Prevention of HIV/STI risk/vulnerability among married women through integration within primary health care in India
A Randomized Controlled Trial (RCT)

I Achievement and Challenge

India ranks third in the world in terms of the number of people living with HIV, estimated at 2.1 million in 2011, with an adult prevalence of 0.27%. The intensive programming efforts of the National AIDS Control Organization (NACO) among high risk groups (e.g., sex workers, men who have sex with men, injecting drug users, and truckers) has resulted in an estimated decline in the HIV incidence rate of approximately 56% between 2000 and 2009. This achievement has guided Phase IV of the National AIDS Control Program (NACP-IV, 2012-2017), which aims to accelerate the process of decline in incidence and further strengthen the response to the epidemic in India.

One of the NACP IV’s objectives is to integrate HIV prevention interventions within the broader health system, using innovative approaches, leveraging partnerships, and addressing stigma and discrimination. In the absence of evidence-based interventions, however, there are several challenges to achieving integration, particularly in low prevalence states that have shown recent increases in incidence and where spousal transmission has become an emerging concern.

I Problem Statement

On a global basis and in India, women’s greatest risk factor for HIV and other sexually transmitted diseases is being married to husbands who participate in high risk sexual behaviors. This risk also relates to gender inequity stemming from patriarchal norms and practices that restrict husband-wife communication, reduces women’s ability to negotiate marital sex, negatively impacts on women’s emotional health and constrains women’s ability to seek testing and treatment. The complex interaction of the marital unit and women’s vulnerability led RISHTA to seek answers to the following questions:

1. How can we identify the women who are most vulnerable to HIV/STI transmission within marriage?
2. What approaches can help to reduce married women’s risk?
3. What outcome indicators should we use to measure program success?

The Policy Context

The evidence-based RISHTA project seeks to contribute to national policy initiatives that include the NACP IV and the National (Urban and Rural) Health Mission, in their effort to develop integrated programming for HIV prevention. The RISHTA project has been conceived and implemented as a demonstration model for HIV/STI risk/vulnerability reduction by addressing a wide range of psychosocial, marital and sexual risk factors through integrating counseling and education within primary health care in the context of community intervention and education. The strategy, model and its measurement has important implications for HIV prevention programming in low epidemic settings in India and elsewhere.
RISHTA Study Setting

The project was conducted in a typical low income urban community of 600,000 in the Northeast quadrant of Mumbai city, India. In the late 1970s, the community was formed of residents relocated from the central part of Mumbai. Over the subsequent two decades the population grew rapidly, with a large number of illegal and unauthorized structures. The community is now 80% Muslim, 15% Hindu and 5% others, with migrants coming from Uttar Pradesh, rural Maharashtra, and Tamil Nadu among other states. Men in the study community are daily wage workers, petty traders and business owners, salaried factory and private workers, drivers, government employees, and construction workers. Women recruited into the RISHTA project through the public urban health center have come from the poorest segment of the community. The mean income for the husbands of women participating in the RISHTA project in 2013 is 5,987 Indian rupees per month (approximately US$107), with a growing number of women working for cash income.

A Marker of Women in Need

RISHTA was built on relevant, culturally-based beliefs, attitudes and behaviors related to sexual health and HIV risk behavior. Our formative research found that safed pani (literally “white water” and relating to vaginal discharge) was the leading symptom that brings women to public and private primary care facilities. The presence of this symptom offered us the opportunity to reach married women at a “point-of-service.” While NACO considers that this symptom is indicative of a sexually transmitted infection (STI) that calls for antibiotic treatment, our formative research established that safed pani is less about physical health and more significantly associated with women’s negative life situation (violence, poor husband-wife communication, low self-esteem, disempowerment and increased tenshun) and sexual risk (husband’s extramarital sex, low STI knowledge and low perceived risk). Thus, we have considered safed pani as one of the most effective means to identify women in the kinds of marital situations that are characterized by negative relationships, which can promote increased exposure to sexual risk and related consequences.

