

# Comparison of Self-reported Symptoms of Gynaecological Morbidity with Clinical and Laboratory Diagnosis in a New Delhi Slum

*Improvements in diagnostic procedures are urgently needed*

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In developing countries, reproductive morbidity commonly affects the quality of women's lives but, until recently, this form of ill health has been

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largely ignored both by health planners and researchers. The tools required to assess the nature and magnitude of the problem in different settings need to be developed if the rhetoric of the 1994 International Conference on Population and Development is to be translated into realistic action.

Three main methods exist for the diagnosis of gynaecological morbidity: self-reported symptoms, clinical examination and laboratory tests. A few studies have found a reasonable degree of consistency between self-reports and clinical or laboratory evidence of infection, provided that the diagnostic criteria are clear (e.g. Zurayak and others, 1993, but many more have found rather low levels of agreement between different diagnostic approaches (Filippi and others, 1997; Kaufman and others, 1999; Bhatia and Cleland, 2000). Several reasons account for this lack of correspondence. Infections may remain asymptomatic for long periods and clinical signs may be non-existent or subtle. Several studies have shown that many patients with reproductive tract infections (RTIs), including sexually transmitted infections (STIs), present without any symptoms (De Schryres and Mehens, 1990; Mabey, 1996). Conversely, some individuals who report symptoms have no biomedically detectable pathology (Abdool, 1994; Hawkes and others, 1999). Such discrepancies reflect the fact that women's perceptions of gynaecological illness are rooted in cultural beliefs. In India, for instance, it has been suggested that the reporting of abnormal vaginal discharge may be more an expression of underlying psychosocial distress than evidence of infection (Patel and Oomman, 1999).

The last decade has seen major advances in laboratory-based diagnostic tests for STIs, and such tests are generally regarded as the "gold standard". However, these tests are too expensive to be used as screening tools in resource-poor settings. In the foreseeable future, control and management of these infections will therefore continue to depend largely on self-reported symptoms and observable clinical signs. The sensitivity, specificity and predictive value of symptoms in the detection of underlying morbidity are not well known, but should be urgently established. The present article addresses this need.

The study on which this article is based is a part of broader study (Garg and others, 2000) and its objectives are twofold: to assess the prevalence of gynaecological morbidity among ever-married women aged 15-45 years in a slum community in New Delhi, and to assess the consistency of women's self-reports, clinical diagnosis and the results of laboratory tests.

## **Material and methods**

### **The study area**

The study was conducted between August 1996 and November 2000 in an urban slum in the vicinity of Maulana Azad Medical College (MAMC), New Delhi. A demographic census of the area was conducted between December 1997 and March 1998 by project staff. The slum colony comprised 826 hutments with a total population of 3,676, spread in four clusters around a peripheral health post. These clusters were uniform in socio-demographic features. The majority of residents had migrated from Uttar Pradesh and Bihar. The sex ratio was unbalanced: 2,248 males (61 per cent) and 1,428 females (39 per cent) were enumerated, a ratio of 635 females per 1,000 males. A total of 500 (14 per cent) men were identified who were single and living without their families. The population was also youthful: only 125 (3.4 per cent) individuals were above 45 years of age.

Health services were provided through a health post of the Department of Community Medicine, MAMC. The health post had existed for eight years prior to the study and provided comprehensive health care to the population under the supervision of doctors (senior residents and faculty members) with a postgraduate degree in community medicine. The site was selected because of its proximity to MAMC, and thus had the distinct advantage of being accessible to researchers from various disciplines, making the multidisciplinary strategy feasible in terms of sample collection, transport and processing.

### **Study population and recruitment procedure**

The study population comprised all 446 ever-married women aged 15-45 years living in the slum community at the time of the demographic census. It was decided to include all women in the study rather than take a sample in order not to deny diagnosis and treatment to anyone. Unmarried women were excluded from the study because internal examination of such women is culturally unacceptable, but widowed and divorced women were included. Out of 446 females, 66 were pregnant and for these, following the ethical committee guidelines of the Indian Council for Medical Research, detailed general physical examinations and abdominal examinations were carried out, followed by collection of blood samples. Detailed general physical and internal examinations of non-pregnant women, along with collection of blood samples, were carried out.

