The Effectiveness and Costs of Two Methods for the Systematic Prevention and Control of STIs, Among Female Sex Workers in Dhaka, Bangladesh

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Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
BCI	Behavior Change Intervention
BWHC	Bangladesh Women's Health Coalition
BSS	Behavioral Surveillance Survey
CA	*Candida albicans*
CT	*Chlamydia trachomatis*
ESM	Enhanced Syndromic Management
FHI	Family Health International
HBsAg	Hepatitis B surface antigen
HIV	Human Immunodeficiency Virus
HPF	High Power Field
HSV-2	Herpes simplex Virus type 2
ICDDR,B	International Centre for Diarrhoeal Disease Research, Bangladesh
IDU	Injecting Drug User
IHC	Integrated Health Centre
IMPACT	Implementing HIV/AIDS Prevention and Care
IRB	Institutional review board
KOH	Potassium hydroxide
MRG	Most At Risk Groups
MOH	Ministry of Health
NASP	National AIDS/STD Program
NG	*Neisseria gonnorhoea*
NGO	Non-Governmental Organization
PCR	Polymerase Chain Reaction
PHSC	Protection of Human Subjects
PLWA	People Living With AIDS
PML	Polymorphonuclear Lymphocytes
PPT	Periodic Presumptive Treatment
RPR	Rapid Plasma Reagin
STI	Sexually Transmitted Infection
TP	*Treponema pallidum*
TPHA	*Treponema pallidum* Particle agglutination Assay
TV	*Trichomonas vaginalis*
USAID	United States Agency for International Development
WHO	World Health Organization
4C's	Condoms, Counselling, Compliance, Contact Tracing

Disclaimer

The views expressed in this document do not necessarily reflect the views of FHI or USAID.

Contents

Executive Summary

Background

Bangladesh is threatened by an HIV epidemic. It is important to identify the best way to achieve rapid reductions in sexually transmitted infections (STI) as an effective approach to HIV prevention. Periodic presumptive treatment (PPT) is suggested as a method for STI control; however, it is considered a short-term solution as the epidemiological justification of this approach is weaker as the STI prevalence declines. Enhanced syndromic management (ESM) is an alternative approach that aims to reduce STI prevalence rapidly, through a single round of presumptive treatment of cervicitis, plus, subsequent monthly clinical care through an ESM protocol based on a risk assessment and laboratory tests.

Methods

In January 2005, a randomised controlled trial to compare PPT to ESM with STI incidence, behavior change, condom use, program durability and cost was conducted. A total of 549 hotel-based sex workers (HBSW) were enrolled in the study. Demographic, behavioral and clinical data were collected from consenting women at two hotel-based sex worker STI clinics in Dhaka. At baseline, all women received presumptive treatment with cefixime 400mg, azithromycin 1g and metronidazole 2g, and then randomized to receive either PPT or ESM at nine monthly visits. STI and behavioral data were collected from both groups at visits 1, 2, 3, 9 and 10.

Results

Most subjects were working as hotel-based sex workers in Dhaka for less than two years. They averaged 21 sex clients per week. By the end of the nine month, follow-up period there was no difference between the two treatment groups in STI incidence or prevalence, behavior or retention. After nine months for all women, retention was 50%; there was a reduction in median clients per week from 22 to 17; the percentage of women who considered themselves at 'high risk' decreased from 80% to 50%; knowledge of STI symptoms improved. Condom use was between 70-35% at baseline and 61-55% after nine months. The *presence of Neisseria gonnorhoea* (NG) and *Chlamydia trachomatis* (CT) decreased from 41% to 7% over the nine-month follow-up period, an 83% reduction. PPT was 50% less expensive than ESM with no loss in retention, STI reduction, or behavior change.

Recommendations

Priority should be given to systematic STI management in this low HIV, high STI prevalent setting. Monthly PPT provides a less expensive and more accessible strategy than ESM. Establish minimum standards and operational guidelines for delivery of STI and behavior change programs in and effort to attract and retain women. Finally, additional studies should include risk perceptions, assessment of STIs in male clients, consistent condom use and where sex workers go after leaving hotel-based sex work in Dhaka.

HIV prevalence among hotel-based sex workers (HBSWs) in Bangladesh is currently under 2%. HBSWs, however, have high rates of sexually transmitted infections, high client turnover, low rates of condom use and poor access to treatment. These factors lead to an increased risk of an HIV epidemic in the near future.

STIs are an important cofactor in the transmission of HIV. Reduction of this cofactor through effective STI control is a critical and cost effective component of HIV prevention programs (3-8). Additionally, STI cofactor effects are greater in populations with HIV infection in a growth phase. Core groups such as female sex workers heavily influence the transmission dynamics of STIs in a population (9).

What is not clear is the best way to deliver consistent STI treatment, promote program participation, facilitate condom use and reduce risk behavior in this young and vulnerable population. Due to their extreme daily risk, standard syndromic algorithms designed for symptomatic STIs are not suitable for hotel-based sex workers (10, 11, and 12).

This report describes a randomised intervention study with HBSWs in Dhaka, comparing two interventions: periodic presumptive treatment (PPT) and enhanced syndromic management (ESM). This paper presents the findings on the comparative effectiveness, costs, program durability, impact on condom use, and knowledge and risk behavior of the two interventions.

Country Context

For many years, Bangladesh has averted the HIV and AIDS epidemics that are affecting many other Asian countries: recent national surveillance data indicate HIV prevalence remains less than 2% among men, women and hijras (transgenders) who sell sex, their male clients, and men who have sex with men. However, prevalence of HIV infection among one population of injecting drug users in Dhaka has reached 9%. Behavioral Surveillance Survey (BSS) data indicate that IDU populations are well integrated into the surrounding urban community, both socially and sexually. In Bangladesh, female HBSW have more male clients per week than anywhere else in Asia and the majority of men do not use condoms in commercial sex encounters. Female sex workers report the lowest condom use in the region and recent data actually indicate a decline in consistent condom use in sexual encounters between IDUs and female sex workers (13). This gives rise to grave concern that HIV will not always be restricted to IDUs, but could soon spread to male and female sex workers and hence their clients and the general population.

The Effectiveness and Costs of Two Methods for the Systematic Prevention and Control of STIs, Among Female Sex Workers in Dhaka, Bangladesh

VIII

1

Table 1
Size Estimates of Most-at-Risk Groups in Bangladesh and Average Estimated Number of PLWHA in Each Group

Most-At-Risk Group	Size Estimate Low	Size Estimate High	Average Estimate of PLWHA
Injecting Drug Users	20,000	40,000	444
MSW & MSM	40,000	150,000	450
Brothel-Based Prostitutes	3,600	4,000	55
Street-Based Prostitutes	37,000	66,000	453
Hotel-Based Prostitutes	14,000	20,000	128
Clients of Female Prostitutes	1,882,080	3,136,800	1,882
Hijras (Transgenders)	10,000	15,000	62
Returnee External Migrants	268,000	536,000	3,015
National Total MARGs	2,274,680	3,967,800	6,489
National Total Pop. at Lower Risk*	1,191,559	2,012,375	1,188
Estimated National Total Average Number of PLWHA			**7,677**
National Range PLWHA: ~ 700 – 19,000		National Avg. PLWHA: ~ 8,000	

* Partners of members of MARGs, TB patients, and blood transfusion recipients

STIs and Hotel-Based Sex Workers in Bangladesh

Sex work in Bangladesh underwent a major upheaval in 1999 with the closure of several large brothels and the eviction of sex workers, resulting in an increase in the hotel-based sex industry (14). Mapping, conducted in 2001, confirmed that 55% (209/378) of hotels in Dhaka are involved in the sex trade with links to nearly 5,000 hotel-based sex workers. These women are mobile, usually changing hotels daily, and working 4-5 hotels per week. Most workers change hotels (and or cities) after 4-5 months, thus ensuring a steady supply of new clients and a higher risk of STI and HIV transmission (15). While curable STI prevalence in the general population of Bangladesh remains low (18, 19), rates in female sex workers are extremely high as shown below in Table 2.

Table 2
Prevalence (%) of Sexually Transmitted Infections in FSWs and Women from the General Population in Bangladesh.

Study Population	N	NG	CT	TP	TV	BV	CA	Reference
Floating FSWs	**269**	35.6	25	32	45	75	-	(16)
Brothel-based FSWs	**296**	19.9	18.2	28.1	-	-	-	(10)
Hotel-based FSWs	**519**	36	43	8.5	4.3	57	18	(11)
Brothel-based FSWs	**436**	14	16	18	16	50	10	(12)
General population women	**320**	0.3	0.6	0.9	1.9	18.8	12.2	(18)

Hotel-based sex workers in Dhaka are particularly at risk for STIs, with some groups reporting up to 47 partners per week, and up to 84% having symptoms of STIs in the last year (13). In 2002 a survey of HBSWs showed that 100% of women had new clients in the past week (n= 325). Last time condom use in vaginal sex with new clients was 24.3% (n=325). Last time condom use in anal sex with new clients was 8.8% (n=57) and consistent condom use with new clients in the last week was 4% (n=352) (20).

Approaches to STI Control

STI case management in developing countries involves a continuum of approaches ranging from presumptive treatment (PT), to classical syndromic management to laboratory based aetiological diagnosis and treatment. Due to the asymptomatic nature of most STIs in women *laboratory-based diagnosis and treatment* is the only sensitive and specific method for accurate diagnosis and treatment of STIs in this group of high-risk women, however, this approach is not feasible in developing countries due to cost and laboratory complexity.

Presumptive treatment is a one-time treatment for a presumed infection in a person, or a group of people, at very high risk of infection. When presumptive treatment for STIs is given over repeated intervals, it is known as *periodic presumptive treatment.* Treating pathogens known to cause specific signs and symptoms in a person is known as *syndromic case management.* The syndromic and presumptive treatment approaches are complementary – while syndromic case management depends on signs and symptoms, presumptive treatment addresses the more problematic asymptomatic infections as well as symptomatic infections in persons presumed to be at high risk with a very high probability of infection. The composition of a group, such as female sex workers (FSWs), receiving PPT may change over time as women come and go. Some members may therefore receive only one, occasional or irregular treatment. However, the public health objective is to identify newcomers through effective outreach, thus ensuring high levels of coverage and uptake and maximising population impact (21).

Previous studies of PPT in Africa and Asia have shown significant reductions in STI rates. A study in a mining community in Free State, South Africa, showed STIs also decreased in male clients (21, 22). However, questions remain over generic issues such as the effectiveness and cost-effectiveness of PPT compared to comprehensive clinical services and the effect of PPT on preventative measures such as condom use. Additional questions on the effects of PPT on

antimicrobial resistance, HIV rates and sustainability need to be considered. Finally, population/country-specific issues such as the optimal periodicity of treatment; approaches to tapering, how to provide interventions of sufficient quality, degree of acceptability to target populations, policy makers and service providers should be raised as well as retention of women in treatment programs.

STI Services and FHI in Bangladesh

In Bangladesh, the major constraints to the diagnosis and management of STIs in sex workers are lack of targeted services, scarcity of trained health workers and inadequate laboratory infrastructure. Since 2000, FHI has been working in collaboration with local non-governmental organizations (NGOs) and other key players to establish a network of Integrated Health Centres (IHCs) across Bangladesh, providing targeted services to female, male and transgender sex workers and their clients, men having sex with men, and injecting drug users across. The package of services includes STI management, risk reduction counselling, condom promotion, voluntary counselling and testing for HIV (VCT) and capacity building to plan, implement and monitor HIV interventions.

Prior to 2004, Bangladesh National STI guidelines recommended syndromic management of STI. However, epidemiological data indicated that as much as 50% of STI cases in female sex workers were asymptomatic with the result that most infections remained untreated in high-risk women (11, 12, and 19).

In order to address this problem, an approach was needed that could rapidly reduce STIs at the first visit, reduce the risk of under-diagnosis of asymptomatic infections at subsequent visits and continue to treat symptomatic patients at all visits. Furthermore, this approach would need to be cost effective, accessible, provided as part of a package of services including condom promotion and safe sex education, feasible to deliver in Bangladesh and taken up by the target population in sufficient numbers to impact on public health.

