Date September 09'97

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ACE SHEET)

ETHICAL REVIEW COMMITTEE, ICDDR,B.

iḋal Investigator Dr.George Fuchs &
~~Dr.Mahmud Khan~~   Trainee Investigator (if any) _____

plication No. 97-019   Supporting Agency (if Non-ICDDR,B) _____

tle of Study Evaluation of the impact Project status:
a home gardening programme in   (✓) New Study   **DMONO**
                                  ( ) Continuation with change
ral Bangladesh.   ( ) No change (do not fill out rest of form)

rcle the appropriate answer to each of the following (If Not Applicable write NA).

Source of Population:
(a) Ill subjects   Yes (No)
(b) Non-ill subjects   (Yes) No
(c) Minors or persons
    under guardianship   (Yes) No
Does the study involve:
(a) Physical risks to the
    subjects   Yes (No)
(b) Social Risks   Yes (No)
(c) Psychological risks
    to subjects   Yes (No)
(d) Discomfort to subjects   (Yes) No
(e) Invasion of privacy   Yes (No)
(f) Disclosure of informa-
    tion damaging to sub-
    ject or others   Yes (No)
Does the study involve:
(a) Use of records, (hosp-
    ital, medical, death,
    birth or other)   Yes (No)
(b) Use of fetal tissue or
    abortus   Yes (No)
(c) Use of organs or body
    fluids   (Yes) No
Are subjects clearly informed about:
(a) Nature and purposes of
    study   (Yes) No
(b) Procedures to be
    followed including
    alternatives used   (Yes) No
(c) Physical risks   Yes ,No, NA
(d) Sensitive questions   Yes No NA
(e) Benefits to be derived   (Yes) No
(f) Right to refuse to
    participate or to with-
    draw from study   (Yes) No
(g) Confidential handling
    of data   (Yes) No
(h) Compensation &/or treat-
    ment where there are risks
    or privacy is involved in
    any particular procedure Yes :No· NA

5. Will signed consent form be required:
   (a) From subjects   (Yes) No
   (b) From parent or guardian
       (if subjects are minors) (Yes) No
6. Will precautions be taken to protect
   anonymity of subjects   (Yes) No
7. Check documents being submitted herewith to
   Committee:

   ____ Umbrella proposal - Initially submit an
        overview (all other requirements will
        be submitted with individual studies).
   ____ Protocol (Required)
   ____ Abstract Summary (Required)
   ____ Statement given or read to subjects on
        nature of study, risks, types of quest-
        ions to be asked, and right to refuse
        to participate or withdraw (Required)
   ____ Informed consent form for subjects
   ____ Informed consent form for parent or
        guardian
   ____ Procedure for maintaining confidential-
        ity
   ____ Questionnaire or interview schedule *
   * If the final instrument is not completed
   prior to review, the following information
   should be included in the abstract summary:
   1. A description of the areas to be
      covered in the questionnaire or
      interview which could be considered
      either sensitive or which would
      constitute an invasion of privacy.
   2. Examples of the type of specific
      questions to be asked in the sensitive
      areas.
   3. An indication as to when the question-
      naire will be presented to the Cttee.
      for review.

gree to obtain approval of the Ethical Review Committee for any changes
lving the rights and welfare of subjects before making such change.

_____
Principal Investigator   _____
                                                    Trainee

TITLE: Evaluation of the Impact of a Home Gardening .
                                        Programme in Rural Bangladesh.

PRINCIPAL INVESTIGATOR(S):   George J Fuchs MD & Mahmud Khan PhD

CO-INVESTIGATORS: KMA Aziz , PhD
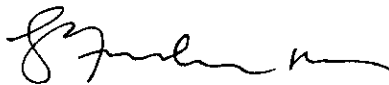   ASG Faruque, MPH
                                        J Patrick Vaughan, PhD

BUDGET: US$ 400,000.00

STARTING DATE: September, 1997

CLOSING DATE: October, 1998

HEAD OF PROGRAM: Division Director, CSD

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Abstract

Vitamin A deficiency is a serious public health concern with long-term health and social consequences. The Helen Keller International (HKI) started implementing home gardening program for promotion of production and consumption of vegetables in rural Bangladesh. Home gardening should increase the supply of food within the household, increase income, and increase the quality of food consumed. This formed the premise that the home gardening programme would increase vegetable production in the home plot and reduce the vitamin A deficiency of household members. However, recent studies indicate poor efficacy of increased intake of dark-green leafy vegetables to improve vitamin A status, perhaps due to poorer than predicted bioavailability of preformed vitamin A in dark-green leafy vegetables. The importance of evaluation of the HKI home gardening project is recognized. The evaluation will emphasize various final outcomes to identify the impact of the project on households. A comprehensive study will be required to understand the direct and indirect effects of the project. This will also enable more concrete analysis of impact for best performing households. The evaluation will use both quantitative and qualitative research methods to collect information on the impact of the project. The quantitative survey will have two components: the biomedical component and the socioeconomic component. In establishing the link between thinking and action, and to ascertain that the respondents carefully evaluated all alternative options and responded in a rational and truthful manner, it is important to supplement the quantitative survey with qualitative assessment.

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Introduction

In Bangladesh, production of cereal increased at an annual rate of more than 2.5% over the years 1980-1993. Taking net food imports into account, energy availability per capita from major cereals increased gradually over the years. Despite the rapid growth in food production, the nutritional status of children shows no or very little significant improvement. According to the 1989-90 and 1992 Child Nutrition Surveys, prevalence of wasting actually increased from 14.7% to 16.7%. Stunting also remained more or less static at around 65% (Bangladesh Bureau of Statistics, Child Nutrition Survey of Bangladesh 1992). About a third of the population in Bangladesh consumed less than 1805 calories per adult equivalent per day during 1990 (BBS, 1993 Year Book). Therefore, vulnerability to food and nutritional stress remains a significant concern in Bangladesh. It is interesting to note that even though income and landownership are considered important determinants of nutritional status of children, nationally representative nutrition surveys indicate that the link between income, asset possession and nutritional status is very weak, if any. Other researchers have also found a low association between economic wellbeing and nutritional status of children in poor developing countries of the world (see Behrman 1993).

The fact that the clinical and social research studies fail to identify a small number of 'core' or most important determinants of nutritional status of children implies that the cycle of malnutrition and poor health among children is a very complex process. Other factors like food preparation methods, diversity of diet, prevalence of other illnesses, poor environmental health situation, low availability of potable water, all influence health and nutritional status. Similarly, deficiency of iron, iodine and Vitamin A appears to be widespread in Bangladesh, implying that economic situation may not be the most important determinant of these deficiencies.

The Helen Keller International (HKI) initiated a home gardening programme for "promotion of production and consumption of vegetables in rural Bangladesh" in 1988. This programme is based on the assumption that home gardening would increase the supply of food within households, increase income and thus improve the quality and quantity of food consumed. It was also assumed that the home gardening programme would increase vegetable production in the homeplot and this would lead to a reduction in vitamin A deficiency of the household members. It is well recognized that in the developed world, diversity in the consumption of vegetables and other food items has reduced the frequency of vitamin A and other micronutrient deficiencies.

Vitamin A deficiency is a serious public health concern that has long-term health and social consequences. Low availability of vitamin A at the cellular level creates a number of physical problems, including loss of appetite, loss of weight, increased keratinization of epithelial tissues, negative nitrogen balance, nervous disorders, and night blindness. However, in many developing countries of the world, xerophthalmia is the most common single cause of blindness in infants and pre-school children (WHO, 1976). The 1982-83 National Blindness Study of Bangladesh estimated that more than 30,000 children under 60 months of age suffer

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from vitamin A deficiency related eye problems (cited in Bloem et al., 1996). In densely populated regions of south Asia, where rice is the principal staple, vitamin A deficiency appears to be common. Rice is virtually devoid of vitamin A and the diet must be supplemented, therefore, with other vitamin A rich food items to prevent the deficiency.

The number of empirical clinical and non-clinical studies on vitamin A deficiency in Bangladesh is quite limited. One study examined vitamin A consumption of women and children in Bangladesh and found that the seasonal variation of vitamin A consumption was high (Zeitlin et al., 1992). This study found that May and June were the highest vitamin A consumption months for Bangladesh mothers while February, March and April had the lowest vitamin A consumption. While main source of vitamin A was dark green leafy vegetables, mango was one of the most important sources of vitamin A during the summer months. In recent years, the need for the consumption of other types of nutrients, such as zinc, to improve the efficiency of conversion of provitamin A carotenoids into retinol has been raised. The importance of consuming yellow and red vegetables and fruits as sources of vitamin A has also being discussed. Clearly, to reduce the vitamin A deficiency through diet, consumption of all types of vegetables has become extremely important. Therefore, home gardening can play an important role in reducing vitamin A deficiency. However, it is also possible to increase the consumption of vitamin A rich food items with or without direct intervention in home gardening. For example, a study at ICDDR,B shows that the consumption of green leafy vegetables can be increased through intensive nutritional education programme (Aziz 1997).

