C1. IMPACT OF ICDS FOOD FORTIFICATION ON CHILD HEALTH IN MADHYA PRADESH AND UTTAR PRADESH

Date of commencement: March 2002 (U.P.) February 2003 (M.P.)

Date of Completion: January 2006 (U.P.), July 2005 (M.P.)

Funding Agency: World Food Programme

Objectives

1. To determine the baseline prevalence of iron and Vitamin-A deficiencies among children 12-59 months;
2. To monitor the supplementation of fortified food; and
3. To undertake end line evaluation for evaluating the impact of supplementation.

Sample Design and Data Collection

The districts/blocks selected for the studies were those where fortified food were to be supplied in phases. Thirty villages were selected by Probability Proportion to Size (PPS) from each of these blocks. From each selected village, 25 children were selected for the feeding practices, anthropometrics measurements, nutritional deficiency disorders and dietary intake. In addition, 10 children were also selected from each village for the Bio-chemical examinations for evaluating the prevalence of anemia on the basis of hemoglobin, Vitamin A deficiency on the basis of serum retinol and worm presence through stool examination. The sample size covered works out as 750 children from the district. The sample size was worked out by assuming $\mu = .05$, 80% of power of test $p_1 = 0.15$, $p_2 = 0.10$ and taking into account the design effect as 1.5. The prevalence of severe anemia was around $p_1 = 15\%$ and it was expected that it will be reduced to the 10% by the fortified ICDS supplementation.

Survey Findings:

Madhya Pradesh

There is considerable improvement in the prevalence of *any anemia* in both the blocks, i.e., intervention and control blocks. Though, there has been significant decline in anemia levels in both the blocks, the decline is significantly higher in the intervention block – Sanchi in comparison to control block – Gyaraspur. In Sanchi, the decline was 23.5 percentage points (from 96 per cent at baseline to 73 per cent at the end line) while in Gyaraspur, the decline in *any anemia* was 15.9 percentage points, from 99.5- 83.6 per cent. The values of 't' for decline in any anemia levels in Sanchi and Gyaraspur are 8.4 and 7.1 respectively. The value of 't' for difference in the decline in any anemia, in intervention and control block is 2.1. All these are statistically significant showing that there was a statistically significant decline in anemia in the intervention block compared to the control block.

Prevalence of severe malnutrition declined considerably in both the blocks. In the intervention block Sanchi, there was a reduction of 13.4% in the prevalence of severe malnutrition while in the control block Gyaraspur, there was a reduction of 19.5% in the prevalence of severe malnutrition. Consequently, the prevalence of moderate malnutrition registered an increase in both the blocks indicating a shift from severe to moderate in the intervention period. There was no significant difference in severe malnutrition by gender.

Uttar Pradesh

Considerable improvement in anemia has been observed among intervention and control blocks. In Maitha, the prevalence of any anemia declined from 86.7 percent at the baseline to 66 percent at endline; while in Rajpur, the decline was from 98.7 percent to 60.6 percent, and in Rajpur, any anemia declined somewhat moderately from 82.3 percent to 60.6 percent. Significant differences were observed in all the blocks. The value of 't' for decline in any anemia levels in Maitha and Rajpur are 8.4 and 7.1 respectively. The value of 't' for difference in the decline in any anemia, in intervention and control block is 2.1. All these are

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statistically significant. This clearly shows that there was a statistically significant decline in anemia in the intervention block compared to the control block.

It is observed that there is significant improvement in Serum levels of children at the benchmark stage. The percentage of children below the cut-off 19.9 has gone down from 37.3 at the baseline stage to 13.3 at end line in Maitha, and from 57 to 14.9 in Rajpur. In Rasulabad, this decline, from benchmark to end line was from 24.9 percent to 10.2 percent. All these values are statistically significant reflecting that the decline in Vitamin A deficiency is statistically higher in the intervention blocks as compared to the control block.

C2. SURVEY ON IMMUNIZATION COVERAGE IN THE STATE OF DELHI

Date of commencement: January 2006

Date of Completion: July 2006

Funding Agency: Directorate of Health Services, Govt. of Delhi

Objectives

1. To estimate the immunization coverage level of children and mothers;
2. To estimate the level ANC coverage level among pregnant mothers in Delhi state.

Methodology

Modified WHO 30 cluster survey methodology was adopted for the survey. Delhi was divided into 9 districts and selection of 30 clusters with in each district was done by Probability Proportion to Size (PPS) after arranging them by size of cluster, SC/ST Population and Female literacy. From each cluster, 15 children and 15 mothers were selected. In the survey information has been collected for 4050 infants and equal number of pregnant women. Immunization Coverage and ANC Coverage has been estimated for each district and combined for Delhi state.

Findings

The survey revealed that the immunization Programme could touch about 96 percent of target children and about 93 percent of pregnant women. About 83 percent of children received all the vaccines (BCG, DPT, OPV, and Measles) and 93 percent of pregnant women received at least one ANC and 91 percent received TT2/Booster. About half of partially immunized children (6%) missed the complete immunization by only measles. Institutional deliveries were 69%. While comparing these figures with the NFHS-2, NFHS-3 as well as DLHS (02-04), the considerable improvement has been seen observed.

Though, coverage levels showed improvements however, coverage was lower among the children belonging to Muslims, Scheduled Caste/ tribes, Illiterate parents and with lower socio-economic status. Institutional deliveries were more in those households who belong to better socio economic conditions. The literacy of mother is the key to the success of the Universal Immunization Programme (UIP).

There is a need to improve IEC activities targeted to educate mothers. Improvement could also be achieved by better follow-up and reducing the drop out rate.

C3. DATA MANAGEMENT AND ANALYSIS OF NACO'S HIV SENTINEL SURVEILLANCE & HIV ESTIMATION 2005

Date of commencement: January 2006

Date of Completion: December 2006

Funding Agency: NACO/WHO

Background

This project is a recurring activity of the Institute every year. Country wide HIV sentinel surveillance was initiated in 1998. National AIDS Control Organization (NACO) invited the National Institute of Medical Statistics (NIMS), Indian Council

of Medical Research (ICMR), in the year 2002, to review the methodology of HIV estimation, validate the assumptions used for deriving the estimate and to carry out in depth epidemiological analysis of the sentinel surveillance data. NIMS is also working out the number of HIV infections in the country since 2003. This round of sentinel surveillance is the last surveillance programme under NACP II. The estimation methodologies also have been reviewed this year. Initial steps have been taken to review the assumptions involved in estimation methods and also to compare different estimation methodologies.

Objectives

- To appraise the methodology for estimation of HIV burden
- To provide epidemiological analysis
- To provide HIV estimate annually

The HIV sentinel surveillance (HSS) in India is carried out mainly to monitor the epidemic trend in specific risk groups and to study the extent of spread of infection to general population to formulate appropriate advocacy and policy measures to generate effective control programmes. Two major subpopulations monitored under surveillance programme are:

- STD Clinic attendees – Proxy for High risk behavior population and
- ANC Mothers – Proxy for Low Risk behavior (general) population

There are a few sites representing other high risk groups, intravenous drug users (IDU), male having sex with men (MSM), and female sex workers (FSW). Number of sentinel sites has been increasing every year to get more representative data on HIV prevalence. Table C4.1 shows the number of sentinel sites for each risk group since 1998 and Table C4.2 presents the number of HIV infections and prevalence/1000 population.

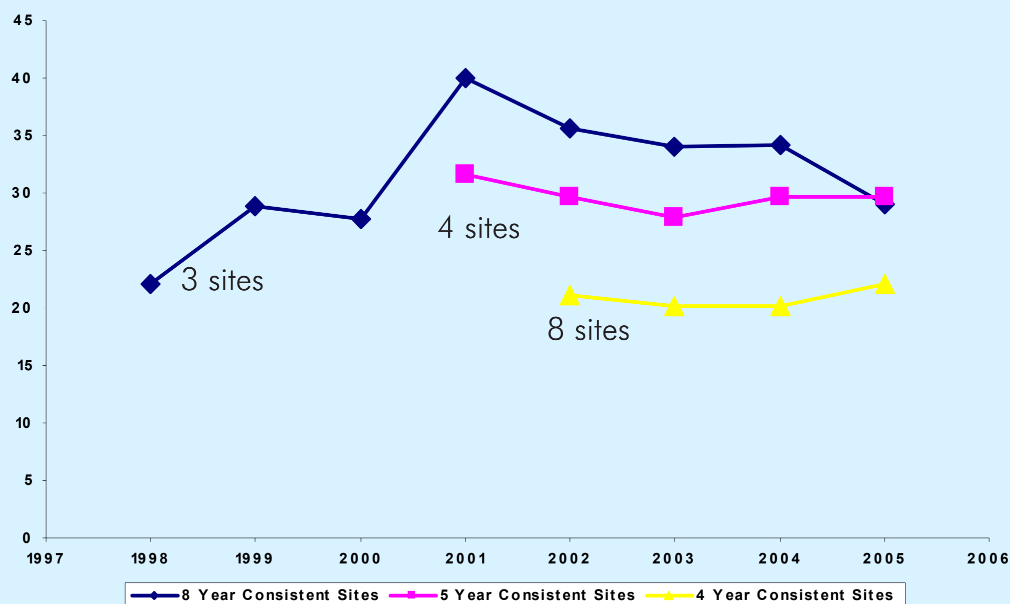
Table-C3.1: Number of HIV sentinel sites for each risk group 1998–2005

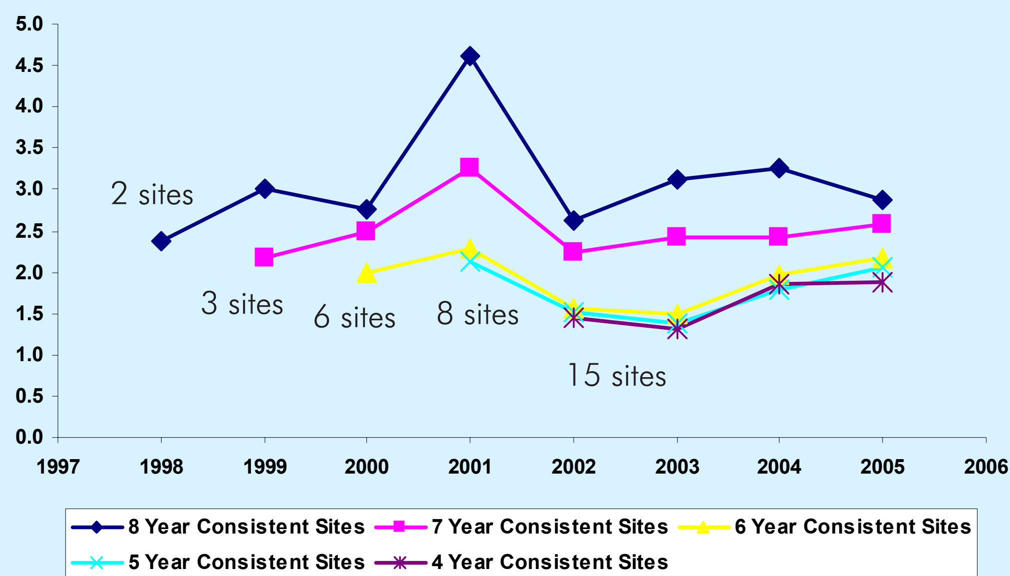
Year	Number of Sentinel Sites							
	ANC	STD	IDU	MSM	FSW	TB	ANC-R	Total
1998	94	77	9	-	-	-	-	180
1999	94	77	9	-	-	-	-	180
2000	118	104	8	2	-	-	-	232
2001	173	131	12	2	2			320
2002	200	166	13	3	2	-	-	384
2003	271	166	13	3	2	-	210	665
2004	271	166	24	15	42	6	122	646
2005	275	178	31	18	87	2	126	717

Table C3.2 Estimated number of HIV infections in India since 1998

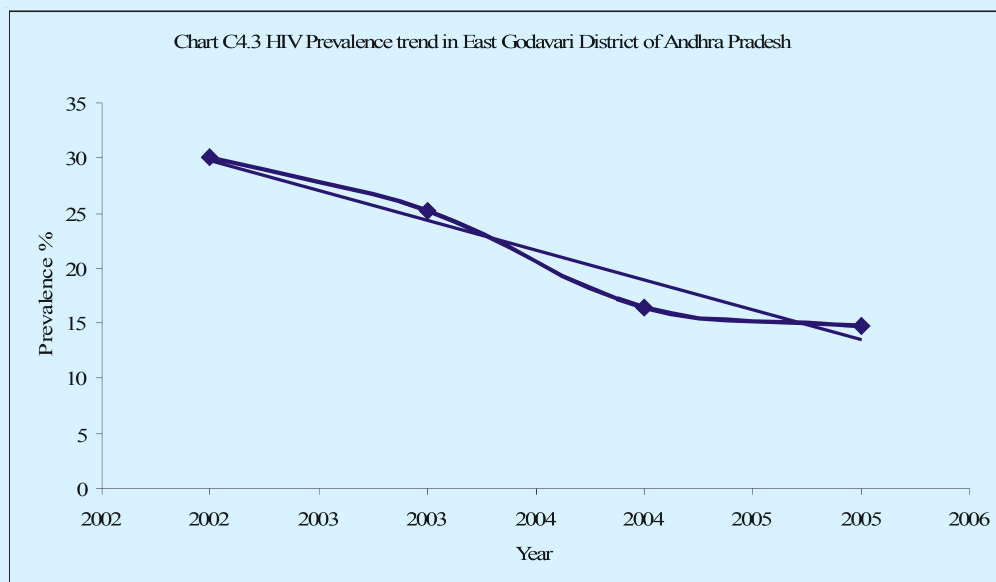
Year	1998	1999	2000	2001	2002	2003	2004	2005
HIV infected (million)	3.47	3.68	3.86	3.97	4.58	5.106	5.134	5.206
Population (million)	496.9	506.9	517.0	528.3	537.9	549.1	560.3	571.8
Prevalence per 1000	7.0	7.26	7.46	7.51	8.51	9.30	9.16	9.11

The stabilizing trend of the number of infections observed during last three years may be a result of increase in number of sentinel sites in low prevalence states and the implementation of validated assumptions for estimation since 2003. However, there is a need to revisit the assumptions and calibrating the results with findings from other large scale surveys. In order to learn the impact of increase in number of sentinel sites trend analysis has been carried out using sites with consistency of varying length. The trend for consistent sites in high prevalence states for STD and ANC sites is presented in following charts.





Charts C3.1 and C3.2 respectively shows the HIV prevalence trend among STD patients and ANC women respectively in Andhra Pradesh for consistent sites. While the level of prevalence has gone down as the number of sites increased initially later the level remains stable even with added number of sites. This shows that HIV prevalence is high only in a very few districts. Only one district, East Godavari in Andhra Pradesh had significantly decreasing trend.



Four other districts, Banaskanta, Vadodara and Rajkot in Gujarat and Ghaziabad in Uttar Pradesh had statistically significant decreasing trend. Decreasing trend was observed in STD sites except in Rajkot where the ANC site had statistically significant decreasing trend.

Statistically significant increasing trend was observed in eight districts (seven STD sites and one ANC sites). Increasing trend of HIV prevalence among general population was observed in Sagar district of Madhya Pradesh. However, there was no STD site in this district to compare the trend in high risk population. Seven districts with statistically significant increase of HIV prevalence among high risk population were Gulbarga in Karnataka, Pune and Chandrapur in Maharashtra, Raipur in Chhatisgarh, Central district of Delhi, Balasore in Orissa and Bardhaman in West Bengal. These districts with p-value for significance are presented in Table C3.3.

The current round of HIV sentinel surveillance being the last one under NACP II a report of the HIV epidemic trend since 1986 is under preparation and will include in-depth epidemiological analysis including trend analysis with standardized prevalence and consistent sites.