Periodic presumptive treatment was suggested as an approach but was considered a short-term solution as the epidemiological justification of this approach is weaker as the STI prevalence declines. Enhanced syndromic management (ESM) is an alternative that aims to rapidly reduce STI prevalence through a single round of presumptive treatment of cervicitis, and subsequently provide monthly clinical care through an enhanced syndromic management protocol based on a risk assessment and bedside laboratory tests. In this way, it was expected that the presumptive treatment element of ESM would become increasingly targeted towards a specific subgroup at higher risk of STIs, while ensuring effective case management and screening for STIs in those at less risk (23). It was decided to evaluate this approach against PPT.

The National STI recommendations drafted in 2004 and published in 2007; recommend single dose combination treatment with azithromycin 1g and cefixime 400mg for the treatment of gonococcal and chlamydial infections (NG/CT) and metronidazole 2 grams stat for vaginal discharge caused by trichomonas and bacterial vaginosis (BV). The guidelines include a risk score for high-risk women, to receive presumptive treatment with azithromycin, cefixime and metronidazole at the first visit, followed by treatment according to a risk assessment, history and examination for subsequent visits. The National STI guidelines were incorporated into the ESM and PPT intervention algorithms being assessed by the study in order that recommendations based on study findings could more easily be scaled up across the country.

This report presents the findings and recommendations from an intervention study comparing ESM vs. PPT in two groups of hotel-based sex workers in Dhaka. The results and discussion will focus on study outputs:

1. Baseline STI/RTI (reproductive tract infection) prevalence in female sex workers, and the change in prevalence after nine months of PPT vs. ESM.

2. The effect of PPT vs. ESM on the early (2-3 months) and late (8-9 months) incidence of NG/CT/BV and incidence stability

3. The identification of risk factors, symptoms and signs associated with infection and modification of risk behaviors after each intervention.

4. The validation of the existing ESM risk score

5. The assessment of costs

6. Knowledge of program durability

7. Validation of the prostate-specific antigen (PSA) assay as a marker of condom use in this high-risk population of female sex workers.

Study Site, Population and Policy Environment

In the first year of the intervention, the project focussed on the establishment of two study sites in central Dhaka. Initially, Bangladesh Women's Health Coalition (BWHC) conducted a consultation and mapping exercise in collaboration with sex workers in order to identify the hotels from which women worked and any potential barriers to clinic access. The two sites in central Dhaka maximised access by ensuring the following:

1. Clinics were discretely and securely located close to the women's places of work

2. Outreach schedules and clinic opening times matched as closely as possible the work patterns of the women

3. Clinic waiting times were kept to a minimum

4. All services were free of charge irrespective of study participation.

In order to promote quality services, minimum standards plus operational and clinical guidelines was developed and staff trained to set-up and run clinics that could attract patients and deliver standardised interventions to women in a way that could be evaluated as part of the research program - and replicated in other STI clinics across Bangladesh. Each STI clinic provided a 6 hour session of STI treatment and counselling to study participants 5 days a week, and to non-participants 2 days a week.

Women attending the clinics came from a population of women that sold sexual services to clients in 70 nearby hotels. The hotels' locations in the business districts of Dhaka ensure a steady supply of new clients from across Bangladesh. In the hotels, BWHC provided outreach services such as peer education and counselling, plus referral to the STI clinics for routine STI services or recruitment and follow-up in the study.

The study was carried out in collaboration with funding agencies USAID and UNICEF, policy makers NASP and service providers ICDDR,B, Marie Stopes Clinical Society (MSCS), and BWHC. In order to ensure that treatment approaches, drugs, target population, guidelines and clinic set-up used in the study would be acceptable to the national program and more likely to be implemented and sustained across the country, collaboration and coordination was seen as an essential component of the study design.

Inclusion, Exclusion and Re-schedule Criteria

All women identifying themselves as a female sex worker aged 15 years and over were eligible for the study. Women were excluded when aged less than 15 years, allergic to macrolide, cephalosporin, and metronidazole and penicillin antibiotics or not intending to stay in the project area of Dhaka for the next nine months. Women who were menstruating or had taken antibiotics in the previous 4 weeks were re-scheduled.

Sample Size and Sampling Methods

The risk score threshold for treatment in the ESM group was assumed low; no major difference in the efficacy of the two interventions was expected. Therefore, true sample size calculations, in terms of demonstrating differences, would have to be based on cost, retention and behavior change for which there was not enough information to perform those sample size calculations.

Critical information to be determined from these data were the STI prevalence at baseline and the cumulative incidence at follow-up by randomized arm. The widths of the confidence intervals were estimated with a sample size of 250 per group. Accordingly, in each clinic, the first 250 eligible and consenting women were enrolled and randomised to receive one of the two interventions.

Recruitment and Retention Procedures of Study Participants

In order to gain initial access to the sex workers, meetings with hotel managers and pimps were arranged to explain the purpose of the study and seek their cooperation with the study activities. While these intermediaries were used to gain access, they were not utilised for any component of recruitment and no information regarding recruitment or study participation was given to these intermediaries. Recruitment and retention depended heavily on maintaining the motivation of the participants and peer educators. The following approaches were used:

Recruitment

Peer educators routinely visited hotels as part of the BWHC intervention. Condoms were distributed and safe sex education sessions were conducted using games and flipcharts. Peer educators provided women with information about the IHC services and encouraged attendance for routine checkups as well as referral for specific health problems.

In addition to routine recruitment, peer educators met with sex workers in the hotels and explained in-group and individual counselling sessions the purpose and general requirements of the study. Those women interested in participating either made their own way to the STI clinic or were taken by the recruiting peer. On arrival at the STI clinic, counselors screened interested participants, and those eligible and willing were asked to consent and enrolled according to the study protocol.

Women were also recruited during routine visits to the clinic and through word of mouth and 'snowball recruitment' among the sex workers in general.

Retention

Retention procedures for study participants were considerably more intense than for non-participants.

At the first study visit and throughout the study period, peer educators and clinic staff reinforced the need for participants to attend follow-up visits. Participants were provided with a study photo identity card at the second visit and participant transport to the clinic was paid for study visits.

Each peer educator had a list of study participants for whom they were responsible and a diary containing the photo and visit schedule of each so that they could remind them of their visit at the correct time. Peer and outreach workers contacted participants through hotel visits, hotel boys and occasionally by mobile phone.

The study database printed a weekly list of participants overdue for visits and the peer educator responsible for their attendance. To increase peer performance and participant retention in the study, monthly motivational meetings were conducted and financial incentives provided. Participants were provided with gifts on completion of 4, 7 and 10 consecutive visits and were able to access STI services 5 days a week as opposed to twice weekly for non-study participants.

IRB Approval and Consent Procedures

The institutional review board (IRB) approval was obtained from the ethical committees of ICDDR, Bangladesh and UNC-Chapel Hill, USA according to standard operating procedures of those institutions. The screening and consent procedure was carried out in a private counselling room. The study counsellor explained that two interventions were offered and that women would be randomly allocated to receive one of these. It was explained that free monthly STI examinations, STI treatment and counselling would be offered to both groups according to the protocol. It was emphasised that the treatment is only effective for a few specific STIs, and that participation in the program is not a substitute for other preventative measures such as condom use. It was explained that participation is voluntary, that subjects may discontinue participation at any time, and that those subjects who decline or discontinue participation may continue to access the routine services provided through the BWHC clinic. Following counselling on the potential benefits and risks of participation, each interested, eligible woman was asked to sign the informed consent agreement. If a woman was unable to read and/or write the informed consent was read to her and a mark was placed in lieu of a signature.

Description of the Interventions

Routine Intervention Provided to Non-study Participants

As part of a package of interventions, the study sites routinely provided presumptive treatment at the first visit, followed by the ESM intervention, peer education, condom promotion, safe sex counselling and every three months syphilis screening was conducted. The procedures for history, examination, counselling and documentation of the intervention were the same as for the ESM arm of the study, minus the additional questionnaire and specimen collection required for the research. Data from the routine services was entered in the clinic register, stored in a confidential file and later entered onto a spreadsheet.

The Study Interventions

The study interventions and their assessment were delivered in the same way as the routine non-study services except for the following: more intense recruitment and retention procedures; greater access to services; randomisation to different interventions; and additional time spent on interviews and specimen collection.

The PPT Group

Women had a simple history taken and a brief external examination for evidence of vaginal discharge, ulcers and other lesions on the external genitalia. Treatment for clinical symptoms and signs was given according to national syndromic guidelines. Regardless of presenting signs or symptoms, presumptive treatment (PT), with azithromycin 1g, cefixime 400mg and metronidazole 2g, was given at the first visit and repeated thereafter at monthly intervals.

ESM Group

Women received the same intervention as the PPT group at the first visit, followed by monthly clinical care according to the ESM algorithm (Figure 1.) in subsequent visits.

Figure 1
Enhanced Syndromic Management Flow Chart for Diagnosis of Cervicitis and Vaginitis
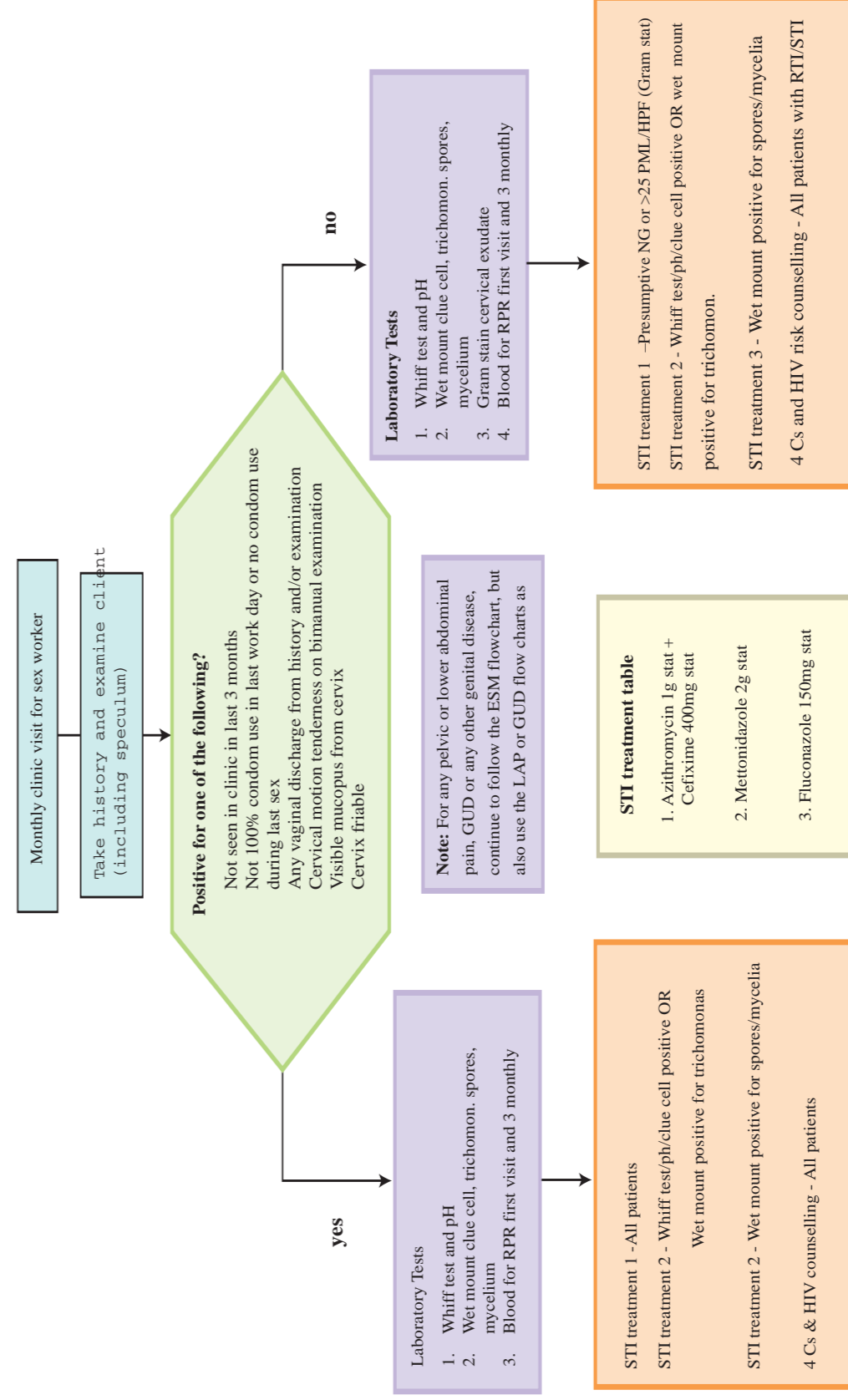
Both Groups

All women were offered counselling on safe sex, compliance, partner notification and condom use. Free male condoms and partner notification cards were provided. RPR testing and TPPA confirmation of positives was performed on the first visit and at three-monthly intervals thereafter. Treatment and follow-up of positive syphilis results and genital ulcer disease syndrome was provided according to national STI guidelines. All symptomatic women, presenting between monthly visits, were treated according to the ESM protocol and these visits were included in the study data. If women reported interim treatment from other sources, this was noted so that they could be excluded from incidence analysis.

