



Published in final edited form as:

Obstet Gynecol. 2014 April ; 123(4): 777–784. doi:10.1097/AOG.0000000000000179.

Using a Checklist to Assess Pregnancy in Teenagers and Young Women

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Abstract

OBJECTIVE—Health care providers should assess pregnancy in women seeking contraceptive services. Although urine pregnancy tests are available in most U.S. settings, their accuracy varies based on timing relative to missed menses, recent intercourse, or recent pregnancy. We examined the performance of a checklist based on criteria recommended in family planning guidance documents to assist health care providers in assessing pregnancy in a sample of U.S. teenagers and young women.

METHODS—Study participants were a convenience sample of sexually active black females aged 14–19 years seeking care in an urban family planning clinic. Each participant provided a urine sample for pregnancy testing and was then administered the checklist in two formats, audio computer-assisted self-interview and in-person interview. We estimated measures of the checklist performance compared with urine pregnancy test as the reference standard, including negative predictive value, sensitivity, specificity, and positive predictive value.

RESULTS—Of 350 participants, 31 (8.9%) had a positive urine pregnancy test. The audio computer-assisted self-interview checklist indicated pregnancy was unlikely for 250 participants, of whom 241 had a negative urine pregnancy test (negative predictive value=96.4%). The sensitivity of the audio computer-assisted self-interview checklist was 71%, the specificity was 75.6%, and the positive predictive value was 22%. The in-person checklist yielded similar results.

CONCLUSION—The checklist may be a valuable tool to assist in assessing pregnancy in teenagers and young women. Appropriate use of the checklist by family planning providers in combination with discussion and clinically indicated use of urine pregnancy tests may reduce unnecessary barriers to contraception in this population.

Health care providers should assess risk of current pregnancy in women seeking contraceptive services.^{1,2} Although urine pregnancy tests are available in most U.S. settings,

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Financial Disclosure

The authors did not report any potential conflicts of interest.

they are not able to detect pregnancies resulting from recent intercourse, their detection rates can vary based on the sensitivity of the test and timing with respect to missed menses, and they may remain positive weeks after a pregnancy ends.^{1,3} Uncertainty about pregnancy status may result in unnecessary delays in contraceptive initiation to rule out pregnancy. Immediate initiation of contraception may reduce time at risk for pregnancy and improve short-term method continuation.⁴ Therefore, accurate assessment of pregnancy at the initial visit is important. Often a detailed history can provide the most accurate assessment of pregnancy. Family planning guidance documents state that a health care provider can be reasonably certain a woman is not pregnant if she has no signs or symptoms of pregnancy and meets any one of six criteria shown in Table 1.^{1,2} A checklist based on these criteria was developed as a job aid for family planning providers to assess pregnancy in their female clients.⁵

If the criteria accurately indicate for whom pregnancy is unlikely, use of the checklist may reduce barriers to contraceptive services and minimize unnecessary urine pregnancy tests. Studies in international settings suggest the criteria perform well in predicting nonpregnant status.⁵⁻⁸ The checklist has not been evaluated in the United States or among teenagers and young women. Delays in method initiation may be an important barrier to contraception among teenagers and young women, because many do not return to the clinic to begin their method⁹ or lose motivation to use contraception while waiting to begin their method. Nonetheless, there may be concerns about the ability of teenagers and young women to provide accurate responses to the checklist questions. We examined the performance of the recommended criteria to assess pregnancy among a sample of U.S. teenagers and young women.

PATIENTS AND METHODS

We used data collected as part of a cross-sectional study conducted to understand black females' attitudes and practices with regard to preventing unintended pregnancy and sexually transmitted diseases. During April to September 2012, participants were recruited at a publicly funded teen clinic in Atlanta, Georgia that provides family planning, sexually transmitted disease, and preventive health services to school-aged youth. Study staff attempted to approach every female client as they checked into the clinic to assess their interest in the study and their eligibility. Eligible participants were females aged 14–19 years who were seeking clinic services for any reason, who reported vaginal sex with a male partner during the past 6 months, were born in the United States, and self-identified as black or African American. Those eligible and interested in participating provided informed written consent (ages 18–19 years) or assent (ages 14–17 years). Parental consent was waived for participants younger than 18 years because of the confidential nature of clinic services. The study was approved by the institutional review boards at the Centers for Disease Control and Prevention and Emory University. Participants were reimbursed \$20 for their time to participate in the study.

