# Validity Assessment of Flowcharts for Syndromic Management of Vaginal Discharge

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## Glossary

| | |
|---|---|
| BV | Bacterial Vaginosis |
| BCC | Behaviour Change Communication |
| BWHC | Bangladesh Women Health Coalition |
| CA | *Candida albicans* |
| CT | *Chlamydia trachomatis* |
| CWFD | Concerned Women for Family Development |
| ESP | Essential Services Package |
| GoB | Government of Bangladesh |
| HIV | Human Immunodeficiency Virus |
| HPSP | Health and Population Sector Programme |
| ICDDR,B | International Centre for Diarrhoeal Disease Research, Bangladesh |
| ICPD | International Conference on Population and Development |
| NG | *Niesseria gonorrhoeae* |
| NGO | Non-government Organization |
| NIPHP | National Integrated Population and Health Programme |
| ORP | Operations Research Project |
| PHC | Primary Healthcare |
| PID | Pelvic Inflammatory Disease |
| QIP | Quality Improvement Partnership |
| RTI | Reproductive Tract Infection |
| STD | Sexually Transmitted Disease |
| STI | Sexually Transmitted Infection |
| TV | *Trichomonas vaginalis* |
| UFHP | Urban Family Health Partnership |
| USAID | United States Agency for International Development |
| WHO | World Health Organization |

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## Executive Summary

Prevention and control of reproductive tract infections (RTIs) and sexually transmitted infections (STIs) is one of the key components of reproductive healthcare in Bangladesh. Their early detection and treatment, preferably during first contact of clients with healthcare providers, is essential for their successful prevention and control. The National Integrated Population and Health Programme (NIPHP), in collaboration with the Ministry of Health and Family Welfare (MOFHW), Government of Bangladesh (GoB), developed a technical standard and service-delivery protocol as an aid to RTI/STI management services at the primary healthcare-level facilities. This protocol includes several RTI/STI syndromic management flowcharts.

Although modifications of the RTI/STI syndromic management flowcharts, starting with the symptom vaginal discharge included in the NIPHP protocol, have been made based on a consensus in the 'National-level Meeting on Syndromic Approach of RTI/STI Case Management' held on 22 May 2000, these are still to be validated. ICDDR,B: Centre for Health and Population Research, in collaboration with Urban Family Health Partnership (UFHP) and Quality Improvement Partnership (QIP), conducted validation exercise with funding support from the United States Agency for International Development (USAID), Dhaka.

This clinic-based cross-sectional study assessed the validity of two modified flowcharts for syndromic management (with and without speculum examination) of vaginal discharge. The assessment included sensitivity, specificity, positive predictive value, and negative predictive value of the flowcharts in diagnosis of common RTIs/STIs. The study was conducted in five NGO-operated clinics during March 2001-July 2002. In total, 2,752 women, complaining of vaginal discharge, were tested at the RTI/STI research laboratory of ICDDR,B for *Niesseria gonorrhoeae* and *Chlamydia trachomatis* in the endocervix using the PCR technique. Of these women, 1,195 were also tested for *trichomonas vaginalis*, bacterial vaginosis, and candidiasis. Laboratory tests on vaginal fluid specimens included Gram-staining for diagnosis of bacterial vaginosis, culture for demonstration of *T. vaginalis,* and microscopic examination and culture for yeasts. Validity of the modified vaginal discharge-management flowcharts at the clinic level was assessed taking the research laboratory tests as the gold standard.

Participants were aged 15-49 years, and most of them were married and housewives. In addition to vaginal discharge which was an inclusion criterion, various other symptoms, such as foul-smelling discharge, genital itching, wet garments, dysuria, and dysperunia, were common. The common signs included oozing of foul smelling in various colours (white, greyish white, greenish yellow, and yellow), type (watery, curd-like, frothy), and quantity (scanty or profuse). Endocervical mucopus and friability of cervix were detected in 17.2% and 33.3% of women studied respectively.

Candidiasis (32.1%) was commonly detected by laboratory tests among women tested for vaginal infections, followed by bacterial vaginosis (22.7%). *T. vaginalis* was detected in 3.5% of women. Gonorrhoea and *Chlamydia* were confirmed in 2.4% and 1.7% of women by PCR.

Among the symptoms and signs included in the management flowcharts as diagnostic criteria for vaginal and cervical infections, unpleasant odour, vulvar itching, and reddish swollen valva were associated with vaginal infection. The criteria, such as greenish yellow and frothy discharge, were highly significant with vaginal infection caused by *T. vaginalis*. Curd-like discharge was associated with *Candida* infection. No signs included in the flowchart for diagnosis of bacterial vaginosis were associated with laboratory-confirmed bacterial vaginosis. Cervical mucopus discharge was significantly associated cervical infections caused by *N. gonorrhoeae* and/or *C. trachomatis.*

Results of validation exercise showed that the flowchart without speculum examination had 100% sensitivity in detecting infections caused by bacterial vaginosis, candidiasis, or trichomoniasis with 52% positive predictive value and indeterminate specificity. The flowchart with speculum examination was 100% sensitive with indeterminate specificity for diagnosis of bacterial vaginosis or trichomoniasis, but the positive predictive value was 24.8%. For candidiasis, the flowcharts had a sensitivity and a specificity of 64.4% and 49.4% respectively and positive and negative predictive values of 37.4% and 74.5%, respectively. The flowcharts had a sensitivity of 37.7% for cervicitis (cervical infection with *N. gonorrhoeae* and/or *C. trachomatis*) with a positive predictive value of 4%. The specificity of the flowchart for cervical infection was 63.9% with the negative predictive value of 96.2%.

In addition to the validation exercise, the study explored some perceived risk factors relating to cervical infections and looked also into the associations of common presenting symptoms and signs by women complaining of vaginal discharge with specific infections. Associations were found with the factors: a woman suspected her husband/partner having sexual relationship with another woman and woman who reported that her husband/partner had STI symptoms. Most symptoms and signs were associated with specific vaginal infections.

The study results confirm that the tested management flowcharts need further modifications with emphasis on their specificity for vaginal discharge and both specificity and sensitivity for cervical infections. The role of speculum examination should be considered in modifying the flowcharts in the diagnosis of vaginal infections. Further modifications of the flowcharts can be made based on the results of the present study, and the validity of further modifications could also be done based on the data available in this study. In addition, the study results suggest further exploration on other causes of vaginal discharge.

For quality RTI/STI services, the Technical Standard and Service Delivery Protocol for Management of RTIs/STIs is very vital to promote and practise medical and professional standards. Efforts have been made to standardize the Protocol. The study results may additionally contribute to the efforts in the standardization of the Protocol and in the improvement of vaginal and cervical infection management.

## Introduction

Reproductive tract infections (RTIs) and sexually transmitted infections (STIs) are major public-health problems in developing countries. In 1994, the International Conference on Population and Development (ICPD) in Cairo recommended that control of RTIs/STIs should be considered as one of the essential components of reproductive health (1). In Bangladesh, the Health and Population Sector Programme (HPSP) and National Integrated Population and Health Programme (NIPHP) have prioritized control of RTIs/STIs as one of the key components of reproductive healthcare in the essential services package (ESP) (2,3). These programmes address behaviour change communication, management of RTI/STI cases, including referral of partners, and promotion of condoms in the prevention and control of RTIs/STIs. Nevertheless, early diagnosis and treatment of RTIs and STIs is crucial for their management.

Three main categories of RTIs are: (a) sexually transmitted infections, (b) endogenous, non-sexually transmitted infections, and (c) iatrogenic infections (e.g. infections introduced at childbirth or as a result of inadequate hygiene practices during insertion of intrauterine device (IUD), unsafe abortion, etc.) (4). This report considers management of some common RTIs at the primary-level health facilities. These include bacterial vaginosis (BV), *Trichomonas vaginalis* (TV), candidiasis, *Neisseria gonorrhoeae* (NG), and *Chlamydia trachomatis* (CT).

The effects of RTIs may be devastating. If left untreated, the consequences of sexually transmitted RTIs have far-reaching implications for women, which may not only inflict physical discomforts, but also can often cause other serious problems, such as pelvic inflammatory disease (PID) with resultant infertility, ectopic pregnancy, cervical cancer, foetal wastage, low birth-weight, infant blindness, neonatal pneumonia, and mental retardation. It can also increase the risk of maternal and neonatal morbidity and mortality. The social burden of STIs, which manifests itself as stigma and discrimination, falls predominantly on women. In terms of economic consequences, STIs rank among the five most important causes of years of productive life lost in developing countries and account for loss of millions of dollars each year (5). Non-sexually transmitted RTIs have an impact on family-planning programmes countering acceptance and continuation of contraceptive methods. This impact can be direct, when the contraceptive user believes that the symptoms of the infection are contraceptive-related side-effects, or indirect, in the occurrence of RTI complications which prevents healthy childbearing resulting in legitimate fear from preventing the practice of limiting or spacing child births. Several epidemiological and biological studies support the fact that both RTIs and STIs, especially those associated with genital ulceration, enhance HIV transmission (6).

Early detection and treatment of RTIs/STIs and promotion of community awareness through behaviour change communication (BCC) are the key issues relating to their prevention. BCC messages should include topics, such as safer sex practices and appropriate and timely healthcare-seeking behaviour. In improving RTI case management to date, the focus has been on diagnosis and treatment. To achieve high rates of cure, drug compliance, referral and treatment of partners, referral linkages, and education of clients are all essential (7).

