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Validation of a WHO algorithm with risk assessment for the clinical management of vaginal discharge in Mwanza, Tanzania

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Objectives: (i) To determine the microbial aetiologies of vaginal discharge in STD clinic and antenatal clinic (ANC) attenders; (ii) to evaluate the performance and costs of a new WHO algorithm for the detection of gonococcal and chlamydial infections in women complaining of vaginal discharge and/or genital itching, using a risk assessment.
Methods: Two groups were enrolled: (i) 395 consecutive female patients attending a hospital outpatient clinic complaining of genital discharge or itching; and (ii) 628 consecutive pregnant women reporting at an urban ANC these symptoms. Patients were interviewed by a nurse, who applied the WHO risk score. They were then referred to the study room for interview concerning the same and other risk factors, examined, and sampled for *Neisseria gonorrhoeae* (NG), *Chlamydia trachomatis* (CT), *Trichomonas vaginalis* (TV), and *Candida albicans* (CA). Sensitivity, specificity, positive predictive value, overtreatment and correct treatment rates, and cost of drugs per true case treated were estimated.
Results: The prevalence of NG and/or CT infections was 11.4% and 8% at the STD clinic and the ANC respectively. The most prevalent pathogens were CA (38% at both clinics) and TV (25% at the STD clinic and 34% at the ANC). The sensitivity of the WHO algorithm for NG and/or CT was 62% at the STD clinic and 46% at the ANC, and the specificities were 64% and 84% respectively. The operational feasibility of the method was good. The cost of drugs per true case treated in applying the risk assessment approach was $3.5 among nonpregnant women and $5.0 among pregnant women. This compared favourably with respective costs of $8.8 and $25.0 in applying the syndromic management alone.
Conclusions: The WHO risk assessment algorithm for the diagnosis of NG and/or CT infections among women complaining of genital discharge can considerably reduce overtreatment of NG and/or CT in both pregnant and non-pregnant women, but in this study it failed to identify 38% of non-pregnant and 54% of pregnant women with these infections. The elements of the risk score may need adjustment in different settings.
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Keywords: vaginal discharge; gonorrhoea; chlamydial infection; STD algorithms; risk assessment; Tanzania

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Introduction

Sexually transmitted diseases (STDs) are a major public health problem in many parts of the developing world.[1] A high prevalence of many STD pathogens has been observed in both pregnant and non-pregnant women in many parts of Africa.[2–4] Such STDs in women are often asymptomatic and therefore are not treated. The consequences can be serious, including infertility, spontaneous abortion, stillbirths, and recurrent abdominal pain.[5–7]

In developing countries, much attention has been drawn to the potential role that classic STDs may play in the transmission of human immunodeficiency virus (HIV) infection.[8 9] Effective STD control programmes might reduce the incidence of HIV infection. In the past, such STD control has been hampered by the lack of laboratory facilities and the lack of training and awareness of many health workers. The World Health Organisation (WHO) has therefore advocated a simpler and more cost effective method for STD case detection and management through the syndromic approach.[10] This means treating the major aetiological pathogens that can cause the symptoms reported by patients.

Using the syndromic approach, the treatment of genital discharge syndrome (GDS) in females has been difficult, owing to the number and diversity of pathogens. Given the serious nature of the consequences most syndromic treatment protocols concentrate on *Neisseria gonorrhoeae* (NG) and *Chlamydia trachomatis* (CT). Other common pathogens or conditions include *Trichomonas vaginalis* (TV), bacterial vaginosis (BV), and *Candida albicans* (CA). To give treatment for all pathogens or conditions can result in overtreatment and poor compliance by patients, increased costs, and potentially negative side effects. To address this problem, the WHO and others have developed a simple risk score for the identification of NG and/or CT infections in women complaining of vaginal discharge.[11 12]

According to the WHO algorithm, all women with GDS should receive treatment for the pathogens or conditions causing vaginal in-