Table C3.3 Districts with Significant Changes in Pravalence

State	District	Risk Group	Direction of Change	Length of consistency	P value
Andhra Pradesh	East Godavari	STD	decreasing	4 Years	0.029
Karnataka	Gulbarga	STD	Increasing	8 Years	0.003
Maharashtra	Pune	STD	Increasing	8 Years	0.017
	Chandrapur	STD	Increasing	8 Years	0.010
Gujarat	Banas Kantha	STD	decreasing	5 Years	0.013
	Vadodara	STD	decreasing	5 Years	0.009
	Rajkot	ANC	decreasing	6 Years	0.021
Chhatisgarh	Raipur	STD	Increasing	7 Years	0.035
Delhi	Central	STD	Increasing	5 Years	0.011
Madhya Pradesh	Sagar	ANC	Increasing	5 Years	0.047
Orissa	Balasore	STD	Increasing	5 Years	0.028
Uttar Pradesh	Ghaziabad	STD	decreasing	6 Years	0.033
West Bangal	Barddhaman	STD	Increasing	8 Years	0.048

C4. "HEALTH SECTOR POLICY REFORM OPTIONS DATABASE (HS-PROD) OF INDIA"

The project on developing "Health Sector Policy Reform Options Database" has been taken up by NIMS with the collaboration and financial grant provided by MoHFW and European Commission Technical Assistance. Health Sector Reform can be described as the sustained and purposeful process of change to improve the performance of health sector, motivated by the failure to deliver outcomes important to society. They are designed to improve functioning and performance of the health sector. Reforms are mainly focused on the needs of poor and under privileged.

The HS-PROD is an online database (www.hsprodindia.nic.in), which is being developed to provide information about Indian good practices and innovations

in health services management. More than 200 entries or document on health sector reforms has been uploaded to the website after reviewed by PMG members (Experts). These entries are distributed across the states and 16 subject areas. This target has been achieved by the working team with their joint effort, proper planning and management of project. Three regional partnership workshops at New Delhi, Bangalore and Bhubaneswer were organized for sensitization of state level partners and stakeholders. The purpose of organizing the workshop is to disseminate about the website to state level programme implementers and policy makers, identify potential partners in the states and identify the resource person who can assist in gathering information about various initiatives started by the States to improve the quality of health care services. A brief summary of the few selected entries of website are presented below.

Cheyutha: A helping hand for people living with HIV/AIDS, Andhra Pradesh [173]

Leprosy Relief Association (LEPRA) Society, an international NGO, launched a programme called 'Cheyutha' (helping hand) in the twin cities of Hyderabad and Secunderabad. The project aims to address: quality treatment for opportunistic infections, create an enabling environment for and strengthen the network of People living with HIV/AIDS.

LEPRA Society joined hands with Network of People Positive (NPP+) Andhra Pradesh, a community based organization established by likeminded PLHA to strengthen the network. A PLHA support center (PLHASC) was set up from where counseling is given to PLHA and their families. Marriages between eligible PLHA have been promoted by Cheyutha.

Weekly clinics are organized for poor patients. LEPRA Society also contributes to the drugs distributed free by the government hospitals to below poverty line HIV patients in the State.

Medical camps are organized the first Saturday of every month to provide treatment against opportunistic infections. The health camps are a platform for PLHA networking and increasing Cheyutha membership so as to improve the outreach services.

For referral of PLHA, LEPRA Society established linkages with government and charitable hospitals, such as Tuberculosis Hospital, Freedom Foundation Hospital and Andhra Pradesh Chest Hospital.

Yeshasvini Health Insurance, Karnataka [111]

The bed occupancy rate in Karnataka's hospitals and medical colleges was as low as 35% and a large number of people were dying without proper treatment because people could not afford hospitalization.

The Yeshasvini health insurance scheme, launched in June 2003, was developed by the Narayana Hrudayala Foundation in association with the Department of Cooperation, Government of Karnataka to cater health services for 17 lakhs farmers. The scheme is self-funded and does not have insurance cover from any insurance company.

The scheme offers free consultations, diagnostics at discounted rates and all types of operations for a yearly premium of INR 90 per person. The Government pays INR 30 per member. In 2005 the yearly premium has gone up to INR 120.

The farmers' cooperatives collect the premiums - in most cases societies pay the annual premium for the members and deduct the amount from their

transactions over the year. The amount from the societies is deposited to the Yeshasvini Trust account.

The first year the scheme had 1.7 million people, which subsequently increased to 2.5 million in the second year. At the end of 18 months more than 22,000 farmers had undergone operations.

Mitanin Programme, Chhattisgarh [49]

With a view to organise and empower women in the community and at the same time, improve the health status of the rural population, a statewide Community Health Volunteer (CHV) programme was established.

The CHV is a married woman called a Mitanin (a special kind of friend in local tradition) belonging to a particular community, selected by her community and endorsed by the Panchayat. The Mitanin is trained and is to provide elementary health education, first aid help and over-the-counter drugs, treat minor ailments, provide prompt referral advice if necessary and play a central role in improving the health of her community by setting up women's committees and helping the *panchayats* in its health initiatives.

The programme is run by a state-civil society partnership at the state, district and block levels. At the State level, the programme is managed and run by an

advisory committee with the help of technical support from the State Health Resource Centre (SHRC- a body formed in partnership with the government and Action Aid India, an NGO).

The evaluation of the programme showed enhanced health awareness within the community and improvement in some of the health related practices.

Model of Out Door Patient Department, Himachal Pradesh [159]

Noticing non-utilization of OPD services due to certain limitations of the existing infrastructure, the Government of Himachal Pradesh decided to develop model OPDs in the State.

One health facility was identified from each constituency and model OPDs were constructed by re-structuring the existing OPD. It included redesigning the facility by making minor changes such as providing shaded waiting areas to the patients, public toilet facilities and identifying spaces for the labour room in order to make the place more comfortable and convenient for patients.

This initiative helped raise service utilization rates by more than doubling the number of new patients visiting these facilities.

Sahiyya Movement, Jharkhand [153]

In order to provide quality healthcare services to the 'last person in the last household of the last village' the Government of Jharkhand initiated the Sahiyya Movement after a pilot in 2004 to encourage community participation in delivering quality health care to the needy and empowerment of women.

The programme aims to focus on women and children in marginalized sections of the community, particularly those in remote, unreachable areas. The key activity is formation of Village Health Committee (VHC) and the establishment of community health workers called Sahiyyas.

Sahiyya works to promote health education and is selected by the community and VHC. She is paid by the community in cash or kind. She facilitates integrated mother and child health care and provides family planning advice and first aid.

She is also the village depot holder for all family planning techniques and acts as a link between the community and service providers and works alongside the Anganwadi Worker and Auxiliary Nurse Midwife. Approximately 1,000 VHCs have been formed and 1,000 Sahiyyas chosen. Seven NGOs have joined the scheme and are working in 34 blocks supporting VHCs and Sahiyyas. There is already better convergence between the health, social welfare, public health education and rural development departments.

ONGOING STUDIES

O1. ASSESSMENT OF THE IMPACT OF FOOD FORTIFICATION OF CHILD HEALTH IN UTTARANCHAL

Date of commencement: November 2003

Expected Date of Completion: July 2007

Funding Agency: World Food Programme

Objectives

1. To determine the baseline prevalence of iron and Vitamin-A deficiencies among children 12-59 months;

2. To monitor the supplementation of fortified food; and
3. To undertake end line evaluation for evaluating the impact of supplementation.

Sample Design and Data Collection

The districts/blocks selected for the studies were those where fortified food were to be supplied in phases. Thirty villages were selected by Probability Proportion to Size (PPS) from each of these blocks. From each selected village, 25 children were selected for the feeding practices, anthropometrics measurements, nutritional deficiency disorders and dietary intake. In addition, 10 children were also selected from each village for the Bio-chemical examinations for evaluating the prevalence of anemia on the basis of hemoglobin, Vitamin A deficiency on the basis of serum retinol and worm presence through stool examination. The sample size covered works out as 750 children from the district. The sample size was worked out by assuming $\mu = .05$, 80% of power of test $p_1 = 0.15$, $p_2 = 0.10$ and taking into account the design effect as 1.5. The prevalence of severe anemia was around $p_1 = 15\%$ and it was hoped that it will be reduced to the $p_2 = 10\%$ by the fortified ICDS supplementation.

Progress

The study shows that at the baseline stage, over 90% of children had anemia and females had higher prevalence (97% in comparison to 86% in males). At the end line stage, there was marked improvement in any anemia, the levels coming down to near 60%. The baseline and end line prevalence were significantly different ($t=9.4$). At the baseline stage, the prevalence of Bitot's spot was 1.2%, and was slightly higher in females, which shows that it is a public health issue. At the end line stage, no case of Bitot's Spot was found. At the baseline, around 44% children were moderately underweight and around 13% were severely underweight as per standard deviation classification. There was not much change at the end line stage though moderate underweight showed some decline. The differences were, however, statistically non significant ($t = 0.43$).

O2. DATA MANAGEMENT AND ANALYSIS OF NACO'S HIV SENTINEL SURVEILLANCE & HIV ESTIMATION 2006

Date of commencement: February 2007

Expected date of completion: July 2007

Funding Agency: NACO/WHO

Background

HIV sentinel surveillance 2006 is the first surveillance program under NACP III. Several steps were taken to strengthen the HIV surveillance system during NACP III. Major change related to data management and analysis is the inclusion at least one ANC site in each district leading increased volume of work both for data management and analysis.

Setting up a set of realistic assumptions for HIV estimation is the major challenge this year. Comparison of different estimation methodologies with various options of assumptions have revealed that some of the assumptions currently in use might be a source for over estimation of HIV burden in the country. Since results of three major population/community based surveys (NFHS-3, BSS 2 and IBBA) will be available this year they will be used to calibrate the HIV estimation results.

Objectives

- To appraise the methodology for estimation of HIV burden
- To provide epidemiological analysis
- To provide HIV estimate annually

Progress

The Estimation process and the assumptions had been discussed in several expert group meetings and the decisions will be finalized in a large group of expert group meeting. The data analysis will be initiated as soon as the data is received from NIHFW.

O3. CAPACITY BUILDING OF THE REGIONAL INSTITUTES ON MODEL BASED HIV ESTIMATION

Date of commencement: February 2007

Expected date of completion: July 2007

Funding Agency: NACO/WHO

Background

A meeting of the National Expert Committee on model based estimation and projection of HIV/AIDS burden in India was held on October 25, 2005 recommended strengthening the capacities of state level stakeholders to analyze the HIV sentinel surveillance data generated by them effectively promoting its ownership and consequently the quality. It was suggested that in view of the complexity of HIV epidemic (mixture of generalized and concentrated epidemics) in India and the known data gaps, the models need to be examined and deliberated for their advantages and disadvantages. Regarding the choice of methods the group considered it appropriate to compare the three methods, the workbook approach and Estimation and Projection Package (EPP) developed by WHO/ UNAIDS and worksheet approach currently used by NACO.

The committee entrusted the National Institute of Medical Statistics (NIMS) to consolidate the estimates at the national level using all the models and provide comparative picture. It would also try to address some of the research issues identified such as estimates of incidence and mortality related to HIV/AIDS, extent of problem in children, utilization of data generated through surveillance etc. and coordinate capacity building of the institutions identified to apply these models based on the data available in the region and motivate the State AIDS Control Societies (SACS) to facilitate using additional data available with them. The institutions identified are: NIE, Chennai - Southern region, IIPS - Central and Western region, RMRC, Dibrugarh - North-East region, PGIMER, Chandigarh - Northern Region.

The organizations in turn will work out the estimates at state level in respective regions and make presentations before the expert group. In this meeting the

international experts from UNAIDS and WHO should also be requested to participate.

Specific Objectives

To consolidate the HIV estimates at the national level using three approaches (the workbook approach and Estimation and Projection Package (EPP) developed by WHO/UNAIDS and worksheet approach currently used by NACO) and provide comparative picture.

To capacitate the regional level organizations identified to apply these models based on the data available in the respective regions.

Strengthen the capacities of state level stakeholders to analyze the data effectively and promote the ownership of data and consequently its quality.

O4. INFRASTRUCTURE AND CAPACITY BUILDING FOR CLINICAL TRIAL REGISTRY

Date of commencement: April 2006

Expected date of completion: March 2009

Funding Agency: DST

Goal and Objectives of Clinical Trial Registry

The specific goal of setting up a clinical trial registry is to ensure that all clinical trials conducted in India are registered and publicly declared and identifiable and a minimum set of information of all clinical trials are freely available to physicians, health researchers, academicians, pharmaceutical industries as well as to the common man which will increase public trust in the conduct of clinical research.

The objectives of the project are to:

- To establish a search portal which will also serve as a public record system by registering all clinical trials on health products that are drugs, devices, vaccines, herbal drugs and made available to both public and healthcare professionals in an unbiased, scientific and timely manner.

- To create a more complete, authentic, and readily available data of all ongoing and completed clinical trials
- To provide a corrective system against "positive results bias" and "selective reporting" of research results to peer review publication..
- Increase awareness and accountability of all the participants of the clinical trials and also for public access.
- To promote training, assistance and advocacy for clinical trials by creating database and modules of study for various aspects of clinical trials and its registration

Current Status

The CTRI has been launched and registration of prospective trials has started.

The establishment of the CTRI would not only enhance accountability and transparency of clinical trials in our country but will also redefine the way clinical trials are being conducted here. Standard of clinical research is sure to be benefited. It will enable better practice of evidence based medicine as today many clinical trials with unequivocal or negative results are not published which can have a significant impact on treatment decisions.

The Key Features of CTRI:

- All clinical trials with drugs, biotech products, vaccines, biologicals and traditional medicines are expected to be registered with the CTRI.
- The CTRI will collect information on all prospective clinical trials to be undertaken in India through an internet linked online portal (Figure 5) and make this information available to the public.

CLINICAL TRIALS REGISTRY-INDIA
NATIONAL INSTITUTE OF MEDICAL STATISTICS,(ICMR)

Home | Trial Search | Register Trials | FAQs | Feedback | Contact Us | Sitemap

Font Size: A | A | A | A

SIGN IN TO CTRI
Username
Password
Forgot Password | New User

Trial Registration Set Download: [Word][Pdf]

SEARCH FOR TRIALS
[Advanced Search]

News & Events

The Clinical Trials Registry- India (CTRI) has been set up by the ICMR's National Institute of Medical Statistics (NIMS) and is funded by the Department of Science and Technology (DST) through the Indian Council of Medical Research (ICMR). It also receives financial and technical support through the WHO, WHO-SEARO, and the WHO India Country office. [Read more...]

Mission

The mission of the Clinical Trials Registry-India (CTRI) is to encourage all clinical trials conducted in India to be prospectively registered before the enrollment of the first participant and to disclose details of the 20 mandatory items of the WHO International Clinical Trials Registry Platform (ICTRP) dataset. [Read more...]

