

<p style="text-align: center;">STD PREVALENCE STUDY AMONG WOMEN IN MIGRANT COMMUNITIES OF KAILALI DISTRICT, NEPAL</p>
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Final Report

For the period of 15 Aug 2001 to 15 Jan 2001

Subproject FCO Number 84623

1. Background to Problem/Issue

Though there is little reliable data, it is estimated that several hundred thousand Nepali men migrate to India for employment yearly. In the context of this study, we are defining migrants as individuals who leave their country of origin, Nepal, voluntarily, and have the intention to return to Nepal. These migrant workers travel to all parts of India, particularly to the large cities and towns, and usually without their regular partners. They live there for periods ranging from 3-6 months to several years at a stretch before returning home. While men from all over Nepal migrate to India for work, this is particularly so in the districts of the Mid and Far West Development Regions of Nepal. There is anecdotal evidence that many HIV infections occur in India and that women having sexual contacts with men who have been in India have a higher risk of being infected by HIV or contracting other STDs than other women do, yet no epidemiological data currently exists for this population.

This research project will focus on the wives of men who migrate to India for work from Kailali District. Kailali is an ethnically diverse part of the country, with large populations of both Hindus and Muslims. This study will be conducted in a rural area, approximately 30 kilometers from the nearest town.

2. Assessment and Project Design

Save the Children/US (SC/US) has been implementing HIV/AIDS and STD prevention interventions since 1991 in different districts in the country, including Kailali. Recent efforts have focused on providing HIV education to wives of seasonal migrant laborers to India, through Active Groups for the Prevention of AIDS (AGPA). In Kailali, SC/US works with its local partner NGO, Nepal Red Cross Society/Kailali (NRCS/K), to implement its programs. NRCS has been involved in the design of this research project since its inception and has provided its support for its implementation. Furthermore, NRCS/K staff and volunteers were at the research site daily to assist the research team.

This study provided high-migration communities with valuable information about STD risk in their communities, as well as information and strategies to reduce risk of STDs, including HIV. The study provided study subjects (as well as women who choose not to participate in the study) with a rare opportunity for medical exams, information about their STD status, as well as treatment and counseling for STDs.

The objectives of the study:

- 1) To assess the prevalence of STDs and HIV among women in a specified area of Kailali District from which male migration to India occurs.
- 2) To assess differences in the prevalence of STDs and HIV among women whose husbands migrate to India and those women whose husbands do not migrate to India, in communities in a specified area of Kailali District from which male migration to India occurs.
- 3) To assess differences in prevalence of STDs among AGPA and non-AGPA group members in communities in a specified area of Kailali District from which male migration to India occurs.
- 4) To identify significant risk factors that increase the susceptibility and vulnerability to STDs and HIV of women whose husbands migrate to India.

Study Population

- Cross-sectional sample of 903 women from two VDC's in Kailali
- Purposive sample from three groups of ever-married women between ages 15-49
- Subjects: AGPA (N = 298), Non-AGPA (N = 301), Non - migrant (N = 304)

Definitions of Respondents

- **AGPA:** women whose husbands currently migrate to India for work or have migrated to India for work within the past five years and who participate in Nepal Red Cross Society Action Groups for Prevention of AIDS program.
- **Non - Agpa:** Women whose husbands currently migrate to India for work or have migrated to India for work within the past five years and who do not participate in AGPA program.
- **Non - migrant:** women whose husbands have never migrated to India for work.

Methodology

- Structured Questionnaire - socio- demographic information, migration information, health behaviors, health knowledge and attitudes, clinical history
- Pretest counseling
- Gynecological exam and specimen collection for GC,CT, TV and BV testing
- Blood drawn for HIV and syphilis testing
- Medicine provided based on syndromic management
- Follow up visit

Findings of the survey questionnaire, clinical history and laboratory data were analyzed using descriptive statistics, cross-tabulations and basic correlation, as well as through a more detailed analysis, using odds ratio and regression techniques.

