Accuracy of Consumer Performed In-home Tests for Early Pregnancy Detection

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Abstract: We investigated the accuracy of the in-home pregnancy test in early pregnancy detection. A total of 109 women volunteered to perform their own pregnancy test using one of three brands. Kit accuracy ranged from 45.7 per cent to 89.1 per cent (95 per cent confidence interval), differing from the 97.4 per cent average of manufacturer claims. Sensitivity was calculated at 56 per cent, while specificity was 83 per cent. Predictive value of a negative result was 56 per cent and the predictive value of a positive test was 83 per cent. (*Am J Public Health* 1986; 76:512–514.)

Introduction

Immunological tests for the presence of human chorionic gonadotropin (HCG) in urine have become the most commonly used tests for the determination of pregnancy.[1] For years, numerous pregnancy test kits have been distributed for professional use. It has not been until recently that kits using the same immunological principle, hemagglutination inhibition, have been made available to the consumer through over-the-counter sales in drug and department stores. Millions of dollars are spent on these products annually. Yet few published studies address the accuracy of these tests when used by the consumer. Sources of documentation rely almost exclusively on authoritative opinion.[2–4]

Furthermore, the Food and Drug Administration (FDA) has never directly approved the in-home pregnancy test kits. The first in-home test (e.p.t.®) was released prior to May 28, 1976. This kit was marketed without FDA approval since it predated the 1976 Medical Device Amendment of the Food, Drug, and Cosmetic Act. This law contained a section that allowed the marketing of new products judged "substantially equivalent" to preamendment products to enter the market place. By 1979, the FDA had six additional brands registered with them, all of which were judged to be "substantially equivalent" to e.p.t.® and, therefore, exempt from regulation also.[5] The FDA has, however, reviewed effectiveness data from each manufacturer to verify labeling claims. The agency reports an average accuracy of all brands combined to be 97.4 per cent.* This claim is very impressive since studies of professional kits do not generate such excellent statistics.[6–8]

In their literature, the companies claim their products to be up to 99 per cent accurate when used to detect pregnancy as early as six to nine days after the missed period.[9–11] Efficacy data submitted to the FDA, however, showed that accuracy claims were actually based on tests run on samples collected after 15 days or more beyond the missed menses.[5] It is crucial to point out that the concentration of HCG in urine at nine days after the missed menses is far less than the hormone concentration at 15 days. Driscoll, in his study of Pregnosis® found that when urine samples were obtained for testing prior to 13 days past the missed period, accuracy was only 69 per cent. Specimens collected beyond 13 days improved accuracy to 96.2 per cent.[7]

This study was designed to evaluate the accuracy of the in-home pregnancy test kit in early pregnancy detection when the test was performed by the consumer at home.

TABLE 1—Characteristics of Pregnancy Detection Study Group

Characteristic	Number of Women				Per Cent Total
	Answer®	Daisy 2™	e.p.t.®	Total	
Age (years)					
18–21	4	5	3	12	11
22–29	24	20	22	66	60
≥30	7	9	10	26	24
Unreported	2	2	1	5	5
Anxiety					
None	19	18	22	59	54
Positive[a]	8	6	8	22	20
Negative[b]	7	10	5	22	20
Unreported	3	2	1	6	6
Menses Days Late					
≤9	10	15	3	28	26
10–15	22	13	24	59	54
>15–20	5	8	9	22	20
Education					
< High School	4	2	5	11	10
High School Graduate	9	14	8	31	28
College	22	18	22	62	57
Unreported	2	2	1	5	5
Income ($)					
<10,000	8	8	4	20	18
10–20,000	10	11	9	30	28
20–40,000	12	11	16	39	36
>40,000	3	3	5	11	10
Unreported	4	3	2	9	8
Ethnic Origin					
Black	3	3	1	7	6
Hispanic	4	3	4	11	10
White	30	30	31	91	84

a) Trying to get pregnant for at least six months.
b) Unmarried.

