

# **ANNUAL REPORT**

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***1999***

**National AIDS Research Institute  
73-G Block, MIDC, Bhosari, Pune**

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## Executive Summary

It is a pleasure to give an account of the activities of the Institute spanning various disciplines. It describes the data generated in four studies that were completed during the year. A Phase I trial for acceptability and toxicity of Vaginal Microbicides N-9 and Buffergel was completed. This has resulted in capacity building for undertaking Phase II and III trials of this woman controlled intervention strategy. A study for promotion of condoms among HIV discordant couples using novel counselling strategies is completed. Final reports of both the studies are under preparation. A study on Indian strains for co-receptor usage demonstrated that there is no switch from R5 phenotype to X4 phenotype in Indian HIV infected persons. This is consistent with the observations in subtype C infected persons in other continents. Another noteworthy observation among three PHCs in Pune district has reemphasized a fact that HIV infection is not only restricted to urban areas but is seen in rural areas too and this should be considered in developing any HIV control strategy.

*A cohort of HIV negative patients attending STD clinics was continued. A retrospective study in this cohort showed high HBV seroprevalence rates among STD patients. This finding is important in that it may indicate the need for controlling spread of HBV among STD patients. The sentinel surveillance for HIV infection among tuberculosis patients and pregnant women continued to show high prevalence. The enrollment for studies on immunological and virological factors in acute primary HIV infection continued. The research activity in basic sciences included characterization of HIV viruses included in the virus repository, study of drug resistance in STD organisms, in vitro testing of anti-retroviral activity in herbal preparations and traditional systems of medicines, subtyping of HIV-1 strains from Western India and studies on CD4 cell counts and association with occurrence of OIs and other clinical manifestations among HIV infected individuals.*

The Institute has been assisting National AIDS Control Programme through various activities. NARI continued to give counselling and diagnostic services through its reference center. NARI is also Chair for NACO's Technical Resource Group on Research and Development in HIV and AIDS. A two-day workshop under the TRG resulted in development of recommendations for prophylaxis in HIV infection. As one of the six centers, NARI contributed towards capacity building in counselling through various training programmes in the states of UP, Rajasthan and Jammu & Kashmir. The Institute's staff contributed to AIDS awareness efforts through lectures, exhibitions, seminars, radio talks etc. A workshop for sensitization of media was one of the high points of World AIDS Day activities. Publication of quarterly 'AIDS Research and Reviews' continued under extra-mural funding.

Some of the major activities the Institute plans to initiate during next year include clinical studies on HIV and TB, immunological and virological studies pertaining to mother to Child transmission of HIV infection, study of impact of counseling on behaviour change, study on women and AIDS and studies in genetic resistance to HIV infection.

Inadequate staff strength and financial allocation continued to place restraints on the expansion of Institute's activities. Nevertheless there was an increase in the financial allocation during the year. While continuing the present activities the Institute also plans to strengthen its community outreach and community based research activities and has planned to initiate new studies especially aimed at intervention in the near future.

**Dr. R. S. Paranjape**

## 1. EPIDEMIOLOGY:

### **1.1 Core HIV transmission study among STD patients: Cohort building, maintenance and follow-up**

Development of the cohort of HIV seronegative STD patients, initiated under the PAVE/ HIVNET project in the year 1993, was continued during the year. The details of patients enrolled in the cohort are given in the table below:

*Summary of data for year 1999*

<b>Category</b>	<b>Male STD patients</b>	<b>Female sex workers</b>	<b>Other females</b>	<b>Total</b>
No. Screened	658	86	446	1190
%	55.3	7.2	37.5	100.0
%HIV prevalence	20.7	58.5	6.5	18.1
<i>Overall HIV incidence</i>				<i>7.6 % per year</i>

With a view to increase enrollment of women, we initiated a clinic in the Gynecology OPD of the Sassoon General Hospitals, Pune and opened the cohort of women presenting with genital discharge and pelvic inflammatory disease. At the clinic, these women presented with pain in lower abdomen. This has led to a substantial increase in enrollment of women in our study.

*HIV prevalence and Incidence summary :1993-97*

<b>Year</b>	<b>HIV Prevalence (%)</b>	<b>HIV Incidence (% per year)</b>
1993	24.4	7.4
1994	20.2	8.0
1995	21.1	6.4
1996	25.0	6.7
1997	24.6	5.9
1998	26.5	3.6
1999	18.1	7.6

### **1.2. HIV Seroprevalence and awareness about AIDS among pregnant women in rural areas of Pune district of Maharashtra**

To determine the HIV sero-prevalence and assess awareness about AIDS among rural pregnant women, a comprehensive, community based sero-epidemiologic study was conducted in the area of three primary health centres (PHCs) (Chakan, Kadus and Khed Shivapur) in Pune district of Maharashtra from September 1998 to November 1998. The target population was identified with the help of records of pregnant women maintained by the staff of the Primary Health Centers.

#### ***Methods***

##### ***Sample collection, storage and testing***

Using dried blood spot collection methodology, standardized and validated at NARI, the samples were tested by Enzyme Linked Immuno-sorbent Assay (ELISA). Positive and borderline samples were subjected to confirmatory ELISA tests using different kits.

##### ***Assessment of knowledge and awareness of HIV/ AIDS***

A structured questionnaire with close-ended questions was developed. It was tested in a pilot study and suitable modifications were made. In addition to recording of basic demographic data, the questionnaire assessed the level of knowledge, access to information, effectiveness of the various means

of education currently being employed, as well as the attitudes and receptiveness towards health education. During the period of the study, questionnaires were administered to 181, 104 and 84 pregnant women from the Chakan, Kadus and Khed-Shivapur primary health centers respectively.

### **Results**

Out of the 1251 blood samples tested, 15 were detected to be sero-positive, thereby indicating an overall prevalence of 1.2 % among pregnant women in rural areas of Pune district. HIV sero-prevalence was significantly higher among villages situated within 1 kilometer of a national or state highway. Analysis of the available data suggested no significant associations between husband's occupation, gravidity, literacy status or age of the participating pregnant women and HIV sero-prevalence.

A large majority (> 95%) of the participating women were housewives. Almost 70% from them were aware of the existence of the disease and had heard about AIDS. Only 33% of the respondents were aware of all the main modes of HIV transmission and almost an equal number were not aware of any of the modes of transmission of HIV. Only 14% women were fully aware and had no misconceptions about the methods of prevention of HIV transmission. Commonly recorded misconceptions were about the spread of HIV and they included possibility of spread of HIV through droplets, mosquito bites, touch, sharing of clothes and utensils, use of public toilets and donation of blood.

Among those women who had heard about AIDS, 78% believed that it was necessary to maintain a single sexual partner relationship to stop the spread of the disease and 58% were aware of the protective role of condoms in HIV transmission. As many as 40% believed that it was necessary to avoid any physical contact with infected persons and use of public latrines. Nearly 30% of the respondents were aware of the unavailability of a vaccine or treatment and very few (7%) were aware that the causative organism is a microorganism.

Almost 70% of the study population gained information through health camps that were periodically held in all the PHC areas. Television was also a major source of information for nearly 45% of the study participants. Participants from the areas under the primary health centers of Chakan and Khed-Shivapur had a much better access to information from television than that in Kadus. Radio was a source for 25-32% participants. Print media were found to be an inadequate source. Participants reported that they also gained information from discussions with health workers and through signboards.

Awareness was found to be significantly associated with higher level of literacy. It was also observed that median scores of awareness for those women who had gained their knowledge of AIDS from either television or signboards or both were significantly lower than the scores of those who had received knowledge, partially or solely, from the health workers. There was no significant difference in the literacy levels of the respondents in the three study areas. **Majority (92.5%) of the respondents felt the need to impart knowledge about AIDS to school going children, either in schools, or at home or on television.**

### **Conclusions**

With better facilities in transport and communication, movement of people from rural to urban areas and rapidly progressing urbanization HIV is making entry in rural areas. It is important to further investigate the dynamics and role of commercial sex work along the highways in disseminating HIV infection to rural areas with a view to identify appropriate prevention and control strategies. Special efforts may be made to create awareness about STDs and AIDS both among men and women for prevention of sexual transmission of HIV.

Perception of the risk and safety by an individual may result in an appropriate change in behaviour in the context of prevention of spread of HIV and this can be achieved by systematic and sustained awareness efforts. As significant rapport and trust between village level workers and the participating women was noticed, emphasis should be placed on intervention involving direct interaction of the population with peripheral health workers and training of these functionaries in issues related to patient care, prevention of secondary transmission of HIV, counseling and communication skills.

In a rural setting and where there is lack of adequate trained manpower, insufficient access to health & where there is infrastructure and low level of literacy; intensive long-term preventive strategies like creating awareness among young people and women must be initiated immediately.

## 2. CLINICAL SCIENCE

NARI has a referral clinic (HIV Reference Center) in Pune. Patients are referred to this clinic by various doctors, hospitals, institutes and organizations in and around Pune for HIV testing, confirmation, counseling and medical advice.

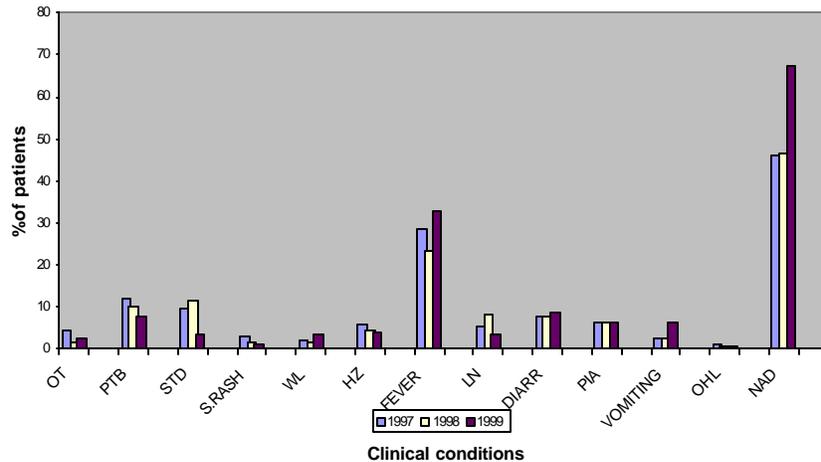
A retrospective study was conducted to examine the referral patterns of the physicians over the last three years. All the referred patients during 1997 to 1999 were included in this analysis.