STUDY PROCEDURES

- 1) The study took place at two health facilities in Darak and Sadepani VDCs and was positioned in the study community as a "Women's Health Camp for Ever Married Women" by peer educators and field workers of the Kailali Chapter of Nepal Red Cross Society (NRCS) and outreach workers of the government health posts and sub-health

posts. The study team moved from the first study site to the second study site after approximately 2-3 weeks of work, depending on subject flow to the clinic. Advertising for the study took place at least one week prior to the start of the study. Women in the community were informed about the dates and location of the camp, the purpose and scope of the camp. Queries about the camp were answered by NRCS and clarifications in relation to the same will be provided. All ever married women in the study area from each of the study sub-populations was reached through this advertising drive, whether they are symptomatic or asymptomatic. No attempt was made to force, coerce or induce women to attend the camp. Motivators were not provided with any targets as to the number of women they are expected to bring to the camp.

2) Potential study subjects was informed about the study and recruited through an Oral Recruitment Script. This recruitment included screening to decide inclusion or exclusion from study. Exclusion criteria included:

- Unwillingness to participate in survey questionnaire, which will take approximately 30-45 minutes to complete
- Unwillingness to undergo clinical/speculum examination and have clinical history information collected
- Unwillingness to have blood drawn
- Currently menstruating - Subject will be asked to return after 7 days
- Taken antibiotics within last 7 days - Subject will be asked to return after 7 days.
- Never married
- Divorced, separated or widowed for more than five years
- Living outside study VDCs
- Pregnant women
- Husband has migrated to India but not within last five years

3) After being assessed fit for inclusion in study, potential subjects was read or be read the Consent Form (see Appendix I) by the enumerator and the purpose of the study was explained. After receiving informed consent, the subject and enumerator was signed the consent form in the study booklet meaning that the subject has understood the purpose of the study. Consent forms were placed in an envelope and returned to Kathmandu each week with survey booklets and lab specimens.

(Note: Women who do not wish to take part in the study and women who are excluded from the study (as long as they are from the study VDCs) was escorted to the nurse and was given the option to have a clinical history taken and a clinical exam performed. If needed, they were provided with appropriate treatment based on national syndrome management guidelines and their prescription will be filled in camp by the ANM. The nurse will provide STD counseling for these women. Excluded women's specimens were not taken or blood drawn. Women who were excluded because they live outside of the study VDCs and referred to local health facilities. Women who were excluded due to pregnancy were not referred to prenatal care facilities.)

4) Each subject was interviewed in privacy by a trained enumerator. The enumerator administered the survey questionnaire and recorded responses in the study booklet. The study booklet had a unique ID number for each study subject. The study subject's names were not written anywhere. Only the enumerator and the study subject were not present in the room while this information is collected.

- 5) After completing the survey questionnaire and STD counselor were provided pre-test counseling to study subjects.
- 6) After completing the survey questionnaire and counseling, subject took study booklet and escorted by NRCS staff or volunteer to exam room where privacy was ensured. There, a clinical history and the clinical examination were completed and recorded in the study booklet by a female nurse. The nurse took the clinical history, asked about present complaints, performed a speculum examination and collected and mounted the following specimens in the following order (method of analysis in parentheses):
 - Cervical smear for NG and CT (PACE2C DNA Probe Assay)
 - Vaginal fluid for BV and Candida (gram stain)
 - Vaginal fluid for Trichomonas (wet mount)
- 7) The nurse prescribed treatment based on syndromic management guidelines, as appropriate and provided subject with prescription, to be served in camp. The prescription was recorded in the study booklet.
- 8) The nurse provided the subject with an individual laboratory ID number on a card (same as ID number on study booklet) and informed the subject of time and place to receive laboratory results for all STDs except HIV (time and place was written on ID card by nurse).
- 9) The nurse handed the study subject her specimens and study booklet and instructed the study subject to carry these to the lab technician escorted by staff or volunteers of the NRCS.
- 10) Lab technician drew 7cc of blood for RPR and TPHA for Syphilis, ELISA for HIV, as well as hemoglobin and blood grouping analysis.
- 11) Subjects with prescription from nurse escorted by NRCS staff or volunteer to ANM, who served the prescription written in the study booklet and advised on use of medicine.
- 12) All subjects were requested to return at a predetermined time and place for post-test counseling and laboratory results, to be provided by NRCS staff. NRCS staff asked study subjects for their ID card that listed medication previously given based on syndrome management guidelines. Subjects were provided with treatment or treatment earlier prescribed modified based on lab results. Subjects with STDs were encouraged to adhere to recommended treatment, to use condoms in all risky sexual encounters and to take their husbands and other sexual partners for STD counseling, testing and treatment at local health facilities.
- 13) After treatment has been prescribed/appropriate advice has been given NRCS staff destroyed the subjects' ID card, write current prescription on a new card and give this to the study subject.

