

**DIVISION OF SOCIAL  
AND BEHAVIOURAL RESEARCH**

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## Division of Social and Behavioural Research

The research priorities set at the brainstorming session of the Social & Behavioural Research Division (SBR) of NARI held in December 2006 in consultation with the National Experts on social and behavioural research were finalized. These discussions along with the draft vision document of NARI that emphasized the significance of interdisciplinary research through collaboration and networking through intra-mural and extra-mural projects paved way for planning newer activities at NARI. National and international collaborative projects of the institute were supported by this division. These included the ongoing CTU project and initiation of collaboration with PATH on 'Formative study on HPV vaccine introduction'. The SBR team members received training on leadership, research methodology and ethical issues in research through national and international sponsorships.

Two extramural projects are being carried out in the Social and Behavioural Research Division. The Psychosocial stressors study is an ongoing project funded by NACO and is being carried out among the HIV infected persons attending the NARI clinic. The second study was initiated last year as a result of collaboration of ICMR with PATH, an international NGO with a base in India. This formative research is prior to demonstration project of HPV vaccine introduction in a state setting.

### **A. Formative study on HPV/Cervical cancer vaccine project:**

*[Principal Investigator: Dr. Nita Mawar]*

#### **Introduction:**

Globally, HPV infection is the precursor to the cancer of cervix that leads to a high number of deaths followed by breast cancer. The newly developed HPV vaccine administered to adolescent girls may prevent the majority of cancers due to HPV serotypes 16 and 18 that are most commonly prevalent types in India.

The formative phase I study has been planned as a part of MOU between ICMR-PATH. This formative study aims to understand the socio-cultural milieu, policy environment and capacity of the health systems prior to introduction of HPV vaccine in the demonstration project.

#### **Objectives:**

The specific objectives of the study are to generate information needed to:

1. To develop an HPV vaccine advocacy strategy
2. To design a communications strategy for HPV vaccine delivery.
3. To design effective and appropriate HPV vaccine delivery systems for 10-14 year old girls.

The HPV vaccine is yet to be licensed in India. The formative study would contribute to plan the demonstration project when the vaccine is available.

The HPV vaccine formative study is guided by the ecological framework by Green and Kreuter that is commonly used as a health program planning tool for disease prevention and health promotion. The ecological approach recognizes that individual health behaviours are actually influenced at different levels within a complex environment. The social ecology framework, as adapted for HPV vaccine introduction study consists of five levels of influence i.e. at the level of the individual, interpersonal, community, institutional and policy.

### **Research Methodology:**

This collaborative study was carried out in Andhra Pradesh and Gujarat. The study used qualitative research methods like Consultative workshops, Group Discussions (GDs), workshops with the various stake holders at the community level like the adolescent girls, parents, teachers, grass-root level providers and face to face interviews (FTFIs) with the national, state, district, block and village level health policy makers, implementers and providers and community members.

### **Area and Population covered:**

The study covered one district in each state. The average performing districts of the two states were shortlisted with the help of State and District officials, Khammam district in AP and Vadodara district in Gujarat were identified. The areas where cervical cancer studies were conducted were excluded from the study. Three study blocks were covered in each district i.e. a tribal, rural and urban block was identified, further in each block 3-4 villages/ wards were identified as per the population distribution in each district area. At each village/ ward level at least 5-6 GDs, one in each community group and service provider group were carried out and about 3-4 FTFIs were conducted (Table 6.1).

Local Advisory Committees were formed in each village and with their help the community was approached. Three Expert Immunization Consultation workshops were held, one in each state and one at the National Level to get perspectives of varied planners, policy makers and implementers.

### **Study Tools:**

#### **1. The group discussions**

used a guideline and involved the participants in developing the diagrams/flow charts around the discussions referred as spider diagrams for a free flow of their thoughts and understanding about the time use data of adolescent girls, the health well being, immunization /vaccination flow charts etc. This participatory approach helped in better understanding of capturing the community's perception, understanding and thoughts about varied issues related to adolescent health matters, decision making, influencers where notes were taken and discussions recorded. A team of two: a moderator and note taker conducted the Group discussion. Verbal consent was taken from the group prior to participation and a log was maintained.

