Ministry of Health

EVALUATION OF THE STI MANAGEMENT PROTOCOL FOR FEMALE SEX WORKERS IN CAMBODIA

2011

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Preface

Vaginal discharge is a main sexual and reproductive health problem usually affects women of reproductive age in Cambodia. The management of sexually transmitted and reproductive tract infections (STIs/RTIs) based on syndromic approach is focused on risk assessment for diagnosis presumptive cervicitis caused by Gonococcus and Chlamydia infections. This approach is used in many primary health care facilities in Cambodia where laboratory facilities are not available. However, it has lead to overtreatment of cervicitis relative to the prevalence of Gonococcus and Chlamydia infections among low risk women in Cambodia.

In response to this issue, the National Center for HIV/AIDS, Dermatology and STIs (NCHADS) introduced the STI case management based on simple laboratory at the family health clinics (FHCs) since 1999 and expanded to all 32 FHCs in 21 provinces and Phnom Penh city. However, the algorithm to diagnose cervicitis, especially among sex workers in Cambodia, was adapted from the World Health Organization (WHO) and some African guidelines. This survey aims to assess the performance or validity of the National Protocol by comparing the "protocol diagnosis" with the results from reference laboratory tests for Gonorrhoea and Chlamydia, among women visiting STI clinics.

I believe that the findings of this study will assist health care providers to improve STI/RTI case management, especially regarding cervicitis diagnosis, to be more appropriate and accurate.

On behalf of NCHADS, I would like to thank to the Institute of Tropical Medicine (ITM), Antwerp, Belgium, for technical and financial support, and the people who involved in this study, especially NCHADS officers and health care providers at the study sites, and to all participants who provided useful information for the study.

Phnom Penh, ...17th...January 2011

Dr. MEAN CHHI VUN

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List of Abbreviations

AIDS	Acquired immune deficiency syndrome
BV	Bacterial Vaginosis
CI	Confidence interval
CT	Chlamydia Trochomatis
CUP	Condom Use Programme
DFSW	Direct Female Sex Worker
GC	Gonococcus.
GUD	genital ulcer disease
HIV	Human Immunodeficiency Virus
HPF	High Power Field
IDFSW	Indirect Female Sex Worker
IEC	Information, Education and Communication
ITM	Institute of Tropical Medicine
MEC	Médecins de l'espoir du Cambodge
NAAT	Nucleic Acid Amplification Test
NCHADS	National Center for HIV/AIDS, Dermatology and STIs
OR	Odd ratio
PCR	Polymerase Chain Reaction
RTI	Reproductive Tract Infections
STD	Sexually Transmitted Diseases
STI	Sexually Transmitted Infections
SW	Sex Worker
WBC	White Blood Cell

1. INTRODUCTION AND RATIONALE

In 1998, a novel protocol was introduced at selected STI clinics of Cambodia for the management of STIs/RTIs among female brothel-based SWs. In order to presumptively diagnose cervical infection associated with Gonorrhoea or Chlamydia the protocol combines a risk assessment, pelvic examination and counting of white blood cells (WBC) on an endocervical smear. Trichomonas, Candidiasis and Bacterial Vaginosis are detected by the current combination of clinical signs and microscopic examination; following the recommendations of WHO. The protocol itself was derived from the experience of STI management among SWs in African countries.

STI care for female sex worker, together with outreach activities were the backbone of the 100% condom use promotion (100% CUP) program in Cambodia, which was initiated in 1998. In 2000, the National Centre for HIV/AIDS, Dermatology and STI (NCHADS) decided to have the 100% CUP expanded to the whole country. As result, STI management protocol for female sex worker has been used in 28 STI clinics, serving mainly but not exclusively a population of female sex workers, throughout the country.

In 100% CUP program, brothel-based and indirect SWs are identified and tallied by outreach teams in each province. Collaboration between outreach staff, 100% CUP monitoring staff and sex establishment managers help ensuring that SWs present each month at the nearest STI clinic for a medical visit. At each visit, regardless of complaints, suspected cervical infection is treated according to the risk assessment, clinical signs observing under speculum examination and/or microscopic examination of an endocervical smear. Other infections are also treated based on clinical symptoms & laboratory results. Again, women also receive general medical care, counselling and condoms and fortunately, the visit is free of charge.

The risk assessment in the protocol for STI management consists of four questions, two related to complaints of having thick vaginal discharge or deep abdominal pain during intercourse, and other two related to client risk behaviours – having five or more clients per day on average and inconsistent condom use with new clients. A positive answer to any <u>two</u> or more questions leads to treatment for cervical infection. Furthermore, treatment is also recommended if there is any other clinical signs suggesting cervical infection, which include purulent discharge from the cervix, yellow secretion on an endocervical swab, erosion or friability, deep pain on bimanual

palpation, or the detection of 10 or more white blood cells per high power field on a cervical smear.

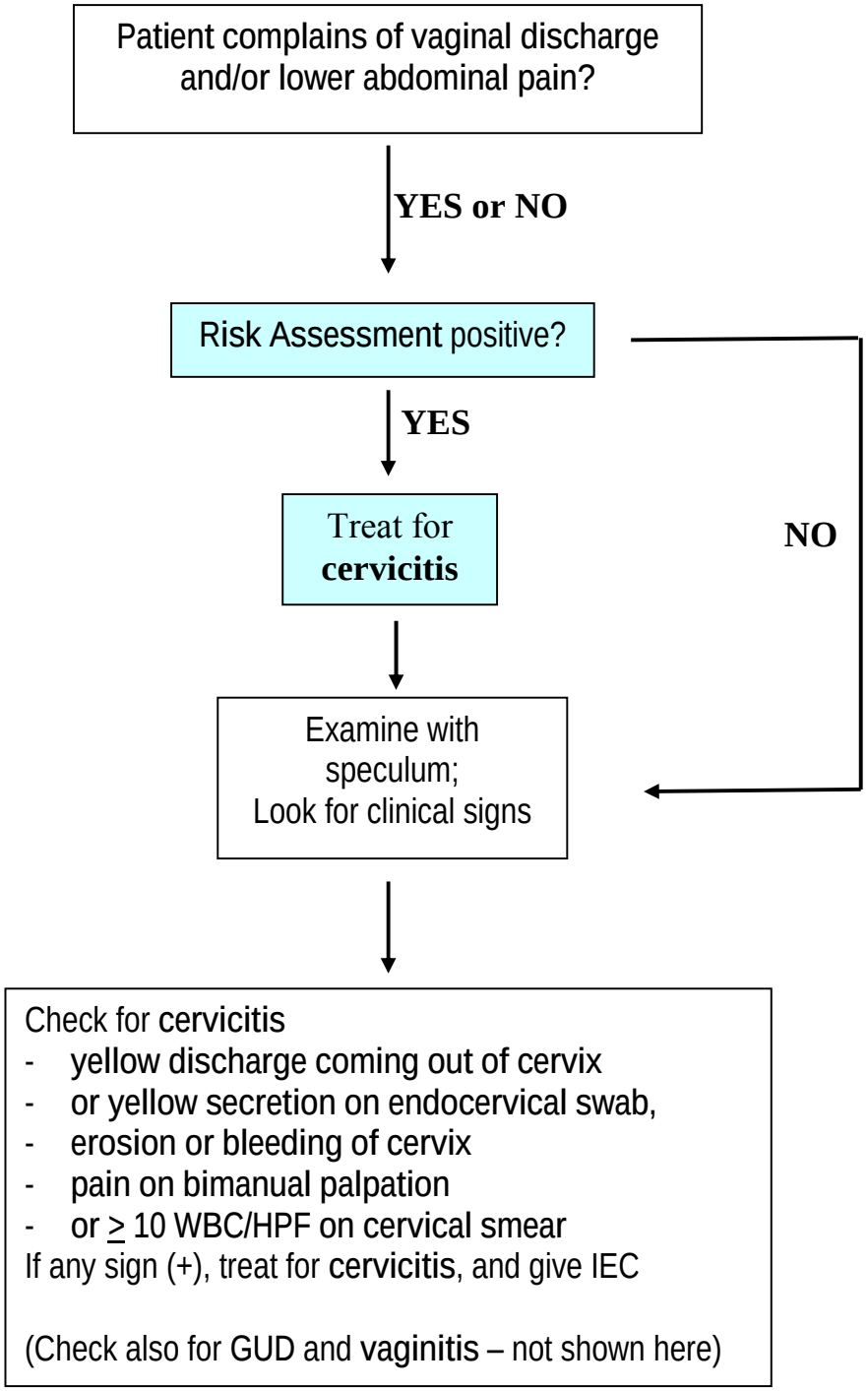
For trichomoniasis, Candidasis or bacterial vaginosis infections, the diagnosis was confirmed by microscopic examination of a vaginal smear.

