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EVALUATION OF NUTRITION INTERVENTION PROJECTS

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Final Report to the Documentation Coordinator,
TA/PPU/EUI, Technical Assistance,
Agency for International Development,
Washington, D.C. 20523

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ABSTRACT

This project was undertaken out of the perceived need for a critical evaluation of nutrition interventions and a desire to provide for a set of guidelines for the design and evaluation of future nutrition programs. After a preliminary screening of several, varied nutrition intervention programs, six were chosen for inclusion in this study. Each study was evaluated in the context of a predetermined methodology devised by the investigators covering several categories of evaluative criteria. After a presentation of reasons for including each study, a summary is presented of the results of each study in light of the present investigators' evaluation and secondary analyses. In the final section, the present investigators conclude that nutrition intervention programs can have a positive effect on the health indices of infants and children, but that much can be done in future nutrition projects to improve project design and thereby assist and facilitate more meaningful evaluations of nutrition interventions. To this end, a list of questions that can be asked by those designing nutrition intervention projects is provided.

INTRODUCTION

Intervention to provide a minimal level of nutrition, or to stabilize or improve the nutritional status of individuals, has become a high priority in public health during the past two decades. The types of interventions are disparate ranging from general agricultural development schemes to provision of a limiting (dietary) factor to individuals whose diet is deficient in this factor. Two of the more popular interventions have been the use of direct food supplementation with or without nutrition education, and fortification of staple foods. These interventions are usually established as "nutrition components" of comprehensive health service programs, and generally encourage community participation including use of traditional health care resources. Indeed in a recent compilation of 180 comprehensive health care programs, 90 percent included one of these nutrition intervention strategies as a principal or adjunct component.(1)

By their nature, nutrition intervention components are service-oriented packages. Often times a given project is a pilot project initiated to study the feasibility of employing the intervention on a larger, regional or national scale. Unfortunately, a cursory review of the literature indicates that those institutions which initiate nutrition intervention projects frequently neglect to take into account the results of other nutrition intervention projects sponsored by the same or other institutions. Moreover, only casual attention is given to evaluating the usefulness of the intervention package in accomplishing the goal of the project using commonly accepted methods of critical evaluation. A major obstacle to evaluation is that in the majority of cases, these studies have made inadequate provision for the generation of data detailed enough for any

but the most rudimentary analyses. This leads to the use of periodic progress reports, final reports issued for public relations purposes, and publications by the investigators as the substance of project evaluation. This situation is most unfortunate, particularly with regard to pilot projects or studies since these are done primarily to test the feasibility and usefulness of subsequent implementation of the more costly regional or national programs.

It was out of this background that this project with its two aims evolved. First, we wanted to examine a wide variety of nutrition intervention studies in various parts of the developing world and compare the effects of these interventions on health indices. Secondly, and based on the results of this analysis, we wanted to develop guidelines for future program evaluation. Our specific objectives include:

1. To determine whether enough information is now available to conclude that nutrition interventions can have significant beneficial effects on nutritional status and mortality of newborn children and children under five years of age;

2. To define some of the major weaknesses which seem to have been repeated in recently executed studies (i.e., methodological problems and gaps in information);

3. To recommend guidelines for future program evaluation with special regard for:

a. Criteria for a significant effect on health;

b. Sample sizes and evaluation methods necessary to establish whether these criteria have been met;

c. Social, economic, cultural and health considerations which must be taken into account in comparisons of programs conducted in different locations.

In the selection of studies for our review, we were guided by three principal criteria:

--ready availability and accessibility of data either in published form or through the principal investigators(s),

--inclusion of as wide a spectrum of nutrition interventions as technically feasible within the constraints of the grant budget, and

--concentration primarily on research efforts and inclusion of service projects only if information from research efforts for the particular intervention package was not available.

Of over fifteen major research and service projects examined, six were finally selected for detailed study. These were neither the "best" nor, of course, were they the "worst"; they merely fulfilled the three criteria most adequately. Among the specific intervention packages included were:

1. Effect of pre- and postnatal (maternal) nutrition supplementation on birth weight and infant mortality (INCAP-I, carried out by the Institute of Nutrition of Central American and Panama (INCAP), Guatemala). This was a longitudinal study into the effects of prenatal supplementation on birth weight, infant growth and infant mortality. Over a period of five years pregnant women in four Guatemalan highland villages received protein or protein plus calorie supplements on a voluntary basis. Birth weight, infant growth and infant mortality were compared between these two groups as well as related to total calorie intake during the pregnancy period.

2. Effect of nutrition supplementation and medical care on growth, morbidity and mortality of preschool children (carried out by The Johns Hopkins University's Department of International Health and the Indian Council of Medical Research in and around Narangwal Village, Punjab, India). Nutrition supplementation and nutrition education with or without infectious disease control was provided to all children below three years of age resident in three villages each, on a voluntary basis and growth (weight and height), prevalence of undernutrition, mortality and morbidity were monitored longitudinally and compared to children in villages receiving infection control alone or no services. In parallel, content, cost and effectiveness of the village-based, auxiliary-staffed health care delivery program were studied.

3. Effects of health education and nutrition surveillance on malnutrition and mortality of preschool children (carried out by the government of Jamaica, the University of the British West Indies and Cornell University, in Cornwall County, Jamaica). The project was started in 1969 in Elderslie, later Hanover Counties. Its objectives were to reduce high child mortality and malnutrition prevalent in these counties. Local, literate residents were recruited and trained as auxiliary health workers, whose main function was to identify malnourished preschool children through periodic home visiting and provide nutrition advice in general, and milk supplement to those found to be under-nourished.

4. Effect of vitamin A supplementation on growth and morbidity of preschool children (carried out by the Department of Pathobiology and the International Center for Medical Research, The Johns Hopkins

University, in Ichag, Bengal, India). This study concerned itself with the effects of administration of massive doses of vitamin A on incidence and prevalence of vitamin A deficiency signs and symptoms (Bitot spots, night blindness) on prevalence of other infectious illnesses, as well as on levels of nutrition and linear growth in the preschool child of an east Indian (Bengal) village.

5. Effect of corn fortification of maternal diet on outcome of pregnancy, child growth, child morbidity and mortality (conducted by INCAP in Santa Maria Cauque village, Guatemala). This study (INCAP-II) was carried out with the objectives of determining the feasibility of corn fortification (with lysine) at the village level and of measuring the effects of ingestion of fortified corn on birth weight, child growth, child morbidity and mortality.

6. Effect of a subsidized food supplement for a targeted group of preschool children on growth and mortality during a famine situation (conducted by UNICEF in Companiganj Thana, Noakhali District, Bangladesh). During 1975, Bangladesh experienced severe food shortages. As part of a comprehensive health service delivery project experimenting with (innovative) ways in providing health and family planning services to a rural population, the project made available a mixture of roasted and ground wheat and pulse at a subsidized price to all families with preschool children who wanted to avail themselves of it. The level of purchase of the subsidized grain meal and its relationship to nutritional and mortality levels of preschool children during the period of the famine were determined.

RESEARCH METHODOLOGY

Our evaluation of the six studies selected encompassed three principal steps:

1. Collection of information on each study through examination of published material as well as unpublished reports made available through either the granting agency or the principal investigator(s);

2. Site visits for clarification of questions remaining after examination of primary documents;

3. Evaluation of the project with or without the aid of a secondary analysis of the data.

More specifically, the following evaluation methodology which was used evolved as we proceeded with the investigation.

1. Familiarization with project or study:

--review of published material;

--review of unpublished material;

--discussions with principal investigator(s), where possible;

--site visit, where necessary and feasible;

--secondary data analysis;

--review of principal investigator(s)' comments and suggestions to preliminary report.

2. Project analyses:

A. Identification of objectives:

--research objectives,

--service objectives;

B. Characterization of the study (project) design. Specifically identified:

--input variables,

--output variables,

--outcome measures;

C. Identification of verifiable results:

--from primary analysis (by principal investigator(s)),

--from secondary analyses in the course of this investigation.

3. Evaluation:

A. Validity of study:

--Documentation of nature and extent of nutritional problem for which intervention was developed:

a. how determined,

b. when determined and by whom;

--Appropriateness of selected intervention (to nature and extent of nutrition problem), determined through:

a. pilot study,

b. evidence from earlier or parallel studies,

c. laboratory or clinical evidence,

d. other;

--Selection of target population:

a. age group,

b. vulnerability to nutrition problem under study,

c. enrolled study population or community inclusive,

d. self-selected, randomly chosen, or other;

B. Validity of results:

--Method of analysis;

--Selection of "control" groups:

a. parallel groups or before and after, or both,

b. how selected if parallel (self-select, group affiliation, random sampling),

c. comparability;

--Measurement of confounding variables:

a. socio-economic, demographic and educational background,

b. genetic background,

c. season-, age-, sex differentials,

d. diseases affecting nutritional status,

e. other;

--Adjustment for confounding variables;

--Sample size;

C. Applicability of results to nutrition problems on broad scale:

--Cost,

--Technical feasibility,

--Acceptability.

While we attempted to evaluate each of the six studies according to this scheme, availability of data and information often precluded examination of specific items. For example, we found it difficult to get cost information in sufficient detail to separate service costs (i.e., the cost of intervention) from research costs. Neither could "acceptability" be judged adequately. Except in one study (INCAP-II) where the process, clearly, was unacceptable to the local population, and in another (Jamaica) where it was equally clearly acceptable, the fact that inputs were provided and accepted throughout the study period does not necessarily

imply that the program would be acceptable under normal, i.e., non-research, conditions or in other geographical/socio-cultural settings.

SUMMARY DISCUSSION AND EVALUATION OF STUDIES

In this section we have attempted to provide a summary of our evaluation of each of the studies selected for inclusion here as well as to compare the objectives, study designs and outcomes of the six projects. A more detailed description and evaluation of each individual study is provided in the Appendices.

Factors Affecting Inclusion of a Study In and Extent of Our Evaluation--The extent to which our evaluation addressed and how well each study fulfilled the evaluative criteria listed earlier depended upon several factors. In the following paragraphs these salient factors are summarized for each project.

The Companiganj price subsidy "study" was inherently interesting because of its unique kind of intervention. It was a situational analysis of conditions prevailing for a given period (famine) and the effect of a relief measure (price subsidy) to lessen the ill effects of that famine. The Companiganj study had been terminated by the time the evaluation reported here was planned. Even though the "parent" project under the auspices of which the investigation was done still existed, it was felt that a site visit to the project would yield few, if any, additional results, especially since the principal investigator had put all available data (both raw and analyzed) at our disposal. In our evaluation of this project, then, we concentrated on an extensive secondary analysis to validate initial impressions of lowered mortality in the treatment group.

The vitamin A supplementation project had been terminated and the research facility, from where the study was directed, had been all but dissolved. While all primary analyses had been completed, extensive secondary analyses were again undertaken to clarify what, we felt, were potentially rather important research findings.

Similarly, the Narangwal study had been concluded. Most of the data had been analyzed and the research center in India no longer existed. It was included mainly for two reasons. First, results from the Narangwal nutrition project seemed to have succeeded in both defining more closely the interrelationship between nutritional status, illness experience and death and in demonstrating means of intervention. What needed to be done was to confirm through secondary analysis of available data that low nutrition indeed affected mortality and, if so, how. Second, all data were readily available and more was known about the project than about any of the other studies since one of the writers of this report was also one of the principal investigators of the study. To review the project as objectively as possible, one of the authors of this evaluation, who was not a participant in the Narangwal study or any of the other studies (C. Ajello), undertook the Narangwal evaluation following the same guidelines set for the other studies.

The nutrition surveillance program (Jamaica) was included here because it had reported rather dramatic results in reducing mortality and malnutrition prevalence. The results were beyond expectation (of the writers of this report) and immediate questions as to comparability of control groups, general (national) trends, and, if the results could be confirmed, feasibility of extending the program to other countries

with similar problems emerged. Circumstances permitted and the study results encouraged our inclusion of a site visit to Jamaica. Given the fact that the principal investigators obtained information on child deaths through the regular (local) channels of vital statistics, our evaluation focused on verifying mortality rates and establishing the validity of the comparison group. Thus, rather extensive data collection and re-analysis of the collected data were undertaken.

The corn fortification study (INCAP-II), for which circumstances also permitted a site visit, generated results which were somewhat disappointing and which along with its innovative and novel approach to intervention make it of interest to us. Even though the final report issued statements of clearcut findings, a site visit was undertaken because we had several questions regarding the methodology of the study plans, conduct of the study, and analysis of the data--information about all of which were available on site.

Lastly, the maternal feeding study (INCAP-I) was well documented, its results were known and extensively published. A field trip served mainly to clarify methods of sample selection and analysis.

Study Approaches--All six projects attempted to study the relationship between food and health, but did so using different approaches. Two of the studies (INCAP-I and vitamin A supplementation) were concerned with basic research questions, namely to determine the effect of a specific input variable--calorie and protein supplementation in the former, vitamin A in the latter--on specific outcome parameters: birth weight, and selected child morbidity.

By contrast, two studies (Narangwal and corn fortification) combined research objectives with applied research or service objectives in their study approach of the relationship between food and health. In the Narangwal project, research on the effects of food supplementation on indices of child health was combined with the search for an effective and comprehensive health care package that could be replicated, eventually, under national constraints. In the INCAP corn fortification project, both the effect of improved food quality (lysine enriched corn) on indices of health (birth weight, child morbidity and mortality) and the feasibility of local, village-based, fortification were examined.

In the Jamaican nutrition surveillance and the Companiganj price subsidy projects, the underlying objective seemed to be primarily provision of services in response to identified needs--general malnutrition and high child mortality in Jamaica and famine in Bangladesh. Enough data were collected in both studies, but especially the latter, to document observed changes.

Study Designs and Methods of Analysis--Selection of suitable controls proved to be a major problem in almost all of the studies.

In the Jamaica project the problem of selecting appropriate controls is reflected in our finding that reduction in child mortality was considerably less once mortality trends from the neighboring county--Trewlany--were examined and once the observed reduction in deaths were related chronologically to specific program activities. In the corn fortification project, the original control group was not used, instead the level of fortification determined comparison groups. Since these

groups (by the mere fact of participating or not participating with the program) were self-selected, differences in other characteristics may have affected the outcome.

Since provision of a service considered essential (supply of food) under the prevailing conditions (famine) was the basic objective of the Companiganj project, controls were neither intended nor would a control group have been acceptable on ethical grounds.

Results on infant mortality in the INCAP-I study are based mainly on comparisons with infant deaths in an urban population matched for identical characteristics through retrospective analysis. Even though the matching may have been quite good, the major difference of urban versus rural population remains. Narangwal used two entire villages as controls and was forced to drop one of them when it became apparent that the population in that village was no longer comparable to that in input villages or in the other control village because a nearby air-base provided progressively more employment to villagers. To compensate for the loss of control population, control villages of a parallel population study were included. These villages apparently were quite similar in their socio-cultural, economic make-up but collection of vital events was less intensive in the new control village, i.e., by two rather than three sources. Underreporting of events in these villages, however, would have tended to have a greater effect on the numerator (deaths) than on the denominator (births or child populations) with an overall effect of reducing rather than inflating observed mortality differentials.

The limitations in the studies examined here and noted above with regard to study design begin to make it apparent that more "sophisticated" design, and, as will be discussed, analyses are needed if evaluation of outcomes is the objective. Indeed, initially positive and important findings (i.e., reduction of preschool child mortality because of improved nutritional status made possible through price subsidy at times of famine) could not be sustained when confounding variables such as socio-economic status, sex, age, etc., were controlled for. The corn fortification study was analyzed by rather simple means (contingency tables) and would have greatly benefited from a multivariate analysis if only to validate the observed morbidity differences and clarify mortality effects. Unfortunately, this was not done because of lack of funds. By contrast, suggestive ill effects of vitamin A on growth at low levels of nutrition not only remained after adjustment for important variables through multivariate analyses, but equally important, it was found that vitamin A may be growth promoting during periods of relative food abundance. Similarly, the effects of lowered mortality with improved nutrition, observed in the Narangwal experiment, is credible because of the method of analysis employed, and was further strengthened by the demonstration that study children below a given weight-for-age suffered from reduced immune competence.

Results from Narangwal highlight the difficulty of selecting "sensitive" outcome measures. Food supplementation caused a reduction in the proportion of malnourished children, but this reduction became statistically significant only at seventeen months and beyond and was much less than the reduction attributable to socio-environmental factors such as high caste, being male, and the cool season. Although the positive effects of supplementation and nutrition education were not sufficient to offset the negative effects

of social, economic, sex and climatic factors in the first sixteen months of life, both weight and height-for-age were significantly improved beyond that period in all villages where nutrition services were provided in comparison to children in control villages. This difference became significant or could be conclusively demonstrated only because a relatively large number of children (around 1,000 at any given point in time) were studied longitudinally. Similarly, mortality differentials between study cells could be demonstrated only because deaths on a relatively large population were aggregated over several years.

As outcome measures, the overall growth and mortality patterns of all children resident in project villages were used in the Jamaica and Narangwal studies. This may have diluted respective program effects, but strengthened the credibility of the results. It is relatively easy to show that a captive or "enrolled" child population will improve its nutritional status if regularly given X grams of supplement. It is much more difficult to demonstrate beneficial effects at the aggregate community level when all residents or specific age groups among residents are the target.

Study Findings--The studies have yielded a number of interesting findings. In the next several pages these are summarized in light of our evaluation and the results of our own secondary analyses. In an effort to enable the reader to be able to compare each of the studies most quickly, as well as to guide the reader in the following discussion, Table 1 has been prepared.

The maternal feeding study (INCAP-I), as well as the Narangwal study, demonstrated conclusively that prenatal child care in the form of maternal supplementation (INCAP-I) and iron and folic acid plus supplementation

Table 1

SUMMARY GUIDE TO SIX NUTRITION INTERVENTION PROJECTS

Objectives of Investigation	Site Visit	Secondary Analysis	Major Results of Primary Investigator	Major Results of Secondary Analysis	Major Study Weaknesses
INCAP-I: Effect of maternal supplementation on birth weight and infant mortality	Yes	No	1. Increased birth weights 2. Lowered rate of prematurity 3. Reduced infant mortality rate	N.A.	1. Invalid mortality control selection
NARANGWAL: Effect of nutrition supplementation and/or medical care on child health	No	Extensive	1. Improved growth through supplementation 2. Reduced child mortality through medical care (except in perinatal period)	1. Establishment of nutritional threshold below which immune capacity significantly decreases in original study population	1. Study design inadequate to demonstrate synergism of combined programs 2. Heavy dependence on recall data in morbidity section of study 3. Controls not really comparable
HANOVER NUTRITION PROJECT: Effect of nutrition surveillance and nutrition education on child mortality and malnutrition prevalence	Yes	Extensive	1. Reduced prevalence malnutrition 2. Reduced child mortality	1. Mortality decline less than that found by principal investigators 2. The decrease in child mortality shown for study areas was also found in other non-study areas as part of a secular trend	1. Data presented in aggregate form only; age-specific data not tabulated 2. Potential time series error not controlled for in data analysis
ICHAG VITAMIN A STUDY: Effects of vitamin A supplementation on child morbidity	No	Extensive	1. Prevention of Bitot spots and night blindness 2. Reduced severity of measles 3. Possible growth retarding effect at times of food scarcity	1. Confirmation of a deleterious effect of vitamin supplementation on child growth during times of food scarcity 2. Determination of a growth-promoting effect of vitamin A during total abundance	1. Study population too small to provide conclusive information
INCAP-II: Effects of corn fortification on child health	Yes	Some	1. Reduced child morbidity 2. Reduced child mortality	1. No clear effect of corn fortification on either child morbidity or child mortality	1. Lack of a pilot study 2. Inadequate data analysis 3. Invalid control group
COMPANIGANJ NUTRITION PROGRAM: Effects of wheat price subsidy on child morbidity, child mortality and child growth	No	Extensive	1. Reduced child mortality	1. No effect of wheat price subsidy on child mortality, child morbidity or child growth	1. Study population sample not representative of the study area 2. No control population 3. Underestimate of amount of supplement needed to maintain adequate nutrition in target children 4. No adjustment for confounding variables

(Narangwal) can significantly improve weight (INCAP-I) and decrease peri- and neonatal mortality (Narangwal).

Although it had been shown earlier that administration of folic acid alone can improve birth weight,[2] the role of maternal nutritional status and, more importantly, that of maternal protein-calorie supplementation, on the outcome of pregnancy had been disputed and, in general, was unresolved. The Guatemalan study has shown that calorie, rather than protein, supplementation was the important factor. This finding may be locality dependent, i.e., valid for a specific population with defined nutritional deficiencies. However, the very finding that an additional 20,000 calories during gestation was associated with improved birth weights is a major breakthrough in health care research since it is known that the reduction in the proportion of low-birth-weight infants will in turn lead to reduced infant mortality.

Results from Narangwal, where peri- and neonatal mortality rather than birth weight was used as outcome criteria, also showed that antenatal care was the most cost-effective means in reducing child mortality. It is unclear from the Narangwal report how the effects on peri- and neonatal mortality were achieved--whether through raising birth weights or through providing a factor deficient in the diet, i.e., folic acid. Birth weights were available on approximately 500 newborns. Birth weights in villages where nutrition care was provided were no higher than those in villages where it was not. According to the investigators, there is strong reason to believe that birth weights taken were not representative of the general child population, and folic acid levels in pregnancy were not determined.

After the postneonatal (first through eleventh months) period, child mortality in villages receiving the supplements were consistently and

significantly reduced. This reduction was considerably greater than might have been predicted from the observed nutritional change. One to four mortality was 9/1,000 population per year in supplemented villages and more than twice as high (21/1,000) in control villages.

Secondary analysis of the Narangwal data carried out to define more precisely the ways in which the nutritional status affects mortality confirmed that immune capacity was in fact decreased below a given nutritional threshold, which in this population was at 70 percent of the Harvard weight-for-age median.(3)

Child mortality as the most serious consequence of childhood malnutrition indeed seems to be a practical and sensitive indicator to monitor and evaluate effects of a nutrition intervention program. However, the number of children at risk and exposed to the services has to be large enough to allow detection and verification of mortality differentials. Results from the Jamaican study and from a previously done project in the Andes(4) illustrate the validity of mortality as a suitable indicator. In the Companiganj project, sample size and mortality levels of the child population were large enough to show up mortality differences had there been any. While several factors may explain the absence of the expected increase in nutrition and decrease in the number of deaths among the target group, too little food in the first place* and distribution of the supplement to all members of the family, and perhaps even preferentially to older children or adults, probably are the most important ones. As the principal investigator stated retrospectively and in response to our analysis:

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*The supplement was intended to cover only ½ of the daily caloric requirements of the target population.

> "We should have stopped all health activities and concentrated exclusively on distribution of food in quantities high enough to make sure that all, but especially small children, would have gotten their share" (C. McCord, private communication).

The Companiganj study, even though it had negative results, represents an important contribution to the field of nutrition intervention. Its results emphasize that mere provision of a food supplement at times of food scarcity is not enough if survival of the most vulnerable segment of the population is one of the objectives. Providing one-third of the daily requirement assumes that parents are able to supply two-thirds on their own. Even if the amount of food provided had been adequate to alone sustain normal growth of the child or children for whom it was meant, it might have been too little to constitute a large enough increment in food supply for the whole family to assure improved nutrition of the target group.

The fact that children from those families participating with the program were socio-economically somewhat worse off than those not participating might explain the failure of the supplement to reach the target group. Food subsidization or supplementation in times of famine and expressly for the sake of children, therefore, appears of questionable value unless given in high enough quantities to totally cover the needs of the target group as well as to allow for some intrafamilial distribution. If the latter is not feasible, means must be found to channel the food specifically to the target group. This could have been achieved in specially established feeding centers or through supervised feeding in the home. Either is impractical, as it requires an inordinate amount of time of either the mothers or the provider.

Decrease in preschool child mortality was the most striking effect in the Jamaican project. The on-site visit incorporating re-examination of vital rates showed this decline to be less than originally assumed. Nonetheless, the fact of a mortality decline associated with intensive nutrition surveillance and selective nutrition rehabilitation remained. In Jamaica, and unlike in Bangladesh or India, malnutrition seems to be more the result of faulty childrearing practice than absolute scarcity of food stuff. Attention to the problem in terms of detection, education, and selective intervention seemed to be all that was necessary to halt deterioration in nutritional levels and through it, reduce child mortality.

While nutrition intervention thus seems to have its clearest and most important effect on child mortality, the prevalence of malnutrition (a precursor to child mortality) is similarly affected. This occurred in both Jamaica and Narangwal. In the latter study, effects could be shown only from seventeen months of age on. Malnutrition incidence was unaffected in Jamaica and not determined (reported) in the Narangwal study. Nutritional status in terms of birth weight or subsequent weight-for-age, weight-for-height, or height-for-age was affected (INCAP-I, Narangwal) to a greater (INCAP-I) or lesser (Narangwal) extent. Furthermore, the direct relationship between this effect and other parameters of child health, i.e., morbidity, remains speculative. In the Narangwal study, where a morbidity survey was done on every child once a week, children in the food supplemented group tended to have higher morbidity

levels than children receiving infectious disease control services, and almost equally high levels as children in control villages. According to the principal investigators, the apparent rise in morbidity prevalence in nutrition villages had resulted from improved reporting in these villages. The resident family health worker that looked after two of the three villages had been responsible for the villages for a longer period than any of the other FHWs (4+ years), had excellent rapport with the mothers and was able to obtain a more complete morbidity history even though she did not provide medical (curative) services. By contrast, in the corn fortification study (INCAP-II) the only health benefit for which clear statistical proof could be established was the decrease in childhood morbidity among children from families with a high fortification index. Although there were some signs of reduction in the child mortality, these were by no means consistent and convincing. Birth weight or preschool child nutrition showed no effects at all, even though both calorie and protein intakes of pregnant women as determined through recall diet surveys were significantly raised in the group with a high fortification index.

Highly specific nutrition intervention as in the case of vitamin A supplementation in an area of endemic vitamin A deficiency confirmed a well-known fact that deficiency signs and symptoms can be prevented. The vitamin A study results indicated that massive doses of vitamin A could reduce the appearance of new cases of Bitot spots and clear up established night blindness, but that vitamin A treatment did not affect already formed Bitot spots in those who had these signs previously. As measured by morbidity, only measles and possibly varicella were affected by vitamin A supplementation. In the case of measles, the rate of complications (pneumonia, diarrhea and eye discharge) was significantly lower in the treatment group than in controls.

By contrast, varicella appeared more frequently in supplemented children. This latter finding was statistically not significant, however. Our extensive secondary analyses supported an earlier (primary investigator) made observation which merits further investigation: that there is a potentially adverse effect of vitamin A on growth in children with severe undernutrition. Additionally, the secondary analysis identified a possible growth promoting effect of vitamin A during times of relative food abundance.

In terms of replicability, both the Jamaican child surveillance and the maternal feeding (INCAP-I) projects seem to lend themselves best to implementation on a large scale. In the former, regular monitoring of child weight and supplementation of those found to be "malnourished" by trained community workers; and in the latter, provision of 20,000 additional calories in form of locally available food stuff during the first two trimesters of pregnancy are the essential program components. Neither would require an elaborate infrastructure nor would the food be prohibitively expensive. Selected aspects of the Narangwal services such as antenatal supplementation with folic acid and calories similarly lend themselves to program implementation on a large scale. Nutrition services to older children were costlier mainly because all children were offered the supplement. Retrospectively, it cannot be stated for certain that selective supplementation of only those identified as at risk, i.e., by being below a given anthropometric index, would have resulted in the observed improvement of mortality and overall growth of the Narangwal children.* Results from Jamaica seem to suggest this strongly.

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*The principal investigators subsequently informed us that prior to 1971 food supplementation was provided on a selected basis, i.e., to those identified as being "undernourished" and that program effects on growth had also then been determined.

Equally important in providing answers to specific research questions were, in our opinion, the findings from "side studies" conducted in parallel with basic research and for the purpose of problem solution as these arose in some of these projects. The finding that villagers were ready and willing to establish and furnish day care centers during the harvest, regularly donate milk and grain to feed the children, and pay the attendants represents a practical solution to the problems of child neglect and rising malnutrition during the harvest. This illustrates, further, the potential for and ways of involving the community. The Companiganj price subsidy study by itself was a "side study" conducted in response to a given situation. It was an unplanned study by comparison with the other five projects reviewed here yet provided some rather startling results. Similarly useful were the simple treatment regimen developed for village women and largely by auxiliary health workers as oral rehydration with sugar and salt solution for summer diarrheas, as well as other treatment regimens (5) developed out of and in response to given situations. "Side findings" are of importance because of their ready applicability, yet would be equally unlikely to have emerged if the strict research frame of the parent study had been adhered to or if the "parent" investigation had never been initiated.

Corn fortification at the village level does not seem replicable nor does its achieved benefits warrant replicability. As it turned out, tortillas made from lysine enriched cornmeal changed in taste following storage of more than one day. Not only was the change in taste

unacceptable to most villagers, but having to prepare tortillas daily was inconvenient to the population. Similarly, we were told that the mill owners could be induced to go ahead with fortification only after being granted certain privileges, i.e., employment of a family member at project cost (J.J. Urrutia, personal communication). Despite its ambiguous results, the study has helped to increase our knowledge about feasibility of and problems with intervention programs, mainly because the project was a research effort with scrupulous collection of important data. In other words, the project could be evaluated objectively and valid conclusions could be drawn.

From a cost point of view, distribution of vitamin A is clearly feasible and, in view of the seriousness of vitamin A deficiency symptomatology, will undoubtedly continue to be part of any rural MCH program. Considerably more research using carefully matched input and control populations and larger samples will need to be carried out before the observed growth effects of vitamin A will justify incorporation into intervention guidelines. Just recently such research has in fact been advocated by a panel of experts.(6)

Lastly, the Companiganj study illustrates perhaps more than any of the other studies, the practical value of objective evaluation. In acute emergencies like the 1975 famine, it is rarely a problem to mobilize government and international, as well as national, agencies alike to respond to the crisis by providing funds, manpower and setting up relief programs. Because of the crisis situation and inherent time pressure, usually no provision other than that which is

rudimentary is made to monitor the program in sufficient detail to enable subsequent evaluation of more than output variables. Yet the seriousness of the prevailing emergency in terms of illness, deaths, long-term cost, and the (usually) high cost of the relief measures clearly warrants more precise information on the effectiveness of the program. From the humanitarian point of view alone, the project clearly was justified. Past relief measures have met with varying degrees of success. Success often (as also initially here) is defined subjectively. On objective examination, we now know that the inputs did not achieve the stated objectives. In this particular sitatuion, considerably more food would have had to reach the families to exert an effect. Whether this "more" was feasible under existing constraints of funds, availability of food distribution facilities, and other resources cannot be answered here.

SUMMARY AND RECOMMENDATIONS OF THIS EVALUATION

Six major nutrition intervention projects were evaluated for the primary purpose of determining the nature and magnitude, if any, of beneficial effects of the programs, and based on this evaluation to attempt to develop general guidelines for nutrition project evaluation.

