Annual Report 2003-2004

National Institute of Epidemiology, Chennai

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NATIONAL INSTITUTE OF EPIDEMIOLOGY

(Indian Council of Medical Research)

ANNUAL REPORT 2003 – 2004

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FETP-MAE TRAINING PROGRAMME AT NIE, CHENNAI

FIELD EPIDEMIOLOGY TRAINING PROGRAMME

Master of Applied Epidemiology (MAE)

A two year MAE programme commenced at NIE in January 2001. The degree is conferred by the Sree Chitra Thirunal Institute of Medical Sciences and Technology (SCTIMST), Thiruvananthapuram, Kerala. The training is provided by NIE as an off campus course. This training programme has been supported by ICMR, Govt. of India- Ministry of Health, WHO, CDC and US Embassy in India.

Each year a maximum of 10-20 candidates will be admitted to the MAE programme. A total of 28 trainees have been admitted to the programme in 4 batches from different states in the country: Kerala, Orissa, Madhya Pradesh, West Bengal, Mizoram, Himchal Pradesh, Maharashtra, Bihar, Uttaranchal, Andaman and Nicobar Islands. The training programme stretches across 24 months. It consists of a total of 6 months contact sessions at NIE and 18 months of practical field postings. A major component of the FETP-MAE course pertains to building competencies related to Disease surveillance, Epidemic Preparedness and Response and Effective Public Health Management. The FETP-MAE training methodology hinges on the philosophy of "Learning by doing" through "practical, hands-on field experience". Trainees evaluation is continuous and based on: class and home assignments, class participation, group discussions, problem solving capabilities, satisfactory completion (identification, design, implementation) and submission of assigned field projects and defense of "Dissertation".

Contact Sessions At NIE, Chennai

Contact sessions were organised for the four batches of scholars during the months of April 2003 (III batch),July 2003 (II batch), October 2003 (III batch), December 2003 (I batch) and January – March 2004 (IV batch).

Field training for scholars

NIE faculty mentors performed supervisory visits to field placement sites of all the scholars to guide and supervise them in the appropriate conduct of assigned field projects.

Participation in outbreak investigations

MAE - FETP scholars and Faculty have participated in several outbreak investigations. These include:

(a) Dengue outbreak in Chennai
(b) Viral encephalitis outbreak, Gummili, Tamil Nadu,
(c) Unknown fever, Yercaud, Salem, Tamil Nadu.
(d) Typhoid outbreak in Dindigul, Tamil Nadu
(e) Investigation of Anthrax and food poisoning in Orissa
(f) Cholera outbreak in Tamil Nadu and Andaman and Nicobar Islands
(g) Outbreak of Influenza like fever at Himachal Pradesh, West Bengal and Mizoram
(h) Outbreak of Chandipura virus infection, Nanded, Maharashtra
(i) Outbreak of Viral Encephalitis, Saharanpur, Uttar Pradesh.
(j) Outbreak of Cholera among inmates of a care centre, Tamil Nadu

(k) Kala-azar in West Bengal

Visits of External Consultants

The following consultants visited NIE during the year 2003-2004.

1. Dr. Yuvan Hutin (WHO Geneva) – prospective long term Resident Advisor for MAE-FETP India at NIE – July 2004.
2. Dr. Mark White (CDC) – July 2003 and January 2004.
3. Dr. Rubina Imtiaz (CDC) – November 2003

Viva Voce Examination for I & II Cohort of MAE-FETP Scholars

Formal discussions were held with the Registrar, SCTIMST, and FETP Faculty at NIE in June 2003 at NIE, Chennai regarding conduct of viva voce examinations, selection of panel of external and internal examiners, deadlines for submission of Bound Volume and dissertation projects and fixing the date for the viva voce examination.

PROJECT ACHIEVEMENTS

1. Two scholars from the I cohort, Dr. A.P. Sugunan and Dr. S. Saravanan, successfully completed all course requirements of the MAE-FETP course including the viva voce examination.
2. Since completion of the MAE course Dr. A.P. Sugunan has resumed his position at ICMR-RMRC Port Blair. His dissertation project on "Cholera Epidemic among the Nicrobarese Tribe of Nancowry, Andaman and Nocobar, India" was submitted and accepted for publication in "American Journal of Tropical Medicine and Hygiene"
3. Dr. S. Saravanan was deputed by the Government of Tamilnadu to the WHO as a Polio Surveillance Medical Officer and placed at Pondicherry.
4. All the six scholars of the II cohort completed all course requirements, submitted the Bound Volumes and dissertation projects by January 2004 and returned to their respective parent organisations. They were informed that their viva voce examination was scheduled on 26th April 2004.
5. Three of the six scholars were placed in training Institutes for Public Health in their respective states and two were assigned to Senior Positions as Public Health Managers within the Health System. One scholar from Mizoram has been posted as Officer in Charge of NSPCD and Statistics at State level in the Public Health Department of Mizoram.
6. The III cohort successfully completed their second contact session at NIE in October 2003 and returned to their field placement sites to pursue the second field posting assignments.
7. In July 2003, the Medical Council of India (MCI) formally recognised the MAE course of SCTIMST and included it in the 1st schedule of the MCI Act 1956.
8. One scholar from I cohort (Dr. Saravanan) and 2 scholars from the II cohort (Dr. S. Parvathy and Dr. Madan Mohan Pradhan) presented their field work at the II SEA-WPR TEPHINET Conference in Manila, Phillipines in November 2003. Their participation was supported by TEPHINET-CDC
9. At the SEA-WPR TEPHINET Conference the scholars participated in the workshop on "Evaluation of Surveillance System" organized by CDC-WHO.

10. The various field projects of the scholars have made useful contributions to enhancement of knowledge and good public health practices in the respective states / districts.
11. The dissertation projects submitted by scholars had identified and addressed problems of high Public Health priority with important implications for programme strategy redesign and significance for forthcoming IDSP in their respective states.
12. A document on AETP workforce development outlining the vision, goals and objectives of the FETP-India was prepared and submitted to CDC, Atlanta. The same is being considered for discussion at the TEPHINET Board of Directors meeting in Lyon, France in June 2004.
13. A document to enhance the status of NIE as a WHO collaborating centre for training in epidemiology was submitted to WHO-SEARO. The response is awaited.
14. Interim progress reports for II cohort was submitted to WHO-SEARO.
15. Sustainability of MAE-FETP at NIE was assured with the ICMR and MOH-GOI undertaking full financial responsibility for the course and integrating it into the regular budget of NIE.
16. The faculty was strengthened through recruitment of a Deputy Director, Research Officer and a short term WHO consultant.
17. The MAE-FETP scholars have assisted their respective State Government Public Health Departments through their active participation in outbreak investigation.
18. Third cohort of FETP scholars have presented their field work in national level conference and also won the best paper awards.
19. The dissertation project of one scholar of the II cohort was funded by CDC-TEPHINET Micronutrient – malnutrition programme.
20. Research proposals submitted by four scholars of the III cohort were accepted by CDC-TEPHINET Micronutrient Malnutrition Initiatives Programme and awarded for funding support. These projects are to be taken up by the scholars for fulfilling dissertation requirements of the MAE-FETP course requirements.

AN EVALUATION STUDY OF SHORT TERM TRAINING PROGRAMME (10 DAYS) ON SURVEILLANCE EPIDEMIC PREPAREDNESS AND RESPONSE WORKSHOPS

The National Institute of Epidemiology has conducted five 10 day WHO – SEAR Workshops on, "Surveillance Epidemic Preparedness and Response", between January 2001 and February 2002. A total of 87 National and 20 International participants were trained through these workshops. Participants were professionals from the Public Health System, Medical Colleges and Research Institutions in India and SEA Region of WHO.

The objectives of these workshops were to strengthen capacity of public health professionals in disease surveillance related activities, epidemic preparedness and outbreak management. Several activities were proposed as a follow-up of the above training programme/ workshops. Important among them is evaluation of such a short-term training programme. In November 2002 a formal evaluation study was proposed and undertaken. WHO – SEARO, New Delhi, supported this evaluation study financially.

The study design and instruments have been developed by me in consultation with the Director, NIE and Advisors / Consultants to NIE for FETP at NIE, Chennai.

OBJECTIVE

- The main aim of this evaluation study is to assess the achievement of the objectives of the short-term training programme.
- Identify unmet training needs.
- Modify existing training programmes to meet unmet needs.

METHODOLOGY

Evaluation was conducted using the following techniques:

- A self administered semi-structured questionnaire to all participants
- Field visits to work sites of a few randomly selected participants from 2 states (Orissa and Tamilnadu)
- In depth interview of Senior Public Health Programme Managers / Policy makers from selected states (Orissa and Tamilnadu)
- Discussion of issues relating to training programme utilization with a few teams members other than participants.

PROJECT ACHIEVEMENTS

- The evaluation study commenced in November 2002
- Self administered questionnaires were mailed/emailed to all participants – total Questionnaires mailed = 87
- One month later (i.e. December 2002) responses from 30 out of 87 participants were received
- An interim analysis and report was presented during the events of the Epidemiology Week organized at NIE, Chennai between 30th December 2002 and 3rd January 2003
- As of end March 2003, a total of 40 responses out of 87 were received
- Reminders to the non-responders with a copy to their respective heads of department to facilitate responses have already been sent
- Third reminders were given to all non responders in mid June 2003 and responses were awaited till end July 2003

- During May-June 2003, site visits to randomly selected work sites of four participants from Orissa and Tamilnadu respectively were undertaken
- Information on surveillance activities and outbreak preparedness and response through records, and reports maintained at the district level, were elicited during site visits. Pre-prepared checklists were used to record information gained
- Discussions were held with selected team members of participants who had **NOT** undergone training to get information on the utilization by/impact on them and their performance, on the training imparted to the participants on surveillance, and outbreak response.
- Indepth interviews of Senior Public Health Managers and Policy Makers from the State of Orissa and Tamilnadu were conducted to understand their assessment of the utility and effectiveness of the SEPR training imparted by NIE.
- During July-August final analysis of the responses to questionnaires commenced. A total of 69 responses out of 89 were received i.e. (70%)
- The findings of this evaluation study were presented in the workshop on "Human Resource Needs and Development in Epidemiology for Public Health", II Epidemiology Week, at NIE, Chennai, October 2003
- An abstract of this evaluation study were submitted to the SEA-WPR Biennial TEPHINET Conference in Manila, Phillipines, November 2003.
- The abstract was accepted for a poster presentation
- This poster presentation was assessed as an "Outstanding" presentation by the judges and the authors awarded a prize for the same
- It was also stated that this poster presentation should be submitted to the Beijing Conference in November 2004 for consideration for oral presentation to enable a discussion on the methodologies adopted
- It was further recommended that this evaluation study is worthy of being published in a reputed journal. In this regard Dr. Elliott Churchill and Dr. Rubina Imtiaz have offered to assist the authors in editing and fine tuning the paper as well as publishing the same in reputed international journals
- The results of this study have been further analysed using appropriate statistical tests to verify significance of results obtained.
- On the whole the findings of this evaluation study suggest that the short term training programmes have been effective in strengthening the capacity of Public health Professionals with respect to surveillance related activities and outbreak management both quantitatively and qualitatively.

ACTIVITIES PLANNED

1. As recommended above it is proposed to submit this evaluation study for oral presentation to the Global TEPHINET Conference at Beijing, China, November 2004
2. A write up of this evaluation study is being undertaken and is expected to be ready as a first draft by July 2004

By December 2004 it is hoped that this evaluation study will be submitted as paper for publication to a suitable international journal(s).

CAUSE OF DEATH BY VERBAL AUTOPSY IN TAMIL NADU

The results of the pilot study on "Cause of death by Verbal Autopsy in a district in Tamil Nadu" was presented in the Annual Report for 2002. It was decided that the Main Study on "Cause of death by Verbal Autopsy in a district in Tamil Nadu" had to be initiated in one district of each of the four zones in Tamil Nadu. Following is the report of the study.

One district viz., Kancheepuram and Tiruvallur, Virudhunagar, Tiruchirapalli and Salem, from each of the four zones; north, south, central and west respectively, is selected. The first round of the survey in the 30 selected villages of Kancheepuram (and Tiruvallur) district of north zone is over and the second round of survey in those villages is in progress. The data entry is through Epi-info software.. The survey in the selected villages of Salem district is initiated from 1st December 2003.

Recruitment of additional staff:

Two posts each of Research Associate (RA) (Medical) and Senior Research Fellow (SRF) and three posts of Field Investigators (FI) were sanctioned. We recruited two SRFs and three FIs. We experienced difficulty in recruiting the two RAs (Medical), as there were no applicants with prescribed MD qualification.

Training of the new project staff

Theoretical as well as field training was imparted to the newly recruited staff. At present, the newly recruited staff are independently eliciting information on cause of death in the selected villages of Kancheepuram and Tiruvallur as well as from Salem districts. One supervisorfrom NIE is posted on rotation basis to supervise and ensure smooth functioning of the projectwork in each district.

Field Survey:

First round of the survey in the 30 selected villages of Kancheepuram and Tiruvallur was completed. The second round of survey in the villages is in progress. So far, information on cause of death was elicited for 692 deaths that occurred in 30 villages/towns with recall period of six months. There are 20 stillbirths, 32 neonatal deaths, 24 child deaths (29 days-5years), 5 maternal deaths (15-49 women) and 611 adult deaths (Above 5 years).

Prematurity (35%) was the main cause among stillbirths. The next major cause (30%) among stillbirths was due to maceration. Out of 32 neonatal deaths, 12 (37.5%) were due to asphyxia, 8 (25%) were due to prematurity. Five (20.8%)out of 24 child deaths were due to diarrhoea and dysentery. Three child deaths were due to accidents and congenital deformities. Out of the 611 adult deaths, 177(29.0%) were due to cardio vascular diseases (CVD), 63(10.3%) due to accidents, 58 (9.5%) due to senility, 55 (9.0%) due to cancer, 53 (8.7%) due to pulmonary tuberculosis, 29 (4.7%) due to suicides, 28 (4.6%) due to renal failure, 5 due to AIDS and the rest were due to other causes.

The details are given in the following tables:

TABLE 1. AGE-SEX DISTRIBUTION OF DEATHS

Age	Males	Females	Total
0	16	29	45
1-4	8	3	11
5-14	10	9	19
15-54	139	83	222
55+	208	167	375
Total	381	291	672

TABLE 2. TYPE OF DEATHS COVERED

Type of Death	Males	Females	Total
Still births (Sb)	15	5	20
Neonatal deaths (Nd)	10	22	32
Child deaths (Cd)	14	10	24
Maternal deaths (Md)	-	5	5
Adult deaths (Ad)	357	254	611
Total	396	296	692

TABLE 3. TYPE OF DEATH BY RECALL PERIOD

Recall period	Sb	Nd	Cd	Md	Ad	Total
Below two weeks	0	1	0	0	7	8
1 month	0	1	0	0	7	8
2 months	0	4	1	0	33	38
3 months	1	2	1	0	48	52
4 months	3	1	2	0	79	85
5 months	2	5	3	0	66	76
6 months	14	18	17	5	371	425
Total	20	32	24	5	611	692

TABLE 4. CAUSE OF DEATH FOR STILLBIRTHS (Sb)

Cause of death	Sb
Prematurity	7
Antepartum haemorrhage	1
Macerated	6
Obstructed labour	3
Premature rupture of membrane	2
Undetermined	1
Total	20

TABLE 5. CAUSE OF DEATH FOR NEONATAL DEATHS (Nd)

Cause of death	Nd
Asphyxia	12
Prematurity	8
Congenital Deformity	4
Low Birth Weight	3
Birth trauma	1
Acute lower respiratory infection	1
Hypothermia	1
Hepatitis	1
Tetanus	1
Total	32

TABLE 6. CAUSE OF DEATH FOR CHILD DEATHS (Cd)

Cause of death	Cd
Diarrhoea/Dysentery	5
Other Congenital abnormalities	3
Accidents	3
Congenital Heart disease	2
Hepatitis	2
Suicide*	2
Meningo Encephalitis	1
Prematurity	1
Malnutrition	1
Whooping cough	1
Hydrocephalus	1
Epilepsy	1
Undetermined	1
Total	24

* Parents killed themselves and their children

TABLE 7. CAUSE OF DEATH FOR MATERNAL DEATHS (Md)

Cause of death	Md
Eclampsia	1
Obstructed Labour	2
Puerperal sepsis	1
Postpartum Haemorrhage	1
Total	5

TABLE 8. CAUSE OF DEATH FOR ADULT DEATHS (Ad)

Cause of death	Ad
CVD	177
Accident	63
Senility	58
Cancer	55
Pulmonary Tuberculosis	53
Suicide	29
Renal Failure	28
Acute abdomen	19
Undetermined	17
Asthma	14
Gastroenteritis	12
Bronchitis / COPD	12
Diabetes	11
Diarrhoea	7
Anaemia	6
Hepatitis	6
AIDS	5
Meningo Encephalitis	4
Depression	4
Gullain barre syndrome	3
Rabies	3
Ankylosing spondylitis	2
Multiple sclerosis	2
Epilepsy	1
Mastoditis	1
Osteoarthritis	1
Otitis media	1
Parkinson’s disease	1
Poliomyelitis	1
Typhoid	1
Puerperal sepsis	1
Pneumonia	1
Homicide	1
Maniac Depression	1
Food poisoning	1
Tetanus	1
Total	611

Thirty areas (villages and towns) were selected from each of the remaining two selected districts viz., Virudhunagar and Tiruchirapalli. During the first round 30 areas are to be covered to elicit cause of death for the deaths that occurred during the first six months from the date of survey. Field teams will revisit later during the second round these selected areas to get information on cause of death for the deaths that occurred during the later part of the year. Logistics of the survey are being worked out. Actual survey in the districts is initiated in May 2004.

MULTICENTRIC FEASIBILITY STUDY ON THE USE OF INTRADERMAL ADMINISTRATION OF TISSUE CULTURE ANTIRABIES VACCINES IN INDIA

Rabies is a highly fatal disease and is an important public health problem in India. It is estimated that 65% of all reported cases of human rabies worldwide are from India. Till recently, anti rabies vaccine prepared from sheep brain was used widely for post–exposure treatment. In view of side effects, this is being phased out to be replaced by Tissue culture derived vaccines. These Human diploid cell rabies vaccine and similar tissue culture-produced vaccines (TCARV) given by intramuscular route are too expensive for widespread use in India, but alternative regimens by intradermal route, can reduce the cost of post-exposure treatment by 60%. Elsewhere, multiple-site intradermal injections of tissue culture vaccine have proved to be effective, economical and safe for widespread use.

To assess the safety and immunogenecity of four indigenously manufactured TCARVs against the standard Aventis vaccine given intramuscularly.

This is a multicentric Phase II study in human healthy volunteers.

a) Participating centres

The following centres participate in the study:

1. Safdarjung Hospital (**SJH**), New Delhi (Dr. N. D. Deshpande)
2. Municipal Corporation of Delhi (**MCD**), Delhi (Dr. Ashok Rawat)
3. Institute of Preventive Medicine (**IPM**), Hyderabad (Dr. G. Sampath)
4. Pasteur Institute (**PIK**), Kolkata (Dr. S.S. Datta)
5. Stanley Medical College Hospital (**SMC**), Chennai (Dr. S. Shantha)

b) Centre for lab investigations

Pasteur Institute of India, Coonoor is the centre for estimating antibody titer of serum samples.

c) Coordinating Centre

National Institute of Epidemiology (NIE), Chennai is the coordinating centre.

d) Selection of subjects

10 healthy volunteers are recruited for each of the five study groups as per the inclusion and exclusion criteria after obtaining a signed informed written witnessed consent.

Total duration of the study is approximately 1½ years. Intake to the study is to be completed in about three months. Follow-up of all volunteers will be completed in the next one year.

Vaccines used

Intramuscular route

1. Standard French PVRV (Aventis) - Freeze-dried

   Intradermal route - Indigenous vaccines
2. Purified vero cell vaccine (PVRV) – Freeze-dried – ABHAYRAB, Human Biologicals Institute, Ooty.
3. Purified vero cell vaccine (PVRV) – Freeze-dried – (Trade name), Pasteur Institute of India, Coonoor.

4. Purified duck embryo vaccine (PDEV) – Freeze-dried – VAXIRAB, Cadila Health Care Ltd., Ahmedabad.
5. Purified chick embryo cell vaccine (PCECV) – Freeze-dried – RABIPUR, Chiron Vaccines, Gujarat.

Intramuscular vaccination schedule

One dose (0.5 ml) of vaccine after reconstitution with the diluent is administered on Days 0, 3, 7, 14 and 28 (Essen schedule).

Intradermal vaccination schedule

2-site (on days 0, 3 and 7) intradermal method with a dose of 0.1ml per site is adopted. After reconstitution with the diluent one dose per site is given intradermally on Days 0, 3, 7, 28 and 90.

SERUM SAMPLES

Intravenous blood samples (5 ml) is drawn on Days 0, 14, 28, 90, 180 and 365 for estimating antibody titer. Serum samples (divided in pair aliquots), after separation, are stored at –20º C in a deep freezer and sent to NIE. These are sent to the Coonoor laboratory after coding.

All serum samples are processed at Pasteur Institute of India, Coonoor. Rapid Fluorescent Focus Inhibition Test (RFFIT) is used to estimate antibody titer.

Proportion of volunteers with protective rabies antibody titers (≥ 0.5 IU / ml) on Days 14, 28, 90,180 and 365.

PROGRESS OF STUDY

Participating center	**No.of volunteers recruited**	**No. of samples received**
Safdurjung Hospital,Newdelhi	42	118
Municipal Corporation of Delhi	45	139
Inst. of Prev.Med. Hyderabad	20	-
Pasteur Institute, Kolkota	30	58
Stanley Medical College, Chennai	52	185

Intake for a few groups, follow up examinations and sample collections for those who are already recruited are going on. Data entry and laboratory tests are in progress. Results are awaited.

MULTICENTRIC STUDY OF INTERFERON-GLYCYRRHIZIN COMBINATION THERAPY AND INTERFERON-RIBAVIRIN COMBINATION THERAPY IN THE MANAGEMENT OF CHRONIC HEPATITIS C

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 glabora*) 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 of the study is 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 are to evaluate the side-effects / toxicity of the trial drugs, to evaluate the cost effectiveness of the two combination therapies and to study the role of certain identified factors, viz., genotype, viral load, 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 trial is progressing in all nine participating centers. 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 2004, we have received a total of 111 forms of admission to the trial from various centers as follows: PGI – 17, AIIMS – 14, MAMC – 16, GBPH – 10, MCLDD – 14, SGPGI – 12, IPGMER – 11, BHMRC – 4 and DCMSH – 13.

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. Available data was analyzed without decoding of the treatment regimen. Results are encouraging in terms of virological and biochemical parameters. The study is in progress at all nine centres.

INTERVENTION STUDY TO FAVOURABLY INFLUENCE CVD RISK FACTORS IN INDUSTRIAL WORKERS IN CHENNAI CITY

(PUBLIC - PRIVATE COLLABORATIVE STUDY)

National Institute of Epidemiology, Sundaram Medical Foundation, Chennai

& ARMA Clinical Services and Hospitals Private Ltd., Chennai.

Base-Line Survey Report

National Institute of Epidemiology in collaboration with Sundaram Medical Foundation has initiated the Cardio Vascular Diseases (CVD) risk factors study, at Brakes India Ltd, in Padi, Chennai. This study is unique, in the sense, it is being carried out in a captive population available in an industrial set-up. This industry has centrally located in-house medical centre, wherein the health records of all the employees are available. Further, there is also a referral centre for providing specialist care.

The objectives of base-line survey are to estimate the prevalence of CVD risk factors, in the study population and to identify a cohort for surveillance for the development of cardiovascular diseases. The data collection commenced on 8th July 2003 and completed on 9th March 2004. The data on socio economic status, tobacco consumption, alcohol consumption, stress, depression, physical activity, diet and physical measurements were collected from all 1163 industrial workers. Blood sample for bio-chemical measurements was collected from 1084 (93.2%) industrial workers.