## **Qualitative data collection**

In-depth interviews and observation were carried out prior to the main phase of the study. This revealed high morbidity, poor health-care-seeking, and poor usage of contraceptive methods. Extramarital sex was an accepted norm in the community and men had access to nearby brothels. The results of this qualitative study were used for the development of a survey questionnaire but are not reported in this article.

## **Face-to-face interviews, referrals and examination**

Face-to-face interviews were conducted with all 446 women by specially trained female field investigators at women's homes. The interview schedule covered socio-demographic characteristics, perceived symptoms of reproductive morbidity, hygiene, care-seeking behaviour, obstetric and contraceptive history, decision-making in the family and perceptions regarding HIV/AIDS. Generally two to three women a day were interviewed. At the end of the interview, each woman was given a referral slip which contained a unique identification number, name, husband's name, house number, cluster number and date of appointment at the clinic (health post) for clinical examination. A counterfoil of the referral slip was retained by the interviewer to ensure screening of every eligible woman interviewed.

Strategies were evolved to enhance participation and all women were encouraged to visit the peripheral health clinic shortly after the home interview. Before the date stipulated for the clinical examination, a team member paid a home visit which served as a reminder of the appointment. Women who failed to report for examination on the due date were followed up to ascertain the reason and were given another appointment.

Women were screened at the health post. Before screening for reproductive tract infections began, supplies to the health post were upgraded. A female health assistant was recruited to assist the gynaecologist in screening. The gynaecologist visited the health post twice a week for screening, examination and treatment of women.

At the clinic, the referral slip was matched with the counterfoil and a clinic data sheet was completed for every woman. This comprised questions about presenting gynaecological symptoms such as discharge, changes in menstrual pattern, pain in the lower abdomen, dyspareunia (painful intercourse), urinary complaints, low backache, prolapse, infertility and abortions. A detailed obstetric history was also obtained from every woman.

A physical examination was then performed. A detailed systemic examination of the cardiovascular system, respiratory system and abdominal examination was undertaken. This was followed by examination of the genital tract. The internal examination involved inspection of vagina and cervix using a speculum, under strict conditions of asepsis and privacy.

The criteria for clinical diagnosis were standardized beforehand (chart 1) and findings were recorded on pre-coded and pre-tested clinic data sheets. During the speculum examination, four vaginal and four cervical samples were taken for direct microscopy and culture for diagnosis of bacterial vaginosis, candidiasis, trichomonas vaginalis, gonorrhoea, chlamydia and for Pap smear screening. Routine microscopy and culture were also carried out for every respondent. A blood sample was taken from every respondent, i.e. 5 ml of venous blood was collected in a universal container. Blood was allowed to clot and serum separated before transportation to the laboratory. The specimens were transported to the microbiological laboratory on the same day by a technician.

The sample sites and criteria for laboratory diagnosis are shown in chart 2. For pathogens with multiple diagnostic tests, the infection was considered positive in the event of either of the laboratory tests being positive, in order to maximize sensitivity.

## **Treatment**

Women with genital tract infections were managed in accordance with the National AIDS Control Organisation recommendations on syndromic management. After the laboratory reports, additional treatment, if required, was provided: for example, in cases of syphilis. The management of STIs included counselling, partner-notification and treatment. Those who required an expert opinion were referred to the Departments of Gynaecology or Skin and Venereology at Lok Nayak Hospital.

## **Ethical considerations**

Ethical clearance was obtained from ethical committees of MAMC and associated hospitals. Face-to-face interviews were conducted in women's homes with due consideration for privacy. Confidentiality of information was not only assured but maintained. Diagnostic and treatment services were made available in a non-stigmatizing manner to all women who underwent examination. Symptomatic women who refused examination at the peripheral health facility were counselled and, if still unwilling, were advised to visit another health care facility; the research team provided no treatment