There are only a few studies that have described the effectiveness of vegetables and fruits to prevent vitamin A deficiency. One well-controlled study showed an increase in serum retinol after consumption of red sweet potato and dark-green leafy vegetables (Jalal F, 1991), however, another study found no improvement of vitamin A status after consumption of dark-green leafy vegetables in women with anaemia (Pee SD, 1995). Studies that have demonstrated positive results were either poorly controlled or had weak designs. Therefore, due to contrasting results it has become essential to re-examine the approach to combat vitamin A deficiency by increasing the consumption of provitamin A carotenoids from vegetables.

Another reason to emphasize home gardening as a strategy to reduce vitamin A deficiency is that it provides additional nutrients to all the members of the household. The biannual distribution of high-dose vitamin A capsules target children of age less than 60 months. Thus, vitamin A deficient adults, specially women, remain at high risk for vitamin A deficiency and its related health consequences. Home gardening is likely to help all the members of the household. Moreover, home gardening increases vitamin A availability within the household and without the need for a continuous supply of vitamin A capsules from outside. Therefore, home gardening as a strategy to supply vitamin A should be more sustainable than periodic capsule distribution (see Bloem et al., 1996).

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Seasonality of the dietary supply is an important aspect of vitamin A status of the population in Bangladesh. Traditional home gardening produces highly seasonal vegetables and could result in vitamin A availability within the household as highly seasonal as well. Therefore, · the impact of a gardening program to successfully reduce vitamin A deficiency is greatly diminished unless the vegetable and fruit production becomes year-round. The HKI programme incorporated year-round production as an important objective of the gardening activity.

In Bangladesh, in addition to the HKI and Bangladesh Government, the Worldview Foundation has also implemented a Nutritional Blindness Prevention Programme in Gaibanda District based on health education and home gardening concepts. This project provides incentives to develop school gardens and to plant vitamin A rich vegetables. The project also encouraged increased consumption of green leafy vegetables, yellow fruits and vegetables, oil-rich food to reduce the incidence of vitamin A deficiency. However, evaluation of this project did not directly test for changes in the prevalence of vitamin A deficiency among the population concerned. Instead, the project used indirect process indicators to measure the impact, including consumption of vegetables by children and prevalence of night blindness (Greiner and Mitr, 1995). ·

HKI Home Gardening Programme

HKI became involved with home gardening in 1988, when a pilot activity in home gardening was undertaken in one of the poorest regions of the country. Currently, HKI works with more than 20 NGOs in 120 thanas of the country, that covers more than 300,000 beneficiary households. Although the scale of the project at present is quite large, it covers only about one-fourth of all the thanas in Bangladesh and only about two percent of total households of the country. Since 120 thanas should have about four and half million eligible households, it implies that the household participation in the project is only 6.5% on the average in the targeted thanas.

According to the HKI documents, the objectives of the home gardening project are to:

(a)   Increase vegetable production throughout the year.
(b)   Increase local level seed production of improved varieties of vegetables.
(c)   Increase awareness of home gardens and their importance in preventing vitamin A deficiency.
(d)   Improve utilization of existing resources and services at the field level.
(e)   Promote use of low cost technology in home gardening.
(f)   Foster government/NGO collaboration at the grassroots level.

Note that, although the objective (c) listed above mention increased awareness of the population on the importance of home gardening in preventing vitamin A deficiency, improving vitamin A status was not an explicit objective of the project.

To implement the pilot project, two to three unions were selected in each thana for targeting. In each union three blocks were selected. The block supervisors and NGO extension workers were trained on different aspects of home gardening. The block supervisors and the NGO extension workers select the nursery farmers. The project provided assistance for arranging irrigation and fertilizer. The target households were defined by using the following criteria: total land ownership no more than 0.32 hectare or 0.8 acre, presence of at least one child under six years of age, and willingness of mother to participate in gardening activities. If land ownership alone is considered, more than 80% of all households would have been eligible for participation in the HKI home gardening project. However, about 10% of households in Bangladesh, who are likely belong to the poorest income category, do not own any home plot. Thus, for these households, home gardening would not be a feasible strategy to improve nutritional status of their members.

The HKI implemented the home gardening and nutrition education pilot project in Panchagaor District from 1990 to 1993. The research design of this specific activity incorporated pre- and post-intervention surveys to assess the impact of gardening on households. HKI also implemented a regular monitoring system to evaluate the impact of gardening on households and village nurseries and the mid-term evaluation survey was carried out in December 1992 and the results were compared with those obtained by the baseline survey carried out in 1990. The mid-term evaluation of the full project will be described in the next section.

The evaluation of the pilot project phase "demonstrated that the home gardening interventions were effective in increasing year-round availability and consumption of vegetables and reduced malnutrition" (Baker and Talukdar, Micronutrients and Agriculture, Number 2, November 1996). However, since the cost of implementing the pilot project was high, at about $46 per garden per year, it was decided to expand and scale-up the project by using the existing developmental non-governmental organizations (NGOs) and the Department of Agricultural Extension (DAE). HKI provided a small grant to the participating NGOs to cover the "core" costs of home gardening activities. This strategy of using the "excess" implementation capacity of NGOs reduced the per-garden costs from $46 to $8.30 per year (Baker and Talukdar, 1996).

Although the HKI evaluation indicated quite significant improvements in efficiency of the collaborative approach, it is not clear whether the cost of $8.30 per garden represents the costs per garden from HKI's point of view or the actual full cost per garden if all sources of financing is taken into account. It is also not mentioned whether the average cost estimate corrects for the number of gardens already in place before the introduction of the project.

1992 Evaluation of the HKI Pilot Project

After the implementation of the HKI pilot project in 81 northern villages in Bangladesh, the project was evaluated in December 1992 by HKI itself. For the purpose of the evaluation, the project incorporated pre- and post-intervention surveys to assess the impact on the

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households. The time interval between these two surveys was two years. The baseline survey, the pre-intervention survey, selected 1,000 households from the total target group. Although the size of the target group is not known, the sample probably represents less than 10% of target households in the 81 villages. Another 200 households were selected as the control group from neighboring villages and 100 households were selected from the same villages as the target group to form an 'interaction group'. The interaction group did not directly participate in the HKI project. The changes in the gardening patterns of the target and interaction groups were considered as the measure of direct and indirect impact of the gardening project.

Although the baseline and mid-term surveys provide valuable information on households participating in the project, the comparison of these two surveys can not indicate the true effects of the gardening project. The method of choosing the target population produced a biased sample, a set of households who are more likely to participate in the home gardening program. Since willingness to participate in home gardening was a criterion for the selection, it is not surprising that all of the target households adopted home gardening in the second year thus inflating the positive impact of the project. According to the HKI documents, the control households from non-HKI villages were selected using the 'same' criteria set. However, the changes in the gardening pattern of this group over the two years is difficult to explain. Although 43% of the control households actually had gardens during the year prior to the baseline survey, only 25% had gardens during the year prior to the mid term survey. It is not clear why the control group shows such a huge drop in home gardening over the two year period.

Due to the limitations of the prior study, and also because of the extension of the program into new areas, it has become important to evaluate the HKI home gardening project again in a more rigorous way. The evaluation should determine any changes in a number of final outcomes indicators that would identify the impact of the project on households and the nutritional status of household members. However, to achieve this a comprehensive study will be required to understand both the direct and indirect effects of the project. Such an evaluation should also allow for a more concrete analysis of what the programme has achieved and what impact might be expected for the best performing households.

Objectives Of the Proposed Evaluation

The purpose of this evaluation is to understand the overall impact of the program on household nutritional status of participating household members, especially vitamin A status, as the result of the implementation of the project in rural Bangladesh. Specifically, the evaluation objectives will be to determine the following:

(a)   Vitamin A status of household members.
(b)   Consumption of vegetables within the household, specially by young children, women of child-bearing age, and lactating mothers.
(c)   Income of the household.

(d)   Effects on social structures and gender-relations.
(e)   Sustainability of HKI introduced home gardening.
(f)   Nutritional status of young children and women of child-bearing age.

Analytical Framework

To evaluate the impact of home gardening activities, it is important to develop an analytical framework to guide the evaluation. The first step in the evaluation will be to define the measurable outcome or impact indicators. A number of outcome indicators will be identified and presented below. Once the outcome indicators are defined, possible determinants of changes in outcome variables will be identified.

To ensure that all relevant determinants and confounders are identified, the outcome variable will be considered the output and a systematic production function analysis will be carried out to identify the relevant inputs or explanatory variables. The explanatory variables can be macro-economy or community related, related to household characteristics or to individual related. Such a broad starting point will ensure that all important explanatory variables are considered. However, such a broad scope may identify too many variables for consideration in the model. Therefore, the variables identified through the production function analyses should be ranked or prioritized so that the most important and relevant ones can be incorporated in the model. In most cases, the priority setting will be carried out by reviewing existing literature or from apriori theoretical considerations.

Methodology

The evaluation will use both quantitative and qualitative research studies to collect information on the impact of the project. The quantitative survey will have two components: socioeconomic and biomedical. In both the qualitative and quantitative surveys, researchers often ask questions about individual's preference or change in behavior and the analyses are based on the responses obtained from the survey participants. It is assumed that people usually do not lie without a reason (see Pederson, 1992) and their thinking process at the time of the survey reflects what they are expected to do when faced with the particular environment or situation on which the survey was trying to obtain information about. In establishing the link between thinking and action, and to ascertain that the respondents carefully evaluated all alternative options and responded in a rational and truthful manner, it is important to supplement the quantitative survey with qualitative studies.