Our opinion with regard to whether or not there is enough information available to indicate whether or not nutrition intervention programs have a beneficial effect is that they do. Our major findings on this point based on the studies we reviewed include:

1. Nutrition intervention in the form of prenatal supplementation to pregnant, undernourished women, significantly reduces peri- and neonatal mortality as well as improves birth weight. It is not clear whether supplementation need be provided to all pregnant women in a given community or whether limiting it to those identified at higher risk (by being below a given nutritional level) would have achieved the same results.

2. During normal, i.e., non-emergency times, nutritional supplementation to preschool children can significantly decrease preschool child mortality. This effect is most marked during and after weaning. Selective supplementation of only those identified as being at risk seems to produce identical results. During periods of extreme food shortage, beneficial effects for the preschool child, if any, are minimal probably because of extensive intrafamilial food distribution.

3. The most important indicator of the success of a food supplementation program, decline in mortality, becomes progressively less sensitive with increase in age because of the concurrent decrease in the number of mortal events. For this reason, mortality as an outcome measure should be used cautiously in projects with relatively small target populations (<1,000 enrolled preschool children) unless the study continues over a sufficiently long period. In the latter case, comparable control groups are essential to adjust for time trends.

4. Nutrition supplementation may significantly lower malnutrition prevalence but seems not to affect incidence. Given the observation that the risk of death rises steeply below a nutritional

"threshold,"[7] malnutrition prevalence would appear to be a good "proxy" measure of the effectiveness of a nutrition intervention project.

5. Overall growth (weight and height) of child communities may be raised by nutrition supplementation. This effect is considerably less than that brought about by socio-economic or climatic variables. There is some evidence suggesting that there exists a nutritional "threshold" above which no further health benefits accrue to the child.

6. The magnitude of the effect and ultimate success of nutrition interventions depends largely on whether the community accepts and participates with the program.

7. Child morbidity levels as determined through recall surveys are poor indicators of nutrition intervention program effects because of the subjective reporting and bias inherent in recall surveys.[8] Child morbidity, though monitored in three of the six studies, showed at best questionable beneficial, at worst startling detrimental effects--neither making much sense.

8. Direct supplementation of children with vitamin A in a vitamin A deficient area averts vitamin A deficiency disease, appears to reduce the severity of measles, and depending on the availability of food (calories plus protein) may act as growth promoting (when food is available) or as growth retarding (when it is not). The latter information clearly needs to be supported by additional research findings before general recommendations can be advocated.

With regard to our second objective, major weaknesses in the six studies concerned two main areas: study design and analysis. In the study design in general much too little consideration seems to have been

paid to selection of valid controls. Five of the projects used either no control group, invalid or weak controls to establish overall or selective program effects.

The second major weakness lay in the methods of analysis. In one of the studies, positive results when adjusted for covariables through multivariate analysis were wiped out. In another study, secondary analysis reduced (but did not negate) the magnitude of intervention results. In two studies the findings were further strengthened or hitherto unknown effects were determined through secondary analyses. Finally, one last weakness related to the failure in one of the six projects to do a valid pilot study.

With regard to serious gaps in the type of information collected by investigators, it appears that with the exception of two studies, total cost of the interventions was not sufficiently documented. This would have been useful for determining the potential for replicating the intervention on a larger scale as well as for ascertaining cost/effectiveness of the various nutrition interventions reviewed here.

With respect to our third objective, elaboration of guidelines for future program evaluation, we have arrived at the following recommendations.

1. Criteria for a Significant Effect on Health

Mortality of Preschool Children--

Where preschool children are, in fact the target group, mortality seems to be the single most important indicator of program success. Death is the ultimate outcome of poor health, and child

mortality in developing countries reflects perhaps better than any other indicator nutritional problems irrespective of their causation at this early age. Mortality as indicator of nutritional status is, however, not equally sensitive throughout the preschool period. It seems to be most sensitive during the peri- and neonatal periods, when it closely reflects maternal nutritional status. During the remainder of the first year, mortality seems to be less useful to monitor program effectiveness in areas where breastfeeding extends through this period; but would seem to continue to be a sensitive indicator where early weaning is the practice. Mortality regains its value as monitor of program effect again during the second year, especially around the time of weaning and rapidly declines in its usefulness from the third year on. The rate of decline is proportional to the level of mortality at these later ages. One serious disadvantage of mortality as an indicator is that it requires a relatively large population before observed program effects become statistically significant.[a]

Prevalence of Protein Calorie Malnutrition--

Prevalence of PCM is probably the second most important indicator to measure effects of a nutrition intervention program aimed at improving the health status of preschool children. It is a "good" indicator of intermediate program outcome since it ultimately effects child mortality.

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[a] Assuming a 30 percent decline in neonatal and second year mortalities as result of a maternal supplementation and child feeding program, and baseline mortality rates to be around 50 (neonatal), 40 (second year) and a birth rate of 35, populations of 200 women 15 to 45 years of age and over 300 children between one and two would need to be observed respectively for more than four years.

If a nutritional "threshold" above which no further gain in child mortality occurs, has been identified for the population under investigation, the program can be specifically targeted to those at risk which may considerably reduce program cost and increase program effectiveness. Malnutrition incidence does not appear to be a sensitive indicator of program effectiveness as yet, probably because of the multifocal causation of malnutrition operative in most of today's developing countries.

Experience with and results from nutrition interventions using malnutrition prevalence as principal outcome measure can realistically be made use of only if effects are measured on whole child communities.

Other Intervention-Specific Criteria--

Depending on the objective of the intervention, other criteria may be used as long as these lend themselves to objective (and precise) measurement. If iron deficiency anemia is the problem, the hemoglobin level, and perhaps cell morphology and serum iron levels would be appropriate outcome criteria.

From our experience it seems that morbidity prevalence or incidence as measured through retrospective recall is not reliable and if surveyed at all, should only be used as adjunct indicator of program effectiveness.

2. Sample Size and Sample Composition

Aside from the relatively large population (sample) required to show mortality effects, sample size becomes critical for proper analysis of all program results irrespective of outcome measurement. This is especially true when the community is the target. Unlike in

the laboratory where one can work with highly standardized (animal) populations, the study population cannot be preselected to the same extent, nor would a preselection make any sense given one major objective of all studies: eventual replication of workable interventions on a larger scale. Individuals within the community differ in their levels of education, their possessions, their number of children or siblings, their age and the age of their parents, and their sex, to mention but the most striking characteristics, all of which have been shown to influence program outcome. Sample size has to be large enough to adjust for these differences. In practical and simple terms, assuming minimally two categories each for education and economic levels, family size and sex and three each for age and parental age, a total of 144 cells results. Filling each of these cells with ten individuals, the minimal number necessary for meaningful analysis, amounts to almost 1,500 individuals to be included in the study. In addition, these will have to be observed for the entire duration of a year if seasonal effects are to be accounted for.

Equally important as selection of sample size is the selection of a control group comparable to the study group with respect to all major population characteristics. Selection of a comparable control group with its attendant duplication of the data collection system in this group, let alone solving the logistic problem of motivating the (control) community to participate without influencing outcome variables, invariably makes for a more costly study and requires, at least initially, more thought and work. However, it is very difficult to

establish convincingly program results without such controls. Properly selected controls prevent the quite commonly committed errors of ascribing results to program inputs that were really due to time trends, season, self-selection, aging of the study population, etc., just to mention the few most frequently encountered "confounding" variables. Selection of a comparable control group further enables us to quantitatively measure the magnitude of the Hawthorne effect, if in fact, there was any through "before and after" measurements of selected program outcomes in both study and control populations.

3. Evaluation Methods Necessary to Establish Whether Preset Criteria Have Been Met

Next to planning of the intervention study, including identification of major input, output and outcome variables, determination of sample size and selection of controls, planning for analysis and evaluation of project activities and results is essential if the efforts put into the study are to come to fruition. Since most interventions are planned with an ultimate outcome as objective, careful consideration must be given to how this outcome is to be measured and analyzed right at the planning-the-project stage. With the ready access to computers and pre-programmed statistical packages, sophisticated statistical analyses are no longer a luxury but a must. Data from community surveys cannot be adequately analyzed by means of simple contingency tables. Multivariate analysis should be the rule rather than the exception. This of course requires considerably more statistical know-how of investigators than the majority of investigators currently seem or

may be expected to possess. It also means that granting agencies should expect and accept higher costs for analyses. It should be neither uncommon nor unreasonable to budget 20 percent to 40 percent of total project costs for analysis of project-generated data and project evaluation. In the evaluation of a project it is clearly not enough to accept unquestioningly the principal investigator(s)' findings--too often, and perhaps unavoidably so, these reflect and include his(their) personal bias. Proper evaluation should minimally include indepth questioning on research design, selection of study population and comparability of study and control populations and on the proposed method of analysis.

4. Social, Economic, Cultural and Health Considerations Which Must Be Taken into Account in Comparisons of Programs Conducted in Different Locations

On the basis of our evaluation as well as our experience with overseas work, we hold the commonly held and much cited belief in cultural and traditional differences as an effective barrier to the adoption by or propagation in other countries of a successful intervention program to be a myth. The studies examined here were carried out in culturally quite different settings yet were directed by essentially very similar people--physicians and social scientists--who though of different nationalities were closer in their outlook and training to each other than to the study populations. None of the studies needed drastic or novel sociological approaches. In all studies, interventions attempted to get at the underlying cause of the problem. If this cause was a traditionally determined

problem, as faulty weaning, the intervention stressed health education; if the cause of the nutritional problem was primarily due to lack of food, it stressed provision of the food. A successful intervention, therefore, requires a correct problem diagnosis. Once that diagnosis has been made, various components of the intervention package can then be put together in a mix suitable for the specific situation. When the nature of the intervention has been decided on, the next important step is to explain it to the population and to pilot test it prior to full-scale implementation. In all studies, whether in India, Bangladesh, Jamaica, or Guatemala, the purpose, the need for cooperation and the nature of potential outcomes and benefits were explained to the concerned population. Problems encountered during implementation of the programs mostly related to rapport with the investigating team, to acceptability of the intervention and to participation of the community with the program in virtually all projects and were usually overcome by a combination of ingenuity, common sense, patience and compromise on both the investigator(s)' and community's parts. This does not mean that there were no real differences between the study populations. Differences affecting program inputs existed but these were more of a physical, economic than cultural nature. Thus, where in Bangladesh, Bengal, and less so Punjab, there was an actual shortage of nutrient, in Jamaica it was more a lack of maternal know-how. The nature of malnutrition similarly seems to affect program outcome. Both the Narangwal results and evidence from an earlier study (9) suggests that preschool children are better able to withstand balanced undernutrition as prevalent for

instance in the Punjab, than selective nutrient deficiency, e.g., vitamin A or protein, as seen in Bangladesh. This effect of the nature of malnutrition on child mortality or severity of infectious illness is suggested by the observation that children with protein or vitamin A deficiency seem to experience higher death rates and more severe clinical measles disease respectively at comparable weight-for-age than those suffering from balanced undernutrition. It further seems that the period of high risk of death passes somewhat earlier in preschool children with balanced undernutrition. In the Punjab, this high risk period was essentially over by the time children had reached two years of age. Deaths at older ages were in the majority due to accidents and conditions also encountered in developed societies, e.g., neoplasms.(10)

CONCLUSIONS

In conclusion, it is the opinion of the authors that nutrition interventions can have a significant beneficial effect on the health of children in the zero to four year age range, but that much can be done to improve the methodological framework in which these interventions are studied.

In the evaluation of future project designs or past projects, all steps necessary in the development of the project need to be examined or re-examined in light of the anticipated or achieved project outcome. These steps may be summarized as follows:

1. Of what importance is (was) the study in its potential (actual) contribution to knowledge in the field?

2. Has the study been done previously? If so, what were the results? In which way is the proposed (completed) study different from the earlier one? In which way and through what means will the proposed study newly add knowledge or confirm ambiguous earlier results?

3. Are (have) assumptions underlying the intervention being (been) clearly identified as such? What evidence is there to justify the validity of the assumptions?

4. Is (was) the study design adequate to achieve the stated objectives? In particular, are (were):

--sample size,

--control group(s),

--criteria for effects,

--methods of analysis,

adequate to determine conclusively the presence or absence of intervention effects?

5. Is (was) a pilot study planned (carried out)?

6. How valid and replicable will (are) the results be as judged through:

--adequacy of controls,

--adequacy of analysis,

--captive or voluntary "beneficiaries,"

--cost and resource requirements?

7. Does (did) the study design include and permit monitoring of overall project cost? Of service versus research costs?

8. Is (was) the budget adequate to perform appropriate analyses?

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APPENDICES

Detailed description and evaluation of individual nutrition intervention studies:

1. Effect of Prenatal (Maternal) Nutrition Supplementation on Birth Weight, Child Growth, and Child Mortality (INCAP-I)

2. Effect of Nutrition Supplementation and Medical Care on Growth, Morbidity and Mortality of Preschool Children (The Narangwal Nutrition Program)

3. Health Surveillance and Nutrition Education (The Hanover Nutrition Intervention)

4. Vitamin A Supplementation (The Ichag Study)

5. Corn Fortification: A Field Demonstration Model (INCAP-II)

6. Price Subsidy During a Famine (The Companiganj Nutrition Program)

Appendix 1

EFFECT OF PRENATAL (MATERNAL) NUTRITION SUPPLEMENTATION ON BIRTH WEIGHT, CHILD GROWTH, AND CHILD MORTALITY

(INCAP-I)

This study was a longitudinal prospective inquiry into effects of maternal and child nutrition on indices of child health and development consisting essentially of three separate investigations performed in parallel and using the same research design and study population. For subsequent evaluation by the primary investigators the investigation was divided into its three principal components:

1. Effects of maternal dietary supplementation on birth weight and infant mortality;

2. Effect of preschool supplementation on growth, morbidity, and child mortality;

3. Effect of maternal dietary supplementation pre- and post-natally, and dietary supplementation of preschool children on psychomotor development.

Only the first component, effects of maternal supplementation on birth weight and infant mortality, was evaluated in the present paper.

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Effects of Maternal Supplementation Pre- and Postnatally on Birth Weight and Infant Mortality

Review of published material:

1. Effect of Food Supplementation During Pregnancy on Birth Weight (Lechtig, A., Habicht, J.P., Delgado, H., Klein, R.E., Yarbrough, C, and Martorell, R.), Pediatrics 4:508, 1975.

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Review of unpublished material:

1. A Simple Assessment of the Risk of Low Birth Weight to Select Women for Nutritional Intervention (Lechtig, A., Delgado, H., Yarbrough, C., Habicht, J.P., Martorell, R., and Klein, R.E.), paper presented at Western Hemisphere Nutrition Congress, Bal Harbour, Miami Beach, Florida, August 1974.
2. Effect of Maternal Nutrition on the Mother-Child Dyad (Lechtig, A., Delgado, H., Martorell, R., and Klein, R.E.), paper presented at the Symposium "The Mother/Child Dyad--Nutritional Aspects," held in Uppsala, Sweden, June 1977.

Discussion with Investigators:

R.E. Klein, October 1977

A. Lechtig, October 1977

Secondary Data Analysis:

Not performed as not felt to yield additional information

Objectives of the Study:

To determine the effects of diet supplementation of pregnant and lactating women on birth weight, infant growth, and infant mortality.

Study Design:

Pregnant (as determined by absence of menstruation) and lactating women in four villages were provided either of two supplements on a voluntary basis. In two villages they were offered a high calorie (163 cals/180 cc), high protein (11 g/180 cc) gruel (atole); in two

control villages they received a drink commonly consumed in Guatemala (fresco) which contained 60 cals/180 cc but no protein. Both foods contained equal amounts of vitamins and minerals.

Frequency and quantity of ingested atole or fresco were monitored on a continuous basis. Recall dietary surveys on food consumption in the home showed similar intakes for both groups. Participation in the program was entirely voluntary. Principal outcome measurements were birth weight and infant mortality. Intermediate output measures were attendance at feeding center and amount of ingested supplement. In addition, a number of socio-economic, demographic and maternal morbidity variables were recorded to adjust for population differences (confounding variables).

The study lasted for a total of five years. All women living in the four villages who in the course of these five years became pregnant or were lactating served as study population.

Results:

A total of 671 children were born into the study; 44 died in their first week of life. Birth weights were available on 405 (60 percent). Caloric supplementation was arbitrarily divided into less or equal to 20,000 calories (low) or more than 20,000 calories over the entire pregnancy period. Mothers in the high supplementation group* of either atole or fresco had significantly fewer babies of less than 2,500 gms than those in the "low" supplementation group. The mean birth weight of newborns from "high" supplemented mothers was 111 gms above the mean

*mean 35,000 cals or 125 cals/day

birth weight for newborns of "low" supplemented mothers. Whether the calories came from atole (high protein) or fresco (no protein) seemed not to make any difference on birth weight. Other factors (gestation age, parity, weight at end of first trimester and maternal morbidity) were corrected for.

Additional analyses performed showed positive correlations between birth weight and maternal indices of nutrition (height, head circumference, arm circumference) suggesting that both the mother's immediate nutritional status and past nutritional history are reflected in their children's birth status; and a negative correlation between maternal morbidity and birth weight mediated probably through reduced dietary intakes during pregnancy as shown by a negative correlation between morbidity and dietary intake.

Investigators estimate that approximately two-thirds of low birth weight babies born could have been prevented by improving health and nutritional status of pregnant women.

Given the small number of infant deaths during the duration of the study, the effects of maternal supplementation on subsequent infant mortality was estimated by comparing the number of infant deaths in the study population to that of an urban population matched for 14 identified risk factors (six of which referred to nutritional status of either mother or child) through retrospective analysis. In addition, infant deaths among the high and low supplementation groups were compared in four 2x2 contingency tables using socio-economic status, maternal height, birth weight and utilization of primary care as dichotomous covariables.

A total of 27 deaths were thus examined. Deaths were less frequent in six of the eight groups if supplementation was provided, identical in one and higher in one group. (Using χ^2 statistics, the difference did not reach significance.)

In addition, they found that mothers who availed themselves of a primary medical care system had fewer of their children die even after correction for maternal height and caloric supplementation. Birth weight seemingly was not corrected for, however.

Within the low birth weight group, IMR was 5.2 percent in those who availed themselves compared to 25.9 in those who did not ($P<.05$). In the higher ($\geq$2,500 gm) group IMR was 4.2 percent in attendees and 7.2 in non-attendees (P = n.s.), suggesting that the low birth weight children profitted more from the medical care.

Validity of Study:

The prevalence of undernutrition in children and adults in these study villages as well as in the general ecological setting had been amply shown in earlier investigations.[1-4] The incidence of births below 2,500 gms in the setting was approximately 30 percent before the onset of the present study. Mean maternal height was 149 cm; mean maternal weight was 49 kg. Infant mortality was close to 15 percent of births. Average daily dietary intakes during pregnancy were approximately 1,500 cals and 50 gm of protein. Mean weight gain during pregnancy was 7 kg--which is approximately half of expected weight gain.

Appropriateness of Intervention:

The appropriateness of the selected intervention was determined through evidence from other studies.(5)

Selection of Target Population:

Appropriate for study objective.

Community inclusive in that two villages were offered atole, two villages fresco, and women could participate voluntarily. Access to primary health care was also provided to all who wanted to avail themselves of it.

Validity of Results:

Method of Analysis:

Analysis consisted mainly of multivariate analysis permitting control for confounding variables.

Selection of Control Groups:

Two groups of controls were used to measure the effects of supplementation on birth weight. First, atole versus fresco, based on village affiliation. Second, high intake versus low intake, based on self-selection. Even though a selection bias was introduced into the experiment, all other major variables were corrected for through means of multivariate analysis.

To determine effects of maternal supplementation on infant mortality, a control group of urban infants was used, matched for major social and health service utilization characteristics through retrospective analysis.

Measurement of Confounding Variables:

It seems that those that may have influenced birth weight were measured and adjusted for in the final analysis.

Sample Size:

Sample size was large enough to measure input effects on birth weights, but not large enough to provide conclusive information on infant mortality (deaths were too few).

Weakness of Study:

No grossly apparent weaknesses in the design, implementation and interpretation of the study and its results. While the results of maternal supplementation on birth weight are clear and undisputable, effects on infant mortality are tenuous. This is largely because the control population selected for measuring this specific effect was not a valid control. Matching the infants on socio-economic and health service utilization was carried out meticulously, yet the basic difference of urban versus rural population remains.

Several questions remain unanswered both after reading the available material and discussion with principal investigators.

1. The investigators compare birth weights of siblings from the same mother and born during the study period. How did they exclude a previously supplemented mother from participation in her next pregnancy and conversely, how did they motivate a previously non-supplemented mother to participate during her subsequent pregnancy?

2. Even though infant mortality as such was (statistically) not affected, were there any clear effects on perinatal, neonatal, or post-neonatal deaths?

Applicability of Results to Nutrition Problems on Broad Scale:

In one of the unpublished papers (presented at the Western Hemisphere Nutrition Congress in Bal Harbour), the investigators examine cost efficiency between providing nutrition supplementation to all women and to women selected for "high risk" on basis of their head circumference, height, or a housing score. On the average, limiting the services to identified "high risk" women produced a cost of $560 per infant death averted; coverage of the entire population (women) produced a cost of $962. Of the three indicators of high risk, head circumference was found to be both highly specific and sensitive. Its use for identifying the women at risk for subsequent supplementation was expected to reduce infant mortality rate by 10.6 percentage points at a cost of $476 per infant death averted.

The program seems technically feasible--both preparations are locally available and regularly consumed.

Conclusion:

The study represents a major contribution to solving the problem of high child mortality in developing countries. It is questionable whether the study could have been undertaken by any less qualified group or on a less expensive scale and still have yielded the same information. Their conclusions lend themselves to practical policy formulation.

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Appendix 2

EFFECT OF NUTRITION SUPPLEMENTATION AND MEDICAL CARE ON GROWTH, MORBIDITY AND MORTALITY OF PRESCHOOL CHILDREN

(THE NARANGWAL NUTRITION PROJECT)

The Narangwal Nutrition Study (NNS) was a research project intended to examine the relationship between nutrition and infection while developing and analyzing the impact of various service packages aimed at severing the malnutrition-infection cycle. The study paralleled a population study also carried out in Narangwal by the same research team. The NNS started in 1966 and was dismantled in 1973. The Narangwal study villages comprised part of a community development block in the Ludhiana district of Punjab. Ludhiana is approximately 200 miles northeast of Delhi.

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Supporting Institutions:

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Review of Published and Unpublished Material:

1. Malnutrition, Infection, Growth and Development: The Narangwal Experience. Draft copy to the World Bank, March 1978.

2. The Narangwal Experiment on Interactions of Nutrition and Infections: I. Project Design and Effects Upon Growth (Taylor, C.E., Kielmann, A.A., De Sweemer, C., et al.); II. Morbidity and Mortality Effects (Kielmann, A.A., Taylor, C.E., De Sweemer, C., et al.); III. Measurement of Services and Costs and Their Relation to Outcome (Parker, R.L., Taylor, C.E., Kielmann, A.A., et al.), Indian Journal of Medical Research 68:(Supplement) 1-54, 1978.

3. Complement (C_3), Nutrition and Infection (Kielmann, A.A. and Curcio, L.), Bulletin WHO 57, No. 1, 1979.

4. The Narangwal Population Study: Integrated Health and Family Planning Services. Rural Health Research Center, Narangwal, Punjab, India, 1975.

5. Nutrition and Infection (Taylor, C.E., Kielmann, A.A. and De Sweemer, C.), (Basel, Switzerland: Rechcigl, 1977).

6. Interactions of Nutrition and Infection (Scrimshaw, N.S., Taylor, C.E., and Gordon, J.E.), Monograph #57 (Geneva: World Health Organization, 1968).

7. The Khanna Study: Population Problems in the Rural Punjab (Wyon, J.B. and Gordon, J.E.), (Cambridge: Harvard University Press, 1971).

8. Nutrition and Infection Field Study in Guatemalan Villages, 1959-1964 (Scrimshaw, N.S., Guzman, M.A., and Gordon, J.E.), Arch. Environ. Hlth. 14:657, 1967.

In carrying out this evaluation, internal documents, working papers, and other published data and papers were freely available and

accessible. Several of the primary investigators were consulted during this evaluation. Some secondary analysis of the data was performed.

Study Objectives:

The purpose, objectives, specific objectives, and hypotheses of the NNS have been abstracted from several NNS documents (1, 2, 3) and presented below.

Purpose:

1. To investigate the dynamics and relative strengths of interactions between nutrition and infection in preschool children (research goal).

2. To develop various health and nutrition service packages sensitive to the needs of the preschool child population and to measure in terms of cost/effectiveness the potential impact of population-wide nutrition and preschool child health care (services or program goal).

Objectives:

1. To determine the effects of medical care (immunizations, early diagnosis, early treatment), nutrition care (food supplementation and nutrition education) singly and in combination on preschool child growth, morbidity, and mortality.

2. To develop a pattern of rural health care which relied upon auxiliary health workers.

3. To measure the relative costs and effectiveness of various service packages.

Specific Objectives:

1. To determine the effect of nutritional status on the incidence of infection in children 0-3 years, as well as the effect of infection episodes on nutritional status.

2. To study the effect of medical care and nutritional supplements on both nutritional status and the incidence of infection.

These interactions were to be studied in Punjab villages, with medical care and nutritional inputs provided in the village by resident workers. The village groups established permit study of:

1. The effect of nutritional status on infection experience;

2. The effect of infection on nutrition status (as measured by growth and development indices, physical examination and simple laboratory tests);

3. The response of nutritional status to:

   a. nutritional supplements,

   b. medical care without nutritional supplements,

   c. medical care combined with nutritional supplements;

4. The infection experience in children with:

   a. nutritional supplements,

   b. medical care without nutritional supplements,

   c. medical care combined with nutritional supplements.

In addition, mortality rates were determined in all the experimental groups, and correlated with sex, caste, age, and nutritional status.

Hypotheses:

Three basic hypotheses were to be tested:

1. Nutrition plays a role in the protection against clinical infection. This protection should be measurable by a decrease in overall mortality rates and a decrease in days of illness per 1,000 children per year. These results will be due to changes in average duration, severity and mortality of most diseases, and changes in incidence of some diseases.

2. Infection is a determinant of nutritional status. Therefore, control of major infections through vaccinations against measles, whooping cough, diphtheria, and tuberculosis will decrease mortality due to protein calorie malnutrition. This should be manifested by a decrease in overall mortality of the population which is greater than the decrease in any specific infectious disease.

3. Simultaneous action to enhance nutrition and lessen infection has a synergistic effect. The effect on infection incidence, duration and severity should be greater than the sum of the effects in the groups that had only nutritional supplements or medical care. The effect on nutritional status will also be greater than the sum of the effects in each single treatment group.

Project Design:

The project design has been abstracted from NNS documents (2) and is presented below.

The Narangwal nutrition project included four groups of villages which were provided one of the following (see Figure 1): (1) nutrition care (surveillance, food supplements, and nutrition education), (2) medical care of infections (immunization, health education, early diagnosis and treatment), (3) a combination of nutrition care and medical care, (4) control (no services beyond minimal symptomatic treatment and emergency care). The effects of these inputs upon the growth, morbidity, and mortality of preschool children between birth and 36 months were measured by means of longitudinal surveys. Cross-sectional surveys measured demographic, socio-economic, and environmental variables.

Each service package was monitored by various output measures in order to validate the extent of participation.

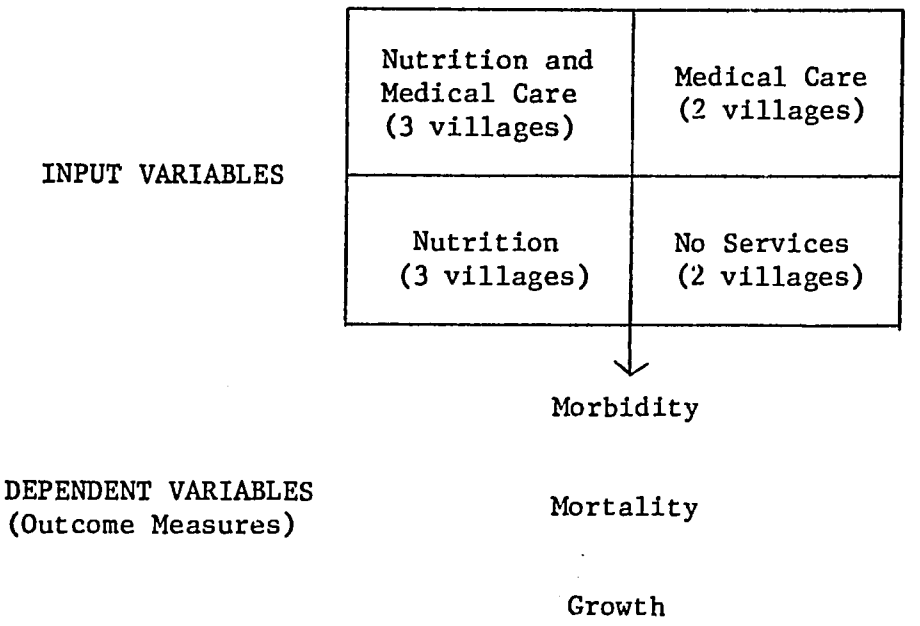
A more detailed description of input services, outcome measures, data collection, and implementation strategy is provided below as abstracted from NNS documents and edited for this evaluation.

Input Services:

Both nutrition and medical care were provided primarily by family health workers (FHW)--lady health visitors--who lived in the villages where they worked. All had special RHRC training. Service inputs were standardized by developing auxiliary-based packages of activities selected and routinized through field testing. Detailed written standing orders and weekly visits by a doctor and a public health nurse

Figure 1

EXPERIMENTAL DESIGN



provided supportive supervision, referral opportunities and quality control of data gathering. For eventual practical implementation the Narangwal researchers selected tasks for a level of competence which could reasonably be considered attainable in mass government programs using auxiliary nurse midwives.

Since all children in the villages were included in the study population, services for both nutrition and medical care relied primarily on surveillance techniques. The comprehensive primary care focused on prevention, early diagnosis, and prompt care. The health workers spent at least half of their time in village homes so as to identify problems early rather than waiting until the parents sought crisis care.

The nutrition input consisted of careful monitoring of growth, food supplementation for those whose growth was lagging, and nutrition education. Nutrition education was incorporated into both surveillance and care activities and was supported by periodic group meetings. Special stress was placed on maintaining prolonged breast feeding.

Food supplementation was provided twice daily in village "feeding centres" staffed by one or two locally recruited women, the number depending on the size of the village. Feeding centre attendants (FCA) prepared and distributed the supplement, calorie-enriched milk in the morning, and a porridge-like gruel consisting of crushed wheat, raw sugar, oil and milk powder in the afternoon. Standard servings of the daily supplement if taken on both occasions provided approximately 400 calories and 11 grams of protein. Children were fed "ad libitum" but few consumed more than one serving at any session. Quantities

taken by individual children were not verified but total amounts were indirectly verified by measuring total supplement prepared and amount of supplement left over at each feeding centre.

FCAs supervised and recorded the fact of food consumption. From the beginning of the project and during the first two years, supplementation was selective, i.e., for those identified as being undernourished. From 1971 on, all children below three years of age, as well as older siblings who accompanied the study children, were encouraged to attend regularly. A daily register of both morning and afternoon attendance was maintained. For children who missed more than seven consecutive days, a sequence of home visits were made by the following personnel: the feeding centre attendant, the FHW, and the public health nurse (PHN) supervisor. They enquired about the reasons for nonattendance and tried to persuade the parents to bring their child more regularly. If the family's social circumstances made this difficult, arrangements were made for the FCA to feed the child at home.

