

# THE SENSITIVITY OF A SYNDROMIC MANAGEMENT APPROACH IN DETECTING SEXUALLY TRANSMITTED DISEASES IN PATIENTS AT A PUBLIC HEALTH CLINIC IN CAPE TOWN

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*Objectives.* To evaluate the sensitivity of a syndromic diagnostic procedure in detecting and treating sexually transmitted diseases (STDs) and genital tract infections (GTIs).

*Methods.* All new patients presenting at an STD clinic were sampled systematically by gender over a 6-week period. After the patient's clinical consultation, the clinical records were reviewed. Thereafter all patients were given a thorough genital examination by the research physician, and specimens were collected for laboratory investigations. In a retrospective simulation clinicians' syndromic diagnoses were validated against the laboratory findings, or for genital ulcer syndrome against the findings of the research physician.

*Results.* 170 men and 161 women were included in the sample. Ninety-five per cent of patients were black and the median age was 22 years for women and 26 years for men. In this setting, the Western Cape syndromic diagnostic procedure achieved reasonable levels of sensitivity in detecting *Neisseria gonorrhoeae* and *Chlamydia trachomatis* in men and women, and in detecting *Trichomonas vaginalis* and bacterial vaginosis in women. However, it was estimated to be only 36.4% sensitive in detecting genital ulcers in women, and between 0% and 12.3% sensitive in detecting *Candida albicans*. With syndromic management 8.2% of men and 32.9% of women would leave the clinic with at least one infection inadequately treated.

*Conclusions.* Despite the introduction of syndromic protocols, it is likely that a proportion of STDs and GTIs are not being detected and treated owing to the high prevalence of multiple syndromes and mixed infections, both symptomatic and asymptomatic.

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This study aims to describe the sensitivity of syndromic management in detecting sexually transmitted diseases (STDs) and genital tract infections (GTIs) in patients presenting at a public STD clinic in Cape Town. This baseline research serves to inform the development of future guidelines and protocols. The syndromic management approach to STDs was introduced by the World Health Organisation<sup>1</sup> in an attempt to increase the effectiveness of STD management. It has been modified for use in South Africa. This approach addresses the difficulties in making accurate aetiology-specific diagnoses in primary care settings where laboratory tests are not accessible or affordable, and where there is a high prevalence of mixed infections in patients. Few formal evaluations of the diagnostic validity of syndromic management protocols for STDs and GTIs have been undertaken in South Africa.

## METHODS

The research was undertaken in a busy local authority STD clinic in Cape Town over a 6-week period in 1995. The clinic had approximately 20 000 patient attendances per year, more than half the total STD clinic attendances for the municipal area. At the time of the research syndrome-based diagnostic and treatment protocols had not been instituted in the Cape Town municipal area.

The study population comprised all new patients who presented at any of the 3-weekly sessions of the clinic and who verbally consented to inclusion in the study. The sample was stratified for gender and cases were systematically recruited. Menstruating women and patients who had received antibiotic treatment within the previous 2 weeks were excluded.

Data were collected after the patient's initial clinical consultation. Demographic, clinical and diagnostic details were transcribed from the patient's record card. Each patient was then examined by a physician on the research team (AvR). Males received a full genital (excluding rectal) examination, and females a full gynaecological (excluding rectal) investigation, including speculum examination and bimanual palpation.

Laboratory investigations included microscopy and culture for *Trichomonas vaginalis* in men and women. Microscopy and culture were performed for *Candida* species in women, and moderate or abundant growth of the yeast was reported. Bacterial vaginosis was detected by means of the presence of 'clue cells', a pH of  $\geq 4.5$  and a positive amine test. A first void urine sample was collected from all patients for ligase chain reaction for *Neisseria gonorrhoeae* and *Chlamydia trachomatis*. All patients had venous blood collected for syphilis serology using standard Venereal Disease Research Laboratory (VDRL) and fluorescent treponemal antibody-absorption (FTA-ABS) tests.

Data were entered in Epi Info Version 6.0 and analysed using Epi Info 6 and SAS statistical software. Frequency distributions and two-by-two tables were generated. Confidence intervals

(CIs) were calculated for certain subgroup estimates and chi-square tests were used for comparing proportions.