Quantitative Evaluation Surveys

Socio-economic Component

For the evaluation of the gardening programme the period of implementation will be critical and therefore it will be important to examine those areas where the project has been in

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operation for at least two seasonal cycles. The impacts may not be observable if the gardening program is in operation for less than two years. For example, the village nurseries take time to develop and to become fully operational. Moreover, one cannot evaluate whether year-round production of vegetables is being adopted by a gardener unless the household has gained experience in home gardening for more than a full year. This constraint restricts the number of thanas that can be included in the evaluation to about 60 and a significant part of these thanas are located in the northern part of the country. Therefore, the evaluation cannot examine the impact of the project in different agroclimatic environments throughout Bangladesh. However, an effort will be made to identify and include at least two agroclimatic zones.

Another control that should be imposed is the nature of the NGO implementing the gardening project. The collaborating NGOs should be categorized into at least two groups: large and small NGOs. Large NGOs are national level NGOs working in almost all districts of Bangladesh, whereas small NGOs are basically regional or local organizations. The management structure, objectives and activities of national NGOs are very different from the local NGOs. National NGOs prefer to participate in activities which have the potential of becoming a national model with wide geographic scope. Given the size and activities of the large NGOs, they may not be very interested in small-scale, moderately funded projects like the home gardening project of HKI.

Diagram 1 shows the steps in the selection of the thanas for the survey. The total number of thanas in the HKI project is about 120, but only 60 have been in operation for more than two years. The project thanas will be categorized according to the geographic location of the thanas and using NGO-type as the basis for stratification. Within each NGO-type, two thanas will be selected at random for the survey which will result in eight thanas selected. A simple classification of NGOs could be to categorize these according to their size. Since the HKI project plans to cover the whole of a thana by the end of the third year of operations, about two-thirds of a project thana should already be under the project. By the time of the household survey for the evaluation, the project should cover the whole thana.

To select non-project area thanas, a list of neighboring thanas will be prepared. Two thanas will be selected from each of the geographic zones where the project thanas are located. If feasible, NGO categorization will also be used. The total number of thanas to be selected for the whole evaluation survey will be 12; eight from the project area and four from non-project area. Diagram 2 summarizes the method of selecting the matched thanas from the non-project area.

For the thanas selected for the survey, two unions will be selected at random from each thana and within each union, two villages will be chosen randomly from the list of all villages under the HKI programme for more than two years. A quick census will be carried out to obtain certain basic information about all the households residing in these two villages selected. From each of the villages, a random sample of 40 households will be drawn using the census list of target households. The number of households selected ensures that we can

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examine the interaction effect of NGO-type and geographic location on gardeners and non-gardeners. Therefore, in 12 thanas, total households to be surveyed becomes about 2,000; sixteen hundred from the project area and the rest from non-project area. Diagram 3 summarizes the sample selection process for the household survey.

The following lists a number of household output indicators that the quantitative survey will try to measure. The list is not intended to be an exhaustive listing and other relevant variables and indicators will be identified before the household survey in November, 1997.

Quantity of vegetables produced:

One of the intermediate effects expected is an increase in the production of vegetables in the home gardens. Home gardens are also a traditional activity and many households produce a number of vegetables on the home plot. The project introduced a new method of gardening, called developed home gardens, to increase their total output. The household gardener will be asked to report the quantity of vegetables harvested from the garden during the past two to three months.

Seasonal pattern of vegetable production:

Traditional gardens produce vegetables with extremely high seasonal variations. In traditional gardens, vegetable outputs are concentrated during the winter months of the year. However, the developed garden should reduce the seasonal peaks by improving vegetable output during other months of the year as well. The survey will examine the seasonal pattern of vegetable production by conducting two surveys, one immediately after the winter season and the other during the later part of the rainy season.

Number of varieties of vegetables produced:

This is also an important indicator of the intervention, since the project introduced new varieties of vegetables for cultivation. To reduce vitamin A deficiency, it is important that several varieties of vegetables are made available at the household for consumption. Therefore, the number of varieties of vegetables produced is an important household indicator.

Marketing pattern of vegetables produced by the household:

To understand the availability of vegetables in the household for consumption, it is important to examine the marketing pattern of vegetables produced. If the households sell most of their production, vegetable consumption may not show a significant increase.

Purchase of vegetables from the market:

Specialization in the production of vegetables, i.e., producing only a limited number of vegetables does not necessarily imply that the household do not consume a variety of vegetables. A household producing only one or two varieties may find it profitable to sell some of the output to the market and then to buy other varieties from the market. This, however, requires that different types of vegetables are available in the market for purchase and sale.

Increased consumption of vegetables:

One of the important outcome at the household level of the HKI home gardening project should be the increased consumption of vegetables among the target households. Information on increased consumption of vegetables and intra-household distribution of vegetables will be obtained through frequency of vegetable consumption. Due to low reliability of food consumption recall data, quantity of vegetable consumed will not be estimated.

Nutritional status of children:

Nutritional status of children is an important outcome measure of the home gardening project. Nutritional status of children will be measured by using standard anthropometric indicators. The survey will measure height, weight and MUAC of children aged two to six years. Nutritional status of children acts both as a control and as a covariate of vitamin A status among children. The gardening program, if successful, should have both long-term and short-term impact on anthropometric indicators. The weight-for-height measure should show the greatest impact due to improved supply of food at the household level over the years.

Nutritional status of adult women:

Although the anthropometric measures of nutritional status are not very specific and sensitive for adults, one can use the Body Mass Index (BMI) and MUAC (Mid-Upper Arm Circumference). The marginal cost of incorporating these nutritional measures should be quite low when the children are being measured during the survey.

Biochemical status of children and women:

2 ml venous blood will be obtained from women or young children for determination of retinol concentration in blood by HPLC. The study subjects will also be screened for iron deficiency anaemia by estimating their haemoglobin and ferritin concentration. C-reactive protein concentrations in serum will also be quantified to assess possible inflammatory process in the subjects which could effect retinol levels.

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The blood will be collected at the field, allowed to coagulate, serum will be separated from clot by centrifugation. Then serum will be transferred to vials by pipette. Serum will be refrigerated. Specimens will be transported to laboratory in thermos.

Health Status of household members:

Health status of individuals is not easy to measure. The reported morbidity status of individuals are often influenced by socioeconomic status of the household. The household members will be asked about their recent illnesses with other relevant information like days of illness, severity and duration of morbidity, medical care seeking behavior and life style related health practices. For acute illnesses, the recall period can be about two weeks but for other chronic illnesses a longer recall period can be used. Mobility and other physical aspect related health status will also be measured using direct interview approach.

Impact of the project on income of the participating households:

The project activities may affect the income of the households directly and indirectly. Due to increased production of vegetables, income status of the population might improve. Indirectly, the households may find their economic position improves due to lower vegetable prices in the market or higher employment opportunities created by the home gardening project. In this analysis, income will be defined in a wider sense to include access to economic resources. Therefore, increases in production in home gardening without affecting outputs in other areas will increase the income of the household irrespective of the level of cash income.

Improved food security at the household level:

Vegetable production and better health status of the population may affect the food security status of the household and household members. Availability of food at the household over the year could lead to an improved diet for the members, sustainability of the program, reduction in the risk of crop failure and improvements in the food security situation. Availability of food at the household level is only one aspect of food security. Household's ability to deal with food shortages, market prices of food and non-food items, etc., also affect food security.

Empowerment of women:

Since the project targets the women of the households, income or resources under the direct control of women may increase. This improved economic situation may encourage women to become more involved in household level decision making. Womens' access to economic and social resources improve their social status.

Sustainability of the gardening program:

Home gardening is not new at all. Traditionally, women have planted a few
vegetables around the home plot. However, the HKI gardening project has
implemented a new type of home gardening, called "developed" home gardening. The
evaluation should directly ask question as to the sustainability of these developed
gardening activities in rural Bangladesh, if the current project were to be withdrawn.
Continuation of the 'developed gardens' will be used to define sustainability of the
project. Traditional gardening is clearly sustainable and remained important without
the existence of the project.

Village Nurseries

The quantitative survey will also select all the village nurseries supplying seedlings to
the households in the project area. Therefore, 16 village nurseries will be selected to
understand the success of the project activities in the long-term. Long-term viability
requires not only a positive economic return, but also a supportive market
environment, appropriate management capacity, ability to market new vegetable
plants, demand for their services in the community.

HKI Monitoring Information

Another important source of information for the quantitative survey is the monitoring
data regularly collected by the HKI implementing agencies. The monitoring data can
indicate the trend in the expansion of gardening programme, characteristics of the
participants, types of vegetables grown and percent of vegetables marketed. The
monitoring data will be used to understand trends in the development of home
gardening in the thanas and the differential rates of growth in different thanas. Other
participant specific characteristics, how the participation rate changed over the years,
variations in production and consumption of vegetables and the role of nurseries in
sustaining the home gardens in rural Bangladesh.