When the project started, severely ill children were hospitalized at the health centre when they required nutritional rehabilitation for marasmus or rehydration for diarrhea. As the FHWs became more proficient the researchers closed the special ward at the health centre because early care in the home essentially eliminated the need for hospitalization.

Medical care had two components. Efforts were made to immunize regularly all children against diphtheria, tetanus, and whooping cough (triple vaccine), tuberculosis (BCG), poliomyelitis and smallpox. Secondly, routines were established for regular surveillance for morbidity, early treatment by FHWs according to clear and specific standing orders, and ready referral to a physician. Analysis of

service records by the researchers subsequently showed that paramedical field staff capably handled more than 95 percent of patient contacts on their own and safely referred the rest to physicians.

At this juncture in discussing the project design it should be mentioned that the NNS was seen in parallel with another related study: the Narangwal Population Study or NPS.[4] Because of financial considerations, the researchers decided to overlap the NNS with the NPS resulting in one set of villages common to both projects. These villages common to both studies received nutrition and medical care services (NUT+MC) from the NNS and received family planning and child care services (FP+CC) from the NPS. Since CC services of NPS were equal to the NUT+MC services of NNS, the basic service components received by these common villages amounted to NUT+MC+FP. The content of FP services is outlined below as well as a diagramatic representation of the overlap (see Figure 2).

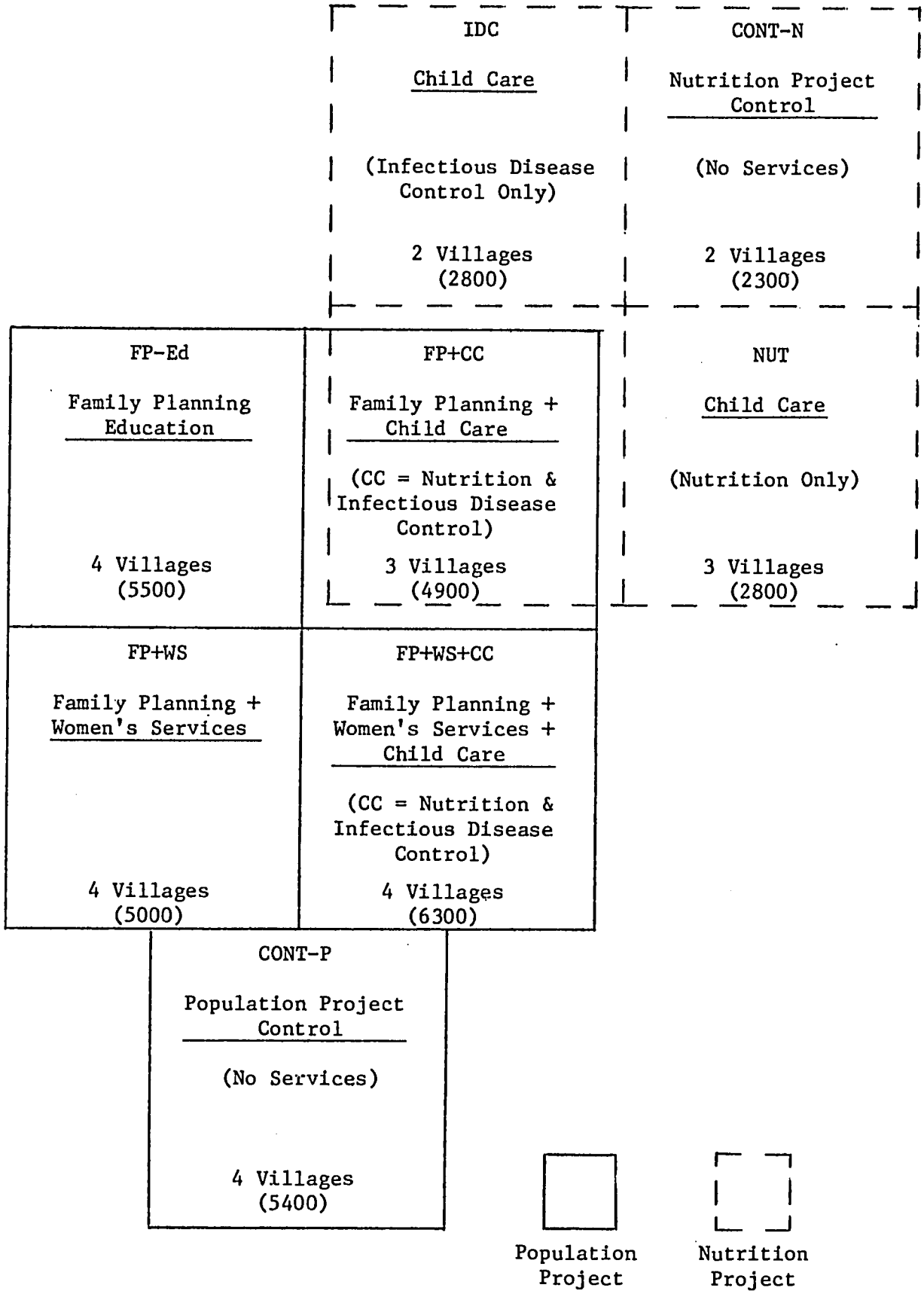
Components and Intensity of Family Planning Service Package:

1. Education and Motivation--Intense educational efforts were provided in FP-Ed; family planning education was well integrated with health care delivery in FP+WS+CC and FP+WS; and poorly integrated in FP+CC.

2. Contraceptive Services--Condoms, pills (Ovulen and an Indian marketed low dose pill, Primovlar); IUDs (Lippes and Narangwal "Taviti"); injectable Depo-Provera; vasectomies and tubectomies were provided under similar conditions in all experimental groups.

3. Follow-Up--The same method and specific patterns of follow-up were established for all groups.

Figure 2


IDC
Child Care
(Infectious Disease Control Only)
2 Villages (2800)
CONT-N
Nutrition Project Control
(No Services)
2 Villages (2300)
FP-Ed
Family Planning Education
4 Villages (5500)
FP+CC
Family Planning + Child Care
(CC = Nutrition & Infectious Disease Control)
3 Villages (4900)
NUT
Child Care
(Nutrition Only)
3 Villages (2800)
FP+WS
Family Planning + Women's Services
4 Villages (5000)
FP+WS+CC
Family Planning + Women's Services + Child Care
(CC = Nutrition & Infectious Disease Control)
4 Villages (6300)
CONT-P
Population Project Control
(No Services)
4 Villages (5400)
Population Project
Nutrition Project

The validity of the research design just described for the demonstration of a real synergistic relation between programs is not without its problems. In deciding to overlap on a common set of villages an intervention (NUT+MC) of the NNS and an intervention (FP+CC) of the NPS, the researchers caused FP services to be superimposed on one study group of the NNS and not on the other study groups (including the control) of the NNS. Moreover, because FP services were offered in the study group where synergism of programs would reveal itself if it existed, a built-in bias to demonstrate synergism was unintentionally included in the study (see Figure 3).

Had the NNS produced results suggesting the synergism of programs, the study design would probably have precluded the conclusion that in fact a real demonstration of synergism had been accomplished. Indeed, a relationship would necessarily have to be concluded.

One final observation should be made here with regard to the study design shown in Figure 3. In addition to nutrition care and medical care, all pregnant women in service villages received prenatal care with the intent of starting child care before birth. Pregnancy was detected in the course of an ongoing longitudinal fertility survey every two months of all women between 15 and 49 years of age. Women with presumed pregnancies were weighed and measured and asked about previous pregnancy or delivery complications for their own or their mother's pregnancies. Women with confirmed pregnancies subsequently received iron and folic acid throughout the remainder of their gestation if they belonged to the NUT villages. A daily supplement of food was also provided for mothers who were underweight if they

Figure 3

SCHEME OF NARANGWAL NUTRITION STUDY

NUT+MC AND FP+PNC	MC + PNC
NUT + PNC	CONTROL

MC = Medical Care

NUT = Nutrition Care

FP = Family Planning

PNC = Prenatal Care

belonged to the NUT villages. In medical care villages three tetanus toxoid injections were given, one month apart during the third trimester.

Data Collection and Study Implementation:

Implementation of services in all villages was according to the following steps. A systematic effort was made to gather baseline data on morbidity and anthropometry for about a year before service programs started. Baseline cross-sectional surveys included census, socio-economic, morbidity and nutritional information. Service components were then introduced sequentially rather than all at once. Logistical problems and the process of getting auxiliaries recruited and trained made it more efficient to introduce service inputs only as methods were worked out. Even after the total program was under way service inputs were progressively improved in an evolutionary manner as better ways of providing care were learned.

Outcome Measures:

Weight and height were measured monthly from birth to nine months of age, every two months from 11 to 21 months, and every three months from 24 through 36 months of life. Morbidity experience was recorded through a weekly visit asking all mothers to recall the occurrence, onset and duration of 44 specified signs and symptoms. Each weekly morbidity recall survey was followed by a physical examination of the child. Mortality and fertility data were collected from three sources, the resident family health worker, the village chowkidar, and specially appointed vital statistics investigators who toured each village once a fortnight to consult 10-12 local informants.

Results:

Summary Results of Child Growth:

A. Scientific Results

1. Standard growth curves for weight and height of Punjabi children have been computed on the basis of 15,365 measurements on 2,951 children. These diverge from the Harvard growth curves after two months of age. At 1½ to 3 years of age, weight was 2½ to 3 kg lower and height 7-9 cm less than the Harvard norms.

2. Within the study groups three variables had major additive effect: nutrition care in two experimental groups of villages, caste and sex. Each variable produced 0.6 to 1 kg and 2 to 2.5 cm increases in average weight and height. A high caste male from a nutrition care village therefore was 2½ kg more in weight and 6 cm more in height at 36 months than a low caste female child from a control village.

3. After a family had two male children, additional siblings averaged 0.26 kg less in weight and 1.3 cm in height than lower birth order siblings.

4. Average birth weight increased with maternal age, suggesting that in the average Punjabi women "maternal depletion" is not a serious problem.

5. Medical care for infection control increased average weight between 30 and 36 months by 0.120 kg and average height by 0.70 cm.

B. Program Results

1. Nutrition care can increase significantly the weight and height of total populations of children. As far as we can determine, this is the first controlled experiment of total child populations under natural conditions where this has been demonstrated.

2. The most useful nutrition program was found to start with surveillance through the regular weighing and measuring of all children. Concentrated effort was then focused on those showing no increments in growth. Great emphasis was placed on nutrition education of the mother. Children who were underweight were offered food supplements twice a day at village feeding centres and about 40 percent of children participated.

3. These services were provided very effectively by family health workers (retrained lady health visitors) and village feeding centre attendants.

4. After the intensive nutrition program there remained a "hard core" group of relatively malnourished children fluctuating from 10 to 50 percent dependency. These were mainly girls born to high parity mothers. To get further reduction in the levels of malnutrition it was apparent that more effective family planning practice and general socio-economic development would be necessary.

Summary Results of Morbidity and Mortality:

A. Scientific Results (refer to Table 1)

1. Morbidity reduction was mainfested mainly in a shorter duration of average episodes of illness in villages receiving medical care. Of the eight conditions for which data were analyzed, significant reductions were recorded for cough (reduction of three days), fever (reduction of one day), diarrhea (reduction of one day), and eye infections (reduction of one day).

2. The combination of nutrition care and medical care as compared with medical care alone produced a significant reduction in duration only in eye infections (further reduction of about one day).

Table 1

CHILD MORTALITY RATES BY EXPERIMENTAL AND AGE GROUPS

1970-1973*

EXPERIMENTAL GROUPS	Stillbirth		1-7 Days		Perinatal		Neonatal		Postneonatal		Infant M.R.		1-3 Mortality	
	# Deaths	Rate/ 1000**	# Deaths	Rate/ 1000***	# Deaths	Rate/ 1000**	# Deaths	Rate/ 1000***	# Deaths	Rate/ 1000***	# Deaths	Rate/ 1000***	# Deaths	Rate/ 1000****
++ Control Villages Births: 805 1-3 Yr. Olds: 1398	49	57.4	40	49.7	89	104.2	62	77.8	42 (41)	52.2 (50.9)	104 (103)	129.2 (128.0)	26	18.6
Medical Care Births: 343 1-3 Yr. Olds: 635	16	44.6	13	37.9	29	80.8	16	46.7	8	23.3	24	70.0	7	11.0
Nutrition Supplementation Births: 352 1-3 Yr. Olds: 634	9	24.9	13	36.9	22	60.9	17 (16)	48.3 (45.5)	17 (15)	48.3 (42.6)	34 (31)	96.6 (88.1)	7 (6)	11.0 (9.5)
NUT+MC Births: 654 1-3 Yr. Olds: 1285	25	36.8	18	27.5	43	63.3	31	47.4	22	33.6	53	81.0	16	13.3
+ NUT+MC+WS Births: 830 1-3 Yr. Olds: 1593	38	43.8	37	44.6	75	86.4	53	63.9	45	54.2	98	118.1	11	7.3
++ All Narangwal Nutrition Study Births: 2984 1-3 Yr. Olds: 5375	137	43.9	121	40.6	258	82.7	179 (178)	60.0 (59.7)	134 (132)	44.9 (44.2)	313 (310)	104.9 (103.9)	67 (66)	12.5 (12.3)
Khanna Study (1957-1959) Births: 1404					89.0		73.5		82.7		156.2		47.8	

*The number of deaths and calculated rates includes those TKO deaths that could be ascribed after careful review as actual statistical deaths. In parentheses the figures are given of the unadjusted deaths and death rates not including the TKOs.

**Live and stillbirths ***Live births ****Population of given age

+Not part of the nutrition project ++Includes villages of the population project

3. As compared with mortality in the third year of life, death rates were 20 times higher in the first year and 6 times higher in the second year of life.

4. Males had higher stillbirth and perinatal mortality rates. After the first week of life, female mortality was greater, with male to female mortality ratios of 0.9 for neonatal mortality and 0.7 for postneonatal mortality and 0.6 for 1-3 year child mortality.

5. Causes of perinatal death were ranked as follows: prematurity, intrauterine asphyxia, birth trauma, congenital anomalies and tetanus neonatorum. Causes of death from eight days to three years of age had the following ranking: diarrhea with dehydration, lower respiratory tract infection, septicemia, marasmus, prematurity, tetanus neonatorum, accidents and congenital malformations.

6. Program interventions had varied effects on mortality depending on age:

a. Nutrition care reduced perinatal mortality (stillbirths and 1-7 day mortality) by 40-50 percent, probably as a result of prenatal supplementation with folic acid, iron and food. Medical care (tetanus toxoid to mothers) reduced perinatal mortality by about 20 percent.

b. Neonatal mortality was reduced by about 40 percent in all groups of villages where either nutrition care or medical care were provided.

c. Postneonatal mortality was reduced by half in medical care villages but by only 7 percent in nutrition care villages. Since

nutritional inputs became effective mainly after six months of age with the start of weaning, most of this reduction in mortality would have been concentrated during this time.

d. Infant mortality rates were reduced by about 40 percent in both groups of villages receiving medical care and by 25 percent in villages receiving nutrition care.

e. Mortality of 1-3 year old children was reduced by about 40 percent in all villages receiving services.

7. Although both Jat and Ramdasia castes benefitted from the services, it was clear that Ramdasia children responded more dramatically to nutrition care than Jat children. This is obviously an indication of their greater nutritional vulnerability.

B. Program Results

1. Nutrition care had its greatest impact on perinatal child mortality. This was apparently because of the provision of prenatal nutritional care through giving mothers folate, iron and food supplements. The reduction in stillbirths and 1-7 day mortality was especially dramatic.

2. Primary medical care provided by FHWs provided excellent coverage of the illnesses of children in Punjab village communities. Not only did they effectively care for 95 percent of illnesses and appropriately refer the remaining 5 percent, but there are also reasons to think that the care they provided for infants was better than would have been provided by making an equivalent number of doctors available in health centres. The greatest impact on health status of children under one year seems to have been related to the frequency of contact with weekly morbidity surveillance and prompt treatment,

producing maximum impact on duration of episodes and infant mortality. There seems to have been little impact as a result of morbidity surveillance very two months or making primary care readily available within the village, i.e., in a situation that required primarily the parents to take the initiative. This presumably means that a care program that was going to rely on parent initiative would have to devote even more attention than we did to parent education so that they would undertake equivalent surveillance activities themselves.

3. Primary medical care impact on 1-3 year child mortality was better in villages where reduced frequency of surveillance was provided and child care was combined with women's services and family planning as it was in villages receiving weekly home visits.

Summary Results of Cost Effectiveness:

1. From the point of view of research methodology, it has been shown that detailed analysis of input variables is both feasible and extremely illuminating. It is now possible to attach relative "price tags" to the various components of the Narangwal service packages, both on a per capita and per service-contact basis.

2. The sorts of services provided at Narangwal are time-intensive. About two-thirds of this time investment was in surveillance activities, especially in home visiting. Since much of this activity occurred also in control villages, the time involved and its associated costs can be attributed partly to the research character of the project. The time spent by project staff per child ranged from an average of seven minutes

per week in NUT+MC to five minutes per week in control villages. In all villages an approximately equal allocation of about 1.5 minutes per week were spent on surveillance and preventive activities and about 0.5 minutes per week in "prenatal child care" visiting and providing services to pregnant women. This means that the variation of from 2.5 to 4.2 minutes per week was almost entirely in contacts with ill children.

3. The number of surveillance and preventive contacts ranged from 23-36 per year per child, while treatment contacts ranged from 3 to 28 per year per child depending on the experimental group.

4. The main impact of the Narangwal services on source of care was that the percent of children who received no care or home remedies for illnesses was reduced from 60 percent to 20 percent. The proportion receiving care from private sources (mostly indigenous practitioners) was reduced from about 40 percent to from 10-20 percent.

5. The total population per capita annual cost of providing combined services averaged Rs. 14. Service costs per child were Rs. 176 per year in NUT villages, Rs. 160 in NUT+MC, Rs. 68 in MC and Rs. 58 in control villages.

6. The costs per contact averaged about Rs. 1.40 overall, with illness contacts being about Rs. 2.50 to 3.70 (depending on the experimental group) and well-child contact being about Rs. 0.35 to 0.60. These compare reasonably well with the average costs in government primary health centres of Rs. 1.50 per patient visit and Rs. 0.80 for an MCH contact.

7. Strong and significant statistical correlations were shown between the number of service contacts and the following dependent variables: (a) negative correlation with infant mortality showing that with greater service contacts, there were less infant deaths; (b) negative correlation between "prenatal child care" contacts and perinatal mortality; (c) negative correlation between illness contacts and mean duration of diarrhea, cough, vomiting, and eye and skin infections; (d) negative correlation between surveillance contacts and mean duration of lower respiratory infection (pneumonia) apparently related to early identification for treatment. No correlation was found with 1-3 mortality. With nutrition contacts the only significant correlation was a positive one between mortality and morbidity in one year and the number of feedings in the following year, indicating the response of the feeding program to the malnutrition that followed infection. There was a consistent but not significant negative correlation between feedings in one year and mortality rates in children over one year in the following year.

8. Cost/effectiveness information is related only to deaths averted. (a) The lowest cost/effectiveness ratios were Rs. 570, Rs. 710, and Rs. 1,010, respectively, for "prenatal child care" costs per perinatal death in NUT, NUT+MC, and MC groups. The prenatal nutrition component was folate, iron and supplemental food. The prenatal medical component was mainly for tetanus toxoid immunization. (b) The lowest child service costs per death averted were in MC villages with a ratio of Rs. 110 per infant death averted. The NUT and NUT+MC ratios were 1½ times greater. After one year of age the ratios were 7 to 11 times

greater if the cost of food were not included, but over 20 times greater if food costs were included.

9. On the important issue of whether there is a measurable synergistic effect of services to match the synergism between infections and malnutrition, a somewhat mixed report must be made. We have not found a clear-cut synergism of effect in the sense that combined services produce a greater impact on any one outcome measurement than would be expected from individual action of either nutritional care or medical care. In fact, it has been striking that the results are not even additive. The combined care villages had about the same effect on growth and development as nutrition care alone. Combined care also had about the same effect on mortality and morbidity as medical care alone. The argument, therefore, for combined services, at least within the Punjab context, is that for only slightly more expenditure of time and money both growth and development and mortality and morbidity effects were obtained.

Validity of the Study:

The NNS attempts to examine whether nutrition and/or infection control can be used to break the synergistic cycle and which combination of control measures is the most cost/effective in this task. Here, synergism is defined as "occurring when infection interferes with normal nutrition or when malnutrition lowers host assistance to infection; aggravation of disease results because the combined impact of both is greater than the sum of the individual effects. Antagonism is the reverse situation." (Taylor, C.E., et al., 1977)[5]

Those who guided the NNS through its years of field work directed its attention to the questions it did for many well documented reasons:

1. The phenomenon of synergism between undernutrition and infection has been known for some time. The investigators site extensive evidence of the phenomenon much of which is complied in the monograph by Scrimshaw, et al. (1968).[6]

2. Specific documentation of the health problems in terms of patterns of morbidity and mortality came from several sources. The Khanna Study[7] which focused on health problems of the Punjab among preschool children and other special studies done by Wyon and Gordon (coincidentaly, in an area only 35 km east of Narangwal) nine years prior to the NNS helped to circumscribe the nature and extent of morbidity and mortality among the preschool population. Baseline surveys before the initiation of the NNS provided additional evidence of an undernutrition problem as well as the information needed to refine the targeting of the NNS.

3. It was, in part, directly as a result of a lack of information and documentation of the cost/effectiveness of preventive programs that interest in a Narangwal type study evolved. Few researchers concern themselves with the implications of cost factors. The investigators recognized firstly, that policy-making bodies rarely base service programs on humanitarian grounds alone, and secondly, that an opportunity was afforded by the kind of study proposed to analyze costs. To help ensure future use of the results of the proposed study would necessitate the investigators to speak in the idiom of policy makers; namely, costs and effectiveness. If the investigators had to be apprised of this fact,

they were probably influenced by a summary statement of the Khanna Study chapter on causes of death in the Punjab:

> "The immediate need is to evaluate the effectiveness of existing proven programs for prevention and control as conditioned by the particular environment, using trained manpower that can be recruited, and working within realistic financial limits."

4. Documentation of the existance of problems on a more global scale similar to those found at Narangwal came from the INCAP study in Guatemala. This project served, unintentionally, as a pilot project for Narangwal. It, in a sense, field tested a study design and tested interventions later refined at Narangwal. The five year prospective INCAP study[8] was the only prior field study of its kind. It attempted to explore the relationships between nutrition and infection. The NNS drew on the INCAP experience in at least two ways. First, the INCAP experience reaffirmed or provided new insights into the "ecology, extent, natural history, and synergistic manifestations of malnutrition and infectious disease in a preschool community" (Taylor, C.E., et al., 1977). Secondly, the researchers at Narangwal were able to study and plan for the shortcomings of the INCAP study. This was important since the INCAP study suggested that intensive feeding did effect beneficial changes in growth, morbidity and mortality--albeit changes that represent trends more often than statistically significant changes. Thus, there was a felt need to clarify the kind of effect that an INCAP type project would produce on a larger scale.

Validity of the Results:

The NNS offers a summary list (presented earlier) of research and program results indicating the effects of the various service inputs on growth, morbidity and mortality. The objective of this section is to appraise just how reliable are the results presented by the researchers.

The researchers of the NNS collected data in three phases:

1. 1966-1968--Baseline cross-sectional data
2. 1968--Onset of the study project; cross-sectional data
3. 1968-1973--Longitudinal survey data

These data were analyzed in a straight forward manner. Cross-sectional data was tabulated for descriptive purposes. Longitudinal data was tabulated and the techniques of regression analysis and significance testing applied. Analysis was performed using standard procedures to account for confounding variables. Weight and height comparisons among control and service groups were made using cohorts starting at birth. Morbidity data was presented by age group, season and by cohort for each study group. Mortality was calculated by age group, caste, sex, season and followed by cohort using data of the last three years of the study only.

Statistical significance in analysis of growth data was achieved among study groups. Although mortality data exhibits certain trends, the whole numbers were too small to assure clear statistical significance, and losses of data due to migration might have affected rates. However, the reader (as did the researchers) can ferret out internal controls which at best leave the reader satisfied with the trends of the mortality data. For several reasons to be discussed, there is a breakdown in the reliability of the morbidity results.

The following observations are made about the reliability of the NNS data. Although comments are made here about interpretation of these data further discussion of the validity of the interpretation along with weaknesses of the study is saved for the next section.

1. Controls needed for the kind of study done at Narangwal are difficult to select without breaching moral-ethical codes of medical conduct. A large amount of care appears to have been taken in balancing research needs with humanitarianism. The NNS used adequate controlling techinques: parallel observation of control versus experimental groups over time. Time series errors were limited by virtue of this study design and because all comparisons made in this study are between the in parallel observed control and experimental groups. "Before-after" comparisons are made in a limited way using information from the Khanna study. (Although these latter comparisons are less useful, they serve to reaffirm trends.)

2. The four study groups are not similar at the outset of the study with respect to birth weight-for-age or birth height-for-age measures. The controls are heavier but shorter than children in the experimental groups. Control villages were chosen for their representativeness of the population with the additional criterion that they be close to a government primary health center so that they could continue to receive all available basic health services. This probably explains a portion of the difference among control and experimental groups. But birth weights and heights tabulated do not reflect the character of the newborn population because of the poor success of researchers in obtaining these measures. Cultural factors mediated against obtaining these measures.

3. Cross-sectional data are probably quite accurate as well as the interpretations which flow from the tabulations. The basis for this assessment is that the target population on which these data were collected was population group inclusive; that is, all children 0-3 years of age were surveyed. Information collected on specified cohorts over time as well as special cross-sectional survey data which depended upon voluntary participation caused self-selection. This fact is recognized by the researchers who found that as the services to the different study groups decreased (i.e., NUT+MC had the greatest service inputs and the controls of least service input) the participation rates dropped off. This of course is highly detrimental to the study in light of the fact that nothing is known of the nonparticipants. This unfortunate fact works much to the detriment of the validity of the morbidity study and its results. In this context several comments with respect to weaknesses in the interpretation of morbidity data are made here rather than in the "Weaknesses of Study" section.

a. The authors conclude the incidence data to be variable and do not discuss prevalence data. Nonetheless the researchers state that underreporting probably was confined to minor illnesses. They site the fact that incidence of lower respiratory tract infections was similar in all experimental groups. It is not clear whether in this context the researchers consider lower respiratory tract infections (LRI) to be a minor or major illness. If it is a minor illness, the statement is confusing (i.e., if minor illness is the source of variability in reporting and if LRI is a minor illness, then LRI should be <u>different</u>

and not similar in each group). If LRI is a major illness and was similar in incidence from group to group (which it apparently was), then this might suggest that the data collected about this major illness was affected equally in all four groups of the study. But the authors imply that reporting of LRI is an indicator of all reporting of major illness. It is, then, only by indirect implication that first, variability in reporting is seated in minor illness reporting, and secondly, that in all cases variability in reporting is due to underreporting of minor illness. Even if these inferences are correct, the basic facts remain that these data are collected from self-selected populations with real doubt as to the reliability of the recall diagnosis among people free to pick and choose the extent to which they take advantage of allopathic diagnostic services.

b. The researchers move on to state that duration of morbid experiences seemed to be "considerably less subject to underreporting than incidence." The researchers state that the main evidence that underreporting contributed only slightly in reducing the mean duration in experimental groups is that "in the nutrition care group villages underreporting seems to have been minimal, but average duration of episodes paralleled that in the control villages." This is only tenuously more reassuring evidence that the duration data are reliable. When the actual data are examined, they do not appear to support this statement and in fact several cases the duration of episodes in experimental groups differs significantly from the control group when statistical tests are applied. Additionally, sight must not be lost of the circumstances under which these data were collected. These will be reiterated

here. The morbidity data were collected by auxiliary health workers asking mothers of varying levels of socio-economic status and who may have been self-selected to recall 44 signs and symptoms of disease in children in their families. Also, individual variation (according to the researchers) among surveyors apparently occurred. Since verification of the reliability of recall information was unable to be made and in view of the growing incidence of the lack of reliability of recall information, there is cast a doubt upon the validity of the interpretation of the duration data.

Since the root problems with the morbidity data are self-selection of participants, no information about nonparticipants, and no verification of recall data, it is curious that the authors reject the validity of the incidence data but use the duration data both of which are equally affected by these root problems.

4. The study data are affected by the fact that many persons migrated temporarily or permanently in or out of the Narangwal study areas. This migration probably exerted its greatest effect on mortality statistics by altering denominators. There is no way to determine if migration was random or perhaps provoked by conditions in the villages. This migration bears an importance with respect to the mortality data since just a few deaths more or less in any group could alter the relationship among the mortality rates of the study groups. Thus, it is important to review here the findings stated by the researchers while the effect of migration is still fresh in the reader's mind. These findings include:

a. In all age groups service inputs, irrespective of their nature, seemed to affect mortality rates;

b. Early detection of potentially serious conditions followed by ready treatment as a part of frequent home visiting was most important in reducing infant deaths;

c. The impact on perinatal deaths in nutrition care villages was presumably because prenatal services included nutrition and health education and regular administration of iron and folic acid to mothers;

d. During postneonatal period, medical care both with and without nutrition care, clearly, was more important than nutrition care alone. Undernutrition did not seem to play a critical role in post-neonatal mortality.

In regard to these findings, because of the extensive lengths to which the researchers went to discover and confirm deaths, it is certain that very few deaths went unrecorded except to the extent that migration played a role. However, in most subgroupings in the mortality study, the numbers of death are too small to make definitive statements of statistical significance. Even one missed death or one misplaced or misallocated death could significantly alter calculated mortality rates. (This could be effected as a result of the migration problem.) But even if these problems did occur to a minor extent, the basic trend and overall significant differences of at least the aggregated data would remain unchanged.

The four findings listed above appear to follow from the mortality data presented by the researchers. That the impact on peri-natal deaths in nutrition care villages was presumably because of

prenatal services is obvious from a glance at the data sheet presented earlier. Since both medical care and nutrition care services and nutrition care groups alone accrue equal benefits to the mortality rates of children, and because medical care groups alone showed a higher perinatal rate than the nutrition supplementation group alone, it is clear that prenatal supplementation--the only service input that could affect nutrition supplemented children--is the most effective way of securing reductions in perinatal deaths among the service inputs used here.

Similarly, internal comparisons of these data reaffirm the other conclusions (listed above) made by the researchers.

As a point of interest, note that the infant mortality rate (IMR) of the Khanna study (1957-1959) is 156. The IMR of the NNS control villages is 129. This is a good indication of the effects of general socio-economic development of a decade. It also serves as an internal control statistic to affirm trends seen in the NNS.

Secondary Analysis:

The nutritional status of children in each study group was monitored for the length of the study. In specific study groups targeting of services depended upon a child's nutritional status. It is common place to employ the "Boston Standard" as a reference against which the level of a child's nutritional status is ascertained. The question arises as to whether some other anthropometric or biochemical measure would have generated better rates of sensitivity and specificity than the anthropometric measures used.

