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Risk-based Screening for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Prior to Intrauterine Device Insertion

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Abstract

Objective—To compare three strategies for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* screening prior to intrauterine device (IUD) insertion.

Study Design—This was a secondary analysis of the Contraceptive CHOICE Project. We measured the prevalence of *C. trachomatis* and/or *N. gonorrhoeae* at the time of IUD insertion. We then compared sensitivity, specificity, negative and positive predictive values, and likelihood ratios for three screening strategies for *C. trachomatis* and *N. gonorrhoeae* prior to IUD insertion: 1) "age-based" – age ≤ 25 years alone, 2) "age/partner-based" – age ≤ 25 and/or multiple sexual partners, and 3) "risk-based" – age ≤ 25, multiple sexual partners, inconsistent condom use, and/or history of prior sexually transmitted infection (STI).

Results—Among 5,087 IUD users, 140 (2.8%) tested positive for *C. trachomatis*, 16 (0.3%) tested positive for *N. gonorrhoeae*, and 6 (0.1%) were positive for both at the time of IUD insertion. The "risk-based" screening strategy had the highest sensitivity (99.3%) compared to "age-based" and "age/partner-based" screening (80.7% and 84.7%, respectively.) Only 1 (0.7%) woman with a chlamydia or gonorrhea infection would not have been screened using "risk-based" screening.

Conclusion—A risk-based strategy to screen for *C. trachomatis* and *N. gonorrhoeae* prior to IUD insertion has higher sensitivity than screening based on age alone or age and multiple sexual partners.

Implications—Using a risk-based screening strategy (age ≤25, multiple sexual partners, inconsistent condom use, and/or history of a STI) to determine who should be screened for *C.*

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trachomatis and *N. gonorrhoeae* prior to IUD insertion will miss very few cases of infection and obviates the need for universal screening.

Keywords

intrauterine device; sexually transmitted infections; contraception; chlamydia; gonorrhea

1. Introduction

One of the most effective methods of reversible contraception is the intrauterine device (IUD). However, some health care providers remain reluctant to place IUDs, in part, because of concerns about safety including risk of pelvic inflammatory disease (PID) and infertility.[1, 2] Studies have demonstrated a low risk of PID with IUD placement with the greatest risk in the first 20 days after insertion (1.6 per 1000 women-years).[3] The risk of PID is higher in women who have chlamydial or gonococcal cervicitis at the time of insertion.[4] Previous studies conducted in areas with a high prevalence of sexually transmitted infections (STI) have shown that algorithms which include demographic and reproductive characteristics can help identify women at high risk for STI prior to IUD insertion.[5, 6]

The Centers for Disease Control and Prevention (CDC) recommends screening women for *C. trachomatis* and *N. gonorrhoeae* who have at least one of the following five risk factors: age ≤ 25 years, new or multiple sexual partners, inconsistent condom use, history of a prior STI, and exchanging sex for money, drugs, food, or shelter (survival sex).[7] Although black and Hispanic women have a higher prevalence of chlamydial and gonorrheal infections than their white counterparts,[8-10] race and ethnicity are not specifically included in the CDC's screening criteria.

The “U.S. Selected Practice Recommendations for Contraceptive Use” from the CDC recommends following the above screening guidelines prior to IUD insertion.[11] The American College of Obstetricians and Gynecologists (ACOG) recommends screening women “at high-risk for STIs” prior to or at the time of IUD insertion.[12] Despite these recommendations, there is no standard practice for STI screening prior to IUD insertion.

Our objectives in this analysis were to describe the prevalence of *C. trachomatis* and *N. gonorrhoeae* infections in IUD users from the Contraceptive CHOICE Project and to compare the performance of three screening strategies: 1) “age-based” – age ≤ 25 years alone, 2) “age/partner-based” – age ≤ 25 years and/or multiple sexual partners, and 3) “risk-based” – including age ≤25, multiple sexual partners, inconsistent condom use, and/or history of a STI.