Intervention Assessment

Assessment data were collected at the baseline visit and the nine-monthly follow up visits. At each visit, data were collected on demographic, social, behavioral, knowledge, cost, clinical and laboratory characteristics of study participants according to the following intervention assessment schedule below (Figure 2 and Table 3).

An episode of new infection was defined by the presence of etiological agents (*T. vaginalis* by wet mount microscopy and BV by Gram staining and Nugent's scoring), by the presence of DNA of the pathogen (*N. gonorrhoeae* and *C. trachomatis by PCR*) or by sero-conversion and titre change (RPR titre and TPPA for syphilis). Each enrolled subject was evaluated for new infections during visits 1, 2, 3, 9 and 10.

Table 3
Intervention Assessment Schedule

	visit 1 baseline	visit 2 month 1	visit 3 month 2	visit 4 month 3	visit 5 month 4	visit 6 month 5	visit 7 month 6	visit 8 month 7	visit 9 month 8	visit 10 month 9	Additional visits	HIV &RPR Results & FU
Administrative, Behavioural and Regulatory Procedures												
Informed consent	O X											
Randomization	O X											
Study photo ID card	O X											
Enrolment/Exit questionnaire	O X									O X		
Monthly questionnaire	O X	O X	O X	O X	O X	O X	O X	O X	O X	O X	O X	
Name, number and code word in study ledger	O X	O X	O X	O X	O X	O X	O X	O X	O X	O X	O X	[OX]
Name, number and code word in clinic ledger	O X	O X	O X	O X	O X	O X	O X	O X	O X	O X	O X	[OX]
Clinical Procedures												
Clinical history (inlcuded in monthly quest.)	O X	O X	O X	O X	O X	O X	O X	O X	O X	O X	OX	
Genital & pelvic examination with speculum	O X	X	X	X	X	X	X	X	X	X	OX	
External genital examination only		O	O	O	O	O	O	O	O	O		
Vaginal swab (1) KOH/ Nugents/wet mount Vaginal swab	O X	X	X	X	X	X	X	X	X	O X	OX	
(2) (PCR-NG, CT) Vaginal secretion	O X	O X	O X						O X	O X	OX	
(Ph litmus BV)	O X	X	X	X	X	X	X	X	X	O X	OX	
Cervical swab (culture Gram's stain for PML/ICD)	O X	[X]	[X]	[X]	[X]	[X]	[X]	[X]	[X]	[X]	[OX]	
Swab if ulcer is observed (PCR-TP,HSV,HD)	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	
Blood collection	O X	[OX]	[OX]	OX	[OX]	[OX]	OX	[OX]	[OX]	O X	[OX]	[OX]
Provide treatment as per ESM protocol		X	X	X	X	X	X	X	X	X	O X	[OX]
Provide presumptive treatment	O X	O	O	O	O	O	O	O	O	O		
Laboratory Evaluations												
PCR (CT, NG)	O X	O X	O X						O X	O X	OX	
Gram's stain cervical swab (PML/ICD)	O X	[X]	[X]	[X]	[X]	[X]	[X]	[X]	[X]	[X]	[OX]	
Gram's stain (Nugent's score BV)	O X	X	X	X	X	X	X	X	X	O X	OX	
Ph (BV)	O X	X	X	X	X	X	X	X	X	O X	OX	
KOH (BV)	O X	X	X	X	X	X	X	X	X	O X	OX	
Wet mount (BV, CA)	O X	X	X	X	X	X	X	X	X	O X	OX	
Wet mount (TV)	O X	O X	O X						O X	O X	OX	
Multiplex PCR (TP, HSV, HD)	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	
HIV serology	O X										O X	
HIV confirmation		[OX]										[OX]
Syphilis serology (RPR)	O X	[OX]	[OX]	O X	[OX]	[OX]	O X	[OX]	[OX]	O X	[OX]	[OX]
Syphilis serology (TPPA)	OX	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]
Sample Transport and Storage												
Serum	O X	[OX]	[OX]	O X	[OX]	[OX]	O X	[OX]	[OX]	O X	[OX]	[OX]
Vaginal swab (2) PCR-CT,NG	O X	O X	O X	O X	O X	O X	O X	O X	O X	O X		
Dry swab for multiplex PCR	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	[OX]	
Gram's stain Nugent's	O X	[X]	[X]	[X]	[X]	[X]	[X]	[X]	[X]	[X]	O X	[OX]

BV, bacterial vaginosis; NG, gonococcus; CT, *Chlamydia trachomatis;* TP, *Treponema pallidum;* HSV, *Herpes simplex virus;* HD, Haemophilus ducreyi; PCR, polymerase chain reaction; RPR, rapid plasma reagin; TPPA, *Treponemal pallidum particle agglutination*;.; TV, *Trichomonas vaginalis*; PML, polymorphonuclear lymphocytes; ICD, intracellular diplococci

O = PPT group; X = ESM group; [ ] = If clinically indicated; 1 = check local HIV testing practices

Table 4
Methods of Data Collection

Data collected	Method of data collection and tools used
Demographic, social, behavioural, knowledge	An interviewer administered an in-depth questionnaire at visits 1 and 10, with a shorter questionnaire at visits 2-9
Clinical	The PPT group received an external genital examination, the ESM group received a full sexual health examination with speculum. Examination findings were recorded by the examining doctor on a clinical questionnaire.
Laboratory data	
— *Neisseria gonorrhoeae*	Vaginal swab PCR (Roche Amplicor)
— *Chlamydia trachomatis*	Vaginal swab PCR (Roche Amplicor)
— *Trichomonas vaginalis*	Wet mount
— *Bacterial vaginosis*	'Whiff test', Gram's stain Nugent's, pH
— *Candida albicans*	Wet mount
— *Treponema pallidum*	RPR (Becton Dickinson), TPPA (Fuji-Rebio)
PSA assay	PSA was measured using the Abbott Laboratories IMx assay in the UNC laboratory, North Carolina.
Costs	Recurrent costs (fixed and variable) were captured through facility assessment, time flow analyses, analysis of spreadsheets for ordering equipment and consumables, staff salaries, municipal services and project activities. The participant questionnaire also included questions on costs related to health care seeking and illness.

Data Management

Data from the interview, clinical examination, specimen collection, on-site laboratory results and treatment were entered onto the same questionnaire either immediately after collection or after results became available. The questionnaire design closely resembled the non-study participants' questionnaire to minimise mistakes in the busy clinic and make the study intervention and its assessment as close as possible to operational reality. Data from laboratory tests conducted at the ICDDR,B and UNC laboratories were entered into spreadsheets on-site. Data on costs were collected on separate forms and entered onto a spreadsheet.

Participants had consecutive identification codes and retained the same code throughout the study. Coding of answers to the questionnaire was done on the same day as collection by the interviewer and doctor. Supervision of data recording to detect partially filled forms, errors and lost forms was carried out daily by the interviewer and doctor and twice weekly by the study supervisor.

All data were stored in a locked cupboard at the study site and at the ICDDR,B laboratory.

Double entry of data into two separate ACCESS databases was carried out daily by two data entry technicians. Merging of the databases and range and consistency checks were carried out monthly and data was backed up regularly.

Analysis of Biomedical Data

Prevalence: At baseline, STIs prevalence was estimated using standard methods. 95% confidence intervals were estimated with exact methods.

Cumulative incidence: Cumulative incidence over one month and two months was determined for CT and GC, based on infections determined at the one and two month visits. Women were able to contribute only one infection to the cumulative incidence. The cumulative incidence over one month was determined, from month one to month two among those women who were treated at month one. 95% confidence intervals for the cumulative incidence are estimated with exact methods. In estimating the cumulative incidence over two months, if there is substantial loss to follow-up, product limit (Kaplan-Meier), methods were used to estimate the two-month cumulative incidence.

The cumulative incidence over one month in the final month of the study was also determined. Using the information from month eight regarding treatment and infection status, the cumulative incidence over one month at month nine for all women who were treated or were negative at month eight was determined.

Effect of interventions over time: The prevalence of infection at baseline and follow-up was compared in the two intervention groups. To account for the repeated measurements aspect of this comparison, a generalized estimating equation (GEE) with a logit link and binomial distribution was used. The structure of the unadjusted model was:

$$\text{logit}(Y) = \alpha + \beta_1(\text{group}) + \beta_2(\text{time}) + \beta_3(\text{group*time})$$

where group = 0 if PPT and 1 if ESM

time = 0 if baseline and 1 if month 9

group*time = 1 if ESM and month 9, 0 otherwise

With this model, the test of $\beta_1 = 0$ is a test of any baseline differences in prevalence; the test of $\beta_2 = 0$ is a test of any temporal changes in the PPT group; the test of $\beta_3 = 0$ is a test of whether ESM differs from PPT over time. This model could only be evaluated for women who complete follow-up.

Untreated infections: The collection of specimens at months 1, 2, 8 and 9 allowed for the determination of the number and proportion of untreated infections. The PPT group did not have untreated infections. However, the ESM group may have experienced asymptomatic infections that were not identified by the risk assessment. These infections constitute untreated infections, which can be enumerated and expressed as a proportion of all infections (untreated/ (untreated + treated)). The number and proportion of untreated infections could be calculated at each of the four months where testing was conducted.

Retention in the interventions: The success of these interventions required a high rate of retention of the participants. Retention rates are described as the mean (± standard deviation) and median number of visits per group, excluding interim visits. Retention rates were compared using two methods: First, the distributions of the number of visits were compared in a 2x9 contingency Table. The statistical comparison was performed with a Fisher's exact test, because of the possibility of small cell sizes for some cells; Second, A Cox proportional hazards model was used to evaluate the rate of discontinuation in the programs. In this model, individuals contributed person-time through their final visit, which was coded as a failure. Because some women skipped one or more months and then resumed participation, discontinuation was defined for this model as missing 1 or 2 (to be decided) consecutive months.

Analysis of Questionnaire Data

Odds ratios were calculated and multivariate analysis was used to analyse data on symptoms, demography, knowledge, attitudes and practices.

Sensitivity and Specificity of ESM Algorithm

The accuracy of the ESM algorithm for detecting gonococcal and chlamydial infections was assessed. The reference standard was the PCR assays for NG and CT. Performance for NG or CT, NG alone, and CT alone was assessed. At baseline, the sensitivity and specificity (along with stratum-specific likelihood ratios) was determined for the algorithm, compared to the reference standard.

To assess the performance using all available data, the sensitivity and specificity was estimated using generalized estimating equations to account for repeated observations on individuals. These models allow for assessment of any change in performance over time. To assess sensitivity, the following two models were specified:

Among persons with positive PCR:

$logit(Y) = \alpha$

$logit(Y) = \alpha + \beta_1(time1) + \beta_2(time2) + \beta_3(time8) + \beta_4(time9)$

Where Y is the algorithm result. Note that in the first model, $e^{\alpha}/(1+e^{\alpha})$ is the probability of test +. Given the limitation of the population to those with positive PCR, this probability may be expressed as P(T+|D+), which is the sensitivity.

In the second model, the time variables represent a series of indicator variables for each month where specimens were collected. The intercept is used to calculate the sensitivity at baseline and the β represent the deviation from that baseline for each time point.

Similar analyses were conducted for specificity, limiting the population to persons with negative PCR assays.

Analysis of Costs

Program costs were calculated for personnel, outreach, clinic and lab consumables, and drugs. A time per visit analysis was directly observed. Salary costs were current (2007).

