ORIGINAL RESEARCH ARTICLE

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Use of Sexually Transmitted Disease Risk Assessment Algorithms for Selection of Intrauterine Device Candidates

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Sexually transmitted diseases (STD) are an important contraindication for intrauterine device (IUD) insertion. Nevertheless, laboratory testing for STD is not possible in many settings. The objective of this study is to evaluate the use of risk assessment algorithms to predict STD and subsequent IUD-related complications among IUD candidates. Among 615 IUD users in Kenya, the following algorithms were evaluated: 1) an STD algorithm based on US Agency for International Development (USAID) Technical Working Group guidelines; 2) a Centers for Disease Control and Prevention (CDC) algorithm for management of chlamydia; and 3) a data-derived algorithm modeled from study data. Algorithms were evaluated for prediction of chlamydial and gonococcal infection at 1 month and complications (pelvic inflammatory disease [PID], IUD removals, and IUD expulsions) over 4 months. Women with STD were more likely to develop complications than women without STD (19% vs 6%; risk ratio = 2.9; 95% CI 1.3–6.5). For STD prediction, the USAID algorithm was 75% sensitive and 48% specific, with a positive likelihood ratio (LR+) of 1.4. The CDC algorithm was 44% sensitive and 72% specific, LR+ = 1.6. The data-derived algorithm was 91% sensitive and 56% specific, with LR+ = 2.0 and LR− = 0.2. Category-specific LR for this algorithm identified women with very low (<1%) and very high (29%) infection probabilities. The data-derived algorithm was also the best predictor of IUD-related complications. These results suggest that use of STD algorithms may improve selection of IUD users. Women at high risk for STD could be counseled to avoid IUD, whereas women at moderate risk should be monitored closely and counseled to use condoms. CONTRACEPTION 1999;59:97–106

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Introduction

Approximately 100 million women worldwide use intrauterine devices (IUD),[1] making the IUD the most commonly used form of reversible contraception. For most women the IUD is a highly effective, safe, inexpensive, and long-lasting contraceptive method. Recent studies suggest that the risk of pelvic inflammatory disease (PID) among IUD users is significantly increased only during the early postinsertion period.[2,3] However, because IUD use is believed to increase risk of PID among women with sexually transmitted diseases (STD),[4,5] particularly cervical gonorrhea and chlamydial infection, women judged to be at high risk for STD are counseled against IUD insertion.[4,6–9]

In most family planning programs worldwide, criteria for specifying a woman's risk for STD are not explicitly stated. Because of the lack of a risk assessment tool, and because of the sensitivity of the information, determination of STD risk status is often limited to sociodemographic characteristics such as marital status. Recently, attempts to make STD risk assessment criteria more explicit for contraceptive decision-making have been undertaken.[4,6] These attempts parallel efforts to define risk assessment criteria for screening and case management of cervical infections in low-risk populations.[10–16] Many of these risk assessment tools have performed poorly in identifying cervical infections among asymptomatic women. However, the use of STD risk assessment criteria for selection of IUD candidates has not been evaluated.

The use of STD risk assessment tools for prediction of cervical infection among IUD candidates and the ability of these algorithms to subsequently predict short-term complications of IUD use were considered. Three STD risk assessment strategies were

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evaluated: 1) an STD risk assessment tool developed specifically for use in family planning settings;[4] 2) CDC guidelines for the prevention and management of chlamydial infections;[10] and 3) a data-derived tool with variable selection based on modeling of cervical infection among the study population.

Materials and Methods

The study was approved by the Ethical Review Committee of Kenyatta National Hospital and by the Protection of Human Subjects Committee of Family Health International.

Study Population

Data for this analysis are drawn from a study of IUD use and HIV infection among women in Nairobi, Kenya; study participant selection and study procedures are described in detail elsewhere.[17] Briefly, women who desired an IUD and met local eligibility criteria for IUD use were recruited from two public family planning clinics in Nairobi in 1994–1995. In addition to other criteria, a woman was eligible for IUD insertion if she had no evidence of active PID or mucopurulent cervicitis or was judged to be at high risk for STD.

