

1. ICMR School of Public Health

VISION:

Achievement of the best possible health for the people of India through services for health care, disease prevention and health promotion, which benefit from excellence in training and research.

Mission:

To collaborate with stake holders to build capacity for a well-trained health systems work force for providing services that meet the need of communities for better health.

Goal:

To identify health service needs for training, and develop curricula and capacity to meet those needs. Build an institution that works in close liaison with partners by identifying their strengths and needs in a supportive and collaborative manner. Rigor in adhering to international academic standards must be complemented by responding to regional and national priorities.

Scope and Concept of Public Health:

Public Health is an ever expanding discipline. The concept and scope of Public Health should change and evolve over time according to socioeconomic developments, patterns of health and disease, advances in technology, and opportunities for developing the capacity of health systems. Although Public Health in India has distinctive needs, but it must also be recognized that diseases do not adhere to national boundaries. Effective public health services must have resilience and a broad scope. Even within India, health status in different regions varies tremendously. Both government services and the private sector must be prepared to respond to inequities.

There is an increasing realization that public health contributes to overall national development and public health professionals play an important role in achieving that goal. Recognizing the impact of health on poverty alleviation and to fulfill its social commitment, the Govt. of India increased the allocation of funds for public health nearly three-fold in the 11th five year plan. Public health is both a cause and effect of growth and development of the nation.

Need for strengthening public health training

In spite of significant development and impressive growth in health care services, enormous challenges remain. There is a wide gap between needs and the capacity of the public health work force.

Appropriate training to develop a cadre of public health professionals is one of the most important ways of meeting the challenges confronting public health in India.

According to Voluntary Health Association of India, one public health school per 20 million of population is required. In India, there are very few schools of public health, Several government and professional committees have stressed the priority of establishing new schools of public health in the country, and improving the quality of training offered through existing medical colleges and public health institutions with more emphasis on health management, health economics, epidemiology, behavioural sciences, environmental science and primary health care.

Training Courses and Training Process:

The Public Health Training mandate has a broad scope, from policy makers to the community health workers. Training needs will obviously be different for each level. There is a need for several short certificate courses as well as two-year degree courses to meet the basic needs of the health professionals. Apart from these, courses are needed to meet specialized demands in specific situations. Opportunities should also be available for specialization in doctoral and post-doctoral research studies relevant for public health.

The process of identifying the training needs and developing various training initiatives should be guided by a careful situational analysis that is attentive to socio-cultural, economic and ecological contexts. The new public health institutes should therefore begin the process by identifying the key stake holders, conducting meaningful discussions with them and documenting the conclusions regarding priority problems, clearly stating objectives and then developing appropriate training proposals. Required inputs, planned activities and the desired outputs and outcomes can be planned

according to a well-developed strategy. Appropriate quantitative, qualitative and behavioural indicators will be needed to assess successful implementation of the activities.

Capacity building for public health requires attention to several domains of activities, including professional training at the master's level, MPH and MAE, which will be the primary focus of the institute. The quality and depth of such programmes will be enhanced by faculty participation in collaborative networks and forums. The expertise developed at the institution should be available for national and international training activities. Planning for health is a matter that needs attention to public and private sectors, which are both major components of the health system in India.

To meet specific needs of the health personnel, several short courses need to be developed. At the National Institute of Epidemiology, we have been engaged in an ongoing process of evaluating training activities and developing new programmes.

- Epidemic preparedness, outbreak response and surveillance
- Integrated Disease Surveillance Programme for Communicable and non-communicable diseases
- Biostatistics- Basic course
- Clinical Trial- Basic course
- Ethics in biomedical research and public health
- Research methods.
- Laboratory support in Epidemiological investigations.

We have developed curricula for MAE and MPH courses by conducting workshops involving national and international experts. We have developed modules that are flexible for meeting training needs of various groups of professionals. In view of the intersectoral nature of public health, training programmes need to cover needs of other overlapping disciplines as well.

Public Health Laboratory and Field Practice Area:

Two essential facilities every Public Health Institute must have are a public health laboratory and a field practice area. These facilities should be planned from the outset. Different models for these

essential facilities are possible, however, based on the available resources and working links with the local Governments.

Accreditation:

Accreditation is a very important consideration. Students and officers investing their time and money in training require a tangible benefit in terms of opportunities for promotions and bettering their career prospects. At NIE our degrees (MAE and MPH) come from Sree Chitra Tirunal Institute of Medical Sciences and Technology, (SCTIMST), Thiruvananthapuram. SCTIMST is an institute of national importance, and these degrees are recognized by the MCI and thus a distinct benefit to the students.

Pathways for Partnerships with National and International Stakeholders

Partnership will be the cornerstone for quality public health training. We in India are looking for the experience and expertise from the international schools of excellence. The international partners are looking for exposure and field experience. There are several modes through which we can achieve this partnership, both for the national and international partners:

1. Memorandum of understanding
2. Collaboration in research and training
3. Participation in professional forums
4. Joint applications for commissioned research.

At NIE we have already established such partnerships with several experts, and we are in process of developing more. Our programmes include all three institutes of national importance, Armed Forces Medical College, All India institute of Hygiene and Public Health, National Institute of Communicable Diseases and various ICMR institutes and centres. On the international arena we collaborate with WHO, CDC, Boston University, Swiss Tropical Institute, Asia Pacific Public Health Training Network, TEPHINET and others. Such partnerships in combination with faculty and curriculum development will ensure excellence for public health training.

1.1. Master of Applied Epidemiology–Field Epidemiology Training Programme (MAE-FETP)

National Institute of Epidemiology (NIE) has been conducting two-year Field Epidemiology Training Programme (FETP) leading to Master of Applied Epidemiology (MAE) degree awarded by the Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram since 2001. The MAE degree is recognized by the Medical Council of India (MCI) and included in the first schedule of the MCI Act. The Scholars/Graduates of MAE-FETP course for 2001 to 2007 batches were from 19 different Indian states, namely, Andaman & Nicobar Islands, Andhra Pradesh, Arunachal Pradesh, Assam, Bihar, Gujarat, Himachal Pradesh, Kerala, Manipur, Maharashtra, Madhya Pradesh, Mizoram, Orissa, Puducherry, Rajasthan, Tamil Nadu, West Bengal, Uttaranchal and Uttar Pradesh. This programme was funded by WHO and technically supported by CDC during the 2001-2003. The programme is now fully funded by ICMR as a regular ICMR activity.

Course organization

The MAE - FETP course is a 24-month competency-based programme. This course consists of two parts. One part extends for 6-months of ‘on campus’ training during which the scholar receives theoretical inputs through residential contact sessions at the NIE.

The other part extends over 18-months, at 3 six-monthly intervals ‘learning by doing’ in a live situation involving planning and execution of epidemiologic projects of immediate relevance to public health practice at field placement sites usually within their district health system.

Curriculum development

We have a curriculum developed based on adult-learning principles. The curriculum includes innovative methods of training including field exercises, Indian case studies, seminars, modular teaching, and technical support during field posting in the form of mini-contact sessions.

MAE-FETP achievements 2001-2007

- 83 scholars from 19 Indian States recruited during 2001-2007
- 28 of 39 scholars were graduated as of March 2007
- 25 of the 28 graduates work as public health professionals at district/state/national level whereas three work in medical research. Of the 25 graduates working in public health, 5 graduates work in IDSP and one graduate is working as Surveillance Medical Officer in WHO-Govt of India National Polio Surveillance project. Two graduates work as the state epidemiologists in NACO.
- MAE curriculum is now made available at the WHO India website for free access by Indian and foreign trainees and faculty members of field epidemiology programmes.
- MAE is recognized by the Government of West Bengal for public health career promotion.
- Several outbreaks (including Chikungunya, Avian flu) investigated across the country in collaboration with state public health departments.
- NIE along with RMRC-Dibrugarh has initiated an ICMR project to strengthen epidemiology services in the North-Eastern states. This includes both short-term and long-term training of health professionals from this region in epidemiology and public health.
- Following table shows the growth of MAE-FETP in terms of number of applicants, scholars admitted and graduates by cohort, 2001-2007

Academic cohort	# applicants	# admitted	# graduates
2001-02	17	9	2
2002-03	16	6	6
2003-04	15	9	7
2004-05	11	6	6
2005-06	21	9	7
2006-07	28	17	Yet to come
2007-08	52	26	Yet to come
Total	160	82	28

1.2. Dissertation Projects of FETP scholars during April 2006 to March 2007

1. Epidemiological study of road-traffic injuries and deaths in the district of Haora, West Bengal, India – 2006 – A hospital based study.
2. Factors associated with persistence of diphtheria at Hyderabad.
3. A cross sectional study for the prevalence of blindness due to cataract and barrier for cataract surgery in fifty years and older in South 24 Parganas, West Bengal, India.
4. Profile of reported suicidal death in the last 10 years in a sub-division of Coochbehar, West Bengal.
5. Protocol for the study of risk factors for scrub typhus and typhoid in Kurseong in the Darjeeling district of West Bengal.
6. Re-emergence of epidemic Chikungunya virus in Maharashtra - Descriptive Epidemiology
7. Prevalence of risk factors for Cardio Vascular Disease in village Tusra of Bolangir district, Orissa.

Abstracts of these studies are as under:

1. Hospital based active surveillance of road traffic injuries and deaths in the Howrah district, West Bengal, India 2006.

Background: In the Howrah district of West Bengal, no injury surveillance existed for road traffic injuries (RTI) in health care institutions. We conducted a hospital-based study to (1) describe the burden of RTIs, (2) understand factors associated with RTIs and deaths and (3) propose preventive measures.

Methods: We conducted active surveillance for RTIs during July 2006-October 2006 in three large hospitals which catered for 80-85% of RTIs in Howrah. We collected information on socio-demographic characteristics, psychosocial and behavioral factors, vehicles factors and environment factors by interviewing admitted RTI patients using structured questionnaires. We collected information about RTI deaths coming to the hospital mortuary from the relatives of the victims. We calculated the proportion of emergency hospital admissions due to RTI and case fatality rate of RTI. We calculated the relative risk of fatality associated with selected factors.

Results: 443 RTIs accounted for 3% of the 16,460 emergency admissions and 58% of the 764 injury admissions. 61 RTI deaths (case fatality rate 14%) accounted for about 7% of emergency deaths and 38% of all injury deaths. 371 patients (84%) were males, 183 (41%) were 15 – 29 years of age. Of the 429 victims interviewed, 134 (31%) were pedestrians, 101 (34.2%) were motorcyclists and fatalities were higher among students (17%). Fatality was significantly higher among motorcyclists who did not wear any helmets (22% versus 0%, $p=0.000235$) and among those using mobile phone while driving (Relative risk = 2.8, 95% confidence interval =1.1-5.8).

Conclusion: In Howrah district, majority of RTIs were pedestrians and motorcyclists. The Government needs to generate road safety awareness among the mass people and awareness needs to be started at school level. The traffic police department needs to ban mobile phone during driving and enforce helmet rule for the motorcyclists in the district.

2. Factors associated with persistence of diphtheria at Hyderabad, Andhra Pradesh, India

Andhra Pradesh, India accounted half the global diphtheria cases in 2005 and Hyderabad accounted 16% of state cases. We conducted a study in Hyderabad to describe diphtheria situation, estimate coverage and efficacy of vaccine. We described cases hospitalized during 2003-2006 by time, place and person. We prospectively compared laboratory-confirmed cases aged <10 years with matched controls to estimate vaccine efficacy. We surveyed children aged 12-23 months, 18-36 months and 54-72 months to estimate coverage for primary vaccination, fourth and fifth diphtheria doses respectively. Annual attack rate was 17/100,000. Attack rates were higher in children aged 10-14 years, women and Muslims. Coverage for primary vaccination, fourth and fifth doses was 90% (95% CI: 86.3-93.2), 60% (95%CI: 53.7-65.6) and 33% (95% CI: 27.3-40.1) respectively. Coverage of diphtheria boosters was significantly lower in Muslims. Four and five vaccine doses were 65% (95% CI= 8-87) and 91% (95% CI=68-98) efficacious. We recommended increasing booster dose coverage.

3. Low coverage of cataract surgical services in the “South 24 Parganas” district, West Bengal, India

Background: The national blindness control programme of India set cataract surgery targets for each district. In the “South 24 Parganas” district of West Bengal State, the target was not based on prevalence and coverage of cataract surgeries was low since 2001. We surveyed individuals aged fifty years or more to estimate the prevalence of blindness due to cataract and identify the factors associated with surgery in the district.

Methods:

We followed the rapid assessment on cataract surgical services developed in collaboration with WHO. We selected a cluster sample of people ≥ 50 years of age. We interviewed patients and their relatives to understand reasons for not availing cataract surgery. We compared individuals with cataract blindness (cases) and those who had cataract surgery (control) with respect to the age, religion, caste, family income and literacy. We calculated cataract surgical coverage in terms of eyes and persons.

Results:

The prevalence of cataract blindness and persons operated in the district was 5.5% (95% CI= 3.9-6.0) and 3.1% (95% CI=2.3-4), respectively. The target of cataract operation in South 24 Parganas was fixed based on the prevalence rate of 1.6%. Surgical coverage in terms of eyes and persons in the district was 37% and 59%, respectively. Cataract blindness was higher among person aged 70 or more (prevalence ratio (PR) =2.6, 95% CI=1.8-3.6) and Muslims (PR=2.4, 95% CI=1.4-4.1). Individuals of low-income group and illiterates were less likely to have had surgery (PR=2.4, 95% CI= 1.4-4.1 and 6.8, 95% CI= 2.8-16.5, respectively). Non-availability of services in nearby villages, affordability and lack of family support were the key reported barriers to cataract surgery.

Conclusions:

Coverage of cataract surgery in the district needs to be increased by setting up base camps in rural areas and increasing the target of cataract surgery. Barriers to surgery could be overcome by making special efforts to bring cataract patients of low income groups, Muslim and illiterate people to the base camps and providing incentives to the self help group in the village for providing post-operative care.

4. High frequency of suicide among socio-economically disadvantaged cultivators, Coochbehar, West Bengal, India, 1996-2005

Background: In 2005, in the Mathabanga sub-division of Coochbehar district, reported suicide rates (31 per 100,000) exceeded the West Bengal State (19/100,000) and National (11/100,000) averages. We described suicide mortality for ten years (1996-2005) to generate hypotheses about factors that may lead to suicide.

Methods: We defined suicide as a self-inflicted unnatural death documented as suicide in the police investigation report. We retrospectively reviewed police inquest report of completed suicides for 1996-2005. We conducted a psychological autopsy of 2005 suicides through interviews of close relatives to validate the quality of the police data.

Results: Of 2,206 unnatural deaths in 1996-2005, 1584 (72%) were suicides. The average annual suicide rate was 28/100,000 (range 22 to 32), with higher rates during the rainy season (49/100,000) and among the socially disadvantaged cultivators of lower caste (55/100,000). Young female adults (58/100,000) and elderly males (76/100,000) had higher rates. Hanging with easily available jute ropes was the most common method used (n=855, 54%), followed by pesticide poisoning (n=586, 37%). Financial crisis (n=539, 34%), marital disharmony (n=238, 15%), physical illness (n=174, 11%) and psychological illness (n=175, 11%) were the most commonly quoted reasons for suicide. For 2005, there was a good agreement between police inquest reports and the psychological autopsy of close relatives (Kappa 0.80; $p < 0.05$) in the identification of the reason of the suicide.

Conclusions: Financial crisis among socially disadvantaged cultivators was the major reported reason for suicide in Coochbehar. We recommended a multi-sector committee with members of the social welfare, police, agriculture and finance departments to implement preventive measures and monitor their impact.

5. Clean environment, personal protection and hygiene could contribute to scrub typhus prevention in Darjeeling, West Bengal, India, 2005

Background: Scrub typhus caused by *Orientia tsutsugamushi* and transmitted by the bite of larval trombiculid mites is endemic to Darjeeling. We conducted a case-control study to identify risk factors and propose prevention measures.

Methods: We recruited scrub typhus cases defined as acute onset of fever with eschar and specific IgM antibody in the hospital. We recruited community controls matched for age and neighborhood. We collected information regarding daily activities, exposure to forests, bushes, domestic animals and rodents. We calculated matched (neighborhood controls) odds ratios (MOR) as well as the fraction attributable in the population (AFP) for the risk factors and the failure to use protection measures.

Results: We recruited 62 scrub typhus cases and 62 neighbourhood controls. Cases were more likely to live close to bushes (MOR 10; 95% Confidence Interval [CI] 2.3-63, AFP 81%) and woodpiles (MOR 3.5; 95% CI 1.5– 9.5, AFP 45%), to work in farms (MOR 10, 95% CI 2.7-63, AFP 64%), to observe rodents at home (MOR 3.6; 95% CI 1.4-11, AFP 64%) and at work (MOR 9; 95% CI 2.4-57, AFP 73%), and to rear domestic animals (MOR 2.4; 95% CI 1.1–5.7, AFP 41%). Cases were less likely to wash after work (MOR 0.4; 95% CI 0.1-0.9, APF 43%) and change clothes to sleep (MOR 0.2; 95% CI 0.1-0.5, APF 35%)

Conclusion:

A cleaner, rodent-controlled environment may prevent exposures to scrub typhus in Darjeeling. Personal protection measures and better hygiene could further reduce the individual risks. Environmental and behavioural interventions are being designed with district authorities and will be evaluated using surveillance data.