Enrollment was completed between February 2005 and December 2005 (Figure 1). Of the 549 women enrolled, 274 were randomly assigned to enhanced syndromic management (ESM) and 275 to periodic presumptive treatment (PPT). In the first two months, there were high rates of enrollment, but as the workload of follow-up visits placed an increasing burden on clinic staff, the intensity of active recruitment was decreased from April to July. This period also coincided with decreased clinic capacity due to clinic renovations and raids by the police on hotel-based sex work, which had the effect of restricting movements of and access to sex workers. In September 2005, enrollment picked up again as the police situation relaxed and additional peer educators were employed for recruitment and retention activities. Again, in order to manage the workload, active recruitment was decreased in October and November and then increased again in December in order to ensure an adequate sample size. In general, there were many women willing to enrol in the study, but care was taken to ensure, as much as was practicable, that women were enrolled only if they planned to stay at least 9 months in the study area

Figure 2
Number of Women Enrolled During each Month of 2005.
Enrollment Began in February and Proceeded through December
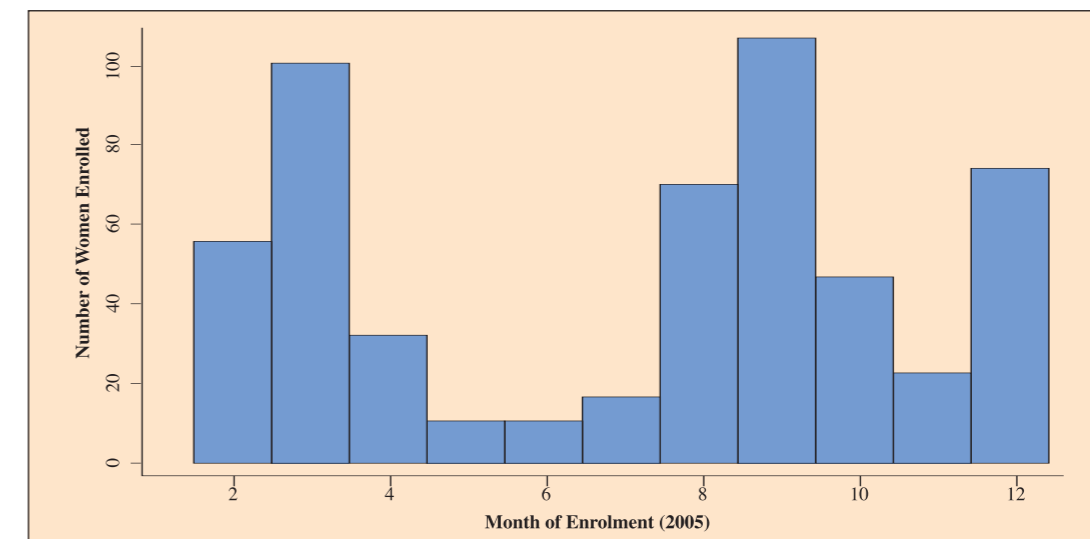
Demographics and Behavior

Key Results

- No differences in demographic and behavioral characteristics between groups
- 60% of women were 20 years of age or less
- 65% had no children and 30% had no formal education
- 66% had sex with 5 or more clients in the last daily session
- Condom use at last sex was reported at only 62%

The Effectiveness and Costs of Two Methods for the Systematic Prevention and Control of STIs, Among Female Sex Workers in Dhaka, Bangladesh

17

- 24% reported home sex work in the last 3 months
- Service and business were the largest source of client vocation; 34% report sex with police
- Injection drug use was very low
- 18% reported physical coercion in previous year

Table 5
Frequencies by Group and by ESM and PPT

Demographic	Overall N	(%)	ESM N	(%)	PPT N	(%)
Age						
≥27	48	(8.7)	24	(8.8)	24	(8.7)
24-26	81	(14.8)	38	(13.9)	43	(15.6)
21-23	88	(16.0)	48	(17.5)	40	(14.5)
18-20	260	(47.4)	130	(47.4)	130	(47.3)
≥17	72	(13.1)	34	(12.4)	38	(13.8)
Number of Children						
4	2	(0.4)	1	(0.4)	1	(0.4)
3	11	(2.0)	5	(1.8)	6	(2.2)
2	46	(8.4)	24	(8.8)	22	(8.0)
1	145	(26.4)	77	(28.1)	68	(24.7)
0	345	(62.8)	167	(60.9)	178	(64.7)
Education (yrs)						
≥ 6	189	(34.4)	89	(32.5)	100	(36.4)
1-5	194	(35.3)	102	(37.2)	92	(33.5)
None	166	(30.2)	83	(30.3)	83	(30.2)
Marital Status						
Divorced/Widowed/Separated	169	(30.8)	81	(29.6)	88	(32.0)
Married	210	(38.3)	110	(40.1)	100	(36.4)
Single	170	(31.0)	83	(30.3)	87	(31.6)
Clients Last Session						
>10	111	(20.2)	62	(22.6)	49	(17.8)
7-10	150	(27.3)	75	(27.4)	75	(27.3)
5-6	104	(18.9)	53	(19.3)	51	(18.5)
3-4	91	(16.6)	39	(14.2)	52	(18.9)
0-2	93	(16.9)	45	(16.4)	48	(17.5)

Behavioral	Overall N	(%)	ESM N	(%)	PPT N	(%)
Condom Use - Last Sex						
Yes	340	(62.2)	171	(62.6)	169	(61.7)
No	207	(37.8)	102	(37.4)	105	(38.3)
Home Sex Work - 3 months						
Yes	133	(24.2)	65	(23.7)	68	(24.7)
No	416	(75.8)	209	(76.3)	207	(75.3)
Guesthouse Sex Work - 3 months						
Yes	45	(8.2)	22	(8.0)	23	(8.4)
No	504	(91.8)	252	(92.0)	252	(91.6)
Student Clients						
Yes	263	(47.9)	129	(47.1)	134	(48.7)
No	286	(52.1)	145	(52.9)	141	(51.3)
Rickshaw Clients						
Yes	25	(4.6)	15	(5.5)	10	(3.6)
No	524	(95.4)	259	(94.5)	265	(96.4)
Police Clients						
Yes	190	(34.7)	96	(35.2)	94	(34.2)
No	358	(65.3)	177	(64.8)	181	(65.8)
Service Clients						
Yes	443	(80.7)	221	(80.7)	222	(80.7)
No	106	(19.3)	53	(19.3)	53	(19.3)
Business Clients						
Yes	474	(86.3)	237	(86.5)	237	(86.2)
No	75	(13.7)	37	(13.5)	38	(13.8)
Day Labor Clients						
Yes	27	(4.9)	10	(3.6)	17	(6.2)
No	522	(95.1)	264	(96.4)	258	(93.8)
Driver Clients						
Yes	146	(26.6)	72	(26.3)	74	(26.9)
No	403	(73.4)	202	(73.7)	201	(73.1)
Unemployed Clients						
Yes	43	(7.8)	24	(8.8)	19	(6.9)
No	506	(92.2)	250	(91.2)	256	(93.1)
Injected Drugs - Ever						
Yes	4	(0.7)	4	(1.5)	0	(0.0)
No	544	(99.3)	269	(98.5)	275	(100.0)
Physical Coercion - Last Year						
Yes	93	(16.9)	43	(15.7)	50	(18.2)
No	456	(83.1)	231	(84.3)	225	(81.8)
Non-physical Coercion - Last year						
Yes	76	(13.8)	35	(12.8)	41	(14.9)
No	473	(86.2)	239	(87.2)	234	(85.1)

Sex Work at Baseline

In order to ascertain levels of risk, data were collected on the duration of sex work, the number of sessions per week, and the number of clients and unprotected sex acts per session. Income comprises a portion of the clients' payment, passed to the women by the hotel boy, plus tips, given directly to the women by the clients.

Key Results

- There were no differences in income or sexual risk behavior between groups
- Average duration of sex work is 22 months (less than 2 years)
- Average 3 sessions per week
- Average 7 clients per session (= an average of 21+ clients per week)
- Average reported condom use is 75% of acts
- Average total income per session is 718 BDT (~$10 per 7 clients)

Table 6
Sex Work Characteristics at Baseline

	Overall		ESM		PPT	
	Mean ±	SD	Mean ±	SD	Mean ±	SD
Sex Work Duration (months)	22 ±	33.1	24.6 ±	40.7	20.3 ±	22.3
Number of Sessions - Last Week	3.2 ±	1.7	3.1 ±	1.7	3.2 ±	1.6
Clients in Last Session	7.4 ±	5.6	7.6 ±	5.7	7.0 ±	5.7
Sex Episodes - Last Session	8.0 ±	5.9	8.3 ±	5.9	7.6 ±	6.1
Condom Use - Last Session	6.0 ±	5.2	6.1 ±	5.3	5.8 ±	5.2
Percentage Condom Use - Last Session	0.753 ±	0.325	0.734 ±	0.338	0.764 ±	0.319
Pay in Last Session (BDT)	602.8 ±	475.2	620.1 ±	472.7	583.1 ±	495.2
Pay last week - maximum	870.9 ±	576.9	894.5 ±	605.9	836.3 ±	558.9
Pay last week - minimum	429.7 ±	408.1	453.1 ±	412.7	404.6 ±	413.9
Tips in Last Session	115.4 ±	187.9	136.2 ±	210	90.6 ±	158.2
Tips last week - maximum	190.1 ±	226.9	200.9 ±	242.5	176.0 ±	212.2
Tips last week - minimum	58.2 ±	148.3	65.8 ±	166.5	46.1 ±	120.8
Total Income Last Session	718.3 ±	551.1	756.3 ±	562	673.7 ±	549.1

Health Values at Baseline

It is important to involve sex workers in the design of targeted STI services in order to promote access and acceptability. For this reason, information on women's previous experiences of sexual health services with regard to treatment for an STI or a pelvic exam was collected. Additional aspects of valued STI service delivery (defined as any sexual health examination) included respectful treatment by staff, assurances of confidentiality with regard to identity and diagnosis, free service package (including condoms, exam, drugs, tests) and low waiting times.

Key Results

- There were no differences between groups
- Over half of women (57%) had previous experience of pelvic examination
- The most important values at baseline were getting an STI check up and confidentiality
- Almost none of the women objected to waiting for services

Table 7
Values and Opinions Regarding STI Care at Baseline

	Overall N	(%)	ESM N	(%)	PPT N	(%)
STI Treatment - Ever						
Yes	339	(61.7)	170	(62.0)	169	(61.5)
No	210	(38.3)	104	(38.0)	106	(38.5)
Pelvic Exam - Ever						
Yes	315	(57.6)	155	(57.0)	160	(58.2)
No	232	(42.4)	117	(43.0)	115	(41.8)
STI Check - Important						
Yes	542	(99.1)	270	(99.3)	272	(98.9)
No	5	(0.9)	2	(0.7)	3	(1.1)
Value-Respect						
Yes	95	(17.3)	56	(20.5)	39	(14.2)
No	453	(82.7)	217	(79.5)	236	(85.8)
Value-Physician's Experience						
Yes	250	(45.6)	126	(46.2)	124	(45.1)
No	298	(54.4)	147	(53.8)	151	(54.9)
Value-Clean Environment						
Yes	113	(20.6)	51	(18.7)	62	(22.5)
No	435	(79.4)	222	(81.3)	213	(77.5)
Value-Low Cost						
Yes	78	(14.2)	34	(12.5)	44	(16.0)
No	470	(85.8)	239	(87.5)	231	(84.0)
Value-Higher Cost						
Yes	20	(3.6)	15	(5.5)	5	(1.8)
No	528	(96.4)	258	(94.5)	270	(98.2)
Value-Free Treatment						
Yes	130	(23.7)	69	(25.3)	61	(22.2)
No	418	(76.3)	204	(74.7)	214	(77.8)
Value-No Waiting						
Yes	1	(0.2)	0	(0.0)	1	(0.4)
No	547	(99.8)	273	(100.0)	274	(99.6)
Value-Confidentiality						
Yes	427	(77.9)	218	(79.9)	209	(76.0)
No	121	(22.1)	55	(20.1)	66	(24.0)

HIV and STI Knowledge at Baseline

Both study interventions were delivered as part of a package utilising peer educators to promote condoms, give safe sex education, and encourage behavior change interventions and to facilitate clinic visits. In order to assess any changes in knowledge between groups and over time, women were asked about knowledge of HIV transmission and STI symptoms at baseline and visit 10.