A retrospective simulation of the Western Cape<sup>2</sup> syndromic diagnostic protocol was generated to assess the sensitivity of a syndromic diagnostic procedure in detecting specific STDs and GTIs. Clinical presentations, as identified by the clinicians in the clinic, were grouped into one of three syndromes, namely urethral discharge, vaginal discharge, and genital ulcerative syndrome (GUS). This protocol diagnoses the presence of *N. gonorrhoeae* and *C. trachomatis* in male patients with urethral discharge and treats accordingly. Similarly, it diagnoses the presence of *N. gonorrhoeae*, *C. trachomatis*, *T. vaginalis* and bacterial vaginosis in patients with vaginal discharge, and treats accordingly. *Candida albicans* is not diagnosed unless it is clinically suspected. The sensitivity of the syndromic diagnosis of urethral discharge was determined by calculating the extent to which it detected infections of *N. gonorrhoeae* and *C. trachomatis* respectively, using microbiological findings as the gold standard. The sensitivity of the syndromic diagnosis of vaginal discharge was determined by calculating the extent to which it detected infections of *N. gonorrhoeae*, *C. trachomatis*, *T. vaginalis* and bacterial vaginosis respectively, again using microbiological findings as the gold standard. The gold standard for calculating the sensitivity of the diagnosis of GUS was considered to be the clinical identification of genital ulcers by the research physician. When determining the adequacy of treatment, correct treatment was assumed if an infection was detected.

## RESULTS

During the study period a total of 1 438 new male and 391 new female patients attended the clinic. The sample included 192 men and 180 women; of this number 22 men and 19 women subsequently withdrew. As such the final sample included 170 men and 161 women.

The median age was 26 years for men (interquartile range: 23 - 29 years) and 22 years for women (interquartile range: 20 - 27 years). In the 14 - 19-year age group there were significantly more women (21.7%) than men (7.1%;  $P < 0.01$ ). Patients were mostly single (75% of men and 85.7% of women), and not living with their regular sexual partner (76.2% of men and 70.8% of women).

Columns 1 and 2 (Table I) show the number of STDs and GTIs as identified by gold standard investigations among all male and female patients. In addition, 14.1% of men and 22.4% of women were infected with syphilis (positive by VDRL and FTA-ABS tests).

In 38 men (22.4%) and 32 women (19.9%), no infections were detected by the laboratory procedures or by the research physician's examination. Only one infection was detected in 97 men (57.1%) and 56 women (34.8%). In 28 men (16.5%) and 35 women (21.7%) two infections were detected; and in 7 men



Table I. Sensitivity of a syndromic diagnostic procedure in detecting STDs and GTIs

Infection	No. of infected patients		Sensitivity — proportion of infections detected by a syndromic diagnostic approach					
	Men	Women	%	Men		Women		95% CI
	(N = 170)	(N = 161)		Freq.	95% CI	Freq.	95% CI	
<i>N. gonorrhoeae</i>	93	49	92	86	85 - 97	84	41	70 - 93
<i>C. trachomatis</i>	20	32	80	16	56 - 94	88	28	71 - 97
<i>T. vaginalis</i>	-	56				80	45	68 - 90
Bacterial vaginosis	-	49				86	42	73 - 94
<i>C. albicans</i>	-	28				0	0	0 - 12
Genital ulcer	40	11	83	33	67 - 93	36	4	11 - 69

Freq. = frequency.

(4.1%) and 38 women (23.7%) three or more infections were detected. Women were significantly more likely to have more than one infection ( $P < 0.01$ ).

Of the male patients with *N. gonorrhoeae*, 18.3% had concomitant chlamydial infection, while among the female patients with *N. gonorrhoeae*, 49.2% had concomitant chlamydial infection. Ten per cent of men and 13% of women had both *N. gonorrhoeae* and *C. trachomatis*. Of the patients with genital ulcers, 19% of the men and 90.9% of the women also had non-ulcerative infections.

Table I also indicates the number of patients with each infection (as determined by the gold standard) who would be detected using the syndromic diagnostic procedure. The proportions reflect measures of sensitivity, where the simulated clinical diagnosis is compared with the gold standard findings.