The information on process of programme implementation will also be useful for the
evaluation. The implementation process, i.e., how the collaborating NGOs were chosen, how
the nurseries were established, what types of vegetables were introduced and why, whether
the HKI changed the vegetable-mix depending upon the local environmental conditions and
food consumption pattern.

Qualitative Research Studies

The success of the project requires not only the quantitative changes in production,
consumption and nutritional status in the short-term, long-term sustainability will depend on

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changes in behavior and willingness to participate in gardening. Sustainability of the project will require success and continuation of the project-initiated activities at various levels. For example, continuation of a developed home garden by households crucially depends on the ability of the village nurseries to maintain production and supply. In fact, sustainability must be examined at several different levels: household and community, village nursery, NGO's ability to plan a smooth transition and national level interests in the continuation of the activities. Sustainability also has three different but interrelated aspects: technical, managerial and economic. All these three aspects will be examined in the evaluation.

To understand the factors that determine the success of home gardening at different levels, the strategy that will be followed is to identify the success and failure case studies and document the cases in detail. For example, from the monitoring information of the project, this evaluation will choose a number of very successful gardeners as well as some relatively poor gardeners. The comparative analysis of the cases might indicate the qualitative aspects of success and failures. For the purpose of this evaluation, at least two cases of success and two cases of failure from each thana selected from the project area, will be analyzed. The case studies will use appropriate qualitative methods and triangulation of the results.

Similarly, at the nursery level, successful and not-so-successful cases will be identified for qualitative investigation. This again will be useful to understand the factors affecting the relative success of the nurseries. The management practice, choice of varieties, cultivation methods, use of inputs will also be examined at this level with references to the community and socio-economic transactions.

The administrative and management practices of the NGOs collaborating in the implementation of the project are also important to understand the reasons behind the success or failure. In this case, the qualitative information gathering can be done by using two approaches. The first approach is to discuss the NGO selection process with the HKI. The selection process itself can indicate certain underlying criteria required for success. The second approach will be to examine the management practices of relatively successful and not-so-successful NGOs. One should also assess the changes in macro environment which may have some impact on the project's success or failure in different villages.

Another important level determining the long-term sustainability of home gardening in the country is the role of national policy makers. The policy environment must be conducive to the adoption and continuation of home gardening activities.

The focus group discussions will be organized to understand the process of selection of households by the project, social institutions affecting the success of the program, and the role of social cohesion, factional groupings and market participation in the process of developing and sustaining developed home gardening.

Small scale surveys with emphasis on open-ended questions will also be undertaken to understand the economic viability of the village nursery as well as the household level home

gardens.

This evaluation will also look into the role of institutions in determining the success and failures of home gardening attempts. In Bangladesh, home gardening is not a new concept; traditional vegetables are grown on the home plot by family members to supplement household food supply. Therefore, home gardening enjoys full support from the traditional social institutions and the project's success in the long run depends on its ability to involve the social institutions conducive to its development. In rural Bangladesh, the majority of the population are still dependent on indigenous institutional arrangements for the management of the resources needed for home gardening. Eight institutional variables are selected as the units of the study which are likely to effect production and consumption of vegetables. These variables are: economy, settlement pattern, family, household, marriage, descent, social stratification, and government. Each of these variables will be assigned two values as follows: Economy: vegetable producing in home garden and food gathering. Settlement pattern: sedentary and nomadic (including semi-nomadic). Family: extended, augmented, and nuclear. Household: small (combining nuclear and mother-child families) and large (combining all the other distinguishable types). Marriage: monogamy and polygyny. Descent: unilineal and collateral. Social stratification: stratified and classless. Government: minimum (in which formal leadership exists at the local level only or is non-existent) and maximum (all forms of political organization beyond local level).

Quantitative and Qualitative Research Methods

Three structured questionnaires will be developed for the quantitative surveys. The first questionnaire will be used for surveying all households within the geographic boundary of the selected villages. Annex 1 reproduces the format of the census questionnaire. The village census will help identify the target households in the project and non-project villages. The second questionnaire is a detailed one to quantify the impact of the project on households. The third questionnaire will be implemented at the village nursery level. The nursery survey will provide information on status of production and marketing.

The household and nursery surveys would be carried out two times during a year to better understand the seasonality of production and consumption and to reduce the recall bias due to long period of recall. In each survey, the gardeners from the household or the wife of the household head (for non-gardeners) will be asked about status of current vegetable gardening and the vegetables grown during the past season. Reasons for not participating in home gardening will also be investigated.

The qualitative research will use focus group discussions, in-depth individual interviews, participant observation and visual anthropological technique to develop the case studies. Informal discussions with managers and administrators of the project and key informants of

the community will provide information on the role of various stakeholder and community influencials in initiating and sustaining behavioural changes in relation to choice of vegetables.

The use of these methods in data collection will help in the understanding of the process and degree of internalization of the new concepts introduced by the HKI project. The quality of data will be ensured by making cross references to the similar data collected by several methods (i.e., by using triangulation approach). The qualitative methods used in this research will provide illumination and insight on how, why and what of home gardening. In that sense, the qualitative and quantitative methods to be used in the research will complement each other to provide a complete, generalized picture of the activities rather than looking at segmented partial analyses.

Biomedical Survey

Hypotheses

The biomedical survey will be based on the following assumptions:

1. Home gardening increases the supply of vegetables within the household and the increase in supply lead to increased intake of beta-carotene-rich foods.

2. The increased vegetable consumption improves vitamin A status of preschool children and women of childbearing age;

3. Home gardening has other beneficial effects on health and nutritional status of women and children.

Objectives of the Biomedical survey

1. To determine the vitamin A status of preschool age children and women of childbearing age participating in the home gardening activity compared to those not participating in the home gardening programme;

2. To study the impact of home gardening on health and nutritional status of preschool children and women of childbearing age, compared to those not participating with home gardening programme.

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Methods

Study population

Two groups will be studied, children 24 months to six years old and women of childbearing age (15-44 years).

Sample size

Assuming a 40% prevalence of serum retinol level <20 $\mu g/dl$ (Sommer A & West KP, 1996), and an improvement by 10% in prevalence after the intervention, with 80% power and type I error=0.05, the sample size with an adjustment for possible withdrawals (10%) is 400 for preschool children and 400 women of childbearing age in each group (intervention or nonintervention). However, there are two types of NGO's that are acting as partner NGOs in implementing the programme. Therefore, the sample size for each group (intervention or nonintervention) would be selected from each of the small or large NGO program area. Finally, the sample size is 1600 children and another 1600 women of child bearing age. Since the evaluation will link the vitamin A and other health indicators with household socio-economic situation, the study will collect biomedical information from women and children belonging to the households selected for the socioeconomic survey.

Eligibility criteria for children:

Inclusion criteria

(a)   Children 24-72 months of age;

(b)   Children who permanently live with family members at the household selected for the socio-economic survey.

Exclusion criteria

(a)   Foster children;

(b)   Children with any chronic or congenital diseases.

Eligibility criteria for women:

Inclusion criteria

(a)   Women of 15-44 years of age who are nonpregnant by history;

(b)   Women who live with family members at household permanently.

Exclusion criteria

(a)   Women living less than three years with the family;

(b)   Women with any chronic or congenital disease.

Main outcome variables:

Vitamin A status:

Secondary outcome variables:

Nutritional status: Nutritional status will be assessed by Z scores and BMI; weight, height, and mid upper arm circumference will be recorded. Measurements will be compared with standards from NCHS.

STUDY SCHEDULE

Data and specimen collection for the biomedical survey will last for 5 months beginning October 1997.

Data collection and quality control

Questionnaires will be developed for data collection. However prior to their use, questionnaires will be field tested for validity, comprehension, and acceptability in 50 children and mothers at the household level in rural Bangladesh.

Clinical examination and recording of findings will be conducted by a trained physicians, trained interviewers will administer the questionnaires to the mothers, and laboratory personnel will record all relevant information in laboratory record forms.

Female interviewers will be kept unaware of the hypotheses being tested. They will be trained on interviewing techniques and taking anthropometric measurements. The performance of interviewers will be monitored by regular observation at the household level, regular checks of data for completeness. Monthly staff meetings will be held to review the progress of the study. In 5% cases data collection on 10 randomly selected variables will be repeated by the investigator(s). Errors detected will be corrected on the spot. Identical forms, equipments, definitions, and methods will be used throughout the study period in both groups.

Data analysis

Data will be transferred to a microcomputer. All data will be validated by a series of logical and

range checks. Finally SPSSPC+ package will be used for data processing and analysis. Data will be summarized and study group will be compared with the control group. Statistical analysis will include descriptive as well as analytical methods, arithmetic mean and standard deviation if the distribution is normal, and median and ranges if the distribution is not normal will be computed. If the outcome is expressed as categorical variable, the significance of differences will be evaluated by chi-square test. When the main outcome measures are continuous variables, the statistical significance of group mean comparisons will be determined by analysis of variance. If necessary equivalent nonparametric tests will be computed because asymmetric distribution of measurements may occur.