A total of 1702 women were referred to the study. On consultation with study staff, five women chose not to have an IUD inserted and 11 women were examined but did not have an IUD inserted for medical reasons (including six women with mucopurulent cervical discharge, overt cervicitis, or abdominal tenderness). Thus, 1686 women received an IUD and were tested for HIV infection at the baseline visit. Between the baseline and 1-month follow-up visit, all 156 HIV-infected women who were identified and 493 randomly selected non–HIV-infected women were chosen to participate in a 4-month follow-up study. Data for this analysis are drawn from the 615 women (95%) (144 HIV+, 471 HIV−) who had at least one follow-up visit.

Study Procedures

On referral, the study nurse explained all study procedures in Kiswahili or English and informed consent was obtained. Study nurses conducted a short interview covering sociodemographic information, recent sexual behaviors, and contraceptive use. Study physicians performed a physical exam, collected Pap smears and a blood specimen for HIV testing, and inserted a Copper T 380A IUD. Participants were then scheduled for a 1-month follow-up visit.

At 1 month, all participants completed a short interview about sexual and contraceptive behavior and about any health problems since the previous visit. Participants then had a pelvic exam and endocervical specimens were collected for diagnosis of chlamydial and gonococcal infections. Pap smear and HIV test results were then provided to clients. At the 4-month and unscheduled visits, similar clinical and data collection procedures were conducted, but cervical specimens were collected only for symptomatic women. Study participation was complete at the 4-month post-insertion visit or earlier if the participant developed a complication or had her IUD removed for any reason.

Outcome Variables

Prevalent cervical infections. A participant was considered to have a cervical infection if she had a positive chlamydial antigen test or gonorrhea culture at any time during her follow-up period. However, routine testing for cervical infections was conducted only at the 1-month visit (80% and 91% of women were tested within 45 days and 90 days of admission, respectively). A total of 580 women (94%) were tested for cervical infections during the follow-up period.

Complications of IUD use. Complications of IUD use were defined as: 1) PID; 2) full or partial IUD expulsion; and 3) IUD removal because of infection, pain, or bleeding. PID diagnosis was based on general criteria suggested by the United States Infectious Disease Society of Obstetrics and Gynecology[18] identification of three tenderness criteria (lower abdominal, cervical motion, and adnexal tenderness), and at least one objective criterion, including: 1) laboratory evidence of gonococcal or chlamydial infection; 2) pyrexia; 3) leucocytosis; or 4) pelvic abscess or inflammatory complex on bimanual examination.

Laboratory Methods

Women were tested for *Chlamydia trachomatis* antigen using Syva MicroTrak II EIA (Syva, Belgium). Endocervical specimens for culture of *Neisseria gonorrhoeae* were taken using sterile swabs and inoculated directly onto Thayer-Martin medium prepared according to standard protocol and stored at 4°C until used. Plates were kept in CO_2 jars at room temperature until transported to the laboratory, where they were incubated in CO_2 at 37°C for 48 h and read as positive or negative.

STD Risk Assessment Algorithms

Three STD risk assessment tools were compared. The first two algorithms were defined a priori and were based on previously developed guidelines. The first algorithm was based on STD risk assessment criteria

Table 1. Definition of STD risk assessment algorithms

STD Algorithm	Definition
1a. Family planning risk assessment (historical risk only)	Any of: Age ≤24 years Marital: single/divorced/widowed ≥2 sex partners* STD symptoms† Partner with possible STD†
1b. Family planning risk assessment (historical risk with signs)	Any historical risk (above) or any of: Abnormal vaginal discharge Abnormal cervical discharge Vaginal or cervical ulcerations Pelvic, adnexal, or cervical motion tenderness
2. CDC risk assessment	Any of: Age <20 years Cervical discharge (yellow/green on swab) Age 20–24 and (sex partners ≥2 *or* no condom use)* Age >25 and (sex partners ≥2 *and* no condom use)*
3a. Data-derived assessment (no weightings)	Any of: Age ≤24 years Marital: single/divorced/widowed Luhya ethnicity Number live births ≤2
3b. Data-derived assessment (with weightings: maximum score equals 6)	Sum ≥2 of: Age ≤24 years (1) Marital: single/divorced/widowed (2) Luhya ethnicity (2) Number live births ≤2 (1)

*In the 3-month period prior to the baseline visit.
†In the 1-year period prior to the baseline visit.
STD, sexually transmitted disease; CDC, Centers for Disease Control and Prevention.

