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## SHORT REPORT

# The reliability of a structured examination protocol and self administered vaginal swabs: a pilot study of gynaecological outpatients in Goa, India

V S Tanksale, M Sahasrabhojane, V Patel, P Nevrekar, S Menezes, D Mabey

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**Objectives:** Low participation rates for gynaecological examination and low reliability of clinical reporting of gynaecological examination findings are problems in community studies of gynaecological morbidity in India. This pilot study aimed to describe the reliability of a new examination protocol for recording the findings of gynaecological examination and the reliability and acceptability of the use of self administered vaginal swabs for the diagnosis of reproductive tract infections.

**Method:** 75 women attending a gynaecology outpatient clinic were purposively sampled. Each woman was examined by two gynaecologists independently who recorded findings on the new examination protocol. Two swabs were collected from each woman, one by the gynaecologist and one by the woman. Swabs were smeared on separate slides which were stained and read for bacterial vaginosis and candidiasis by laboratory technicians blind to the mode of collection of the slides.

**Results:** The study showed a high inter-rater reliability for most of the items of the examination protocol. The interslide agreement for the diagnosis of the two RTIs was high. One third of women preferred the self administered swab.

**Conclusions:** The examination protocol is a reliable method of recording gynaecological examination findings, and self administered swabs a useful way of obtaining vaginal specimens from women who did not wish to undergo gynaecological examinations in studies in the Indian setting.

Vaginal discharge is one of the commonest complaints in women in south Asia.<sup>1,2</sup> There is poor concordance between self reported symptoms and laboratory confirmed reproductive tract infections (RTIs) limiting the usefulness of the syndromic approach to the management of RTIs.<sup>3,4</sup> Many studies on gynaecological symptoms have suffered from low participation rates as a result of women's reluctance to undergo gynaecological examinations and the unreliability of gynaecological examination reports. This pilot study aimed to evaluate the reliability of a new examination protocol for vaginal examination<sup>5</sup> and to evaluate the acceptability and reliability of self administered vaginal swabs for the collection of vaginal specimens for the detection of candidiasis and bacterial vaginosis. The study was a pilot investigation aimed to guide the methodology of community studies of the aetiology of vaginal discharge where the use of self administered swabs could improve participation rates.

This study aimed (1) to evaluate the inter-rater reliability of a new examination protocol for recording the findings of gynaecological examination; (2) to evaluate the acceptability of the use of self administered swabs versus gynaecologist

administered swabs; and (3) to estimate the reliability of detection of RTIs (candidiasis and bacterial vaginosis) of such swabs by comparing the diagnostic yield of self administered and gynaecologist administered swabs.

## METHOD

### Setting and sample

Women between 18–45 years of age attending the gynaecological outpatients department of Goa Medical College, were purposively sampled to include those who did or did not have the complaint of vaginal discharge. Pregnant and postnatal women were excluded.

### Data collection

Each woman was examined by two gynaecologists; the examination findings were recorded separately and independently on the examination protocols. The items on the protocol are shown in table 1. Examples of the structured nature of recording examination findings are shown in table 2. The vaginal examination protocol was based on the criteria set out in recently developed guidelines,<sup>5</sup> which provide specific definitions for each finding. The first gynaecologist would guide the woman to insert a sterile cotton swab into the vaginal vault herself and to roll the specimen gently onto a clean glass slide in a circular pattern to prepare a smear. Women were instructed to insert the swab as deep as possible without causing discomfort, and at least one inch into the vagina, as described by earlier investigators.<sup>6</sup> Then, the same gynaecologist would collect a vaginal swab and prepare a smear. The order in which the two gynaecologists examined women and collected swabs was randomly assigned. Women who were unmarried virgins did not have a vaginal (speculum) examination. The Gram stained smears were read blind as to whether the smears were from the gynaecologist or a self administered swab. Candidiasis was recorded as present or absent. For bacterial vaginosis, scoring was by Nugent's method.<sup>7</sup>

### Analysis

The preferences the women had for either method of swab collection was noted along with reasons. The interslide reliability for identification of candida or bacterial vaginosis and the inter-rater reliability of items on the examination protocol was examined using the  $\kappa$  statistic. Agreement for Nugent's scores was estimated using a cut off of 6/7. Values of 0.4–0.6 signify moderate agreement, >0.6 signify good agreement, and >0.8 signify perfect agreement.<sup>8</sup>

### Ethical issues

Only women who were able to give informed consent were recruited. The pilot study was part of a larger research protocol which had been approved by the ethics committees of the London School of Hygiene and Tropical Medicine and the independent ethics commission in India.

