

NATIONAL INSTITUTE OF EPIDEMIOLOGY

(Indian Council of Medical Research)



ANNUAL REPORT 2001 – 2002

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The contents of this report should not be reviewed, abstracted or quoted

PREFACE

The National Institute of Epidemiology was established on July 2, 1999 by merging the CJIL Field Unit, Avadi with the Institute for Research in Medical Statistics (IRMS), Chennai as approved by the Governing Body (GB) of the Indian Council of Medical Research.

The broad objectives of the Institute cover the following areas:

- 1. To develop the sciences of epidemiology and biostatistics*
- 2. To develop human resource in epidemiology and biostatistics*
- 3. To act as a clearing house for the two disciplines and emerge as a resource for epidemiology*
- 4. To do networking of the various ICMR and non-ICMR Institutes at the national level for epidemiological purposes*
- 5. To provide consultancy*

One of the main objectives of the Institute is to develop manpower in the fields of Epidemiology and Biostatistics. Towards achieving this goal, several training programmes are being conducted by the Institute. Six scholars were selected for the second cohort (2002 – 2003) of the 2-year Field Epidemiology Training Programme (FETP) leading to Master of Applied Epidemiology (MAE) degree. Intensive training on basic concepts of epidemiology and biostatistics was given to them during their first contact session of 3 months from January 2002. Six of the eight scholars of the first cohort are continuing the course. All of them have completed their field projects successfully. They had developed their major project proposals in consultation with the FETP-Consultants and Faculty members during their 3rd contact session in March / April 2002. Four 10-day ICMR-WHO Regional Workshops on ‘Surveillance,

Epidemic Preparedness and Response” were organized during the year. Annual 5-day Basic Course in Statistics for Medical Doctors and a 2-week Training Programme on Controlled Clinical Trials with special reference to Good Clinical Practice (GCP) guidelines were also conducted.

Investigation of an outbreak of leptospirosis among residents of nurses hostel in Chennai city was carried out. Use of contaminated water from a sump was identified as the most likely source of infection. An awareness programme on leptospirosis and dengue was carried out in Thodupuzha Taluk, Idukki Dist., Kerala following an outbreak of febrile illness among agricultural labourers and rubber plantation workers. A dengue fever outbreak in Chennai city and a food poisoning episode in a school hostel in Trichy were investigated.

Towards initiation of surveillance activities, information on deaths was collected from vital events registers of 2 Health Unit Districts in Tamil Nadu for the years 1995 – 1999. This activity was carried out with help from the Tamil Nadu State Government. Analysis of this data revealed elevation of mortality rates among males aged 40 - 59 years. The finding was consistent both at District and PHC level and also for each year. In order to implement the Integrated Disease Surveillance Programme of the Govt. of Tamil Nadu, concerned personnel of the Department of public Health were trained on the use of computers in health information system.

Third resurvey of the Leprosy Vaccine Trial (LVT) population to assess the sustainability of the candidate vaccines is progressing. 75 incidence cases detected in the vaccinated cohort out of about 250,000 subjects screened.

LQAS can be used for leprosy elimination monitoring in high endemic areas. However, repeated LQAS activities are desirable. Geographical Information System was utilized to study the spatial autocorrelation of leprosy prevalence in the LVT area. Counts of leprosy cases observed in the “field - validation study on LQAS” in Tamil Nadu showed ‘no clustering’. On the other hand, the number of cases in a small area such as Leprosy Vaccine trial(LVT) area showed ‘positive spatial autocorrelation among leprosy prevalences’, i.e. ‘clustering’. This phenomenon is verified by examining the number of cases in each Village Panchayat of the LVT area. This issue is being examined.

Follow-up of 1,595 PB cases with 2-5 lesions and 1,263 single lesion cases recruited for the multi-centric clinical trial of single dose of Rifampicin, Ofloxacin and Minocycline (ROM) for PB leprosy cases is underway. Modification in the simulation model for leprosy transmission and control to make it user-friendly for programme managers is nearing completion.

In the area of HIV / AIDS, a study to assess gender differences in HIV risk behaviour among 206 STD clinic attendees has revealed a strong need for tailoring HIV preventive intervention for each gender separately. Data collection from 511 STD clinic attendees of the Government General Hospital, Chennai was completed to study their attitude towards HIV testing

*Involvement in co-ordination of Council’s Traditional Medicine Research programme continued this year also. Trial of Vijayasar (*Pterocarpus marsupium*) among specific groups of Type 2 diabetes mellitus patients has been completed. The protocol for*

extending this trial with a higher dose (up to 6g) of Vijayasar among those who could not achieve plasma glucose control with 4g has been finalized.

Activities on several collaborative works continued which included (1) ICMR-sponsored clinical trial for Chronic Hepatitis C; (2) ICMR study to estimate the Cause of Death by Verbal Autopsy and (3) ICMR-funded study on maternal transmission of HBV & HCV.

To build a new campus for the Institute, a plot of land of about 3 acres at Ambattur, Chennai has been purchased from the Tamil Nadu Housing Board. The process of selecting a Government or Public Sector undertaking to plan, design and construct the buildings is going-on.

I wish to place on record the enthusiasm and support shown by all staff of the Institute without which the reported work could not be possible.

(Dr. M. D. Gupte)

Director

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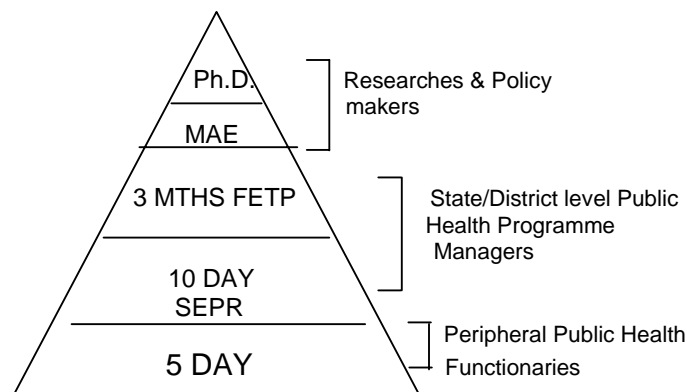
1. FIELD EPIDEMIOLOGY TRAINING PROGRAMME (FETP)

An important mandate of the National Institute of Epidemiology (NIE) is to strengthen capacity of Public Health Professionals in Field / Applied Epidemiology. It is envisaged that this will build competencies related to improving Disease Surveillance Systems, Epidemic Preparedness & Response and ultimately effective Public Health Action.

The need for effective Public Health Action was urgent. But paucity of Field Trained Epidemiologists impeded efficient outbreak management. It is estimated that for a country of India's size, over 600-700 Field Trained Epidemiologists are required. Currently only a handful are available.

NIE, therefore, proposes a pyramidal structure (Fig.1) of training programme in Field Epidemiology. Through these programmes NIE-ICMR-Govt. of India expect to cater to the unmet needs in Field Epidemiology of different cadres of Health Professionals operating at various levels of the Public Health System.

Fig.1 Pyramidal structure of training programme in Field Epidemiology



Ph.D. programme

NIE is recognized by the University of Madras for providing Research Training to scholars leading to the Ph.D. degree in Epidemiology and Biostatistics.

Efforts to secure Research positions (SRF & JRF) as well as funds for prospective research scholars have been mobilized.

Master of Applied Epidemiology (MAE)

A two year MAE degree programme commenced at NIE since 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. Those eligible for admission to the MAE course are:

- (i) Medical graduates with MBBS degree recognized by the Medical Council of India.
- (ii) Minimum of three years experience preferably in the Public Health field
- (iii) Central / State government sponsored candidates.

Each year a maximum of 10-20 candidates will be admitted to the MAE programme. A total of 12 trainees have been admitted to the programme in the first two batches.

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 & home assignments, class participation, group discussions, problem solving capabilities, satisfactory completion (identification, design, implementation) and submission of assigned field projects and defense of “bound volume”.

Progress calendar of FETP-MAE programme

First cohort (2001-2002)

Total number of trainees – 8

22nd April 2001 - 1st contact session at NIE completed

23rd April – 24th April- 2001 - I Field posting

Field projects assigned: Situation analysis, Lab facilities, Disease Burden Assessment, Critical Assessment of Existing Surveillance System. All assigned field projects were to be executed at the trainees duty / field station

25th Sept. – 22nd Oct. 2001 - II contact session at NIE

Trainees attended 1st SEPR workshop conducted by NIE, Review of work done during 1st field posting, Two trainees unable to attend second contact session, Two trainees dropped out of the course.

23rd October - 24th March 2002 - *II Field postings*

Field projects assigned: Preparation of Timeline of Activities for FETP-MAE field projects assignments submission, Critical review of literature on Selected topic-identified by trainee, Cross sectional survey / case-control study on a project selected by the trainee.

25th March – 27th April 2002 - *III Contact session at NIE*

Trainees attended workshop on “Excellence in Scientific Writing” at NIE, Review of work done during II field posting

Second cohort (2002-2003)

Sept. 2001 - Advertisement for second cohort of trainees

Total No. of applications received – 16 approximately.

15th January 2002- Selection committee meeting at NIE.

7 candidates selected for admission.

6 confirmed participation.

1 dropped out for personal reasons

All 6 trainees admitted as full time deputed candidates from their respective State Governments to NIE for 2 years.

24th January 2002 – 27th April 2002 - *1st Contact session*

Inauguration of 2nd cohort of Trainees participation of Prof. K. Mohandas in the inauguration. Participation of trainees in the 4th SEPR conducted by NIE

at Chennai. Participation of trainees in workshop on “Excellence in scientific writing”

FETP related activities

Board of studies

A Board of Studies for the FETP-MAE programme was constituted with the approval of the Vice Chancellor of SCTIMST. The first meeting was convened on 3rd June 2001 at NIE, Chennai. The issues discussed included various aspects of the MAE course e.g. course eligibility, selection of trainees, course organization, course duration, course contents and assessment process.

In principle, the Board of Studies has its approval for the FETP-MAE programme to be conducted as on off campus course of the SCTIMST. Minor changes suggested have been incorporated. A major area suggested and which still needs to be addressed is “Assessment of trainees”. NIE is presently looking into the assessment procedures followed by (i) SCTIMST for their M.PH. Course and (ii) the M.Phil / MHA course on Hospital & Health Systems Management – an off campus course offered by CMC, Vellore. After carefully studying the assessment procedures for these two programmes, NIE will develop an assessment procedure most appropriate to the FETP-MAE programme. After finalization, details of the assessment procedures will be shared with members of the Board of Studies for their comments and approval.

FETP-India – Partnership Development (27th & 28th July 2001)

A two days Partnership Development workshop was organized. On 27th July 2001, a workshop for local preceptors of FETP-trainees was conducted. The main objective of this workshop was to identify roles & responsibilities of local preceptors as local field supervisors for the trainees and also forge partnerships with them on a long term basis.

The meeting was chaired by the Director of Public Health & Preventive Medicine, Government of Tamil Nadu. Local preceptors had an opportunity to interact with NIE faculty as well as WHO and CDC visiting consultants.

On 28th July 2001, a meeting of local preceptors, FETP-MAE scholars, WHO-CDC consultants and NIE faculty was organized. The objective was to enable scholars meet their local preceptors and discuss details of their proposed field projects. During the meeting, FETP scholars each, presented details of their job functions, workplace situation and proposed field projects. Comments and suggestions were offered to individual trainees on the field projects they could consider taking up for study.

NIE-ICMR workshop on Field Epidemiology Training in Kerala, Challenges and Opportunities (August 2001)

This was an advocacy workshop organized in collaboration with the SCTIMST, Deptt. of Health Services, Government of Kerala & Kerala State Institute of Virology and Infectious Diseases (KSVID).

The main objectives of this one day workshop were to: (a) Appraise the participants on the need for training in Field Epidemiology (b) Provide information on the availability of Field Epidemiology Training facilities in India and at NIE and (c) suggest a plan for providing such training involving NIE / ICMR, MOH, Government of Kerala and SCTIMST.

The 45 participants were drawn from the Public Health System & Medical Colleges in Kerala. Facilitators were from WR Office, New Delhi, NIE / ICMR, KSVID and Government of Kerala, Department of Public Health.

Specifically the workshop highlighted the following: (a) General context of Epidemiology Training needs (b) Specific Training needs in Field Epidemiology in Kerala and (c) Facilities for Training in Field Epidemiology. The workshop consisted of plenary scientific sessions followed by group activities.

In their concluding remarks, Dr. Robert K. Farley (WR India) and Prof. K. Mohandas emphasized (i) the need to effect structural changes in the system (ii) evolve a definite career plan for Public Health Professionals and (iii) the need for networking with all concerned to strengthen training efforts in epidemiology that support and facilitate effective Public Health Action.

Meeting of ICMR Epidemiologists for FETP (Sept. 2001)

A meeting of the ICMR Epidemiologists was conducted at Vector Control Research Centre (VCRC), Pondicherry on 13th September 2001 to facilitate

the role of ICMR Epidemiologists as field supervisors for the FETP scholars during their field postings.

Participants included ICMR Epidemiologists and their Director [from VCRC (3), TRC (1) and NARI (2)], WR India, WHO-SEARO and NIE SAC Chairman.

The objectives of this workshop were to: (i) appraise the ICMR Epidemiologists on the status of the FETP programme and progress of trainees (ii) enlist support of ICMR Epidemiologists as field supervisors for FETP trainees at their field posting sites (iii) specify role-responsibilities of ICMR Epidemiologists as field supervisors and (iv) strengthen quality of field supervision of trainees.