Incidence of Hypertension, Type-2 Diabetes Mellitus and Cardiovascular diseases (Myocardial infarction etc) for the year 2002 and 2003 for the study population were collected from 1096 worker's individual medical records. Number of new cases for Hypertension, Type-2 Diabetes Mellitus and Cardiovascular diseases (Myocardial infarction etc.) reported were 22, 35 and 8 for the year 2002 and 24, 26 and 5 for the year 2003 respectively (Fig. 1). It is observed that the new cases of the above-cited diseases were similar in the past two years.

Base-line Survey Report

The base-line data analysis is in progress. Some of the findings are presented in this report. In all, we have covered 1163 workers from different grades of employment. The respondent's age varied from 18 to 69 years. The mean ± s.d. for age is 42.5 ± 12.84. However 38% were in 45-54 age group and only 19.1% were above 55 years of age. (Fig. 2).

Workers were predominantly males (98.8%). It was found that 78.4% of the industrial workers were married. The family size of less than five members was 62% and above five members was 38%. It was observed that more than 90% were educated above primary school. Regarding socio economic status, 99.7% were in "middle& high" socio economic status category.

It was reported that 14.6% and 9% of them were suffering from diabetes mellitus and hypertension respectively. Only 3.6%, 2.8% and 0.1% gave history of myocardial infarction, peripheral vascular disease and stroke respectively. It was reported that 26.6%, 34.3%, 10.9%, 4.3% and 9.8% were having family history of hypertension, diabetes, myocardial infarction, stroke and sudden death respectively (Table 1). It was reported 456(39.2%) of them had ever consumed tobacco.

Regarding type of Tobacco consumption 397(87.1%) reported cigarette smoking and smokeless tobacco consumption varied from 0.7-12.5% for different varieties (Table 2). Mean age at which smoking started was 24.5 $\pm$ 7.4 years. Mean duration of cigarette smoking was 15.8 $\pm$ 11.5 years. It was observed that 45% of them had history of ever-consumed alcohol.

The stress at work place was assessed by "Likert scale"on the basis of "Work demand", "Job control" and "Effort reward imbalance". It was noted that the stress due to "Job strain" was intermediate in almost all subjects (97.7%). As regards to "Effort reward imbalance", it was present among 70% of the subjects. However, the intermediate level household stress was only 21.1%. When compared to the magnitude of stress, the depression among the subjects was only 11.7%

Average nutrient intake per day was estimated through dietary assessment by "Semi Food Frequency Questionnaire (SFFQ). It was observed that mean intake of macronutrients such as carbohydrate, fat and protein was 604.2 $\pm$ 205.1, 54.8 $\pm$ 27.3 and 107.8 $\pm$ 42.0 grams/day respectively. Mean energy intake was found to be 3992 $\pm$1163 kcal per day. Regarding the type of oil consumption, it was found that 17.4 $\pm$ 15, 9.3 $\pm$ 7.8, and 5.3 $\pm$ 8.3 grams per day of polyunsaturated fatty acids, monounsaturated fatty acids and saturated fatty acids respectively. With respect to intake of micronutrients such as calcium, phosphorus and iron, it was found to be 700.5 $\pm$ 375.8, 970 $\pm$ 507.5 and 19.2 $\pm$12.3 mg per day respectively. The mean fibre intake was found to be 7.3 $\pm$ 5.2 grams per day.

It is observed from the blood pressure measurements that 27.6% of individuals were suffering from hypertension of varying Grades as per WHO criteria. (Figure 3). Body mass index was computed for 1162 individuals and one individual is physically handicapped. It was noted 514 (44.2%) and 186(16%) were found to be having increased risk and high risk for cardiovascular disease as per WHO cut off levels for Asians. (Table 3). Waist hip ratio (WHP) was estimated for all subjects and found that 823(71%) were having central obesity. Further analysis of data is in progress.

TABLE 1

REPORTED MEDICAL HISTORY
(N= 1163)

Description	Personal History		Family History	
	No.	%	No.	%
Hypertension	105	9.0	309	26.6
Diabetes	170	14.6	398	34.3
Myocardial Infarction	42	3.6	127	10.9
Stroke	1	0.1	50	4.3
Peripheral Vascular disease	33	2.8	-	-
Sudden death	-	-	114	9.8

TABLE 2

FORM OF TOBACCO CONSUMPTION
(N = 456)

Description	No.	%
Cigarette	397	87.1
Beedi	10	2.2
Chewing	57	12.5
Snuff	13	3.1
Pan with Zarda	44	9.6
Others	3	0.7

TABLE 3

BODY MASS INDEX (WHO Indian Cut off levels)
(N = 1162)

BMI Classification	*No*	%
Below Normal (< 18.5 Kg/m^2)	61	5.2
Normal (18.5 – 23 Kg/m^2)	401	34.5
Increased Risk (23.1 – 27.5 Kg/m^2)	514	44.2
High Risk (> 27.5 Kg/m^2)	186	16.0
Total	1162	99.9

Fig. 1 INCIDENCE OF HYPERTENSION,TYPE-2 DM AND CVD IN BRAKES INDIA, CHENNAI. (N = 1096)

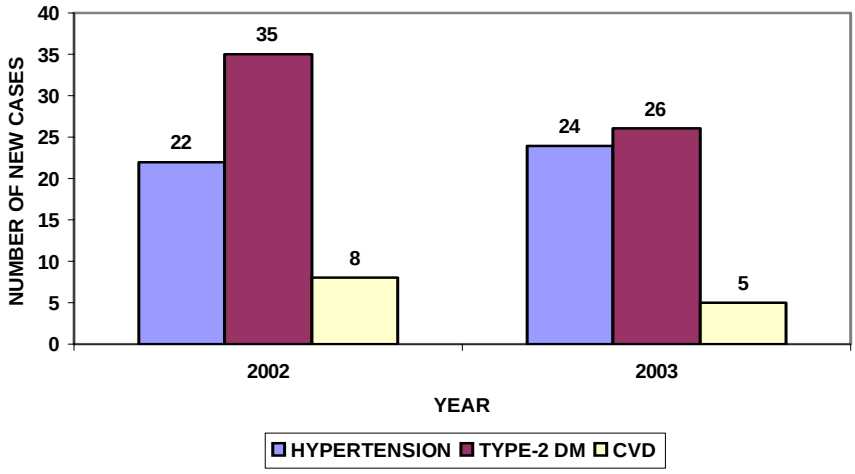


Fig. 2 AGE DISTRIBUTION

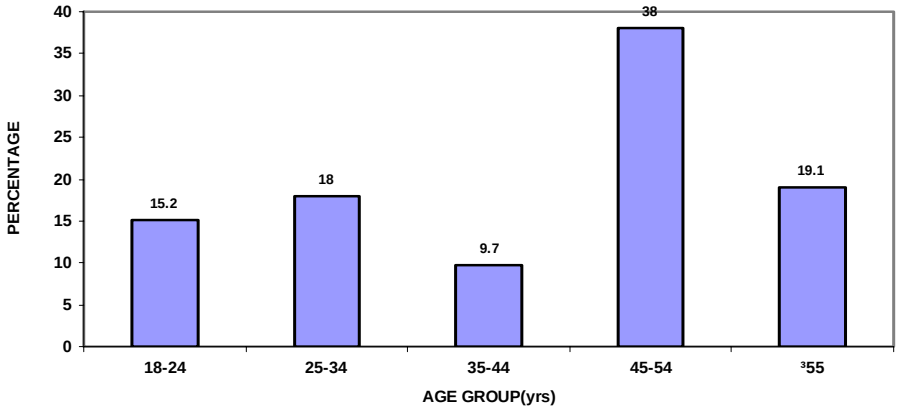
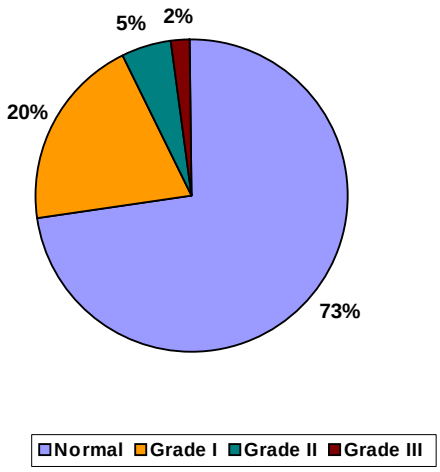


Fig. 3 HYPERTENSION BY WHO CLASSIFICATION



EPIDEMIOLOGY OF REPRODUCTIVE TRACT INFECTIONS (RTIS)/ SEXUALLY TRANSMITTED INFECTIONS (STIS) IN A RURAL COMMUNITY ADJACENT TO TRUCK STOPS

This is a longitudinal three-phase study in a rural population surrounding two major truck stops on National Highway No. 4. The aims are to describe epidemiology of STIs including HIV in the rural population adjacent to major truck-stops on a National Highway, establish social & behavioral correlates of STIs, estimate level of awareness about STIs, to initiate interventions for controlling STIs and to assess the impact of interventions objectively.

The study area covers twenty-five villages - with a population of about 37, 000, adjacent to (in a radius of 10 kms.) Santha Vellore and Sendhamangalam truck stops . They are located at about 55 kms. away from Chennai city. Seven villages namely, Mambakkam, Kunnam, Santhavellore, Pappankuzhi, Sendha mangalam, Ramanujapuram and Madhuramangalam are the sample villages.

The study is divided into three phases. Phase I has two parts namely, a) Feasibility study and b) Baseline survey. Feasibility study had 28 Focus Group Discussions among various groups like men, women, male-youth, female-youth, male-local leaders, female- local leaders, Mixed-(male & female) local leaders and adults, conducted in all the study villages.

Report of this Feasibility study has been already presented last year. All the Group participants (both males and females) informed that they would be readily willing to participate in our proposed main study and extend their full co-operation.

This report presents the Baseline survey of the study

The Objectives of this survey are to estimate the prevalence of symptomatic RTIs/STIs among eligible adults (15-49 yrs) in villages adjacent to and away from highway truck stops, to evaluate the level of awareness of STIs and HIV in a rural population and to understand the health seeking behaviour .

Door to door survey was done by trained male and female field investigators for collecting the data on demographic, socio-economic, illnesses and health seeking behaviour, by using qualitative and quantitative data collection methods.

Before proceeding with the data collection consent was taken from all the study subjects. If the respondents were minors, consent was taken from their parent or guardian. There was no force applied in collecting data from the study subjects. All symptomatic RTIs/STIs were identified and referred to the nearby/preferred Government health facility. The Medical Officers of these centres were visited by the investigators of NIE & briefed about the purpose of the study and were requested for their co-operation in treating the referred symptomatics. The symptomatics who visited the government centres for treatment were paid for their conveyance (bus fare) by NIE on production of their OP chit identity and bus tickets.

The investigators carried minimum medicines (Paracetamol and multivitamins) for minor ailments to be distributed for needy persons belonging to the community.

Preliminary information:

The survey work was started on 16th July 2003 at Mambakkam village. Data collection was over on 5th July 2004 after covering all the sample villages (n=7). From the day- to- day recording, this preliminary information is provided.

Total eligibles (15 – 49 yrs.) covered were (Table – 1) 5,279. In this, eligibles upto a radius of 3 kms from the truck stops, were 2,402; beyond 3 kms and up to 6 kms were 1,394 and beyond 6 kms and up to 10 kms were 1,483. Overall reported symptomatic RTIs/STIs were 699 (13.2%). From this table we could see as the distance increased from the truck stops, the prevalence of symptomatic RTIs/STIs was on decrease; Nearer to the truck stops, the prevalence of symptomatic RTIs/STIs was comparatively on increase.

Interim Report

Out of the 7 villages selected as sample, this interim report presents data for 6 villages namely, Mambakkam, Kunnam, Santhavellore, Sendhamangalam and Pappankuzhi. Total number of households covered was 1,549 (Table-2). In these households number of eligible persons (15 – 49 years) interviewed were 3,325.

Eligible males interviewed were 1,614 (49%) and females were 1,711 (51%).

Common illnesses and treatment seeking behaviour reported by males:

Males reported (Table 3) fever (76%), headache (46%), Cold (40%), urinary tract infection [UTI] (22%) and stomach ache (19%) as common illness in them (Table-3).

For fever (48%), headache (56%) and cold (34%), respectively they purchased tablets from medical shops or local petty shops. For UTI none of them mentioned of seeking any effective treatment. They were taking either herbal treatment (32%) or some local native treatment- like taking sugar water, soda or lime juice (38%). For stomach ache 29% mentioned going to private doctors, whereas 33% of them reported taking soda or aerated water or seeking other treatment (11%).

Common illnesses and treatment seeking behaviour reported by females:

Females reported (Table 4), fever (60%), head ache (55%), cold (27%), white discharge (26%) and stomach ache (25%), as common illness in them (Table-4).

For fever (47%)and cold (41%), they sought private doctor's service for remedy. For head ache 50% mentioned buying tablets from medical shop or local petty shop. For the complaints of white discharge 45% reported of not taking any treatment. For stomach ache 37% mentioned of taking soda or aerated water. Only 24% and 13% of women with stomach ache and white discharge respectively reported of going to private doctor.

Symptomatic RTI/STIs : Out of the total 1,614 males and 1,711 females, 85 males (5%) and 323 females (19%) were symptomatics. So a total of 408 (12%) RTI/STI Symptomatics were reported in the baseline survey (Table-5).

Among the males, the major complaints mentioned were (Table-6), urinary tract infection (59%, n=50), itching and burning in the genital area (29%, n=25),or foul smelling discharge from genitals (20%, n=17).

In females, major complaints mentioned were abnormal white discharge (58%, n=188), hip pain and swollen lymph glands in the groin (49%, n=157), continuous pain in genitals & lower abdomen (46%, n=148) and foul smelling discharge from genitals (45%, n=144).

Among the 408 persons who reported symptomatic RTIs/STIs at the time of interview, only 53 (13%) were reported to be taking treatment (Table – 5). In this 81% were taking allopathic treatment. And, in this 16 (30%) were taking treatment from Govt. health facility and 37 (70%) from private doctors. Among the identified symptomatics who were not taking any treatment (n=355), 314 (89%) opted for free treatment from Govt. health facility, all of whom were referred to nearby or preferred Govt. health facility. The remaining 41 persons (11%) were not referred, as they wanted to go to private doctors, take alternate treatment or decide later.

Since 14th of July, (after one year of Baseline survey) we have started a survey to find the incidence of symptomatic RTIs/STIs in the same cohort. Details will be present in the meeting.

Table 1

Eligibles (15 – 49 yrs) Completed

(Preliminary information)

*** Survey started on 16th July 2003** **Completed on 5th July 2004**

Distance	Eligibles			Symptomatic RTI/STI	
	To be completed	Available	Already completed	No.	%
Up to 3 kms. Santhavellore Sendhamangalam Pappankuzhi	**2,091**	**2,944**	**2,402**	**350**	**14.6**
<3 kms – 6kms Mambakkam Kunnam	**1,453**	**1,499**	**1,394**	**189**	**13.6**
<6 kms – 10 kms Ramanujapuram Madhuramangalam	**1,180**	**1,645**	**1,483**	**160**	**10.8**
Total	**4,724**	**6,088**	**5279**	**699**	**13.2**

Table: 2

Eligible persons (15 –49 years)	**3325**
Males	1614
Females	1711

Table: 3

Common illness reported by Males

	Nos.	**%**
Fever	1229	76.1
Head ache	747	46.3
Cold	655	40.6
UTI	356	22.1
Stomach ache	306	19.0
Treatment sought for :		
Fever		
Medical / Petty shop	588	47.8
Private Doctors	511	41.6
Hospitals	32	2.6
Others	98	8.0
Head ache		
Medical / Petty shop	419	56.1
Private Doctors	135	18.1
Pain balm / Ointment	99	13.3
Native treatment	44	5.9
Others	50	6.7
Cold		
Medical / Petty shops	222	33.9
Private Doctors	220	33.6
No treatment	62	9.5
Ointments	29	4.4
Ginger Juice	25	3.8
Others	97	14.8
UTI		
Herbal/Native treatment	115	32.3
Sugar water	75	21.1
Soda / Aerated water	42	11.8
Lime Juice	17	4.8
Others	107	30.1
Stomach ache		
Soda / Aerated water	100	32.7
Private Doctors	89	29.1
Native treatment	34	11.1
Others	83	27.1

Table : 4
Common illness reported by Females

	Nos.	%
Fever	1026	60.0
Head ache	937	54.8
Cold	459	26.8
White discharge	436	25.5
Stomach ache	427	25.0
Treatment sought for :		
Fever		
Private Doctors	480	46.8
Medical / Petty shop	429	41.8
Hospitals	69	6.7
Others	48	4.7
Head ache		
Medical / Petty shop	468	49.9
Pain balm / Ointment	276	29.5
Private Doctors	119	12.7
Others	74	7.9
Cold		
Private Doctors	186	40.5
Medical / Petty shops	93	20.3
Hospitals	57	12.4
Pain balm / Ointment	47	10.2
Ginger Juice	32	7.0
Others	44	9.6
White discharge		
No treatment	197	45.2
Private Doctors	57	13.1
Native treatment	42	9.6
Hospitals	40	9.2
Others	100	22.9
Stomach ache		
Soda / Aerated water	159	37.2
Private Doctors	103	24.1
No treatment	59	13.8
Hospitals	26	6.1
Native treatment	24	5.6
Others	56	13.1

Table : 5

Present history of Genital problems

	No.	%
No. of cases with RTI / STI symptoms	408	-
Males	85	20.8
Females	323	79.2
Nos. taking treatment	53	13.0
Nos. not taking treatment	355	87.0
Treatment type :		
Allopathy	43	81.1
Others	10	18.9
Treatment taken at		
Govt. Hospital	16	30.2
Private Hospital	37	69.8
Location of the hospitals		
Within the village	11	20.8
Outside the village	39	73.6
Chennai	3	5.7
Nos. opting for free treatment (out of 355 not taking any treatment)	314	88.5
Referred for free treatment at PHC		
Sriperumbudur	188	59.9
Madhuramangalam	90	28.7
Kancheepuram	29	9.2
Walajabad	4	1.3
Others	3	1.0

Table : 6

Present RTI / STI symptoms reported

Males :	**Nos.**	**%**
Pain / burning during urination (a feeling to pass urine often)	50	58.8
Itching / burning	25	29.4
Foul smelling discharge from genitals	17	20.0
Sores, blisters or Ulcers	5	5.9
Swelling rashes	2	2.4
Females		
Abnormal white discharge	188	58.2
Hip pain, swollen lymph gland	157	48.6
Continuous pain in genitals & lower abdomen	148	45.8
Foul smelling discharge from genitals	144	44.6
Itching / burning	92	28.5
Pain / burning during urination (a feeling to pass urine often)	57	17.6
Unbearable pain during intercourse	36	11.1
Sores, blisters or Ulcers	15	4.6
Swelling, rashes	14	4.3

PSYCHO-SOCIAL CHALLENGES FACED BY HIV INFECTED PERSONS ATTENDING INSTITUTE OF VENEREOLOGY, GOVT. GENERAL HOSPITAL, CHENNAI

Aim of this study is to understand the impact of HIV positive status, personally, emotionally and socially on the infected individuals.

All HIV infected persons attending Institute of Venereology, Govt. General Hospital, Chennai were interviewed personally using interview guide through in-depth interviews. Before proceeding with the interview, the respondents were informed about the purpose, and informed consent was obtained. The study was started in November 2001 and it is ongoing. Data has been collected for 553 persons (364 males & 189 females) so far.

Interim Report:

More than three fourths of the respondents (80%) mentioned Tamil Nadu (Table 1) as their native place and most of the patients' (82%) current place of stay was also Tamil Nadu. Thirty three per cent were from rural areas and 19% from out station - urban. Nearly half (46%) of the patients were in the age group of 21 to 30 yrs. of age. In this 35% were from males and 67% from females. Most (91%) of them were Hindus. Nearly two thirds (61%) were married. In females, 32% were widowed. In all 26% were illiterates; in this more were from females (35%). Fifteen percent of the males were truck/lorry/Auto drivers. Nearly half of the respondents (45%) had less than Rs. 1000 as their monthly income. Sixteen per cent were staying away from their family.

When the study subjects came to know about their HIV positive status, their initial reactions varied. It was a shock for 28%; 25% mentioned that their initial reaction was sad or upset. Females (Fe=37%, Male=24%) were more shocked, while more males were more sad or upset (Males=44%, Fe=21%). There were other reactions like, fear/fear of death (13%) and depression (3%). There was no reaction in 13% of the individuals.

Overall 35% of them did not disclose about their HIV positive status to anybody. Among the married 18% have not disclosed to their spouse, for reasons like, spouse may leave (26%), family problems may arise (26%) or spouse may refuse for sex (16%). With respect to disclosing their HIV positive status initially, 26% informed to their spouse, 15% informed to their mother or father and 9% to their brother or sister. Nine per cent have informed to other family member (in-laws/relatives) and, 6% to their friends.

In males, major source of getting this infection was reported (56%) as from sex workers and in females it was reported as from their husbands (81%). In all, sexual route was mentioned by 89% of the infected persons; 4% mentioned of blood transfusion/ unsterilized needles; another 3% gave irrelevant responses and there was no response in 4% of the respondents.

Since getting this HIV infection 84% of them have mentioned that their life has changed. In this, 63% have said that they have either stopped having sex or reduced the sexual acts; 41% mentioned that they could not work as before; 38% said they could not eat as before due to health reasons and 24% reported of increased health problems.

Impact of HIV on the infected and their family:

The foremost problem mentioned due to HIV positive status was social stigma (45%). The other problems were, health problems (37%), financial problems (15%), family stigma (14%), inability to have sex (8%), fear of death (8%) and others (8%).

The impact on family were, children's future getting affected (22%), family problems (7%), Children's education (7%) & and others (10%). Fifty five per cent of the respondents mentioned their families did not have any problems due to the respondents' HIV positive status.

When they were asked about the biggest problem for HIV infected persons in general, social stigma (35%) ranked the foremost. Other problems mentioned were mainly health problems (31%), lack of proper treatment (30%), fear of death (9%), family stigma (6%) and financial problems (5%). For this, 62% mentioned that the Govt. should arrange for a cure for AIDS.

Table 1. Basic Characteristics of the Respondents

S. No.	Variables	Male (n=364) %	Female (n=189) %	Total (n=553) %
1.	**Native place**			
	Tamil Nadu	80	81	80
	Others (A.P & Karnataka)	20	19	20
2.	**Current place of stay**			
	Tamil Nadu	81	84	82
	Others (A.P & Karnataka)	19	16	18
3.	**Place of Residence**			
	Urban	33	26	30
	Semi-urban	19	16	18
	Rural	29	42	33
	Outstation-urban	19	16	19
4.	**Age (in yrs.)**			
	<= 20	1	5	2
	21 – 30	35	67	46
	31 – 40	49	22	40
	>40	15	6	12
5.	**Religion**			
	Hindu	91	93	91
	Muslim/Christian	9	7	9
6.	**Marital Status**			
	Single	24	1	16
	Married	63	56	61
	Separated/divorced	8	11	9
	Widowed	5	32	14

7.	**Literacy**			
	Literates	78	65	74
	Illiterates	22	35	26
8.	**Occupation**			
	Unemployed/Housewife	4	51	20
	Skilled workers	27	6	20
	Agricultural cooly	14	17	15
	Truck/Lorry/Auto drivers	15	-	10
	Building construction & other coolies	11	6	10
	Helper/Assistants	3	8	5
	Vendor/Sales man	7	3	5
	Others(Supervisor, own business, sex worker,etc.)	19	9	15
9.	**Monthly Income (in Rs.)**			
	<500	7	69	28
	500 – 999	17	18	17
	1000 – 1999	40	11	30
	2000 – 2999	23	2	16
	3000 & above	13	1	9
10.	**Staying**			
	With family	78	91	82
	Away from family	20	7	16
	No family	2	2	2

STUDY ON SEXUAL BEHAVIOUR AND DRINKING HABIT IN STD CLINIC ATTENDEES, OF GOVT. GENERAL HOSPITAL, CHENNAI.