Key Results at Baseline

- Essentially all had heard of AIDS and 95% agreed that condoms were protective for HIV infection
- 20% didn't know to avoid anal sex
- 11% thought you could identify an HIV-infected person by the way they looked
- 49% thought HIV could be transmitted by mosquito bite
- 98% knew that HIV could be transmitted through sharing needles
- Without prompting, very few of the women identified many genital symptoms as being related to an STI: vaginal discharge and itching, were volunteered by < 50%
- When prompted, most could identify most symptoms of STIs

Table 8
HIV and STI Knowledge at Baseline

	Overall N	(%)	ESM N	(%)	N	PPT (%)
Heard of AIDS						
Don't Know	0	(0.0)	0	(0.0)	0	(0.0)
Yes	548	(99.8)	273	(99.6)	275	(100.0)
No	1	(0.2)	1	(0.4)	0	(0.0)
Condom Use						
Don't Know	3	(0.5)	2	(0.7)	1	(0.4)
True	522	(95.3)	259	(94.9)	263	(95.6)
False	23	(4.2)	12	(4.4)	11	(4.0)
Avoid Anal Sex						
Don't Know	109	(19.9)	56	(20.5)	53	(19.3)
True	400	(73.0)	200	(73.3)	200	(72.7)
False	39	(7.1)	17	(6.2)	22	(8.0)
Anal Condom Use						
Don't Know	99	(18.1)	49	(17.9)	50	(18.2)
True	413	(75.4)	205	(75.1)	208	(75.6)
False	36	(6.6)	19	(7.0)	17	(6.2)
Mosquito Bite						
Don't Know	63	(11.5)	30	(11.0)	33	(12.0)
True	271	(49.5)	140	(51.3)	131	(47.6)
False	214	(39.1)	103	(37.7)	111	(40.4)

HIV and STI Symptom Knowledge at Baseline

	Overall N	(%)	ESM N	(%)	N	PPT (%)
Sharing Meal						
Don't Know	19	(3.5)	9	(3.3)	10	(3.6)
True	201	(36.7)	96	(35.2)	105	(38.2)
False	328	(59.9)	168	(61.5)	160	(58.2)
Sharing Needles						
Don't Know	2	(0.4)	2	(0.7)	0	(0.0)
True	533	(97.3)	267	(97.8)	266	(96.7)
False	13	(2.4)	4	(1.5)	9	(3.3)
HIV by looking at them						
Don't Know	9	(1.6)	3	(1.1)	6	(2.2)
True	62	(11.3)	37	(13.6)	25	(9.1)
False	477	(87.0)	233	(85.3)	244	(88.7)

Table 9
HIV and STI Knowledge at Baseline – Symptom Knowledge - Volunteered

	Overall N	(%)	ESM N	(%)	N	PPT (%)
Symptom Knowledge - Volunteered						
Vaginal D/C						
Yes	264	(48.1)	136	(49.6)	128	(46.5)
No	285	(51.9)	138	(50.4)	147	(53.5)
Odour						
Yes	121	(22.0)	56	(20.4)	65	(23.6)
No	428	(78.0)	218	(79.6)	210	(76.4)
Itching						
Yes	246	(44.8)	128	(46.7)	118	(42.9)
No	303	(55.2)	146	(53.3)	157	(57.1)
Ulcers						
Yes	154	(28.1)	76	(27.7)	78	(28.4)
No	395	(71.9)	198	(72.3)	197	(71.6)
Warts						
Yes	76	(13.8)	39	(14.2)	37	(13.5)
No	473	(86.2)	235	(85.8)	238	(86.5)
Dyspareunia						
Yes	128	(23.3)	69	(25.2)	59	(21.5)
No	421	(76.7)	205	(74.8)	216	(78.5)
Lower Abdominal Pain						
Yes	97	(17.7)	55	(20.1)	42	(15.3)
No	452	(82.3)	219	(79.9)	233	(84.7)

Table 10
HIV and STI Knowledge at Baseline – Symptom Knowledge - Prompted

	Overall N	(%)	ESM N	(%)	N	PPT (%)
Symptom Knowledge - Prompted						
Vaginal D/C						
Don't Know	2	(0.4)	0	(0.0)	2	(0.7)
Yes	500	(91.1)	251	(91.6)	249	(90.5)
No	47	(8.6)	23	(8.4)	24	(8.7)
Odor						
Don't Know	6	(1.1)	3	(1.1)	3	(1.1)
Yes	513	(93.4)	261	(95.3)	252	(91.6)
No	30	(5.5)	10	(3.6)	20	(7.3)
Itching						
Don't Know	2	(0.4)	1	(0.4)	1	(0.4)
Yes	535	(97.4)	269	(98.2)	266	(96.7)
No	12	(2.2)	4	(1.5)	8	(2.9)
Ulcer						
Don't Know	6	(1.1)	3	(1.1)	3	(1.1)
Yes	524	(95.4)	262	(95.6)	262	(95.3)
No	19	(3.5)	9	(3.3)	10	(3.6)
Warts						
Don't Know	20	(3.6)	9	(3.3)	11	(4.0)
Yes	491	(89.4)	243	(88.7)	248	(90.2)
No	38	(6.9)	22	(8.0)	16	(5.8)
Dyspareunia						
Don't Know	10	(1.8)	3	(1.1)	7	(2.5)
Yes	510	(92.9)	256	(93.4)	254	(92.4)
No	29	(5.3)	15	(5.5)	14	(5.1)
Lower Abdominal Pain						
Don't Know	12	(2.2)	6	(2.2)	6	(2.2)
Yes	510	(93.1)	252	(92.3)	258	(93.8)
No	26	(4.7)	15	(5.5)	11	(4.0)

Self-Risk Assessment at Baseline

An important pre-requisite to changes in risk and health care seeking behavior is an individual's recognition of their own risk status and health needs. This was assessed at baseline and visit 10.

Key Results at Baseline

- 80% of women assessed their risk of sexual infection as high
- Reasons identified for high risk assessment were high-risk job and not using condoms
- Reason identified for low risk assessment was using condoms

Table 11
Self Risk Assessment and Actions to Reduce Risk at Baseline

	Overall N	(%)	ESM N	(%)	N	PPT (%)
Self Risk Assessment						
High	437	(79.7)	215	(78.8)	222	(80.7)
Some	76	(13.9)	38	(13.9)	38	(13.8)
Low	35	(6.4)	20	(7.3)	15	(5.5)
Among High and Some Risk Women – Reasons for High Risk						
High-Risk Job						
Yes	252	(49.1)	120	(47.4)	132	(50.8)
No	261	(50.9)	133	(52.6)	128	(49.2)
Frequent Anal Sex						
Yes	1	(0.2)	1	(0.4)	0	(0.0)
No	512	(99.8)	252	(99.6)	260	(100.0)
No Condom Use						
Yes	337	(65.7)	176	(69.6)	161	(61.9)
No	176	(34.3)	77	(30.4)	99	(38.1)
Share Needles						
Yes	0	(0.0)	0	(0.0)	0	(0.0)
No	513	(100.0)	253	(100.0)	260	(100.0)
Among Low-Risk Women – Reasons for Low Risk						
Use Condoms						
Yes	30	(85.7)	18	(90.0)	12	(80.0)
No	5	(14.3)	2	(10.0)	3	(20.0)
Have Clean Partners						
Yes	5	(14.3)	4	(20.0)	1	(6.7)
No	30	(85.7)	16	(80.0)	14	(93.3)
No Sex with Foreigners						
Yes	0	(0.0)	0	(0.0)	0	(0.0)
No	35	(100.0)	20	(100.0)	15	(100.0)
Treated in the Study						
Yes	0	(0.0)	0	(0.0)	0	(0.0)
No	35	(100.0)	20	(100.0)	15	(100.0)
Actions to Reduce Risk						
No Actions						
Yes	70	(12.8)	31	(11.3)	39	(14.2)
No	479	(87.2)	243	(88.7)	236	(85.8)
Wash with Savlon						
Yes	103	(21.5)	56	(23.0)	47	(19.9)
No	376	(78.5)	187	(77.0)	189	(80.1)
Wash with Urine						
Yes	119	(24.9)	67	(27.6)	52	(22.1)
No	359	(75.1)	176	(72.4)	183	(77.9)
Use Condoms						
Yes	448	(93.5)	226	(93.0)	222	(94.1)
No	31	(6.5)	17	(7.0)	14	(5.9)

STIs at Baseline

On the first visit, all women received a full sexual health history and examination including inspection for genital herpes, warts, lice and scabies. Bedside laboratory tests such as cervical swab Gram's stain (presumptive cervicitis), wet mount (TV, CA), pH, 'Whiff' test (Nugent criteria for BV), RPR and TPPA (syphilis) were provided on-site. Women received their results on the same day. PCR for NG and CT were done at the STI laboratory of ICDDR,B. Tables 6 and 7 describe infections and symptoms detected at baseline.

Key Results at Baseline

- The two groups were similar at baseline
- Prevalence of STIs was remarkably high at baseline
- Over 41% of women had either CT or NG. The prevalence of NG was 31.7% and CT 26.6%
- Bacterial vaginosis was exceedingly common (67%)
- Syphilis and trichomoniasis were identified in 3% each.
- Symptoms were common at baseline
- Vaginal symptoms (discharge and odour) predominated
- 44% complained of dyspareunia and 24% lower abdominal pain

Table 12
Baseline Prevalence of Sexually Transmitted and Reproductive Tract Infections (N=549)

	Overall N Pos	Prev	Group	N Pos	Prev	RR	(95 % CI)	p-value
Ct or GC	227	0.413	ESM	111	0.405	0.96	(0.8 - 1.2)	0.691
			PPT	116	0.422	Ref		
Ct	146	0.266	ESM	73	0.266	1.00	(0.8 - 1.3)	0.980
			PPT	73	0.265	Ref		
GC	174	0.317	ESM	80	0.292	0.85	(0.7 - 1.1)	0.209
			PPT	94	0.342	Ref		
Other STIs								
BV	366	0.667	ESM	151	0.64	0.9	(0.8 - 1.0)	0.118
			PPT	169	0.707	Ref		
Tv	16	0.029	ESM	6	0.025	0.8	(0.3 - 2.2)	0.604
			PPT	8	0.033	Ref		
Candida (dx)	81	0.148	ESM	34	0.144	1.0	(0.6 - 1.5)	0.941
			PPT	35	0.146	Ref		
Candida (wet)	76	0.138	ESM	33	0.14	1.0	(0.7 - 1.6)	0.851
			PPT	32	0.134	Ref		
RPR	22	0.04	ESM	10	0.042	1.3	(0.5 - 3.2)	0.612
			PPT	8	0.033	Ref		

	Overall N Pos	Prev	Group	N Pos	Prev	RR	(95 % CI)	p-value
Syphilis	18	0.033	ESM	7	0.03	1.0	(0.4 - 2.8)	0.981
			PPT	7	0.029	Ref		
Herpes	0	0	ESM	0	0	.	. .	.
			PPT	0	0	Ref		
Warts	40	0.073	ESM	14	0.059	0.7	(0.4 - 1.4)	0.303
			PPT	20	0.084	Ref		
PID	14	0.026	ESM	10	0.042	2.5	(0.8 - 8.0)	0.099
			PPT	4	0.017	Ref		
Scabies	4	0.007	ESM	2	0.008	1.0	(0.1 - 7.1)	0.990
			PPT	2	0.008	Ref		

Symptoms at Baseline

Table 13
Symptoms at Baseline

	Overall N	(%)	ESM N	(%)	PPT N	(%)
Vaginal D/C						
Present	226	(41.2)	115	(42.0)	111	(40.4)
Absent	323	(58.8)	159	(58.0)	164	(59.6)
Vaginal Odour						
Present	119	(53.1)	62	(54.9)	57	(51.4)
Absent	105	(46.9)	51	(45.1)	54	(48.6)
Genital Ulcer						
Present	23	(4.2)	6	(2.2)	17	(6.3)
Absent	522	(95.8)	267	(97.8)	255	(93.8)
Genital Warts						
Present	66	(12.2)	28	(10.3)	38	(14.1)
Absent	477	(87.8)	245	(89.7)	232	(85.9)
Dyspareunia						
Present	245	(44.6)	122	(44.5)	123	(44.7)
Absent	304	(55.4)	152	(55.5)	152	(55.3)
Lower Abdominal Pain						
Present	135	(24.6)	66	(24.1)	69	(25.1)
Absent	414	(75.4)	208	(75.9)	206	(74.9)

Study Retention Over 9 Months

Retention is key to a successful program of treatment for the women. Efforts were made to find out reasons for leaving the program. The main reason given was that women had moved out of the study area, with two women missing visits due to being imprisoned.