Methods

Subjects

We studied 109 women of childbearing age whose menses were late by at least six days, but not more than 20 days. Volunteers came from obstetrician offices, community health centers, and women's health clinics. They were primarily educated and Caucasian (Table 1). Valanis has shown that this is the group that uses the test most often.[12]

In-home pregnancy test kits used included: 36 Daisy 2™ Home Pregnancy Test Kits (Ortho Pharmaceutical Corporation, Consumer Products Division, Raritan, New Jersey 08869), 72 e.p.t.® In-Home Early Pregnancy Test Kits

*Stewart W: OTC-PTK. Presentation at FDA's Consumer Affairs Officers' Conference, June 1979.

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TABLE 2—Combined Accuracy and Brand Accuracy of In-Home Pregnancy Tests for Early Detection Compared to Manufacturer Claims

Menses Days Late	All Brands Combined FDA	%Acc	95% Confidence Interval
6–20 (All Samples)[a]	97.4	77.1	68.0 to 84.6
≤9	—	65.5	45.7 to 82.1
>9	—	81.3	71.0 to 89.1
	Answer®		
	Claim[b]	%Acc	95% Confidence Interval
9–20	98	72.9	55.9 to 86.2
≤9	—	70.0	34.8 to 93.3
>9	—	74.1	53.7 to 88.9
	Daisy 2™		
	Claim[b]	%Acc	95% Confidence Interval
6–20	98.9	75.0	57.8 to 87.9
≤9	—	60.0	32.3 to 83.7
>9	—	85.7	63.7 to 97.0
	e.p.t.®		
	Claim[b]	%Acc	95% Confidence Interval
9–20	72–99 (84.6)	83.3	67.2 to 93.6
≤9	—	66.6	9.4 to 99.2
>9	—	84.8	68.1 to 94.9

FDA = FDA average accuracy claim for all brands in per cent.
%Acc = Accuracy for Study Population.
a) Answer® and e.p.t.® 9–20 days.
b) Claim = Manufacturer advertised claim in per cent.
c) Range given.

(Warner/Chilcott, Division of Warner-Lambert Company, Morris Plains, New Jersey 07950) and 74 Answer® At-Home Early Pregnancy Test Kits (Carter Products, Division of Carter-Wallace, Inc., New York, N.Y. 10153). The hospital diagnostic kit, Sensi-Tex™ (Roche Diagnostics, Division of Hoffmann-LaRoche Inc., Nutley, New Jersey 07110) was used for contrast. Multistix® SG Reagent Strips (Ames Division, Miles Laboratories, Inc., PO Box 70, Elkhart, Indiana 46515) were used to screen the urines.

The first morning urine specimen that participants brought to a consortia site was divided in half. One portion of the sample was returned to the participant to use in performing a pregnancy test at home. Kits to be used for the home testing were given out at this time. Brands were randomly distributed if the menstrual period was late by at least nine days. If the period was late six to eight days, a Daisy 2™ kit was dispensed, since this was the only brand claiming accuracy that early. The participant was instructed to follow the package directions in performing the test, call the consortia with the results she obtained, and complete and return the data collection survey to the investigator.

The remaining urine sample was taken to the research laboratory and checked for adequate concentration and the presence of interfering substances. The investigator performed an in-home pregnancy test using an identical brand and lot number as that given to the participant. Results of a Sensi-Tex™ tube test were also reported. All tests were reported as positive or negative. Accuracy was defined by agreement with actual outcome: pregnant, not pregnant.