suggested by a United States Agency for International Development (USAID) Technical Working Group for use in family planning settings.[4] The purpose of such an algorithm is to aid in contraceptive counseling (use of IUD, barrier methods), to guide the syndromic management of STD in symptomatic patients (especially among women with vaginal discharge), and to identify asymptomatic clients who might need further clinical examination or laboratory evaluation.[4] Factors suggested by this group to be included in an algorithm were age (<20 years old), not married, multiple or new sex partners in the past three months, partner having multiple sex partners, history of STD or PID, a partner with symptoms of STD, and current symptoms or signs of STD. Based on these factors, two risk assessment algorithms were developed. The first was a "family planning risk assessment" algorithm incorporating only historical risk factors but excluding signs based on physical examination (Table 1: algorithm 1a). The presence of any single factor was considered a positive risk assessment. A related algorithm (1b) was based on having any historical risk factor or a current sign indicative of an STD. Two algorithms were considered because health centers providing family planning in developing countries may or may not have the ability to conduct speculum examinations before providing a contraceptive method.

Algorithm 2 stems from the CDC guidelines for identifying women who should be tested for chlamydia. In particular, CDC recommends that these criteria be used among adolescents, family planning and prenatal care clients, women attending STD clinics, women undergoing induced abortions, and women in detention facilities. These guidelines include: women with mucopurulent cervicitis, sexually active women <20 years of age, women 20–24 years who are either inconsistent users of barrier contraception or have new or multiple sex partners (in the previous 3 months), and women >24 years who are both inconsistent barrier contraceptive users and have new or multiple sex partners.[10]

The above predefined algorithms were compared with two variants of a data-derived algorithm with variable selection based on modeling of cervical infections among the study population. These algorithms were developed in the following manner. Variables considered as candidates for inclusion in the algorithms were grouped into four clusters: 1) sociodemographic (age, marital status, education, ethnicity, number of live births); 2) behavioral (coital frequency, number of recent sexual partners, recent condom use, prior IUD use); 3) STD history (STD symptoms in last year, STD diagnosis in previous year, partner with an STD in previous year); and 4) clinical signs at the baseline visit (abnormal vaginal or cervical discharge, cervical edema, cervical ectopy, cervical friability, strawberry cervix, vaginal or cervi-

cal ulcers). Because no participant had signs of mucopurulent cervicitis or pelvic tenderness at baseline, these variables were dropped from consideration. Each cluster of variables was then regressed on the cervical infection variable using logistic modeling. Variables with a Wald χ^2 probability <0.25 in the cluster models were selected for further modeling. These variables were age, marital status, number of live births, ethnicity, prior IUD use, and STD symptoms in prior year. Log likelihoods were then compared among hierarchical models using these six variables. Because prior IUD use and STD symptoms were associated with little change in log likelihood statistics, they were dropped from the model. Exclusion of any of the four remaining variables resulted in sizeable decreases in the concordance between predicted probabilities and observed responses; thus, all four variables were retained. Thus, the data-derived algorithms were defined as: age ≤24 year, being single or divorced; Luhya ethnicity; and number of live births ≤2 (Table 1). Algorithm 3a was unweighted with high risk defined as a woman meeting any of the criteria. Algorithm 3b weights the criteria on the relative sizes of the odds ratios, where marital status and ethnicity are weighted as 2, and age and number of live births weighted as 1. A woman was considered high risk when she had a risk score ≥2. The data-derived models were not validated on an independent data set.

Complications Risk Assessment Algorithm

To evaluate whether a better algorithm for prediction of IUD-related complications could be created, a data-derived complications algorithm was constructed. The methods used for creation of this algorithm were exactly the same as for the STD data-derived algorithms except that the analysis modeled the odds of having an IUD complication.