This study aims to understand the relationship between the drinking habit and the sexual behaviour (risk behaviour) of the patients attending the STD clinic of Govt. General Hospital.

All STD clinic male attendees who have the exposure of taking drinks form the study subjects. Semi-structured interview schedule is being used for collecting the data. Before proceeding with the interview, the respondents were informed about the purpose of the study and informed consent was obtained. The study was started in May 2002 and it is still ongoing. Data has been collected for 365 men.

Interim Report : Among the study subjects 30% were aged 25 years or less than that. Forty percent were single, 50% married and 5% were widowed or separated. Eighteen percent were illiterates. The interim analysis showed that, for 67%, their age at first drink was 20 years or less. Twenty five percent of the patients had their first drink between the age 21 and 25 years. More than three fourths (78%) of the patients mentioned enjoyment as the reason for their first drink and 83% reported it was with their friends. Eleven percent said that they used to drink daily while 20% mentioned, bi/tri weekly consumption. Age at first sexual intercourse for 50% of the study subjects was 20 years or less. Seventeen percent had 2 or more sexual partners in the last 3 months. Fifty eight percent of the patients had a desire to have sex after drinking. Among them 13% said that they always had the desire to have sex after a drink; 8% said often and 50% mentioned sometimes they used to have that desire. When they were questioned with whom they would like to have sex after a drink, 34% mentioned, with wife and 31% mentioned of female sex workers. Sixty eight percent of them reported of never using condom when they had sex after the drink. More than three fourths (80%) of the patients reported drinking brandy or beer; 63% mentioned of beer only, 57%, toddy and 42% arrack. Because of drinking 78% reported of interpersonal problems with their family and major problem of health. Analysis is continuing

Voluntary Counselling and Testing Centre (VCTC)

NIE, ICMR, Avadi, Chennai

(From February 2002 – 8th July, 2004)

Background

Counselling and testing are important components of HIV prevention and care. Counselling and testing can increase self-perception of risk as well as assist individuals initiate behaviour change that reduce their risk of becoming infected or, if infected, prevent transmission to others. There are three VCTCs in the city of Chennai. However people from suburban areas do not have a nearby VCTC and they have to depend only upon these VCTCs for testing. In Avadi, a sub-urban area, about 25 kms. away from the city of Chennai, there are number of private medical practitioners, nursing homes, hospitals and, people of different cadre. The persons interested to go in for HIV testing from in and around Avadi area need to depend mainly on the HIV testing laboratories situated in the city. Having a VCTC at Avadi will cater to the needs of all these groups and also help us in the prevention of HIV infection. With this background, National Institute of Epidemiology (NIE) established a VCTC at Avadi, sponsored by Tamil Nadu State AIDS control Society on 30th Jan, 2002. This is a community based VCTC.

Recruitment so far:

The VCTC of NIE enrolled a total of 881 (Table 1.) clients since February 2002 to 8th July, 2004. The types of clients who attended the centre were, voluntary, after VCTC counsellor's visit and motivation and referrals from NGOs namely, SAHAI trust (IDUs & their contacts) and SWAM (MSM). Out of the total 881 clients, 547 (62%) were males, 319 (36%) females and 15 (2%) were eunuchs. In this 40 (5%) attended voluntarily, 606 (69%) attended after motivation and 235 (26%) were referred (17% from SAHAI Trust & 9% from SWAM) cases.

Table 1. Distribution of VCTC clients

Clients	Male (62%)		Female (36%)		Eunuch (2%)		Total		
	No.	Positive	No.	Positive	No.	Positive	No.	Positive	%
Voluntary	33	**01**	07	**01**	--	--	40	**02**	**5**
After Motivation	332	**13**	259	**16**	15	**03**	606	**30**	**5**
Referred: SAHAI Trust (IDUs)	100	**37**	53	**05**	--	--	153	**41**	**27**
SWAM (MSM)	82	**10**	--	--	--	--	82	**10**	**12**
Total clients	**547**	**11%**	**319**	**7%**	**15**	**20%**	**881**	**10%**	
Total positive		***61***		***22***		***3***		***86***	**10**

Observations

With respect to year wise attendance of clients to the VCTC, (Table 2. and Figure 1) we could observe, a marked increase in the number of clients attending after the counsellor's motivation. Since the VCTC is a community based centre and not situated in a Govt. Hospital, we could see a slight increase in the number of voluntary cases attending the centre. Increasing trend could be observed in the number of referred cases.

Table 2. Year wise distribution of VCTC clients

Year	**2002**			**2003**			**2004**			
Clients	**Voluntary**	**Motivated**	**Referred**	**Voluntary**	**Motivated**	**Referred**	**Voluntary**	**Motivated**	**Referred**	
									SAHAI	**Swam**
Male	05	98	-	09	109	20	19	125	80	82
HIV Positive	-	04	-	01	07	05	-	02	32	10
Female	02	17	-	03	91	10	02	151	43	-
HIV Positive	-	02	-	01	08	01	-	06	04	-
Eunuch	-	12	-	-	01	-	-	02	-	-
HIV Positive	-	02	-	-	-	-	-	01	-	-
Total	07	127	-	12	201	30	21	278	123	82
Total HIV positives	-	08	-	02	15	06	-	09	36	10

In all more males have attended the centre (Figure 2.) than the females and eunuchs. With respect to seropositivity in these clients, (Table 1. & Figure 3.) 11% of the males, 7% of the females and 20% of the eunuchs were found positive. And, among the voluntarily attended clients, 5% were positive, in clients who attended after motivation, 5% were positive and in the referred cases the seropositivity was 22% (27% in IDUs & 12% in MSM). Since the cases referred were injecting drug users and men having sex with men, involved in high risk behaviour, seropositivity was found higher than the other two categories.

Table 3. Routes of transmission of HIV in VCTC clients

Route of transmission	Voluntary		After Motivation			Referred			
	Male	Female	Male	Female	Eunuch	SAHAI Trust		SWAM Total	
						Male	Female	Male	%
Hetero	04	02	11	15	-	05	03	-	**40 46%**
Homo	-	-	-	-	03	-	-	09	**12 14%**
Mother to child	-	-	-	01	-	-	-	-	**01 1%**
Others (IDU & hetero/ bisexual)	-	-	-	-	-	31	02	01	**34 39%**
Total	**04**	**02**	**11**	**16**	**03**	**36**	**05**	**10**	**87**

With respect to routes of transmission (Table 3.) among the VCTC clients, in 46% it was reported as heterosexual, 39% reported of injecting drug (blood) and also through heterosexual contacts or being bisexuals and 14% through homosexual contacts and for 1% it was through mother-to-child transmission**.**

Follow-up activities

i) Supportive Counselling

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.

ii) 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.

- Tuberculosis Research centre/Tambaram Sanatorium
- Institute of Venereology, Govt. General Hospital
- Nearby Govt. Health facility

WHO INTERNATIONAL MULTI-CENTRIC STUDY ON

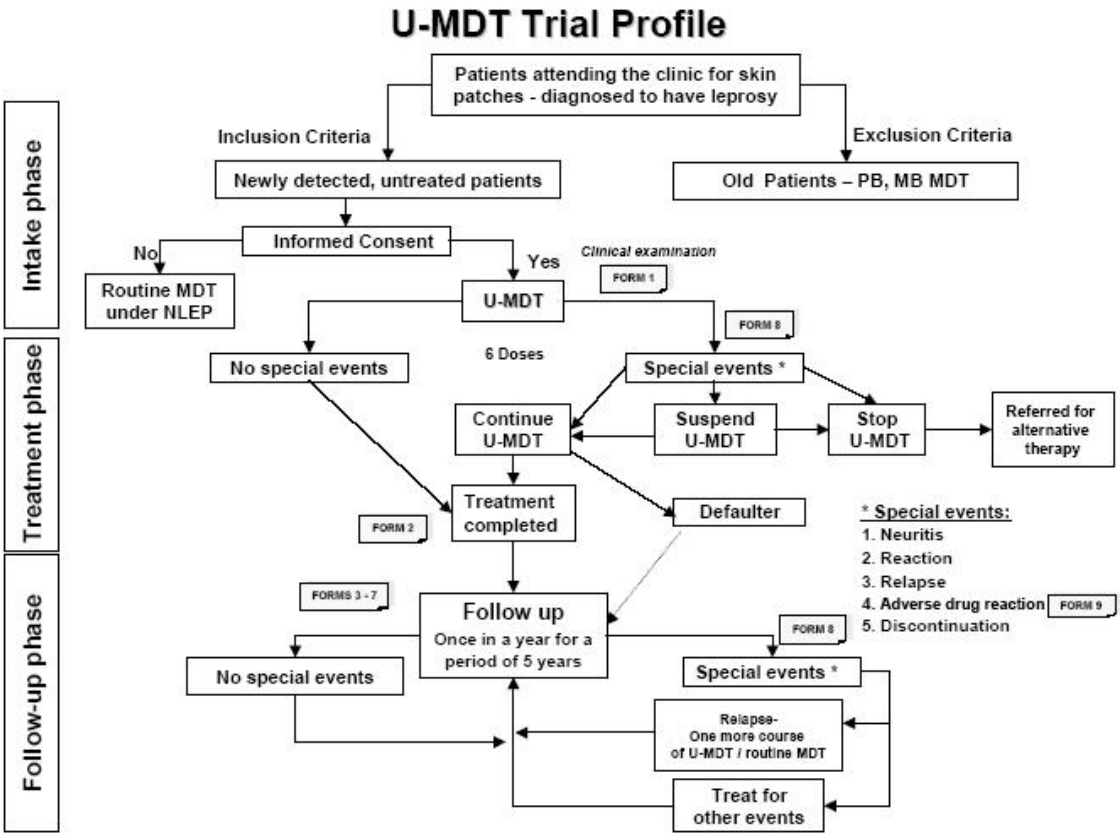
'UNIFORM MDT REGIMEN FOR ALL TYPES OF LEPROSY PATIENTS'

NIE is the international co-ordinating centre for the multicentric 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. Trial is conducted in 4 centres in India and one centre in China

To implement six-months' Uniform MDT under programme conditions for all types of leprosy patients and to closely monitor response in terms of an acceptable cumulative level of 5% relapse rate at the end of five years.

The study is an open design with emphasis on close monitoring of patients during treatment and for at least five years after completion of Uniform MDT.

Study outline (Figure):



The study requires a total of 2500 MB and 2500 PB patients. It is a multicentric study and each participating centre is expected to contribute a minimum of 500 newly detected, previously untreated patients (250 PB and 250 MB).

The following State Governments/ Research institutions are currently participating from India:

- Government of Maharashtra (Pune District)
- Government of Tamil Nadu (Tiruvannamalai and Villupuram Districts)
- Central JALMA institute for Leprosy, Agra (Kanpur)

Internationally, Srilanka is about to join the study. Bangladesh and Myanmar have evinced keen interest in the study.
Nationally, two centres from New Delhi have shown interest in participating the study.

Workshop for Principal Investigators:

Workshop for the Principal Investigators' (P.I.) of the participating centres (Both Indian and Chinese) was conducted at NIE during 11,12 September 2003 with regard to study activities, such as selection of cases, clinical examination, filling up of proformae and follow-up procedures. Dr. Pannikkar (WHO, Geneva) and Dr. Shen Jianping (China) participated in the workshop.

Training of the field staff involved in U-MDT trial:

Training was given to all field workers, including District Leprosy Officers, Medical Officers, Statisticians, Paramedical Workers and Non-Medical Supervisors by the Principal Investigators at their respective centers during September to November 2003.

Number of patients enrolled: (Table 1)

Totally 1019 patients were enrolled into the study as on 23rd July, 2004 (666 PB; 336 MB; 19 pure neuritic patients). As recommended by Technical Advisory Group for Leprosy during its meeting in February, 2004, all the participating centres have been advised not to include pure neuritic patients in the study.

Table1. Number of patients enrolled for U-MDT trial, by gender and type of leprosy

Centre	Month study started	PB		MB		Total	Released from Treatment
		Male	Female	Male	Female		
Thiruvannamalai	Oct-2003	107	114	38	35	296*	64
Villupuram	Oct-2003	83	61	48	25	217	43
Pune	Oct-2003	99	74	50	41	278†	38
Agra (Kanpur)	Jan-2004	72	43	38	14	169‡	-
China	Nov-2003	9	4	37	8	59	5
	Total	370	296	211	123	1019	150

Includes pure neuritis patients * (n= 2) † (n=14) ‡ (n=2) (n=1)

CBMU - CLINICAL TRIALS MONITORING

EXTENDED MULTICENTRIC TRIAL OF VIJAYASAR (*PTEROCARPUS MARSUPIUM*) IN THE MANAGEMENT OF TYPE 2 DIABETES MELLITUS

Encouraged by the findings from the earlier trials of Vijayasar on newly diagnosed or untreated NIDDM cases, a flexible dose open trial of Vijayasar drug with 3g to 4g dosage was started by relaxing an inclusion criteria to include cases treated with single anti-hyperglycemic drug. But there was some indication to show that the dosage prescribed was **not** sufficient to control the plasma glucose. Hence, amendment was made in the protocol to allow the maximum dosage to 6g per day.

To assess the anti-diabetic effect of Vijayasar in the management of the following two groups of Type 2 diabetes patients:

(1) Uncontrolled by allopathic oral hypoglycemic drugs
(2) Controlled, but opted Vijayasar treatment.

Trial treatment

The trial treatment period is 20 weeks. Assessments will be done at weeks 2, 4, 6, 8, 12, 16 and 20. The starting daily dose will be 3g for 2 weeks. At week 2, if plasma glucose is not controlled, the daily dose will be increased to 4g for the next 2 weeks. At the end of this period (at week 4), if still not controlled, the daily dose will be increased to 5g for the next 2 weeks. If not controlled (at week 6) by this dose also, the daily dose will be further increased to 6g for the next 2 weeks. If the plasma glucose is not controlled (at week 8) even by this maximum dose, the patient will be labeled as 'treatment failure' and withdrawn from the trial. On the other hand, if the plasma glucose is controlled with any dose, the treatment will be continued with that dose until 20 weeks have elapsed from the commencement of the trial.

Trial Design

This will be a multicentric flexible dose open trial. The trial is being carried out at the existing 3 centres at Chennai, Cuttack and Kottayam and also at a new centre in New Delhi (AIIMS). The Research Associate, Biochemist and Dietician from New Delhi were given three days intensive training at Chennai on trial procedures, laboratory estimation procedure and on eliciting information on dietary intake.

The trial was started in July 2002 at New Delhi and subsequently at the other three centres by October 2002. 429 cases were admitted against a target of 600 patients by March 2004. The trial is in progress and the intake will be completed by July 2004.

Table 1: Status as on 31-5-2004

Group I (Uncontrolled)

No. of cases	Chennai Aug. 2002	Cuttack Sep. 2002	Kottayam Oct. 2002	New Delhi Oct. 2002	Total
Admitted	109	27	41	63*	240*
Dropped out	5	5	12	26	48
Withdrawn	60	11	23	24	118
Under treatment	13	3	0	11	27
Completed treatment	31	8	6	2	47

* Excluding one ineligible patient

Table 2 : Status as on 31-5-2004
Group II (Controlled, but opted Vijayasar)

No. of cases	Chennai Aug. 2002	Cuttack Sep. 2002	Kottayam Oct. 2002	New Delhi Oct 2002	Total
Admitted	39	84	86	25	234
Dropped out	1	7	12	11	31
Withdrawn	15	21	31	3	70
Under treatment	6	10	13	7	36
Completed treatment	17	46	30	4	97

COMPONENTS OF SMALL AREA VARIATION IN FERTILITY RATES IN SOUTH INDIA

Health information system is needed at small area such as sub-centres (SC), Primary Health Centres (PHC) or district level for health planning. This includes monitoring of maternal and child health services, providing warning signals to identify specific problematic areas and improving them through necessary interventions.[1] One of such problematic situations has been the high levels of fertility; Crude birth rate (CBR), General marital fertility rate (GMFR), Total fertility rate (TFR), Children ever born (CEB), Children surviving (CS) etc. and constant infant mortality. As there is no routine surveillance system, information on fertility rate at the local level is often based on specific sample surveys conducted by various Research Institutes / Organizations. Monitoring the fertility levels in a specified local area is therefore difficult. Studies on fertility rates and their differentials are many but they are based on the data at the state or country level.

There are many statistical problems associated while analysing variation in rates, ratios, prevalences, incidences among small areas.[2] The concept of small area variation had been developed and applied to death rates [3], risks of cancer[4], surgical operation rates,[5] hospital admission rate[6], health behaviour patterns[7], incidence of insulin-dependent diabetes mellitus[8] and low birth weight[9]. Earlier studies showed that the amount of variation explained in the dependent variable by associated predictors depended heavily on the **level of aggregation**[10]. The lower the level of aggregation say, at village / household / individual level the lower the variance explained by the associated factors. This might be due to considerable amount of random variation between the small areas compared to within variation. The variation between associated factors also influences the amount of random variation while measuring the variation between small areas. There is a need to know whether there is more variation between areas i.e. systematic variation than what is expected, if so, to what extent vis-à-vis the level of random variation.

Study of small area analysis is gaining importance in the health field especially on the variation between indicators of mortality and / or morbidity[3]. The same can be applied to fertility rates and its associated predictors. This is because among other things there is growing socio-economic status of the population, constant use of contraceptives including sterilization by the community. In this context, fertility level at the local area level is needed for formulation of the intervention strategies or programmes. A number of factors have been identified as predictors of fertility based on the judgement whether they are manipulable for intervention or not.

The methodology for small area analysis has not been fully developed to estimate the effect of random as well as systematic variation while considering the effect of the predictors. Methodological approach is needed for analysing small area variation and estimating its components. The study is focused on (i) to adapt and develop methods for small area analysis of non-random component of the variation in fertility, (ii) to apply the method to examine the variation in fertility rates among 20 sub-centres for selected socio- economic indicators in a district of Tamilnadu.

The data regarding fertility profile of women was obtained through a well-planned sample survey conducted in one Health Unit District of Tamilnadu. The design of the study was as follows:
The selected district had 82 PHCs covering a total of 551 sub-centres. Twenty sub-centres were randomly selected for the study using a two-stage sampling design. In the first stage, a random sample of 10 PHCs was selected using probability proportional to size (PPS) technique. In the second stage, a simple random sample of 2 sub-centres was chosen from each selected PHC.

In each of the 20 selected sub-centres, well-trained graduate female field investigators interviewed all currently married women of the age group of 15-49 years and collected data on fertility using a standardized pre-tested questionnaire. The data includes the outcomes of the recent pregnancies, if any, for the women, and different socio-economic indicators of the household and the individual women during the year 1993. Quality control measures such as spot scrutiny and consistency checks were assiduously employed. The survey was carried out from June 1994 to November 1994. Similar survey was done during 1995 in the same sub-centres to collect similar data on fertility profile for the year 1994 with approximately similar recall period.

The explanatory variables (predictors) for the present study were selected based on a review of literature available so far. There were micro as well as macro studies on fertility and its determinants but no single theoretical operational framework had emerged. Empirical research on variation in fertility suggested that the type of predictors change depending upon the level of aggregation. However, education of women and their husbands, their marital pattern, breastfeeding practices, age-structure of the population is found to be important, irrespective of the aggregation. Some researchers observed socio-economic development of the community had potential link with fertility pattern. Frame works independently by Davis and Blake[11] and Easterlin[12,13] with criticisms) viewed that "intermediate variables" had direct impact on fertility. This led Bongaarts[14]o consider at the aggregate level four proximate determinants viz., marriage, and postpartum infecundability due to breastfeeding practices, contraception, and foetal wastage including induced abortion. Wilmsen[15] observed that Bongaarts[14] framework was not appropriate. Women's age at marriage was considered in the present analysis because both Jain [16] and James[17] suggested that age at marriage for females had a bearing on fecundability. It was also considered by Mason[18] as an indicator of status of women. Occupation of women and their husbands' was also considered to be a measure of development and thus expected to influence fertility.

Most of the theories on fertility change deal mainly with the identification and classification of a set of biological, demographic, social, economic and cultural variables as potential predictors and study the interrelationships among them and their association with the observed fertility. Recent developments in this regard were to assess quantitatively the effects of these selected predictors on fertility. But, these approaches to estimate the effects on fertility due to a set of selected predictors had generally been limited to macro level. The types of analyses usually carried out to study the causal relationships of different selected social and economic variables on fertility were at macro level with either the country or a state or a region within the country as the unit of study. There were a few studies conducted at the micro level to assess the effects of a set of selected predictors directly on fertility. However, none of these studies in India and elsewhere have undertaken a detailed 'small area analysis' of the effects of selected socio-economic variables (predictors) and especially the variation in fertility rates between small health areas. Such an opportunity is made available in this study with the data available on predictors from a sample survey conducted in south India.

Using age-specific rates of socio-economic characteristics and fertility for the state in 1993, we indirectly standardized all crude rates for each centre for age. Similarly standardized rates for socio-economic indicators as well as for fertility were computed for 1994. The interest in this study was to examine the extent of systematic variance between the areas and if so whether it was statistically significant. Since the expected number of births for each predictor was at least 5 Cochran's heterogeneity χ^2 test was used with k-1 degrees of freedom (k = number of small areas analysed i.e. 20). This test can be related to the binomial distribution. Suppose o_i and e_i are observed and expected number of births, respectively in the sub-centre for illiterate women then

follows a $\chi^2_{(k-1)\ df.}$ The expected number of births for each sub-centre was obtained on the basis of age-specific marital fertility rates applied to the age-distribution of the married females in that area. The observed variance was calculated by dividing the χ^2 value by the number of births studied for each predictor. The total number of expected births, by definition should be equal to the total number of observed births and accordingly the expected number of births for each sub-centre was worked out. Since the population sizes varied considerably between the sub-centres, the expected number of births and the resulting observed variance varied substantially. The observed variance was derived as the variance of the ratio of the observed and expected numbers of births with the expected mean value as 1. The observed variance could be written as the weighted variance with weight being proportional to population size in that area.

With simple algebra the observed variance could be split into two components viz., systematic variance and random variance. Under the Null Hypothesis all the variation was due to random variance and the expected value of χ^2 was the degrees of freedom i.e. k-1. The random component of the variance = (k-1)/n. The systematic variance component was then

The proportion of systematic variance component to the total variance was calculated as the ratio of systematic variance with the observed variance. The above procedure was repeated for each

$$\sum_{i=1}^{K} \frac{(o_i - e_i)^2 / e_i}{n} - \frac{(k-1)}{n}$$

predictor variable considered in the analysis.

To estimate both systematic and random components of variance for each predictor variable, Poisson regression[19] was done with observed births as the dependent variable and the expected number of births as the independent variable. The deviance provided χ^2 value for the test of goodness of fit for the model. In this model, the ratio of observed number of eligible women for a given predictor (say, illiterates) to the expected number of eligible women was introduced as the independent variable. This adjusted value of χ^2 for the predictor was reduced indicating the improvement in goodness of fit of the model. This χ^2 value was used for the systematic variance given in the earlier formula with k-2 df. The expected random variance component had k-2 as numerator in the formula. Similarly corresponding change was made in the formula for systematic variance. This modified systematic variance was labelled as the predictor adjusted systematic component of variance in births. The significance of the systematic variance was examined and the corresponding P-value was computed based on the χ^2 value. The predictor related systematic component of variance in birth rates was calculated as the balance of the adjusted systematic component of variance from the total systematic variance in birth rates.

19173 households were identified in the 20 sub-centres; of these 1% could not be contacted as the inmates were away at the time of field visit. The levels of predictors (socio-economic factors) in each sub-centre for both the years were very close (Table 1). The fertility rates were higher in 1994 for all the predictors. For women belonging to the marginalized population fertility rates were higher in 1994 for all the predictors. For women belonging to SC/ST the GMFR in 1994 was 13% higher than that in 1993.