Field Collection, Storage and Transport of Biological Samples

Field lab technicians were responsible for preparing all samples for storage and transport.

Lab technicians assured that slides for BV, candida, TV and gonorrhoea are marked with subject's ID number and stored in a slide box. These slide boxes were kept at room temperature and were sent to the SACT lab every week. At the SACT lab, the slide containing vaginal fluid was gram stained and analyzed for the detection of bacterial vaginosis and candida according to published criteria. The vaginal fluid taken for TV and analyzed by wet mount by field lab technicians was reanalyzed in Kathmandu, using a procedure proposed by Dr. Gurubacharya.

7cc of blood were collected by venipuncture. The blood was collected in a 7cc-serum separation tube labeled with the subject's ID number. This tube was centrifuged to separate the sera from the clot. After centrifugation, the sample was divided into two tubes, one labeled with the subject ID number, the other with a colored sticker denoting migration status only. These were both stored in a cold box. The cold box was kept cold by cold packs. At the conclusion of each day, the blood samples were transported to Dhanghadi where they were placed in a +4°C refrigerator. Once per week all samples collected in the refrigerator was re-packed in the cold box and flown to Kathmandu. Once the sample reached the SACT lab in Kathmandu blood was analyzed immediately for the detection of syphilis, unless otherwise notified. Once all STD results have been returned to study subjects, samples were analyzed for the detection of HIV.

Lab technicians were assured that gonorrhoea and chlamydia samples were labeled with the subject's ID number and properly stored in PACE2C transport tube. These samples has taken to Dhanghadi each night and kept at room temperature. Once a week, these samples were transported to the SACTS laboratory in Kathmandu with all other biological samples. Once they have reached Kathmandu, these samples were prepared (vortex specimen, express and remove swab) and kept in -20 °C freezer. Approximately every two weeks, samples were packed in dry ice and shipped to Dr. Zaveri's lab in Ahmedabad, India.

Note that all samples were voluntary and confidential except HIV, which was voluntary and unlinked.

Analysis

- 1) Trichomonas wet mount was examined immediately by lab technician.
- 2) Lab technician in Kathmandu completed gram stain for candida, bacterial vaginosis. The diagnosis of BV has made with a gram stain of the vaginal swab based on the presence of clue cells and bacterial organisms consistent with the syndrome of BV. The diagnosis of candida was made with a gram stain of the vaginal swab based on the presence of yeast cells consistent with candida. The diagnosis of gonorrhoea was made with a gram stain of the cervical swab based on the presence of organisms consistent with gonorrhoea.
- 3) Lab technician in Kathmandu completed analysis of sera samples to detect syphilis and HIV. The diagnosis of syphilis was made by Rapid Plasma Reagin (RPR) analysis with quantification and confirmed by Treponema Pallidum Hemagglutination Assay (TPHA). RPR is significant when the titre is 1:8 or greater. TPHA was performed on RPR non-reactive specimens to indicate past infection with syphilis. The diagnosis of syphilis was completed immediately upon receipt, unless otherwise notified. HIV was detected by

repeat positives of two ELISA tests (kits made by different manufacturers) after ten-day STD notification and treatment period has ended.

- 4) Analysis of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* were completed through the use of PACE2C DNA Probe Assay (Gen-Probe USA) by Dr. Zaveri's laboratory in Ahmedabad, India. Positive results were confirmed using PACE2 CT and PACE2 NG DNA Probe Assays.
- 5) An independent laboratory in Kathmandu for confirmation and quality control purposes reanalyzed 10% of negative tests as well as all positive tests for syphilis, HIV and BV. The samples were selected randomly and have given a separate code number provided only by the researcher. This will assure that the person who will perform quality control will have no access to test results. A second lab technician in Dr. Zaveri's lab in India reanalyzed 10% of negative NG and CT samples. All positive NG and CT samples were reanalyzed through a second PACE2 test.
- 6) Results of laboratory tests conducted in Kathmandu were entered into SPSS by SACT. Results of laboratory tests conducted in India were entered and sent to SC/US and HSPH in Excel or other appropriate software program by Dr. Zaveri.