Initially a descriptive analysis will be very much helpful to get a grasp of the magnitude of the task. Data will be tabulated into 2X2 or 2X3 tables from beginning, thus frequency tables will be prepared. Moreover, if the outcome is expressed as a categorical variable, for example; none, low, medium, or high, a X^2 test for trend will be computed to assess whether the proportion of children/women belonging to the intervention group, as opposed to the nonintervention group, increases with increasing level of outcome variable (vitamin A status). More sophisticated techniques such as multiple regression for outcome expressed as continuous variable or logistic regression when analyzing a dichotomous outcome will be performed for adjusting biasing effects of confounders or when needed to investigate the effects of several variables at once. If necessary multiple regression models will be fitted with additional variables without confounding effects to increase precision of estimate and power, and reduce residual error. The analysis will be guided by a sequence of hypotheses that will attempt to refute or confirm an association. For possible existence of any interaction (i.e. the association may not apply equally to all subgroups), searches for that will also be made. Such testing for interactions in any of the multivariate methods will avoid misleading public health conclusions.

Main outcome variables will be young childhood or maternal serum retinol. It will be assessed as deficient, low or adequate (<0.35 μmol/L, <0.70 μmol/L, and =>0.70 μmol/L respectively, WHO/UNICEF, 1994).

Time schedule

August-September '97	Finalizing the survey design, selection of thanas, unions, villages. Qualitative studies to understand what to be included in the quantitative surveys.
	Designing the household census questionnaire and detailed household questionnaire, piloting and field testing of the questionnaires.
	Selection of households for the survey
October-December '97	Survey of households

Survey of village nurseries
Biomedical survey of households
Data entry, cleaning of the data and initial analysis of the .
first phase of data collected. Qualitative survey design
finalized. Focus groups defined and objectives of focus
group discussions identified.

January-February '98   Qualitative survey work in the field.
Biomedical survey of households

March-April '98   Second round of the quantitative survey. Survey of
households and nurseries.

April-June '98   Data entry, data cleaning, initial analysis of the data,
comparison of the data with the first round of data
collected, comparative study.

July-September '98   Report writing, first draft available by the end of October.
Report sent to outside reviewers.

September-October '98   Finalizing the report

omments on the ICDDR,B proposal 'Evaluation of the impact of a home gardening
rogramme in rural Bangladesh'   Reviewer # 1

. Because the programme has been going some time and because an answer is required within a
short period of time, the study will have to rely on observations at one time point: therefore either
a cross-sectional study in areas where the programme has been operating or a comparison
between intervention and non-intervention areas will need to be carried out. However, such study
designs make it very difficult to avoid or correct for the effects of confounders or mismatching. In
the proposal, insufficient attention is paid to these problems.

2. In developing a proposal, I think that it is important to develop a model, to design a study in which
are laid down the parameters to be measured, and to determine the criteria for saying that there
is an effect. The simplest model would be that home gardens would increase production of foods
including those containing provitamin A which would lead stepwise to improved vitamin A status,
health and well-being. Instead of, or in addition to being consumed, produce could be sold and
the proceeds used for purchasing (pro) vitamin A-rich foods, which could improve vitamin A
status, etc., or other foods, goods or services which could lead to improved nutritional status,
health and well being. For me, the most important criteria is improvement of vitamin A status
directly. Otherwise, the question would arise as to whether inputs from USAID via HKI and the
HKI-associated NGOs may have been better spent on promoting other money-generating
activities. If home gardens are to be the method of choice for eliminating vitamin A deficiency
before the year 2000, the criteria could be t what extent home gardening, if pursued to the full,
could reach this goal. A realistic endpoint would probably be the halving of the excess proportion
of children under 5 years over the cut off-point of serum retinol levels < 0.70 µmol/L or < 0 70
0.70 µmol/L. Similar criteria could be developed for lactating and/or pregnant women. Such
concrete endpoints are not defined in the proposal. A minor effect of one percentage point
reduction would not be of practical significance.

3. If food sold leads to an improvement of nutritional status, the question would need to be asked is
whether alternative use of resources from HKI/USAID may not have resulted in a greater
improvement. If the NGOs used resources to teach people to make footballs for example, more
money may have been generated allowing an improvement in nutritional status. Thus increased
consumption of home-grown produce would be an import link.

4. It is proposed that a comparison between intervention and non-intervention areas will be
made. I agree that this is possibly better than a cross-sectional study within intervention
areas. However in a comparative study, it is really necessary to ensure that any
differences seen are attributed to the factors responsible and not to confounders.
Insufficient attention in the proposal is made to the possible effect of confounders. In
addition, details of the statistical procedures to be used should be defined in advance.
These aspects are essential in order to define which parameters should be measured and
the sample size required.

5. If serum retinol levels are used as a measure of vitamin A status, the possible effect of
infection on these parameters needs to be considered. This can be done by only using
results from subjects without current infection as determined by leucocyte count,
erythrocyte sedimentation rate or the level of a number of acute phase proteins. The
effect of infection on serum retinol levels has not been considered in the proposal.

6. Thus, in conclusion, I think that you need to state the parameters you intend to measure,
the extent that they need to change in a given pre-determined model, and to correct for
the effect of any likely confounders. As far as I am concerned, the most important
parameter is an increase in vitamin A status coupled to an increase in dark-green leafy
vegetable consumption. Thus the design should be directed to these end The
parameters measured should be related to the endpoints and to possible confounders.
Other hypotheses and parameters would in my opinion, be of less importance.

The objective of this project is to evaluate the impact of a home gardening programme of Helen Keller International (HKI) in rural Bangladesh. HKI launched this programme to increase the vegetable production in the home plot with improved varieties and increased member of vegetable covering all seasons, to increase the food supply within the household round the year, increase income, and improve the quality of food consumed. It is also expected that the programme will reduce Vitamin A deficiency, a major public health problem in Bangladesh and probably other deficiencies as well. Year round production of vegetables was an important component of the programme. An earlier pilot programme by HKI in Northern Bangladesh (Panchagaor District) was reported to have had substantial positive impact. However, methodological flows made the conclusions unreliable. The present evaluation project is being designed to conduct an objective and valid evaluation of this important health intervention.

The stated objectives of the KHI home gardening project are :

1. Increase vegetable production throughout the year;
2. Increase local level seed production of improved varieties of vegetables
3. Increase awareness of home gardens and their role in preventing vitamin A deficiency;
4. Improve utilization of existing resources and services at the field level;
5. Promote utilization of low cost technology in home gardening; and
6. Foster government/NGO collaboration.

The stated objectives of the present evaluation plan are:

1. Vitamin A status of household members;
2. Consumption of vegetables, specially by women and children;
2. Income of target households;
4. Social structures and gender relations;
5. Sustainability of HKI-introduced home gardening;
6. Nutritional status of young children and women of child-bearing age.

The unstated hypothesis of the HKI intervention may be stated as follows:

| Improved Home Gardening → | • Increased food supply at home round the year
• Increased income
• Improved quality of food consumed round the year | → | Improved Nutrition
? Improved quality of life |

Some comments on the objectives of the evaluation:

Given the stated objectives of the KHI programme, it will not be fair to HKI to judge the success of the programme based on the health impact i.e. vitamin A status and nutrition status of children and women. The evaluation should be at two levels, at the first level one should evaluate whether the primary targets of a) increasing the vegetable production, b) sustaining increased production round the year, c) maintaining production of a reasonable mix of varieties of vegetables, and c) sustaining the infrastructure for the supply of seeds and seedlings, fertilizers, loans (?) if any.

All the second level one should look at the health impact.

Furthermore, successful home gardening should have a positive impact on the quality of life by sustaining participation in a pleasurable activity that generates income as well as food for the family: and this activity has a sustained effect on the quality of food consumed round the year; a sense of security from the fact that food is available at home and the sheer variety should have an impact on the quality of life.

Comments on outcome indicators:

The investigators have done a commendable job in describing a number of outcome indicators each of which may be providing a different dimension to our understanding of the impact of this intervention. They are -

1. Production of vegetables;
2. Production in lean months;
3. Varieties of vegetables produced;
4. Marketing pattern (? types marketed and types produced);
5. Purchase of vegetables;
6. Increased consumption;
7. Food consumption - energy and protein;
8. Nutritional status of children (?clinical/anthropometric);
9. Nutritional status of women (?clinical/anthropometric);
10. Biochemical indicator of nutrition (children, women);
11. Morbidity among household members;
12. Income of participating households;
13. Food security at household level;
14. Empowerment of women (? who gets the money from the sale of vegetables)
15. Sustainability of the programme.

The following are my comments on the numbered indicators above:

Indicators 1 and 2 are important primary outcome measures and a valid way of estimating these two needs to be established after careful testing. For indicators 3,4 & 5 i.e.

varieties and marketing pattern, one important factor that may determine household consumption is the marketability of the vegetable produced. Better marketability of a vegetable will reduce its consumption at home while increasing the household income. Conversely, a vegetable that cannot be marketed is more likely to be consumed at the household level. Status of some vegetables may be more complex. A fleshy vegetable like white gourd(? green gourd) has a high market value while its eminently edible and popular leaves are not that easy to market. Therefore, the same vegetable plant can serve the dual purpose of increasing income and household consumption. It should be possible to classify the vegetables according to their marketability before starting the evaluation. One could classify them into so called "cash crop" and "food crop".