A number of key issues relating to strategies for controlling RTIs/STIs have been identified by the intervention team of the former Operations Research Project (ORP) on prevention and management of RTI/STD through reviewing literature, visiting projects in Bangladesh, and discussions with the Government of Bangladesh (GoB) and NIPHP partners. The identified issues were shared and discussed formally with the United States Agency for International Development (USAID) and with all the NIPHP partners in the 3rd Intervention Design Workshop in June 1998 at ICDDR,B. "Validity assessment of vaginal discharge-management flowcharts" was one of the operations research issues that was prioritized in this meeting and subsequently endorsed at two meetings of the NIPHP Operations Research Working Group meetings held in August 1998.

## Rationale

Although limited data are available on the prevalence and aetiology of RTIs/STIs in Bangladesh, results of studies conducted by ICDDR,B, Save the Children (USA), Population Council, and Bangladesh Women Health Coalition (BWHC) indicate that RTIs are prevalent in Bangladesh (8-11).

Primary healthcare facilities in developing countries face several constraints in relation to optimal management of patients with STIs (12). These constraints include limited access to laboratory technology necessary for aetiological diagnoses of STIs, shortage of trained staff resulting in high workloads and, therefore, limited staff time available per patient. The World Health Organization (WHO) has advocated a simpler and more cost-effective method for detection and management of RTI/STI cases through a syndromic approach (13). This approach is to manage common RTIs using clinical flowcharts based on identifying a syndrome—a group of symptoms and signs associated with a number of well-defined aetiological pathogens that cause the symptoms reported by patients.

The advantages of syndromic management include immediate care, treatment at the first visit, and cost-saving by not requiring expensive laboratory tests. Treatment at the first visit results in not loosing the patient for follow-up before treatment is initiated, and also results in the reduction of further transmission and complications from

untreated infections and in eliminating the need for a return visit for collecting laboratory test results. The use of flowcharts in the management of RTIs/STIs standardizes diagnosis, treatment, referral, and reporting (14). However, the main disadvantages of syndromic management are: (a) the costs relating to over-diagnosis and over-treatment when multiple antimicrobials are given to a patient with no or only one infection and (b) excessive use of antimicrobials which increases selective pressure for resistant pathogens in the community.

The flowcharts for syndromic treatment of urethral discharge and genital ulcers that have been shown to be sufficiently valid in various settings can be used widely without repeating validity tests. In contrast, the validity of hierarchical flowcharts starting with the symptom vaginal discharge is under discussion. Vaginal discharge is a common symptom and sign reflecting a cervical and/or vaginal infection, which may be related to a sexually transmitted pathogen (*N. gonorrhoeae*, *C. trachomatis,* or *T. vaginalis*) or to abnormal vaginal flora (yeast or bacterial vaginosis). Thus, being a common symptom, vaginal discharge is often incorrectly associated with gonococcal infection or *Chlamydia* associated with cervicitis.

At present, many non-government organizations (NGOs) use the syndromic approach in managing RTIs. The majority use the flowcharts developed and recommended by WHO. These flowcharts have not been undergone the process of standardization, evaluation, or validation in the context of Bangladesh. Results of a study showed that there was a lack of standardization in following important management steps that include history-taking, physical examinations, follow-up, partner notification, and referral (15). Management of RTIs has been given a high priority by both NIPHP and HPSP aiming at managing RTI/STI services in a standardized way. NIPHP developed a Technical Standard and Service Delivery Protocol for Management of RTIs/STIs as a joint effort of the NIPHP partners, GoB, and other NGOs (16). The Protocol was published in April 1999 and its copies were distributed among NIPHP NGOs.

The syndromic management flowcharts of vaginal discharge, which were modified by the Family Planning, STI/RTI and HIV/AIDS Task Force of NIPHP in the context of Bangladesh were not validated. However, in the 'National-level Meeting on Syndromic Approach of RTI/STI Case Management' held in May 2000, a consensus was reached to modify the 'vaginal discharge' case management algorithm to improve sensitivity and specificity of the specific flowcharts to reduce the possibility of over-diagnosis and on treatment. The Task Force meeting held in August 2000 decided to validate the modified algorithms (Figs. 1 and 2) by the ICDDR,B, in collaboration with the Urban Family Health Partnership (UFHP) and Quality Improvement Partnership

(QIP). The validation refers to the sensitivity, specificity, positive predictive value, and negative predictive value of the vaginal discharge-management flowcharts in the diagnosis of common RTIs. This report includes the results of the validation exercise of the modified vaginal discharge-management flowcharts. This was one of the research components of the research project titled "Strategies to improve prevention and management of RTIs/STDs". The research project was funded by USAID, Dhaka.

### Objective

The objective of the study was to assess the validity of NIPHP-developed modified vaginal discharge-management flowcharts without and with speculum examination in the diagnosis of common RTIs/STIs

## Methodology

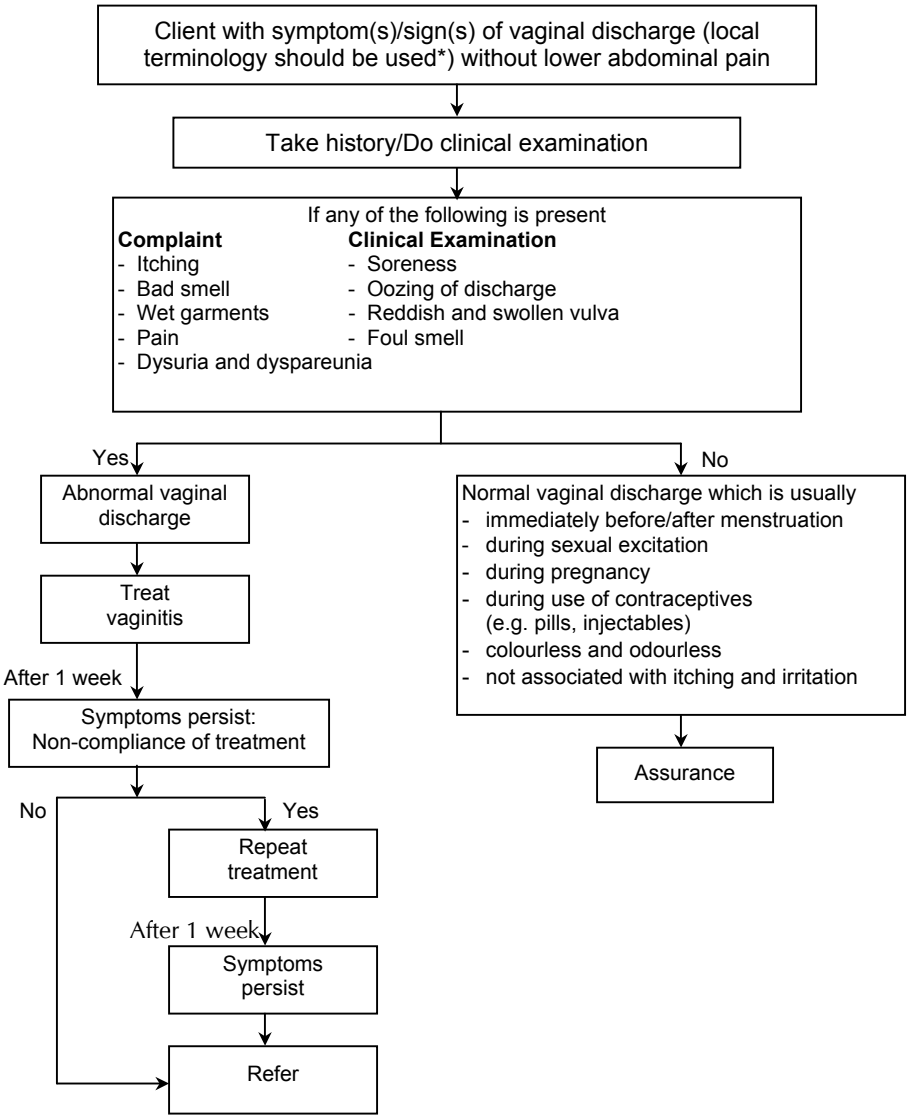
### Study design

This clinic-based cross-sectional study was designed to assess the sensitivity, specificity, positive predictive value and negative predictive value of the vaginal discharge-management flowcharts without (Fig. 1) and with (Fig. 2) speculum examination. The sensitivity of the flowcharts was defined as the proportion of infections detected correctly by the management flowcharts, and the specificity is the proportion of uninfected clients who are correctly identified by the flowcharts. The positive predictive value represents the proportion of diagnoses confirmed by a gold standard laboratory diagnosis. The negative predictive value represents the proportion of negative results confirmed by laboratory diagnosis.