To answer this question two secondary data analyses were performed, only one of which will be discussed here. (Both indicated similar

interpretations.) It has been shown that C_3 (complement) levels are significantly reduced in undernourished children (even in borderline undernourished children free from infection). Therefore, it was of interest to examine the same group of children using different criteria for classification. In that C_3 levels themselves might be responding to variations in protein, calorie, iron or folic acid levels, the effect of these variations on C_3 levels was also studied. Data gathered on 53 children fully ambulatory and free from intercurrent infection were examined. Data included anthropometry, morbidity, hemoglobin, whole blood folate, and C_3 level for a period of about 250 days.

None of the three biochemical indicators (hemoglobin, blood folate or total serum protein) showed any statistically significant correlations with C_3 or C_3 ratio. Other analysis suggests a high sensitivity of C_3 levels to nutritional status at low levels of nutrition (i.e., <60 percent of the Boston Standard weight-for-age). C_3 levels plateau at 70-80 percent of the Boston weight-for-age standard. It might be noted that arm-muscle circumference showed a lower correlation with C_3 than weight-for-age. (See Attachment 1.)

Not withstanding the comments just made, the researchers chose to use weight-for-age as an indicator of malnutrition for all children 0-3. It has been pointed out elsewhere in this review of nutrition studies that weight-for-height is a more reliable indicator of nutritional status after one year of age. Use of weight-for-age for all children 0-3 leads to a systematic overestimation of the number of children undernourished. The import of the error is limited because it affects measures in children >1 year of age, and because all rates in the study are calculated

for children <1 and ≥1 year of age. Moreover, the most critical rate comparisons are made for children <1 year of age.

Study Weaknesses:

Major weaknesses in the NNS occur in the research design and in the validity of the morbidity results. However, these problems are self-limiting problems and do not interfere to any significant degree with the many other important findings which emerge from the study. The objective of this section is to describe anew or reiterate the shortcomings of this study. Once this is done, the task is then to ascertain the cummulative effect of these shortcomings on the relationships described in the study summary.

1. Study design--The way in which overlapping of the NNS was done with the NPS created a situation where FP services were included only in the NUT+MC group of the NNS. The NNS was then biased from the outset to show a synergism of programs. True synergism of combined programs is not able to be demonstrated by this study design.

Although this means that a major objective of the study could not be fulfilled it has little bearing on the validity of the results or conclusions independent of this major objective.

2. Rural Punjab is not representative of other rural areas of India. This fact is not so much a weakness of the study as it is a factor in the generalizability of the results to other places.

3. The morbidity study suffered from:

a. unverified and too much sophisticated recall required of mothers;

b. a lack of information about nonparticipants;

c. lack of assured standard uniformity of diagnosis;

d. decreasing participation rates in groups of great service inputs to groups with lesser or no service intervention;

e. use of the duration data by the researchers with tenuous justification while rejecting the incidence data as unreliable.

The cumulative effect of these problems makes it reasonably plausible that the relationships described about morbidity could be nothing more than spurious ones. Parenthetically, it should be added that the major contribution of the morbidity portion of the NNS is demonstrating the hazards and unreliability of the recall survey when a recall of one week or greater is used.

4. The study data suffered from the exclusion of data about individuals from longitudinal measures because of seasonal migration. Although the net result of this migration on growth data was probably negligible, it is less clear what the effect of migration was on mortality data.

5. The actual amount of food supplementation taken by individual children was not able to be verified. Verification of supplementation was limited to knowing who attended the center (but not if or what he or she ate) and to knowing in aggregate that each feeding center was supplied with so much supplement. It was assumed that if a child made it to the center (by walking there himself or by being carried by an older sib) he took the supplement. The effect of precluding supplementation of some children who could not get to the center and the effect of nonpreschool sibs who ate food too at the center are not known.

Obviously, food supplementation was of little consequence to the perinatal child, for whom prenatal care (i.e., supplementation of the mother) was important.

For postneonatal mortality, a food supplement effect might be important, although medical care groups reported far better postneonatal mortality rates. But because of the lack of information to verify who received a supplement and how much they ingested, medical care and food supplementation might exert an equal effect on mortality rates. Thus, the validity of the researchers interpretation that medical care was the most important factor in reducing postneonatal mortality is tentative.

6. The effectiveness of the FHW may have been diluted as a result of the extra work required in villages where combination interventions were implemented. Since there is no indication of FHW evaluation, it is difficult to assess the effect of worker overload on the study. However, this might be a contributing factor to the high mortality rates (relative to other service groups) of the NUT+MC group, especially since the mortality reporting was judged to be quite reliable with little under-reporting.

7. That the control group children were on average heavier and shorter than their counterparts in the experimental groups is of concern. If this is a true difference then the study demonstrates more forcefully the beneficial effects of the program interventions over the control group. Yet, there is indication that these differences in birth weight and height reflect peculiar, non-random, cultural factors which mediated collection of birth weight and height. At worst the initial survey statistics simply makes it harder to show a program effect. When an effect is observed, it is all the more convincing.

8. Parents were able to pick and choose among the services offered in their community. This encouraged differential participation within the different groups. From a study design point of view this is a hazardous type of design because it makes it more difficult for the study to demonstrate its effect. On the other hand any effect demonstrated is more convincing--a kind of internal control. In the case of this study it was a doubly hazardous assumption to make (that an effect would be seen) in light of the kind of results obtained by INCAP. The reason why it is difficult to cite this type of internal control with regard to the morbidity statistics is because nothing is known about the nonparticipants.

Broad-Scale Applicability

A. Cost

The summary of service measures and cost with regard to outcome is interesting. The following points have particular bearing on the broad applicability of service packages used in Narangwal.

1. Both PHCs (primary health centers) and the average Narangwal cost per contact were similar (PHC patient visit = Rs. 1.50; NNS service contact = Rs. 1.40).

2. Only a small percentage of persons near a PHC are actually served by the PHC. For instance, only 10-20 percent of children under three had access to limited MCH activities of the PHC and its subcenters. By contrast, the services of the Narangwal study were able to be extended to a great majority of the target populations.

3. If a NNS type program were to be implemented nationwide so as to take advantage of government economies of scale, costs per child per year could be brought down substantially. However, the government of

India would still have to spend in absolute numbers of rupees 5-10 times what they currently spend.

4. In preventing death at different ages, different methods of achieving reductions in death rates have varying cost/effectiveness ratios. For instance, prenatal child care is most cost/effective in averting perinatal deaths. MC provides the lowest child service cost per death averted (in all years). (Cost/effective ratios did not include indirect impact of such things as health and nutrition education provided to the mother during child care contacts.) It is noteworthy that in calculating cost/effective ratios for each type of service in terms of deaths averted in that service program, the NUT+MC was least cost/effective. Yet, combined care villages did about as well in the impact on mortality as the MC villages and as well as growth measures as NUT care villages. These combined effects were achieved for a cost less than the amount obtained by adding the costs of services in NUT villages to other cost of services in MC villages--a "financial synergism" as the researchers call it.

These observations have several implications for the broad applicability of the nutrition interventions used at Narangwal. The results suggest that integrated services offering the most cost/effective inputs targeted at the appropriate population segment can have a significant impact at a reasonable cost per capita. But countrywide distribution of these services may be prohibitive in cost when the total monies budgeted for use by a health ministry are known (i.e., the cost per capita may be realistic, but the total program cost may exceed the budget). In this case governments will have to opt for continuing to spend their available monies in a similar fashion as in the past (i.e.,

spread thinly over the whole population with great inefficiency and poor real coverage) or, might elect to spend the same level of money but redirected as guided by the results of this study covering some large areas more efficiently but still other areas not at all. The third alternative is for governments to allocate more money to health ministries so that they can redirect their programs as guided by this study but effecting total population coverage. Nonetheless, preschool community care serves a limited population. The rest of the population has medical care problems that are not addressed by the program. Further, although the total monies available (charity, government, and private) are relatively constant, the governments will find it difficult to control the spending of both private and charity monies for health care even though this sum of money probably approximates the amount of money to effect the third alternative (at least in India). Broad coverage of population with a NNS type intervention then, although technically cross feasible, is probably realistically improbable and not generalizable without a fundamental change of attitudes toward the importance of health on the part of governments.

B. Technical Feasibility

The NNS was set up primarily to show the effects of nutrition and medical care on selected indices of child health. How to provide these services was a secondary issue. However, the NNS does not appear to present a problem from the technical side in terms of its broad applicability. Certainly any broadly introduced program would necessarily be less intensive if for no other reason than the fact that the implementers of the NNS had a vested interest in at least the study being

carried out. A great deal of bureaucratic inertia would have to be overcome to keep the surveillance and MC and/or NUT components up to a level to ensure improvements in growth and reduction in mortality would and could occur to justify the continuance of the program.

C. Acceptability

It seems that at least in rural India based on the very high participation rates in the service villages that the kinds of service packages offered would probably be generally acceptable.

Conclusions:

In summary, the NNS does not appear to have met in full the first objective of the study to determine the effect of medical care and nutrition care singly and in combination on preschool child growth, morbidity and mortality--primarily because of the research design. The research design precludes demonstration by the researchers of a synergism of program services because of a built-in bias in favor of demonstrating synergism. The objective to develop a pattern of rural health care which relies upon auxiliary health workers apparently was effected, but linkage of the objective to outcome measures and/or data interpretation and quantitative evaluation of the family health workers is lacking. These problems are self-limiting and do not undermine the study as a whole.

Certain other important relationships or effects of service packages are demonstrated: differences in growth and mortality as mediated by different service packages, the effect of prenatal care on perinatal mortality.

The study was much less successful in demonstrating relations with the morbidity data because of procedural and design problems. Given the fact that even with a seven-day recall of morbidity, results showed clear evidence for subjective reporting, one questions the validity of any quantitative data arrived at by recall.

The NNS shows certain service packages to be cost/effective and on a per capita basis perhaps less expensive than what the country spends as a whole for health services. However, at least two problems limit the generalizability of the study to all India or other parts of the globe. Firstly, a major shift in total spending would be required to effect any of these service packages over an entire nation. (Services which in any case meet the medical needs of only a single portion of the population--those under three years of age and pregnant or lactating mothers.) Secondly, given insufficient funding, a critical political decision to use most available money in well circumscribed areas to the exclusion of other areas would have to be made.

ATTACHMENT 1

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Complement (C_3), nutrition, and infection *

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Complement (C_3) was determined and related to various parameters of nutritional status and past infectious disease experience in a group of 53 rural preschool children in North India. Mean complement level was 25% lower than in an age-matched European reference population. Low complement (C_3) levels were associated mainly with children who were both stunted and wasted, as well as with those who had experienced frequent purulent skin infections in the past.

Malnutrition has been shown conclusively to impair nonspecific cell-mediated and specific humoral defence mechanisms, resulting in increased incidence and prolonged duration of infectious diseases and ultimately in high childhood mortality. The complement system is one of the major components of the defence mechanisms against infection; knowledge about complement function in malnutrition is, therefore, of critical importance to the understanding of disease patterns in poorer countries. Since Smythe et al. (*14*) originally demonstrated impairment of complement function in children with severe PEM (protein-energy malnutrition), several investigations have shown that C_3 levels are significantly reduced in malnourished children (*2, 12, 13*), but rapidly increase following nutritional rehabilitation (*3, 11*). Complement levels have also been found to be significantly reduced during acute infectious diseases, chronic tropical parasitoses, and autoimmune disease (*1, 4, 9*). Most studies concerned with nutritional effects on complement have been done on children in severe states of undernutrition, i.e., third degree according to the Gomez classification, frank marasmus, or kwashiorkor. Recently we have shown that complement (C_3) levels were significantly reduced even in borderline undernourished children free from infection at the time of examination (*7*). Since our earlier publication and largely in response to it, a number of questions have arisen. Was weight-for-age the appropriate indicator for measuring the level of nutrition or would another anthropometric or biochemical parameter, for instance weight-for-height or haemoglobin concentration, have yielded better results? It would similarly be important to know whether any specific nutrient deficiency state—protein deficiency, energy deficiency, or other nutrient deficiency (iron, folic acid)—was principally responsible for the observed reduction in C_3 levels. Though other investigators had stressed the effects of acute illness on complement levels, little was known about whether, past illness had affected complement levels and whether illness and nutritional levels interacted in their effects on complement synthesis and utilization. Lastly, we wanted to re-examine our data to determine more precisely the interrelationship between nutritional levels and complement (C_3).

METHODS

The study was done at the former Rural Health Research Center of the Johns Hopkins University, Department of International Health, at Narangwal, Punjab, North India. Blood samples were obtained from 53 children belonging to the study population of a larger longitudinal investigation into interactions of nutrition and infection (*8*). All children were normally active and free from intercurrent infections. The children were weighed to the nearest 20 g; height, arm circumference, and biceps skinfold thickness were determined according to Jelliffe (*6*). Complement (C_3) levels were determined by radial diffusion (*10*); haemoglobin was determined colorimetrically (*15*); total serum protein was measured

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by refractometer. Information on past morbidity incidence was available for all 53 children who had been examined physically at weekly intervals for a total of 13 144 days (mean: 248 days per child). Since these were most likely to have triggered the complement system, we examined mainly the records concerning bacterial infections, fever, eye infections, and purulent skin infections. Fever was chosen as a general indicator of the occurrence of past infectious disease, purulent skin infections and eye infections because they are readily identifiable conditions usually (purulent skin infection) or frequently (eye infection) caused by bacteria.

RESULTS

Complete anthropometric data (weight, height, arm circumference, and skinfold thickness) and data on past morbidity (fever, eye infections, skin infections) were available for 53, haemoglobin levels

Table 1. Mean age, complement (C_3), nutritional status, and past morbidity incidence of study population

Characteristic	*n*	Mean	S.D.	Range
age (months)	53	14.2	7.49	4.0 – 38.0
complement (C_3) [a] [mg/litre]	53	1097	259.6	500 – 1581
C_3-for-age [b] [percent]	53	76.8	18.00	33.3 – 117.0
weight-for-age [% of Harvard median]	53	72.1	14.40	38.0 – 98.0
weight-for-age [% of Narangwal median]	53	94.4	19.43	51.5 – 127.4
height-for-age [% of Harvard median]	53	91.2	7.20	72.0 – 103.0
height-for-age [% of Narangwal median]	53	98.6	4.41	97.5 – 109.7
weight-age [c] [percent]	53	68.3	16.71	31.9 – 111.5
height-age [c] [percent]	53	77.2	17.15	30.7 – 107.9
weight-for-height [% of exp. Harvard weight]	53	85.0	9.20	55.8 – 106.3
arm circumference [% of Wolanski Standard]	53	78.5	9.50	55.0 – 94.0
skinfold thickness [mm]	53	5.6	2.58	3.1 – 13.5
arm muscle circumference [cm]	53	10.2	1.19	7.6 – 14.5
haemoglobin [g/litre]	44	89	17.1	57 – 120
total serum protein [g/litre]	43	76	3.7	60 – 79
whole blood folate [pg/litre]	18	178	111.1	36 – 450
fever incidence [d]	53	1.2	0.11	0 – 3.6
fever duration [days]	53	3.3	1.44	1 – 9.0
fever prevalence [e]	53	3.9	2.8	0 – 10.1
skin infection incidence	53	0.2	0.04	0 – 1.3
skin infection duration [days]	53	4.5	6.13	1 – 24.0
skin infection prevalence	53	0.2	3.9	0 – 15.8
eye infection incidence	53	1.0	0.10	0 – 3.3
eye infection duration [days]	53	8.1	5.0	1 – 23.5
eye infection prevalence	53	9.2	8.0	0 – 35.2

[a] Adjusted for batch differences by linear regression (unadjusted mean = 870 mg/litre).
[b] C_3 level of study child as percentage of C_3 level of age-matched European children.
[c] Percentage of expected age by Harvard growth standards.
[d] Number of episodes per 100 child days of observation.
[e] Number of days ill per 100 child days of observation.

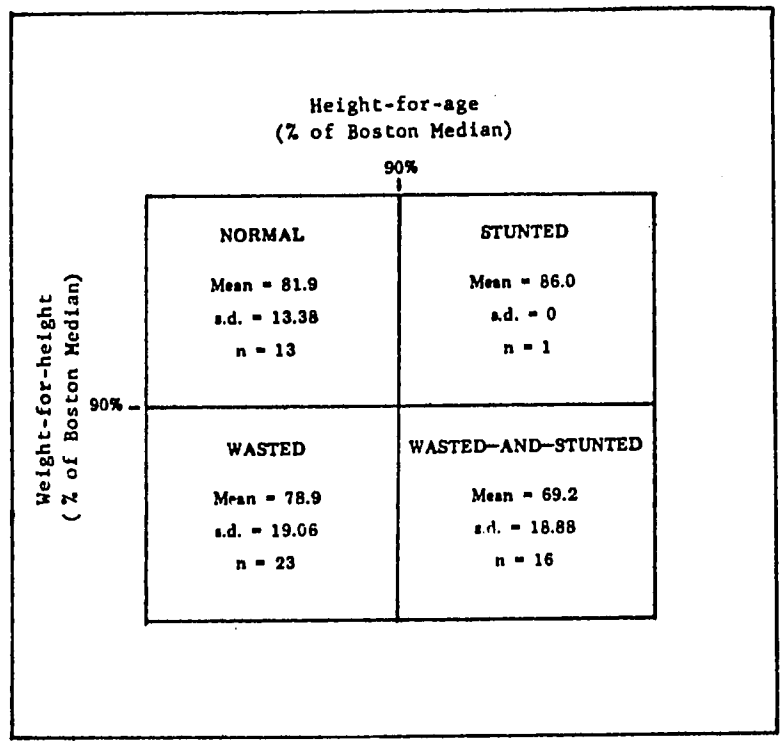

Fig.1. Complement (C_3)-for-age in children of differing nutritional status.

or 44, and whole-blood folate for 18 of the children on whom complement (C_3) was determined. The means, standard deviations, and ranges of these characteristics of the study children are shown in Table 1.

The mean adjusted (for batch differences) complement (C_3) level was 1100 mg/litre, 25% lower than in an age-matched European reference population. Although the mean weight-for-age corresponded to second degree malnutrition according to the Gomez classification, it was only slightly below the median of the total Narangwal child population. Mean height was below the third percentile of the Boston data and at the 50th percentile of all Narangwal children, respectively. The anthropometric indices suggest chronic, primarily energy undernutrition resulting in stunting and wasting. Total serum protein concentration was 76.0 g/litre. Mean haemoglobin and whole blood folate levels were low at 89.0 g/litre and 178 pg/litre, respectively. The incidences of fever, eye infections, and skin infections were high at 1.2, 1.0, and 0.3 episodes per 100 child-days of observation, respectively, but did not differ from the incidence rates of these conditions for the total Narangwal child population.

In a first step of the analysis, study children were grouped according to Waterlow's (*16*) classification of levels of nutrition into " normal ", " stunted ", " wasted ", and " wasted-and-stunted " by using 90% of the Boston median curves as cut-off points for both height-for-age and weight-for-height. According to these criteria, 13 (24.5%) of the children were of " normal " nutritional status, 1 (1.7%) was " stunted ", 23 (43.4%) were " wasted ", and 16 (30.2%) were " wasted-and-stunted ". The distribution of these children as well as their mean complement (C_3)-for-age values[a] are shown in Fig. 1. Since only one child was "stunted" according to preset criteria, little can be said about mean C_3-for-age in this group. The result seems to suggest that

[a] Complement (C_3)-for-age, determined by dividing the C_3 level of the study children by the mean C_3 level of an age-matched European reference population, was used to (1) eliminate need to correct for age; and (2) establish points of reference in the absence of concrete knowledge about " adequate C_3 " levels.

Table 2. Simple correlation coefficients between complement (C_3) and anthropometric and morbidity variables

	Statistics	Complement (C_3)	Log of C_3	C_3-for-age	Log of C_3-for-age
log (weight-for-age[a] − 1)[3]	r	0.444	0.470	0.474	0.495
	n	53	53	53	53
	$P <$	0.001	0.001	0.001	0.001
log weight-for-age[a]	r	0.388	0.415	0.429	0.448
	n	53	53	53	53
	$P <$	0.01	0.01	0.01	0.01
log weight-for-height[a]	r	0.324	0.352	0.350	0.379
	n	53	53	53	53
	$P <$	0.05	0.01	0.01	0.01
log percent Wolanski arm circumference-for-age	r	0.319	0.331	0.371	0.377
	n	53	53	53	53
	$P <$	0.05	0.05	0.01	0.01
log arm-muscle circumference[b] (cm)	r	0.307	0.315	0.303	0.308
	n	52	53	53	53
	$P <$	0.05	0.05	0.05	0.05
log weight-age[c]	r	0.153	0.164	0.267	0.262
	n	53	53	53	53
	$P <$	n.s.	n.s.	0.10	0.10
skinfold thickness (mm)	r	0.191	0.207	0.188	0.210
	n	53	53	53	53
	$P <$	n.s.	n.s.	n.s.	n.s.
log height-for-age[a]	r	0.168	0.191	0.243	0.253
	n	53	53	53	53
	$P <$	n.s.	n.s.	0.10	0.10
log height-age[c]	r	0.111	0.117	0.226	0.214
	n	53	53	53	53
	$P <$	n.s.	n.s.	n.s.	n.s.
skin infection incidence (no. of episodes/100 days observed)	r	−0.210	−0.198	−0.244	−0.220
	n	53	53	53	53
	$P <$	n.s.	n.s.	0.10	n.s.
log eye infection incidence	r	−0.192	−0.191	−0.120	−0.125
	n	53	53	53	53
	$P <$	n.s.	n.s.	n.s.	n.s.
log fever incidence	r	0.150	0.145	0.195	0.180
	n	53	53	53	53
	$P <$	n.s.	n.s.	n.s.	n.s.

[a] As percentage of Harvard median.
[b] Gurney & Jelliffe (5).
[c] Percentage of expected age by Harvard growth medians.

children in the wasted-and-stunted category have the largest (and significant, $P < 0.01$) deficit in complement-for-age. Wasted children had a slight reduction in mean C_3-for-age but this difference was not statistically significant.

In a second step, complement (C_3) and C_3-for-age levels were correlated with the remainder of the anthropometric or morbidity variables.

Complement (C_3) levels and C_3-for-age yielded statistically significant positive correlations with most of these (Table 2). Scattergrams of complement (C_3) or C_3-for-age against nutritional status suggested nonlinearity of most correlations except those in which nutritional status was measured by skinfold thickness or weight-for-age.[a] Linearization was done through logarithmic or exponential transformation. Use of C_3-for-age instead of C_3 level, as well as the logarithm of both C_3-for-age and the logarithm or the exponential of the anthropometric variables, improves the correlations. High correlation coefficients were obtained with weight-for-age ($r = 0.495$), weight-for-height ($r = 0.379$), and arm circumference-for-age ($r = 0.329$); arm muscle circumference showed larger correlation coefficients

[a] Percentage of expected age by Harvard weight standards.

either C_3 level ($r = 0.315$) or C_3-for-age ($r = 0.308$) than skinfold thickness ($r = 0.207$; 0.210). Skin and eye infection incidence gave negative correlations with C_3 level or C_3-for-age. Statistical significance was reached only between C_3-for-age and skin infection. Fever showed a positive though statistically not significant correlation with C_3 level and C_3-for-age.

None of the three biochemical indicators of nutrition status—haemoglobin, total serum protein, and whole blood folate—showed any statistically significant correlation with either C_3 levels or C_3-for-age. To facilitate interpretation of results, C_3-for-age rather than its logarithm was used in subsequent multiple regression analyses.

Multiple regression with nutritional status[a] (continuous) and pustular skin infection (categorical)[b] as independent variables and C_3-for-age as a dependent variable suggested a positive effect of the nutritional status and a negative effect of skin infection (Table 3). According to this equation (model A), previous pustular skin infection resulted, on the average, in a reduction of 11 percentage points in C_3-for-age. To clarify the role of incidence and duration of pustular skin infection on complement, the regression of C_3-for-age on nutritional status[a] skin infection incidence, duration, and prevalence (model B) was determined.

The regression resulted in a highly significant equation explaining 37% of the variance of C_3-for-age

[a] Expressed as the complement of the ratio: weight/Harvard median weight at given age raised to the third power.

[b] $x = 1$ if past pustular skin infection was present; zero if not.

Table 3. Partial values for variable in multiple regression model A[a] (complement (C_3)-for-age as dependent variable)

Variable[b]	b	Standard error (b)	Partial r^2	F (1,51)	P
nutritional status	185.2	42.7	0.22	18.8	< 0.005
skin infection	− 11.0	4.2	0.09	6.8	< 0.025
(constant)	89.3				

[a] Multiple $R^2 = 0.317$; $S_{y \cdot x} = 15.2$; $F(2,50) = 11.61$; $P < 0.005$ for the total model.

[b] Nutrition status = (weight-for-age − 1)^3; skin infection variable value is 1 if it was present in the past; zero if it was absent.

(Table 4). According to the model, an increase of 0.1 units of skin infection incidence was associated with a fall of approximately 3.6 units of C_3-for-age, keeping nutritional status and skin infection duration constant. An increase in 1 unit of skin infection duration changed C_3-for-age by 1.2 units. The combined effects of duration of skin infection and incidence on C_3-for-age were subadditive. Their coefficients were both negative while that of their product (skin infection prevalence) was positive. The interaction term (prevalence = incidence × duration) thus "balanced off" the main effects. In Fig. 2, actual values of C_3-for-age have been plotted, together with the curves derived from the exponential equation over the examined range. The curve suggests a high sensitivity of C_3 levels to nutritional status at low levels of nutrition (< 60% of the Harvard weight median) after which the complement levels formed a plateau at approximately 70–80% of the Harvard weight median. Purulent skin infection of low ($\bar{x} - 1$ standard deviation) incidence and

Table 4. Partial values for variables in multiple regression model B[a] (complement (C_3)-for-age as dependent variable)

Variable[b]	b	Standard error (b)	Partial r^2	F(1,51)	P
nutritional status	193.1	42.3	0.224	20.8	< 0.005
skin infection incidence	− 36.2	14.7	0.060	6.1	< 0.025
skin infection duration	− 1.2	0.5	0.066	5.0	< 0.05
skin infection prevalence	3.5	1.5	0.027	5.6	< 0.05
(constant)	90.1				

[a] Multiple $R^2 = 0.372$; $S_{y \cdot x} = 14.9$; $F(4,48) = 7.1$; $P < 0.005$ for the total model.

[b] Nutrition status = (weight-for-age − 1)^3; skin infection incidence = no. of episodes/100 days of observation; skin infection duration = mean no. of days ill/episodes; skin infection prevalence = incidence × prevalence.

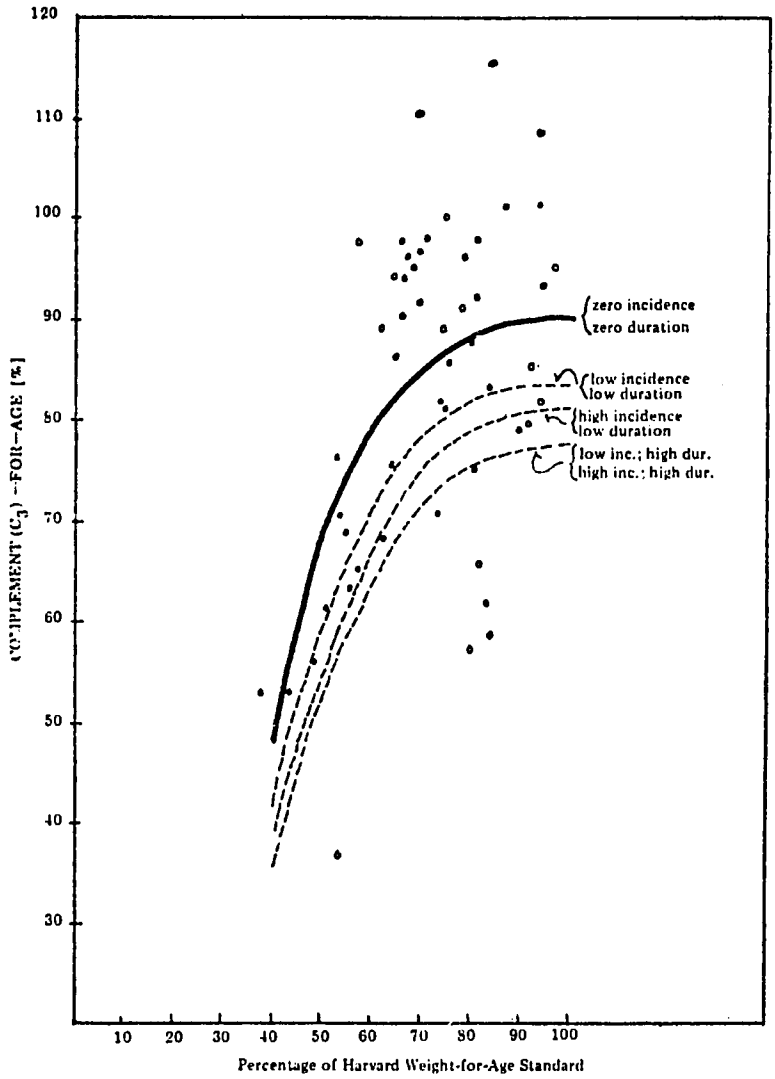

Fig. 2. The effects of nutritional status and past purulent skin infection on complement (C_3)-for-age.

low duration (1 day)[a] had the least depressing effect on C_3-ratio; high incidence and high duration ($\bar{x} - 1$ standard deviation) or low incidence and high duration appeared to result in a maximum decrease of C_3-for-age, while high incidence and low duration occupied an intermediate position (Fig. 2). Examination of the residual plot shows a symmetrical distribution of residuals around zero suggesting homoscedasticity and linearity of the (linearized) function over the examined range. Suggested effects of purulent skin infection incidence and duration at both high and low levels of nutrition on complement levels (Table 4) were further examined in Fig. 3. According to the two models, a child of high nutritional status (90% Harvard weight median) and maximum purulent skin infection incidence and duration still has a level of complement (C_3) of more than 70% of his/her European counterpart. A child of poor nutritional status (50% Harvard weight median) at maximal skin infection incidence and duration has only about 50% of the C_3 level of

[a] First value greater than zero when ranked in order of magnitude.