The Key Outcome Measures in the General Population

We began our work (2001-2007) in the study community with a focus on sexual risk among married men. Baseline STI testing in 2003 indicated a rate of gonorrhea of 3.9% among a random sample of married men. In 2006, after three years of community education and provider (allopathic and AYUSH) training in prevention and syndromic management, that rate had decreased to 1.2%. When recruitment began for the current project in June 2009, married women were tested for STIs using vaginal and cervical swabs at the urban health center. Of the first 230 women tested, only one case of gonorrhea was detected using gold standard procedures. These results were an extreme form of the trend toward lower rates of STIs in the general population in India. If HIV and STIs were this low what could researchers and interventionists use to measure the impact of their programs in the general population?

The World Health Organization’s (WHO) concept of sexual health offered a solution to this dilemma. In 2002 WHO defined sexual health as “a state of physical, emotional, mental and social well-being in relation to sexuality; not merely the
absence of disease, dysfunction or infirmity. Sexual health requires a positive, respectful approach to sexuality and sexual relationships and the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination and violence…”

At the individual level, assessment of the efficacy of the RISHTA project focused on sexual health as a key indicator of HIV prevention. We used the WHO concept to create a scale that consisted of four subscales: (1) Sexual competence (composite indicator of whether sex is consensual, with no regret, protected from STI and unplanned pregnancy), and decision to have sex made autonomously; (2) women’s perceptions of sexual enjoyment and positive attitudes; (3) sexual violence, including intimidation and physically forcing sex; and (4) knowledge of sexual health and risk. The Sexual Health Scale provides the basis for evaluating the project’s impact on prevention in general population settings where HIV/STI rates are low.

Our formative research identified the importance of emotional health as a key factor in prevention of HIV/STI among women. We utilized the emotional status subscale drawn from the Subjective Well-Being Inventory (SUNBI, normed for India) at the individual level that consisted of a series of statements that assessed, on a Likert-type scale, the emotional status of individual women. Items included ease of upset, degree of feeling sad, ease of irritation, degree of anxiety and tension, feeling that life is uninteresting, worrying about the future, feeling life is useless, upset at minor things and criticism.

At the clinical level, a baseline medical examination was conducted with all women (n = 1,125) in the sample that included medical history, an internal gynecological examination and testing for gonorrhea, Chlamydia, trichomoniasis, HSV2 (for an initial sample of 230), candida and bacterial vaginosis using cervical and vaginal swabs. Women's reported problems at baseline at a primary health care center were compared to their reports at one-year follow-up for common physical problems such as pain in the body, weakness, genital problems and saifed pani.

At the community level, the project measured the change in gender norms across the years 2009, 2010 and 2011 due to the intervention, using the project-developed Gender Equity Scale (GES), a 29-item instrument that assessed attitudes concerning men’s and women’s roles, privileges and responsibilities, marital sex, and women’s mobility. The GES was administered in each year to random, cross-sectional samples in the study community (n = 450) and in a nearby control community (n = 150). In addition, the GES was administered to NGO staff (n = 28) and Imams (n = 48) over the same three time periods.

**Intervention Approach: Narrative Prevention Counseling (NPC)**

Our goal was to develop an approach to work with the community, the marital couple and individual women that would be evidence-based (informed by research), culturally situated and adaptable to individuals as well as sub-groups in the community. At the individual level, the NPC reflects empirically validated health risk prevention approaches in several ways. First, the practitioner elicits the individual’s culturally constructed cognitive schemas or scripts (mental models) that influence risky behavior, treatment seeking, and service provision (construction). Second, the practitioner targets the individual’s cognitive script to examine alternative explanations that produce negative outcomes in women’s lives producing discrepancies between what people wish to accomplish and what they are doing (deconstruction). Third, the practitioner plans for implementation of new approaches to solve problems and reduce risk (reconstruction). NPC considers the biological, psychological, sociocultural, and political dimensions of illness or health risk, such as risky lifestyle, gender discrimination, and power relations. The holistic approach of the NPC (e.g., involving the person in consideration of multiple factors that produce perceived ill health and sexual risk) is consistent with the epistemology
of the Indian systems of medicine. This approach in combination with improvements in health services for women and community efforts to change gender inequitable norms constituted our multilevel approach.