### Summary:

Total 3574 subjects came for HIV confirmation by WB test from January 1997 to December 1999. Of these, 2043 (57.2%) were symptomatic and 1531 (42.8%) were asymptomatic at the time of presentation. 2761 (77.3%), 15 (0.4%) and 25 (0.7%) tested positive for HIV-1, HIV-2 and HIV-1 and 2 respectively. Trend test was applied to study if there was significant trend in the clinical presentations of HIV positive subjects in this cross-sectional study. The clinical conditions like oral candidiasis, tuberculosis, skin rash and sexually transmitted diseases showed decreasing trend over the study period ( $p= 0.03, 0.02, 0.004$  and  $0.0007$  respectively). Conversely, the number of HIV positive patients without any clinical findings showed a significantly increasing trend over three years of study. The changing trend in the clinical presentations of the referred HIV positive patients probably reflects increased awareness among the clinicians about HIV detection.

This might have public health implications. Early diagnosis may help in prevention of secondary transmission, decisions on prescribing chemoprophylaxis for opportunistic infections and may allow clinical trials to be taken at a relatively early stage of HIV disease.

**Trend in the clinical presentations of HIV infected subjects in Pune, India (1997-99)**



*OT – Oral Thrush, PTB – Pulmonary Tuberculosis, STD – Sexually Transmitted Disease, S. Rash – Skin Rash, WL – Weight Loss, HZ – Herpes Zoster, LN – Lymphadenopathy, Diar – Diarrhoea, PIA – Pain in Abdomen, OHL – Oral Hairy Leukoplakia, NAD – No Abnormality Detected.*

Past history of illnesses within 5 years of the clinic visit as given by the patients revealed that tuberculosis was very common HIV related illness in our population and Herpes zoster was the commonest cutaneous manifestation. So if a patient presents or reports past episodes of these conditions, possibility of HIV

should be kept in mind. The table below shows the percentages of patients giving history of different conditions among HIV sero-positive patients attending HIV clinic, Pune.

	Clinical Presentation	Percent reporting the clinical presentation		
		1997 n=867	1998 n=968	1999 n=597
1	Pulmonary tuberculosis	3.6	3.4	3
2	Herpes zoster	7	13.9	8.7
3	Sexually Transmitted Diseases	0.9	---	0.9
4	Viral Hepatitis	2.3	0.2	1.1

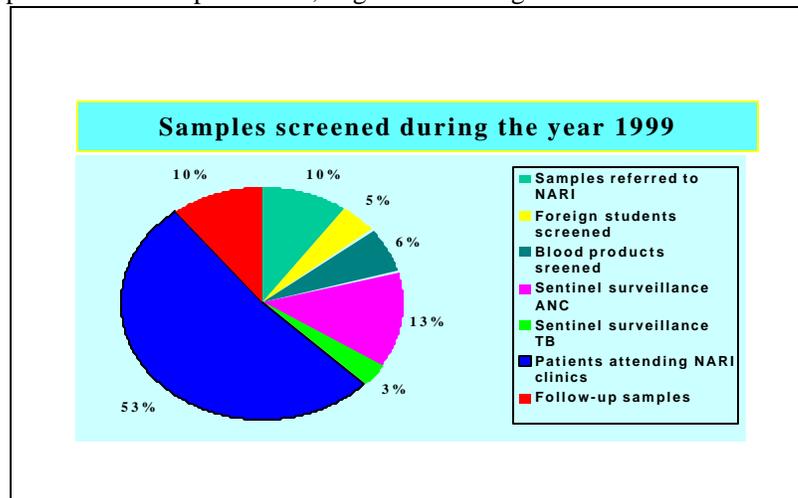
n= number of HIV positive persons from whom past history was elicited

*Clinical presentation among concordant couples attending HIV clinic, Pune*

Total 933 couples were seen during the study period. Of these, 517 were concordant HIV sero positive & 416 were discordant for HIV sero reactive. Among them 379 were discordant in which male partners were positive and 37 were discordant in which female partners were positive. The clinical features of men and women in the concordant couples during last three years showed that males were more symptomatic than females. This may be attributed to the introduction of HIV infection earlier in males than females. This temporal difference in HIV acquisition would essentially result in a time gap of several years by which AIDS epidemic in women would follow that in men.

**3. SEROLOGY:**

Serodiagnosis was provided to all patients attending five clinics of the Institute. In addition, samples were received from various organizations in and around Pune and other parts of Maharashtra state for confirmation of HIV diagnosis. Sentinel surveillance for HIV prevalence was undertaken once every year in ANC and TB cases. Serology lab also tested samples of foreign students admitted to Pune University. Being National reference center, services were also provided for testing of blood products for anti-HIV antibody and evaluation of anti-HIV antibody kits. A total of 12,086 samples were screened during the year. The breakup of various samples tested, is given in the figure below:



**3.1 Patients attending NARI clinics :**

HIV prevalence was estimated in different groups of patients who attended NARI clinics during the year. A high positivity rate was seen in persons having multiple sex partners (54.3%), STD patients (42.8%), female sex workers(44.2%) and in patients who received blood products (54.7%). Positivity rate among

RTI clinic attendees worked out to be 6.2 percent. Sentinel surveillance revealed 26.5 % HIV prevalence in tuberculosis patients and 2.6 % in ANC cases. The number of cases in various categories and the positivity rate is shown in table below:

*HIV antibody reactivity in patients attending NARI clinics*

<b>Risk Group</b>	<b>No. Tested</b>	<b>No. Positive (%)</b>
Persons having multiple sex partners	2304	1252 (54.3)
STD Patients	70	30 (42.8)
Female sex workers	249	110 (44.2)
Recipient of blood products	95	52 (54.7)
TB patients	1965	520 (26.5)
ANC cases	1600	41 (2.6)
RTI clinic attendees	551	34 (6.2)
Total	6834	2039 (29.8)

*Note: The percentages refer to clinic attendees and do not represent the figures in the general population*

### **3.2 Samples referred to NARI :**

A very high rate of reactivity for HIV antibody was seen in all samples from patients belonging to different risk groups referred to NARI. A majority of these samples were from patients who were found positive in screening done outside. This probably indicates improved HIV testing in the peripheral laboratories.

*HIV antibody reactivity in samples referred to NARI*

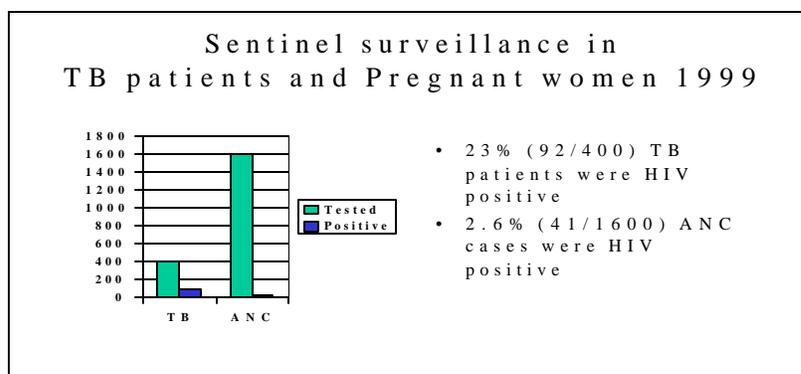
<b>Risk Group</b>	<b>No. Tested</b>	<b>No. positive (%)</b>
Persons having multiple sex partners	210	204 (97.1)
STD Patients	21	17 (80.9)
Blood donors	181	128 (70.7)
Spouse of sero-positive	28	27 (96.4)
Total	440	376 (85.5)

### **3.3 Sentinel Surveillance:**

Sentinel surveillance for anti-HIV antibody was conducted among the consecutive ANC cases and Tuberculosis patients attending respective out patient clinics at Sassoon General Hospitals in Jan-Feb, 1999.

Of the 800 ANC samples from Sassoon General Hospitals, Pune, 28 (3.5%) were HIV positive; four hundred blood samples were collected from consecutive new TB patients and 92 (23%) were positive for HIV antibody .

The surveillance activity was extended to Pimpri-Chinchwad Municipal Corporation, where NARI is located. Eight (2%) samples were positive out of the 400 ANC samples obtained from Talera hospital while, five (1.2%) were positive among four hundred samples collected from Pimpri-Chinchwad Corporation dispensary at Bhosari.



### **3.4 Evaluation of Kits:**

Two ELISA kits, for detection of anti- HIV-1 & 2 antibody, were evaluated during the year, on request received from the manufacturers. Both kits were tested by a panel of 90 coded serum samples, developed at NARI laboratory. Both kits were found to be 100% sensitive. However, two kits differed in specificity, 97 % & 93 %.

## **4. IMMUNOLOGY:**

### **4.1. Cytotoxic T lymphocyte (CTL) response:**

Eighteen HIV-1 seropositives were tested for their CTL response against HIV-1 subtype B and C *env* antigen in the standard <sup>51</sup>Cr release assay. Three patients showed detectable CTL response. Two of these three patients showed cross-clade response to both *env* B and C. One patient showed subtype-specific response i.e. only against *env* C antigen. This patient showed very low CD4 count and high viral load.

*CTL response in HIV-1 seropositives*

Sample No.	Stimulating antigen	Target antigens (percent specific Lysis)		CD4 counts /cumm	Viral Load (copies/ml)
		<i>env. B</i>	<i>env. C</i>		
S-1	<i>env B</i>	26%	21%	ND	721
	<i>env C</i>	--	3%		
S-2	<i>env B</i>	14%	13%	756	27,328
	<i>env C</i>	20%	10%		
S-3	<i>env B</i>	--	6%	140	2,69,840
	<i>env C</i>	--	7%		

### **4.2 ELISPOT assay for quantitation of Interferon-g producing cells:**

Antigen induced production of interferon- $\gamma$  is used as a surrogate marker of CD8 positive CTL response in HIV infection. The assay has the advantage of quantitation, technical simplicity and does not require the use of radioactivity. This assay has been standardized in laboratory. In the preliminary experiments, 9 HIV-1 seropositives were analyzed for antigen induced interferon-g response. PBMCs from these seropositives were stimulated with Vaccinia constructs expressing different HIV antigens such as *env C*, *env B* & *gag* for 2 hrs. & interferon-g producing cells were quantitated by the ELISPOT assay. The PHA stimulated PBMCs were used as Positive control & unstimulated cells were used as negative control. The results are shown in the Table:

*HIV-specific Interferon  $\gamma$  secretary responses in HIV-1 seropositives*

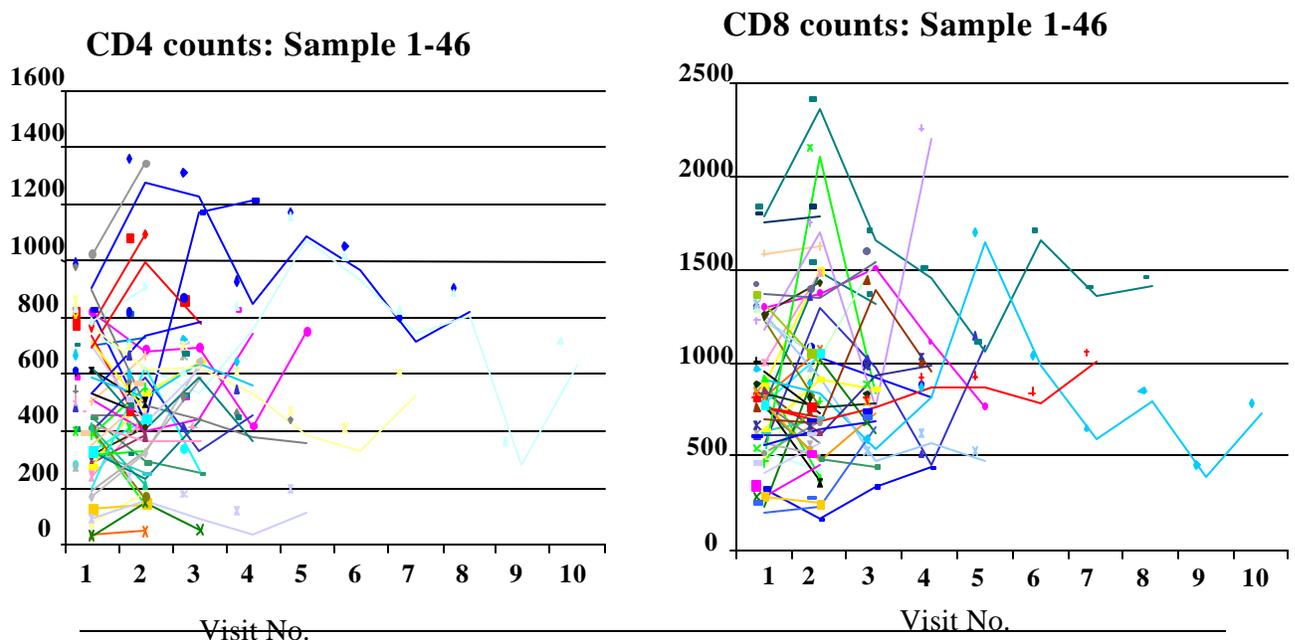
Sample No.	Elispot response (spot forming units/ $10^6$ cells)		
	env. B	env. C	gag
1	ND	160	60
2	ND	100	640
3	ND	220	440
4	10	10	ND
5	35	35	ND
6	40	35	ND
7	35	20	ND
8	20	85	ND
9	100	100	ND

**4.3. Lymphoproliferative response in HIV-1 seropositives**

The *in vitro* lymphoproliferative response can be used to measure the degree of immune dysfunction. In this ongoing activity, Peripheral Blood Mononuclear Cells (PBMCs) from four discordant couples were tested for the proliferative response against mitogen (PHA), recall antigens (Tetanus Toxoid, PPD) and HIV antigens(gp120, gag, p24). The seronegative partners showed good proliferative response to PHA and recall antigens. For two of them the CD4 counts were available. Both had high CD4 counts. None of the seropositive partners showed HIV-specific proliferative response which probably indicates the degree of T cell dysfunction.

**4. Estimation of CD4 and CD8 Counts in HIV infected patients:**

During the year 1999 total of 376 samples were tested for CD4 & CD8 counts. Thirteen samples enrolled under RO1 project (6 Group A & 7 Group B) were also tested for CD4 & CD8 counts. Data from forty six referred samples is used for plotting the graphs. Some of these samples were from earlier years i.e. 1996, 97 and 98. CD4 counts of these patients ranged from 5-2504 whereas CD8 counts ranged from 31-3389. Rest of the samples had their CD4, CD8 counts at single time point.



## 5. MICROBIOLOGY:

STD diagnosis was provided to the patients screened under HIVNET project at NARI clinics. Tests such as Gram staining, wet mount, light and dark ground microscopy, VDRL, RPR were performed in the clinics to make a provisional diagnosis of STDs. During 1999, of the 1711 patients attending NARI clinics, 714 presented with STDs. Of these 229(32 %) were suffering from genital ulcers disease (GUD); 33.6 % of GUDs represented chancroid, 24.4 % herpes and 3 % had primary syphilis ulcers. Of the 58 patients with genital discharge, 59 % had gonococcal etiology. Remaining patients were diagnosed as having other STD infections.

Core Microbiology laboratory at NARI performed isolation, identification and antibiotic sensitivity testing of *N. gonorrhoeae* and *H. ducreyi* during the year. Serological testing for syphilis, hepatitis B and hepatitis C viruses was carried out. Results are shown below.

### **N. gonorrhoeae :**

A total of 34 isolates were obtained from patients suffering from genital discharge. Isolates were confirmed by using Minitest. Antibiotic sensitivity of the isolates, was tested by disc diffusion technique. Results are shown in the table below.

Sr. No.	Antimicrobial agent	Resistant (%)	Intermediate	Sensitive
1	Trimethoprim	23 (69.7)	1	9
2	Sulphamethazole	16 (48.4)	1	16
3	Penicillin G	8 (24.2)	1	24
4	Tetracycline	2 (6.1)	1	30
5	Ceftriazone	2 (6.1)	-	31
6	Kanamycine	1 (3.0)	-	32
7	Norfloxacin	1 (3.0)	1	31

As expected, considerable number of isolates were resistant to Sulpha and trimethoprim. Significant number of strains, were resistant to Penicillin also. Only one strain was resistant to current drug of choice-Norfloxacin

### **H. ducreyi :**

*Antibiotic sensitivity tests (disc diffusion technique) on 33 isolates yielded following results –*

Sr. No.	Antimicrobial agent	Resistant (%)	Intermediate	Sensitive
1	Tetracycline	14 (42.4)	1	18
2	Erythromycin	8 (24.2)	7	22
3	Co-trimoxazol	8 (24.2)	1	24
4	Ciprofloxacin	8 (24.2)	-	25
5	Ceftriazone	5 (15.1)	-	28
6	Azithromycin	3 (9.1)	-	30

This study on limited number of *H. ducreyi* isolates suggested that significant resistance to antibiotics including newer antibiotics prevails in *H. ducreyi* organism. It is felt that similar studies need to be undertaken on larger samples.

Resistant strains of *N. gonorrhoeae* and *H. ducreyi* are presently being tested by Minimum Inhibitory Concentration (MIC) method.

**Chlamydia :**

As a part of condom promotion study, chlamydia antigen detection by EIA was carried out on 200 cervical swab samples obtained from females attending STD clinic. Antigen was detected in 13 (6.5%) samples thereby confirming low prevalence of chlamydia infection among these women.

**Syphilis :**

Serum samples of all patients attending STD clinics were tested by VDRL test. 8.2 % samples were found to be positive. All positive samples were subjected to TPHA test wherein positivity was confirmed in 85 % of VDRL positive patients.

**Hepatitis B :**

As a part of HBV prevalence and incidence study, 960 serum samples from study participants (including follow-up samples were tested for the presence of antibody to surface antigen (anti-HBs). Three hundred twenty (33.3%) samples were found positive.

**Hepatitis C :**

Of the 1612 serum samples of STD clinic attendees tested for the presence of antibody to hepatitis C virus (HCV), 18 (1.1%) were found positive. HCV positivity was higher in HIV positive samples (8/288,2.8%) than HIV negative samples (10/1324, 0.7%). Results indicated low prevalence of HCV infection in this population.

**6. BEHAVIOURAL AND SOCIAL SCIENCE :**

It is ethically imperative that in the absence of a vaccine and an affordable cure for HIV/AIDS, good quality counselling be provided to an individual, the spouse and family members. Since counselling methods are also evolving over a period of time, good counselling practices need to be established within an ethical framework. Also there is a need for capacity building at varied levels for establishing good practices in counselling on HIV/AIDS. NARI being a referral clinic for HIV testing; pre-test, post-test and ongoing counselling for referred patients, their spouses and the family members is provided by the trained counsellors. Considering the increase in the number of cases at this clinic a formative intervention programme is being initiated to establish good practices in counselling. Also, the long experience of counselling at NARI has enabled it to be a part of National Counselling Training Programme for states of Rajasthan, Uttar Pradesh and Jammu and Kashmir.

**6.1. Impact of Counselling on Behaviour Change:**

A large number of persons are referred to NARI clinics for HIV test, for confirmation of their screening tests for HIV and some also come for voluntary testing. Pre test and post test counselling is provided keeping all ethical concerns that includes taking an informed consent, maintaining confidentiality without discrimination, partner notification concerns etc. Risk assessment and other demographic details help to direct specific counselling. This is aimed at making behaviour modification for the individual taking a test and also after being tested. While no specific follow-up services exist at present at this referral clinic, a large number of clients continue to come alone, with spouse or other family members for psycho-social support. The visits are made by these clients on several occasions for discussing matters related to their spouse, support for increasing inter-spouse communication, decision-making related to marriage, pregnancy, also those related to human rights, employment, discrimination etc. An intra-mural study to understand the impact of counselling on behaviour change was initiated at this clinic.

The number of referrals as well as those volunteering for a test are on the increase from 425 last year to 864 this year. The number of women referrals have more than doubled since last few years. This year a total of 555 men and 309 women came for a test. These clients are mostly the ever married men and women (73%); the unmarried being more in men(21%) and very few in women(4%) while there are more widows (18%) than widowers(1%), with few separated men and women(3%). Men

reported consumption of alcohol (67%), smoking (36%), while this was reported by only a few women

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(1.5%). The reported number of partners for past one month was around 0.45 (n=555) for men and 0.41 (n=309) for women. The mean decreased at post-test counselling stage for the same period which was 0.38 (n=154) for men and 0.31 (n=82). The difference was not statistically significant. Similarly, at enrollment (pre-test counselling) 50% men and 31% women were condom users: with about a fifth reported using it for family planning; at post-test counselling condom usage reported with spouse (17%) and one-tenth of men also reported its usage with sex workers. This duration of observation is for short period, but the study plans to observe these changes during follow-up visits with longer duration of observation period. This is an ongoing study.

## 7. PROJECTS:

### **A. Phase I Trial of an Intervention to Increase Condom Use by HIV-Discordant Couples (HIVNET 013).**

The risk of transmission of HIV infection to the regular partner in an HIV discordant couple setting has been reported to be about 8% per year. This risk tends to be higher due to a high sex act frequency and low perception of risk in a couple setting along with lower programmatic intervention. Therefore, a phase I multinational study to assess the willingness to participate in a behavioural intervention trial along with evaluation of the acceptability and likelihood of the occurrence of adverse events associated with the use of a newly devised innovative tool was designed and undertaken in India, Uganda and Thailand. The intervention module was specifically designed for this study and it focussed on enhancing risk perception, discussing risks and benefits of condom usage along with the barriers in condom use, enhance communication on sexuality and influencing peer norms about condom usage.