## Chart 1. Criteria for clinical diagnosis

<b>Abnormal discharge</b>	<p>a) Presence of abnormal discharge during examination. The discharge was described in terms of amount, colour, consistency, smell, site and its association with itching.</p> <p><i>or:</i></p> <p>b) Microscopically<sup>a</sup> – Five pus cells per high-power field was also considered as abnormal discharge.</p>
<b>Genital ulcers</b>	Presence of vesicles, papules, ulcers at labia, vulva, cervix.
<b>Genital warts</b>	Cauliflower lesions involving external genitals, perineum area; “flat” condylomata of cervix was diagnosed by cervical cytology.
<b>Cervicitis</b>	<p>a) Presence of cervical erythema, inflammation or cervical bleeding on touch, with or without discharge.</p> <p><i>or:</i></p> <p>b) Microscopically<sup>a</sup> – Presence of cervical pus cells <math>\geq 10</math> per high-power field.</p>
<b>Cervical erosion</b>	A bright red, clearly defined area on the vaginal aspect of the cervix where squamous epithelium is replaced by columnar epithelium.
<b>Pelvic inflammatory disease</b>	Presence of abdominal tenderness and uterine tenderness with or without adnexal tenderness.
<b>Prolapse</b>	<p>Confirmed by direct examination and making the patient cough to determine anterior or posterior vaginal wall collapse.</p> <p>a) Rectocele prolapse = descent of posterior vaginal wall below its normal position.</p> <p>b) Cystocele prolapse = descent of anterior vaginal wall below its normal position.</p> <p>c) Uterine prolapse = descent of the uterus below its normal position.</p>
<b>Tuba-ovarian mass</b>	Diagnosed by fullness in adnexa, presence of mass, if any.

*Note:* Major clinical entities were diagnosed according to standard criteria (W.E. Stamm, S.M. Kaetz, MB. Beirne and J.A. Ashman (1988). “The practitioner handbook for the management of STDs”, Health Sciences Centre for Education Resources, University of Washington).

<sup>a</sup> Diagnosis was done on the results of the microscopy report.

without examination. Probing revealed that the opposition of the women’s husband was a major cause of refusal. Accordingly, screening and management for men’s reproductive and sexual health problems were initiated in the community in February 2000.

### Data analysis

Each woman was identified by a unique number (given at the time of initial interview). Consistency checks were performed to avoid duplication of records. The data were analysed by the software packages, Foxbase and Epi

**Chart 2. Sample sites and criteria for laboratory diagnosis of reproductive tract infections**

<b>RTI</b>	<b>Sample site</b>	<b>Laboratory methods</b>	<b>Diagnosis</b>
<b>Bacterial vaginosis</b>	Vagina	1 a) Examination for characteristic vaginal discharge b) Vaginal pH measurement c) Amine test d) Direct microscopy for "clue cells" 2 Gram-stained vaginal smear examination and scoring	Amsel's criteria: (3 out of 4 clinical tests positive)  Nugent's criteria: Score of $\geq 7$
<b>Trichomonas vaginalis</b>	Vagina	a) Direct microscopy of saline wet mount b) Culture in Fineberg-Whittington medium	Positive by either or both methods
<b>Candidiasis</b>	Vagina	a) Direct microscopy of KOH (potassium hydroxide) mount and gram-stained smear b) Culture on Sabouraud's dextrose agar	Positive by either or both methods
<b>Neisseria gonorrhoeae</b>	Cervix	a) Direct microscopy of gram-stained smear b) Culture on modified Thayer-Martin medium c) ELISA (enzyme-linked immunosorbent assay) for detection of antigen	Positive by any one or more methods
<b>Chlamydia trachomatis</b>	Cervix	a) Direct fluorescent antibody test for detection of elementary bodies in cervical smear b) Polymerase chain reaction (PCR)	Positive by any one or both methods
<b>Cervical inflammation dysplasia</b>	Cervix	Pap smear	
<b>Human papilloma virus (type 16 &amp; type 18)</b>	Cervix	PCR	Positive by PCR
<b>Syphilis</b>	Blood (serum)	a) VDRL test for screening b) Treponema Pallidum Haemagglutination Test (TPHA) for confirmation	Positive by both tests <sup>a</sup>
<b>Hepatitis B virus</b>	Blood (serum)	Detection of hepatitis B antigen by: a) Latex agglutination b) ELISA	Positive by both methods
<b>Hepatitis C virus</b>	Blood (serum)	Detection of anti-HCV (hepatitis C) IgM (immunoglobulin class M) antibodies by ELISA	Positive on repeat test also

<sup>a</sup> VDRL (Venereal Disease Research Laboratories) and TPHA (treponema pallidum haemagglutination test) testing were used for diagnosis of syphilis. On VDRL screening, those who were found positive were tested by TPHA, thus ruling out false-positive cases.

Info. Categorical data were compared using chi-square or Fisher's exact test, as applicable. Sensitivity, specificity and predictive values were calculated to compare women's reports, clinical and laboratory diagnoses. The calculation of predictive values of reported symptoms was considered important to assess the relative accuracy of positive and negative predictions of infection from the women's reports.