The simulation indicates that the syndromic diagnostic procedure failed to detect 7 infections of laboratory-confirmed *N. gonorrhoeae* in male patients. Clinicians had reported only the following clinical findings for these patients: 'no STD' (3 patients), genital ulcer (1 patient), genital warts (1 patient) and scabies (1 patient). No clinical diagnostic details were recorded for 1 patient. Four infections of laboratory-confirmed *C. trachomatis* in male patients were not detected by the syndromic diagnosis of urethral discharge. Clinicians had described these patients as having genital ulcers (2 patients), scabies (1 patient), and 'no STD' (1 patient).

The syndromic diagnostic procedure failed to detect 8 infections of laboratory-confirmed *N. gonorrhoeae* in female patients. For these women the clinical findings reported were: 'no STD' (6 patients), latent syphilis (1 patient), and a genital ulcer (1 patient). Four infections of laboratory-confirmed *C. trachomatis* in women were not detected by syndromic diagnosis. These patients were recorded by the clinicians as having 'no STD' (3 patients), and a genital ulcer (1 patient). Eleven infections of *T. vaginalis* were not detected by the syndromic diagnostic procedure. The infected women were described as having 'no STD' (6 patients), a genital ulcer (4 patients), and latent syphilis (1 patient). Seven infections of

bacterial vaginosis were not detected. The infected women were described as having 'no STD' (3 patients), a genital ulcer (1 patient) and latent syphilis (1 patient).

None of the laboratory-confirmed *C. albicans* infections were detected by the clinicians. In most cases of laboratory-confirmed *C. albicans* the clinicians did report a discharge, but failed to recognise it as *Candida*. Where clinicians did report clinical signs of *Candida*, no infection was found on microbiological investigation.

The syndromic diagnostic procedure failed to detect 7 genital ulcers in men. In these patients the clinicians had reported either no clinical signs (3 patients) or a discharge (4 patients). The procedure failed to detect 7 genital ulcers in women; in all 7 instances clinicians had reported a discharge only.

In total 8.2% of male patients and 32.9% of female patients would leave the clinic with at least one infection inadequately treated. Syphilis was not included in this calculation.

## DISCUSSION

It appears that syndromic management was not 100% sensitive in detecting infections of *N. gonorrhoeae*, *C. trachomatis*, *T. vaginalis* and bacterial vaginosis because patients in this setting were presenting with multiple infections across syndromes. Furthermore clinical practice was inadequate in screening for and detecting signs of infections or syndromes other than those of the presenting problem. A further reason appears to be that in some cases there was a true absence of symptoms or clinical signs of the infections.

Infections of *C. albicans* were not detected by clinicians in this setting. In-service training is needed to improve clinicians' diagnostic skills in this regard.

Most of the genital ulcers in women and some of those in men were not detected by the clinicians. The discrepancy between patients diagnosed by the clinicians as having a genital ulcer and those identified by the research physician as having one highlights the importance of thorough examination, including speculum examination in women. In addition to the

missed opportunities for detecting and treating GUS reported in this study, there were also several female patients not included in the study because they were too fearful to permit genital examination. This may account for further missed opportunities for detecting GUS in STD services.

The gold standard for the detection of a genital ulcer used in this study, namely thorough examination by the research physician under ideal circumstances, is a contentious and poor one. It probably over-estimates the sensitivity of the syndromic diagnostic procedure in detecting genital ulcers. It is, however, a measure of pragmatic value in that it illustrates the extent to which the sensitivity of the clinicians' diagnoses could be improved through training or changes in examination conditions.

Patients presenting at this dedicated STD clinic may be very different from those presenting at integrated primary health services, or from those presenting at services in other regions of the country. These results may therefore not be applicable in other settings.

## CONCLUSION

Despite the introduction of syndromic protocols it is likely that a proportion of STDs and GTIs are not being detected and treated owing to the high prevalence of multiple syndromes and mixed infections, both symptomatic and asymptomatic. In order to effectively implement a syndromic approach, standard clinical practice needs to include thorough genital examinations and the screening of each patient for signs and symptoms of every syndrome. Changes in the prevalence of STDs presenting at this and other services in the Western Cape can be anticipated. It is crucial that evaluations of this nature take place regularly so that future protocols may be adjusted.

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