Fifteen HIV discordant couples were to be recruited at each study site. The module was implemented in four sessions- the first two being in the same gender settings; and remaining two in mixed gender settings. The participants were followed up at one and three months after the completion of the four modules. India was the only site to complete the enrollment and follow up of all the 15 couples envisaged in the study. In order to recruit 15 couples, 45 seropositive patients were screened, of which 37 were found to be eligible to participate in the study after applying the inclusion and exclusion criteria. Of these, 18 HIV seropositive couples actually enrolled in the study ( 49%). As the study protocol required only 15 couples, first 15 couples underwent the intervention. Of these 15 HIV discordant couples, four were female index HIV discordant couples.

<b>Category</b>	<b>Male Index Case</b>	<b>Female Index Case</b>
Screened	40	5
Eligible on Screening	33	4
Enrolled	14	4
Intervention Initiated	11	4
Completed Intervention	11	4
Completed Follow up (1 month)	11	4
Completed Follow up (3 month)	11	4
Adverse Events	0	0

All the couples participating in the intervention completed the study protocol including the follow ups. There were no reports of occurrence of adverse events including domestic violence. The sessions were very well accepted. The participants felt that the intervention was very informative and it helped them develop a positive attitude towards life. Fear of condom tear and consequent transmission of HIV infection to the HIV sero-negative partner was identified as the greatest barrier in condom use by both males and females in the focus group discussion. Of the couples enrolled in the study, 10 were abstinent after detection of HIV status in the partner, three did not use condoms while one used it irregularly and one couple resorted to premature withdrawal, at the baseline evaluation. Of the 11 couples who were sexually active at one month, all used condoms during every sex act. Similarly, of the 8 couples who were sexually active at three months follow up visit, all used condoms during each sex act. According to

the participants, the intervention enhanced communication between partners on sexuality and brought the risk perception about the sex using condoms to an appropriate level. The detailed analysis of data from all the sites is being undertaken.

### **B. Completion of Phase I Vaginal Microbicide Study**

Because of higher vulnerability of females to HIV infection due to various socio-cultural, structural and inherent biological factors and non-acceptance of male condoms in a commercial and non-commercial sex setting, research on female controlled barrier methods is getting more and more importance. We carried out Phase I studies on vaginal microbicides Nonoxynol-9 and Buffergel to assess local toxicity and acceptability in user women as well as among their sexual partners. These studies were initiated last year and were completed this year. Details of enrollment & follow up are given in the table below:

Category	Nonoxynol-9			Buffer gel		
	Total	Abstinent group	Active group	Total	Abstinent group	Active group
# Women Screened	37	14	23	39	11	28
# Women excluded during screening	11	5	6	11	4	7
#Women excluded during enrollment	3	2	1	7	1	6
#Women enrolled	23	7	16	21	6	15
#Women completed day 7	23	7	16	21	6	15
#Women completed day 14	22	7	15*	20	5**	15

\* Participants discontinued due to adverse event

\*\* Participants discontinued due to non-adherence to protocol.

No major side effects were found after N-9 as well as Buffer gel use. Minor side effects subsided after follow up with or without treatment depending upon the condition. The adverse events reported at Pune study site were minor and treatable. These need to be reviewed together with reporting of adverse events from other sites of this multi-centric study. The analysis is presently being done.

#### *Exit Focus Group Discussion*

Exit focus group discussions were conducted for both active and abstinent groups. The following is a summary of the views expressed by the participants:

#### *Sexually active group of women*

All the participants expressed that it was very important to take partner's consent. Main concerns of women before participation were possible side effects of the products and lack of adequate privacy to keep and use the product. Most expressed embarrassment while answering questions on sex and sexual history. Women liked the product as it was colourless. Some suggested that it should be thicker. Every one said that if this product proves to be useful for prevention of the sexually transmitted diseases, they would recommend it to their friends if needed. Other problem areas identified were use of an applicator and storing and disposing of condoms without anyone else noticing them.

*Sexually abstinent group of women*

Although the comments were almost similar in the abstinent cohort, there were some differences of opinion. Women from the abstinent cohort said that they would have participated in the study even without their husband's consents. Most of the women in abstinent cohort said that they would not recommend this product to anyone as they would be required to answer a lot of questions.

**C. Acute Pathogenesis of HIV-1 Infection Study**

The clinical, laboratory and data management infrastructure established to support this longitudinal study has enabled us to detect HIV sero-converters and persons with p24 antigenemia. These two categories of HIV infected persons are being evaluated to study changes in virologic and immunologic parameters in a laboratory intensive study. Follow-up at definite short intervals is the crucial component of this study. In all, 11 persons have been enrolled by the end of the period of reporting.

*Group A: p24 antigenemics*

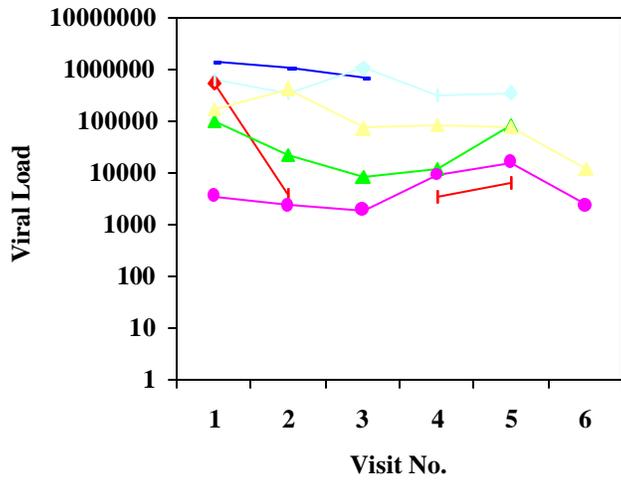
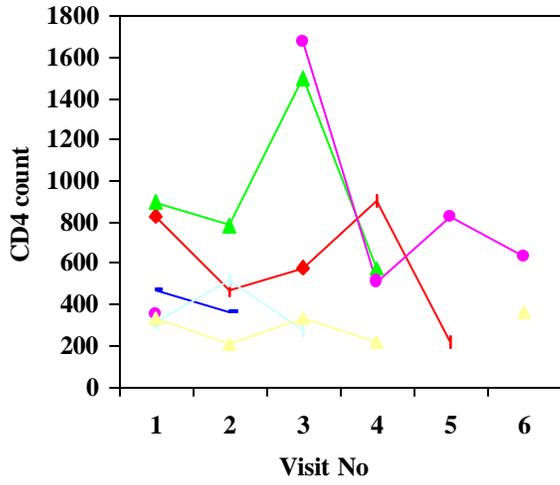
No	Day 0	Weeks				Months		
		2	4	6	8	6	12	24
1	√	√	√	Defaulter				
2	√	√	√	√	√	√	F/U due 22.03.00	
3	√	√	√	√	√	√	F/U due 16.03.00	
4	√	√	√	√	√	√	Defaulter	
5	√	√	√	√	√	F/U due 12.02.00		
6	√	√	√	√	√	F/U due 04.03.00		

*Group B: Sero-converters*

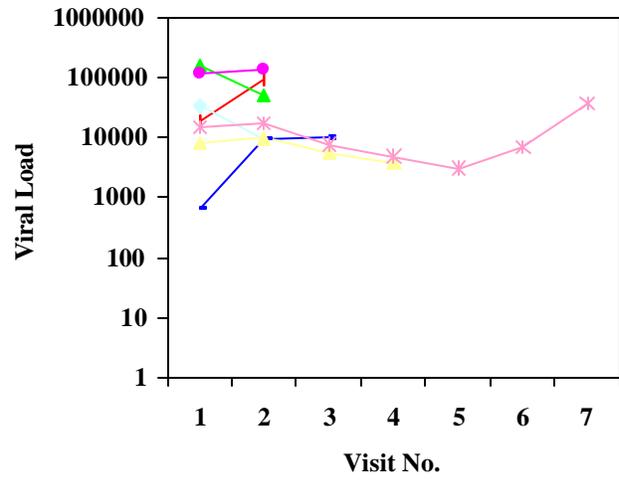
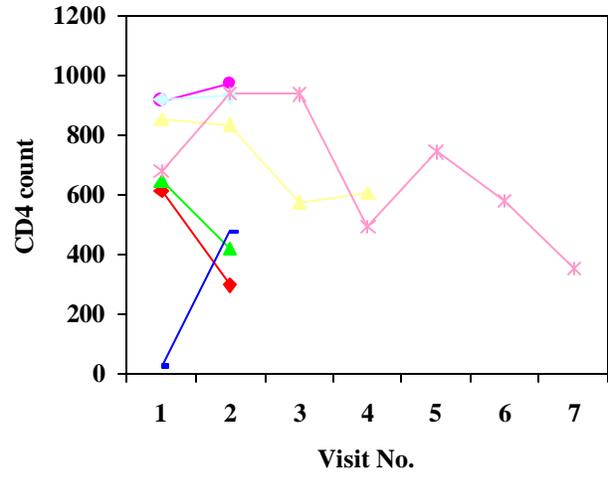
No	Day 0	3 months	6 months	1 year	2 years
1	√	√	Defaulter		
2	√	√	√	F/U due 12.05.00	
3	√	√	√	F/U due 14.06.00	
4	√	F/U due 15.02.00			
5	√	√	F/U due 24.06.00		

Serial blood samples are collected from patients enrolled in the study. The samples will be tested for various immunological and virological parameters. While the testing for virus quasi-species, isolation of HIV and ELISPOT assays for quantitation of HIV-1 induced interferon- $\gamma$  producing cells, absolute CD4 lymphocytes and other lymphocyte subpopulations are estimated at each visit besides estimation of plasma virus load. Figure below shows the absolute CD4 cell counts and plasma virus load at each of the follow up visits in p24 antigenemics group as well as in seroconverters group. The follow up is continued. The data on the serial estimations of viral load & CD4 counts in two groups is presented in figures given below :