### Study sites

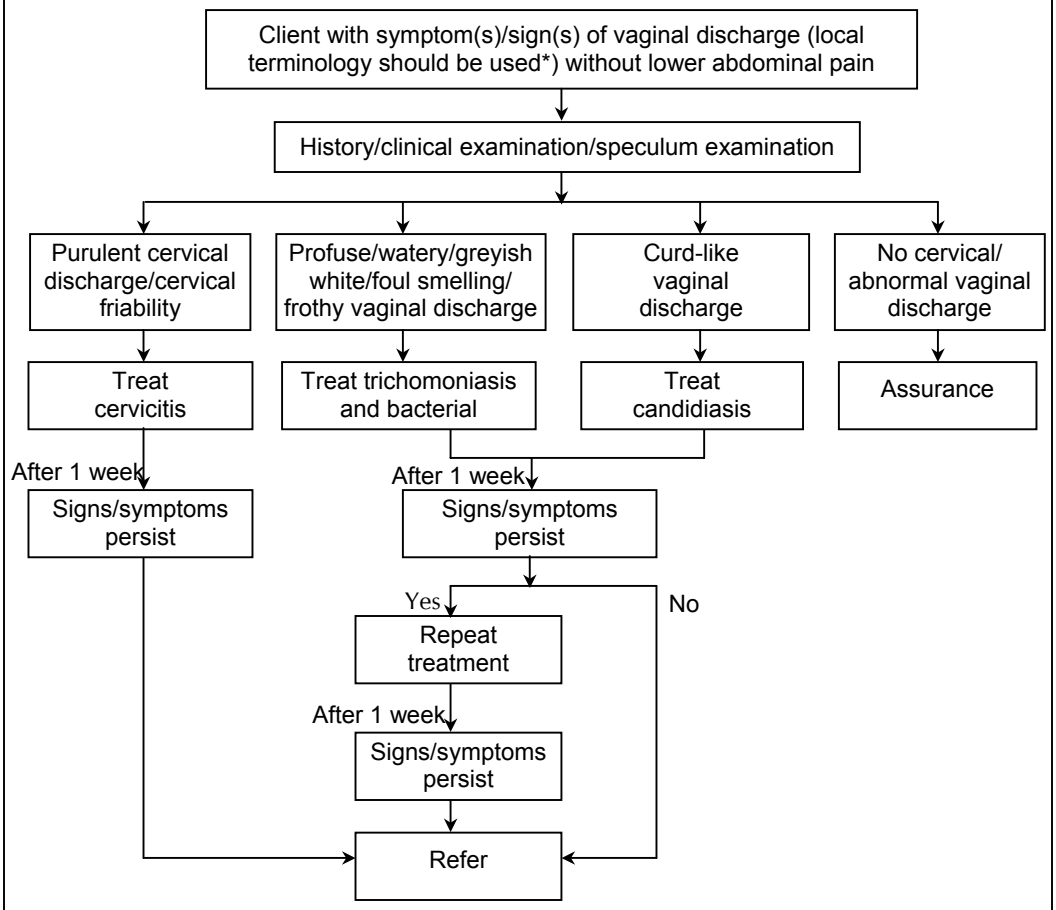
The study was conducted at five UFHP NGO service-delivery sites located in Tejgoan (Ward 37 and 38), Manikdi (Ward 15 and 17), Shajadpur (Ward 18), Lalbagh (Ward 60 and 61), and Gandaria (Ward 76, 78, 80, and 81) of Dhaka city. Progoti Samaj Kallyan Prothisthan (PSKP) operated the clinics of Tejgoan, Shajadpur, and Manikdi, and the clinics located in Lalbagh and Gandaria were managed by the Concerned Women for Family Development (CWFD). All clinics located in Dhaka city offered primary healthcare services and adopted the syndromic approach in the diagnosis and management of RTIs/STIs. The female paramedics provided RTI/STI services.

**Fig. 1.** Vaginal discharge
(If speculum examination is not possible)




* Possible local terminologies of vaginal discharge are*: shada srab, dhatu jhora, dhatu jaowa, srab jaowa, dhatu rog, prodol or bijal jaowa, etc.*

**Fig. 2.** Vaginal discharge
(If speculum examination is possible)




* Possible local terminologies of vaginal discharge are: *shada srab, dhatu jhora, dhatu jaowa, srab jaowa, dhatu rog, prodol or bijal jaowa, etc.*

**Study population and their recruitment**

The study population was women of reproductive age (15–49 years) seeking services at the study clinics for vaginal discharge. Women with complaint of lower abdominal pain in addition to vaginal discharge were not included in the study. The study also did not include women who were menstruating.

Women with complaint of vaginal discharge were selected after registration, in order of arrival at the study clinics, and before any interview or physical examinations or specimen collection were performed. Each woman was informed about the purpose of

the study, and written consent was obtained in a pre-printed consent form. Illiterate women were requested to provide fingerprint.

**Study activities**

***Interview***

Each enrolled woman was interviewed twice. A paramedic took a detailed clinical history from each subject using a structured clinic record-keeping form as part of the management process. Field research assistants collected risk assessment and other related information during exit-interviews.

***Clinical examination and therapeutic decision***

The paramedics performed clinical examination of the external genitalia of the study subjects and speculum and bimanual pelvic examinations following history- taking. At each study site, the providers made two diagnoses for each subject. The first diagnosis was based on the management algorithm without speculum examination, and the second was based according to the directives of the management algorithm with speculum examination. Clinical findings were recorded on a standardized form.

***Specimen collection for laboratory tests***

During speculum examination, vaginal and cervical swab samples were collected for laboratory tests. Three high vaginal swabs and one endocervical swab were collected from each subject for gold standard tests in the reference laboratory. The swabs so collected were sent to the ICDDR,B laboratory regularly on the day of collection maintaining the necessary cold chain.

***Treatment and follow-up***

The study participants were managed according to the directives of the modified vaginal discharge-management flowchart with speculum examination. The laboratory test results were supplied to the clinics from the ICDDR,B laboratory regularly, and the women were requested to return to the clinics for collecting test results after 7 days. If required, the treatment was modified based on the laboratory test results. Partners of clients were treated when necessary and also when the partners could be traced.

***Reference laboratory gold standard tests***

In the study, the research laboratory of the Laboratory Sciences Division (LSD), ICDDR,B, was the reference laboratory for conducting all the gold standard tests on the collected samples.

At the laboratory, the following tests were performed to diagnose *Chlamydia, gonococcal infection, T. vaginalis, Candida* infection, and bacterial vaginosis:

| **Organism/infection** | **Sample site** | **Method** |
|---|---|---|
| *N. gonorrhoeae* | Endocervical swab | PCR |
| *C. trachomatis* | Endocervical swab | PCR |
| *T. vaginalis* | Vaginal swab | In pouch detection and culture |
| *Candida* infection | Vaginal swab | Microscopy + culture |
| Bacterial vaginosis | Vaginal swab | Microscopy* |

*Nugent's scoring method was used for diagnosis of bacterial vaginosis

Endocervical swab specimen from each woman was placed in PCR buffer and tested using chlamydia and gonorrhoeae PCR (Amplicor; Roche Diagnostic Systems), according to the manufacturer's instructions. Swab specimens for bacterial vaginosis, *T. vaginalis,* and candidiasis were collected from posterior fornix of the vagina. A smear was made on a glass slide and fixed for Gram-stain preparation. Gram-stains were assessed at a magnification of x1000 under oil immersion for Nugent's scoring. The Gram-stains were also assessed for candidiasis. In addition, candidiasis was also detected by direct inoculation of specimens in selective Sabouraud dextrose agar plates for culture. The plates were then incubated at 36 $^{0}$C for 2 days. Specimens for identification of *T. vaginalis* were inoculated directly into an InPouch TV test (Biomed Diagnostics) for culture. The pouches were incubated at 37 $^{0}$C. Direct microscopic examination of the plastic pouch was performed at 24 hours, and if the results were negative, evaluation was repeated at 48 hours on day 5.

**Ethical issues**

After explaining the aim of the study, written consent was obtained from each study woman. Neither any special diagnostic procedures nor any hazardous materials were used in the study. Treatment of RTIs/STIs conformed to the standardized guidelines. Data obtained during the study were kept strictly confidential. The interviewers regularly submitted the completed questionnaires to the investigators on the day of each interview. The investigators kept those in a separate place where they only had access to collected information. Clinical and laboratory data were kept separately in files where medical officers or medical or any laboratory personnel not directly involved in the study had access. Since diagnosis was performed according to the standard methods and since recommended treatment regimens were used, the study women were not at any higher risk of adverse reactions. They retained the right to leave the study at any time.

**Data-collection instruments**

The data-collection instruments included clinical and laboratory record-keeping sheets and an interview questionnaire. The paramedics completed the clinical record-keeping sheets. The laboratory investigator completed the laboratory record-keeping sheets. The information recorded in the clinical record-keeping sheets included detailed clinical history, findings of physical examinations, and syndromic diagnoses. The laboratory diagnoses by the reference laboratory were recorded in the laboratory record-keeping sheets.

The interview questionnaire contained structured and pre-coded questions. Information collected during these interviews included: sociodemographic characteristics (age, religion, civil status, education, monthly household expenditure, family-planning method currently used, and occupation of husband and woman); risk factors of RTIs/STIs relating to husband/partner's sexual behaviour (current signs of STDs and extramarital relationships reported by woman); sexual and personal hygiene behaviour of women; and past medical and reproductive health history (number of marriages, extramarital relationships, menstruation, sanitary protection, pregnancy, parity, symptoms of vaginal discharge, medical history, etc). A female interviewer interviewed each subject on a one-to-one basis. No problems were encountered during data collection.

**Standardization and training**

Prior to data collection, several preparatory tasks, such as pre-testing and necessary revision of all data-collection tools, and recruitment and training of paramedics and research assistants, were undertaken.