## Results

### Participation levels

Of the eligible women identified in the study area, 380 (85.2 per cent) reported to the health care facility. Clinic schedules were completed for all 380 women by the doctor at the health post. Of the 322 non-pregnant women, 79.2 per cent agreed to an internal examination, and samples (vaginal and cervical) were collected for laboratory tests. All 58 pregnant women underwent general physical and abdominal examinations, and blood samples were collected. Overall, blood samples for examination were collected from 332 (87.4 per cent) women. Socio-demographic characteristics of responders and non-responders were not significantly different in terms of age, religion, literacy, occupation and income.

### Reported morbidity

Of the 380 women who attended the clinic, only 12.1 per cent reported no symptoms. The most common symptoms were low backache (63.9 per cent), vaginal discharge (56.8 per cent) and pain in the lower abdomen (42.1 per cent) (table 1). Together low backache and pain in the lower abdomen were reported by 76.0 per cent of women. These two symptoms were considered as a single entity for comparison with clinical and laboratory diagnosis.

Among 301 women who underwent internal examination, 91 per cent complained of one or the other symptom of reproductive morbidity. The highest reported morbidities were low backache (67.8 per cent), vaginal discharge (61.8 per cent) and pain in the lower abdomen (44.9 per cent) (table 1).

### Observed gynaecological morbidity

On clinical examination, abnormal vaginal discharge was detected in the majority of women (94.6 per cent). Cervicitis was diagnosed in 36.2 per cent, cervical erosion in 43.9 per cent, pelvic inflammatory disease (PID) in 26.2 per cent and prolapse in 14.3 per cent of women. Overall gynaecological morbidity was detected by the gynaecologist in 74.1 per cent of women (table 2).



**Table 1. Gynaecological morbidity reported at a clinic by women in a New Delhi slum**

<b>Reported morbidity</b>	<b>Percentage of all women who attended the clinic (n = 380)</b>	<b>Percentage of women who underwent internal examination (n = 301)</b>
Menstrual problems	25.8	24.6
Dysmenorrhoea	2.4	2.6
Menorrhagia	7.6	5.7
Oligomenorrhoea	10.8	11.9
Dysfunctional uterine bleeding (DUB)/irregular	5.0	4.3
Vaginal discharge	56.8	61.8
Infertility	8.2	10.0
Primary	5.8	7.0
Secondary	2.4	3.0
Pain in lower abdomen	42.1	44.9
Lower backache	63.9	67.8
Prolapse	15.8	18.6
Urinary complaints	20.5	21.6
Genital ulcers	2.9	3.3
Dyspareunia	23.0	25.2
Any morbidity	88.0	91.0
Total morbidities	986	838
Mean morbidities per woman	2.6	2.8

### **Prevalence of reproductive tract infections**

The results of the laboratory tests revealed that 41.5 per cent of the women had bacterial vaginosis, 18.6 per cent candidiasis and 4.3 per cent trichomonas vaginalis. Chlamydia was detected in 28.7 per cent of the cases. No case of gonorrhoea was detected, but tests for syphilis were found positive in 4.2 per cent, and 5.8 per cent of the cases were positive for hepatitis B antigens. Human papilloma virus (HPV) types 16 and 18 (the prime cause of cervical cancer) were found in 11.8 per cent and 3.3 per cent of the women respectively (table 3).

The combined prevalence of seven infections (bacterial vaginosis, candidiasis, trichomoniasis, chlamydia, gonorrhoea, syphilis and hepatitis B) was 72 per cent (188/261). When inflammatory smears were also included with these seven infections, 79.4 per cent of women were found to be infected.

**Table 2. Prevalence of gynaecological morbidity by clinical examination among women in a New Delhi slum**

Gynaecological condition	Number of women (n = 301)	Percentage
Abnormal vaginal discharge	285	94.6
Cervicitis <sup>a</sup>	109	36.2
Cervical erosion	132	43.9
Pelvic inflammatory disease (PID)	79	26.2
Prolapse	43	14.3
Anterior	40	13.3
Posterior	3	1.0
Tubo-ovarian mass	43	14.3
Suspected carcinoma of cervix	4	1.4
Any gynaecological morbidity	223	74.1

<sup>a</sup> Comprising cervical inflammation or induced endo-cervical bleeding on touch.