Evaluation of Algorithm Performance

Performance of the algorithms was assessed by calculating sensitivity, specificity, positive predictive value and negative predictive value and by the percentage of women categorized as high risk for STD by the various algorithms. Likelihood ratios (LR), representing the changes in odds of disease for a given test result, were calculated as the probability of a given test result among persons with the outcome divided by the probability of a given test result among persons without the outcome. Positive likelihood ratios (LR+) are equal to sensitivity/(1−specificity) and negative likelihood ratios (LR−) are equal to (1−sensitivity)/specificity.[19]

Receiver-operator characteristic (ROC) curves were plotted for the family planning and data-derived algorithms (the CDC algorithm could not be plotted because its categories are mutually exclusive, not additive). The ROC curves were generated by plotting sensitivity versus 1-specificity for each possible cut-off value. Areas under the curve based on nonparametric curves were calculated using ROC Analyzer (v 0.9b, available from Robert Centor, M.D., University of Alabama at Birmingham). All other analyses were conducted using SAS version 6.12 (SAS Institute, Inc., Cary, NC).

Table 2. Selected characteristics of study participants

Characteristic	Study participants,% (n = 580)
Sociodemographic factors	
Age: ≤24 years	31.7
Marital status: married/cohabiting	86.6
Live births: ≤2	58.1
Education: ≥secondary school	61.0
Ethnicity:	
Kikuyu	54.8
Luo	12.9
Luhya	14.8
Other	17.4
Sexual/Contraceptive behavior*	
Coital frequency: ≥3/week	46.6
≥2 Sex partners	1.2
Any condom use	12.2
Previous IUD use (lifetime)	35.5
STD history	
STD symptoms (in last 1 year)	13.6
Told had STD (in last year)	5.3
Partner with possible STD (in last year)	18.1
Clinical signs	
Abnormal vaginal discharge	3.1
Abnormal cervical discharge	3.8
Cervical edema	3.6
Cervical ectopy	60.0
Cervical friability	20.0
Any pelvic tenderness	0.0
Laboratory findings	
HIV infection	23.4
C. trachomatis	5.0
N. gonorrhoeae	0.5

*Sexual/contraceptive behavior in 3 months before baseline interview.

Results

Participant Characteristics

Most study participants were ≥25 years of age (68%), were married or cohabiting (87%), had ≤2 live births (58%), had at least a secondary education (61%), and were of Kikuyu ethnicity (55%) (Table 2). Few study participants had multiple sex partners or used condoms in the 3 months before the baseline interview and few reported STD symptoms during the previous

Table 3. Performance of STD algorithms for predicting cervical infections (n = 580)

STD algorithm	High risk* (%)	Performance criteria					
		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	PLR	NLR
1a. Family planning (historical risk only)	53.6	75.0	47.6	7.7	97.0	1.43	0.52
1b. Family planning (historical risk *or* signs)	55.3	75.0	45.8	7.5	96.9	1.38	0.55
2. CDC risk assessment	29.0	43.8	71.9	8.3	95.6	1.56	0.78
3a. Data-derived assessment (no weightings)	69.8	96.9	32.9	7.8	99.5	1.44	0.10
3b. Data-derived assessment (with weightings)	46.9	90.6	55.7	10.7	99.0	2.04	0.17

*Proportion of women classified by algorithm as high-risk for cervical infections.
PPV, Positive predictive value; NPV, negative predictive value; PLR, positive likelihood ratio; NLR, negative likelihood ratio.

year. Clinical signs of STD at the baseline visit were also rare; 4% of participants had abnormal (but not mucopurulent) cervical discharge, 4% had cervical edema, and 20% had a friable cervix. Of the participants, 23% were HIV-infected at baseline. Of the 580 study participants, 32 (5.5%) had a cervical infection diagnosed during follow-up (5.0% chlamydia, 0.5% gonorrhea).

Prediction of cervical infections

The family planning risk algorithm (1a) had moderately high sensitivity (75%) and high negative predictive value (97%) but poor positive predictive value (8%) and specificity (48%) (Table 3). Positive and negative likelihood ratios (1.43 and 0.52, respectively) indicate that the algorithm might be marginally useful for clinical decision-making concerning contraceptive use and STD care. Considered another way, this algorithm detected 75% of the cervical infections by classifying 54% of the participants as high risk. The ROC curve demonstrating all possible cut-offs for this algorithm is shown in Figure 1. The area under the curve is 0.62. The family planning algorithm incorporating physical signs in addition to historical risk factors (algorithm 1b) identified no additional infections while classifying an additional 10 participants as high risk and, thus, performed slightly worse than algorithm 1a.

