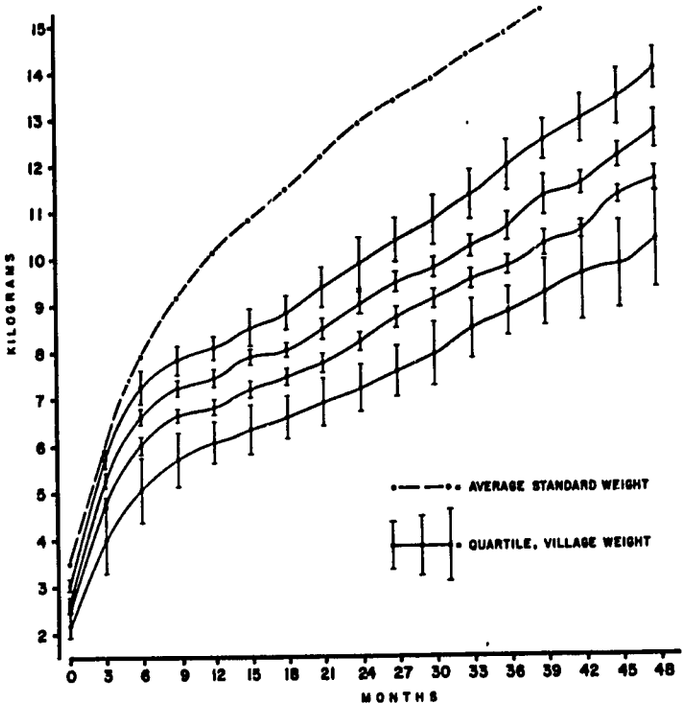
Weight, g	No. of infants	Mortality		
		0-28 days	29 days 12 months	Total
< 2100	33	6 (18.2)**	10 (30.3)	16 (48.5)
2100 - 2499	95	3 (3.1)	5 (5.3)	8 (8.4)
2500 - 2899	137	2 (1.4)	8 (5.8)	10 (7.3)
2900 +	53	0	0	0

* From Mata (10).
** Number of deaths and percentage in parenthesis.

Postnatal growth is adequate during the first 3 months of life, as revealed in the weight curves for all children born in the village during 1964 and 1965 (Graph 2). Growth begins to falter at an early age, and by one year of age all children show marked growth deficit when compared with any accepted standard (6, 12).

Possible Solutions to the Problem

There is sufficient evidence showing the contribution of poor diets and infections to deterioration of nutrition, growth and general health of the population of Central America. Corrective measures to improve nutrition and hygiene are already known. Implementation of orthodox or conventional solutions, however, is not practical and, in many cases, is virtually impossible considering the low socioeconomic level of the countries. Measures such as agricultural development, and diversification of the diet are not easy to implement. Agriculture and food industry are generally stimulated to increase exports and not specifically to



GRAPH 2

Weight curves for the first four years of life, by quartiles, Santa María Cauqué (6), in comparison with the standard adopted by INCAP (20).

improve the food intake of the population. On the other hand, people normally do not show marked tendencies toward improving dietary habits, as has become evident through several years of INCAP activities in the Central American area. Finally an improvement of environmental hygiene and general health does not have political implications in these countries.

In view of the mentioned considerations, investigation of other alternatives, like fortification of cereals, becomes a priority. The justifications to carry out such enterprise are: (a) the existence of serious nutritional problems; (b) the demonstration in the laboratory and metabolic ward of the effectiveness of fortification; (c) the necessity of showing the feasibility of the measure in the field; (d) the impossibility of alternative measures under the prevailing conditions; and (e) the low cost of the measure in function of the expected results.

These considerations have stimulated the design of a maize fortification model applicable at the community level.

Maize Fortification

INCAP studies have shown that the protein concentration of varieties of Guatemalan maize fluctuates between 6.5 and 10% (13, 14). Besides, biological tests in animals indicate that lysine and tryptophane are the limiting amino acids and that the addition of 0.31% of L-lysine to "nixtamal" (lime-treated maize) improves the protein efficiency ratio (PER) from 1.2 to 1.5, while 0.31% of L-lysine and 0.05% of DL-tryptophane increases the PER to 2.76 (15). A similar result is obtained adding 8% of soy flour (52% protein) and 0.12% of L-lysine HCl.