In general there was consensus regarding (i) the need for the FETP-MAE programme at NIE to succeed, (ii) limited faculty resources at NIE that requires strengthening (iii) whole hearted support offered by ICMR Epidemiologists identified for the FETP-MAE programme at NIE and (iv) details of supervision logistics to be worked out between NIE Director and ICMR Epidemiologists.

Conferences / Seminars attended by FETP Trainees

1. International Epidemiological Association – South East Asia Congress held in Jhansi between 24th February – 27th February 2002.

Three FETP trainees of the first cohort attended this Conference. One made a poster presentation on Dengue surveillance.

2. Sir Dorabji Tata Trust Annual symposium on Diarrhoeal Diseases at IISC, Bangalore. March 21-22, 2002.

Six FETP trainees of the II cohort participated in this symposium. One trainee made a brief presentation on the diarrhoeal disease problem experienced in Orissa during and after the super cyclone.

Visits by external consultants / experts for FETP-MAE programme.

1. Dr. Gunaratnae – WHO – SEARO – April 2001
2. Dr. Umesh Parashar , CDC, May 2001
3. Dr. Mohammed Patel – ANU, Australia July – August 2001
4. Dr. George Convay – CDC, July 2001 & October 2001
5. Dr. William Keene – CDC- WHO – SEARO, October 2001
6. Dr. Elliott Churchill – CDC – March 2002

2. CLINICAL TRIALS

a) Traditional remedies

The Institute continues to be actively involved in clinical trials of traditional remedies sponsored by the Council. A flexible dose of open trial of Vijayasar (*Pterocarpus marsupium*) among specific groups of Type 2 diabetes mellitus patients is being carried out at Chennai, Cuttack and Kottayam centres. If necessary, the starting daily dose of 3g was increased to 4g. Total duration of treatment was 20 weeks. Following two groups of patients were studied:

(1) Patients uncontrolled by allopathic oral hypoglycaemic drugs
(Group 1)

(2) Controlled patients, but opted for Vijayasar treatment (Group 2)

In all, 180 and 103 patients were admitted to the trial in Group 1 and Group 2, respectively. Data on 103 patients of Group 1 and 68 of Group 2 who completed the stipulated 20-week treatment period were analysed.

Among 103 patients of Group 1 (uncontrolled), 43% remained uncontrolled after 20 weeks of treatment (Fig.2). In 68 controlled patients (Group 2), 61% remained controlled after 20 weeks of treatment (Fig.3). It is now proposed to increase the dose upto 6g for those who could not achieve plasma glucose control with a daily dose of 4g. The protocol for this extended trial is being finalized.

Figure 2 Percent uncontrolled by Week of Treatment (Group 1)

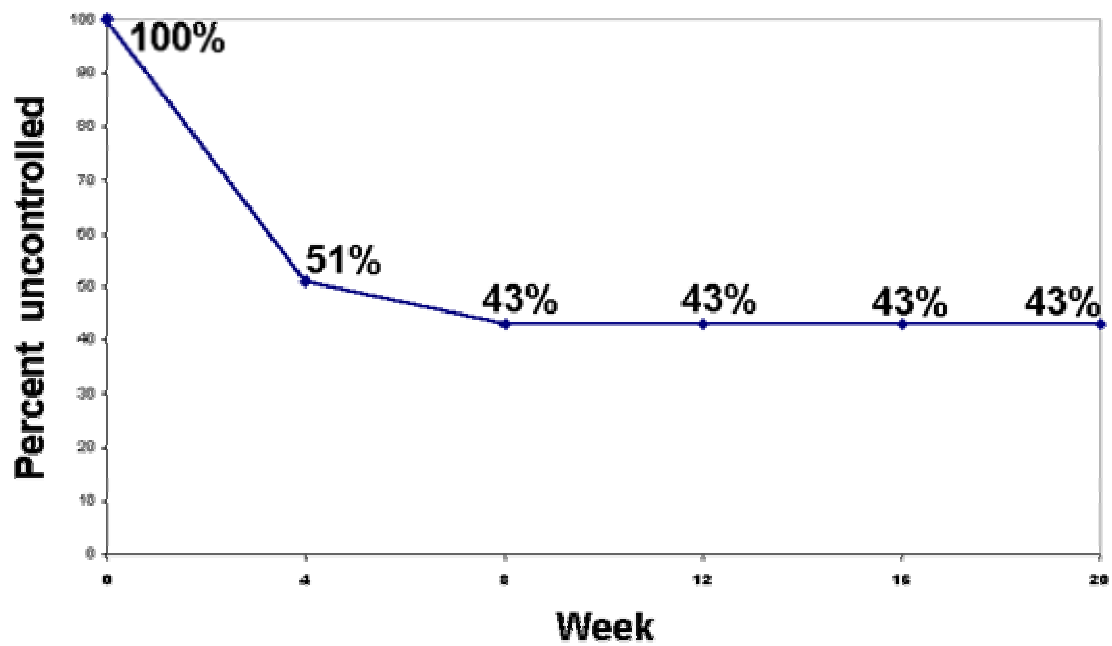
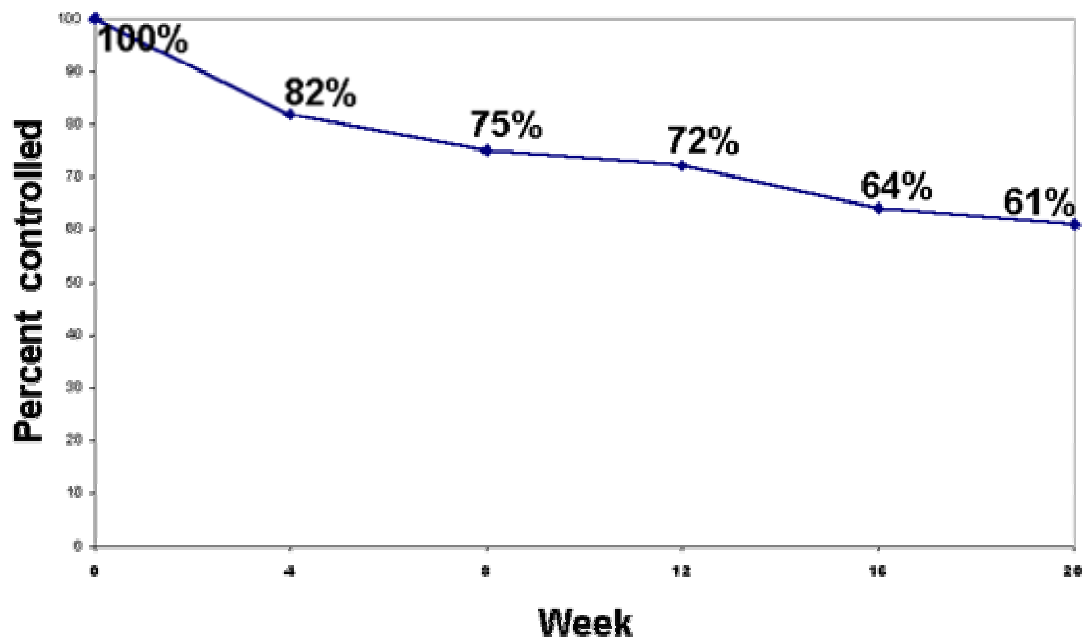


Figure 3 Percent Controlled by Week of Treatment (Group 2)



b) Chronic hepatitis C (Collaborative project)

The Council is undertaking a multicentric trial of Interferon-Glycyrrhizin combination therapy and Interferon-Ribavirin combination therapy in the management of Chronic Hepatitis C (CHC). Our Institute is co-ordinating the conduct of this trial. The objectives of the trial are given below:

Primary objective

To assess whether the combination therapies of (a) Interferon – Glycyrrhizin and (b) Interferon – Ribavirin against CHC are effective to the tune of 70% in Indian patients.

Other objectives

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

This is a multicentric, randomized, controlled, double-blind trial in nine centres spread all over the country. It is proposed to admit about 250 patients to the trial in all centres put together. The trial is expected to be completed in three years. All the virological investigations will be carried out centrally at the National Institute of Virology, Pune. The histopathological studies will be done at the trial centres under the supervision of the Dept. of Pathology, All India Institute of Medical Sciences, New Delhi.

Training workshop for the Research Associates of the trial centres was organized by our Institute at the ICMR HQs, New Delhi on January 9, 2002. During this workshop, the Research Associates were explained about the basic principles of controlled clinical trial methodology and the need for maintaining uniform set of standards for various assessments in the trial. The importance of standardized methods in data collection and uniformity in reporting was highlighted with real-life examples. All of them were given a complete orientation of various procedures to be adopted for efficiently conducting the trial at their respective centres.

Trial manual, master copies of various proformae and coded drugs for the first five patients have been sent to all trial centres during March 2002. Screening of eligible patients for inclusion into the trial is under progress at all the centres.

c) The transmission pattern (s) of HBV/HCV in symptomatic and asymptomatic pregnant women and their impact on the children born to them (Collaborative work)

The objectives of the study are as follows: (i) To assess the pattern of vertical / perinatal transmission of HBV/HCV in symptomatic and asymptomatic carrier mothers (ii) to conduct a prospective study of HBV/ HCV carrier mothers and the children born to them up to one year for sequelae analysis (iii) to evaluate the effectiveness of HBV vaccination for children born to HBsAg positive carrier mothers.

The study was started in the month of August 2000. Till now 3000 samples have been collected from asymptomatic and 30 from symptomatic pregnant women attending the antenatal out patient clinic at Institute of Obstetric and Gynaecology, Egmore, Institute of Basic Medical Science , Kasturibai Gandhi Hospital and examined for HBsAg antigen positive. If found positive for HBV/HCV cord blood from the mother and blood samples from the newborns were taken and follow up was done for clinically diagnosed jaundice pregnant women and healthy carrier pregnant women. The serum samples were separated and stored at -80°C . The samples were screened for HBsAg, HBeAg, and Anti-HBe. & Anti -HCV by ELISA. Preliminary results showed HBsAg positive 5.9 %(178/3000) among healthy pregnant women and in 70%(21/30) among clinically diagnosed jaundice pregnant women. Among healthy carrier women 0.63% (19/3000) were positive for anti-HCV. No HCV positive was found among Jaundice cases. The study is in progress.

My involvement in this study is 1) Monitoring the study work 2) Collecting samples from babies and carrying out follow up works.

d) Clinical trial for treatment of paucibacillary leprosy cases with single dose of ROM

The study comprises of two components

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

OBJECTIVE

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 cases (Mono lesion and 2 to 5 skin lesions), compared to the standard six monthly doses of WHO MDT regimen for paucibacillary leprosy.

METHODOLOGY

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 and 36 months of post-treatment follow-up).

The intake phase commenced in April, 1998 and the study is expected to be completed by September, 2003.

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.

The intake phase commenced in March, 1998 and the study is expected to be completed by January, 2003.

ACTIVITIES OF THE STUDY

Selection of study area

6 centres for 2-5 lesions study and 2 centres for mono lesion study had been selected after discussing with concerned authorities and obtaining their willingness for participation in conducting the trial. Availability of manpower / expertise were also taken into consideration.

Centres involved in 2-5 lesion study

2 in Andhra Pradesh (Chittoor and Cuddapah)

2 in Tamilnadu (Chennai, CLT & RI)

1 in Madhya Pradesh (Champa, TLM)

1 in Uttar Pradesh (Naini, TLM)

Centres involved in mono-lesion study

2 in Andhra Pradesh (Chittoor and Cuddapah)

Training of persons

Training was given to all field workers, including District Leprosy Officers, Medical Officers, Statisticians, Paramedical Workers, Non-Medical Superintendents and Supervisors with regard to study activities, such as selection of cases, clinical examination, filling up of proforma and follow –up procedures.

Selection of patients

Eligible patients for 2-5 lesions trial were selected based on the following criteria

- Untreated, smear negative
- 2 to 5 skin lesions
- Not more than one peripheral nerve trunk involvement

Distribution of drugs

In 2-5 lesions study, separate centre code was given to each centre. Randomized list was prepared for each centre for adults and children separately. The drugs were packed and labeled with centre, adult child codes, and serial random numbers. Printing of proforma and body charts was done at National Institute of Epidemiology (NIE). Drugs were distributed before starting the trial. Reporting Forms were periodically distributed as per the centres' need. Preparation of punch code and database was done prior to data entry. Data monitoring and management were also taken care.

Recruitment of patients

During intake phase Medical Officers from NIE helped the investigators in selection of patients for Chittoor and Cuddapah.

Monitoring of the study

Frequent visits to the participating centres by Medical Officers, Statisticians and Technical Assistant from NIE were conducted. They assessed the progress of the trial, collected and distributed the reporting forms, and clarified the discrepancies in the proforma at intake and follow-up phases. During their visits they also helped the staff in clinical examination, filling up the forms and collection of data.

A Medical Officer from NIE also examined some of the patients with special events.

Reminder-list of patients for every month was sent in advance to avoid delays in examinations.

Timely backlog list of patients were prepared and sent to respective centres to obtain complete / maximum coverage.

Constant data monitoring is being done by scrutiny of forms, checking for transcription and logical errors. An offer-free database structure for data entry and data updation was done on routine basis. Frequent data validation if being done to check for the out-liers in data.

For confirmation of special events, especially in cases with appearance of new lesion(s), it had been decided that a Medical Officer would reexamine these cases.

DISTURBANCES OCCURRED DURING THE TRIAL

Few disturbances were observed due to transfer of District Leprosy Officers (Chengalpet, Chittoor, Cuddapah and Naini), Medical Officers and Investigators in participating centres and retirements/long leave of staff involved in the study had affected the study considerably with the backlog in patient examination. Due to transfer of DLO, the information from Chengalpet is not adequate and the centre was suspended from the trial.

Clinical examinations were simplified by reducing few variables (erythema, infiltration and hypopigmentation) in some centres due to difficulties faced by the examiners.

