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Reassessing Risk Assessment: Limits To Predicting Reproductive Tract Infection In New Contraceptive Users

By Eugênio Teles, Ellen Hardy, U.M. Oliveira, Christopher J. Elias and Anibal Faúndes

The high costs and technical complexity of testing for reproductive tract infection make routine screening difficult in resource-poor reproductive health service environments. An analysis of 407 women visiting a Brazilian family planning clinic to initiate contraceptive use finds that 35% had reproductive tract infections, with bacterial vaginosis (26%) and chlamydia (7%) the most common types of infection. Only a history of sexually transmitted diseases and fewer years of education were significantly associated with having an infection of the reproductive tract. However, 95% of infections occurred among women who met neither of these risk criteria. The findings highlight the need for further research on cost-effective strategies for identifying women at risk for reproductive tract infection. (International Family Planning Perspectives, 23:179–182, 1997)

Increased awareness of the prevalence and consequences of reproductive tract infections has prompted calls for clinicians to use every available opportunity to diagnose, treat and prevent such infections.¹ Routine screening for the presence of reproductive tract infections during clinic visits initiated for contraceptive services is one potentially effective intervention for improving women's reproductive health.² Identifying preexisting cervical infections

is particularly important prior to insertion of an IUD. Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoea* is a high priority, as these organisms are responsible for most cases of upper reproductive tract infection (pelvic inflammatory disease), which in turn can lead to infertility, ectopic pregnancy and chronic pelvic pain.³

Unfortunately, the cost of laboratory screening tests often makes them unavailable in resource-poor service environments. While efforts continue toward the development of less expensive and complex diagnostic methods,⁴ some authors have suggested that clinicians adopt a risk-assessment approach, in which social and demographic characteristics and sexual behavior indicators are used to predict which women are likely to have infections.⁵ Expensive bacteriological investigations or empiric treatment can then be focused on those clients most likely to have an infection.

To explore whether this approach has utility in a population group generally assumed to be at relatively low risk of sexually transmitted infection, we conducted a descriptive study of new contraceptive users at the family planning clinic of the State University of Campinas in Brazil.

Methods

The study population consisted of 407 sexually active women attending the clinic to initiate use of a new contraceptive

method. Women were eligible if they reported having coitus at least once a week, were not bleeding due to menses at the time of sample collection and reported that they had not used antibiotics during the previous 15 days.

Between November 1991 and July 1992, two nurses with experience in family planning care who had been trained to collect data for this study solicited clients eligible for participation, obtained their consent and administered interviews. The questionnaires used in the interviews had been developed and pretested in a pilot study involving 200 women.

Data were collected on the women's age, marital status, race, years of schooling, reproductive history, age at first intercourse, total lifetime number of sexual partners, years living with current sexual partner, coitus with someone other than the current partner during the preceding six months and history of sexually transmitted diseases (STDs). Participants were also asked for information on their regular partner, including his years of schooling, occupation, condom use, other sexual partners during the last two months and history of STDs.

To ensure that specimen collection, conservation, preparation, analysis and test interpretation were done in a standardized manner, a single clinician performed all clinical examinations and specimen management. After conducting an external examination of the genitalia, the clinician used a speculum to examine the cervix and vagina and collected specimens for saline wet mount, Gram stain and Pap smear. Endocervical specimens were also obtained to isolate gonorrhoea and chlamydia antigen for testing.

Saline wet mount and Gram stain were used to search for evidence of infection with *Candida albicans* and *Trichomonas vaginalis*, as well as for evidence of clue cells that indicate infection with *Gardnerella vaginalis*

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Table 1. Percentage distribution of women initiating contraceptive use at a Brazilian family planning clinic and percentage with a reproductive tract infection, by selected characteristics, Campinas, Brazil, 1991–1992