After undergoing the consent process, participants provided a urine sample that was tested for pregnancy by trained clinic laboratory personnel by using the Clearview human chorionic gonadotropin Combo II test, which detects human chorionic gonadotropin in urine

at concentrations of 20 mIU/mL or higher. Participants then answered questions reflecting the criteria recommended by the Centers for Disease Control and Prevention and the World Health Organization to assess pregnancy.^{1,2} The questions were asked in two interview modalities: in-person interview and audio computer-assisted self-interview. The sequence in which participants underwent the in-person interview and the audio computer-assisted self-interview questionnaire was assigned randomly to assess whether the performance of the in-person checklist differed according to whether it was given before or after the audio computer-assisted self-interview questionnaire.

The checklist questions (Table 1) were developed in consultation with clinic teenage peer educators who reviewed the previously developed checklist questions⁵ and provided feedback to improve comprehension for the target population. The questions were then pilot-tested with females from the target population. Along with the checklist questions, participants were also asked if they were experiencing nausea, breast tenderness, abdominal pain, and sleepiness to assess symptoms of pregnancy. The wording and order of the questions were the same for both interview modalities. In-person interviews were conducted by trained research assistants. The audio computer-assisted self-interview questionnaire took approximately 30 minutes to complete and covered additional topics, including demographics, reason for the clinic visit, contraceptive history, and reproductive history. Participants were also asked whether they thought they might be pregnant that day with response options of “yes,” “no,” or “maybe.”

To examine the performance of the checklist compared with the urine pregnancy test as the reference standard, we calculated estimates of sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) along with corresponding exact 95% confidence intervals (CIs) for the checklist when administered using the audio computer-assisted self-interview and in person. If a participant’s responses to the checklist questions indicated they met any one of the six recommended criteria for being reasonably certain a woman is not pregnant (Table 1), it was considered that pregnancy was unlikely. If none of the criteria were met, it was considered that pregnancy was possible. For our study, we defined sensitivity as the proportion of those with a positive urine pregnancy test (the reference standard) for whom the checklist indicated possible pregnancy, specificity as the proportion of those with a negative urine pregnancy test for whom the checklist indicated pregnancy was unlikely, PPV as the proportion of those for whom the checklist indicated possible pregnancy who had a positive urine pregnancy test, and NPV as the proportion of those for whom the checklist indicated pregnancy was unlikely who had a negative urine pregnancy test. Negative predictive value is of particular interest because it is a measure of the ability of the checklist to accurately indicate for whom pregnancy is unlikely.

In addition, we calculated performance measures of the checklist including the absence of symptoms of pregnancy as a criterion for indicating that pregnancy is unlikely. We examined the performance of self-perception of pregnancy as an additional criterion in the checklist. We calculated the kappa statistic to assess the agreement between results from the checklist when administered in person compared with audio computer-assisted self-interview. We compared the sensitivity and specificity of the audio computer-assisted self-interview and in-person checklists using McNemar’s test for correlated proportions to

account for the pairing of checklist assessments within a participant. We compared PPV and NPV for the audio computer-assisted self-interview and in-person checklist according to the method described by Leisenring et al.¹⁰

The Centers for Disease Control and Prevention recommends that when a health care provider is uncertain whether a woman might be pregnant, starting hormonal contraception should be considered with a follow-up pregnancy test in 2–4 weeks.¹ We reviewed the medical records of participants who were classified as possibly pregnant by either the in-person or audio computer-assisted self-interview checklist and abstracted whether they were asked to return for a repeat urine pregnancy test, whether they returned and were tested, and the test results.

RESULTS

Of 698 females approached for study participation, 525 (75.2%) were screened for eligibility. Of those screened, 374 (71.2%) were eligible to participate. Of those eligible, 350 (93.6%) participated. Among those ineligible (n=151), the most common reason for ineligibility was not having vaginal sex during the past 6 months (78%).