Since the beginning, it had been suspected that the protocol for STI management was highly sensitive but not specific enough to detect false positive cervical infection, resulting in nearly 50% of women coming to the clinics receiving treatment for gonorrhoea and Chlamydia at each monthly visit. However, there is a supportive argument saying that over-treatment, among population at higher-risk of infection, should be considered as preferable to under-treatment and the waste of drugs was considered acceptable because the targeted population was small (the total number of brothel-based and indirect SWs is reasonably estimated at about 6,000 and 13,000 in the whole country).

In early 2004, data from selected STI clinics showed that the percentage of women receiving treatment at regular monthly visits had gone down significantly. Thus, there is a possibility that the true prevalence of cervical infection among female sex worker declined or the drop was just due to the error of the implementation of the protocol or the protocol itself. Therefore, it is important to assess the current protocol, especially its sensitivity and specificity so that readjustment could be made if necessary.

Figure 1: Current STI Management Protocol

Management of presumptive cervical infection
And other STIs/RTIs
Among female sex workers



2. OBJECTIVES

2.1. Main objective

To assess the *performance* or *validity* of NCHADS' protocol by comparing the "protocol diagnosis" with the results from reference laboratory tests for Gonorrhoea and Chlamydia, among women visiting STI clinics.

2.2. Specific objectives

1. To document the prevalence of cervical and vaginal infections among female SWs who present at study clinics for the 1st time or follow-up visit.
2. To assess the strength of association between individual and combined risk factors, and/or clinical signs, and/or number of white blood cells per high-power field (WBC/HPF), and Gonococcal or Chlamydial infections.

3. METHODOLOGY

3.1. Study sites

Clinics in Phnom Penh (MEC & Toul kork), Battambang and Sihanouk Ville were selected for the study. The selection has been decided on the following criteria:

1. Site equipped with materials for clinical examination (including pelvic examination)
2. At least 100 female SWs visiting the clinic each month
3. Clinical staff familiar with STI management protocol for SWs,
4. Staff are willing to involve in this research activities.
5. Clinic laboratory equipped with appropriate operationals (including refrigerator) and laboratory technicians have been trained in microscopic examination of vaginal and endocervical smears.
6. Availability of regular transport (of specimens) to the national STD clinic in Phnom Penh, where specimens storage for PCR in ITM in Belgium and the quality control of slides reading for WBC, BV and Candidasis are available.

3.2. Study population

The study population consisted of female Sex workers who present at one of the selected clinics and meet the following criteria:

1) 18 years or older
2) working either as brothel-based or non-brothel based sex workers (indirect sex worker)
3) willing to provide informed consent
4) For the non Cambodian women - mainly Vietnamese, speaking and understanding enough Khmer to give informed consent and answer the questionnaire

All women who meet the inclusion criteria will consecutively be invited to participate in the study. They will be enrolled after giving an oral informed consent. The process continues until reaching the total number of participants needed.

3.3. Sample size

The sample size depends on the following two elements:

3.3.1. Assessment of the protocol for the management of cervicitis

Based on available evidence, we estimate that the protocol is more sensitive than specific (see introduction). The sensitivity and the specificity of the flowchart were therefore tentatively set at 70% and 30% respectively. Using the Epi-Info package for single proportions in descriptive surveys with random sampling (confidence level 95%, power 80%), we calculate that 126 infected women will have to enrolled to confirm a sensitivity of 70% ± 8%.

3.3.2. Assessment of prevalence rates of STIs/RTIs

Sample size calculations are based on the findings of the national STI survey of 2001 and expected values in 2004, using the same Epi-Info statistical package for descriptive surveys using random sampling. Since the prevalence rate for GC/Ct is expected to be around 10%, no fewer than **1,260** women will have to be enrolled in the study in order to reach the necessary number of infected patients.

3.4. Enrolment procedure and interview

At each selected clinic, a trained female staff invited client one by one into a private room isolated from the waiting room. A female nurse explained in detail the purpose of the research and the meaning of providing informed consent. The clients also had the opportunity to request any clarification before making a decision. For those who gave consent to participate a study number was assigned. Then, the study participants were interviewed by using structured study questionnaires followed by the standard medical history (SMH) form.

Clients declining to take part in the study were simply asked the questions of the SMH by the same staff in the same room. Each client received a bag with all necessary items for the consultation – see details below – and then went to the consultation room where she were examined in private by the assigned female medical provider using current STI management protocol. That is; the provider must carry out clinical examinations of external genital and anal regions before doing the speculum examination and collecting specimens.

Each visitor then was asked to go to the laboratory room for specimen collections and blood drawing for RPR in 1st visitors. Except for the nurse asking for consent and completing the questionnaire and SMH, the medical provider doing the examination and the laboratory technician processing the specimens, nobody was able to differentiate participants from non participants.

3.5. Clinical and Laboratory Procedures

3.5.1. Preparation of specimen collection

Two types of plastic bags were prepared in advance, one type containing all items necessary for the study (questionnaire, SMH forms, specimen containers, etc.), while the other one only contained the SMH and standard specimen collection material for non-participants.

'Participant bags' had each item identified in advance by means of self-adhesive stickers (resistant to humidity) with the study number assigned to each participant (20 stickers with the same number).

Specimens for PCR in Belgium were kept in refrigerators (cool box) until ready for transport to the reference laboratory in Phnom Penh. Once a week, specimens were sent to the reference laboratory. Refrigerated specimens were put in cool boxes with ice packs while transporting.

3.5.2. Clinical examination and specimen collection

Clinical exams were routinely conducted as follow; inspection of the genital area and local lymph nodes for local changes: erythema, warts, abrasions, ulcers, swelling, discharge. Then, examination of the abdomen: careful evaluation of the location and severity of any reported abdominal pain and followed by Speculum examination without lubrication, inspecting the vaginal discharge for colour, amount, odour, consistency and density. Finally, there is an examination of the vaginal walls and cervix for warts or ulcers and discharge.

In addition to clinical exam, vaginal fluid was collected from the posterior fornix using two to three cotton swabs avoiding cervical secretions. One swab were rolled on a microscope slide for Gram stain and air-dried. The other swab were be used for wet preparation.

One cotton swab was rolled in the endocervix for 10 seconds after cleaning of cervix; it was then rolled on a microscope slide for Methylene blue stain. A special BD Culturette swab were used to take a specimen of endocervical material for Nucleic Acid Amplification Testing (NAAT) and placed in the original container.

After speculum examination, a bimanual examination was carried out to complete the examination.

3.5.3. Laboratory procedures at the clinic

In the laboratory, as a routine procedure for 1st time visitors, collection of 10cc of venous blood in a dry sterile test tube with stopper. Serum was separated from blood cells by centrifugation. The serum was then used for qualitative RPR testing following the standard procedure in use at STI clinic laboratories. Women waited in the waiting room

while sera were being tested, so that those with positive result could get treatment immediately. The following procedures were performed at each lab.

Slides for wet mount were examined by the laboratory technician for the detection of motile flagellates as well as signs of active yeast development (hyphae and bugging yeasts).

Slides for Gram stain were stained following the routine instructions and examined immediately under the microscope for the detection of yeast infection, or bacterial vaginosis (BV) using the Nugent score.

Slides for methylene blue staining were processed and examined under the microscope for counting of white blood cells (WBC) per high power field. Cells will be counted on 10 adjacent fields before the average is calculated.
Lab technicians reported all results on the standard laboratory form and pass it to the health care provider for any additional treatment (e.g. following positive RPR test or elevated number of WBC).

Individul sample of methylene blue and Gram-stained slides was kept at the laboratory before being sent with other specimens to the reference laboratory for quality control.

