Validity of the vaginal discharge algorithm among pregnant and non-pregnant women in Nairobi, Kenya


Objective: To evaluate the validity of different algorithms for the diagnosis of gonococcal and chlamydial infections among pregnant and non-pregnant women consulting health services for vaginal discharge in Nairobi, Kenya.

Methods: Cross sectional study among 621 women with complaints of vaginal discharge in three city council clinics between April and August 1997. Women were interviewed and examined for symptoms and signs of sexually transmitted infections (STIs). Specimens were obtained for laboratory diagnosis of genital infections, HIV, and syphilis. The data were used to evaluate the Kenyan flow chart as well as several other generated algorithms.

Results: The mean age was 24 years and 334 (54%) were pregnant. The overall prevalence rates were: 50% candidiasis, 23% trichomoniasis, 9% bacterial vaginosis, 7% gonorrhoea, 9% chlamydia, 7% syphilis, and 22% HIV. In non-pregnant women, gonococcal and chlamydial infection was significantly associated with (1) demographic and behavioural risk markers such as being single, younger than 20 years, multiple sex partners in the previous 3 months; (2) symptom fever; and (3) signs including presence of yellow or bloody vaginal discharge, cervical mucopus, cervical erythema, and friability. Among pregnant women only young age, dysuria, and fever were significantly associated with cervical infection. However, none of these variables was either sensitive or specific enough for the diagnosis of cervical infection. Several algorithms were generated and applied to the study data. The algorithm including risk markers performed slightly better than the current Kenyan algorithm.

Conclusion: STIs form a major problem in the Nairobi area and should be addressed accordingly. None of the tested algorithms for the treatment of vaginal discharge would constitute a marked improvement of the existing flow chart. Hence, better detection tools for the specific aetiology of vaginal discharge are urgently needed.

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Keywords: algorithm; sexually transmitted diseases; pregnancy; Kenya

Introduction

Neisseria gonorrhoeae (NG) and Chlamydia trachomatis (CT) are two common causes of genital tract infections that have a major impact on health, particularly of women and neonates in developing countries. These infections are also known to facilitate the sexual transmission of human immunodeficiency virus (HIV). Therefore, sexually transmitted disease (STD) control activities not only prevent complications but also offer an additional strategy for the prevention of HIV.

As laboratory detection methods for genital infections are expensive and not widely available in developing countries, diagnostic algorithms based on clinical signs and symptoms have been proposed by the World Health Organisation (WHO) as a tool for better management of patients presenting with genital tract problems at the primary healthcare level. The algorithms for genital ulcer disease as well as for urethral discharge have been successfully adapted for use in different countries. The flow chart for vaginal discharge, however, poses problems owing to the number and diversity of the pathogens. To address this problem, a simple risk score for the identification of NG and/or CT infections in women with complaints of vaginal discharge has been developed; hence, this would result in a reduction of overtreatment costs as well as the occurrence of side effects.

In Kenya, the algorithms for STD treatment have been derived from the WHO guidelines and locally adapted by an expert committee. The current vaginal discharge algorithm has been in use for several years. At the initial visit, a woman with vaginal discharge without abdominal pain receives treatment for vaginal pathogens while treatment for pelvic inflammatory disease (PID) is reserved for accompanying abdominal pain and tenderness (fig 1). Upon follow up after 7 days, women previously treated for vaginal conditions are treated for cervical infections if there is no improvement. No risk scores or genital examination are included in the flow chart.

Following this flow chart, women with cervical infections are systematically missed at the first visit unless abdominal pain is present. In addition, many of the women with NG/CT infection might be lost to follow up especially if their symptoms have improved as a result of the vaginal infection treatment received. On the other hand, many pregnant women with
Follow PID flow chart

Patient complains of vaginal discharge

Lower abdominal pain present

No

Tenderness on bimanual examination

Yes

Treat for vaginitis

Improvevement after 7 days

No

Treat for cervicitis

Yes

Discharge patient

Tenderness on bimanual examination

Yes

Treat for cervicitis

No

Treat for vaginitis

Figure 1  Algorithm for vaginal discharge used as the national policy in Kenya.

discharge and abdominal pain—two conditions often occurring in pregnancy—might unnecessarily be treated for cervical infections at the first visit. From personal communications with healthcare workers it became obvious that they often rely on their personal (clinical) judgment to treat women for cervical infection at the first visit. To this effect they seem to take into consideration risks, signs, and symptoms to make a diagnosis. Hence, very often this algorithm defeats its public health goal, the control of cervical infections, and risks of undermining the credibility of the services.