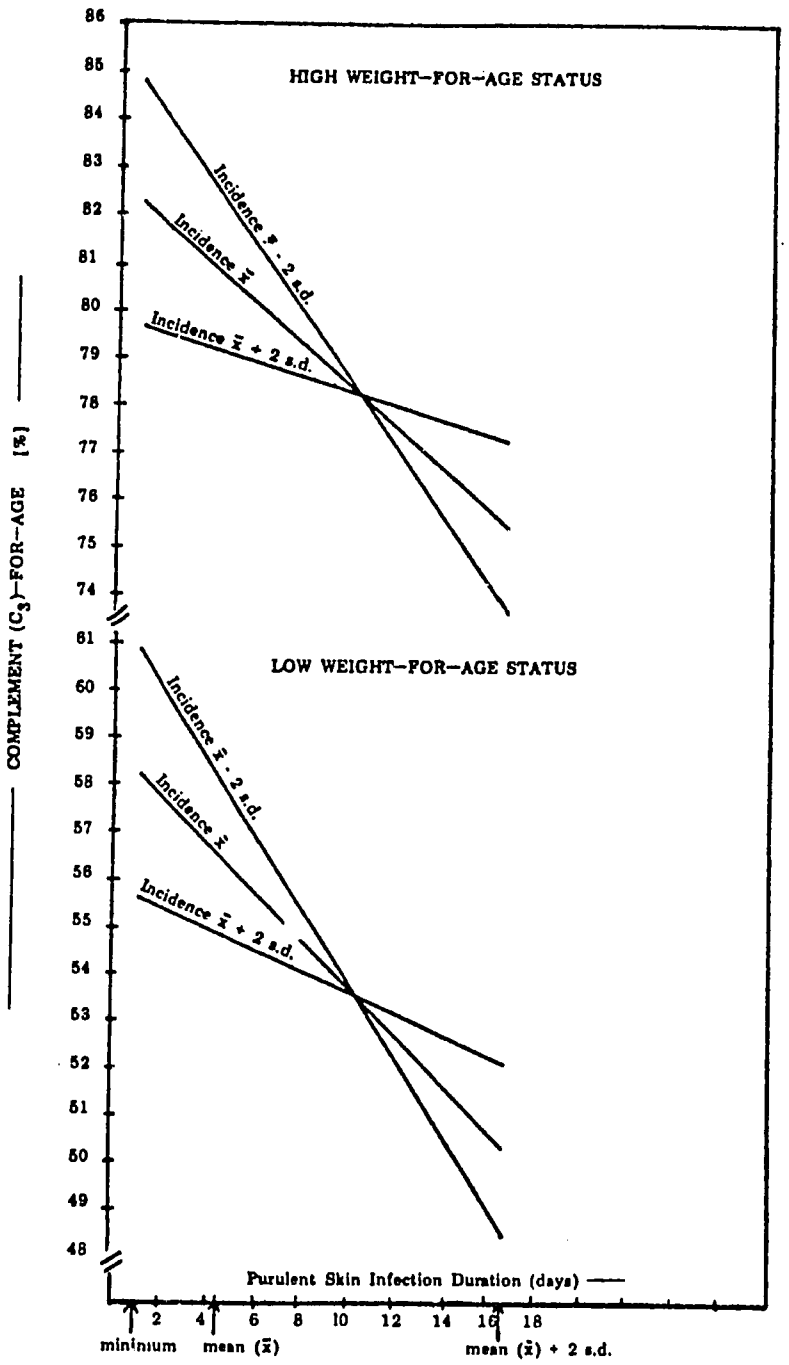

Fig. 3. The effects of purulent skin infection incidence and duration on complement (C_3)-for-age at high (90 %) and low (50 %) weight-for-age status.

European children of his/her age; one with low incidence but high duration has less than 50%.

DISCUSSION

Deleterious effects of undernutrition on complement (C_3) levels were demonstrated some time ago. The results of this investigation may possibly help in understanding the nature of the interrelationship between nutritional status, C_3, and infectious disease.

From our results it seems that maximum C_3 levels were reached at approximately 70–80% of the Harvard weight median, corresponding to first degree malnutrition on the Gomez scale. Below that level, serum C_3 concentration was extremely sensitive to nutritional fluctuations. Thus in the interval between 40 and 50% of the Harvard weight median, the mean C_3 concentration rose by approximately 60%, whereas between 70 and 80% of the Harvard median it rose by less than 10%. While we presume that the specific patterns that we observed between nutrition and C_3 levels apply mainly to children living in the Punjabi ecosystem, the shape of the curve is probably similar for most child communities, with the prevalence of specific infectious diseases and the nature of undernutrition determining the nutritional threshold at which maximum complement (C_3) levels are maintained. Use of Waterlow's classification of nutritional status further helped to identify wasted-and-stunted children as the ones with minimum C_3 levels and, therefore, most vulnerable to infections. The commonly observed excess mortality in this group is thus not surprising.

In our children, complement (C_3) was determined more by the immediate level of nutrition as measured by weight-for-age or weight-for-height than by measures of long-term nutrition such as height. Surprisingly arm-muscle circumference, an accepted indicator of lean body muscle mass, showed a lower correlation with C_3 than weight-for-age. This is probably because Punjabi children get relatively high amounts of protein in their diet[a] and, even though total food intake may be low, specific protein deficiency was not the limiting factor in C_3 production.

A history of purulent skin infections was associated with a significant reduction in C_3 concentration. From our data it seems that both frequency and duration of skin infection episodes determined the extent of the reduction. Several mechanisms may explain these results: (*a*) complement levels do not return to normal even in disease-free intervals in children with frequent skin infections, suggesting that the time required for C_3 repletion is longer than the mean duration of the disease-free interval; (*b*) even though they showed no signs of overt infection, the majority of children with a high prevalence of past skin infection were suffering from subclinical infections at the time of the survey, suggesting remission and exacerbation of a chronic condition rather than new infection.

Unfortunately, our sample size was too small to examine interaction patterns between levels of nutrition and skin infections and their combined effects on complement (C_3) levels. Thus we had only very few children with a high level of both nutrition and skin infection prevalence and even fewer with a low level of both nutrition and disease prevalence. While it seems fairly clear from the results that the underweight child (< 70% of the Harvard weight median) with a high prevalence of skin infection seems to have minimal C_3 reserves, the effects of infection on C_3 synthesis at high levels of nutrition remain unclear.

Complex statistical manipulations of relatively few samples is a less reliable and less satisfying method of identifying possible variable interactions than examination of contingency tables with a large enough sample in each cell to permit simple Chi-square analysis or analysis of variance. Under field conditions, however, blood samples are not easy to come by and statistical approximations help identify trends. Because of the limited number of samples in our study, our conclusions, therefore, can be but tentative and require verification by means of a more extensive follow-up study.

[a] On the average, 8% of energy was found to come from high-quality protein.

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RÉSUMÉ

COMPLÉMENT (C_3), NUTRITION ET INFECTION

Les niveaux de complément (C_3) ont été déterminés pour un groupe de 53 enfants âgés de 4 à 38 mois et appartenant à la communauté villageoise de Narangwal (Pendjab, Inde), où était alors installé le Centre de Recherches en Santé rurale du Département de la Santé internationale de l'Université Johns Hopkins. A l'époque de l'examen, tous les enfants présentaient un développement moteur normal et étaient exempts d'infection. Les niveaux de complément (C_3) se sont révélés, à ladite époque, en corrélation positive — mais non linéaire — avec la position par rapport à la norme de poids en fonction de l'âge. Dans les cas de niveau nutritionnel médiocre, à un faible accroissement du pourcentage de la norme poids/âge correspondait une forte élévation de C_3; au-dessus de 70–80% de la norme, le niveau de C_3 atteignait un plateau se situant à environ 90% de ce niveau dans une population de référence européenne d'âge correspondant. Les niveaux de complément étaient particulièrement bas chez les enfants présentant à la fois une insuffisance de poids (maigreur) et de taille (nanisme). Les épisodes antérieurs d'infection cutanée purulente exerçaient sur le niveau de C_3 des effets négatifs proportionnels à leur fréquence et à leur durée. En revanche, on n'a pas constaté de relation entre ce niveau et la concentration d'hémoglobine, les protéines sériques totales ou la concentration d'acide folique dans le sang.

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Appendix 3

HEALTH SURVEILLANCE AND NUTRITION EDUCATION

(THE HANOVER NUTRITION INTERVENTION)

A primarily service program established for the purpose of reducing high childhood malnutrition and mortality prevalent in this area of Jamaica. Community health workers were recruited to survey preschool children, to provide nutrition education, and to provide, selectively, supplements to those identified as malnourished.

Investigators:

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A.J. D'Souza, Senior Medical Officer (Health), Cornwall County, Jamaica

Supporting Institutions:

The Government of Jamaica; United States Department of State, Agency for International Development; and Cornell University

Published Material Reviewed:

1. A Young Child Nutrition Program in Rural Jamaica (Alderman, M.H., Husted, J., Levy, B., and Sharle, R.), The Lancet 2:1166-1169, 1973.
2. A Student Rural Health Project in Jamaica (Alderman, M.H., Cadien, D.S., Haughton, P.B.H., Johnston, M.H., and Johnson, K.G.), West Indian Medical Journal 21:1-20, 1972.
3. A Rapid Survey to Assess the Nutrition of Jamaican Infants and Young Children in 1970 (Gurney, J.M., Fox, H., and Neil, J.), Transactions of the Royal Society of Tropical Medicine and Hygiene 66:653-662, 1972.

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8. Interactions of Nutrition and Infection (Scrimshaw, N.S., Taylor, C.E., and Gordon, J.E.), Monograph #57 (Geneva: World Health Organization, 1968).

9. Reduction of Young Child Malnutrition and Mortality in Rural Jamaica (Alderman, M.H., Wise, P., Ferguson, R., Laverde, H., and D'Souza, A.), in press.

Discussion with Investigators, Site Visit, and Secondary Data Analysis:

A site visit was undertaken during January 1978, at which time extensive discussions with the resident investigator were held and vital statistics for the project years were reexamined. Major questions related essentially to the large drop in child mortality and malnutrition prevalence. In particular, we wanted to determine whether and to what extent these changes were part of an overall trend. Secondary analysis consisted essentially of recalculation of mortality rates in the study area and comparison of these with those for a neighboring county not part of the project.

Introduction:

Cornwall County, Jamaica, has been the site of a series of non-research, community-based health care intervention projects since 1969. Attachment I has been prepared for the reader to familiarize him or herself with a chronology, the goals and specific objectives (where this information is available) of those many projects which were implemented during the period since 1969. These projects have been a vehicle for merging curative and preventive medicine into a more comprehensive health program for all Jamaica. In this appendix, the nutrition component (H-YCNP or the Hanover Young Child Nutrition Program) of the Hanover Community Medicine Project (HCMP) is examined. Additionally, the role of non-nutrition services in the HCMP is addressed briefly in this evaluation. This review is not an evaluation of the community health workers (CHAs) in Jamaica and this document should not be taken to imply that CHAs are either effective or ineffective in the context of nutrition or other preventive or curative services.

That the H-YNCP was intended as a service program should be underscored here. Service programs attempt to apply to real situations the information gleaned from research studies. Qualitative information and judgement often become more important than an exacting experimental study design in evaluating the impact of a service program. This occurs for several reasons. Since it is the purpose of a research study to describe or demonstrate that an effect is due to a specified constellation of input variables, it is assumed that a service program which employs those same input variables will mimic the research

study. Further, the elaborate study controls and design of a research project are much too expensive to employ routinely in a service program where cost is a major concern. Thus, it becomes the objective of those running the service program to effect the program and to document changes in outcome measures over a period of time. Whatever other information the service program managers can provide to document that specific input variable(s) were linked to specific outcome measures is that much more helpful in evaluating the program. Because the program managers were able to take advantage of constraints to rapid geographical and temporal implementation of their service program, the H-YCNP is more than a service program. Yet it cannot be viewed in the strict sense as a research project. To the extent that the H-YCNP is a research-pilot project, we have applied the evaluative criteria we have developed for the research studies. However, we have also supplemented this evaluation with the project leaders' qualitative observations. We cannot overemphasize how tenuous it is for researchers to evaluate a service program in retrospect where one is shielded from and ignorant of the circumstances under which decisions were made which perhaps facilitated the service program to the detriment of secondary and only potential research concerns that program leaders might have had. However, the magnitude of the reductions in malnutrition prevalence and child mortality observed at Hanover along with the wealth of information readily available about the project, make it a project at which a closer look should be directed.

The results presented by the primary investigators of the H-YCNP included a dramatic reduction during a one-year period in the prevalence of malnutrition and mortality among children 0-48 months of age. No change was observed in the incidence of malnutrition. A secondary analysis by the authors of this evaluation, of death records was made possible by an on-site examination of death certificates and hospital records. However, secondary analysis of malnutrition prevalence data was not performed because of the prohibitive expense. It is our opinion that real reductions in mortality and malnutrition did occur among children 0-48 months of age in Hanover Parish while the H-YCNP was in effect (1973-1975). At least with regard to child mortality, a significant portion of the reduction in child mortality can be explained by a secular, island-wide trend apparently due to general development. Indeed, our secondary analysis demonstrated similar patterns of decline in child mortality in Hanover and in a control parish, Trelawny, both before and during the program (i.e., the period 1971-1975). However, although both Hanover and Trelawny Parishes experienced a similar reduction in child mortality, Hanover Parish appears to have enjoyed a somewhat accelerated reduction of child mortality during the period of time in which the program was in effect. The H-YCNP investigators suggest that the program effect was due to surveillance and educational inputs. It is our contention that while a program effect probably occurred, it was a small effect and it is not easily ascribable to any particular component of the project in Hanover. It is probable that our conclusions about the observed reductions in child mortality apply equally to the observed

reductions in malnutrition prevalence, although we could not examine, directly, malnutrition prevalence data in our secondary analysis.

Apparently only two papers have been published (1, 2) which bear upon the young child nutrition projects in Jamaica. Therefore, the following evaluation is based on these published papers, on discussions with the primary investigators, an on-site visit, and on information abstracted from internal documents provided, kindly, by Dr. A.J. D'Souza, Senior Medical Officer (Health), Cornwall County.

Geographical Facts About Jamaica:

Jamaica is subdivided into three counties:

1. Cornwall (western third of the county),
2. Middlesex (central third of the island), and
3. Surrey (eastern third of the island).

It is Cornwall County with which we are concerned in this evaluation. Cornwall comprises five parishes: Hanover, St. James, Trelawny, St. Elizabeth, and Westmoreland. The H-YCNP was implemented, as its name suggests, in Hanover Parish. Hanover Parish is about 23 miles east to west and about 8-9 miles north to south, and lies on the northwest coast of Jamaica. Montego Bay is located at Hanover's northeast corner, and Negril Beach at its southwest corner. The distance between Hanover in the west and St. Andrew Parish in Surrey County in the east is roughly 130 miles. This also approximates the distance between Montego Bay and the capital, Kingston, just south of St. Andrew Parish.

Project Goals and Objectives:

The H-YCNP goals and objectives are presented below. A fuller discussion of the goals and objectives of the HCMP as they related to other programs in Jamaica appears in the attachment. Although the goals of the H-YCNP were stated at the outset of the project, the specific objectives were not. However, all documents suggest that the specific objectives were similar to those of an earlier program, the Elderslie Young Child Nutrition Program (E-YCNP) which served as an ex-officio pilot project of H-YCNP and did list specific objectives.

Goals:

1. To combat malnutrition in young children

2. To reduce excess mortality

Specific Objectives:

1. To further develop the disease and demographic profile

2. To reduce morbidity in children under 48 months of age

3. To reduce mortality among children under 48 months of age

4. To improve nutrition of Hanover children as compared to Boston weight-for-age standards (i.e., reduce incidence and prevalence of malnutrition)

5. To operate at a budget level the community could support

6. To train and to use community health aides (CHAs) to execute community health projects

Study Design:

The following is an edited version of the study design protocol used in the H-YCNP project taken from an internal document prepared by

Dr. D'Souza, Senior Medical Officer (Health), Cornwall County. A summary list of input variables, output measures and outcome measures is also presented.

During the summer of 1972, the Ministry of Health recruited and trained 275 community health aides (CHAs) in the parishes of St. James and Hanover of which 150 community health aides were posted in the parish of Hanover. The aides were given eight weeks of training in basic nursing, first aid, communications, nutrition and family planning, as well as training to give assistance at maternal and child welfare clinics and to identify the health needs of their communities.

In June/July 1973, the Young Child Nutrition Program was introduced in eastern Hanover. After a period of orientation, the aides conducted a house-to-house census. The whole of eastern Hanover was divided into 77 districts corresponding to the house location of the aides, each household being assigned to a specific aide. Voluntary screening sessions were then held, during which demographic and anthropometric data on 90 percent of the children in eastern Hanover under four years of age was obtained and entered on Gomez charts. Those in Gomez grades II and III became part of a treatment group whose homes were visited twice weekly by community health aides to ensure that instructions regarding nutrition were being carried out and to instruct parents in food preparation. Thereafter, the CHA monitored the nutritional status of each child under four years of age in her area by obtaining monthly weights of malnourished children and bi-monthly weights on youngsters in grades N (normal) and I. This information was obtained either at field clinics or home visits.

During the series of 43 field clinics (held monthly), a clinical supervisor (usually a final-year medical student from Cornell University Medical College) would appear on the same day each month and with the active assistance of the CHA would review the current anthropometric status of the children (usually 30-90 children), examine malnourished and other sick children and treat them for minor complaints. Children requiring hospitalization were referred to the hospital, but the emphasis was on preventing hospitalization by (a) nutrition education under the guidance of the Nutrition Officer of the parish so as to educate the people in the use of locally grown, easily available foodstuffs to provide a balanced diet; and (b) providing nutritional supplements, e.g., skimmed milk, CSM, multivitamins, iron, etc., to mothers for their children who fell into grade II or III malnutrition.

This process was repeated in western Hanover beginning in June, 1974, so that by October 1974 a total of 86 field clinics were set up and 6,200 children under the age of four years were enrolled in the program, i.e., 90 percent of a total under four population of 6,600.

Summary of Variables:

Input variables:
1. CHAs (basic medical care and preventive-nutrition services)
2. University faculty support (supervision)
3. Food for Peace supplements
4. Local resources (food families could grow or buy)

Output variables:
1. Number of children between 0-4 years attended

Outcome measures: 1. Percent children 0-4 years malnourished (classified by weight-for-age against Boston standard)

2. Mortality 0-4 years

Validity of Project:

By the time the H-YCNP was initiated, the nature and extent of the nutrition problem in Jamaica was well documented by the disease profiles obtained in the various health projects which preceded the H-YCNP (and which are discussed in the attachment), and by corroborating evidence of research studies.[3,4,5,6] Each of these studies described or effected surveys of random samples or complete village child populations to ascertain the prevalence and grade of malnutrition at a point in time or longitudinally. That malnutrition was not merely a seasonal problem was described in 1969.[7]

The phenomenon that malnutrition works synergistically with infection was first described at length by Scrimshaw, et al.[8] Although death certificates could not identify whether death had been a result of this synergism in Jamaica, malnutrition with or without specific infection has been ascribed as the cause of death or as a contributory factor to death in two-thirds of all child deaths among children 0-4 years of age,[7,8] and child deaths until recently have made up about 50 percent of all Jamaican deaths. Yet, preschool children 0-4 years made up only 20 percent of the population. These figures are comparable to those found elsewhere in the developing world.

Documentation of a nutrition problem in Jamaica, then, was more than sufficient to underscore the need for some action. There are but two observations made below with respect to the specific program approach used to correct the nutrition problem and which reflect upon the validity of the project.

1. The intervention modalities used in the H-YCNP are now familiar ones. Food supplements, local resources, community-level health workers, and nutrition counseling are logical input variables. Yet based on the pilot studies at Elderslie, the evidence that these particular input variables as used in Elderslie were anticedent to changes in outcome measures is not completely clear. For example, the outcome measures for both the Elderslie pilot project and the H-YCNP were prevalence of graded malnutrition and child mortality. Yet, the major findings of the E-YCNP were firstly no change in the prevalence of graded malnutrition, and, secondly, a 50 percent reduction in under-five mortality. It is curious that although the specific objective of the E-YCNP to reduce the prevalence of malnutrition was not met by the input variable(s), project leaders of the H-YCNP did not alter the input variables aimed at dealing with malnutrition prevalence at the start of the H-YCNP.

It might be assumed that program leaders in Elderslie observed that the incidence of malnutrition decreased at Elderslie but that the recovery time for those malnourished had not passed before the end of the study--thus, the persistence in prevalence.

2. Continuing in an examination of the linkage among specific objectives, input variables and outcome measures, it becomes apparent that limited resources precluded the project leaders' efforts to verify

the fulfillment of the specific objectives to use local resources and to operate at a budget within the reach of the local community. For a similar reason the quantity, quality, and availability of local garden products and Food for Peace supplements were not monitored. Finally, maternal and child health and family planning input variables of the HCMP (of which the H-YCNP was a part) were not linked to outcome measures or otherwise evaluated for their impact. These input variables had to be evaluated for their impact qualitatively.

Validity of the Results:

Results from the H-YCNP are presented in Tables 1 and 2 and Figures 1 and 2. These data are of two types: data describing malnutrition and data describing child mortality. These thoughts are offered:

1. The H-YCNP was not blanketed over the entire parish of Hanover overnight. The researchers took this as an opportunity to use to some advantage the western half of Hanover as a control while the program was implemented in eastern Hanover. The project was sequenced so that an initial survey (demographic profile) was completed before the implementation of the program. The sequence was effected first in east Hanover and one year later in west Hanover. This type of control design leaves itself open to criticism particularly in terms of potential time-series error in interpretation. Negating for the moment the potential time-series error, however, that the two phases of the project overlap and are instituted so closely together leads one to believe that the control grouping was satisfactory to demonstrate changes in outcome measures.

Table 1

INITIAL PREVALENCE OF MALNUTRITION†

	EAST*		WEST**	
GOMEZ GRADE	NUMBER	PERCENT	NUMBER	PERCENT
N	1660	57.7	1604	50.1
I	907	31.5	1179	36.8
II	281	9.8	369	11.5
III	31	1.1	48	1.5

Gomez Grades: 1 = 75-90 percent

II = 60-74 percent

III = below 60 percent standard weight-for-age

*July-August 1973

**July-August 1974

†Data reprinted here by permission of Dr. M. Alderman.

Table 2

MORTALITY RATE PER THOUSAND CHILDREN
1-48 MONTHS IN HANOVER PARISH†

	EAST n = 3357	WEST n = 3294
7/71-6/72	13.7 (46)	12.7 (42)
7/72-6/73	15.4 (52)	17.6 (58)
7/73-6/74	☐ 5.6 (19)	13.3 (44)
7/74-6/75	☐ 7.4 (25)	☐ 5.7 (19)
7/75-6/76	☐ 5.6 (19)	☐ 5.7 (19)

☐ = Existence of Hanover YCNP

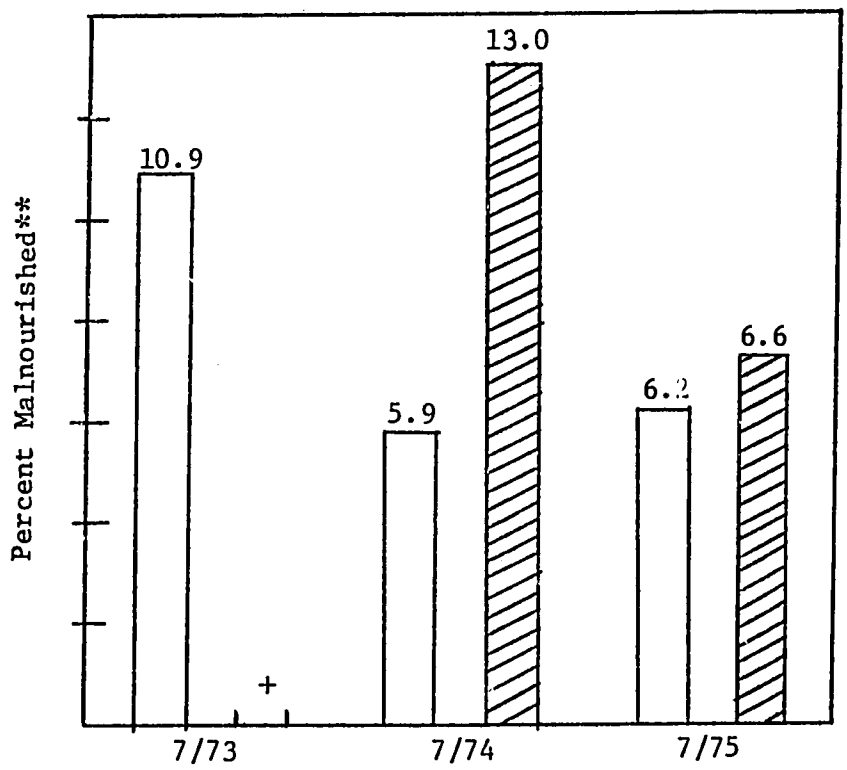
( ) = Number of deaths

The difference between pre and post YCNP years was significant (P<.001)

†Data reprinted here by permission of Dr. M. Alderman.

Figure 1

PREVALENCE OF MALNUTRITION*†



East Hanover

West Hanover

*The declines from 1973 to 1974 and 1975, and those from 1974 to 1975 were statistically significant (P .00005)

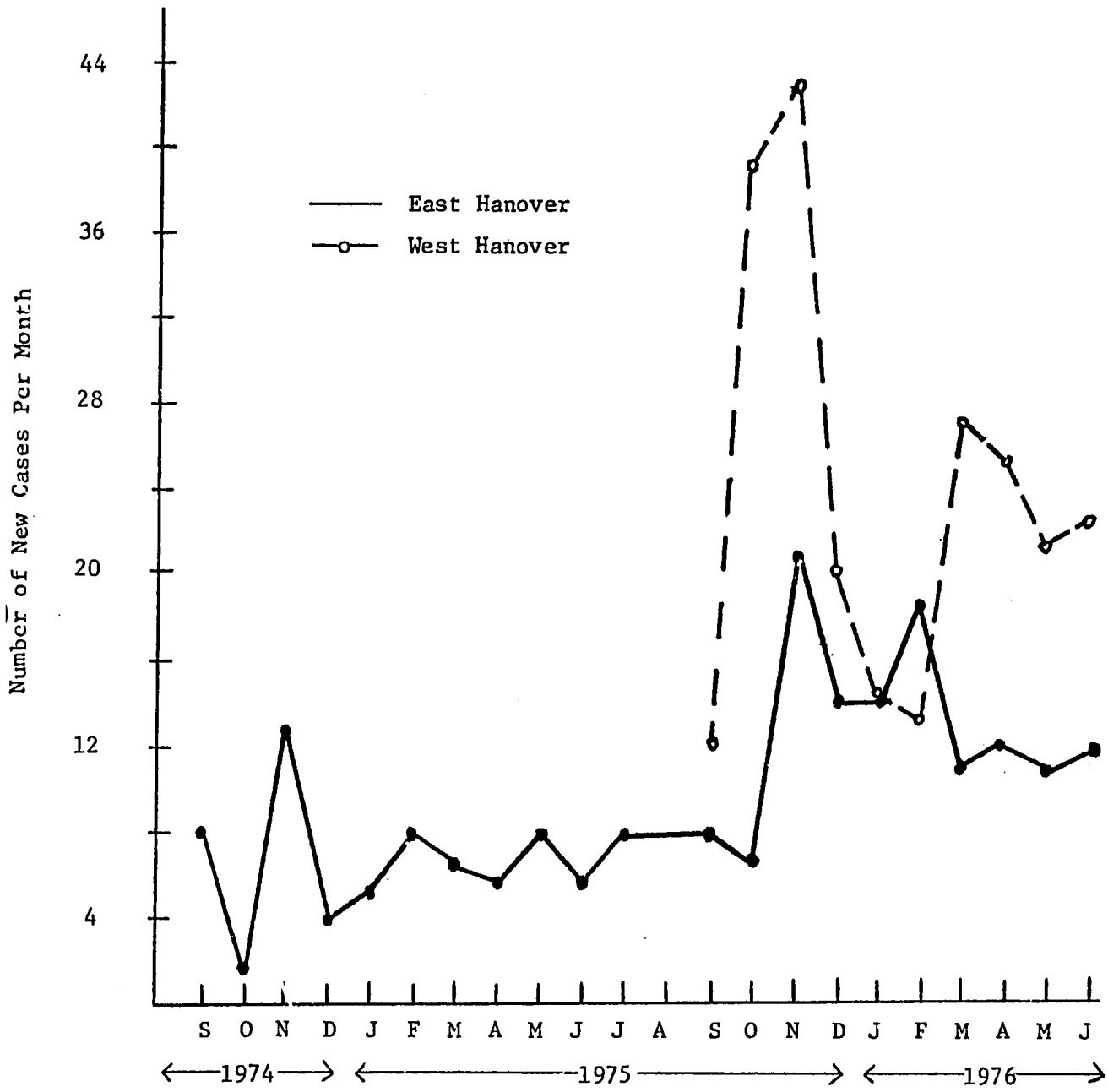
**Percentage of children falling below 75 percent of standard weight-for-age (Gomez Grade II and III)

+ Data not available for West Hanover until 1974 when YCNP was instituted

†Data reprinted here by permission of Dr. M. Alderman

Figure 2

INCIDENCE OF MALNUTRITION†



†Data reprinted here by permission of Dr. M. Alderman.

2. Table 1 and Figure 1 show the changes in malnutrition prevalence observed by H-YCNP researchers. The reductions are impressive but could be reinforced with such information as:

a. Age-specific prevalence in order to determine which children 0-48 months of age are the ones experiencing the reductions in malnutrition prevalence. That age-specific rates are not presented does not necessarily impinge upon the validity of these results, but without this information these data become less useful for future program planning.

b. A knowledge of recent, historical trends in the prevalence of malnutrition prior to the onset of the H-YCNP in both east and west Hanover can do much to assure that a time-series error of interpretation is avoided.

Figure 1 gives an historical overview, indirectly, of only west Hanover. Assuming both east and west Hanover have always had similar rates of malnutrition prevalence, we can assume that west Hanover had a prevalence of grade II and III malnutrition among children under four years of age in 1973 (the year before the onset of the program there) similar to that of east Hanover (i.e., 10.9). In 1974 it was 13.0 as measured. In 1975 it was 6.6 as measured. We do not have three comparison figures for east Hanover starting with 1972, which would be the year before the program started in the east. A trend cannot be surmised from only two points. It is noteworthy that Ashworth and Picou[4] present data which placed the prevalence of grade II and III malnutrition in 1970 among children under four years of age at 12.1 percent for all Jamaica. Other studies[3,6] place "rural" grade II and III malnutrition for this same age group of children at 28 percent during 1968-1974.[4]

Therefore, it is unclear whether the apparently real reductions in malnutrition prevalence observed in 1973-1975 in Hanover are part of an unexpected (i.e., program induced) decline or part of a general decline in child malnutrition which started prior to the onset of the H-YCNP and had continued through the decade.

3. The study population was enumerated separately from the national Jamaican census by door-to-door survey. The survey indicated the under-four population to be 6,651. Even though the subsequent initial screening to determine the disease profile of the children was a voluntary meeting, the disease profile survey attracted 86 percent of east Hanover children (1973) and 97 percent of west Hanover children (1974). This averaged out to 91 percent turnout. This extensive coverage was maintained throughout the course of the project by monthly field clinics and home visits. The nutritional status of all children 0-4 years of age who were initially enumerated was monitored through monthly field clinics to which mothers voluntarily attended. Home visits were made by the CHA to all children 0-4 years of age with grade II or III malnutrition. All children initially surveyed as normal or grade I were encouraged to come to the clinics bi-monthly. The turnout rate for this project is extraordinarily high, but there is no sound reason readily apparent to doubt the figures of the initial survey or the extent of follow-up. If, however, many children who were well at the outset of the study did not attend the clinic but did fall into a malnourished state, the conclusions of the study might be biased in favor of the clinic attenders and could cause underestimation of the prevalence of undernutrition. Nonetheless, extensive population coverage and follow-up was a strong point of this study.