SACTS Laboratory Responsibilities

The laboratory personnel at the SACT laboratory was responsible for the following tasks:

1. Supervision of the field laboratory technicians
2. Maintaining the cold chain of the samples from collection to analysis
3. Analysis of blood sera for HIV and syphilis
4. Analysis of gram stains for BV, candida and gonorrhea
5. Reanalysis of TV samples
6. Providing laboratory results for data merging and analysis
7. Shipping frozen samples to Dr. Zaveri's lab in India

Other Issues

Once a week, the completed study booklets and laboratory samples were collected by the Project and returned to Project Staff in Kathmandu. Harvard School of Public Health was responsible for entering all survey, clinical history and clinical exam information.

If field staff encounter any problems, they had contacted Dr. Gurubacharya or NRCS, according to the nature of the problem.

All data obtained through this investigation were delivered to SC/US and Harvard School of Public Health, as described in the consultant TOR.

PRELIMINARY RESULTS

Preliminary results from the study are below. Table 1 provides socio-demographic information about the study sample while Table 2 provides information about study subjects' health knowledge and sexual behavior. Results of laboratory analyses were presented for the entire sample as well as for the three populations of interest, namely women whose husbands migrate and who participate in the NRCS intervention (*AGPA*), women whose husbands migrate to India and who do not participate in the NRCS intervention (*NON-AGPA*), and

women whose husbands have either never migrated or have not migrated within the past five years (*NON-MIGRANT*).

Within these two groups (entire sample and by group), results were also presented by specific infections, as well as by three syndromes. The syndromes chosen include: *Any STI/RTI* (study subjects who tested positive for any STI or RTI), *Any Except Candida* (study subjects who tested positive for any STI or RTI except candida) and *Any Except Candida or TPHA* (any study subject who tested positive for any STI or RTI except candida or past syphilis infection).

More detailed analyses, to identify significant risk factors for infection, are currently being conducted. Once completed, these results were sent FHI/RO and FHI/Nepal.

Table 1: Socio-demographic characteristics of female study subjects attending clinic in Kailali District, Nepal (N=895)

FINDINGS	TOTAL	AGPA	NON-AGPA	NON-MIGRANT
Mean Age	28.0	27.8	27.5	28.8
Currently Married	99.1%	99.3%	99.3%	98.7%
Any formal education	15.8%	18.1%	10.7%	18.5%
Mean age at marriage (range 6-29)	15.9	16.2	15.7	16.0
Mean age at first birth (range 13-35)	18.4	18.5	18.3	18.5
Husband mean time in India in past 12 months (range 1-12)	6.2	6.3	6.0	NA
Mean number of years husband migrating (range 1-20)	3.6	3.9	3.2	NA
% Husbands working in Mumbai	27%	30%	23%	NA

Table 2: Knowledge and sexual behavior characteristics of female study subjects attending clinic in Kailali District, Nepal (N=895)

FINDINGS	TOTAL	AGPA	NON-AGPA	NON-MIGRANT
Heard of condoms	87.2%	96.6%	82.7%	82.5%
Ever used condoms	29.3%	46.7%	16.3%	25.2%
Ever used condoms to prevent STI	14.4%	32.4%	4.7%	6.6%
Condom use last sex	7.5%	13.3%	3.3%	6.0%
Heard of AIDS	41.5%	76.8%	19.0%	29.5%

Table 3a: Prevalence of infections among entire study subject population attending clinic in Kailali District, Nepal

FINDING	N=	Positive N	Positive %
<i>Trichomonas vaginalis</i>	895	52	5.81%
Bacterial vaginosis	895	73	8.16%
<i>Candida albicans</i>	895	131	14.64%
<i>Neisseria gonorrhoeae</i>	892	5	0.56%
<i>Chlamydia trachomatis</i>	892	9	1.01%
Active Syphilis (RPR 1:8 or greater)	894	2	0.22%
Past Syphilis (TPHA)	894	40	4.47%
HIV	894	3	0.34%

Table 3b: Prevalence of infection among entire study subject population attending clinic in Kailali District, Nepal by syndrome

FINDING	N=	Positive N	Positive %
ANY STI/RTI	895	274	30.61%
ANY EXCEPT CANDIDA	895	154	17.21%
ANY EXCEPT CANDIDA OR TPHA	895	126	14.08%