2. Material and Methods

This study is a secondary analysis of the Contraceptive CHOICE Project (CHOICE). CHOICE is a large prospective cohort study designed to promote the use of LARC methods and reduce unintended pregnancy. CHOICE provided no-cost contraception to 9,256 women in the St. Louis area. The methods of CHOICE have been previously described.[13] Participants were eligible to participate in CHOICE if they: 1) were aged 14-45 years, 2)

desired reversible contraception, 3) were not currently using a contraceptive method or willing to switch to a new method, 4) wanted to avoid pregnancy for at least 12 months, 5) were at risk for unintended pregnancy, 6) were a resident of the St. Louis region, and 7) were English or Spanish speaking. If eligible, participants had an in-person enrollment visit and were provided with the FDA-approved reversible contraceptive method of their choice at no cost. IUDs were placed by a study clinician at the university research site or by the participant's clinician at community partner sites. Approval from the Washington University Human Research Protection Office was obtained prior to recruitment and all study participants provided written informed consent.

At the enrollment visit, all participants completed self-obtained vaginal swabs which were sent for nucleic acid amplification testing (NAAT) for *C. trachomatis* and *N. gonorrhoeae*. Treatment was provided to participants and partners if they tested positive for *C. trachomatis or N. gonorrhoeae*.[8] Previous studies have demonstrated that detection of chlamydia and gonorrhea by NAAT from self-obtained vaginal swabs is equal to or greater than clinician-obtained endocervical or vaginal swabs.[14, 15]

Because the CHOICE enrollment survey did not ask specifically about “new or multiple partners,” as described in the CDC screening guidelines, we combined women who reported more than one sexual partner in the prior 30 days and women who stated that they had an “other” partner (in addition to a main partner) in the last 30 days into a single variable for multiple partners. A woman was considered an inconsistent condom user if she reported using condoms “sometimes,” “almost never,” or “never;” whereas, we considered a woman who reported using condoms “every time” or “almost every time” to be a consistent user. A woman was defined as having a history of a prior STI if she reported a history of *C. trachomatis, N. gonorrhoeae, T. vaginalis,* syphilis, HIV, or genital herpes.

Eligibility criteria for this analysis included participants who chose an IUD at baseline and had satisfactory results available for chlamydia and gonorrhea testing. Demographic characteristics of the IUD users were described using frequencies, and percentages. Chi-square tests were used to compare categorical variables. We calculated sensitivity, specificity, positive and negative predictive values, and negative likelihood ratios for the previously described screening algorithms compared to results of the NAAT testing for *C. trachomatis* and *N. gonorrhoeae*. A multivariate regression model was developed using variables that represent the CDC's screening criteria with the exception of survival sex. Of the six women who reported a history of survival sex, none tested positive for *C. trachomatis* or *N. gonorrhoeae* at the time of IUD insertion, therefore, survival sex was not included in our “risk-based” screening strategy. A multivariate logistic regression model was also developed using significant variables from the univariate analysis and the variables that represent the CDC's screening criteria (with the exception of survival sex). Statistical analyses were performed using STATA 11.0 software (StataCorp, College Station, TX). The significance level was set at 0.05.

3. Results

Among the 9,256 CHOICE participants, 5,362 women received a levonorgestrel intrauterine system or copper IUD at baseline. There were 121 women with an unsatisfactory specimen (due to missing preservative or collection swab), and 154 women who refused testing, leaving a total of 5,087 women with satisfactory gonorrhea and chlamydia test results available. Of these, 140 (2.8%) were positive for *C. trachomatis*, 16 (0.3%) were positive for *N. gonorrhoeae*, and 6 (0.1%) were positive for both at the time of IUD insertion. Table 1 shows the baseline demographic and reproductive characteristics of women stratified by infection status at baseline. Women were more likely to have tested positive for *C. trachomatis* or *N. gonorrhoeae* at baseline if they were between the ages of 14-25 years, of black race, had high school education level or less, were single, had no insurance or had public insurance, chose the levonorgestrel intrauterine system, had multiple partners, or had a history of a STI. Neither inconsistent condom use nor a history of survival sex (exchanging sex for money, food, drugs, or shelter) was associated with infection status.

Table 2 shows the sensitivity, specificity, negative and positive predictive values, negative likelihood ratios, and number of infections that would have been missed for each screening strategy employed. “Risk-based” screening has the highest sensitivity (99.3%) but the lowest specificity (7.6%) and only 1 (0.7%) woman with *C. trachomatis* or *N. gonorrhoeae* infection would not have been screened; whereas, 29 (19.3%) and 23 (15.3%) infections would have been missed if “age-based” or “age/partner based” screening had been employed.