3.5.4. Laboratory procedures at the reference laboratory in Phnom Penh

For the purpose of quality control a randomly selected sample of Gram-stained and methylene blue-stained slides from participating clinic laboratories were re-examined at the central laboratory by an experienced technician. The random sample included slides with positive and negative results. Ten percent of slides with negative results were arbitrarily re-examined. A 50% sample was randomly selected among slides positive for bacterial vaginosis infection and cervicitis, whereas all slides positive for yeast infection were revised. The discordant result slides between the central and the clinic laboratories were re-examined by two experienced technicians (1 from reference lab and 1 from Sihanouk Ville) and an experienced staff of the STI/RTI Unit of NCHADS. The results from this recheck and concordant results between the central and the clinic laboratories are considered the final ones.

Table 1: Summary of Laboratory Tests

Organism	Test	Biological Specimen	Quality control
Presumptive diagnosis of cervical infection	Counting of white blood cells on methylene blue-stained smear	Cervical swab	Random sample of 10% of negative slides; random sample of 50% of positive slides
Neisseria gonorrhoeae & Chlamydia trachomatis	NAAT	BD Culturette swab	(-)
Trichomonas vaginalis	Wet preparation	Vaginal swab	N/A
Bacterial vaginosis & Candida infection	Detection of budding yeasts and hyphae; Nugent scoring on Gram-stained slide;	Vaginal swab	Random sample of 10% of negative slides; random sample of 50% of positive slides for BV and all for yeast

3.6. Handling of Structure Interview Forms

The procedure for conducting the interview was described earlier. A draft questionnaire accompanied with the protocol was submitted to the National Ethical Committee.

Completed interview forms were cross-checked in the field and collected by a supervisor and placed in a sealed box before delivering to NCHADS. Forms were then kept in a locked cabinet in a secure place for data entry.

3.7. Treatment and Follow up of Participants

Participants (as well as non-participants) presenting with any symptom and/or sign suggestive of RTI/STI were treated on the spot using NCHADS' treatment guidelines for SWs. Treated clients were also offered condom and condom use demonstration before leaving clinic and were encouraged to use it with all clients and to invite their STI symptomatic regular clients to clinics.

4. RESULTS

4.1. Socio-demographic characteristics

A total of 1,325 female sex workers were recruited into the study. There are two groups of female – direct (45.8%) and indirect female sex workers. The refusal rate was 2%.

The mean age of the study participants was 24 years old (median 24 years old). About 95% of them speak Cambodian as mother language and 5% speak Vietnamese. It has been observed that about 8% of DSW are Vietnamese, while only about 1% of them working as IDSW.

The proportion of female sex workers who were divorced or widow was 52%, 5% was separated and 34% was unmarried. It has been learned that the proportion of these women who were married and still living with their husbands was about 9%.

Regarding to level of education, 37% of the participants report no schooling. Furthermore, direct female sex worker have higher proportion of having no school compared with indirect female sex worker (50% Vs 27%). Among those who had attended school, the mean year of schooling is 5.5 years. However only 34% of these women reported they can read and understand (newspapers or magazine) and 23% can read and understand some.

It has been shown that the mean duration of staying for the sex workers in the current working place was10 months (median: 5 months, IQR: 2-12 months). There was no difference in term of duration of stay in the current working place for DSWs and IDSWs.

Table 2: Socio – demographic among different female groups

	DSWs	IDSWs	TOTAL
Mean age (years)	24.3	24.1	24.2
Having Khmer as mother tongue	91%	99%	95%
Marital status			
Single	40%	29%	34%
Married	6%	12%	9%
Separated or divorced	54%	59%	57%
No schooling	50%	27%	37%

4.2. Reproductive health

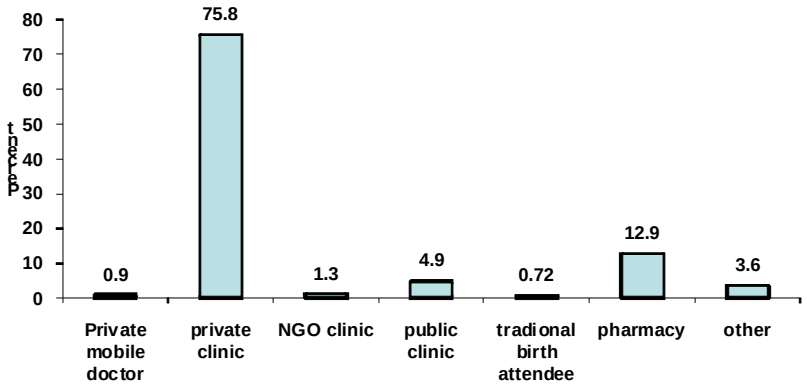
Most of the participants reported using some method for preventing pregnancy. Only, 4% reported no using any means to avoid pregnancy. The most common method use reported is condom (94%), followed by taking contraception tablet (1%). Thirty five percent of women reported have never been pregnant, 56% never delivered a baby and 59% reported currently had no child. The proportion of no pregnancy is high among women reported never married (65%) and 80% of those ever married reported having at least one pregnancy.

Induced abortion was found to be quite common among study participants. It has been reported that 43% of study participants reported having at least one abortion after becoming sex worker. Approximately, 90% of abortion was induced before 14 weeks of the pregnancy (mean: 8 weeks, median: 8 weeks). These induced abortion was commonly performed at private clinics (76%) followed by pharmacies (13%). (See Figure 2)

Table 3: Reproductive information among different female groups

	DSWs	IDSWs	TOTAL
Use of modern contraception			
Condom exclusively	98%	90%	94%
Contraceptive pill	1%	1%	1%
% of having at least one pregnancies	64%	66%	65%
% of at least one pregnancies among those reported never married	34%	36%	35%
% of having at least one living children	40%	42%	41%
Mean of abortion (median)	1.9 (1)	1.7 (1)	1.8 (1)
% of having at least one abortion after becoming SW	43%	43%	43%
% of at least 2 abortions after becoming SW	19%	16%	18%
Median duration of pregnancy the last abortion	8 weeks	6 weeks	8 weeks
Median price for abortion (mean) (1US$ = 4000 riels)	80,000 riels (137,052)	62,000 riels (99,391)	80,000 riels (116,666)

Figure 2: Places of Last Induced Abortion



There were many different ways for inducing abortion. The way that mostly reported was the aspiration (57%) (Figure 3). Among those who had induced abortion, 73% reported having no complications, but among those who reported having problems in their last induced abortion. The most common problems were having a lot of bleeding (13.4%) and abdominal pain (11%) (Figure 4). The course of induced abortion is 80,000 riels.

Figure 3: Induced Abortion Methods reported

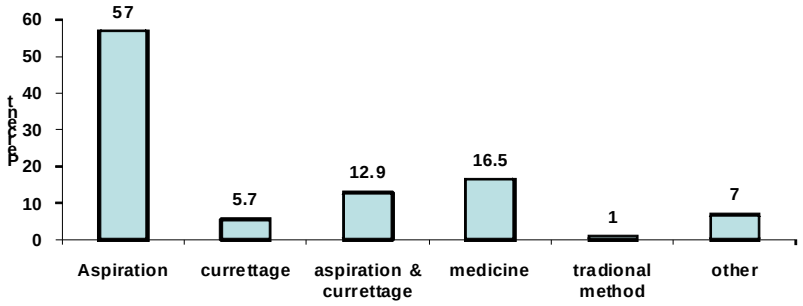
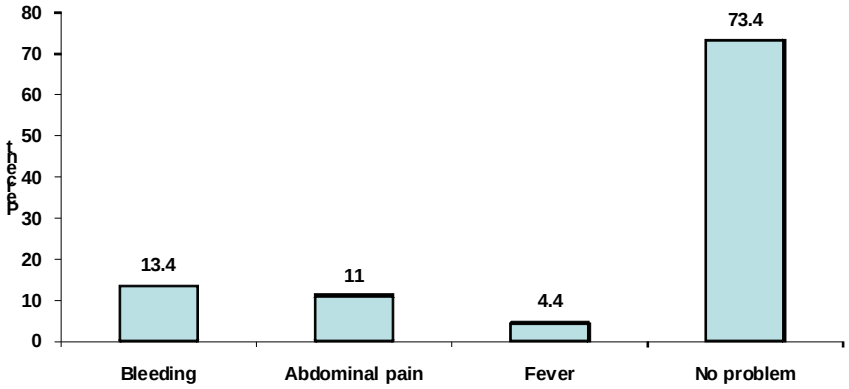