Vision

The vision of the CTRI is to ensure that every clinical trial conducted in the region is prospectively registered with full disclosure of the 20-item WHO ICTRP dataset, as well all items of the CTRI dataset, in order to 1) improve transparency and accountability, 2) improve the internal validity (details of the methods of the trial that produce reliable

WHO ICMR DST

Clinical Trials Registry-India (CTRI)

The CTRI is an online register of clinical trials being conducted in India. Any researcher who plans to conduct a trial involving human participants, of any intervention (drug, surgical procedure, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies and complementary therapies) are expected to register the trial in CTRI before enrollment of the first participant. Registration is voluntary but some fields marked* are mandatory for registration to proceed. Some fields marked WHO also need to be filled if the trial is to receive a registration number and fulfill WHO/ICMJE requirements. Incomplete entries will be given a provisional registration number that will not suffice for purposes of publication in journals that endorse the ICMJE recommendations for trial registration. Registration of trials in the CTRI is free. All registered trials will be made publicly available. The CTRI will be searchable by anyone free of charge. The

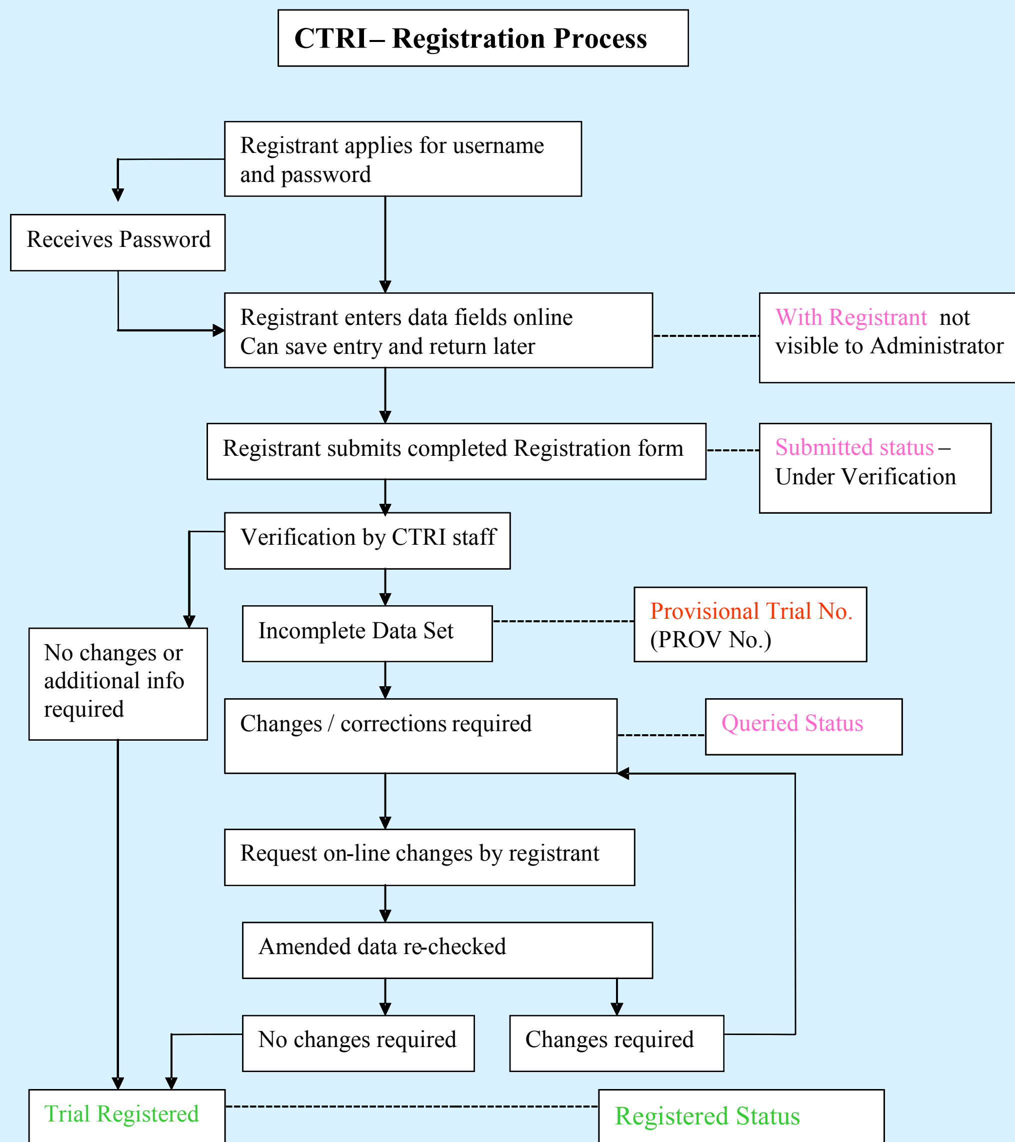
- The CTRI is a freely available and searchable Primary register which is linked to the WHO search portal, like other Primary Registers (Figure 3 and see box 1 for WHO requirements of a primary register).

Future Plans

- Put in place mechanism to encourage registration through discussion with ethics review board members to facilitate verification of trials and generate awareness regarding the need for clinical trial registration
- A meeting with the journal editors has been planned to work out the possibility of having a mechanism put in place by them to ensure trial registration in the lines of the ICMJE.
- To conduct workshops and training sessions at regional centers in India to sensitize those who are involved in clinical trials on the importance of registering with the CTRI.

Additional Activities

- Compilation and dissemination of CTRI Bulletin to generate awareness of the CTRI has been launched by WR-WHO on 20th July.
- Special Issue of CTRI Bulletin covering Launch of CTRI is under process.
- Flyer / Brochure of CTRI are under process.



Booklet of CTRI with key features and SOP is under process.

NIMS

O5. ESTIMATION OF AIDS RELATED MORTALITY

Date of commencement: November 2005

Expected date of completion: December 2007

Funding Agency: UNAIDS

Background

In pursuit of the UNAIDS supported activity to facilitate the AIDS deaths estimation, a meeting of the National Expert Committee on estimation of AIDS Mortality was held on October 25, 2005 for consultation and consensus regarding the methodologies to be adopted for estimation under the chairmanship of Prof. Mari Bhatt, Director, International Institute for Population Sciences and in the presence of Additional Project Director, National AIDS Control Organization (NACO). The group unanimously agreed that such an exercise is essential to promote the ownership and utilization of the surveillance data in programme planning and monitoring. Regarding the choice of methods the group considered it appropriate to compare the different available methods (Spectrum method currently used by WHO/UNAIDS, Kink regression method using data from Sample Registration System and Causes of deaths data from the Civil Registration System). It was suggested that Kink regression method will be used to estimate AIDS deaths for all the states in India, civil registration system from two states, one city each from low and high HIV prevalence states by three different institutions

The group tentatively identified the following Institutions for undertaking the estimation of AIDS deaths exercise under the overall coordination of National Institute of Medical Statistics (NIMS):

a. International Institute for Population Sciences (IIPS) and National Institute of Medical Statistics (NIMS) New Delhi for estimating AIDS mortality using the spectrum model.

b. National Institute of Health and Family Welfare (NIHFW), New Delhi, for estimating excess deaths by state level using SRS data, and using civil registration system in urban India.

c. The overall coordination will be with NIMS, New Delhi

Objective

1. Estimation of AIDS deaths using different methodologies dissemination of results

Deliverables:

1. AIDS deaths estimation using different methodologies will be completed and reports presented to the group in March 2006.
2. The results of the various methodologies will be disseminated through a medical journal supplement.

Progress:

The work related to estimating excess death using Kink regression is completed and submitted by the National Institute of Health and Family Welfare (NIHFW). The steps on using spectrum model to estimate AIDS related mortality are finalized wherein HIV prevalence is the basic input along with other epidemiological and demographic parameters. The preliminary findings indicated that the AIDS related deaths under the current methodology were coming to be very high and required further look into reasons for such overestimation.

O6. ESTIMATION OF NUMBER OF ORPHANS AND VULNERABLE CHILDREN IN INDIA DUE TO HIV/AIDS AND CHILDREN REQUIRING ART

Date of commencement: June 2006

Expected date of completion: December 2007

Funding Agency: UNAIDS

Background

The HIV/AIDS epidemic has increased adult and child mortality rates substantially in many countries. Adult deaths from AIDS often occur to men and women in their thirties and early forties. As a result many people who die from

AIDS leave behind young children as orphans. In India many more children are orphaned from other causes, than from AIDS. But AIDS orphans bear a special burden since they are more likely to lose both their parents than a child who loses a parent through an accident or childbirth. AIDS orphans may also be more likely to be clustered in extended families or communities than other orphans, making it harder for support to be mobilized. They may also face stigma as a result of their parent's infection.

Objective

1. To estimate the number of HIV+ Children, Orphans, AIDS orphans, children need for treatment by state and specifically,
   - HIV+ children
   - AIDS and non-AIDS orphans
   - Maternal, paternal and double orphans
   - Orphans by age
   - New cases
   - Children need for treatment
2. To support strategic planning for support to orphans in need
3. Organize training program to capacitate at state level to generate state specific estimate

Progress

The problems faced with the estimation of AIDS related mortality remains a constraint for the estimation of children needing ART and orphans and vulnerable children.

O7. STATISTICAL MODELING OF HIV/AIDS EPIDEMIC

Date of commencement: February 2006

Expected Date of Completion: July 2007

Funding Agency: ICMR

Background

This project has been taken up as a follow up of the earlier intramural project, 'exploratory research on HIV/AIDS Epidemic', where we explored some simple models to study some of the epidemiological characteristics of HIV/AIDS such as the probability distribution of time to develop AIDS (incubation distribution) since HIV infection, estimation of HIV intensities and projection of AIDS cases from reported AIDS cases, classification of progression of AIDS since HIV infection using simulated CD4+ count and viral load values at the time of seropositivity diagnosis and estimation of HIV transmission rate among different risk groups and project the number of HIV infections in various stages. ICMR Task Force on Statistics sanctioned a project on 'Statistical Modeling of HIV/AIDS Epidemic' with the following objectives:

1. To determine the appropriate distribution of incubation period (time to develop AIDS after sero-positivity detection)
2. To study the variation in incubation period in relation to biological variables like CD4 cell count and viral load
3. To estimate the mortality rate due to HIV infection using double decrement Life table techniques (the two forces of the decrement are mortality in the status of HIV and the probability of transition from HIV to AIDS) and
4. To compare the mortality rates due to HIV/AIDS and other causes
5. To study the disease burden due to opportunistic infection in AIDS patients and similar infections in non-AIDS patients.

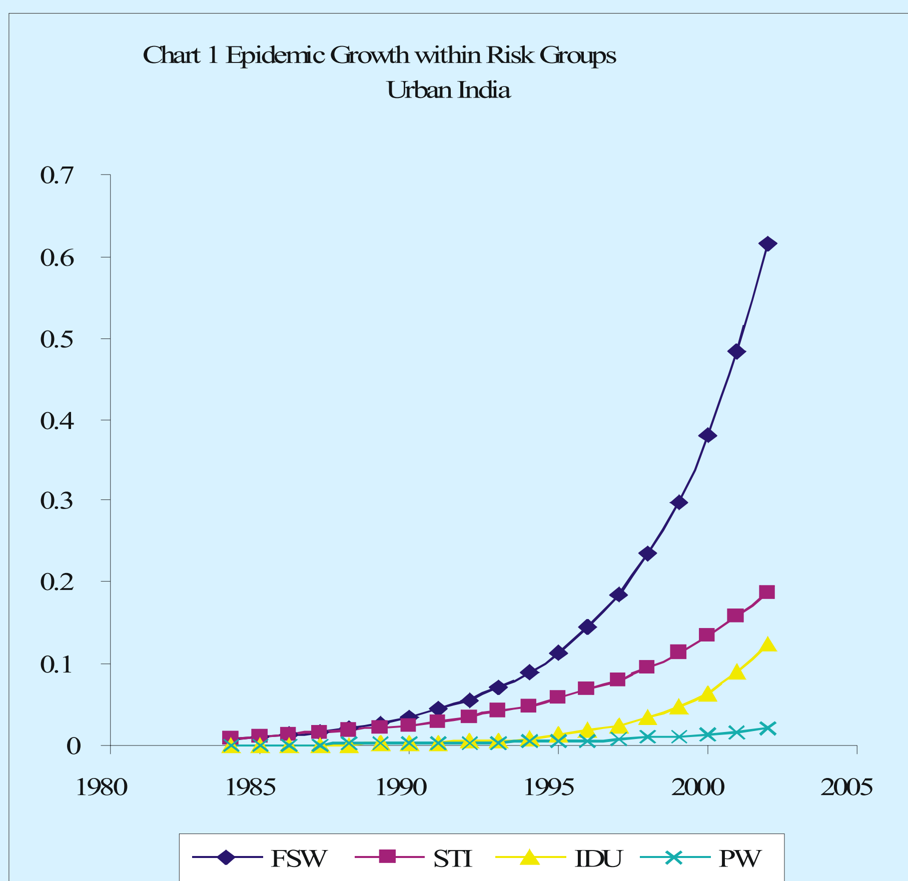
The statistical modeling exercise has been initiated to study the spread of HIV infection within each risk group using published data on HIV/AIDS prevalence in the website (Epidemiological Fact Sheets on HIV/AIDS and sexually transmitted infection, UNAIDS, UNICEF and WHO). Though the website provides data sheet for all countries sufficient data to carry out analysis was available only from three countries, India, Thailand and Vietnam. Major source of HIV infection in three countries is presented in Table 1.

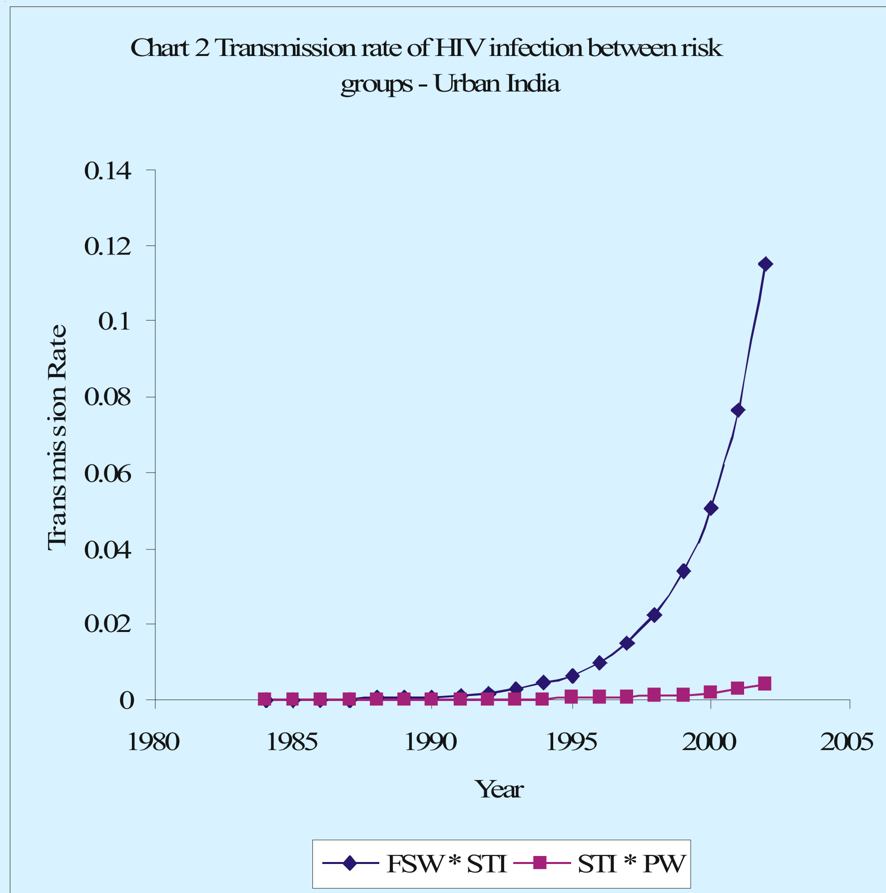
Table 1: Major source of HIV infection in India, Thailand and Vietnam

Country	Major Source
India	FSW & Clients (STI individuals)
Thailand	IDU, FSW and clients
Vietnam	IDU, FSW and clients

The Epidemic Growth

The HIV epidemic was initiated among the high risk behavior groups, i.e. sex workers and their clients and injecting drug users. It started growing among themselves initially because of their sexual interaction and sharing of needles. Slowly, the infection started spreading to low risk behaviour group, the spouses of the high risk behavior individuals.