The Interventions

Using the principles of NPC, the RISHTA project developed interventions at four levels: The community, the health care system, the marital dyad and for the individual women. These interventions are summarized as follows:

- **Community intervention** consisted of messages delivered in collaboration with community-based NGOs, the health service sector and community mosques. Training and message development sessions were held with NGOs and messages were embedded in regular NGO activities as well as special events that included International Women's Day and AIDS Day and booths set up as a part of festivals such as Eid and Ganpati. Workshops with Imams resulted in the co-construction of messages related to women's equity and sexual and reproductive health, which were delivered to congregations as a part of the takrir (Friday prayer lecture); a significant opportunity to reach out to Muslim men on a weekly basis.

- **Women's Health Clinic (WHC)** was established at the municipal urban health center (UHC) in association with the Topiwala National Medical College and a female STI/RTI initiative by the Mumbai District AIDS Control Society (MDACS). The development of the WHC within the primary health center provided services for women with special emphasis on gynecological problems that included safed pani, burning micturition, inguinal swelling, lower abdominal pain, genital ulcers, itching in the genital area and menstrual problems. Services were provided by female doctors that included an internal examination per speculum, STI/RTI testing, treatment, health education, follow-up and referral for HIV testing and counseling.
Individual Counseling (IC), one of the experimental intervention conditions for women enrolled in the project, consisted of three to five therapeutic sessions by a counselor trained on NPC. IC consisted of moving through the NPC stages of “construction,” “deconstruction,” and “reconstruction.” Based on analysis of the content of these sessions and the counselor’s ability to reach reconstruction, it was determined that three sessions were optimal.

Couples’ Intervention (CI), the second experimental intervention condition consisted of groups of five to six couples involved in six (6) sessions: four single gender sessions and two in which both wives and husbands participated. The first single-gender session involved “roles and responsibilities in marriage,” the second session discussed “tensions in marriage,” the third session dealt with “sexuality and sex in marriage” and the fourth session addressed sexual risk and prevention and reviewed risk behaviors and preventive measures related to sex. The fifth and first joint session on “violence in the marital relationship” sought to give the couples a better understanding of violence and to develop skills to resolve contentious issues in the marital relationship through non-violent communication. The final and second joint session addressed “good marital relationships” and focused on the importance of communication and listening in marriage and the factors that led to a good marital relationship.

A Randomized Controlled Trial (RCT)

An RCT design was implemented to test the efficacy of individual counseling (IC) and couples’ intervention (CI) in terms of sexual health and emotional health as well as other variables. Eligible participants (married women, ages 18-40, living in the study community with their husbands and not pregnant, presenting to the Women’s Health Clinic at the UHC with safedpanti and related gynecological symptoms) were randomly assigned to IC or not, and to CI or not, resulting in the formation of four a priori groups: IC only, CI only, IC + CI, and control (neither IC or CI). The Women’s Structured Survey (WSS) was administered at the time of enrollment (baseline),
at the six-month point after IC/CI intervention and again at one year. The implementation of the RCT design involved the following:

- Married women, who consented, were recruited on a rolling basis to participate in the RCT intervention from June, 2009 to March, 2012; final one-year WSS administrations were completed in March, 2013.
- A sample of 1,200 women was established as the target for recruitment in the RCT through power calculation. The final baseline sample of 1,125 represented 94% of the target.
- Of the baseline sample of 1,125, 195 (17%) were lost to follow-up at the 6-month WSS administration, and an additional 93 (7%) were lost to follow-up at the one-year WSS administration, for a total loss to follow-up across the three time points of 24%.
- For those 275 women assigned to IC only, 271 (98.5%) received at least one session; for those 284 women assigned to CI only, 204 (71.8%) received at least one session; and for those who were assigned to IC + CI, 147 (51.9%) received at least one session of both.
- Individuals assigned to an intervention but who did not subsequently participate (n = 218) were reassigned to Control (Total = 503) after it was determined that there were no significant demographic differences between them and the controls.

**Results**

The results of the interventions at the community, clinical and individual levels (as a result of participation in IC and CI) are presented below.

**Community-level Intervention Findings**

- There was a significantly greater improvement in gender-equity perceptions in the study (experimental) community, where community education and messaging was conducted through the NGOs and the Imams, than in the control community where there was no intervention.