We thus undertook this study to validate the use of the current Kenyan clinical algorithm for vaginal discharge, which is one of the most frequent reasons for consulting the health service. We validated addition of risk scores as well as inclusion of signs and symptoms among pregnant and non-pregnant women.

Patients and methods

DATA COLLECTION

The study was conducted between April and August 1997 at two peripheral health centres (PHC) and at the major STD referral clinic (STC) run by the Nairobi City Council (NCC). The contact with the patient took place in Kiswahili. All women with spontaneous or prompted complaints of vaginal discharge with or without other symptoms, attending any of these clinics, were enrolled into the study after obtaining informed consent. After being routinely examined by the healthcare workers it became obvious that they often rely on their personal (clinical) judgment to treat women for cervical infection at the first visit. From personal communications with the healthcare workers it became obvious that they often rely on their personal (clinical) judgment to treat women for cervical infection at the first visit. To this effect they seem to take into consideration risks, signs, and symptoms to make a diagnosis. Hence, very often this algorithm defeats its public health goal, the control of cervical infections, and risks of undermining the credibility of the services.

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LABORATORY PROCEDURES

Wet mounts were analysed directly at STC and from the PHC clinics they were transported in a drop of saline to the laboratory of the department of medical microbiology, University of Nairobi. The wet mounts were examined for the presence of motile Trichomonas vaginalis and of yeast cells indicative of Candida albicans. In the laboratory, vaginal smears were heat fixed, Gram stained, and examined for the presence of clue cells, indicative of bacterial vaginosis, and for yeast. The diagnosis of C albicans was made by wet prep and Gram stain. Bacterial vaginosis was defined by the presence of at least three of the following criteria89: (1) vaginal fluid pH $>$ 4.5; (2) release of a fishy amine odour from vaginal fluid mixed with 10% potassium hydroxide; (3) presence of clue cells; and (4) vaginal discharge. Cervical swabs for N gonorrhoeae isolation were inoculated directly onto Thayer–Martin medium and incubated in a candle extinction jar at 33–35°C for 24–48 hours. Cervical swabs for C trachomatis PCR were processed in the laboratory (Abbott). Venous blood samples were tested for syphilis using the rapid plasma reagin test (RPR test, Becton Dickenson) and for HIV-1 using ELISA Detect (Biotech) and Recombigen (Cambridge).

DATA ANALYSIS AND DEFINITIONS

Data were entered and analysed in SPSS for Windows (SPSS, Chicago, IL, USA). In univariate analysis, the odds ratio (OR) and 95% confidence intervals (CI) were used for the measurement of associations. Comparisons were made using Pearson’s $\chi^2$ and Fisher’s exact tests. Means were compared using the Student’s t test. Stepwise logistic regression was used to take into account risk factors, symptoms, and signs related to the presence of gonococcal and chlamydial infection.

The principal outcome was the presence of cervical infections. Cervical infections were defined as the presence of either gonococcal or chlamydial infections or both. Different algorithms were applied to the study population based on personal data from the interview and physical examination. We used the results of the analysis of association between risk, symptoms, and signs to create six different algorithms. Algorithm A was the flow chart as in use in Kenya (fig 1). Algorithm B is the Kenyan algorithm but without the abdominal examination. Algorithm C includes a risk assessment of the patient. This is based on the WHO algorithm with risk score, but without presence of symptoms in the partner. Also, the risk assessment we used was simplified and considers the risk score positive if any of the risk factors are present whereas the WHO algorithm...
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Table 1  Demographic characteristics of 287 non-pregnant and 334 pregnant women with vaginal discharge in Nairobi, Kenya

<table>
<thead>
<tr>
<th></th>
<th>Non-pregnant</th>
<th>Pregnant</th>
<th>OR (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age</td>
<td>25 (15–52)</td>
<td>23 (16–41)</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Younger than 20 years</td>
<td>55 (19)</td>
<td>72 (22)</td>
<td>0.9 (0.7–1.2)</td>
<td>0.3</td>
</tr>
<tr>
<td>Single</td>
<td>114 (40)</td>
<td>69 (21)</td>
<td>1.9 (1.5–2.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Housewife/unemployed</td>
<td>146 (51)</td>
<td>220 (66)</td>
<td>0.5 (0.4–0.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Schooling up to primary</td>
<td>163 (57)</td>
<td>193 (58)</td>
<td>1.0 (0.7–1.3)</td>
<td>0.06</td>
</tr>
<tr>
<td>&gt;1 partner past 3 months</td>
<td>32 (11)</td>
<td>11 (3)</td>
<td>3.4 (1.7–6.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ever used condoms</td>
<td>128 (45)</td>
<td>112 (34)</td>
<td>1.3 (1.1–1.6)</td>
<td>0.002</td>
</tr>
<tr>
<td>Mean age at sexual debut</td>
<td>18 (10–30)</td>
<td>18 (12–30)</td>
<td>0.7</td>
<td></td>
</tr>
<tr>
<td>New partner past 3 months</td>
<td>38 (13)</td>
<td>14 (4)</td>
<td>3.2 (1.7–5.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Schooling up to primary</td>
<td>163 (57)</td>
<td>193 (58)</td>
<td>1.0 (0.7–1.3)</td>
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</tr>
<tr>
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<td>128 (45)</td>
<td>112 (34)</td>
<td>1.3 (1.1–1.6)</td>
<td>0.002</td>
</tr>
<tr>
<td>Mean number pregnancies</td>
<td>2.0 (0–11)</td>
<td>1.3 (0–6)</td>
<td>0.002</td>
<td></td>
</tr>
</tbody>
</table>