6. Risk levels of vector indices for Dengue are poor surrogates for predicting chikungunya outbreaks

Background: Large number of chikungunya outbreaks has been reported from several states in India since December 2005. In Maharashtra State outbreaks were reported from 161 villages/towns of 27

districts. Dengue and chikungunya infections are transmitted by *Aedes aegypti*, which breeds mainly in man made containers. No risk levels of vector indices for chikungunya infections are available. Therefore risk levels for dengue were used as surrogate measures for chikungunya. We assessed whether risk levels of vector indices used for dengue infections are appropriate for chikungunya infections.

Methods: All 161 town/villages reporting outbreaks were included. Vector survey data for *Aedes aegypti* i.e. House Index (HI) container Index (CI) and Breteau Index (BI) from these 161 villages / towns were calculated and their corresponding attack rates were compared with the risk levels suggested for dengue. Receiver Operating Curves (ROC) for HI and BI were constructed to determine their performance as predictors of chikungunya transmission using attack rate of 5 per 1000 population as outcome variables.

Results: Using risk levels of vector indices for dengue we could identify only 7.5% (12 outbreaks in 10 districts) of chikungunya outbreaks with BI of >50 and 46% (74 outbreaks in 21 districts) of chikungunya outbreaks with HI >10. Using ROC, we observed that a BI of 7.0 had sensitivity of 73% specificity of 65% and a HI of 4.0 had sensitivity of 78% and specificity of 62% for identifying high-risk areas for chikungunya outbreaks.

Conclusion: We confirmed that risk levels of vector indices for dengue are poor surrogates for predicting chikungunya infections. Lower risk levels i.e. BI of 7.0 and HI of 4.0 are better thresholds for identifying high risk areas for chikungunya outbreaks with attack rates of 5 per 1000 population. Since morbidity associated with chikungunya infections is high, local health authorities were advised to adopt lower risk levels of vector indices for vector surveillance for Chikungunya after assessing their operational feasibility.

7. Prevalence of risk factors for cardiovascular disease in a rural population, Orissa, India using WHO STEPs surveillance

Background: Cardiovascular diseases account for 29% of all deaths worldwide. The burden is rising in India, contributing to 17 % of global CVD mortality. CVDs are preventable at underlying risk

factor level. In India, Integrated Disease Surveillance Project is launched since 2004 and includes non-communicable disease risk factor surveillance as a component. We conducted a pilot study on prevalence of CVD risk factors in a rural population.

Methods: We conducted a cross-sectional survey in village Tusra (Population: 4234) and included those aged 25-64 years (n=2398). We adopted WHO STEPS approach; collected data on behavioural risk factors: smoking, use of smokeless tobacco, alcoholism, dietary patterns, physical inactivity, history of diabetes and history of hypertension by pre-tested structured questionnaires (Step 1) and measured anthropometrics, blood pressure (Step 2). We calculated prevalence of risk factors and prevalence ratio of hypertension, diabetes in relation to various risk factors.

Result: Prevalence of CVD risk factors were as follows: 38% men and 1% women were smokers, 40% men and 34% women were smokeless tobacco users, and 28% men and 14% women reported alcohol use. Insufficient fruit and vegetable consumption identified with 80% men and 74% women; physical inactivity with 54% men and 62% women; 6% men and 25% women were overweight, central obesity observed among 30% men and 69% women, and 25% men and 24% women reported hypertension.

Conclusion: Our study demonstrated high level of CVD risk factor among a rural population. The prevalence of hypertension was higher in the relatively younger age group e.g. 35-44 (27%). We recommended (1) promotion of healthy dietary patterns and physical activities by organizing awareness campaigns in the village and (2) training of health care workers on CVD risk factors, organization of intermittent screening camps for early detection of risk factors and availability of antihypertensive medicines at the local health institution.

1.3. Investigation of leptospirosis outbreak at Gujarat

At the request of the Govt. of Gujarat, Emergency Medical Relief Department of Directorate General of Health Services and ICMR nominated one Research Officer as a member of the central team to visit the leptospirosis affected districts of Southern Gujarat 10-16 August 2006. The team members were:

- Dr. PK Patanaik, Joint Director, NICD, Delhi
- Dr. Shyamal Biswas, Joint Director, NICD/PSU, Bangalore (*Laboratory scientist*)
- Dr. Anil Gurtoo, Professor of Medicine, LHMC, New Delhi (*Clinician*)
- Dr. P Manickam, Research officer, NIE (ICMR), Chennai (*Epidemiology*)

We conducted following work

- a. Investigated the suspected outbreak of leptospirosis, South Gujarat
- b. Rapidly assessed the flood-affected areas of Surat city

Investigation of suspected outbreak of leptospirosis, South Gujarat, 2006

South Gujarat (Surat, Navsari, Valsad and Ahwa-Dang) reported 88 leptospirosis cases. During this year cases were reported from villages which did not report cases in the past. However, case fatality over the period has increased (21% in 2005 Vs 31% in 2006). Attack rate was highest among age group 45 and above. Attack rate was three times higher among males as compared to females. Surveillance and reporting of leptospirosis was timely and the district health team followed the national guidelines for the same.

1.4. Outbreak investigations by FETP Scholars during April 2006 to March 2007

1. Card food poisoning in 24 Parganas-North District, West Bengal
2. Measles outbreak - 1 in Jalpaiguri District, West Bengal
3. Measles outbreak - 2 in Jalpaiguri District, West Bengal
4. Cinni – food poisoning outbreak in Jalpaiguri District, West Bengal
5. Anthrax - 1 outbreak in Murishabad, West Bengal
6. Anthrax - 2 outbreak in Murishabad, West Bengal
7. Measles outbreak in Murishabad, West Bengal
8. Mass hysteria outbreak in Hoogly district, West Bengal
9. Cholera - 1 outbreak in Vellore, Tamilnadu
10. Cholera - 2 outbreak in Vellore, Tamilnadu
11. Measles outbreak in Vellore, Tamilnadu
12. Tick typhus outbreak in Kangra district in Himachal Pradesh

13. Typhoid outbreak in Kangra district in Himachal Pradesh
14. Acute Gastroenteritis outbreak in Solan district, Himachal Pradesh
15. Unknown disease in Chamba district, Himachal Pradesh
16. Acute Gastroenteritis outbreak in Hoogly district, West Bengal
17. Cholera outbreak in Kolkata, West Bengal
18. Acute Gastroenteritis outbreak in Nadia district, West Bengal
19. Acute Gastroenteritis outbreak in Howrah district, West Bengal
20. Measles outbreak in Cuttack district in Orissa
21. Pertusis outbreak in Papum Pare District in Arunachal Pradesh
22. Typhoid outbreak in Jodhpur district, Rajasthan
23. Anthrax outbreak in Kalahandi district, Orissa
24. Hepatitis outbreak in Shimla, Himachal Pradesh

1.5. Strengthening field epidemiology services in North-Eastern states of India

This is an ICMR grant-in-aid project which proposes to conduct various training activities to strengthen field epidemiology services in the North-East region. The project envisages training for different levels of health personnel. We conducted a Surveillance, Epidemic Preparedness and Response workshop at Itanagar, Arunachal Pradesh during April 2006.

Meeting with CDC-HHS Delegation to Field Epidemiology Training Programme, 9th September, 2006, NIE, Chennai



Viva voce examination for the MAE-FETP, June, 2006



MAE Scholars and faculty team at Brazil – TEPHINET Conference visit



**Cholera outbreak investigation at South 24 Paragana district in West Bengal
by MAE-FETP VI Cohort Scholars**



2. Integrated Disease Surveillance Programme (IDSP)

2.1. Private Sector Participation in Integrated Disease Surveillance Programme (IDSP) – Current status - an assessment

Introduction

The Government of India (GOI) has launched an Integrated Disease Surveillance Programme (IDSP) in the country in November 2004. Funded by the World Bank, the programme has been initiated first in 9 states during Phase I and will later be extended to the entire country in a phased manner. An important component of the IDSP for surveillance mechanisms is enlisting support and participation of the private sector, where more than 70% of the disease burden is encountered and treated. Involvement of the private sector is to be achieved by integrating private care delivery systems and medical colleges in rural and urban areas in surveillance activities. The objective of integrating the private health sector is to improve the sensitivity and overall quality of surveillance data.

Despite experiences of Public Private Partnerships (PPPs) in selected ongoing national disease control programmes, this is perhaps the first time when such a large scale venture is being planned

on a nationwide basis. Hence there is a need to study the processes and performance of the PPPs at an early date to assure efficiency and sustainability. *In this context a study to make an interim assessment of the status of private sector participation in IDSP in selected Phase I states is proposed.*

Objectives

The objectives of this study are to :

- (1) Describe the experiences of private sector participation in Phase I IDSP states with respect to ongoing national disease control programmes (e.g. Polio Surveillance, RNTCP – DOTS, etc.) and its implications for private sector participation for IDSP
- (2) Make an interim assessment of the current status of private sector participation for IDSP in terms of: (a) the criteria and processes adopted to identify and select PPs for IDSP, (b) the performance of the PPs using indicators developed by NIE and suggested by Thomas, K.T. et al (2003).
- (3) Identify constraints / barriers to smooth participation of private sector based on (1) and (2).
- (4) Suggest strategies to overcome constraints / barriers identified in (3) and strengthen public – private partnership for IDSP .

Methods

Study Design : Survey methods will be used for this study

Sample Size : Three states and two districts within each state will be selected for study..

Data Collection : Interview and Observational techniques will be used to collect data

Duration of Project

The project is expected to be completed with 1 ½ - 2 year from the date of commencement

Project achievement

The study has been approved by NIE SAC in August 2005. There is general consensus among collaborators regarding the study protocol and data collection instructions. Verbal approval has been obtained from some states for conduct of the study. Data collections instruments have been pilot tested in Tamilnadu. The methods and instruments have been pilot tested in 2 states viz. Tamilnadu and Maharashtra.. Pilot tests suggest the need to (a) modify data collection instruments (b) restrict data collection to 2 selected districts for Objective 1 as will be done for Objective 2. The selected 3

state viz Tamilnadu, Maharashtra and Himachal Pradesh will have fully implemented IDSP by July 2007. Thereafter it is proposed to commence data collection.

2.2. IDSP –Training for State and District level Surveillance teams

NIE has been recognized as a National level (Level 1) training institute by the GOI-WB-WHO-IDSP Project for imparting training to state and district level surveillance teams in different states.

Objectives

The objective of these Trainer of Trainees (ToT) programmes is to strengthen capacity of state and district level surveillance teams from various states to: (a) enable them train Block and PHC level public health professionals for IDSP and (b) assure successful implementation of IDSP in their respective states

Achievements

Training of state and district level surveillance teams in Tamilnadu in July – August 2005. Six batches totaling 90 state and district level officers from Tamilnadu were trained at NIE. Training of five batches – 1 in Pondicherry in April 2006 and 4 in Orissa during May 2006.

3. Clinical Trials Monitoring

3.1. Multicentric Study of Interferon-Glycyrrhizin Combination Therapy and Interferon-Ribavirin Combination Therapy in the Management of Chronic Hepatitis C

Introduction

Hepatitis C Virus (HCV) is an important cause for chronic liver disease in India. Studies indicate that one-fourth of chronic liver disease is HCV-related. There are about 10 million HCV carriers in our country and at least half of them are likely to develop chronic liver disease in the next 10 to 15 years. Recently in an ICMR Symposium on Interferon Therapy in chronic hepatitis, it was evident

that 50-60% of Indian chronic hepatitis C patients, treated with Interferon showed a sustained viral clearance. Indigenous herbs and plants have been in use for many centuries in India for the treatment of liver disorders. The plant product Glycyrrhizin (*Glycyrrhiza glabra*) has been found to have antiviral properties through endogenous interferon induction as well as hepatocytoprotective effect. Glycyrrhizin has also been shown to inhibit ribonucleic acid (RNA) viruses through a hitherto unknown mechanism. Glycyrrhizin is a safe drug with minimal side-effects. The modern medication available for the treatment of chronic hepatitis C (CHC) has known side-effects. Therefore, there is a need to explore the scope of plant products with minimal side-effect in the treatment of CHC. The combination of Interferon with Glycyrrhizin may have synergistic effect in achieving better virological clearance and histological improvement among patients with CHC. Hence, the Council has undertaken a multicentric trial of Interferon – Glycyrrhizin combination therapy and Interferon-Ribavirin combination therapy in the management of CHC. The Institute is coordinating the conduct of this trial.

Primary Objective

To assess whether the combination therapies of Interferon-Glycyrrhizin and Interferon-Ribavirin against Chronic Hepatitis C are effective to the tune of 70% in Indian patients.

Secondary Objectives

1. To evaluate the side-effects / toxicity of the trial drugs;
2. To evaluate the cost effectiveness of the two combination therapies;
3. Study the role of certain identified factors, viz., genotype, viral load, and some host factors in deciding the outcome of therapy.

Trial design

This is a multicentric double-blind randomized controlled equivalence trial in nine centers spread all over the country. Participating centers are PGI, Chandigarh; AIIMS, New Delhi; MAMC, New Delhi; GBPH, New Delhi; MCLDD, Noida; SGPGI, Lucknow; IPGMER, Kolkata; BHMRC, Mumbai and DCMSH, Hyderabad.

It is proposed to admit 270 patients (135 patients to Interferon-Glycyrrhizin regimen and 135 patients to Interferon-Ribavirin regimen) to the trial from all centers put together. The total duration of the trial is 2½ years. The intake to the trial is expected to be completed in 1½ years. The follow-up of all patients will be completed in the next 1 year.

The intake to the trial was stopped by 31st May 2004 and the treatment period was completed by November 2004. Further the follow up period was completed by May 2005. Completed study proformae are being received from the participating centers once a month. Forms were scrutinized and the inaccuracies and inconsistencies were rectified through correspondence. Trial drugs are being sent to the participating centers as and when the request comes from the Principal Investigator of the concerned centre. As on 31st March 2007, we have received a total of 131 forms of admission to the trial from various centers as follows: PGI – 20, AIIMS – 17, MAMC – 17, GBPH – 11, MCLDD – 21, SGPGI – 12, IPGMER – 13, BHMRC – 4 and DCMSH – 16.

Progress reports are being sent to the ICMR Headquarters and to all Principal Investigators once in fortnight. Meetings of the experts and principal investigators had been organized periodically at ICMR Headquarters to review the progress of the trial. In one of the meetings, it was decided to reduce the treatment duration from 48 weeks to 24 weeks. Data was analyzed with decoding of the treatment regimen. Results are encouraging in terms of virological and biochemical parameters. Manuscript is being prepared for publication in a reputed journal.

In view of the encouraging results from the above study, ICMR decided to initiate two more trials viz. (a) Multicentric Open Labeled Clinical Trial Using Combination of Interferon and Ribavirin for 3 months among patients with Chronic Hepatitis C (b) Multicentric Open Randomized Controlled Clinical Trial of Combination Therapy with Ribavirin and Oral Glycyrrhizin in Decompensated HCV – Induced Cirrhosis. Details are given below.

(a) Multicentric Open Labeled Clinical Trial Using Combination of Interferon and Ribavirin for 3 months among patients with Chronic Hepatitis C

The objective of this study is to assess whether the combination therapy of Interferon and Ribavirin against Chronic Hepatitis C is effective to the tune of 70% in Indian patients with 3 months treatment duration. This study was initiated at 8 out of 9 above centers (except BHMRC, Mumbai) from June 2004 onwards.

As on 31st March 2007, 113 cases were admitted to the trial from various centers as follows: PGI – 11, AIIMS – 25, MAMC – 17, GBPH – 1, MCLDD – 31, SGPGI – 1, IPGMER – 6 and DCMSH – 21. The intake to the trial was stopped by 31st August 2006 and the treatment period was completed by November 2006. The follow up will continue till May 2007. Results available so far indicate encouraging response in terms of virological and biochemical parameters.

(b) Multicentric Open Randomized Controlled Clinical Trial of Combination Therapy with Ribavirin and Oral Glycyrrhizin in Decompensated HCV – Induced Cirrhosis.

The objective of this trial is to assess whether a combination of oral Glycyrrhizin as an immunomodulator and hepato-protective drug and Ribavirin as an antiviral drug will improve the clinical, bio-chemical and virological outcome of HCV-induced cirrhosis of liver. Expected efficacy for this combination therapy is to the tune of 50% in Indian patients. This study is also being initiated at the above mentioned 8 centers from August 2004 onwards.

As on 31st March 2007, 82 cases were admitted to the trial from various centers as follows: PGI – 10, AIIMS – 2, MAMC – 10, GBPH – 6, MCLDD – 23, SGPGI – 12, IPGMER – 8, and DCMSH – 11. The intake to the trial was stopped by 31st August 2006 and the treatment period was completed by November 2006. The follow up will continue till May 2007. Results available so far indicate encouraging.