The expected number of births to illiterate women in 1993 varied between 34 and 104 while the expected number of eligible women varied between 325 and 871. The ratio of observed to expected

number of births varied between 0.8 and 1.5 between the 20 sub-centres. As an illustration the basic data on illiterate women in 1993 for all the sub-centres and births to them was considered in Table 2.

The estimated systematic component of variance was significant ($P<0.001$) for all the predictors (Table 3). The proportion of the observed variance that was attributable to the systematic variance component varied between 82% and 97%. The highest systematic variance obtained for

1994 was for women belonging to the marginalized population (variance varied between 0.008 and 0.156). The corresponding SD was the square root of the variance, which varied between 9% and 39%. The variation found in this analysis was substantial.

The proportion of estimated systematic variance in the ratio of births was significantly high for most of the predictors (Table 4). The non-significant predictors were: family planning (FP) users, women living in kutcha households, women belonging to the marginalized population and illiterate husbands. The highest systematic component of variance in the ratio was for 'age at marriage < 18 years' in 1993 while it's was for FP users in 1994. The systematic component of variance in the ratio in fertility varied between 0.011 and 0.136 in 1994 the corresponding SDs varied considerably between 10% and 37%.

For illiterate women the systematic component of variance was estimated as 0.019 and 0.037 in 1993 and 1994 , which led to considerable SD, 14%, and 19%. For SC / ST women the systematic variance was between 0.02 and 0.027 and the corresponding estimated SD between 14% and 16%. For women living in kutcha households however the systematic SD was low, between 10% and 13%. For women who were illiterate, married before 18 years, agricultural coolies, users of family planning and whose husband were coolies, 51% to 81% of the observed variance was accounted for systematic variance. In the other predictors' systematic component accounted for between 30% and 54% of the observed variance. In these predictors the observed variance was more attributable to random effects than to systematic variation.

For all the predictors the systematic variance in fertility rate was lower after adjustment for the level of each predictor (Table 5). In both the years for FP users, agricultural coolies living in kutcha households and whose husbands were illiterate the adjusted systematic variance was zero or nearer to zero. In 1994 for most of the predictors, the adjustment was small varying between 0% and 1.5%.

The systematic variance in fertility was divided into the predictor adjusted and predictor related systematic components of the variance in fertility for both years. In Table 5 the period of the data on predictors preceded the period for the fertility data. In both the years the predictor related systematic variance in fertility was explained by the variation in most of the predictors. However, for women belonging to the marginalized population in 1993 the variation was due to random effects.

The first point of interest from this study is that a specific method is suggested and attempts are made in a novel way to study the variation in fertility rates between 20 sub-centres for selected predictors. Various statistical methods had been suggested for small area variation between geographical areas while analysing relatively rare cases in mortality /morbidity. The concept of χ^2 test for testing the heterogeneity of the rates in different geographical areas is quite old (Cochran's χ^2)[20]. The concept of weighted observed variance has been used earlier to estimate the components of small area variation. Estimation of systematic variance is important even if it is not significant, when the concept of 'avoidable fertility' is attempted in examining the variation among the small areas with high birth rates The second point of interest is that a considerable part of the variation in fertility rates for selected predictors is systematic. The idea of small area analysis meant that the population and the resulting outcomes in the study areas should be relatively small. This indicates that the concept of small area analysis for fertility rates seems appropriate. The Poisson regression is used to estimate adjusted systematic component of variance. The systematic component of variance decreased after adjustment, suggesting it is sensitive to changes in the study factor levels. However, a fairly large amount of variation is found to be systematic.

The third point of interest is that the results of the analysis shows pathways for further studies at the community level. For example, the illiteracy of eligible women is one of the variables, which needs attention and intervention. On the whole, the available predictors could explain only 66% of the variation in fertility. It was not possible to include data on other proximate variables such as breast feeding practices, abstinence, foetal wastage, secondary sterility etc., and therefore, it could not be possible to judge whether variation is due to these factors. The present analysis did not explain more than what was due to selected predictors and random effects.

The systematic component of variance in fertility rates was significant mainly due to illiterate women and the women married before attaining the age of 18 years. Fertility rates were higher in these conditions suggesting the need for in depth studies for necessary intervention. The fertility rates in these sub-centres were found to be higher among the marginalized population. Attention needs to be drawn to lower the fertility rates at the local area level that can change the variation due to selected variables (predictors). The levels of these variables also provide warning signals earlier to the fertility experience. The inter relationships among the predictors influencing fertility might vary between different areas. In the present study, the time period between two fertility performances was only one year. Thus, the trend in fertility pattern cannot be noticed for possible changes in the levels of predictors.

In both the years 1993 and 1994, the use of family planning methods was found to be important. This was to be expected since the effective use would result in lowered levels of fertility. For women using family planning methods, it might be possible to study the fertility rates further. Small area analysis of the consistency between fertility rates and predictors was needed because high degree of association had been shown between fertility and the predictors. For both the years, systematic component of variance was significant. The variations in fertility rates were not fully explained by the variation in the predictors. Other plausible explanations need to be sorted out, for example, the effects of population policy for early identification of predictors affecting fertility. Reproductive and child health programmes (RCH) showed the influence of proximate determinants on fertility. Organised RCH programmes need to be introduced at local area levels at different time points in the state. It would be of interest to study the relation between RCH programmes and the systematic components of variance in fertility rates. The systematic variation in fertility rates is also dependent on age at marriage, children ever born and children surviving to the eligible women.

It is important to emphasize that measuring adjusted systematic variance in fertility may not solve the problem of separating the effects of predictors from the effects of improved health. The data on predictors and fertility is easily available when compared to the data on health. The predictors and the fertility experienced refer to a district and the potential bias in measuring them is considered small in the sub-centres studied. Inclusion of live births in the study was, however, another important variable for the analysis of possible explanation for systematic component of variation in the predictors as well as in fertility.

Draft National Health Policy of Govt. of India is characterized by rapid progress with new programmes being continually introduced for the reduction in fertility. The selection of useful indicators of avoidable fertility under decentralized planning differs from one period to another. Analysis of systematic component of variation in fertility rates at the local area level should be useful for further studies on population.

Table 1. Levels of some selected socio-economic indicators of women and GMFR* in 1993 and 1994

Socio-economic characteristic of Eligible women	1993				1994			
	No. of Eligible women	Rate (%)	No. of births	GMFR	No. of Eligible women	Rate (%)	No. of births	GMFR*
Illiterate	10 694	67.7	1 050	98.2	10 968	68.6	1 149	104.8
Age at marriage < 18 yrs	10 370	65.7	956	92.2	10 165	63.6	1 014	99.8
FP Users	7 097	45.0	482	67.9	7 321	45.8	506	69.1
Living in Kutcha households	10 453	66.2	1 171	112.0	10 448	65.4	1 250	119.6
Coolies	8 022	50.8	853	106.5	8 242	51.6	913	110.8
Marginalized population	5 164	32.7	599	116.0	5 116	32.0	671	131.2
Husband coolie	8 412	53.3	951	113.1	8 523	53.3	1 005	117.9
Husband illiterate	6 598	41.8	640	97.0	6 895	43.2	735	106.6

*Standardized for age

Table 2. The observed and expected number of illiterate women and births to them in 1993 with ratio of observed to expected values among 20 sub-centres (SCs)

Sub-centre	Illiterate women		Births to illiterate women		Ratio = Observed births / Expected births
	Observed	Expected	Observed	Expected	
1	502	511	53	48	1.1042
2	391	405	56	37	1.5135
3	466	492	38	46	0.8261
4	314	325	35	34	1.0294
5	391	397	40	39	1.0256
6	540	533	46	59	0.7797
7	752	669	67	83	0.8072
8	955	871	82	104	0.7885
9	580	555	59	50	1.1800
10	455	394	51	41	1.2439
11	422	503	51	40	1.2750
12	586	585	63	54	1.1667
13	550	620	48	49	0.9796
14	496	553	54	45	1.2000
15	508	429	58	52	1.1154
16	740	616	65	78	0.8333
17	476	567	35	43	0.8140
18	436	464	40	39	1.0256
19	667	730	57	64	0.8906
20	467	472	52	44	1.1818
Total	10694	10691	1050	1049	1.0010

Table 3. Systematic component of variance in the ratio observed to expected for selected **characteristics among sub-centres in 1993 and 1994**

Socio-economic Characteristic of eligible women	1993				1994			
	Eligible women	Total Variance	Systematic Comp. of Variance	Prop. Of Systematic Comp. of variance	Eligible women	Total variance	Systematic Comp. of Variance	Prop. Of Systematic Comp. of variance
Illiterate	10 694	0.011	0.009	0.82***	10 968	0.010	0.008	0.80***
Age at marriage < 18 yrs	10 370	0.018	0.016	0.89***	10 165	0.021	0.019	0.91***
FP Users	7 097	0.019	0.016	0.84***	7 321	0.016	0.013	0.81***
Living in Kutcha households	10 453	0.022	0.020	0.91***	10 448	0.021	0.020	0.95***
Coolies	8 022	0.022	0.020	0.91***	8 242	0.017	0.015	0.88***
Marginalized population SC/ST	5 164	0.156	0.152	0.97***	5 116	0.159	0.156	0.98***
Husband coolie	8 412	0.024	0.021	0.88***	8 523	0.020	0.018	0.90***
Husband illiterate	6 598	0.017	0.014	0.82***	6 895	0.016	0.013	0.81***

*** P value <0.001

Table 4. Systematic component of variance in ratio of observed to expected births sub-Centres in 1993 and 1994

Socio-economic Characteristic of eligible women	1993				1994			
	Total Births	Total Variance	Systematic Component of Variance	Prop. of Systematic Comp. of Variance	Total Births	Total variance	Systematic component of variance	Prop. Of Systematic Component of Variance
Illiterate	1 050	0.037	0.019	0.51*	1149	0.054	0.037	0.69**
Age at marriage < 18 yrs	956	0.054	0.034	0.63**	1 014	0.043	0.025	0.58*
FP Users	482	0.054	0.014	0.26	506	0.167	0.136	0.81***
Living in Kutcha households	1 171	0.028	0.011	0.39	1 250	0.033	0.018	0.55*
Coolies	853	0.047	0.025	0.53**	913	0.053	0.032	0.60*
SC/ST Marginalized population	599	0.051	0.020	0.39	671	0.056	0.027	0.48*
Husband coolie	951	0.053	0.033	0.62**	1 005	0.050	0.031	0.62**
Husband illiterate	640	0.050	0.020	0.40	735	0.037	0.011	0.30

* P value <0.05
** P value <0.01
*** P value <0.001

Table 5. Adjusted and related systematic components of variance in ratio of observed births to expected births from selected socio-economic characteristics of women among sub-centres in 1993 and 1994

Socio-economic Characteristic of eligible women	1993			1994		
	Total SCV in fertility	Incidence adjusted SCV in fertility	Incidence related SCV in fertility	Total SCV in fertility	Incidence adjusted SCV in fertility	Incidence related SCV in fertility
Illiterate	0.019	0.002	0.017**	0.037	0.001	0.036***
Age at marriage < 18 yrs	0.034	0.004	0.030**	0.025	0.001	0.024***
FP Users	0.014	0.000	0.014***	0.136	0.015	0.121*
Living in Kutcha households	0.011	0.003	0.008**	0.018	0.000	0.018***
Coolies	0.025	0.002	0.023**	0.032	0.000	0.32***
Marginalized population	0.020	0.017	0.003	0.027	0.001	0.026***
Husband coolie	0.033	0.001	0.032***	0.031	0.001	0.030***
Husband illiterate	0.020	0.000	0.020***	0.011	0.000	0.011***

SCV: Systematic component of variance

* P value <0.05
** P value <0.01
*** P value <0.001

REFERENCES

1. Draft National Health Policy. New Delhi, Ministry of Health and Family welfare 2001

2. Diehr, P. Small Area Statistics: Large statistical problems. American Journal of Public Health 1984;74: 313-314.

3. Westerling, R. Components of small area variation in death rates: a method applied to data from Sweden. Journal of Epidemiology and community Health. 1995; 49:214-221.

4. Osnes comparing methods for estimating the variation of risks of cancer between small areas:J Epidemiology & Biostatistics. 2000 ; 5(3):193-201

5. McPherson, K. Wennberg, J.E. Hovind, O.B. Clifford, P. Small area variations in the use of common surgical procedures: an international comparison of New England, England, and Norway. New England Journal of Medicine 1982; 18:1310-1314.

6. Twigger & Jessop. Small area variation in hospital admission In: random or systematic? Public Health 2000; 114: 328-329

7. Ecob & Macintyre. Small area variations in health related behaviours; do these depend on the behaviour itself, its measurement, or on personal characteristics? Health Place.2000;6(4)261-74

8. Staines A, Bodansky HJ, McKinney PA, et al. Small area variation in the incidence of childhood insulin-dependent diabetes mellitus in Yorkshire, UK: links with over crowding and population density. International journal of Epidemiology 1997 Dec; 26(6): 307-313

9. Crosse EA, Alder RJ, Ostbye T, Campbell MK. Small area variation in low birth weight: looking beyond socio-economic predictors. Canadian Journal of public Health 1997 Jan-Feb: 88(1): 57-61.

10. Srinivasan, K. and Murthy, B.N. Finding from two Large-scale surveys in Bihar and Rajasthan, chapter 9 In: Dynamics of Population and Family Welfare, Bombay Himalayas Publishing House, 1983:223-2

11. Davis K. and Blake, J. Social structure and fertility: An analytic framework for fertility analysis. Studies in Family Planning 1956; 6: 54-63.

12. Easterlin, R. A., Economic framework for fertility analysis. Studies in Family Planning 1975; 6: 54-63.

13. Easterlin, R. A. and Crimmins, E. M. Fertility Revolution: A Supply Demand Analysis. The University of Chicago Press Chicago. 1985

14. Bongaarts, J. A framework for analysing the proximate determinants of fertility. Population and Development Review 1978: 4: 105-132

15. Wilmsen, E. N. Biological determinants of fecundity and fecundability: An application of Bongaart's model to Forager fertility, In: W. Penn Handworker (ed.), Culture and Reproduction, 1986; 59-82, West view Press London.

16. Jain, A. K. Fecundity and its relation to age in a sample of Taiwanese women. Population Studies 1969; 23: 69-86.

17. James, W. H. The fecundability of U.S. women, Population Studies. 1975; 25: 493-500

18. Mason, K.O. Status of women: A review of its Relationship to Fertility and Mortality. The Rock Eller Foundation, New York.1984

19. Breslow, N.E. Extra-Poisson variation in log-linear models. Applied Statistics 1984; 33: 38-44.

20. Armitage, P and Berry, G. Statistical methods in medical research 2nd ed. In: Oxford and Edinburgh Black well Scientific Publications, London.1987.

SIMPLE MEASURES FOR REPORTING THE MAGNITUDE OF SMALL AREA VARIATION IN RATES

Small area, by definition, depends on the context, as it relates to the number of cases of disease/vital events/counts of a particular screening method/results of recording system that are observed at a particular point of time. As a rough guide, any region containing fewer than 20 cases of disease/10 births/ 5 deaths in an area can be considered a small area (1). In the case of leprosy, a small area can be a district because the number of cases of leprosy may be around 20 in an endemic district containing a population of around three million. In the case of cancer, the small area can be with a population of at least 100,000 individuals. The geographical area thus depends upon the incidence rate of the disease, the population density and the time period over which the data has been collected. The concept of "small area variation" was developed as a useful tool for public health services research (2-4). It allows one to compare often mortality(2), fertility rates(5), risks of cancer(6), surgical operation rates(4), health behaviour patterns(7), incidence of insulin dependent diabetes mellitus(8) and low birth weight(9) among small areas. . For this purpose, Primary Health Centre (PHC) / Sub centre (SC) / village/ward within a district can be taken as "Small area".

The small area analysis and its comparisons involve too large number of statistics to interpret. Single measure of variation in rates among small areas is needed and efforts should be made to measure and interpret(3). More complicated measures based on hierarchical models are statistically robust but public health officials will not be able to comprehend them for meaningful interpretation. Extremal quotient (EQ), the ratio of lowest to highest rate, was suggested as a satisfying measure for small area variation(3), but could not be recommended because it lacked good statistical properties(10). Though standard deviation (SD) and coefficient of variation (CV) are simple measures of small area variation, they are also statistically not robust(4). Sophisticated techniques, such as estimation of systematic variation (SV), that is excess variation over and above the chance variation (random variation) was suggested as a popular technique(4) to measure small area variation, but this technique had limitations such as i) it has no proper methods for estimation of standard error and ii) the estimates of SV can sometimes be negative(11). To overcome these limitations, empirical Bayes, multi-level or random coefficient models have been used (11-13). A brief account on the methods and their limitations are given elsewhere(14).

Since there exists heterogeneity in rates among small areas, suggesting a single figure for the entire area could be misleading. Therefore, two or at most three measures of variation in rates among small areas are needed and efforts should be made to measure and interpret them. These measures may help the public health administrator to identify and monitor the areas with high, median and low rates and accordingly plan the delivery of health services.

Recently, using the hierarchical model, three new measures were suggested for reporting small area variation viz., i) the ratio of high versus low rates among small areas; (ii) number; and (iii) the percentage of deaths that might be avoided if causes of small area variation are removed (14). Though the above measures had good statistical properties, the estimation of number and the percentage of avoidable deaths were not tenable because the assumption that 'if the causes of the variation between areas could be removed' was not practicable. Further, while suggesting the above three measures it was pointed out that the approach of using centiles to derive them was arbitrary(14). This article attempts to address these issues and suggest simple and practicable measures to public health professionals to understand and

interpret them meaningfully. These measures were illustrated using fertility data surveyed in a health unit district of Tamil Nadu, south India.

The above measures were suggested to describe small area variation in death rates. However, the methodology suggested would not be applicable for other health outcomes such as fertility because it suffers from all the properties with which the three measures were derived. The foremost in making assumptions is that the number of births in an area follows 'Poisson distribution' may not be true. Public health professionals cannot understand systematic variance among small areas easily. Second, the computation of centiles using hierarchical model and then the ratio of 95^{th} percentile to 5^{th} percentile is rather difficult to comprehend. More important is the assumption that all small areas have the same rate as areas with low rates is not tenable under programme conditions. Besides, the first statistic is similar to extremal quotient (EQ) as suggested earlier but based on centiles. Methods on components of small area variation suggest random variation (within each area variation) of the observed rates vary around the true rate and systematic variation (variation among the observed rates across areas). Study on systematic variance is important for public health(3). We proposed a populist method for computing and identifying the factors affecting systematic variance (5). It was assumed that observed births o_i (standardized general marital fertility rate) in an area follows binomial distribution with mean e_i where e_i is the age-sex standardized number of births in i^{th} area. In all the methods attempted so far, attaching importance of systematic variance to public health was found difficult. For example, it was reported that the systematic variance for births in 20 sub centres in Tamil Nadu in South India was 0.023 (5). This value has no public health importance. Instead Public health professionals tend to ignore size of small area variation and concentrate on statistical significance. Usually the approach is to compare the test statistic with χ^2 distribution and to obtain a P-value and examine whether the variation in rates is larger than, can only be examined by binomial/Poisson fluctuations(2,15).Other suggested methods also depend on significance testing(16,17).

However, in recent years and coinciding with increasing availability of computers, statistical software packages and programmable pocket calculators, there has been an upsurge of significance testing, sometimes bordering on the indiscriminate(18-20). This unfortunate development led the authorities to lament regarding the excessive use of hypothesis testing at the expense of other ways of assessing results (19,20). A serious limitation of basing interpretation entirely on the basis of findings of a significance test arises from the naïve, but often held view by many nonstatisticians that a significant result proved the existence of a real and important variation and that conversely, a nonsignificant result demonstrates that there is no real variation. The over emphasis on significance testing has also side tracked investigators from using the more useful approach of 'estimation' for interpreting study findings. Unfortunately, not all of them realize that the aim is not merely to state whether the observed small area variation is significant or non-significant, but also to estimate the size of the small area variation among rates.

In this report, simple measures are suggested using rates across small areas as well as SV to derive three statistics: i) the median rate across small areas; ii) the median SV; and iii) the number and percentage of births that could be averted, if all small areas had the same rate as areas with median rate. More importantly, no assumption was made on the distribution of the fertility events to derive the above statistics. These measures have good statistical properties. The point estimates and their 95% confidence intervals can easily be computed even if rates in some areas are zero, and between and within variation among the rates is considered. The

suggested methodology was applied to fertility data collected in a well-planned survey conducted in a health unit district of south India.

The data regarding the fertility profile of married women was obtained through a well-planned sample survey conducted in one health unit district (HUD) of Tamil Nadu. Twenty sub centres were randomly selected for the study using a two-stage sampling design. In the first stage, 10 PHCs were selected using probability proportional to size (PPS) technique and two sub centres were randomly selected from each selected PHC.

Well-trained graduate female field investigators interviewed all currently married women aged 15-49 years in each of the 20 selected sub centres and collected data on fertility using a structured pre-tested questionnaire. The data included information on the outcome of recent pregnancies, socio-economic characteristics of the households and the individual woman for the year 1993. Similar survey was conducted in the same HUD in 1995 to collect the information on the fertility profile of women for the year 1994. Quality control checks were carefully employed. More details of the two surveys were available elsewhere(5). The fertility data for the two successive years 1993 and 1994 was combined in order to eliminate the spill over effect and to comprehend better.

To illustrate the simple measures for reporting small area variation, selected socio-economic characteristics, which had varied GMFRs, were chosen (Table 1). The GMFR for each of the 20 sub centres were indirectly standardized using the age-specific fertility rates for Tamil Nadu state of south India as standard (5-year age-groups were used).The population data, the observed number of currently married women, their observed births and standardized GMFR by sub centre (Table 2) were obtained from the sample survey. Since the study is concerned with the fertility in the sub centres, the currently married women in the age group of 15-49 years in the sub centres were considered. The analysis was limited to GMFR alone because i) the selected socio-economic predictors may not affect fertility before 15 years, ii) the GMFR could be regarded as 'reproductive index' in the population and the aim of small area variation analysis with this index is to generate hypothesis that may lead to future studies to identify pathways for preventing unwanted pregnancies; the concept which can be adjudicated in the public health programme and simplify the art of decision making by public health administrators.

Median and its 95% confidence interval of the GMFR for each selected socio-economic predictors were computed using the observed GMFRs of all the sub centres. The number of births averted was computed under the hypothesis that all the sub centres had the median GMFR. This was done for each of the selected socio-economic predictors and the percentage of births that could be averted for each factor were computed . Further, the number and percentage of births that could be averted was computed under the assumption that all the sub centres had the lowest GMFR. The latter measure may be treated as an optimal and ideal solution. To estimate SV, no assumption was made on the distribution of the fertility events in small areas. In this context, nonparametric bootstrap technique was employed to estimate the median rate across small areas and systematic variance and its 95% confidence interval(21).

An accurate estimate of the uncertainty associated with parameter estimates is necessary to avoid misleading inference. This uncertainty is usually summarized by a confidence interval, which is claimed to include the true parameter value with a specified probability. In many statistical problems information is sought about the value of a population parameter θ by

drawing a random sample Y from that population and constructing an estimate $\hat{\theta}(y)$ of the value of θ from the sample. The bootstrap principle is to obtain information about the relationship between θ and the random variable $\hat{\theta}(y)$ by looking at the relationship between $\hat{\theta}(y_{obs})$ and $\hat{\theta}(y^{\bullet})$, where y* is a resample characterized by the sample y_{obs}. y* can either be constructed by sampling with replacement form the data vector y_{obs}, the so-called non-parametric bootstrap or by resampling from the distribution function parameterized by $\hat{\theta}(y_{obs})$ the so-called parametric bootstrap.

Let there be 'k' small areas (subcentres) from a health unit district of south India. Let o_i and e_i be the number of observed and expected births in the i^{th} subcentre. Then (o_1, e_1), (o_2, e_2),……. (o_k, e_k) are k pairs of observed and expected births in the k subcentres.