Therefore we need to study the growth of the epidemic within each risk group and the rate at which they are spreading between the risk groups. The growth of the epidemic within each risk group can be estimated from the HIV prevalence data available for each of the risk groups, FSW, STI (the clients of FSW), IDU and pregnant women (the low risk group). The growth function was estimated using linear curve. However, the observed prevalence was smoothed using moving average of three year lag and then normalized with log transformation.

HIV epidemic growth within each risk group during 1984 to 2004 in the urban and rural areas of India is presented in Charts 1-4. Though, in India, the first case of HIV was detected in 1986 it is assumed that the infection was prevailing some time before 1986 and hence the projection started from 1984.

The weibull distribution has also been tried to study the growth within and between risk groups and also the spread from urban to rural areas.

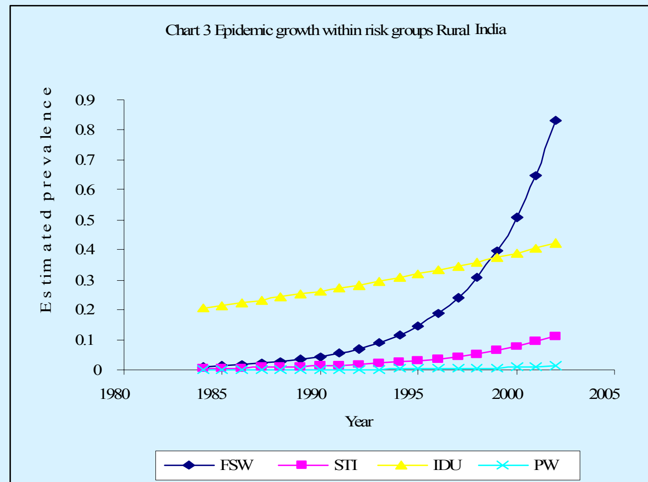


Chart 3 Epidemic growth within risk groups Rural India
Estimated prevalence
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
1980
1985
1990
1995
2000
2005
Year
FSW
STI
IDU
PW

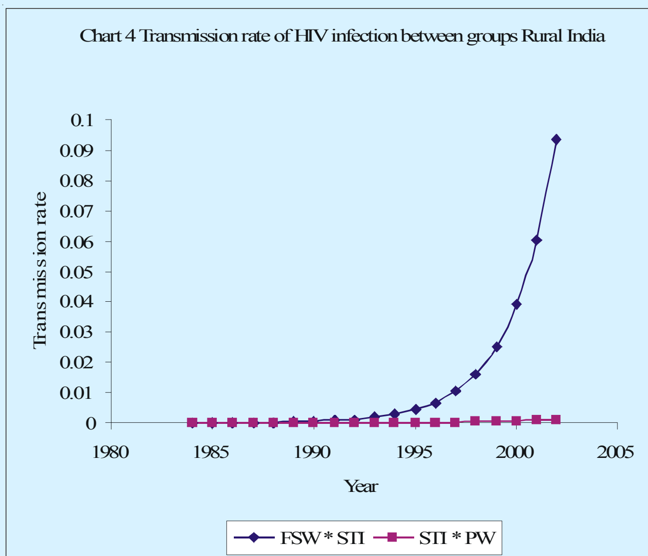


Chart 4 Transmission rate of HIV infection between groups Rural India
Transmission rate
0.1
0.09
0.08
0.07
0.06
0.05
0.04
0.03
0.02
0.01
0
1980
1985
1990
1995
2000
2005
Year
FSW * STI
STI * PW

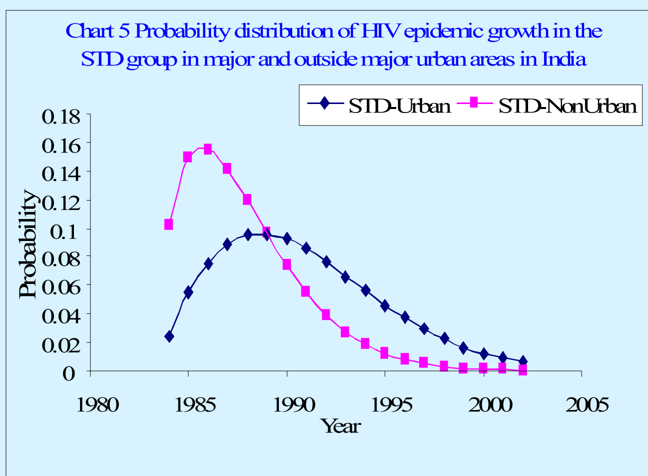


Chart 5 Probability distribution of HIV epidemic growth in the STD group in major and outside major urban areas in India
STD-Urban
STD-NonUrban
Probability
0.18
0.16
0.14
0.12
0.1
0.08
0.06
0.04
0.02
0
1980
1985
1990
1995
2000
2005
Year

Chart 6 Probability distn of transmission of HIV infection from urban STD group to outside urban STD group in India

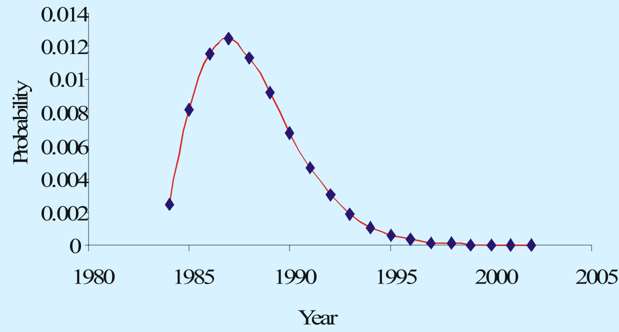


Chart 7 Probability distn of the HIV epidemic growth within urban STD and Sex Workers in India

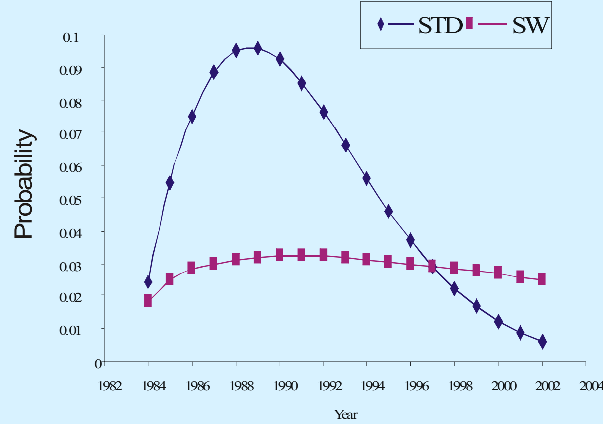
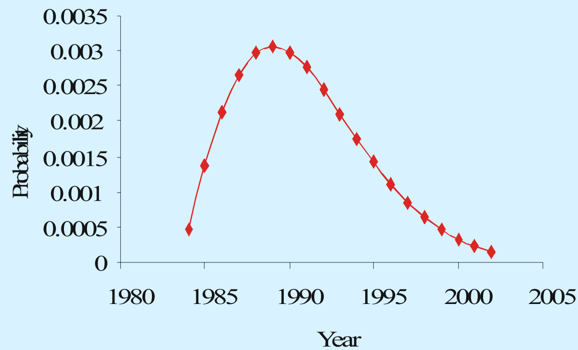


Chart 8 Probability distn of transmission of HIV infection from Sex Worker to STD patients in urban areas of India



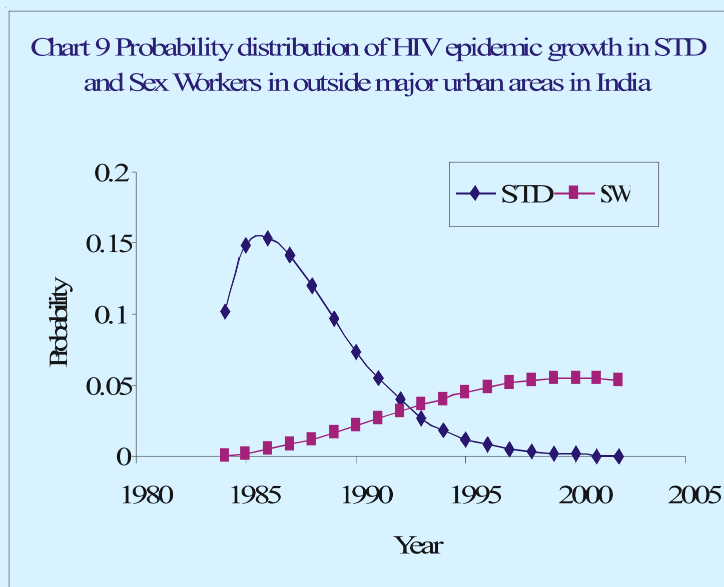


Chart 9 Probability distribution of HIV epidemic growth in STD and Sex Workers in outside major urban areas in India

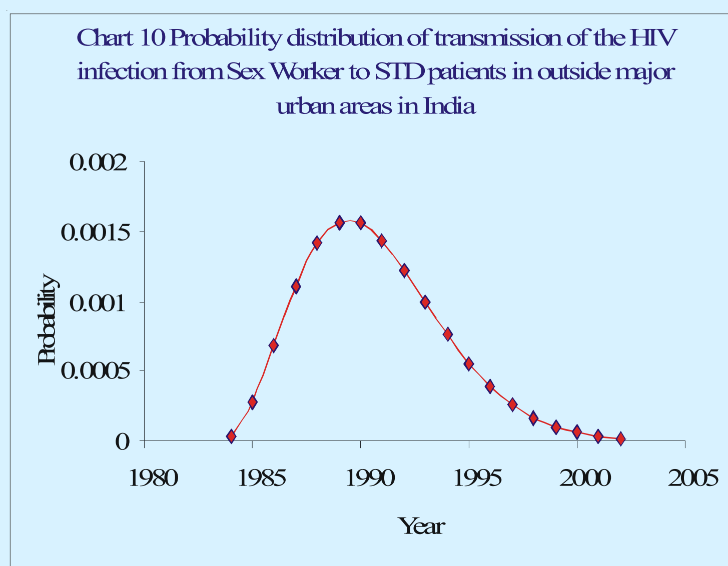


Chart 10 Probability distribution of transmission of the HIV infection from Sex Worker to STD patients in outside major urban areas in India

Study of Incubation Period and Disease Progression using Surveillance data

An attempt has also been made to estimate the annual new HIV infections and the number progressing AIDS which will be an estimate for number needing ART and also the estimate for AIDS deaths in the absence of ART. An example has been presented using Andhra Pradesh data.

Risk Groups and Prevalence Considered

Risk Groups	Prevalence
1. STD Males	HIV prevalence among STD patients (i)
2. STD Females	(i)/1.2
3. FSW	HIV prevalence among FSW/(i)
4. MSM	HIV prevalence among MSM/ 60% of (i)
5. General Population Females	HIV prevalence among ANC women (ii)
6. General Population Males	1.2 ´ (ii)

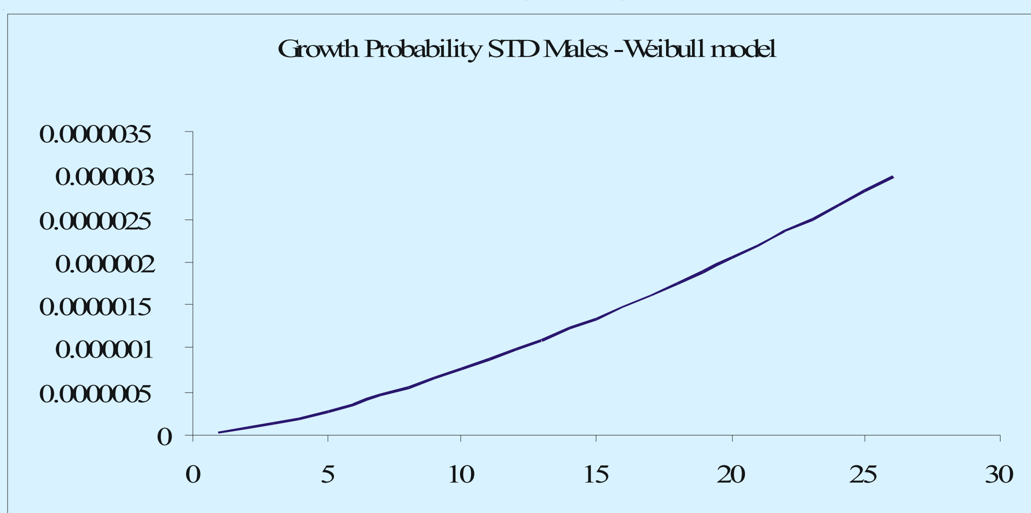
Step 1: Observed prevalence was smoothed using best regression fit.

Step 2: Growth probability $P_{tgr}(i)$ distribution within i[th] risk group estimated using both Weibull and Gamma model.

- Gamma model fitted well for all populations in Andhra Pradesh
- $P_{tgr}(i)$ represents the growth rate of prevalence within i[th] risk group

Step 3: Transmission force $P_{ttr}(ij)$ between risk groups i & j is derived assuming the interaction (contacts) between two risk groups in large population is random and independent

$$P_{ttr}(ij) = P_{tgr}(i) \times P_{tgr}(j)$$



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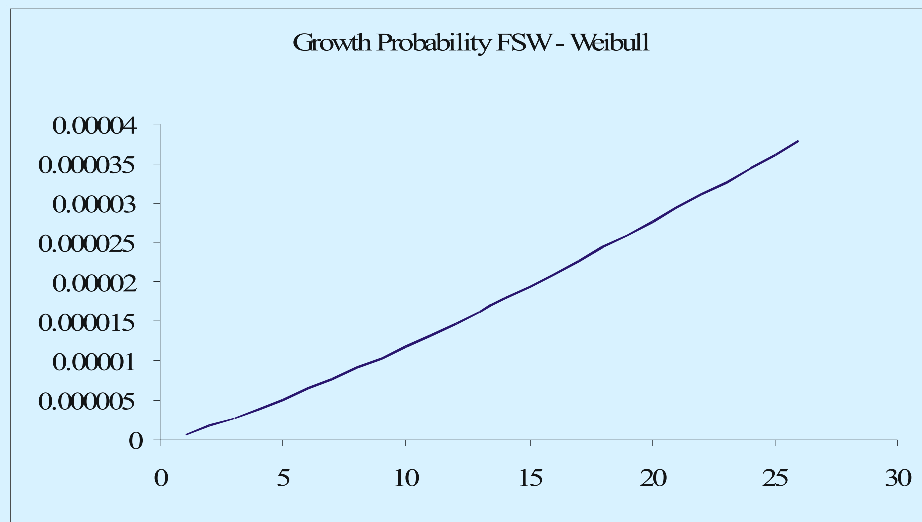
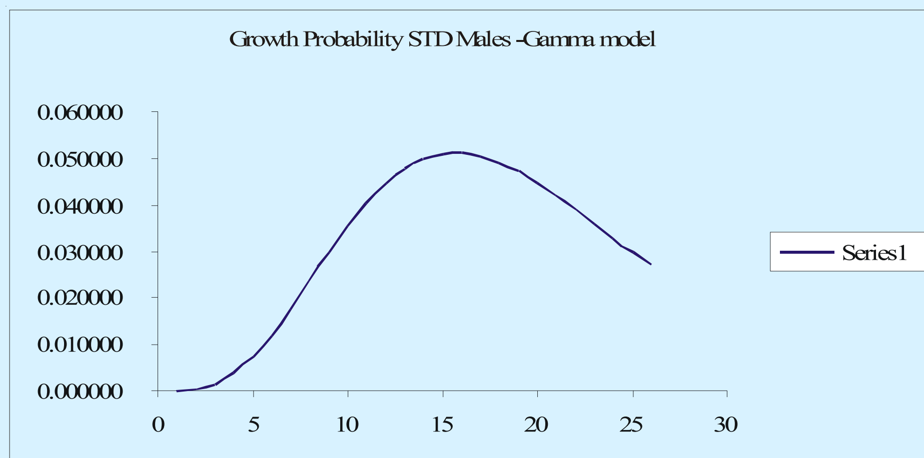
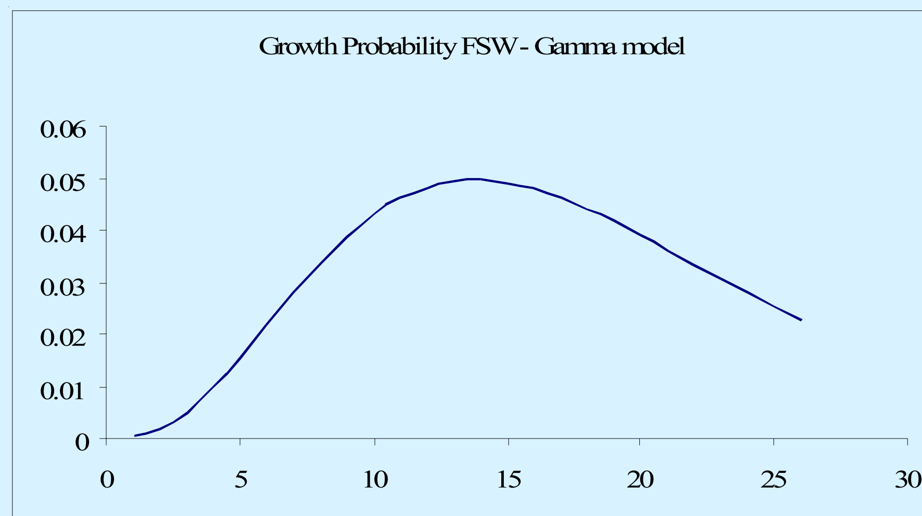