Figure 4: Reported complain from their last abortion



4.3. Sexual behaviors

Age at first sex for money for both groups ranged from 12 years old to 44 years old. The median age of commercial sex was 21 years old (means of 22 years old). Furthermore, DFSW tends to start selling sex at younger age compared to IDFSW (21.5 yr Vs 22.7 yr). On average, study subjects reported having sex with 1.5 clients the day before the interview date (median of 1 client per day). Sixty seven percent of IDFSW and 15% of DSW reported

no sex with clients a day before the study interview date. Among those who had sex yesterday, direct female sex worker reported having sex with a median of 3 clients, while indirect female sex worker had sex with a median of 1 client. In short, 4.4% of women in the study reported having sex with 5 clients per day. Interestingly, none of indirect female sex worker reported having such high number of clients per day. Regarding to the condom use, approximately 99% of DSW and 97% of IDSW included in the study reported always use condom when having sex with new clients.

Table 4: Sexual behaviors among female groups

	DSWs	IDSWs	TOTAL
Mean clients yesterday (median)	2.9 (2)	0.4 (0)	1.5 (1)
% of no sex yesterday	15%	67%	44%
Mean number of sex yesterday among SW who had sex yesterday (median)	3.5 (3)	1.3 (1)	2.8 (2)
Mean average number of clients in 24h (median)	2.8 (2)	0.4 (0.14)	1.6 (1)
% of SW with average of >5clients/day	9%	0%	4.4%
% of always use condom with new clients	99%	97%	98%

4.4. Reproductive Health Symptoms

Approximately, 28% of those who agree to participate in the study reported having abnormal vaginal discharge in the past year. Furthermore, direct female sex workers reported slightly higher proportion of having abnormal vaginal discharge compared to indirect female sex workers (34% Vs 24%).

Among those who reported having discharge in the past year, 65.8% and 45.7% presented with bad smell and yellow in color, respectively. Having sores or blister on genital areas in the past year was rarely reported (4%).

Likewise about 33% women reported having abnormal vaginal discharge in the past month. The most common symptoms accompanied these complaints were bad smell (57%) and yellow in color (33%). Not many women reported suffering from sores or blisters on their genital areas (2.4%) in the past month. Another important symptom of STI, having lower abdominal pain during sex in the past month was reported by 18% of women.

Regarding to health seeking behavior, for those who have been returned at least one, the mean duration between one visit to another visit is 1.3 month (median=1 month). Again, among returning patients, 32.5% reported being treated in their previous visits. Approximately 25% of women in the study experienced self-medicated outside visits.

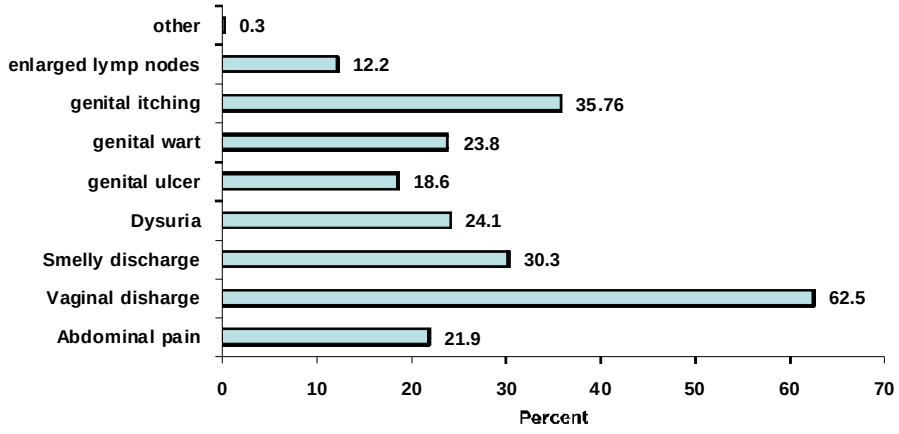
Table 5: Reproductive health symptoms & health seeking behavior among female groups

	DSWs	IDSWs	TOTAL
Abnormal discharge in the past month	33%	33%	33%
% of SW reported thick yellow discharge in the past month	25.8%	39.1%	32.9%
% of SW reported LAP during intercourse in the pas month	19.3%	16.5%	17.7%
Any sores/blisters in the past month	3.60%	1.40%	2.4%
# of month since last visit	1.2 (1)	1.5 (1)	1.3 (1)
Among those returning, % of treated previous time	32.1%	32.8%	32.5%
Self-medication outside visits	20.6%	33%	24.9%

4.5. Basic STI knowledge

Each woman was asked to list all the symptoms they knew associating with the presence of any STIs among women and men. The STI symptom among women most known by study participants was vaginal discharge (62.5%) followed by genital itching (35.6%)(Figure 5). Generally, 73% of women could cite at least one sign of STIs among women.

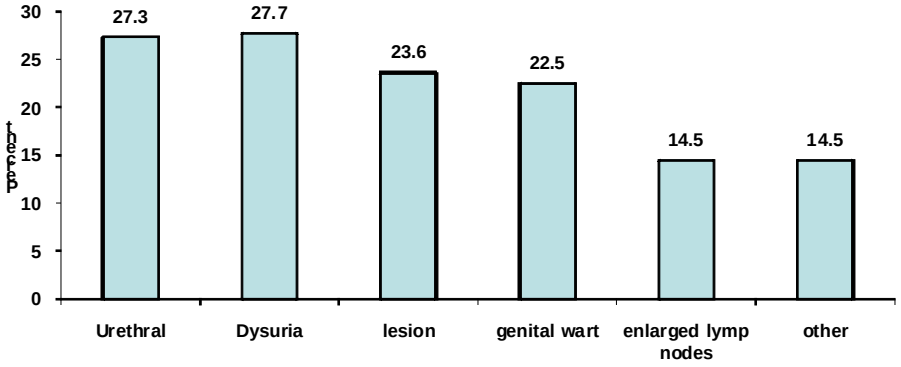
Figure 5: Describe any symptoms of STI/RTI of women



In the response to the question related to the symptoms of STI among men, there was no symptom that was distinctively known by women. Urethral discharge, dysuria, genital sores and genital warts were reported almost at similar frequent (Figure 6). This may mean that women generally do not have a clear knowledge about STI symptoms among their male

partners. As result, only 45% of women could cite at least one symptom of STIs among men.

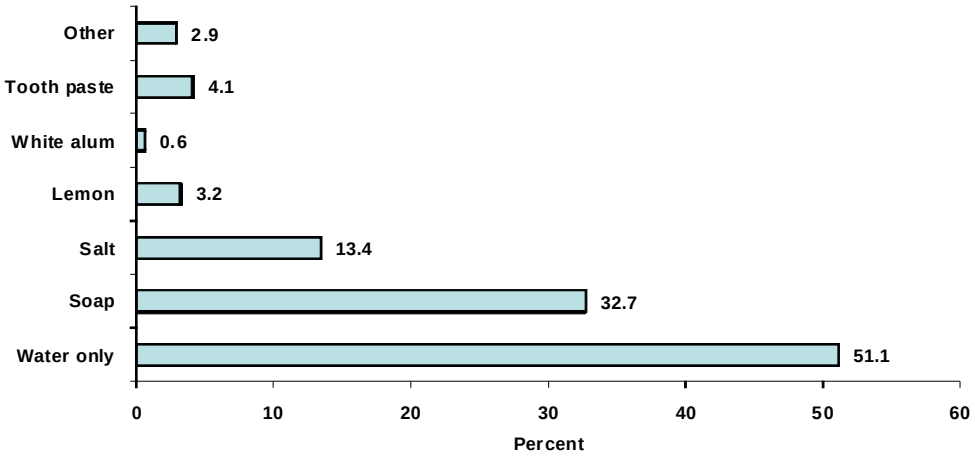
Figure 6: Describe any symptoms of STI/RTI among men



4.6. Vaginal douching

Majority of women in the study (57.6%) reported having douching inside vagina after having sex. Higher proportion of direct female sex workers seem to practice douching after sex compared indirect sex workers (84% Vs 38%). Water and soap were the most common material used for their douching practice as it was reported at 51% and 32.7% for only water and soap, respectively (Figure 7). Among those who practiced douching after sex, 54% reported having vaginal douching no more than 6 hours before the survey interview started. It is important that, this douching practice may have some effects on the lab results which based on vaginal swap.