4. That the incidence of malnutrition (Figure 2) did not decrease is not surprising since the input variables (as mentioned in the "Validity of the Study" section) did not include one to address prevention of malnutrition. The study was designed to spot those already malnourished or becoming malnourished. Figure 2 does not specify duration as a parameter of incidence; thus, Figure 2 appears to reflect point prevalence more than it does incidence. In either case, Figure 2 presents data from two different groups in the form of whole numbers not rates.

5. Table 2 attempts to present the changes in 1-48 month mortality among children in Hanover Parish. Although mortality data are discussed in full as part of our discussion of the secondary analysis using our own data, these points about Table 2 are pertinent to the present discussion:

a. The 0-4 year old population of Hanover in 1973-1974 as enumerated by the researchers in baseline surveys was 6,651. The researchers used the same denominators, respectively 3,357 for the east and 3,294 for the west, to calculate mortality in five different 12-month periods. This becomes important because the birth rate decreased during the period 1971-1975; and thus, the 0-4 population decreased during the period 1971-1975 (excluding migratory effects). The data computations carried out by the author do not address births into the study population and thus do not address cohort effects.

b. Mortality data, as was malnutrition prevalence data, is not presented as age-specific rates. Age-specific rates could only serve to clarify the impact of the program.

6. As mentioned in the previous section, FP, MCH, and basic health services (of the HCMP) were not linked to specific outcome measures.

Although the H-YCNP results suggest a program impact on the prevalence of malnutrition, it is difficult to ascribe real reductions to specific input variables of the H-YCNP or the HCMP. This point will be more fully addressed in the next section.

7. The effect of a new regional hospital at nearby Montego Bay in a parish contiguous to Hanover is not clear. This problem, also, is discussed as part of our secondary analysis.

8. The problem of seasonal migration is not addressed by any of the available documents but apparently occurs in Hanover Parish. The effect of this on denominators is not discussed, and would be difficult to assess in any case.

Validity of the Results--A Secondary Data Analysis:

Of concern to those who might desire to draw on the experience of those who conducted the H-YCNP is the limited usefulness of the data in its present form for program planning. Malnutrition prevalence and mortality data are presented in grouped rather than age-specific form. This grouping of data makes it difficult to assess whether reductions observed were confined to certain age groups or spread evenly over several age groups. A further age-specific breakdown of these data can also reassure others that the intervention used in the program could have impacted, logically, upon the specific age group(s) in which the reductions are observed. Additionally, it is important to distinguish between observed reductions as a result of the specific project considered here and those historical declines or trends in mortality and malnutrition prevalence which might have occurred prior to the onset of a specific project and which continued through the project period.

For these reasons, a secondary data analysis was undertaken of the mortality data to obtain age-specific mortality rates. A similar analysis of the malnutrition prevalence data would have been prohibitively costly. However, we feel that our comments about the mortality data are relevant to an understanding of the malnutrition data as well. Our secondary analysis of mortality data was conducted with the cooperation of the Government of Jamaica using an actual count of death certificates on file in the Registrar General's Office in Spanish Town, Jamaica. The Registrar General's Office is the central repository for all such documents and the source of all official vital statistics.

Mortality records were examined of all persons whose death was registered during the period 1971 to 1976 in Hanover, Trelawny, and St. James Parishes. Trelawny Parish was chosen as a comparison to Hanover Parish and was selected based on its similarity to Hanover in population size, geography, type of employment opportunities, and age structure. St. James Parish was examined for reasons soon to be discussed. Tables 3 and 4 summarize the age-specific mortality statistics of Hanover and Trelawny Parishes.

These points should be considered in order to clarify the usefulness of the official vital statistics available from the Government of Jamaica.

1. The mortality statistics published by the Government of Jamaica apparently rest upon reliable information (at least with regard to deaths occurring in children greater than 28 days of age). Yet, the infant mortality rates reported by the Jamaican Government fluctuate beyond expectation on a yearly basis as demonstrated by a review of the officially reported infant mortality rates 1970-1975 for Hanover Parish:

Table 3

AGE SPECIFIC DEATH RATES--HANOVER PARISH, 1971-1975[1]
(1,000)

	0-7 Days	0-28 Days	0-1 Year	1-2 Years	2-3 Years	3-4 Years	1 Month-48 Months
1971	2.80 (5)	5.04 (9)	25.78 (45)	15.24 (26)	4.35 (7)	2.15 (4)	10.49 (73)
1972	1.08 (2)	4.86 (9)	37.26 (69)	17.52 (30)	4.02 (8)	1.34 (2)	14.90 (99)
1973	1.25 (2)	6.24 (10)	25.58 (41)	9.57 (17)	3.13 (5)	2.72 (4)	8.84 (57)
1974	2.59 (4)	5.17 (8)	20.70 (32)	12.35 (19)	0 (0)	1.35 (2)	7.23 (45)
1975	7.79 (11)	9.21 (13)	24.07 (34)	4.05 (6)	2.79 (4)	1.30 (2)	5.29 (31)

[1] Note that it is the opinion of the authors that 0-28 day deaths are underreported in this parish. All rates are calculated using denominators generated in a life table using adjusted live births from the reference year 1970 (a census year).

( ) refers to the number of deaths in that time period.

Table 4

AGE SPECIFIC DEATH RATES--TRELAWNY PARISH, 1971-1975[1]
(1,000)

	0-7 Days	0-28 Days	0-1 Year	1-2 Years	2-3 Years	3-4 Years	1 Month-48 Months
971	11.78 (24)	14.21 (29)	38.71 (79)	6.50 (11)	4.14 (7)	1.63 (3)	9.77 (71)
972	8.74 (17)	10.28 (20)	28.80 (56)	9.19 (18)	1.27 (2)	0 (0)	7.94 (56)
973	5.37 (10)	8.59 (16)	19.86 (37)	5.89 (11)	1.64 (3)	2.01 (3)	5.41 (38)
97[illegible]	5.94 (10)	11.88 (20)	26.14 (44)	5.03 (9)	3.44 (6)	.59 (1)	5.10 (40)
975	5.64 (10)	9.03 (16)	19.75 (35)	3.72 (6)	3.00 (5)	1.24 (2)	4.79 (32)

ote that it is the opinion of the authors that 0-28 day deaths appear to be more accurate han those obtained in Hanover. All rates are calculated using denominators generated in a ife table using adjusted live births from the reference year 1970 (a census year)

)refers to the number of deaths in that time period.

Year	Rate*
1970	40.1
1971	26.3
1972	30.2
1973	47.4
1974	17.5
1975	10.6

Official rates from other parishes reflect a similar oscillating pattern.

On our visit to the Registrar General's Office (RGO), it became apparent that these fluctuations were readily explainable. Frequently, a death which occurs in one year is not recorded with the central RGO until the following or even subsequent years. A variety of reasons delay deaths registered at a local level from being registered at the central RGO, but most deaths in children over 1 month of age are eventually registered in Spanish Town where the RGO is located. Up to 60 percent of deaths which occurred during 1970-1975 were registered in some year other than the one in which the death occurred. Thus, official publications reflect a rate of death registrations in any given year irrespective of the actual year of death. It should be noted that the Government of Jamaica is aware of this difficulty and is addressing the problem. Apparently this problem does not occur with the registration of births. Since death certificates do provide the actual date of and age at death, it was possible to review all death certificates for the parishes of interest for the years 1971-1976 in order to recalculate age-specific death rates.

2. Additionally, with regard to mortality rates, all deaths are registered in the parish where the death occurred and are included in

*per 1,000

the mortality rate of that parish. Mortality rates are not assembled according to the deceased person's usual place of residence. A child resident of Hanover Parish who dies in the Cornwall Regional Hospital in St. James Parish would be included in the numerator of the mortality rate of St. James Parish. Indeed, the Cornwall Regional Hospital opened in April 1974 and began drawing child patients in 1974 and 1975 from Hanover (and Trelawny)--the second year of the H-YCNP in eastern Hanover and the first year of the project in western Hanover. The secondary analysis corrected the mortality rates for this problem. It is of interest that during 1971-1976 no Hanover death certificates were issued for a child from some other parish, while St. James Parish had registered several death certificates for children whose usual place of residence was some parish other than St. James.

Both comments 1 and 2 are more important in understanding the official mortality rates rather than understanding those rates observed by those who conducted the H-YCNP. Indeed, those conducting the H-YCNP knew about deaths in Hanover far more quickly than did the central RGO.

In conjunction with the age-specific mortality rates obtained from the secondary analysis (refer to Tables 3 and 4), we offer these thoughts about the validity of these data when compared to the mortality rates observed in the H-YCNP.

1. During 1973-1975, the time when the H-YCNP was in effect, a 60 percent reduction in 1-48 month mortality was observed in Hanover Parish. The secondary analysis indicated that a 50 percent reduction occurred <u>but during the period 1971-1975.</u>

The mortality data of the H-YCNP and that of the secondary data analysis diverge for identifable reasons. The probable reason for diverging rates is that the rates cited in Table 2 used a constant denominator obtained in 1973 during the survey census for the Hanover project to calculate the mortality rate for each year 1971-1975. Since births apparently declined from 1970-1975, use of an inflated denominator would cause mortality rates to be underestimated after 1973 and overestimated before 1973. The rates calculated in the secondary analysis utilized denominators projected from the 1970 census figures. Since the H-YCNP did not begin until 1973, it is unclear how numerators for yearly rates for the July 1971 to June 1973 period (Table 2) were obtained. This too would cause the H-YCNP and secondary data analysis results to diverge. It should be reassuring that even though the researchers of the H-YCNP used staggered calendars (i.e., July to June), and we used regular calendar years, both the H-YCNP and the secondary analysis (which cites figures corrected for St. James deaths) cite quite similar numerators.

2. Criticism which implies that reductions in child mortality observed in the H-YCNP are as a result of severely ill children dying in Cornwall Regional Hospital in St. James Parish and not tabulated as part of those deaths in Hanover appear to be unfounded. While many children from Hanover Parish did die in Cornwall Hospital, their deaths were apparently added to the running tally of deaths kept by the H-YCNP. This was supported not only by the similar numerators that we obtained independently, but also by the fact that the H-YCNP actually recorded slightly more deaths than we uncovered by a complete search of death certificates. Additionally, although Hanover children died in St. James Parish each year (even before the hospital was built), this number never

was more than eight except in 1975. In that year the number rose to 17. It seems that the Cornwall Hospital did not attract increasing numbers of sick children until after the H-YCNP ended in 1975.

3. Although 1-48 month mortality was halved in Hanover Parish during the years 1971-1975, a similar decrease in mortality was seen in Trelawny Parish during the same years when neither a Young Child Nutrition Program nor CHAs were active in Trelawny (see Table 4).

4. Table 3 shows that significant reductions appear to be confined to the 1-2 year age group. This would be the expected age group to benefit from the kind of interventions offered by the H-YCNP. However, almost 50 percent of the 1-2 year age group reduction occurred between January 1971 and January 1973, the two years before the onset of the program. While Table 3 also shows a 19 percent decline in 0-1 year mortality during the period 1973-1974 in Hanover, it is difficult to attribute this to a program effect since the 19 percent decline is followed in 1975 by a 19 percent increase in 0-1 mortality at a time when the program was still in effect.

5. Table 4 shows that Trelawny experienced a similar pattern of reduction in 1-2 year mortality, although of a lesser order of magnitude.

6. All mortality statistics usually suffer from underreporting. As noted on the tables, we have identified areas of underreporting. Personal communication with Dr. K. Standard of the University of the West Indies revealed that in the Kingston area, there is significant underreporting of perinatal deaths. Because of the unusually low 0-28 day mortality rates, it is likely that Hanover and Trelawny Parishes' mortality statistics suffer from underreporting of perinatal deaths. Our discussions with local health personnel in Hanover seem to support this notion.

7. Misallocation of deaths to specific age groups might be a problem. There is no quick way to verify the age of death of children reported on the death certificate. What effect this would have on mortality statistics is questionable.

8. Children 28 days to 2 years of age accounted for the majority of deaths in both Hanover and Trelawny. The relative magnitude of the causes of death remained virtually unchanged during the period 1971-1975 except in one category. This category, broncho-pneumonia, malnutrition, gastroenteritis, and pneumonia in some combination accounted for the large majority of deaths in these children 28 days to 2 years of age. Yet, similar reductions in death from these causes (broncho-pneumonia, malnutrition, gastroenteritis, and pneumonia) during 1971-1975 occurred in both Hanover and Trelawny for all age groups except 1-2, for which Hanover benefitted from a somewhat sharper reduction than did Trelawny. However, about 50 percent of this reduction (in both Hanover and Trelawny) occurred prior to the onset of the H-YCNP.

Our secondary data analysis of mortality in Hanover as presented, falls short in two ways. Firstly, by not breaking the data down into time periods similar to those used in the study, it is possible that a program effect might be washed out, although we feel that if this were the case, the program effect could not have been very large to begin with. Secondly, further masking of an effect might occur as a result of not breaking deaths down according to east Hanover versus west Hanover as the authors have done. Table 5 has been calculated in an attempt to correct for these deficiencies in our analysis. There is discrepancy between the numbers of deaths (numerators) and rates shown in Table 5 as compared to Table 2 for at least three reasons.

Table 5

MORTALITY RATE PER THOUSAND CHILDREN 1-48 MONTHS
IN HANOVER PARISH
(As Recalculated for Secondary Analysis)[1]

	EAST	WEST
7/71-6/72	10.1 (37)	11.7 (42)
7/72-6/73	9.4 (33)	14.8 (51)
7/73-6/74	5.1 (17)	13.4 (44)
7/74-6/75	4.4 (14)	5.4 (17)

[1]All rates are calculated using denominators generated in a life table using adjusted live births from the reference year 1970 (a census year).

( ) = Numbers of deaths

= Existence of program

1. Thirty-seven deaths were deleted from Table 5 because of a lack of information needed to place them as having died in east or west Hanover or during a specific month of the year.

2. Thirteen more deaths were tallied in the H-YCNP than we were able to find certificates for in the central Registrar General's Office.

3. Table 5 does not include any deaths registered after 1976 for persons who died before 1976.

4. Rates calculated in Table 2 and 5 use different denominators: the former using a constant denominator for all time periods.

The magnitude of necessary data deletions cited in the preceding comments should temper the interpretation of these data in Table 5, especially since over half of the deaths cited in "1" occurred in the years 1974 and 1975. These are critical years since it is during these two years that a program effect would show itself. It might be argued that even if all the unaccounted deaths occurred evenly spaced geographically and in time during 1974 and 1975, the observed rates still show an accelerated reduction in the child mortality rate during the period when the program was in effect. Nonetheless, viewed in the context of similar declines in mortality during the two years before the H-YCNP and in Trelawny (see age-specific rates in Tables 3 and 4), it would be difficult to attribute anything more than a modest mortality reduction in Hanover to the H-YCNP.

Under the sections dealing with validity, we have indicated that if real reductions in the measured parameters did occur, it would be difficult to attribute these to specific input variables of the H-YCNP because the contribution of several input variables could not be documented. The H-YCNP investigators owe any reductions in child mortality and

malnutrition prevalence to surveillance and education rather than other program inputs. From an evaluative perspective and within the framework of epidemiological research, clinical or other impressions alone are tenuous evaluative tools. Nonetheless, impressions based on sound logic govern day-to-day decisions in a service program and will be entertained here. The project leaders feel that the medical care offered as part of the H-YCNP, specifically the provision of minor medications while a "popular feature of the field clinic and probably enhanced attendance, the nature of the diseases being treated and the methods for their diagnosis provide little reason to believe that any specific chemotherapy had a significant impact" to cause the observed reductions in mortality or malnutrition prevalence.(9) The authors also suggest that it was their experience that food supplements, when available, were added to the "family pot" rather than reserved for the malnourished child. The supplements' main effect according to the investigators at Hanover was to serve in emphasizing the educational effort. The possible effect of other variables including family planning is felt by the authors of the H-YCNP to be minimal but is not discussed at length.

The salient features, then, of the H-YCNP were according to H-YCNP investigators, identification of malnourished children and the institution of home visits to those homes with malnourished children for the purpose of informing the parents of the situation and for passing on nutritional information and supplements when available. One might conclude that simply identifying malnourished children and making parents aware of the situation can lead to reductions in the prevalence of malnutrition and child mortality. In a country which is relatively affluent when

compared to other developing nations, this conclusion should be explored. However, in the absence of several outcome measures in this project and in light of our secondary analysis, it can only be a tentative one.

Study Weaknesses:

An attempt has been made to point out the weaknesses of the study particularly in the sections that deal with validity. A brief summary list is presented below.

1. Methods used by the project planners to ascertain that there was a need for more medical manpower were not described.

2. The effect of opening a major hospital in contiguous St. James Parish (Cornwall Regional Hospital) is not clarified fully by the main study. However, our secondary analysis suggests that this hospital probably did not affect the recording of deaths among Hanover children who happened to die in St. James Parish or any other parish.

3. Because the financial support for evaluation during the program was not available, linkage between all objectives, input variables and outcome measures could not be established.

4. Age-specific data were not tabulated and morbidity data were not collected.

5. No cost records were kept to facilitate cost/effectiveness study.

6. Mortality rates were calculated using a constant denominator for each year of a five year period while birth rates were declining.

Applicability:

It is difficult to ascertain the technical generalizability of this project since it is a concept which was at its inception a citizens' group idea rather than a government designed and pronounced program (August Town/Hermitage).

Conclusion:

The H-YCNP was intended to effect changes in the rate of mortality and the prevalence of malnutrition among children under the age of four years. With regard to child mortality, our evaluation indicates that Hanover Parish experienced historical, real reductions as did the control parish of Trelawny from 1971-1975. However, it appears that although the magnitude of these reductions were similar for both parishes, the reductions may have been somewhat accelerated in Hanover during the period in which the program was in effect (1973-1975). Thus, declining trends in child mortality are probably due in part to general socio-economic development on the islands as well as to the specific program evaluated here. It is difficult to ascribe to specific input variables of the H-YCNP the accelerated reductions observed in child mortality during the period of the program (1973-1975), since not all of the input variables were quantified at the outset, during or at the end of the program.

It seems reasonable that if historical trends in the prevalence of malnutrition could be examined, they too would mimic the trends seen in the pattern of child mortality--especially since mortality and malnutrition are allied so closely in the developing world.

Attachment 1

Figure 1 shows, diagrammatically, the chronology of the various health projects undertaken in Jamaica between 1967 and 1975.

The reader should be aware that each of the following projects discussed was effected in western Jamaica either Hanover or St. Elizabeth Parish in Cornwall County except for the Hermitage/August Town pilot project which was carried out in St. Andrew Parish (just outside of Kingston) in Surrey County, located on the eastern third of Jamaica.

Figure 1

Jan. 1967	Jan. 1968	Jan. 1969	Nov. 1969	Oct. 1970	Dec. 1972	Jan. 1973	June 1973	June 1974
	August/Town Hermitage Community Health Aide CHA) Initiative		Elderslie Rural Health Project Starts	Elderslie Young Child Nutrition Project Starts	Elderslie Projects Complete	CHA Training Starts for Hanover Community Medicine Project and for St. James Parish	East Hanover Young Child Nutrition Program	West Hanover Child Nutrition Program

The Health Projects:

The Health Ministry of Jamaica concluded in 1966-1967 that there was a need for more medical personnel in Jamaica. It is not clear how it was determined that the then current number of personnel was inadequate. We will not attempt to second guess this determination. However, an attitude prevailing in 1966 (as well as today) was expressed by Dr. K. Standard at the Symposium on the Role of the Community Health Worker, Arlie House, Virginia, October 1977:

> "One of the biggest problems in the organisation and management of the health services is the lack of adequate coverage of the population needing service. There are many reasons for this situation, but among them is the need for more staff. It is, therefore, necessary to make sure that the available staff is properly utilised and that efforts are made to increase the health manpower. It was in this context that the Community Health Aide programme was developed in Jamaica."

Meanwhile, in two villages outside Kingston (Hermitage and August Town), towns with no resident doctor, community associations and community health committees were actively planning and participating as volunteers in community health projects using the village clinic as a focus of operation. Although the University of the West Indies did provide some health care for these towns, the communities eventually decided that the community volunteers or community health aides (CHAs) working in the clinics should have some training. A pilot training program was established for both of these towns in 1967.

From this pilot study it was decided that CHAs could be used to help define the health needs and problems of an area. Thus, in November, 1969, the Government of Jamaica, officials of Elderslie in St. Elizabeth Parish, Cornwall University, and University of the West Indies collectively decided to transplant the Hermitage/August Town idea in the form of a second pilot project to Elderslie. They called it the Rural Health Project.

The goals of this project were to use CHAs to (1) evaluate the health needs and resources of Elderslie, and (2) to design appropriate systems of health delivery.

Specific Objectives:

1. Train CHAs using the Hermitage/August Town model
2. Use CHAs to execute community health projects
3. To obtain basic health data (this did not include gathering mortality data--only its tabulations as received from government sources)
4. To define the health objectives for Elderslie

In October of 1970 the preliminary training of CHAs was completed and a basic framework in which they could work was established. Preliminary data (not available) and observations led the leaders of the program to believe that 0-4 mortality was a significant problem about which they could do something. A closer look at the 0-4 mortality (other independent studies discussed in text) revealed that child malnutrition was a major contributing cause of the death of children 0-4 in Jamaica.

Therefore, in October 1970, the Young Child Nutrition Program (YCNP-Elderslie) was established as a focus of attention and action for CHAs. The goals of the YCNP-Elderslie were:

1. Development of improved young child nutrition
2. To improve the health and welfare of youngsters using local resources

Specific Objectives:

1. To further develop the disease and demographic profile
2. To reduce morbidity among children under 4 years of age
3. To reduce mortality among children under 4 years of age
4. To improve nutrition of Elderslie children as compared to Boston weight-for-age standards (i.e., reduce incidence and prevalence of malnutrition)
5. To operate at a budget level the community could support
6. Use health educators

The YCNP-Elderslie had two major findings:

1. Mortality decreased,
2. Prevalence and incidence of malnutrition appeared to remain constant.

These results were used to substantiate the impact of the YCNP-Elderslie. In 1973, it was decided to institute a YCNP in Hanover Parish as part of the responsibility of the CHAs who would be trained in the new Jamaican tradition of clinic assistant and public health advocate.

The goals here were similar to those of Elderslie, but stated in such a way as to make it clear that nutrition work, although the main thrust of the project, was not the only duty of the CHA. It was the intent of the program leaders that CHAs were to be community-based

workers whose responsibilities comprised MCH, FP, nutrition and first aid advice/services for the populous.

Goals:

1. To organize a community-based system of health workers
2. To combat malnutrition in young children — specified goals of nutrition component
3. To reduce excess mortality

Again the specific objectives of the YCNP-Hanover are assumed by us to be similar to those of YCNP-Elderslie.

In the summer of 1973, the CHA program was expanded to St. James Parish. All CHA work to this point had been aimed primarily at young child nutrition. On expansion to St. James Parish, the project became known as the "Cornwall County Community Health Project" which refined the original intent and goals of the Hermitage/August Town model. An even more intense effort was made to re-recognize the non-nutrition components of the program as had been attempted to Hanover. This can be seen by the goal statement (a composite of several statements in the internal documents).

Goals:

To train and use CHAs with responsibility for the delivery of MCH, FP, nutrition services as an integrated part of first link basic health services. All other goals were similar to those of the pilot projects but flawed from this integrated approach.

Specific Objectives:

A. Health Status of the Community, 1980

The specific objectives established for the maternal and child health,

family planning, and nutrition services for the county of Cornwall for the five years, 1976-1980, are:

1. To provide adequate antenatal care to 90 percent of pregnant women (14,000 individuals);
2. To reduce the percentage of deliveries unattended by trained health personnel to 0;
3. To provide adequate postnatal services to 70 percent (12,375) of newly delivered women;
4. To have at least 33 percent of the women of reproductive age groups (15-44 years) as continuing users of family planning services (30,000);
5. To provide adequate preventive health services to 90 percent (27,500) of children under two years of age and to 70 percent (32,750) of children between 2-5 years of age;
6. To achieve adequate immunization coverage for 80 percent (61,500) of children under five years of age;
7. To provide nutrition surveillance services for 90 percent (27,500) of children under two years of age.

By providing the above services, it is hoped to:

1. Reduce maternal mortality from 14/10,000 to 7/10,000;
2. Reduce maternal morbidity and complications associated with pregnancy by 50 percent (reduce hospital admissions from 2,000 to 1,000);
3. Reduce incidence of anemia in pregnant women by 90 percent (11,150 cases);
4. Reduce fertility in females (15-44 years) from 180 to 150;

5. Reduce birth rate from 30.6/1,000 to 25/1,000;

6. Reduce neonatal death rate from 19 to 15/10,000 live births;

7. Reduce infant mortality rate from 26 to 20/10,000 live births;

8. Reduce incidence of malnutrition grades II and III by at least 60 percent (30,000 children).

B. Health Care System Objectives (not listed in report)

Appendix 4

VITAMIN A SUPPLEMENTATION

(THE ICHAG STUDY)

A longitudinal prospective study into the effects of periodic administration of massive doses of vitamin A on ocular pathology, night blindness, other specific child morbidities, and child growth.

Investigator:

D.P. Sinha, Department of Maternal and Child Health, School of Hygiene and Public Health, The Johns Hopkins University

Supporting Institutions:

The Department of Pathobiology and the International Center for Medical Research, School of Hygiene and Public Health, The Johns Hopkins University

Discussion with Investigator:

Although extensive discussions were held with the principal investigator, no site visit was undertaken as the project had been terminated by the time this evaluation was undertaken.

Review of Published Material:

1. The Children of Ichag, a Longitudinal Study of Health and Disease in Rural West Bengal (Sinha, D.P.), Doctoral Dissertation, School of Hygiene and Public Health, The Johns Hopkins University, Baltimore, Maryland, May 1976.

2. Seasonal Variation in the Signs of Vitamin A Deficiency in Rural West Bengal (Sinha, D.P. and Bang, F.B.), The Lancet ii:228, 1973.

3. The Effect of Massive Doses of Vitamin A on the Signs of Vitamin A Deficiency in Preschool Children (Sinha, D.P. and Bang, F.B.), American Journal of Clinical Nutrition 29:110, 1976.

4. The Effect of Massive Doses of Vitamin A on the Growth and Illness Pattern of Preschool Children (Sinha, D.P. and Bang, F.B.), submitted to American Journal of Clinical Nutrition.

Secondary Data Analysis:

In order to clarify the effect of vitamin A on growth, extensive secondary analyses were performed on unpublished data made available by the principal investigator.

Study Objectives:

1. To confirm the previous observation that periodic massive doses of vitamin A can prevent signs and symptoms of vitamin A deficiency (Bitot spots and night blindness).

2. To assess the effect of massive doses of vitamin A on illness patterns of children.

3. To assess the effect of massive doses of vitamin A on physical growth.

Study Design:

The study was carried out in two phases each lasting a period of twelve months. The first phase (October 1971-September 1972) was the

observational phase. During this period baseline levels of vitamin A deficiency signs and symptoms, incidence and prevalence of infectious illness, dietary patterns, and the nutritional status of the preschool child population were established. In the second phase (October 1972-September 1973), half of the children served as controls, while the other half were given massive doses of vitamin A at four monthly intervals. The predetermined indicators of child health were measured in both groups at regular intervals.

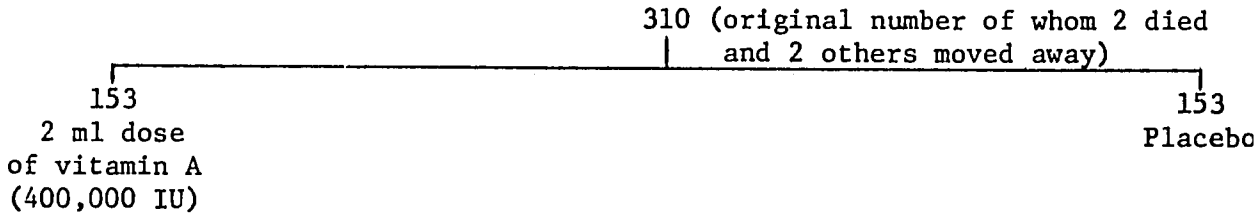
A total of 310 children between 2 and 54 months formed the study population during the first twelve months (phase 1). Data collection on a continuing basis comprised:

1. Weekly morbidity history to determine incidence, nature and duration of illness by trained paramedicals. Once every four weeks the survey was done by a pediatrician (principal investigator) who also complemented the survey by a physical examination, including examination for signs of vitamin A deficiency. During the weekly morbidity history taking, mothers were asked specifically about night blindness in their children. If the mother's response suggested that the child suffered the signs of night blindness, the condition was verified by asking the child to pick out a certain object in the dim evening light.

2. Collection of dietary history data by trained paramedicals every week during the home visit.

3. Anthropometric measurements were taken in each quarter of the year.

In the second phase of the study, the children were divided into two groups each with 153 children matched by age, sex, socio-economic status, and playmate contacts. As indicated in the figure below, half the children received doses of vitamin A; the other half, placebo doses.



Vitamin A was given three times, four months apart, during this phase starting in January 1973 in a double blind experiment. Data collection proceded as during phase I. Children in either group developing progressive xerophthalmia were treated with vitamin A.

Data from both phases of the project were grouped (24 months of data) into eight quarters.

Results:

A. Primary Data Analysis (by principal investigator)

1. Night blindness

a. Complete elimination of night blindness, and prevention of new cases of Bitot's spots in statistically significant numbers of children.

b. No effect on already formed Bitot's spots.

c. No preventive effect on reappearance of Bitot's spots on those children who had this sign in the previous year.

2. Morbidity

a. There was no difference in the prevalence of upper respiratory tract infection in the two groups.

b. There was a significant difference ($P < .01$) in conjunctivitis rate between the two groups during February, March, and April; but during an outbreak of conjunctivitis during summer months, the difference was no longer significant.

c. No difference in prevalence of diarrheal disease.

d. No difference in skin disease and vitamin B deficiency signs.

3. Post-measles effects

In 40 cases of measles, there was no difference in incidence between the groups; however, associated complications such as pneumonia, diarrhea, and eye discharge were significantly higher in the placebo group.

4. Varicella

During a chickenpox outbreak in the year following completion of the study (1974), the percentage of children developing the disease was almost twice as high in the vitamin A group as in the placebo group. This difference was on the border of statistical significance.