- The improvement in the study community was almost totally a function of very significant positive changes in attitudes towards gender equity among men in the study community as compared to men in the control community. No differential improvement among women was seen as a function of experimental versus control community.

- The baseline values (2009) for Imams in the study community showed this group to be at the lowest level in terms of gender equity, whereas NGO staff showed the most positive gender attitudes initially.

- By the third year, and after extensive work by RISHTA in the study community, both Imams and NGO staff showed significant positive changes, respectively, as well as significant improvement in the second and third years.

- Imams showed significantly more positive changes than NGO staff in the second and third years.
Women's Health

In Table 1, we match women's self-reporting of symptoms at baseline to those reported at one-year follow-up. Almost all the symptoms reported by women in baseline show a significant reduction in the one year follow-up due to a significant degree to the treatment and follow-up at the Women’s Health Clinic.

When we created a composite scale of all Women’s Health Symptoms, there was a significant reduction in the total number across time (from baseline to one-year follow-up, \( b = 0.725, p < .001 \)). There was a significantly larger reduction among women who participated in IC, \( b = 1.130, p < .001 \) and CI, \( b = 1.003, p = .001 \) relative to their respective control conditions.

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**Table 1: Self-Reported Symptoms at Baseline and One Year Follow-up**

<table>
<thead>
<tr>
<th>Problem</th>
<th>Baseline n</th>
<th>Baseline %</th>
<th>1 Year Follow-up n</th>
<th>1 Year Follow-up %</th>
<th>Change ( Z^2(2-t) )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Backache</td>
<td>732</td>
<td>84.9</td>
<td>553</td>
<td>64.1</td>
<td>23.13***</td>
</tr>
<tr>
<td>Headache</td>
<td>721</td>
<td>83.6</td>
<td>568</td>
<td>65.8</td>
<td>29.00***</td>
</tr>
<tr>
<td>Giddiness (Dizziness)</td>
<td>646</td>
<td>74.9</td>
<td>402</td>
<td>60.6</td>
<td>40.69***</td>
</tr>
<tr>
<td>Pain in Body</td>
<td>738</td>
<td>85.6</td>
<td>523</td>
<td>60.6</td>
<td>12.91***</td>
</tr>
<tr>
<td>Loss of Appetite</td>
<td>428</td>
<td>49.7</td>
<td>212</td>
<td>24.6</td>
<td>34.80***</td>
</tr>
<tr>
<td>Chest Pain</td>
<td>371</td>
<td>43.0</td>
<td>181</td>
<td>21.0</td>
<td>43.61***</td>
</tr>
<tr>
<td>Palpitations</td>
<td>529</td>
<td>61.4</td>
<td>291</td>
<td>33.7</td>
<td>7.13*</td>
</tr>
<tr>
<td>Pain in Lower Abdomen</td>
<td>591</td>
<td>68.6</td>
<td>281</td>
<td>32.6</td>
<td>23.63***</td>
</tr>
<tr>
<td>Swelling of Glands in Groin</td>
<td>197</td>
<td>22.9</td>
<td>163</td>
<td>18.9</td>
<td>0.97</td>
</tr>
<tr>
<td>Irregular Menses</td>
<td>284</td>
<td>32.9</td>
<td>126</td>
<td>14.6</td>
<td>25.23***</td>
</tr>
<tr>
<td>Pain or Cramps during Menses</td>
<td>362</td>
<td>42.0</td>
<td>142</td>
<td>16.5</td>
<td>18.90***</td>
</tr>
<tr>
<td>Excessive Bleeding from Vagina</td>
<td>175</td>
<td>20.3</td>
<td>59</td>
<td>6.8</td>
<td>11.30**</td>
</tr>
<tr>
<td>Infertility</td>
<td>63</td>
<td>7.3</td>
<td>19</td>
<td>2.2</td>
<td>89.45***</td>
</tr>
<tr>
<td>Obstructed Urine Flow</td>
<td>120</td>
<td>13.9</td>
<td>34</td>
<td>3.9</td>
<td>44.97***</td>
</tr>
<tr>
<td>Pain while Urinating</td>
<td>135</td>
<td>15.7</td>
<td>47</td>
<td>5.4</td>
<td>23.08***</td>
</tr>
</tbody>
</table>