### Comparison of self-reports, clinical diagnoses and laboratory tests

Women's reports of symptoms were compared with clinical diagnoses (table 4) and the laboratory diagnosis of reproductive tract infections (table 5). Table 6 compares clinical diagnoses with the results of laboratory tests. Measures of sensitivity, specificity and predictive power were used to summarize the results. The implicit assumptions underlying these comparisons are that clinical diagnoses are nearer the "truth" than self-reports and that laboratory test results are nearer the "truth" than clinical diagnoses. Thus, the validity of self-reports can be assessed against either of the other two types of measurement (the gold standards), and clinical diagnoses can be validated by laboratory tests (the ultimate gold standard). The four summary measures for assessing validity are defined as follows:

- *Sensitivity*: the percentage of individuals found positive (i.e. infected) by the gold standard test who were also found positive by the other test.
- *Specificity*: the percentage of negative cases (i.e. uninfected) by the gold standard test who were also found negative by the other test.
- *Positive predictive value (PPV)*: the percentage of individuals found positive by the other test who were also found positive by the gold standard test. Departures from 100 per cent indicate the level of "false positives".
- *Negative predictive value (NPV)*: the percentage of individuals found negative by the other test who were also found negative by the

**Table 3. Prevalence of major reproductive tract infections detected by laboratory tests among women in a New Delhi slum**

Infection	Number of women tested	Prevalence (percentage)
Bacterial vaginosis	301	41.5
Candidiasis	301	18.6
Trichomonas vaginalis	301	4.3
Chlamydia <sup>a</sup>	286	28.7
Gonorrhoea	301	0
Inflammatory/dysplastic smears <sup>b</sup>	273	37.4
Human papilloma virus type 16 <sup>c</sup>	152	11.8
Human papilloma virus type 18 <sup>d</sup>	152	3.3
Syphilis	332	4.2
Hepatitis B virus <sup>d</sup>	329	5.8
Hepatitis C virus <sup>e</sup>	166	1.8

<sup>a</sup> 15 samples were not tested because the smear were too thick.

<sup>b</sup> 273 out of 301 smears were adequate for testing.

<sup>c</sup> Samples with DNA extracts were processed for HPV16 and HPV18.

<sup>d</sup> Three samples had insufficient quantity of blood.

<sup>e</sup> Testing was done on alternate samples.

gold standard test. Departures from 100 per cent indicate the level of “false negatives”.

### Validation of self-reports by clinical diagnoses

Observation of vaginal discharge by the gynaecologist was much more common than self-reports of this condition, resulting in a very high PPV but extremely low NPV: 115 women reported no discharge but absence of discharge was confirmed by examination in only four cases. Conversely, self-reports of discharge were more common than diagnoses of cervicitis, leading to higher NPV but lower PPV.

The validation of self-reported pain in the lower abdomen or low backache against clinical diagnoses of cervicitis and PID reveals relatively high sensitivity values. Three quarters or more of the women diagnosed with these conditions also reported symptoms. Specificity, however, was low. Only about one quarter of the cases diagnosed as negative by the gynaecologist reported the absence of symptoms. The low PPVs imply that only about one third of the women complaining of pain in the lower abdomen or low backache were found to have clinical signs of cervicitis or of PID.

**Table 4. Comparison of self-reported gynaecological symptoms with clinical diagnosis among women in a New Delhi slum (numbers of women)**

Self-reported symptoms	Clinical diagnosis			
	Yes	No	Yes	No
Vaginal discharge	Abnormal discharge		Cervicitis	
	Yes	12	70	116
	No	4	39	76
	<i>S 61.0, SP 25.0, PPV 93.5, NPV 3.5</i>		<i>S 64.2, SP 39.5, PPV 37.6, NPV 66.0</i>	
Lower abdominal pain/lower backache	Cervicitis		Pelvic inflammatory disease	
	Yes	148	64	165
	No	44	15	57
	<i>S 74.3, SP 22.9, PPV 35.3, NPV 61.1</i>		<i>S 81.0, SP 25.7, PPV 27.9, NPV 79.2</i>	
Dyspareunia	Cervicitis		Pelvic inflammatory disease	
	Yes	49	32	43
	No	143	47	179
	<i>S 23.8, SP 74.4, PPV 34.6, NPV 63.2</i>		<i>S 40.5, SP 80.6, PPV 42.7, NPV 79.2</i>	

*Note:* Abbreviations: S = sensitivity, SP = specificity, PPV = positive predictive value, NPV = negative predictive value. See text for definitions.