Most paramedics who participated in this evaluation had institutional nursing training and had 3-5 years of working experience as providers of basic reproductive health services at the urban primary healthcare facilities. At these clinics, they followed the syndromic management approach to manage women with complaint of vaginal discharge. The paramedics received training on the syndromic management approach from the Marie-Stopes Clinic, one of the NIPHP-identified training institutes. In addition, before initiating sample collection, all received refreshers training at the same institute. All paramedics were oriented with the modified vaginal discharge-management flowcharts by the investigators. Operations researchers, who were medical graduates trained and experienced in speculum examinations, provided further training on collection of vaginal and cervical swab samples. The paramedics were further trained by the research officers from the Laboratory Sciences Division of ICDDR,B on storage

and dispatching collected specimens for the 'gold standard tests' at the Centre's laboratory. At the ICDDR,B laboratory, the specimens were kept at an optimal temperature. Two microbiology research officers performed laboratory tests under the supervision of scientists of the Laboratory Sciences Division.

There was a one-month preparatory phase to standardize syndromic management of vaginal discharge according to the modified management flowcharts by paramedics at the clinics and also to standardize data, sample-collection procedures, and transportation of specimens to the reference laboratory. During the preparatory phase, the investigators visited several times to oversee the performance of the paramedics and interviewers.

The interviewers had previous experience in administering interviews for research purposes. The questionnaire was piloted by the interviewers and was revised 3-4 times to reflect their comments. Throughout the study period, two Operations Researchers made regular visits (at about two-week interval) to the study clinics to monitor the performance of the paramedics during patient-encounter and to supervise the interview process.

**Study period**

After the preparatory period from March to May 2001, data were collected during June-July 2002.

**Sampling and sample size**

The sample size was calculated for a binomial proportion using the following formula:

$N = \{Z^2 x p x (1-p)\}/L^2$

Z score, which is 1.96 for the confidence level 95%
Expected sensitivity of the flowchart: p
Desired precision of this expected proportion: L
Prevalence of STD in the group to which the flowchart will be applied
The expected sample size = N/prevalence rate

According to the results of a recently-performed clinic-based study by Bogaerts *et al.*, the prevalence rate of gonococcal/chlamydial infections among women from general population with abnormal vaginal discharge was about 3% (17). In addition, the prevalence rate of *T vaginalis* and vaginal candidiasis/bacterial vaginosis was about 7% and 20% respectively. For validation of the syndromic management flowcharts, we expected a sensitivity of 70% with a 10% precision (range of sensitivity from 60% to 80%). Therefore, the minimum size of the population sample needed to test the validity of those management flowcharts in the detection of gonorrhoeal/chlamydial cervicitis, vaginal trichomaniasis, and vaginal candidiasis/bacterial vaginosis was 2,700, 1,157, and 405 women respectively.

### Data analysis

Data were analyzed to determine the sensitivity, specificity, positive predictive value, and negative predictive value of the flowcharts and the microscopic examination at the clinic level. The following cross-tabulation was used for this analysis:

| | Reference laboratory test results | | |
|---|---|---|---|
| | + | - | Total |
| Flowchart + | A (true +) | B (false +) | A+B |
| Flowchart - | C (false -) | D (true -) | C+D |
| Total | A+C | B+D | A+B+C+D |

Here,

Sensitivity (proportion of infections detected by the flowchart correctly) = A/A+C
Specificity (proportion no infections correctly identified by the flowchart) **=** D/B+D
Positive predictive value (proportion of flowchart diagnosed infections confirmed by gold standard laboratory diagnosis) = A/A+B
Negative predictive value ((proportion of flowchart diagnosed no infections confirmed by gold standard laboratory diagnosis) = D/C+D

In addition, $\chi^2$ analysis was used for assessing the associations of signs and symptoms with vaginal infections, such as bacterial vaginosis, candidiasis trichomoniasis, or with infection by cervical pathogens, such as *N. gonorrhoeae* or *C. trachomatis*. Odds ratios (OR) were calculated with 95% confidence interval (CI).

## Results

The study included 2,752 of 3,051 women who were eligible for enrollment during the study period. Refusal, occurred in 299 cases, was related to the sensitive nature of the tests and refusal of speculum examination.

### Sociodemographic characteristics

All the study women lived in close proximity to the clinics. Of them, 27% were from slum areas. The women were aged 15-49 years (median 25 years) (Table 1). Approximately, 9.9% were aged less than 20 years. Most (93.7%) were married, 2.3% were divorced/separated, 1.65% were widowed, and 2.4% were unmarried. Twenty-five percent had no education. The large majority (78.7%) were housewives, 11.9% worked outside the textile industry, and 5.1% were employed outside the home in some kind of services, e.g. teaching, tailoring, clerical work, and as unskilled labours, e.g. domestic servants, cleaners, factory labourers, etc. Two-thirds of the study subjects had a monthly family expenditure of less than Tk 5,000.00.

| **Table 1.** Background characteristics of enrolled women | |
|---|---|
| Characteristics | % of women (n=2,752) |
| Residence | |
| Slum | 27.1 |
| Non-slum | 72.9 |
| Age (years) | |
| 15-19 | 9.9 |
| 20-24 | 34.3 |
| 25-29 | 27.4 |
| 30-34 | 15.7 |
| 35-39 | 8.0 |
| 40-49 | 4.7 |
| Completed years of schooling | |
| 0 | 24.9 |
| 1-5 | 26.6 |
| 6-10 | 38.0 |
| 11+ | 10.4 |
| Marital status | |
| Married | 93.7 |
| Unmarried | 2.4 |
| Others* | 3.9 |
| Number of children | |
| No children | 17.8 |
| 1-2 child(ren) | 58.9 |
| More than 2 children | 23.3 |
| Occupation | |
| Housewife | 78.7 |
| Garments workers | 11.9 |
| Other services** | 5.1 |
| Others† | 4.4 |

*(Contd.)*

| **Table 1.** *Contd*. | |
|---|---|
| Characteristics | % of women |
| Monthly family expenditure (taka) | |
| <2,000 | 10.4 |
| 2,001-3,000 | 21.5 |
| 3,001-4,000 | 18.4 |
| 4,001-5,000 | 16.4 |
| >5,000 | 32.6 |
| Current use of contraception | |
| Modern method†† | 53.9 |
| Sterilized | 1.6 |
| Others | 1.4 |
| Currently pregnant | 8.4 |
| No method | 34.7 |
| History of abortion (one or more) | |
| Induced | 28.0 |
| Spontaneous | 10.8 |
| No abortion | 61.2 |

*Divorced/widowed/separated
**Tailor/tailor's assistant/service holder/office attendant/house tutor
†Housemaid/cleaner/factory labourer/day wager/business/others (not specified)
††Pill/condom/injection/IUD/norplant

Occupations of husbands as reported by the women were rickshaw-pulling, van driving, automobile driving, unskilled labour, small business, tailoring, vendoring, office service, etc. (Table 2). Husbands of 4.4% of all married women were living outside Dhaka city and 3.6% abroad. Of those who lived in Dhaka city, 22.2% spent at least a night outside the house in last month. Thirteen percent had been married previously. About 7% suspected their husbands having sexual relationships with another woman.

Eleven percent of the 173 unmarried or widowed, divorced, or separated women had a recent history of sexual intercourse. Of the married women, 4% had been previously married. Overall, 40% had history of abortion, and 11% reported spontaneous abortion. Either oral contraceptives or injectables, or slow release implant method norplant were currently used by 32.8% of women. About 11% were currently using IUD, and 13.4 % were using condoms.

In response to the question regarding practices relating to menstrual protection, multiple responses (n=2,752) were accepted. About 78% of women used reusable materials, such as rags/self-made towels (76.2%) and panty (14.5%), 14% used disposable materials, such as sanitary pad (14.1%), tampoon (7.6%), and cotton (8.0%), and about 9% did not use anything during menstruation. With regard to information about the practices during menstruation, multiple responses were accepted.

| **Table 2.** Characteristics of husbands/partners of women | |
|---|---|
| Characteristics | % of husbands/partners (n=2,590) |
| Occupation | |
| No occupation | 2.7 |
| Rickshaw-pulling/van driving | 5.9 |
| Automobile driving | 7.2 |
| Labour | 10.5 |
| Business | 35.4 |
| Service* | 35.9 |
| Others** | 2.4 |
| Completed years of schooling | |
| 0 | 16.8 |
| 1-5 | 17.9 |
| 6-10 | 43.2 |
| 11+ | 22.1 |
| Married more than once† | 12.4 |
| Spent night away | |
| For work | 19.6 |
| For other reasons | 3.0 |
| Did not spend night out | 77.5 |
| Suspected to have sexual relationship with another woman | 7.4 |
| Yes | 81.1 |
| No | 11.5 |
| Uncertain | |
| *Tailoring/service/vendor<br>**Unspecified<br>†This question was asked only to those women (n=2,571) who were married and had sexual experience | |

**Symptoms and signs**

In addition to vaginal discharge which was an entry criterion, various other symptoms were common (Table 3). The majority of women described the discharge as being thick white (71.5%), watery (52.8%), and curd-like (32.3%). Thirteen percent described the discharge with multiple responses as 'pus-like' (2%, n=54), 'yellow' (2.6%, n=71), 'sputum' (1.5%, n=40), and 'slimy' (5.2%, n=145). 2.9% (n=80) could not specify the type of vaginal discharge. About 93% complained of garments getting wet by the discharge. Other common complaints included 'foul-smelling' discharge and itching.