(contd...)
<table>
<thead>
<tr>
<th>Problem</th>
<th>Baseline n (%)</th>
<th>1 Year Follow-up n (%)</th>
<th>Change $\chi^2(2 \text{-} df)$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burning Urination</td>
<td>294 (34.1)</td>
<td>119 (13.8)</td>
<td>22.62***</td>
</tr>
<tr>
<td>Safed pani</td>
<td>771 (89.4)</td>
<td>303 (35.1)</td>
<td>7.62*</td>
</tr>
<tr>
<td>Ulcers in and around vagina</td>
<td>98 (11.4)</td>
<td>40 (4.6)</td>
<td>23.25***</td>
</tr>
<tr>
<td>Itching in and around vagina</td>
<td>330 (38.3)</td>
<td>119 (13.8)</td>
<td>20.78***</td>
</tr>
<tr>
<td>Swelling in Ankles</td>
<td>179 (20.8)</td>
<td>75 (8.7)</td>
<td>3.60</td>
</tr>
<tr>
<td>Pain during Intercourse</td>
<td>337 (39.1)</td>
<td>168 (19.5)</td>
<td>24.90***</td>
</tr>
<tr>
<td>Sexual Dissatisfaction</td>
<td>229 (26.6)</td>
<td>125 (14.5)</td>
<td>9.12**</td>
</tr>
<tr>
<td>Loss of Sexual Desire</td>
<td>332 (38.5)</td>
<td>183 (21.2)</td>
<td>20.60***</td>
</tr>
<tr>
<td>Body Weakness</td>
<td>660 (76.6)</td>
<td>470 (54.5)</td>
<td>15.37***</td>
</tr>
</tbody>
</table>

n = 863 | * p < .01 | ** p < .005 | *** p < .001

**Safed pani and Antibiotics**

We have seen that there was one (1) case of gonorrhea as the only STI among the first 230 women (0.4%) in which STI testing was conducted. Despite these laboratory results, over 70% received a treatment kit that included an antibiotic consistent with the national guideline for syndromic treatment, as shown in Table 2.

**RCT Outcomes**

The outcome variables of the RISHTA project at individual level were a part of the longitudinal

<table>
<thead>
<tr>
<th>Type of Kit</th>
<th>Content of Kit</th>
<th>Frequency Prescribed (n and %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green (Vaginitis)</td>
<td>2 gm Secnidazol (antibiotic and anti-parasitic) &amp; 150 mg fluconazole (anti-fungal)</td>
<td>99 (43.0)</td>
</tr>
<tr>
<td>Grey (Cervicitis)</td>
<td>1 gm Azithromycin &amp; 400 mg cefixime (both antibiotics) stat dose</td>
<td>58 (25.2)</td>
</tr>
<tr>
<td>Yellow (Lower Abdominal pain)</td>
<td>400 mg cefixime stat, 100 mg Doxycillin BD for 14 days &amp; 400 mg Metrogyl BD (all antibiotics) for 14 days</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td>Red (Herpetic genital ulcer)</td>
<td>200 mg Acyclovir TDS (antiviral) for 7 days</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Black (Inguinal Bubo)</td>
<td>1 mg of Azithromycin stat dose, 100 mg of Doxycillin BD (both antibiotics) for 14 days</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Blue (Non-Herpetic ulcer)</td>
<td>100 mg of Doxycillin BD for 14 days &amp; 400 mg cefixime (both antibiotics)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>None</td>
<td>No kit given</td>
<td>70 (30.4)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>230 (100.0)</td>
</tr>
</tbody>
</table>

8
assessment (baseline, six month post intervention and one-year) to assess the relative efficacy of interventions (individual counseling, couples intervention, or both) in comparison with no intervention. All analyses examined longitudinal change in the measures using Hierarchical Linear Modeling (HLM). The resultant three-time-point variables were modeled to assess their linear trajectory (i.e., change across time or slope) and intercept (i.e., did the value of a given variable increase over time as hypothesized). In order to control for potential non-randomness as a function of some participants not participating in either or both of their randomly assigned experimental groups, the intercept and trajectory were analyzed as a function of six demographic variables (Wife's Age, Couples' Age Difference, Wife Born in Mumbai, Wife's Education, Religion, and Couples' Income), as well as seven self-reported baseline measures (Social Support, Empowerment, Tension Concerns, Gender Equity, Women's Health Problems, Husband's Physical Violence, and Marital Communication). A sample of n = 1,125 cases, representing participants who had a baseline value, was used for the analysis. There were 861 cases which had all three valid measures at baseline, 6 months, and 12 months.