**Table 1** Inter-rater reliability of examination protocol items

| Variable                    |              | Gyn1 % (n)  | Gyn2 % (n)  | $\kappa$ , p value |
|-----------------------------|--------------|-------------|-------------|--------------------|
| <b>External examination</b> |              |             |             |                    |
| Pallor                      | Present      | 40 (30)     | 40 (30)     | 0.33, <0.001       |
| Abdominal contour           | Distended    | 1 (1)       | 1 (1)       | 1.0, <0.001        |
| Abdominal tenderness        | Present      | 13 (10)     | 9 (7)       | 0.53, <0.001       |
| Abdominal mass              | Present      | 5 (4)       | 5 (4)       | 1, <0.001          |
| Abdominal scar              | Present      | 37 (28)     | 37 (28)     | 1, <0.001          |
| <b>Vaginal examination</b>  |              |             |             |                    |
| Vaginal discharge (VD)      | Present      | 68 (51)     | 73 (55)     | 0.61, <0.001       |
| Colour of VD                | White mucoid | 82 (42/51)  | 84 (46/55)  | 0.54, <0.001       |
| Amount of VD                | Moderate     | 41 (20/51)  | 46 (23/50)  | 0.73, <0.001       |
| Odour of VD                 | Odourless    | 100 (51/51) | 100 (55/55) | 1, <0.001          |
| Endocervical discharge (CD) | Present      | 17 (12/69)  | 17 (12/69)  | 0.49, <0.001       |
| Colour of CD                | White mucoid | 87 (13/15)  | 83 (10/12)  | 0.56, <0.001       |
| Amount of CD                | Moderate     | 33 (5/15)   | 25 (3/12)   | 0.49, 0.01         |
| Cervical congestion         | Present      | 27 (19/69)  | 27 (17/69)  | 0.77, <0.001       |
| Cervical ectopy             | Present      | 31 (22/69)  | 32 (24/69)  | 0.93, <0.001       |
| Vaginal congestion          | Present      | 17 (12/70)  | 11 (8/70)   | 0.53, <0.001       |
| Genital warts               | Present      | 3 (2/70)    | 3 (2/70)    | 1, <0.001          |
| Pelvic tenderness           | Present      | 17 (12/70)  | 13 (9/70)   | 0.72, <0.001       |
| Uterine size                | Enlarged     | 20 (14/69)  | 22 (15/69)  | 0.86, <0.001       |
| Adnexal mass                | Present      | 3 (2/69)    | 3 (2/69)    | 1, <0.001          |

Unless otherwise specified, the denominator is 75—ie, total number of women. The denominator is 69 for cervical examinations since speculums were not inserted in 5 women, and one woman had had a hysterectomy.

## RESULTS

### The sample

Seventy five women were recruited with a mean age of 33.2 years (SD 7.8). Most subjects (80%) did not work outside the home. Twenty five per cent were illiterate while 21% had completed high school education. Most (88%) were married. On inquiry, 77% of women had a complaint of vaginal discharge. 25% of subjects complained of vulval itching, while nearly half (49%) complained of pain in the lower abdomen; 19% of women complained of dyspareunia and 15% had dysuria.

### Clinical examination

The findings of the clinical examination as recorded by the two gynaecologists are shown in table 1. More than two thirds of subjects were recorded to have vaginal discharge; endocervical discharge was recorded in a fifth of the subjects. None of the subjects had urethral discharge. The inter-rater reliability was lowest for the external examination finding of pallor; for all other findings the  $\kappa$  value ranged from 0.49–1 (table 1).

### Self administered swabs

Most women (60%; n=45) preferred swabs collected by gynaecologists while 29% (n=23) preferred self administered

swabs; the remainder (11%) felt that both methods were equally acceptable. The commonest reasons for preferring self administered swabs were that they were easy to collect (65%), could be done at home and thus precluded the need for a hospital visit (13%), and were more convenient (13%). The commonest reason for preferring a gynaecologist to collect the swab was that self administered swabs were uncomfortable or painful to collect (42%), or because women felt scared or lacked confidence to insert the swab themselves (36%). Candida was detected in 22 subjects (29%) with perfect agreement ( $\kappa = 1$ ,  $p < 0.001$ ). Two subjects scored 7 or more on the Nugent's score and there was high agreement between the two sets of specimens ( $\kappa = 0.98$ ,  $p < 0.001$ ).