Growth Probability FSW - Weibull
0.00004
0.000035
0.00003
0.000025
0.00002
0.000015
0.00001
0.000005
0
0
5
10
15
20
25
30


Growth Probability STD Males -Gamma model
0.060000
0.050000
0.040000
0.030000
0.020000
0.010000
0.000000
0
5
10
15
20
25
30
Series1


Growth Probability FSW - Gamma model
0.06
0.05
0.04
0.03
0.02
0.01
0
0
5
10
15
20
25
30

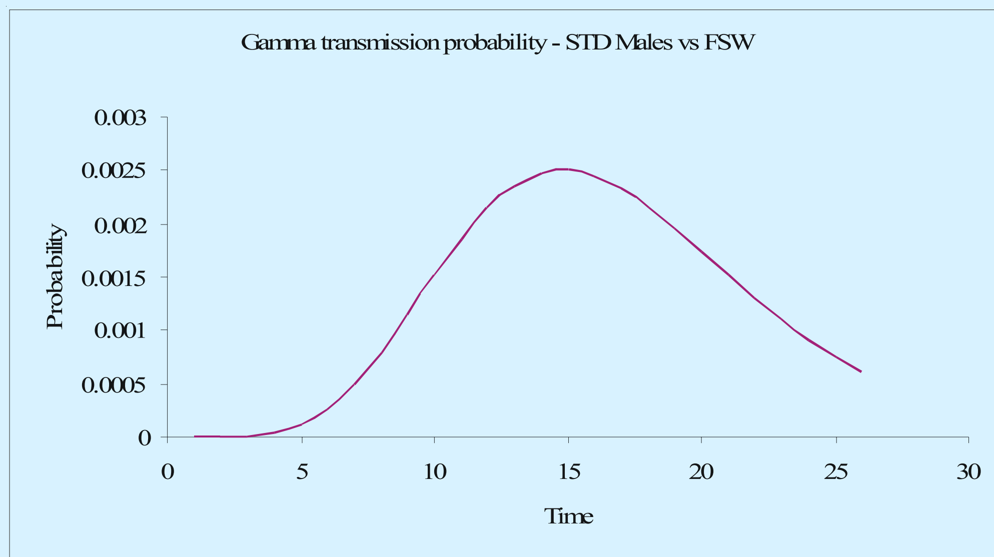
In the context of 6 risk groups assumed HIV infection is transmitted between

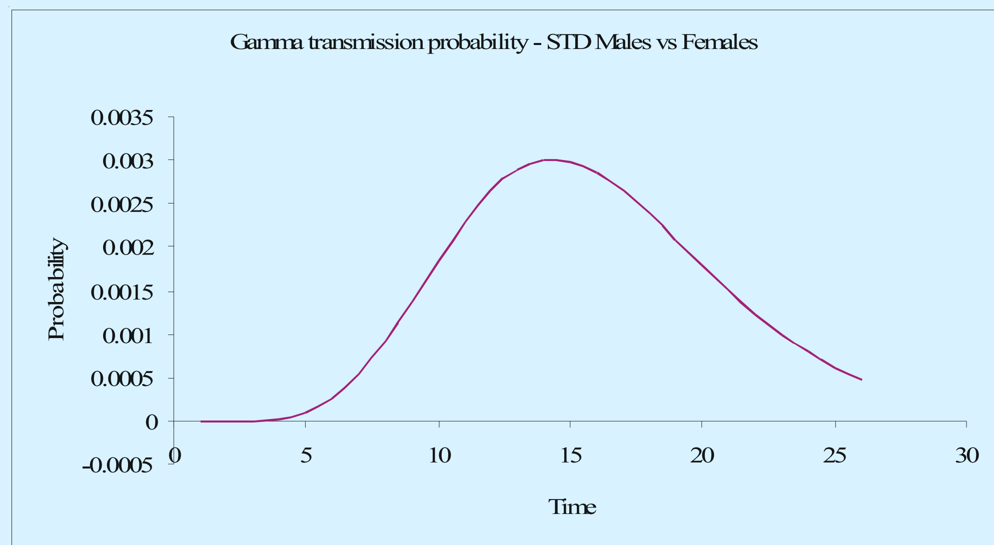
STD males & FSW

STD males & STD females

Between MSMs themselves

STDs (Bridge Popn) & general population (average of STD males & females ´ average of GP males & females)





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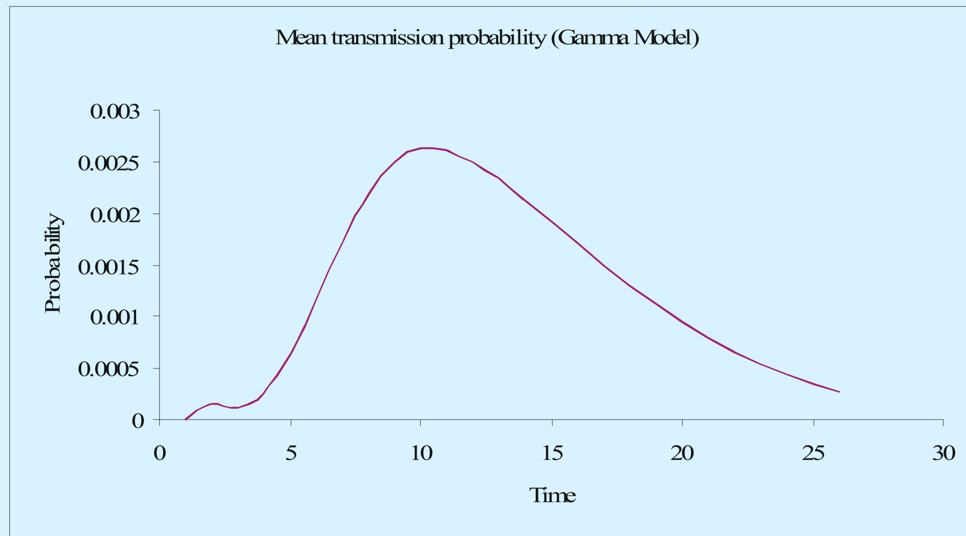
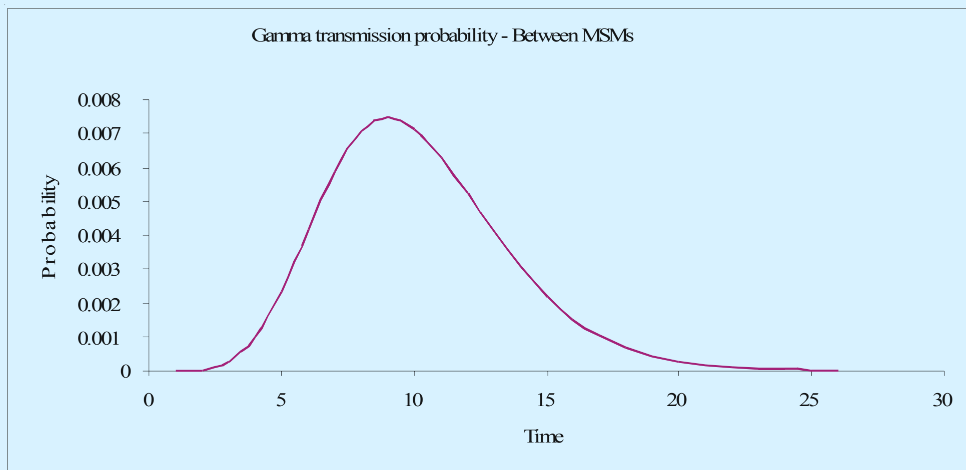
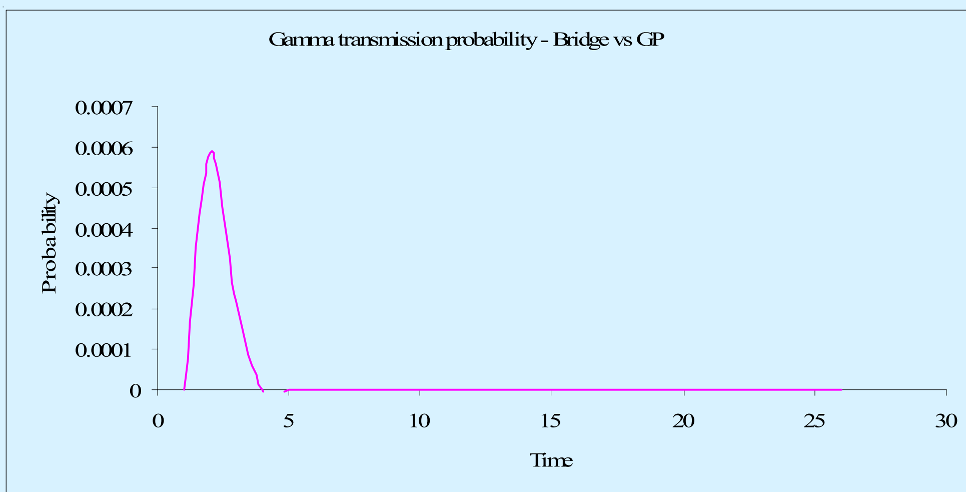

Mean transmission probability (Gamma Model)
Probability
0.003
0.0025
0.002
0.0015
0.001
0.0005
0
0
5
10
15
20
25
30
Time


Gamma transmission probability - Between MSMs
Probability
0.008
0.007
0.006
0.005
0.004
0.003
0.002
0.001
0
0
5
10
15
20
25
30
Time


Gamma transmission probability - Bridge vs GP
Probability
0.0007
0.0006
0.0005
0.0004
0.0003
0.0002
0.0001
0
0
5
10
15
20
25
30
Time

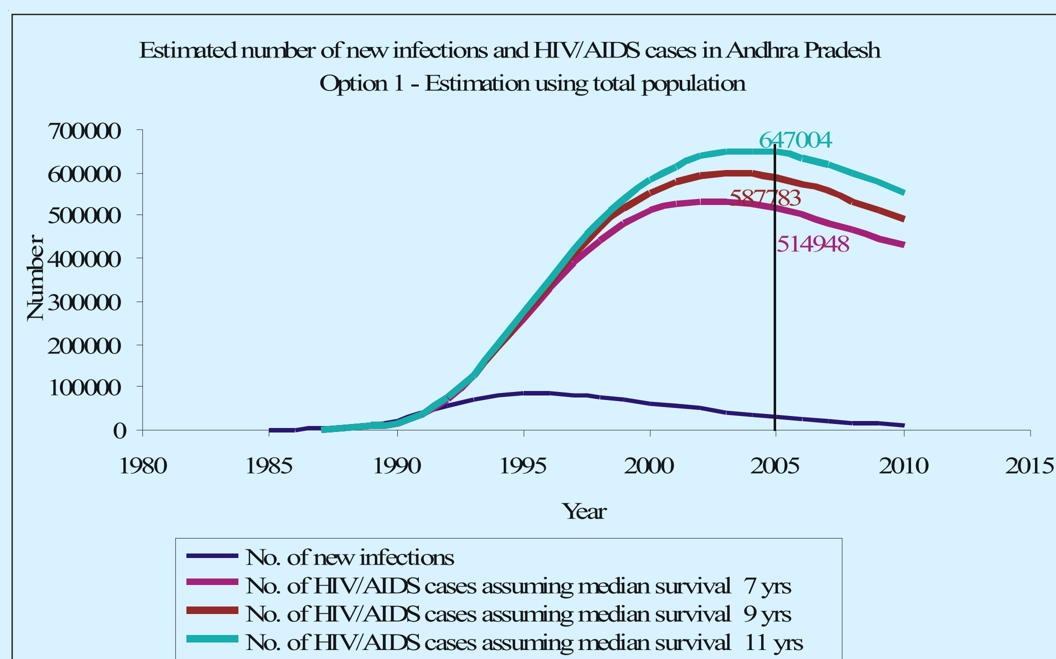
Step 4: Mean transmission probability is applied to population over time to estimate the new infections every year.

Step 5: Applying Weibull survival probabilities with median survival 7, 9 and 11 years to the number contracted diseases every year, number progressing to AIDS and remaining as HIV positives have been calculated. Natural death rate also has been applied to each group.

Results for Andhra Pradesh

Median incubation	Number of infections HIV/AIDS	ART Needs
7 yr	514948	39552
9 yr	587783	38504
11yr	647004	34555

The cases needing ART with 7 yr median survival (incubation) is expected to die in next two yrs in the absence of treatment. In other words, median survival period 7, 9 & 11 years can be assumed to be either time to develop AIDS or time to death.



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Option 2

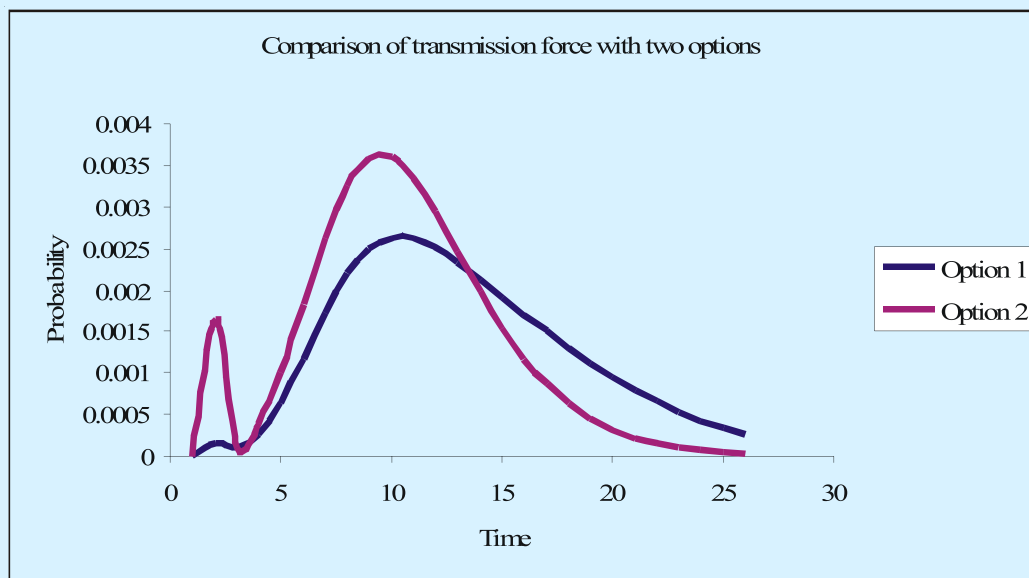
Under option 2 we consider only the population at risk to estimate the number of new infections.

