

## ANNEX E

### MICRONUTRIENT HEALTH RESEARCH INITIATIVE

Epidemiological studies have shown the effectiveness of micronutrient supplementation in decreasing the burden of micronutrient malnutrition. National programs for supplementation of iodine, iron, folic acid and Vitamin A have been established. As part of India's efforts against iodine deficiency disorders (IDD), the National Goiter Control Program was established in 1962. However despite four decades of its existence, there are many key issues in the program implementation that need to be addressed.

In January 2002, IndiaCLEN identified "Micronutrient Nutrition" as one of its new initiatives. The IndiaCLEN members initially focused on IDD and a full spectrum of work from research to policy to program. More recently the IndiaCLEN Program Evaluation Network (IPEN) completed the evaluation of Vitamin A and iron-folic acid supplementation programs in 15 Indian states.

The Tenth Plan envisages a paradigm shift from food security to nutrition security to meet the needs of the macro-, micro- and phyto-nutrients through dietary diversifications. There will be sustained efforts to reduce/eliminate micronutrient deficiencies including universal salt iodization to eliminate IDD and a multi-pronged strategy to reduce the prevalence of anemia and associated health hazards.

To respond to this lingering challenge, the Indian Council of Medical Research organized a National Workshop on Micronutrients in New Delhi on November 24-25, 2003. The future course of action broadly encompasses political advocacy, collection-collation-dissemination of technical information and alliance building and networking. Collaboration and partnerships among national and international agencies and national and state governments will be important for this macro activity. IndiaCLEN then organized and conducted workshops on Micronutrient Malnutrition Control in India on March 26-28, 2004 and on June 25-27, 2004.

Operational and policy-relevant studies will be identified that will have greater and wider impact on supplementation programs on prevalent micronutrient malnutrition in the country. The current focus will be on the following micronutrients: iron, iodine, Vitamin A, zinc and folic acid.

**Table E-1. Estimated Budget for Projects under the Micronutrient Health Research Initiative**

Title	Duration	2004-2005 (Year 1)		(Year 2 Onwards)		Total	
		Operating Funds (58%)	Total from USAID*	Operating Funds (58%)	Total from USAID*	Operating Funds (58%)	Total Funds from USAID*
Evaluation of Vitamin A delivery systems	30 Months	79,800	137,585	170,200	293,445	250,000	431,030

\* Covers all other IPHIDE charges (IndiaCLEN program activities, administrative fees and indirect costs).

# VITAMIN A

## 1. Evaluation of Vitamin A Delivery Systems

### Background

Vitamin A deficiency (VAD) is the leading cause of preventable blindness in children. It increases the risk of disease and death from severe infections. To a great extent, VAD results from deficient dietary intake and use of Vitamin A. Despite recent positive trends, VAD remains to be a significant problem in India. Recommended interventions include: periodic pharmaceutical supplementation, food fortification and dietary diversification to increase consumption of food sources of the vitamin through nutrition, education and social marketing programs.

In a recent survey by the Indian Council of Medical Research regarding micronutrient deficiency disorders in 16 districts, the prevalence of night blindness among 113,202 children (24-71 months) was 1.03%. The prevalence of Bitot's spots was 0.7% and that of corneal scars was 0.12%. All these indicate that VAD is a public health problem in the country. The NFHS-II survey of 1998-99 showed that only a minority (30%) of the children aged 12-35 months had received one dose of Vitamin A syrup, the only intervention currently in place at the national level for VAD prevention.

IndiaCLEN conducted an evaluation of the National Vitamin A Prophylaxis Program. The evaluation revealed a passive program overall, with lack of social mobilization, program guidelines and product issues like acceptability, supply, etc. A recent paper which compared the cost of vitamin A supplied as applicaps and syrup showed a lower cost for capsules. There needs to be a better means of delivering Vitamin A to children than what is currently being used. The options available are: shifting to a capsule/applicap form of supplement, using a micronutrient fortified premix for ICDS food, or other multi-dose dispensers currently available.

**Goal:** To identify the most appropriate delivery system for provision of Vitamin A to the target children.

### Objectives:

1. To evaluate the impact of different Vitamin A delivery systems in terms of effectiveness in improving serum retinol levels of children at 12 -36 months of age;
2. To assess the cost-effectiveness of different Vitamin A delivery systems; and
3. To assess the perceptions of health care providers and clients towards different Vitamin A delivery systems.