## 2. Face to face interviews:

A team of two, a moderator and note taker conducted the face to face interview using a guideline where the interview was tape recorded. Written consent was taken from all the participants to be interviewed and also if they consented for the discussion to be tape recorded prior to participation. Accordingly, the interview was tape recorded along with notes. In Gujarat three consented for interview but refused their interview to be tape recorded while in AP all consented for the FTFI.

## 3. Exit Interviews:

The participants attending the vaccination sessions were interviewed using a semi-structured questionnaire.

## 4. Session Observations:

The vaccination program session was observed in the PHC/Sub-centre setting using a guideline

## 5. Immunization Expert Consultation Workshops:

Three consultative workshops were held, one each at National level, in states in AP and in Gujarat.

**Table 1.1: The coverage of the participants according to the methods used in the two states:**

Tool	Andhra Pradesh District Khammam	Gujarat District Vadodara	National
	Events (No. of participants)	Events (No. of participants)	Events (No. of participants)
Group Discussion (GD)	67 (564)	53 (407)	-
Face-to face interviews (FTFI)	50	50	10
Exit Interviews	34	15	-
Observations	8	3	-
Immunization Expert Consultation Workshop	1(14)	1(20)	1(09)



HPV Formative Study Team - Gujarat



HPV Formative Study Team - Andhra Pradesh



GDs with mother group in Andhra Pradesh



GDs with father group in Gujarat

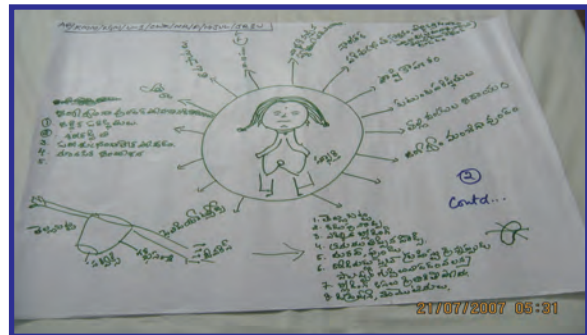
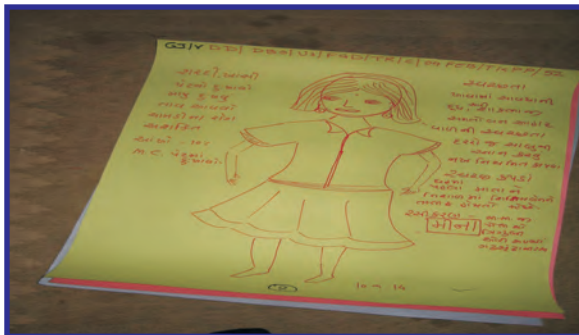
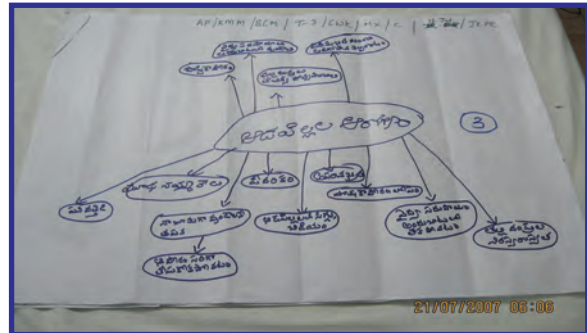
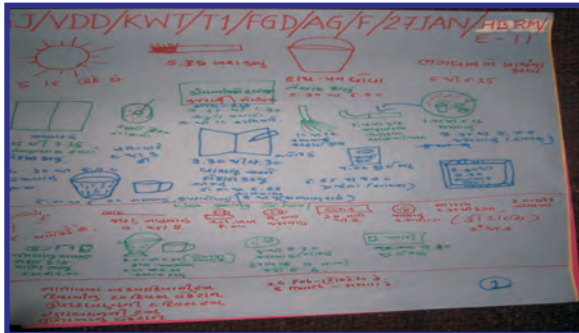


GDs with teachers group in Andhra Pradesh



GDs with adolescent girls group in Gujarat

**Figure 2 Spider diagram: Free time (Top left), immunization flow (top right) and Girls Wellbeing Andhra Pradesh (Bottom left) and Gujarat (bottom right).**



### Ethical Approval:

The study protocol, study tool guidelines, the consent forms and their translated versions in Telugu and Gujarati were approved by NARI Ethics committee before they were used in the field. All the data collected were given a number and the group and area was anonymized by a number.