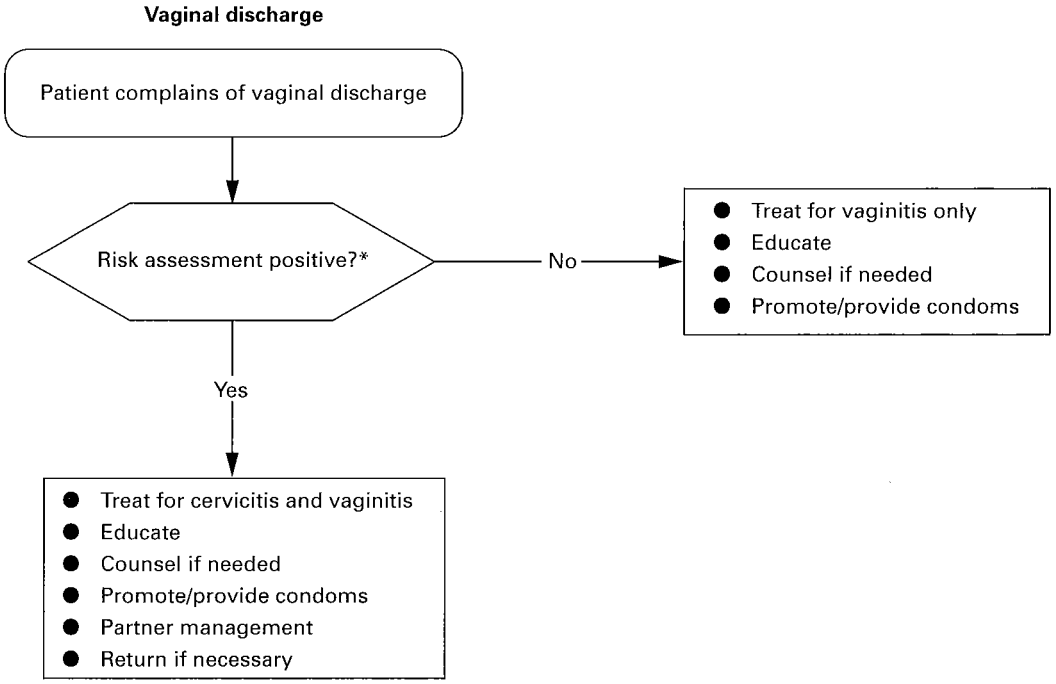

Figure 1 WHO flow chart for the management of vaginal discharge with risk assessment.

fections (TV, BV, and CA), while only women positive on the risk assessment should be treated for gonococcal and chlamydial infections. Thus, the specificity of the algorithm for the treatment of NG and CT is expected to increase and the costs per true case treated to decrease. This paper reports the validation of the WHO risk score in pregnant and non-pregnant women in urban Mwanza, north western Tanzania.

Methods

Two groups of women were identified for the evaluation of the WHO risk score algorithm over the period from June 1993 to April 1994. Firstly, consecutive non-pregnant women presenting with the complaint of vaginal discharge or genital itching at an outpatient clinic in Sekou Toure municipal hospital. Secondly, consecutive pregnant women spontaneously complaining of vaginal discharge or genital itching at a routine antenatal clinic in Makongoro clinic. All women were over 15 years of age and gave informed written consent before enrolment in the study.

At the outpatient clinic, women complaining of GDS related symptoms ("dirty vaginal discharge" or "profuse watery vaginal discharge" or "itching around the genitalia" were the terminology these women mostly complained of in Kiswahili) were referred to the STD clinic located in the same building. At the antenatal clinic, health education talks encouraged women to report any STD symptoms and women with spontaneous GDS related complaints (as above) were referred to a private adjoining room. Eligible women in both clinics were interviewed by a screening nurse (HCW-A), who asked each woman, in Kiswahili, the five simple questions which comprise the WHO risk score.

(1) Are you aged less than 21 years?
(2) Are you single?
(3) Have you had a new sexual partner in the last 3 months?
(4) Have you had more than one sexual partner in the last 3 months?
(5) Has your partner experienced urethral discharge and/or dysuria within the last month?

Using the WHO flow chart (fig 1) which accompanies the risk assessment score, the health worker could make a decision for treatment of the vaginal discharge. If the patient answered "Yes" to at least two of questions 1–4, or if the patient answered "Yes" to question 5, treatment was prescribed for vaginal and cervical infections. If the answers were negative to at least four questions, including question 5, then treatment was given only for vaginal infection. The screening nurse performed the exact duties that are expected in the application of the risk score algorithm, without actually delivering the STD drugs.

The patient was then seen by an STD clinician (HCW-B) in a separate, private room. A standard questionnaire elicited information on demographic characteristics, obstetric history, sexual behaviour, past STD experience, and STD symptoms. In the detailed questionnaire, the five questions which comprise the WHO score were also included, without the knowledge of the previous response to HCW-A. A general and pelvic examination was done and sampling performed. The patients were treated syndromically, following national guidelines, counselled, and given follow up appointments at 7 days.