Figure 7: Douching Practice

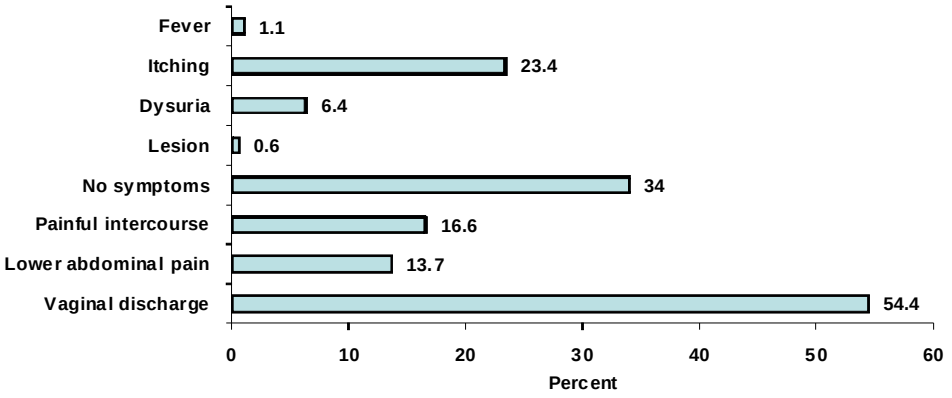


4.7. Standard Medical History

Similar to face-to-face interview, medical record history were filled by health care workers through the combination of asking questions and physical exam during visit in clinic. One thousand and twenty three medical records were collected for the purpose of this study, among which 923 records were for the first visits and other 401 were the follow up visits.

The main complaining voiced by at the clinics were vaginal discharge (54.4%), followed by painful intercourse (16.6%) and lower abdominal pain (13.5%) (Figure 8)

Figure 8: Complain when visiting STI Clinics



On average, women (direct and indirect female sex workers) came to the clinics for their STI symptoms after 9 days of the problem (median of 4 days). During their visit, women were asked to assess their risk behavior, as well as to assess the risk of having cervicitis which based on set of questions and/or speculum exam.

The risk assessment was conducted systematically among women who reported having vaginal discharge and/or lower abdominal pain. The assessment was based on the reported symptom and/or physical exam. Four questions were asked, and answered 'Yes' to two of these questions were sufficient to classify women as having cervicitis and the treatment was provided accordingly. Those four questions are; having thick yellow discharge, having lower abdominal pain during intercourse, having sex with more than 5 clients per day and having unprotect sex with new clients.

From the medical records, 30% of women reported their vaginal discharge was thick and yellow. 25% of women said they had suffered from lower abdominal pain while having sex. By taking in consideration all criteria to assess the risk of having cervicitis, it has been found that 43% of women attending the clinics were diagnosed as at high risk of cervicitis by solely based on self-reported information. In addition to the collection of self-reported health information, health workers also performed physical exam. It has been found that 2.4% of

women had tender inguinal lymph nodes, 2.3% had genital warts and 12% had pain by bimanual examination. However it is a surprise that for bimanual examination the proportion of IDSW who had painful bimanual examination is much higher than that of DSW (19% vs 4%).

All women who participated in the study were examined by health care workers using speculum. 66% were found to have vaginal discharge. The characteristics of vaginal discharge found during speculum examination among those who have VD were, lait discharge (10%), eau-de riz discharge (87%), and greenish discharge (3.1%).

Speculum examination was also used to diagnose cervical discharge. It has been found that 15% of women receiving speculum exam were found to have cervical discharge (visible discharge and/or positive swab test). Among women who were suffering from cervical discharge, 29% were visible and 71% were positive swab test. Cervical erosion and cervical bleeding were found 23% and 6 % of women respectively. Surprisingly the study found that the proportion of IDSW who had cervical erosion is much higher than that of DSW (36% vs 6%).

Table 6: Clinical examination among female groups

	DSWs	IDSWs	TOTAL
Vaginal discharge seen by using speculum at the visit	68%	64%	66%
Curd-like VD among those with vaginal discharge seen by speculum	8%	11%	10%
Eau-de-riz VD among those with vaginal discharge seen by speculum	90%	84%	87%
Green VD among those with vaginal discharge seen by speculum	1%	4%	3%
Cervical discharge seen by speculum or positive swab test	16%	15%	15%
Cervical erosion	6%	36%	23%
Cervical bleeding	8%	4%	6%
Pain by bimanual examination	4%	19%	12%

4.8. Laboratory Examination

Syphilis was found among 2.9% of women who were the first visit. This low prevalence of syphilis was among both direct and indirect female sex worker (2.9% Vs 3%). Wet preparation was done on 1322 specimen of which 27 samples or (2%) showed the presence of Trichomonas, 117 sample or (8.9%) had Budding yeast and 466 samples or 35.3% had clue cells. Unfortunately, results from all tests performed on wet preparation were unable to confirm with quality control.

Another laboratory test done on 1324 specimens was Gram Strained Vaginal smear. In this lab exam, Nugent score were counted. Among all specimens, 11.6 presented BV intermediate and 32.6 represents BV infection. However, 86 women of 1322 (6.5%) presented Budding yeast or Candidas. After the quality control of test for budding yeast and Nugent Score were performed, the prevalence of quality adjusted prevalence of Candidasis and BV were 13.4% and 36%, respectively.

Endocervical Smear was also performed among all women (1324) participated in the study but unfortunately there were on1102 slides that had endocervical smear on them after staining. The median number of white blood cells (WBC) presented in the specimen was 6 WBCs/HPF with the mean of 12 WBCs/HPF. Based on this laboratory exam, 47% of

women had 10 WBCs/HPF or more reflecting that they might have been suffering from cervicitis caused by Gonorrhea and/or Chlamydia.

Table 7: Laboratory examination among female groups

	DSWs	IDSWs	TOTAL
Prevalence of serologic syphilis (presumptive)	2.9%	3%	2.9%
Microscopic exam of wet preparation showing Trichomonas	1.8%	2%	2%
Microscopic exam of wet preparation for yeast	8.0%	10%	8.9%
Microscopic exam of wet preparation for clue cells	40.0%	31%	35.3%

4.9. Assessment of the Current STI Algorithm

4.9.1. Prevalence of presumptive cervical infection among high risk women based on recommended national algorithms

Among 1324 women came to the clinics and after the consultation, 793 women (59.9%) complained of having either vaginal discharge and/or lower abdominal pain (Figure 9).