More than half of the study participants (52.3%; n=183) came to the clinic to get or change birth control. Characteristics of the overall sample and those seeking contraceptive services are shown in Table 2. Approximately one-third of participants were aged 14–16 years, more than half had public health insurance, more than 40% reported a previous sexually transmitted disease, and more than one-fourth reported a previous pregnancy. At last sex, 35% of the overall sample and 28% of those seeking contraceptive services used no method of contraception. After classifying the most effective contraceptive method used at last sex, we found that depot medroxyprogesterone acetate was used most often by participants (23% of the overall sample and 34% of those seeking contraceptive series) followed by the condom (21% of the overall sample and 19% of those seeking contraceptive series), and pill, patch, or ring (11% of both the overall sample and those seeking contraceptive series) (Table 2).

In the overall study sample, 31 participants had a positive urine pregnancy test (8.9%, 95% CI 6.1–12.3%). The audio computer-assisted self-interview checklist indicated pregnancy was unlikely for 250 participants, 241 of whom had a negative urine pregnancy test, for an estimated NPV of 96.4% (95% CI 93.3–98.3%) (Table 3). Of the 319 participants with a negative urine pregnancy test, the checklist indicated pregnancy was unlikely for 241 for an estimated specificity of 75.6%. Of the 31 participants with a positive urine pregnancy test, the audio computer-assisted self-interview checklist indicated possible pregnancy for 22 for an estimated sensitivity of 71.0%. The audio computer-assisted self-interview checklist indicated possible pregnancy for 100 participants of whom 22 had a positive urine pregnancy test for an estimated PPV of 22.0%. Results for the checklist administered in person were similar to those for the audio computer-assisted self-interview checklist (*P* values for all comparisons >.2). The performance of the checklist was similar among younger (ages 14–17 years) and older (ages 18–19 years) participants (data not shown).

We examined the checklist responses in more detail for participants with a positive pregnancy test but for whom the checklist indicated pregnancy was unlikely, ie, false-negatives (audio computer-assisted self-interview checklist, n=9; in-person checklist, n=11). The most common reasons for the checklist resulting in a false-negative were participants reporting their last menstrual period began within the last 7 days (audio computer-assisted self-interview checklist, n=4; in-person checklist, n=6) and participants reporting not having sex since their last menstrual period (audio computer-assisted self-interview checklist, n=2; in-person checklist, n=4).

Among those seeking contraceptive services (n=183), seven had a positive urine pregnancy test (3.7%, 95% CI 1.5–7.4%). The performance of the checklist was similar among those seeking contraceptive services to that in the overall sample (Table 4).

Symptoms of pregnancy were common in the study sample with 145 (41.4%) of the sample reporting at least one symptom in the audio computer-assisted self-interview (data not shown). The most commonly reported symptom was sleepiness (31.4%) followed by breast tenderness (13.7%), abdominal pain (12.9%), and nausea (9.1%). The reporting of any symptoms was more common among those with a positive urine pregnancy test (74.2%) compared with those with a negative urine pregnancy test (38.2%); however, more than 80% of those reporting symptoms had a negative urine pregnancy test. The addition of the absence of symptoms of pregnancy as a checklist criterion increased the sensitivity and decreased the specificity without an appreciable change in the NPV. Inclusion of absence of symptoms of pregnancy as a criterion in the audio computer-assisted self-interview checklist decreased the number of false-negatives by correctly classifying an additional seven participants with a positive urine pregnancy test as possibly pregnant. However, there was also an increase in the number of false-positives; the number of women with a negative urine pregnancy test for whom the audio computer-assisted self-interview checklist indicated a possible pregnancy increased from 78 to 160, meaning an additional 26% of participants with a negative urine pregnancy test would be inappropriately classified as possibly pregnant (n=82). Results were similar for the in-person checklist in the overall sample and for both the audio computer-assisted self-interview and in-person checklist among those seeking contraceptive services.

When asked on the audio computer-assisted self-interview whether they thought they might be pregnant that day, 62.3% of participants responded “no.” The addition of perceiving oneself as not pregnant as a checklist criterion did not change the performance of the checklist in comparison to the urine pregnancy test. In addition, the performance of the in-person checklist was similar when given before (n=161) or after the audio computer-assisted self-interview (n=188) (data not shown). Agreement between the audio computer-assisted self-interview checklist and the in-person checklist was high (κ 0.75, 95% CI 0.68–0.83); the agreement was somewhat higher when the in-person checklist was administered before (κ 0.84, 95% CI 0.74–0.93) compared with after the audio computer-assisted self-interview (κ 0.69, 95% CI 0.57–0.80).