Step 1. Draw a random sample of k pairs from the observed sample with replacement. Denote them as (o_1^*, e_1^*), (o_2^*, e_2^*),……. (o_k^*, e_k^*)

Step 2. Compute o_i^* / e_i^* and systematic variance as follows:
Where n is the total number of observed births in all the k subcentres.

$$s^* = \text{systematic variance} = \sum_{i=1}^{k} \frac{(o_i^* - e_i^*)^2 / e_i^*}{n} - \frac{(k-1)}{n}$$

Step 3. Repeat the steps 1 and 2 1000 times to obtain a set of 1000 replications of s^*

Step 4. The estimated median of the empirical distribution of s^* is computed and denoted as s_m^*

Step 5. Let K_1 estimates of s_m^* be generated.

Step 6. Draw a random sample of K_1 values with replacement from the generated s_m^*. Let it be denoted by s_m^{**}.

Step 7. Estimate the mean. Let it be denoted by $s_{m_1}^{\bullet\bullet}$

Step 8. Repeat steps 6 and 7 1000 times.

Step 9. Find out the distribution of $s_{m_1}^{\bullet\bullet}$

Step 10. Estimate 95% BCa interval of $s_{m_1}^{\bullet\bullet}$

It is assumed that the systematic variation separately for each factor among all the sub centres ranges in the interval of its 95% BCa. Suppose, for illiterate women the 95% BCa interval for systematic variance is $[S_L, S_u]$. Then it is assumed that the systematic variance for illiterate women among small areas (sub centres 1 to 20) ranges from S_L to S_u. The percentage of births that might be averted might be calculated under the assumption that all the sub centres had the lowest limit (S_L) of the 95% BCa interval is given by

[1 – (lowest systematic variance / highest systematic variance)] x 100

$$= \left(1 - \frac{S_L}{S_u}\right) \times 100$$

Using this percentage, the number of births that could be averted by illiterate women was computed for each sub centre. Similarly, the number and percentage of births that could be averted for each socio-economic predictor were computed under the assumption that all the sub centres had the lowest systematic variance. On the other hand, if we assume that all the sub centres had the median systematic variance, the percentage of births that could be averted for each of socio-economic predictor could be calculated as

$$= \left(1 - \frac{\text{Median systematic variance}}{\text{systematic variance}}\right) \times 100$$

Using this predictor-specific percentage and the corresponding births in all the small areas, the number of births that can be averted due to the predictor are estimated.

$$= \left(1 - \frac{s_{m_i}^{**}}{s^*}\right) \times 100$$

Table III shows the median GMFR for eight selected socio-economic predictors of the currently married women. A better approach is to use the median GMFR that may be feasible and pragmatic instead of ratio of highest to lowest rates across small areas. For example, for births to illiterate women, the median GMFR was 99.3 per 1000 (95%CI: 95.0 – 103.5); the number of births that could be averted was 44, which was 4%. The percentage of births that could be averted for the selected socio-economic predictors varied between 2.4% and 5% under this assumption. The number of births that could be averted under the assumption that all the sub centres had the lowest GMFR was 107 for illiterate women, which accounted for 9.7%. The percentage of births that could be averted under this assumption varies from 9.7% to 17%. These simple measures expressed small area variation in tangible way that can help public health officials as well as programme managers to make judgement about whether to proceed with more detailed studies.

Table IV shows the SV for eight selected socio-economic predictors. Although it provides a way of ranking of fertility rates according to the size of the small area variation in terms of GMFR, it is difficult to interpret. For example, the systematic variance for the family planning users among women (0.044) was not statistically significant from 0 (P =0.2) but the point estimate was larger than that for illiterate women (0.028), which was statistically significant (P=0.02). This occurred because the characteristic ‘illiterate’ is more common socio-economic predictor than ‘family planning’ among married women. Hence, the strategy of dichotomising small area variation into ‘significant’ or ‘not significant’ can obscure possibly the importance of small area variation.

Useful and additional information could be obtained by computing the number of births that could be averted per year on the basis of median systematic variance and lowest systematic variance (Table IV). For example, for illiterate women the point estimate of SV was 0.028(95%CI: 0.0190 to 0.0511) and the point estimate of median SV was 0.0302(95%CI), the percentage of births that could be averted under the assumption that all the small areas had the median systematic variance, was 40.9%. These measures expressed small area variation in a more meaningful way that can help the public health officials to identify important and manipulable predictors and make necessary interventions. It combines the

information on the systematic variance and the average number of births attributed to particular socio-economic characteristic per year.

Even if the median GMFR across the small areas or the percentage of births that might be averted is large, number of births that could be potentially averted might be small and the ranking of socio-economic characteristics of fertility might be different from that obtained using the other suggested measures. Because the approach in this paper is innovative and exploratory, the choice of median GMFR has been evaluated as a measure for the calculation of rate ratio across areas. The values that were less extreme than the 95% CI of Median GMFR do not define the areas with low or high rates. Using more extreme values than 95% BCa interval, should be discouraged because only 5% of the areas would have more extreme values and the number of births that could be averted is a linear function of percentage of births that could be averted.

The first point of interest from the study was that three simple measures were used in this paper to describe small area variation among fertility rates. These simple measures need not be limited to use with fertility data. For example, these could also be used to report on small area variation in surgical or hospital admission rates. The main advantage of the two simple measures is that they direct attention to the size of small area variation and its precision. Public health authorities have been advocating this type of statistical reasoning rather than mechanically determining statistical significance for many years(18). These simple measures are based on the assumption that all areas could achieve rates similar to those in the areas with median rate if only we knew all that might be reasonably known about the socio-economic characteristics of the fertility in question, such as GMFR, and could apply this in practical programs in the community. The concept has been applied to comparisons among large areas where the effects of random variation are small and are often ignored. The present approach extends the idea to small areas by accounting for the effects of random variation in fertility rates.

For some socio-economic characteristics (the family planning users, those living in kuchha households, labourers, illiterate husbands) unimportant small area variation was found (5). This does not mean that the overall GMFR for these factors cannot be improved. However, in setting priorities for future research, it will be useful for public health managers to concentrate initially on those factors of fertility with substantial small area variation. In other words, if small area variation is substantial; the opportunity for improving the overall GMFR by identifying the modifiable factors for small area variation may be greater or else being equal.

Definition of small areas varies depending on (i) the geography/location of the area, (ii) the fertility or the parameter of interest and (iii) administration. The analysis in this paper was based on 20 sub centre level data which are under the control of district health authorities. However, these comparisons were of particular interest to public health administrators. Any future action that might be taken to reduce regional variation will require action by the concerned district health authorities. The method used in this paper could also be used to other geographical units such as census blocks, taluks or PHCs.

The limitations of routinely collected data should also be considered. For example, this study was carried out on the basis of the data collected through a representative sample survey in a district of south India. It may be possible that some of the small area variations might be due to inconsistencies reported in the birth certificates. Studies in India such as National Family

Health Surveys (NFHS I & II) had shown that 'marginalized' population are inconsistently reported as the significant socio-economic predictor for fertility(22). This might explain the large variations in fertility rates due to various socio-economic predictors across sub centres and warrant further investigation.

Also, changes in the prevalence of socio-economic indicators among women/households for fertility may take several years to be reflected in reductions in fertility rates. For example, increase in age at marriage had resulted reductions in fertility among women after 10 to 15 years. Hence, for some factors substantial variation in fertility rates does not mean that there is currently substantial variation in modifiable socio-economic predictors(5).

Although some might argue that a weakness of the method is that the choice of median, as a simple measure, is arbitrary, the situation is similar to converting standard error to confidence interval. The most commonly used confidence level in practice is 95% and hence the same is employed in this analysis. Similarly, instead of using the routine high versus low rates across small areas, median GMFR is suggested, because it is simple, easy to compute and more importantly understandable by the public health managers.

'The number and percentage of births that can be averted' suggested that at least 5% of the births could be averted under the given situations. However, this can be increased further with necessary intervention. Simple measures of small area variation described in this paper rely on the nonparametric bootstrap technique and thereby no assumption was made on the distribution of births and this is an advantage to study the small area variation among fertility rates over the standard way of parametric modelling that used to be employed in practice. For example, we assumed that the births followed binomial distribution. If The variation in observed births is larger or smaller than the mean, assumption of binomial distribution theory will underestimate or overestimate the within area variation leading to overestimation/under estimation of the systematic variance. Most of the analysis on this issue has concentrated on the fertility events, for example, GMFR. Similar work for events, such as hospital admission rates is an important area for future study.

As discussed earlier, 'the number needed to treat' (the reciprocal of absolute risk) is a better way of expressing the results of clinical trials than the traditional measures such as relative risk. In other words, the interpretation (the number of women who can be educated to prevent one birth) is easily understood by public health managers as understood by the clinicians. It helps to demystify the art of the decision to treat some and not all small areas. An effort is made, in this direction, in this paper, which may help the public health managers to demystify the results of studies on small area variation. This may help public health managers as well as policy makers to decide future course of action for more detailed studies based on the simple measures for reporting small area variation and not on the statistical significance of an obscure index.

Though more complex and better bootstrap confidence intervals are available, BCa confidence intervals have been used here.

Small area variation in health outcomes for example, morbidity, mortality, fertility rates and health behaviour patterns is a useful tool for Public health Services Research. Comparisons of small area variation among rates generate large volume of data. The Public health professionals need two or three simple measures for use and meaningful interpretation. Extremal quotient(EQ),standard deviation (SD) and coefficient of variation (CV) are simple

measures but they have poor statistical properties. More complicated measures based on hierarchical models are statistically robust but public health officials will not be able to comprehend them for meaningful interpretation. Although new measures of variation, for example, (i) the ratio of high versus low rates across small areas; (ii) the number; and (iii) percentage of adverse events, such as deaths had good statistical properties, they are not pragmatic from the programme point of view, because the assumption, 'if causes of variation are removed' with which (ii) and (iii) are measured, is not practicable. Further, the approach of using centiles to derive the above statistics is weak. In this paper, simple measures of variation, namely; (i) the median and its 95% CI of the observed rates; (ii) non-parametric bootstrap estimate of median SV and its 95% BCa; and (iii) the number and percentage of events of interest, such as births that might be averted if all the small areas had the median rate, are suggested. This method was applied to fertility survey data collected from a Health unit district of Tamil Nadu, south India. The important point in this study is that no assumption is made about the distribution of the events of interest. The suggested three measures are simple, easy to compute and interpret. These measures can help Public health officials to demystify the art of decision to initiate necessary intervention for some and not all areas. This in turn helps Public health officials to make judgments whether to proceed with detailed studies without depending entirely on statistical significance of the test statistics / measures.

REFERENCES

1. Michael Coory, Robert Gibberd. 'New measures for reporting the magnitude of small – area variation in rares',Statistics in medicine,**17,**2625-2634(1998).

2. Diehr P,Cain K, Connel F,Volin E. ' What is too much variation? The null hypothesis in small area analysis', Health Services Research, **24**,741-771(1990).

3. McPherson K, Wennberg JE, Hovind OB, Clifford P. ' Small – area variations in the use of common surgical procedures: an international comparison of New England, and Norway", New England Journal of Medicinf,**307**,1310-1314(1982).

4. Ministry of Health and Family Welfare. ' Draft National Health Policy", Government Of India, New Delhi (2001).

5. Diehr P. ' Small area statistics: Large statistical problems", American Journal of Public Health, **74**, 313-314(1984).

6. Westerling,R. ' Components of small area variation in death rates: a method applied to data from Sweden', Journal of Epidemiology and Community Health, **49**,214-221(1995).

7. Osnes, K. ' Comparing methods for estimating the variation of risks of cancer between small areas', Journal of Epidemiology and Biostatistics,**5(3)**,193-201(2000).

8. Twigger, JP, Jessop,EG, ' Small area variation in hospital admission random or systematic?' , Journal of Public Health, **114**, 328-329(2000).

9. Ecob , R, Macintyre,S, ' Small area variations in health related behaviours; do these depend on the behaviour itself, it's measurement, or on personal characteristics?', Health place,**6(4)**,261-274(2000).

10. Staines A, Bodansky HJ, McKinney PA et.al , ' Small area variation in the incidence of childhood insulin-dependent diabetes mellitus in Yorkshire,UK: links with overcrowding and population density.", International Journal of Epidemiology,**26(6)**,307-313(1997).

11. Crosse EA, Alder RJ, Ostbye T, Campbell MK. ' Small area variation in low birth weight: looking beyond socio-economic predictors.', Canadian Journal of public health, **88(1)**,57-61(1997).

12. Srinivasan K, Murthy BN. ' Finding from two large scale surveys in Bihar and Rajasthan.' , Dynamics of Population and Family Welfare,Himalays Publishing House,Bombay.**Ch(9)**,223-245(1983).

13. Kingsley Davis K, Judith Blake. ' Social structure and fertility: an analytic frame work.', Economic Development and Social Change,**6(3)**,211-235(1956).

14. Easterlin RA. ' Economic framework for fertility analysis.', Studies in Family Planning, **6**, 54-63(1975).

15. Easrerlin RA, Crimmins EM. ‘ Fertility Revolution: A supply demand analysis.’, The university of Chicago Press, Chicago, 1985.

16. Bongaarts JA. ‘ A frame work for analyzing the proximate determinants of fertility.’, Population Development Review, **4**, 105-132(1978).

17. Wilmsen EN. ‘ Biological determinants of fecundity and fecundability: An application of Bongaart’s model to Forager fertility.’ In:W. Penn Handworker(ed), Culture and Reproduction, West View Press , London,59-82(1986).

18. Jain AK. ‘ Fecundity and its relation to age in a sample of Taiwanese Women.’ , Population Studies,**23**, 69-86(1969).

19. James WH. ‘ The fecundability of U.S women.’ , Population Studies,**25**, 69-86(1975).

20. Mason KO. ‘ Status of women: A review of it’s relationship to Fertility and Mortality.’, The Rockfeller Foundation, Newyork, 1984.

21. Breslow NE. ‘ Extra- Poisson variation in log-linear models.’, Applied Statistics,**33**,38-44(1984).

22. Armitage P, Berry G. ‘ Statistical Methods In Medical Research .’, **2nd Ed** , Oxford and Edinburgh, Blackwell Scientific publications,London(1987).

CLINICAL TRIAL FOR TREATMENT OF PAUCIBACILLARY LEPROSY PATIENTS WITH SINGLE DOSE OF ROM

NIE is the co-ordinating center for WHO sponsored trials on single dose of ROM. The study comprised of two components:

a) Double blind randomized controlled trial covering PB leprosy patients with 2-5 lesions who were randomized to receive single dose ROM or 6 months PBMDT.
b) Single patch cases (mono lesion) who received single dose of ROM

The objective of the study is to evaluate under routine programme conditions, the efficacy of a combination of rifampicin plus ofloxacin plus minocycline (ROM) administered as a single dose for the treatment of skin smear negative paucibacillary 2 to 5 skin lesions cases, compared to the standard six monthly doses of WHO MDT regimen for paucibacillary leprosy.

1. 2-5 Lesions study

2-5 lesions study is a randomized double-blind controlled clinical field trial. The randomization will be at the individual patient basis, with some patients getting a single dose of ROM with appropriate placebos and others with WHO MDT with appropriate placebos. The total duration of the study will be 48 months (6 months of intake phase, 6 months of treatment phase & 36 months of post-treatment follow-up).

2. Mono Lesion Study

Mono lesion study is an open-trial with a single dose of ROM. The total duration of the study will be 48 months.

Participating centres:

1. 2-5 Lesions study

Andra Pradesh	**:**	Chittoor & Cuddapah
Tamil Nadu	**:**	Chennai & CLTRI, Chengalpet
Uttar Pradesh	**:**	Naini

2. Mono Lesion study

Andhra Pradesh : Chittoor & Cuddapah districts

Meetings conducted:

- Meeting with District Leprosy Officers of Chittoor and Cuddappah regarding follow-up survey for mono-lesion study patients, 6th January, 2004

- Decoding for Multicentric Field Trial of single dose ROM in PB Leprosy patients with 2-5 lesions was conducted in the presence of Prof. K. Ramachandran, Advisor, NIE on 23rd January, 2004

Results after decoding: 'Comparative trial of single dose chemotherapy in paucibacillary leprosy patients with 2-5 skin lesions'

The distribution of patients at intake in five centers is given in Table 1. Overall coverage at the end of 42 months is 99.5%.

Table 1: Distribution of patients at intake by participating centres

Centre	Number	(%)
Chittoor	698	(45.7)
Cuddapah	384	(25.2)
Chennai	76	(5.0)
Chengalpet	250	(16.4)
Naini	118	(7.7)
TOTAL	1526	(100.0)

Out of 1526 patients admitted in the study, 762 were randomly allotted to ROM and 764 randomly to WHO PB MDT. Comparison of various baseline characteristics in two groups is given in Table 2. It is observed that the all characteristics like age, sex, number of lesions, number of parts affected, nerve involvement and mean clinical score were similar at intake in both the regimen. For the calculation of mean clinical score, the variables anaesthesia and appearance of lesion were only taken for the uniformity.

Table 2: Comparison of Baseline Characteristics in two groups

Variable	ROM		WHO		p
	N	(%)	N	(%)	
Age					
Adult	560	(73.5)	566	(74.1)	0.83
Child	202	(26.5)	198	(25.9)	
Sex					
Female					
Male	393	(51.6)	360	(47.1)	0.09
	369	(48.4)	404	(52.9)	
No. of lesions					
1					
2	57	(7.5)	37	(4.8)	0.13
3	387	(50.8)	405	(53.0)	
4	187	(24.5)	196	(25.7)	
5	100	(13.1)	86	(11.3)	
	31	(4.1)	40	(5.2)	
No. of parts affected					
1					
2	450	(59.1)	446	(58.4)	
3	267	(35.0)	251	(32.9)	-
4	42	(5.5)	57	(7.5)	
5	3	(0.4)	9	(1.2)	
	0	-	1	(0.1)	
Nerve involvement					
Yes					
No	149	(80.4)	156	(79.6)	0.72
	613	(19.6)	608	(20.4)	
Clinical score					
Mean (SD)					
	13.72	(5.33)	13.92	(5.22)	0.47

The mean clinical score (SD) during follow-up periods is given in Table 5. The mean scores decreased constantly in both groups at the end of every six months. The mean (SD) intake score in ROM was 13.72 (5.33) and it decreased at the end of 42 months to 2.79 (3.95). In the same way, the mean (SD) intake score in WHO was 13.92 (5.22) and it decreased at the end of 42 months to 2.72 (4.01). The difference of mean clinical scores between two treatments at all time point was not statistically significant.

Table 3: Mean Clinical score during follow-up

Follow-up	ROM		WHO		p
	n	Mean (SD)	n	Mean (SD)	
At intake	762	13.72 (5.33)	764	13.92 (5.22)	0.47
6 months	735	6.81 (5.21)	735	6.92 (5.07)	0.67
12 months	726	5.49 (5.08)	722	5.49 (4.94)	0.99
18 months	713	4.69 (4.81)	710	4.69 (4.63)	0.98
24 months	693	4.11 (4.60)	705	4.01 (4.40)	0.66
30 months	687	3.61 (4.32)	696	3.54 (4.26)	0.76
36 months	681	3.29 (4.08)	692	3.16 (4.12)	0.53
42 months	672	2.79 (3.95)	683	2.72 (4.01)	0.75

Table 4 gives the special events by treatment observed in the study. There are about 38 suspected relapses (new skin lesions and new skin with nerve lesions). Deaths observed are not related with leprosy. Misclassifications were at the time of intake and these cases were appropriately treated. Drug reactions, reversal reactions and neuritis were treated as per the protocol.

Table 4: Distribution of Special Events in two groups

Special events	ROM	WHO	Total
Death	12	10	22
Drug Reactions	2	8	10
Migration	34	38	72
Misclassification	2	1	3
Neuritis	1	3	4
New Skin Lesion	26	8	34
New Skin + Nerve Lesion	2	2	4
Refusal	5	6	11
Reversal Reaction	1	1	2
Temp. Migration	2	3	5
TOTAL	87	80	167

Complete clearance was defined as ‘total disappearance of all lesions at 42 months’. Complete clearance at every six-month interval and for both treatment is given in Table 5. Complete clearance in ROM group was from 24.4% at 6 months to 71.6% at the end of 42 months and In WHO group it was 25% at the end of 6 months to 71.3% at the end of 42 months.

Table 5: Complete Clearance (%) in two groups

Follow-up	*ROM*		*WHO*	
	n	*Clearance (%)*	*n*	*Clearance (%)*
6 months	735	24.4	735	25.0
12 months	726	37.7	722	38.4
18 months	713	46.0	710	47.0
24 months	693	51.4	705	54.0
30 months	687	57.4	696	58.1
36 months	681	63.4	692	64.6
42 months	672	71.6	683	71.3

Table 6 gives the percentage of patients completely cured in the two groups according to age, sex, number of lesions and number of body parts affected. There was no statistically significant difference with respect to treatment.

Table 6: Patients with complete clearance (CL) at the end of 42 months

Variable	**ROM**		**WHO**		**p**
	CL (%)	**N**	**CL (%)**	**N**	
Age					
Adult	62.7	(351/ 560)	62.2	(352/ 566)	0.91
Child	64.4	(130/ 202)	68.2	(135/198)	0.48
Sex					
Female	64.1	(252/ 393)	62.0	(223/360)	0.59
Male	62.1	(229/ 369)	65.3	(264/ 404)	0.38
No. of lesions					
1	63.2	(36/ 57)	70.3	(26/ 37)	0.63
2	66.4	(257/ 387)	63.2	(256/ 405)	0.38
3	57.8	(108/ 187)	65.8	(129/196)	0.13
4	58.0	(58/ 100)	61.6	(53/86)	0.72
5	71.0	(22/ 31)	57.5	(23/40)	0.35
No. of parts affected					
1	64.2	(289/ 450)	66.4	(296/446)	0.54
2	62.6	(167/ 267)	62.6	(157/251)	0.93
3 or more	55.5	(25/ 45)	50.8	(34/67)	0.76

Table 7 gives relapses by treatment. There was more number of relapses in ROM group. There is significantly larger proportion of ROM cases getting more relapses. About 68% of the relapses were observed within 18 months in ROM group and 80% of the relapses were observed within 18 months in control group.

Table 7:Relapse by treatment

Relapse	ROM	WHO
Yes	28	10
No	734	754
Relapse (%)	3.7	1.3

Table 8 gives relapses after confirmation by NIE medical officers.

Table 8:Relapses by confirmed status

Relapse	ROM	WHO
Confirmed	4	2
Reversal reaction	10	4
Misclassification	2	2
Not done	12	2

Rate of relapse was calculated using person year concepts. Survival time of the patient was calculated to get the average follow-up of this cohort without experiencing any special event. If a special event occurs for an individual, the case was censored. Each patient's last follow-up date was taken for the duration of the patient follow-up for uncensored cases. And in case of censored cases, the date of special event was taken for the calculation of duration because the patient till then contributes to the cohort. Table 9 gives the details of person-year of the cohort and rate of relapses.

Table 9: Relapse rate per 1000 person-year by treatment group

	ROM	WHO
Number of relapses	28	10
Total person-year of the cohort	2574.16	2585.57
Relapse rate per 100 person year	1.09	0.39

Results of Mono-lesion study: (upto 42 months of follow-up)

Number of patients enrolled for this study was 1262. Baseline characteristics of the patients are shown in Table 1.

Table 1: Baseline characteristics

Variables	Number	(%)
Age (years)		
Adult (≥ 15)	822	(65.1)
Child (< 15)	440	(34.9)
Sex		
Male	619	(49.0)
Female	643	(51.0)
Parts affected		
Face	225	(17.8)
Arm	529	(41.9)
Leg	408	(32.3)
Trunk	100	(7.9)

Table 2 gives the distribution of special events (n=80) that occurred in the study. There were suspected relapse in 18 cases, 46 migrations and 15 deaths not associated with leprosy or ROM treatment. One case was misclassified at intake and was changed to WHO MB treatment. Relapsed cases were reexamined by the medical officer from the coordinating center (NIE, ICMR). After the re-examination, only 7 (n=18) were classified as confirmed relapses, 4 cases were identified as reversal reactions, 3 cases were misclassifications (one was not evident of leprosy and 2 had nerve trunk involvement) and 4 cases were not available for reexamination. Time distribution for 'relapsed' cases was as follows: there were 2 cases at the end of 6 months, 6 cases at 12 months, 4 cases at 18 months, 1 case at 24 months, 4 cases at 36 month and 1 case at 42 months.