4. Leprosy studies

4.1. WHO multicentric study on 'Uniform MDT regimen for all types of leprosy patients'

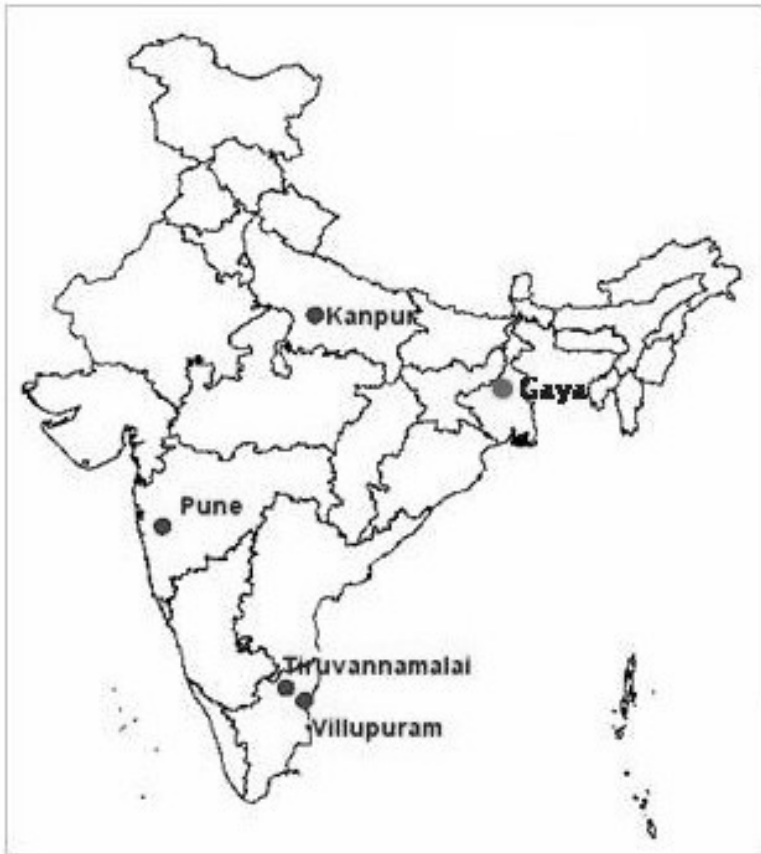
NIE is the international co-ordinating centre for the multi-centric trial to assess the efficacy and effectiveness of 6-month multi-bacillary MDT (=Uniform MDT) for all types of leprosy patients through general health services assuming a cumulative relapse rate not exceeding 5% over five years of follow-up. We intended to recruit 2500 patients each in multi-bacillary (MB) and pauci-bacillary (PB) groups from India (five centres) and China (two centres) (Figure 1). Standardized clinical criteria were used to assess skin lesions in field situation.

We could enroll 2912 patients from November 2003 to May 2007 (India: 2746; China: 166) [Table 1]. MB patients constituted 39% and 3% had grade 2 disability (Table 2). During follow-up, 27 patients developed new lesions (Table 3). Of these, 21 were on account of reactions. Six patients had clinically confirmed relapse. Clofazimine related skin pigmentation was short-lived and was acceptable to patients. We analysed data for clinical status of skin lesions (Figure 2). Eighty four patients were lost to follow-up as on May 2007. Of the 2912 patients, 2503 completed treatment. Of the 2503 patients, in 472 (19%) skin lesions were inactive. PB patients responded better than MB patients (27% Vs. 6%) [Table 4]. At the end of first (n=2013) and second year (n=807) of follow-up post-U-MDT, in 1004 (49%) and 373 (46%) patients, lesions were inactive respectively (59% and 57% in PB, 37% and 28% in MB).

The study results are promising with respect to clinical status of skin lesions. Five-year follow-up will be completed by 2013 and we expect final results by 2014.

Figure 1: Location of centres participating in U-MDT trial

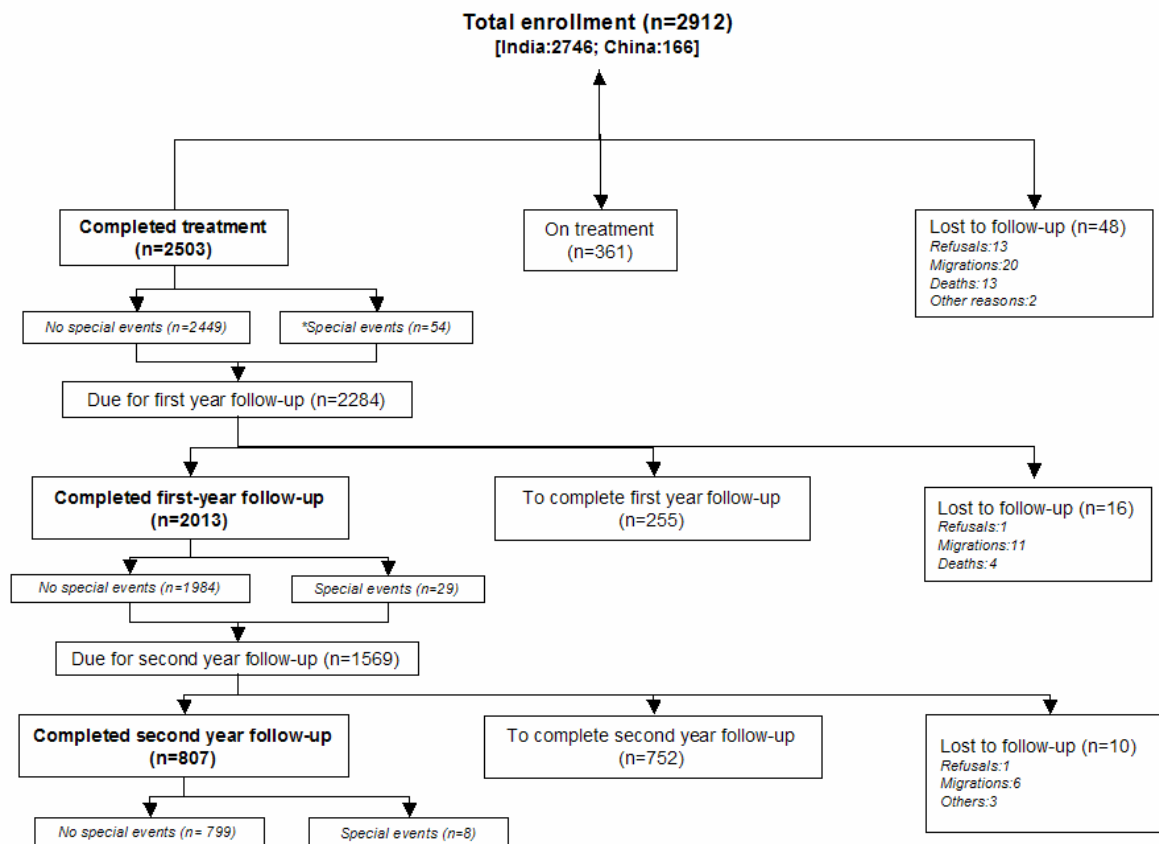
India



China



Figure 2: Uniform multi-drug therapy regimen for all types of leprosy patients, profile of the trial, May, 2007



*Special events include occurrence of new lesions, reactions, neuritis and adverse drug effects

Table 1: Enrolment status by type of leprosy patients, U-MDT trial, November 2003 to May 2007 *

Centres	Patients enrolled		
	PB	MB	Total
<i>India</i>			
▪ Tiruvannamalai	281	237	518
▪ Villupuram	277	228	505
▪ Pune	537	284	821
▪ Kanpur	194	128	322
▪ Gaya †	432	148	580
<i>China</i>			
▪ Guizhou	44	86	130
▪ Yunnan	12	24	36
Total	1777	1135	2912

* As of May 2007; † Trial started in July, 2005;

Table 2: Baseline characteristics (% in parentheses) of 2912 patients enrolled for U-MDT trial, May 2007

Characteristic		PB	MB	Total
		1777	1135	2912
Number of patients		(61)	(39)	(100)
Age group	≤ 14	319	103	422
		(76)	(24)	(14)
	15-64	1414	976	2390
	(59)	(41)	(82)	
	65+	44	56	100
		(44)	(56)	(3)
Male gender		968	747	1715
		(56)	(44)	(59)
Nerve lesions				
	0	1222	457	1679
		(73)	(27)	(58)
	1	345	206	551
		(63)	(37)	(19)
	2	125	207	332
		(38)	(62)	(11)
	≥ 3	85	265	350
		(24)	(76)	(12)
Disability (WHO grade2)		45	53	98
		(46)	(54)	(3)
Mild reactions		17	32	49
		(35)	(65)	(2)
Neuritis		26	45	71
		(37)	(63)	(2)

Table 3: Special events (n=218) reported by 174 patients by type of leprosy during U-MDT trial, May, 2007

Special events	PB	MB	Overall
New lesions on account of reactions	3	18	21
Clinically confirmed relapse	2	4	6
Reactions			
<i>Type 1</i>	3	35	38
<i>Type 2</i>	3	14	17
Neuritis	11	28	39
Adverse drug reaction	3	10	13
Discontinuation from the study			
<i>Refusals</i>	9	5	14

Table 4: Clinical status of skin lesions by type of leprosy at the completion of treatment and first and second year of post-U-MDT treatment, May, 2007

Clinical status	PB									MB								
	Improved		Lesion inactive		Static		Deteriorated		Total	Improved		Lesion inactive		Static		Deteriorated		Total
	#	(%)	#	(%)	#	(%)	#	(%)	#	(%)	#	(%)	#	(%)	#	(%)	#	
At the completion of treatment	1049	(70)	408	(27)	37	(3)	1	(0.1)	1495	89	(89)	64	(6)	44	(4)	3	(0.3)	1008
First year post-treatment	491	(41)	702	(59)	5	(0.4)	0	-	1198	7	(62)	302	(37)	7	(1)	1	(0.1)	815
Second year post-treatment	212	(42)	290	(57)	3	(1)	0	-	505	5	(71)	83	(28)	3	(1)	0	-	302

4.2. Activities of NIE as WHO collaborating centre for leprosy epidemiology and research

In consultation with Dr. V Pannikar Chief, WHO - Global Leprosy Programme, NIE, as the WHO collaborating centre for leprosy epidemiology and research has developed number of research activities 27-28, September 2006. The following is the list of activities discussed:

- Research agenda for patient-centered leprosy control
- Publication of papers on
 - Clinical trial for treatment of pauci-bacillary leprosy patients with single dose of ROM
 - WHO International multi-centric study on ‘Uniform MDT regimen for all types of leprosy patients’
- Initiating Uniform MDT trial in Sri Lanka and Bangladesh
- National leprosy control monitoring and evaluation tool
- Data on leprosy trends
- Assessment of magnitude of disability
- Assessment of leprosy burden
- Review of global case detection trends

4.3. Disability status in Pauci Bacillary leprosy patients after Release From Treatment (RFT)

In order to assess the disability status of Paucibacillary (PB) leprosy patients 5 or more years after release from multi drug therapy (RFT) this study was undertaken by NIE in the LVT area.

Area: Primary Health Centres:

Poonamalli, Somangalm, Nemam, Maduramangalam.

Work done

It is an ongoing study. So far 774 RFT patients were attempted for screening. 458 examined for disability and other symptoms of leprosy. Remaining were dead (86) and migrated (230). It is observed that crude incidence of disability is 2.8 % (12/433).

4.4. Leprosy surveillance:

Introduction:

India has achieved the Elimination of Leprosy in National level after integration of leprosy services into general health services. But in parallel it was observed that there is no decline in prevalence less than one per thousand. Hence our institute is conducting leprosy surveillance as a part of Demographic surveillance in field practice area.

Objective:

1. To explore the feasibility of merging the surveillance of leprosy into Integrated Disease Surveillance Programme (IDSP).
2. To assess trend of new case detection of leprosy under integrated system and identify the post elimination issues in leprosy with respect to quality of services.

Data Collection:

Area: Primary Health Centres:

Poonamalli, Nemam, Maduramangalam, Sunkuvarichatram.

Size of the population :2,00,000.

The information on identification particulars and demographic and socio economic characteristics of the head of the household such as religion, caste, occupation, type of the house,

source of water supply, sanitary facilities, education, movement, morbidity, the marital status of each member of the household, whether the person is a normal resident or visitor to the household. Particulars of vital events that occurred during the last one year from the date of enquiry, knowledge of health and medical facilities available in and around the village and morbidity conditions will be collected. The vital events such as births, deaths will be collected once in a month from Primary Health Centre and once in 15 days from the identified local heads from the village (It includes marital status, divorce at the time of enquiry with the local leaders). Local heads include the following: local dais, members from self help groups, anganawadi workers, local health worker, village administrative officer, responsible person in the village.

At the time of census, persons available and volunteering were examined for leprosy by field investigators and suspects and definite leprosy cases initially detected were referred to senior officials trained in leprosy for confirmation. Clinical charts were prepared for all suspects and definite cases of leprosy. All new cases of leprosy were referred to nearest Primary Health Centre (PHC) for treatment. Census was done on 41,848 and 33,078 were screened for leprosy and detected 165 definite leprosy cases .26 new cases were referred for treatment.

5. STDs/HIV/AIDS studies

5.1. STDs /AIDS related Risk behaviors in Female Sex Workers of Ellapuram Panchayat Union, Tamil Nadu

Introduction

NIE has undertaken this study in collaboration with SWCWS (Social Welfare Centre for the Weaker Section) - an NGO working for Female sex workers (FSWs)

Social Welfare Centre for Weaker Section (SWCWS): This NGO provides services on Counselling, condom promotion and STDs/AIDS related behaviour change education to FSWs and their clients. The NGO has an office at Ellapuram, which is at Periyapalayam, about 50 Kms. from Chennai. The NGO has identified 5 sites namely, Ellapuram, Vengal, Thamaraiakkam,

Latchivakkam and Uthukottai to work for FSWs under Ellapuram Panchayat Union (Thiruvallur district), covering a population of about 1,10,000. There are

Objectives

- a) To find out HIV seroprevalence of FSWs belonging to Ellapuram Panchayat union
- b) To find out the STD/AIDS related risk behaviours
- c) To know their attitude towards their profession and perception of STDs/AIDS risk

Methods:

This is a pilot study. Both qualitative and quantitative methods were used for data collection. Before starting the study with FSWs, ethnographic data on sex work at Periyapalayam was collected through key informant interviews (KIIs) using Interview guide. The findings of ethnographic study have been already reported in the last year's annual report.

Data Collection with FSWs was started in April 2006 and completed in June 2007, after enrolling 248 FSWs. The interview schedule for the FSWs contained questions on their demographic & socio-economic details, STDs and AIDS related risk behaviors, attitude towards their profession and their risk perceptions.

Results

Preliminary findings: Nearly one third (32%) of the FSWs were less than 30 years of age and 52% were 30 to less than 40 years. Most of the FSWs (92%) were from outside Periyapalayam area. With respect to type of their residence, 54% were from thatched houses. Eighty two percent and 72% of them reported of not having drinking water and toilet facilities in their residences, respectively. Forty percent were illiterates who have not gone for any formal schooling. More than half of them (56%) were married and 31% were separated.

Nearly half of them (48%) reported that their age at first sexual intercourse was less than 18 years and 75% reported of less than 20 years (Mean age 18years). Mean age of entry into the sex work profession was 27 years. Three fourths informed poverty/financial situation as the reason

for their entry into the profession. More than one third ((35%) informed that their location of sex work was brothel based. With respect to type of clients, 50% reported of truck/lorry/bus/car/auto drivers and 32% informed of getting daily wage earners as their clients. Mean number of casual clients and regular clients in the previous month was 6 and 5, respectively. Most of them (93%) informed that the type of payment was only by cash; 57% informed that the payment was decided as per the time and 31% informed, as per the number of acts.

In the last one month, 30% reported that they were asked for anal sex by their clients; in that 25% of the FSWs had accepted for anal sex. Overall only 16% reported of consistent condom usage. Alcohol consumption was reported by 27% of the FSWs and 91% of them reported of drinking before the sexual act. More than one third of them (36%) informed “for giving good company” and 32% “to avoid any inhibitions” as the reason for their drinking before the sexual act.

It was observed that there was a significant association between frequency of condom use and type of clients. That is, significantly higher proportion of drivers (52%) used consistent condom use whether they were casual clients ($p=0.045$) or regular clients (0.032).

There was a significant association ($p=0.036$) observed between literacy and condom usage by casual clients during last sexual encounter, showing more literate FSWs (78%) reported of condom usage with casual clients during last sexual encounter than the illiterate FSWs (65%). Similarly, there was a significant association between consistent condom usage among casual clients and FSWs having a history of STDs ($p=0.004$). This showed that history of STDs was reported less (26%) by the FSWs who informed of consistent condom usage with casual clients than the FSWs who did not report of consistent condom usage by their casual clients and history of STDs were more (44%) in them.

In all HIV seroprevalence in the FSWs was 3.6% (9 out of 248)

Further analysis is going on.

5.2. Recruitment and Retention of Couples Requiring STD Care at Govt. General Hospital, Chennai

Introduction

Understanding of diseases transmission and behavioural dynamics in STD patients and heterosexual couples in particular, is of utmost importance particularly when we are planning for developing any STDs/HIV prevention strategy.

National Institute of Epidemiology, ICMR, in collaboration with University of California, Los Angeles has undertaken a study at Institute of Venereology, Govt. General Hospital, Chennai with the following objectives.