Key Results

- No retention difference between groups

- Mean number of visits ~6 out of a possible 10 visits

- Mean number of days retained in the study ~180 out of a possible 270 days

- Increasing retention with increasing age (mean number visits for ages 17 and under= 4.9 compared to 7.6 for ages 27 and over)

- Most of the loss is between the initial visit and the first follow-up, followed by the second and third (Table 9)

- Women who remained in the study by visit 5 tended to stay in for the rest of the study

- Overall there was a 55% loss to follow-up

Table 14
Study Retention by Group and Age

	Overall N	Mean	±	SD	ESM Mean	±	SD	PPT Mean	±	SD	p-value
Number of Visits	549	5.9	±	3.3	5.7	±	3.3	6	±	3.3	0.276
Follow-up Duration (days)	549	176.7	±	108.4	174.7	±	109.1	178.8	±	107.8	0.657

By age

	N	Mean	±	SD	p-value
Number of Visits					
Age = 17	72	4.9	±	3.0	
18-20	260	5.7	±	3.3	0.396
21-23	88	5.2	±	3.5	0.991
24-26	81	7.0	±	3.2	0.004
≥ 27	48	7.6	±	3.0	0.002
Follow-up Duration (days)					
Age = 17	72	158.2	±	114.4	
18-20	260	170.3	±	107.8	0.061
21-23	88	158.4	±	117.5	0.509
24-26	81	207.7	±	94.2	0.000
≥ 27	48	220.4	±	86.1	0.000
*p-values for age from linear regression					

Table 15
Retention in the Study by Visit – Number of Women and Percent of Cohort Retained

Visit	Overall N	(%)	PPT N	(%)	ESM N	(%)
1	549	(100.0)	275	(100.0)	274	(100.0)
2	411	(74.9)	202	(73.5)	209	(76.3)
3	340	(61.9)	176	(64.0)	164	(59.9)
4	316	(57.6)	163	(59.3)	153	(55.8)
5	290	(52.8)	155	(56.4)	135	(49.3)
6	294	(53.6)	152	(55.3)	142	(51.8)
7	275	(50.1)	142	(51.6)	133	(48.5)
8	249	(45.4)	135	(49.1)	114	(41.6)
9	241	(43.9)	125	(45.5)	116	(42.3)
10	252	(45.9)	129	(46.9)	123	(44.9)

Changes in Sex Work Activity, Knowledge and Behavior

The effect of each intervention on sexual risk behavior, knowledge and perceived self-risk was assessed at baseline and visit 10 by asking about the number of clients per week, numbers of clients who used a condom in the last session, knowledge of HIV transmission and STI symptoms/signs, and episodes of sexual coercion. Changes in pay were also noted in order to assess whether changes in risk behavior affected income.

Key Results

- There were no important differences between groups

- Significant reduction of weekly sessions (3.3 to 2.5) and hence clients (22.1 to 17) per week.

- The self-reported number of clients using condoms in the last session decreased from visit 1: 5.3 (72%) to visit 10: 4.3 (55%).

- Total income remained the same

- Women reporting experiencing coercion decreased from 11.9% to 2.4% (Table 11)

- Improved knowledge in HIV transmission, fewer thought you could recognize an HIV-infected person by how they looked

- Improved knowledge in recognizing STI symptoms

- Perception of being at high risk decreased over time from 82% to 52%

Table 16
Changes in Sex Work Activity During Study Participation**

	Overall Visit 1	Visit 10	p-value	PPT Visit 1	Visit 10	ESM Visit 1	Visit 10	p-value
Number of Sessions - Last Week	3.3	2.5	0.000	3.4	2.6	3.2	2.5	0.798
Clients in Last Session	6.7	6.8	0.790	6.5	7.3	6.9	6.2	0.060
Sex Episodes - Last Session	7.3	7.3	0.970	7.2	7.7	7.5	6.9	0.166
Condom Use - Last Session	5.3	4.3	0.004	5.3	4.4	5.3	4.2	0.750
Percentage Condom Use - Last Session	0.721	0.545	0.000	0.749	0.525	0.692	0.565	0.100
Pay in Last Session (BDT)*	550.4	566.7	0.655	544.4	578.7	556.6	554.2	0.617
Pay last week - maximum	809.4	749.4	0.116	817.4	754.4	801.1	744.2	0.937
Pay last week - minimum	381.8	407.9	0.353	358.4	408.5	406.4	407.3	0.380
Tips in Last Session	109.5	129.1	0.319	91.4	129.8	128.6	128.5	0.328
Tips last week - maximum	177.8	146.6	0.079	172.5	146.5	183.4	146.7	0.763
Tips last week - minimum	52.6	54.5	0.893	51.0	61.8	54.3	46.8	0.505
Total Income Last Session	659.9	695.9	0.393	635.8	708.4	685.1	682.6	0.371
*BDT=Bangladesh Taka								

**Comparisons limited to those with both visit 1 and visit 10. Overall visit 1 means differ from means in Tables in baseline section above because these means are limited to those with both visit 1 and visit 10

Table 17
Changes in Risk Behavior and Knowledge Regarding HIV and Sti's During Study Participation

Overall Percent Visit 1	Visit 10	p-value	PPT Percent Visit 1	Visit 10	ESM Percent Visit 1	Visit 10	p-value
Condom Use - Last Sex	59.9	54.0	0.118	62.8	54.3	56.9	53.7	0.488
Physical Coercion - Last Year	11.9	2.4	0.000	13.2	2.3	10.6	2.4	0.514
Non-Physical Coercion - Last Year	10.3	2.4	0.000	11.6	2.3	8.9	2.4	0.475
HIV Transmission Knowledge								
Condom (True)	96.0	98.8	0.033	95.3	98.4	96.7	99.2	0.800
Mosquito (False)	55.3	21.5	0.000	51.7	22.0	59.4	20.8	0.251
Sharing Meals (False)	36.1	14.9	0.000	34.4	17.6	37.9	12.1	0.178
Injecting Drugs (True)	97.2	97.2	1.000	95.3	96.9	99.2	97.5	0.279
Tell by Looking (False)	9.8	4.9	0.022	8.0	3.2	11.7	6.7	0.963
STI Symptom Knowledge								
Vaginal Discharge	49.6	63.9	0.000	48.1	66.7	51.2	61.0	0.240
Odor	21.4	33.3	0.001	25.6	32.6	17.1	34.1	0.149
Itching	48.0	81.3	0.000	40.3	83.7	56.1	78.9	0.006
Ulcer	27.4	61.5	0.000	24.0	58.1	30.9	65.0	0.996
Warts	11.1	41.3	0.000	7.8	43.4	14.6	39.0	0.106
Dyspareunia	22.6	26.2	0.304	21.7	28.7	23.6	23.6	0.315
Lower Abdominal Pain	19.8	25.8	0.094	15.5	25.6	24.4	26.0	0.234
Perceived Self Risk*								
Low	5.6	20.2	0.000					
Moderate	11.9	27.4						
High	82.5	52.4						
*Note: Comparison across groups with perceived self risk is statistically difficult								

STI Prevalence and Incidence Changes Over the Course of the Follow-up Period

As noted above, prevalence was extremely high at baseline for CT, NG and CT/NG combined (41%).

Key Results

- The groups did not differ in prevalence or incidence and there were no major differences between the two groups over time (because of extreme risk (score) 99% of women in the ESM group were treated each month).

- Incidence over the first two months was high, but significantly reduced after each month of treatment:

    - Cumulative incidence over the first month for CT or NG was approximately 20%

    - Cumulative incidence over the second month for CT or NG was approximately 14%

- Prevalence of CT or NG after 8 months (i.e. visit 9) decreased to 15-18% (Note: This is referred to as prevalence because although women received treatment, STIs were not measured between visit 3 and visit 9)

- The cumulative incidence over the last month of the study, representing the burden of CT and NG at the end of the 9 month follow-up period was significantly decreased to ~7%

- Between visit one and visit nine, the combined groups experienced a relative reduction in prevalence of 60% for CT or NG (Table 13)

- Between visit two and visit ten , the combined groups experienced a relative reduction in 1 month incidence of CT or NG of 65% (Table 13)

- Between visit one and visit 10 CT and GC were reduced from 41% to 7%. An 83% reduction

- A clear increase in prevalence was seen at visit 9 with increasing time since the previous visit (Table 13)

- The longer between treatment intervals (visits), the higher the prevalence. Rates roughly doubled for each monthly visit missed

- Except for BV, other STIs and reproductive tract infections were diagnosed infrequently (Table 15)

- There was no significant reduction in BV despite regular treatment with metronidazole

- Substantial reduction in vaginal discharge (40% to 16%), dyspareunia (42% to 15%) and lower abdominal pain (26% to 11%) comparing baseline presentations with presentations at the end of the follow-up period (Table 16)

The Effectiveness and Costs of Two Methods for the Systematic Prevention and Control of STIs, Among Female Sex Workers in Dhaka, Bangladesh

Table 18
Prevalence and one Month Cumulative Incidence (risk) of Chlamydia (ct),
Gonorrhea (gc), and Either Infection (ct Or Gc) by Treatment Group

Ct or GC		N Inf	Prev	PR	(95 %	CI)	p-value
Visit 1	ESM	111	0.405	0.96	(0.8 -	1.2)	0.691
	PPT	116	0.422	Ref			
Visit 9	ESM	21	0.154	0.84	(0.5 -	1.4)	0.506
	PPT	26	0.184	Ref			
		N Inf	Cum Inc	RR	(95 %	CI)	p-value
Visit 2	ESM	41	0.203	0.92	(0.6 -	1.4)	0.676
	PPT	44	0.220	Ref			
Visit 3	ESM	18	0.133	0.91	(0.5 -	1.6)	0.764
	PPT	21	0.146	Ref			
Visit 10	ESM	7	0.074	1.08	(0.4 -	3.0)	0.875
	PPT	7	0.068	Ref			
Ct		N Inf	Prev	PR	(95 %	CI)	p-value
Visit 1	ESM	73	0.266	1.00	(0.8 -	1.3)	0.980
	PPT	73	0.265	Ref			
Visit 9	ESM	12	0.088	0.83	(0.4 -	1.7)	0.611
	PPT	15	0.106	Ref			
		N Inf	Cum Inc	RR	(95 %	CI)	p-value
Visit 2	ESM	17	0.084	0.94	(0.5 -	1.8)	0.836
	PPT	18	0.090	Ref			
Visit 3	ESM	8	0.059	1.22	(0.5 -	3.3)	0.694
	PPT	7	0.049	Ref			
Visit 10	ESM	3	0.032	1.63	(0.3 -	9.5)	0.586
	PPT	2	0.019	Ref			
GC		N Inf	Prev	PR	(95 %	CI)	p-value
Visit 1	ESM	80	0.292	0.85	(0.7 -	1.1)	0.209
	PPT	94	0.342	Ref			
Visit 9	ESM	12	0.088	0.78	(0.4 -	1.6)	0.486
	PPT	16	0.113	Ref			
		N Inf	Cum Inc	RR	(95 %	CI)	p-value
Visit 2	ESM	32	0.158	1.02	(0.7 -	1.6)	0.925
	PPT	31	0.155	Ref			
Visit 3	ESM	12	0.089	0.91	(0.4 -	1.9)	0.811
	PPT	14	0.097	Ref			
Visit 10	ESM	6	0.063	1.08	(0.4 -	3.3)	0.885
	PPT	6	0.058	Ref			

Table 19
Change in Prevalence and Cumulative Incidence
Over the Course of the Study

Ct or GC	PR	(95%	CI)	p-value
Visit 1	1.00	---		
Visit 9	0.40	(0.31 -	0.53)	0.000
Ct				
Visit 1	1.00	---		
Visit 9	0.37	(0.25 -	0.54)	0.000
GC				
Visit 1	1.00	---		
Visit 9	0.31	(0.22 -	0.45)	0.000
Cumulative Incidence				
Ct or GC	RR	(95%	CI)	p-value
Visit 2	1.00	---		
Visit 3	0.66	(0.47 -	0.92)	0.014
Visit 10	0.35	(0.21 -	0.58)	0.000
Ct				
Visit 2	1.00	---		
Visit 3	0.63	(0.36 -	1.10)	0.102
Visit 10	0.29	(0.12 -	0.72)	0.007
GC				
Visit 2	1.00	---		
Visit 3	0.59	(0.39 -	0.88)	0.011
Visit 10	0.40	(0.23 -	0.70)	0.001