### P24 Antigenemics

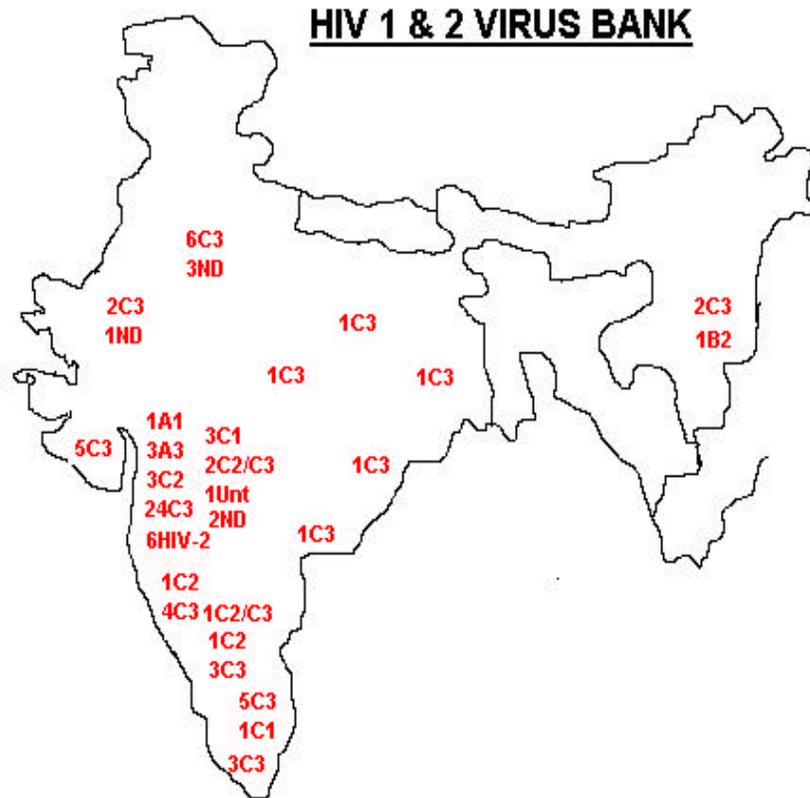


### Seroconverters



#### **D. Establishment of HIV-1 And HIV-2 Virus Bank In India**

This DBT funded project was continued in 1999. By the end of the year, 90 HIV isolates were obtained using blood samples obtained from different parts of India. These included 84 HIV-1 isolates and 6 HIV-2 isolates. The geographical distribution of the source of these isolates is given in the figure below.



ND = Not done (results awaited)

Unt = Untypable

Of the 90 isolates, 46 isolates were obtained from symptomatic HIV infected individuals and the remaining 44 isolates from asymptomatic HIV infected individuals. Some of the individuals had more than one opportunistic infection. The clinical presentation of the symptomatic individuals is given in the Table

*Clinical Presentation in Symptomatic Individuals*

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Pulmonary tuberculosis	13
Abdominal tuberculosis	3
Tuberculous lymphadenitis	3
Cold abscess	1
Disseminated tuberculosis	1
Oral candidiasis	8
Chronic diarrhoea	4
Cryptococcal meningitis	2
Herpes zoster	2
Jaundice	2
Molluscum contagiosum	1
Wasting syndrome	2
Distal muscular atrophy	1
Pustular bacterial cutaneous infection	1
Sensory neuropathy	1
Amoebic liver abscess	1
Pulmonary aspergillosis	1
Tonsillitis with impetigo	1
Duodenal ulcer	1
Psoriasis	1
Uterine fibroma with PID	1
Myelopathy involving thoracolumbar cord	1
Deafness	1

Absolute CD4 counts were available in 42 of the 90 infected persons from whom the blood samples were collected and the details are given below:

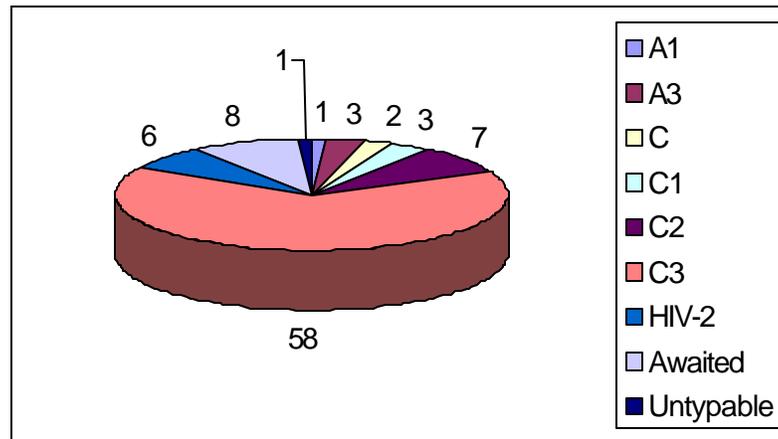
*CD4 Counts In Samples Collected*

<b>CD4 counts (cells/cu.mm.)</b>	<b>Number of cases</b>
<200	24
200 to 500	10
>500	8
Not available	46

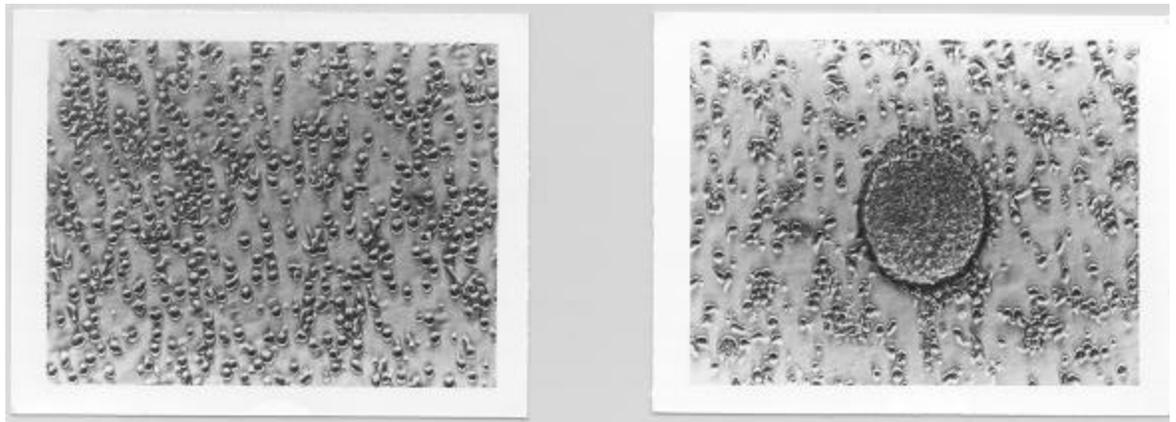
Genotypic characterisation of the isolates has been carried out by the heteroduplex mobility

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assay and is given in the figure below:



Of the 90 isolates, phenotypic characterisation into syncytium inducing (SI) and non-syncytium inducing isolates (NSI) has been completed for 42 isolates. Of these 42 isolates, 41 were NSI isolates and one was an SI isolate. The work on the remaining 48 isolates is ongoing. The ability of the isolates to grow in monocytic cell line U937 is also being studied. The figure shows uninfected cells and infected with a large syncytium:



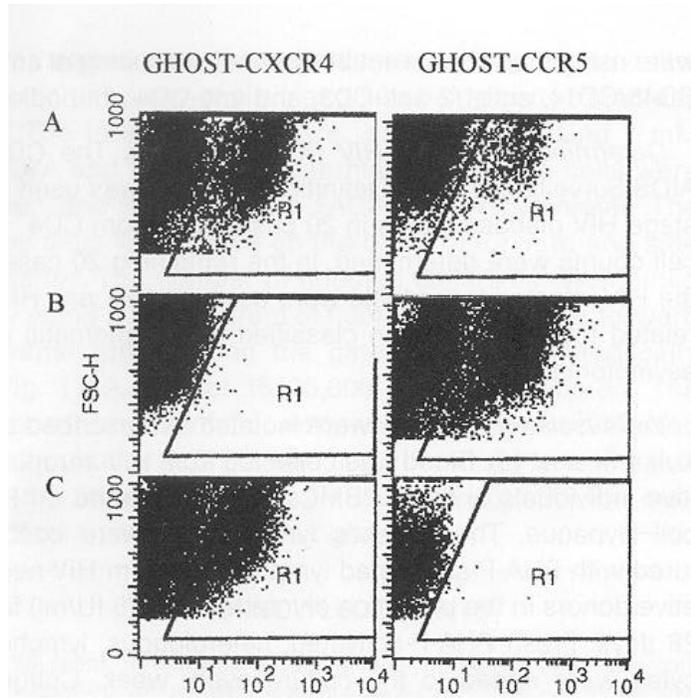
Un-infected Sup T1 cell line

SupT1 cell line infected with HIV-1 showing syncytia

### Coreceptor usage by HIV Isolates

Shifting from R5 to X4 phenotype has been reported towards AIDS stage in HIV-1 subtype B infected patients. Such shift has been found to be absent in some non-B subtypes. We studied 47 isolates for R5/X4 phenotype by a ghost cell assay. Of 47, 46 isolates were CCR5 tropic (R5) and one was dual tropic for CCR5 and CXCR4 (X4) co-receptors. This showed that R5 to X4 shift does not occur in HIV-1 subtype in Indian patients. The single HIV virus which was found to be dual tropic was an HIV-2 virus. The co-receptor studies in the remaining 43 isolates is ongoing.

Scattergrams below show the scatter of GHOST-CXCR4 & GHOST-CCR5 cells infected with different HIV-1 isolates. The region R1 delineates the fluorescence-positive infected cells. (A) The dualtropic HIV-2 primary isolate, (B) a CCR5-tropic HIV-1 primary isolate, and (C) the CXCR4-tropic laboratory adapted RF strain.



**E. HIV-1 Subtype Identification In Western India**

One fifty eight HIV-1 samples were collected, from different regions from Western India and HIV-1 subtyping was carried out by the Heteroduplex Mobility Assay. The subtype together with the genotype results of the 158 samples are given in the table:

Subtype/Genotype	Number of samples
<b>Gujarat</b>	
A1	0
A2	0
A3	0
C1	1
C2	2
C3	24
Total	27
<b>Goa</b>	
A1	0
A2	0
A3	0
C1	0
C2	6
C2/C3	1
C3	36
Untypable	1
Total	44
<b>Maharashtra</b>	
A1	1
A2/3	1
A3	3
C1	0
C2	9
C2/C3	3
C3	66
C3/C4	1
Untypable	3
Total	87
<b>Grand Total</b>	<b>158</b>

Thus, subtype C was the commonest subtype obtained from Western India. Of the subtype C samples, C3 genotype was the commonest genotype detected.

#### **F. Counselling Training Programme**

##### ***National Counselling Training Programme in Rajasthan, UP and J&K:***

Under this programme, six regional centres have been identified for undertaking training in counselling in all states and union territories of India. NARI has responsibility to cover three important low prevalence states viz. Uttar Pradesh, Rajasthan and Jammu & Kashmir. The main objective of the programme is to impart skills on counselling for HIV/AIDS/STDs at three levels: Master Level Training Programme (two weeks), Training of Trainers (TOT for one week) at the district level, Grass root Level Training (GLT for three days) for the peripheral level workers, through TOTs with help of the Master Trainers of NARI. The guiding principles for the training programme envisage commonality in the training all over the country, yet has provision of flexibility to suit local conditions. The built-in monitoring and evaluation of the training programme helps in improving the future training activities: in planning, organization, and other operational aspects of the training programme.