Dyspareunia was less commonly reported by women than pain. Accordingly, this symptom has low sensitivity when compared with diagnoses of cervicitis or PID. PPVs were also low. The majority of women reporting dyspareunia were not diagnosed with cervicitis or PID.

### Validation of self-reports by laboratory tests

The overall numbers of women reporting vaginal discharge and those diagnosed by laboratory tests as having a lower reproductive tract infection (bacterial vaginosis, candidiasis or trichomonas vaginalis) are similar: 186 compared with 168. However, this aggregate similarity conceals a poor consistency at the individual level, with low sensitivity and specificity values (table

**Table 5. Comparison of self-reported symptoms with results of laboratory diagnosis among women in a New Delhi slum (numbers of women)**

Self-reported symptoms	Laboratory diagnosis	
	Yes	No
	<b>Any lower reproductive tract infection<sup>a</sup></b>	
<b>Vaginal discharge</b>		
Yes	95	91
No	73	42
	<i>S 56.5, SP 31.6, PPV 51.1, NPV 36.5</i>	
	<b>Chlamydia</b>	
<b>Lower abdominal pain/ lower backache</b>		
Yes	65	152
No	17	52
	<i>S 79.3, SP 25.5, PPV 30.0, NPV 75.4</i>	
	<b>Syphilis (VDRL + TPHA)</b>	
<b>Genital ulcer</b>		
Yes	2	8
No	8	262
	<i>S 20.0, SP 97.0, PPV 20.0, NPV 97.0</i>	

*Note:* Abbreviations: S = sensitivity, SP = specificity, PPV = positive predictive value, NPV = negative predictive value, VDRL = Venereal Disease Research Laboratories, TPHA = treponema pallidum haemagglutination test. See text for definitions.

<sup>a</sup> Bacterial vaginosis, candidiasis, trichomonas vaginalis.

5). About half of the women with reported discharge were found to be infected (PPV = 51); only about one third without this symptom were found to be uninfected (NPV = 36.5).

Pain in the lower abdomen or low backache has high sensitivity as a symptom of chlamydial infection but low specificity. Four fifths of women found by laboratory tests to be infected reported symptoms, but among uninfected women, only one quarter reported no pain. Low PPVs indicated that 30 per cent of the women reporting pain were infected with chlamydia.

Ten women reported genital ulcers and an identical number were diagnosed with syphilis. Such a low prevalence guarantees high specificity. However, sensitivity is low. Only two of the ten women infected with syphilis reported genital ulcers.

**Table 6. Comparison of clinical diagnoses with laboratory-confirmed infections among women in a New Delhi slum**

Clinical diagnoses	Laboratory results	
	Yes	No
<b>Any lower reproductive tract infection<sup>a</sup></b>		
<b>Abnormal vaginal discharge</b>		
Yes	164	121
No	4	12
	<i>S 97.6, SP 9.0, PPV 57.5, NPV 75.0</i>	
<b>Chlamydia</b>		
<b>Cervicitis</b>		
Yes	31	73
No	51	131
	<i>S 37.8, SP 64.2, PPV 29.8, NPV 71.9</i>	
<b>Abnormal Pap smear</b>		
<b>Cervicitis</b>		
Yes	51	48
No	51	123
	<i>S 50.0, SP 71.9, PPV 51.5, NPV 70.6</i>	
<b>Chlamydia</b>		
<b>Pelvic inflammatory disease</b>	27	51
Yes	27	51
No	55	153
	<i>S 32.9, SP 75.0, PPV 34.6, NPV 73.6</i>	

*Note:* Abbreviations: S = sensitivity, SP = specificity, PPV = positive predictive value, NPV = negative predictive value. See text for definitions.

<sup>a</sup> Bacterial vaginosis, candidiasis, trichomonas vaginalis.

### Validation of clinical diagnoses by laboratory tests

The gynaecologist observed abnormal discharge in a large majority of women (285). Laboratory tests showed that 168 women had some lower reproductive tract infection. Sensitivity is very high but specificity is very low (table 6). Nearly all infected cases were observed to have abnormal discharge, but only 9 per cent of uninfected cases were observed to have normal discharge. Of women observed to have abnormal discharge, a little over half were found to be infected (PPV = 57.5).