Migration of few patients (temporarily and permanently) was also another problem, Champa unit had migrations of cases which appears to be serious. Even with intensive monitoring of this unit, the problem was recurrent in all follow-ups.

Refusal of patients for examination due to some social problems during treatment and follow-up phases was also observed.

OTHER ACTIVITIES

Workshops

- Workshop to review the progress of the participating centres of 2-5 lesions and Mono lesion study was conducted on 20th and 21st December, 1999 at Chennai.
- Workshop with special focus on Chittoor and Cuddapah district to review the progress and to sought out the problems with respect transfer of DLO and migrations within and between districts was conducted on 26th and 27th of May, 2000 at Tirupati.
- Workshop with special focus on Chittoor and Cuddapah district to review the progress 2-5 lesions and mono lesion study was conducted on 2nd April, 2001 at Chennai.

Paper presentations

- A paper titled 'Multicentric field trial in PB Leprosy with 2-5 lesions' was presented in Asian Leprosy Congress at Agra 2000.
- A paper titled 'Role of data monitoring and management system in multicentric clinical trials' was presented in Indian Society for Medical Statistics at Agra, 2000.
- A paper titled 'Single dose multidrug therapy (ROM) for single lesion PB leprosy under programme condition' was presented in International Leprosy Congress at Patna, 2001.

SPECIAL EVENTS IN THE STUDIES

Through the follow-ups, information on the clinical conditions of the patients on anti-leprosy treatment is collected periodically. In addition, information is collected on special events, viz., appearance of new lesions(s), involvement of nerve trunk, reversal reactions, serious adverse drug reaction, migrations (temporary and permanent) and deaths. Special events are recorded only once in whichever follow-up period it occurs, except for temporary migrations.

PROGRESS REPORT AS ON 31ST DECEMBER 2001

2-5 LESIONS PB LEPROSY STUDY

Centre	Intake	6 months	12 months	18 months	24 months
Chittoor	698	697	690	568	618
Cuddapah	384	383	363	341	306
Naini	118	117	113	113	112
Chennai	76	76	72	68	57
CLT & RI	250	250	250	250	246
Champa	70	70	67	40	60
TOTAL	1596	1593	1555	1380	1399
Cases for analysis *	1596	1517	1489	1340	1342
Complete clearance **	-	265	405	475	574
% clearance	-	17.5	27.2	35.4	42.8

* These are cases without any special event in that follow-up.

** complete clearance is defined as: 'the scores of appearance and anaesthesia of all lesions are 0 (nil)'

SPECIAL EVENT CASES

Centre	New lesion	RR	SADR	Migration	Refusal	Death	Others
Chittoor	8	4	2	18	5	5	1*
Cuddapah	12	1	-	14	3	2	1*
Naini	2	8	-	6	-	-	1**
Chennai	1	1	-	12	1	-	2***
CLT & RI	1	1	6	1	2	5	-
Champa	5	1	-	36	-	-	-
TOTAL	29	16	8	87	11	12	5

RR – Reversal Reaction

SADR – Serious Adverse Drug Reaction

Others - * Misclassification ** Tuberculosis *** Jaundice

PROGRESS REPORT : MONO LESION PB LEPROSY STUDY

Centre	Intake	6 months	12 months	18 months	24 months
Chittoor	649	634	612	520	483
Cuddapah	614	596	590	516	463
TOTAL	1263	1230	1202	1036	946
Complete clearance	-	335	426	450	514
% clearance	-	27.2	35.4	43.4	54.3

SPECIAL EVENT CASES : MONO LESION PB LEPROSY STUDY

Centre	New lesion	RR	SADR	Migration	Refusal	Death
Chittoor	5	-	-	18	-	4
Cuddapah	7	1	-	31	-	4
TOTAL	12	1	-	49	-	8

RR – Reversal Reaction

SADR – Serious Adverse Drug Reaction

3. VACCINE TRIAL

a) Leprosy

Based on second re-survey, 2 vaccine candidates (ICRC and BCG + killed *m.leprae*) were found to provide protective efficacy of about 65%. The III Re-survey of LVT was initiated during August 1999 to know the sustainability of the immunoprophylactic effect of the candidate anti leprosy vaccines. During the period between April 2001 and March 2002, 1,33,523 Individuals were registered. Out of the total registered, 15,312 (11.5%) were new. In all 98,228 (73.6%) were eligible for examination. Screening of the eligible population was carried out by three examination teams. About 93% of the eligible individuals were screened for Leprosy. During this period 54 of 148 groups were completed for all the activities. 3,017 cases were detected and subjected for confirmation by senior workers (SWs). To ensure quality of the screening 10% of the households were subjected for re-examination.

ICRC Vaccine strain C-44 used in the leprosy Vaccine Trial as one of the vaccine arms has been maintained in the laboratory in the enriched modified Dubos medium. Currently vaccine strain has completed 40th passage.

b) Providing guidance and consultancy services for diseases such as leishmaniasis, malaria, Human Papilloma Virus (HPV)

4. HIV / AIDS RELATED STUDIES

a) Attitudes towards HIV testing among STD clinic attendees of the Govt. General Hospital, Chennai.

As HIV testing is an important component in HIV preventive intervention programmes this study was planned to find out the concerns involved in HIV testing among a high risk population – STD clinic attendees.

Semi-structured interview schedule was used for data collection. Data collection was done only after taking informed consent from the study subjects. Interview schedule contained questions on, demographic details, sexual and other risk behaviours and attitude and acceptability of HIV testing.

No.of patients interviewed was 511 and the data analysis is in progress.

b) STD prevalence and Risk factors in STD patients from the Institute of Venereology, Govt. General Hospital, Chennai.

(Data collected from the case records – From 1st Jan – 30th June, 2001 – for 6 months)

No of cases recorded: Males	: 2630
Females	: 1364

Data entry is in progress.

c) Evaluation study on Injecting Drug Users who were on Sublingual Buprenorphine intervention.

This was a collaborative study with SAHAI Trust – an NGO from Chennai, providing services for injecting drug users.

Objectives: 1. To evaluate risk behavioural change – after the intervention of providing sublingual buprenorphine and
2. To find out HIV incidence

Out of the total Injecting Drug Users who were given Sublingual Buprenorphine data was collected from 279 persons.

Status : Data entry is in progress.

d) Gender differences in HIV Risk Behaviours among STD Clinic attendees in Govt. General Hospital, Chennai

Purpose: The present study was to assess gender differences in sexual risk behaviours, perception of HIV risk and willingness to participate in HIV preventive interventions, in addition to overall HIV seroprevalance, among STD clinic attendees at Government General Hospital, Chennai.

Procedure

All new patients attending the STD outpatient department at Government General Hospital, Chennai over the course of one week were the study subjects, for a confidential research study. Fifteen minute face-to-face

interviews were conducted by trained research staff from the National Institute of Epidemiology. Routine VDRL testing was conducted along with unlinked anonymous testing for HIV. Patients were instructed to return three days following the interview to receive their VDRL test results, as is routine at the clinic. Persons testing VDRL reactive were offered free treatment.

Participants

Of 206 new STD clinic attendees, three persons were excluded from participation due to inability to comprehend the consent process and two declined to participate. Sixty-two percent (n = 124) of the 201 participants were male. The mean age was 32.4 years; 94% self identified as heterosexual, 4% bisexual, and 1% each as gay or lesbian.

Assessment

Questions assessed demographics (gender, age, marital status, place of residence, education and occupation), sexual risk behaviors (age at first sexual contact, number of sexual partners in past three months and in ones lifetime, frequency of sexual intercourse, frequency of condom use, gender of sexual partners, sex in exchange for money) and alcohol and other drug use. One question each assessed perception of HIV risk and willingness to participate in an STD/HIV prevention program. Routine blood testing for VDRL was conducted for all participants and HIV antibody testing was unlinked and anonymous.

All data were compared by gender using T-tests and Chi-square statistics (except HIV seroprevalence which was unlinked, and thus not available by gender).

Demographics

No gender differences were found for age or primary language spoken (Tamil). Gender differences were found on marital status ($p < .001$): 39% of males and 7% of females were single; 60% of men and 70% of women were married; 23% of females and 1% of males were separated/divorced/widowed. Significant gender differences were found for education ($p < .001$): 53% of males and 32% of females had a high school diploma or greater; 37% of females and 2% of males were illiterate. The median income was 500 to 1000 rupees per month, with differences by gender ($p < .001$): 53% of women and 16% of men reported income of less than 500 rupees per month. Significant gender differences were found in occupation: 55% of females and 11% of males were unemployed outside the home; 72% of males and 26% of females were day laborers, office or skilled workers. Twelve percent of females and no males were sex workers. Difference were found in primary residence by gender ($p = .02$): female (55%) STD clinic attendees were more likely to live in the Chennai metro area than males (33%); males were more likely to reside in rural villages (34%) than females (20%).

Sexual Behaviors

The average age of first sexual contact was 19.8 years. Females (18.1) engaged in sexual intercourse at an earlier age than males (20.8; $p < .001$).

Males (1.9) had greater numbers of sexual partners in the past 3 months than females (1.7, $p < .04$; excluding sex workers). Males (3.6) had significantly greater numbers of lifetime sexual partners than females (2.1, $p = .03$; excluding sex workers). Excluding sex workers, 73% of females reported one lifetime sexual partner, 11% no sex, and 16% more than one partner. Among males, 7% reported none, 19% one, 16% two, and 58% three or more lifetime sexual partners. Twelve percent of males and 1% of females reported engaging in oral sex; 9% of males and 1% of females reported engaging in anal sex. Seven percent of men and 14% of women had reported of condom usage at least once in their life time. Significant gender differences were found in sex for money and nonconsensual sex. Thirteen percent of females ($n=10$) and 1% of males ($n=1$) reported engaging in sex for money ($p < .001$). Twenty-one percent of females and no males reported being the victim of nonconsensual sex.

Alcohol and Other Drug Use

Significant gender differences were found in tobacco and alcohol use. Fifty nine percent of males and no females reported smoking cigarettes. Fifty-eight percent of males and 6% of females reported drinking alcohol ($p < .001$). No other drug use was reported.

Perception of HIV Risk and Willingness to Participate in HIV Preventive Intervention

Significant gender differences were found on HIV risk perception and willingness to participate in an HIV preventive intervention. Thirty-nine

percent of males and 53% of females perceived themselves as “not at all” at risk for HIV. Forty-three percent of males and 16% of females perceived slight/moderate risk of contracting HIV. Eight percent of males and 15% of females (n = 12; all sex workers) perceived themselves to be at high risk for HIV. Seventy-six percent of males and 40% of females were definitely willing to participate in HIV preventive interventions; 34% of females and 12% of males were not at all willing to participate.

HIV Seroprevalence and STDs

The HIV seroprevalance rate was 15.8% overall. In all 44% of the males and 53% of the females had STDs. Blood VDRL was positive in 6% of the males and 8% of the females. Overall, 31% did not return for their VDRL results by 2 ½ weeks after testing; no differences were found by gender.

The majority of women attending the STD outpatient clinic at Government General Hospital in Chennai, were married and had one lifetime sexual partner, their husband. Half were symptomatic for sexually transmitted disease. With an overall HIV seroprevalence rate of 16% among STD clinic attendees, these women are clearly at high risk for HIV. Yet, the majority of women perceived themselves to be at no risk for HIV and one-third indicated no willingness to participate in HIV preventive interventions.

The disproportionate and high rates of illiteracy and poverty among these women, in addition to low perception of personal risk for HIV, suggest significant obstacles to HIV prevention. Our results suggest a strong need for

HIV preventive intervention among STD clinic attendees in Chennai, must be tailored by gender.

5. TECHNICAL RESOURCE

a) Use of a simulation model in national leprosy eradication programme

An epidemiological simulation model for leprosy transmission and control has been developed in collaboration with the CDTDC, Erasmus University, Rotterdam. The ICMR National Institute of Epidemiology (NIE), Chennai is financially supported by the World Health Organization for this activity. The basic structure of the SIMLEP, an example of a simulation experiment, potential applications and known limitations of the model are detailed in a publication (*Meima A et al, Int J Lepr 1999; 67(3): 213-236*). A report on specific experiments carried out to examine the immediate application of the model has also been published (*Gupte, M.D. et al, Ind J Lepr 2000; 72(3): 305 – 316*). The model should benefit the programme administrators. It was proposed to expand the scope of the model for programme purpose as a good managerial tool to monitor leprosy elimination.

A project was proposed with the following objectives for linking the model with the programme :

1. Extending the model to programme
 - a) Further testing with programme based data sets
 - b) Making it user friendly for use by programme managers
 - c) Projecting effects of various interventions
2. Expanding the technique to other diseases
3. To organize a workshop on sentinel units

Further testing of the model

Application of this model as a tool useful for programme monitoring by administrators was considered. The availability of such a tool is considered of particular importance at the present stage. As a first step towards this goal, further testing of the model with programme based data sets was attempted.

NLEP Independent evaluation data

Data generated through the “Independent evaluation of MLEC II activities under NLEP” undertaken during March-April 2001 in 5 states viz., Bihar, Madhya Pradesh, Orissa, Uttar Pradesh and West Bengal were considered. Initial scrutiny of the data received by us has revealed the following discrepancies:

- Difference in record structures across the 5 states
- Presence of duplicate records
- Presence of ‘junk’ records
- Multiple entries against type of leprosy
- Coding errors in demographic variables.

Attempts are being made to resolve these issues so that the data can be used for the leprosy model.