5. Growth

For this part of the analysis only children were included on whom anthropometric measurements (weight, height) were available in two consecutive quarters over the last twelve months' period. Children in both the vitamin A supplemented and control groups were classified according

to sex and three nutritional groups and their change in weight-for-height-for-age was monitored at three monthly intervals over the 24-month period. According to initial results obtained by the principal investigator he concluded:

> "The effect of massive doses of vitamin A on the growth of children is shown in Figure 1. The two groups were growing identically prior to receiving vitamin A or the placebo. Administration of vitamin A did not seem to affect the growth of the well-nourished children in either group. The percentage of severe PCM children declined in both the groups during January-March after the first dose but during the April-June period the rate of severe PCM increased significantly in those who received vitamin A supplement, and declined slightly in the next quarter. The differences were apparent in both sexes but were more pronounced in girls than boys (Figures 2 and 3)."
>
> "Administration of massive doses of vitamin A did not change the growth pattern of the children who were well nourished. During the January-March period when there was adequate food after the single harvest, severe PCM declined in both the groups, but when food was in short supply the numbers of children in the supplemented group who developed severe PCM increased sharply. The marked differences in the two sexes during the scarcity season may have been due to the practice of preferential feeding of boys in this culture. It is suggested that in the presence of optimum food both the supplemented and non-supplemented groups improved nutritionally, but during the season when food was scarce, the supplement had temporary adverse effects on nutritional status."
>
> "Since the massive dose schedule seems to be effective in controlling xerophthalmia and will apparently be an established procedure in countries where vitamin A deficiency is endemic, there is urgent need to determine whether the side effects of massive doses which are indicated in the Ichag study will be seen elsewhere. Both the adverse and the beneficial features of this regimin should be clearly identified."

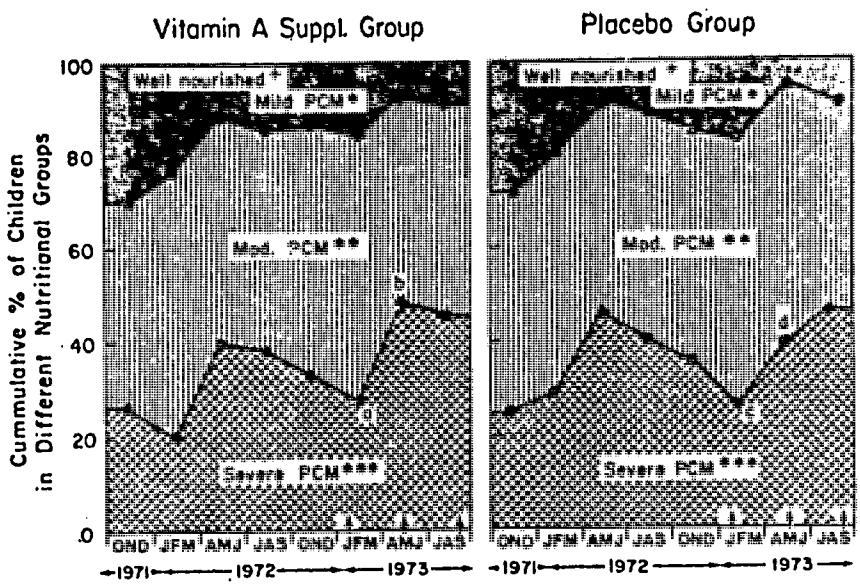
B. Secondary Data Analysis--Results

The last finding that large doses of vitamin A affected growth seemed least conclusive yet most important from a policy-making point of view.

Figure 1

DISTRIBUTION OF NUTRITIONAL LEVE

IN VITAMIN A SUPPLEMENTED AND CONTROL GROUPS



*>80 percent weight-for-age

**70-80 percent weight-for-age

***<70 percent weight-for-age

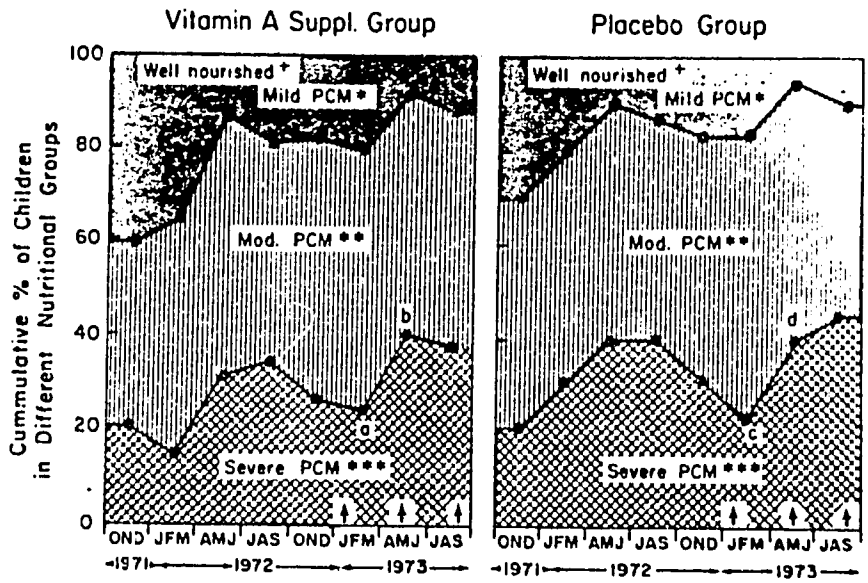
↑Administration of vitamin A

Figure 3

DISTRIBUTION OF NUTRITIONAL LEVELS

IN VITAMIN A SUPPLEMENTED AND CONTROL GROUPS

(Male Children)



*>80 percent weight-for-age

**70-80 percent weight-for-age

***<70 percent weight-for-age

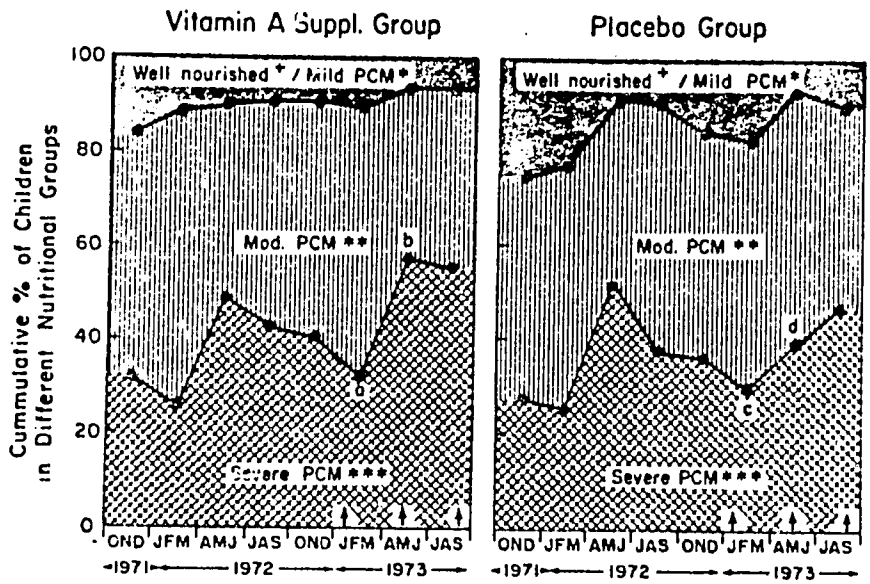
↑Administration of vitamin A

Figure 2

DISTRIBUTION OF NUTRITIONAL LEVELS

IN VITAMIN A SUPPLEMENTED AND CONTROL GROUPS

(Female Children)



*>80 percent weight-for-age

**70-80 percent weight-for-age

***<70 percent weight-for-age

↑Administration of vitamin A

For this reason the original data on which the preliminary conclusions were based were re-examined with the permission and in consultation with the principal investigator. Those data resulting from the secondary analysis are shown in Tables 1 and 2. These data show:

1. Initially (October-December 1971) there were more males in the well-nourished (>80 percent weight-for-height-for-age) group in both vitamin A supplemented and placebo subgroups than females (approximately 48 percent vs. 38 percent); the proportion of children below 70 percent were similar in male (16 percent) and female (12 percent) children.

2. Over the subsequent 21 months the proportion of males and females in supplemented groups above 80 percent progressively declined from approximately 55 percent to 23 percent (approximately 1.5 percentage point decline per month) in males, and from approximately 34 percent to 10 percent (1 percentage point decline per month) in supplemented females. A similarly large decline in the percentage of children above 80 percent occurred also in the nonsupplemented groups.

The proportion of male children below 70 percent rose from approximately 10 percent to 22 percent (0.5 percentage point per month) in both supplemented and from 17 percent to 23 percent in nonsupplemented groups; and from 14 to 37 percent in supplemented females and from 12 percent to 25 percent in control female children.

3. In vitamin A supplemented female children, the proportion of those above 80 percent of the weight-for-height-for-age declined from 34 percent to 10 percent (1 percentage point per month) and the proportion of the supplemented females below 70 percent increased from 14 percent to 37 percent (1 percentage point per month).

Table 1

WEIGHT-FOR-HEIGHT-FOR-AGE OVER A 24 MONTH PERIOD

(Males)

Nutritional* Status		1971 1st Qtr. Oct-Dec	1972 2nd Qtr. Jan-Mar	1972 3rd Qtr. Apr-June	1972 4th Qtr. July-Sept	1972 5th Qtr. Oct-Dec	1973 6th Qtr. Jan-Mar	1973 7th Qtr. Apr-June	1973 8th Qtr. July-Sept
Vitamin A Supplemented Children									
>80	n	39	42	23	22	24	27	19	18
	%	52.7	54.5	29.5	27.5	30.4	34.6	23.5	22.5
70-80	n	28	27	39	46	48	46	47	45
	%	37.8	35.1	50.0	53.8	60.8	59.0	58.0	56.3
<70	n	7	8	16	12	7	5	15	17
	%	9.5	9.1	19.2	15.0	8.8	6.4	17.3	21.3
						← Vitamin A Supplemented			
Control Children									
>80	n	33	42	16	22	21	32	14	18
	%	50.0	52.5	20.8	27.2	29.6	42.7	17.9	22.8
70-80	n	26	24	46	44	34	33	46	43
	%	39.4	30.0	59.7	54.3	47.9	44.0	59.0	54.4
<70	n	17	14	15	15	16	10	18	18
	%	10.6	17.5	19.5	18.5	22.5	13.3	23.1	22.8

*Weight-for-Height-for-Age

Table 2

WEIGHT-FOR-HEIGHT-FOR-AGE OVER A 24 MONTH PERIOD

(Females)

Nutritional* Status		1971 1st Qtr. Oct-Dec	1972 2nd Qtr. Jan-Mar	3rd Qtr. Apr-June	4th Qtr. July-Sept	5th Qtr. Oct-Dec	1973 6th Qtr. Jan-Mar	7th Qtr. Apr-June	8th Qtr. July-Sept
Vitamin A Supplemented Children									
>80	n	21	24	11	14	15	16	9	6
	%	33.8	34.3	15.7	20.9	22.7	25.8	13.8	9.6
70-80	n	33	36	41	39	40	38	36	34
	%	53.2	51.4	58.6	58.2	60.6	61.3	55.4	54.0
<70	n	8	10	18	14	11	8	20	23
	%	12.9	14.3	25.7	20.9	16.7	12.9	30.8	36.5
						← Vitamin A Supplemented →			
Control Children									
>80	n	28	33	13	19	21	25	14	16
	%	43.8	50.0	19.7	27.5	31.3	39.1	21.9	22.5
70-80	n	29	25	38	33	39	29	37	37
	%	45.3	37.9	57.6	47.8	46.3	45.3	57.8	52.1
<70	n	7	8	15	17	15	10	13	18
	%	10.9	12.2	22.7	24.6	22.3	15.6	20.3	25.3

*Weight-for-Height-for-Age

It seemed important to investigate further these findings for the obvious program implication that vitamin A supplementation might act as a growth retarding factor at low levels of nutrition. Multiple linear regression was used to clarify this implicitly stated hypothesis.

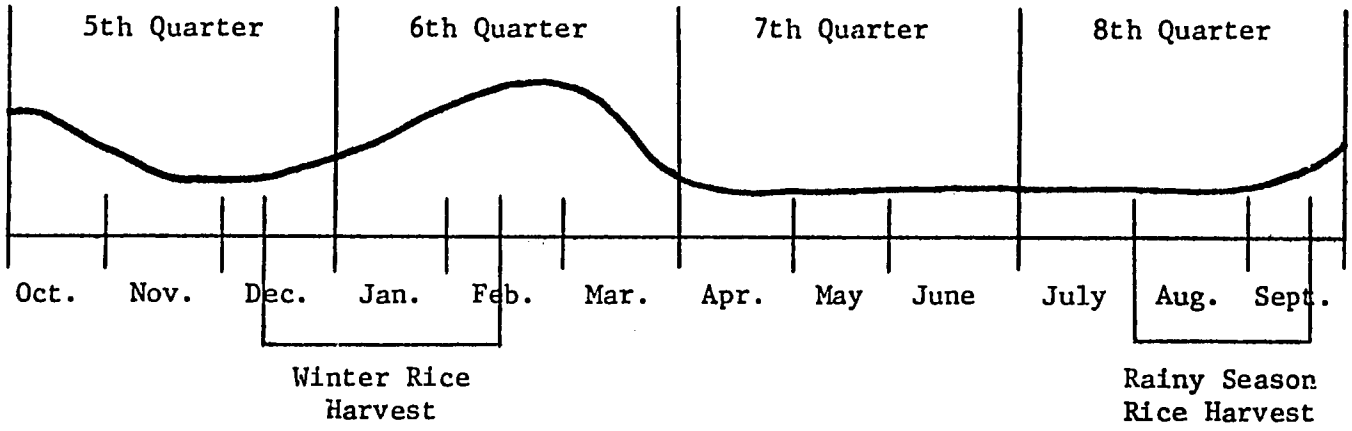
The difference in weight-for-height between two quarters was used as the dependent variable and sex, weight-for-height and height-for-age at the beginning of the interval; age, exact duration between the two measurements, administration of vitamin A (as a categorical variable), and interaction variables for vitamin A and weight-for-height and vitamin A and sex were used as independent variables.

The annual rice harvests usually occur in December, January and August and September; hence, nutritional status during the last and first quarters of the year are relatively better than during the other quarters. From the fifth to the sixth quarters children enter a period of relative food availability which decreases from the sixth to the seventh and partly through the eighth quarters, as shown in Figure 4.

The combination of anthropometric variables selected exactly describes the nutritional status of each child at the outset of each interval as it allows, for instance, to differentiate between children of recent and concurrent undernutrition (tall and low weight-for-height--wasted); long-term and concurrent undernutrition (short and low weight-for-height--wasted and stunted); earlier, presently compensated undernutrition (short, with normal weight-for-height--stunted); and normally nourished children. Weight-for-height at the beginning of the interval was used as indicator of the child's recent dietary adequacy. This variable was further linked

Figure 4

RELATIVE FOOD AVAILABILITY
IN FIFTH, SIXTH, SEVENTH, AND EIGHTH QUARTERS



with a "dummy" variable to indicate whether the child received vitamin A (variable = 1) or was a control child (variable = 0). In the Indian (Hindu) culture girls are traditionally less favored than boys and it stands to reason that during times of acute food shortage girls might receive considerably less food than boys (initial nutritional status being corrected for). If, therefore, in times of food shortage as in the interval between the sixth and seventh periods, the girls were selectively discriminated against, vitamin A might interact synergistically with the undernutrition and cause a greater nutritional deficit than in control girls, or in male counterparts not subjected to this discrimination. If vitamin A acts as a growth retarding agent we would, therefore, expect to find a negative effect of vitamin A at the time of greatest food shortage, i.e., between the sixth and seventh quarters. Because of female neglect this effect should be larger in the female than in the male and less in those of initially higher weight-for-height (as expressed by the complex variable vitamin A times weight-for-height). At times of relative food abundance between the fifth and sixth quarters and less so the seventh and eighth quarters, vitamin A should show no negative effects.

Results:

In Table 3, data from the multiple linear regression analyses are shown by interval.

Interval 1 (5th to 6th quarters)

In general, all children except those of already high weight-for-height gain in weight. This gain is greatest in tall and thin

Table 3

MULTIPLE LINEAR REGRESSION MODEL WITH DELTA WEIGHT-FOR-HEIGHT AS DEPENDENT VARIABLE DURING THREE TIME INTERVALS

(t-values in parentheses)

Interval	Dependent Variable	Constant	Sex[2]	Age[3]	Length of Interval[4]	Vitamin A[5]	Initial Weight/Height	Initial Height/Age	Vitamin A x Weight/Height	Vitamin A x Sex	F[a]	R^2	n
5-6	Δ wt/ht[7] x 1,000	+11,049.4	-123.8 (0.22)	-1.2 (2.27)*	-39.3 (3.17)**	+10,215.4 (1.85)	-0.2[1] (1.93)	+10.6[6] (3.54)***	-0.1[1] (1.96)*	-41.2 (0.23)	9.29	0.18	264
6-7	Δ wt/ht[1] x 1,000	-2,595.1	-789.6 (1.36)	-0.9 (2.95)**	-9.1 (1.76)	-1,520.6 (2.04)*	+2,149.5[7] (6.12)***	-1,135.7[7] (3.72)***	+104.4[7] (1.69)	+2,172.9 (2.52)*	7.30	0.19	257
7-8	Δ wt/ht[1] x 1,000	-4,121.2	+598.1 (1.00)	-0.7 (1.46)	-11.9 (1.91)	+9,561.8 (1.91)	-0.2[1] (3.05)**	+19.8[6] (3.53)***	-0.1[1] (1.96)*	+388.9 (0.43)	4.48	0.12	259

(1) weight-for-height x 1,000

(2) male = 1; female = 0

(3) age in days

(4) days

(5) vitamin A = 1; control = 0

(6) height-for-age x 10

(7) above average = 1; average = 2; below average = 3

*significant at 0.05 level

**significant at 0.01 level

***significant at 0.001 level

Note: t-values refer to significance or lack thereof of the independent variable on the dependent variable

[a] The F value refers to significance of the entire regression equation. All three F factors are at <0.001 level of significance.

The R^2 explains how much of the variation in the dependent variable is explained by the 8 independent variables used. In the above modes, 18 percent, 19 percent, and 12 percent of variation in delta weight-for-height during the three time intervals are thus explained by these eight variables.

children. Children of initially high weight-for-height receiving vitamin A seem not to do as well as those not receiving vitamin A. With increase in age and length of interval between measurements in the two quarters, the weight-for-height gain becomes progressively less.

Interval 2 (6th to 7th quarters)

In general all children except those already stunted and wasted lose weight. Most of the loss is encountered by short children of relatively high weight-for-height at the beginning of the interval. Whereas in male children vitamin A supplementation has virtually no effect, in females it further increases the loss in weight-for-height status. Also, the older the child, the greater the loss.

Interval 3 (7th to 8th quarters)

On the average children again start to mildly improve their weight-for-height. The gain is inversely proportional to both the length of the interval and to the weight-for-height at the beginning of the interval, i.e., those of already good weight-for-height don't gain as much as those whose weight-for-age was low. Thus, children of normal height (wasted) tend to gain more than stunted children of normal weight for their height. While vitamin A tends to help in this gain, noted positive effects are but marginally significant. As in the first interval children of high weight-for-height at the beginning of the interval who also received vitamin A showed a significantly lower weight gain than control children.

Interpretation of Results:

Secondary analyses of this project's data has helped little to clarify the issue, if anything more questions have arisen. It is

difficult to explain why administration of vitamin A at times of relative food abundance should selectively reduce weight-for-height gain in those nutritionally better off, unless one assumes that it promoted the weight gain of those more undernourished. This latter mechanism may also be the reason for an overall growth stimulating effect of vitamin A on weight-for-age in the first and third intervals even though this effect was only marginally* significant. During times of food shortage, administration of vitamin A seems to act indeed as suspected from the primary analyses, namely synergistically with the under-nutrition causing an overall greater loss.

Validity of Study:

The prevalence and severity of vitamin A deficiency was provided by the results on vitamin A deficiency signs and symptoms observed over the initial twelve month period of the study and had also been documented for this area earlier.

A study of the effects of the administration on massive doses of vitamin A on not only ocular pathology but also other parameters of health is appropriate and urgently required in light of the routine administration of vitamin A in many countries.

The investigator performed a valid pilot study consisting of:

1. a twelve-month baseline data collection including all measurements to be performed in the second year of the study,

2. preparing and field testing a placebo.

While it was well known from laboratory and clinical evidence that vitamin A deficiency was responsible for night blindness, keratomalacia

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*$p<.05$

and blindness and that administration of vitamin A would cure or improve all but irreversible scarring or perforation of the cornea and opacification of the lens, relatively little was known about the role of vitamin A in the appearance or disappearance of Bitot spots.

Validity of Results:

Since all children from a village formed the study population and since these were randomly divided into supplemented and placebo groups following stratification according to age, sex, caste, and play groups, the results are valid.

Secondary data analysis by our group was performed not because of inherent weakness in the primary analysis, but rather to further the primary analysis for which funds had run out while attempting to clarify the effect of vitamin A on growth.

Weaknesses of Study:

No major weaknesses in either project design, methodology, implementation or analysis seem apparent. The study population was unfortunately too small and the study too short to provide conclusive information on potentially ill effects of high doses of vitamin A on growth of severely underfed children, or to reveal relationships between administration of vitamin A and childhood mortality.

Conclusions:

Overall, the study has provided answers to a number of questions that have been asked.

Aside from reducing the severity of measles, vitamin A seems to have no effect on infectious illness incidence or severity. Bitot spots

may reoccur once present even while under massive doses of vitamin A and do not necessarily disappear with vitamin A therapy even though other ocular pathology clears up. However, vitamin A prevents primary occurrence of Bitot spots.

Large doses of vitamin A may exert a growth (weight gain) retarding effect in nutritionally severely deprived children. This finding clearly needs to be validated through further research. Additionally, and because of the secondary data analysis, there is strong evidence suggesting that vitamin A aids in the improvement of nutritional status when food is available.

Appendix 5

CORN FORTIFICATION: A FIELD DEMONSTRATION MODEL (INCAP-II)

The corn fortification study was a longitudinal prospective study examining the feasibility of fortification of corn with lysine, minerals, and vitamins at the village level, while monitoring the effects of consumption of fortified corn on outcome of pregnancy, child growth, child morbidity, and child mortality.

Investigators:

Juan J. Urrutia and L.J. Mata

Supporting Institution:

Institute of Nutrition of Central America and Panama (INCAP), Guatemala

Material Available for Review:

1. Final Report to AID (1971-1976)
2. Completed questionnaire (J.P. Habicht) related to amino acid fortification field studies
3. Unpublished material (progress reports to AID) made available by principal investigators

Discussion with Investigator:

Juan J. Urrutia, October 1977

Secondary Data Analysis:

Only minor secondary analyses were done, limited essentially to statistical tests and rearrangement of presented tables.

Objectives of the Study:

1. Research objectives--to determine the effects of corn fortification on:

   a. Nutrition of pregnant women and on fetal growth,

   b. Growth and development of children,

   c. Disease incidence and intestinal shigellosis.

2. Service (applied research) objectives:

   a. To study the feasibility, management and economics of corn fortification at the community level through addition of a mixture containing protein, lysine, vitamins, and iron to nixtamal;

   b. To evolve realistic operational guidelines and economic data applicable to a regional or national program of corn fortification.

Study Design:

The entire population from two villages comparable in size, socioeconomic, and health (child growth and child mortality) indicators served as the study population. In one village--Santa Maria Cauque--provisions were made for inhabitants to have (on a voluntary basis) their own corn fortified at any of the two (later four) local mills while it was being ground. The other village--Santo Domingo Xenocoj--was to serve as a control.* The fortification mixture consisted of 97 percent

*Because of poor participation of the community with the program, population segments of differing levels of fortification within Santa Maria Cauque were eventually compared with each other with respect to outcome variables.

soybean flour, 1.5 percent lysine HCl, 0.03 percent thiamin, 0.02 percent riboflavin; 0.2 percent niacinamide, 0.6 percent iron as ferric orthophosphate, and 0.03 percent vitamin A.

With this mixture corn was planned to be fortified at a level of 8 percent (by weight). Subsequent analyses showed, however, that a fortification level of only 4 percent was reached. Participation in the fortification program (output) and effect on nutrition and health indicators (outcome) served as principal dependent variables. The study lasted from January 1971 until February 1976 when it was unexpectedly terminated as a result of a major earthquake destroying all but a few houses. Fortification started at the beginning of June, 1972 and continued for 44 months. The level of participation with the program was established by determining a fortification index* for each family as well as each child in the village.

The fortification index was related to child growth, morbidity, and mortality through the following indices:

1. Intrauterine growth measured by birth weight;

2. Subsequent growth measured by weight, height, head and chest circumference at three monthly intervals from 6-96 months;

3. Morbidity of children and of pregnant women (in the course of weekly home visits);

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*Calculation of fortification index (F.I.)

$$\text{Family weekly F.I.} = \frac{\text{Days of attendance to the mill}}{\text{Days of the week (6)}} \times \frac{\text{\# of units of fortifying mixture added to cooked maize}}{\text{Pounds of cooked maize}}$$

$$\text{Average family F.I.} = \frac{\text{Sum of family weekly F.I.}}{\text{Sum of weeks of observation}}$$

$$\text{Average child F.I.} = \frac{\text{Sum of family weekly F.I.}}{\text{Age of child in weeks} + \text{39 weeks of gestation}}$$

4. Mortality (infant and 1-4 years).

Dietary intakes of pregnant women and preschool (0-3 years) children were also determined through recall dietary surveys.

Results:

Output

An initially high (95 percent) participation of the village community with the program dropped to 30 percent within a few days, and only after an intensive public relations, education, and general promotional campaign could participation be raised again to an average of 40 percent over the remainder of the study. The reason for the sharp drop lay essentially in the rapid deterioration of taste of fortified tortillas when stored for more than a day due to bacterial growth (because of improved protein quality and higher water retention due to fluffiness of fortifying mixture). For the analysis of program effects, participants in the program were divided into three (arbitrary?) groups, depending on the extent to which they fortified their cornmeal: low participation, F.I. = 0-19 (108 families; 88 preschool children, 166 births); medium participation, F.I. = 20-39 (22 families; 24 preschool children, 23 births); and high participation, F.I. = 40-100 (93 families; 118 preschool children, 115 births).

Dietary Intakes--

Dietary intakes of pregnant women were significantly augmented (+200 calories, 9+ grams protein/day); those of preschool children were unaffected.

Outcome

Growth--

There was no statistically significant correlation between the F.I. and fetal (birth weight) or child growth (weight, height, head and chest circumference). Growth increments between three and five years were positively correlated with the increment of fortification index but not to a statistically significant degree.

Comparison between sibling pairs to rule out differences in socio-economic status and level of participation, also did not show any significant difference in weight and height measurements.

Morbidity--

No effect on morbidity incidence or duration of children in first year of life or of pregnant women. In second and third years of life duration of upper respiratory tract infection (URTI), lower respiratory tract infection (LRTI), diarrhea, fever, as well as of associated illness, was significantly reduced.

No marked differences in the incidence of the shigella infections in the three groups of children were found.

Child Mortality--

In Table 1 mortality for the first year of life before and during the program are shown.

--Stillbirths

Drop from 70/1,000 live and stillbirths to 17/1,000 live and stillbirths before and during fortification in the highly fortified group (statistically not significant). Drop from 36/1,000 live and

Table 1

BIRTHS, STILLBIRTHS AND INFANT DEATHS BEFORE AND DURING THE FORTIFICATION PROJECT
BY LEVELS OF FORTIFICATION

Fortification Index	# of Deliveries		# of Live Births		# of Stillbirths				# 0-11 Months Deaths			
	Before	After	Before	After	Before	Rate	After	Rate	Before	Rate	After	Rate
0-19 (I)	255	166	247	160	8	31.4	6	36.1	26**	105.3	15+	93.8
20-39 (II)	43	23	43	23	0	0	0	0	5	116.3	4	173.9
40-100 (III)	206	115	198	113	8	69.6	2	17.4	14**	70.7*	3+	26.6*

*χ^2 = 2.71 P = n.s.

**χ^2 = 1.60 P = n.s.

+χ^2 = 4.86 P = <.05

stillbirths to 17/1,000 live and stillbirths during fortification between high and low fortified groups (statistically not significant). These effects are shown in Table 2.

--Infant Mortality

Drop from 105/1,000 live births to 94/1,000 during the fortification in the poorly fortified group (P = n.s.). Rise from 116/1,000 live births to 174/1,000 live births during the program in the intermediate fortified group (P = n.s.) and fall from 71/1,000 live births to 27/1,000 live births in the highly fortified group (P = n.s.). The difference between the IMR of the low and highly fortified group during the fortification program (Δ = 67/1,000 live births) was statistically significant (P = <.05). These relationships are shown in Table 3.

--One to 4.9 Year Mortality

One to 4.9 year mortality for the three fortification groups prior to the program were not provided separately. Mortality dropped from 29/1,000 to 22/1,000 in the low fortified group to 10/1,000 in the highly fortified group. The difference in mortality rates between these two groups was statistically not significant. If we assume that 1-4.9 year mortality in the highly fortified group prior to the program was the same as for the low fortified group, 29, than the difference from before to during the program (Δ = 19/1,000) was statistically significant (P =<.05) in the highly fortified group (Table 4).

Validity of Study:

The nutrition problem in Guatemala and in Santa Maria Cauque in particular had been well documented earlier as well as in a parallel study carried out by the Division of Human Development of INCAP.

Table 2

EFFECT OF FORTIFICATION ON STILLBIRTH RATE

Fortification Index	Stillbirth Rate		
	Before	After	
High (III)	70	17	→ (n.s.)
Low (I)	31	36	→ (n.s.)
	↓ (n.s.)	↓ (n.s.)	

Table 3

EFFECT OF FORTIFICATION ON INFANT MORTALITY RATE

Fortification Index	Infant Mortality		
	Before	After	
High (III)	71	27	→ (n.s.)
Low (I)	105	94	→ (n.s.)
	↓ (n.s.)	↓ P <.05	

Table 4

EFFECT OF FORTIFICATION ON 1-4.9 YEAR MORTALITY

Fortification Index	1-4.9 Year Mortality		
	Before	After	
High (III)	} 29	10	→ P <.05
Low (I)		22	→ (n.s.)
	↓ ?	↓ (n.s.)	

Dietary surveys (1965) done by Flores, Behar, and the Ministry of Health in Guatemala have shown a deficit in protein and calorie intakes in rural Guatemala; calorie intakes being judged more deficient than that of protein. It was also found that 76 percent of protein intake was of vegetable origin with poor biologic quality.

From 1964-1971 a prospective study was carried out in Santa Maria Cauque, in a cohort of 45 children, representing 50 percent of children born over a period of two years. Thirteen percent of all children below one year, 27 percent below two years, and 9 percent below three years, were found to suffer from some form or other of PCM during 1964-1969. In 1970, 13 percent and in 1972, 19 percent of all sample children showed evidence of PCM.

Laboratory studies by Bressani showed the marked deficit of lysine and tryptophan in maize which could be corrected by adding soyflour enriched with lysine to the corn dough. The intervention thus was appropriate especially since it had been shown earlier by Baertl, et al. (1970) that consumption of fortified pasta in a hacienda population brought about a reduction in infant and preschool child mortality. According to Dr. Urrutia the fortification mixture was tested both at INCAP and in the field in the preparation of tortillas prior to the start of the program. Prepared tortillas could not be distinguished from regular ones. Neither the INCAP staff nor the villagers could detect which of <u>freshly</u> prepared tortillas contained the fortification mixture.

A pilot study involving all phases of the project, i.e., milling, preparation at village level by village community, was, however, not done. Selection of the target population--pregnant women and preschool children--was appropriate. Inasmuch as participation was by self-selection, the three groups needed either to be comparable on all other variables that might influence outcome variables or have large enough target populations to permit "before" and "after" comparisons.

Validity of Results:

Even though data on child growth and mortality was collected in a control village this data was not used in the final analysis. Instead, the low fortification group was used as control.