Table 2  Prevalence of RTI and HIV among 287 non-pregnant and 334 pregnant women with vaginal discharge

<table>
<thead>
<tr>
<th></th>
<th>Total (n=621)</th>
<th>Non-pregnant women (n=287)</th>
<th>Pregnant women (n=334)</th>
<th>Odds ratio (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical or vaginal pathogens</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N. gonorrhoeae (NG)</td>
<td>44 (7)</td>
<td>34 (12)</td>
<td>10 (3)</td>
<td>4.0 (2.0–7.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>C. trachomatis (CT)</td>
<td>58 (9)</td>
<td>22 (8)</td>
<td>36 (11)</td>
<td>0.7 (0.4–1.2)</td>
<td>0.1</td>
</tr>
<tr>
<td>NG and/or CT</td>
<td>97 (16)</td>
<td>53 (19)</td>
<td>44 (13)</td>
<td>1.4 (1.0–2.0)</td>
<td>0.05</td>
</tr>
<tr>
<td>C. albicans</td>
<td>314 (51)</td>
<td>132 (46)</td>
<td>182 (55)</td>
<td>0.8 (0.7–1.0)</td>
<td>0.02</td>
</tr>
<tr>
<td>T. vaginalis</td>
<td>145 (23)</td>
<td>59 (21)</td>
<td>86 (26)</td>
<td>0.8 (0.6–1.1)</td>
<td>0.08</td>
</tr>
<tr>
<td>Bacterial vaginosis</td>
<td>31 (5)</td>
<td>14 (5)</td>
<td>17 (5)</td>
<td>2.3 (1.1–4.9)</td>
<td>0.02</td>
</tr>
<tr>
<td>No cervical or vaginal pathogens or flora changes</td>
<td>172 (28)</td>
<td>82 (30)</td>
<td>90 (27)</td>
<td>1.1 (0.8–1.4)</td>
<td>0.3</td>
</tr>
<tr>
<td>Serology</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RPR+</td>
<td>42 (7)</td>
<td>20 (7)</td>
<td>22 (7)</td>
<td>1.1 (0.6–1.9)</td>
<td>0.5</td>
</tr>
<tr>
<td>HIV-1+</td>
<td>137 (22)</td>
<td>72 (25)</td>
<td>65 (20)</td>
<td>1.2 (1.0–1.7)</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Results

SOCIODEMOGRAPHIC FACTORS AND PREVALENCE OF STDs

A total of 621 women with complaints of vaginal discharge were enrolled in the study. In STC, located in downtown Nairobi, 214 women were recruited and 255 and 152 were recruited in the two health centres, both located in the suburbs of Nairobi. The women attending the STD clinic were more often single, employed, and had more sex partners. Three hundred and thirty four (54%) of the women were pregnant at the time of the interview. The demographic and social characteristics of pregnant women compared with non-pregnant women are shown in table 1. Significantly, there were more single non-pregnant women and they had had more sex partners in the past 3 months. Pregnant women on the other hand were younger.

The overall prevalence of reproductive tract infections (RTI) is shown in table 2. The prevalence of N. gonorrhoeae and C. trachomatis was 7% and 9% respectively and the overall cervical infection prevalence was 16%. The majority of women had vaginal infections caused by C. albicans (51%), T. vaginalis (23%), and bacterial vaginosis (9%). The prevalence of HIV was 22% and 7% of the women were RPR positive. One of the peripheral health centres had the highest prevalence for almost all conditions whereas in the STD referral clinic C. albicans was most prevalent. The prevalence of the RTI for pregnant and non-pregnant women showed in table 2. Non-pregnant women had significantly more N. gonorrhoeae, genital ulcers, and HIV-1 infection. Pregnant women had more candidiasis.