Indicator 6 i.e. increase in consumption is important, particularly the intra-family distribution. Given that most leafy vegetables are traditionally regarded as low caste among food items unlike say fish or meat, it is more likely that such foods will be consumed by women and children. However, the study should carefully look into intra-family distribution of the produce from the home gardens.

Concerning indicators 8,9 and 10 it would be most gratifying if a positive health impact can be shown. However, lack of a demonstrable effect does not necessarily mean the home gardening project has failed. If one can establish that a large variety of vegetables and fruits are produced in larger amounts round the year some or many of which are consumed by the family and that some income is generated and a sense of security on food availability has been imparted by the programme should be enough to call it a success. Health impact may require a longer time frame and/or changes in some other prevailing adverse conditions.

About morbidity among household members (indicator No.11), it is a weak one and probably can be dropped without loosing anything.

Indicators 12 and 13 i.e. income and household food security, are relevant and important. One would need to workout specific ways (indicators) for these two outcomes.

Finally, indicator 15 i.e. sustainability of the home gardening programme is a crucial one. It is particularly important to find out about the institutions sustaining the home gardens including nurseries. Viability of nurseries is an important factor.

Increased consumption, food/calorie consumption. It is unlikely that leafy vegetables or fleshy vegetables will increase the calorie intake given their low calorie density. However, certain fruits, nuts and oil bearing seeds and legumes can substantially increase calorie content of the produce from home gardens. The varieties of plants promoted by HKI should be examined to evaluate their potential for

contributing to calorie consumption.

Effect on other micronutrient deficiencies. While a sustainable home gardening leading to round the year increased consumption should improve Vitamin A nutrition status, it is unlikely to have an impact on the other two micronutrient deficiencies identified as of public health importance i.e. iodine and iron. However, effect on B-Vitamin and Vitamin C deficiency could be substantial. The evaluation may consider to look at indicators for these deficiencies.

Comprehensive review of the inputs:

I would suggest going into the details of the HKI programme, the process, the inputs, examining the plant varieties for their characteristics nutritional values and seasonality etc. This exercise will help in better defining the outcome indicators.

Sample size:

Some attempt should be made to do sample size calculations. Admittedly, there will be some problem in coming to an agreement as to what is a valid unit for sample size: a household, a village, individuals in some cases? Such an exercise will help further define the outcome indicators and help prioritize.

A time frame in the evaluation:

The investigators have done a commendable job of producing an excellent project document. Admittedly, experienced and highly competent researchers of ICDDR-B will carry out the project. Yet in its present form the evaluation programme appears quite ambitions. One may consider downsizing the programme by retaining only the most important indicators.

Concluding remarks:

I find the project document well written and support the project. The most important outcome of the intervention are – a) whether the target households are able to produce more vegetables (and fruits) in a sustainable manner round the year, b) whether it leads to increased consumption of vegetables and fruits by the family members with satisfactory distribution among the members, and c) whether it generates income and creates a sense of food security in the family.

Nutritional benefits may or may not be discernible at this stage although impact on the quality of life may be apparent.

An exercise on sample size calculation will help further define the outcome indicators. In addition a detailed study of the KHI programme to define and characterize the plants promoted should be undertaken and the information used in

further revising the programme.

A careful documentation of the process of implementation of the home gardening programme, problems arising and how they were addressed may be an useful addition to the evaluation.

Finally, I fully support the project proposal.

1. The HKI Home Gardening programme is in operation for some time in rural Bangladesh and this study will address a specific question by relying on estimations at a given point in time. One of the apparent limitations of the study is that the comparability of the preexisting intervention group and the proposed nonintervention group for the variables of interest was not established prior to intervention as evidenced by lack of baseline data. Therefore, it may appear to be difficult to conclude that the observed differences in variables under consideration are due to the intervention and not due to an independent secular trend. Moreover, there may be many confounders that may influence individuals' decision to change behaviour. In order to convincingly demonstrate the positive impact of the intervention it is necessary to show that outcome variables are relatively more common and behaviour is more positive in the intervention group than the control while the sources of bias are being removed. Therefore, biasing effect of confounding variables will be measured and controlled at the data analysis stage. The adjustments can simply be done by comparing matched sub-samples. However, for more definitive conclusions, multiple regression or logistic regression analysis will be performed to remove effects of several confounders simultaneously. Variables which are not source of bias will also be added in multiple regression models to increase precision of estimate and power of test, and to reduce residual error.

2,3. Our model is that home gardens would increase production of foods containing provitamin A which would ultimately lead to improved vitamin A status, health, and well being. However, in addition to that or in lieu of that, home garden produce could also be sold to purchase (pro)vitamin A rich foods which could improve vitamin A status. In our study, we will measure the impact of increased consumption of foods from home gardens while removing the effects of those variables which are likely to influence either directly or indirectly the increased consumption of (pro)vitamin A foods purchased from local markets.

While calculating the sample size, a change in prevalence of vitamin A deficiency (serum retinol <20 μg/dl) from 40% to 30% (25% reduction, not 50%) has been considered with caution. Such 'conservative' estimate in calculating sample size has been assumed because of 'negative' results obtained by some researchers while measuring the impact of home gardening. However, 'conservative' estimate results in reasonably large sample size. When this is the case (i.e. reasonably large sample size), any baseline imbalance is likely to be small and can easily be taken into account in the analysis without substantially diminishing the power of the study. Moreover, it is important to explicitly search for interactions in multivariate analysis. For that, a sample size about four times as large as those required to detect main effects are needed to demonstrate statistical significance.

In our study, if we use a cut-off point of serum retinol levels <0.70 μmol/L instead of <20 μg/dl even then it will give similar estimate of sample size for children less than 5 years old. The sample size (calculated based on retinol concentration of breast milk) for women of child

bearing age (assuming a 25% reduction in prevalence) will be less than that required for studying young children. Therefore, largest one of the two sample sizes (i.e. 400 children or women) in each sub-group has been considered for this study.

4. During analysis, for a simple comparison of intervention and nonintervention groups, a t test or equivalent nonparametric test will be performed if the outcome is expressed as a continuous variable. If the outcome is expressed as a categorical variable, for example; none, low, medium, or high, a X^2 test for trend will be computed to assess whether the proportion of children/women belonging to the intervention group, as opposed to the nonintervention group, increases with increasing level of outcome variable (vitamin A status).

More sophisticated techniques such as multiple regression for outcome expressed as continuous variable or logistic regression when analyzing a dichotomous outcome will be performed for adjusting biasing effects of confounders or when needed to investigate the effects of several variables at once. If necessary multiple regression models will be fitted with additional variables without confounding effects to increase precision of estimate and power, and reduce residual error. For possible existence of any interaction (i.e. the association may not apply equally to all subgroups), searches for that will also be made. Such testing for interactions in any of the multivariate methods will avoid misleading public health conclusions.

5. Changes over time in serum retinol distribution within a population is a good indicator of positive impact of the intervention. However, due to lack of baseline data, we will compare the serum retinol levels between two groups at a given point in time. Retinol concentrations of population may decrease despite availability of vitamin-A rich foods at households due to acute or chronic underlying infections. Adjustment for level of
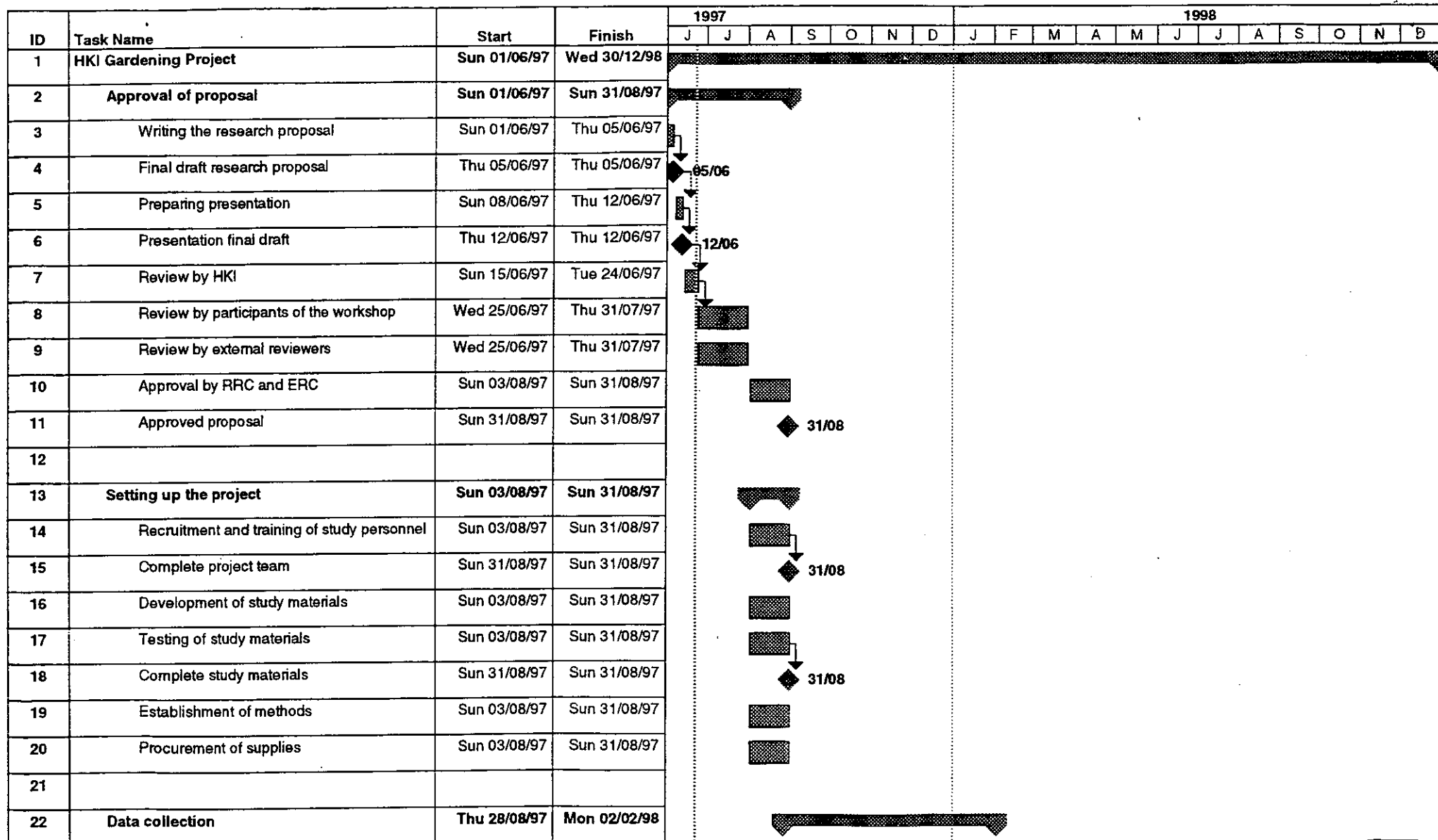
acute phase protein is important while comparing serum retinol distributions as specific indicator of vitamin A status among two populations. Therefore, we will also estimate the levels of acute phase protein of our study subjects for 'refined' measurement of the impact of intervention.