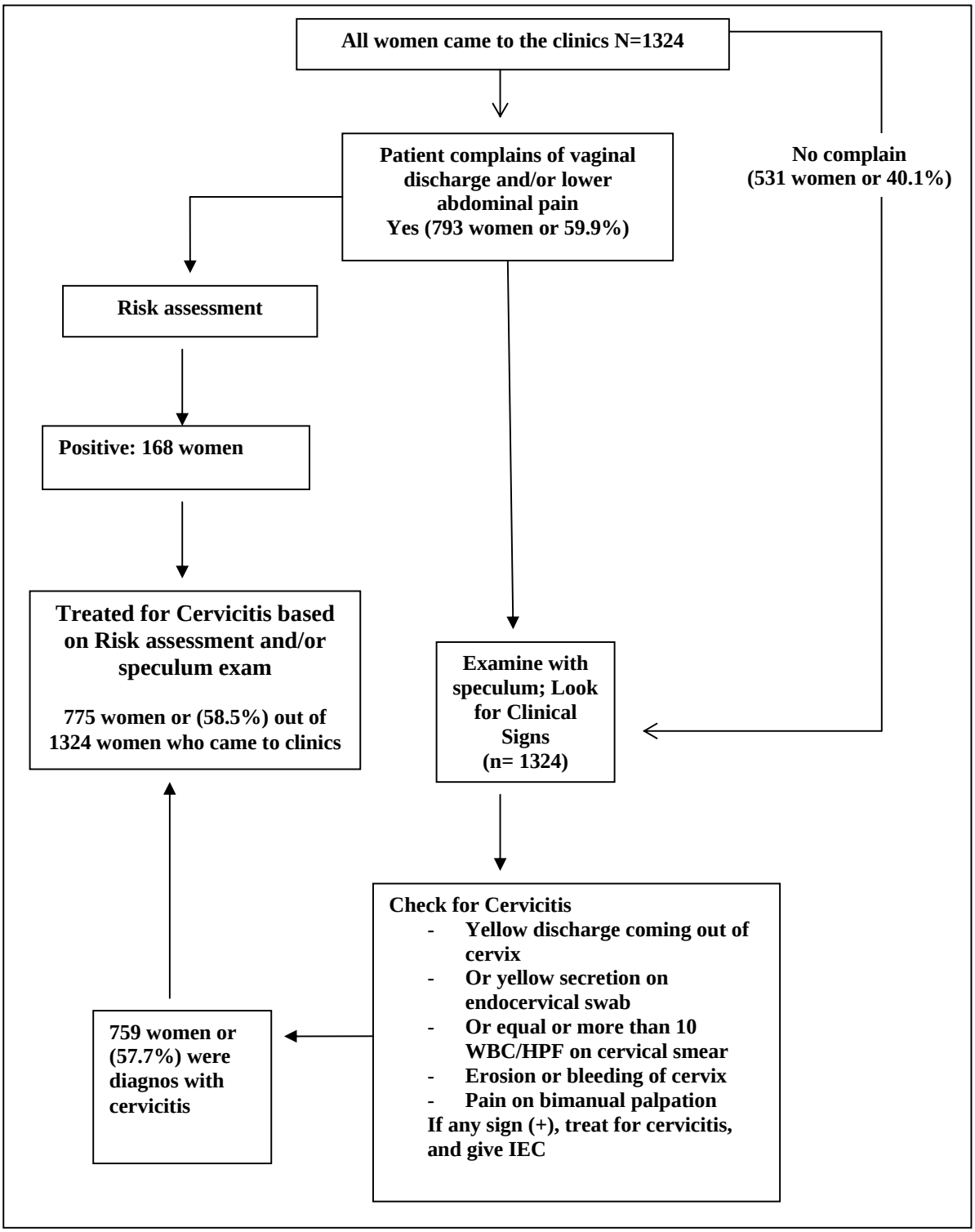
All these women were assessed for their risk of having cervicitis. Based the risk assessment algorithms, four questions were used, in which having least 2 affirmative answered was *considered as having positive risk assessment. Among 793 women* complaining of having either vaginal discharge and/or lower abdominal pain,*168* women *were found to have positive risk assessment for cervicitis. In response, these women were treated for cervicitis.*

Speculum exam were performed among all women complain or not complain of having vaginal discharge or lower abdominal pain to check for cervicitis. It has been observed that 759 women (or 57.7%) were found to have cervicitis based on the combination speculum examination and laboratory work (white blood cells count). Consequently, there were a total of 775 women (58.5%) were identified as having cervicitis based on either standard risk assessment or speculum exam algorithms (Figure 9).

Table 8: Presumptive cervical infection among female groups

	DSWs	IDSWs	TOTAL
% of risk assessment positive	8.9%	16%	12.7%
Presumptive diagnosis of cervicitis, based on clinical exam and laboratory	48.7%	65.2%	57.7%
Presumptive diagnosis of cervicitis, based on either risk assessment or clinical exam and laboratory	50.6%	65.2%	58.5%

Figure 9: Management of presumptive cervical infection in female sex workers



4.9.2. Prevalence of Cervicitis among high risk women based from Laboratory confirmation

Among those who came to the clinics for their presumptive STIs symptoms, only 1316 had their confirmatory result for the diagnosis from laboratories because there were 9 specimens were broken.

The prevalence of Chlamydia among those women came to the clinics was 11.3% and the prevalence of Gonorrhea was 6.3%. Thus, the proportion of women having either Chlamydia or Gonorrhea were 15.2%, corresponding to having 200 women positively confirmed having cervicitis. Furthermore, it has been found that direct female sex workers have higher prevalence of Chlamydia (11.8% Vs 10.5%) and Gonorrhea (9.8% Vs 3.5%) compared to indirect sex workers.

4.9.3. Sensitivity and Specificity of the current STI for STI management

Assessing sensitivity and specificity of the risk assessment

	True Positive	True Negative	Total
Assessment Positive	19	149	168
Assessment Negative	181	966	1147
Total	200	1115	1315

Based on the table, the sensitivity of risk assessment alone is 19/200 = 9.5% and the specificity is 966/1115=86.6%. That is, using risk assessment alone will miss a lot of cervicitis cases. In order word, among 100 true cervicitis cases, the risk assessment can only detect correctly about 10 cases.

Assessing sensitivity and specificity of algorithm if only clinical signs and/or WBC are considered

	True Positive	True Negative	Total
Risk positive	132	623	755
Risk negative	68	484	552
Total	200	1107	1315

Based on the table, the sensitivity of this risk alone is 132/200 = 66% and the specificity is 484/1107=43.7%. That is, using this risk alone to diagnose cervicitis may lead to over as well as under treat of cervicitis cases. The algorithm using only clinical signs and/or WBC also have poor positive predicted value (132/755= 0.1748).

Assessing sensitivity and specificity of the standard algorithm

In order to assess the specificity and sensitivity of the testing algorithm, only sample both have value for lab results and standard algorithm was used. The standard algorithm is the combination of using risk assessment, clinical signs and WBC when making diagnosis of cervicitis among female sex workers coming to STI clinics.

	True Positive	True Negative	Total
Test Positive	135	636	771
Test Negative	65	479	544
Total	200	1115	1315

Based on the table, the sensitivity of the algorithm is 135/200 = 67.5%, the specificity is = 479/1115=43%. Compared to previous two components, its combination helps raising sensitivity to 67.5%. However, its specificity drops to just 43%. Alternatively, the standard algorithm currently in use has very low capability of making correct diagnosis of STI cases. It has found that among 100 cases identified as positive for STIs through the algorithm, only 18 are truly STI cases.

Therefore, the performance of the standard algorithm was not satisfactory since while the algorithm let go 32.5% of cervicitis without treatment, it also over treat 57% of the non-cervicitis cases. Thus, a more sensitive and specific protocol should be developed in order to improve the STI case management for female sex worker.

4.10. Suggested model for STI case management

One of the main principles for generating a new STI case management was to learn from the weakness of the existing algorithm. Therefore, all parameters used in current standard algorithm will be individually checked via univariate and multivariate analysis to examine their associations with the occurrence of cervicitis. All variables were originally classified into 3 groups; risk assessment, lab and clinical exams and speculum exam groups.

There are 4 parameters were currently in use for assessing the risk of having cervicitis. From the univariate analysis, it has been found that none of the parameters have a statistically significant association with the diagnosis of cervicitis at 5% level of significance. That means, the prevalence of cervicitis among those who have all these parameter does not differ from the one among those who do not have these parameters. Furthermore, same results were obtained from multivariate analysis and subgroup analysis among only those who complained of having vaginal discharge or lower abdominal pain at the time of their visit.

Table 9: Univariate analysis of the associations of all parameters in the risk assessment of the current algorithm

Parameters	Odd ratios	P-values
Having more than 5 clients per day on average	1.46	0.27
Having thick yellow discharge	.74	0.09
Having lower abdominal pain during intercourse	.93	0.70
Do not use condom with new clients	.43	0.25
Risk assessment (having at least 2 of the above)	.68	0.13

Regarding to variables collected from lab and clinical exams, it has been found that having yellow discharge coming out of cervix, bleeding from cervix, having eau de riz or greenish discharge are significant predictors for cervicitis. However, these clinical signs can only be accurately examined via speculum examination. Thus speculum examination should be one of the important components in the new proposed algorithm for STI management. Interestingly, it has been found that symptoms complained by high risk women are not good predictors for the existence of cervicitis.

