

## Qualitative Determination of Pregnancy by Home Pregnancy Test Kit: A Survey on Purchase and Use of Kits in Saudi Community

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**Abstract:** There is a general consensus that many users of the Home Pregnancy Test (HPT) kits do not have proper knowledge of the test kits, their proper use and hence end up with erroneous results. Hence, the present study on 120 (known users of HPT kit) attending a family clinic in Riyadh was undertaken to investigate the knowledge of purchase and use of the HPT kits, confidence in the test results, selection of a specific brand and the role of pharmacist's intervention to enhance the use and accuracy of the kits among the regular users who responded to the survey. The results obtained showed that majority of the users are ignorant of reasons for using HPT kits relevance of the kits as compared to the routine self reported testing; importance of early recognition of pregnancy; advantages and drawbacks of the kits; the existence of different brands of kits and their variations; confidence on the test results. It is concluded that brief intervention by education and consultation from a pharmacist can increase the utilization of HPT kits.

**Key words:** Pregnancy, test, kit, quality, determination, Saudi Arabia

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### INTRODUCTION

Detection of pregnancy at an early stage prompts women to take measures that can benefit the fetus as well as mother. The prenatal care includes avoiding harmful drugs, exertion and stress. The obese and diabetic pregnant can improve conditions of co-morbidity which are harmful for the fetus (Phillips, 2007). In detection of pregnancy, there are some symptoms (amenorrhea, nausea and vomiting, breast enlargement and tenderness, urinary frequency, fatigue, food cravings, bloating and constipation) which give an indication of a probable pregnancy (Sayle *et al.*, 2002). However, these signs are not sufficiently reliable to diagnose or exclude a definite pregnancy (Ramoska *et al.*, 1989).

The only one way to confirm the pregnancy for sure is by Home Pregnancy Test (HPT) kit. The HPT kits were introduced in the year 1975 and as of now over a dozen and a half different brands are available in the market. They are very popular and work by detecting human Chorionic Gonadotropin (hCG) in the urine using immunometric assay methods (Cole *et al.*, 2004). About 2 weeks after the conception, hCG is produced by the trophoblast cells of the fertilized ovum (blastocyst) and is available in the urine. The hormone can be detected when sufficient levels are available. The number of days after the last menses before a pregnancy test becomes positive depends on several factors including the day of implantation and the sensitivity of the test. The test is performed 7-10 days after missing the period in order to ensure minimal amounts of false negative tests. The HPT

kit involves placing urine on a prepared chemical strip and waiting for 1 or 2 min for the strip to show the result (Cole *et al.*, 2009).

The most common error with HPT kits is a negative result because of the timing of the performance of the test. Many users do not have any idea about the variability of the intervals between the cessation of menses, ovulation, fertilization, implantation and production of sufficient hCG. If the test is performed too soon after the expected onset of menses, the results might be erroneous (McChesney *et al.*, 2005). Furthermore, the accuracy of the test is greatly affected by the users' technique and interpretation. In a study on accuracy, Bastian *et al.* (1998) found that the test sensitivity was 91% when the urine samples were tested by the volunteers while the sensitivity was only 75% in studies where subjects were actual patients who used the HPT kit on their own urine samples. Although, the manufacturers of different brands claim their product to be 99% accurate, the accuracy of different brands is variable. The erroneous results are also possible when the subjects drink too much of water, use fertility drugs and/or suffer with some diseases like renal disease with elevated lipids, high immunoglobulin levels and low serum protein levels which can interfere with the test results. The present study for these drawbacks of HPT kits, the pharmacists are the best educators to guide the patients on the reliable brand, the timing of its use and the methods to use and when to not use the kits so that the results obtained are accurate (Nettleman *et al.*, 2009).