Table 2 : Special Events (n = 80)

Special Events	Number	(%)
Relapses (New Lesions)	18	(22.5)
Migrations	46	(57.5)
Deaths	15	(18.7)
Changed to MB	1	(1.3)
TOTAL	**80**	**100.0**

The total follow-up duration of the study was 42 months from intake. Clinical scores for each individual were calculated by addition of scores for anaesthesia and physical appearance of lesion. Complete clearance was defined when the lesion became invisible or a scar. Table 3, gives the summary report of number of patients followed at every 6th month examination, the mean clinical score at each follow-up, complete clearance and percentage complete clearance for every follow-up.

Table 3: Summary report of the clinical scores in all the follow-ups

Follow-up	No. of cases	Clinical Score Mean (SD)	% Complete Clearance*	
Intake	1262	5.33 (0.79)	-	
6 Months	1262	2.87 (2.00)	39.2	(487/1241)
12 Months	1251	2.34 (2.00)	52.9	(647 /1224)
18 Months	1235	2.02 (1.97)	59.7	(726 / 1217)
24 Months	1217	1.72 (1.90)	66.9	(806 /1205)
30 Months	1206	1.45 (1.84)	72.4	(868 /1199)
36 Months	1199	1.18 (1.71)	79.3	(941 / 1186)
42 Months	1188	1.05 (1.63)	82.5	(975 / 1182)

* - % complete clearance = (complete clearance / cases without special events)*100

The improvement and deterioration of an individual was calculated using the clinical scores. Improvement / deterioration was defined as difference in total score of intake value and total score at the end of the follow-up for every individual. Improvement that was partial or total was observed by any 'positive value'. Static condition was the persisting same condition and are indicated by the value '0'. Deterioration was indicated by any negative value. The improvement / deterioration (I/D) scores at the end of 42 months are given in Table 4.

Table 4: Improvement / Deterioration Scores at the end of 42 months

I/D Scores	**Number**	**(%)**
-1	1	(0.1)
0	48	(4.1)
1	44	(3.7)
2	141	(11.9)
3	62	(5.2)
4	275	(23.3)
5	212	(17.9)
6	399	(33.8)
Total	**1182**	**(100.0)**

Rate of relapse was calculated using person year concepts. Survival time of the patient was calculated to get the average follow-up of this cohort without experiencing any special event. If a special event occurs for an individual, the case was censored. Each patient's last follow-up date was taken for the duration of the patient follow-up for uncensored cases. And in case of censored cases, the date of special event was taken for the calculation of duration because the patient till then contributes to the cohort. Table 5 gives the details of person-year of the cohort and rate of relapses.

Table 5: Incidence of relapse in the cohort

	Suspected	Confirmed
Number of relapses	18	7
Total person-year of the cohort	4366.52	4366.52
Relapse rate per 100 person year	0.412	0.162

Totally 4 reversal reactions (which were earlier misclassified as new lesions) were reported during the follow-up period, which amounted to incidence of 0.092 per 100 person-years. Assuming 4 four cases that was not available for reexamination as the confirmed cases, the rate of relapse is 0.254 per 100 person year.

Final follow-up survey for mono-lesion and 2-5 lesion patients in Chittoor and Cuddappah Districts:

NIE completed the follow-up of the all the study subjects as per the original protocol approved by WHO. The follow-up was about 95% in both the studies. The results obtained were encouraging, notably high proportion of patients had complete clearance (as given in Table 3). It was considered worthwhile to conduct one more year of follow-up of these studies to see if the results achieved so far is sustained or not. Hence, follow-up survey has been planned and WHO has approved the same.

The follow-up coverage in Cuddappah was around 99%. Chittoor is yet to complete the survey.

PREVALENCE OF DISABILITIES IN MB PATIENTS, FIVE YEARS OR MORE AFTER COMPLETION OF WHO/MDT/MB REGIMEN.

The objective of he study was to assess the disability status of multibacillary (MB)leprosy patients 5 or more years after release from multi drug therapy (RFT)

It was a prospective cohort study

COHORT SUBJECTS:
All the MB patients who were treated with WHO/MDT/MB regimen and declared release from treatment (RFT) from 1986-97. (Because one year duration of MB/MDT was introduced from 1997). 547 MB patients declared RFT upto 1997.There are two cohorts: Cohorts consisting of 251 MB patients treated with MDT more than 24 pulses and 296 MB patients treated less than or equal to 24 pulses.

INCLUSION CRITERIA: All the MB patients in Avadi who were treated with MB/MDT and were RFT after completion of the course.

WORK DONE: 397 M.B leprosy Patients were assessed by the field investigators without referring to previous status of disability.
Internal assessment of Patients showing worsening of disabilities was done by the senior workers by following the procedures of blindness.
To maintain the quality of examination, 10% random check was taken up by an external leprosy expert.

Analysis: Preliminary analysis is being done by comparing the disability status at the time of R.F.T. and 5 or more years after R.F.T.

COMPARISON OF DISABILITY STATUS R.F.T Vs PRESENT SURVEY:

A/B	0	I	II	III	Total
0	**71**	13	10	1	95
I	58	**38**	36	11	143
II	1	5	**40**	43	89
III	-	-	3	**40**	43
Total	130	56	89	95	**370**

A= at the time of RFT, B= present survey

Static 189/370=51.08% ,Improve 67/370= 18% ,Worsening 114/370 = 30.8%
Worsening from Gr.0 24/95=25.26%
Gr.I 47/143=32.9%
Gr.II 43/89=48.3%

A Cross-Sectional study on the prevalence of HIV infection and other STDs among male Injection Drug Users and their sexual partners in Chennai *(A collaborative study of SAHAI Trust – NIE – YRG Care – ALMPGIBMS)*

Introduction

The scope of transmission of HIV from injection drug users (IDUs) to their regular sex partners has gradually been assuming a bigger dimension in view of the diffusion of injection drug use that has taken place in the recent past in different metropolitan cities of India. A few studies have looked at the sexual risk for HIV infection that regular and casual sex partners of IDUs carry or that IDUs themselves have as a result of high-risk sexual behavior under the influence of drug. However there is some evidence that these risks may be high. For example in the northeastern Indian state of Manipur, 45% of the non-injecting spouses of HIV positive IDUs were found to be HIV infected. Other northeastern states of India such as Mizoram and Nagaland also observed the introduction of HIV first among local IDUs in the early 1990s.

Until 1991, the vulnerability of the heroin smokers of the Chennai city to HIV, not much talked about. Although, injection drug use was existent in Chennai even before, due to sudden street scarcity of heroin caused many heroin users in Chennai to switch to the easily available injection preparation of synthetic opioid analgesic named buprenorphine (trade name tidigesic). Since 1991, buprenorphine use thus escalated among opiate users and even when heroin was available again after some time. Although, government supported drug detoxification centers were operating since 1985, responses to this added dimension of HIV vulnerability in the city of Chennai came mostly from NGOs and Catholic Churches of Madras Diocese who, with the help of local researchers, documented different risk practices of the local IDUs.

Meanwhile, research from different countries revealed that HIV lives in an epidemiological synergy with other sexually transmitted diseases (STDs) and a range of STDs do facilitate transmission of HIV. Scarcity of Sexually transmitted Infection (STI) prevalence data from IDUs from different parts of India however limited the scope of examining further transmission of HIV in and from IDUs to the other linked population groups such as their spouses. A few studies of course looked into the self reported sexual behavior of IDUs; in one such study from Chennai, the capital of Tamilnadu, one third of the study population even had a history of having sexually transmitted illness in the past year. A community based study in men in Tamilnadu that reported lifetime occurrence of syphilis (indicated by TPHA positive test results) and another community based study in rural women reported TPHA positive test results and presence of syphilis was reported in industrial workers, transport workers and male patients attending primary health care centers. The present cross-sectional study was therefore designed to generate epidemiological data on HIV and STD/STIs from IDUs and their sex partners in Chennai. This was a collaborative study of National Institute of Epidemiology (ICMR) Chennai and two Non-Governmental organizations SAHAI Trust and YRG Care and another Government Institute A.L.Mudaliar Post Graduate Institute of Bio Medical Sciences, chennai.

Aim of the research study and research questions

The aims of the proposed study were primarily two folds; firstly to assist the design of an intervention aiming at reducing the rate of STI and HIV transmission among IDUs and their regular sex partners through enhanced treatment of STIs. Secondly it was intended to make

the HIV and STI prevalence data from IDUs and their wives/regular sex partners available to the State and National AIDS Control Organization (NACO), research institutions and funding agencies for informing and enhancing the HIV/STI containment program in the country.

The major research questions were 'what are the prevalence of HIV infection and other STIs among male IDUs and their regular female sex partners' and 'what proportion of the IDUs and their partners live in HIV discordant relationship thus having one partner at risk of HIV transmission' which had direct implication for designing of future intervention trial.

In the light of the self reported sexual behavior mentioned above in the introduction, we thought that the prevalence of curable (caused by bacteria and protozoa) STIs in IDUs and their spouses / regular sex partners would be high. As a very negligible proportion of the wives / regular sex partners of IDUs in India inject drugs, social norms in the country expect married women to be monogamous and condom use among married couples is generally low, we assumed that reduction of HIV incidence through improved STD management would be possible for IDUs and their sex partners in Chennai. What seemed important was finding out an effective mechanism to reach out to them and with a right mix of intervention elements. No biologic data except HIV prevalence in IDUs was however available to help researchers make realistic assumptions for designing such an intervention trial and the present cross-sectional study was expected to generate data in this regard.

Design and Methodology

The design of the study presented here was cross-sectional in nature. The present exercise was designed as an epidemiological study.

Study population and site for the study: inclusion and exclusion criteria

The study population comprised injection drug users and their spouses / regular sex partners in central Chennai. Eligible were the IDUs and their sexual partners who had been residing in the study area for at least 2 months, who indicated that they expected to live in the study area for at least 18 months (in view of the planned future intervention trial), who were 18 years old (considered as major in India) or above and who agreed to be registered and subsequently to participate in the cross-sectional study survey itself.

IDUs who did not have regular sex partners were not eligible. Female partners of IDUs were only eligible if their male partners were successfully enrolled.

Development of study tools / questionnaire

The questionnaires were developed by the research study coordinator and subsequently received inputs from the principal investigator, head of the HIV/STI research program of Population Council-New Delhi, field researchers, intervention facilitators and study-physicians of SAHAI-Trust as well as the data managers and data analysts from NIE (ICMR). This participatory process of developing questionnaire went through the phases of ‘checking appropriateness of the issues to be explored in the cross-sectional study’, ‘incorporation of field experience in the questionnaire’, ‘translation and back translation of the questionnaire from English to Tamil to English’ and ‘making it user friendly for computerized data entry and analysis'. The final version of the questionnaire was drafted both in English and Tamil. Forms for taking informed consent and forms for registering IDUs and their spouses / regular sex partners were also translated in the local language from the English version which was

approved by the Institutional Review Board (IRB) of Population Council New York as well as the local IRB of SAHAI-Trust.

Sample size covered through cluster identification

The whole of central-Chennai for the present study was divided into north, west and east zone respectively and named as north-central-Chennai, west-central-Chennai and east-central-Chennai. Through outreach activity established contact with a representative population of married IDUs in the city. The aim was to identify the clusters in the city where IDUs used to hang out. This should however be noted that the nature of the present cross-sectional study and the inclusion criteria had a limitation in terms of knowing the HIV prevalence among IDUs of Central Chennai as the study was only about married IDUs or IDUs in live-in relationship with their regular female sex partners.
Outreach workers and field researchers, some of whom had past experience of opiate drug use, had helped the research fellows under study and intervention facilitators in preparing a preliminary spot map that had 23 clusters in the north, 9 in the west and 6 in the eastern zone of central Chennai. A total of 126 married IDUs could be identified and recruited from these known clusters with a distribution of 78 in the north, 32 in the west and 16 in the east. New outreach workers were subsequently recruited who could expand the area of 'reach' and identify new clusters through snowballing. Obtaining a representative baseline prevalence of HIV and other STIs in IDUs and their regular sexual partners in central-Chennai was thus possible at a later stage of the cross-sectional study. Three new clusters were identified in the north, 6 in the west and 4 in the east-central-Chennai through this outreach expansion plan from where respectively 7, 28 and 11 IDUs were recruited in the study; a total of 46 IDUs more. From the older clusters also, new clients not known previously to the outreach workers were identified and recruited in the study and the numbers of such IDUs were 36, 17 and 35 respectively from the north, west and east zone of central-Chennai; a total of 88 newly known clients from old clusters. The universe of interest for the cross-sectional study was therefore exhaustively covered through outreach intervention and the whole of it was recruited in the cross-sectional study that speaks about the representative-ness of the study findings.

'Injection drug user' (IDU) was defined in the present study as one who had ever injected drugs and the 'current injectors' were considered as someone who had at least injected drug once within the last six months. Ex-users were those who had injected drug before six months and none was recruited in the current cross-sectional study who had injected drug just once in life.

STIs screened

STIs were screened using two levels of laboratory diagnostic facilities. Firstly, bedside microscopy at the clinic based laboratory, and secondly by sending samples to the microbiology laboratories having facilities for gold standard techniques such as Polymerase Chain Reaction (PCR by Roche- Molecular System Inc.).

Bedside Microscopy Trichomonas vaginalis (TV)in wet mount preparation from vaginal swab of women and urethral swab from men and put in the incubator at 36° Celcius located at the clinic based laboratory itself and examined everyday morning for the growth of Trichomonas vaginalis for the next seven days

HIV ELISA test and Herpes Simplex type-2 on Serum and NG/CT-PCR from cervical swab of females and NG/CT-PCR on urine samples from males were examined at YRG-Care laboratory and RPR and TPHA tests on Serum were examined at ALMPGIBMS laboratory.

Following speculum examination, three vaginal swabs were taken from each of the consenting female participants- one was used for wet mount preparation in normal saline on glass slide for identifying motile trophozoites of *Trichomonas vaginalis* and wet mount preparation in KOH for identifying the yeast cells of Candida, the second one for preparing a smear on glass slide for gram staining and diagnosing Bacterial Vaginosis by using Nugent's criteria and the third one for culturing *Trichomonas vaginalis* in In-Pouch system. One dacron swab was used for collecting cervical specimen from each of the female participants for NG/CT duplex-PCR.

Each of the male IDUs and wives / female regular sex partners of IDUs who participated in the study also donated blood for serological tests, which was collected by using vacutainer system. In situations where drawing blood with the needle that usually comes with the vacutainer system was difficult due to venous sclerosis in injection drug users, thinner butterfly needles were used to collect specimens of blood.

Dacron urethral swabs were taken, one from each male participant, for culturing *Trichomonas vaginalis* in In-Pouch system. IDUs also provided the researchers with a sample of first void urine captured in a clean sterile container after abstaining from urination for two hours. The samples of urine were preserved in cold and subsequently transported to the designated laboratory for NG/CT-PCR tests.

At the end of each day, the clinical samples were transported in cool-box to the respective laboratories for tests. A proportion of randomly drawn clinical samples were sent to different laboratories for quality control. The test results for STIs except for that of HIV reached from the laboratories to the study physicians and based on the these test results the patients were further contacted and treated as appropriate along with their partners.

Ethical considerations

The proposal for the current cross-sectional study submitted to the 'Institutional Review Board' (IRB) of the Population Council, New York through the Population Council country office in New Delhi, India and the local IRB of SAHAI-Trust- the implementer of the study reviewed and approved along with the consent forms. Final approval of IRB was obtained following a critical examination of this revised version and when the reviewers were satisfied that all the points raised by them were adequately addressed by the researchers in the modified proposal. Final version of the IRB-approved protocol was shared among all the partners of different collaborating agencies.

Only the data analysts (NIE-ICMR, Chennai) responsible for data entry and computerized data analysis were able to link the HIV test results with the corresponding behavioral data and they were in charge of archiving all the records under strict confidentiality. They were of course not in a position to link any HIV test result with any particular name, as they were not having names of the participants with them. As consent was obtained from the study participants that they will be treated for curable STIs along with their partners based on laboratory test results notification for HIV was therefore not an issue. However this was also told to the participants that anybody seeking HIV-VCTC (Voluntary Confidential Testing and

Counselling) would be helped to access such services from an independent team who would deal with all the matters linked to it. The other STI test results were of course linked to the respective study participants and treated as described.

Procedures observed in the clinics and laboratories during the study
Two field-based clinics operated, each on alternate day, from 9-30 a.m. in the morning to 4-30 p.m. in the evening. After a couple was registered and informed voluntary consent (either through signature or left thumb impression by the respective participant on the consent form) was obtained from them, male interviewers interviewed male IDUs and female interviewers interviewed the wives / regular sex partners of the IDUs. Following completion of interviews, a male physician took clinical history and examined the IDUs whereas a female physician did the same for the female study participants. Information obtained during history taking and clinical examination findings were recorded in a separate pre-designed and field-tested health questionnaire format.

Data entry and analysis

In addition to daily checking, experienced statisticians looked for the internal consistency of the filled in questionnaire once they reached National Institute of Epidemiology (NIE-ICMR). The research fellows under study immediately sorted out any discrepancy identified by the statisticians during regular checking of the filled-in questionnaires. The data entry operators then entered the data under supervision of a senior system analyst from the NIE. A senior statistician subsequently worked with the research study coordinator, principal investigator and the Director of NIE-ICMR for data analysis

Results and analysis

The results of the cross-sectional study presented here describe the socio-demographic profile of the study participants and also provide a detailed account of the injection as well as sexual practices of them. These findings details the vulnerabilities of injection drug users (IDUs) and their wives/regular sexual partners in Chennai to getting HIV and other sexually transmitted infections (STIs). We have also examined the association of HIV prevalence, if any, with the exposure of the study participants to different risk practices as well as risk environment such as being in prison or injecting drug in shooting galleries or residing in any particular area of the city.

HIV prevalence in IDUs and their wives/regular sex partners

HIV in couples
Thirty percent of the IDUs (68/226) recruited in the present study were found to be HIV infected; all the HIV positive ELISA test results were confirmed by a second ELISA test system that used different antigen source for capturing antibodies. On the other hand, 4% (9/202) of the wives and 8% (2/24) of the regular sex partners of the IDUs were HIV positive (not a significant difference; Fischer's exact test p=0.3). All the female respondents considered together had an HIV prevalence of 5% (11/226). A detailed distribution of HIV status in couples can be obtained from the table below (table-1).

Table- 1 HIV Sero-status in couples

HIV Status	Distribution	Proportion with 95% CI
HIV+ve IDUs & HIV +ve wives/regular sex partners	11/226	5% (3 – 9)
HIV+ve IDUs & HIV -ve wives/regular sex partners	57/226	25% (20 – 31)
HIV-ve IDUs & HIV -ve wives/regular sex partners	158/226	70% (64 – 76)

While the HIV status of the regular sex partners (not married to IDUs) were examined separately along with their respective IDU partners, concordance for HIV positive test results was a little higher (2/24; 8%) compared to the overall picture described in table-5 and similar was the situation also for discordance (8/24; 33%). These differences accounted for low concordance rate for HIV negative test results (14/24; 58%) in this subpopulation of IDUs and their regular sex partners who were not in marital relationship.

Age and educational status versus HIV

A similar proportion (around 30%) of IDUs in each of the different age groups (except in groups where cell frequency was low thereby precluding generalization) classified as 'below 20 yr', '20-24 yr', '25-29 yr', '30-34 yr', '35-39 yr', '40-44 yr' and 'equal to or above 45 yr' were HIV infected that indicates HIV in central Chennai has by now penetrated almost equally in different age categories of IDUs. On the other hand, women younger than 29 yr of age were having higher prevalence of HIV in them compared to the older ones (table-2).

Table-2 Age distribution of the participants and HIV in them

Age categories in years	Number of IDUs in a particular age category	HIV positive IDUs in a particular age category (%) (Total number of HIV positive IDUs 68)	Number of wives / regular sex partners in a particular age category	HIV positive wives / regular sex partners in a particular age category (%) (Total number of HIV positive wives / regular sex partners of IDUs 11)
<20	-	-	2	-
20 – 24	4	2 (50)	41	3 (7)
25 – 29	25	7 (28)	66	4 (6)
30 – 34	57	14 (24)	53	1 (1)
35 – 39	78	27 (35)	48	2 (2)
40 – 44	41	11 (27)	14	-
>= 45	21	7 (33)	2	1 (50)

It is important to note that while 13% (29/226) of the IDUs were in '29yr or below' age bracket, 48% of the women participants (109/226) fell into this category. It is also important to note that although there was no difference in age composition between HIV positive and HIV negative IDUs, the prevalence of HIV was higher among those who had primary or lower level of education (56/166; 34%) compared to the IDUs having higher educational background (12/60; 20%; p=0.04).

HIV and injecting practices

Types and frequency of injecting versus HIV prevalence

None except one of the IDUs reported injecting drugs always through intra-muscular route and 84% of the IDUs (190/226) were intra-venous drug users; the rest switched between intravenous and intra-muscular injecting particularly when they lost their veins due to soft tissue damage resulting from repeated injecting. It is worth noting here that the clinical examination during the present study revealed venous sclerosis in 29% of the IDUs (66/226).

As no significant difference in HIV prevalence was found, between current and ex-IDUs (table-4), similar was the case also with different injecting practices (intravenous versus sometimes intravenous and sometimes intra-muscular injecting). However, IDUs who had reported injecting drugs infrequently or stopped injecting six months ago or earlier, were found to be infected with HIV at a much lower prevalence compared to those who are regular injectors; the difference in these subgroups were statistically significant (table- 3).

Table-3 Association between injection frequency and HIV prevalence

Injection frequency	HIV prevalence	
Do not inject daily or last injected six months ago or even before	32/136	23%
Once a day	11/32	34%
Twice a day	12/32	37%
More than twice a day	13/26	50%

χ^2 =8.80; p=0.03; df=3
Trend χ^2 =8.52, p=0.004

Places, practice and HIV: issues with regard to environment

Evidence abounds from different parts of the world that drug injecting in jail by IDUs mostly involve multi-partner use of injecting equipment. We explored issues around imprisonment in the present study and found out that a significantly higher proportion of the IDUs who were ever in jail were HIV positive (37%; 48/129) compared to those who were never incarcerated (20/97; 21%). The difference was statistically significant (χ^2 = 6.48; p=0.01; OR 2.28; 95% CI 1.19-4.39). Due to the cross-sectional nature of the present study, we could not know which one was the antecedent event between incarceration and HIV infection in IDUs. However, eight percent of the HIV infected (4/48) and ten percent of the HIV uninfected IDUs (8/81) who had ever been to jail reported that they had managed to inject drug while in jail.

An association was also found with HIV prevalence in IDUs and the place (physical location) of injecting. While 36% of the IDUs who had reported ever injecting drug at a drug selling place were HIV infected (47/132), only 22% of the IDUs who did not report such practice contracted the virus- a statistically significant difference (Chi square value 3.98; p=0.04 and OR= 1.92; 95% CI 1.01-3.67).

On the other hand, we failed to see any positive association between proportion of IDUs being ever admitted to detoxification centers and lower HIV prevalence in IDUs. In fact, HIV prevalence in IDUs who had ever sought admission to any detoxification center was much higher (37/101; 37%) compared to that in IDUs who did not get admitted (31/125; 25%) to any detoxification center (p=0.05; OR=1.75; 95% CI 0.95-3.24). Attempt was not made to examine associations between HIV prevalence in IDUs and their contact with other kinds of drug services such as needle syringe exchange or oral sublingual buprenorphine substitution

as these services were initiated only in the last quarter of 1999 in parts of Chennai. In the mean time HIV prevalence in IDUs had already reached a figure of 27%- a level first observed through sentinel surveillance in 2000 and has ever since stayed almost at the same level except for the sentinel surveillance round 2003 when IDUs were recruited from north-Chennai and 63% HIV sero-prevalence was recorded. Moreover, buprenorphine substitution program that was catering to a regular clientele of 300 IDUs from north and south Chennai came to a halt in July 2002 after operating for a period of approximately two and half years since 1999 November.