The multivariate regression model presented in Table 3 includes variables from the CDC screening criteria. Women aged ≤ 25 years were more likely to have *C. trachomatis* or *N. gonorrhoeae* (OR 3.72, 95% CI 2.34—5.91) when compared to women >25 years. The odds of having a chlamydial or gonorrheal infection was also higher in women who had multiple sexual partners (OR 1.99, 95% CI 1.17—3.41) and in women who had a history of a STI (OR 1.49, 95% CI 1.01—2.19). Inconsistent condom use was not significantly associated with increased odds of chlamydia or gonorrhea in our model (OR 0.90, 95% CI 0.29—2.81).

The multivariate logistic regression model presented in Table 4 includes significant variables from the univariate analysis as well as the CDC screening criteria: multiple partners, history of prior STI, and inconsistent condom use. Women aged ≤ 25 years were more likely to have *C. trachomatis* or *N. gonorrhoeae* (OR 3.17, 95% CI 1.94—5.17) when compared to women >25 years. The odds of having a chlamydial or gonorrheal infection was also higher in women of black race (OR 2.09, 95% CI 1.31—3.33), those with a high school education or less (OR 2.49, 95% CI 1.25—4.94), and those who identified themselves as single or having never been married (OR 1.81, 95% CI 1.15—2.85). With the addition of demographic characteristics to the model, the reproductive and sexual activity characteristics in the CDC screening criteria were no longer significantly associated with increased odds of chlamydia or gonorrhea.

4. Discussion

We found that of the three screening strategies, the “risk-based” screening had the highest sensitivity for identifying women with *C. trachomatis* or *N. gonorrhoeae* infections. In addition, the negative predictive value was high, meaning that if a woman did not have any of the listed risk factors, she was unlikely to be infected with *C. trachomatis* or *N. gonorrhoeae*. “Age-based” and “age/partner-based” screening had lower sensitivities, although the negative predictive values remained high. Using “risk-based” screening for *C. trachomatis* and *N. gonorrhoeae* testing prior to IUD insertion would fail to identify only 0.7% of these infections among our study participants. In comparison, “age-based” screening alone would miss 19.3% of cases and “age/partner-based” screening would miss 15.3%. In our population, the screening strategy appears to benefit from including history of STIs and inconsistent condom use as recommended by the CDC. All three screening algorithms had poor specificity which is an acceptable trade-off for high sensitivity in a screening test.

Interestingly, similar sensitivity can be achieved using screening criteria comprised of the significant variables from our second multivariate analysis that included both demographic characteristics and the CDC screening criteria. Using these significant variables (age ≤ 25, black race, no insurance or public insurance, single or never married, and a high-school education or less) only 1 patient (0.7%) who tested positive for *C. trachomatis* or *N. gonorrhoeae* would have gone unscreened. However, a screening strategy for STI based on demographic factors potentially stigmatizes these patient characteristics.

Our study population of IUD users had a *C. trachomatis* prevalence of 2.7% and a *N. gonorrhoeae* prevalence of 0.3%. This is slightly lower than reported by McNicholas et al for the overall CHOICE population: 3.1% and 0.4% for *C. trachomatis* and *N. gonorrhoeae*, respectively.[8] However, our rates were higher than the reported rates for *C. trachomatis* and *N. gonorrhoeae* in St. Louis City (1.4% and 0.6%) and nationally (0.6% and 0.1%).[16]

A study of U.S. women enrolled in a large managed care organization found that the risk of PID was 0.54% among women undergoing IUD insertion.[17] A recently published study of CHOICE IUD users found that the rate of self-reported PID at 6 months was 0.46%.[18] Even given this low rate of PID with IUD insertion, prior studies have shown that approximately one-third of IUD providers believe that the IUD increases a patient's risk of pelvic inflammatory disease at times other than the peri-insertional period, and that up to two-thirds of IUD providers do not recommend the IUD to women with a prior history of STIs.[2, 19, 20] In addition, the risk of PID is similar regardless of whether screening is performed on a day prior to insertion or on the same day as insertion.[17] Evidence-based contraindications to IUD placement include current *C. trachomatis* and *N. gonorrhoeae* infection, current mucopurulent cervicitis, or PID within the past 3 months.[21] Concerns about the risk of PID in a woman with no clinical evidence of cervicitis should not influence a healthcare provider's decision about whether a woman is eligible for an IUD.