The common symptoms of pregnancy are not sufficient to diagnose or exclude pregnancy hence the

first test of pregnancy available is by HPT kit. The general consensus is that many users do not have any knowledge of test kits, their proper use and hence end up with erroneous results. The present study on Qualitative Determination of Pregnancy by Home Pregnancy Test Kit: A survey on purchase and use of kits in Saudi community was undertaken to assess the knowledge of HPT kits among the users and the role of pharmacist to enhance the utilization of the kit.

## MATERIALS AND METHODS

A Survey questionnaire on the use of Home Pregnancy Test (HPT) Kit were served to 120 women, attending a family clinic in Riyadh during the period 1st April to 30th September, 2010. All the respondents are known users of HPT kit and were in the reproductive age group with a mean age of 28 years. The survey consisted of five parts to assess the objectives of the study.

**Part 1:** Preliminary knowledge about the HPT kit (relevance of the kit, importance of early recognition of pregnancy, appropriateness of the use, scientific know how, disadvantages and quantitative test).

**Part 2:** Reasons for using the HPT kit (quick results, convenience, privacy, cost, accuracy).

**Part 3:** Determinant factors in selection of a specific brand (leaflet information in the packing, cost of HPT kit, recommendation of a friend, recommendation of the pharmacist, recommendation of other health professional).

**Part 4:** Confidence in the results (0-100% in the range of 1-24, 25-49, 50-74, 75-99).

**Part 5:** Role of pharmacist to enhance the importance of HPT kits (Provision of information on, suitable brand, ease of use, date of expiry, cost and storage of the kits, educate customers on importance of the kit, on timing and method of use).

## RESULTS AND DISCUSSION

**Preliminary knowledge:** Results on the preliminary knowledge of the respondents indicated that 25% of the respondents had the knowledge on the relevance of HPT kit as compared to the routine self reported testing. Another 20.83% knew the importance of early recognition of pregnancy and an equal percent of respondents knew the appropriate use of the kit. The percent of those who were familiar with the disadvantages of the kits was 16.67. Almost 90% of the respondents were ignorant in each of the two components (Table 1).

Table 1: Knowledge of the purchase and use of HPT-kit among the participants

Knowledge of HPT-kit*	No. of respondents who had the knowledge (n = 120)	Percentage
Knowledge on relevance of the HPT kit as compared to the routine self reported testing	30	25.00
Importance of early recognition of pregnancy	25	20.83
Appropriateness of use of the kit	25	20.83
Scientific know how	10	8.33
Knowledge of the disadvantages of HPT	20	16.67
Knowledge of the relevance of a quantitative test	10	8.33

\*HPT = Home Pregnancy Test

Table 2: Reasons for using the home pregnancy test kits

Reason for use	No. of respondents (n = 120)	Percentage
Quick results	58	48.33
Convenience	30	25.00
Both speed in obtaining results and convenience	41	34.12
Privacy	16	13.33
Cost	9	7.50
Accuracy	6	5.00

Table 3: Determinant factors in selection of a specific brand

Determinant factors	No. of respondents (n = 120)	Percentage
Packing leaflet information	5	4.17
Cost of the HPT kit	6	5.00
Recommendation of a family friend	14	11.67
Recommendation of the Pharmacist	50	41.67
Recommendation of other health professionals	25	20.83

Table 4: Percent confidence in test results

Confidence (%)	No. of respondents (n = 120)	Percentage
75-100	65	54.17
50-74	25	20.83
25-49	20	16.67
1-24	10	8.33
0	0	0.00

The percent respondents who preferred the kits for different reasons were as follows: quick results (48.33%), convenience (25.0%), both speed and convenience (34.12%), privacy (13.33%), cost (7.5%), accuracy (5.0%) (Table 2).

The determination of a specific brand of the HPT kit was based on the recommendation of a pharmacist (41.67%), other health professional (20.83%) and a family friend (20.83%). The cost of the kit (5.0%) and information on the packing insert (4.17%) were the least important factors (Table 3).