LABORATORY METHODS

Blood was collected for syphilis serology (a positive rapid plasma reagin test (VD 25,

Murex Diagnostics, UK), confirmed by TPHA (Fujirebio, Tokyo, Japan)) and HIV-1 serology (Organon Teknika ELISA, Organon, Boxtel, Netherlands, confirmed by Wellcozyme GA-CELISA, Murex Diagnostics, UK).

Vaginal swabs were collected from the vaginal wall and fornix: (i) to be directly applied on a pH strip; (ii) to prepare a wet saline mount and a wet preparation with potassium hydroxide to detect typical amine odour ("whiff" test); (iii) to prepare a Gram smear (to detect the presence of "clue cells"). This enabled the diagnosis of *Candida albicans* (CA) by wet preparation and vaginal Gram smear, and of *Trichomonas vaginalis* (TV) by wet preparation. A high vaginal swab was also collected for culture of *Neisseria gonorrhoeae* (NG) on a modified Thayer–Martin (MTM) media plate. After cleaning the ectocervix with a large cotton swab, cervical specimens were collected and tests carried out for NG on MTM culture plate and *Chlamydia trachomatis* (CT) by an antigen capture enzyme immunoassay (IDEIA, Novobio Diagnostics, Cambridge). All IDEIA positive tests were confirmed using an antibody blocking assay provided by the same manufacturer. After removal of speculum and cleaning of the vulva with a clean cotton swab, a final swab was collected from the urethra for the diagnosis of NG.

Lastly, each woman was requested to provide a first catch urine sample in a clean 50 ml plastic container after clinical examination. The urine sample was mixed and immediately tested with a leucocyte esterase dipstick test (LED, Nephur test+Leuco, Boehringer-Mannheim, Lewes, Sussex) and read after 2 minutes by comparing the colour development on the stick with a standard scale provided by the manufacturer. Results were reported as negative, 1+, 2+, and 3+.

Gonorrhoea was defined as a positive MTM culture from any of the three sites sampled. Bacterial vaginosis (BV) was defined by the presence of at least two of the following criteria[13 14]: (i) presence of "clue cells" on vaginal Gram stain; (ii) KOH ("whiff") test positive; (iii) vaginal pH >4.7. Cervical infections were defined as the presence of either gonococcal (NG) or chlamydial (CT) infections or both. Vaginal infections were defined as the presence of TV, BV, or CA, or any combination.

STATISTICAL METHODS AND PERFORMANCE ESTIMATES

The principal outcome in this study was the presence of cervical NG and/or CT infections. To adequately ascertain the sensitivity and specificity of the risk assessment algorithm, 50 cervical infections were required in each group. Initial sample size calculations were based on the assumption that the prevalence of NG and/or CT infection was 30% among women attending the outpatient clinic complaining of vaginal discharge or itching (that is, an expected sample size of 150), and 10% among antenatal clinic attenders with these symptoms (that is, an expected sample size of 500). In the event, prevalences were considerably lower than this, necessitating the enrolment of 395 consecutive women with these complaints at the outpatient clinic, and 628 at the antenatal clinic.

Data were compiled using DBASE and simple analysis carried out in EPI-INFO. The risk score was assessed for its acceptability and feasibility by patients and staff. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for detection of NG and/or CT infections were calculated.

The WHO and other experts[15] recommend that the *correct treatment rate* and *overtreatment rate* are also estimated. We defined the *correct treatment rate* as the proportion of patients who would receive adequate treatment if they were infected with NG and/or CT or no treatment if they were not infected, among all women undergoing the risk score. The *overtreatment rate* was determined by the proportion of patients who would receive treatment among those who were not infected—that is, 1−specificity.

COST CALCULATIONS

Two types of cost evaluations were made, according to suggestions made by WHO and other experts.[15] The *cost per patient (A)* is the cost incurred by the health structure in applying the flow chart for one patient. It is defined by "the sum of all the costs of diagnosis and of treatment for individuals identified as infected by the flow chart divided by the total number of individuals for whom the flow chart is used. It is given by the formula: $A = (P_d \times \text{diagnosis cost}) + (P_t \times \text{treatment cost})$, where P_d is the proportion of patients who undergo the diagnosis (examination and tests) and P_t is the proportion of patients who are treated according to the algorithm".[15] In the present study, P_d did not need to be calculated since all women underwent the same laboratory procedures for the purpose of validation and the cost of applying the risk score questions would be negligible. Thus the relevant cost estimate determined in this study was: $A = P_t \times$ treatment costs.