Risk Groups	Prevalence
1. Clients	60% of HIV prevalence among STD patients (Assuming all clients does not have STI, the observed HIV prevalence among STD patients is reduced to 60%, the ratio of HIV prevalence in sites located in medical colleges and other district hospitals.)
2. FSW	HIV prevalence among FSW/ STD patients
3. MSM	HIV prevalence among MSM/ 60% of STD patients
4. IDU	HIV prevalence among IDU

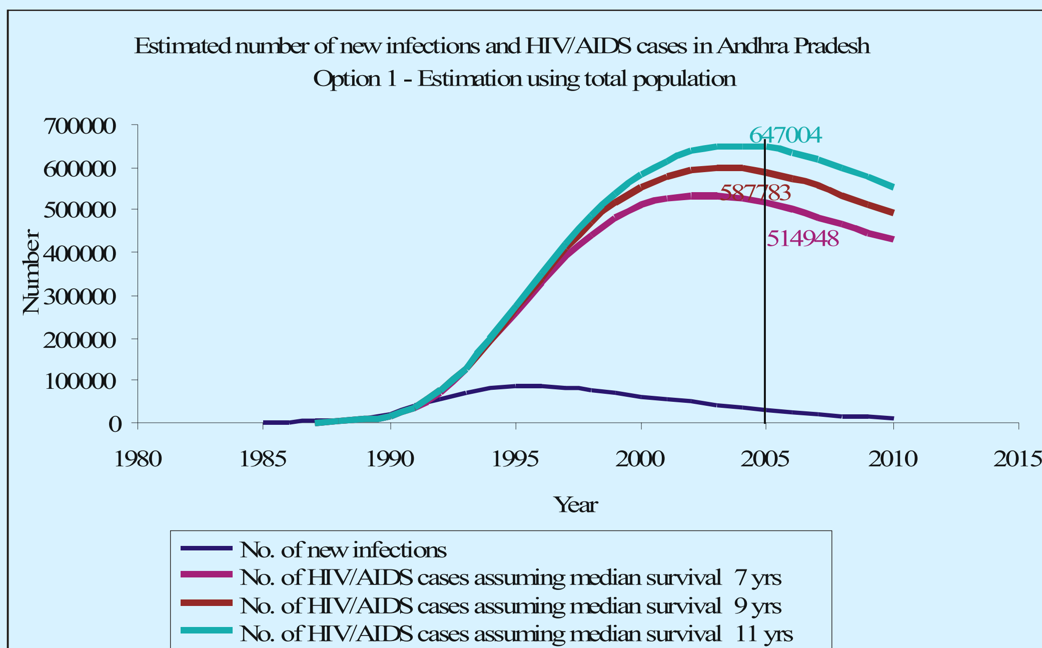
5. General Population Partners of clients, MSM & IDU

Steps 1-5 are carried out and the results for Option 2 is as below

Results – Andhra Pradesh



	Option 1		Option 2	
Median incubation	Number of infections HIV/AIDS	ART Needs	Number of infections HIV/AIDS	ART Needs
7 yr	514948	39552	111255	8358
9 yr	587783	38504	130104	9137
11yr	647004	34555	146552	8787



O8. INTEGRATED BIOLOGICAL AND BEHAVIOURAL ASSESSMENT ON NATIONAL HIGHWAY

Date of commencement : June 2005

Expected Date of Completion: 5 years

Funding Agency: BMGF/ICMR/NARI

Background

In India, sentinel surveillance is used annually to estimate the prevalence of Human Immunodeficiency Virus (HIV) infection in the country and to monitor trends in the epidemic. Sentinel surveillance for HIV in India began in 1994, at 55 sentinel sites, under the National AIDS Control Program-I (1992–1999). The

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population groups and sites for HIV sentinel surveillance are selected based on information about the risk behavior of various risk groups for HIV infection. The high-risk groups of the population include patients attending sexually transmitted disease (STD) clinics, female sex workers, injecting drug users (IDUs), and men who have sex with men (MSM); a low-risk group of the population includes women attending antenatal clinics. The rationale for selecting sentinel sites in the clinics attended by these subgroups of the population is that blood samples are collected from the people who attend the clinics for various purposes, and the samples can be tested for HIV in an unlinked anonymous manner. Since 1994, the number of sites in the sentinel surveillance system has been increasing. In 2002, sentinel surveillance was conducted at 384 sites and in 2003, at 455 sites.

Despite the HIV, Sexually Transmitted Infection (STI) and risk behavior surveillance activities currently underway in India, there are considerable gaps in the information available to understand both the course of the epidemic as well as the STI correlates and behavioral risks that fuel it. To measure the major outcomes and impacts of the interventions funded by the Bill & Melinda Gates Foundation (BMGF) under the Avahan India AIDS Initiative (Avahan), the existing surveillance system must be strengthened and expanded. A robust surveillance system will allow BMGF and its governmental and nongovernmental partners not only to follow key trends in HIV, STIs and risk behaviors, but also to use the data to project trends into the future.

The purpose of this assessment is to gather data for impact monitoring and evaluation of the Avahan India AIDS Initiative funded by the BMGF in 71 districts of 6 States and five highway sites. The proposed mapping, size estimation and integrated behavioral and biological assessment (IBBA) will provide some of the key data needed to assess major outcomes and impacts of the interventions funded by BMGF. This is the first independent impact-level evaluation of this scale of targeted interventions with sex workers and clients, high risk men and IDUs on HIV/AIDS. The project will be implemented in close collaboration with National AIDS Control Organization (NACO) and State AIDS Control Societies (SACS) and will provide valuable information to feed back into and strengthen the National AIDS Control Program in India.

The IBBA will be conducted three times during the five-year project period of Avahan. The baseline assessment will be undertaken in 2005, mid-line in 2007 and end-line in 2009. This protocol aims to cover the baseline, mid-line and end-line assessments.

Objectives

The overall objective of the IBBA is to collect necessary information for assessing the outcomes and the impact of HIV interventions in Avahan project districts in six high prevalence states and along National Highways. The survey will collect data in selected districts of the Avahan project states of Andhra Pradesh, Maharashtra, Tamil Nadu, Karnataka, Manipur and Nagaland and along the National Highways:

- To measure the major outcomes and impacts of the interventions funded by the Bill & Melinda Gates Foundation (BMGF) under the Avahan India AIDS Initiative by collecting behavioral and biological trend data in populations targeted by the interventions.
- To make available data that will be used for estimating sizes of populations targeted by the project.
- To make information available to a partner organization under Avahan for modeling the impact of the intervention.

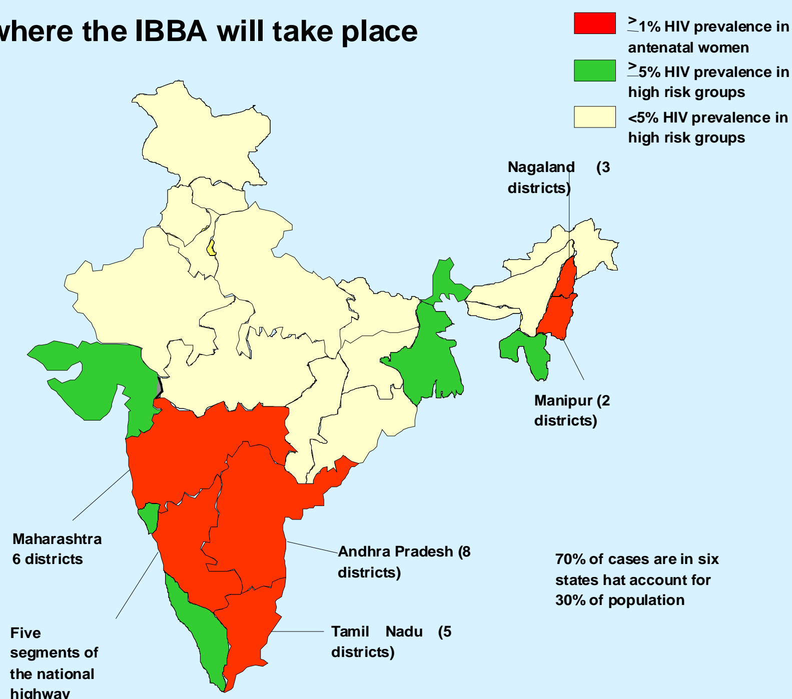
In addition, conduct of the IBBA will strengthen the capacity of national and state level institutes including ICMR's National AIDS Research Initiative (NARI), National Institute of Epidemiology (NIE), National Institute of Nutrition (NIN), Regional Medical Research Council (RMRC), and National Institute of Medical Statistics (NIMS).

Methods

IBBA populations

The populations that will be included for mapping, size estimation and IBBA in five Avahan States namely Tamil Nadu, Andhra Pradesh, Maharashtra, Nagaland, Manipur are female sex workers that are brothel based (FSW-BB),

female sex workers non-brothel based (FSW-NBB), male who have sex with men (MSM)/male sex workers (MSW), male clients of female sex workers and male injecting drug users (IDU); and those on the national highway, i.e. truckers drivers and helper (TD/H) and female sex workers highway-based (FSW-HB).



O9. IMPACT OF THE FIRST PHASE OF RCH PROGRAMME: ANALYSIS OF DATA OF INDIA'S DISTRICT LEVEL SURVEY

Objectives

* To undertake a comprehensive review of the RCH Programme and find out the impact of the first phase of RCH Programme.

Methodology

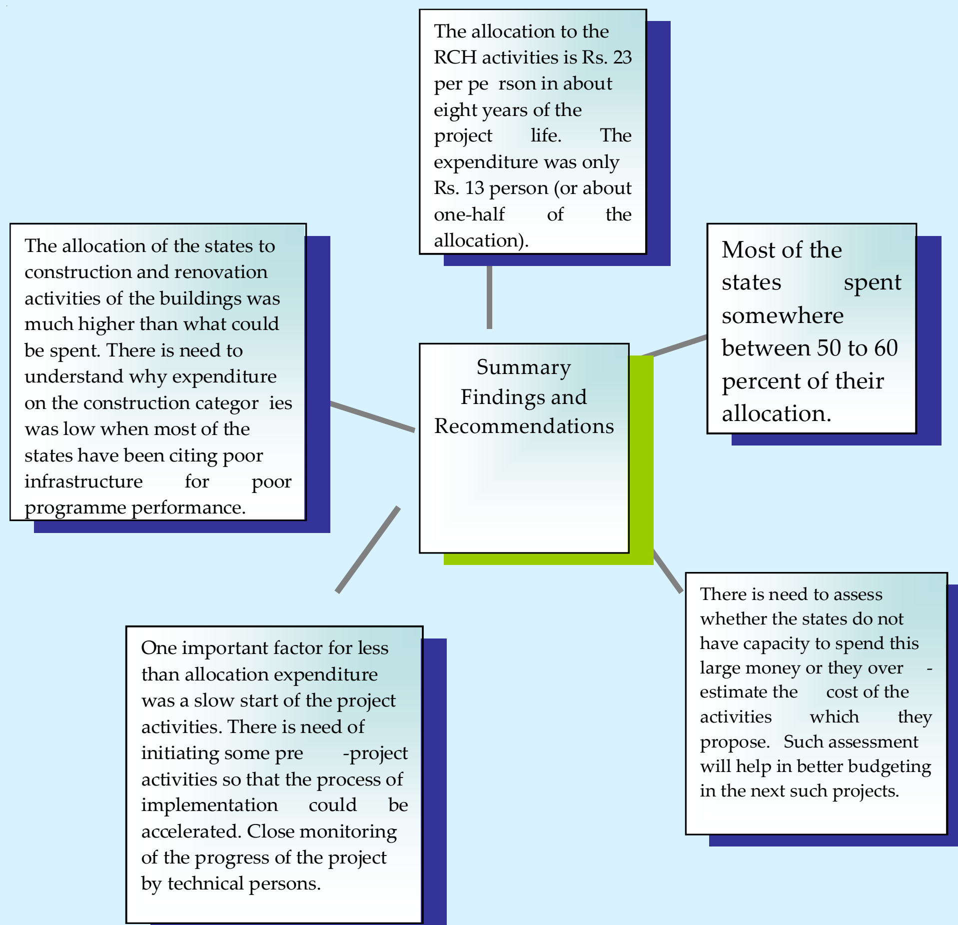
Following specific tasks are set to be carried out in order to meet the aforesaid objective:

1. To analyses the primary data collected in DLHS in the two phases in 1998-1999 and 2002.

2. To identify the common districts covered in the two phases.
3. To make a analysis of Health Status of the Country in these two periods.
4. To make out the Indicators as contained in the annexure to the Project Agreement Document (PAD) of RCH-1.

Progress

- Having organized consultative meetings among a group of experts to finalize indicators contained in the Project Agreement Document (PAD) of RCH-1, analyzed the contents of RCH Project Agreement and the RCH programme inputs.
- RCH-1 and RCH-2 (Phase I) data has been collected from International Institute for Population Sciences (IIPS), Mumbai. In consultation with IIPS, data validation, consistency and scrutiny has been completed and necessary correction has been done.
- Districts of RCH-1, RCH-2 and Census are compared.
- Tabulation plan in respect of linking various inputs with the output indicators has been done.
- Under the budget and expenditure analysis in RCH-1, the financial analysis of RCH-1 has been reported for three categories of states separately. The first category consists of larger states, numbering 20, second category is composed of eight smaller states/Union Territories (except north-eastern states) and the third is seven North-eastern states.