The CDC risk assessment algorithm (2) performed worse than the family planning algorithms (Table 3). The algorithm detected only 44% of infected participants while categorizing 29% as high risk. Thus, although predictive values and the positive likelihood ratio were essentially equivalent to the family planning

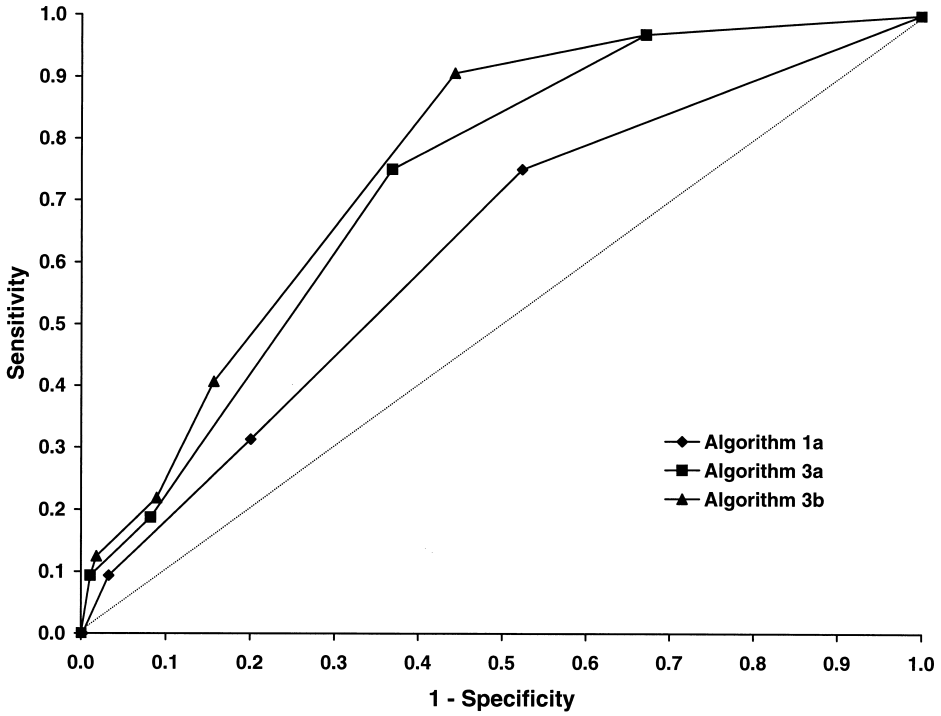

Figure 1. ROC plots of family planning (1a) and unweighted (3a) and weighted (3b) data-derived algorithms. ROC curves plot sensitivity versus 1 − specificity for all possible cutoffs of an algorithm. A perfect algorithm would arch to the upper left corner; an algorithm with no useful discrimination is a diagonal line connecting the lower left to upper left corners.

