Public Health Briefs

Home Pregnancy Testing Kits: Prevalence of Use, False-Negative Rates, and Compliance with Instructions

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Abstract: This study investigated the prevalence of home pregnancy kit use, incidence of false-negative results, and compliance with testing procedures. Among 144 pregnant women, identified through three health care settings, prevalence of test-kit use was 28.5 per cent. The false-negative rate was 24.3 per cent. Total compliance with instructions was reported by only 32 per cent of users. Women testing less than nine days after menstrual period was due had false-negative rates of 33 per cent contrasted with 21 per cent for those testing after the nine days. (*Am J Public Health* 1982; 72:1034–1036.)

Introduction

Since their introduction in the mid-1970s, home pregnancy testing kits have been well publicized. Some obstetricians routinely advise patients to test themselves at home before scheduling prenatal appointments.

These kits all test for elevated human chorionic gonadotrophin (HCG) in the urine as an indication of pregnancy.[1] HCG levels, not detectable at the beginning of pregnancy, rise to maximum levels between 6–10 weeks.[2] Reports on the accuracy of the test results range from "no better than chance" to predictive values of about 98 per cent for a positive test and 80 per cent for a negative test.[1,3–5] Results appear to vary by brand of kit and by compliance with testing procedures. False-negatives can occur from exposure to environmental factors such as sunlight, refrigerator vibrations, or soap scum on testing equipment.[6,7]

Early confirmation of pregnancy is desirable, since it provides motivation to change behaviors such as smoking or use of drugs and alcohol which are potentially harmful to the fetus, and to take precautions if scheduled for medical x-rays, surgery, etc. If the test kits are highly sensitive when used by consumers, they would be most helpful. If they produce high false-negative rates, they are potentially harmful, as use of damaging substances may continue. This study was done to evaluate prevalence of kit use, incidence of false-negative results, and degree of compliance to testing procedures by kit users. Variation by age, race, treatment setting, and income is also assessed.

Subjects and Procedures

Subjects were 144 pregnant women from three treatment settings—a private obstetrician's office, a Planned Parenthood clinic, and a public OB-GYN clinic at a large general hospital. These settings were chosen to provide a range of socioeconomic status and age among subjects. Characteristics of the study population are shown in Table 1. Ages ranged from 15–39 years with a mean of 24.5. Blacks comprised 24 per cent of the sample. Subjects were questioned at the time of their first prenatal visit.

A self-completion questionnaire including sections on demographic characteristics, current and prior kit use, and compliance to kit instructions was filled out in the treatment setting. Six compliance factors were assessed: 1) number of days waited after menstrual period was due, 2) number of drops of urine, 3) mixing procedure, 4) length of time specimen sat, 5) interpretation of results, 6) repeating a negative test. Since only negative results required test repetition, subjects with positive results were given credit for compliance on this item in computing compliance rates.

Agresti and Wackerly's computer program[8] was used to compute exact tests for comparison of observed frequencies. The Student's t was used to compare means.

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TABLE 1—Distribution of Subjects, Prevalence of Kit Use, and False-Negative Rates by Age, Race, Treatment Setting and Income

Variable	Number of Subjects	Percentage of Subjects	Percent using Kit	False-Negative Rates (%)
Age (years)				
15–20	71	49.3	31.0	31.8
21–25	37	25.7	13.5	20.0
>25	36	25.0	38.9	14.2
Race				
Black	35	24.4	11.4*	25.0
White	108	75.5	34.3	24.3
Treatment Setting				
Private MD	50	34.7	38.0	21.1
Public Clinic	45	31.3	22.2	40.0
Planned Parenthood	49	34.0	24.5	16.7
Income				
$0–9,999	37	44.1	16.2**	50.0
$10,000–20,000	24	26.7	54.2	30.8
>$20,000	25	29.1	32.0	12.5

*p <. 01
**p <. 05

Results

Overall prevalence of kit use was 28.5 per cent (Table 1). Use by Whites was 3.5 times that of Blacks. Income, available for only 86 subjects, showed a significant association with kit use.

The overall incidence of false-negative results was 24.3 per cent. The number of subjects using kits was small (41) so that few statistically significant associations can be expected. Rates varied inversely by age and income, and public clinic patients had about half the false-negative rates of those from the other two treatment settings (Table 1).