Programme based data

We do not have the complete information from the programme based data available from some districts where MDT campaigns are in vogue for over a decade. Using these data sets, some generalization are possible. Ideal data sets are almost impossible to get and hence, we have to make the best use of

the available information. The following general observations were made based on the programme based data which were observed through the model also. In some districts, the delay in case-detection is about 5-6 years or even more. This kind of delay in case-detection hardly reflects the overall change in the NCDR. Also, if there is a declining trend already existing, an intervention with the available delay in case-detection is unlikely to change this trend. Attempting rigorous predictions utilizing the limited data could be misleading as we have to make judgment on the actual levels of various rates based on the information available. This exercise may not be a simple and straight forward one. Therefore, the information available on programme based data is useful from the programme monitoring point of view only.

Understanding the model

This model was developed in collaboration with the CDTDC, Erasmus University, Rotterdam. Epidemiological inputs for the development of the model were generated by us and the mathematical modelling aspect was taken care by them. The internal mechanism of the model was reviewed and algebra involved in the model was studied completely. Also, links between various parameters of the model was examined and possible reduction of input parameters was identified. Source code of the programme was looked into and developed capacity to modify the model. Through this process, we developed capacity to modify the model to suit our requirements to make it user-friendly accommodating various differing epidemiological scenarios.

Modifications in the inputs screen are being done to make it user-friendly. It is planned to have windows oriented input screens with parameters that require frequent changes to appear first. Parameters that remain constant would appear next and so on. Standard terminology is being adopted for all input parameters. Once such a version of the model is ready, it would be passed on to a few state level managers for testing the use of the model under routine programme conditions.

Review by MTR Team

The joint Mid Term Review (MTR) team of Govt. of India and Govt. of Denmark visited the Institute on March 24, 2001 and reviewed the various activities of the Institute pertaining to NLEP and those supported by DANLEP. The work done on the Simulation model for leprosy was also presented and the Team Members expressed their appreciation on the work done.

Work under progress

Projecting effects of various interventions, identifying activities that could be cost-effective and cost-efficient, identifying priority areas to increase efficiency of managerial and operational activities using the model would be completed soon. The important aspects to be considered in these experiments include changed scenarios in the integration set-up, changes in MDT treatment duration, changes in treatment methods, various methods of case detection, data generated on single lesion cases, different patterns in leprosy endemicity and changes in disability development due to delays.

b) Application of Lot Quality Assurance Sampling for leprosy elimination monitoring – examination of some critical factors

Standard methods are needed to identify whether progress towards the goal of elimination of leprosy is satisfactory particularly at the country level in smaller countries and sub-national level in large countries, where leprosy has been endemic. Once low levels of prevalence of leprosy reached the health administrators' concern will be drifted towards targeting small areas such as state/region with high leprosy prevalence for necessary intervention and additional strengthening. Programme based surveys undertaken in the state / region may not detect these areas and traditional sample surveys in each state / region are laborious, expensive and time-consuming. Further, leprosy prevalence rate / new case detection rate through routine programme records has limitations. Alternative and rapid assessment technique is needed by health administrators / programme managers for monitoring and necessary additional intervention.

In this context, it is demonstrated through internal as well as through external validation, using real life data that Lot Quality Assurance Sampling (LQAS) is expected to be of particular importance in initially high endemic areas for Leprosy Elimination Monitoring. There are certain methodological issues to be addressed before it could be recommended for implementation. First, it is assumed that leprosy cases are randomly distributed and second the number of cases follows a Poisson distribution. Selection of individuals at random for leprosy examination is operationally inconvenient in the field. Household as equivalent sampling unit has been suggested. Third, Instead of selecting

households at random, operationally convenient two-stage cluster survey of households is adopted. The above critical factors need to be examined using real life data before considering the applicability of LQAS for Leprosy Elimination Monitoring.

LQAS is a quality control tool in Industry. Items or goods of the same type, size or grade in a production process are grouped to form homogeneous lots. A simple random sample (n) of items from each lot is taken for inspection to identify number of defectives. If the number of defectives is less than or equal to maximum acceptable number (Critical value) then the lot is regarded as having prevalence below the target level. On the other hand if the number of defectives exceeds the critical value even before the complete examination of all the items in the sample, further examination of the sample items is discontinued and the lot is regarded as having prevalence above the target level and needs necessary intervention and strengthening. A lot in the Health field may be a cluster of villages and towns in a state / region. More details of LQAS will be available elsewhere.

The use of LQAS has gained importance in the health field for the last 15 years. However, its use for Leprosy Elimination Monitoring has only recently been suggested. The objective of this paper is to examine using real life data, whether the distribution of cases (a) is random, (b) if so, whether it is Poisson, and (c) there is design effect if two-stage cluster sample survey is employed.

Reported prevalence in an endemic state (Tamil Nadu) was 5 per 10,000. State leprosy authorities anticipated certain level of under estimation in the prevalence. However, they assumed that the leprosy prevalence in the state might not be above 7 per 10,000. The Null Hypothesis to be examined was whether the prevalence of leprosy in the state was at or below 4 per 10,000. While designing this exercise we provided a safeguard for the sample size such that the samples in which the prevalence was regarded as having less than 7 per 10,000 the prevalence in each of them should not be at or below 4 per 10,000. More details of the design are available elsewhere.

The sample size using Poisson approximation at 5% level of significance and Power of 90% required to test the Hypothesis was determined as 53,000 people. Allowing 20% as the margin of non-response a sample of 64000 people in the state was considered sufficient. The maximum allowable number of leprosy cases (d , critical value) in this sample was 25. If the number of cases in the sample exceeds the critical value (d) i.e. 25 then the prevalence in the state will be regarded as above 7 per 10,000 (definitely more than 4 per 10,000) and certainly needs necessary intervention by the health administrators.

The state had been divided into North, South Central and West Zones. To have a representative sample in the state two districts in each of the four zones were selected using probability proportional to size (PPS) linear systematic sampling. In each district 8000 people were to be examined. This sample size is further divided into rural / urban proportionate to the rural /

urban ratio of the population in the district. Villages and towns were selected using PPS linear systematic sampling. Within each selected village / town, a fixed number of households was selected using linear systematic sampling. For operational convenience 100 households were selected in each selected village / census enumeration block. Thus, in order to cover the entire sample 18 villages / towns were selected. The first household in each village / town was selected at random and subsequent households systematically.

Directorate of Rural & Health Services of Tamil Nadu and National Institute of Epidemiology, Chennai were involved to monitor the quality of data. Leprosy inspectors screened all the resident members of the household. Supervisory staff confirmed the diagnosis of the cases. All the cases were classified by its type, i.e. single skin lesion (SSL), paucibacillary (PB) or multibacillary (MB).

The survey was conducted from 6th January 2001 to 30th March 2001. Information on age, sex and residential status of every member in the household was collected from the head of the household or any senior member of the family through a structured questionnaire. It was decided to continue the survey irrespective of the number of cases crossing the maximum acceptable number. An individual was defined as a PB case if he / she had five or less number of skin lesions, with not more than one nerve lesion, and all the slit skin smears were negative for acid fast bacilli (AFB). The person was considered as an MB case if he / she had more than five skin lesions or more than one nerve lesion or skin smear positive for AFB.

In each village including the hamlets the approximate number of households were estimated by enumerating or by consulting village officials (President, Village Administrative Officer, Panchayat Assistant, etc.). Sampling interval (K) was computed by dividing the number of households of the main village and the hamlets by 100. A random number below K for the household was taken and the hamlet / village containing the random number became the starting hamlet / village. The reason for choosing a household and not the individual was that (i) sampling frames of individuals were not available and (ii) selection and examination of only certain individuals in the household would be embarrassing and practically difficult.

A random entrance / exit to the village / hamlet was selected. With this as the starting point the first household was identified by using the random number already selected. From this every k^{th} household was selected till 100 households were attained.

The Number of census enumeration blocks (EBs) was obtained from the Municipal administration. Electoral lists available with the municipality were used because the number and names of streets with door numbers including approximate member of households was not readily available. The procedure for the selection of the first random household and subsequent households was similar to that adopted for the rural area.

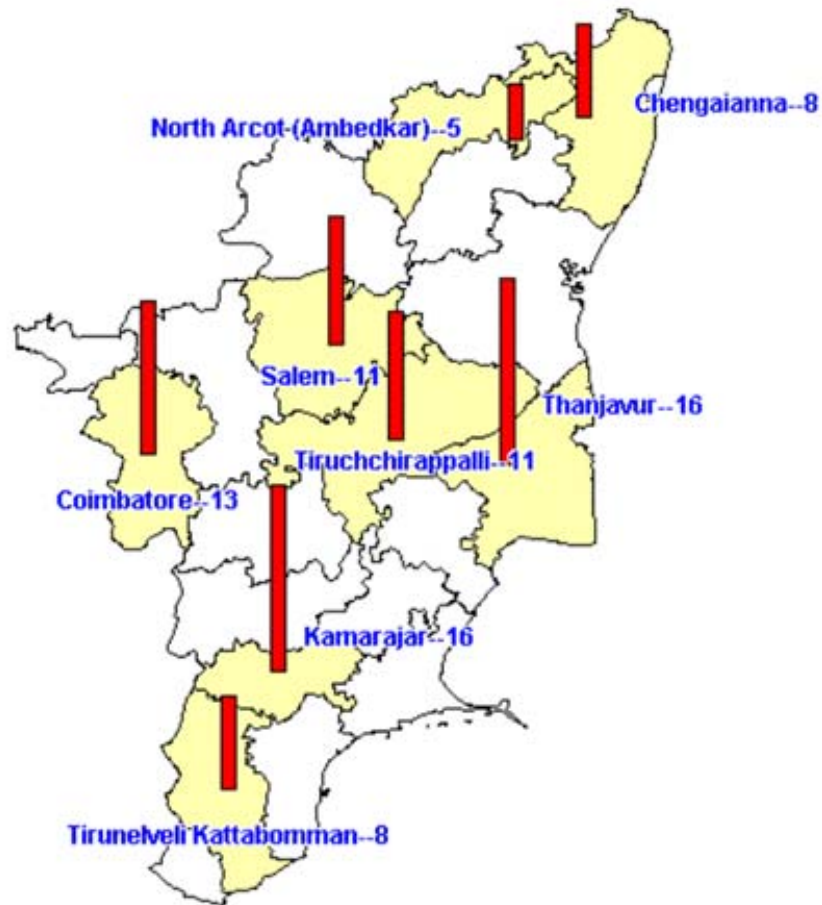
Five to six teams were formed to cover one district. Each team consisted of one health educator, three to four leprosy inspectors and one lab technician.

Laboratory technicians were involved to take slit-skin smears. Medical officers from the Directorate of Public Health, Tamil Nadu and National Institute of Epidemiology, Chennai were involved to monitor the quality of data.

To investigate whether the distribution of cases is at random or tend to occur in clusters the following procedure is adopted. The counts of observed leprosy cases by districts, with expected numbers for the districts, calculated from reference rates and the numbers at risk. The Null Hypothesis is that the cases are located at random with average number of cases per district proportional to number at risk. The departure from this situation is called clustering. This is examined through χ^2 . If there is no clustering of cases, the cases are fitted for a Poisson distribution. The goodness of fit of the distributions is examined through χ^2 . The design effect of the two-stage cluster sampling design instead of the simple random sampling adopted in LQAS was computed

The population enumerated was 62,157 and 56,469 (90.8%) individuals were examined. The average household size was 4.3. By the time 14036 individuals (households) were examined 27 cases were detected. However, the survey was further continued. In all, 83 new cases were diagnosed in the survey and 13 old cases detected were under treatment (UT). Of the 96 cases 31 belonged to SSL type, 48 belonged to PB type and the remaining 17 cases were diagnosed as MB type (Table 1). Distribution of leprosy cases for each district is given in (fig. 4). In all these cases the skin smears were negative for

Fig. 4 District-wise leprosy cases in the LQAS study



acid fast bacilli. Five cases with Grade I disability and 2 cases with Grade II disability were observed. Out of 13 UT cases 8 and 5 belonged to PB and MB, respectively (Table 2). The observed prevalence of leprosy in the examined population was 17 per 10,000. Seven SSL cases, 153 PB cases and 21MB 7cases under released from treatment (RFT) regimen while 32 PB cases and 8 MB cases under released from control (RFC) regimen were detected in the survey (Table 3).

Table 4 shows that coverage for clinical examination was about 98% in children. The coverage was more (96% and above) among adult females than adult males (80%). Similar findings were observed in each selected district. Within each selected district, coverage for examination was more than 90%. Out of 29 cases examined by the experts' 28 cases were confirmed (Table 5).

Table 6 shows that there is no obvious spatial pattern but district 3 has a high ratio (1.4) of observed to expected cases. The Poisson probability of observing 11 or more cases when only 7.68 are expected is 0.154. Among 8 ratios, 5 are more than 1. Districts 1 & 8 had the smallest ratio (0.6) of observed to expected number of cases. The Poisson probability for district 1 of observing 5 or more cases when 8.38 are expected is 0.02. The Poisson Probability for district 8 of observing 8 or more cases when 14.08 are expected is 0.07. If viewed in isolation district 1 had significantly smaller ratio than 1. All the remaining ratios had Poisson probability more than 0.15. Under the Null Hypothesis that all the ratios are equal to 1, $\chi^2_7 = 7.25$ with $P > 0.2$.

This shows that there is no evidence of clustering. The distribution of cases by villages for the state followed Poisson (Table 7). The distribution of cases by villages for the individual districts also followed Poisson. The goodness of fit was tested through χ_1^2 with $P = 0.5$. The design effect for six districts ranged between 0.8 and 1.01 (Table 8). The design effect for the remaining two districts was 0.2 and 1.9. The design effect for the entire state was 1.06.