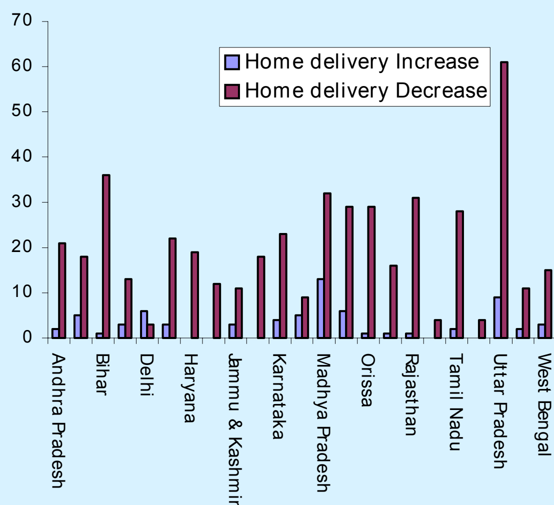


Fig. 1: Improve performance of health indicators, surveyed in 1998–99 and 2002–03

Improve performance of health indicators by districts, surveyed in 1998-99 and 2002-03									
State/Union territory	Number of Districts	Home delivery		Safe delivery		Birth order 3+		Girl married <18	
		Increase	Decrease	Increase	Decrease	Increase	Decrease	Increase	Decrease
Andhra Pradesh	23	2	21	21	2	2	21	12	11
Assam	23	5	18	14	9	6	17	9	14
Bihar	37	1	36	34	3	10	27	6	31
Chhatisgarh	16	3	13	12	4	10	6	2	14
Delhi	9	6	3	4	5	6	3	6	3
Gujarat	25	3	22	20	5	12	13	11	14
Haryana	19		19	18	1	3	16	5	14
Himachal Pradesh	12		12	11	1	3	9	7	5
Jammu & Kashmir	14	3	11	11	3	2	12	4	10
Jharkhand	18		18	17	1		18	3	15
Karnataka	27	4	23	22	5	3	24	7	20
Kerala	14	5	9	8	6	7	7	4	10
Madhya Pradesh	45	13	32	37	8	25	20	6	39
Maharashtra	35	6	29	30	5	9	26	1	34
Orissa	30	1	29	29	1	5	25	3	27
Punjab	17	1	16	17		4	13	6	11
Rajasthan	32	1	31	31	1	6	26	5	27
Sikkim	4		4	4		1	3	3	1
Tamil Nadu	30	2	28	29	1	8	22	9	21
Tripura	4		4	3	1		4	1	3
Uttar Pradesh	70	9	61	59	11	13	57	8	62
Uttaranchal	13	2	11	9	4	1	12	1	12
West Bengal	18	3	15	14	4	3	15	7	11

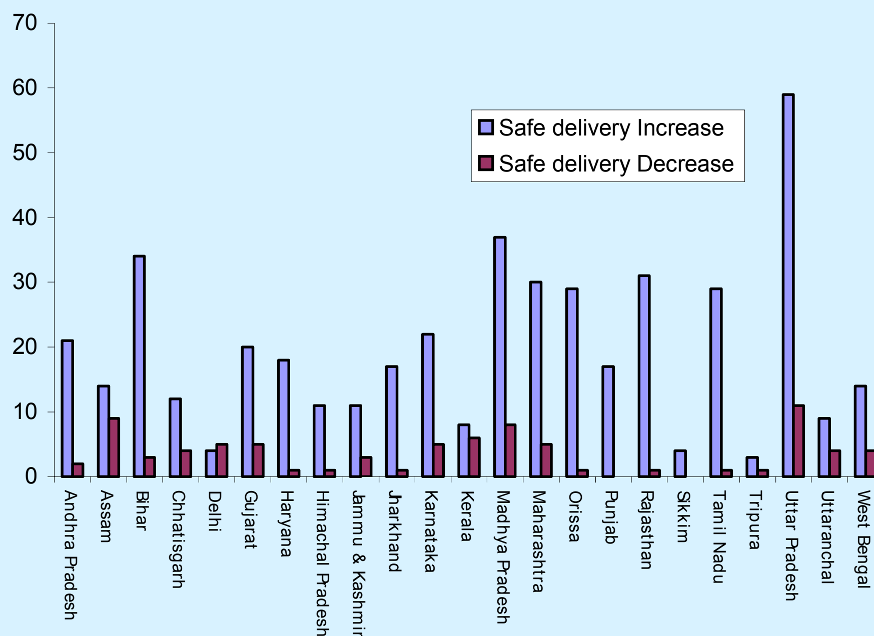


Fig.2: Improve performance of health indicators – safe delivery

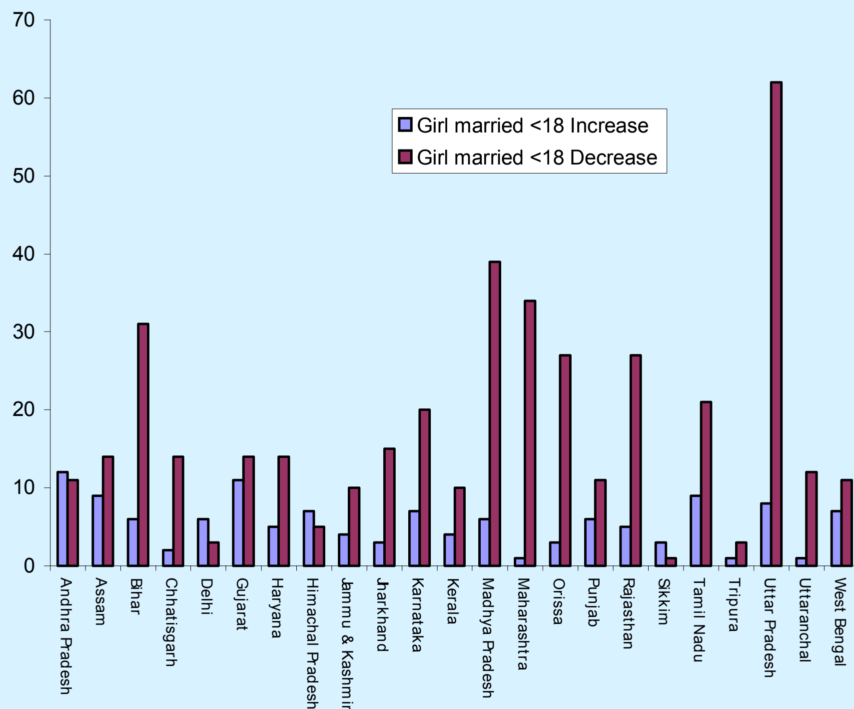


Fig.3: Improve performance of health indicators – Girls marrying before 18 years of age

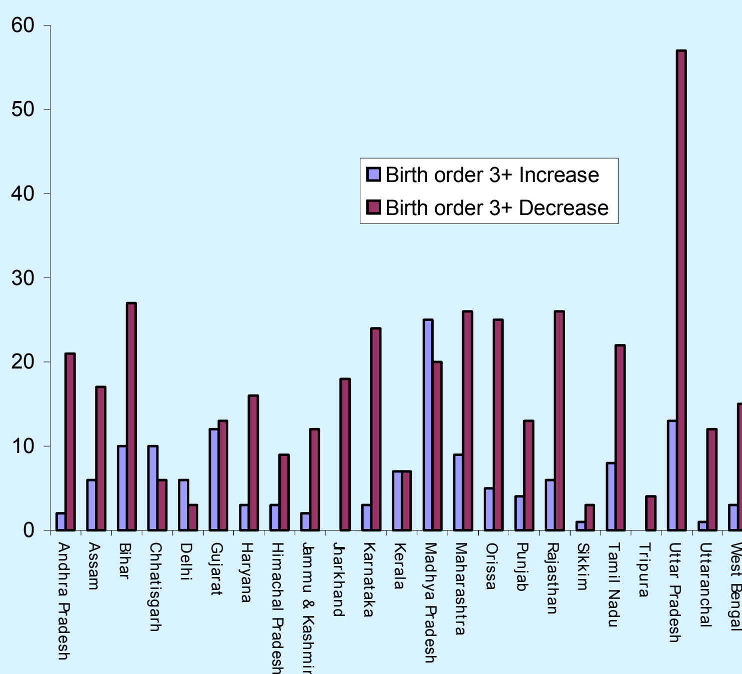


Fig.4 : Improve performance of health indicators – Birth order 3+

O10. INTEGRATED DISEASE SURVEILLANCE PROJECT - NCD RISK FACTOR SURVEILLANCE

Date of commencement: March 2006

Funding Agency: NICD/ICMR/World Bank

Period of study: March 2009 (3years)

The Government of India, with the assistance of the World Bank is implementing the Integrated Disease Surveillance Project (IDSP) to develop a system of decentralized state-level surveillance of selected risk factors of non-communicable diseases throughout the country. The surveillance of risk factors of non-communicable diseases (NCD) is an important component of the project. Periodic community based surveys would form an integral part of the surveillance.

Objectives

- Estimate the prevalence and distribution of risk factors in different strata in various States of India;
- Establish a data base of NCD risk factors and monitor trends of important risk factors over a period of time
- Support evolving strategies and interventions of identified risk factors to reduce the burden of diseases due to non-communicable diseases;

The NCD Risk factors identified for inclusion in NCD survey are behavioral (Tobacco and Alcohol use, Dietary habits), physical activity (levels of physical activity) and physical measurements (Height, Weight, Pulse rate, Blood pressure and Waist circumference) including the biochemical assessments (Blood sugar and Blood cholesterol).

The NIMS has been identified as National Nodal Agency (NNA) for implementation of this project in the country. The survey methodology, survey instruments and training materials for conducting the survey has been prepared. The survey instruments has been piloted and modified.

In the first phase, survey will be conducted in eight selected States. The survey in randomly selected 50 rural PSUs and 50 urban CEB of wards will be conducted by the State Survey Agency by using the uniform survey methodology.

Progress

- Survey methodology for Phase-I states has been finalized;
- List of randomly selected rural PSUs and Urban wards (CEB) has been finalized;
- Trainer's Guide and Survey Manual have been prepared;
- Survey Instruments are prepared and pre-tested.
- TOT has been conducted at NIMS, Delhi
- Data Management module is ready
- Data entry training is being planned.

O11. A STUDY ON THE PREVALENCE, EPIDEMIOLOGY AND CONSEQUENCES OF OBSTETRIC FISTULAS IN INDIA

Date of Commencement: Sept 2006

Expected date of completion: May 2007

Funding Agency: UNFPA

Background

In India the prevailing maternal morbidity and mortality is a cause of concern. Chronic obstetric morbidity is a much ignored aspect of woman's health. There is hardly any information on community based estimates of obstetric morbidities. One of the chronic obstetric morbidities, obstetric fistula is most severe disability. In terms of numbers involved, fistula may not be regarded by many a priority but it has devastating effects on woman's personal, sexual and social life. In India, apart from few hospital based studies, there is little epidemiological data. Given high maternal mortality ratio and high adolescent fertility rate we expect it to be a significant problem in numbers. Seven percent of maternal deaths are due to obstructed labour, a lot more women who survive would develop obstetric fistula. Of women who developed complications in pregnancy 18 percent developed obstructed labour (RCH-RHS, 1998). Obstructed labour, obstetric fistulas are indices which reflect the antenatal and intra-natal care in a community.

WHO estimates 50,000 to 100,000 new cases annually, with over 2 million women in developing countries living with fistula untreated. Bhatia et al conducted a community based study to asses gynecological morbidity in Karnataka state, the prevalence of fistula was 0.3% in 385 women included in the study. Between 1989-1993, some community bases studies were conducted in selected sites in four states in India to assess the extent of obstetric fistula. In 650, 385, 803, 3600 women surveyed in four surveys the prevalence was 0.5%, 0.5%, 7.6% and 0.3% respectively. These surveys employed varying definitions and methodologies. As far as social morbidity is concerned, these women are ostracized by family and society, as many as 70-90 percent is either divorced or separated. They live a life of shame and poverty. Its is a pity because the condition is preventable with good antenatal and intra-natal care, early diagnosis of prolonged/ obstructed labour, prompt referral to a centre with facility for cesarean section. Surgery can cure up to 90% of fistulas, but requires an experienced and trained surgeon. Until recently fistulas have been a low-priority issue on national agenda. Its time policy makers gave it more importance.

Objectives

Short term

1. To document the first effort to collect national prevalence data on vaginal fistulas (community based survey).
2. To develop and administer proper tools to record the prevalence, for more reliable data, previous studies have used varying definitions and methodologies.
3. To establish the burden of disease, its epidemiology and consequences both social and economic.

Long term

1. To consider needs and opportunities for translating data to policy, in specific need based approach depending on the prevalence in different part of the country. Prevention by improving ante and intra-natal services, transport facility. Provide treatment by trained personal, establish centres of excellence for training

2. To prioritize research with respect to treatment and rehabilitation, service provision and outcomes.

Methods

In the first phase, meeting of researchers and programme managers to develop the methodology and tool for community based survey to study prevalence, epidemiology and consequences of obstetric fistulas, after extensive literature search. Develop the manual of operations.

In the second phase community based survey will be carried out, results analyzed and conveyed to policy makers.

O12. ADOLESCENT FRIENDLY HEALTH SERVICES IN INDIA – AN EVALUATION OF QUALITY AND ACCESS TO SERVICES

Date of commencement : April 2006

Expected date of completion : Sept 2007

Funding Agency: WHO

Objectives

1. Role of adolescent friendly health services vis-à-vis RCH-II ARSH strategy and their feasibility and sustainability
2. Whether the establishment of adolescent friendly centres has increased the quality and access to health services.
3. The effects of school based outreach activities on the school environment and access to adolescent friendly health services.

Methods and Approaches to be Used

Site selection

It is proposed to select only 3 sites from the 14 sites included in the project that are tertiary care hospitals located in medical colleges and have been functional

without interruption for the last over 3 years. The sites have established a centre and trained health providers in other departments of their hospital as well as beyond their sites and all three sites have run an outreach programme to schools.

Design of the evaluation

A qualitative assessment will be carried out to evaluate the role of the adolescent friendly clinics (AFCs) and their feasibility, sustainability through interviews with key stakeholder including but not limited to facility coordinators, hospital / institution chief, and review of relevant documents.

Since there is no baseline data on the quality of services for adolescents, the evaluation will assess levels of quality (using Standards Framework for determining quality of services) in the dedicated adolescent centres as well as in out patient departments (Obstetrics, Skin care etc) where health workers have not been oriented in adolescent friendly approaches ('Control Group')

To assess the influence of the outreach intervention on the schools and the level of access to information and health services of adolescents in the schools, students and teachers of selected schools will be a sampled. Student data will be compared with baseline data collected in the needs assessment carried out at the start of the project.

Tools

- The study will develop survey tools based on the objectives of the AFCs and adaptations of WHO tools used in India, Russia and Mongolia. Additional tools will be developed as needed.
- The methodology for assessing the quality of AFHS (Client, facility and provider checklist) developed by WHO will be used for the description of
  - the interventions in the AFHC; and
  - the quality of the organization of the AFHC, its procedures and preparedness of the staff
- An adaptation of the WHO client exit-interview tool will be used with the clients.

- Tools will be developed based on WHO community survey tools (created for coverage studies in Russia and Tanzania) in order to assess the health seeking behaviours of adolescents in the schools.
- In addition, a self administered tool for parents will be developed to obtain relevant information from adults accompanying adolescents to the clinic, and that will be administered while the adolescent will undergo the client exit interview.

Sample Size

The following sample sizes are being proposed for the intervention and control group. In each site:

Target	Primary group	Secondary group
Staff	All AFHC staff (4)	Similar number in secondary OPD
Client exit Interview	25-50 AFHC	25 in secondary OPD
Parents	Max 25-50 AFHC	Max 25 in secondary OPD
Students	100-200	
Teachers & principals	2-3	

It is projected that the client sample will be quite small based on the reported average daily attendance levels reported in existing sites (which vary from less than 3 clients on the lower end to approximately 5-8 clients in others). A suitable time period to collect the sample, including all clients, will be identified that may be at least five weeks.