Clinical diagnosis of cervicitis or PID is weakly linked with laboratory evidence of chlamydial infection. Sensitivity is only 37 and 33, respectively. A higher sensitivity value (50) is found between cervicitis and abnormal Pap smears.

## Discussion

### Prevalence of reproductive morbidity

All three methods of measurement (self-reports, clinical diagnosis and laboratory tests) revealed a high prevalence of gynaecological morbidity in the urban slum community. The majority (88 per cent) of the women reported one or more symptoms of morbidity. The results of the clinical examination also revealed a high level of gynaecological morbidity in the study population. Three quarters (74.1 per cent) of the women had at least one clinically diagnosed gynaecological morbidity. These findings are broadly consistent with other community-based studies in India (e.g., Bhatia and others, 1997). A high prevalence of cervicitis (36.2 per cent) and cervical erosion (43.9 per cent) was observed. In a comprehensive review of six community-based studies in India, the prevalence of clinically diagnosed cervicitis ranged from 8 per cent to 48 per cent and cervical erosion from 2 per cent to 46 per cent (Koenig and others, 1998). Thus, the results of this study lie at the upper end of the range of estimates found elsewhere in India. However, in this population, the prevalence of chlamydia (29 per cent) is unusually high. As chlamydia is a major cause of PID and infertility, this result is of great public health significance.

### Consistency of self-reports, clinical diagnoses and laboratory tests

In this study, 57 per cent of women who attended the clinic reported abnormal vaginal discharge, the complaint typically concerning the amount of discharge rather than its odour or colour. Abnormal vaginal discharge is regarded as one of the key symptoms of lower reproductive tract infections (RTIs). However, self-reported symptoms of discharge correlated poorly with laboratory evidence of lower RTIs, with a sensitivity of 56 and specificity of 32. Thus, nearly half of the infected cases reported no discharge and the majority of uninfected cases did report discharge. These values imply that treatment on the basis of reported symptoms alone would have missed half of the infected women, but would also have resulted in substantial treatment of uninfected cases.

Pain in the lower abdomen and lower backache are classic symptoms of cervicitis and/or PID. Over three quarters (76 per cent) reported such pain. Such a high prevalence ensures high sensitivity when compared with gynaecological diagnoses. However, specificity was very low; only about one quarter of those found not to have cervicitis or PID reported no pain. Management on the

basis of reported symptoms thus would have resulted in massive over-treatment of uninfected cases. Using the complaint of dyspareunia as a guide to treatment would also have been inadequate. Only a minority of diagnosed cases of cervicitis or PID reported dyspareunia.

One major cause of cervicitis and PID is chlamydia, but there are also many other possible causes. It is therefore not surprising that consistency between clinical diagnoses of these conditions and laboratory-confirmed chlamydial infection is low. Only about one third of cases with confirmed chlamydia were observed by the gynaecologist to have either cervicitis or PID. The correspondence between observation by the gynaecologist of abnormal discharge and laboratory evidence of any lower reproductive tract infection was equally disappointing. Only 57 per cent of women observed to have abnormal discharge were found to be infected. This evidence is consistent with other recent studies that have pointed out the weaknesses of syndromic management (Hawkes and others, 1999; Sloan and others, 2000)

These results add to the growing body of evidence that treatment on the basis of reported symptoms is inadequate in the Indian setting. Women do not seek care for symptoms such as vaginal discharge because they do not perceive the implications of this symptom for health and, even if they do, the likelihood of misdiagnosis is high. There is an urgent need to create awareness in the population regarding symptoms, modes of acquisition and available treatment of RTIs by specially trained health care workers. Women who report to the health care facility should be examined by sensitive and trained health care providers, namely paramedical workers and medical officers available at the primary health care level. It is easier to sensitize and train these workers as they are already providing reproductive and child health services under the country's Reproductive and Child Health Programme. However, this approach will be effective only if concurrent efforts are made to improve the efficacy of diagnosis by developing better standardized diagnostic criteria and simple guidelines for training paramedical workers. Indications of what can be achieved come from a community-based study conducted by the Department of Community Medicine, MAMC, and the Institute of Cytology and Preventive Oncology of the Indian Council for Medical Research. The study assessed the feasibility of involving general health staff in the prevention and early detection of precancerous and cancerous lesions of the cervix. It demonstrated an agreement level of 83 per cent between the diagnoses of ANMs (auxiliary nurse midwives) and those of gynaecologists (Garg and others, 1993).