Table 10: Univariate analysis of the association of all parameters in clinical and speculum exams of the current algorithm for STI

Parameters	Odd ratios	P-values
Having yellow discharge coming out of cervix	2.63	0.001
Having yellow secretion on endocervical swap	0.97	0.91
Having erosion of cervix	0.77	0.19
Having bleeding of cervix	1.83	0.03
Having curt like/lait vaginal discharge	0.81	0.54
Having eau de riz discharge	1.67	0.002
Having greenish/frothy discharge	3.61	0.002
Having fever	0.93	0.92
Having Itche	0.82	0.30
Pain on bimanual palpitation	0.72	0.21
Complaining of having vaginal discharge	1.03	0.82
Complaining of lower abdominal pain	0.88	0.57
Complaining of lower abdominal pain during intercourse	0.94	0.78
Complaining of having dysuria	1.00	0.98

In addition to the risk assessment and clinical examinations, laboratory examination is also included in the existing algorithm. Few parameters were checked by lab technicians in order to help making accurate diagnosis of STI. Most of the lab results are good predictors for cervicitis, except having yeast infection diagnosed by gram stained vaginal smear. Therefore, laboratory component is also vital for improving the validity of the diagnosis of cervicitis.

Table 11: Univariate analysis of the association of all parameters in lab exam of the current algorithm for STI

Parameters	Odd ratios	P-values
Having 10 or more white blood cell count on cervical smear	1.65	0.003
Having yeast infection (by using wet preparation)	0.55	0.07
Having clue cells	1.74	0.0001
Having Nugent score more than 7	1.83	0.0001
Having yeast infection (by using Gram Stained)	0.64	0.22

5. PROPOSED NEW ALGORITHMS

Based on the previous analysis, it has been shown that parameters used for the risk assessment of cervicitis are not good enough so new variables should be explored for that purpose and that clinical exams, especially speculum exam, and lab exams are crucial in the process of making accurate diagnosis of cervicitis. Conceptually, we want to classify all the criteria for detecting cervicitis among high risk women in 3 components; socio-demographic information, behavioral information, clinical signs and laboratory results.

5.1. Risk related to socio-demographic

Two variables which have been shown having associations with the presence of Gonorrhea and Chlamydia infection is education and age. The risks of having cervicitis among those who have no schooling and those who have some schooling are 17.49% vs 13.69% respectively with p=0.064. The risk of having cervicitis among those aged equal or less than 20 year old is higher than those aged more than 20 years old (21.26% Vs 13.35% p=0.001).

Besides, occupation is also associated with cervicits. It has been found that direct female sex workers have a high prevalence of cervicitis compared to indirect female sex workers (18% Vs 12.6%, p=0.006).

High risk women who aged less than 20 years old and having no education were at higher risk of having cervicitis (OR= 2.02, 95%CI: 1.25 – 3.27). This model is still hold for individual groups of direct and indirect female sex workers. Thus, having younger age and have no education could be used as criteria used to assess the risk of cervicitis.

5.2. Risk related to behaviors

Surprisingly, It has been found that behaviors have no relationship with the prevalence of cervicitis. From univariate analysis, having more than 5 clients per day and reporting consistent use condom do not have any association with the presence of cervicitis. However it has been found that the prevalence of cervicitis among those who douche were a bit higher than those who do not douche inside vagina (16.54% vs 12.52%, p=0.054)

5.3. Risk related to clinical signs and laboratory results

Six clinical signs and laboratory results showed association with the presence of cervicitis. Those variables are; having vaginal discharge as eau-de-riz, green vaginal discharge, having yellow discharge, having cervical bleeding, clue cell, Nugent score and white blood count.

It has been observed that women who have at least 2 of sing above (at least one sign from clinical and another one from laboratory signs listed above, the prevalence of

cervicitis was significantly higher than those who have less than 2 signs (63.5% Vs 36.5%, p=0.0001).

In the new algorithm, high risk women who are complaining of having lower abdominal pain or vaginal discharge, aged less than 21 years old and having no education or having at least 2 clinical/laboratory symptoms will be considered as having suffered from cervicitis. As the result of the new algorithm, 70% of true cervicitis case will be detected and 53% of those who have no disease will be categorized as no disease by the algorithm.

Note that, the inclusion of variables such as having abortion, lower abdominal pain during or not during intercourse and vaginal discharge are also included into the new algorithm although it is not statistically significance. (Figure 10)

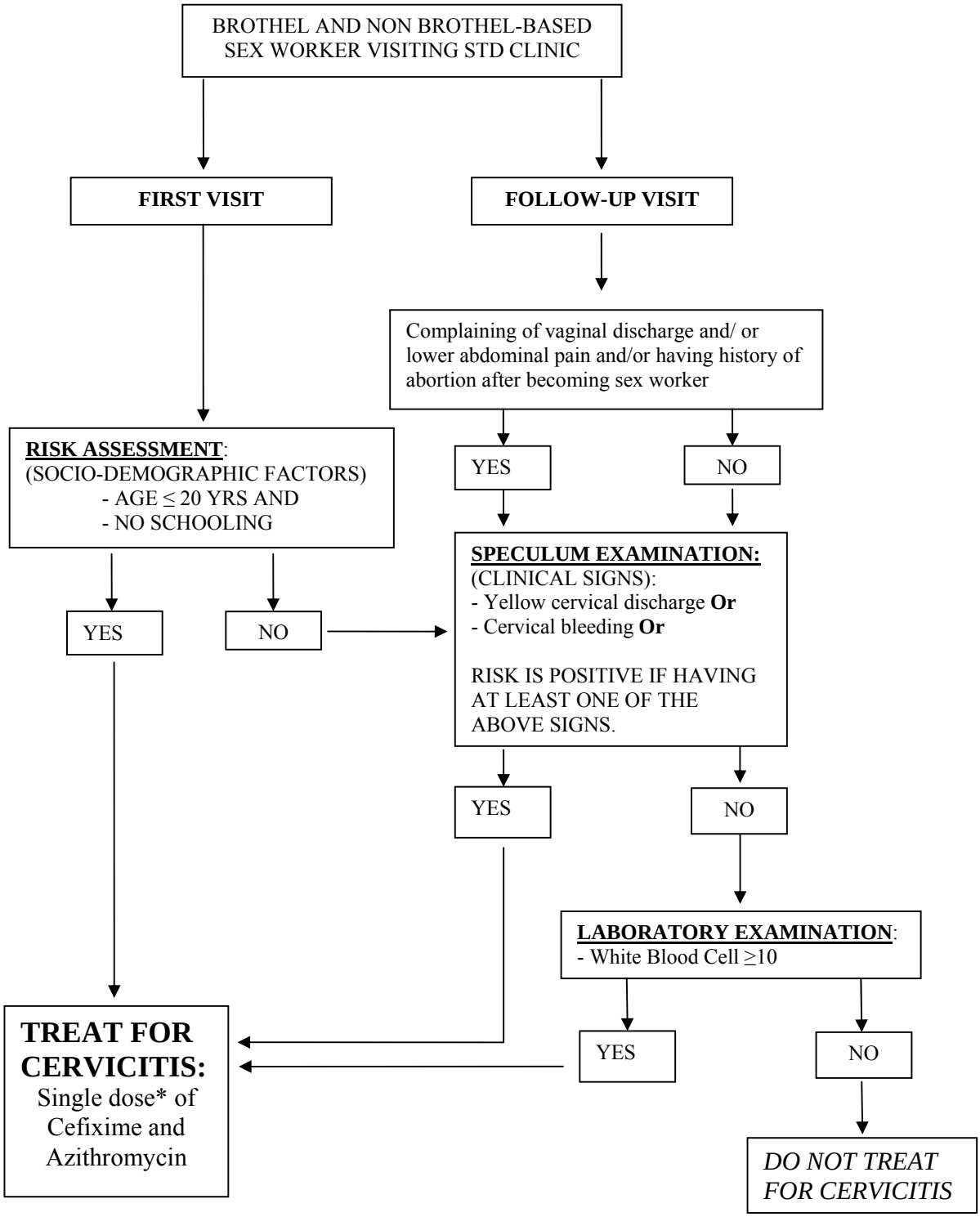
5.4. Flow of the proposed algorithm for STI management

Women who come to the clinics will be assessed to categorize into 2 groups: those complaining of having vaginal discharge and/or lower abdominal pain and/or having history of abortion after becoming female sex workers and those who do not have any symptoms.