**Study Design:** Four-limbed community trial of the following:

1. Routine Vitamin A supplementation using syrup form with the added IEC (information, education and communication) and supply components
2. Use of Vitamin A capsules/applicaps instead of syrup form
3. Use of Vitamin A-rich premix for fortification of ICDS food supplement.
4. Use of a multi-dose dispenser

## **Outcome Variables:**

*Primary:* Serum retinol

- Secondary*
- i) Vitamin A coverage
  - ii) Cost (Rs.) per increase in unit serum retinol levels
  - iii) Perceptions of healthcare providers and clients

## **Methodology:**

The study will utilize both quantitative and qualitative study designs.

*Study setting:* Rural areas and urban slums in five different regions of the country. The study population would be selected so as to have states with different levels of VAD based on the NNMB survey or any other latest information available.

*Study duration:* Two years: the first six months for preparatory work and baseline survey; one year of intervention and last six months for endline survey and data analysis.

*Study subjects:* Children in the age group 12-36 months.

*Sample size:* Based on an anticipated increase of serum retinol from baseline of 0.62  $\mu\text{mol}$  (SD 0.32 $\mu\text{mol}$ ) to endline 0.73 $\mu\text{mol}$ , with an  $\alpha$  error of 5% and  $\beta$  error of 10%, the sample size will be 175 children per group. As the allocation would be at cluster level, a design effect of 3 will be used, yielding a sample size of 525 in each group.

*Allocation:* The allocation would be at the primary health center (PHC) level. At each site, four PHCs would be included in rural areas and four census wards in urban areas.

*Study procedures:* The proposed interventions would be implemented at the PHC level. A baseline survey of a random sample of 525 children in the PHC area/ward would be carried out for estimation of baseline Vitamin A status (night blindness, Bitot spots, serum retinol, receipt of Vitamin A supplement). Each of the PHCs/wards would then implement the intervention as per the allocation. The ICDS system would be a joint stakeholder in the process. A training program would be held in all study centers for appropriate implementation of the intervention. The intervention would be regularly monitored by supervisors of the project. At the end of the intervention, a repeat survey on a random sample of children would be conducted to assess the vitamin A status of the population on the same parameters as above. Blood samples would be collected by the filter paper method and hemoglobin and serum retinol levels estimated by a centralized laboratory. In addition, qualitative research methods (FGDs and in-depth interviews) would be conducted with the major stakeholders (PHC medical officers, health workers, *Anganwadi* workers and clients) to understand their perceptions of the different interventions.

*Analysis:* Comparison of mean serum retinol levels between the four intervention groups, done separately for each site and subsequently adjusted for cluster randomization through multivariate analytic techniques..

*Ethical Issues:* The District Health team would be briefed about the project and their consent and co-operation sought before the study. Written informed consent would be taken from the children, their legal guardians and other respondents. All children identified with Vitamin A deficiency would be treated as per the national guidelines for their treatment. A record of this would be kept.

## Estimated Budget

### Budget per site

		INR
1. Personnel	Includes 2 research assistants and one supervisor for 24 months and one DEO for 12 months	623,100
2. Training of health staff	includes health workers / AWWs apprx. 75 per PHC for 4 PHCs “ Rs. 200 per person	60,000
3. Stationery / supplies		25,000
4. Travel and communication		75,000
5. Blood collection		15,000
6. Contingency including establishment costs		50,000
Total		8,48,100
<b>Total for five sites</b>		<b>4,240,500</b>

### Central Coordinating Office

		INR
1. Personnel	SRF (1), Assistant (1), Res. Asst. (2) for two years and DEO (1) for 12 months	681,000
2. Travel including for supervisory visits	10 days per site for five sites: Rs. 1,500 per day	225,000
Office support		200,000
3. Laboratory tests	Serum retinol & Hb: Rs. 250 per test for 525 x 4 x 2 x 5 tests	5, 250,000
4. Stationery / supplies		200,000
5. Contingency	Including establishment charges	500,000
	Total for CCO	7,056,000
	Total for sites	4,240,500
	<b>Total project budget</b>	<b>11,296,500</b>

**Approximately US\$ 250,000**

**Year 1: US\$ 79,800**

**Table 2c. Proposed budget for the new projects for 2005-2008**

<b>Project Proposed</b>	<b>Duration</b>	<b>Approx. Budget (Operative Funds)</b>
<b>Anemia</b>		
Childhood anemia	5 years	USD 250,000
<b>Zinc</b>		
Research Initiative- 1: Continuous versus episodic supplementation of zinc	2 years	52,000
Research Initiative – II: Feasibility of incorporating zinc supplementation in the NACP: dose- determination study and acceptability study	1 year	10,000
<b>Iodine</b>		
Screening for iodine deficiency in pregnancy	1 year	40,000
Monitoring iodine content of salt	10 months	130,000
People’s perceptions about iodine deficiency disorders	1 year	40,000
<b>Network studies</b>		
State-level laboratories	6 months	42,000
Research Initiative – III: Best strategy for micronutrient supplementation	2 years	100,000
Micronutrient Network	2 years	42,000
<b>Total</b>		<b>USD 706,000</b>