Objectives:

1. To determine the feasibility of recruitment and retention of a cohort of couples requiring treatment for STDs in STD clinic
2. To understand the behavioural and attitudinal correlates of STDs in these couples

Methods:

All the married STD symptomatics would be assessed for this study. As per the eligibility criteria, patients who are willing to be our study subjects as couples were recruited. After getting the written informed consent from both the index case and the respective spouse, each person is being interviewed separately in private. Routine VDRL test is done and as per the symptoms other required laboratory investigations would be undertaken. They would be sent for HIV testing also. Once the data collection, investigation procedures and treatment were over for the couple, they would be asked to come for a follow-up after a period of 3 months, during which HIV testing and VDRL tests would be repeated. And also a brief interview would be conducted after obtaining written informed consent.

The data collection for this study was from May 2006 to October 2007. Out of 209 eligible couples, a total of 126 couples were recruited during this period. In all, there were 71 male and 55 female index cases. The reasons for inability to be recruited as study subjects were, time constraint, language problem, too sick to respond and not interested to participate due to stigma.

Data entry is over and analysis is just started

5.3. Development of STDs/AIDS Prevention Intervention package for STD patients

Sexually Transmitted disease clinics in India treat number of high-risk individuals and it is extremely important from a public health perspective. Intervention studies in such settings will have obvious relevance to public health planners for conducting STDs/AIDS prevention interventions. In order to develop suitable STDs/AIDS prevention intervention strategy for STD patients this study was planned.

Objectives

1. To explore the determinants of sexual behaviour of STD symptomatics and their sexual partners
2. To understand barriers and enhancers with respect to STD, treatment seeking behaviour and safe sex practice
3. With the information obtained from objectives 1 and 2, to develop prevention intervention package for STD symptomatics

Methods

Formative research is being conducted to understand the sexual behaviour and the decision making processes, barriers and enhancers in health and treatment seeking behaviour of STD patients. Required data is being collected through in-depth interviews and focus group discussions with patients and their care takers using interview guides. The interview guide has the areas for eliciting information of the respondents' socio-economic details, knowledge on STDs, their treatment seeking behaviour, knowledge on factors influencing STDs and on over all

prevention of STDs. The findings of these two methods will be used to design and develop an intervention package to reduce the sexual transmission of STDs/AIDS.

Results

A total of 60 key informant interviews were conducted. In this there were 31 males and 29 females. In-depth interviews were conducted among 44 STD patients and 16 care providers. Data entry is just completed and analysis will follow soon.

5.4. Nutritional status of HIV–Positive and HIV–Negative Injection Drug Users in Chennai, India

This Study was initiated on 28th March 2007. In all 300 Study Subjects in age group age group 18 – 65 years, irrespective of HIV Status were enrolled for a cross-sectional study. This study is being conducted by National Institute of Epidemiology and Tufts University School of Medicine, Boston. This cross-sectional study was designed to:

- To determine the demographic and drug use correlates of poor nutritional status. In IDUs living in Chennai.
- To characterize a Nutritional Status of HIV Positive and HIV- Negative Injection Drug users attending SAHAI Trust Community Health care center in south Chennai
- To examine the association between Nutritional Status, immune function, and HIV –1 disease status in IDUs living in Chennai.

Methods:

This study is carried out at SAHAI trust (NGO) health care center in Chennai during 2007. All procedures were carried out after obtaining consent from each enrolled case. In this study the parameters on Socio-demographic information, HIV History, Drug use history, Personal Medical history and Physical Examination, Diet and Nutritional Assessment were studied. In addition, the study also included Laboratory investigations of blood tests for HIV, Hepatitis B and C, Fasting

Blood glucose, complete haemogram Insulin Level, SAHAI trust Health care centre provided pre-test and post test counseling for all new cases.

Eligibility criteria:

- Age of the participant between 18 and 65 years
- Injection drug use in the last five years (Heroin, Buprenorphine, Spasmoproxyvon, Fortwin, Avil / Diazepam Phenergan)
- Participant understands the study, agrees to the procedures and signs the consent.

Current Status of the study:

In all 306 IDUs Subjects were covered irrespective of HIV Status were registered into the study (*6 cases deleted due to non co-operation*) during 2007. Data analysis is in progress. However few preliminary analysis tables showing coverages are presented in this report.

Socio-Demographics:

There were 300 subjects enrolled into the study with a history of injection drug use. Of these 108 IUDs were HIV positives and the remaining 192 were HIV Negatives. The mean age of IDUs was 37 years and all were males attending SHAI Trust Health care centre in Chennai.. Twenty nine percent (87) of them were studied upto secondary school education and It was found that 20% (60) were never went to school, There were no significant differences in HIV prevalence in relation to education. Other particulars of socio-demographic features were given (Table 1).

Duration of injecting drug use (IDU):

Only 49 out of 300 IDUs (16%) of the IDUs were reported injecting drug use within the last six months, these were classified as current drug injectors (Table 2).

HIV prevalence:

Among 300 IDUs, It was found 36% (108) were infected with HIV infection. In this 22.7% IDUs (68) were reported past history of HIV infection, but only 13.3%IDUs (40) were newly detected as having HIV infection during investigation (Table 3).

Reported Drug Use In Last 6 Months and HIV status:

It was observed that the primary drugs of choice were Marijuana drug use (188) ranked as first, followed by Heroin (46) and Buprenorphine (30) ranked as second and third common drug consumed. Multiple drug use was also common; about 143 IDUs were reported consumption of mixed drugs. The prevalence of HIV ranged from 22.9% to 66.7% (Table 4).

HIV- Infection by Viral Load And CD Cell Count:

The viral load was assessed in blood sample of 100 HIV positive cases. It was found that 34. (34%) HIV positive cases showed viral load suppressed copies <1000. With regards to CD cell counts, blood samples of 102 HIV positive cases showed the mean CD4 count as 345.03 ± 187.92 and the mean CD8 count as 1059.96 ± 703.84 (Table 5).

Old HIV positives on ART:

In all 22.7% (68) of participants reported, history of old HIV infection. Of these only 14.7% (10) were on regular ART and eight participants initiated ART but discontinued later due to side effects. Further 73.5% (50) participants had not taken any ART (Table 6).

Current Cigarette Smoking by IUDs and HIV status:

Out of 300 IDUs, 92% (276) were current cigarette smokers and 8% (24) were non-smokers. Among current smokers 35.1% (97) and in non-smokers 45.8% (11) were HIV positives respectively (Table 7).

Reported Tuberculosis Cases by HIV:

A total of 17.3% (52) Tuberculosis cases were reported in 300 IDUs. Of these 61.5% (32) cases were also having HIV infection and 20 (38.5%) cases were without HIV infection (Table 8).

Use of Anti T.B drugs by IDUs:

In all 84.6% (44) of Tuberculosis cases reported that they had anti- tuberculosis treatment. Only 15.4% (8) cases reported as not taken any treatment for Tuberculosis (Table 9).

Hepatitis Infection: Hep B; Hep C (Based on Hepatitis Markers):

Blood samples from 299 IDUs, It was found that 85.9% (257) showed exposure to Hepatitis B infection and 221 (96.5%) showed exposure to Hepatitis C infection. Further it was observed that 38.1% (98) and 44.3% (98) showed HIV infection among Hepatitis B and Hepatitis C exposed individuals (Table 10).

Serological markers of Hepatitis:

Serological Tests were done on 299 cases; it was found that active Hepatitis B infection was present in 25 (8.3%) cases and Hepatitis C infection in 221 cases (74.2%) (Table 11).

Interpretation of Serologic Markers of HBV Infection:

In all 257 IUDs were exposed to Hepatitis B infection. Out of these 25 (8.4%) were in active phase, 80 (26.8%) were in Recovery phase, and 140(46.8%) cases had past exposure to Hepatitis B infection (Table 12).

Nutritional Status by Body Mass Index (BMI) Under Nourished:

Nutritional Status by Body Mass Index (BMI) was assessed on all 300 IDUs. Using a cutoff BMI level <18.4 for under nutrition, it was observed 52.8% (57) IUDs were found to be undernourished in 108 HIV-positive cases compared to 49.5% in HIV negative cases (Table 13).

Other Co – Morbidities among IUDs:

It is reported that prevalence of diarrhoea (155), depression, (103) diabetes (blood glucose >106mg/dl) (39) and Hypertension (12) reported by the participants (Table 14).

In-depth analysis is in progress

Table 1: Socio-Demographics

Socio – Demographic Details	Overall (n = 300)	HIV-Positive (n = 108)		HIV-Negative (n = 192)	
		No.	%	No.	%
Age					
Mean ± SD	37.0 ± 6.9	36.8 ± 6.25		37.1 ± 7.25	
Marital Status					
Single/Never married	132	51	38.6	81	61.4
Married/ Common-law married	123	44	35.8	79	64.2
Divorced/Separated/Widowed	45	13	28.9	32	71.1
Race					
Tamil/Non- Tamil*	289	107	37.0	182	63.0
Anglo-Indian	11	1	9.1	10	90.9
*(Non-Tamil includes Telugu –7, Malayalam –1, Urdu-5. They are similar to Tamilians in culture in this part of the country)					
Education					
Never gone to school	60	24	40.0	36	60.0
Primary school (1-5)	84	35	41.7	49	58.3
Secondary school (6-9)	87	33	37.9	54	62.1
Tertiary (10-12)	55	13	23.6	42	76.4
Vocational Training/University/ Other	14	3	21.4	11	78.6
Jail or Prison					
Ever Gone	204	82	40.2	122	59.8
Never Gone	96	26	27.1	70	72.9
Sexual Orientation					
Heterosexual/Straight	274	94	34.3	180	65.7
Bisexual/Homosexual	26	14	53.8	12	46.2
Exchanged Sex					
Ever Had Sex	45	16	35.6	29	64.4
Never Had Sex	255	92	36.1	163	63.9
Exchanged Sex (Last 6 Month)					
Had Sex	15		46.1	8	53.3
Never Had Sex	285	10	35.4	184	64.6

Table 2: Duration of injecting drug use (IDU)

	No.	%
a. IDU with past history (more than 6 months)	251	83.7
b. Current IDU less than 6 months	49	16.3
	-----	-----
Total	300	100.0
	-----	-----

Table 3: HIV prevalence in IUDs (n=300)

	No.	%
a. HIV positives		
1. Already reported by past history	68	22.7
2. Newly detected during investigation	40	13.3
b. HIV negative	192	64.0
	-----	-----
Total	300	100.0
	-----	-----

Table 4: Reported Type of Drug Use in last 6 Months and HIV status

Drug Use Details	Overall	HIV-Positive		HIV-Negative	
		No.	%	No.	%
Marijuana	188	65	34.6	123	65.4
Heroin (Injected)	46	11	23.9	35	76.1
Heroin (Smoked)	35	8	22.9	27	77.1
Buprenorphine, Tidigesic (Injected)	30	9	30.0	21	70.0
Tidigesic (By mouth)	3	2	66.7	1	33.3
Cocktail of Drugs with Heroin Or Buprenorphine (Injected)	24	7	29.2	17	70.8
Spasmoproxyvon (Injected)	6	2	33.3	4	66.7
Sedatives, Sleeping pills or Tranquilizers	30	9	30.0	21	70.0
Opium	15	5	33.3	10	66.7
Calmpose	18	6	33.3	12	66.7
Fortwin	8	2	25.0	6	75.0
Tidi/Calmpose / Avil cocktail	16	4	25.0	12	75.0
Promethazine / Avil / Tidi Combination	16	5	31.3	11	68.8
Avil /Diazepam	27	8	29.6	19	70.4

Note: The above categories are not mutually exclusive so, p-value could not be done.

Table 5: HIV- infection by viral load and CD cell count

Viral load suppressed Copies (%) (n=100)	<i>HIV-Positive</i>	
	<i>No</i>	<i>%</i>
<1000 suppressed	34	34.0
>1000 suppressed	66	66.0
<i>Cell count</i>	Mean ± SD	
CD4 (n = 102)	345.03 ± 187.92	
CD8 (n=102)	1059.96 ± 703.84	

Table 6: Old HIV positives on ART		No.
a. Regular use	-	10
b. Initiated, but discontinued due to side effects	-	8
c. Not taken any ART	-	50

Total	-	68

Table 7: Current Cigarette Smoking by IUDs and HIV status

Current Cigarette Smokers	Overall (n=300)	HIV-Positive		HIV-Negative	
		NO.	%	NO.	%
Cigarette smoker currently	276	97	35.1	179	64.9
Currently not smoking	24	11	45.8	13	54.2

Table 8: Reported Tuberculosis Cases by HIV		No.
a. With HIV	-	32
b. Without HIV	-	20

Total no of Tuberculosis cases	-	52

Table 9: Use of Anti T.B drugs by IDUs		No.
a. T.B cases had treatment	-	44
b. No treatment reported	-	8

Total	-	52

Table 10: Hepatitis infection: Hep B and Hep C (Based on Hepatitis Markers)

Hepatitis Infection	Overall	HIV-Positive		HIV-Negative		P-Value
		NO.	%	NO.	%	
Hepatitis B (N = 299)						
Exposed *	257	98	38.1	159	61.9	0.055
Unexposed	42	9	21.4	33	78.6	
*Exposed means positive for any one of the Hepatitis B markers.						
Hepatitis C (N = 298)						
Exposed*	221	98	44.3	123	55.7	0.000
Unexposed	77	9	11.7	68	88.3	
*Exposed means positive for Anti HCV						

Table 11: Serological markers of Hepatitis

Serological Tests were done for 299 cases, 42 cases (14%) showed negative results for all Hepatitis markers, the remaining 257 cases showed positivity as mentioned below:

Hepatitis Markers	No.	%
i. HBs Ag + Anti HBc Total (Positive)	19	6.4
ii. Anti HBc- Igm + Anti HBc Total (Positive)	6	2.0
iii. Anti HBs (Protective =>10mlU/ml) + Anti HBc Total (Positive)	80	26.8
vi. Anti HBs (Protective =>10mlU/ml)	12	4.0
v. Anti HBc Total (Positive)	140	46.8
	-----	-----
Total	257	86.0
	-----	-----

Table 12: Interpretation of Serologic Markers of HBV Infection

	No.	%
1. Active phase:		
a. [i.e HBs Ag + Anti HBc Total (Positive)/ Anti HBc- Igm + Anti HBc Total (Positive)]	25	8.4
2. Recovery phase:	No.	%
a. [i.e Anti HBs (Protective =>10mlU/ml) + Anti HBc Total (Positive)]	80	26.8
b. [i.e Anti HBs (Protective =>10mlU/ml)]	12	4.0
3. Past exposure:	No.	%
a. [i.e Anti HBc Total (Positive)*	140	46.8

Note: * Some of the cases may be false positives. False positives could not be separated, because tests such as HBV DNA, anti HBc IgG, HBe Ag and Anti HBe were not included in this study.

Table 13: Nutritional Status by Body Mass Index (BMI) Under Nourished

[BMI < 18.4]	Normal	Under Nourished	Total
a) HIV- Positive	- 51	57 (52.8%)	108
b) HIV- Negative	- 97	95 (49.5%)	192
	-----	-----	-----
Total	148	152	300
	-----	-----	-----

Table 14: Other Co – Morbidities among IUDs

	No.
a. Diarrhoea	: 155
b. Depression	: 103
c. Diabetes (Glucose >106 mgs/dl):	39
d. Hypertension	: 12

5.5. Integrated Behavioural and Biological Assessment (IBBA)

IBBA Data management

The task of management and analysis of the Integrated Behavioural and Biological Assessment (IBBA) survey data required well-delineated, clear and systematic procedures given the multi-centric nature of the survey, anonymity of data, multiple categories of sub-populations, large number of behavioural variables, evolving versions of questionnaires, biological data from various laboratories and appropriate analysis methods to suit different study designs and sampling procedures.

IBBA Data Management Group (DMG) headed by Prof. M.D. Gupte, Director, NIE, Chennai was formed with a team of Statisticians with extensive experience in handling large-scale survey. This team coordinated multiple activities pertaining to management, analysis and reporting of the large volume of data generated by the IBBA.

The multiplicity of tasks of the Data Management Group included receiving datasets, data cleaning, performing quality control checks, query processing, merging data files that were received in various formats, data preparation for statistical analysis, calculating standardized weights, recoding of variables, programming, analysis and report generation. Visiting various state ICMR Institutes by Data Management Group personnel for on the spot clarification (if problem could not be sorted through communication) was also one of the tasks, which further facilitated the data management process. Safe custody and confidential storage of the datasets was the responsibility of the Data Management Group. All these activities were carried out for 59 survey groups (30 FSWs, 12 MSM / Hijras, 5 IDUs, and 12 clients of female sex workers). The DMG maintains and updates the IBBA database and necessary backups. Data is shared amongst partners as per the Data Management Policy.

The Data Management Group was also responsible for preparation of the IBBA National Summary Report in coordination with various agencies.

Calculation and assigning precise weights at the district level was an important step in the analysis process. This required extensive review of sampling frames and cluster information sheets; the instruments used for mapping exercise. Discrepancies in the sampling frame and cluster information sheet received from various centres were sorted out through communication. In some instances, site visits were made by the team to discuss with the research agencies / state ICMR key personnel to resolve the issues. Usage of different terminology was one of the major problems of the DMG in understanding the sampling frame and cluster information sheets used for mapping by different research agencies. A manual documenting the weight calculation procedure for each survey group has been prepared for standardized approach.