### Field work and data collection

Data collection has been completed. All the qualitative data has been coded by developing a code book based on the themes emerging from the study data. This coding of data has been done as a team to avoid individual bias. The coding of the data from GD,FTFI and IEC Meeting is done on N-6, software for qualitative data analysis.

Analysis of Gujarat data was completed by end of March 2008. Study findings are being prepared for presentation in the two states. Also National dissemination meeting at NARI is been planned later in the year.

## **B. Psychosocial stressors Among HIV infected individuals**

### **B.1. Psychosocial stressors Among HIV infected individuals with reference to partner support issues.**

*[Principal Investigator: Dr. Seema Sahay]*

This is ongoing study of psychosocial stressors among HIV infected individual and the intervention training for the 'significant other.' This study aims at assessing the level of anxiety and depression in HIV positive individuals and to assess the impact of involvement of significant other/s in providing care and support to people living with HIV/AIDS and to develop novel approach to provide psychosocial support to the PLHAs at HIV testing and counseling facilities. The study has two components: 1. Clinic based intervention study 2. Clinic and field based mental health needs development study.

#### **Intervention Study Component:**

An eight chapter intervention module has been developed for training of significant others to provide informal help to the HIV infected individuals having anxiety and depression. The study arm comprised of training of significant other to provide informal help while the other arm participant where index could not involve significant other received standard counseling. The cumulative total screenings of 316 HIV infected individuals was done, of which 167 showed anxiety and depression based on their HDRS scores and 162 individuals consented to get enrolled in the final study. The screening procedure required 3 visits. After enrollment, patients were assessed for disclosure status of their HIV diagnosis. Of the 162 enrolled participants, 127 (78.3%) reported having their HIV status report disclosed to someone voluntarily or someone else had done that for them. Finally, 120 individuals gave information on their communication with the significant other after the significant other came to know of their status at the baseline. Seven individuals refused any discussion about their communications with their significant other. A total of 82 screenings and 50 enrollments were done during the period of reporting.

In the further intervention process, a purposive sampling technique was used where those who had disclosed their status were given the choice to self select their significant other in the study for eight chapter training module to support the index case. Of the 120 individuals with known disclosure, 94 individuals self selected their significant other and were assigned to the study arm. The significant others participated after a separate informed consent process. Fifty six individuals who had reportedly either disclosed their status to someone but did not want to involve significant other (45) or had not disclosed their status to any significant other (11) at all were purposively selected for standard arm. The median CD4 count among the study arm participants and standard arm participants was 275 and 266 respectively ( $p=0.330$ ). Based on HDRS scale, the mean anxiety

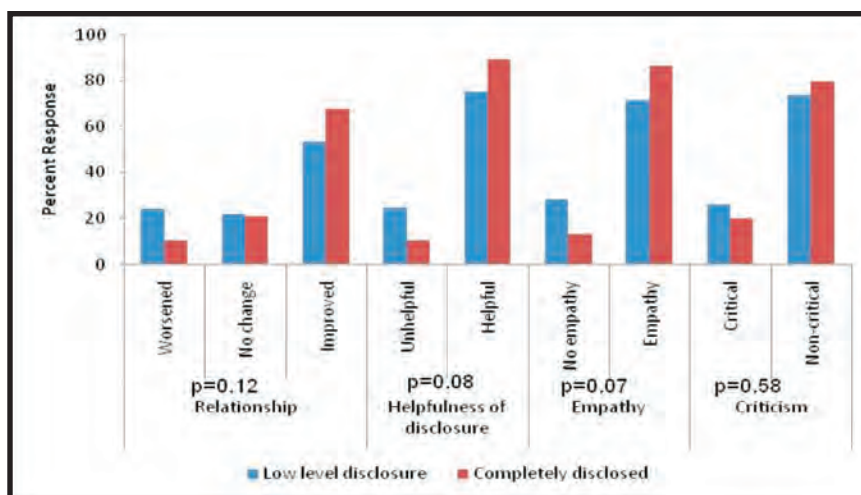
scores were 15.75 and depression scores were 22. At end line, the anxiety and depression in the intervention arm was (5.29 and 7.05) respectively. The endline anxiety and depression scores were higher in non-intervention arm (7.87 and 10.26). Twelve individuals did not come after initial enrollment because some had expired (8) prior to assessment and could not complete enrollment or some refused to come back (4). Therefore a total of 12 individuals were excluded from the study. The preliminary data analysis is based on 150 study participants. Overall, 97 study participants have completed their study participation. Follow-ups for remaining participants are ongoing.