NARI initiated this programme in early 1999, starting with the Master Level Training in collaboration with Tata Institute of Social Sciences. Subsequently four TOTs: two in UP and one each in J&K and Rajasthan in collaboration with the State AIDS Control Society (SACS) of each state were also

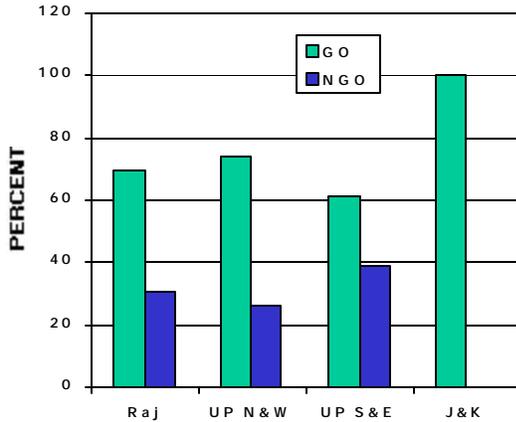
completed. Later four Grass-root level Training with the TOTs in UP have been completed, two in Lucknow, one each in Varanasi and Kanpur.

**Training of Trainers (TOT) in Rajasthan (1), Uttar Pradesh (2) & Jammu & Kashmir (1).**

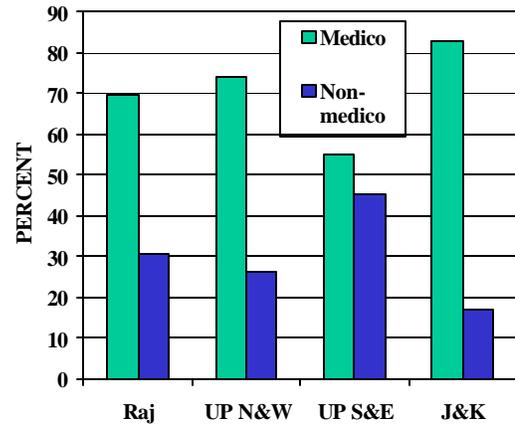
**A. Participants at the Training :** The participants and most Resource Persons were identified by State AIDS Cell (SAC) of each state. A total of 106 participants from GOs and NGOs participated in the six day training workshop. The participants represented medical colleges in UP and Rajasthan, while the participants from the district hospitals, blood banks, STD clinics, TB clinics and other government departments like women welfare, education, youth welfare etc were represented in each state TOTs .

Overall, majority of participants were men (59%), although there were more women participants in J&K (45%) and Rajasthan (44%) than those in UP (36%). More than two-third of the participants were medicos (70%), highest being in J&K (83%).

**Distribution according to institutions of participation**



**Distribution according to occupation of participation**



**Approaches:** Training sessions were interfaced with group exercises, role-play, games and video film followed by discussion to keep alive the interest of the group, breaking barriers of communication due to gender/ occupation and increasing interaction within the group to understand varied perspectives. This was done by creating an ambience where discussions with resource persons, clarification on specific issues related to content and methodology was also made possible. Similarly group-work exercises with the help of facilitators were productive.

**Pre-Training Evaluation:**

This evaluation was aimed at understanding the knowledge about AIDS/HIV, its mode of transmission, prevention, testing of HIV infection and also the expectations of the participants from this workshop.

**Knowledge of HIV and AIDS:** Most participants knew the full form of AIDS (89%) and HIV(82%) highest being for UP participants; the difference in AIDS and HIV was not very clear to some. Most reported the sexual mode of transmission as a major mode, followed by transmission by blood and blood products while mother to child route was reported by only a third and by still fewer the transmission by needles and injections. This knowledge was highest for J&K while the overall knowledge of the different modes was similar for UP and Rajasthan.

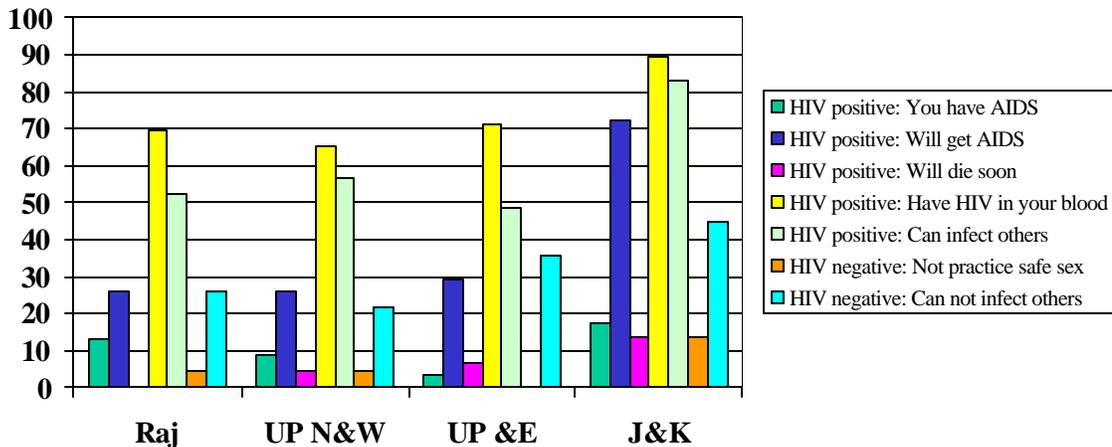
It is seen that the modes of transmission and non-transmission are known to most participants, being higher for J & K, yet myths like transmission occurs by caring for HIV infected person, and through casual contact persist. Correct knowledge about the transmission of infection through body fluids is

lacking in participants, specially for menstrual blood, breast milk, especially so among those from the southern and eastern UP.

*Correct Knowledge of HIV/AIDS : Modes of Transmission*

HIV is transmitted by:	Raj N=23	UP I (N&W) N=23	UPII N=31	J&K N=29	Total N=106
Unprotected sex	22	23	30	29	104
Caring for HIV infected person	NIL	NIL	2	8	10
Mosquito bite, Casual contact etc.	20	22	23	26	91
Semen	18	18	24	29	89
Vaginal fluids	19	17	19	27	82
Blood	19	21	26	29	95
Menstrual blood	5	9	11	17	42
Breast milk	4	12	11	24	51

**Perception related to HIV test:** The participant’s knowledge about HIV test was inadequate at the start of the study. They perceived the meaning of positive and negative tests differently. Variations in perception of both positive and negative results was observed in all state. The data is represented in the figure below:



**Expectations from Workshop:** The participants expectations in attending the Workshop was to gain more information on AIDS/HIV, counselling or learn about counselling training. These participants hoped to train others in their area that included their colleagues and also those at the peripheral/ grass-root level. After the training most participants reported a fulfillment of expectations specially in learning about counselling, improving their current knowledge and also clarity about carrying out future programmes. The important lessons learnt in the TOT programme can be summed up by SWOT analysis:

**Strengths of the programme**

- Establishment of a good collaboration with SACS that would pave way for future activities in each

state.

- Completed the Training programme covering different geographic areas.
- Representations from both GOS and NGOs (except in JK where no NGOs were represented).
- Representations from both genders
- A group of active participants
- Established a link with participants
- Blue-prints of training plans developed and presented by participants at the end of training would help in planning grass-root Level Training with them

#### **Weakness**

- Lesser representation of areas away from State capitals and urban centers
- Number of resident participants was very small
- Lack of easy access to infrastructural facilities like vehicle, fax, telephone
- Absence of clear administrative guidelines from NACO

#### **Opportunities**

- Majority of participants keen to continue the programme
- Support by SACS and SIHFW
- Establishment of network that may be useful for other ICMR and NACO programmes

#### **Threats**

- A few participants not interested in the Training in future due to wrong selection.
- Uncertainty of continuation of programme and slow release of funds.

**Lessons learnt:** This experience should pave way for planning future activities of the Training programme. Resource Persons from Jaipur, Lucknow, Varanasi and Srinagar may help in future programmes although heavy dependence has to be on the TOTs. Feed-back information would help in making more effective GLT programmes in Rajasthan, UP and J&K and pave way in planning Training Workshops by the NARI team in Pune.

### **G. AIDS Research & Review**

A quarterly exclusively devoted to HIV/AIDS and related issues is brought out by the institute. The quarterly disseminates updated information on epidemiological, basic, clinical, social science and prevention aspects related to HIV infection. In a short period, it has established its presence in this field as a quality periodical.

### **H. HIV Reference Centre:**

NARI has been recognized as a reference center for HIV testing and confirmation. The institute has two clinics which provide clinical and laboratory support to the suspected HIV positive patients referred to these clinics. The standard pre and post-test counselling is provided by trained counselors.

### **I. Testing of traditional medicines for their anti-HIV activity-**

As a continuation of the earlier project, twenty-two additional preparations were referred to NARI to test their anti-HIV activity. These preparations were mainly derived from herbs available in India. The cytotoxic concentrations of these preparations were determined and the sub toxic concentrations were used to check their anti-HIV activity against cell free as well as cell associated HIV. The methods used for testing of these preparations were first standardized with a known anti-retroviral agent, AZT. It was also included as a positive inhibitor while testing every compound. All of the preparations tested failed to inhibit HIV by using both methods.

It is reported in literature that plants containing high tannin content show anti-HIV activity. In collaboration with the National Chemical Laboratory, Pune, following plant parts were selected for testing their anti-HIV activity. The plant extracts were prepared as follows. The plant material was shade dried, powdered, and extracted with 70% alcohol on three subsequent days. The extracts were pooled, distilled, vacuum dried and tested in the similar manner as described earlier. None was found to have

anti-HIV effect.

Sr. No.	Common Name	Botanical Name	Plant part used	AntiHIV activity
1	Awala	<i>Phyllanthus emblica</i>	Fruit	No
2	Walnut	<i>Juglans regia</i>	Fruit skin	No
3	Pomegranate	<i>Punica granatum</i>	Fruit, Fruit skin	No
4	Rakta chandan	<i>Pterocarpus santalinus</i>	Wood	No
5	Babhul	<i>Acacia nelotica</i>	Fruit, bark	No
6	Combination of 1,2,4 &5			No

#### **J. Genetic Resistance to HIV Infection**

The discovery of the role of chemokine receptors in transmission and disease progression among HIV infected individuals opened up new vistas for research. Of the 15 chemokine receptors reported in literature, CCR5 is studied most extensively as  $\Delta 32$  mutation was found to be associated with the resistance to HIV infection. The CCR5 mutation is reported to have up to 10% gene frequency among Caucasians. However, Orientals are reported to have a lower frequency. There is a report of an Indian having heterozygous CCR 5 gene mutation. This study aims at finding out various chemokine receptor mutations among 'exposed but uninfected' individuals and HIV infected long term non-progressors. Thirty samples from different parts of the country have been collected along with their socio-demographic, geneologic, behavioural, clinical and relevant laboratory test results information. The laboratory testing is in progress.