Table 4a: Prevalence of infections by groups of women (defined by husband's migration status) attending clinic in Kailali District, Nepal

FINDING	AGPA		NON-AGPA		NON-MIGRANT	
	Positive N	Positive %	Positive N	Positive %	Positive N	Positive %
<i>Trichomonas vaginalis</i>	19	2.12%	17	1.90%	16	1.79%
Bacterial vaginosis	29	3.24%	22	2.46%	22	2.46%
<i>Candida albicans</i>	48	5.36%	35	3.91%	48	5.36%
<i>Neisseria gonorrhoeae</i>	2	0.22%	1	0.11%	2	0.22%
<i>Chlamydia trachomatis</i>	1	0.11%	4	0.45%	4	0.45%
Active Syphilis (RPR 1:8 or greater)	1	0.11%	0	0.00%	1	0.11%
Past Syphilis (TPHA)	15	1.68%	12	1.34%	13	1.45%
HIV	0	0.00%	2	0.22%	1	0.11%

Table 4b: Prevalence of infections by groups of women (defined by husband's migration status) attending clinic in Kailali District, Nepal by syndrome

FINDING	AGPA		NON-AGPA		NON-MIGRANT	
	Positive N	Positive %	Positive N	Positive %	Positive N	Positive %
ANY STI/RTI	103	11.51%	81	9.05%	90	10.06%
ANY EXCEPT CANDIDA	60	6.70%	49	5.47%	45	5.03%
ANY EXCEPT CANDIDA OR TPHA	48	5.36%	41	4.58%	37	4.13%

DISCUSSION OF RESULTS

A total of 904 women were enrolled in the study. Nine of these women were excluded from analysis because of missing data, for a final N=895. Socio-demographic characteristics of the sample are shown in Table 1. The mean age was 28.0 years. Over 99% of the sample was currently married, while fewer than 16% had any formal education. The mean age of marriage was 15.9 and mean age at first birth was 18.4. Women whose husbands migrated to India for work reported that their husbands were, on average, away from home 6.2 months during the past twelve months (or during their last year of migration) and the mean number of years of migration was 3.6. While women reported their husbands working throughout India, 27% reported Mumbai as their husband's destination.

Differences between the three groups were identified. These differences were most pronounced for education level (especially the NON-AGPA group versus the other two groups) and for the percentage of women reporting Mumbai as their husband's place of work.

Knowledge and sexual behavior characteristics are shown in Table 2. Over 87% of the sample had heard of condoms, but only 29% had ever used condoms. Fourteen percent of women reported ever using condoms to prevent sexually transmitted infections, and 8% reported using a condom during last intercourse. Finally, 42% of women had heard of AIDS. When compared to socio-demographic characteristics, relatively larger differences were found between the three groups of women. The AGPA group (who participate in an HIV/AIDS prevention intervention facilitated by Nepal Red Cross Society in Kailali) reported higher knowledge of condoms and AIDS, and reported significantly higher condom use.

Table 3a and 3b present laboratory results for the entire study population. Overall, 14% (125) of women tested positive for either *Trichomonas vaginalis* or bacterial vaginosis. *Candida albicans* was diagnosed in 15% (131) of study subjects while chlamydia and gonorrhea infections were diagnosed in 14 study subjects (under 2%). Less than 1% of the sample had active syphilis, while 4.5% of the population tested positive for a past syphilis infection. Three women from the study population tested positive for HIV, which accounts for less than half of one percent of the sample.

Diagnoses were then grouped into syndromes. Over 30% of the study population had at least one infection, while 17% of women had an infection other than candida. Further exclusion of women who only had candida or past syphilis generated an active STI rate of 14%.

Analysis by groups of women is found in Tables 4a and 4b. Differences in rates of infection were found among the three groups of women, although these differences were small and for individual infections, not statistically significant. The AGPA group, which had greater knowledge of AIDS and condoms, also showed higher infection rates for trichomonas, bacterial vaginosis and syphilis (combined active and past infection). This may suggest self-selection into the AGPA intervention due to a perception of higher personal risk of infection. The AGPA group also had the highest rate of infection for all three syndromes and this difference is marginally significant in bivariate analyses. It will be critical to assess whether group membership (or migration status) remains a significant risk factor in multivariate analyses.