On the basis of existing knowledge on nutritional deficiencies in rural populations of Guatemala and other countries of the area, a formulation to supplement maize has been calculated, to be added in a concentration of 8% on the basis of dry maize (Table 6). The formulation contributes approximately with 4 g of protein to the 7.8 g (average) of maize, rendering a total of 12 g % protein. The biological value is significantly improved (PER of 2.5 or more), and at the same time deficient vitamins and iron are provided to the diet (16). The concentration of vitamins and iron has been calculated according to the needs and considering the cooking that maize must undergo. As illustrated in Table 6 an additional contribution of calories has not been considered despite the fact that the Santa María Cauqué study showed an inadequate caloric intake. INCAP studies in animals have shown that the provision of calories does not produce any additional benefit when the animals receive a diet fortified with amino acids and vitamins. Furthermore, the theory in support of maintenance of the ratio calories/protein has been challenged (17); there is evidence that appetite improves when a protein deficiency is corrected, thus increasing the intake of total calories in the diet (18). The formulation to be used in Santa María Cauqué does not include, therefore, an additional contribution of calories. Moreover, the decision avoids the introduction of changes in the kind of diet, according to the

TABLE 6

Fortifying mixture for maize*

Ingredient	Composition of supplement %	Content in 8% added to maize, g
Soybean flour	97.5000	7.800000
L-lysine HCl	1.5000	0.120000
Thiamin	0.0268	0.002144
Tiboflavin	0.0162	0.001296
Niacinamide	0.1930	0.015440
Ferric orthophosphate**	0.6000	0.058000
Vitamin A 250-SD***	0.0313	0.002504
Maize starch	0.1327	0.010616
Total	100.0000	8.000000

* Developed by R. Bressani, unpublished data.
** Contains 28.17% Fe.
*** 75,000 mcg Retinol/g.

philosophy of no modification of the usual dietary pattern, which is of key importance in field work.

Maize Fortification Model in the Field

The fortification model is being implemented in two Maya-Cakchiquel communities in the highlands of Guatemala, with similar socioeconomic and health problems. One community, Santa María Cauqué (1500 inhabitants), will be identified as the Fortification Village; the other, Santo Domingo Xenacoj, (2700 inhabitants), as Control Village.

Fortification Village. In this locality, as is typical in Guatemala, there are maize mills operated with gasoline. Villagers transport "nixtamal" to the mill where it is emptied into the hopper for grinding. The cost of grinding is approximately US$0.01 per pound, a stable price for all the region. Fortification is carried out during grinding, since it has been demonstrated that incorporation of the supplement to the dough is almost 100%. Fortification is implemented in the two existing mills. The development of the project will take care of selecting a group of noncooperative families that will refuse the supplement.

Seven trials on palatability have been carried out in the Fortification Village. The triangle method was used with children and adults, both sexes, to determine discriminatory capacity for the fortified "tortilla" (flat cooked pancake of nixtamal). The results of the trials are presented in Tables 7 and 8. They show that there is no discriminatory capacity for the flavor of enriched tortillas. Table 7 illustrates four tests in 140

TABLE 7

Tests to establish discriminatory capacity of flavor of fortified tortillas*, Santa María Cauqué, 1971-1972

Test	No. of adults	No. of sets of fortified tortillas	No. of correct answers observed** No.	%	expected for $p < 0.05$
1	36	1	6	(16.7)	18
2	29	2	10	(34.5)	16
3	24	3	9	(37.5)	14
4	25	0	12	(48.0)	14
Total	114		37	(32.5)	50

* Fortified with 8% of supplement.
Test were by the triangle method.
** Number of answers and percentage in parenthesis.

TABLE 8

Test to establish discriminatory capacity of flavor of fortified tortillas*, Santa María Cauque, 1971-1972

	Correct answers	
	20 children	20 adults
Fresh tortillas		
1st. table	6**	9**
2nd. table	8	7
Reheated tortillas		
1st. table	8	7
2nd. table	7	9

* Fortified with 8% of supplement.
Tests were by the triangle method.
** The number of correct answers to reach significance ($p < 0.05$) is 11 for each group of 20 subjects.

subjects. In each test three piles of tortillas were used; 1, 2, 3 or none of the piles were of fortified tortillas. Table 8 summarizes another test in which two tables were used, each with three piles of tortillas, one of which was fortified. The test was repeated with tortillas prepared the preceeding day and reheated before consumption. In total, 274 observations were made in 154 persons, yielding 35.8% of correct answers which is what can be expected by random. It can be safely concluded that the inhabitants do not detect a different odor or flavor between the usual and the unfortified tortillas. Fortified tortillas do not have either different color or texture.