The *cost per true case of cervical infection (NG and/or CT) treated (B)* is defined as "the sum of all costs of diagnosis and treatment incurred in following the algorithm, divided by the number of truly infected cases".[15] It is given by the formula: $B = [(P_d \times \text{diagnosis cost}) + (P_t \times \text{treatment cost})]$ divided by $P_{NG/CT}$, where $P_{NG/CT}$ is the proportion of patients truly infected with NG and/or CT. As for the *cost per patient* above, the only relevant costs were those of drugs, thus we determined $B = [P_t \times \text{treatment costs}]/P_{NG/CT}$.

The unit cost of treatment was taken as the cost of drugs for managing vaginal discharge according to the Tanzanian guidelines, and at the time the study was carried out (1994). The cost of drugs used for the treatment of NG and/or CT was obtained from the 1993 price list of the International Dispensary Association (IDA) and the WHO/GPA recommendations.[16] This was approximately $1 for non-pregnant women (regimen of co-trimoxazole five tablets twice daily × 2 days, and doxycycline 100 mg twice daily × 7 days) and $2 for pregnant

Table 1 Sociodemographic characteristics and obstetric history of 395 non-pregnant women attending an outpatient clinic and 628 pregnant women attending routine antenatal clinic services with vaginal discharge or itching, in Mwanza, Tanzania

Characteristics	Non-pregnant women (n=395)	Pregnant women (n=628)
Age		
Under 21 years	106 (27%)	222 (35%)
21 to 30 years	225 (57%)	342 (54%)
Over 30 years	64 (16%)	64 (10%)
Marital status		
Monogamous marriage	192 (49%)	489 (78%)
Polygamous marriage	52 (13%)	48 (7.6%)
Widow/separated/divorce	58 (15%)	23 (3.7%)
Single	93 (24%)	67 (11%)
Occupation		
Housewife	266 (67%)	526 (84%)
Bar worker	19 (4.8%)	6 (1.0%)
Other work	110 (27%)	95 (15%)
Education		
Primary <standard 4	75 (19%)	104 (17%)
Primary ≥standard 4	277 (70%)	446 (71%)
More than primary	42 (11%)	78 (12%)
No of previous pregnancies		
None	84 (21%)	173 (28%)
1–2	163 (41%)	253 (40%)
3–5	104 (26%)	164 (26%)
≥6	34 (11%)	37 (6%)
Abortion ever*		
No	194 (63%)	340 (75%)
Yes	112 (37%)	114 (25%)
Stillbirth ever*		
No	294 (96%)	423 (94%)
Yes	12 (4%)	29 (6%)
Contraceptive use ever		
Oral contraceptives	80 (20%)	99 (16%)
Condoms	79 (20%)	48 (7.6%)
Both oral and condoms	52 (13%)	37 (5.9%)
Sexual debut		
Under 15 years	80 (20%)	76 (12%)
15 to 18 years	240 (61%)	395 (63%)
Over 18 years	75 (19%)	157 (25%)

* Excluding women with no previous pregnancy.

Table 2 Prevalence of reproductive tract infections (RTI), HIV, and results of urine LED testing among 395 non-pregnant women attending an outpatient clinic and 628 pregnant women attending routine antenatal clinic services with vaginal discharge or itching, in Mwanza, Tanzania

Laboratory tests	Non-pregnant symptomatic (n=395)	Pregnant symptomatic (n=628)
Cervical or vaginal pathogens/condition:		
N gonorrhoeae (NG)		
by culture only	29 (7.3%)	14 (2.2%)
by culture or Gram stain	33 (8.4%)	25 (4.0%)
C trachomatis (CT)	19 (4.8%)	38 (6.1%)
NG (by culture) and/or CT	45 (11.4%)	50 (8.0%)
C albicans (CA)*	150 (38%)	238 (38%)
T vaginalis (TV)	97 (25%)	214 (34%)
Bacterial vaginosis (BV)†	147 (37%)	133 (21%)
TV/BV	206 (52%)	303 (48%)
No cervical or vaginal pathogen/condition	92 (23%)	169 (27%)
Serology:		
Syphilis (TPHA and RPR+)	23 (5.4%)	46 (7.2%)
HIV-1	102 (26%)	112 (18%)
LED on urine		
Neg	66 (17%)	110 (18%)
1+	132 (34%)	115 (19%)
2+	102 (26%)	156 (25%)
3+	91 (23%)	238 (38%)