IC and CI outcomes: Sexual Health

The Sexual Health Scale (35 items) drawn from the WSS had high reliability (Cronbach's α = .86). There was a significant overall improvement across time, b = 0.172, p < .001, independent of the intervention variables (see chart below).

There was a significant differential slope as a function of CI, b = 0.021, p < .001, such that those receiving CI showed significantly more improvement over time in Sexual Health than those who did not receive CI.

There was a significant differential slope as a function of IC, b = 0.020, p < .001, indicating that those women who participated in IC showed significantly more improvement over time in Sexual Health than those who did not participate in IC.

The relationships of the design variables (IC/CI) were examined (co-varied) with demographic and socio-behavioral variables. There were no significant effects for any of the six demographic factors. There were significant effects for four of the eight social-behavioral covariates, such that the better the Marital Communication, b = 0.018, p = .031, and the worse the Empowerment, b = -0.009, p = .032, b = -0.024, p < .001, the more the Gender Inequity, b = -0.030, p < .001, and the greater Women's Health Problems, b = -0.074, p < .001, the better the improvement.
In terms of the subscale of *Sexual Competence*, there was a trend toward a significant differential slope as a function of IC, $b = 0.027$, $p = .063$, such that those receiving IC showed more improvement across time than those not, but not for CI, $b = 0.022$, $p = .17$. In terms of the subscale of *Sexual Knowledge*, there was a significant differential slope as a function of IC, $b = 0.015$, $p = .018$, and of CI, $b = 0.013$, $p = .047$, such that those receiving either treatment improved significantly more than those not. In terms of the subscale of *Sexual Attitudes*, there was a trend toward significance for a differential slope as a function of IC, $b = 0.012$, $p = .087$, and a significant differential slope as a function of CI, $b = 0.019$, $p = .015$, such that those receiving either treatment showed more improvement across time than those not. Finally for the subscale of *Sexual Violence*, there was a significant differential slope as a function of IC, $b = 0.015$, $p = .018$, and of CI, $b = 0.013$, $p = .047$, such that those receiving either treatment improved significantly more than those who did not.

**IC and CI Outcomes: Emotional Health**

The results showed that there was a significant differential slope for longitudinal positive change in the Emotional Health Status scale both as a function of IC, $b = 0.045$, $p = .030$, and of CI, $b = 0.071$, $p = .001$. Those receiving IC as well as those receiving CI treatments showed more improvement across time than those in their respective control groups.
Conclusions: Answers to Our Project Questions

1. How can we identify the women who are most vulnerable to HIV/STI transmission within marriage?

_Safed pani_ and related gynecological symptoms presented to primary health care services are an effective approach to engage those women who are hard to reach from low income communities and low epidemic settings in efforts to reduce their vulnerability to HIV/STI. In addition, _safed pani_ is a marker of a negative life situation involving poor marital communication, disempowerment, _tenshun_, and violence for women that results in poor sexual health and other negative outcomes.

2. What approaches can help to reduce women’s risk?

The RISHTA project has generated supportive evidence for several approaches to reduce women’s risk of HIV/STI. First, a dedicated woman’s health clinic within a primary care center that goes beyond maternal and child health to focus on the physical and mental health needs of married women is a necessary part of comprehensive primary care for women and in the effort to prevent HIV/STI. Second, Narrative Prevention Counseling (NPC), a holistic counseling and education approach and consistent with Indian systems of medicine, has been shown to be an effective approach in the RISHTA project to structuring community education, health care, couples’ intervention and individual counseling. Third, the project has demonstrated that community intervention in collaboration with NGOs and Muslim religious leaders can change community norms with regard to gender equity, particularly with community men. This change in community norms provides a necessary supportive context for women’s equity. Pairing an RCT focused on individual change with community intervention recognizes that individual change must be supported and facilitated by normative change in the community. Finally, the syndromic approach to _safed pani_ and related gynecological problems results in significant overuse of antibiotics, resulting in further symptoms and can contribute to antibiotic resistance. Therefore, the basis of treatment should depend on laboratory testing for STIs. These women require comprehensive counseling rather than just medical treatment alone.