Among participants reporting sex since their last menstrual period (n=236), we compared the most effective contraceptive method they reported using at last sex in the audio

computer-assisted self-interview with their response to the checklist question “Have you been using a reliable birth control method consistently and correctly since your last menstrual period started?” The responses were generally in agreement. Among those who reported using a reliable method on the audio computer-assisted self-interview checklist (n=103), the majority (66%) reported using an intrauterine device (IUD), implant, or depot medroxyprogesterone acetate at last sex (19% IUD or implant, 47% depot medroxyprogesterone acetate), whereas 18% used the pill, patch, or ring; 10% used a condom; and 6% used withdrawal or no method. Among those who did not report using a reliable method (n=133), the majority (66%) reported using no contraceptive method at last sex, whereas 4% reported using an implant, IUD, or depot medroxyprogesterone acetate; 8% used the pill, patch, or ring; 19% used a condom; and 2% used withdrawal.

Nineteen participants classified as possibly pregnant by the audio computer-assisted self-interview or in-person checklist and who had a negative urine pregnancy test were asked to return to the clinic for a follow-up urine pregnancy test after starting a hormonal contraceptive method. Ten participants returned to the clinic and eight underwent a follow-up urine pregnancy test; all of the results were negative. Follow-up pregnancy tests were performed on average 18 days after the initial test.

DISCUSSION

This study demonstrates that a checklist based on criteria recommended by the World Health Organization and the Centers for Disease Control and Prevention is useful in assessing pregnancy in a sample of U.S. teenagers and young women. Our results are generally consistent with previous international studies, which reported some variation in the performance of the checklist with sensitivity ranging from 55% to 100% and specificity ranging from 39% to 89% but consistently high NPV of 99–100%.³ Our estimated NPV was slightly lower; some characteristics of our study population may explain this difference. The prevalence of pregnancy in our study population was considerably higher than the prevalence in previous studies, which ranged from 1%^{5,6} to 4%.⁷ With regard to test performance measures, an increase in prevalence results in a decrease in NPV.¹¹

Unlike previous studies, our sample only included teenagers and young women. Health care providers may be concerned that teenagers and young women may have some difficulty understanding the checklist questions or providing accurate responses. To address this concern, we adapted the questions from the previously developed checklist after receiving feedback from our target population. We compared responses to the checklist question about use of a reliable birth control with participants’ reported method used at last sex, and the results were reassuring. Nonetheless, we did not validate method use with medical records and we did not have information on consistent or correct use. Several of the checklist questions refer to last menstrual period. Teenagers and young women may have some difficulty determining their last menstrual period, given their cycles may be irregular, or they may mis-interpret irregular uterine bleeding related to other causes such as hormonal contraceptive use as menses.

The performance of the checklist was similar when administered in person and by audio computer-assisted self-interview. Health care providers may wish to consider administering the checklist in various formats. Teenagers and young women may feel more comfortable answering some questions (eg, about recent sex or abortion) in a written or computerized format, whereas some checklist topics such as use of reliable contraception or timing of last menstrual period may benefit from discussion with a health care provider for clarification.

Similar to a study conducted among family planning clients in Kenya,⁸ we found that the addition of absence of symptoms of pregnancy as a checklist criterion did not improve the NPV. Although considering symptoms of pregnancy decreased the number of false-negatives, there was also a considerable increase in the number of false-positives, participants with a negative urine pregnancy test classified as possibly pregnant by the checklist. This could mean an increase in the number of women for whom health care providers may unnecessarily delay initiation of contraception because of concerns about contraceptive use in women with an unrecognized pregnancy.