* By wet preparation or Gram stain.
† BV defined by two out of three criteria: whiff test, Gram stain (clue cells), vaginal pH >4.7 (all women have discharge).

women (regimen of co-trimoxazole five tablets twice daily × 2 days, and erythromycin (500 mg three times × 7 days). The additional costs for metronidazole were not included since all women were to receive this drug in case of discharge. It was not within the scope of this paper to calculate the long term costs associated with failure to treat cervical infection.

ETHICAL ISSUES

The ethical regulations of the Tanzanian National Institute of Medical Research, the London School of Hygiene and Tropical Medicine, and of WHO were complied with. Written informed consent was sought from all participants.

Results

A total of 1029 women were eligible for enrolment, but at the antenatal clinic, three refused permission for sampling and three were referred for obstetric complications. Data were collected and analysed from 1023 women, 395 at the outpatient/STD clinic and 628 at the antenatal clinic. The demographic and social characteristics of the women are shown in table 1. When compared with pregnant women, non-pregnant women were slightly older, less often engaged in monogamous marriages, less predominantly housewives, and were more likely to have used contraceptives, particularly condoms, in their life. There were no major differences between the two groups concerning educational background, previous obstetric history, and age of sexual debut.

PREVALENCE OF REPRODUCTIVE TRACT INFECTIONS, AND HIV AND LED RESULTS

The microbiological spectrum of vaginal discharge is shown in table 2. The prevalence of NG and/or CT was relatively low in both populations with more NG among non-pregnant women (prevalence of positive NG culture was 7.3% *v* 2.2% in pregnant women) and more CT in pregnant women (6.1% *v* 4.8% in non-pregnant women). Most women who were seen with vaginal discharge had vaginal infections caused by TV (25% in non-pregnant and 34% in pregnant women), BV (37% and 21%), or CA (38% in both).

Women were frequently found to have multiple infections: 50% of the women with a cervical or vaginal pathogen or condition had more than one reproductive tract infection (RTI) diagnosed. However, there was also a high proportion of symptomatic women with no demonstrable pathogen from the vagina and cervix (23% at the STD clinic and 27% at the ANC clinic). There was a high prevalence of HIV in both clinics (26% at the STD clinic and 18% at the ANC clinic) and serological syphilis was found in 5% of non-pregnant and 7% of pregnant women.

The proportion of LED positive results was similar in both groups, with only a minority of women having no detectable leucocytes in their urine samples (17–18%).

RISK FACTORS FOR CERVICAL INFECTION

Infection with NG and/or CT was associated with the responses given to the five questions asked by the screening nurse as shown in table 3. Very few pregnant women reported a change in sexual partner, and this risk factor was not significantly associated with NG and/or CT infection. All other questions were significantly

Table 3 Association between the responses to the five risk score questions given to the screening nurse and NG and/or CT infection, among 395 non-pregnant women attending an outpatient clinic and 628 pregnant women attending routine antenatal clinic services with vaginal discharge or itching, in Mwanza, Tanzania

		Non-pregnant symptomatic		*Pregnant symptomatic*	
Elements of the score		*NG/CT+ve N (%)*	*Odds ratio (95% CI)*	*NG/CT+ve N (%)*	*Odds ratio (95% CI)*
Q1. Are you aged less than 21 years?	No	30 (7.6%)	1.53	24 (6.0%)	2.06
	Yes	15 (15%)	(0.74, 3.15)	26 (12%)	(1.11, 3.85)
Q2. Are you single	No	21 (8.6%)	1.98	31 (6.0%)	3.28
	Yes	24 (16%)	(1.01, 3.90)	19 (17%)	(1.69, 6.34)
Q3. Changed partner in the past 3 months?	No	28 (8.9%)	2.66	49 (7.9%)	1.66
	Yes	17 (21%)	(1.30, 5.44)	1 (12%)	(0.00, 14.09)
Q4. More than one partner in the past 3 months?	No	29 (9.2%)	2.51	42 (7.1%)	4.04
	Yes	16 (20%)	(1.21, 5.18)	8 (24%)	(1.56, 10.2)
Q5. Partner having a genital discharge or genital itch?	No	3 (5.7%)	4.08	26 (5.7%)	3.76
	Yes	12 (19%)	(0.98, 19.7)	7 (18%)	(1.35, 10.1)
			2.16		2.51
	D/K	30 (11%)	(0.59, 9.36)	17 (13%)	(1.24, 5.02)
Risk score	Neg	17 (7.1%)	2.93	27 (5.3%)	4.44
	Pos	28 (18%)	(1.47, 5.88)	23 (20%)	(2.33%, 8.47)
LED urine	Neg	1 (1.5%)	1	6 (5.5%)	1
	1+	12 (9%)	6.5	6 (5.2%)	0.95
			(0.83, 51.0)		(0.30, 3.1)
	2+	14 (14%)	10.3	14 (9.0%)	1.71
			(1.33, 80.6)		(0.64, 4.6)
	3+	16 (18%)	14.5	24 (10%)	1.94
			(1.79, 107.0)		(0.77, 4.9)
			χ^2 for trend =13.9		χ^2 for trend =2.1
			p=0.003		p=0.4