6. Comments and suggestions of the reviewer are thoughtful, relevant and helpful. Therefore, necessary changes accordingly will be made in the research proposal.

responses to the comments and suggestions made by

Reviewer #2

1. **Objectives**: The most important parameter we consider is an increase in vitamin A status coupled to an increase in dark-green leafy vegetable consumption. Therefore, the study would evaluate the differences in intervention and nonintervention-areas with regard to serum retinol level and nutritional status.

2. **Outcome indicators**: Suggestions are quite relevant and have been incorporated in the research proposal. Since serum retinol level is used as a measure of vitamin A status, the possible effect of infection on this parameter needs to be considered. Therefore, to see the effect of infection on serum retinol level estimation of level of acute phase protein has been considered. We intend to limit our biochemical assays to only vitamin A and iron status.

3. **Comprehensive review of the inputs**: The suggested exercise has already been done.

4. **Sample size**: We consider that the sample size is adequate for this study and valid unit for calculating the sample size is individual.

5. **A time frame in the evaluation**: Only the most important indicators have been retained for this study.

6. **Conclusion**: All suggestions are relevant and have been incorporated in the research proposal.
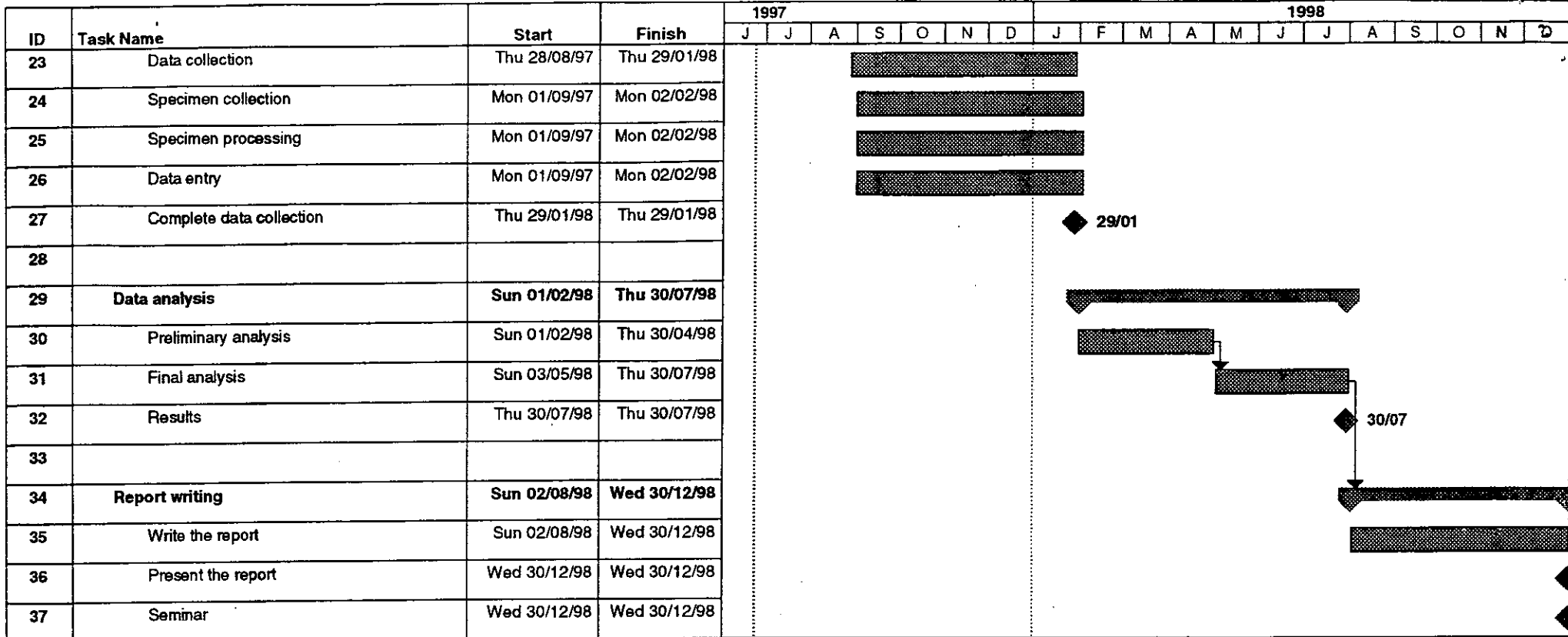
	(Budget in US Dollars)				
	HKI Home Gardening				
			Sept-Dec'97	Jan-Oct'98	Total
1	PI, George Fuchs, MD	5%	2,040	5,100	7,140
2	Co-investgator, Prof. Patrick Vaughan	5%	2,500	6,250	8,750
3	Economist, Dr. Khan	10%	4,600	11,500	16,100
4	Social Scientist, Dr. K.M. A. Aziz	60%	5,518	13,794	19,312
5	Local consultant	100%		6,516	6,516
6	Field Coordinator, Dr. ASG Faruque	70%	4,200	12,600	16,800
7	Medical Officer (2)	100%	4,200	12,600	16,800
8	Health Assistant (3)	100%	6,213	15,531	21,744
9	Survey Enumerators, GSIV/III (4)	100%	4,168	10,420	14,588
10	Survey Supervisor, GS-V (2)	100%	3,000	7,500	10,500
11	Field Attendant (1)	100%	809	2,023	2,832
12	Data Entry Technician (1)	100%	896	2,240	3,136
13	Data Processing Assistant (1)	100%	1,200	3,000	4,200
	Sub-total :Personnel		**39,344**	**109,074**	**148,418**
14	Per diem		5,500	10,500	16,000
15	Local transportation		5,000	10,000	15,000
16	International travel		4,000	-	4,000
	Sub-total: Local and International travel, Per		**14,500**	**20,500**	**35,000**
17	Questionnaires		1,000	1,000	2,000
18	Office supplies		2,000	3,000	5,000
19	Housekeepng supplies		1,000	2,000	3,000
20	Tel/fax/utilities		500	500	1,000
21	Computers/accessories		8,000	1,000	9,000
22	Biochemical assays		17,100	43,700	60,800
23	Audiovisual unit		250	250	500
	Sub-total: Supplies and materials		**29,850**	**51,450**	**81,300**
24	**Capital Expenditure**		**7,000**	**3,000**	**10,000**
	TOTAL		**90,694**	**184,024**	**274,718**

ID	Task Name	Start	Finish	1997	1998
				J J A S O N D	J F M A M J J A S O N D
1	HKI Gardening Project	Sun 01/06/97	Wed 30/12/98		
2	Approval of proposal	Sun 01/06/97	Sun 31/08/97		
3	Writing the research proposal	Sun 01/06/97	Thu 05/06/97		
4	Final draft research proposal	Thu 05/06/97	Thu 05/06/97	05/06	
5	Preparing presentation	Sun 08/06/97	Thu 12/06/97		
6	Presentation final draft	Thu 12/06/97	Thu 12/06/97	12/06	
7	Review by HKI	Sun 15/06/97	Tue 24/06/97		
8	Review by participants of the workshop	Wed 25/06/97	Thu 31/07/97		
9	Review by external reviewers	Wed 25/06/97	Thu 31/07/97		
10	Approval by RRC and ERC	Sun 03/08/97	Sun 31/08/97		
11	Approved proposal	Sun 31/08/97	Sun 31/08/97	31/08	
12					
13	Setting up the project	Sun 03/08/97	Sun 31/08/97		
14	Recruitment and training of study personnel	Sun 03/08/97	Sun 31/08/97		
15	Complete project team	Sun 31/08/97	Sun 31/08/97	31/08	
16	Development of study materials	Sun 03/08/97	Sun 31/08/97		
17	Testing of study materials	Sun 03/08/97	Sun 31/08/97		
18	Complete study materials	Sun 31/08/97	Sun 31/08/97	31/08	
19	Establishment of methods	Sun 03/08/97	Sun 31/08/97		
20	Procurement of supplies	Sun 03/08/97	Sun 31/08/97		
21					
22	Data collection	Thu 28/08/97	Mon 02/02/98		