A major strength of our study is the large cohort of diverse women who underwent systematic screening for *C. trachomatis* and *N. gonorrhoeae* at the time of study enrollment.

The CHOICE cohort included women both at high- and low-risk for STIs. In addition, we collected extensive baseline demographic and reproductive characteristics about our participants.

There are several potential limitations to this analysis. First, in contrast to the CDC's recommendations, inconsistent condom use was not significantly associated with increased odds of chlamydia or gonorrhea infection in our model. This finding could have resulted from several factors. It is likely that, to some extent, report of condom use is affected by social desirability bias, leading participants to inaccurately report condom use. However, we feel that this is unlikely given the large number of women who reported inconsistent condom use. Lastly, it is possible that our definition of inconsistent condom use is inaccurate (doesn't measure what we intended for it to measure). In order to evaluate this last possibility, we ran our multivariate regression model defining women as inconsistent condom users if they reported use of condoms “almost all of the time,” “sometimes,” “almost never,” or “never.” Only women who reported using condoms “every time” were considered consistent users. This definition did not alter the significance of inconsistent condom use in our model.

In CHOICE, women with a recent diagnosis of chlamydia or gonorrhea, current mucopurulent cervicitis, or PID within the past 3 months were not candidates for same-day IUD insertion. We did not routinely collect data about contraindications to same-day insertion and therefore it is not known how many women did not receive an IUD due to one of these contraindications.

Finally, contrary to the CDC's recommendations, we found that survival sex was not significantly related to *C. trachomatis* or *N. gonorrhoeae* infection. This may, in part, be due to the small number of women who reported ever exchanging sex for drugs, money, food or shelter in our sample. Therefore, we chose not to include this characteristic in our risk-based screening algorithm.

While screening for *C. trachomatis* and *N. gonorrhoeae* prior to IUD insertion is important in at-risk women, both ACOG and the CDC recommend screening on the same day as IUD placement and not waiting for a negative result prior to placement. If the patient tests positive for either *C. trachomatis* and/or *N. gonorrhoeae*, she can be treated with the IUD in place.[11, 12] Clinicians should not delay IUD insertion until the results of testing are available as this requires the patient to make an additional visit and creates a barrier to IUD placement. The results of our study support that healthcare providers do not need to provide universal screening for *C. trachomatis* and *N. gonorrhoeae* prior to IUD placement. Instead, they can follow the CDC's recommendations for STI testing. Very few cases of *C. trachomatis* and *N. gonorrhoeae* infection will be missed using this approach.

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Table 1

Baseline demographic and reproductive characteristics of IUD users by baseline infection status

	Results of *C. trachomatis* or *N. gonorrhoeae* testing		
	Negative N=4937	**Positive N=150**	**p-value**
	n (%)	**n (%)**	
Age			<0.01
14-19	455 (9.2)	32 (21.3)	
20-25	2110 (42.7)	89 (59.3)	
26-45	2372 (48.1)	29 (19.3)	
Race			<0.01
Black	2261 (45.8)	102 (68.0)	
White	2304 (46.7)	39 (26.0)	
Other	372 (7.5)	9 (6.0)	
Hispanic	241 (4.9)	5 (3.3)	0.38
Education			<0.01
High school/GED or less	1465 (29.7)	69 (46.0)	
Some college	2167 (43.9)	66 (44.0)	
Completed college or graduate degree	1304 (26.4)	15 (10.0)	
Marital Status			<0.01
Single	2683 (54.4)	112 (74.7)	
Married/partnered	1861 (37.7)	32 (21.3)	
Separated/divorced/widowed	390 (7.9)	6 (4.0)	
Low socioeconomic status	2880 (58.4)	98 (65.3)	0.09
Insurance			<0.01
None	1958 (39.8)	63 (42.0)	
Private	2267 (46.1)	54 (36.0)	
Public/Medicaid	696 (14.1)	33 (22.0)	
Parity			0.41
0	1979 (40.1)	64 (42.7)	
1-2	2318 (47.0)	72 (48.0)	
3+	640 (13.0)	14 (9.3)	
History of Abortion	1845 (37.4)	57 (38.0)	0.88
History of prior STI[a]	1622 (32.9)	62 (41.3)	0.03
Multiple sexual partners	363 (7.4)	23 (15.3)	<0.01
Inconsistent condom use	3647 (98.5)	111 (96.5)	0.10
History of survival sex[b]	8 (0.16)	0 (0.0)	0.63
IUD chosen at baseline			0.001
LNG-IUS	3895 (78.9)	135 (90.0)	
Copper IUD	1042 (21.1)	15 (10.0)	