Only 32 per cent of users complied with all test-kit instructions (Table 2). Of a possible six compliance factors, the highest mean score, 5.6, was for those with post-high school education.

Subjects with true-positive results complied with an average of 5.3 factors while subjects with false-negative results complied with an average of 4.6 factors. The most frequent omission was failure to repeat the negative test. For the total sample, the range of days waited after a missed period to conduct the test was from 4–81, with a mean of 19.4 and a median of 14 days. Women waiting less than the nine days recommended by kit instructions had false-negative results of 33 per cent contrasted with 21 per cent for those testing later in pregnancy.

Discussion

With nearly one-third of pregnant women using the home pregnancy test kits, the high rate of false-negatives is of concern. Kit inserts printed by the manufactures claim sensitivity rates of 90–98 per cent and stress the predictive value of a positive test. This study found a sensitivity of only 75.6 per cent. Kit instructions urge women to test for pregnancy as early as the ninth day after a missed menstrual period. Since HCG levels are not detectable early in pregnancy and rise to a maximum at 6–10 weeks, the earlier the test is done, the greater the chances are of obtaining a false-negative result. False-negative rates in this study were higher among those testing earlier in pregnancy.

Young women who have recently began menstruating are more likely to have irregular periods. Menstrual cycle irregularity could affect test outcome in two ways: 1) it may be difficult to know when a period is due and, therefore, difficult to judge when to do the test; and 2) HCG levels may not be sufficiently high for detection. Our findings of higher false-negative rates among younger women could be related to these factors. These young women, and those from lower

TABLE 2—Compliance with Testing Procedures by Age, Race, Treatment Setting, Education, and Test Result

Variables	Average Number Factors Complied with	Confidence Intervals
Age (years)		
15–20	5.3	4.94–5.66
21–25	5.0	3.37–6.63
>25	5.2	4.33–5.67
Race		
Black	4.0*	1.10–6.90
White	5.5	5.27–5.73
Treatment Setting		
(Private MD)	5.4	4.97–5.83
(Public clinic)	5.1	4.47–5.73
(Planned Parenthood)	5.5	4.99–6.01
Education		
8–11th grade	5.2	
High School	5.4	
Post-High School	5.6	
Test Result		
False-Negative	4.6	3.83–5.37
True-Positive	5.3	5.08–5.72

*p <. 05

income groups, who also had high false-negative rates, are at high risk of complications of pregnancy and for presence of risk factors such as poor nutrition or smoking. Delay in obtaining medical care and counseling could increase fetal risk. Further, delay in seeking medical care has implications for elective abortion since abortion is safer earlier in pregnancy.

An unanswered question is what effect kit use has on prenatal care; although we asked how long women waited after using the kit before making an appointment, nonresponse rates on this item, which came near the end of the questionnaire, were high. Among responders with a positive test result, appointments were made immediately to as long as 30 days later. One woman with a false-negative waited 60 days. However, the small numbers and self-selection to respond make us wary of making any inferences. A study focusing on the effect of kit use on prenatal care and on whether women change behaviors such as smoking in response to kit results would be helpful in determining a need for public prenatal education programs and a responsibility on the part of kit manufacturers to include the importance of prenatal care and preventive health behavior in their advertisements.

Clearly, since one-third of the pregnant women were willing to purchase the kits to test for pregnancy, the kits have gained public acceptance. In view of this, we feel that kit instructions should be revised to: 1) make them easier to read; 2) encourage women with irregular menstrual periods to wait at least two weeks after a missed period before doing the test; 3) emphasize the need to repeat a negative test one week later. Including two testing packets in each kit, as one company has done recently, will probably increase the likelihood that women comply with this step.

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ACKNOWLEDGMENTS

An earlier version of this paper was presented at the meeting of the Society for Epidemiological Research, Snowbird, Utah, June 17–19, 1981.

18th Annual Meeting of the Society of Prospective Medicine

The Society of Prospective Medicine announces "Health Hazard Appraisal and Risk Reduction: The Effectiveness of Intervention Programs" as the theme of their 18th annual meeting to be held October 20–24, 1982 in Quebec, Canada. Dr. Lester Breslow, UCLA Dean Emeritus and epidemiologist, will be the keynote speaker.

Additional information may be obtained from:

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