Project: HKI Gardening Project Date: Mon 23/06/97	Task		Summary	Rolled Up Progress
	Progress		Rolled Up Task	
	Milestone ◆		Rolled Up Milestone ◇	

ID	Task Name	Start	Finish
23	Data collection	Thu 28/08/97	Thu 29/01/98
24	Specimen collection	Mon 01/09/97	Mon 02/02/98
25	Specimen processing	Mon 01/09/97	Mon 02/02/98
26	Data entry	Mon 01/09/97	Mon 02/02/98
27	Complete data collection	Thu 29/01/98	Thu 29/01/98
28			
29	**Data analysis**	**Sun 01/02/98**	**Thu 30/07/98**
30	Preliminary analysis	Sun 01/02/98	Thu 30/04/98
31	Final analysis	Sun 03/05/98	Thu 30/07/98
32	Results	Thu 30/07/98	Thu 30/07/98
33			
34	**Report writing**	**Sun 02/08/98**	**Wed 30/12/98**
35	Write the report	Sun 02/08/98	Wed 30/12/98
36	Present the report	Wed 30/12/98	Wed 30/12/98
37	Seminar	Wed 30/12/98	Wed 30/12/98

Timeline markers: 29/01 (task 27), 30/07 (task 32)

Legend:

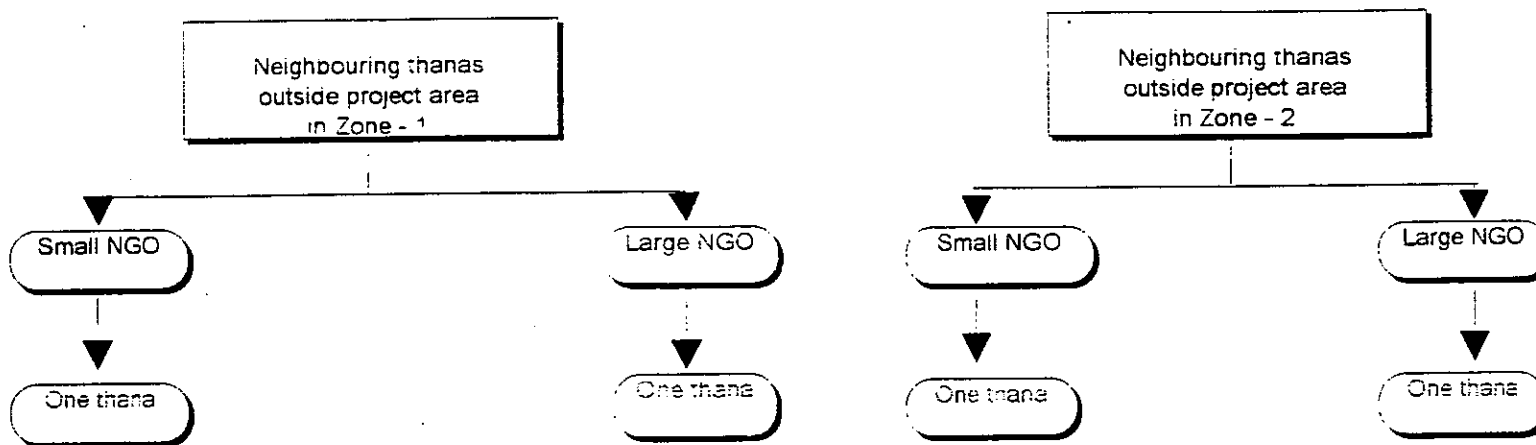|					
Task		Summary		Rolled Up Progress	
Progress		Rolled Up Task			
Milestone	◆	Rolled Up Milestone	◇		

Project: HKI Gardening Project
Date: Mon 23/06/97

Diagram 1: Selecting Project
Area Thanas for Survey

```
Number of thanas in the
project : 120 thanas
```

Less than two years
in operation : 60 thanas

More than two years
in operation : 60 thanas

Agroclimatic Zone - 1
n = ?

Agroclimatic Zone - 2
n = ?

Small NGO
n = ?

Large NGO
n = ?

Small NGO
n = ?

Large NGO
n = ?

Random
Selection

Random
Selection

Two thanas

Two thanas

Two thanas

Two thanas
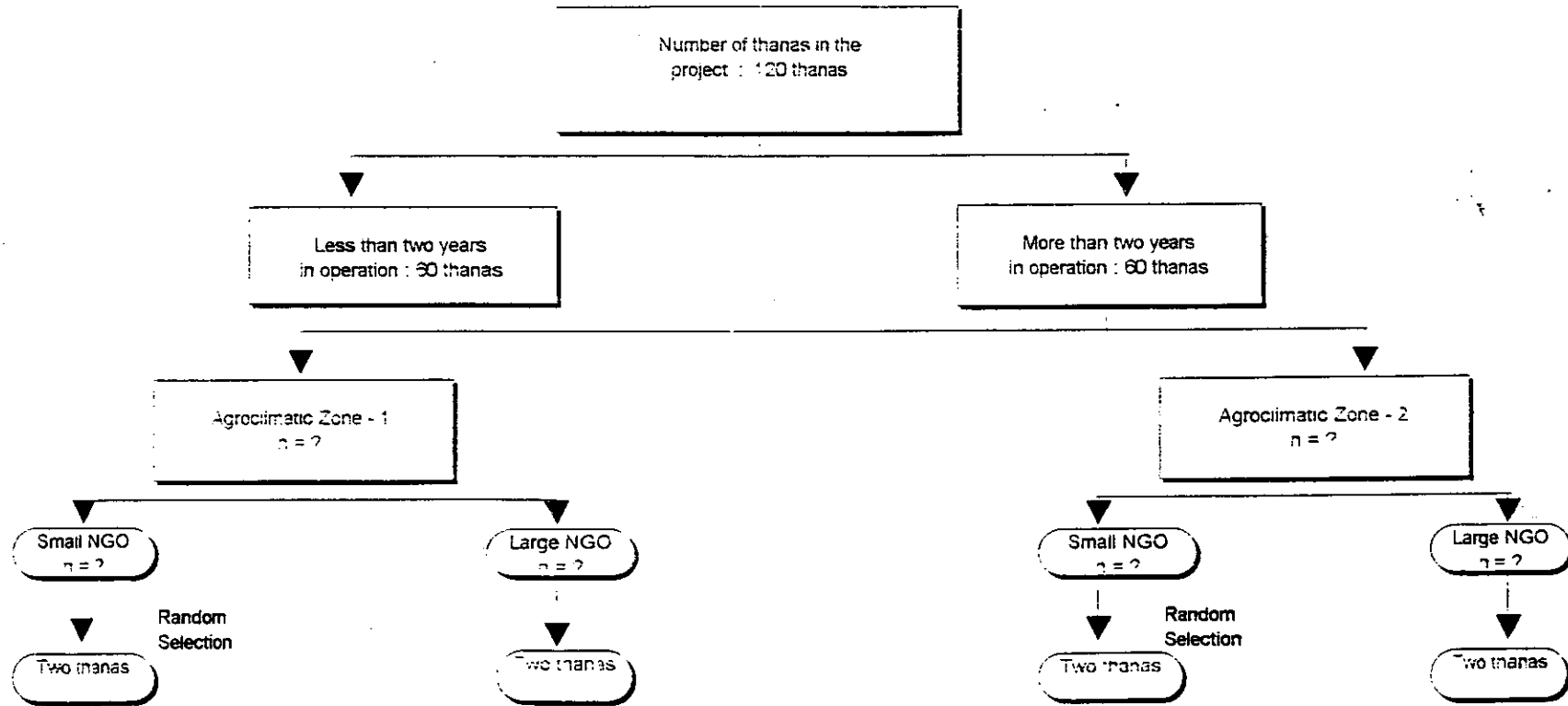
Diagram 2:
Selection of Matched Thanas

| Neighbouring thanas outside project area in Zone - 1 | | Neighbouring thanas outside project area in Zone - 2 | |

Small NGO   Large NGO   Small NGO   Large NGO

One thana   One thana   One thana   One thana

Diagram 3:
Selection of Unions and Households
for Survey

Thanas Selected
for Survey

| Union name | Union name | Union name | Union name | Union name | Union name |

Random selection of two Unions

Union - 1

Randomly selected
2 villages

Village - 1   Village - 2

Union - 2

Randomly selected
2 villages

Village - 1   Village - 2

[Census of all these four villages in a thana]
[Identify target households in these four thanas]

Village Selected

Randomly select
from target households

40 Households in
each village

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