#### **K. Feasibility of Extending Syndromic Approach through Paramedical Workers**

Presence of STDs is known to facilitate the transmission of HIV infection. Therefore, early management of STDs using appropriate medicines has assumed importance in prevention and control of HIV infection. However, there are many hurdles in making aetiologic diagnosis of STDs. Hence World Health Organisation evolved a simple, feasible treatment approach also known as syndromic approach based on the presence of symptoms & signs involving minimal laboratory back up. The coverage for STD treatment is very poor in rural area. Hence, this study envisages extension of syndromic approach through paramedical workers. The project will be launched as soon as the field testing of the proforma is complete.

## 8. PUBLICATIONS:

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  3. Kulkarni SS, Tripathy S, Paranjape RS, Mani NS, Joshi DR, Patil U & Gadkari DA. Isolation & preliminary characterization of two HIV-2 strains from Pune, India. *Indian Journal of Medical Research*, 1999; 109:123-130.
  4. A Kunte, V Misra, R Paranjape, V Padbidri, S Gonjari, V Kakrani, M Thakar & S Mehendale. HIV seroprevalence and awareness about AIDS among pregnant women in rural areas of Pune district, Maharashtra, India. *Indian Journal of Medical Research* 1999; 110: 115-22.
  5. Gadkari DA. HIV subtypes: Indian scenario. *AIDS Research & Review*, 1999; 2,1:16-18
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  15. Mehendale S. AIDS : History, Origin & Epidemiology. *HIV/AIDS : Diagnosis and Management - A Physician's Handbook*, Ed : Dr Vinay Kulkarni. Publisher : PRAYAS, 1999;15-28.
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21. Nita Mawar, Rewa Kohli, Neelam Joglekar, Rajani Bagul. Children and young people in context of HIV/AIDS : Listen, Learn, Live! World AIDS Campaign with children and young people. ICMR Bulletin, December, 1999;29,12.

## **9. CONFERENCES/ SEMINARS/ WORKSHOPS CONDUCTED:**

### **1. Counselling Training Programme**

- Master Level Training of NACO's Counselling Training Programme at NARI on Counselling on AIDS : Methods and Issues from 15<sup>th</sup> to 25<sup>th</sup> March 1999 in collaboration with TISS.
- Training of Trainers Level programme of NACO's Counselling Training Programme on Counselling on AIDS : Methods and Issues on following dates & places:
  - 17<sup>th</sup> May to 22<sup>nd</sup> May 1999 in Jaipur (Rajasthan)
  - 2<sup>nd</sup> August to 7<sup>th</sup> August 1999 in Lucknow (UP)
  - 9<sup>th</sup> August to 14<sup>th</sup> August 1999 in Lucknow for Varanasi region (UP)
  - 30<sup>th</sup> August to 4<sup>th</sup> September 1999 in Srinagar (J&K)

**2. Counselling on AIDS : Methods and Issues** : Workshop conducted on 16<sup>th</sup> June to 18<sup>th</sup> June 1999 in collaboration with Pimpri-Chinchwad Municipal Corporation for the counsellors.

### **3. TRG meeting on Chemoprophylaxis**

The National AIDS Control Organisation identified NARI as the chair for the Technical Resource Group on Research & Development on HIV/AIDS. A thematic meeting on "*Chemoprophylaxis in HIV Infected Persons*" organized by the TRG on R & D between April 15-16, 1999 at Pune. Eminent persons working in various aspects related to HIV infection participated in the meeting. After extensive deliberations on the global and national experiences and study findings, guidelines were developed for chemoprophylaxis against tuberculosis, against other opportunistic infections, mother-to-child transmission of HIV-1 and occupational exposure to HIV infection. These guidelines were subsequently published in the "*AIDS Research & Review*". This effort has been appreciated well in the country.

### **4. Media Workshop**

A media workshop was organised at this institute on December 10, 1999 as a part of World AIDS Day activity. The workshop was sponsored by MSACS. A total of 20 representative from different Media Organisations participated. A total of Ten resource persons provided information of various HIV/AIDS related topics. Dr. Waghmare and Ms. Seema Shroff from MSACS enlightened participants on Govt. of Maharashtra's perspective and future activities for HIV control in the state. Mr. Sadanand Dumbre from 'Sakal' and Mrs. Vineeta Deshmukh from 'Indian Express' spoke on 'Role of media in HIV prevention & control'. Workshop turned out to be very interactive. Lot of discussion on important issues was generated. Resource persons provided information on queries asked by the participants. Efforts were well appreciated by the participants. Some of the local newspapers covered the event.

## 10. CONFERENCES/ SEMINARS/ WORKSHOPS/ INVITED LECTURES:

### *Dr. R. S. Paranjape*

1. Indo-US Workshop on “ Behavioural prevention research to stop the further spread of HIV and AIDS” Organized jointly by ICMR, NACO and US. January 12-13, 1999. New Delhi.
2. Meeting of Chairpersons of TRGs at New Delhi. February 26, 1999.
3. National Meeting on “ Social and Behavioural Aspects on Sexuality”.School of Health Sciences, University of Pune, Pune. March 8-9, 1999.
4. Conference held at the Indian Public Health Association at AFMC in April 1999. Presented a talk on “Ethical Issues and AIDS”. Talk on ‘HIV Vaccine Trials’.
5. Attended National Institutes of Health/ AIDS Vaccine Research Committee workshop on “ New Concepts in HIV Vaccine Development” at National Institutes of Health, Bethesda, Maryland, USA. May 3-5, 1999.
6. Attended Workshop on “ HIV vaccine developments and challenges and Opportunities for Developing Countries” at Johns Hopkins University, Baltimore, MD, USA. Under Fogarty International programme and the Johns Hopkins University. May 7, 1999.
7. Meeting of Technical Review Committee to review projects under Capacity Building project of School of Health Sciences, Pune University, Pune. July 9, 1999.
8. “2nd International Conference on AIDS India 2000” at The Tamil Nadu Dr. MGR Medical University, Chennai, 6-8 December 1999. Gave invited talk on ‘CTL responses in Indian HIV infected patients’.
9. “ Expert Group Meeting on HIV and AIDS Research” at WHO/ SEARO, New Delhi From Dec 15-Dec 17, 1999.

### *Dr. S. M. Mehendale*

1. Workshop on Good Clinical Practices (GCP). Organized by WHO Programme on Research and Training in Tropical Diseases (TDR) and UNAIDS. 5 to 10 April 1999 at Mae Sot, Thailand.
2. Workshop on International Research Ethics. Organized by the Johns Hopkins Bioethics Institute and Fogarty International AIDS Training Programme. Baltimore, USA on 5-6 January 1999. *Moderated a session on Global Inequities and Accountability to Communities.*
3. 2nd National Conference on HIV/ AIDS: Opportunistic Infections- Diagnosis and Management. Organized by the Association of Physicians of Ahmedabad and National AIDS Control Organization on 6-7 February 1999 at Ahmedabad. *Guest Speaker: Epidemiology of HIV in India.*
4. Workshop on Ethics in Bio-Medical and Social Science Research. Organized by Tata Institute of Social Sciences and International Institute of Population Sciences on 12 February 1999 at Mumbai, India. *Participated and chaired a session on Ethics, Law and Research.*
5. First National Meeting on Research Priorities in Social and Behavioural Aspects of Sexuality. Organized by School of Health Sciences, Pune University on 8-9 March 1999. *Presentation: Socio-Behavioural Components in Bio-Medical Research on HIV/ AIDS.*

### *Dr. A. R. Risbud*

1. The International Conference “ HIV Vaccine Development; Global, Regional, and Thailand Update 1999”. Organized by Center for vaccine development, Mahidol University; AIDS division, Department of Communicable disease control; Ministry of Public Health of Thailand and UNAIDS.Bangkok, Thailand- March 15-19,1999. Oral presentation – Perspective on HIV vaccine development from India.

### *Dr. S. P. Tripathy*

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1. “Accelerating an HIV/AIDS Vaccine for Developing Countries”: Issues and options for the World Bank”. Meeting at New Delhi on August 1999.

***Dr. N. Mawar***

1. Indo-US Meeting on Behavioural Research Priorities at IIC, New Delhi from 10<sup>th</sup> to 12<sup>th</sup> Jan.1999. Presented findings from the youth sexuality study.
2. National Meeting on “ Social and Behavioural Aspects of Sexuality” at School of Health Sciences, Pune University from 8<sup>th</sup> to 9<sup>th</sup> March 1999. Presented “ Youth Sexuality in Context of HIV/AIDS for planning Behavioural Change Interventions.
3. Conference held at the Indian Public Health Association at AFMC from 16<sup>th</sup> to 18<sup>th</sup> April 1999. Presented a talk on “Ethical Issues and AIDS”.
4. Invited to attend a National Meeting organized by TARSHI, a NGO and sponsored by Mc. Arthur Foundation a Workshop on “ Sexuality and HIV/AIDS at Naukuchiatal, Nainital from 25<sup>th</sup> to 27<sup>th</sup> May 1999.
5. Participated in the International Meeting on Behaviour and Social Aspects of Vaccine Research in developing countries organized by UNAIDS at Geneva from 29<sup>th</sup> June to 18<sup>th</sup> July 1999.
6. Indo-US Meeting organized by YRG Care, at Chennai from 29<sup>th</sup> to 30<sup>th</sup> October 1999.
7. Attended as member of Project Consultative Group attended several meetings of Blackstone Market Facts, Mumbai for their FHI funded project on “Sexwork Mapping Study in Maharashtra”.
8. TRG meeting on Research and Development at NARI from 15<sup>th</sup> to 16<sup>th</sup> April 1999 and TRG meeting on counselling at TISS in ( Dec. 1999 ) to prepare a document on TRG Counselling, prepare action plan & related activities.