3. What outcome indicators should we be using to measure program success?

In low prevalence communities in which there is a risk associated with spousal transmission of HIV/STI, the RISHTA project has shown that the WHO concept of sexual health is an important indicator of prevention-related behavior and that it is a sensitive indicator of the impact of individual, couple and community intervention for married women. In addition, emotional health status also responded to individual counseling and couples intervention, indicating that women’s emotional health, linked to their reported health symptoms, is an important component of the overall prevention effort and needs to be incorporated into risk reduction intervention and primary care services.

Policy Recommendations

Promote structural (NGO, social and religious groups) initiatives to change gender equity attitudes among men, women and key stakeholders to facilitate HIV/STI risk reduction.

Integrate sexual health and mental health services within primary care settings that focus on the needs of women over and above basic maternal and child health services.

Abandon the syndromic approach to women’s RTI/STIs in the general population and focus on the ways in which _safed pani_ and other gynecological symptoms are indicators of women’s health and mental health status through the holistic counseling approach of the NPC, as implemented in RISHTA project.
Acknowledgements

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In addition to our partner institutions and organizations, we thank the Mumbai Municipal Corporation, non-governmental organizations (NGOs), the Imams and Muslim religious leaders, the anganwadi teachers, and the community health volunteers for their support and participation in this project.

Most of our field and intervention staff has been with RISHTA for many years and without their hard work and dedication, it would not have been possible to conduct this comprehensive project.

Finally, we want to thank the RCT participants for their support and patience as we made repeated visits over the course of the year; we are committed to ensuring that their contribution will result in the sustainability of key project components in the community and replicability in other similar communities facing the same challenges.

Project Structure

RISHTA (an acronym meaning “relationship” in Hindi and Urdu) has involved Indo-US collaboration on a series of research, intervention and evaluation projects funded by the US National Institutes of Health from 2001-2013. The current project, “The Prevention of HIV/STI among Married Women in Urban India”, is a collaboration of:

- **International Center for Research on Women (ICRW, Dr. Ravi K. Verma, PI on the India-side), the lead coordinating and implementing agency in India**

- **University of Connecticut School of Medicine (Dr. Stephen L. Schensul, PI on the US-side), the lead institution on the US-side**

- **Population Council (Dr. Niranjan Saggiurti, co-PI), responsible for the research design and data analysis**

- **Tata Institute of Social Sciences (Dr. Shubhada Maitra, co-PI), responsible for providing interventions for individual women and couples**

- **Tulane University, USA (Dr. Bonnie K. Nastasi, co-PI), responsible for providing culturally specific psychological input to counseling and group process interventions**

- **Institute for Community Research, USA (Dr. Jean J. Schensul, co-PI), providing technical assistance in interventions, design and analysis**

- **Topiwala National Medical College (Dr. S.R. Suryawanshi), integrating the project into the Urban Health Center and implementing the Women’s Health Clinic**

- **National Institute of Medical Statistics (Dr. Arvind Pandey, co-PI) linking the project to the national level and national data.**

- **National Institute for Research in Reproductive Health (Dr. Jayanti Mania), providing biological testing and procedures**

- **CORO for Literacy (Ms. Sujata Khendakar) providing community education**

As the project progressed, the study developed important collaborations with: NGOs including Apnalaya, Stree Mukti Sangathan, Niramaya Health Foundation, Lok Seva Sangam, and SNEHA; the Mahila Mandal Federation; the service sector (Community Health Volunteers and anganwadi teachers); the Imams and leadership in Muslim religious institutions and the AYUSH (non-allopathic) providers in the study community.