Although the NPV of the checklist was high in our sample, the checklist indicated pregnancy was unlikely for a few participants with a positive urine pregnancy test. The most common reasons for these false-negatives involved awareness of menstrual cycles and timing of intercourse related to their last period. In a clinical setting, health care providers may be able to probe more with regard to cycles and potentially reduce related false-negatives. It is also possible that some participants did not accurately report their recent sexual activity. The reporting of sexual activity may be improved when asked using alternate formats to in-person interviews.¹² The consequences of false-negatives differ depending on the contraceptive method being used; although there is no evidence that fetal exposure to hormonal contraceptives is harmful,¹³⁻¹⁷ pregnancies with IUDs in situ are at increased risk of preterm delivery, septic abortion, and spontaneous abortion.¹⁸

When considering how to use the pregnancy checklist and urine pregnancy tests in clinical practice to assess pregnancy, it is important to consider their advantages and disadvantages. The pregnancy checklist is simple to use, incurs no cost, and can be used to predict early pregnancies before they can be detected by urine pregnancy tests. Nonetheless, it may not work for women with irregular cycles, and it largely depends on self-reported information. Urine pregnancy tests are highly effective in identifying pregnancies, but not before the menstrual period is missed. In practice, there may be a role for both the checklist and urine pregnancy tests. For example, the checklist may provide an initial determination of likelihood of pregnancy so that pregnancy tests would only be used when needed on the basis of clinical judgment. Routine pregnancy testing in every woman is not necessary. In most cases, among women for whom the checklist suggests possible pregnancy, a pregnancy test will not provide further assurance because of their limited ability to detect early pregnancy.

Our results should be interpreted within the context of several limitations. Our study was conducted in a convenience sample of black females seeking care at an urban family planning clinic and may not be generalizable to other populations. We used the urine pregnancy test as the reference standard to assess checklist performance; however, urine

pregnancy tests also have limitations in detecting pregnancy and in some cases such as early pregnancy, the checklist may be more accurate in assessing pregnancy. Finally, although pregnancy was more common in our study sample than in previous studies, the absolute number of pregnancies was still small, resulting in unstable estimates of sensitivity.

Our study suggests that a simple checklist based on criteria recommended in family planning guidance^{1,2} may be a valuable health care provider tool to assess pregnancy in teenagers and young women. Use of the checklist, health care provider discussion, and clinically indicated use of urine pregnancy tests may yield the best results to assess pregnancy in teenagers and young women. Health care provider education on how to assess pregnancy and on the safe initiation of contraceptive methods may result in more effective provision of contraceptive services. Appropriate use of the checklist by family planning providers serving teenagers and young women may reduce barriers to contraception and unintended pregnancies in this population.

Acknowledgments

Supported by Cooperative Agreement Number U48DP001909-01 from the Centers for Disease Control and Prevention.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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Table 1

Criteria and Related Questions Used in the Checklist to Assess Pregnancy Among Female Teenagers and Young Women Seeking Care in a Family Planning Clinic

WHO and CDC Criteria to Be Reasonably Certain a Woman Is Not Pregnant		Question in Study Checklist and Determination of Pregnancy Status*		
1	Is 7 d or less after the start of normal menses	1	Did your last menstrual period start within the last 7 d?	Yes: Pregnancy unlikely
2	Has not had sexual intercourse since the start of last normal menses	2	Have you had sex since your last menstrual period started?	No: Pregnancy unlikely
3	Has been correctly and consistently using a reliable method of contraception	3	Have you been using a reliable birth control method consistently and correctly since your last menstrual period started?	Yes: Pregnancy unlikely
4	Is 7 d or less after spontaneous or induced abortion	4	Did you have a miscarriage or abortion in the last 7 d?	Yes: Pregnancy unlikely
5	Is within 4 wk postpartum	5	Did you have a baby in the last 4 wk?	Yes: Pregnancy unlikely
6	Is fully or nearly breastfeeding, amenorrheic, and 6 mo or less postpartum	6	Did you have a baby in the last 6 mo?	Yes to all: pregnancy unlikely
		a.	Are you breastfeeding now?	
		b.	Are your periods still gone since you had the baby?	

WHO, World Health Organization; CDC, Centers for Disease Control and Prevention.

* Pregnancy was considered to be unlikely if the participant fulfilled any of these criteria: answered “yes” to questions 1, 3, 4, or 5; answered “no” to question 2; or answered “yes” to questions 6, 6A, and 6B.