## **2. Research Initiatives in Zinc**

### **Research Initiative 1 – Continuous versus episodic supplementation of zinc**

#### **Specific Objectives**

1. To assess the impact of twice a week zinc supplementation vs. zinc for two weeks during diarrhea on the following outcomes:
  - a. Number of infection episodes (fever days, pneumonia days, diarrheal days) following the supplementation
  - b. Weight velocity during the year after supplementation
2. To measure compliance, acceptability, of episodic supplementation versus continuous supplementation

#### **Description of Activities**

- Randomization at the level of two primary health care facilities
- Target population – preschool children
- Children attending one PHC will receive zinc with ORS during episodes of diarrhea (“Episodic Cohort”)
- Children attending the other PHC would have received at least 6 months of bi-weekly zinc along with IFA regardless of diarrheal episodes (“Continuous Cohort”)

#### **Outcomes**

- Infection episodes beginning after the first episode of supplementation in the “episodic cohort” and after 6 months of supplementation in the “continuous cohort”
- Weight velocity
- Serum Zn, serum Fe, serum ferritin, Hb at baseline and at the end of 1 year of follow-up
- Acceptability and compliance with the supplementation in both groups
- Costs of the two interventions

#### **Timeframe and Budget**

- Protocol development – 3 months
- Study 2 years
- Budget: \$ 52,000

### **3. Childhood Anemia**

#### **Objectives**

1. To reduce prevalence of adolescent anemia
2. To ensure effective once-a-week iron-folic acid supplementation through the existing system of health and education, Panchayat, ICDS.
3. Improve diet and enrich iron and its bioavailability

#### **Time Frame and Budget**

- Depending upon the number of center involved and areas covered: 2004-2007
- Budget: \$250,000

#### **4. Research Initiative II - Feasibility of incorporating zinc supplementation in the NACP**

##### **Goal**

To decrease childhood morbidities such as anemia, acute diarrhea, pneumonia and malaria and accelerate weight gain in children, with bi-weekly zinc supplementation in addition to iron.

##### **Specific Objective**

To assess the feasibility of incorporating twice weekly zinc supplementation in the NACP, through existing primary health care infrastructure and with assistance of the ICDS network

##### **Description of Activities**

- To determine the appropriate dose of zinc for twice-weekly administration with IFA (bioavailability study)
- Target population – preschool children
- To determine the most acceptable form of supplementation: syrup or dispersible tablets
- To form private-public partnerships based on the existing infrastructure for IFA

##### **Timeframe and Budget**

- Timeframe – 1 year
- Proposed budget - Dose-determination study: \$5,000. Acceptability study: \$5,000

## **5. Screening for Iodine Deficiency in Pregnancy**

### **Overall Goal**

To prevent iodine deficiency in pregnancy and the effects of iodine deficiency on the developing fetus

### **Specific Objectives**

1. Collect baseline information on the variation of urinary iodine in various stages of pregnancy, in comparison with non-pregnant women
2. Based on the data collected, create a distribution of urinary iodine in pregnancy

### **Description of Activities**

- Collection of spot urine samples from a representative sample of pregnant and non-pregnant women
- Analysis of the samples for urinary iodine concentration

### **Products / Outcomes**

- Data on variation of urinary iodine levels in pregnant women in different stages of pregnancy, as compared with non-pregnant women
- Criteria for establishing iodine deficiency based on cut off values of urinary iodine

### **Timeframe and Budget**

- Timeframe: 1 Year
- Budget: Approximately Rp 180,000 per site (US\$ 4,000)  
Budget for 10 sites: US \$ 40,000

## **6. Monitoring Iodine Content of Salt**

### **Overall Goal**

To ensure adequate iodine content in salt, through quality assurance at various levels of salt distribution in rural and urban areas

### **Specific Objectives**

To recommend the best strategy for monitoring of iodine content of salt

### **Description of Activities**

- A representative sample of wholesalers, retailers, households and schools will be selected from a selected study area
- Salt samples from these selected centers will be collected prospectively over a period of 6 months
- Salt samples will be analyzed in the state laboratories