Progress

Data has been analysed per site and report is being finalized. Salient findings are as under:

Chandigarh

		Adolescent Friendly Clinic	Other OPD
Satisfaction level of client with the service received	very much	90.0	65.7
	not so much	10.0	31.4
	no		2.9
Client liked the Best about service	physical environment	65.0	88.6
	staff friendliness	45.0	22.9
	staff attitude		20.0
	lack of confidentiality		11.4
	long waiting hrs	55.0	45.7
	other	5.0	
Doctor talked to client separately		90.0	80.0
Health workers did something that the client would not prefer them to do in the future		90.0	68.6
Would come back in future for a health problem		100.0	77.1
The client think adolescent would be happy to come here for services		20.0	8.6
Client would encourage friends to use these services		100.0	82.9
Suggestions for creating awareness among adolescents health facility and the service	Advertise through media	25.0	25.7
	Advertise through peers and friends	40.0	54.3
	Publicize services to school / organizations	25.0	
	Others	5.0	11.4

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Clients perception of difficulties in availing the services	Nothing	35.0	5.7
	Location	10.0	20.0
	Distance	25.0	34.3
	Fees		2.9
	Clinic hrs	10.0	17.1
	Waiting time	10.0	8.6
	Staff attitude		5.7
Clients suggestions to remove obstacles removed so adolescents to use the services more?	Service fees	25.0	34.3
	Inconvenient working hrs	5.0	22.9
	Judgmental staff attitude	5.0	5.7
	Long waiting time	25.0	28.6
	Other	5.0	
Things that were most important to client whilst he/she visiting that facility.	Cost of service Location of the facility Clinic hrs	50.0 15.0 10.0	62.9 5.7 2.9
	Appearence of facility		11.4
	Friend lines of staff	25.0	11.4
Facility gives opportunity for making suggestion for improving the quality services		90.0	65.7

Delhi

		Adolescent Friendly Clinic	Other OPD
Satisfaction level of client with the service received	Very much	88.9	77.8

What did you like best about service?	Physical environment	11.1	11.1
	Staff friendliness	88.9	44.4
	Useful advice		38.9
Did the doctor talked to you separately?		100	27.8
Was there any thing, the health workers did that you would not prefer them to do in the future?		33.3	58.3
Would you come back here again if you had a health problem?		100.0	80.6
Do you think you would be happy to come here for services?		44.4	36.1
Would you encourage your friends to use these services?		100	83.3
What could be done to make your friends aware of the health facility and the service it provides?	Advertise through media	33.3	36.1
	Advertise through peers and friend	44.4	30.6
	Publicize the services to school and other organization s	22.2	13.9
	Advertise through peers and friend	11.1	8.3
Is there anything that makes it difficult to use these service?	Nothing	33.3	30.6
	Distance	11.1	5.6
	Fees	11.1	5.6
	Clinic hrs		5.6
	Waiting time	22.2	36.1
	Staff attitude		2.8
	Lack of confidentiality	11.1	

	Other (specify)		2.8
	Waiting time		2.8
	Lack of confidentiality		5.6
What obstacles should be removed so that Adolescents may use these services more?	Service fees	11.1	5.6
	In convenient working hrs	55.6	5.6
	Lack of confidentiality judgmental staff attitude		13.9 2.8
	long waiting time	33.3	61.1
	judgmental staff attitude		2.8
	long waiting time		5.6
Please indicate (X) top three things that most important to you whilst you visited that facility.	cost of service	11.1	22.2
	location of the facility	22.2	2.8
	appearance of facility/ waiting area		8.3
	friend lines of staff	33.3	19.4
	motivation of staff	11.1	5.6
	knowledge and skill of staff	22.2	22.2
	information and advice given		5.6
	location of the facility		8.3
	clinic hrs		2.8
	friend lines of staff	22.2	2.8

	motivation of staff	22.2	
	knowledge and skill of staff	22.2	27.8
	information and advice given	11.1	11.1
Does the facility provide you an opportunity to suggest what they can do to provide better quality services, if you wanted to?		55.6	8.3

Kolkatta

		Other OPD	AFHS
In general do you feel satisfied with the service you have just received?	Very much	80.0	81.6
	Not so much	12.0	14.3
	Not at all	4.0	2.0
What did you like best about service?	Physical environment	40.0	16.3
	Staff friendliness	40.0	46.9
	Useful advice	16.0	32.7
What did you like least about service?	Physical environment	40.0	42.9
	Staff attitude	4.0	
	Lack of confidentiality		6.1
	Long waiting hrs	28.0	20.4
	Other	16.0	18.4
Did the doctor talked to you separately?		92.0	93.9
Was there any thing, HW did which you not prefer to do in future?		96.0	91.8

Would you come back here again if you had a health problem?		92.0	89.8
Do you think adolescent would be happy to come here for services?		56.0	63.3
Would you encourage your friends to use these services?		96.0	93.9
What could be done to make your friends aware of the health service it provides?	Advertise through media	32.0	30.6
	Advertise through peers & friend	44.0	32.7
	Publicize the services to school		22.4
	Others	20.0	8.2
Is there anything that makes it difficult to use these service?	Nothing	44.0	36.7
	Location	8.0	8.2
	Distance	28.0	34.7
	Fees	8.0	4.1
	Clinic hrs	4.0	6.1
	waiting time	4.0	2.0
	lack of confidentiality		2.0
Is there anything that makes it difficult to use these service?	nothing		4.1
	distance	8.0	2.0
	fees	8.0	8.2
	clinic hrs	4.0	2.0
	waiting time	16.0	20.4
	staff attitude	4.0	4.1
	lack of confidentiality	4.0	4.1

What obstacles should be removed so that Adolescents may use these services more?	service fees	28.0	22.4
	In convenient working hrs	24.0	20.4
	lack of confidentiality		8.2
	judgmental staff attitude		10.2
	long waiting time	8.0	12.2
	other	4.0	8.2
What obstacles should be removed so that Adolescents may use these services more?	in convenient working hrs		2.0
	long waiting time	4.0	12.2
	other	4.0	2.0
Please indicate (X) top three things that most important to you whilst you visited that facility.	cost of service	48.0	18.4
	location of the facility		12.2
	clinic hrs	12.0	18.4
	appearance of facility & waiting area		28.6
	friend lines of staff	28.0	10.2
	information and advice given		2.0
	friend lines of staff	20.0	2.0
	motivation of staff	12.0	4.1
	knowledge and skill of staff	24.0	8.2
	knowledge and skill of staff	12.0	6.1

	information and advice given	40.0	8.2
Does the facility provide you an opportunity to suggest what they can do to provide better quality services, if you wanted to?		60.0	59.2

Overall impressions and Suggestions About the Facility-Parents (%)

	Chandigarh	Delhi	Kolkatta
Requirement of your consent when ward got health services from doctor	96.4	85.0	93.5
Allowance of yours to be present at doctor's chamber at the time of medical check-up / counseling	90.6	85.7	97.8
If no, then your comfort ability with the fact that the provider wanted to see the adolescent alone	50.0	66.7	
Yours expectation	72.7	33.3	
Knowing the reasons	65.0	33.3	
The doctor should ask your consent for the advice	91.2	62.5	63.0

O13. EVALUATION OF KISHORI SHAKTI YOJANA

Date of commencement : Feb 2007

Expected date of completion : March 2008

Funding Agency: DWCD

Background

The Kishori Shakti Yojana (KSY) envisages to: (1) Improve the nutritional and health status of girls in the age group of 11-18 years; (2) Provide the required literacy and innumeracy skills through the non-formal stream of education; (3)

Train and equip the adolescent girls to improve upgrade home-based and vocational skills; (4) Promote awareness of health, hygiene, nutrition and family welfare, home management and child care; (5) Gain a better understanding of their environment related social issues and the impact on their lives.

The KSY is being implemented using ICDS infrastructure and is operationalised in 2000 projects through out the country.

Objectives

In order to appraise the progress and achievement of the project as well as the impact of various inputs, it was felt necessary to examine the impact of the programme. As the baseline parameters of several process and impact indicators are not available, It is proposed to collect data on certain identifies processes and impact indicators, and also compare some indicators within the ICDS projects area among adolescent girls in the age group 11-18 years registered under KSY as well as non-registered under KSY.

Process and impact indicators

From ICDS System

- Profile of AGs, Educational status of AGs
- Main occupation of families of AGs and family income profile of mothers
- Time devoted by AGs at AWC
- Community support available to AWCs
- Nature of AGs contribution
- Enrolment of AGs
- Criteria for selection of AGs
- Services provided to AGs at AWC
- Organizing NHE under KSY
- Impact of NHE on AGs
- Nutrition & Health Practices after attending NHE session

NIMS

- Knowledge and skill acquired by Age
- Option provided under the scheme being implemented
- IFA Supplementation, de-worming intervention etc.
- Convergence with health department and Health education department
- Reaction of the beneficiaries community towards the scheme
- Usefulness / drawback of the scheme
- Role-played by them & problems faced in the implementation of the scheme.

From the Beneficiaries/Non-beneficiaries

- Information on socio-economic profile & family composition of Adolescent girls.
- The utilization of services provided at the AWC such as non-formal education, nutrition & health education, IFA supplementation and de worming, nutrition, by the adolescent girls.
- Motivation for training and coverage and utility of training.

Non-Beneficiaries

- To know the views of adolescent girls who were not attending the AWC
- Reasons for not attending AWC
- To know about their knowledge and awareness of the advantages likely to be accrued to beneficiaries of their age group.

From the Families

- To find out the mother's perception of the programme.
- The awareness about the scheme
- Improvement in the activities at home of beneficiaries
- Involvement in the activities of the *Anganwadi* centres

The findings of the study would provide rationale for continuation expansion of project in the country.

Coverage

It is proposed to cover approximately 10% of the Projects sanctioned for the KSY in States. As such, a sample of 200 projects area selected from all the States may be drawn for the study.

The respondents

The respondents for the evaluation study include village level respondents & project level functionaries

a. Village level respondents

b. Beneficiaries

c. Mother of beneficiaries

d. Non-beneficiaries (a control Qr9up of adolescent girls from the same population residing in selected *Anganwadi* area but not availing the services under the scheme to be interview to draw a comparative picture of the advantages accrued to Adolescent girls under the scheme).

e. Local leaders

Project Level Functionaries

a. Anganwadi workers

b. Supervisors

c. CDPOs

d. Block / District level officer concerned with ICDS

Progress of the Study

Survey questionnaires have been modified and data collection work is in progress.

O14. PRIMARY HEALTH CENTRE FACILITY SURVEY OF DEMOGRAPHICALLY WEAK DISTRICS IN INDIA

Date of commencement :

Expected date of completion :

Funding Agency : ICMR

NIMS

Objectives

a. To take stock of the existing health facilities at the PHC level with regard to the available manpower, Infrastructure and Family Welfare services provided by them in the recent period.

b. Strengthening of PHCs under Social Safety Net Scheme- Infrastructure, Facilities, Training, and Equipments.

c. Improvement in the Services due to Strengthening

d. To undertake survey on quality of care from beneficiaries on a sample basis for 5-10 percent of sites.

e. To collect information from the Private sector including Private clinic/ nursing homes/NGO/ voluntary organizations on RCH services provided by them for co- opting them in Public Private partnership.

The study would cover 460 PHCs i.e, 15 per cent of the 3056 primary health centers from 83 districts (out of 90 demographically weak districts) from the states of U.P., Uttarakhand, M.P., Chhatisgarh, Bihar, Jharkhand and Rajasthan. The selection of these would be random sampling giving due representation to all regions in the state.

The following instruments are used.

1. PHC Schedule
2. Sub center Schedule
3. Exit interview Schedule
4. Private sector Schedule

Progress of the Study

Survey questionnaires have been modified and data collection work is in progress.

O15. BEHAVIOURAL SURVEILLENCE SURVEY (BSS-II) – YOUTH POPULATION

Date of commencement : June 2006

Expected date of completion : 2008

Funding Agency : NACO/UNICEF

Background

Undertaking Behavioral Surveillance Survey (BSS) is an important effort by the NACO to monitor changes in behavioral aspects of general population as well as specific population groups vulnerable to HIV infection. This is expected to help NACO to derive necessary implications from the resultant changes between the 'recommended behavior' and 'reported behavior' for strategizing appropriate programmatic solutions. In the above context NACO conducted the first BSS in the year 2001 as a part of the NACP II. Towards the end of the NACP II i.e. after a gap of five years since the first wave of BSS, NACO has commissioned the end line BSS to measure the changes in behavioral indicators. The end line BSS is being carried out among General populations as well as HRG (FSW, MSM, Client of FSW and IDU) following similar approach adopted in base line BSS. The aim of carrying out the second wave Behavioral Surveillance Survey is to assess current risk behavior in specific population in India and to develop a database so as to measure behavioral changes from Baseline BSS, 2001 (BSS-1) to end-line BSS 2006, (BSS-2). It aimed to measure changes in the key knowledge and behavioral indicators of general population, young population and key high-risk and bridge groups since the baseline BSS, which was carried out in 2006. This will also to an extent, assess the success of the NACP-II project and identify persistent problem areas. This basic objective can broadly be divided in to the following specific objectives:

- To estimate key knowledge and behavioral indicators of general population and important high-risk and bridge groups on HIV/AIDS and related areas;
- To measure changes in the key knowledge and behavioral indicators of all the above mentioned groups, based on the baseline estimates of the indicators;
- To highlight the possible impact of the project and identify persistent problem areas; and
- To provide data for cross-country and cross regional comparisons of behavioral risks.

NIMS

Methodology

The survey work has been undertaken by ORG-MARG at all India level. The survey of the General Population would also cover about 30,000 respondents aged 15-24 years as a part of the same. In order to have adequate sample of youth population who are more vulnerable to HIV/AIDS, it was estimated that an additional sample of 48858 respondents need to be covered. With this number of respondents a detailed analysis could be provided.

After having considerable discussions in the TAG meetings, it was decided to conduct an independent survey among the population aged 15-24 years in the same PSUs sampled for BSS-2 Survey. UNICEF has provided funds for the additional sample. The rational behind the study is that the young people have an important role to play in fuelling the HIV/AIDS epidemic in India and therefore they need focused intervention that can result in changing risk behaviour. The study will be repeated periodically for trend analysis which will indicate the impact of the intervention as well as generate invaluable information about the behaviour and life style of adolescent and youth and people in the country.

A sample of 3220 young people in the age group of 15-24 is required in each states/groups of the states to provide the state level estimates. Thus the total sample size for 25 states /group states works out to be 80500. Out of 80500, 31642 have been covered during end-line BSS Survey and additional 48858 are proposed to be covered separately by the same organization, i.e., ORG MARG.

National Institute of Medical Statistics has been given task to provide the technical support and monitor the survey.

Activities

The team conducted two workshops at NIMS conference hall and carried out many meeting in the Institute to discuss the sampling and tabulation plan. They visited at different places to monitor the survey. The team members actively participated in review meetings organized at NACO and ORG offices. The draft report for Youth Survey has been received. The report has been reviewed. The comments have been sent to ORG for incorporating in the report.

O16. EVALUATION OF VIRAEMIA IN HEALTHY VOLUNTEERS AFTER SINGLE DOSE VACCINATION WITH JE SA 14-14-2: LIVE ATTENUATED VACCINE – AN OPEN LEVEL PROSPECTIVE UNCONTROLLED SINGLE CENTRE TRIAL

Date of commencement : Jan 2006

Expected date of completion : Dec 2008

Funding Agency: ICMR

Primary Objective

To determine levels of viraemia after administration of a single dose of live attenuated SA14-14-2 Japanese encephalitis vaccine in adult subjects between days 1-8 and day 15.

Secondary Objectives

1. To determine neutralizing antibody response at 30 days, 6 months and one year after administration of a single dose of live attenuated SA14-14-2 Japanese encephalitis vaccine in adult subjects.
2. To evaluate safety from the time of administration of a single dose of live attenuated SA14-14-2 Japanese encephalitis vaccine in adult subjects till one year.

NIMS is Involved in the Design, Monitoring and Data Management Activities

Data Management

- Development of Data Management Plan *(completed)*
- Develop database design in Visual Basic MS Access *(completed)*
- Consistency checks and Validation

Processing of Data

- CRF Tracking, Data Entry, Query Generation, Quality
- Generation, Quality Control, Final Database Lock

Statistical Analysis

- Develop Statistical Analysis Plan
- SPSS Programming
- Data listing and production of summary tables for demographic, efficacy and safety data

Sponsor – Chengdu Institute of Bilogical Products (CDIBP) Chengdu 610063, Sichuan, PR, CHINA.

Funding Agency

- Ministry of Health& Family Welfare, Government of India;

Monitored by Indian Council of Medical Research,

Monitoring Committee

Chaired by Dr. U.C Chaturvedi, Emeritus Scientist,

Industrial Toxicology Research Center, Lucknow, INDIA

Data Management/Statistical Analysis –

National Institute for Medical Statistics, New Delhi, INDIA