The physical signs recorded by the paramedics at the clinics are also shown on Table 3. The paramedics recorded signs of vaginal discharge on examination for most women complaining of vaginal discharge. None of these women were reported or were found on examination to have lower abdominal pain. In about 94% of cases, the paramedics recorded the discharge as profuse and commonly noted white and malodorous discharge.

**Table 3.** Symptoms and signs presented by women (n=2,752)

| Symptom/sign | No. | % |
|---|---|---|
| Symptoms | | |
| Vaginal discharge | 2,752 | 100.0 |
| Thin watery | 1,452 | 52.8 |
| Thick white | 1,968 | 71.5 |
| Curd-like | 888 | 32.3 |
| Others | 358 | 13.0 |
| Foul-smelling discharge | 1,320 | 48.0 |
| Genital itching | 2,121 | 77.1 |
| Wet garments | 2,563 | 93.1 |
| Dysuria | 1,097 | 39.9 |
| Dysperunia | 1,265 | 46.0 |
| Signs on inspection | | |
| Vulval soreness | 215 | 7.8 |
| Oozing of discharge | 2,715 | 98.7 |
| Reddish and swollen vulva | 576 | 20.9 |
| Foul smell | 1,438 | 52.3 |
| Signs on speculum examination (vagina) | | |
| Discharge present | 2,731 | 99.2 |
| Colour | | |
| White | 1,954 | 71.5 |
| Greyish white | 667 | 24.4 |
| Greenish yellow | 249 | 9.1 |
| Yellow | 35 | 1.3 |
| Type | | |
| Watery | 1,261 | 46.2 |
| Curd-like | 1,502 | 55.0 |
| Frothy | 347 | 12.7 |

*(Contd.)*

| **Table 3.** (*contd*.) | | |
|---|---|---|
| Symptom/sign | No. | % |
| Quantity | | |
| Scanty | 168 | 6.2 |
| Profuse | 2,561 | 93.8 |
| Smell | | |
| Malodorous | 1,619 | 59.3 |
| Signs on speculum examination (cervix) | | |
| Endocervical mucopus | 473 | 17.2 |
| Friable cervix | 916 | 33.3 |
| *Pus-like/yellow-like sputum/could not specify<br>Multiple responses were acceptable | | |

Signs of cervicitis (cervical mucopus or friable cervix) as per the flowcharts with speculum examination were recorded in the case of 36.2% of women. Ulcer in valva and vagina was observed in 1.7% and 2.4% of women respectively.

**Microbiological evidence of reproductive tract infections**

Based on the tests done at the reference laboratory, microbiological evidence of bacterial vaginosis, candidiasis*, T. vaginalis, N. gonorrhoeae,* and *C. trachomatis* is shown in Table 4. The most common aetiology detected by the reference laboratory was candidiasis, followed by bacterial vaginosis. Gonorrhoea was confirmed in 2.4% of women by PCR tests. In Table 4, mixed infections refer to those women who had more than one vaginal or cervical infection.

| **Table 4**. Prevalence of vaginal and cervical infections among women | | | |
|---|---|---|---|
| Infection | No. | % | 95% CI |
| Vaginitis (n=1,195) | 621 | 52.0 | 49.2-54.8 |
| Bacterial vaginosis | 271 | 22.7 | 20.3-25.1 |
| *Candida albicans* | 383 | 32.1 | 29.4-34.7 |
| *Trichomonas vaginalis* | 42 | 3.5 | 2.4-4.5 |
| Mixed vaginal infection | 73 | 6.1 | 4.8-7.6 |
| Cervicitis (n=2,752) | 106 | 3.9 | 3.2-4.6 |
| *N. gonorrhoeae* | 65 | 2.4 | 1.8-3.0 |
| *C. trachomatis* | 48 | 1.7 | 1.2-2.2 |
| Mixed cervical infection | 7 | 0.3 | 0.1-0.5 |
| CI=Confidence interval | | | |

**Association of symptoms and signs included in flowcharts with microbiological evidence of infection**

The study explored symptoms and signs included in the flowcharts without (Fig. 1) and with (Fig. 2) speculum examination separately. The flowchart without speculum examination was only to diagnose vaginal infection among women complaining of vaginal discharge based on additional symptoms and signs indicated in the flowchart.

In total, five symptoms and four signs were considered in the syndromic diagnosis of vaginal infection without speculum examination. Bivariate analyses of the association of these symptoms and signs with presence of vaginitis (bacterial vaginosis, candidiasis, and *T. vaginalis*) are presented in Table 5. Unpleasant odour, valvar itching, and reddish swollen valva were associated with vaginal infection. However, wet garments, dysuria, and dysperunia as symptoms were not associated with vaginal infection.

**Table 5.** Association of diagnostic symptoms and signs included in flowchart (without speculum examination) with vaginal infections (n=1,195)

| Symptom/sign | Infected | | $\chi^2$ | p value | Odds ratio | 95% CI |
|---|---|---|---|---|---|---|
| | % | No. | | | | |
| Vulvar itching | | | | | | |
| Yes | 54.8 | 958 | 15.5 | <0.001 | 1.8 | 1.3-2.4 |
| No | 40.5 | 237 | | | | |
| Unpleasant odour* | | | | | | |
| Yes | 56.9 | 680 | 15.4 | <0.001 | 1.6 | 1.3-2.0 |
| No | 45.4 | 515 | | | | |
| Wet undergarments | | | | | | |
| Yes | 51.7 | 1124 | 0.58 | 0.45 | 0.8 | 0.5-1.3 |
| No | 56.3 | 71 | | | | |
| Dysuria | | | | | | |
| Yes | 54.3 | 582 | 2.5 | 0.12 | 1.2 | 0.9-1.5 |
| No | 49.8 | 613 | | | | |
| Dysperunia | | | | | | |
| Yes | 54.0 | 567 | 1.7 | 0.19 | 1.2 | 0.9-1.5 |
| No | 50.2 | 628 | | | | |
| Valvar soreness | | | | | | |
| Yes | 56.8 | 139 | 1.5 | 0.22 | 1.2 | 0.9-1.8 |
| No | 51.3 | 514 | | | | |

(C*ontd*.)

**Table 5.** (*contd*.)

| Symptom/sign | Infected % | Infected No. | $\chi^2$ | p value | Odds ratio | 95% CI |
|---|---|---|---|---|---|---|
| Oozing discharge | | | | | | |
| Yes | 52.5 | 1182 | 10.3 | <0.001 | 13.2 | 1.7-102.1 |
| No | 7.7 | 13 | | | | |
| Reddish/swollen valva | | | | | | |
| Yes | 62.4 | 295 | 17.0 | <0.001 | 1.7 | 1.3-2.3 |
| No | 48.6 | 900 | | | | |
| Foul smell** | | | | | | |
| Yes | 54.5 | 680 | 3.8 | 0.05 | 1.2 | 1.0-1.6 |
| No | 48.7 | 515 | | | | |

*Complained
**Observed
CI=Confidence interval
Multiple responses were acceptable

Associations of specific diagnostic signs included in the management flowchart with speculum examination with specific vaginal and cervical infections are presented in Table 6. The flowchart considered presence of endocervical pus or friability of cervix as the diagnostic criteria for cervical infection. Of these two signs, only cervical pus discharge was significantly associated with cervical infections caused by *N. gonorrhoeae* and/or *C. trachomatis*.

The criteria, such as greenish yellow and frothy discharge, were highly significant with vaginal infection caused by *T. vaginalis*. The only finding associated with candidiasis was curd-like discharge, and it was significantly associated with *Candida* infection. No signs included in the flowchart for diagnosis of bacterial vaginosis were associated with laboratory-confirmed bacterial vaginosis.

**Table 6.** Association of diagnostic signs included in flowchart (with speculum examination) with cervical and vaginal infections

| Sign | Infected by *N. gonorrhoeae* or *C. trachomatis* | | $\chi^2$ | p value | Odds ratio | 95% CI |
|---|---|---|---|---|---|---|
| | No. | % | | | | |
| Discharge of pus | | | | | | |
| Yes | 473 | 5.9 | 6.6 | 0.01 | 1.8 | 1.1-2.8 |
| No | 2,279 | 3.4 | | | | |
| Friable cervix | | | | | | |
| Yes | 916 | 4.0 | 0.1 | 0.72 | 1.1 | 0.7-1.6 |
| No | 1,836 | 3.8 | | | | |
| Bacterial vaginosis | | | | | | |
| Watery | | | | | | |
| Yes | 507 | 21.7 | 0.5 | 0.49 | 0.9 | 0.7-1.2 |
| No | 688 | 23.4 | | | | |
| Greyish white | | | | | | |
| Yes | 241 | 25.3 | 1.2 | 0.27 | 1.2 | 0.9-1.7 |
| No | 954 | 22.0 | | | | |
| Foul smelling | | | | | | |
| Yes | 792 | 24.6 | 5.1 | 0.02 | 1.4 | 1.0-1.9 |
| No | 403 | 18.9 | | | | |
| *Trichomonas* | | | | | | |
| Profuse | | | | | | |
| Yes | 1,114 | 3.3 | 1.8 | 1.8 | 0.5 | 0.2-1.4 |
| No | 81 | 6.2 | | | | |
| Greenish yellow | | | | | | |
| Yes | 158 | 10.1 | 23.5 | <0.001 | 4.4 | 2.3-8.4 |
| No | 1,037 | 2.5 | | | | |
| Frothy | | | | | | |
| Yes | 195 | 9.2 | 22.4 | <0.001 | 4.1 | 2.2-7.8 |
| No | 1,000 | 2.4 | | | | |
| Malodorous | | | | | | |
| Yes | 792 | 4.4 | 5.7 | 0.02 | 2.6 | 1.1-5.9 |
| No | 403 | 1.7 | | | | |
| *Candida* | | | | | | |
| Curd-like | | | | | | |
| Yes | 657 | 37.4 | 19.5 | <0.001 | 1.7 | 1.4-2.2 |
| No | 538 | 25.5 | | | | |

CI=Confidence interval

**Validation of management flowchart**

The vaginal discharge-management flowchart without speculum (Fig. 1) has been considered a syndromic approach for the health facilities where the speculum examination facility is not available. This flowchart can only identify whether a woman complaining of vaginal discharge has or has not any vaginal infection. According to the flowchart, a woman would get the same management for any of the vaginal infections.