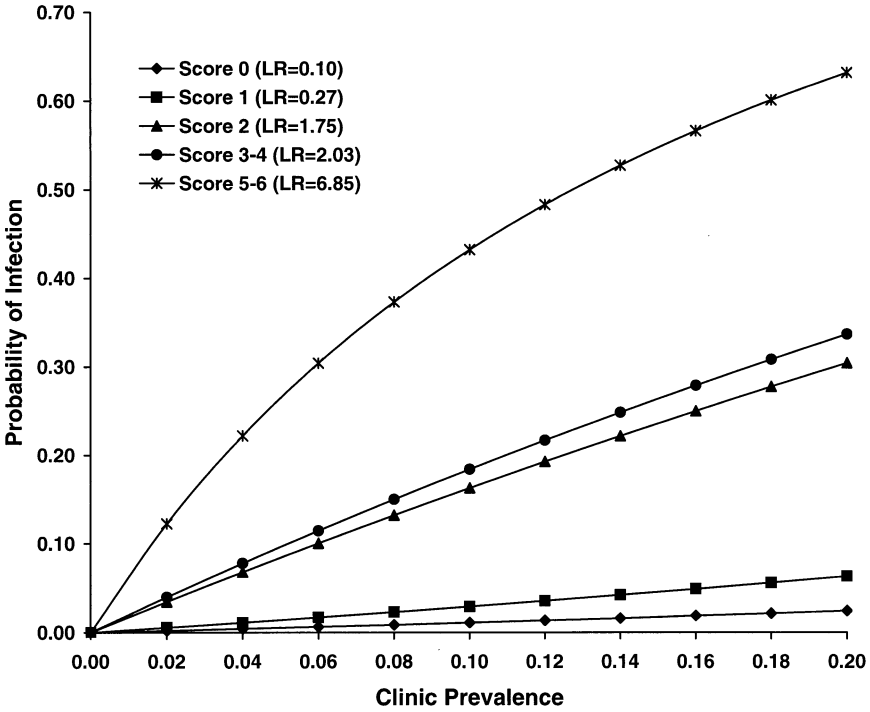

Figure 2. Probability of infection by prevalence and risk score for algorithm 3b. The probability of an STD is plotted as a function of clinic prevalence and risk score using algorithm 3b. Probability of an STD is determined using the clinic prevalence as an estimate of prior probability and the likelihood ratios for each risk score category. The prevalence in the current study population was 5.5%.

algorithms and the specificity was better, the sensitivity and negative likelihood ratios suggested that the CDC algorithm did not perform well in this population. No ROC curve could be calculated for the CDC algorithm because there were only two possible categorizations.

The unweighted data-derived algorithm (3a) was much more sensitive (97%) but less specific than the family planning and CDC algorithms (Table 3). Compared with the family planning algorithm, overall performance of algorithm 3a was better as estimated by the area under the ROC curve (area = 0.73 vs 0.62, $p < 0.01$). The negative predictive value (99.5%) and LR− (0.10) also suggested enhanced performance compared with algorithms 1 and 2. Given the low overall frequency of infections, women with a low risk score on algorithm 3 have a very low probability of infection after IUD insertion (<1%).

The weighted algorithm (algorithm 3b) performed slightly better than the unweighted algorithm. Sensitivity remained high and specificity increased. The area under the ROC curve increased slightly, although this difference was not statistically significant (0.76, $p = 0.3$). Negative predictive value and LR− remained excellent, whereas LR+ increased substantially to 2.0. This algorithm detected 91% of infections by classifying 47% of women as high risk.

Category-specific likelihood ratios provide more complete and clinically useful information than dichotomous measures. The category-specific likelihood ratios for algorithm 3b are as follows: score 0 (LR = 0.10), score 1 (LR = 0.27), score 2 (LR = 1.75), score 3–4 (LR = 2.03), and score 5–6 (LR = 6.85). The proportion of women receiving each of these scores was as follows: score 0, 31%; score 1, 22%; score 2, 30%; score 3–4; 15%; and score 5–6, 2%. Given the infection prevalence of 5.5%, a woman with a score of 0 has a probability of infection of <1%, and women with scores of 3–4 and 5–6 have infection probabilities of 11% and 29%, respectively. The probability of infection associated with varying STD prevalences for each category of risk scores from algorithm 3b is shown in Figure 2.

Prediction of complications of IUD use

Among the 615 women with follow-up data, 47 women had complications related to IUD use, including: three cases of PID; 24 IUD removals for infection, pain, or bleeding; and 20 IUD expulsions. Of interest was whether cervical infections were associated with complications of IUD use in this study. Of the 580 women tested for cervical infections, six of 32 women with cervical infections (18.8%) and 35 of 548 women without cervical infections (6.4%) had a complication of IUD use (risk ratio = 2.94; 95% CI 1.33–6.46). Specifically, PID was diagnosed in one of 32 (3.1%) women with cervical infections and in two of 548 (0.4%) women without cervical infections.

None of the STD algorithms predicted IUD-related complications well, although the weighted data-derived algorithm (3b) again performed best (Table 4) with the most discriminating likelihood ratios and highest predictive values. This algorithm detected

Table 4. Performance of STD and complications algorithms for predicting short-term complications of IUD insertion (n = 615)

STD algorithm	High risk* (%)	Performance criteria					
		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	PLR	NLR
1a. Family planning (historical risk only)	53.0	63.8	47.9	9.2	94.1	1.22	0.76
1b. Family planning (historical risk *or* signs)	55.3	68.1	45.8	9.4	94.6	1.26	0.70
2. CDC risk assessment	28.4	34.0	72.1	9.2	92.9	1.22	0.91
3a. Data-derived assessment (no weightings)	68.6	78.7	32.2	8.8	94.8	1.16	0.66
3b. Data-derived assessment (with weightings)	47.2	68.1	54.6	11.0	95.4	1.50	0.58
Complications algorithm							
Data-derived assessment	24.2†	46.8	77.6	14.8	94.6	2.09	0.69

*Proportion of women classified by algorithm as high risk for cervical infections.
†Proportion of women classified by algorithm as high-risk for IUD-related complications.
PPV, positive predictive value; NPV, negative predictive value; PLR, positive likelihood ratio; NLR, negative likelihood ratio.