Results

Table 2 compares the confidence intervals found by the investigator with the FDA expected accuracy of in-home pregnancy test kits and individual manufacturer claims.[13] The 95 per cent confidence intervals determined in this study do not include the claim made by Answer® and Daisy 2™; however, they do coincide with the range reported for e.p.t.®

Sensitivity, specificity, and predictive value[14] of the tests for each of the three kit brands appear in Table 3. Although it is difficult to establish sensitivity and specificity at the ideal

TABLE 3—Combined and Brand Comparison of In-Home Pregnancy Tests for Sensitivity, Specificity, and Predictive Value (expressed as per cent)

Menses Days Late	All Brands Combined All	≤9	>9	Answer® All	≤9	>9	Daisy 2™ All	≤9	>9	e.p.t.® All	≤9*	>9
Sensitivity	80	56	88	78	50	88	82	64	75	81		83
Specificity	68	83	61	64	100	44	64	60	63	—		75
Predictive Value of a Positive Result	84	83	84	78	100	79	78	78	77	84		84
Predictive Value of a Negative Result	62	56	70	64	57	67	69	43	100	62		56

$$\text{Sensitivity} = \frac{TP}{TP + FN}$$

$$\text{Specificity} = \frac{TN}{TN + FP}$$

$$\text{Predictive Value of a Positive Test} = \frac{TP}{TP + FP}$$

$$\text{Predictive Value of a Negative Test} = \frac{TN}{TN + FN}$$

TP—True Positive
FP—False Positive
TN—True Negative
FN—False Negative
*Only three cases examined.

TABLE 4—Combined Accuracy of In-Home Pregnancy Tests in Relation to Psychological and Socioeconomic Variables

Variables	Per Cent Accuracy (95% Confidence Intervals)
Age (years)	
≤21	21.1 to 78.9
22–29	67.0 to 87.9
≥30	65.1 to 95.6
Anxiety	
None	65.3 to 87.7
Positive[a]	59.7 to 94.8
Negative[b]	49.8 to 89.3
Education	
< High School	23.4 to 83.3
High School Graduate	62.5 to 92.5
College	66.8 to 88.3
Yearly Income ($)	
<10,000	45.7 to 88.1
10–20,000	43.9 to 80.1
>20,000	60.3 to 83.9

a) Trying to get pregnant for at least six months.
b) Unmarried.

100 per cent, values should approach that level for a pregnancy test to be useful.

Participant accuracy was evaluated in relation to a variety of variables. Accuracy confidence intervals overlapped in all cases and the coefficient of mean square contingency was small[15] (Table 4). It is worth noting that results for participants who were under 21 years of age or had less than a high school education deviated the most from manufacturer claims.

Discussion

Manufacturers claim accuracy rates of 98–99 per cent for specimens collected (in one case) as early as six days after the missed menses.[9–11] This claim was not duplicated in this study, nor in other studies, of accuracies of the in-home kit clinical counterparts.[6–8] The proportion of false negative results concurs with a study done by Valanis.[12] The 56 per cent sensitivity obtained by the consumer for specimens collected is disconcerting, as prenatal care may be delayed and discontinuation of teratogenic substances postponed. The manufacturers urge women to test as early as six days after the expected menses. However, the sensitivity of these kits was demonstrated to be inadequate 27 per cent of the time for early detection, paralleling the results of clinically used kits tested by Bell.[6]

Manufacturers should be encouraged to reevaluate their claims. Accuracy would be improved by increasing the number of days a woman should wait before testing. Fewer false negative results were obtained with specimens collected later than nine days after the missed menses. If the manufacturers do not wish to change this parameter, then reagents with improved sensitivity should be prepared.

Another concern not previously discussed in the literature nor addressed by the manufacturer is specificity. One out of 10 specimens tested by the consumer in this study was identified to contain HCG, when in fact no hormone was present. This result could lead to a purposeless abortion procedure as well as psychological trauma for a woman who wants to be pregnant, thinks she is, and in reality is not.

Any number of factors can cause a false positive result, including vibration of the test tube, prolonged timing, presence of foreign material in the test system, or deteriorated reagents. In the clinical laboratory, a known control sample would be run parallel with test samples to monitor for errors. The consumer does not have this safeguard. Manufacturers should be urged to emphasize the vast sources of error in product literature as well as to include control samples with each test kit.

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