In evaluating the flowchart, the study explored its validity in the detection of bacterial vaginosis, vaginal candidiasis, and *T. vaginalis.* The flowchart with speculum examination has been left to make it possible to identify women with cervical infections, bacterial vaginosis, or vaginal infection caused by *T. vaginalis,* or vaginal candidiasis.

When applying the flowchart without speculum examination, most women were positive for at least an additional symptom or a clinical sign. As a consequence, most women were considered as having 'abnormal' discharge. The sensitivity approaches 100% with a specificity of nearly zero. Considering that 52% of women had laboratory evidence of vaginal infection (bacterial vaginosis, candidiasis, or trichomoniasis), the overall positive predictive value of the flowchart was 52% (Table 7).

**Table 7.** Performance of the vaginal discharge-management flowchart without speculum examination

| Entering population | Vaginal discharge-management flowchart without speculum examination | | | |
|---|---|---|---|---|
| | Sensitivity (95% CI) | Specificity (95% CI) | PPV (95% CI) | NPV (95% CI) |
| Performance evaluated in terms of all cases of bacterial vaginosis, *T. vaginalis,* or candidiasis | | | | |
| Women tested for bacterial vaginosis, *T. vaginalis,* and candidiasis (n=1,195) | 100% (100.0, 100.0) | 0.00 N/A | 52.0 (49.2-54.8) | 0.00 N/A |

CI=Confidence interval
PPV=Positive predictive value
NPV=Negative predictive value

The flowchart with speculum examination had a sensitivity of 100% for cases of bacterial vaginosis or trichomoniasis with 24.8% PPV and indeterminate specificity (Table 8). For candidiasis, the flowchart had a sensitivity and a specificity of 64.4% and 49.4% respectively and the positive predictive value and negative predictive value of 37.4% and 74.5% respectively.

The flowchart had a sensitivity of 37.7% for cervicitis (cervical infection with *N. gonorrhoeae* and/or *Chlamydia*) with a positive predictive value of 4%. The specificity of the flowchart for cervical infection was 63.9% with the negative predictive value of 96.2%.

**Table 8.** Validation of vaginal discharge-management flowchart with speculum examination

| Entering population | Vaginal discharge-management flowchart with speculum examination | | | |
|---|---|---|---|---|
| | Sensitivity (95% CI) | Specificity (95% CI) | PPV (95% CI) | NPV (95% CI) |
| Performance evaluated in terms of all cases of bacterial vaginosis or trichomoniasis | | | | |
| Women tested for bacterial vaginosis and *T. vaginalis* (n=1,195) | 100.0 (100.0-100.0) | 0.0 | 24.8 (22.4-27.3) | 0.0 |
| Performance evaluated in terms of all cases of valvovaginal candidiasis | | | | |
| Women tested for candidiasis (n=1,195) | 64.2 (61.5-66.9) | 49.4 (46.6-52.2) | 37.4 (34.7-40.1) | 74.5 (72.0-77.0) |
| Performance evaluated in terms of all cases of gonorrhoea or C*hlamydia* | | | | |
| Women tested for *N. gonorrhoeae* and *C. trachomatis* (n=2,752) | 37.7 (35.9-39.5) | 63.9 (62.1-65.7) | 4.0 (3.3-4.7) | 96.2 (95.5-96.9) |

CI=Confidence interval
PPV=Positive predictive value
NPV=Negative predictive value

**Association of symptoms and signs with cervical and vaginal infections**

Symptoms, recorded as either chief or elicited complaints, are compared in Table 9 for those with and without various infections. The symptom of foul-smelling discharge was significantly associated with bacterial vaginosis, as was the specified elicited symptom of dysuria. Dysuria was also associated with *T. vaginalis.*

**Table 9.** Association of cervical and vaginal infections with genital symptoms

| Chief or elicited complaint | Cervical infection (n=2,752) | | | | Vaginal infection (n=1,195) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | GC OR (95% CI) | p value | CT OR (95% CI) | p value | BV OR (95% CI) | p value | TV OR (95% CI) | p value | CA OR (95% CI) | p value |
| Foul-smelling discharge | 1.19 (0.73-1.96) | 0.48 | 1.53 (0.86-2.73) | .86 | 1.41 (1.08-1.88) | 0.01 | 1.72 (0.88-3.34) | 0.11 | 1.14 (0.89-1.45) | 0.31 |
| Watery discharge | 0.67 (0.41-1.10) | 0.67 | 1.37 (0.77-2.46) | 0.28 | 0.91 (0.69-1.19) | 0.48 | 1.37 (0.73-2.56) | 0.32 | 0.94 (0.73-1.19) | 0.59 |
| Curd-like discharge | 0.74 (0.42-1.29) | 0.29 | 0.86 (0.46-1.62) | 0.64 | 1.05 (0.79-1.39) | 0.73 | 0.55 (0.27-1.14) | 0.10 | 0.98 (0.76-1.26) | 0.84 |
| Yellow discharge | 4.10 (1.71-9.84) | <0.01 | 2.58 (0.78-8.52) | 0.11 | 1.03 (0.50-2.13) | 0.93 | 3.01 (1.02-8.84) | 0.04 | 1.02 (0.54-1.96) | 0.94 |
| Profuse vaginal discharge | ⊗ | - | 0.64 (0.18-2.26) | 0.49 | 0.84 (0.56-1.26) | 0.39 | 0.99 (0.38-2.57) | 0.99 | 0.97 (0.67-1.41) | 0.87 |
| Valvar pruritis | 0.99 (0.55-1.78) | 0.98 | 0.79 (0.42-1.52) | 0.49 | 1.19 (0.84-1.69) | 0.32 | 1.50 (0.63-3.61) | 0.36 | 1.88 (1.34-2.63) | <0.01 |
| Dysuria | 1.39 (0.85-2.27) | 0.19 | 1.39 (0.79-2.47) | 0.25 | 1.62 (1.23-2.13) | <0.01 | 2.42 (1.25-4.70) | <0.01 | 0.81 (0.64-1.04) | 0.09 |
| Dysperunia | 1.57 (0.95-2.58) | 0.07 | 1.66 (0.93-2.96) | 0.08 | 1.01 (0.77-1.32) | 0.95 | 0.83 (0.44-1.54) | 0.54 | 1.10 (0.86-1.40) | 0.44 |
| Partner had symptom/s* | 2.54 (1.46-4.42) | <0.01 | 1.49 (0.72-3.12) | 0.27 | 1.22 (0.86-1.74) | 0.26 | 1.39 (0.65-2.95) | 0.39 | 0.88 (0.63-1.23) | 0.46 |

⊗ One of the 2x2 table cells had count "0"
* Husbands/partners with symptoms of urethral pus discharge or dysuria or genital ulcer
BV=Bacterial vaginosis
CA=*Candida albicans*
CI=Confidence interval
CT=*Chlamydia trachomatis*
GC=*Gonococcal cervicitis*
OR=Odds ratio
TV=*Trichomonas vaginalis*

A complaint of yellow vaginal discharge was associated with cervical GC and TV. Valvar pruritis was associated with CA. An elicited complaint of partner having a symptom of STI (urethral pus discharge/dysuria/genital ulcer) was associated with GC.

The association of specific infections with specific signs is shown in Table 10. The signs included in the table were findings from physical examinations, including examination of the external genitalia and speculum-assisted examination. Reddish/swollen valva was significantly associated with CA, but was negatively associated with GC. Ulcer in valva was associated with GC. On speculum examination, yellow discharge on vaginal wall and cervical mucous pus were the only signs associated with GC and CT respectively. White and curd-like vaginal discharge was associated with CA. But white discharge was negatively associated with CT, BV, and TV. Signs of greenish yellow, foul smelling, and frothy discharge were associated with BV and TV. In addition, ulcer on vaginal wall was associated with TV. Thus, most signs were associated with vaginal infections.