Table 4 Performance and costs of the WHO risk score for the detection of cervical infections (NG and/or CT) among 395 non-pregnant women attending an outpatient clinic and 628 pregnant women attending routine antenatal clinic services with vaginal discharge or itching, in Mwanza, Tanzania

	Non-pregnant symptomatic (n=395)	*Pregnant symptomatic (n=628)*
Prevalence of score positive women	155 (39%)	124 (20%)
Prevalence of NG (by culture) and/or CT	45 (11.4%)	50 (8.0%)
Performance of WHO score:		
Sensitivity (%)	28/45 (62%)	23/50 (46%)
Specificity (%)	223/350 (64%)	477/578 (82%)
PPV (%)	28/155 (18%)	23/124 (18%)
NPV (%)	223/240 (93%)	477/504 (95%)
Correct treatment rate (%)[1]	251/395 (63%)	500/628 (80%)
Overtreatment rate (%)[2]	127/350 (36%)	101/578 (17%)
Cost of drugs per patient ($)[3,5]	0.4	0.4
Costs of drugs per true case treated ($)[4,5]	3.5	5.0
Cost of drugs per true case treated using the syndromic approach ($)[4,5]	8.8	25.0

PPV = positive predictive value; NPV = negative predictive value.
1 % of infected cases receiving treatment + % uninfected cases appropriately not receiving treatment.
2 % of uninfected cases receiving treatment unnecessarily.

3 $$\text{Cost per patient} = \frac{[\text{No of patients treated} \times \text{unit costs of drugs}]}{\text{Population}}$$

4 $$\text{Cost per true case} = \frac{[\text{No of cases of NG and/or CT treated} \times \text{unit costs of drugs}]}{\text{No of true cases of NG and/or CT in the population}}$$

5 Unit cost of drugs for treating cervical infections according to Tanzanian recommendations was $1.0 for non-pregnant women and $2.0 for pregnant women.
(Regimen was: cotrimoxazole = 5 tablets twice daily for 2 days, PLUS doxycycline 100 mg twice daily for 7 days; in case of pregnancy, doxycycline is replaced by erythromycin 500 mg three times daily for 7 days.)

associated with these infections, except for age <21 among non-pregnant women. The overall WHO risk score was associated with NG and/or CT infection, with an odds ratio of 2.93 in non-pregnant women and 4.44 in pregnant women.

The risk score was not significantly associated with TV, BV, or CA infection. The LED test was associated with NG and/or CT infection in both non-pregnant and pregnant women although this did not reach statistical significance in pregnant women (table 3).

PERFORMANCE AND COSTS OF THE WHO RISK ASSESSMENT FOR CERVICAL INFECTIONS

Overall, 155 (39%) non-pregnant and 124 (20%) pregnant women were positive on the WHO risk score as applied by HCW-A. Among them, 28 (18%) non-pregnant and 23 (18.5%) pregnant women had NG and/or CT infection, which corresponds to the positive predictive value (PPV) of the score. The sensitivity of the score was 62% (28/45) in non-pregnant women and 46% (23/50) in pregnant women, and the corresponding specificities were 64% and 82.5%. This meant that, using this risk score, 63.5% of non-pregnant women and 80% of pregnant women would be correctly treated (that is, receiving treatment if infected or not receiving treatment if not infected). The cost of drugs per patient was $0.4 in both non-pregnant and pregnant women, and the cost of drugs per true case treated was $3.5 and $5.0 in non-pregnant and pregnant women respectively. Treating all women using the syn-