Characteristic	% dist.	% with infection
Race (N=397)		
White	73.8	33.1
Nonwhite	26.2	40.4
Age (N=400)		
≤19	8.7	45.7
20–29	58.5	35.1
≥30	32.8	31.3
Schooling (N=400)		
≤elementary	84.8	36.6
>elementary	15.2	24.6
Marital status (N=400)		
Has no partner	5.5	31.8
Has partner	94.5	34.9
Age at 1st coitus (N=400)		
≤17	52.5	39.0
>17	47.5	30.0
Lifetime no. of sexual partners (N=399)		
1	63.4	32.8
≥2	36.6	37.7
No. of years living with current partner (N=399)		
<1	4.0	43.8
1–5	37.1	35.1
6–12	32.1	32.8
>12	26.8	34.6
Had sex with someone other than current partner in preceding 6 months (N=399)		
Yes	2.3	44.4†
No	97.7	34.4
Has history of STDs (N=399)		
Yes	3.3	61.5*,†
No	96.7	33.9
Partner's schooling (N=383)		
≤elementary	80.7	35.9
>elementary	19.3	29.7
Partner has history of STDs (N=390)		
Yes	6.4	52.0
No	93.6	33.4
Partner uses condoms (N=398)		
Always	8.8	31.4
Sometimes	20.1	33.8
Never	71.1	35.7
Total	100.0	na

*p < .05. †Significance tested using Fisher's exact test rather than χ^2 test. Notes: Some women did not provide information on all characteristics. na=not applicable.

(bacterial vaginosis). Trichomonas was also detected by Pap smear. Human papillomavirus infection was determined by presence of koilocytes in the Pap smear. We used fluorescent-labeled monoclonal antibody (SYVA Microtrack) to detect chlamydia, and isolated gonorrhea using Thayer-Martin medium and identified it using standard bacteriological methods.⁶ Where a large

number of leukocytes (15 or more per high-power field) were observed in the Gram stain of vaginal content but no specific microorganism could be identified, the woman was recorded as having a nonspecific vaginal infection. Chlamydia test results were unavailable for five women, as were the results of Pap smears for two women. We included these seven cases in calculating the percentage of women with other infections, but excluded them from further analysis.

We performed statistical analyses using χ^2 test and a two-tailed Fisher's exact test.⁷ Stepwise multivariate logistic regression analysis was performed as described by Hosmer and Lemeshow,⁸ using SPSS.

Results

Background Characteristics

Almost three-fourths of the women in the study population were white, more than half were 20–29 years of age and few were younger than 20 (Table 1). Eighty-five percent had only a primary education, and just 5% did not have a permanent partner. More than half had had first intercourse before age 18. More than one-third of the women had had two or more sexual partners, while almost three-fifths had lived with their current partner for six years or more. Both the women and their male partners reported a similar level of education. Few women reported having had sex with anyone other than their main partner in the previous six months or having a history of STDs. Six percent of women reported that their partners had a history of STDs. Less than 10% reported always using condoms.

Prevalence of Infection

The prevalence of infection was low for most of the microorganisms studied (Table 2). Almost two-thirds of the women in the sample were completely free of reproductive tract infections. Bacterial vaginosis was the most prevalent condition, affecting 26% of the women. Chlamydia was present in 7% of women. No other type of infection exceeded 4% in prevalence. Similar proportions of women were identified as having candida and trichomonas (approximately 2% for each). The prevalence of human papillomavirus infection (as determined by Pap smear) was even lower (1%). No women were found to have gonorrhea.

Variables Associated with Infection

Very few of the women's characteristics were significantly associated with the likelihood of infection in a univariate analysis (Table 1). Only a history of STD infection was associated with the likelihood of

any reproductive tract infection (p=.042). When specific infections were examined, the only significant association found was a positive association between the number of years a woman had lived with her current sexual partner and infection with chlamydia (p=.005).

We also performed a separate analysis for any cervical infection (not shown). Because of the low prevalence of human papillomavirus and the absence of gonorrhea, these results were similar to those for chlamydia alone. We repeated the analysis excluding candida and bacterial vaginosis to explore the possibility of using the social, demographic and sexual behavior data to identify women specifically at risk for sexually transmitted infections, but this analysis also provided no significant associations.

In the multivariate logistic regression, having a history of STDs and having received elementary education only were significantly associated with an increased risk of a reproductive tract infection (p=.038 and p=.043, respectively). When each reproductive tract infection was considered separately, we found that both chlamydial infection and bacterial vaginosis were associated with the number of years a woman had lived with her current sexual partner, but in different directions: The duration of the relationship was positively associated with chlamydial infection (p=.002), but was negatively associated with bacterial vaginosis (p=.046).