The group with symptoms will be assessed based on their socio-demographic characteristic; such as having age 20 years old or less and have no schooling. If this assessment is affirmative, cervicitis treatment will be prescribed without further clinical or laboratory examination. However, for those with negative assessment, they will be further investigated.

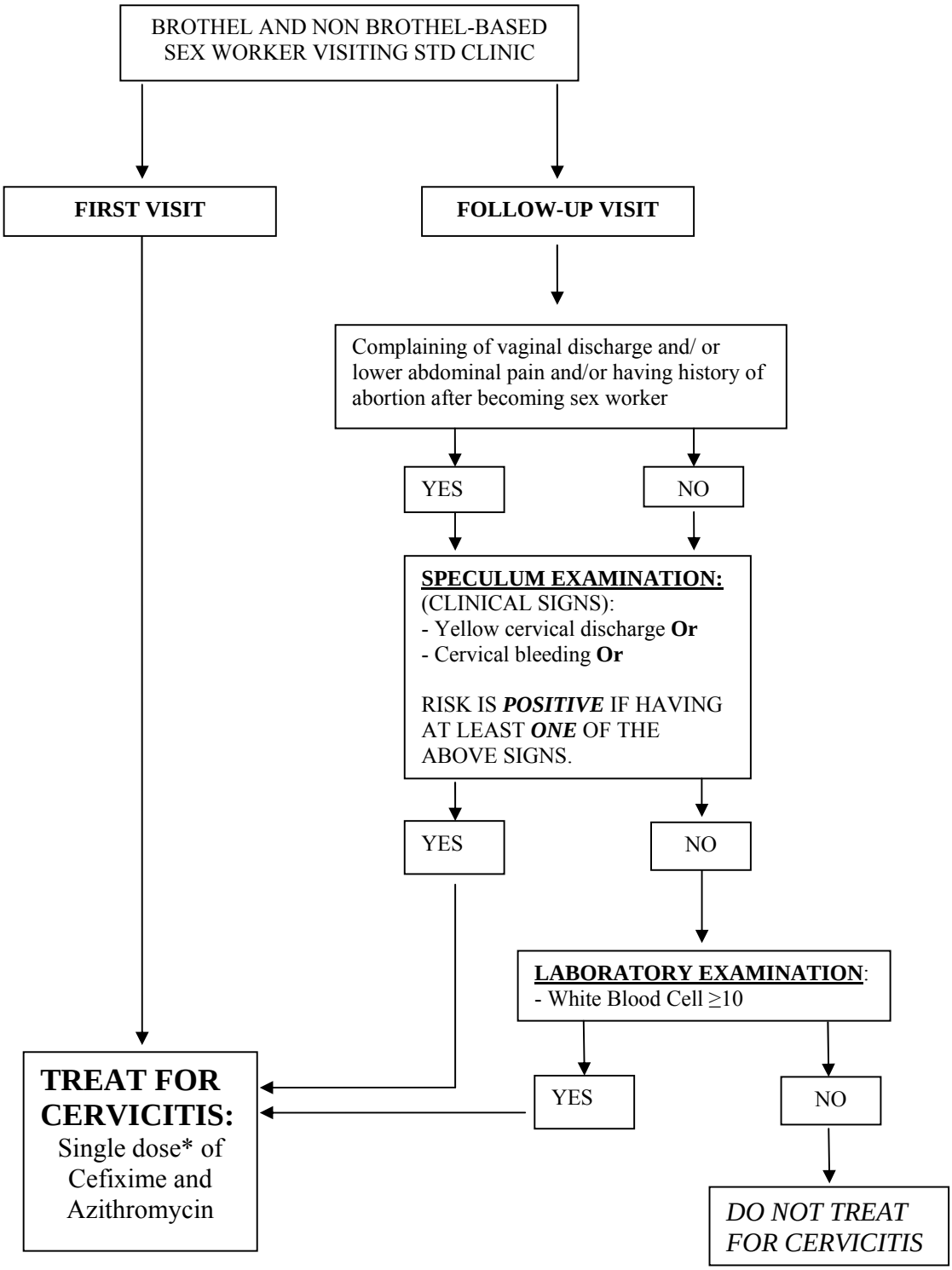
Women who come to the clinic but have no complain related to STI symptoms and those who have negative assessment, will be examined by using speculum and series of laboratory tests. If they present at least 2 signs (one clinical sign and one laboratory sign), they will be treated for cervicitis, otherwise no cervicitis treatment is needed.

Figure 10: Proposed algorithm for cervicitis management in sex workers (Option 1)



**Alternative regimen is applied only when single dose regimen is not available*

Figure 11: Proposed algorithm for cervicitis management in sex workers (option 2)



**Alternative regimens is applied only when single dose regimen is not available*

6. CONCLUSION

This study is the first one conducted in Cambodia to evaluate the validity of the existing STI management protocol. However, it was not the first one investigating the prevalence of STIs among female sex workers which included both direct and indirect female sex workers.

It has been observed that the prevalence of Chlamydia was 11.3%, followed by 6.3% of Gonorrhea infection. In STI survey in 2005, the prevalence of Chlamydia was 14% and Gonorrhea was 12% among direct female sex workers. The prevalence of Chlamydia and Gonorrhea of in STI survey in 2005 were different from this study showing the prevalence of Chlamydia and Gonorrhea among direct female sex worker of 11.8% and 8.9%, respectively. Despite the difference, it is impossible to claim that the prevalence of STI among direct female sex worker dropped in 2007 since the two studies different in terms of its objectives and methodology. Besides, the prevalence of Syphilis among direct female sex worker was 2.3% in 2005 and in this survey it was 2.9%. Again, direct comparison between the two prevalence is discouraged.

Interestingly, it has been found that condom use while having sex with new clients was very high in both female groups, however about 43% of them reported having at least one abortion after becoming sex worker. This contradiction may reflect the possibility that the condom use among sweetheart may remain very low as suggested in other studies.

Regarding knowledge about reproductive health, majority of female identified having vaginal discharge and genital itching as signs of STI/RTI symptoms occurring among female patients. However, the group was not sure in recognizing the STI/RTI symptoms occurring among male patients. This may result in the potential high transmission of STI if condom is not used when having sex with their sweetheart.

In terms of the validation of the current algorithm for STI management, the study showed that its sensitivity and specificity was quite low (67.5% & 43%, respectively). This may result in over treatment especially in the population where the prevalence of cervicitis is not high. Thus, this may responsible for the over treatment of cervicitis reported in Cambodia. In depth investigation illustrated that some components used in current algorithm do not have any association with having cervicitis, leading to low specificity of the current algorithm. Components that have no association with cervicitis is 'the risk assessment'. That is; the risk assessment does not have a ability to differentiate between those who have cervicitis and those who do not have cervicitis (OR=0.68, p=0.13). Furthermore, some clinical and laboratory signs were also not associated with the presence of cervicitis. Only clinical sign collected through speculum examination (having yellow discharge from cervix, bleeding of cervix, having eau de riz discharge, and having greenish discharge) has a predictability on the presence of cervicitis. Thus, other parameters that are not relevant with the presence of cervicitis should be excluded from the algorithm in order to improve it.

Consequently, a new algorithm with the sensitivity of 70% and specificity of 53% was proposed though both its sensitivity and specificity are still relatively low. The new algorithm could have a higher specificity so that over treatment could be reduced. However if possible it should be considering about presumptive treatment of cervicitis among first visitors. If presumptive treatment for first visitors is applied, it is expected that the prevalence of follow up visitors will become very low then the proposed new algorithms may be more helpful so that under treatment could be solved as well.

Importantly, before the full implementation of these newly proposed algorithms, a pilot stage could be conducted to evaluate its feasibility. The new algorithm may require more skills in performing speculum examination and laboratory capacity. This higher requirement may not be met at some STI clinics without full support from the ministry of health of Cambodia and especially from the national center for HIV/AIDS Dermatology and STIs.