Types of injection equipment used

IDUs in Chennai use syringes of two different sizes- 2 ml and 5 ml; those injecting cocktails of different drugs (diazepam, chlorpheniramine and buprenorphine) requiring bigger size syringe to accommodate a large volume of fluid in it. Most of the IDUs (159/226; 70%) in the current study reported using 2 ml syringes whereas 18% of the IDUs said that they were sometimes using 2 ml syringes and sometimes 5ml and only 12% were exclusive users of 5 ml syringes. We looked into the difference in HIV prevalence in IDUs using different types of syringes and did not find any association (HIV sero-prevalence in 2 ml users 52/159-33%; in 5 ml users 5/27-18%; and HIV sero-prevalence in those who sometimes used 2 ml and sometimes used 5 ml 11/29-38%; Chi square value 2.36; p=0.30).

Borrowing and lending of injection equipment

Borrowing injection equipment from others during the recent injection episodes (within the last two weeks) were reported by 30% (43/144) of the current IDUs of whom 25 were HIV negative. This clearly depicts the vulnerability of the IDUs to getting HIV through sharing of injection equipment in a setting where almost one in every three IDUs was HIV infected. A little over half of those who had reported borrowing syringe and needle from others at the time of injecting drug over the last two weeks, borrowed it from three or more different IDUs. Specific inquiry about lending of injection equipment during the last injecting episode revealed that altogether 57 (39% of the current IDUs) injecting drug users did so of whom 22 were HIV positive.

Onset of injecting and HIV: a trend analysis of what happened when in Chennai

Self-reported onset of injecting drug dates back to 1968 in our study population and 20% of the cohort enrolled in the current cross-sectional study started injecting drug before 1986. In each five-year period following 1986 about 25% of the IDUs recruited in the present study initiated injection drug use. Examination of the cohort that reportedly started injecting between 1986 and 1994 (covering the event of first detection of HIV in Chennai in female sex workers that also marks the beginning of HIV epidemic in the country) and their current HIV status reveals that those who started injecting during 1986-1988 have three times higher risk of being HIV positive compared to the initiators of injection drug use during 1992-1994 (table-4).

Table-4 Analysis of trend of current status of HIV infection in cohorts of IDUs who initiated injecting drug use at different points in time

Initiation year of injecting drug	Currently HIV positive	Current HIV status negative	OR
1992-1994	6	21	1.00
1989-1991	11	29	1.33
1986-1988	18	23	2.74

Chi-square value for linear trend was 3.806 and p value was 0.05

Knowledge and risk perception about HIV and STIs

A relatively high proportion of IDUs said that they had heard about sexually transmitted diseases (198/226; 88%) as well as of HIV/AIDS (225/226; 99%) compared to female respondents who reported a low knowledge about STDs (90/226; 40%). More women of course had heard about HIV/AIDS (219/226; 97%). Knowledge about symptoms of HIV/AIDS was however significantly lower among women (31% did not know about symptoms) compared to men (9% did not know).

Although the knowledge about HIV/AIDS was high among IDUs, their own risk perception about the possibility of contracting HIV as well as HIV-VCTC uptake was quite low. Only five (5/68; 7%) of all the IDUs who were infected with HIV knew that they were HIV positive. Moreover, fifty percent of all the IDUs did not perceive that they had any chance of being infected with HIV and this low level of risk perception was present in the study participants irrespective of their actual HIV status. A similarly high proportion of women (117/226; 52%) did not perceive their own risk of getting HIV/AIDS; while 41% of the women were ambiguous about their risks 6 of them said that they did not even hear about HIV/AIDS.

Sexual practices and prevalence of different STIs and STDs:

Sexual debut

Mean and median age at sexual debut among IDUs was 19 yr (SD$\pm$ 3 range 10 to 29 yr) and no difference was observed in this mean age between groups of IDUs who were HIV infected compared to those who were not. One third of the IDUs had had their first sex with female sex workers and forty two percent of the IDUs had their first sex with casual partners or friends. The rest reported having sex for the first time in life with their wives. Mean and median age at first sex among the wives/regular sex partners was a little lower compared to that of IDUs (18 yr; SD$\pm$ 3, range 12 to 33 yr) and almost all of them (217/ 226; 96%) had their first sex in with their husbands except 5 who had it with friends and the rest 4 had it with casual partners.

Sex within marriage and vulnerability of women

Most of the IDUs (195/226; 86%) reported having sex with their wives from a few times in a month to more frequent sexual acts; it is important to note that one fourth of them were even HIV positive (49/195). Commonly practiced sex by the study participants with their spouses was peno-vaginal sex as only 21 (9%) and 16 (7%) IDUs reported having peno-anal and peno-oral sex respectively within marriage. Condom use while having sex with wives was disconcertingly low in this population- while only ten of the IDUs reported always using condom with wives, as high as 85% (193/226) had never used condom with their wives. 'Most of the time' and 'always' use of condom while having sex with female sex workers was also reported by as low as 30 IDUs (30/137; 22%) although 61% (137/226) of all the IDUs had reported having sex with sex workers and 16% (22/137) of them even had such an experience in the last year.

Sexual activity outside marriage

A very high proportion of IDUs (184/226; 81%) reported having sex with some one apart from their spouses and 63% of them even had it with five or more different partners in their lifetime. On the other hand, 7% of women participants (17/226) reported having sex outside marriage of whom majority (14/17, 82%) had it with only one partner and the maximum number of different partners with whom women had sex apart from their husbands were two

that clearly speaks about the higher vulnerability of IDUs compared to their wives/regular sex partners to getting HIV and other STIs through unsafe sex.

Nearly two third of the IDUs (137/226) reported ever having sex with sex workers and no significant difference was found between exposure to sex workers and HIV prevalence in them.

Drug sex interface

Inquiry about the present practice of drinking alcohol in our study population revealed that 59% (134/226) were regular drinker with a frequency from once a week to almost every day drinking and a total of 167 IDUs recruited in the study (74%) admitted currently consuming alcohol. Fifty-five IDUs however said that they used to drink alcohol in the past, which they discontinued later which indicates that almost all the IDUs recruited in the cross-sectional study had had alcohol at some point of time in their lives and many of them are actually poly drug users as they do drug and alcohol simultaneously. While 23% (52/226) of the IDUs also reported having sex currently with their spouses under the influence of alcohol / drug; a much higher proportion (102/226; 45%) reported doing so within the first year of marriage.

IDUs who had sex with men

Twenty two percent of the total IDUs (49/226) recruited in the study had reported ever having sex with men. While 83% of this subpopulation (41/49) experienced sex with men even before getting initiated into injecting, almost half of them said that they had such experience after they took to injection drug. No body except two reported using condom during these sexual encounters. As all of the IDUs in the study were married or in heterosexual relationship with female partners, future risk reduction interventions and research on sexual health in IDUs should therefore take the issue of bisexuality into account. A summary of the sex practices of the study population can be obtained from the table below (table-5)

Table-5 Sex practices at a glance in IDUs and their wives/regular sex partners in Chennai

Practice	IDUs n=226	Wives/regular sex partners N=226
Had had sex with someone other than spouse	184 (81%)	17 (7%)
Ever had sex with casual sex partners	122 (54%)	None
Ever had sex with female sex worker	137 (61%)	Not applicable

Prevalence of different STIs (table- 6)

A high prevalence of antibody to Herpes Simplex type-2 infection was noted in both IDUs (40%) and their wives / regular sex partners (39%) recruited in the study. On the contrary, prevalence of classical bacterial STIs was low in this population group.

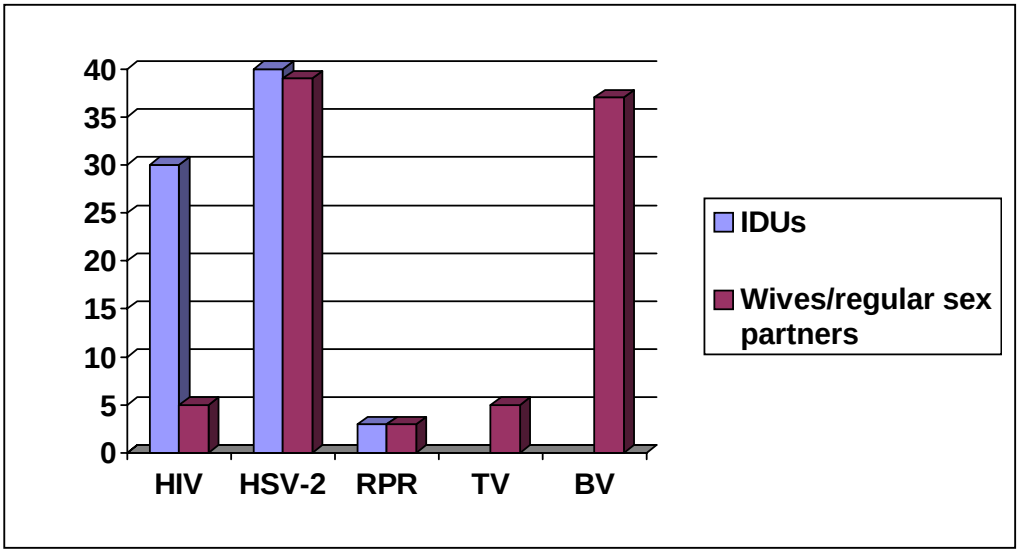
Table – 6 Prevalence of STIs in the study population

Tests for different STIs	IDUs		All women participants*	
	226	(%)	226	(%)
Life time occurrence of syphilis (indicated by positive TPHA test results)	23	(10)	11	(5)
Current syphilis (TPHA +ve & RPR +ve)	7	(3)	6	(3)
CT-PCR		-		
HSV-2 antibody positive	91	(40)	89	(39)
TV in normal saline wet** mount from vaginal swab	Not applicable		11/224	(5)
Candida yeasts in KOH wet mount from vaginal swab	Not applicable		204 /224	(90)
BV scoring - 0-3 - 4-6 - >=7	Not applicable		 58 82 84	 (26) (37) (37)

* Two women did not give consent for collection of vaginal swabs ** TV culture in In-pouch from urethral swab yielded a prevalence of 1% TV infection in men and from vaginal swab yielded a prevalence of 3% in women

Bacterial vaginosis in women, diagnosed by using Nugent's criteria had a prevalence of 37% (84/224); 6 cases occurred in HIV positive women and the rest 78 in HIV negative female study participants which had no statistically significant association. While 40 cases of bacterial vaginosis (48%) were in women in the age group of 'less than or equal to 29', 17 (20%) in the age group '35-39 yr' and 22 (26%) in '35 to 39 yr' age bracket, the rest (5; 6%) were in the age group '40 or above'. None of the study participants was infected with *Neisseria Gonorrhoeae* and only one woman was infected with *Chlamydia* on NG/CT-duplex PCR test. *Trichomonas vaginalis* could be cultured in in-pouch from only one urethral swab taken from IDUs.

Figure-4 Prevalence (%) of STIs in IDUs and their wives/regular sex partners in Chennai



HIV and Herpes Simplex virus type-2 co-infection

In view of the high HSV-2 antibody prevalence in the study population and very low bacterial STIs, we looked into the distribution of lifetime occurrence of HSV-2 with respect to HIV status in couples. A cross tabulation (Table - 7) revealed that 73 couples (32%) were concordant for negative test results and 4 for positive test result (2%) for both HIV and HSV-2 infection. On the other hand, both husbands and wives in 31 couples who were concordant for HIV negative test results, were infected with HSV-2 that indicates a high prevalence of viral STI even in those who escaped HIV infection.

In 57 discordant couples where IDUs were positive and wives were negative for HIV infection, HSV-2 co-infection was present in 36 of them. While in 18 cases both husbands and wives had it, in 7 husbands only and in 11 cases wives only had HSV-2 infection in these couples. This leaves us with 31% (18/57) of HIV discordant couples where HSV-2 could work as a synergistic factor for transmission or acquisition of HIV infection from IDUs to their wives / regular sex partners. Apart from the 11 wives mentioned above, 24 wives in HIV negative concordant couples and 1 in HIV positive concordant couples were positive for HSV-2 antibody while their husbands were negative for HSV-2- a fact indicative of risk taking sexual practices among 16% of the total female respondents.

Table – 7 HIV and HSV-2 co-infection in couples in Chennai
(Cross-sectional study on IDUs and their wives / regular sex partners)

Couples with Herpes serology status	HIV+ve IDUs & HIV-ve wives / regular sex partners	HIV+ve IDUs & HIV +ve wives / regular sex partners	HIV-ve IDUs & HIV-ve wives / regular sex partners
HSV-2 antibody+ve IDUs & the respective HSV-2 antibody+ve wives / regular sex partners	18	4	31
HSV-2 antibody+ve IDUs & the respective HSV-2 antibody-ve wives / regular sex partners	7	1	30
HSV-2 antibody-ve IDUs & the respective HSV-2 antibody+ve wives / regular sex partners	11	1	24
HSV-2 antibody-ve IDUs & the respective HSV-2 antibody-ve wives / regular sex partners	21	5	73

Clinical examination findings and associated laboratory infections in IDUs and their wives / regular sex partners

Very few IDUs had any obvious sexually transmitted disease on clinical examination. Only three IDUs had urethral discharge and one had ulcer on the penis; no combination of symptoms was seen in these cases. Only one IDU had anal ulcer of non-specific nature. The three other IDUs who had presented with genital warts, all of them also had positive antibody test for HSV-2 and only one was HIV positive whose wife was also positive for HIV, HSV-2 antibody and Bacterial Vaginosis. None of these three cases of warts had shown RPR reactivity.

In the history of past illnesses, a significantly higher proportion of HIV positive IDUs reported suffering from long continued diarrhea for more than one month (13/68; p=0.01), long continued fever for more than one month (15/68; p=0.03) and pulmonary tuberculosis (10/68; p=0.03) compared to the HIV negative IDUs (8/158; 13/158 and 8/158 respectively).

Women compared to men in the present cross-sectional study had more clinical morbidity. Fifty women (25%) were clinically diagnosed as having cervical ulcers of whom two were HIV positive and 25 had positive antibody tests for HSV-2. RPR reactivity was present in only two of these 50 women who had ulcers. The occurrence of ulcers in the rest of the cases remained unexplained. It is worth remembering that the study investigation procedures did not employ diagnostic tests for Chancroid that could explain presence of ulcers in some of these cases. However, all the cases presenting with ulcers in the study clinic were treated with a drug regimen that was effective for treatment of Syphilis as well as Chancroid.

Abnormal vaginal discharge was present in 82% (186/226) of the study participants and prevalence of commonly occurring infections was significantly more in them as indicated below (table-8).

Table-8 STIs in vaginal discharge

Vaginal discharge*	Presence of TV on wet mount	Bacterial vaginosis with Nugent's score =>7	Presence of Candida yeast cells
Clear scanty and / or clear normal discharge considered together as normal (38)	1	18	30
The rest of the vaginal discharge considered abnormal (186)	10	66	174

* Two women refused to provide vaginal specimens for bedside microscopy

RPR and other associated risk markers in a subgroup of the study population: a case study approach

In seven couples, IDUs had RPR reactivity when their female counterparts were not positive either for acute or lifetime occurrence of syphilis. All but one couples in this group were concordant for HIV negative test results and in one that was discordant, the IDU was HIV infected. While four couples in this group were discordant for antibody test results for HSV-2 with husbands having the infection in three, in one, wife was positive for HSV-2 antibody test. The two couples were concordant for negative HSV-2 antibody tests and in one both husband and wife were positive. Self reported sexual practices revealed that five IDU husbands in this group had five or more life time sexual partners apart from their spouses while the rest one had reported having sex with just one partner beyond spouse. None of the women ever had sex with anyone except their spouses in this group.

Interestingly in another group of 6 couples, where wives were positive for RPR, the respective husbands were non-reactive. Two of these IDU husbands had TPHA reactivity that

probably reflects more opportunity for men to be treated compared to women for any illness in a low socio-economic setting from where the study participants were recruited as a result of which the husbands sought treatment for syphilis and turned out to be RPR negative but still remained positive for TPHA tests. RPR reactivity in the rest four women without any evidence of acute or lifetime infection of syphilis in their IDU husbands / partners are however indicative of independent unsafe sexual practice in these women. Four of these 6 couples were concordant for HIV negative test results and two were discordant where husbands were HIV infected. On the other hand three couples in this group were concordant for positive HSV-2 antibody tests and one was concordant for negative test results; two were discordant for HSV-2 infection where wives were positive that once again reinforces independent unsafe sex practices in these women. While one of the women in this group admitted having sex with one partner beyond her spouse, five IDUs reported having sex with five or more partners and one IDU had sex with two partners apart from their spouses.
A summary of occurrence of syphilis (having both RPR and TPHA positive test results) examined against HIV infection in male IDUs and their wives / regular sex partners recruited in the study can be obtained from the table below (table- 9).

Table- 9 Syphilis and HIV infection in the study participants

HIV status	**RPR and TPHA reactive**	**RPR non-reactive**	**Prevalence of RPR positive test results when TPHA was also positive in IDUs and their wives / regular sex partners**
HIV+ve IDUs	1	67	7/226 (3%) IDUs
HIV-ve IDUs	6	152	
HIV+ve wives/regular sex partners of IDUs	-	11	6/226 (3%) Wives / regular sex partners
HIV –ve wives / regular sex partners of IDUs	6	209	

The city of Chennai and HIV infection in IDUs

Intra-city difference in HIV prevalence

HIV prevalence was significantly higher among IDUs who were recruited from north zone of central Chennai compared to that in IDUs recruited from east or west zone (see map in figure-3 below). The HIV prevalence among wives/regular sex partners also had a similar geographical distribution- 7% of the female study participants in the north and 3% in both east and west zone being HIV positive. While northern part of the city of Chennai has more number of slums and economically poor people, anecdotes reveal that in the late eighties north-central Chennai started seeing initiation of many pockets of heroin selling.

PROFILES OF MIGRANT WORKERS OF GANJAM DISTRICT (HIV PREDOMINANT BLOCKS): A PILOT STUDY

It is reported that a large number of migrant workers from Ganjam District of Orissa seek work in Surat city(Lokanath mishra et.el Unpublished data).

A serological study conducted by Kamala Gupta et. al at Surat 2002 observed that lone migrant workers from Orissa, in good numbers, work in textile industries and steel industries. More than three-fourth of migrants in Surat are male aged 15-35 years who have migrated alone leaving their wives and children at the place of origin. Almost four –fifths of them are poorly educated, employed in low paid contractual jobs and hence forced to live in slums.

They develop social net working at place of work and keep sexual relation with co -female workers or visit Commercial Sex Workers(CSW). As Surat has high seropositivity for HIV, risk of getting infected by HIV could be high. They visit their families at Ganjam time to time, usually once in a year.

A study reported by Sahoo.A.et al 2003 confirmed this finding. Patients who attended the STD clinic of MKCG Medical College Hospital Berhampur were selected and screened for HIV infection .Among them 93% HIV infected were migrant workers . All the female were infected by their husband.

It is believed that migrant workers who indulge in high-risk activities in Surat can transmit the infection to their wives, resulting in higher prevalence of these diseases in Ganjam.

Preliminary information was collected from the following sources for STD/HIV prevalance

1.Orissa AIDS Cell, 2) Superintendents MKCG Medical college Berhampur,3)STD Clinic at Skin and VD Department of MKCG Medical College4)VCTC department of Microbiology MKCG Medical college 5.Retrospective data collection at clinic of Dr.R.K.Mohapatra (Private Practitioner)

6) Association of Rural Upliftment and National Allegiances (ARUNA)7) Chief Medical Officer Ganjam District

OBSERVATION

Table-1

Prevalence of HIV among ANC in Orissa and Ganjam

from 2001- 2003

	Orissa			Ganjam		
Year	Sample size	HIV +	%	Sample	HIV +	%
2001	1600	2	0.125	400	1	0.25
2002	2000	3	0.150	400	1	0.25
2003	1940	0	0.000	400	0	0.00

Source: AIDS CELL ORISSA

Table-2

Prevalence of HIV among STD's in Orissa and Ganjam

from 2001- 2003

	Orissa			Ganjam		
Year	**Sample size**	**HIV+**	**%**	**Sample size**	**HIV+**	**%**
2001	1750	23	1.31	250	12	4.80
2002	1750	17	0.97	250	8	3.20
2003	1750	44	2.51	250	17	6.8

SOURCCE: ORISSA AIDS CELL

Table-3

Prevalence of HIV among VCTC in Orissa and Ganjam

from 2001- 2003

	Orissa			Ganjam		
Year	Sample size	HIV +	%	Sample size	HIV +	%
2001	Not			Available		
2002	2932	312	10.64	388	122	31.44
2003	3414	529	15.49	582	206	35.39

SOURCCE: ORISSA AIDS CELL

STD/HIV cases recorded is higher in Ganjam district than cases recorded in the whole of Orissa. While comparing Sentinel surveillance data of Ganjam district with Orissa data it is seen

Prevalence of HIV among STD cases is 6.8% in 2003, where as it was 3.2% in 2002 and 4.8 in 2001.

Rate of HIV at VCTC are higher in Ganjam district than in the whole of Orissa. (VCTC Table shows HIV percentage in Ganjam district in 2002 31.44, & 2003- 35.39, in Orissa in 2002 10.64 and 2003 –15.49)

Table-4

HIV cases recorded in the STD clinic. Of (M.K.C.GMCH)Berhampur,
From 2000- 2002.

Year	No of STD patients attended STD clinic	No of serum screened for HIV	HIV +	%
2000	324	230	21	9.13
2001	355	171	34	19.88
2002	387	100	10	10.00

Source's clinic of Skin & V. D Dept.Of (M.K.C.G MCH) Berhampur

Blocks from where No of HIV + was found when tested in VCTC

Berhampur NAC-29,Aska.-20, Khalikotem –16, Purusottampur-15,Polsora –15
Hinzilikut-10 , Chiki -10, Bhanja Nagar-9 Kabisurya Nagarr-5Chatrapur -2

SOURCE:CHIRF MEDICAL OFFICER , GANJAM DISTRICT

No. of migrant workers migrated blockwise to Surat inGanjam District

Aska-27, Belguntha- 1, Bhanjanagar-11,Buguda- 5,Chatrapur-2, Chikiti-2
Kodala-5Dharakut-10Digapahandi -17, Ganjam-1,Sorada-9Hinjilikut-8
J.Prasad-4,KS.Nagar-6,Patrapur-3Khalikut-9, Sanakhamundi –19 Polsara3
Kukudakhandi-14, Purusattampur-4 Rangeilunda-6, Seraguda-18,

*Source:*ASSOCIATION OF RURAL UPLIFTMENT AND NATIONAL

ALLEGIENCASSOES (ARUNA) BERHAMPUR
Out of 22 blocks of Ganjam district from 7 blocks (Aska, Khaolikote , Purusottampur , Polsora, Hinzilikot, Chikiti and Kabisurya Nagar) maximum HIV cases have been recorded from where maximum workers migrate to Surat and other states

Table-5
Percentage of migrant workers to different cities of India from Ganjam district of Orissa n=193

Name	No of Migrants	Percentage
Surat	178	92.23
Mumbai	3	1.55
Bhaba Nagar	12	6.22
Total	193	100

Source:ASSOCIATION OF RURAL UPLIFTMENT AND NATIONALALLEGIENCASSOES (ARUNA) BERHAMPUR

Table-6
Migrant workers recorded from various hospital and private practitioners of Ganjam District n=94

Place of Migration	No Migrants	%
Surat	63	67.02
Mumbai	18	19.10
Vizag	8	8.51
Assam	2	2.12
Kolkota	1	1.06
Delhi	1	1.06
Ahamadabad	1	1.06
Total	94	100

Sources:From different hospitals and private practioners

From the above information it is concluded that Prevalence of HIV is high in Ganjam district. From all blocks of Ganjam district workers migrate to other states.