## DISCUSSION

This pilot study was designed with the objective of informing the methodology of studies of gynaecological morbidity and reproductive tract infections in India. The study has demonstrated that the structured clinical examination guidelines have moderate to high inter-rater reliability for all the items. Thus, an examination protocol following these guidelines will be a reliable basis for recording gynaecological examination findings for studies on their sensitivity for the diagnosis of

**Table 2** Examples of criteria for recording findings on the structured examination protocol

| Condition         | Definition and rationale   | Guidelines for recording observations  |
|-------------------|--|--|
| Vaginal discharge | The presence of vaginal secretions that are malodorous, excessive in amount, or yellow/green in colour. (This term is preferred to "vaginitis" or "vaginal infection" since the presence of observable discharge cannot be consistently correlated with either vaginal inflammation or infection.)                                       | Record characteristics of vaginal secretions as follows:<br>Odour: (a) normal, (b) malodorous<br>Amount: (a) scanty, (b) normal, (c) profuse<br>Colour: (a) clear, (b) white, (c) bloody, (d) yellow/green<br>"Abnormal vaginal discharge" is present if results underlined are found or if there is a bloody discharge in a non-menstruating woman. |
| Pelvic tenderness | The presence of pain (as evidenced by changes in facial expression or muscle tone and/or bodily motion) during pelvic examination. (To minimise variation in the occurrence of mild discomfort or pain, this definition excludes pain verbally reported by the woman being examined unless it is accompanied by an observable reaction.) | Record the occurrence of pelvic tenderness as follows:<br>Was pain experienced by the woman during bimanual examination?<br>(a) No, (b) Yes  |

Adapted from Elias *et al.*<sup>5</sup>

### Key messages

- Self administered swabs are an acceptable method of collection of vaginal specimens in women attending gynecological clinics in India
- The reliability of specimens collected using self administered swabs for the detection of candidiasis and bacterial vaginosis is high when compared to gynecologist administered swabs.
- A structured examination protocol has high reliability for the recording of findings on clinical gynaecological examination.

RTIs. Self administered swabs have a great potential for surveillance of RTIs in settings where either women do not wish to be examined, or cannot access gynaecological clinics. They are potentially of great use in community studies of RTIs. While there have been reports of their use in Africa and in developed countries<sup>6-9,10</sup> in studies of sexually transmitted diseases, there is no record of their use in India. This is also one of the few studies examining the usefulness of self administered swabs for candidiasis and bacterial vaginosis. This study has found that, even in a clinical sample of women attending a gynaecological outpatient department, almost a third preferred self administered swabs. Furthermore, the laboratory diagnoses of candidiasis and bacterial vaginosis revealed high concordance when comparing specimens collected by self administered and gynaecologist administered swabs. Thus, self administered swabs are acceptable to a substantial group of women and are reliable in terms of the detection of RTIs and they may be used in studies of RTIs in India and population based surveillance of RTIs.

We acknowledge the limitations of this study, in particular that the sample size was small and the study was located in a clinical setting. Also, the swabs were not examined for their sensitivity for the diagnosis of STDs. However, this was a pilot study and we felt it was reasonable to assess an examination protocol and the use of self administered swabs for the first time in a treatment setting. Furthermore, there was already evidence of the use of self administered swabs for the diagnosis of STDs.<sup>6-10</sup> RTIs such as candidiasis and bacterial vaginosis are common in south Asian community settings<sup>3</sup> and thus, we were interested to determine whether self administered swabs were reliable ways of detecting these infections. The outcome of this pilot study has now led to the use of self administered swabs as an optional method of specimen collection and the use of the structured examination protocol in an ongoing community cohort study of gynaecological morbidity and RTIs in India. Experience from the study has shown that self administered swabs are preferred by a large number of women, even when the instructions on collection are given by community researchers, as opposed to gynaecologists as in the pilot study.

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### CONTRIBUTORS

VST and MS were the two gynecologists who carried out all the examinations and the swab collections. Both were involved in the writing of the draft paper, analysis of data and approval of the final version of the paper; VP coordinated the entire study, from its design to the writing of the final version of the paper; PN participated in the design of the study, the supervision of the two gynaecologists during the data collection, and commenting and revising the draft of and final version of the paper; SM supervised the laboratory aspects of the study, including supervision of the blind assessments of the specimens and analysis of the laboratory data; DM participated in the design of the study, advised on the analysis and commented and revised the first and final versions of the paper.

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### Authors' affiliations

**V S Tanksale, M Sahasrabhojane**, Sangath Society, Goa, India

**V Patel, D Mabey**, London School of Hygiene and Tropical Medicine, London, UK

**P Nevrekar**, Department of Gynecology, Goa Medical College, Goa, India

**S Menezes**, JMJ Hospital, Goa, India

Correspondence to: Dr Vikram Patel, Sangath Society, Alto Porvorim, Goa 403521, India; vikpat@goatelecom.com

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