The first point of interest from this study is that LQAS can be used for assessing progress towards leprosy elimination. However, this procedure needs to be repeated once a year to help the programme managers in understanding in which direction the progress is made over a period of time. There were 13 known cases of leprosy indicating that the known prevalence of leprosy was only 2.3 (67.1%) per 10000 population. This is far below the expected prevalence of 7 per 10000 in the state. Thus there is underestimation of known prevalence of leprosy in Tamilnadu. On the other hand if the number of new cases of PB or MB leprosy is included then the prevalence will be 11.5 per 10000. This gives an overestimate (64.3%) of 4.5 per 10000. Large number of RFT cases of PB and MB were found because PB and MB cases will be under surveillance for 2 and 5 years, respectively after the treatment.

The second point of interest from this study is that the number of leprosy cases in the population of each and the combined selected districts of Tamil Nadu follows Poisson distribution. Similar observation is made earlier in an endemic district of Tamil Nadu. This phenomenon of observing Poisson

distribution of leprosy cases in endemic areas may be true because the prevalence leprosy is rare in statistical sense.

The third point of interest is that there is no clustering of cases indicating that the cases are located at random. However the cases are not equally distributed not only at district level but also at village level. This shows that lower the prevalence of leprosy the more the clustering of cases. The leprosy cases follow a Poisson distribution also suggests that they are clustered in certain districts/villages. The intraclass correlation coefficients are nearer to 0 indicating that the distribution of leprosy among households is similar. In other words the risk of leprosy for household contacts and noncontacts is similar. This observation is true in previously hyper endemic district of Tamil Nadu state in India⁴. This phenomenon definitely needs to be tested in endemic areas. Though various studies across the world indicate that the risk of household context of particularly multi-bacillary cases of leprosy is much higher than the risk of non-household context this type of differential risk between context and non-context is not observed at village level (Unpublished observations, Gupte, M.D. et al).

The fourth point of interest from this study is that while carrying out LQAS operationally convenient two-stage cluster-sampling design can be adopted in place of simple random sampling. Further, there is no need to increase the sample size. Earlier study also demonstrated similar finding. Modification to the LQAS design is a feasible proposition. However, LQAS should not be

used indiscriminately. It should not be viewed as a method of sampling since it is a strategy for analysis.

Even if these critical factors are not met for considering the applicability of LQAS for leprosy elimination monitoring, the problem can be overcome to some extent by increasing the sample size. Modification to the LQAS and its potential effect on the evaluation in endemic and low endemic areas need to be explored.

The surveillance system was good in the sense that all the 13 cases under treatment were confirmed giving Positive Predictive Value of 100%. However, only 13 out of a total of 65 cases could be detected through the system. The sensitivity of the system was only 20% according to the survey.

Table 1: District-wise total number of cases detected in the survey by type

District	Type of cases		
	SSL	PB	MB
Tanjavur	7	6	2
Trichy	5	4	2
Kacheepuram & Tiruvallur	2	3	3
Vellore	2	1	2
Tirunelveli	6	9	2
Virudhunagar	3	6	2
Coimbatore	4	11	2
Salem	2	8	2
Total	31	48	17

Table 2: Age-Sex distribution of known cases by type of Leprosy

Age-group	PB		MB	
	MALE	FEMALE	MALE	FEMALE
5 – 14		2		
15 – 24		1		2
25 – 34	2			
35 – 44	1		1	
45 – 54				
55 – 64		2	1	
65+				1
Total	3	5	2	3

Table 3: Cases released from treatment (RFT) and released from control (RFC)
by type of leprosy and by the selected districts in Tamilnadu

District	RFT			RFC		
	SSL	PB	MB	SSL	PB	MB
Tanjavur	-	23	1	-	5	1
Tiruchirapalli	-	19	3	-	4	1
Kancheepuram & Tiruvallur	-	23	4	-	5	1
Vellore	1	20	3	-	4	1
Tirunelveli	-	15	6	-	3	2
Virudhunagar	-	18	3	-	4	1
Coimbatore	-	2	1	-	-	1
Salem	6	33	-	-	7	-
Total	7	153	21	-	32	8

Table 4. Examination coverages and leprosy prevalence rate (per 10,000) by age and sex for Tamil Nadu

Age Group (Years)	Males				Females			
	Number enumerated	Number examined	%	Prevalence Rate per 10,000	Number enumerated	Number examined	%	Prevalence Rate per 10,000
0-4	2645	2606	98.5	3.84	2480	2432	98.1	8.22
5-14	6222	6062	97.4	13.20	5985	5879	98.2	6.80
15-24	5663	4960	87.6	16.13	6306	6044	95.8	16.55
25-34	4976	3938	79.1	12.69	5370	5219	97.2	11.49
35-44	4446	3233	72.7	15.47	4400	4252	96.6	18.81
45-54	3294	2429	73.7	37.05	3199	3053	95.4	26.20
55-64	2137	1703	79.7	11.74	2092	1997	95.5	45.07
65+	1456	1262	86.7	23.77	1351	1290	95.5	62.02
Total	30839	26193	84.9	15.65	31,183	30,166	96.7	18.23

Age Group (Years)	Both sexes			
	Number enumerated	Number examined	%	Prevalence Rate per 10,000
0-4	5125	5038	98.3	5.95
5-14	12207	11941	97.8	10.05
15-24	11969	11004	91.9	16.36
25-34	10346	9157	88.5	12.01
35-44	8846	7485	84.6	17.37
45-54	6493	5482	84.4	31.01
55-64	4229	3700	87.5	29.73
65+	2807	2552	90.9	43.10
Total	62,022	56359	90.9	17.03

Table 5: Number of cases examined and confirmed

Dist.	No. of cases	Cases examined	Cases confirmed
Virudhunagar	11	8	8
Kancheepuram & Tiruvallur	8	6	6
Tanjavur	12	3	2
Coimbatore	13	12	12
Total	44	29	28

Table 6. Counts of observed and expected number of leprosy cases by selected district

Selected District	Number of leprosy cases		Ratio = $\frac{Observed}{Expected}$
	Observed	Expected	
1	5	8.38	0.60
2	7	8.45	0.83
3	11	7.68	1.43
4	12	11.15	1.08
5	11	9.89	1.11
6	16	12.41	1.29
7	13	11.00	1.18
8	8	14.04	0.57
Total	83	83.00	

$$\chi^2_7 = 7.23 \quad P = 0.4$$

Table 7. Fitting of Poisson distribution of leprosy cases in the selected villages

Number of Cases / Village	Number of villages	
	Observed frequency	Expected frequency
0	84	82.69
1	47	47.01
2	11	13.36
3	2	2.53
4+	2	0.41

$$\chi_1^2 = 0.5478 \quad P = 0.5$$

Poisson Distribution of cases

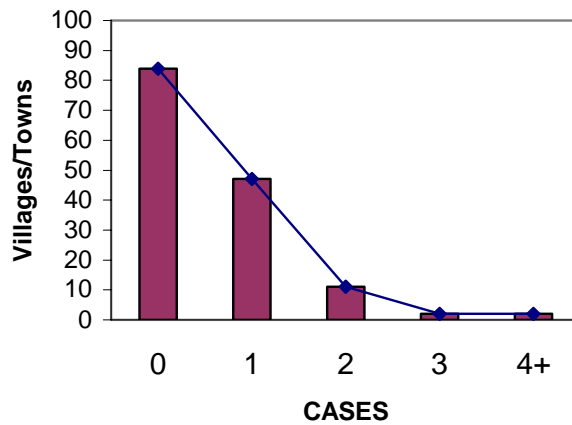


Table 8. Intraclass Correlation Co-efficient (ρ) and the design effect (D) for each and the combined selected districts

District	Intraclass Correlation Co-efficient	Design effect (D)
1	- 0.000257	0.9
2	- 0.001046	0.6
3	- 0.000505	0.8
4	-0.000239	0.9
5	-0.000257	0.9
6	-0.002137	0.2
7	0.002530	1.9
8	0.0	1.0
Total	0.000144	1.1

c) Spatial autocorrelation of leprosy prevalence in two districts of Tamil Nadu

Spatial autocorrelation arises whenever the intensity (value) of a variable at one location is related to its intensity at other locations. Most data will exhibit positive spatial autocorrelation such that nearby locations tend to have similar intensities. This theme is so common that the pre-eminent geographer, Waldo Tobler coined the first law of geography to be “nearby things tend to be alike.” It applies because nearby places have a common history and also environments in nearby locations are themselves similar. Moreover boundaries are geographic zones of rapid change in the intensity of a variable and are often of scientific interest in their own rights.

It is of interest to know whether the leprosy data display any spatial autocorrelation, i.e. do places that are near in space have values (of leprosy prevalence) that are similar, in contrast to places that are far apart. Put another way, does nearness in space go together with nearness in value? This is important because spatially correlated data cannot be regarded as independent observations. If the analysis does not take account of the correlation structure of the data, the estimates obtained may be inaccurate. Geographic patterns in the data may be assessed using measures of spatial autocorrelation or significance tests evaluating the similarity of adjacent values.

The study area consists of 148 panchayats (rural administrative units) comprising of 264 contiguous villages from Sriperumbudur and Kancheepuram district, Tamil Nadu, South India. The values used were the active prevalence rate for the year 1998. Let w_{ij} denote the weight (or connectivity) associating panchayats j ; and i for instance, we may define w_{ij} as 1 for adjacent panchayat pairs and 0 for non-adjacent pairs. Weights chosen should be large for points that are near in space and small or zero for points that are distant in space.

Three measures of spatial clustering are evaluated with the leprosy prevalence rates for two districts of Tamil Nadu using binary weights. The three indices being the Non Parametric D-statistic (the rank adjacency statistic), Moran's Geary's and I C. The later two (Moran's I and Geary's C) were chosen as being the best-established measures in the general statistical literature on spatial analysis¹.

Chou² et.al applied Moran I statistics to the distribution of wildfires in California, but used weighting matrices based not only on contiguity, but also distance between centroids, areas of adjacent polygons and lengths of the boundary common to adjacent polygons. They found that the contiguity values themselves performed satisfactorily, yielding Moran I value that was highly significant. Related work has shown that the rank adjacency statistic D to be quite stable when the regions are quite variable in size and shape, relatively constant in size and also when regions highly variable in size and shape. Also quite stable in the presence of small samples in each region and to the

presence of tied ranks. Hence an attempt was made on the above three measures (non parametric and parametric) using binary weights.

The non-parametric D-statistic is a weighted average of rank differences in the values of observations, with the average taken over all pairs of points. Since it is based on the ranks of the data rather than the actual values, the D-statistic is not dependent on normality of the data. Generally negative autocorrelation is not likely, since this would assume distant points to be more similar than near ones. Therefore, a one-sided significance z test was used, rejecting the null hypothesis of random spatial pattern if the value D is sufficiently small.

Usually a significance test was obtained for D-statistic by simulation. But for mutual binary weights an analytical test was used³, which is computationally less demanding and eliminating the previous need for simulation.

The I statistic is similar to the usual correlation coefficient; it measures the covariation between the data of neighboring regions. Data with a random spatial distribution give an expected value of I close to zero, spatial aggregation or clustering leads to positive values, with an upper limit of one for extreme clustering.

The Geary's C statistic incorporates direct-paired comparisons of data values, in place of the covariation approach for I. The expected value of C with spatially random data is one, while spatially clustered data give values less than one, and an extreme value of zero.

I and C can usually be considered as normally distributed for more than 20 regions⁴. So the usual method for testing the significance is to use approximate z tests with the theoretical means and variances. Here one-sided tests will be used, since one is usually interested in detecting positive spatial autocorrelation when neighboring regions tend to have similar rates, rejecting the null hypothesis of random spatial pattern with sufficiently large value of I, and sufficiently small value of C.

No. of panchayats (n) 148

No. of adjacent regional pairs 758

STATISTIC	MEAN	SD	Z	P-Values	Critical values		
					5%	1%	
D	41.83	49.67	1.22	-6.44	0.00	47.66	46.83
I	0.36	-0.01	0.07	5.05	0.00	0.11	0.16
C	0.59	1.00	0.08	-5.14	0.00	0.87	0.81

Here the D-statistic is 41.83, which is highly significant (P <0.000) with theoretical mean of 49.67 and SD deviation of 1.22. Also looking at the critical values it is observed that the leprosy prevalence has a significant

spatial aggregation if statistic $D < 47.66$ at 5% level and if $D < 46.83$ at 1% level.

All the three indices, D-statistic, Moran's I and Geary's C are highly significant (P-value < 0.000) shows positive spatial autocorrelation and neighboring regions tend to have similar rates.

There is highly significant spatial correlation of leprosy prevalence in two districts of Tamil Nadu, for the year 1998. It is shown by all the three statistical measures of spatial pattern using binary weights. Spatial clustering of disease is almost inevitable since human populations generally live in spatial clusters rather than distribution of space. An infectious and social disease like leprosy is likely to be spatially clustered even if population distribution was not clustered. It can be concluded that there is a strong indication of regions (panchayats) with high prevalence of leprosy to be spatially aggregated (which is highly significant) as opposed to being distributed randomly.

Definition of Indices of Spatial Autocorrelation

Suppose that a map has n regions (e.g. counties), and that the data value for region i is x_i . Let w_{ij} denote the weight (or connectivity) associating counties j ; and for instance, we may define w_{ij} as 1 for adjacent county pairs and 0 for nonadjacent pairs.

The non-parametric D is defined by

$$D = \frac{\sum_i \sum_j w_{ij} \text{mod}(y_i - y_j)}{\sum_i \sum_j w_{ij}}$$

Where y_i refers to the rank of the value at any region i ,

$E(D) = (n+1)/3$; $V(D) = (n(n-1)-2A)/18A$ where A is the number of

Distinct adjacent pairs of regions.