Tables and cross-tables were generated extensively and reviewed to check for consistencies. Most of the issues were resolved by referring to the original filled-in forms stored at the respective state centres. Discrepancies that could not be resolved were documented to facilitate possible explanations for unusual results, if any. During site visits to the states, their laboratories were also visited to ensure compliance to the step-by-step procedures laid down for recording the coded results in the pre-specified formats.

Programs and SPSS syntax were developed to generate recoded data files so that response values were made uniform across various questionnaires. Detailed documentation of data dictionaries and data merging process were done. SPSS (version 14.0) and RDSAT (An evolving software to analyze data generated through Respondent Driven Sampling, version 5.6.0) software were used for data analysis. Different versions of the questionnaire for a given group is a challenge in developing standardized program for generating reports and doing statistical analysis. Complex sample analysis procedure of SPSS was used for estimates and their confidence intervals for this survey data.

Results

Major findings of the first round of the IBBA among FSWs, MSM, Clients of female sex workers and IDUs are briefly given below.

Female Sex Workers (FSWs)

The majority of FSWs were illiterate in all districts. Consistent condom use with clients was generally high, but lower with regular commercial clients compared with occasional clients except in districts like Chittoor and Prakasam of Andhra Pradesh. Many of the sex workers have regular non-commercial partners with whom the consistent condom usage was generally low. The reported coverage of interventions by any agency was relatively lower in bigger cities. Forced sexual activity was reported by small proportion of sex workers. Syphilis was the predominant STI. HIV prevalence was high in many districts, with Maharashtra having the highest prevalence rates. Among the IBBA districts, Pune-Brothel Based (Maharashtra) had the highest HIV prevalence of 38.7% and Chennai (Tamil Nadu) had the lowest prevalence of 2.2%.

Men Having Sex with Men (MSM) / Hijra

The MSM group covered in the IBBA included male sex workers and hijra. Most of the MSM were literate across all districts in contrast to FSWs. Their exposure to various interventions by any agency was only moderate. Condom usage for anal sex with their regular partner in all districts was low except Bangalore. Twenty percent of MSM had reported that they had paid female partners. However it was high in the districts of Andhra Pradesh. Condom use with them was low. Consistent condom use with non-commercial male/hijra partners was below 40% except Mumbai-Thane (56%) and Pune (79%) districts of Maharashtra. Hyderabad (Andhra Pradesh) had the highest HIV prevalence of 24.7% and the lowest was 4.8% in Chennai (Tamil Nadu).

Injecting Drug Users (IDUs)

The usual place of injecting the drug by the IDUs was their home or the homes of their partners. Heroin was the most commonly injected drug in Manipur and Spasmoproxivon was common in Nagaland. A large proportion of IDUs in Manipur reported using brand new needles and syringes last time. Only small proportion reported having commercial sex partners and condom use with them was low. Unlike Nagaland, the STI prevalence was very low and the HIV prevalence was high in Manipur. HIV prevalence was low (1.1%) in Phek district (Nagaland) and high (32.2%) in Churachandpur district (Manipur).

Clients of Female Sex Workers

Many of the clients of female sex workers reported low consistent condom use. HIV prevalence was between 5% and 11% among clients of sex workers in East Godavari, Guntur, Vizag and Warangal in Andhra Pradesh and in Parbhani, Pune, and Yevatmal of Maharashtra. In all the above districts, except Vizag (3.4%), the prevalence of syphilis was between 4% and 10%.

Conclusion

This exercise underscores the need for more concerted effort for prevention. Non availability of condoms was the primary reason reported by clients for non- use of condoms by clients.

Size estimation

Size estimation of high-risk population groups involved in covert, stigmatized and socially ostracized activities, is a very demanding exercise. There is no standard method that can be used universally. Multiple methods were explored for IBBA, since a single common method is unlikely to be adoptable for all the groups in all the districts. The choice of sampling method for selecting study individuals, depended on the specific high-risk population assessed. The type of populations surveyed was Female Sex Workers, Men having Sex with Men, Hijras and Intravenous Drug Users. Except for Intravenous Drug Users, this survey involved both conventional and time location clusters sampling method.

The size estimation methods finally proposed for these various high-risk populations in the IBBA survey were capture-recapture (unique object distribution) and other multiplier based methods. As these methods were assumption dependent, a probability based method with minimal assumption was developed, by DMG, named as “**Reverse Tracking Method (RTM)**” and used for size estimation of the population for whom some kind of sampling frame was possible.

Reverse Tracking Method: Profession of sex work and the habit of injecting drug use are stigmatized and most of the times clandestine activities. A reliable sampling frame for individuals indulging in these activities was not available. In addition, these populations are generally mobile and frequently change their activity sites. However their socializing venues (but

for the IDU groups) are mostly concentrated and clustered in urban areas and the places where the movement of general populations are high. IBBA used the information generated by NGO mapping data, augmented by data from key informants (including the members of high-risk population), to develop broad sampling frames for FSW and MSM groups. This sampling frame was further updated by IBBA mapping team. The team also verified existence of the sites, included new sites and obtained characteristics such as intensity (approximate size), and time of activities for possible formation of Time Location Clusters (TLCs) within a site. This mapped information with approximate estimate of size of each site (clusters), hereafter called as “measure of size” of the time location / conventional cluster, was used for the probability selection of sample clusters. This measure of size of a cluster acted as the surrogate/auxiliary to actual size of a cluster. The data generated through this exercise and the methods of sample selections were used to estimate the size of the high-risk population in the district. Procedure followed for drawing sample clusters was a single stage ‘Probability proportional to size’ cluster sampling.

If a cluster (either time location or conventional) was selected for the survey, the IBBA team further refined the estimate of size of that cluster, using at least six key informants including members of the high – risk population. This size, called hereafter as “estimated size” of the time location / conventional cluster, is the reflection of true size of high-risk population of a selected cluster. This information was generated for all the selected clusters in the district. To estimate the size of the population, the proportion of this “estimated size” of the selected cluster to the corresponding “measure of size” for that cluster was exploited to reverse track the entire process by utilizing the properties of PPS sampling. This approach, referred to as “Reverse Tracking” method can be used to estimate population size for most of the high-risk populations in the districts, where conventional and TLC sampling was used. In this application the measures of sizes need not be accurate, “as it is enough to be indicative of the bigness that may be thought to be highly correlated with the actual sizes of a cluster. As far as the theoretical results are concerned the ratio of the measure of size to the total measure of sizes of all the clusters of a district can be any set of positive numbers that add to 1 over the population”. Since these ratios are positive, they may be treated as acceptable set of probabilities. It is possible to calculate the 95% confidence interval for the estimated sizes through a complex process for this design.

This procedure is less assumption dependent and robust. It is probability based method using the best available information from the Sampling Frames even if they are approximate. It is most appropriate to estimate the size of the population in a situation where they are hard to reach.

5.6. Prevalence of HIV infections in Tamil Nadu based on Sentinel Surveillance

Background: The purpose of this study was to evaluate HIV prevalence rates in Tamil Nadu by using sentinel surveillance data collected for the year 2005.

Methods: In the year 2005, sentinel surveillance for antenatal women was conducted in 69 sites (n=27600), STD in 11 sites (n=2576), MSM in 2 sites (n=500), IDU in 2 sites (n=500) and FSW in 11 sites (n=2750). Consecutive blood samples are collected till the predetermined sample size is reached over a twelve-week period. The minimum sample size required for surveillance purposes is determined for each sentinel group based on some assumptions. Unlinked anonymous testing method is used, as it minimizes participation bias and also assures that HIV test results cannot be linked with the individuals. For screening purposes 2 consecutive tests showing HIV positivity are considered adequate. The second test is performed only if the first test is positive. These two tests are of two different kinds for HIV antibodies.

Results: A total of 27600 blood samples were collected from all the 69 ANC sites and 153 of them were positive for HIV. The median prevalence of HIV infection among ANC attendees is 0.50%. The prevalence values of the district headquarters with their first referral units (FRU) were compared (Fig. 1 a & b) and found that there was hardly any correlation ($r=0.11$). There was a clear increase in the prevalence values when the centers were getting closer to the National Highways (Fig. 2). The observed pattern of relationship with the national highways suggests that the epidemic is mainly restricted and follows the pattern of national highways and perhaps has not percolated to the same extent in the entire area. We looked into the proportion of individuals according to the number of children and plotted a map. It was seen that percentage of women with 2 or more living children was much higher in the eastern coastal area of the State (Fig. 3). Thus it is evident that once HIV infection gets introduced in the area, higher sexual activity, seen

in terms of number of children, is likely to lead to higher HIV prevalence. However, the penetration of HIV towards east coast of the State is obviously very limited.

A total of 2576 samples were collected from STD patients out of whom 311 were positive for HIV. The median prevalence for HIV Infection among STD patients in the sentinel sites was 9.2%. Sero-positivity values for males and females for STD patients are considerably different. In the younger females, sero-positivity is much higher compared to the males. The high rate of 8.33% and 11.27% sero-positivity in the age groups 15–19 and 20–24 years, respectively in the females suggests that the females attending STD clinics do not represent the general population.

A total of 500 samples were collected from two IDU sites, out of which 90 were positive. The prevalence was 18%. There was only one female participant in the study. She was negative for HIV. In this survey all the participants are from urban locale. Except two, all of them were non-migrant and out of the two migrants, one was positive for HIV.

A total of 500 samples were collected from two MSM sites, out of which 31 were positive for HIV. The prevalence of HIV among MSM was 6.2%. Majority of the MSM were in the age group of 20-29 years age group.

There were 11 sites assigned for commercial sex workers. Out of 2750 samples collected for the year 2005, 311 were positive. The median prevalence rate was 4.8%. Most of the female attendees were between the age group of 25-29 year age group. Illiterate commercial sex workers had higher positivity rate than educated ones.

Conclusions: HIV epidemic in Tamil Nadu is varied in various parts of the state. It apparently covers both urban and rural areas, but still concentrated in and around the national highways. It is perhaps not penetrating deeper into the state. There are some good examples like the City of Chennai where in spite of several high risk factors, HIV still remains very much limited. These factors need to be identified for further containing and controlling the spread of HIV epidemic.

It has been seen that the positivity rates observed in ANC population are very similar to PPTCT data available (Fig. 4). PPTCT data is collected uniformly all along the year and covers the entire

population for the centre. Hence it is a total representative data than the sentinel surveillance data. It is of course comforting to see the close matching over the years between the sentinel sites and the PPTCT centers data. It is noted that the ANC population is distinctly different from the general population with respect to age pattern (Fig. 5). There are variations in the public and private sectors as well, in the age pattern as well as HIV sero-positivity pattern. It is therefore unrealistic to apply the observed rates of HIV sero-positivity in the ANC population to the general population with respect to Tamil Nadu for the purpose of HIV estimation. The HIV infection for the state is estimated using present procedure and calculated that there are 1.5 to 3.4 lakhs HIV infections in the state for the year 2005.

Information from the female STD clinics suggests that HIV positivity rates in the commercial sex workers might be somewhat higher than that are actually observed through the STD surveillance for that group. Positivity in the female STD clinic attendees was much higher than the one observed for the female sex workers sentinel surveillance sites. So it was suspected that females attending the STD clinics both comprise of sex workers in a greater proportions.

Figure 1 (a). HIV infection prevalence among ANC mothers – Head Quarters:

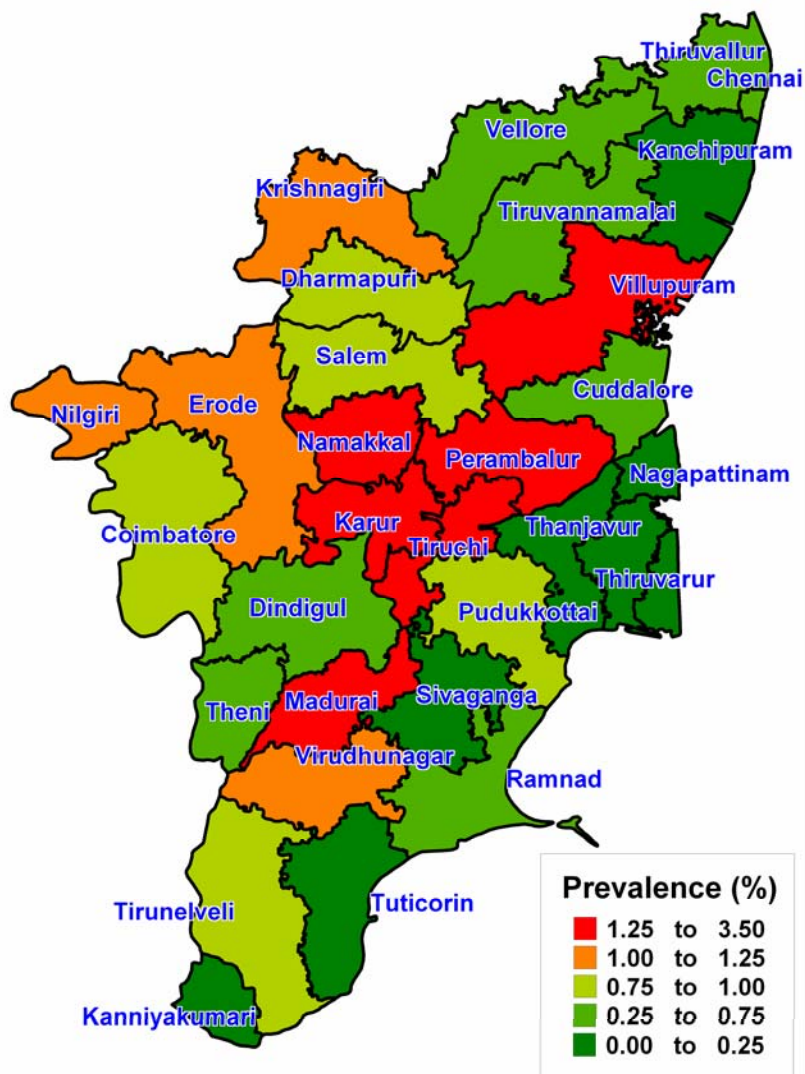


Figure 1 (b). HIV infection prevalence among ANC mothers – FRUs:

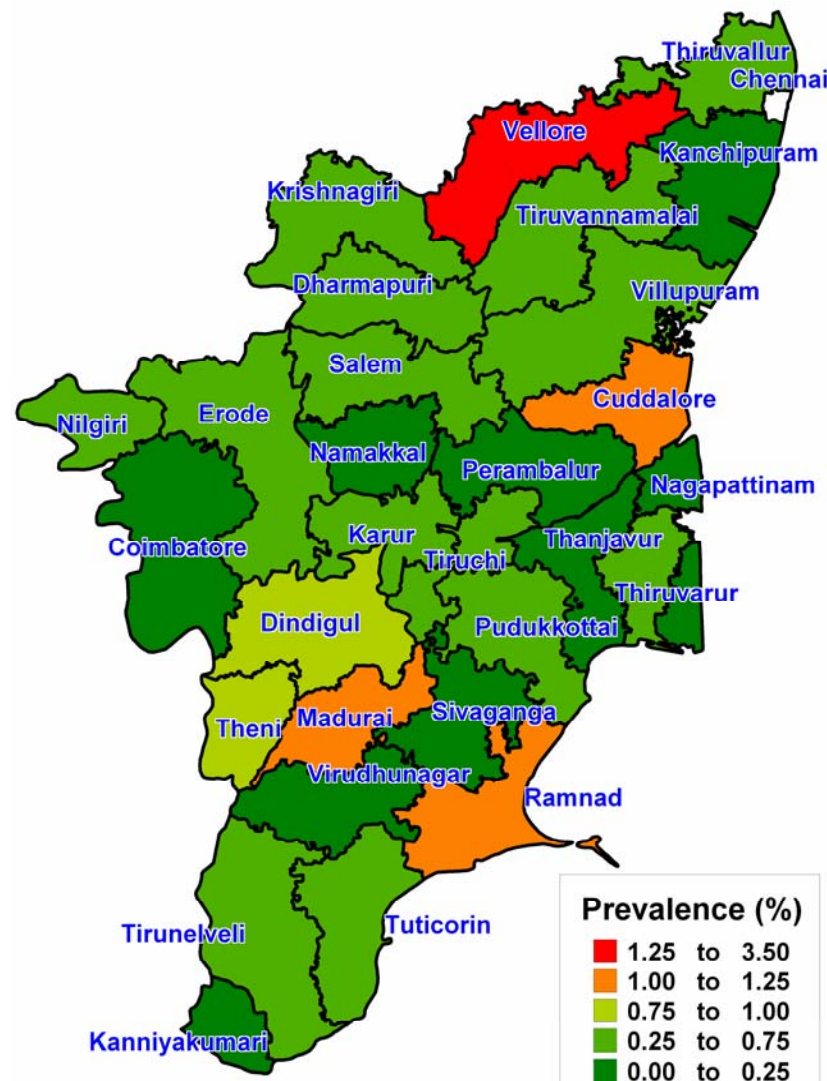
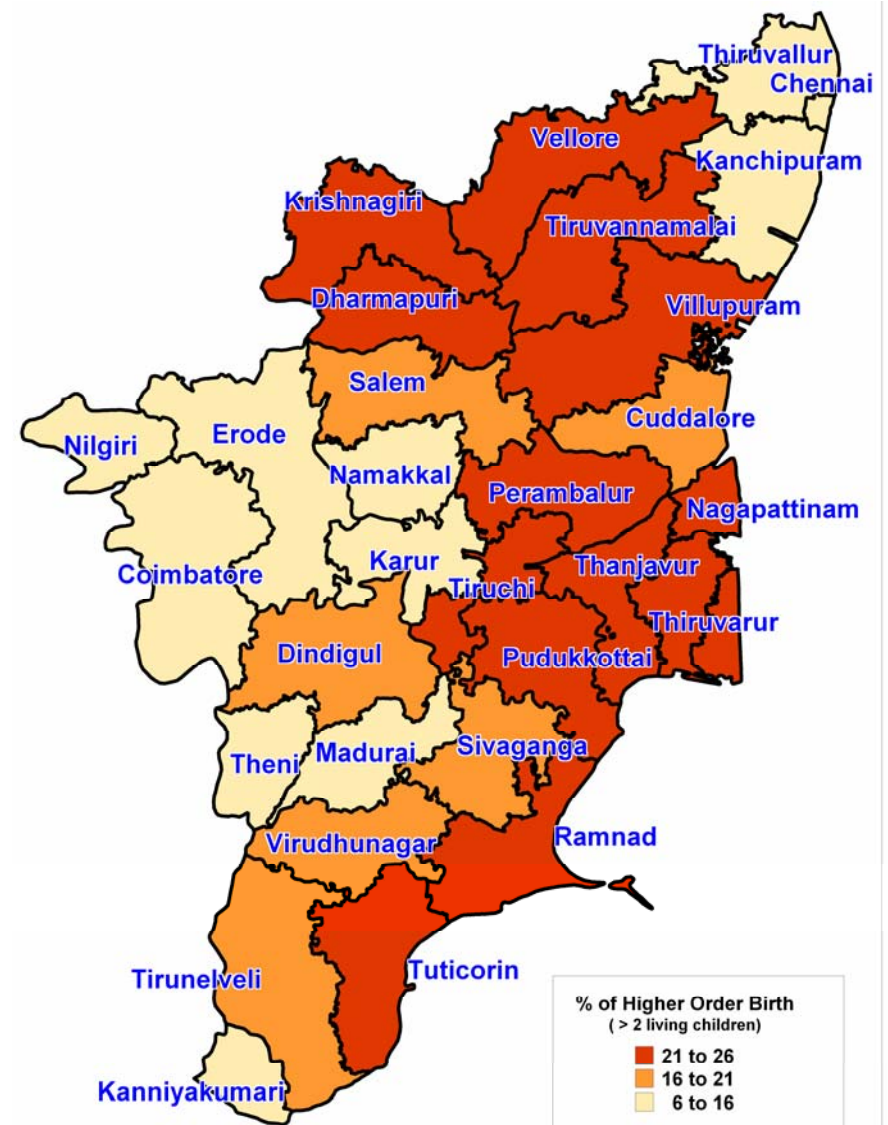
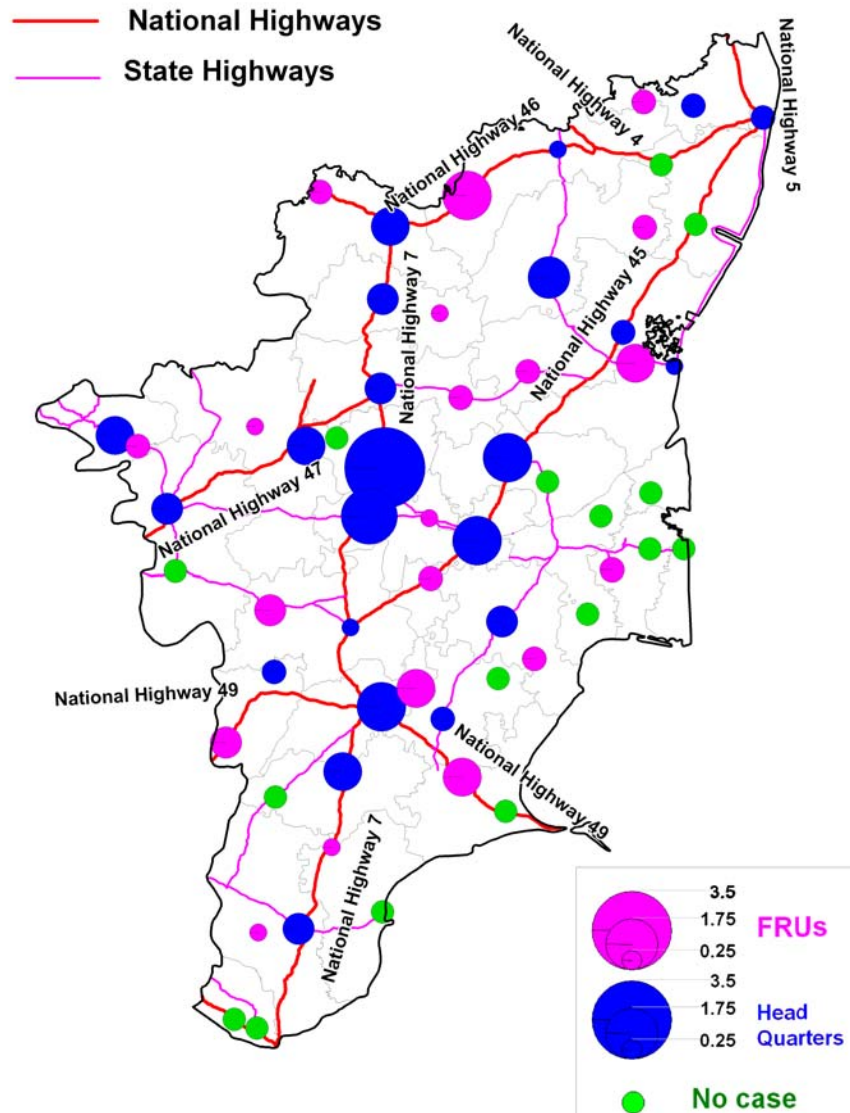


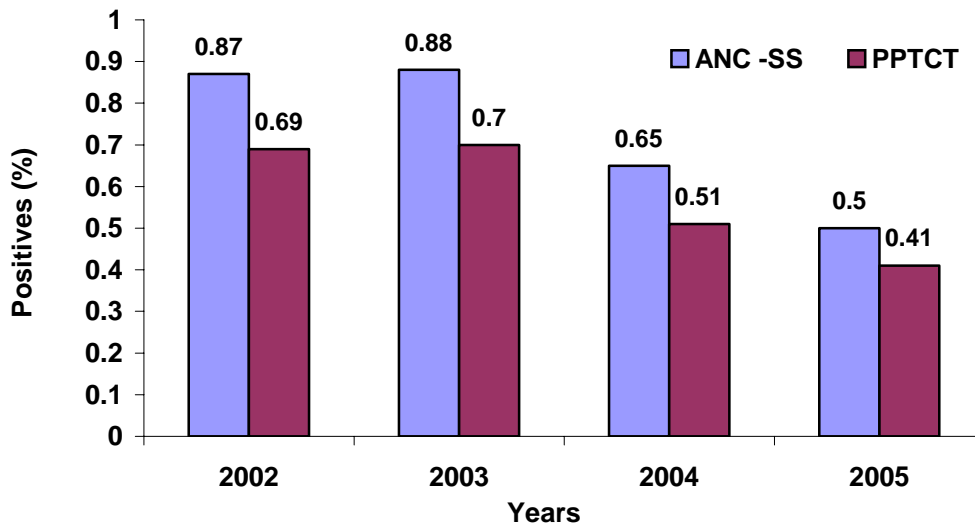
Figure 2. Distribution of HIV infection along with Highways:

Distance between the centers and highways was measured using ArcView GIS software. Distance between the center and the national highways prevalence level were negatively correlated ($r=-0.32$). This was statistically significant ($p=0.01$)

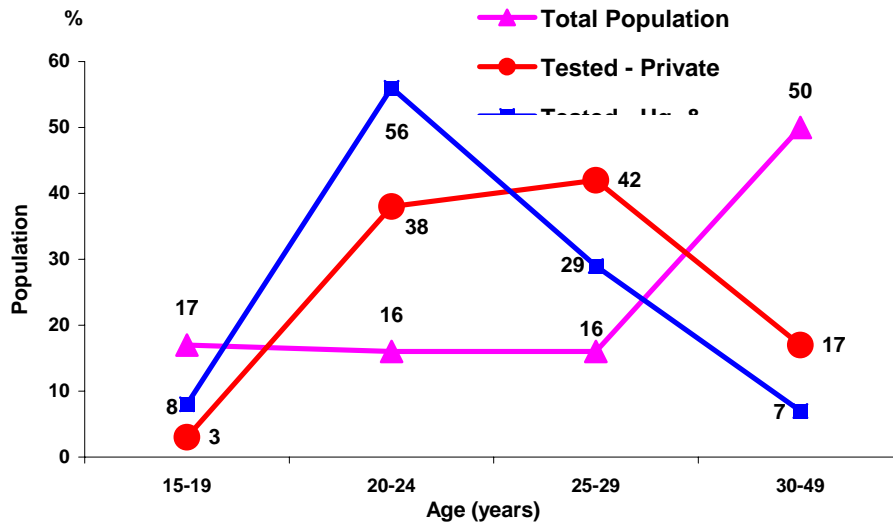
Figure 3. District wise distribution of higher order births



**Figure 4. HIV positivity from ANC sentinel surveillance and PPTCT data:
Tamil Nadu Sentinel Surveillance, 2005**



**Figure 5. Age structure of ANC attendees:
Tamil Nadu Sentinel Surveillance, 2005**



5.7. HIV SENTINEL SURVEILLANCE-2006 (HSS-2006):

National AIDS Control Organization, Govt.of India has identified our Institute as one of the Regional Surveillance Institute (RSI) for co-ordinating with States AIDS Control societies (SACS)of Southern Region

Objectives:

- 1.To monitor the trend of HIV prevalence over time and place in different states in different groups of population,
- 2.To measure the prevalence of HIV infection in the general population indirectly by testing antenatal clinic attendees,
- 3.To determine the geographical spread of HIV infection by covering all districts and
- 4.To decide the priorities by using the data for appropriate planning of health and medical care services.

METHODOLOGY:

AREA: .Andhra Pradesh,Orissa,Tamil Nadu,Karnataka,Kerala,Pondicherry,Andaman&Nicobar and Lakshadweep islands.

DURATION: 3 months(from September 2006 to November 2006).

National Institute of Epidemiology (NIE) has to co-ordinate, monitor and supervise all SACS and help them in organizing surveillance activities.

ACTIVITIES:

1. Organizing the Pre Surveillance Work-Shop:

Developing the modified formats by co-ordinating with experts from NACO and WHO, selection of kits for testing blood for HIV and VDRL in testing centres, developing criteria for identifying new sites, methodology for blood collection and serum separation at collecting sites and transport of serum samples to testing centers and procedures to be followed to maintain External Quality

Assurance Systems (EQAS), were discussed with members of all SACS. Time lines were developed for different activities.

2. Assisting the SACS in Orientation training:

At the time of orientation training of In-Charges of all sentinel sites and testing centers, experts from NIE supervised the training programme .

3. Identification of new sentinel sites:

Experts from NIE helped in identifying the new sites in Orissa, Ponicherry and Kerala states.

4. Monitoring and Supervision:

Field visits were made for supervision of sentinel sites and testing centers and suggestions were made to improve the quality and supervised to follow procedures for collecting blood, separation of serum and transport of specimens to testing centers with proper coding and maintenance of confidentiality.

5. Data collection and Data Entry:

Experts from NIE helped all the SACS to get training in double data entry.

6. Organizing the Post Surveillance Work-Shop:

Discussions were made by members of all SACS and preliminary results were presented.

The details of the survey population are as follows:

General population: The low risk or general population is represented by the pregnant woman attending the antenatal clinic. Sample size is 400. High risk population is represented by the STD patients attending the STD clinics, Female Sex Workers, Men having Sex with Men, Injecting Drug Users, Truck Drivers and Migrants. Sample size is 250. In STD sites 150 samples were collected in STD clinics and 100 samples from Gynaecological clinic from patients having STI. All consecutive pregnant woman attending antenatal clinic for the first time during the surveillance period and all consecutive STD patients presenting with genital ulcers, urethral discharge, cervical discharge and genital warts were included.

Data collection:

During the period of surveillance, consecutive blood samples were collected serially till the predetermined sample size was reached. Blood was collected at the clinic site. The study was conducted clinic based as unlinked anonymous to avoid participation bias. 5 ml blood was collected from each patient. Serum was separated as per the guidelines of NACO on the same day by following sterile precautions. Each serum sample was separated into two parts; one part with name for Rapid Plasma Reagin (RPR) testing and the result was informed to the patient. The other part with code number, age, sex, date and site code was sent to the respective testing center for HIV and VDRL testing.

External quality assurance system(EQAS):

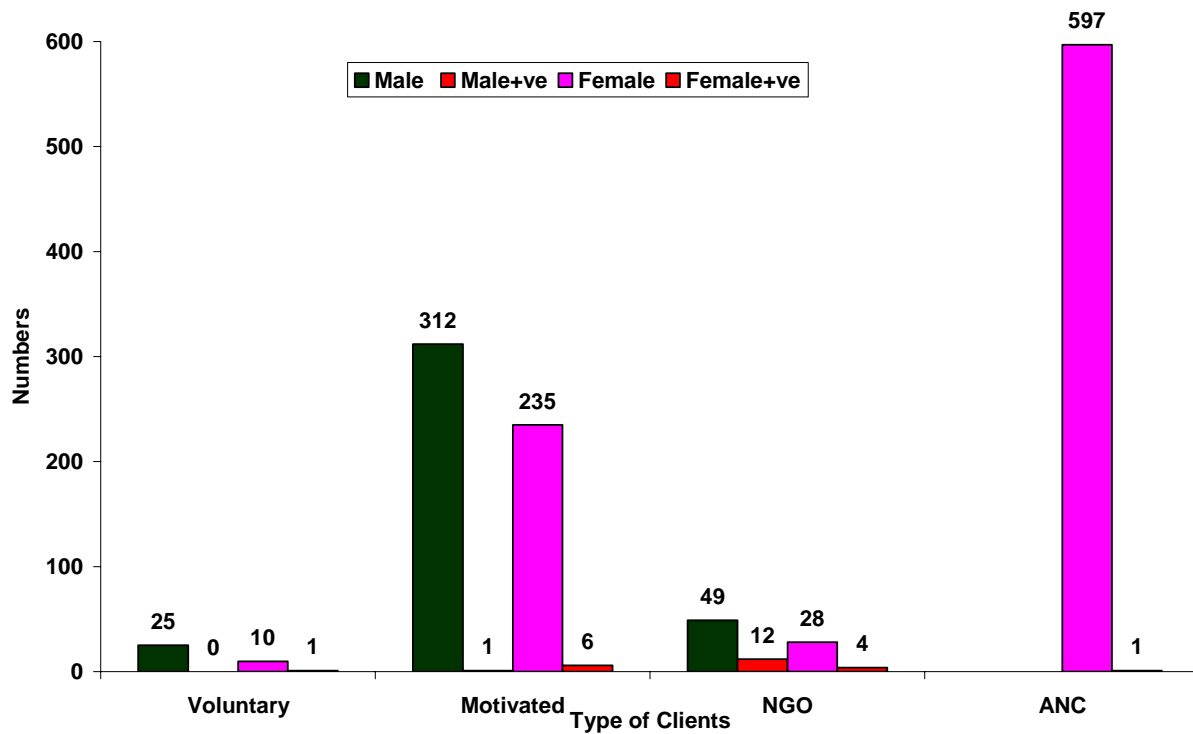
A sample of 5% of negatives and all positives for HIV were sent to reference laboratory for quality check.

5.8. Voluntary Counselling and Testing Centre (VCTC),Chennai**Background**

Counselling and testing are important components of HIV prevention and care. To cater to the needs of the population of, in and around the institute area including Avadi and Ayapakkam, NIE has established a VCTC sponsored by Chennai AIDS Prevention And Control Society (CAPACS)/Tamil Nadu State AIDS Control Society (TANSACS). This is the only community based VCTC.

During April 2006 to March 2007, a total of 1272 clients have attended the VCTC. In this 392 were males (31%) and 880 were females (69%). Among them, 35 (2.75%) attended voluntarily, 547 (43%) attended after counsellor's motivation, 597 (47%) were ANC mothers and 77 (6%) were referred by an NGO (SAHAI Trust) Figure 1. The HIV positivity rates were 10%, 2.2%, 0.16% and 20%, among voluntary clients, clients who attended after motivation, ANC mothers and IDUs respectively. HIV seroprevalence was found to be high among the IDUs..