***Dr. R. R. Gangakhedkar***

1. Delivered a talk on “*HIV infection: Epidemiology, Basic Facts, Management & Prevention*” in the workshop on HIV/AIDS: The Law & Ethics organised by the Lawyers Collective at Mumbai for High Court and District Judges from Maharashtra State between January 7-9, 1999.
2. Discussion for a session on “Contribution of Counselling & Testing to HIV Prevention” on “*Results of AIDSCAP/WHO Voluntary HIV Counselling & Testing Efficacy Study*” in a workshop entitled “Current Issues in HIV Counselling and Testing in the South and East Asia Region” organised by Horizon Project at Mumbai between February 1-3, 2000.
3. Delivered a talk on “*Chemoprophylaxis for Prevention of Mother-to-Child Transmission of HIV Infection*” in a thematic meeting on “Chemoprophylaxis in HIV Infected Persons” organized by the TRG on R & D between April 15-16, 1999 at Pune.
4. Invited Speaker. Delivered a talk on “*HIV/AIDS: Epidemiological Scenario*” in a workshop on HIV/AIDS held on April 18, 1999, during the XLIII All India Annual Conference, Indian Public Health Association, Armed Forces Medical College, Pune, April 16-18, 1999 at Pune .
5. Delivered a talk on “*Strategies For Behavioural Interventions*” in a Training Workshop on development of targeted intervention programme in the state of West Bengal organized by STD/HIV Intervention Programme, Sonagachi, Calcutta, May 3-5, 1999.
6. Delivered a talk on “*Functioning of Technical Resource Groups: A Critical Review*” at the HIV/AIDS Strategic Planning Retreat organized by UNAIDS at Mussoorie between May 31- June 2, 1999.

7. Participated in a consultative meeting on “ *Accelerating an HIV/AIDS Vaccine for Developing Countries: Issues and Options for the World Bank*”, organized by World bank on August 18, 1999 at New Delhi.
8. Invited Speaker. Delivered a talk on “ *Recent Advances in HIV/AIDS*” at the IndiaCLEN Annual Meeting on September 24, 1999 at the Hotel Tuli International, Nagpur.
9. Participated in a meeting on finalisation of Feasibility Study of AZT Prophylaxis to Reduce Mother-to-Child Transmission of HIV-1 Infection organized by the National AIDS Control Organisation on September 25 , 1999 at New Delhi.
10. Invited Speaker. Delivered a talk on “ *Perinatal Transmission of HIV & Its Prevention*” on October 10, 1999 in the 2nd National Conference of Pediatric Infectious Diseases organised by the Indian Academy of Pediatrics, New Delhi, October 9-10, 1999 at New Delhi.
11. Chaired a Session on “*Prevention of HIV Infection from Mothers-to-infants and Management of HIV Disease in Children*” and delivered a talk on “*Chemoprophylaxis against Opportunistic Infections*” at the India Consensus development Workshop on Standards of Care in HIV Disease organized by YRG Care between October 29-30, 1999 at Chennai.
12. Invited Speaker. Delivered a talk on “*Biological Basis of Diagnosis and Treatment of HIV/AIDS*” on November 25, 1999 at the National Conference “*Challenges HIV/AIDS in the Next Millenium*” organized by the Dept. of Medicine, All India Institute of Medical Sciences, New Delhi, November 25-27, 1999 at New Delhi.
13. Invited Speaker. Delivered a talk in the Plenary Session on December 8, 1999 on “*Syndromic Management of Sexually Transmitted Diseases: Implications for Prevention and Control of HIV Infection*” in II International Conference on AIDS - India 2000, organized by MGR Medic al University, Chennai, December 6-8, 1999.

***Dr. S. Sahay***

1. Training programme for students and adolescents. Organized by Population Education Centre. Venue: Shivaji Hall, University of Pune. Date: 28<sup>th</sup> –29<sup>th</sup>, September 1999

***Dr. M. V. Ghate***

1. International workshop on Ethical issues in HIV/AIDS. Organized by Tata Institute of Social Sciences, Mumbai on Feb.12<sup>th</sup> 1999.

## **11. TRAINING**

***Dr. M. V. Ghate:***

**Clinical Methodology Training programme:**

This training was jointly organized by Institute for Research in Reproduction, F.H.I and N.I.H. in Mumbai from October30<sup>th</sup> to November 5<sup>th</sup> , 1999.The training was regarding conducting various clinical trials, some important aspects of epidemiology and use of EPI 6 programme for this purpose

## 2. LIST OF STAFF MEMBERS

Deputy Director & Officer-In-Charge	Dr. R. S. Paranjape, MSc., Ph.D.
Deputy Director	Dr. S. M. Mehendale, M.B.B.S., M.D., M.P.H.
Assistant Director	Dr. A. R. Risbud, M.B.B.S., M.D., M.P.H.
	Dr. (Miss) Nita Mawar, M.Sc., Ph.D.
	Dr. S. P. Tripathy, M.B.B.S., M.D.
	Dr. A. D. Divekar, M.B.B.S., DMV
Senior Research Officer	Dr. R. R. Gangakhedkar, M.B.B.S., DCH., M.P.H.
	Dr. Seema Sahay, M.Sc., Ph.D. (From 17/08/1999)
Research Officer	Dr. P.A. Menon, M.B.B.S. (Upto 15/10/1999)
	Dr. M.V. Ghate, M.B.B.S., DCH
Technical Officer	Dr.(Mrs) S.S. Kulkarni, M.Sc., Ph.D.
Statistical Assistant	Mr. R. Yadav, M.Sc., M.Phil.
Research Assistant	Dr.(Mrs) M. R. Thakar, M.Sc., Ph.D.
	Mrs. R.D. Bagul, B.Com., MSW
Administrative Officer	Mr. R.V. Ambi, M.A., D.L.L.A.L., PGDPM
Asst. Maintenance Officer	Mr. S. D. Gadwale, DCE

## 12.1 List of project staff

Lady Medical Officer	Dr. Smita Joshi, M.B.B.S.
Behavioural Scientist	Mrs. Neelam Joglekar, M.Sc Dr. Mrs.Rewa M.Kohli,M.A. Ph. D
Part Time Medical Officer	Dr. Ajay Deshpande M.B.B.S.,D.V.D. Dr. (Mrs).Sheela Godbole , M.D.
Part Time Accounts Consultant	Mr. T.B. Kundur, B.Com
Project Secretary	Mrs. Radhika Brahme, B.Sc, M.C.M.
Senior Investigator	Mrs. Aparna Parkhe, B.Com, M.S.W., L.L.B Mrs. Kavita Pardeshi , M.S.W.
Counsellor	Mr. Mahesh Kharat., M.S.W.
Research Assistant	Ms. Shubhangi Nawlakha.M.S.W. Mrs. Varsha Kale, M.Sc. Ms.Gauri Vaidya, M.S.W. Mr. Sudhakar Wankhede, M.S.W. Mr. Mycal Pereira, M.Sc. (Up to 25/11/99) Mrs. Sushma Jadhav, M.Sc. Mr. Ritwij Kulkarni, M.Sc. Ms. Leena Bhonge, M.Sc. Mr. Saif Shaikh, M.S.W. Ms. Yasmin Shaikh, M.S.W. Ms. Sangeeta More, M.S.W.
Data Entry Operator	Mrs. Madhavi Chavan
Administrative Assistant	Mrs. Manik Nawle, B.Com. Mrs. Shubhangi Borhade, M.Com

### 13. LIST OF SCIENTIFIC ADVISORY COMMITTEE MEMBERS

1. Prof. P.N. Tandon  
Dept. of Neurosurgery, All India Institute of Medical Sciences,  
New Delhi
  2. Dr. Alka Deshpande  
Prof. and Head, Prof. of Medicine  
Grant Medical College, Mumbai
  3. Dr. M.D. Gupte  
Director, National Institute of Epidemiology,  
Chennai
  4. Prof. N.K. Ganguly  
The Director General, Indian Council of Medical Research,  
New Delhi
  5. Dr. K. Jacob John  
Prof. & Head, Dept. of Psychiatry, Christian Medical College,  
Vellore
  6. Dr. Smarjit Jana  
Field Epidemiologist, STD/HIV Intervention Program,  
Calcutta
  7. Dr. V.N. Karandikar  
Dean, Bharati Vidyapeeth Medical College,  
Pune
  8. Dr. Lalit Kant  
Sr. Deputy Director General (ECD), Indian Council of Medical Research,  
New Delhi
  9. Dr. A. Mahashur  
Prof & Head , Dept. of Chest Diseases, K.E.M. Hospital,  
Mumbai
  10. Dr. G.C. Mishra  
Director, National Centre for Cell Sciences,  
Pune
  11. Prof. V.R. Muthukaruppan  
School of Biological Sciences, Madurai Kamraj University,  
Madurai
  12. Dr. Vimla Nadkarni  
Prof & Head, Dept. of Medical & Social Work, Tata Institute of Social Sciences,  
Mumbai
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13. Dr. K.M.Pavri  
Mumbai
14. Dr. R.S. Paranjape  
Officer-In-Charge, N.A.R.I  
Pune
15. Shri R.V. Prasada Rao  
Additional Secretary & Project Director, National AIDS Control Organisation,  
New Delhi
16. Dr. R.S. Radhakrishna  
Hyderabad
17. Dr. Q.B. Saxena  
Deputy Director General (AIDS), Indian Council of Medical Research,  
New Delhi
18. Dr. Pradeep Seth  
Prof. & Head, Dept. of Microbiology, All India Institute of Medical Sciences,  
New Delhi
19. Dr. S.P. Tripathy  
Pune
20. Dr. R.S. Wadia  
Consultant Neuro-Physician, Ruby Hall Clinic,  
Pune
21. The Director of Health Services  
Govt. of Maharashtra,  
Mumbai

#### **14. LIST OF ETHICAL COMMITTEE MEMBERS**

1. Dr. D.S. Shrotri  
Retired Professor of Pharmacology
2. Dr. H.A. Sardesai  
General Practitioner
3. Dr. U.L. Waghlokar  
Consultant Pathologist
4. Dr. K.S. Nair  
Professor, Department of Anthropology, University of Pune
5. Dr. Vinay Kulkarni  
Consultant Dermatologist & Venerologist
6. Dr. Anita Kar  
Professor, Department of Health Science, University of Pune
7. Mrs. Roma Nahar  
Advocate
8. Mr. Roger Khoma  
NGO Representative
9. Ms. Mary D'souza  
NGO Representative

**15. NARI PLAN BUDGET (in lakhs) for the YEAR 1999-2000**

<b>Budget Head</b>	<b>Amount in Lakhs</b>
Pay & Allowances	61.17
Other Charges	52.00
Equipment	48,73,908
T.A.	2.00
Capital	4,62,657
Pension	5.00
<b>TOTAL</b>	<b>173,53,565</b>

**15.1 Project Funds Received : 1999-2000**

<b>Projects</b>	<b>Amount in Lakhs</b>
Indian	6,125,466
Foregin	4,093,037
<b>TOTAL</b>	<b>102,18,503</b>