To better measure the efficiency of the risk criteria, we calculated for each the sensitivity, specificity and positive and negative predictive values (Table 3). These indicate that when education and STD history were considered together, there was a fairly high likelihood that someone identified by the criteria as at risk of being infected actually was infected (a positive predictive value of 70%). However, because only 10 women in the sample shared these two characteristics, using the two risk criteria together identified only 5% of all infected women (sensitivity).

Table 2. Percentage of women with various reproductive tract infections, by type of infection (N=407)

Infection	%
None	64.1
Bacterial vaginosis	25.8
Chlamydia	6.7
Nonspecific vaginal infection	3.7
Candida	2.2
Trichomonas	1.7
Human papillomavirus	1.0
Gonorrhea	0.0

Note: Some women had multiple infections.

Similarly, with use of the STD history criterion alone, 98% of the women not infected were correctly identified as uninfected (specificity) and 62% of women with a history of STD infection were indeed infected; on the other hand, because so few women had a history of STDs, this criterion had a sensitivity of only 6%. And while focusing on a low level of schooling as the sole marker appeared much more effective at identifying infected women (sensitivity of 83%), such information is of limited utility in this setting, since the vast majority of the women (85%) were not educated beyond the elementary level. Thus, this criterion's ability to accurately identify uninfected women (specificity) and to single out only the infected women (positive predictive value) is limited (18% and 37%, respectively).

Discussion

We attempted to identify social and demographic characteristics and sexual behavior indicators for women and their partners that were statistically associated with the presence of STDs and other reproductive tract infections. In this population, however, the prevalence of infection was relatively low, and only a prior history of STDs and fewer years of schooling were significantly associated with any infection of the reproductive tract.

An association between a history of STDs and current sexually transmitted infection has been previously described.⁹ This association highlights the importance of including a thorough medical and sexual history as part of contraceptive counseling.¹⁰ However, although we found an association between prior STD infection and current reproductive tract infection, we observed no link between prior infection and current infection with a specific STD. While this may be the result of limited statistical power, given the low STD prevalence in this population, it may also reflect an imprecision in current terminology. Further qualitative research to identify local terminology regarding reproductive tract morbidity and to understand health-seeking behavior patterns among women with infections is required to more fully understand such observations.¹¹

If we consider education as a socioeconomic indicator, the association between reproductive tract infection and fewer years of schooling may be in keeping with the findings of other studies, in which lower socioeconomic status is often associated with a higher prevalence of reproductive tract infection.¹²

Our findings regarding chlamydial in-

fection are particularly important in light of the fact that 42% of the women chose the IUD. The association between chlamydial infection and women's longer cohabitation with their current partner is difficult to interpret, though, because it contrasts with results of previous studies, which have shown that chlamydia is typically associated with more recent partner change or multiple partnership.¹³ Additional data on the duration of infection and the sexual behavior of the women and their male partners might have been helpful in interpreting this observation.

Our attempts to use history of STDs and years of education to identify women at high risk of current infection proved unsuccessful. The vast majority of infected women in the study population could not be identified using these criteria. Similar problems have also been noted in attempts to apply the risk approach to other serious health events, such as maternal morbidity and mortality.¹⁴

While a risk-assessment approach may sometimes achieve high levels of specificity, it may have poor sensitivity, as seen in our results. The limited utility of this approach must be weighed against its costs in terms of training, provider time, and the mistaken impression it may foster among service providers that they are adequately addressing an important problem simply by applying an incompletely developed form of risk assessment.

Based on our findings, the risk approach appears to have limited value among new contraceptive users in a typical family planning service delivery setting, although the predictive value of these variables may be higher where the prevalence of either current infection or STD history is greater. This is likely to be the case in a clinic specializing in the treatment of STDs, for example.

Our findings have significant implications for family planning service provision. We found that despite relatively little reported high-risk sexual behavior, new contraceptive users in the clinic had a moderate prevalence of chlamydia. These women were not easily identified on the basis of other variables.