Table 20
Time Since Previous Visit and Infection Status at Visit 9

	Time Since Last Visit (days)	Prev	PR	(95%	CI)	p-value
Ct or GC						
	≥ 69	0.368	3.5	(1.9 -	6.4)	0.000
	38-68	0.224	2.1	(1.2 -	4.0)	0.016
	0-37	0.105	Ref			
Ct						
	≥ 69	0.263	5.7	(2.4 -	13.4)	0.000
	38-68	0.134	2.9	(1.2 -	7.2)	0.018
	0-37	0.047	Ref			
GC						
	≥ 69	0.184	2.4	(1.0 -	5.7)	0.039
	38-68	0.119	1.6	(0.7 -	3.6)	0.282
	0-37	0.076	Ref			

The Effectiveness and Costs of Two Methods for the Systematic Prevention and Control of STIs, Among Female Sex Workers in Dhaka, Bangladesh

Table 21
Prevalence of Other STIs and Reproductive Tract Infections at Baseline (visit 1) and Follow-up (Visit 10)

		VISIT 1 N Infected	Prev	PR	(95% CI)	p-value	VISIT 10 N Infected	Prev	PR	(95% CI)	p-value
BV	ESM	173	0.631	0.90	(0.80 - 1.01)	0.080	67	0.545	0.99	(0.79 - 1.24)	0.928
	PPT	193	0.702	Ref			71	0.550	Ref		
Tv	ESM	8	0.029	1.00	(0.38 - 2.64)	0.994	0	0	0.00	----	0.089
	PPT	8	0.029	Ref			3	0.023	Ref		
Candida (dx)	ESM	40	0.146	0.98	(0.65 - 1.46)	0.918	31	0.252	1.02	(0.66 - 1.56)	0.942
	PPT	41	0.149	Ref			32	0.248	Ref		
Candida (wet)	ESM	38	0.139	1.00	(0.66 - 1.52)	0.986	30	0.244	0.98	(0.64 - 1.52)	0.939
	PPT	38	0.138	Ref			32	0.248	Ref		
RPR	ESM	12	0.044	1.20	(0.53 - 2.74)	0.657	7	0.057	1.85	(0.56 - 6.16)	0.308
	PPT	10	0.036	Ref			4	0.031	Ref		
Syphilis	ESM	9	0.033	1.00	(0.40 - 2.49)	0.994	7	0.057	2.47	(0.65 - 9.33)	0.167
	PPT	9	0.033	Ref			3	0.023	Ref		
Herpes	ESM	0	0	----	----	----	0	0	----	----	----
	PPT	0	0	Ref			0	0	Ref		
Warts	ESM	16	0.058	0.67	(0.36 - 1.23)	0.193	6	0.049	0.90	(0.31 - 2.60)	0.844
	PPT	24	0.087	Ref			7	0.054	Ref		
PID	ESM	10	0.036	2.51	(0.80 - 7.90)	0.103	0	0	----	----	----
	PPT	4	0.015	Ref			0	0	Ref		
Scabies	ESM	2	0.007	1.00	(0.14 - 7.07)	0.997	7	0.057	1.22	(0.42 - 3.54)	0.709
	PPT	2	0.007	Ref			6	0.047	Ref		

Table 22
Symptoms at Baseline (Visit 1) and Follow-up (Visit 10)

Symptom	Percent (Yes) Visit 1	Visit 10	p-value	PPT Visit 1	Visit 10	ESM Visit 1	Visit 10	p-value
Vaginal Discharge	0.405	0.179	0.000	0.403	0.163	0.407	0.195	0.708
Vaginal Odor	0.474	0.263	0.078	0.429	0.286	0.500	0.250	0.666
Warts	0.120	0.080	0.112	0.102	0.087	0.138	0.073	0.328
Dyspareunia	0.425	0.151	0.000	0.457	0.124	0.390	0.179	0.096
Lower Abdominal Pain	0.262	0.115	0.000	0.287	0.147	0.236	0.081	0.816

Risk Assessment

Key Results

- In the ESM group nearly all women (99.4%) were treated based on the risk assessment
- Consequently, sensitivity was high (99%), but specificity was very poor (27%).
- Specificity of vaginal discharge was particularly poor (12.7%), while cervical mucopus, cervical bleeding and cervical motion tenderness were both more than 90% specific
- The number of risk assessment factors that were identified as positive decreased over time. At baseline, women had a mean of 2.5 out of 5 risk assessment factors positive. At visit 10, this decreased to a mean of 1.6 (p < 0.001). So presumably, their risk of having an STI actually decreased.

Table 23
Performance of Risk Assessment Algorithm Overall and at Visit 1 and Visit 10

Overall	(N=355 Ct or GC infections) Sensitivity	(95% CI)	(N=955 observations without Ct/GC) Specificity	(95% CI)
Risk Score Positive	0.994	(0.976 - 0.999)	0.027	(0.018 - 0.041)
First Visit/3 Months	0.605	(0.552 - 0.657)	0.770	(0.744 - 0.794)
<100% Condom Use	0.674	(0.619 - 0.724)	0.426	(0.390 - 0.462)
Vaginal D/C	0.914	(0.879 - 0.939)	0.127	(0.104 - 0.153)
Cervical Motion Tenderness	0.051	(0.032 - 0.080)	0.970	(0.956 - 0.980)
Cervical Mucopus	0.209	(0.169 - 0.255)	0.927	(0.908 - 0.942)
Inducible Cervical Bleeding	0.075	(0.051 - 0.110)	0.972	(0.959 - 0.981)
Visit 1 Only	**(N=227)**		**(N=322)**	
Risk Score Positive	0.996	(0.987 - 1.000)	0.003	(0.003 - 0.009)
First Visit/3 Months	0.877	(0.834 - 0.920)	0.292	(0.242 - 0.342)
<100% Condom Use	0.683	(0.622 - 0.744)	0.379	(0.326 - 0.432)
Vaginal D/C	0.899	(0.859 - 0.938)	0.143	(0.104 - 0.181)
Cervical Motion Tenderness	0.075	(0.040 - 0.109)	0.966	(0.946 - 0.986)
Cervical Mucopus	0.247	(0.190 - 0.303)	0.888	(0.853 - 0.923)
Inducible Cervical Bleeding	0.097	(0.058 - 0.136)	0.950	(0.926 - 0.974)

Performance of Risk Assessment Algorithm Overall and at Visit 1 and Visit 10

Overall	(N=355 Ct or GC infections)		(N=955 observations without Ct/GC)	
	Sensitivity	(95% CI)	Specificity	(95% CI)
Visit 10 Only				
	(N=31)		(N=221)	
Risk Score Positive	1.000	---	0.032	(0.008- 0.055)
First Visit/3 Months	0.129	(0.004 - 0.254)	0.982	(0.964- 1.000)
<100% Condom Use	0.645	(0.467 - 0.824)	0.475	(0.409- 0.541)
Vaginal D/C	0.968	(0.902 - 1.034)	0.090	(0.052- 0.129)
Cervical Motion Tenderness	0.000	(0.000 - 0.000)	1.000	(1.000- 1.000)
Cervical Mucopus	0.097	(0.000 - 0.207)	0.937	(0.904- 0.969)
Inducible Cervical Bleeding	0.032	(0.000 - 0.098)	0.982	(0.964- 1.000)

Notes: Sensitivity/Specificity calculated with GEE with exchangeable matrix for overal 95% CI for Visit 1 and Visit 10 calculated with exact methods

Costs

Program costs were calculated for personnel, outreach, clinic and lab consumables, and drugs. Peer educators each had a list of women they were responsible for bringing to appointments and they used various methods (with different costs) to encourage visits. Methods included telephone and bringing patient in by rickshaw.

Key Results
- 50% reduction of total costs per visit per woman for PPT (Table 17)
- 17% reduction in time per visit per woman (67 minutes for PPT and 81 minutes for ESM) (Table 18)
- Out of every 6 hour session/day, PPT saves 1 hour and can increase number of patients by 17% (Table 18)
- The number of extra patients that can be seen by a doctor per day = 1hr/ time spent on 1 PPT patient = 60/11 = 5.45pts
- 11% reduction in personnel costs per year for PPT (Table 19)

Table 24
Cost Per Follow-up Visit Per Woman

	ESM (USD)	PPT (USD)
Personnel (lab tech)[0]	4.00	0.00[1]
Outreach[2]	0.17	0.13
Clinic consumables	0.25	0.10
Lab consumables	2.90[3]	0.87[4]
Drugs	4.30	4.70
Total	**11.62**	**5.80**

[0]Yearly salary X2 / #ESM visits 2-9
[1]lab technician left out as PPT would use rapid tests for 3 monthly syphilis tests
[2](Per peer cost for bringing FSW to clinic + telephone calls)X # visit per group 2-9
[3]25USD/100visits
[4]10USD/100visits; PPT received rapid test for syphilis

Table 25
Time Costs For Personnel (Directly Observed)

	PPT n=59 Median time in minutes/pt/visit (mean)*	% time	ESM n=44 median time in minutespt/visit (mean)	% time
Whole visit	**67 (77)**	**100%**	**81(85)**	**100%**
Reception	2 (3)	3%	2 (3)	2.5%
Physician	11 (13)	16.4%	13 (15)	16%
Lab (ESM n=18, PPT n=29)	3 (7)	4.5%	14 (15)	17.3%
counsellor	7 (7)	10.4%	6 (7)	7.4%
Total provider time	23	34.3%	35	43.2%
Wait time	42 (51)	65.7%	53 (54)	56.8%

*visit times are calculated from time flow analysis as a median. There is no differentiation between initial or follow up visit.

Table 26
Salary Costs For Personnel

Annual salary	ESM	PPT
Peer educator (11)	11, 928	11, 928
Physician (1)	2,640	2,640
Counsellor (2)	3,528	3,528
Nurse (1)	1,164	1,164
Lab technician (1)	2,556	-
Receptionist (1)	1,056	1,056
Total	**22,872**	**20,316**

G PSA

The presence of prostate-specific antigen (PSA) in the vagina is a surrogate for the presence of semen and means no or improper condom use in approximately the last 24 hours.

- There appears to be an over-estimation of self-reported condom use from 30-50%
- Based on these PSA results, there appears to be an increased trend in condom use from 56-61%, compared to a reduction based on self report of 72% to 55%.