### **Products / Outcomes**

- Validity and reliability in salt sample collection will be assessed through various indicators
- The best strategy for monitoring iodine content of salt, and at which level, will be delineated

### **Timeframe and Budget**

- Timeframe: Preparatory phase: 1 month; data collection: 6 months; data management and analysis: 2 months; report writing: 1 month
- Budget: Approximately Rs. 600,000 per site (US\$ 13,000)  
Budget for 10 sites: US \$ 130,000

## **7. People's Perceptions about Iodine Deficiency Disorders**

### **Overall Goal**

Integrate the people's perceptions into the planning and implementation of the National IDD Control Program (NIDDCP)

### **Specific Objective**

To assess the knowledge, attitudes, practices of various stakeholders about iodine deficiency disorders, and iodization of salt using a pre-designed pre-tested questionnaire as a add-on component of the quantitative survey in 4 states of India

### **Description of Activities**

The Micronutrient Initiative and UNICEF are conducting state-level surveys to assess the status of IDD in selected states. ICCIDD has designed a questionnaire to assess the knowledge, attitudes, practices of various stakeholders contacted during the survey about iodine deficiency disorders and iodization of salt. IndiaCLEN can contribute its expertise in qualitative research.

### **Products / Outcomes**

- Valuable qualitative data on people's perceptions on IDD
- This information can be fed into the National Program to fine tune its IEC activities

### **Timeframe and Budget;**

- Timeframe: 1 years. Preparatory phase: 2 months; data collection: 6 months; data management and analysis: 3 months; report writing: 1 month
- Budget: Approximately Rs. 460,000 for 1 state (US\$ 10,000)  
Approximately Rs. 1,840,000 for 4 states (US\$ 40,000)

## **8 State Level Laboratories**

### **Overall Goals**

To build the capacity of state level laboratories to ensure quality of iodized salt, in association with an appropriate monitoring strategy

### **Specific Objective**

To upgrade state level laboratories for the accurate analysis of iodine levels in salt in 6 states

### **Description of Activities**

- To strengthen the resources to undertake salt iodine analysis, as part of the envisaged monitoring strategy in the selected states
- To train technicians in internal and external laboratory quality assurance procedures

### **Products / Outcomes**

- Trained manpower in states
- Provide technical support to the monitoring strategy, making it more effective and with better response times

### **Timeframe and Budget**

- Timeframe: 6 months. Preparatory phase: 2 months; training: 3 months; report writing: 1 month
- Budget: Approximately Rs. 400,000 for 1 state (US\$ 7,000)  
Approximately Rs. 2,400,000 for 6 states (US\$ 42,000)

## **9. Research Initiative III – Best Strategy for micronutrient supplementation**

### **Overall goals**

To decrease childhood morbidities such as anemia, acute diarrhea, pneumonia, malaria and to accelerate weight gain in children, with bi-weekly zinc supplementation in addition to iron.

### **Specific Objectives**

To determine the acceptability and impact of food fortification on serum iron, Hb, zinc and vitamin A levels as compared to bi-weekly IFA, zinc and half-yearly vitamin A supplementation

### **Description of Activities**

- Target population: Pre-school children, adolescents and pregnant women
- Health center-based randomization to receive food fortification for delivery of micronutrient mix or existing practice of IFA, Zn, and Vitamin A supplementation

### **Product / Outcomes**

Infection morbidity, weight gain, Hb, fetal outcomes (in pregnant women)

### **Timeframe and Budget**

- Timeframe: 2 years
- Budget: \$100,000

## **10. Micronutrient Network**

### **Overall Goal**

To ensure sustainability of the existing Micronutrient Network

### **Specific Objectives**

To strengthen the existing Micronutrient Network established by the Micronutrient Initiative and ICCIDD

### **Description of Activities**

- Strengthen and support Regional Centers of the Micronutrient Network established by the Micronutrient Initiative and ICCIDD for two years
- Undertake site-specific activities envisaged by the Micronutrient Initiative and ICCIDD
- Implement a process by which the Centers become sustainable after 2 years

### **Product / Outcomes**

Capacity building at the regional centers

### **Evaluation Plan**

Independent evaluation of the implementation of the Micronutrient Network Proposed  
Timeframe

### **Timeframe and Budget**

- Timeframe: 2 years
- Budget: Approximately Rs. 400,000 for 1 Center (US\$ 7,000)  
Approximately Rs. 2,400,000 for 6 Centers (US\$ 42,000)