68% of complications by identifying 47% as high risk. Thus, if all women categorized as high risk by this algorithm had been denied IUD, 290 of 615 women would not have received IUD and 32 of the 47 complications would have been avoided. The other STD algorithms discriminated poorly between women who developed and those who did not develop complications, as evidenced by likelihood ratios close to 1.

Variables in the data-derived algorithm based on modeling IUD-related complications directly included low educational attainment (primary school or less), low coital frequency, no previous use of an IUD, and having an STD in the previous year. Because weighted and unweighted algorithms performed equally well, the unweighted algorithm (women meeting at least three criteria are considered as high risk) is presented in Table 4. This algorithm performed somewhat better than the STD algorithms for predicting complications of IUD use (LR+ = 2.09) but categorized as high risk only 47% of women who later developed complications.

Discussion

Women at high risk for STD are counseled against receiving IUD because they are believed to be at increased risk of upper reproductive tract infections including pelvic inflammatory disease. However, data demonstrating such an association are scarce. Among women with cervical infections in this study, 3.1% (one of 32) developed PID, whereas, among women without cervical infections, 0.4% (two of 548) were subsequently diagnosed with PID. Also, women with chlamydial and gonococcal infection were at threefold higher risk for any complication related to IUD use. In a recent study by Faundes et al. of women receiving IUD,[5] PID was diagnosed in two of 19 women with chlamydial infection and in 0 of 308 women without chlamydial infection. Although most women with cervical infections in the present study did not develop PID or other complications related to IUD use, attempts to identify persons with gonorrhea or chlamydial infection at the time of IUD insertion appear justified. However, in many settings, laboratory diagnosis of these infections is limited. Use of a risk assessment tool may facilitate identification of appropriate candidates for IUD insertion.[20]

Among women seeking family planning services, women who are referred for IUD insertion are a special population with reduced risk for STD. Practitioners are likely to suggest IUD insertion for women they perceive as being at low risk for complications. Thus, the population referred for insertion is preselected and represents a relatively low-risk population. Nevertheless, a substantial number of potentially preventable complications of IUD insertion occur, as evidenced by the 5.5% of women identified with cervical infections after IUD insertion.

The risk assessment algorithms assessed here have utility in identifying women at high or low risk of STD. Given the reasonable sensitivities of most algorithms and the low frequency of infection in this study population, the algorithms had high negative predictive values. In particular, the data-derived algorithms had negative predictive values of ≥99%.

The dichotomous algorithms did not perform as well for identifying high-risk women. With single cut-off points, positive predictive values were only marginally greater than the overall frequency of infection.

Performance of the data-derived algorithms (3a and 3b) was improved considerably by using the information categorically in the form of likelihood ratios. Examination of Figure 2 reveals that women may be considered in three largely distinct groups. Women with risk scores of 0–1 in algorithm 3b are at very low

risk for infection, even with high baseline infection frequencies. In contrast, women with risk scores of 5–6 are at substantially increased risk of STD (approximately a 30% infection probability in the present population). Women with mid-range risk scores (2–4) have moderate risks of infection especially in high prevalence populations.

This information may be quite useful clinically, particularly with reference to the baseline risk of infection.[21] Women with low risk scores need no special attention with regard to development of STD. Women at high risk could be counseled against IUD insertion or, at a minimum, should be followed closely. Prophylactic antibiotic therapy could also be considered in these women.[22] For women with intermediate risk scores, the appropriate action must consider the frequency of STD. In low prevalence settings (below 3–4%), no special attention is necessary. In moderate prevalence settings, counseling for dual contraceptive use seems appropriate. In high prevalence settings, these women are at comparable risk for infection as those in the high risk score group (Figure 2), and should receive similar counseling and close follow-up if an IUD is inserted.