The I statistic, proposed by Moran is defined as

$$I = n \frac{\sum_i \sum_j w_{ij} (x_i - \bar{x})(x_j - \bar{x})}{\sum_i \sum_j w_{ij} (x_i - \bar{x})^2}$$

Under the null hypothesis of spatial random data, the mean and variance

Of I are

$$E(I) = -1/(n-1); \text{var}(I) = (n^2 S_1 - n S_2 + 3 S_0^2) / S_0^2 (n^2 - 1) - E^2(I)$$

$$S_0 = \sum_i \sum_j w_{ij}, S_1 = 1/2 \sum_i \sum_j (w_{ij} + w_{ji})^2, S_2 = \sum_i \left(\sum_j (w_{ij} + w_{ji}) \right)^2$$

where

$$C = (n-1) \frac{\sum_i \sum_j w_{ij} (x_i - x_j)^2}{2 \sum_i \sum_j w_{ij} \sum_i (x_i - \bar{x})^2}$$

Geary's C statistic is defined as

The mean and variance under the null hypothesis as follows:

$$E(C) = 1; \text{var}(C) = \frac{((2S_1 + S_2)(n-1) - 4S_0^2)}{2(n+1)S_0^2}$$

d) Estimation of cure, relapse and success rates of short-course chemotherapy in the treatment of pulmonary tuberculosis : a Meta-Analysis

The success of Tuberculosis Control Programme depends on many factors, especially on the cure and relapse rates following anti-TB treatment. Studies on the estimation of success rate of Short-course Chemotherapy (SCC) in the treatment of pulmonary Tuberculosis are many through Operational Research studies and Randomised Controlled Trials (RCTs). Here we consider RCTs because of its robustness. However, there are only 29 RCTs in the world to study the success of SCC in the treatment of Pulmonary Tuberculosis.

Among these studies considerable variation in the sample sizes ranging from 159 to 1040 was observed. The cure rates varied from 84% to 100% across the studies, while 95% confidence intervals gave lower bound as 79%. Similarly, relapse rates also varied from 1% to 16%. In this study, an attempt is made to make a global estimate for the cure, relapse and success rates of SCC, through Meta-analysis of eligible RCTs.

There existed heterogeneity among studies on each of these rates ($p < 0.001$). After correction for heterogeneity, the estimated cure rate was 97.7% (95% confidence interval (CI) 96.5% to 98.8%), the relapse rate estimated to be 6.1% (95% CI 4.0% to 8.2%); and the success rate estimated as 91.5% (95% CI 88.7% to 94.4%). Drug resistance to one or more drugs contributed 24% of the estimated relapse rate which suggests that a surveillance activity on drug resistant Tuberculosis should be undertaken.

6. SURVEILLANCE RELATED ACTIVITIES

a) Surveillance, Epidemic Preparedness & Response (SEPR)

Four 10-day workshops on SEPR have been conducted by the Institute and supported by WHO-SEARO between Sept. 2001 and February 2002. Through these four workshops of 91 Public Health professionals have been trained. Of these, 20 were international (WHO-SEARO) and 71 were national (India). Workshop participants were State / District level Public Health professionals (medical), involved in or responsible for outbreak management, faculty from Deptt. of Community Medicine of Medical Colleges and Researchers from various ICMR Institutes.

The main objective of the training programme are: (i) To strengthen capacity for effective Diseases Surveillance and efficient Outbreak of Management and (ii) Improve quality of Public Health Response.

The entire training programme consisted of lecture presentations followed by group activity. It focused on Disease surveillance as well as rapid and effective preparedness & response to outbreaks of varying magnitudes and occurring at different levels of the Public Health System.

The response and demand for such a training programme has been overwhelming. Therefore NIE proposes to undertake a minimum of 2 such courses, on a yearly basis, as one of its ongoing activities.

Experienced and qualified officers from NIE, other sister ICMR Institutes, visiting consultants from WHO, CDC, State Deptts., of Public Health, Medical Colleges and Research Institutes constitute the faculty for the FETP-MAE & SEPR training programmes.

Conduct of Surveillance Epidemic Preparedness and Response Workshops (Sept. 2001- Feb. 2002)

Two batches of FETP trainees – totaling 12 have been trained. Totally 20 International Public Health professionals from the SEA Region of WHO and 71 Indian professionals from different states of the country have been trained. Details of these workshops have been included under the section Field Epidemiology Training programmes at NIE.

Workshop on Curriculum Development for Capacity Building for Bio-Terrorism Management – (January 2002)

A workshop on the above theme was conducted on 11th January 2001, with the objective of developing a suitable curriculum for training professionals from various sectors to strengthen capacity for Bio-Terrorism management. Participants were drawn from the Deptts. of Public Health, Medical Colleges, Veterinary Medical University & IndiaCLEN. Two FETP trainees participated in this workshop.

b) Use of computers in Health Information Systems

In response to a felt-need expressed by the Director of Public Health & Preventive Medicine, Govt. of Tamil Nadu, the Institute has assumed responsibility for the

conduct of 5-days training programmes in “use of computers in HIS”. Approximately 60 senior and middle level state Public Health statistical officers are expected to be trained. So far NIE has conducted four such training programmes and trained 33 persons. Another 4-5 training programmes will be conducted in due course.

c) Workshop on “Excellence in Science Writing” (March 2002)

A five days workshop on “Excellence in Science Writing” was conducted at NIE under the guidance of Dr. Elliott Churchill from CDC, Atlanta. The objective of the workshop was to strengthen capacity of FETP trainees & NIE faculty in Scientific Writing. 8 FETP trainees and 8 NIE faculty participated in the training programme.

d) Participation in outbreaks by FETP trainees & NIE Faculty

1. Outbreak of Leptospirosis in a nurses hostel in Chennai – July 2001
2. Outbreak of food poisoning in a Girl School in Trichy, Tamil Nadu – Aug. 2001
3. Outbreak of Dengue Fever & DHF in Chennai city – October 2001
4. Outbreak of Encephalitis in Gummidistrict of Tamil Nadu, March 2002

e) Epidemic / outbreak investigations

i) Leptospirosis

Chennai City was experiencing drought conditions in early to mid 2001, forcing people to use water from any available source. We started the investigation of the outbreak of leptospirosis occurred among residents of nurses hostel. We interviewed the 69 residents and staff, collected blood, and followed them to the end of outbreak. Twenty-four respondents became ill (attack rate of 35%). The epidemic curve suggested continuous or intermittent exposure to infection over a five-week period. Twenty residents (three asymptomatic) developed laboratory confirmed *Leptospira icterohemorrhagiae* on the basis of assays on acute and convalescent sera specimens (Microscopic agglutination test). Water from an underground storage tank that was filled twice weekly from a mobile water tanker, yielded leptospira on Dark Field Microscope; residents collected water from this tank with a bucket and rope, and the tank was usually left open. The most likely source of infection was using contaminated storage tank water for drinking, brushing teeth, bathing, or washing clothes. The control measures included cleaning the large backyard with its many stray dogs and rats, chlorinating water supplies, boiling drinking water and health education. No further cases occurred twelve days after implementing control measures. It was difficult to identify the specific source of infection from exposure data, but standard hygienic measures immediately arrested the outbreak. When water is scarce, access to clean water is essential to prevent water-borne outbreaks.

ii) Leptospirosis & Dengue fever

An outbreak of febrile illness occurred in Thodupuzha Taluk of Idukki district in Kerala during May – July 2001. Cases were reported from various Government and private hospitals in the Taluk. There were five deaths. An outbreak investigation cell was set up at Thodupuzha Taluk Headquarters, which conducted various investigations.

A working case definition was made for identifying cases. The investigation team visited daily the hospitals that reported suspected cases and collected blood samples. Clinical and basic epidemiological information was also collected. The samples were sent to Kerala State Institute of Virology and Infectious Diseases for serological tests for leptospirosis and dengue fever. A preliminary entomological investigation was carried out in the affected villages. During the period 20th May to 26th July 2001 a total of 736 suspected cases were reported to the investigation cell. Lepto-dipstick was done on 224 samples and dengue immunochromatography on 169 samples. Lepto-Dipstick was positive in 79 cases and dengue immunochromatography in 16 cases. The affected persons were mainly agricultural workers and rubber plantation workers. Awareness programmes on leptospirosis and dengue were carried out in the affected areas.

iii) Dengue Fever

During the month of September 2001, 1078 cases were reported in Chennai city that was clearly in excess that confirmed the existence of the Outbreak. The detection of dengue specific IgM antibody & viral isolation verified the diagnosis. The outbreak

started in the first week of September 2001 and ended in the month of February 2002. Incidence of cases was very high in three zones (out of 10 zones) in Chennai. The overall incidence of reported cases was 2.3 per 10,000. The incidence was much higher among children below 14yrs of age group as compared to ≥ 15 yrs age group ($P < 0.0001$). The case fatality rate was 1.02%. The predominant signs & symptoms in a group of hospitalised and confirmed cases ($n=228$) of Dengue fever were: fever (95%), vomiting (55%), hepatomegaly (62%), pleural effusion (42%) & hemorrhagic manifestation (28%). Entomological study showed that the Breteau's Index (BI) was very high during ($BI=42$) as well as before ($BI=34$) the outbreak ($BI < 5$ low risk). Meteorological study revealed that there was intermittent rainfall well before the onset of monsoon in September 2001.

Epidemiological surveillance mechanism is essential for monitoring the endemic transmission, for early recognition of impending epidemics. This will help in preventing and controlling Dengue outbreaks in future.

iv) Food Poisoning

On the morning of 24-8-2001 at the Sevasangam girls school hostel, breakfast was served at 7.30 AM to the 472 inmates. Immediately afterwards at about 8.30AM some of the girls complained of nausea, vomiting, and giddiness. The number of cases started increasing and all the girls were taken to the nearby Government Hospital, Trichy.

The breakfast served on that morning was rice, buttermilk and onion chutney prepared in the hostel kitchen. The water supplied by the Municipality was stored

and used for drinking and washing purposes. The Corporation Health officer immediately investigated the outbreak and collected food and water samples for microbiological examination and analysis. The unusual occurrence of number of cases of gastroenteritis at the same time in the hostel after the breakfast confirmed the outbreak. The cases were line listed after interviewing 320 available inmates of the hostel on 11-9-2001. 87 of the interviewed had the illness confirming to the case definition. The Epi-curve showed clustering of cases between 8.30 and 10.30 hours, with the peak between 8.30 and 9 hours. The Median Incubation Period was about 1 hr. The Attack rate for exposure to Rice and Water was 26.5%, RR 1.85 (CI = 0.30 – 11.50) and for Buttermilk and Chutney 26.2%, RR 0.92 (CI = 0.28 – 3.00). The Lab. report was negative for the food samples. The water sample was found positive for coliforms and inadequately chlorinated. The short incubation period is in favour of bacterial toxins; the source could be the cooked rice that was kept overnight and served in the morning.

f) Recent trends in age and sex-specific mortality rates in a rural area (1995-1999)

Information on morbidity pattern is deficient particularly in rural areas. In the absence of reliable morbidity data, mortality indicators are used as indirect indicators of health. Information on deaths due to all causes was collected from vital events registers in two Health Unit Districts (HUDs) namely Thiruvallur and Kancheepuram .The population covered was approximately 12 lakhs and 9 lakhs, respectively (Towns were excluded from the study). Crude death rates, age and sex- specific death rates were calculated for each year. The secular trend in age-specific mortality rate was compared for gender differentials for the period 1995-

1999. Possible bias and confounding factors were evaluated and taken into account in the analysis.

The crude death rates (CDRs) for the period 1995-1999 ranged from 5.3 to 6.8. in the two selected HUDs. However, the overall CDR was significantly higher (6.5) in Kancheepuram ($p < 0.001$) compare to Thiruvallur (5.9). Information on age-sex specific mortality showed substantially elevated rates for males (40-59 yrs). This finding was consistent both at macro level (District) and at micro level (primary health centre) and also year-wise (figures 5&6). This raised several questions, such as, whether certain non-communicable diseases, newly emerging diseases or other environmental factors such as alcohol or traffic accidents, were responsible for this phenomenon. Further in-depth studies on causes of death may offer possible explanation for the above occurrence.