While these findings reinforce the specific need for less expensive chlamydia tests, they also suggest an urgent need to explore alternative options for improving the safety of contraceptive service provision. This poses a significant problem for clinicians in a setting where routine testing of all new contraceptive clients is not financially viable. For example, should scarce chlamydia testing be rationed to

Table 3. Percentage of women detected as or predicted as having reproductive tract infection, by risk factor, according to performance indicator

Indicator	Risk factor		
	Less schooling	STD history	Both
Sensitivity	83	6	5
Specificity	18	98	99
Positive predictive value	37	62	70
Negative predictive value	75	66	66

those at greatest risk of pelvic inflammatory disease and its complications, such as infertility?

Selective screening of women requesting an IUD and women who have yet to attain their desired family size would be one approach to rationing such costly case finding. Alternatively, perhaps improved counseling to encourage new clients to self-screen for their risk of STDs would be more effective than provider screening. Or perhaps the most effective strategy is careful follow-up and management of incident infections to minimize long-term complications, such as infertility. These important programmatic issues, along with an exploration of their relative cost-effectiveness, urgently require additional research.

An important limitation of our findings concerns the tests we used to determine reproductive tract infections. Several of the reference tests that we employed are less sensitive than more expensive alternatives. For example, diagnosing trichomonas infection by wet preparation is only approximately 60–80% sensitive compared to trichomonas culture.¹⁵ The sensitivity of using clue cells as a diagnostic criterion for bacterial vaginosis is 80–98% when compared with more elaborate criteria for determining bacterial vaginosis.¹⁶ Similarly, a fluorescent antigen detection test for chlamydia is less sensitive than cell culture or DNA amplification tests.¹⁷ The use of koilocytosis on Pap smear as a proxy for human papillomavirus infection may be particularly insensitive.¹⁸ Our results must be considered in this context.

Nonetheless, recent literature on the design of STD prevention and control programs has repeatedly stressed the need for STD and reproductive tract infection case-finding and management strategies guided by local epidemiology and validated whenever possible in local service environments.¹⁹ Such local adaptation is impossible if we insist on the exclusive use of the latest "gold standard" technology, since these tests will be available only in atypical service settings associated with tertiary care and centralized research facilities.

Until simpler and more affordable diagnostic tests for reproductive tract infection are available, we must face the difficulty of interpreting results obtained in settings where the reference tests themselves are somewhat lacking in sensitivity.

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Resumen

Los elevados costos y la complejidad técnica de los exámenes para detectar infecciones en el aparato reproductivo obstaculizan los exámenes de rutina en los ambientes donde faltan los recursos para servicios adecuados de salud reproductiva. Un análisis realizado a 407 mujeres que asistieron a una clínica brasileña de planificación familiar para iniciar el uso de anticonceptivos revela que el 35% tenían infecciones en el aparato reproductivo, con casos de vaginosis bacteriana (26%) y clamidia (7%) los tipos más comunes de infecciones. Solamente el hecho de haber tenido una enfermedad transmitida por vía sexual y haber cursado pocos años de escuela fueron relacionados en forma significativa con el problema de tener una infección en el aparato reproductivo. Sin embargo, el 95% de las infecciones se registraron entre mujeres que no reunían ninguno de estos factores de riesgo. Los resultados destacan la necesidad de realizar mayores estudios sobre estrategias a bajo costo para identificar a aquellas mujeres que corren un riesgo de contraer infecciones en su aparato reproductivo.

Résumé

Les coûts élevés et la complexité technique des tests de détection des infections de l'appareil reproducteur rendent difficile le dépistage systématique dans les centres de services de santé génésique dénués des ressources nécessaires. Une analyse menée sur 407 femmes désireuses de pratiquer une méthode de contraception s'étant rendues dans une clinique de planning familial brésilienne a révélé une infection de l'appareil reproducteur chez 35% d'entre elles. Il s'agissait, pour la plupart, de vaginoses bactériennes (26%) et de chlamydias (7%). Des antécédents de maladies transmissibles sexuellement et un nombre moindre d'années de scolarisation étaient les seuls facteurs significativement associés à la présence d'une infection de l'appareil reproducteur. Quarante-cinq pour cent des infections ont cependant été relevées chez des femmes qui ne répondaient à aucun de ces critères de risque. Ces observations soulignent la nécessité d'une recherche continue sur les stratégies économiques rentables d'identification des femmes qui présentent un risque d'infection de l'appareil reproducteur.

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