### Interpersonal communication with significant other: a subset analysis:

At the enrollment visits, those who informed that they had disclosed their HIV diagnosis to some one, baseline information on interpersonal communication with the disclosee and emotional experience of the index case after disclosure of HIV status was collected using semi-structured questionnaire among 120 HIV infected individuals having anxiety and depression diagnosed on HDRS scores. The present report is based on quantitative data only.

Of the 120 participants, 69 (57.5%) were women and 51(49.2%) were men. A strong association was found between participants disclosure (64.1%) and holding back of their emotions (72.4%),  $P<0.01$ ). The most preferred significant other for disclosure was spouse (79%). Disclosure reportedly brought positive support and relationship improvement independent of the disclosee being spouse or others. A significant improvement in relationship was observed when the participants reported that they had disclosed their HIV infection status to someone voluntarily (67.8%) as compared to disclosure done by some one else ( $P= 0.05$ ). Levels of disclosure showed different impact on communication. Positive response from the significant other was associated with higher levels of disclosures (Figure: 6.1)

**Figure 1: Level of disclosure and responses**



When index cases disclosed completely i.e. talking about HIV, its implications, the response from the significant became more supportive. The index found the disclosure to be helpful with complete disclosure and empathy on the part of significant other increased likewise. Negative emotions like criticism a worsening of relationship was associated with low level of disclosure.

## B. 2. Mental Health Needs Instrument Development

*[Principal Investigator: Dr. Seema Sahay]*

In order to make a comprehensive assessment of an individual's needs, health care provider is expected to develop an appropriate package of care to meet those needs. A standardized needs assessment tool can have potential to compare identified needs across time and between settings, improved inter-rater reliability and cost-saving in terms of new instrument design.

The Psychosocial stressor study also aims to develop a mental health needs scale for HIV infected population in India. The instrument would assess mental health needs of HIV infected individuals. This scale will be user centered and designed to be used in care setting (NGO/VCTC/ clinic) expected to be either self administered or administered by health care provider. Therefore it would promote a dialogue between user (HIV infected individual) and the health care provider, inform care planning and management and produce information regarding unmet needs. This scale is conceptualized on user's perspective attempting to know user's view on one's own needs, thus facilitating user's involvement in their own care management. Following steps are involved in psychometric analysis:

1. Instrument development
2. Item analysis
3. Content validity
4. Domain analysis (construct validity)
5. Criterion validity
6. Reliability

This is an ongoing component of the study and the preliminary psychometric analysis till domain development is follows:

A cross-sectional 49 itemed interview administered questionnaire (0-3 Likert) was used. Cumulatively, 680 participants were recruited through NARI clinics, private practitioners' clinics and NGOs like PATHWAY, Swadhar, Bahujan Hitaya, NMP+, John Paul Slum Development Society and Deepgruha Society in Pune. These NGOs work with HIV infected individuals in Pune city and two of these NGOs have their own clinics. Along with demographic history, this questionnaire aims at assessing the most distressing problems faced by the HIV infected individuals. The format of the questionnaire used 4 point Likert scale based on percentages. Of the 680 individuals, 34% were men and 66% were women Two hundred forty-nine participant (37%) reported to have been diagnosed as HIV infected within last 12 months and rest 423 (63%) had received their diagnosis prior to that. One hundred and twenty one participants account for enrollment during the reporting period.

### Domain Development:

During content validity analysis, the items which are not relevant to the study outcome were eliminated. In this process 4 items were eliminated. The reliability analyses were conducted on 45 item instrument. After reviewing the items' performance, 12 items were eliminated based on higher or zero inter-item correlation scores. The remaining 33 items were utilized for further analysis and refinement of instrument. Four more items were eliminated with low communalities (<0.40) and finally the 2 factors consist of 29 items.

The 2-factor solution accounted for 49.5 % of the variance, factor 1 representing “Disclosure and its impact on care & support” factor, factor 2 representing “Disease condition & Services”. The reliability of the factor 1 “Disclosure and its impact on care & support” subscale, as measured by the Cronbach coefficient, was 0.93, the reliability of the factor 2 “Disease condition & Services” subscale was 0.89.