FIG. 5. AGE & SEX SPECIFIC DEATH RATES IN THIRUVALLURE HUD (1995-1999)

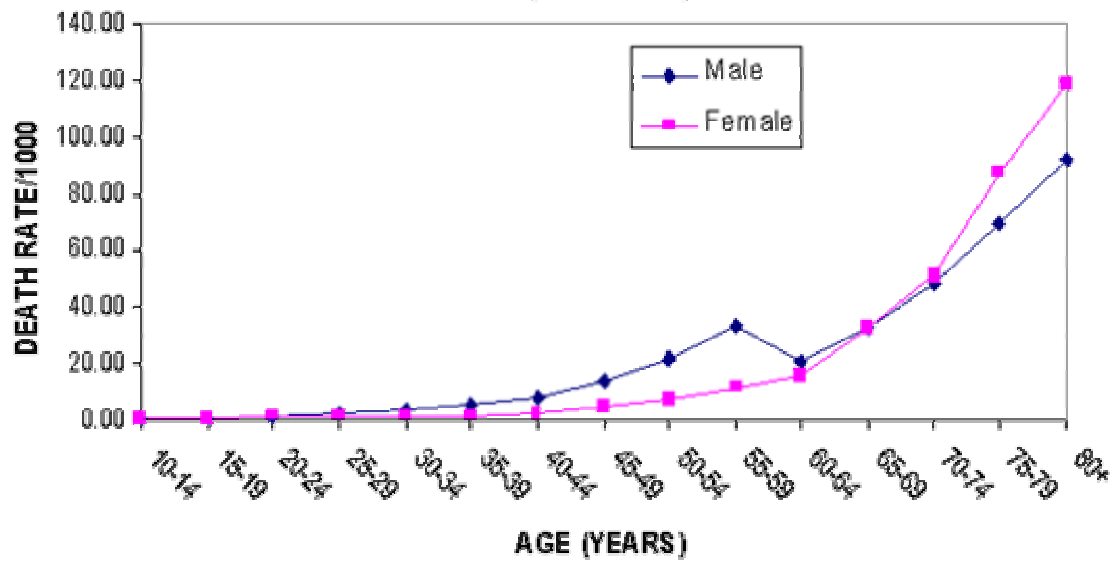
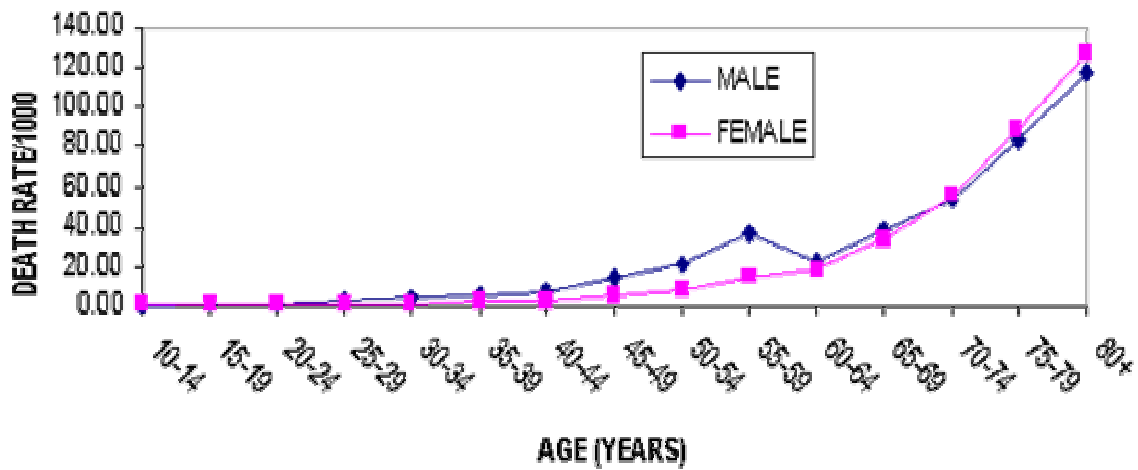


FIG.6. AGE & SEX SPECIFIC DEATH RATES IN KANCHEEPURAM HUD (1995-1999)



g) Cause of death by Verbal Autopsy – a pilot study (Collaborative project)

Mortality information in the country is not reliable. Though the Registration of Births and Deaths Act is promulgated, only about 40% of urban deaths and 11% to 12% of rural deaths are registered. Reliable information on the number of deaths in the country due to some major diseases is essential for proper health planning. During the year 1989, the Registrar General's office conducted study. In some urban areas where the data is based on medically certified deaths from selected hospitals.

There are some studies by the Indian Council of Medical Research to ascertain cause of death by verbal autopsy in some specific groups. Ministry of Health and Family Welfare, Govt. of India requested ICMR to undertake a study on cause of death in different states of the country in Phases. ICMR in turn asked NIE to take up the studies in south zone. In the I Phase it was decided to take up a Pilot study in Kancheepuram district (rural) and Chennai city from Tamilnadu.

Two medical officers of the Institute were deputed for training in the Institute of Health Systems (IHS), Hyderabad. The fieldwork was initiated after the training. The field team consisted of one Investigator who identified the households, one SRF (Social Sciences) who interviewed the respondent one medical supervisor who guided the SRF to take the interview. The SRF (Social Sciences) after collecting the information on the prescribed schedules assigned the probable cause of death using the algorithms provided to him. The results for total deaths enumerated (hospital deaths and from the community) are as under.

One hundred and eighty eight deaths have been collected, of which 5 have been independently collected by the SRF (medical) for comparison. There were 13 stillbirths, 30 neonatal deaths (1 - 28 days), 20 child deaths (29 days – 5 years), 17 maternal deaths, and 108 adult deaths (5+ years).

There are 110 deaths with reference period below 1 year. Stillbirths have been identified as caused by obstructed labour (O66.9) (3 deaths), 2 each by ante-partum haemorrhage (O46.9), 1 each by prematurity (P07.3), low birth weight (P07.1), eclampsia (O15.9), severe anaemia, premature rupture of membrane (O42.9) & undetermined(R 69). In neonates, asphyxia (9 deaths) was to be the major cause of death followed by prematurely (8 deaths), followed by low birth weight (6 deaths), congenital defect (4 deaths), acute LRI (2 deaths) and one due to birth trauma. Diarrhoea / Dehydration (7 deaths) was found to be the major cause among post-neonates and 1 or 2 deaths each due to pneumonia, congenital defects, meningo encephalitis, Bronchitis, sarcoma, whooping cough, epilepsy, tubercular meningitis, and tetanus. Of the 17 maternal deaths 4 were due to post-partum haemorrhage, 3 were due to eclampsia, and 2 each were due to indirect obstetrical and abortion and 1 each obstructed labour and congenital heart disease. Of the 53 deaths evaluated independently by SRFs of the project and hospital records, discrepancies were observed in 6 deaths while eliciting information on cause of death.

This shows that there is good agreement between cause of death elicited through VA instruments and hospital records.

The main study is to be carried out.

APPENDIX I

MEETINGS / WORKSHOPS / TRAINING PROGRAMMES ORGANIZED

1. ICMR-WHO workshop with special focus on Chittoor and Cuddappah districts to review the progress of '2-5 lesions and mono lesion study' on 2nd April 2001.
2. Board of studies meeting for the FETP-MAE programme with the approval of the Vice Chancellor of SCTIMST on 3rd June 2001.
3. Two-day 'partnership development workshop' on 27- 28 July 2001.
4. 'NIE-ICMR workshop on Field Epidemiology Training in Kerala- Challenges and opportunities' during August 2001.
5. Four ICMR-WHO Regional workshops on 'Surveillance, Epidemic Preparedness and Response' during Sept. 2001 – Feb. 2002.
6. Training programme on "Controlled Clinical Trials with special reference to Good Clinical Practice" during November 19-30, 2001.
7. ICMR training workshop for the research associates of the chronic hepatitis C multicentric trial on January 9, 2002.
8. Basic Course in statistics for Medical Doctors during January 21-25, 2002.
9. Workshop on curriculum development for capacity building for Bio-Terrorism Management in January 2002.
10. Workshop on "Excellence in Science Writing" during 25-29 March 2002.

APPENDIX II

LIST OF PUBLICATIONS

1. Murthy, B.N., Subbiah, M., Boopathy, K., Ramakrishnan, R., Gupte, M.D., "Lot Quality Assurance Sampling (LQAS) for Monitoring Leprosy Elimination in an endemic district in Tamil Nadu". Indian Journal of Leprosy, **73(2), 11-19, 2001**.
2. Asha Bai, P.V., Murthy, B.N., Chellamariappan, M., Gupte, M.D. and Krishnaswami, C.V.
"Prevalence of known diabetes in Chennai city". Journal of Association of Physicians of India, **49, 974-981, 2001**.
3. Gupte, M.D., Vidya Ramachandran, Mutaatkar, R.K.
"Epidemiological Profile of India" – Historical and Contemporary Perspectives". Journal of Biosciences, **26(4) Suppl, 437-464, 2001**.
4. Gupte, M.D., Leprosy Epidemiology. In : Valia, R.G., Ameet R.V., Editors. IADVL Text Book & Atlas of Dermatology. Tata McGraw-Hill Publication Co-Ltd., **PP: 1543, 2001**.

APPENDIX III

PARTICIPATION OF STAFF MEMBERS IN WORKSHOPS / CONFERENCES / SEMINARS

Workshop / Conference / Seminar Date & Venue	Staff member	Title / Role
Review meeting on clinical trial for the treatment of 2-5 lesions PB leprosy cases with a single dose of ROM April 2, 2001, ICMR HQ, New Delhi.	M.D. Gupte	Member
Meeting of the sub – group I on Leprosy, TB, STD & AIDS April 3, 2001, NICD, Delhi.	M.D. Gupte	Member
Regional consultation on Public Health & Human Rights April 10 & 11, 2001, New Delhi.	M.D. Gupte	Member
Workshop on “ Challenges in mobilizing community support in HIV and TB prevention and control” April 17, 2001, Chennai.	M.D. Gupte Thilakavathy Subramaniam	Member Participant
Expert Group meeting on Elimination of Leprosy April 24, 2001, IOP, New Delhi.	M.D. Gupte	Member
Expert committee meeting on multicentric clinical trial of Rasayana drugs April 27, 2001, New Delhi.	P. Jayabal	Participant

Rapid Situation Assessment (RSA) Dissemination workshop on Injecting Drug use in Chennai-Related booklet prepared by SAHAI Trust on HIV prevention in Injecting Drug use April 27, 2001, Chennai.	M.D. Gupte	Member
	Thilakavathy Subramaniam	Participant
	Vidya Ramachandran	Participant
Meeting of working Group on Communicable diseases May 4 & 5, 2001, Delhi.	M.D. Gupte	Member
SEAR – WPR, Bi – Regional seminar on Field Epidemiology Training. May 9 –11, 2001, Thailand, Rayong.	M.D. Gupte	Member
SAG Meting of the ECD Division May 17-18, 2001 ICMR, New Delhi.	M.D. Gupte	Member
Expert Group meting on investigations carried out at Siliguri. May 19, 2001, ICMR New Delhi.	M.D. Gupte	Member
SAG Meeting of BMS Division May 25, 2001, ICMR, New Delhi	M.D. Gupte P. Jayabal	Member Participant
Workshop on “Ethical issues in Epidemiological Research” May 29-30, 2001, Kolkata.	M.D. Gupte	Member
HIV/STD Training programme for PHC medical officers, Government of Tamil Nadu. May 2001, Chennai.	Vidya Ramachandran	Resource person

Meeting of the Global Forum on TB Vaccine Research and Development and to share expertise in mycobacterial Epidemiology with a particular emphasis on the conduct of large scale vaccine trials of anti mycobacterial vaccine. June 7-8, 2001 WHO, Geneva.	M.D. Gupte	Member
Meeting on simulation model and Verbal Autopsy June 14-16, 2001 IHS, Hyderabad.	M.D. Gupte B.N. Murthy A. Elangovan B. Kishore Kumar	Organiser Participant Participant Participant
Meeting on a major programme on the "Diseases of most Impoverished" June 18, 2001, ICMR, New Delhi.	M.D. Gupte	Member
"CIPRA Interactive workshop (at India International Centre)" June 18-19, 2001, New Delhi.	Thilakavathy Subramaniam	Participant
NACO Expert Group meeting on estimation of incubation period and survival time in HIV infection June 25-26, 2001, Chennai.	M.D. Gupte P. Jayabal Thilakavathi Subramaniam	Organiser Participant Participant
"Decentralized management of Rural Health Services" organized by National Institute of Rural Development June 4-9, 2001, Hyderabad.	Vidya Ramachandran	Participant
Short course on Model based Geostatistics, Royal Statistical Society (RSS) July 3, 2001, London	Vasna Joshua	Participant
Royal Statistical Society Conference, 2001 on "spatial Modelling" July 4-6, 2001, London	Vasna Joshua	A Geostatistical kriging to the analysis of covariates of Infant Mortality rates in India.

<p>“Independent study on Cause of Death Classification System”</p> <p>July 16-20, 2001 Institute of Health Systems, Hyderabad.</p>	<p>B. Nagaraju</p> <p>S. Balasubramaniam</p>	<p>Participant</p> <p>Participant</p>
<p>Expert Group meeting on Malaria Vaccine related field sites.</p> <p>July 18, 2001, ICMR HQ, New Delhi.</p>	<p>M.D. Gupte</p>	<p>Member</p>
<p>“Meeting to formulate Research proposal in the Area of HIV/AIDS” at Institute for Research in Reproduction.</p> <p>August 1-2, 2001, Mumbai.</p>	<p>Thilakavathy Subramaniam</p>	<p>Participant</p>
<p>Regional Conference on “Public / Private practitioners HIV / TB”</p> <p>August 7-9, 2001, New Delhi.</p>	<p>M.D. Gupte</p>	<p>Member</p>
<p>“Meeting on HIV-TB Co-infection”.</p> <p>August 21, 2001, Chennai.</p>	<p>Thilakavathy Subramaniam</p>	<p>Participant</p>
<p>ICMR-WHO Workshop on “Use of information Technology (IT) in Biomedical research.</p> <p>August 23-25, 2001, TRC, Chennai.</p>	<p>B.N.Murthy</p> <p>S. Balasubramanian</p>	<p>Participant.</p> <p>Participant</p>
<p>Anomaly Committee Meeting</p> <p>August 28-29, ICMR, New Delhi</p>	<p>J.P. Verma</p>	<p>Participant</p>
<p>WHO Technical Advisory Group meeting on Elimination of Leprosy</p> <p>September 2-8, 2001, Geneva.</p>	<p>M.D. Gupte</p>	<p>Chairman</p>