STI – sexually transmitted infection; IUD – intrauterine device

[a] Prior STI – history of gonorrhea, chlamydia, trichomoniasis, herpes simplex, HIV, or syphilis

[b] Survival sex – defined as exchanging sex for money, food, drugs, or shelter

Table 2

Screening test characteristics for three screening strategies for *C. trachomatis* and *N. gonorrhoeae* at the time of IUD insertion

Variables	Sensitivity % (95%CI) [# true positive/ total # infected]	Specificity % (95%CI) [# true negative/total # uninfected]	NPV % (95%CI) [# true negative/# screen negative]	PPV % (95%CI) [# true positive/# screen positive]	Negative LR	Number of missed infections n (%)
Age-based (age ≤25)	80.7 (73.2, 86.4) [121/150]	48.1 (46.6, 49.5) [2372/4937]	98.8 (98.3, 99.2) [2372/2401]	4.5 (3.8, 5.4) [121/2686]	0.4	29 (19.3)
Age/Partner-based (age ≤25 and multiple sexual partners)	84.7 (77.7, 89.8) [127/150]	44.8 (43.4, 46.2) [2211/4937]	99.0 (98.5, 99.3) [2211/2234]	4.5 (3.7, 5.3) [127/2853]	0.3	23 (15.3)
Risk-based (age ≤25, multiple sexual partners, history of prior STI, and inconsistent condom use)	99.3 (99.5, 100) [149/150]	7.6 (6.8, 8.3) [375/4937]	99.7 (98.5, 99.9) [375/376]	3.2 (2.7, 3.7) [149/4711]	0.1	1 (0.7)

NPV – negative predictive value; PPV – positive predictive value; LR – likelihood ratio; STI – sexually transmitted infection

Table 3

Multivariate logistic regression of CDC screening criteria variables[a] and their association with *C. trachomatis* and/or *N. gonorrhea* infection

	Odds Ratio	95% CI	
Age ≤ 25	3.72	2.34	5.91
Multiple partners	1.99	1.17	3.41
History of prior STI	1.49	1.01	2.19
Inconsistent condom use	0.90	0.29	2.81

[a]There were no cases of chlamydial or gonorrheal infection in women who reported survival sex and, as a result, survival sex was dropped from the model.

Table 4

Univariate and multivariate logistic regression of the association between demographic characteristics and CDC screening criteria with *C. trachomatis* and/or *N. gonorrhoea* infection

	Univariate			Multivariate[a]		
	Odds Ratio	**95 % CI**		**Odds Ratio**	**95 % CI**	
Age<=25	3.86	2.56	5.81	3.17	1.94	5.17
Multiple partners	2.28	1.44	3.60	1.68	0.97	2.91
History of prior STI	1.44	1.03	2.00	1.08	0.72	1.63
Inconsistent condom use	0.43	0.15	1.20	1.02	0.32	3.23
Race						
White	Ref			Ref		
Black	2.67	1.83	3.87	2.09	1.31	3.33
Others	1.43	0.69	2.97	1.52	0.71	3.25
Education						
College/Grad	Ref			Ref		
High school or less	4.09	2.33	7.19	2.49	1.25	4.94
some college	2.65	1.51	4.66	1.64	0.84	3.18
Marital status						
Married/with partner	Ref			Ref		
Single/never married	2.43	1.63	3.61	1.81	1.15	2.85
Divorced/Separated/Widowed	0.89	0.37	2.15	1.20	0.40	3.55
Insurance						
Private	Ref			Ref		
None	1.35	0.93	1.95	0.97	0.63	1.49
Public/Medicaid	1.99	1.28	3.09	0.78	0.43	1.40
Low socioeconomic status	1.35	0.96	1.89	-	-	-

[a]Multivariate logistic regression odds ratio (OR) estimates were adjusted for age, multiple partners, history of prior STI, inconsistent condom use, race, education, marital status, and insurance status