Method of Analysis--essentially limited to simple cross-tabulations of three groups of fortification levels with output or outcome variables. For this analysis to be valid, the three groups need to be comparable on all other confounding variables that may similarly effect outcome. Socio-economic status was assessed on the basis of land tenure, cattle and poultry possessions, type of housing, availability of water, fecal and waste disposal, literacy, scholarity,* and shoe wear by assigning each factor a value from one to three followed by adding all values. According to this method, there were no differences in socio-economic status between the three groups. This method assumes that each of the factors influenced output or outcome variables to the same extent as every other factor. More appropriately, these variables should have

*Number of years of completed schooling

been used separately as confounding variables in a multivariate analysis with the outcome as dependent and the fortification index as main independent variables.

We also question why the originally designated control village was not used for comparison with any or all of the three experimental groups.

As far as mortality results go, the sample size was clearly too small to permit other than strong suggestion. This, of course, was largely necessitated by the unexpected termination of the study because of the earthquake.

It seems plausible that child mortality may have been affected without any apparent change in levels of nutrition. However, the finding that pregnant women ingested 200 calories and 9 grams of protein per day more during their pregnancy yet birth weights were unaffected is in direct contradiction to results from a parallel study carried out in essentially the same area and social system.

Results were not interpreted in a consistent manner. Thus, a decrease in child mortality was based on a before and after (within) for one age group and on group differences (between) for another age. The dividing points for the three levels of fortification seem arbitrary, especially since the intermediate group is of a much smaller sample size than either the high or low groups. This group also has consistently higher mortality rates, suggesting that the population may be different from the other two groups in some important manner. Multiple linear regression using continuous variables would probably have provided more valid results.

Given the fact that morbidity findings in general tend to be less reliable than anthropometric data or information on deaths, beneficial effects from the fortification though suggestive are not proven.

Weaknesses of Study:

The main weaknesses are: (1) in the implementation of the study no valid pilot study was undertaken; (2) when the participation with the program fell from 95 percent during the first two days to 30 percent on the third day, an intensive laboratory research to find a "better" fortification mixture should have been undertaken before the program continued; (3) another weakness lies in the analysis and interpretation of the results. Thus, the grouping of levels of participation seems arbitrary and unbalanced; the analysis lacks sophistication--more valid means such as multiple regression, using independent variables appropriately, could have been employed. The results do not conclusively support the effects on mortality claimed.

Applicability of Results to Nutrition Problems on Broad Scale:

While the technical feasibility of fortifying corn at the village level appears high, major problems encountered in this study, lack of acceptance by population and continued participation of mill owners are probably representative of the rule rather than the exception. Some of the problems can probably be overcome by producing a fortification mixture that will not cause additional moisture to be retained in the prepared tortilla. However, unless the community becomes convinced of the value of the fortified corn and out of its own conviction puts a

premium on fortified corn, or, alternatively has no choice, such a program will probably not succeed on any but a small demonstration project and even there will require an inordinate amount of input.

Conclusions:

The study is important from several points of view. It not only highlights the difficulty implementing seemingly simple health promoting innovations in a traditional community, but provides a good account of what can go wrong, why it went wrong, and thus, may serve as a baseline of a subsequent research into feasibility of food fortification at the community level. The study achieved only part of its objectives. We don't know whether corn fortification has an effect on fetal growth, mainly because we cannot be sure that women indeed received more food--as indicated by the diet surveys. For us, the contradiction with the results from the parallel maternal supplementation study is too apparent, and the hypothesis that the extra food went into additional physical labor is too tenuous. It is likely that the results from the dietary surveys (by recall) were not as reliable as was assumed.

Since the children's diet was not changed, at least quantitatively, no improvement in growth was expected. It is unlikely that improved protein quality resulted in improved immune capacity in an ambulatory, clinically not protein deficient population, and the observed mortality effects are probably due to other causes (self-selection of groups, socio-economic, etc., differences), especially since they are marginally significant to begin with. It is somewhat more difficult to rule out observed effects on morbidity, unless one postulates that the same

factors that caused the differential participation with the program also affected conditions that bear on disease duration.

Because the study was done meticulously, the results, when objectively looked at, nevertheless contribute to the understanding of planning and implementation of nutrition interventions, and the information gained on as difficult subjects as community dynamics during planning, implementation, and evaluation of a seemingly simple nutrition intervention program may compensate for the absence of convincingly positive results.

Appendix 6

PRICE SUBSIDY DURING A FAMINE

(THE COMPANIGANJ NUTRITION PROGRAM)

A food supplement for children 0-3 years was provided at a subsidized price through clinics. The program was conducted as a service effort during a famine and since information on socio-economic and nutritional status on all families and preschool children respectively were available through the larger Companiganj Comprehensive Health Project, effects of this particular program were analyzed retrospectively. A survey designed to determine seasonal fluctuations of nutriture and utilization of the supplement has been used to evaluate the effectiveness of the project.

Investigators:

Colin McCord

Radheshyam Bairagi

Supporting Institutions:

UNICEF, CARE, World Food Program, Church World Service, Government of Bangladesh

Material Available for Review:

1. Companiganj Health Project Annual Reports, 1975, 1976, 1977
2. Master's thesis (Bairagi, R.), The Johns Hopkins University, 1977
3. Integration of Health, Nutrition and Family Planning: The Companiganj Project in Bangladesh (McCord, C.), International Food Research Institute, Stanford, 1977
4. The Demographic Impact of a Famine (McCord, C.), report prepared for AID, October 1977

Secondary Data Analysis:

Multilinear regressions were done to confirm and amplify contingency tables.

Objectives of the Study:

Retrospectively designed to determine levels of malnutrition in the population and levels of utilization of a supplement. Data has been further analyzed to determine the effect of supplement utilization on the population.

Objectives of the Program:

To provide food supplements at low cost for children 0-3 years attending clinics.

Introduction:

In 1972, just after the establishment of Bangladesh as an independent country, the Ministry of Health proposed an extensive reorganization and expansion of the existing rural health services. Companiganj thana of Noakhali district was selected as an area for a demonstration of the integration of health and family planning services.

The Ministry of Health proposed to integrate, administratively, preventive programs in malaria, smallpox and cholera control, food and water quality, and a family planning program with a newly proposed maternal and child care program. Immediately after starting delivery of services it became apparent that malnutrition was the most important medical problem. What follows is an evaluation of the Companiganj Project Nutrition Program (CPNP), a portion of the CHP.

While many interesting relationships between nutritional status and socio-economic indicators are made, the investigators conclude that the nutrition program as it was set up for the demonstration project did not impact significantly on the nutritional status of the children 0-36 months of age. There may have been an effect on mortality, but the observed mortality differences are not statistically significant.

Situation of the Project:

Noakhali is a grain deficit area in Bangaldesh. The nutrition project was begun and the surveys conducted during a famine which resulted due to external economic and political forces. Harvests were normal but grain prices were 2-3 times normal.

Objectives of the Project:

The objective of the retrospective study was described in the "Interim" report on nutrition survey of Companiganj (1) as follows:

1. To determine whether socio-economic factors and seasonal variation of food supply in Companiganj were reflected in the nutritional status among small children;

2. To measure the utilization of a subsidized food supplement program;

3. To determine the effect of this program on nutritional status of these children.

Study Design:

Monthly weight measures were collected for children age 0-36 months in the study area. Through home visits by three trained field workers

anthropometric data were collected. Weight-for-age measures as a percentage of Harvard standard were calculated and used as the indicator of nutritional status. Data on a variety of socio-economic and demographic variables such as income, land, father's education, mother's education, religion, father's age, mother's age, housing conditions, source of drinking water, age of the children, sex of the children, birth order, parity, etc., were collected in a baseline survey. With regard to age of children, very few families remembered the date of birth of their children even of the age group 0-3 years. Date of birth was estimated by a well-qualified sociologist using a calendar of local events. It is thought that estimated age remains plus or minus fifteen days of actual birth. There were two major tragic events which people could remeber very easily. One was the cyclone of November 13, 1970 which took the life of about half a million people; the other was the liberation war from March 25, 1971 through December 12, 1971, which took the life of about 1.5 million people and compelled ten million people to migrate to the neighboring country of India.(2) The latter event was very useful for screening the older children.

Food shops were established adjacent to all CHP clinics, which provided a locally produced mixture of wheat and pulse to be used as a food supplement for small children. A flour made from 75 percent wheat and 25 percent chickpeas was used. The supplements were sold for a price fixed at one-half the market price for wheat, so that most of the production and distribution cost as well as the cost of the pulse was recouped. (Wheat was available for free for use in Companiganj from the World Food

Program.) Families who brought under-three children to a clinic were given a ration card and as long as they continued to come regularly to the clinic they were allowed to purchase an amount of the supplement equivalent to about one-third of the child's caloric requirement.

Although the supplement was sold throughout the Companiganj Health Project area, the nutritional survey was undertaken only in a part of the area within two miles of one of the most active clinics. All the children of that sub-area (about 500 in number) were included in the study.

Results:

1. Landed parents had a greater proportion of children up to six months of age who fell above 70 percent of the Harvard median than non-landed parents.

2. Similarly, parents with a monthly income greater than 275 Takas ($34.00 at the exchange rate up to May 1975, $17.00 after this time) had a greater proportion of children at all ages over six months who fell above 70 percent of the Harvard median than parents with income less than or equal to 275 Takas, particularly in the seasons November-January and May-July.

3. Parents with greater amount of education had a greater proportion of children at all ages over six months of age who fell above 70 percent of the Harvard median than parents with little or no education.

4. A lower proportion of male children over six months of age showed signs of malnutrition (all grades) than female children.

5. Figures 1 and 2 show that the extent of malnutrition in this population is more serious than that found in other parts of the world. These figures show comparative weight-for-age curves for Boston (Harvard), Narangwal (India), and Companiganj.

6. Figure 3 shows the nutrition status of participants (of varying duration) and non-participants in the nutrition program.

Multiple linear regression analysis and analysis of covariance were performed.[3] These analyses suggested:

1. Income contributes positively to nutritional status after infancy. But the regression coefficient of income is quite low. This indicates that the nutrition problem could not be solved completely by increasing income alone, but probably would require an overall improvement in living conditions.

2. Mother's education contributes positively to nutritional status of the child after infancy, and the regression coefficient is as strong as that of income. However, education of mother is of no benefit to children in the lowest income group.

3. Religion influences nutritional status. Hindu children appear to suffer, nutritionally, during infancy when compared to Muslim children.

4. Increasing birth order affects nutritional status of the child.

5. Nutritional status is influenced by season after infancy.

6. Participation in the nutrition program did not appear to influence nutritional status.

7. Sex was a highly significant predictor of nutritional status at older ages, but not during the first six months of life.

Figure 1

WEIGHT-FOR-AGE (MALES)

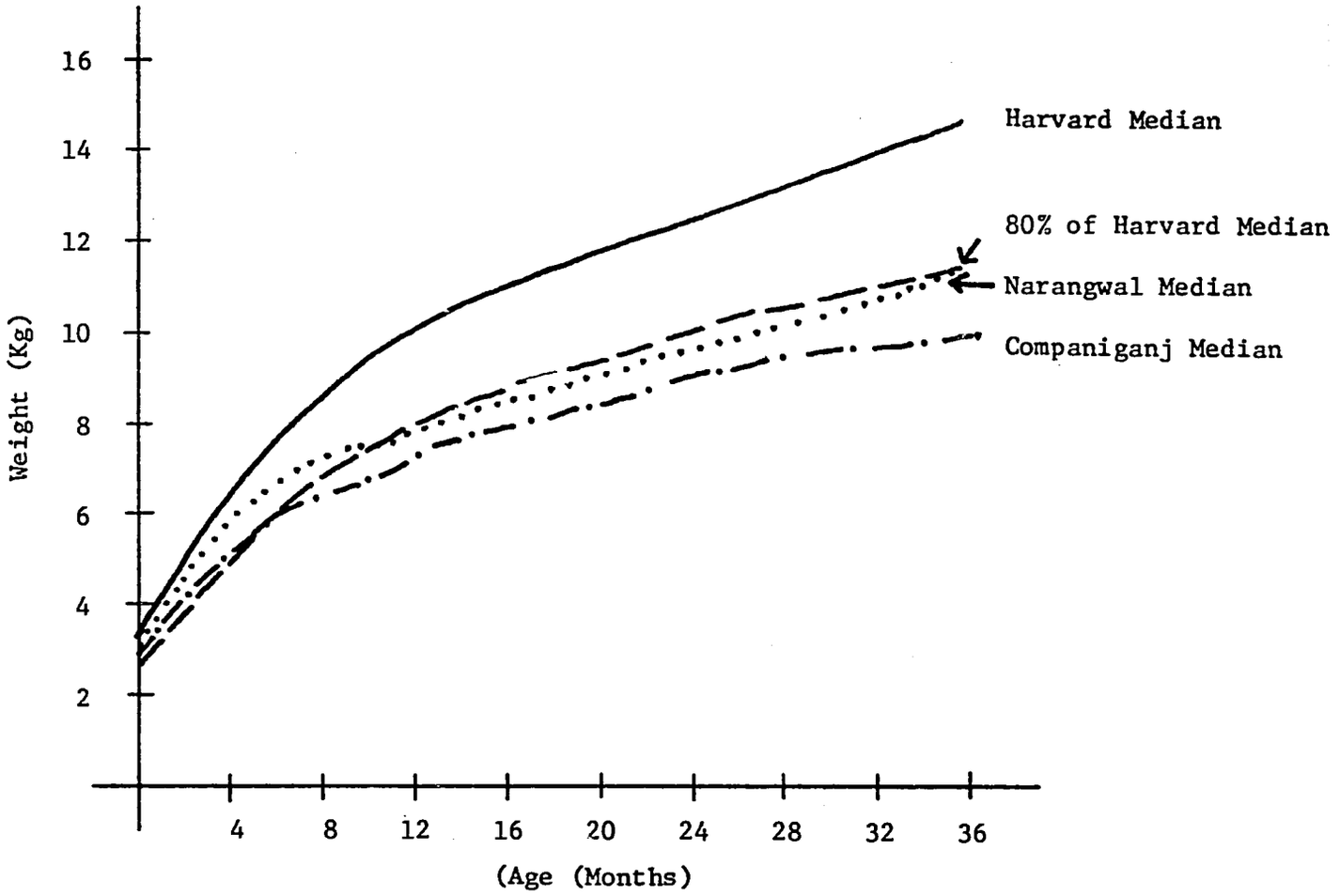


Figure 2

WEIGHT-FOR-AGE (FEMALES)

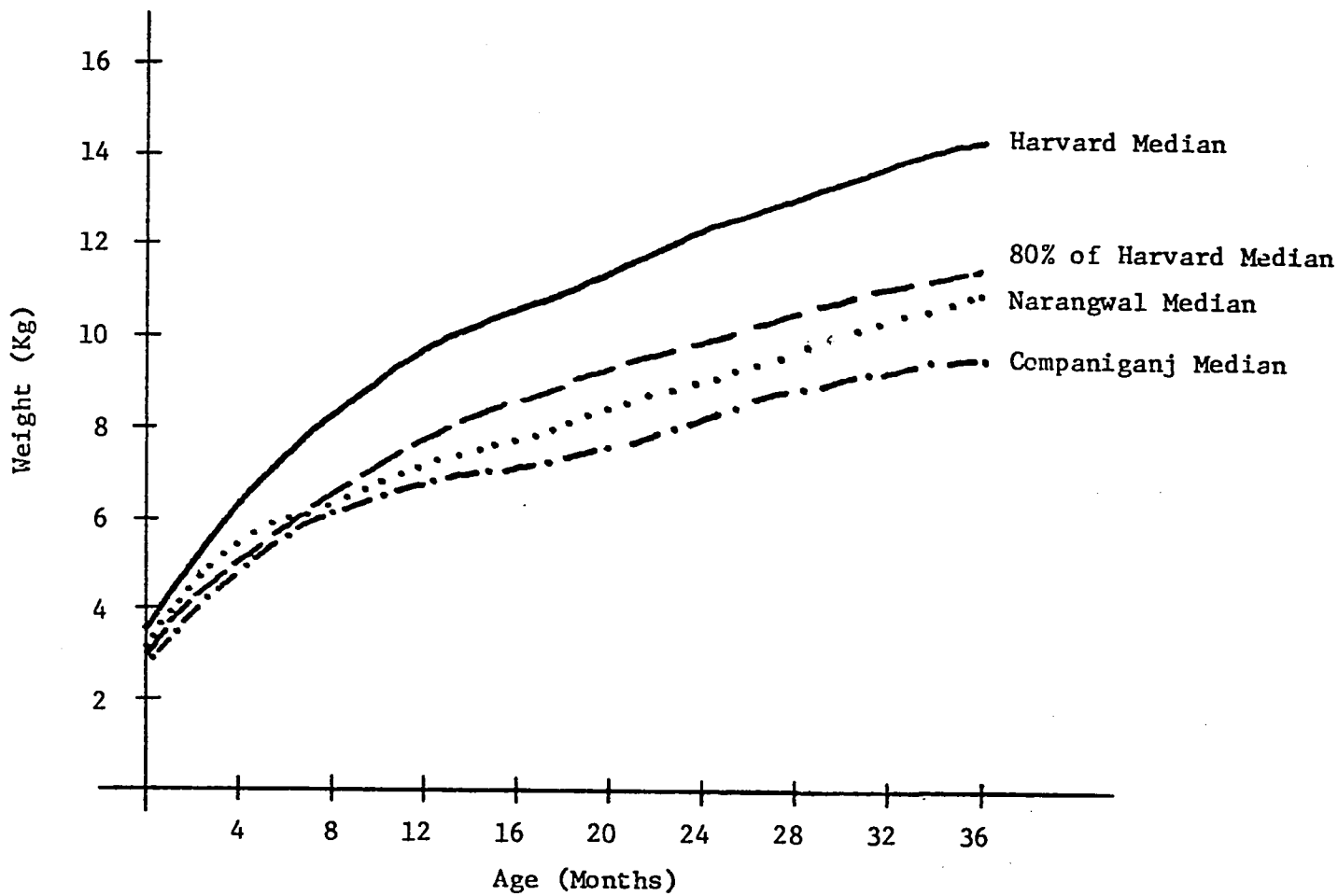
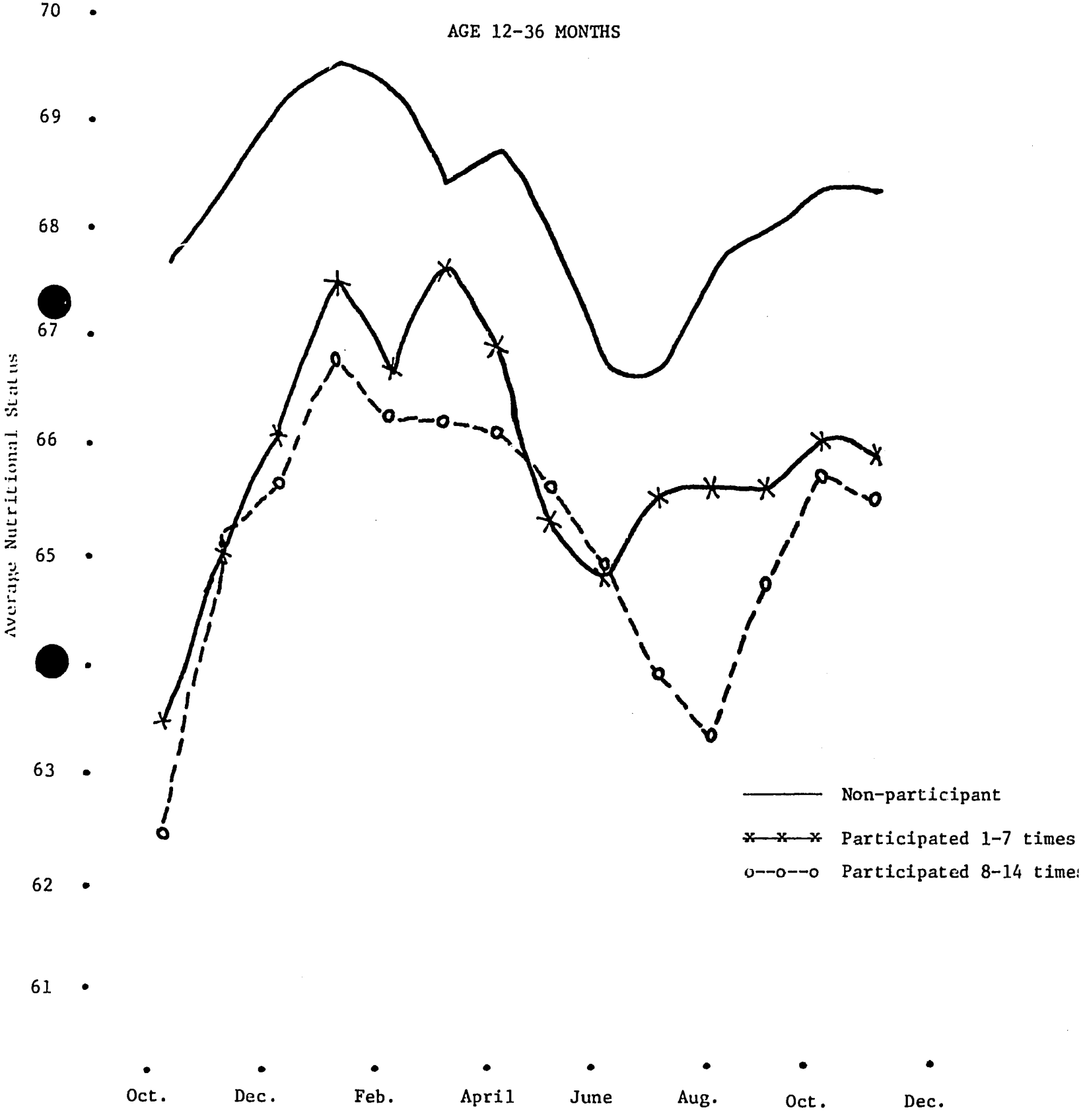


Figure 3

NUTRITIONAL STATUS AND PARTICIPATION IN
FOOD SUPPLEMENTATION PROGRAM

AGE 12-36 MONTHS



8. Housing and father's occupation did not appear to influence the child's nutritional status to any significant degree.

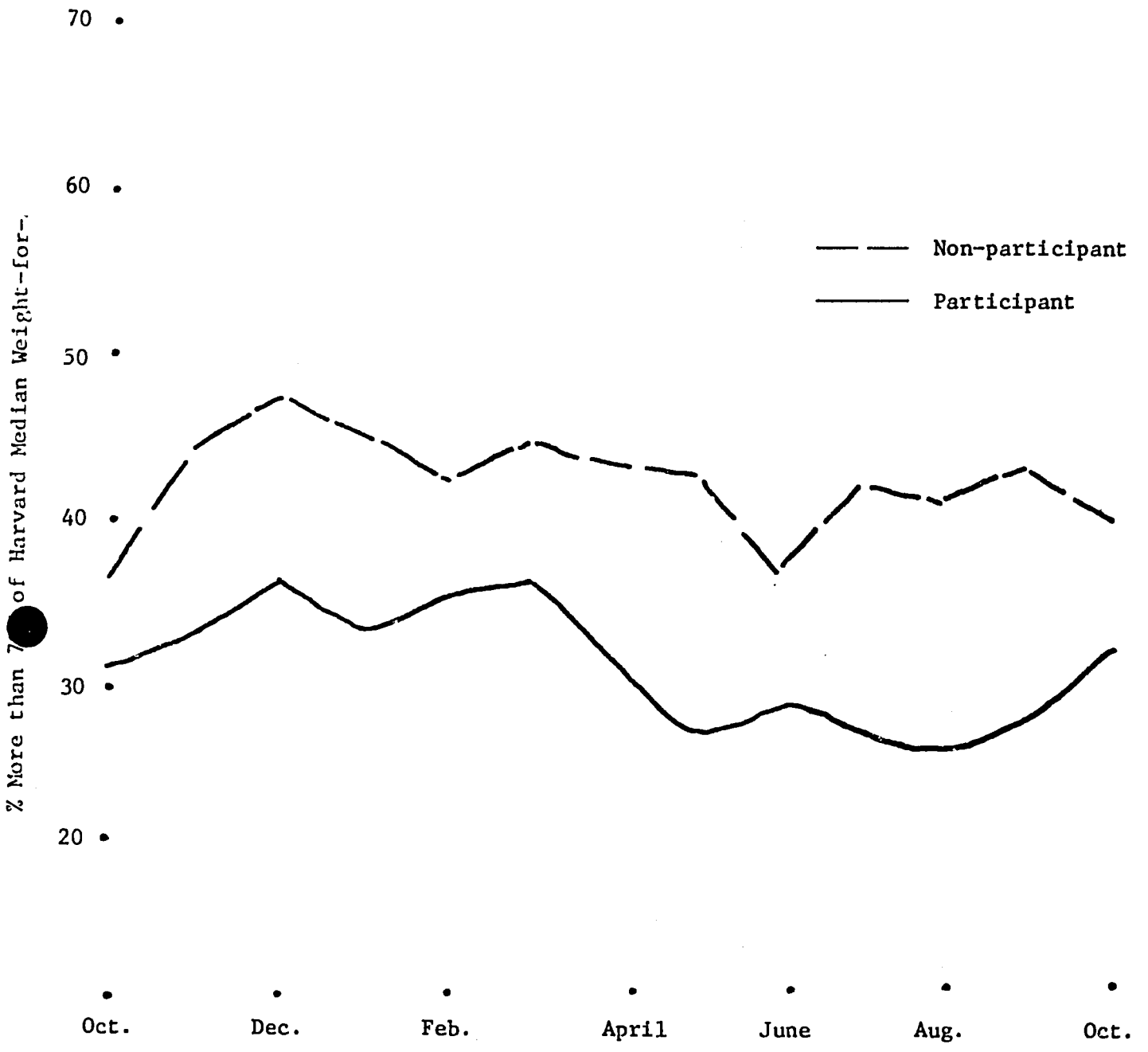
Figure 3 shows that the nutritional status of participants was consistently below that of non-participants after 12 months of age. This finding is consistent with the fact that analysis showed participants were almost exclusively low income families. Further, in Figure 4, we see that participation did little to increase the proportion of children with a nutritional status >70 percent of the Boston standard over an 18 month period. The slopes of the two curves are almost the same. If food supplementation had improved the nutritional status of the children of purchasers, then the curve for the purchaser group would have had a higher positive slope. At least it might be said that although participation appeared to do little to pull severely malnourished children up to a level of more moderate or even milder malnutrition, it might well be that within the group of severely malnourished children, the program prolonged life for some children and possibly prevented more deaths from occurring than might have occurred without the program.

The investigators offer several reasons for the failure of the program to have had an impact. (1) Only 34 percent of the eligible families took part one or more times in the program. This would limit impact on overall child mortality no matter what benefit accrued to the participants. Although the supplement was offered at half the market price, still the market price was so high at this time that many families probably could not afford it. The low negative correlation coefficient between income and food purchaser and the low value of the regression coefficients give some indication that probably the poorest families could not buy it.

Figure 4

NUTRITIONAL STATUS AND PARTICIPATION IN
FOOD SUPPLEMENTATION PROGRAM

AGE 6-36 MONTHS



(2) The quantity of supplement available per month per child provided only one-third of the monthly calorie requirement. Even among the purchasers, the children's nutritional status did not improve over time. This raises doubt about both the adequacy of the supplement, as well as its final destination. Although supplements were purchased for the young child, they might have been added to the family pot. (3) Finally, a group of other reasons might have contributed to the failure of the program: the opportunity cost of transportation time to the purchasing center for this small amount of supplement or cultural barriers which might preclude accepting a non-prestigious food could have worked against the program.

Validity of the Study:

Just prior to the institution of the nutrition program, the extent of malnutrition and the need to undertake an immediate solution was documented by systematic clinic observation.[2,4] It was during the years just prior to 1975 that the observation was made that malnutrition was a seasonal phenomenon in Bangladesh. The change of season appeared to bring dramatic changes in the proportion of children suffering from malnutrition. The improvement seen in the clinics during and after a harvest was so great as to suggest that simple availability of food was overwhelmingly the most important factor affecting the nutritional status of small children. As a result of this observation, the food supplementation program was initiated.

Validity of the Results:

Validity of the results of food supplementation program of this study appears to be quite high. Results of the regression analysis and

the analysis by graph are in the same direction.[3] Regression analysis considered a number of variables including income to investigate the effect of food supplementation. Figure 3 does not give any evidence that the nutritional status is improved over time as a result of the food supplementation program. The shape of three curves provides evidence that those who took the supplement did not have a better nutritional status record than those who did not take the supplement. It is a possibility that in the absence of this program a further deterioration of the nutritional status of severely malnourished children might have occurred leading to excess deaths over those that actually occurred. Thus, what would have happened in the absence of the program could not be measured.

Weakness of the Study:

The selected sub-area of the nutrition survey is not a representative sample of the Companiganj Health Project area in all respects. The distribution of father's occupation in the project area and study area appears to be quite different,[3] but the father's occupation was not a significant determinant of the nutritional status of the children in the study. Religion appears to be a significant determinant of the nutritional status at infancy.[3] The percentage of those who are Hindu in the project area is 15 percent and in the study area is 6 percent. No attempt was made to investigate the interaction between food supplementation and father's occupation or religion.

In this study weight-for-age expressed as a percentage of the Harvard standard is used as an indicator of nutritional status of the children. The recommended method for collecting the weight of the children is to the nearest 100 gms while in this study weight was taken to the nearest one-fourth of a kilogram (250 gms). The age is not the exact age but

an estimate age collected by a sociologist using calendar of local events. It is expected that the estimated age is either plus or minus fifteen days of the actual age.

The main problem with this study is that it does not have a control and it does not include enough children to conclusively determine effects on mortality (with statistical significance). Nevertheless, the absence of any nutritional benefit among the self-selected experimental group indicates that the program's benefits fell far short of expectations.

Applicability of Results:

This program is an example of a targeted food subsidy. The target group was children identified through clinics, but the aim was to reach all the children in the community. The program clearly did not have much effect and it seems likely that similar programs mounted during famine conditions would have equally poor results. It is likely that a program like this could be beneficial as an adjunct to an educational program for mothers in non-famine conditions, but another study would be needed to determine the additional benefit of subsidized supplements over simple education.

The reasons for failure to improve the target group seem almost certainly to have been that the amount provided was too little and that the supplement intended for the child was used by the entire family. The important questions raised are:

1. Would a larger program with bigger supplements at lower cost have produced a better result?

2. If so, how much larger?

3. Since it is administratively impossible (and probably undesirable) to control the distribution of subsidized food within the family, particularly in a famine situation, is there any point to identifying children as the target group?

Conclusion:

It is our opinion that the nutrition program was able to adequately measure relationships between socio-economic and seasonal variation of food supply and nutritional status in children 0-36 months. However, it was of great interest to find that food supplementation of children had only a marginally significant ($P = 0.10$) impact on the participating children. We agree with the investigators that while dramatic improvements were not seen in the proportion of children at the higher levels of nutritional status, the study could not ascertain if more deaths would have occurred without the program. Season, income, mother's education, sex, religion, birth order, all were found to be significant predictors of nutritional status.

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