Meeting on multicentric study entitled “ A randomized Control trial of interferon and combination of Interferon with Glycyrrhizine” September 15,2001, ICMR, New Delhi.	M.D. Gupte P. Jayabal	Member Participant
IAL workshop on Experiences in the treatment of Leprosy with ROM therapy and MB Regimen of 12 months duration. September 21, 2001, Chennai.	Sreevatsa	Participant
“Sixth International congress on AIDS in Asia and the Pacific” October 5 –10, 2001, Melbourne, Australia.	Thilakavathy Subramaniam	“HIV seroprevalance types of STDs and Readiness for HIV prevention Intervention among STD clinic attendees”.
Shriprakash continuing Medical Education programme organized by the Department of Diabetes of voluntary Health services. October 6-7, 2001, Chennai.	B.N. Murthy	Invited talk on “ sizing up the problem of diabetes prevalence vis-à-vis diabetes in the young – statistical methodology”.
Tuberculosis Research Centre Scientific Advisory Committee meeting October 10, 2001, Chennai.	M.D. Gupte	Member
Seminar on Biostatistics October 10, 2001, Chennai.	P. Jayabal	Statistical methods in medical research
Scientific Advisory Committee meeting of Vector Control Research Centre October 13, 2001, Pondicherry.	M.D. Gupte	Member

ICMR-WHO regional workshop on “Epidemic preparedness and response” October 29 - November 8 2001, Chennai.	H.K. Nayak	Participant
Service & Personal Matters – Workshop conducted in Delhi by Third Development Centre in Operational Subjects of Administration and Management November 1-3, 2001, New Delhi	N.K.S. Brahaspathy	Participant
Anomaly Committee Meeting November 6, 2001, ICMR, New Delhi	J.P. Verma	Participant
Pay & Allowances Administration – Workshop conducted in Delhi by Third Development Centre in Operational Subjects of Administration and Management November 8-10, 2001, New Delhi	W. Michael Anthony Joseph	Participant
Retirement Benefits Calculation – Workshop conducted in Delhi by Third Development Centre in Operational Subjects of Administration and Management November 8-10, 2001, New Delhi	S. Kumaravel	Participant
Workshop on GIS Health mapper for disease surveillance November 6-9, 2001, Pune.	A.Elangovan Vasna Joshua	Participant Participant
SAC meeting of RMRC November 8-10, 2001, Bhuvaneshwar.	M.D. Gupte	Member
Bhuvaneshwar P.H. meeting on Anthrax November 12, 2001 Secretariat.	M.D. Gupte	Member

Purchase procedure – Workshop conducted in Delhi by Third Development Centre in operational Subjects of Administration and Management November 22-24, 2001, New Delhi	R. Balakrishnan	Participant
International Conference on Medical Informatics November 23-24, 2001, Hyderabad.	S.K. Suresh Kumar S. Satish	Medical Informatics and Biomedical Research in India: an appeal for up gradation.
Golden Jubilee conference of the Indian Association of leprologists November 23-25, 2001, Patna.	M.D. Gupte B. Nagaraju B.N.Murthy Sreevatsa	Member Single dose multi drug therapy (ROM) for single lesion PB leprosy under programme conditions “Applicability of Lot Quality Sampling (LQAS) for Leprosy elimination monitoring in Tamil Nadu – examination of some critical factors” Participant
Advisory Committee meeting of the SAHAI TRUST for a project on “A Rapid Situation Assessment of sexual Risk behaviour and substance use in sex workers and clients of sex workers in Chennai” November 28, 2001 Chennai.	M.D. Gupte	Member

19 th Annual Conference of the ISMS December 1-3, 2001, Lucknow.	P. Jayabal	Good Clinical Practice (GCP) guidelines for clinical trial
	B.N.Murthy	“Calculations of Sample size based on Conditional Power in Group Sequential Multi-arm Clinical Trials”.
	M.C. Satagopan	“Statistical Analysis in the Articles published in Indian Medical Journals”
	B. Kishore Kumar	Participant
	V. Selvaraj	Generalised Estimating Equation approach for analysing correlated data.
	Vasna Joshua	“A Spatial pattern of Infant mortality rates in India”
	R. Ezhil	Confidence interval for Relative risk in cluster sampling.
	A.K. Mathai	Is it necessary to do Univariate prior to Multivariate regression analysis?
S. Anitha	Radial basis function Neural networks and its Biomedical application.	

<p>3rd International Conference on AIDS, India 2000, December 1-5, 2001, Chennai.</p>	<p>M.D. Gupte B.N.Murthy Thilakavathy Subramaniam</p>	<p>Co-chaired a session Participant a)“Prevalence of HIV and STDs and Readiness to participate in STD/AIDS Prevention Intervention among STD - clinic Attendees, Chennai” b) “Sexual Risk Behaviour in Government STD clinic Attendees” at Chennai</p>
<p>Informal meetings of the Sasakawa Advisory Meeting for Global Alliance for Elimination of Leprosy. December 5-7, 2001, WHO, Geneva.</p>	<p>M.D. Gupte</p>	<p>Member</p>
<p>SAC meeting of CJIL, Agra. December 9, 2001, CJIL, Agra.</p>	<p>M.D. Gupte</p>	<p>Member</p>
<p>“International Conference on HIV/AIDS”. December 16-19, 2001, Mumbai.</p>	<p>Thilakavathy Subramaniam</p>	<p>Invited talk on “HIV and Sexual Risk Behaviour” under the plenary session on “HIV and vulnerability”</p>
<p>“Health Sector Reforms” India CLEN Meeting organized at MMC December 2001, Chennai.</p>	<p>Vidya Ramachandran</p>	<p>Participant</p>
<p>Meeting of the Task Force Group Meeting on “Cause of death by Verbal Autopsy” January 3, 2002, New Delhi</p>	<p>Dr. B.N. Murthy</p>	<p>Participant</p>
<p>Issues related to Elimination of Leprosy Task Force on Leprosy January 7, 2002, ICMR New Delhi.</p>	<p>M.D. Gupte</p>	<p>Member</p>

XX Annual Conference of IAPSM – Talk on Disease surveillance system – An overview (National Global perspective) January 12, 2002 IAPSM, Orissa.	M.D. Gupte	Member
Workshop on effective management of Library and information resources in the cyber age January 15-19, 2002, Hyderabad.	S.K. Sureshkumar	Participant
All India Annual Conference of Indian Health Association January 25-27, 2002, Kolkata	T.Venkata Rao	Prevalence of disability and handicaps in geriatric population in rural South India.
EPR-Trial run workshop organized by WHO – SEARO & AHEAD January 15-19, 2002, Agra.	Vidya Ramachandran	Observer
Meeting of the Directors of the ICMR Institutes February 2-3, 2002, Kolkata.	P. Jayabal	Participant
ICMR Training programme on R & D Management February 4-6, 2002, Kolkata.	P. Jayabal	Participant
International Course on Clinical Trial - Design & Conduct February 4-5, 2002, New Delhi.	S.K. Sureshkumar B. Kishore Kumar	Participant Participant
WHO collaborative centres (WHO- CCs) meeting February 5-6, 2002, Jaipur.	R.L.J. De Britto	Participant

8 th International Congress of Assisted Reproduction Technology and advances in Infertility Management. February 15-17, 2002, Ooty.	S. Jabbar S.K. Sureshkumar	“Epidemiological Aspects of Infertility in a South Indian District: Results of a community based survey”. Participant
“Asian workshop on Rapid Assessment and response on Psychoactive substance use and sexual Risk Behaviour (SEX RAR) February 18-21, 2002, Chennai.	Sreevatsa Thilakavathy Subramaniam	Participant Participant
IEA South East Asia Congress of Epidemiology February 24 – 27, 2002, Jhansi.	M.D. Gupte T. Venkata Rao R.Ramakrishnan P.Manickam	Member Higher Mortality among males aged 40-60 years in two health unit districts of Tamil Nadu in South India An institutional outbreak of leptospirosis during a drought in Chennai, South India. Participant
Seminar on “Gender Inequities – challenges and opportunities” February 2002, KMCH Chennai.	Vidya Ramachandran	Resource person
Meeting on “Iron & Folic Acid Administration in Tamil Nadu” organized by DPH & PM, Government of Tamil Nadu. February 2002, Chennai	Vidya Ramachandran	Participant
Academic committee of SCTIMST, Trivandrum. March 9, 2002, Trivandrum	M.D. Gupte	Member

Sensitisation meeting for key policy makers at the state level for HIV-TB co-infection control at TB Association of India. March 14, 2002, Chennai.	Thilakavathy Subramaniam	Participant
Conference on “Responding to new challenges in a changing world”. March 14-15, 2002, Canberra, Australia.	R. Ramakrishnan	An Institutional outbreak of leptospirosis during a drought in Chennai, South India.
National Symposium on Statistical Methods and Applications March 15-16, 2002, Chidambaram	B. Kishore Kumar V. Selvaraj R. Ezhil	Participant Estimating Equation approach for analysis of Correlated data – An illustration with the data from a survey on AIDS awareness among college students of Chennai. Comparison of Event rates and Construction of Confidence interval for risk ratio in clustered binary data.
Annual Review Meeting of the Diabetes Mellitus trial March 18, 2002, New Delhi	M.D. Gupte P. Jayabal B. Kishore Kumar	Member Participant Participant
Third Sir Dorabji Tata symposium March 21-22, 2002, Bangalore.	M.D. Gupte Vidya Ramachandran	Participant Participant
Meeting of the Task Force on the Management of Cancers March 26, 2002, New Delhi	P. Jayabal	Member

APPENDIX IV

STAFF DEVELOPMENT

1. Dr. B. Nagaraju, Deputy Director (Medical) underwent training on “Independent study on Cause of Death Classification System” from 16-7-2001 to 20-7-2001 at Institute of Health Systems, Hyderabad.
2. Dr. R. Ramakrishnan, Assistant Director (Statistics) is pursuing a two-year Field Epidemiology Training Program (FETP) at the Australian National University, Canberra, Australia.
3. Dr. R. Ramakrishnan, Assistant Director (Statistics) awarded Ph.D. degree by the University of Madras for his thesis titled “Evolution of age-independent index to detect under nutrition among children aged 5-10 years”.
4. Dr. R.L.J. De. Britto, Assistant Director (Medical) was awarded with WHO Fellowship on “International Communicable Diseases” between 3-9-2001 to 14-9-2001 at MOPH, Thailand
5. Dr. S. Balasubramanim, Senior Research Officer (Medical) underwent training on “Independent study on Cause of Death Classification System” from 16-7-2001 to 20-7-2001 at Institute of Health Systems, Hyderabad.
6. Mr. A. Elangovan, Senior Research Officer (Programming) registered for a two year course (M.Tech) on Information Technology under distance education mode from Punjab University, Punjab.
7. Mr. M. Ravi, Data Processing Assistant completed a 1½ year course on M.S. (Software Systems) at BITS, PILANI.

APPENDIX V

STAFF MEMBERS AS ON 31.03.2002

Director	M.D.Gupte, M.D.,D.P.H.
Deputy Directors	B.Nagaraju, M.B.B.S.,D.P.H. P.Jayabal, M.Sc. B.Narasimha Murthy,M.Sc.,Ph.D.
Assistant Directors	Sreevatsa, M.Sc., Ph.D. 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.Lit. Vidya Ramachandran, M.Sc.,M.P.H. Ph.D.
Senior Research Officers	S.Balasubramanyam, M.B.B.S. M.C.Satagopan, M.Sc. H.K.Nayak, M.B.B.S. A.Elangovan, M.Sc. S.Jabbar, M.Sc., B.Ed. J.Arockiasamy, M.Sc. S.K.Suresh Kumar, M.B.B.S. (Resigned -30.4.02)
Senior Technical Officer	D.S.Anantharaman, M.A. (V.R.S - 15.03.02)
Assistant Research Officer	S.Kannan, M.Sc.
Technical Officers	R.Jayasri, M.Sc. N.Ramalingam, M.Sc. V.Selvaraj, M.Sc. Vasna Joshua, M.Sc. R.Ezhil, M.Sc. L.Sundaramoorthy, M.Sc. S.Harikrishnan, B.Sc.

Research Assistants	S.Venkatasubramanian, M.Sc., PGDOR V. Periannan, M.Sc. R.Sudha, M.Sc. N.Uthayakumaran, M.Sc., Ph.D. V.N.Mahalingam, M.Sc. P.Kamaraj, M.Sc., M.Phil K.Boopathi, M.Sc.
Research Assistants	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 Assistants	K. Kanagasabai, M.Sc., PGDCA B.K. Kirubakaran, M.Sc., PGDCA M. Ravi, B.Sc., M.C.M., M.S.
Data Entry Operators	A.G. Ananthakrishnan, B.A. S. Boopalan, B.Sc.,
Senior Technical Assistants	T.S. Manoharan, S.S.L.C.
Technical Assistants	M. Dhakshinamurthy, M.A. B. Arumugam, S.S.L.C. Paul S.K. Rao, Intermediate M. Gangadhara Rao, Intermediate S. Lucas Leonard, B.A. Y.Livingstone, M.A. C. Ahas Danielraj, P.U.C. (Expired - 8.4.02) M.Mercy Mallika, S.S.L.C. M. Kirubanithy, B.Sc.
Library Information Assistant	S. Satish, B.A., MLIS

ADMINISTRATION

Senior Administrative Officer	:	J.P. Verma, B.A.
Administrative Officer	:	R. Balakrishnan, 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 Officers	:	A. Rajeswari, B.Sc. S. Rangarajan, M.A., B.G.L. S. Ravi, B.A. - Relieved on 3.5.02
Personal Assistants	:	A. Murugarasan, B.Com. Uma Manoharan, B.A.
Assistants	:	D. Parvathi, B.Sc. R. Udayalakshmi, B.Com. Michael Antony Joseph, B.Sc. S. Kumaravel, B.Com.

CENTRAL BIostatistical MONITORING UNIT
FOR TRADITIONAL MEDICINE RESEARCH [ICMR SCHEME]

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

Systems Analyst : Paul Alexius Tamby, M.Sc.

Research Officer : B. Kishore Kumar, M.Sc