VARIABLES RELATED TO GONOCOCCAL AND CHLAMYDIAL INFECTIONS

The univariate relation between NG/CT infection and risk factors, symptoms, and clinical signs for pregnant and non-pregnant women is shown in table 3. Several risk markers were associated with NG/CT infection in non-pregnant women, whereas being younger than 20 years old is only associated with NG/CT infection in pregnant women. Having more than one sex partner is a rare event among pregnant women.

Of the symptoms, only fever is consistently associated with NG/CT infection for both groups of women although its prevalence is low. Some symptoms on the other hand are more indicative of not having NG/CT infection.

Signs associated with NG/CT infection among non-pregnant women were yellow or bloody vaginal discharge, presence of purulent or bloody endocervical mucopus, cervical erythema, and cervical friability. None of these signs was associated with NG/CT infection in the group of pregnant women. None of the variables, however, was both sensitive (>60%) and specific (>60%) enough for the presence of cervical infection. Multivariate analysis including all variables significantly associated with NG/CT infection (p ≤0.05), was performed for both groups of women. Among non-pregnant women, only reporting multiple sex partners in the past 3 months and yellow or bloody vaginal discharge remained significantly associated. Among pregnant women, only age and dysuria remained significantly associated.
EVALUATION OF ALGORITHMS

The results of the validation of the different diagnostic algorithms for vaginal discharge, among 621 women, and comparing pregnant with non-pregnant women, are presented in table 4. Applying the Kenyan national policy algorithm resulted in a sensitivity of 42% and a specificity of 63% for gonococcal or chlamydial cervicitis, with a PPV of 18% (algorithm A). The Kenyan algorithm relying on the complaint of abdominal pain alone (B), resulted in a higher sensitivity and somewhat lower specificity. The algorithm with risk score C gave a sensitivity of 59% and a specificity of 61% with a PPV of 22%. Algorithm D relies on the inspection of the colour of the vaginal discharge and does not necessarily require a speculum examination. Algorithm E requires inspection of the cervix by speculum examination. Both algorithms D and E result in a sensitivity and a specificity similar to algorithm A but with marginal higher PPV. Algorithm F, a combination of risk score and presence of yellow or bloody vaginal discharge, resulted in the highest sensitivity but had low specificity. Among non-pregnant women, all algorithms produced a higher sensitivity. Among pregnant women, however, the different algorithms had a lower sensitivity.

The overall correct treatment rate of the different flow charts varied and was in general higher among non-pregnant women, except for flow charts D and E. The cost per case varied from $US0.5 to $0.9. The cost per true cervical infection treated varied from $6.7 for the risk score algorithm to $8.3 for the Kenyan algorithm. Algorithm F identified more true cervical infections than the other flow charts but the overall cost was substantially higher (table not presented here).

Discussion

The most common pathogens found among women complaining of vaginal discharge in this study were Candida albicans and Trichomonas vaginalis. This is not surprising and has been shown in similar studies among women presenting with vaginal discharge in other African settings. The prevalence of bacterial vaginosis in our study was low compared with other studies in the region and is probably an underestimation. Indeed, we used the clinical
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...diagnosis for bacterial vaginosis, which is subject to interpretation by the clinician. Furthermore, the identification of clue cells depends on the level of training of the person performing the microscopic examination. Also, the quality of the Gram stain might have influenced the results. The combination of these factors might have resulted in an underestimated prevalence.

Overall, no cervical or vaginal pathogen or condition was found in 28% of the women. Again, this is similar to the findings in Mwanza where 23% of the women at the STD clinic and 27% at the antenatal clinic had no demonstrable pathogen. We found a prevalence of cervical infections of 16%. Non-pregnant women had significantly more gonococcal infection, genital ulcers, and HIV infection but pregnant women had more candidiasis. The high proportion of pregnant women with an STD is a cause for concern. Gonococcal and chlamydial infections, as well as syphilis and HIV, are associated with adverse obstetric outcome.