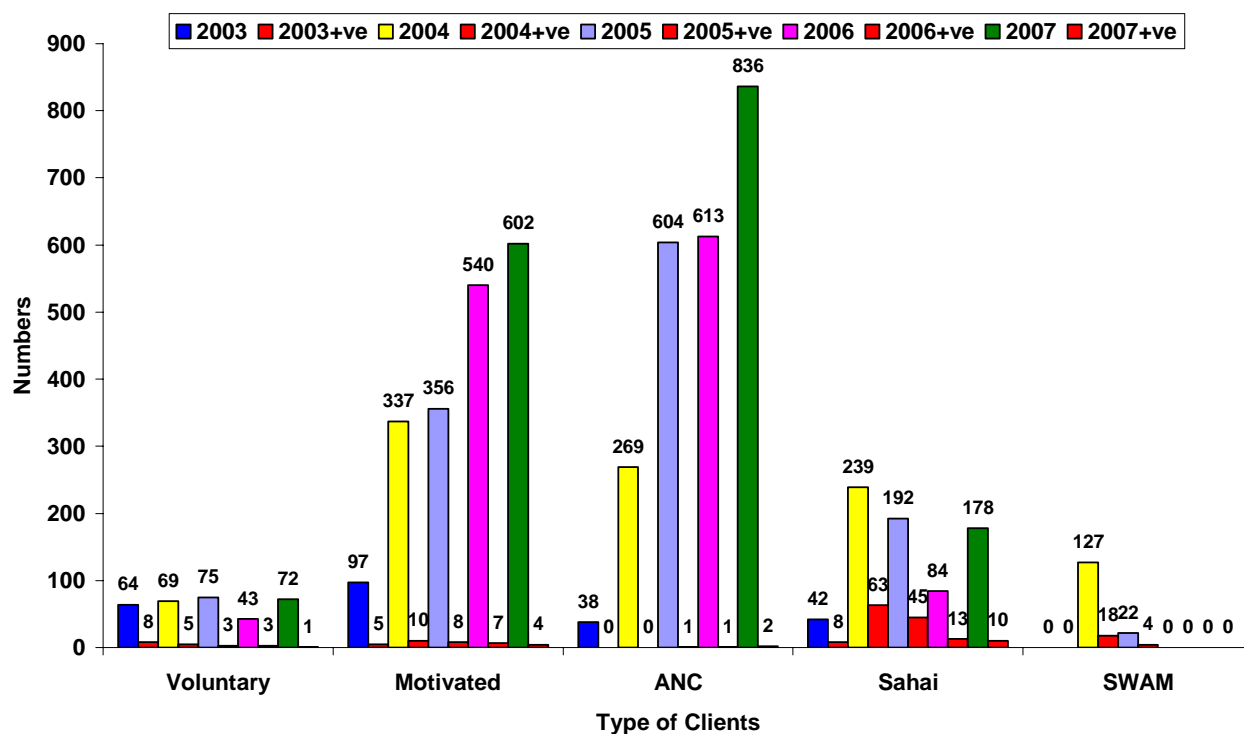
VCTC CLIENTS : April 2006 - March 2007



Observations

With respect to year wise attendance of clients to the VCTC, (Figure 2) we could observe, increase in number of ANC mothers and clients after counsellor’s motivation. On the whole the rate of attendance of clients to our VCTC is on increase. HIV seropositivity continues to be high among the NGO referral cases – as they come under high-risk group (injecting drug users).

YEAR WISE HIV POSITIVITY OF CLIENTS ATTENDING VCTC : 2003 - 2007



All the clients are motivated to come for follow-up, related to their HIV status, opportunistic infections and psycho-social problems. Supportive and family counselling are provided to the needy persons / whoever attended after post-test counselling.

Referral service

Almost all the HIV positive cases are referred to the following centres to get investigated and treated for tuberculosis, STIs and other opportunistic infections wherever required.

1. Near by Govt. Health facility
2. Institute of Venereology, Govt. General hospital

5.9. Molecular epidemiology of HIV in STD clinic attendees

Introduction

Number of studies in India has indicated that subtype C is the most predominant subtype with more than 90% infections belonging to this subtype. However, recent emerging data from the Northeast

part of the country is pointing towards more complex subtype patterns. The emergence of increasing number of recombinant viruses indicates that subtype distribution is a dynamic process. Understanding the molecular Epidemiology of recently transmitted HIV viruses circulating in diverse risk groups and geographic regions in India will be very critical for the selection of appropriate vaccine candidates for future vaccine trials in India.

This proposal is aimed at generating data on the HIV incidence in different parts of India and molecular characterization of HIV viruses in India, thus filling the gaps in the knowledge that is critical for vaccines research for control of HIV Infection.

Objectives

1. To generate data on HIV incidence in different risk groups and geographical locations using detuned assays in cross- sectional studies
2. To undertake detailed molecular epidemiologic studies to better characterize the viruses circulating in these areas.
3. To undertake full-length analysis of selected incident infections to better understand the complexity and distribution of subtypes and recombinant strains.

Research Plan

The study will require identification of prevalent and incident HIV-1 infections in different part of the country, inclusive of Northeast region due to its close proximity to East Asia where HIV epidemic is already very heterogeneous. We will then do genetic analysis of 5' and 3' end of the genome to understand the HIV subtypes pattern. Specimens with discordant subtypes in two regions will be used for more extensive analysis, and selected incident infections will undergo full- length sequence analysis.

Methods

In order to fulfill these objectives, NARI will utilize the network of institutions of Indian Council of Medical Research in different parts of the country. The groups that will be selected for HIV incidence analysis will include persons attending Sexually Transmitted Diseases clinics in Pune,

Jaipur and Chennai, Intravenous drug users from the North- Eastern states of Manipur and Nagaland and men having sex with men in Mumbai.

All samples will undergo detuned ELISA at NARI. Currently two Detuned ELISA procedures are being evaluated at NARI. The two procedures are BED-EIA and Avidity assay.

BED-EIA- Procedure in brief

Avidity Assay-procedure in brief

A proportion of the samples found to be positive in the screening will be further investigated for recombination. Sub typing will be carried out by Heteroduplex Mobility Assay for two structural genes gag and env genes methods as described by.

Full length DNA sequencing HIV-1 genome will be carried out for characterizing the recombinant strains. Molecular virological analysis will be carried out of for sequence variations, glycosylation patterns and length variations in env gene.

Procedure :

Collect approximately 6ml intravenous blood samples in EDTA

Send the samples to the laboratory

In the laboratory, aliquot 2 ml of blood (1ml each) in cryovials and store at -70° C

Remaining blood is layered on Ficoll Hypaque and centrifuged for PBMCs and plasma separation

Perform HIV testing using standard procedures as per the manufacturer's instructions on plasma samples

Store remaining plasma at -70° C

Perform Detuned ELISA on HIV positive samples as per the manufacturer's instructions

Store PBMCs in liquid Nitrogen / -70° C until tested

6. Non-communicable Diseases

6.1. Prevalence of cardiovascular risk factors in a rural population in Tamil Nadu, India

Background

The study on prevalence of Cardiovascular Risk factors in an industrial population was carried out during 2003-2004. The findings of this study were presented at Scientific Advisory Committee (SAC) meeting on 5th & 6th August 2004. It was recommended by SAC members that a similar study should be carried out in a general community. In view of the recommendations, pilot study was carried out in rural area. In Oct, 2005 the study proposal for cardiovascular risk factor survey was presented and approved by SAC members. The data collection has been completed. Currently data analysis is in progress.

Objective

To determine the prevalence and distribution of cardiovascular risk factors in a select rural population in Tamil Nadu.

Methods

Study Design: Cross sectional survey

Study population

Rural population from eleven purposely selected villages in SriPerumbudur and Ponnammalle Taluks from Kancheepuram and Thiruvallur districts respectively in the state of Tamilnadu were included in the study. These villages are approximately 30-40 km from Chennai city.

Sample size

Target sample size to study risk factor prevalence is 10,000 in 25-64 age group with near equal proportion of males and females. Total population of nearly 25,000 will be covered to achieve target sample size; as 40% of the adults are in 25-64 year age-group. Minimum sample size based on WHO recommendations is 250 subjects in each 10 year age and sex group should be covered. Age distribution of the population from data collected in one of the villages in study area shows lowest proportion in 55-64 age group (10%). To achieve target number of 500 in this age group, minimum

sample size needed is 5000. Sample size has been inflated to 10,000 taking into account attrition of the cohort over period of time and to study mortality patterns.

Study variables

The risk factors included in the survey were selected as per WHO-STEPS recommendations.

Step 1 – Questionnaire based

Socioeconomic and demographic variables, Tobacco, Alcohol, Physical inactivity and Dietary patterns

Step 2 – Physical measurements

Weight, Height, Waist girth, Hip girth and Blood pressure

Results

The data from three villages has been analyzed and results are presented here. Population in these three villages was 5671 from 1271 households. Family size was less than five for 665 (52.3%) households and the type of house was pucca in 754 (59.3%) households.

The eligible population in the age group of 25-64 was 2451(43.2%). Out of these subjects, 2397(97.8%) were registered. Among the 2397 subjects, 1146 (47.8%) were males and 1251(52.2%) were females. (Table 1) Majority of the subjects (84.1%) were married. The number of illiterate subjects was 539 (22.4%). Among illiterates, one third of them were females. Only 90 (3.7%) of the total subjects had college level education. The number of male subjects who were labourers was 309 (3.7%) and 552(44.1%) female subjects were homemakers. 533(22.2%) subjects were either government /private employees.

Prevalence of cardiovascular risk factors is given in table 2. Tobacco consumption was prevalent in 451(39.3%) male subjects. Two third of the male subjects were current alcohol consumers. The physical activity levels could be assessed only for 2336 subjects. Based on the physical activity levels (PALS), 689 (29.5%) were sedentary and 707 (30.3%) had heavy physical activity level.

Prevalence of over weight (BMI 23.0 kg/m²-27.4 kg/m²) and obesity (BMI≥27.5 kg/m²) using WHO recommendations for defining risk thresholds among Asians was 21.8% and 6.2% respectively. Central obesity using WHR criteria (>0.90 for males and 0.85 for females) was present in 509(44.4%) males and 183(14.6%) female. Hypertension was prevalent in 458(19.1%) subjects. During the study, 362(79.0%) subjects were newly diagnosed. Hypertension was prevalent in 228(19.9%) males and 230(18.4%) females.

Ongoing activities

The data collection has been completed for 10500 subjects. Data analysis is in progress.

Table 1 Socio economic/demographic profile of population in three villages, SriPerumbudur Taluk, Kancheepuram district, Tamil Nadu 2006. (N =2397)

Variable	No.	%
Age Distribution (years)		
25-34	883	36.8
35-44	729	30.4
45-54	459	19.1
55-64	326	13.6
Sex		
Male	1146	47.8
Female	1251	52.2
Marital Status		
Married	2016	84.1
Widowed	263	10.9
Unmarried	118	4.9
Education		
Never attended school	539	22.4
Primary	833	34.7
Middle	460	19.2
Secondary	475	19.8
Diploma/Degree	90	3.7
Occupation		
Labourer	793	33.0
Cultivators	75	3.1
Artisan	84	3.5
Self employed	314	13.0
Govt/Private employees	533	22.2
Home makers	552	23.0
Others	46	1.9

Table 2- Prevalence of cardiovascular disease risk factors in the study population in three villages, SriPerumbudur Taluk, Kancheepuram district, Tamil Nadu 2006. (N =2397)

Variables	Males N=1146		Females N=1251		Total N=2397	
	No.	%	No.	%	No.	%
Tobacco use						
Current smokers	451	39.3	0	0	451	18.8
Ex. Smokers	115	10.0	0	0	115	4.7
Alcohol Consumption						
Current Consumer (past 12 months)	725	63.2	8	0.006	733	30.5
Binge Drinking	93	8.1	0	0	93	3.8
Body Mass Index-Classification recommended for Asians (kg/m²)						
<18.5	364	31.8	401	32.1	765	31.9
18.5 - 22.99	490	42.8	472	37.7	962	40.1
23.0 - 27.49	250	21.8	272	21.7	522	21.8
≥27.5	42	3.7	106	8.5	148	6.2
Central Obesity						
Waist-Hip Ratio >0.90 males, >0.85 females	509	44.4	183	14.6	692	28.9
Hypertension	228	19.9	230	18.4	458	19.1

7. Other studies

7.1. Safety of an Aerosol attenuated Measles vaccine in healthy subjects with Omron's Nebulizer

Phase I: Open, non-controlled, sequential by age group, parallel trial

Introduction:

The current measles vaccine, which has been available for more than 40 years, is safe, effective and inexpensive. This vaccine is administered parenterally. In some countries the availability of trained personnel to safely administer injections is limited and there is concern over injection practices. These problems are more critical during mass measles immunization campaigns when millions of doses of vaccine are administered. A measles vaccine, which could be inhaled, would avoid potential problems related to the use of needles, their cost, disposal and waste management. Several studies in Mexico and South Africa have reported the safety and immunogenicity of this route of administration. The measles aerosol project is carried out by a partnership: WHO, the American Red Cross and the United States Centre for Disease Control and Prevention. Its goal is to develop and license at least one method (vaccine plus delivery device) for respiratory delivery of currently licensed measles vaccines.

Objectives:

1. To determine the safety of aerosol administration of live Edmonston Zagreb attenuated measles vaccine given to healthy volunteers.
2. To measure the serum plaque reduction neutralization titres before and after aerosol administration of live attenuated measles vaccine given to healthy volunteers.

Study Design

All study participant in the following sequence of age group,

Group 1 – 18- 35 years

Group 2 - 5- 17 years

Group 3 – 1- 4 years

receives the Measles aerosol vaccine and they will be followed for 365 days after vaccination for safety and immunogenicity of vaccine. Subjects will be evaluated for initial safety (clinical and laboratory assessment) at 14 days after vaccination. Safety and immunogenicity will be assessed 28 days after vaccination.

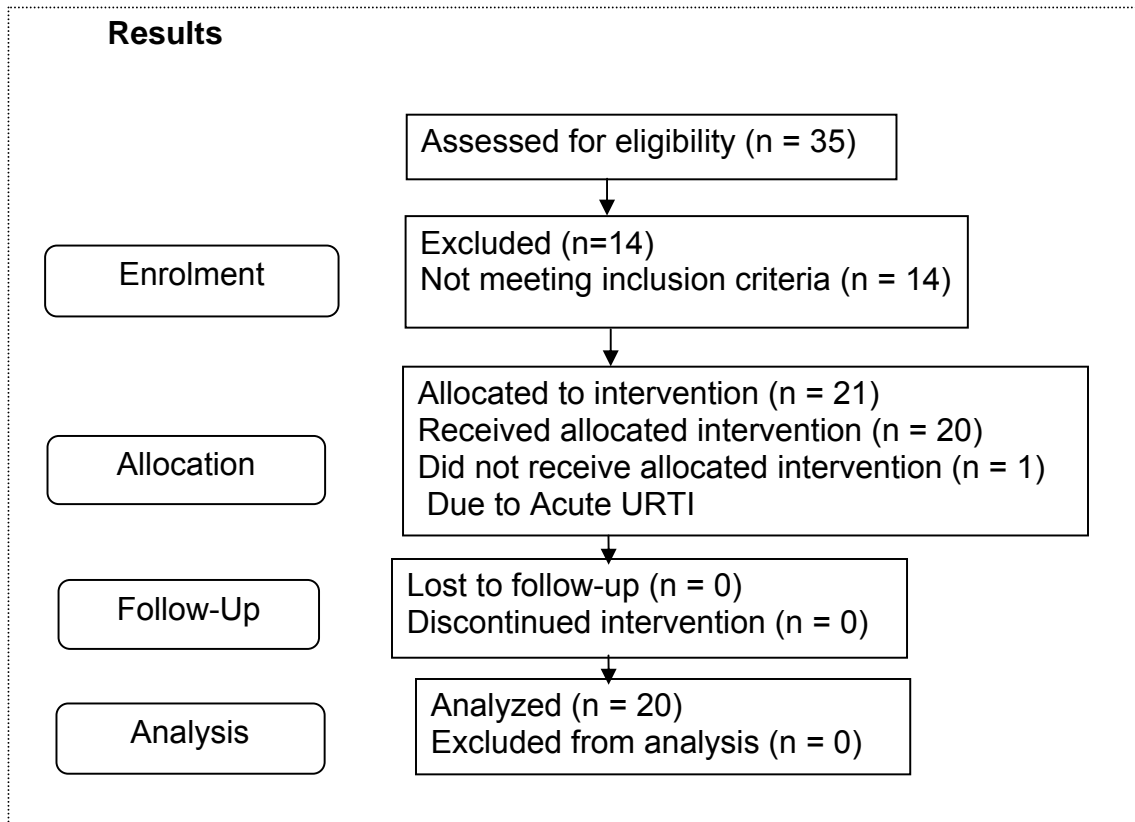
Activities:

WHO consultants and monitors visited Chennai by December first week of 2005 and changed the study site for the second age group 5-17 years as Nandivaram PHC since this PHC is working as a model PHC. The standard operating procedures were prepared to conduct this trial. Based on the revised January-2006 protocol we conducted Good Clinical Practice (GCP) for investigators and device training in first week of April 06.

The recruitment procedure of subjects in the age group of 18 – 35years started in June 2006.

Methods & highlights:

Twenty healthy male participants were selected and they were been vaccinated with measles aerosol in two batches. The following are the results of our enrolment process.



Only few Acute Reactogenicities (Adverse events) detected within 14 days of follow-up and none has developed serious adverse events. All the participants recovered within few days. The details are as follows

6 participants developed highly probable mild adverse events within 3 days of vaccination and the symptoms are as follows:

Conjunctivitis, fatigue, head ache, loss of appetite, sore Throat, redness of eyes, coryza. All these persons were not treated but recovered from these symptoms.