For the implementation of the model in the Fortification Village there is a team of field workers with an experience of 5 to 10 years and with capacity to develop field methodology for the collection of adequate data on the selected parameters. The team consists of a physician, a technician in dietary surveys, three nurses, an inspector of hygiene and two field workers. There are physical facilities and equipment to carry out observations on nutrition and growth, epidemiology, public health and microbiology. The field workers know the way of life and customs of the inhabitants, and have obtained the cooperation of almost all families.

Control Village. INCAP administers the health center of Santo Domingo Xenacoj. The team is formed by a physician and two nurses; several members of the team working in the Fortification Village are helping sporadically in the Control Village. Preliminary work has revealed willingness of the inhabitants to colaborate with INCAP programs.

Study of pregnant women and newborn. Fortification Village. During the first two years approximately 130 pregnant women will be recruited for a four year prospective observation. Pregnancy is followed to termination.

The measurements programmed for children are depicted in Table 9. The methodology used has been partially described (1, 2, 6, 8, 12). Diet, nutrition and morbidity of the mother is investigated during pregnancy and lactation. In the child, the diet, *Shigella* infection, general morbidity, growth and survival is also investigated.

For the surveillance of fortification, quality control analysis of every lot of the supplement has been programmed. Furthermore, tortillas are collected at regular intervals from a series of representative families (100 per month) to determine lysine levels, which in turn, indicate changes in tryptophan content. A supervisor controls the incorporation of the supplement, and keeps a record of the families refusing fortification.

Other studies such as biochemistry of blood and urine, have been programmed at the beginning of the intervention, and one and two years after its commencement. Also, evaluation of psychomotor development and neurointegrative capacity of children have been considered awaiting the availability of adequate techniques for the Maya-Cakchiquel culture.

Control Village. Approximately 200 pregnant women will be recruited through bimontly interviews of all women at risk; urine pregnancy test will not be carried out. The morbidity and general health will be recorded during pregnancy. Anthropometric measurements will be practiced in each child and a follow up for survival will be maintained for every one of them (Table 9).

Recording and analysis of data. Nine years of experience with the prospective study in the Fortification Village have permitted the establishment and development of systems for data recording in precoded forms, rendering them susceptible for easy transfer to IBM cards. Information will be analyzed by computers.

TABLE 9

Programme of examinations for children of the communities of the study

	Fortification	Control
Weight, height, and head circumference	At birth, Weekly (1 month) Bimonthly (1 year) Monthly (2 years)	At birth, Every 3 months (3 years)
Study of weaning Measurement of dietary intake	Weekly (3 years)	No
Clinical evaluation	Weekly (1 month) Bimonthly (1 year) Monthly (2 years)	No
Stool culture for *Shigella*	Weekly	No

Comparison groups. The selection of the two villages and the availability of a great amount of basic data, will allow for several comparisons as illustrated in Table 10. The cohorts of pregnant women and babies could be compared as follows: (a) in the Fortification versus Control Village; (b) in the Fortification Village before and after the nutritional intervention; and (c) in the Fortification Village according to acceptance or rejection of the supplement. It should be emphasized that, except for the nutritional intervention in the Fortification Village, the only other intervention introduced consists in delivery of medical care to both communities with similar intensity. It is feasible that years after the commencement of the study, the Control Village would be initiated in a fortification program, thus producing a new type of experimental control.

Dates for the Developing of a Model

The preliminary phase consisting of a census, developing of logistics and review of methodology, has been completed. Meetings with leaders of both communities have been held with the purpose of explaining the nature of the study. The villagers welcome the project and are happy that the incorporation of the supplement to nixtamal is a reality. The beginning of fortification was in June 1972. The first results will be available in December 1973, but the study will terminate in 1977. By then, adequate data will be available on any effect the supplement may have had on the parameters investigated.