Table 5 Discrepancies in answers given to the screening nurse and to the STD clinician by 395 non-pregnant women attending an outpatient clinic and 628 pregnant women attending routine antenatal clinic services with vaginal discharge or itching, in Mwanza, Tanzania

Elements of the score	*Non-pregnant symptomatic (n=395)*	*Pregnant symptomatic (n=628)*
Aged less than 21 years?		
Screen nurse	101 (26%)	225 (36%)
STD clinician	106 (27%)	221 (35%)
Concordant positive*	101 (26%)	217 (35%)
Are you single?		
Screen nurse	152 (38%)	110 (18%)
STD clinician	151 (39%)	90 (14%)
Concordant positive*	138 (35%)	82 (13%)
Changed partner in the past 3 months?		
Screen nurse	82 (21%)	8 (1.3%)
STD clinician	68 (17%)	6 (1.0%)
Concordant positive*	44 (11%)	2 (0.3%)
More than one partner in the past 3 months?		
Screen nurse	79 (20%)	34 (5.4%)
STD clinician	71 (18%)	18 (2.9%)
Concordant positive*	45 (12%)	9 (1.5%)
Partner having a genital discharge or genital itch?		
Screen nurse	64 (16%)	36 (6.1%)
STD clinician	57 (14%)	34 (5.4%)
Concordant positive*	42 (12%)	20 (3.1%)
Positive to risk score†		
Screen nurse	154 (39%)	116 (18%)
STD clinician	148 (37%)	85 (14%)
Concordant positive*	118 (30%)	68 (11%)

* Same "positive" answer given to both the nurse and the STD clinician.
† Positive for risk score if either Question 5 is answered affirmatively, or 2 of the questions 1 to 4 are positive.

dromic management would have cost $8.8 and $25.0 per true case in non-pregnant and pregnant women respectively (table 4).

FEASIBILITY OF THE RISK ASSESSMENT STRATEGY

In both clinics, applying the risk score by the screening nurse took less than 3 minutes and the correct treatment decisions were recorded in 99% of cases. The wrong treatment decisions were made for only six women, in all cases resulting in overtreatment of women who had answered only one question in the affirmative.

Responses by the women to the questions asked by the screening nurse and by the STD clinician are shown in table 5. In both clinics the questions about age and marital status were answered consistently to both the screening nurse and the clinician. Data regarding the sexual partners were less consistent. Change of partner was reported to both the screening nurse and the STD clinician by only 44 (11%) of the women, but a further 62 reported a change of partner on only one occasion (24 to the clinician and 38 to the screening nurse). Very few pregnant women gave an affirmative response to the questions on sexual partners. A positive risk score was recorded by the screening nurse for 270 women, 186 (68%) of whom were recorded as positive by the responses to the STD clinician.

Discussion

Health workers implicitly use risk assessment all the time, even in the area of STD case management. Often this takes the form of questioning patients who mention STD related symptoms, before referring for laboratory tests or deciding on treatment. Syndromic treatment advocated by the WHO[10] makes such laboratory tests unnecessary, but can result in overtreatment of uninfected patients. The use of the WHO risk assessment for the diagnosis of cervical infection (NG and/or CT) in women complaining of genital discharge and/or itching would greatly reduce unnecessary treatment for these infections resulting in considerable financial savings.

In Mwanza, the use of the WHO risk score by the screening nurse was both feasible and acceptable to the staff, despite initial scepticism from staff working at the antenatal clinic at the start of the study. The score was simple and quick to administer, thus not interfering with the normal flow of patients, and a correct treatment decision was made in 99% of cases. Other scores have been suggested[4 12] which are more complicated and may not be as acceptable to the staff. In this study no attempt was made to ascertain the acceptability of the WHO risk assessment by the patients. However, it must be noted that over 99% of patients participated in the process including the lengthy delays at times while patients were fully examined by the clinician.

There were no difficult questions in the WHO score but the cultural acceptability or appropriate translation of some questions could be a challenge in some places. None the less, questions about partners during the past 3 months were not answered consistently. This may be because of several factors including shyness, failure to understand the question (despite its being asked in Kiswahili), or motivation of the patient. Overall, this meant that the consistency of the risk score was poor with only 67% of those found positive by the screening nurse being found positive by the STD clinician. This limitation may affect further the performance of the risk score under routine circumstances.