The prevalence of the different RTI varied between the different clinics under study. Surprisingly, the prevalence rates for most RTI were higher in one of the PHC clinics than in the STD referral clinic. Although the two PHC clinics where enrollment took place are located very close to each other, the prevalences varied here also, indicating that the populations attending the different clinics are quite different. Lower socioeconomic conditions seem to be the basis for higher STI prevalences. Health staff at all levels of medical facilities should become aware that all women are to be considered at high risk, and that their treatment inclusive of health education and counseling has to be stressed. The stereotype image that only patients attending the STD clinic are at high risk has to be revised urgently so as to eliminate the stigma still attached to STDs and hence to make STD control more effective. In this study of symptomatic women, the association of the classic clinical symptoms and signs with the presence of gonococcal and/or chlamydial infection was quite different among pregnant and non-pregnant women. Several demographic risk determinants and signs were predictive of cervical infection among non-pregnant women while hardly any were among pregnant women. As a result, the various flow charts that were tested performed systematically better in the group of non-pregnant women. The algorithm in use in Kenya as national policy had a sensitivity of 42% and a specificity of 63% for the detection of N. gonorrhoeae or C. trachomatis and thus failed to discriminate between infected and uninfected women. This algorithm relies on bimanual examination of the patients, and hence requires an examination table and gloves, items often not available in the health centres. As a result, the algorithm is, in practice, often applied without performing this examination. Furthermore, the bimanual examination is subject to interpretation and depends on the experience of the person performing it. In our study the physical examinations were done by medical doctors, and they reported almost all women in the study to have abdominal tenderness. In practice in the health centres, the examinations are performed by nurses who are less well trained; hence we can assume that the results would be worse. We therefore also tested the Kenyan algorithm but without performing the bimanual examination (algorithm B). The results are similar and in fact have a higher sensitivity.

The risk score used to discriminate cervical infection, as promoted by the WHO, has been evaluated in several African settings. We used a simplified risk score without symptoms in the partner as this information is sensitive and difficult to obtain. Personal communication with healthcare workers and data from our other studies (unpublished) suggested that symptoms in the male partner are seldom known by the woman and are hence unreliable. This was confirmed in a study by Thomas et al. who found that only 2% of mostly married women reported partners having symptoms. Hence, including this risk factor would only increase the specificity but not the sensitivity of the flow chart. The algorithm we tested (C) was based on presence of any of the risks: being single, being less than 20 years old, having had multiple or a new partner in the past 3 months. An earlier study in Nairobi also reported being single and having multiple sex partners to be associated with gonococcal infection in pregnant women. We considered that for a risk score to be applicable it has to be simple to use. The healthcare worker in a busy health centre has no time and patience to apply scoring systems with weighted risks or calculations of scores. In our study a risk score based on presence of at least two of the risks would have resulted in a sensitivity of only 30%. Our risk score algorithm (C) resulted in a sensitivity of 66% with PPV of 24% among non-pregnant women. The results among pregnant women were less good and comparable with what Mayaud et al had found in Mwanza. Using this flow chart, the rate of overtreatment in non-pregnant women was 46% while it was 33% in pregnant women.

We included several signs in the flow chart. Among pregnant women, however, none of these signs was associated with cervical infection. This is contrary to findings from Thomas et al who found that among asymptomatic women in Nairobi, cervical friability was associated with cervical infection. An earlier study in Nairobi among pregnant women had identified friability and endocervical mucopus as predictors of cervical infection. And in another study in Nairobi, Temmerman et al reported an association between gonococcal infection post partum and cervical mucopus. We tested algorithm D based on observation of the colour of vaginal discharge. This algorithm does not require the use of a speculum. Algorithm E was based on observation of the cervix hence requiring speculum examination that is seldom possible in health centres in Kenya. Both resulted in too low sensitivity to...
be of value. Algorithm F combined the risk assessment and the inspection of the vaginal discharge. In both groups of women high sensitivity was reached but with low specificity. Several other combinations of risks, symptoms, and signs were tested but all performed worse.

While none of the tested algorithms reached acceptable levels of sensitivity and specificity, the algorithm with risk score performed somewhat better than the algorithm actually in use in Kenya and would identify more true cervical infections although at a higher overall cost. Introducing the risk assessment among non-pregnant women could be an option. It is, however, doubtful that the introduction of the risk score into the existing algorithm, which would imply printing of new charts and retraining of health staff, is worthwhile. Among pregnant women this flow chart would fail to identify cervical infections. Treatment of pregnant women with vaginal discharge might be considered for both vaginal and cervical infections on the first visit. Further operational research is needed to assess the rate of follow up and return visits among these women. We can conclude that simple, cheap, and reliable tests for the diagnosis of cervical infection in women are still urgently needed.

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Contributors: KP designed the study, supervised the implementation, data analysis, interpretation, and writing the paper; NK, WJ, and BE were responsible for actual fieldwork, data analysis, and interpretation, and review of draft of paper; PC interpreted the results, reviewed the draft; JN–A was responsible for design of the study, facilitation of implementation of fieldwork, review of draft; PK facilitated actual fieldwork and reviewed the draft; JB was responsible for the laboratory aspect of the study, and review of draft; MT designed the study, interpreted the results, reviewed drafts, and had overall responsibility for the study.