Some caution must be exercised, however, in generalizing algorithms 3a and 3b to other populations. These algorithms were derived and assessed in the same study population and have not undergone external validation. If these algorithms are used, validation of performance should be conducted in the local population.

The inclusion of an ethnicity variable is potentially problematic from both scientific and societal perspectives. Risk assessment linked to ethnicity can be inflammatory. The inclusion of a variable linked to a specific ethnic group in Kenya also limits the generalizability of the data-derived algorithms (3a and 3b). However, ethnicity has been frequently linked to STD prevalence and has been identified as a significant predictor of cervical infection. For example, race/ethnicity has been included in selective screening criteria for chlamydial infection in the United States.[13,23] It is important to note that ethnicity is likely not a true risk factor, but instead a marker for other unmeasured or unmeasurable variables, such as prevalence of infection within a sexual network, polygamy/multiple partners, or circumcision status.

Because of the difficulty and expense of universal screening, a number of attempts have been made to identify women with cervical infections through the use of risk assessment tools. The CDC risk assessment criteria for the screening of chlamydia has achieved high sensitivity levels (≥85–88%) in both family planning and STD populations in the US, with significant reductions (24–42%) in the number of tests conducted when compared with universal screening.[24,25] Identification of effective risk assessment tools for the identification of cervical infections is even more important in many developing countries, where the burden of cervical infections and their sequelae are high and where laboratory testing is generally unavailable. Unfortunately, risk assessment algorithms for the detection of cervical infections in developing countries have generally performed poorly (low sensitivity and positive predictive value) in both family planning[15,16,26] and in antenatal clinic[27,28] populations.

The relative poor performance of the family planning and CDC algorithms compared with the data-derived algorithms is to be expected for several reasons. The population presenting for IUD insertion is unique, and these algorithms were developed for application in a broader range of clinical settings. The present study population was comprised of older, married women in stable partnerships with no recent STD history. Thus, risk markers such as age <20 years and cervical discharge provided little useful information. The algorithms also were limited by their dichotomous implementation. As noted above, the data-derived algorithms performed much better when considered with categorical information.

The study has several important limitations. The family planning and CDC algorithms were approximated, as some criteria incorporated in these algorithms were either not directly measured or had no variation in the study population. An enzyme immunoassay was used to detect chlamydial infections. This assay has reduced sensitivity compared with the best available molecular techniques and may result in a sizeable proportion of chlamydial infections going undetected. Such misclassification of infection status serves to limit the predictive ability of the algorithms to detect cervical infections. The diagnostic criteria for PID were largely based on clinical criteria, which may result in significant misdiagnosis of PID when compared with laparoscopy.[29] Also, the study was conducted in East Africa in populations with high prevalence of HIV and other STD. Thus, the study results may not be generalizable to populations with lower STD rates. Finally, as noted above, the data-derived models were not validated on an independent data set.

Strengths of this analysis include its prospective nature and the ability to evaluate the risk assessment algorithms both in terms of cervical infections and IUD-related complications, the ultimate outcome of interest. The study had high levels of follow-up (95%). The use of categorical likelihood ratios provides more clinically useful information than algorithms that provide only dichotomous (high vs low)

measures of risk. Finally, the use of ROC curves provides a comparison of the performance of the algorithms across all combinations of sensitivity and specificity.

In addition to providing potentially useful algorithms, one objective was to provide a framework for evaluating screening tools in other settings. The results demonstrate that local validation of "general" algorithms, such as the family planning algorithm, is an important step in implementation. Furthermore, local generation of an algorithm may be possible by considering those factors commonly assessed in the clinic setting. Although individual health centers may not have the resources to evaluate or generate algorithms, these activities could be conducted at national, regional, or municipal (such as Nairobi) levels, where data collected from multiple health centers can be used to evaluate or develop algorithms. Clearly, algorithms evaluated or developed based on data from multiple health centers within a region should be more highly generalizable to other health centers within the region than those based on data from a single center.

Sexually transmitted diseases are associated with increased risk for complications after IUD insertion. Simple risk assessment criteria can assist in the identification of women at high and low risk for STD among women presenting for IUD insertion. Use of a simple risk assessment tool may facilitate identification of women who require close observation and may thus reduce the incidence of IUD-related complications.

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