This instrument can measure the inter-correlation patterns of the two components viz. disclosure and its impact on care and support needs and distress pertaining to disease condition and services need. The next step of model development for actual utilization of the instrument can be done with Confirmatory Factor Analysis is ongoing.

Linear multiple regression was done to check the association of dependent variable with demographic characteristics. The dependent variables were the two factors. Associations were observed between Disclosure & its impact on care & support component and socio-economic status ( $\beta = -0.175$ ,  $p = 0.006$ ;  $\beta = -0.194$ ,  $p = 0.004$ ) & Help during crisis ( $\beta = +0.246$ ,  $p < 0.0005$ ). There was no association with the second factor of Disease condition and services. The +ve  $\beta$  value informs the care giver that if HIV status has been disclosed to someone, the patient would be able to get care and support indicating a counseling need for disclosure. The ve  $\beta$  value again informs the caregiver that disclosure will be difficult in persons from lower socio-economic strata.

### Recruitment support in other NARI studies (other than clinic trials) during reporting period

IVC study (Immunology)	<ul style="list-style-type: none"> <li>• ICTC Strategy</li> <li>• Partner NGO</li> </ul>	6/12 Enrollments 1/12 Enrollments
Nevirapine Study	<ul style="list-style-type: none"> <li>• Doctor's Strategy</li> </ul>	1/27 Enrollments
Smear -ve Study (Clinical Sciences)	<ul style="list-style-type: none"> <li>• ICTC Strategy</li> </ul>	11/105 Enrollments
Psycho social Study (Social & Behavioral Sciences)	<ul style="list-style-type: none"> <li>• Partner NGO peers</li> </ul>	121/121 Partner NGO

### Future plan:

We would be further developing summary sheets to allow data aggregation to get minimum and maximum scores for both met and unmet mental health needs of the HIV infected individual. Psychometric validation studies will be planned for MHN scale with Lehman's or WHO QoL scale.

**C. Multi disciplinary activities****C1. Social and behavioral Sciences component in Multidisciplinary research activity pertaining to clinical trials**

[Lead Investigators: Dr. Seema Sahay, Mrs. Neelam Joglekar]

**A. Core Community Program**

NARI core Community involvement plan was initiated in year 2002 with the beginning of clinical trials involving human volunteers. The objectives were

- a. To raise awareness about HIV in the community
- b. To introduce the concept of research in the community
- c. To motivate community for HIV test and identify potentially eligible and willing volunteers for different NARI studies.

**NARI-NGO Networking:**

NARI has partnership with 7 NGOs from Pune and Pimpri Chinchwad that are active in the field of HIV/AIDS. NARI reaches the grass-root community through community based peers who work under the partner NGO jurisdiction and administration. Under each of the partner NGOs, a maximum of 20 peers function.

Peers are identified through a structured peer identification process. The focus of the identification process is as follows:

1. Ability to communicate in public
2. Acceptance in the community: measured by extempore request for visit to at least 5 house holds in the community
3. Knowledge about HIV / AIDS
4. Willingness to work in the community for HIV awareness.
5. Willingness to make house to house visits
6. Willingness and ability and able to spend three hours daily for activities facilitated by NARI in the community.

**Figure 2: A peer from one of the partner NGO creating awareness about research in the community**



**Outreach at the grass roots level:** Currently there are 143 peers trained by NARI. The peers are supervised by two supervisors employed by the respective partner NGO. The identified peers have completed rigorous training about HIV /AIDS, human rights, communication skills and NARI research studies. The last round of training was conducted between 1st January and 10<sup>th</sup> January 2008. The training involved post training evaluation and 78 peers were then selected to work for NARI's community program.

## C2. Monitoring and Evaluation

### Annual Core CIP evaluation

Core CIP generates monthly reports of strategy wise activities done through each partner NGO and their peers. The activities recorded through baseline forms, weekly report of different meetings and actual referrals made by them or referrals through their effort are reviewed. Following graph indicates NGO wise distribution of important indicators viz. baseline forms completed by peer (door to door activity), couple meeting and female meetings.

**Figure 3: Yearly NGO evaluation report Jan 2007 to Dec 2007**