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Table 2

Characteristics of the Study Sample of Black Females Seeking Care in a Family Planning Clinic, Overall, and Among Those Seeking Contraceptive Services*

Characteristic	Overall Sample (N=350)	Seeking Contraceptive Services (n=183)
Reason for visit [†]		
To get or change birth control	183 (52.3)	183 (100)
To get a check-up	173 (49.4)	77 (42.1)
To get a pregnancy test	130 (37.1)	55 (30.1)
To get tested for STDs	149 (42.6)	71 (38.8)
Physical complaint	82 (23.4)	36 (19.7)
To talk to a health care provider or health educator	51 (14.6)	27 (14.8)
To get treatment	49 (14.0)	16 (8.7)
Because clinic staff asked you to come in	13 (3.7)	7 (3.8)
Age (y)		
14–16	122 (34.9)	68 (37.2)
17–19	228 (65.1)	115 (62.8)
Health insurance		
Public	188 (53.7)	101 (55.2)
Private	28 (8.0)	12 (6.6)
None or do not know	134 (38.3)	70 (38.3)
Reported previous STD	153 (43.7)	75 (41.0)
Reported previous pregnancy	92 (26.3)	54 (29.5)
Contraceptive method used at last sex [‡]		
IUD	10 (2.9)	4 (2.2)
Implant	17 (4.9)	7 (3.8)
Depot medroxyprogesterone acetate	82 (23.4)	63 (34.4)
OCP, patch, or ring	40 (11.4)	21 (11.5)
Condom	72 (20.6)	34 (18.6)
Withdrawal or other	5 (1.4)	3 (1.6)
None	124 (35.4)	51 (27.9)

STDs, sexually transmitted diseases; IUD, intrauterine device; OCP, oral contraceptive pill. Data are n (%).

* Defined as those who reported coming to the clinic “to get or change birth control.”

[†] More than one reason could be selected.

[‡]Classified as the most effective method under typical use. Some participants used condoms with a more effective method (n=72 in overall sample and n=47 in those seeking contraceptive services).

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Table 3

Comparison of Checklist to Assess Pregnancy (Administered by Computer or in Person) With Urine Pregnancy Test Results Among Overall Study Sample

	Comparison of Results			Checklist Performance Measures (vs Urine Pregnancy Test as Reference Standard)				
	Urine Pregnancy Test–Positive	Urine Pregnancy Test–Negative	Total	Sensitivity	Specificity	PPV	NPV	
Audio computer-assisted self-interview checklist	Pregnancy possible	22	78	100	71.0 (52.0–85.8)	75.6 (70.5–80.2)	22.0 (14.3–31.4)	96.4 (93.3–98.3)
	Pregnancy unlikely	9	241	250				
	Total	31	319	350				
In-person checklist	Pregnancy possible	20	80	100	64.5 (45.4–80.8)	74.8 (69.7–79.5)	20.0 (12.7–29.2)	95.6 (92.2–97.8)
	Pregnancy unlikely	11	238	249				
	Total	31	318	349				

PPV, positive predictive value; NPV, negative predictive value.

Data are n or % (95% confidence interval).

One participant did not complete the in-person checklist.

Table 4

Comparison of Checklist to Assess Pregnancy (Administered by Computer or in Person) With Urine Pregnancy Test Results Among Those Seeking Contraceptive Services*

		Comparison of Results			Checklist Performance Measures (vs Urine Pregnancy Test as Reference Standard)			
		Urine Pregnancy Test-Positive	Urine Pregnancy Test-Negative	Total	Sensitivity	Specificity	PPV	NPV
Audio computer-assisted self-interview checklist	Pregnancy possible	4	26	30	57.1 (18.4–90.1)	85.2 (79.1–90.1)	13.3 (3.8–30.7)	98.0 (94.4–99.6)
	Pregnancy unlikely	3	150	153				
	Total	7	176	183				
In-person checklist	Pregnancy possible	3	29	32	42.9 (9.9–81.6)	83.5 (77.2–88.7)	9.4 (2.0–25.0)	97.4 (93.4–99.3)
	Pregnancy unlikely	4	147	151				
	Total	7	176	183				

PPV, positive predictive value; NPV, negative predictive value.

Data are n or % (95% confidence interval).

* Defined as those who reported coming to the clinic “to get or change birth control.”