67- 92 % of migrant workers migrate to Surat,2-19% to Mumbai 1.5-10% to Vizag and rest to Kolkata, Assam, Ahamadabad and Delhi. From the above information it is evident that migrants from Surat indulge in high risk behaviour and they may transmit the infection when they return back home.

Conclusion: Further in-depth study is suggested regarding prevalence of HIV/AIDS in Ganjam district at community level in different blocks.

Library Facilities

The library continued to cater to the information need of institute's staff, MAE scholars, corporate Institutes in Chennai and other ICMR Institutes expanding its services with the help of modern information technology viz., Internet based online-database search. About 300 books on Epidemiology, Biostatistics, Social Science, Demography, Clinical Trials, Public Health, Computers and other related fields were added during this year increasing the total collection to 3800 reference books. Also, several titles were received on gratis basis from publishers and institutes. Subscriptions were renewed for 37 international and national periodicals and 6 journals were received on gratis. Institutional membership with British Council Library, Chennai and American Information Resource Centre, Chennai was continued.

Library management was computerized with GLAS software, which is an integrated multi-user library management system that supports all in-house operations of the Library. The database of books available in the Library is updated on day-to-day basis with details of recently acquired books. Records of all the Library patrons are being created in the GLAS software package. The editing and updating activities are in progress. The Library is implementing bar-code based computerized circulation system.

Free Trial for "Science Direct" online journal access (full text) was made available to the staff members. Link with libraries at the National Institute of Nutrition, Hyderabad and ICMR HQs, New Delhi were established for proquest online database access. The first issue of the library newsletter was released during the first quarter of 2003.

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Dr. M. D. Gupte	Director, National Institute of Epidemiology, ICMR, Spur Tank Road, Chetput, Chennai

Special Invitees

Dr. A. V. George	Registrar, Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram – 695 011
Dr. P.K. Das	Director, Vector Control Research Centre, Indira Nagar, Pondicherry – 605 006.

List of Institutional Ethics Committee members

Chairman

Shri. Sriram Panchu	Senior Advocate, High Court, Chennai

Members

Father. Desmond Daniel	Director, SAHAI Trust , Centre For Drug/HIV Research and Care, Chennai
Shri. S. Jayaraman,	Advocate, High Court, Chennai
Dr. P. Manorama	Pediatric Gastroenterologist, Director, Community health Education Society, Kodambakkam, Chennai
Dr. R. Prabhakar	Director (Retd.), T.B. Research Centre, ICMR, Chennai
Dr. Raji Swamy	Bio-chemist, Blood Bank, Devaki Hospital, Chennai
Dr. Shuba Kumar	Social Scientist, Manager, India CLEN, Chennai
Shri. G. Srinivasan	Area Commandant , Home Guards, Avadi, Chennai
Dr. M. Suresh Kumar	Consultant Psychiatrist, SAHAI Trust, Chennai

Member-Secretary

Dr. Thilakavathi Subramania	Assistant Director, National Institute of Epidemiology, ICMR, Chennai.

APPENDIX I

Meetings/Workshops/Training Programmes Organised

- WHO-SEARO sponsored two 5-day Trainer of Trainees programme for medical and allied health professionals from the WHO-South East Asia Region, 9-13 and 23-27, June 2003.

- Workshop for Principal Investigators of Uniform MDT regimen for all types of leprosy patients was conducted during 12-13, September, 2003.

- Organised Institutional Ethics Committee meeting on 19th September, 2003.

- Training for Uniform Multi-drug Trial was given to all field workers, District Leprosy Officers, Medical Officers, Statisticians, Para-medical Workers, Non-Medical Supervisors by the Principal Investigators at their respective centers during September to November, 2003.

- WHO-SEARO sponsored 4 week training programmes in Epidemic Investigation for eight para-health professionals from the Government of Nepal held in October, 2003.
- Epidemiology Week, 12-17 October 2003, Chennai included the following events:
    - 12 – 13 Second meeting of the ICMR forum for Epidemiology
    - 14 – 15 Second annual FETP Conference: Theme: "FETP in India-Experiences and Avenues
    - 16 – 17 Workshop on "Human resource needs and development in epidemiology for public health in India"

- As part of 4 week training programme in Epidemic Investigation for Nepal Scholars, organised and facilitated a two-day training at Institute of Vector Control and Zoonoses, Govt. of Tamil Nadu, Hosur during 29-30, October 2003.

- Workshop for Principal Investigators (P.I.s) of all the participating centres in the "Multicentric Feasibility Study on the use of Intradermal Administration of Tissue Culture Antirabies Vaccines in India" was conducted during 17-18 November, 2003 at NIE.

- Conducted 5 days basic Course in Statistics and 5 days training on Controlled Clinical Trials from 8-19 December, 2003 for medical doctors and health research workers at NIE,Chennai

- Meeting with District Leprosy Officers of Chittoor and Cuddappah regarding follow-up survey for mono-lesion study patients was organised on 6th January, 2004.

- Meeting for Decoding of Multicentric Field Trial of single dose ROM in PB Leprosy patients with 2-5 lesions was conducted in the presence of Prof. K. Ramachandran, Advisor, NIE on 23rd January, 2004.

APPENDIX II

List of Publications

Published

International

Implications of genetic traits on vaccine efficacy. Murthy, B.N. *Statistics in Medicine* 2003, 22: 1989-98.

Components of small area variation in fertility rates among married women in south India. Murthy, B.N., Jabber, S., Venkatarao,T., Sureshkumar, S.K., Gupte, M.D. *International Journal of Epidemiology* 2003; 32: 639-644

Application of lot quality assurance sampling for leprosy elimination monitoring – examination of some critical factors. Gupte M. D., Murthy B. N., Mahmood K., Meeralakshmi S., Nagaraju B. and Prabhakaran. International Journal of Epidemiology 2004; 33: 344-348.

National

Gender Differences in Sexual Risk Behaviours among STD Clinic Attendees, Government General Hospital, Chennai. Thilakavathi Subramanian, Balasubramaniam, M.P., Peter A. Newman, Sreevatsa**,** Ganapathy, M., Boopathi, K., Robert F. Schilling, John L. Fahey , Mohan D. Gupte., India. *Indian Journal of Sexually Transmitted Diseases,* 2003, 24; 1: 14 – 19.

An institutional outbreak of leptospirosis in Chennai, South India. Ramakrishnan R, Patel MS, Gupte MD, Manickam P and Venkataraghavan S. Journal of Communicable Diseases. 2003, 35 ;1 : 1-8.

Trends in case detection influenced by leprosy elimination campaigns in certain areas of China. Jianping, Shen., Gupte M. D., Manickam, P., Meiwen, Yu., Li Wenzhong., Liangbin, Yan. Indian Journal of Leprosy, 2004, 26; 1: 41 – 52.

Accepted for publication

National

Prevalence of Disability and Handicaps in Geriatric population in Rural South India. Venkatarao, T., Ezhil, R., Jabbar, S., Ramakrishnan, R. Indian Journal of Public Health.

AIDS: An Understanding in Rural Women . Thilakavathi Subramanian, Ezhil, R., Gupte, M. D. Indian Journal of Preventive and Social Medicine

Factors associated with HIV seroprevalence among STD patients attending a Govt. STD clinic in Chennai, South India. Thilakavathi Subramanian**,** Gupte, M. D., Mathai A.K., V. S. Dorairaj. Indian Journal of Public Health.

Submitted for publication

International

Nutritional Status and dietary habits of tribals of Kashipur, Orissa, India. Madhan Mohan Pradhan, Venkatarao T., Ezhil R., Kar, S.K., Das, Sunil Kumar, Paikre, Sukhalata and Gupte.M.D. Regional Health Forum for South - East Asia, WHO.

Utility of serodiagnostic tests : A study in an endemic population in South India. Sinha, Sudhir, Kannan, S., Nagaraju, B., Sengupta U., Gupte, M. D. Leprosy Review.

APPENDIX III

Participation of Staff members in Workshops/Conferences/Seminars/Meetings

Workshop / Conference / Seminar/ Meeting Date & Venue	Staff member	Subject
52nd Annual Epidemic Intelligence Service Conference. April 1-4, 2003, CDC, Atlanta	M.D.Gupte	Participant- Presented a paper on "FETP-India"
Workshop on Collaborative Research between SAHAI Trust & Population Council on HIV/STI prevalence in IDUs and their Regular sex partners April 3, 2003 at NIE, Chennai.	Thilakavathi Subramaniam S.Jabbar	Participant Participant
IAVI Meeting April 4, 2003, Chennai	B. Nagaraju	Participant
IDSP consensus workshop April 4-5, 2003, New Delhi.	R.Ramakrishnan	Participant
District level sensitization meeting on urban leprosy April 10, 2003. Poonamallee	B. Nagaraju	Faculty
National Diabetes Control Programme meeting. April 12-13, 2003, MDRF, Chennai.	M.D.Gupte	Expert
Meeting on "Working together for an AIDS Vaccine for India: A Partnership of Science and Society" April 17, 2003 at IMAGE Auditorium,	M.D.Gupte B.Nagaraju Thilakavathi Subramaniam	Presented a paper on "Learnings from Vaccine Trials" Participant

Chennai.		Participant
Discussion on SARS epidemiology and preparedness for Airport and Seaport officials, Directorate of Public Health and Preventive Medicine April 21, 2003 Chennai.	M.D.Gupte P.Manickam	Participant Participant
SARS meeting. April 22, 2003, ICMR HQs., Delhi	M.D.Gupte	Participant
SAG meeting of ICMR BMS Division. April 23, 2003, Institute of Pathology, New Delhi	M.D.Gupte	Participant
46th Seminar and Hindi Workshop on Official Language Management, Policy implementation, conducting workshop information & technology & computerization organized by RajBhasha Sansthan. April 23-25, 2003, Shimla.	S. Rangarajan S.Kumaravel	Participant Participant
Panel discussion on "SARS - A Global Threat", Respiratory Research Foundation of India April 25, 2003 Chennai.	M.D.Gupte P.Manickam	Panelist Participant
Workshop to discuss plans strategies to implement HIV Surveillance System conducted by APAC & TANSACS. April 30, 2003, Chennai, Tamil Nadu.	M.D.Gupte	Participant

District leprosy society meeting -discussed about NLEP activities in Kanchipuram and Trivellore districts. May 2, 2003 Poonamallee	B. Nagaraju	Participant
SARS – Facts and FAQs, meeting held at Sundaram Medical Foundation May, 3, 2003, Chennai.	P.Manickam	Participant
ICMR-WHO workshop on "Guidelines for management of Type II Diabetes mellitus. May 2-3,2003, Chennai.	M.D.Gupte	Participant
Meeting at RMRC, Bhubaneshwar May 5,2003, Bhubaneshwar	M.D.Gupte	Talk on "Epidemilogical Investigation, Preparedness and SARS
SARS Advisory Group Meeting May 6, 2003, NICED, Kolkata	M.D.Gupte	Participant
SARS – Epidemiology Update, National Technology Day May 11, 2003, NIE, Chennai.	S.Jabbar P.Manickam	Participant Participant
Meeting on SARS held at the Secretariat, Govt. of Tamil Nadu May 14, 2003, Chennai.	M.D.Gupte	Member

Measles Outbreak Investigation Training Workshop organized by WHO May 27, 2003, Chennai	M.D.Gupte	Participant
Annual Review meeting Diabetes Mellitus. May 29, 2003, ICMR HQs. New Delhi	M.D.Gupte	Officer-in-Charge
A workshop on "Genetic epidemiological methods for dissection of complex human traits" conducted by TCG-ISI June 2-11, 2003, Kolkata.	B.N. Murthy	Participant
Fourth Steering Committee meting of WHO for Rabies Control in Asia. June 3-5, 2003, NIMHANS, Bangalore	M.D.Gupte	WHO Temporary Adviser
Workshop on Iodine Deficiency Disorder and Anemia Prevention in Adolescent Girls by Directorate of Public Health and Preventive Medicine, Govt. of Tamil Nadu, and UNICEF, Chennai. June 5, 2003, Chennai.	Vidya Ramachandran P.Manickam	Participant Participant
Dissemination workshop of two-year research project on "Integrating Reproductive health and Rights in the context of Reforms in the National RCH programme in Tamil nadu, India" June 12, 2003 Chennai	M. C. Satagopan	Participant

Annual meeting of the Joint Co-ordination Board of the WHO's Tropical Disease Research. June 25, 2003, New Delhi	M.D.Gupte	Presentation made on Leprosy
"Measles Surveillance in Tamil Nadu" organized by WHO and Govt. Tamil Nadu June 2003, Chennai	Vidya Ramachandran	Participant
WHO meeting of Regional Consultation on strengthening of National capacity for Prevention & Control of SARS. July 1-3, 2003, Chennai.	M.D.Gupte	WHO Temporary Adviser
Evaluation of Diagnosis of leprosy under NLEP July, 11 - August, 2, 2003, Tamil Nadu	B. Nagaraju	Team leader
IAVI Site Assessment Process. Tamil Nadu, Andhra Pradesh & Maharashtra July 21-31, 2003.	M.D.Gupte	Member
Training programme on full text electronic databases Proquest and Ovid July 26, 2003, NIN, Hyderabad	S.Satish	Participant
DANLEP – Experience sharing conference. August 21, 2003, Chennai	M.D.Gupte	Participant
Chronic Hepatitis C study Annual Review Meeting. September 4, 2003, ICMR HQs. New Delhi	M.D.Gupte	Coordinator of the trial

9th Maharashtra State Chapter Conference of IAMM. September 5-6, 2003, AFMC, Pune.	M.D.Gupte	Participant -Delivered a talk on "Leprosy Vaccine: An update"
Tamil Nadu HIV / AIDS Data Review Conference organized by TANSACS – UNICEF. September 11, 2003, Chennai.	M.D.Gupte A.Elangovan Vasna Joshua	Participant - Presentation made on "HIV-AIDS Epidemiology - Challenges &Cautions in data analysis and interpretation and overview of the current situation. Use of models for estimation of HIV / AIDS Geographical mapping of HIV spread in India based on HIV Sentinel Surveillance & Behavioral Surveillance Data
SAC meeting. RMRC, Bhubaneshwar September 25-26, 2003 Bhubaneshwar.	M.D.Gupte	Member
Seminar on Data management and transformations in SPSS September 26, 2003, Chennai.	P. Manickam	Participant

A core group meeting on study on tracking financial flows for health research September 29, 2003, ICMR HQ, New Delhi.	B.N. Murthy	Participant
IAVI Clinical Trials Sub-committee meeting. October 2-3, 2003, New York, USA.	M.D.Gupte	Member
CIPRA meeting on Behavioural part of the CIPRA proposal at National AIDS Research Institute, ICMR, Pune October 14, 2003, Pune.	Thilakavathi Subramaniam	Participant
Joint Govt. / WHO / Partners meeting on "Leprosy Elimination Program" organized by WHO. October 20-21, 2003, New Delhi	M.D.Gupte	Participant
Advisory Board Meeting of the Diabetes Research Centre – World Diabetes Foundation. October 22, 2003, Chennai	M.D.Gupte	Member
Meeting on Review of Annual Survey Report on Performance of NLEP undertaken by TLM-India. October 27, 2003, New Delhi	M.D.Gupte	Participant
Global Training Network Clinical Evaluation Course. November 3-7, 2003, Thailand.	M.D.Gupte	Participant

"Fourth International Conference on AIDS India-" organized by TN. Dr. MGR Medical University. November 8-12, 2003 at IMAGE Auditorium, Chennai.	M.D.Gupte Thilakavathi Subramaniam B.N. Murthy A.K.Mathai	Impact of HIV /AIDS on mortality & morbidity in India. Psycho-social challenges faced by HIV infected persons. Participant Participant
"The Fundamentals of International Clinical Research Workshop" November 11-12,2003, New Delhi.	B.N. Murthy P.Manickam	Participant Participant
SAC meeting, CJIL, Agra November 15-16, 2003, Agra.	M.D.Gupte	Member
Epi Info 2003 Instructor's Course conducted by Dr. Rubina Imtiaz, Chief, PHSDB, Division of International Health, Epidemiology Program Office, Centers for Disease Control & Prevention, USA. November 18-19, 2003 at NIE Chennai.	R.Ramakrishnan Vidya Ramachandran A.Elangovan P.Manickam K.Kangasabai	Participant Participant Participant Participant Participant
Workshop on "Evaluation of Surveillance Systems", during Second Southeast Asia and Western Pacific Bi-regional Training Programs in Epidemiology and Public Health Interventions Network (TEPHINET) Conference.	M.D.Gupte Vidya Ramachandran R.Ramakrishnan	Participant & Moderator for a session on "Maternal & Child Health" Maternal Mortality in Tamilnadu -A descriptive analysis Outbreak of Typhoid

November, 24-28, 2003 at Boracay Island, Philippines	P.Manickam	fever in a village in Tamil Nadu, S. India Participant
Workshop Development for FETP, organised by CDC-TEPHINET, SEA-WPR Biennial TEPHINET Conference. November 24 – 28, 2003. Manila, Phillipines.	Vidya Ramachandran R.Ramakrishnan P.Manickam	Participant Participant Participant
XXI Annual Conference of Indian Society for Medical Statistics (ISMS) held at DMRC (ICMR) November 28-30, 2003, Jodhpur	B.N.Murthy R.Ezhil K.Boopathi C.Govindhasamy & V.Selvaraj	Simple measures for reporting Small Area Variation in rates. Stratified analysis of clustered binary data in maternal and child health data A 2 LC random effects model approach for evaluating the performance of diagnostic tests when some of the tests are correlated.
Workshop to design the study on "Burden of Disease & Socio-economic Impact of HIV / AIDS". December 2-3, 2003, Hyderabad	M.D.Gupte S.Jabbar	Participant & Coordinator of the study for Maharashtra, Tamil Nadu, Manipur & Nagaland Participant

Meeting to extend and enhance facilities of providing "E" databases December 4, 2003, ICMR HQ, New Delhi	M.C.Satagopan S.Satish	Participant Participant
Inter-country meeting of National Leprosy Programme Managers of SEAR Countries. December 9-11, 2003, Dhaka, Bangladesh.	M.D.Gupte	WHO Temporary Adviser
Indo-French workshop on "Tele-epidemiology of Dengue". December 18-19, 2003, NIV, Pune.	M.D.Gupte A.Elangovan	Participant Participant
Workshop on "Environmental and Occupational Epidemiology" January 7-10, 2004 Chennai	M.C.Satagopan	Participant
National conference on elimination of leprosy January 27 – 30, 2004 Raipur	B. Nagaraju	Participant
Workshop on" Measles aerosal vaccine : Good clinical Practices & Good Laboratory Practices for undertaking vaccine Evaluation Studies. March 8 –10, 2004, Chennai	B. Nagaraju	Participant
Fourth Sir Dorabji Tata Symposium on Leshmanasis March 10 –11 Bangalore	Vidya Ramachandran	Participant

Dissemination workshop on "Formative Research to identify protective and risk factors for the sexual transmission of HIV and STIs among IDUs and their partners" and a cross sectional study on "Sexual behaviour and the prevalence of HIV and other STIs among IDUs and their sexual partners" March 18, 2004, Chennai	M. D. Gupte M.C. Satagopan	Chairman Participant

APPENDIX - IV

Staff Development

- Smt. Vasna Joshua has submitted her Ph.D. thesis entitled "Spatio-statistical modelling and mapping of epidemiological data" to Madras University in December, 2003.

- Shri. S. Jabbar has submitted his Ph.D. thesis entitled "Measures for reporting small area variation – Application to health data" to Madras University in January, 2004.

- Shri. S. Venkatasubramaniam has submitted his Ph.D. thesis entitled "Evaluation of small area estimation technique for health data" to Madras University in January, 2004.

- Shri. T. S. Manoharan, Technical Officer, Shri. G. Stephen, Technician and Shri. M. Gandhiraj, Counsellor of VCTC of the Institute had training in "HIV/AIDS Counselling" from 2^{nd} – 6^{th} February, 2004 at Department of Psychiatry, C.M.C. Vellore, sponsored by APAC Project, VHS, Chennai.

STAFF MEMBERS AS ON 31.03.2004
[Technical Assistant or equivalent and above]

Director	:	M.D. Gupte, M.D., D.P.H.
Deputy Director	:	B. Nagaraju, M.B.B.S., D.P.H. P. Jayabal, M.Sc. (Retired on 31.07.2003) B. Narasimha Murthy, M.Sc., Ph.D.
Assistant Director	:	Sreevatsa, M.Sc. Ph.D. (Retired on 1.1.2004) T. Venkata Rao, M.B.B.S., M.Sc. R.L.J. De Britto, M.D. R. Ramakrishnan, M.Sc., Ph.D. S. Thilakavathi, M.A., Ph.D. D.Litt. Vidya Ramachandran, M.Sc., M.P.H., Ph.D. H.K. Nayak, M.B.B.S. S. Balasubramanyam, M.B.B.S.
Senior Research Officer	:	M.C. Satagopan, M.Sc. A. Elangovan, M.Sc. S. Jabbar, M.Sc., B.Ed. J. Arockiasamy, M.Sc.
Research Officer	:	P. Manickam, B.S.M.S., M.Sc.(Epid)
Senior Technical Officer	:	S. Harikrishnan, B.Sc.
Assistant Research Officer	:	S. Kannan, M.Sc.
Technical Officer	:	R. Jayasri, M.Sc. N. Ramalingam, M.Sc. V. Selvaraj, M.Sc. Vasna Joshua, M.Sc. R. Ezhil, M.Sc. L. Sundaramoorthy, M.Sc. T.S. Manoharan
Research Assistant	:	S. Venkatasubramanian, M.Sc. B. Kishore Kumar, M.Sc. V. Periannan, M.Sc. R. Sudha, M.Sc. N. Uthayakumaran, M.Sc. V.N. Mahalingam, M.Sc.

Research Assistant	:	P. Kamaraj, M.Sc., M.Phil. K. Boopathi, M.Sc. P. Jayasree, M.Sc., M.Phil. T. Daniel Rajasekar, M.Sc. C. Govindhasamy, M.Sc. A.K. Mathai, M.Sc., M.P.S. V. Ramachandran, M.Sc., M.Phil. G. Elavarasu, M.Sc.
Data Processing Assistant	:	K. Kanagasabai, M.Sc., PGDCA B.K. Kirubakaran, M.Sc., PGDCA M. Ravi, B.Sc., M.C.A.
Data Entry Operator	:	A.G. Ananthakrishnan, B.A. S. Boopalan, B.Sc.
Senior Technical Assistant	:	M. Dhakshinamurthy, M.A.
Technical Assistant	:	B. Arumugam Paul S.K. Rao M. Kirubanithy, B.Sc. M. Gangadhara Rao S. Lucas Leonard, B.A. M. Mercy Mallika Y. Livingstone, M.A. A. Mohan M. Thiyagarajan, B.Sc.
Library Information Assistant	:	S. Satish, B.A., M.L.I.S.

ADMINISTRATION

Senior Administrative Officer	:	J.P. Verma, B.A.
Assistant Accounts Officer	:	T. Jegan, B.Com., ICWAI (Inter)
Private Secretaries	:	V. Jayalekshmy Krishnan, B.A N.K.S. Brahaspathy, B.Sc.
Section Officer	:	R. Balakrishnan, B.A. A. Rajeswari, B.Sc. S. Rangarajan, M.A., B.G.L.
Personal Assistant	:	A. Murugarasan, M.A. Uma Manoharan, B.A.
Assistant	:	D. Parvathi, B.Sc. R. Udayalakshmi, B.Com. Michael Antony Joseph, B.Sc. S. Kumaravel, B.Com. (WHO Project)

CENTRAL BIOSTATISTICAL MONITORING UNIT
FOR TRADITIONAL MEDICINE RESERARCH [ICMR SCHEME]

Officer-in-Charge : M.D. Gupte, M.D. D.P.H.

Systems Analyst : Paul Alexius Tamby, M.Sc.