The most common pathogens or conditions found in women with vaginal discharge or genital itching were *Trichomonas vaginalis*, *Candida albicans*, and bacterial vaginosis. This is not surprising and all women presenting with vaginal discharge or genital itching should thus be routinely treated for these pathogens or conditions under the syndromic guidelines suggested by WHO.[10] In addition to providing symptom relief, the benefits of treating such infections during pregnancy have been demonstrated and include prevention of early rupture of membranes, and the resulting reduction in preterm delivery and low birth weight.[17–19] Moreover, recent studies have suggested that non-ulcerative STDs such as trichomonosis[20] or bacterial vaginosis[21 22] may be associated with an increased risk of HIV infection and treatment of these conditions could reduce transmission of HIV.

The prevalence of cervical infections was much lower in the studied populations which confirms that syndromic management of vaginal discharge does result in considerable overtreatment (around 90%). Using the risk score would reduce the overtreatment rate for cervical infections to 36% and 17% in non-pregnant and pregnant women respectively. But the WHO risk score failed to identify 38%

of non-pregnant and 54% of pregnant women with cervical infections, leaving a high proportion of women with potentially serious infections untreated while they were attending a clinic, thus representing an important missed opportunity from the public health point of view.

Each of the five questions in the WHO risk score algorithm was significantly associated with NG and/or CT infection in this study, as was the overall risk score. This accords with findings from the study which originally identified these factors as predictors of NG and/or CT infection among women in Kinshasa, Zaire[12] and this was encouraging. However, the risk factors for NG and/or CT infection in urban Mwanza were slightly different from risk factors identified in rural antenatal clinics of Mwanza region.[4] In the rural setting, using a different cut off for age (less than 25 years), another classification for marital status (any marital status other than monogamous marriage), some elements in the past obstetric history of the women (last pregnancy over 5 years ago) and other reproductive health symptoms (such as dyspareunia), were better predictors of cervical infection.[4] In a study performed among pregnant women with or without vaginal discharge in Nairobi, Thomas *et al*[23] found that none of the demographic or behavioural factors of the WHO score were associated with cervical infection. Only a few clinical criteria such as "friability of the cervix" were associated with NG and/or CT infection. The authors found very low sensitivities for both the WHO score (13%) and syndromic management (20%). These findings suggest that the elements of the score may vary in different settings and a careful evaluation of the proposed score should be conducted before its widespread utilisation.

The presence of leucocytes in urine detected by LED was also associated with cervical infection. This finding is in parallel with that of the Zairian study.[12] In fact, results of LED testing were included in the locally developed score in the Zairian study. In contrast, a positive LED test was not predictive of cervical infection in the Nairobi study[23] but rather was associated with vaginal infection. Testing urine by LED to screen for male urethritis has been validated in east Africa,[24,25] but this has not been the case for female genital infections, though it may prove an equally efficient and feasible strategy. However, LED testing would also complicate the routine flow of patients and may not be as effective in the conditions of busy routine clinical or antenatal services in developing countries. There is clearly scope for further operational and validation research in this area.

Applying the WHO risk score could result in important immediate financial savings. Treating the NG and/or CT infections identified using the WHO score would have incurred a cost of drugs of $3.5 per true case treated among non-pregnant women and $5.0 among pregnant women. The alternative of treating all 1023 women for NG and/or CT, as proposed in syndromic management, to ensure that all 95 cases were correctly treated would incur a cost of drugs of $8.8 and $25.0 per true case treated among non-pregnant and pregnant women respectively. The difference in cost for treating GDS may, however, be largely offset by the costs of caring for potential sequelae when cervical infections are left untreated.

It may be difficult to decide on which grounds to recommend the management of female GDS, the short term cost effectiveness factor or the public health goal of controlling cervical infections. At present, syndromic management has remained the most acceptable way of managing GDS in women in Mwanza, from the public health point of view.

The proved link between sexually transmitted infections and the incidence of HIV makes the treatment of STDs more urgent than ever.[26,27] In the recent community randomised trial in Mwanza, syndromic treatment of STDs in health centres and dispensaries reduced the prevalence of STDs in the general rural population but not among antenatal clinic attenders.[28] Innovative ways to reduce the burden of STDs among such a vulnerable group deserves more vigorous exploration. The need for simple and reliable tests to diagnose gonococcal and chlamydial infections among women remains a high priority.[29]

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