5 participants developed possible / probable mild AE after 3 days of vaccination and the symptoms are as follows:

Cough, anorexia, head ache, fatigue, fever, coryza, runny nose, sore throat, diarrhoea, vomiting and shivering

Some of these participants were treated symptomatically and all recovered.

None of the adverse events were detected as moderate, serious or severe.

The acute toxicity assessment after 14 days of vaccination for the entire 20 participant resulted that only one participant had the significant abnormality in SGPT (Bio–chemistry) and the same was repeated and found normal on 90th day.

After Visit 9 and within 90 days of vaccination one had cervical lymphadenitis and one had a viral conjunctivitis. We followed these cases till they were asymptomatic. The consultant physician of these two participants declared that these two events were not related to vaccination.

Current status

In one of the 3 sites of measles aerosol vaccination in India was observed that the eosinophil count of their participants was raised after the vaccination. So they did a comparative trial on healthy adults and found that the increase in the eosinophil count is almost equal in both routes (subcutaneous and aerosol). To record these changes the parameters IgE and eosinophil count were included for the next two groups.

The screening process for the next age group (5 – 17years) commenced in July 2007 at Nandivaram, Tamil Nadu.

7.2. Hospital Based Surveillance For Rota Virus Disease And Strains

Introduction

In India, an estimated 100,000 children die each year because of rotavirus gastroenteritis. Rotavirus is a wheel shaped (rota) virus belonging to the family Reoviridae. About 20 – 70% of hospitalizations and 20% of deaths are attributable to rotavirus. Considerable research has been carried out in India on rotavirus disease in different settings. The collation of data from these studies is frequently not possible due to differences in study design, population examined and methodologies used. Therefore, ICMR proposed to establish a multicentric surveillance system in India jointly under the supervision of DG, ICMR India and CDC Atlanta. Standardized protocols for enrolment and diagnostic evaluation of children hospitalized with diarrhoea for rotavirus data will be used. Strains of rotavirus circulating in the study population will be characterized by standardized molecular methods.

Objective

The study objective is to assess the load of rotavirus disease in India and provide essential information before introduction of new interventions against rotavirus. The surveillance network will provide timely and geographically representative information on the disease burden and strain prevalence of rotavirus in India.

Study duration : Initially 2 years, with a possible extension to 3 years. The study was started in December 2005.

Primary objectives of the project

- (1) To estimate the magnitude and proportion of diarrhoea hospitalizations attributable to rotavirus among children below 5 years of age.
- (2) To characterize (G and P) types prevalent strains of rotavirus in the population under surveillance.

Secondary objectives of the project

1. To generate information about descriptive epidemiology for rotavirus associated hospitalizations among the population under surveillance.
2. To monitor trends in incidence of hospitalizations.
3. To perform intensive evaluation of strains not identified/typed by standard techniques including sequencing the genome of these strains.

Enrollment criteria

Any child fulfilling the following conditions is **included** into the surveillance system.

Age in completed months, 0-59 months (below 5 years).

Suffering from acute diarrhoea, or dysentery.

Hospitalized for at least 6 hours for the purpose of supervised oral rehydration or receiving any duration of intravenous rehydration.

Parent/guardian should be willing for enrollment of the child into the study. Informed consent from the parent/guardian of the affected child will be obtained first.

Any child ≥ 60 months (older than 5 years), without diarrhoea or with diarrhoea not requiring supervised oral rehydration or intravenous rehydration is **excluded**.

Case definitions

For the purpose of surveillance

A Probable Case: A child below 5 years of age admitted to a hospital in the surveillance system for treatment of diarrhoea /dysentery.

A Confirmed Case: A confirmed case of rotavirus diarrhoea is a probable case whose stool demonstrates the presence of rotavirus using ELISA.

The study design

The study is multicentric and conducted in five Centers.

Participating Centres

National Institute of Cholera and Enteric Diseases (NICED), Kolkata.

National Institute of Virology (NIV), Pune.

Christian Medical College (CMC), Vellore.

LTMMC, Mumbai and

Enterovirus Research Center (EVRC) Mumbai.

All centres are having peripheral hospitals attached to them for sample (stool specimens) collection. The above labs test the stool specimens for the presence of rotavirus.

Study coordinator / monitor

National Institute of Epidemiology (NIE), Chennai will co-ordinate /monitor the centers with Director, NIE as the study Coordinator.

CMC will purchase all ELISA kits and reagents for PCR and provide them to the respective centers every six months. Only the extraction and gel electrophoresis reagents will need to be procured directly by each individual site, but from common manufacturers, as identified in the protocol.

This multicentric study is coordinated by ICMR who is responsible to institute guidelines and monitor the progress of the work meticulously on administrative and scientific aspect by visits to study sites to ensure that study is being conducted at all sites adhering to the protocol, following SOPs. ICMR will ensure the quality control of data and analysis is maintained, and timely report preparation/submission for its review so that national standard is maintained and the funds to the 5 participating centres are released in time.

Method of data collection

All children less than 5 years of age admitted for diarrhoea is enrolled after obtaining informed and written consent from the parent/guardian. Clinical information and a stool specimen are obtained from each enrolled child. The stool sample is tested for the presence of rotavirus by ELISA. Rotavirus positive stool specimens are further characterized to determine the G and P types of strains using a variety of molecular methods, including multiplex RT-PCR and specific priming and PCR for specific genotypes.

For enrolled patients, clinical information is collected and recorded in the case report form (form 1). Stool specimens (sufficient amount of whole stool (5 – 10 ml)) are collected within 48 hours of hospitalization in a sterile screw capped container. Project staff record each enrolled case in a logbook and case-reporting form by daily survey of inpatient wards. Specimens are kept at 4°C if

testing will take place in the two weeks following collection with proper labeling including identification number and date of collection.

If the specimens can not be transported and processed on the same day at the labs, they are kept and stored at +4°C. From peripheral sites, samples are stored at -20°C and shipped to labs in a vaccine carrier. Stool specimens are tested for the presence of rotavirus and for G and P typing.

Lab investigations

Long-term storage of aliquots of all positive samples are kept in freezer at -20°C. A sample of rotavirus positive stools is chosen for further characterization. All untypable samples will be sequenced if first round products are available. If no first round amplification takes place, a PAGE gel will be run. Rota EIA, multiplex PCR for G and P typing, specific priming and G and P typing, other genotyping and sequencing

End points

Primary: Rotavirus positivity.

Secondary: Genotyping (for rotavirus positive cases)

Progress of the Study

All centres are sending a monthly report (form 4) to NIE each month indicating total number of children admitted with diarrhea, number of children enrolled, no. of children whose stool specimen have been collected, number of stools tested positive for rotavirus. Quarterly report (form 5) in electronic format are also sent to NIE. All case report forms (Form 1) and laboratory log books (Form 2) for the previous 3 months are sent to NIE.

Forms are scrutinized for completeness at NIE and identified errors/omissions are communicated to the respective centers for clarification. Scrutinized forms are sent for data entry.

Data analysis will be carried out and results/reports will be prepared at NIE in tune with the objectives of the study.

Hospital based surveillance for Rotavirus diseases and strains (Dec2005–Mar2007)

Center	No. Admitted	No. Enrolled	No. Stools Collected	No. Positive for Rotavirus (%)
NICED	442	311	252	147 (58.3)
NIV	480	431	431	181 (41.9)
CMC	1667	1344	1206	540 (44.8)
LTMGH	1089	620	447	167 (37.4)

Hospital based surveillance for Rotavirus diseases and strains (Dec2005–Mar2007)

Period	NICED		NIV		CMC		LTMGH	
	Stools tested	Rotavirus +ve (%)	Stools tested	Rotavirus +ve (%)	Stools tested	Rotavirus +ve (%)	Stools tested	Rotavirus +ve (%)
Dec 2005	5	4 (80.0)	57	36 (63.2)	79	42 (53.2)	14	8 (57.1)
Jan–Mar 2006	50	33 (66.0)	84	26 (31.0)	245	118 (48.2)	55	28 (50.9)
Apr–Jun 2006	41	21 (51.2)	70	24 (34.3)	276	86 (31.2)	62	6 (09.7)
Jul–Sep 2006	37	13 (35.1)	66	9 (13.6)	251	116 (46.2)	104	28 (26.9)
Oct–Dec 2006	78	60 (76.9)	81	46 (56.8)	194	94 (48.5)	129	64 (49.6)
Jan–Mar 2007	41	16 (39.0)	73	40 (54.8)	161	84 (52.2)	83	33 (39.8)

7.3. Medical causes and Associated determinants of Infant Mortality in a Rural District of Tamilnadu

Background: Infant Mortality is a sensitive index of health and socio economic development in a country. The Infant Mortality Rate (IMR) has declined significantly from 129 and 113 (1971), to 58 and 41(2004) in India and Tamilnadu respectively. The Tenth Five Year (2002-2007) health plan goal of Government of India and State of Tamilnadu is to reduce IMR to <30 by 2012 and 2007 respectively. To monitor effectiveness of interventions valid and reliable baseline data on causes and determinants of IMR are required. Such information are available at national and state levels but not at district level.

Objectives: A study was conducted to identify the causes and associated determinants of IM in Tiruvannamalai district, Tamilnadu at baseline (2001-2002)

Methods : All infant deaths reported to the government health system are audited and data collected through enquiry forms by local health workers and physicians. Data from these forms were coded, abstracted and analysed for the whole district using SPSS software.

Results: Total infant deaths= 660.*Profile of infant deaths: Age at death:* Neonates = 70%.(n=660). Among neonates early neonates=74%(n=460). Deaths within 24hrs=27% (n=660); Sex: more among females (57%); *Caste:*SC=27%,ST=8% and others=65% ; *Parity:* 1=37%, 2=29%, 3=21%, 4=12%; *Delivery place:* Home=45%, peripheral facility=20%, Tertiary hospital=23%, private facility=11% ;*Birth Type=* Single=93.5%, Twins=6%, triplets=0.5%; *Death Place:* home=73%, *Delivery type:* Normal=96%, *Birth weight:* <2500=33.8%; *Major causes of death were* Birth Asphyxia(27%), LBW(15%), Prematurity(10%), Congenital Heart Disease(7%), Congenital Anomalies(5%), Pneumonia(7%), Septicemia(6%) High proportion of deaths due to the above causes (i) occur during the neonatal period and among primiparous women, (ii) were more among female infants (except deaths due to prematurity which is more in males). (iii) were delivered at home and (iv) died at home.

Conclusions: Major causes are highly preventable through strengthening maternal antenatal care, institutional deliveries, and home based neonatal care. Since 20% of these deaths are delivered at peripheral institutions, strengthening infrastructure, staff, supplies and transport facilities would effectively improve infant survival..

7.4. Burden of disease, Quality of life and Cost of illness attributable to Chikungunya outbreak in Gowripet area of Avadi Municipality, Chennai, Tamilnadu, India

Introduction

Chikungunya is a relatively rare but debilitating viral infection caused by a single stranded RNA virus of the Togaviridae family and genus alphavirus. The virus is transmitted by the bite of an infected aedes aegypti mosquito. The disease was first described by Marion Robinson and W.H.R. Lumsden in 1955 following an outbreak on the Makonde Plateau in 1952 along the border between Tanganyika and Mosambique. Chikungunya thus derived its name from the Makonde word meaning “that which bends up” in reference to the stooped posture that results from the arthritic symptoms of the disease. Chikungunya is characterised by sudden onset of fever (upto 102⁰F), chills, headache, nausea, vomiting, joint pain and rash.

Chikungunya is endemic in parts of Africa, Southeast Asia and on the Indian subcontinent. In India, the disease was first reported and isolated in Calcutta in 1963. Thereafter several outbreaks were reported with the last one in 1971. Since then it seemed that the virus had disappeared until late 2005 when it reappeared with large outbreaks being reported from Andhra Pradesh, Maharashtra, Orissa, Karnataka, Tamilnadu, Madhya Pradesh and Gujarat. As of end August, 2006, over 11 lakhs cases have been reported from India and the numbers seem to be increasing.

In Tamilnadu, since June 2006, over a lakh of cases have been reported from 31 Districts, with Chennai, the capital city, being the worst affected. During the third week of June, 2006, 604 cases (population 2649) of fever with joint pain were reported from the Avadi municipality. The overall Attack Rate (AR) was 23% with ARs being significantly ($p < 0.001$) higher among women (56%) than men (43%). and highest (26%) among those aged 25-44 years and lowest (12%) among the <5 years age group. Cases were clustered in 2 streets with ARs between 14%-38%. Five out of nine sero samples tested positive for IgM antibodies against Chikungunya virus. Entomological survey confirmed presence of aedes aegypti larvae and adults, with house index=22% ($> = 10%$ high risk) and Breteau Index=34.7% ($> = 20%$ high risk).

Although no deaths were reported, joint pain among those affected seemed to persist for between 15 days to over 3 months resulting thus in prolonged periods of disability, treatment and sickness

absenteeism. Therefore there is a need to document the magnitude of the disability, quality of life and cost of illness associated with such an illness. The present study is one such effort.

Objectives

The objectives of this study are to estimate: (1) Disability associated with Chikungunya outbreak (2) Quality Adjusted Life Years (QALYs) associated with Chikungunya outbreak (3) Cost of Illness (COI) attributable to Chikungunya outbreak

Methodology

Study Area : The present study will be conducted in the Gowripet area of Avadi Municipality

Study Design: A survey method will be adopted

Sample Size : For estimating DALYs and COI all 604 cases identified during the outbreak investigation and who are willing to participate will be included in the study. To estimate QALYs, in addition to the 604 cases, 604 age and sex matched non cases for comparison purposes will be included.

Data Collection Techniques and Tools : An interview method using an interview schedule consisting of semi structured questions will be used to collect data from cases and non cases. where n is the population in the age group x , i is the incidence of disease in each

Study Duration: About 8 months from the date of commencement.

Project achievements

- All field investigators, supervisors and Research Assistants were trained. The data collection instruments were pilot tested. Data collection will be completed by end of July. Data entry will commence by August 2007. Data will then be analysed to provide details on disease burden, Quality of Life and Cost of illness due to Chikungunya outbreak.

7.5. Effectiveness of supplementation of Double Fortified salt in reducing the prevalence of Iron deficiency anemia (a collaborative study between Tamilnadu Salt Corporation, Chennai – National Institute of Epidemiology, ICMR, Chennai)

Background:

Tamilnadu Salt Corporation (TNSC) is involved in the manufacturing of salt and its allied chemicals since 1976. TNSC is producing salt fortified with iron and iodine since 1991. The double fortified salt (DFS) is being distributed through the Mid-day Meal programme in seven goiter prone districts of Tamilnadu Viz. The Nilgiris, Coimbatore, Salem, Namakkal, Trichy, Perambalur, Karur and the Union Territory of Pondicherry. Under the Mid-day Meal programme, children studying in government schools from class 1 to 12th standard are covered.

The objective of providing double fortified salt to school children is to: (1) Provide daily requirement of Iodine at a level of 150mcg per day and iron at a level of 10-15 mg per day and (2) eliminate Micronutrient deficiencies associated with Iodine and Iron. The DFS distribution programme has been ongoing since 1998 in the above 7 districts. TNSC proposes to assess the impact of DFS supplementation.

Objectives of the proposed evaluation are to : (1) Assess the effectiveness of DFS supplementation in reducing the prevalence of Iron deficiency anemia and goiter among school children receiving DFS through mid-day meal scheme.(2) Identify factors likely to influence effectiveness of DFS supplementation (3) Based on the findings of (1) and (2) make appropriate recommendations

Methods:

Study Setting: School children who received DFS supplementation through the midday noon meal scheme in Karur district (treated group) will be compared with school children in Ramnad district who did not receive DFS supplementation through mid-day meal scheme (untreated group).

Study population: In both districts government school children of both sexes aged 7, 8 and 9 years (Standard 3, 4 and 5) will be included in the study and assessed for presence/absence of anemia and

goitre. Children in these age groups are selected as they would have received DFS supplementation at least for two academic years.

Sample size and sampling: The sample size is calculated based on following assumptions:

1. Mean Hemoglobin (Hb) among the children in untreated group is 10gm %
2. Mean Hemoglobin (Hb) among the children supplemented with DFS for a minimum of two academic years is 11.25gm %
3. Standard deviation of Hb estimation by cyanmethaemoglobin method is 1.2%
4. Alpha error of 5% and power of 90%

Based on the above assumptions, the sample size for each age and sex group in DFS supplemented and non-supplemented children is 20. As the study will be carried out in three age groups of both sexes, the required sample size for evaluation would be 120 each in DFS supplemented and non-supplemented group of children. The required number of children for the evaluation will be selected from one representative school receiving DFS supplementation. Similarly a representative school not providing DFS supplementation will be selected as untreated group

Data Collection Techniques and Tools:

Observations, Lab investigations, Anthropometry and. In-depth interview methods will be used for data collection.

Project achievements

The evaluation proposal was shared with TNSC and NIE experts and their consensus obtained. Several preparatory activities were carried out in consultation with the state departments of Health, Education and Social Welfare at Chennai, Karur and Ramnad districts. Data collection team consisted of Epidemiologist, FETP scholars, Microbiologist, laboratory technicians and field investigators. Data collection has been completed and the study report will be submitted by July-August 2007.