## **Policy implications**

In developing countries, validation studies focusing on a range of gynaecological morbidities provide empirical evidence that self-reported and observed morbidity measure different aspects of reproductive health. Though self-reports of symptoms provide insights into the perceptions of ill health in the community, the results from this study show that symptoms alone may not be appropriate for the identification of specific gynaecological conditions. Symptoms and clinical signs together (i.e. syndromic management) may help in diagnosis and treatment of reproductive morbidity but, clearly, improvements in diagnostic procedures are urgently needed. While many laboratory tests for the confirmation of RTIs or STDs are expensive or not suitable for use in the field, a compromise solution should be to use simple cheap tests (which are available for certain conditions) until inexpensive laboratory tests become available. These simple tests include: pH testing for bacterial vaginosis, wet mount microscopy for trichomonas vaginalis, and microscopy for pus cells for cervicitis.

Such tests are also already available for syphilis, and routine screening for this disease among antenatal clinic attenders is a priority. In terms of policy implications, it is necessary to train peripheral workers and provide microscopes to all peripheral health facilities. This provision is already envisaged under the Reproductive and Child Health Programme, but full implementation is urgently required.

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## References

- Abdool, Karim, S. S. (1994). "Challenges to the control of sexually transmitted diseases in Africa" *American Journal of Public Health* 84:1891-93.
- Bhatia J., J. Cleland, L. Bhagavan and N.S.N. Rao (1997). "Levels and determinants of gynaecological morbidity in a district of South India" *Studies in Family Planning* 28(2):95-103.
- Bhatia, J. and J. Cleland (2000). "Methodological issues in community-based studies of gynaecological morbidity" *Studies in Family Planning* 31(4):267-273.
- De Schryves, A. and A. Meheus (1990). "Epidemiology of sexually transmitted diseases: the global picture" *Bulletin of the World Health Organization* 68:639-654.
- Filippi, V., T. Marshall, A. Bulut, W. Graham and N. Yolsal (1997). "Asking questions about women's reproductive health: validity and reliability of survey findings from Istanbul" *Tropical Medicine and International Health* 2 (1):47-56.
- Garg, S., N.S. Murthy, P. Sodhani, M. Roy, K. Sahgal and K. Luthra (1993). "Feasibility study of a module for involving general health infrastructure in prevention and early detection of precancerous and cancerous lesions of uterine cervix". Draft report. Institute of Cytology and Preventive Oncology, Indian Council of Medical Research.
- Garg, S., N. Sharma, R. Sahay, P. Bhalla, R. Saha, N.S. Murthy, P. Sodhani, S. Sharma, B.C. Das and N. Gulati (2000). "An epidemiological and sociological study of symptomatic and asymptomatic RTIs/STIs among women in an urban slum". Report of Community Medicine, Maulana Azad Medical College, New Delhi.
- Hawkes, S., L. Morison, S. Foster, K. Gausia, J. Chakraborty, R.W. Peeling and D. Mabey (1999). "Reproductive tract infections in women in low-income, low prevalence situations: assessment of syndromic management in Matlab, Bangladesh" *The Lancet* 354:1776-1781.
- Kaufman, J., Y. Liqin, W. Tongyin and A. Faulkner (1999). "A study of field-based methods for diagnosing reproductive tract infections in rural Yunnan province, China" *Studies in Family Planning* 30(2): 112- 119.
- Koenig, M., S. Jejeebhoy, S. Singh and S. Sridhar (1998). "Investigating women's gynaecological morbidity in India: not just another KAP survey" *Reproductive Health Matters* 6(11):84-96.
- Mabey, D. (1996). "Sexually transmitted diseases in developing countries" *Transactions of the Royal Society of Tropical Medicine and Hygiene* 90:97-99.
- Patel, V. and N. Oomman (1999). "Mental health matters too: gynaecological symptoms and depression in South Asia" *Reproductive Health Matters* 7(14):30-38.
- Sloan, N., B. Winikoff, N. Haberland, C. Coggins and C. Elias (2000). "Screening and syndromic approaches to identify gonorrhoea and chlamydial infection among women" *Studies in Family Planning* 31(1):55-68.
- Zurayak, H., H. Khattab, N. Younis, O. Kamal and M. El-Helw (1995). "Comparing women's reports with medical diagnosis of reproductive morbidity conditions in rural Egypt" *Studies in Family Planning* 26(1):14-21.