**Table 10.** Association of cervical and vaginal infections with genital signs

| Sign | Cervical infection (n=2,752) | | | | Vaginal infection (n=1,195) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | GC | | CT | | BV (I) | | TV (G) | | CA (H) | |
| | OR (95% CI) | p value | OR (95% CI) | p value | OR (95% CI)) | p value | OR (95% CI)) | p value | OR (95% CI) | p value |
| Signs on inspection | | | | | | | | | | |
| Oozing discharge | 0.42 (0.10-1.7) | 0.22 | 0.63 (0.09-4.7) | 0.65 | ⊗ | - | ⊗ | - | 5.73 (0.74-44.23) | 0.06 |
| Valvar soreness | 0.77 (0.28-2.14) | 0.61 | 1.38 (0.54-3.52) | 0.49 | 1.02 (0.67-1.56) | 0.92 | 1.28 (0.53-3.09) | 0.59 | 1.22 (0.84-1.77) | 0.29 |
| Urethral pus discharge | ⊗ | - | ⊗ | - | ⊗ | - | ⊗ | - | 2.12 (0.13-34.03) | 0.59 |
| Reddish/ swollen valva | 0.31 (0.12-0.77) | <0.01 | 0.64 (0.29-1.44) | 0.28 | 0.88 (0.64-1.21) | 0.43 | 0.60 (0.26-1.37) | 0.22 | 2.18 (1.66-2.86) | <0.01 |
| Ulcer in valva | 3.59 (1.39-9.25) | <0.01 | ⊗ | - | 1.73 (0.73-4.08) | 0.21 | 2.57 (0.58-11.31) | 0.19 | 1.53 (0.67-3.47) | 0.31 |
| Signs on speculum examination | | | | | | | | | | |
| Cervix | | | | | | | | | | |
| Cervical mucopus | 1.33 (0.73-2.43) | 0.34 | 2.97 (1.64-5.37) | <0.01 | 1.37 (1.00-1.88) | 0.05 | 1.48 (0.75-2.94) | 0.26 | 0.80 (0.59-1.09) | 0.16 |
| Cervical friability | 1.03 (0.61-1.73) | 0.92 | 1.44 (0.81-2.573) | 0.21 | 0.76 (0.57-1.02) | 0.06 | 1.21 (0.65-2.27) | 0.55 | 0.98 (0.76-1.26) | 0.85 |

*(Contd.)*

**Table 10.** (*contd*.)

| Sign | Cervical infection (n=2,752) | | | | Vaginal infection (n=1,195) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | GC | | CT | | BV (I) | | TV (G) | | CA (H) | |
| | OR (95% CI) | p value | OR (95% CI) | p value | OR (95% CI)) | p value | OR (95% CI)) | p value | OR (95% CI) | p value |
| Vagina | | | | | | | | | | |
| White discharge | 0.68 (0.41-1.13) | 0.13 | 0.47 (0.62-0.83) | <0.01 | 0.64 (0.48-0.85) | <0.01 | 0.21 (0.11-0.41) | <0.01 | 1.35 (1.02-1.77) | 0.03 |
| Greyish discharge | 1.28 (0.75-2.21) | 0.36 | 1.56 (0.85-2.86) | 0.15 | 1.61 (0.81-3.20) | 0.27 | 1.02 (0.75-1.38) | 0.17 | 1.83 (1.27-2.64) | 0.91 |
| Greenish yellow discharge | 1.61 (0.79-3.29) | 0.19 | 1.15 (0.45-2.93) | 0.77 | 1.83 (1.27-2.64) | <0.01 | 4.38 (2.29-8.37) | <0.01 | 0.74 (0.51-1.08) | 0.11 |
| Yellow discharge | 4.02 (1.20-13.46) | 0.02 | 3.52 (0.82-15.10) | 0.07 | 0.85 (0.28-2.57) | 0.77 | 3.15 (0.71-14.05) | 0.11 | 0.525 (0.17-1.59) | 0.24 |
| Thin watery discharge | 1.07 (0.65-1.75) | 0.78 | 1.28 (0.72-2.26) | 0.40 | 0.91 (0.69-1.19) | 0.49 | 0.92 (0.49-1.72) | 0.69 | 0.86 (0.67-1.10) | 0.23 |
| Curd-like discharge | 0.74 (0.45-1.21) | 0.24 | 0.75 (0.42-1.33) | 0.33 | 0.78 (0.59-1.02) | 0.07 | 0.40 (0.21-0.76) | <0.01 | 1.75 (1.36-2.25) | <0.01 |
| Frothy discharge | 1.25 (0.63-2.48) | 0.52 | 1.17 (0.52-2.63) | 0.70 | 1.82 (1.30-2.55) | <0.01 | 4.14 (2.20-7.78) | <0.01 | 0.83 (0.59-1.16) | 0.28 |
| Scanty discharge | 1.27 (0.50-3.19) | 0.62 | 1.38 (0.49-3.89) | 0.54 | 0.84 (0.48-1.48) | 0.55 | 1.94 (0.74-5.09) | 0.17 | 0.96 (0.59-1.57) | 0.87 |
| Profuse discharge | 0.80 (0.32-3.02) | 0.64 | 0.73 (0.26-2.07) | 0.56 | 1.21 (0.69-2.12) | 0.52 | 0.52 (0.20-1.37) | 0.18 | 1.06 (0.65-1.73) | 0.81 |
| Foul-smelling discharge | 1.01 (0.66-1.82) | 0.72 | 1.68 (0.90-3.14) | 0.10 | 1.41 (1.04-1.89) | 0.03 | 2.62 (1.15-5.94) | 0.02 | 0.79 (0.61-1.02) | 0.07 |
| Odourless discharge | 0.91 (0.55-1.52) | 0.73 | 0.54 (0.28-1.03) | 0.06 | 0.70 (0.52-0.94) | 0.02 | 0.32 (0.13-0.76) | <0.01 | 1.29 (1.00-1.67) | 0.05 |
| Ulcer on vaginal wall | ⊗ | - | 0.88 (0.12-6.46) | 0.89 | 0.61 (0.21-1.79) | 0.37 | 3.77 (1.10-13.12) | 0.03 | 0.50 (0.17-1.33) | 0.16 |

⊗ One of the 2x2 table cells had count "0"

**Risk assessment**

Although the flowcharts evaluated in this study did not include any risk assessment as an indicator of cervicitis, the study explored some perceived risk factors for acquiring STIs; for example, husband spent night away, husband married more than once, woman who suspected that her husband had a sexual relationship with another woman, and woman who reported that her partner had a symptom of STI.

Among the study population, 22.3% of married women indicated that their husbands spent at least one night away during the previous month, and 12.4% reported that their husbands were married more than once. Suspicion regarding husband having sexual relationships with other women was expressed by 7.3% of women. The detection of cervical pathogens (NG and/or CT) had no association (OR 1.4; 95% CI 0.9-2.2) with husbands spending nights away from home. Husband married more than once had also no association ((OR 1.7; 95% CI 1.0-3.6) of cervical infection. Cervical infection was, however, associated (OR 2; 95% CI 1.1-3.6) with the suspicion of women about sexual relationships of their husbands with another woman. This association was stronger (OR 3.2; 95% CI 1.4-7.2) in the case of cervical infection with CT.

Thirteen percent of women reported that their partners had at least a symptom of STI. The symptoms included urethral pus discharge, dysuria, genital ulcer, and scrotal swelling, and swelling of inguinal lymph nodes. A partner having at least a symptom of STI was associated (OR 1.8; 95% CI 1.1-2.9) with cervical infection in a woman complaining of vaginal infection. The association was higher in the case of the partner's symptoms of urethral pus discharge (OR 2.1; 95% CI 1.2-3.6) and dysuria ((OR 2.6; 95% CI 1.5-4.3).

## Discussion

In our study, the modified vaginal discharge-management flowcharts were evaluated in managing women complaining of vaginal discharge. A number of studies explored the association of abnormal vaginal discharge with vaginal and cervical infections (18-21). With regard to clinical manifestations of RTIs among symptomatic women, all these studies found a variable degree of association between complaint of vaginal discharge and vaginal and/or cervical infections. The World Health Organization has recommended syndrome management guidelines for women with vaginal discharge (22). These management guidelines recognize that bacterial vaginosis and vaginal infections are the most likely potential causes of vaginal discharge complained by women and the reason for seeking care by them and, as such, recommend that all symptomatic women be treated for vaginitis/vaginosis. Furthermore, the importance of their early detection and treatment has been progressively underscored by the implication of bacterial vaginosis as a risk factor for PID (23); of bacterial vaginosis and trichomoniasis as causes of preventable preterm

delivery (24); and of bacterial vaginosis and trichomoniasis as a possible risk for acquisition of HIV infection. Women included in this study were all seeking care with the chief complaint of vaginal discharge. Bacterial vaginosis, candidiasis, or *T. vaginalis* were confirmed in about half of women tested for vaginal infections. Infections caused by *N. gonorrhoeae* and/or *C. trachomatis* were confirmed in 4% of women tested for cervical infections. All women came to the clinic to seek care for vaginal discharge, but the findings showed that a large proportion of them did not have any common vaginal or cervical infections. The other causes of vaginal discharge might include side-effects of contraceptive use (25), or misconceptions about normal physiological discharge (26).

In our study, the management flowcharts without speculum examination had a high sensitivity with a positive predictive value equivalent to the actual prevalence of vaginal infections. But the specificity was very poor. In addition to the complaint of vaginal discharge, a number of symptoms and signs were included as diagnostic criteria for vaginal infections in the flowchart without speculum examination. Only itching was associated with vaginal infections and 3 of the 4 signs used in the flowchart. Thus, one of the possible reasons for poor specificity could be the inclusion of criteria that had no association with common vaginal infections. In contrast to the statement, Table 8 shows that the flowchart with speculum had the same sensitivity for TV and BV (100%). There was only a lower sensitivity for candidiasis. The intention of speculum examination was not to improve the sensitivity for vaginal infection.