Table 27

Percentage of Women with Positive Psa Results by Visit, Condom Use, and Timing of Last Sex and Work Sessions

	Overall (Last Session) % PSA Positive	(95% CI)	P-value	Reported 100% Condom Use at Last Sex % PSA Positive	(95% CI)	p-value	Reported Condom Use at Last Sex % PSA Positive	(95% CI)	p-value	Reported No Condom Use at Last Sex Positive	(95% CI)	p-value
Visit			0.207			0.481			0.000			0.138
10	38.9	(33.1 - 45.0)		40.2	(29.9 - 51.4)		28.3	(21.4 - 36.4)		50.8	(41.8 - 59.8)	
1	43.4	(39.3 - 47.6)		44.7	(39.2 - 50.5)		34.1	(29.3 - 39.3)		59.3	(52.4 - 65.8)	
Condom Used - Last Sex			0.000			0.000						0.000
Yes	32.6	(28.5 - 37.0)		35.7	(29.9 - 42.0)		---			---		
No	56.3	(50.8 - 61.7)		56.9	(48.9 - 64.5)		---			---		
Last Sex			0.000			0.000			0.000			0.000
This Morning	65.3	(56.4 - 73.3)		76.6	(62.6 - 86.5)		50.5	(39.4 - 61.5)		88.2	(76.0 - 94.6)	
Last Night	51.2	(46.3 - 56.1)		49.7	(43.0 - 56.4)		39.0	(32.9 - 45.4)		68.2	(60.8 - 74.8)	
Yesterday Morning	29.1	(18.5 - 42.7)		44.1	(25.7 - 64.3)		23.9	(12.7 - 40.5)		43.5	(22.5 - 67.0)	
Yesterday Afternoon	23.5	(9.5 - 47.3)		32.8	(8.3 - 72.4)		13.9	(2.3 - 52.9)		30.3	(10.0 - 63.0)	
2 Days	10.3	(5.7 - 17.9)		11.5	(4.9 - 24.7)		10.7	(5.3 - 20.3)		9.7	(3.1 - 26.2)	
>2 Days	17.3	(11.0 - 26.1)		18.6	(10.2 - 31.3)		17.1	(9.0 - 30.1)		17.5	(9.0 - 31.1)	
Last Session - Start			0.000			0.000			0.011			0.000
This Morning	53.8	(41.0 - 66.2)		53.6	(37.8 - 68.7)		36.2	(22.6 - 52.5)		90.4	(67.6 - 97.7)	
Last Night	51.4	(40.5 - 62.2)		49.9	(33.9 - 66.0)		39.3	(26.7 - 53.5)		70.6	(52.5 - 83.9)	
Yesterday Morning	51.7	(46.4 - 57.1)		54.7	(46.7 - 62.4)		39.5	(33.1 - 46.3)		72.9	(64.8 - 79.8)	
Yesterday Afternoon	24.4	(17.8 - 32.5)		28.8	(19.1 - 40.8)		20.1	(12.9 - 30.0)		32.5	(20.3 - 47.6)	
2 Days	30.3	(23.6 - 38.0)		31.6	(21.9 - 43.1)		22.6	(14.5 - 33.5)		38.4	(28.2 - 49.8)	
>2 Days	22.6	(11.3 - 40.1)		15.4	(3.7 - 46.1)		22.0	(5.2 - 59.0)		22.7	(9.8 - 44.4)	
Last Session - End			0.000			0.001			0.001			0.000
This Morning	55.1	(48.8 - 61.3)		55.1	(46.6 - 63.3)		42.9	(35.3 - 50.9)		77.1	(67.3 - 84.6)	
Last Night	49.9	(43.5 - 56.4)		50.5	(41.0 - 60.0)		37.3	(29.8 - 45.5)		71.0	(60.6 - 79.6)	
Yesterday Morning	39.4	(23.3 - 58.1)		63.3	(31.8 - 86.4)		25.4	(11.2 - 47.7)		70.3	(37.0 - 90.5)	
Yesterday Afternoon	25.8	(12.9 - 44.9)		21.6	(6.9 - 50.5)		19.2	(6.6 - 44.7)		32.7	(12.5 - 62.3)	
2 Days	17.7	(11.3 - 26.9)		26.7	(16.1 - 40.8)		14.1	(7.5 - 25.0)		26.6	(13.8 - 45.1)	
>2 Days	31.3	(24.3 - 39.4)		32.6	(22.5 - 44.6)		23.9	(15.2 - 35.5)		38.6	(28.2 - 50.2)	

Results Summary

- Most of the hotel-based sex workers were adolescents with less than two years of hotel-based sex work in Dhaka. They averaged 21 sex clients per week.

- Sex workers valued a place to go for STI treatment, and did not mind waiting at that service site.

- Retention by the end of the follow-up period was 50%. Consistent with the fact that the duration in Dhaka hotel-based sex work was 22 months.

- Between the two treatment groups there was no difference over time in STIs, behavior or retention.

- Reported condom use decreased between 70-35% at baseline to 61-55% after nine months of follow up. However, PSA results suggest a modest increased trend in condom use from 56% at baseline to 61% at nine months.

- There was a reduction in clients per week from 22 to 17.

- The percentage of women who considered themselves at "high risk" decreased from 80% to 50% over the course of follow-up.

- Knowledge of STI symptoms improved during the follow-up period.

- Most STIs were cervical (i.e. CT or GC). Syphilis, genital ulcer disease and trichomonas were rare. BV was found in 2/3 of women and this is consistent with frequent sex and low condom use.

- The presence of GC and CT decreased from 41% to 7% over the 9 month follow-up period, an 83% reduction. This is phenomenal.

- There was no reduction in BV despite monthly treatment with metronidazole.

- There was an overall reduction in genital symptoms of 50% over the follow-up period.

- There was a reduction in self –reported sexual coercion from 12% to 2%.

- Positive risk assessment factor showed a 30% reduction over the follow-up period.

- PPT was 50% less expensive than ESM with no difference in STI rates, retention or behavior change.

In a public health emergency such as the threatened HIV epidemic in Bangladesh, it is important to identify the best way to achieve rapid reductions in STI transmission in the short term. The epidemiological model of STI transmission shown below indicates that a reduction of transmission of STI through interventions to reduce C (increased condom use, reduced rate of partner change) and D (early and effective treatment of STI).

> Box 1: Reproductive Rate Equation
> **Ro = ß c D**
> **ß -** Probability of transmission
> **c -** Number of sexual contacts
> **D -** Duration of infectiousness

Results indicate a significant reduction in NG/CT rates from visit 1 to visit 10 (NG/CT from 40% to 7%) but no differences in effectiveness of interventions between groups. BV was very common at baseline and although women received metronidazole as part of the treatment package in both interventions, there was no reduction in prevalence at visit 10.

There was a significant reduction in average clients per week from 22 to 17, but with continued low condom use it seems likely that the decreased incidence of these STIs is mainly due to a reduction in the duration of infectiousness through the STI treatment. This would suggest that in the short-term at least, the most effective method for rapid reduction of NG and CT transmission is STI treatment on a regular basis or a 100% condom use policy.

Tapering

PPT is a short-term option for treatment of STIs, and as such, the issue of tapering (gradually increasing the treatment interval) is important. Previous studies suggest that decisions on tapering be made on an individual basis considering risk behavior, condom use, STI rates and clinic attendance. These data show that women who attend clinic visits up to four months usually stayed in the study until nine months. It may be worth considering an approach to tapering only in women who fall into the group who attend for four months or more.

Conversely, the short time these women spent in the hotel-based sex trade means that the average duration of treatment would be approximately 22 months, even if the monthly program of PPT were permanent. The biggest reductions in NG/CT rates were in women whose last clinic visit was less than 37 days ago, and rates double with each additional month since last treatment. This indicates that to achieve consistent reductions, all women need to be treated monthly, although it is not clear what additional reduction in incidence would occur after nine months of treatment.

Recruitment and Retention

One study requirement was the selection of women who planned to stay in the area for at least nine months. This may have created selection bias, nonetheless, the study population is considered representative of the HBSW population targeted by FHI and BWHC in terms of demographic and behavioral characteristics. Routine demographic data were compared from the study sites with study demographics to assess the degree of bias. Additional enrollment constraints included police activity, civil unrest in Dhaka, hotels closing and seasonal floods. However, these constraints affected participation of women in routine programs and were not exclusive to study participation. Furthermore, the study design ensured that the clinical intervention provided to study participants was almost identical to interventions offered to non-study patients. Both study and non-study groups received treatment in the same locations by the same staff.

However, the issue of regular treatment raises some concerns as to whether either STI intervention will achieve similar results in the current program setting.

There were two important differences between the intervention population for the study and the non-study women. First, the study group had a proactive approach to recruitment and retention for those women in the study. Second, there was greater access to services for the study group (5 days/week vs. 2 days/week). These factors are likely to have contributed to the 55% retention rate among study participants, as compared to reported 2nd visit rates among the general program of less than 20%. (NB: 55% retention is quite low, but given that the average time spent in sex work is 22 months, there was the expectation of losing half of the women within a year anyway.) The low return rate among non-study women, plus the rapid increase of incidence rates with each untreated month suggests that without regular visits, the STI treatment intervention may have no impact on overall rates. Further work needs to be done to develop sustainable approaches to improve retention and compare the cost effectiveness of the intensive study approach to the routine approach for retention.

Behavior Change Interventions

It is essential to provide STI treatment as part of a package of services including intensive behavior change interventions. FHI and BWHC provide an extensive program of education and behavior change communication through trained peer educators, outreach workers and clinic staff in hotels and in the clinics. Women in the study probably had more exposure to outreach and clinic-based education than those not in the study, due to allocated peers, regular visits to the clinic, and more time during consultations due to specific clinic days for study participants. In spite of this intensive BCI exposure and a significant increase in knowledge of STI transmission and symptoms, there appears to have been no increase in condom use.

The PSA results, do however suggest lower levels of unprotected sex overall (43% in visit 1 PSA positive vs. 39% in visit 10), and although the differences are not significant, they may indicate a trend in increasing condom use. Additionally, it is possible women are giving more genuine answers at visit 10 as they become more confident and familiar with clinic staff.

A concern with PPT is that it may create a false sense of security and lead women to take additional risks. These data show that in both groups, in spite of knowledge increases, women had a decreased perception of self-risk over time. However, there was a significant reduction in number of clients per week and considerable decreases in STI rates and genital symptoms.

Women were actually at decreased risk of having an STI, although it is not clear whether their perception of decreased risk relates to risk of current infection or risk of acquiring new infections based on their continued sexual risk behavior.

Even with numerous health promotion messages going out to the hotel-based sex workers, the number of partners decreased and there may be a trend towards increased condom use during last sex, the possibility remains that both ESM and PPT may result in no change in condom use and a decrease in perception of self-risk. Moreover, the high mobility of many women in the hotel-based sex trade may mean that a *culture change* in this sex work community does not happen. Any behavior change intervention, as part of an STI treatment program, needs to consider these factors.

Choice of Treatment Approach

There was no difference between the two interventions in terms of effectiveness or retention. Therefore, coverage and cost should guide decisions on the selection of appropriate interventions. Setting-up a clinic with a laboratory and clinical room for speculum examination and specimen collection, requires significant input in terms of design, staff training, quality management and consumables. Once the basic clinic infrastructure is set-up and staffed, the marginal cost of a follow-up visit for PPT is less than ESM. This is due to less investment in terms of staff (no laboratory technician), consumables (both laboratory and clinic) and time per patient visit.

PPT can treat more people more cheaply than ESM: the cost per PPT visit is half that of an ESM visit and about 5 extra patients can be seen per day for PPT. As noted above, PPT has traditionally been thought to be a short-term solution in the context of overall service improvement. However, given the clear benefits in terms of cost and coverage, together with the high mobility of HBSW, the short-term approach for PPT may translate into a long-term approach for short-term populations. On this basis, PPT would be the preferred choice of intervention where there is policy and funding support together with a commitment to provide it as part of a package including intensive behavior change interventions and perhaps equally intensive retention procedures. For both interventions, the package would also include robust operational guidelines and minimum standards for service delivery,

Empowerment of Women

An important finding is the significant decrease in physical and non-physical coercion over time. This may be due to an increased confidence in women, because of respectful treatment they received at the STI clinic. Alternatively, it may reflect a degree of protection offered by study identity cards, which was suggested by women when consulted about study design in the preparatory phase.

One important question is where women go when they leave hotel-based sex work. It is notable that at baseline, 24% of women had worked in home-based sex work in the last three months and one possibility is that as women build up a client base through hotel work, they move into home-based work. Alternatively, they saved enough money to return to their village or set-up a business in Dhaka. Additional research should be conducted to investigate how accessible or needy these mobile women are in terms of continuing STI prevention and treatment options.

1. Prioritize systematic STI management in this low HIV, high STI prevalent setting.

2. Establish monthly PPT, as it is less expensive and a more accessible strategy than ESM while retaining a high effectiveness without behavior or retention sacrifice. Both strategies resulted in significant positive behavioral changes.

3. Continue to focus retention efforts on younger sex workers.

4. Encourage metronidazole as an optional drug for PPT due to the persistent recurrence of BV and the low TV burden. As an optional drug for PPT, this will further reduce costs.

5. Encourage availability of identity cards to sex workers as part of the STI program.

6. Establish minimum standards and operational guidelines for the delivery of STI treatment, health promotion and recruitment/retention activities to attract and retain women in the program.

7. Determine priorities for additional studies that aim to answer the following questions:

    • Where do hotel-based sex workers go after finishing sex work in the Dhaka hotels?

    • How to increase consistent condom use?

    • Why women consider themselves at lower risk while in the program?

    • Cost analysis of intensive vs. routine recruitment and retention procedures

    • How to assess STI rates in male clients of HBSW?

The Effectiveness and Costs of Two Methods for the Systematic Prevention and Control of STIs, Among Female Sex Workers in Dhaka, Bangladesh

44

45

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45

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