TABLE 10
Comparisons

Fortification vs Control Village

A. Cohorts of children 1972 - 1976
   a. fetal growth
   b. post natal growth
   c. infant mortality

Fortification Village

B Cohorts of children 1964 - 1971 vs 1972 - 1976
   a. fetal growth
   b. post natal
   c. dietary intake
   d. infant mortality
   e. morbidity
   f. *Shigella* infection

C. Cohorts 1964 - 1971 before and after fortification
   a. post natal growth
   b. dietary intake

D. Cohorts 1972-1976, supplemented vs non supplemented
   As in B.

Goals of the Model

The objectives of the model are biologic, administrative and political. The biologic is to demonstrate a substantial improvement in the health of the inhabitants, particularly children, evidenced by an increase in birth weight, decrease of rates of infection and infectious diseases, improvement of postnatal growth, and reduction of infant mortality.

The administrative goal is to show that fortification of maize is economically feasible, susceptible of being surveyed and evaluated, and attractive to community participation.

The political objective is to demostrate before the authorities responsible for health planning, the feasibility of the nutritional intervention at the level of a community, region or country.

Comments

The nutritional and health problems affecting the Central American countries are so serious as to demand the exploration of alternatives for their solution. Due to the socioeconomic and political conditions that prevail in those countries, very limited change is expected from the application of conventional

measures for the improvement of nutrition. Fortification of cereals, that constitute the staple food, seems to be a solution of great potentiality. Careful studies in experimental animals and in children in a metabolic ward, have demostrated that maize fortification significantly improves its nutritive value (19). It is not known, however, if maize fortification would improve the nutrition and health when implemented at the community level, because of the existence of other factors contributing to malnutrition such as infection and other varieties of stress. Therefore, the measure must be studied as soon as possible and without denial of the necessary recources to carry out the project in a proper way. The existence at INCAP of a long-term prospective study permiting the observation of children from the fetal stage to 7 years, in their ecosystem, and with a multidisciplinary approach, provides a unique opportunity for environmental intervention with a nutritional measure - fortification - to determine its effects. The above mentioned study revealed a high frequency of fetal growth retardation, a marked deficit in postnatal growth, a high frequency of intestinal infection and morbidity, and a high mortality in children in the first 4 years of life. Since deficient diet is one of the most important factors in the genesis of these problems, a substantial improvement of the diet expectedly will induce changes in those parameters.

The basic knowledge, personnel, research methodology, and analytic capacity to determine changes, already exist. Therefore, it is expected that the study will develop without significant drawbacks and that important observations will be derived from the model.

Summary

Maize is the staple flood in hundreds of Central American communities, and provides 70% or more of the total protein and calories of the usual diet. A long term prospective study in one of such communities, in the highlands of Guatemala, revealed that: a) as many as 40% of all babies experience fetal growth retardation or are premature; b) most infants show physical growth retardation by one year of age; c) infant mortality is 100 per 1000 live births; and d) certain infectious diseases tend to become chronic. In this study village, as in most Guatemalan communities, "nixtamal" (lime-cooked maize) is ground in mechanical mills. Taking this into consideration, a prospective study is being implemented, whereby a supplement will be added to nixtamal during milling. The supplement, in a concentration of 8%, provides 7.82% soy bean flour, 0.12% lysine, and a mixture of vitamins A, B_1 and B_2, niacin and iron. Field trials by the blind triangle method showed that the supplement is not detected by villagers: fortified "tortillas" (cooked flat pancakes of nixtamal) have a color, odor, flavor and texture similar to that of regular tortillas. Most villagers have accepted the product, and fortification began in June 1972. Effects of the intervention could be noticeable in fetal growth, weight curves in the first year of life, infant mortality, and duration of disease. The controls will be: a) cohorts of babies recruited during the period 1964-1971; b) cohorts born after 1971 from families not

receiving the supplement; c) cohorts of babies studied in a neighboring village, with similar health problems to those of the study village, but where fortification will not be conducted. It is expected that the nutritional intervention will have a benefitial effect on the parameters studied.

Acknowledgements

The authors wish to thank Dr. Moisés Béhar for the stimulus and collaboration necessary to undertake this study. This research is financed by the Agency for International Development (AID), the Pan American Sanitary Bureau, and the General Direction of Health Services of Guatemala. The lysine used was donated by Ajinomoto Co., Inc., Japan.

The authors wish to thank Silvia Corado and Patricia Solé for their helph in the preparation of this manuscript.

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