This study has shown that bacterial vaginosis and candidiasis are the most common conditions or infections among women complaining of vaginal discharge. Now the question is whether all women presenting with vaginal discharge should be routinely treated for these conditions or infections. In this study, the flowchart without speculum examination was high enough to ensure the treatment of all the infected women. Therefore, in addition to the symptomatic relief, the benefit of treating such cases would reduce the risk of PID, preterm delivery, and/or HIV transmission. On the contrary, the specificity of the flowchart was very poor, and therefore, this poor specificity might have resulted into over-treatment. Abnormal vaginal discharge should be treated spontaneously for all vaginal pathogens, irrespective of discharge characteristics (17). In addition, treatment for all women for vaginitis with a chief complaint of abnormal vaginal discharge would certainly be appropriate and inexpensive at the primary healthcare settings (27). However, possible efforts should be made to increase the specificity of the flowchart to reduce over-treatment by further modifications through selecting signs and symptoms that would contribute to its specificity in addition to its high sensitivity.

The disproportionate impact of untreated gonococcal and chlamydial infections on the health of women and children is well-recognized. Unfortunately, detection and treatment of cervical infections are complicated by their frequent symptomatic nature, lack of specificity of lower genital tract symptoms, difficulty in collecting cervical specimens, and cost and

technical difficulty of currently-available sensitive and specific diagnostic tests. Several investigators have evaluated clinical signs, demographic and behavioural risk factors, and simple laboratory tests for the identification and management of cervical infections (28-32). In general, these studies consistently show low specificity and low positive predictive value of the WHO algorithms for detection of cervical infection, and often the positive predictive value is only a few percentage points higher than the prevalence of cervical infection in the study population. The findings of our study also show poor performance of the evaluated algorithm for detection of cervical infection.

In this study, the flowchart considered for diagnosis of cervical infection did not include risk assessment. Only the signs, cervical pus discharge and/or friable cervix, were included as the diagnostic signs for cervical infection. Despite this, the study attempted to explore women's possible risk factors in acquiring cervical infection. There is a general credence that a vast majority of women in Bangladesh do not have sexual relationships before or outside the marriage compared to men (33,34). A survey showed that non-marital sex is prevalent among Bangladeshi males, and many of these sexual contacts occur with sex workers with low use of condom (35). A recently-accomplished study found that cervical infection of women was associated with the husband not at home, unfaithful husband, and a polygamous marriage (9). This study did not find any association of cervical infection with husband's staying away from home and husband married more than once. Nevertheless, it was found that partners' putative sexual relationships with another woman had a significant association with cervical infection. In addition, association of cervical infection was found with signs or symptoms of RTIs/STIs in partners.

Much of the emphasis on syndromic management of vaginal symptoms until now has focused on cervical infection rather than on vaginal infection. It is reasoned that, in settings with high STD prevalence rates, a subset of these symptomatic women would have infections with *N. gonorrhoeae* or *C. trachomatis* associated infections with severe complications and sequelae. However, treatment of cervicitis is expensive. Thus, emphasis on increasing the specificity is important in the diagnosis of cervicitis among the population with low prevalence of *N. gonorrhoeae* and *C. trachomatis* to avoid the cost of over-diagnosis. Of the two diagnostic signs for cervicitis, cervical pus discharge was significantly associated with gonococcal and chlamydial infections of cervix. Therefore, consideration of only endocervical mucopus as a diagnostic criterion could further increase the specificity of the flowchart for cervical infection.

At the present scenario of the primary health service facilities, the syndromic approach in the management of common RTIs and STIs would be the most feasible approach. The national policy on HIV/AIDS and STD-related issues emphasizes the sydromic approach in the management of STIs (36). The validity of RTI/STI sydromic management approach is essential with regard to its capacity to detect vaginal and cervical infections to ensure necessary management. The diagnostic capacity of the syndromic approach depends on the inclusion of combinations of diagnostic criteria in relation to the

common RTIs and STIs. To help further modifications of the management algorithms, this study looked into the possible symptoms and signs presented by women in relation to their absence and presence with specific infections. It also looked into the risk factors that might be associated with specific infections. The results of the present study showed that the diagnostic criteria included in the evaluated flowcharts can be reorganized by selecting symptoms and signs which can act as a better predictor of specific infections. Thus, further modifications of the flowcharts would perform better in the diagnosis of common RTIs and STIs.

## Conclusion

### Focus of syndromic management of vaginal discharge

The prevalence of bacterial vaginosis and candidiasis was much more higher than that of *T. vaginalis*, *C. trachomatis,* and *N. gonorrhoeae* among women from general population, complaining of vaginal discharge, and seeking care. Therefore, the current focus in the syndromic management of women complaining of vaginal discharge needs to put more emphasis on correct diagnosis of symptomatic women with bacterial vaginosis and candidiasis. Nevertheless, the prevalence of *T. vaginalis*, *C. trachomatis, and N. gonorrhoeae* was not trivial among women attending the primary healthcare clinics in Bangladesh where data on prevalence of STIs among the general population are quite limited. Focus of syndromic management of STIs should need further caution to avoid over-treatment. Because over-treatment of women for STIs would have problems in populations with low prevalence of GC and/or CT, where women do not seek evaluations for STIs and where unwarranted partner notification could lead to domestic violence. Moreover, the additional cost of over-treatment includes adverse effects of antibiotics, and other very important societal effects which are harder to measure, including the emerging problem of antibiotic-resistant bacterial pathogens.

### Syndromic management of vaginal infections

The evaluated syndromic management flowcharts with and without speculum examination for vaginal discharge had high sensitivity for vaginal pathogens, while the specificity of these flowcharts was either indeterminate or poor. Although the positive predictive value of the management flowchart without speculum examination was higher than that of the flowchart with speculum examination, the performance of vaginal discharge-management flowchart without speculum was better than that of the flowchart with speculum examination.

For syndromic diagnosis of vaginal infections, speculum examination would not be indispensable, particularly when a paramedic does the examination. But the situation could be different if applied to doctor providers as speculum examination might contribute to differentiating between various aetiologies of vaginal infections and to their specificity. Nevertheless, in the case of paramedics, this differentiation could also be possible by further

modification of the flowcharts without speculum examination based on the findings of this study by identifying and selecting the more sensitive and specific symptoms and signs in addition to vaginal discharge, so that the flowchart would be able to differentiate the aetiology of vaginal infections with increased specificity in addition to its high sensitivity. In addition, the vaginal discharge-management flowchart without speculum examination would be very useful in the resource-poor settings for wider coverage of treatment where there are lack of skilled providers and lack of availability of required instruments for speculum examination and where it is difficult to ensure infection measures.

**Syndromic management of cervical infection**

Cervical infection was a less-frequent cause of consultation by a woman complaining of vaginal discharge. The evaluated management flowchart with speculum examination for diagnosis of cervical pathogens has limitations. Nonetheless, reconsideration and reassessment of the diagnostic factors for cervical infection can improve its performance.

Despite the limitations of the evaluated sydromic management flowchart for cervical infection, research for simple, rapid, reliable, and inexpensive tests for detection of *N. gonorrhoeae* and *C. trachomatis* remains a high priority for the control of cervical infections. In the mean time, however, the management flowchart with speculum examination that has been evaluated in this study for cervical infection should be made useful in the resource-poor settings by further modifications.

**Modification of diagnostic guidelines for women complaining of vaginal discharge**

Evaluation of the vaginal discharge-management flowcharts demonstrated that further modifications of the flowcharts are essential. The study explored a number of possible associated factors, chief and elicited complaints, and signs with regard to vaginal and cervical infections among women complaining of vaginal discharge. Based on these factors, symptoms and signs, the existing diagnostic guidelines have to be modified by redesigning the diagnostic algorithms further aiming at minimizing subjective variation in diagnosis. This redesigning could be done by including the most sensitive and specific entry criteria and excluding all the non-specific and insensitive decisive factors in the diagnosis of vaginal and cervical infections or by introducing a scoring system to the associated factors, symptoms, and signs considering both positive and negative associations with specific vaginal and cervical infections.

The data available in this study can facilitate further modifications of the diagnostic algorithms for the management of women complaining of vaginal discharge. In addition, further validity testing of the modified algorithms can be conducted based on the data collected for this study.

**Future exploration**

Vaginal discharge is one of the most common symptoms of women seeking reproductive healthcare. As in other studies, our study has shown that a large proportion of women complaining of vaginal discharge did not have any common reproductive tract infections. Now the question is “What are the other causes of vaginal discharge?” This is an under-researched area. Further exploration on this area would contribute to the proper management of women complaining of vaginal discharge.

For quality RTI/STI services, the Technical Standard and Service Delivery Protocol for Management of RTIs/STIs is vital to promote and practise medical and professional standards. Efforts have been made to upgrade the Protocol with minimum acceptable standards at different levels of NGO and government health services. The findings of this study additionally contribute to these efforts in the standardization and improvement of vaginal and cervical infection management. This contribution would be based on the study findings discussed in this report and recommends future analysis of available data.

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