The confidence percent in the test results was as follows: Not even a single respondent (0%) had confidence in the use of HPT kit. The other confidence limits were 75-100% (65%), 50-74% (25%), 25-49% (20%) and 1-24% (10%) (Table 4). The percent compiled responses on information provided by pharmacists were variable (Table 5). Information on easy use of the kit with fewest steps was 81.67% while cost, storage and expiry date was 71.67%. Reliable and accurate brand of test kits was 65% and information on when to discard the kit after using was 43.33%.

Table 5: Role of pharmacists to enhance the importance of HPT kits

Role of pharmacist	No. of respondents (n = 120)	Percentage
Provide information on most reliable/accurate brand of test kits	78	65.00
Provide information on when to discard the kit, if used properly	52	43.33
Provide information on which kits have the fewest steps to get quick results	98	81.67
Cost, storage and expiry date	86	71.67

The results on preliminary knowledge of the respondents indicated that majority were ignorant about importance of the kits as compared to the routine self testing, relevance of early detection of pregnancy, appropriate use of the kit, the scientific know how, relevance of the quantitative tests and disadvantages of the kits. The response to questionnaires on reasons for using the HPT kit, determinant factors in selection of a specific brand, confidence in the results and role of pharmacist to enhance the importance of HPT kits have clarified the views of the respondents on status, utility and probable improvement of these kits.

Many respondents were of the opinion that the routine self testing observations based on the observations of the individual are sufficient enough to predict a positive pregnancy. However, the concept is refuted as it might give scope for negligence of the prenatal care. Although, the characteristic findings upon cessation of menses and the follow up of the observations are useful to help the clinician to distinguish normal pregnancy from coexistent disorders, it is argued that these findings are not very sensitive for a proper diagnosis (Ramoska *et al.*, 1989).

Early diagnosis of gestation may prompt women to seek prenatal care and to take measures that can benefit both fetus and the mother (Ventura *et al.*, 1999). The prenatal care includes avoiding harmful drugs, exertion and stress. The obese and diabetic pregnant can improve conditions of co-morbidity which are harmful for the fetus (Phillips, 2007). Awareness on appropriateness of the use of kit was lacking among most of the participants. Despite the presence of instructions contained in the manufacturers' leaflet, the majority of women are confused and are unable to perform the test properly. Actually, they do not wait till the end of the test and jump to conclusion that they are not pregnant or out of anxiety think they are pregnant. Errors in performing the tests lead to a false negative than a false positive and results in waste of money when out of curiosity; they want to repeat the tests (Smith *et al.*, 1988). According to their own experience, many returned to the pharmacies with a complaint that the kit is not working. The results confirmed that the majority of women have no idea as to how the HPT kits work.

Knowledge of the relation between ovulation and intercourse is very important especially when a sperm is known to live in the fallopian tube for 5 days waiting for the ovulation to occur. However, most of the respondents

had no awareness on the importance of timing. They were of the opinion that accuracy of the test is related to the act of intercourse. This revealed lack of scientific knowledge about the relation of ovulation and intercourse. The timing to perform the test is very significant as it results in negative results if the test is performed much earlier to the expected onset of menses. Unfortunately, the respondents have less information about the significance of ovulation and timings to perform the test.

HPT kits are more sensitive than many pregnancy kits used in laboratories or health centers (Wheeler, 1999). Although, these kits are accurate (<77%), they do not show the quantitative development of the pregnancy. The quantitative tests in the laboratory show increase in the concentrations of hCG during the first 30 days after confirmation of the pregnancy (Cole *et al.*, 2009). The present study found that the respondents were not conscious of the difference between the conduct of tests by HPT kits and laboratory tests. There are many drawbacks of the HPT kits for example if the test is not done correctly or done too early, the result can be inaccurate. The cost of retests would increase due to less confidence and false negative and/or false negative tests. A false negative result may put off the consumer to see a physician and take appropriate steps on time. The present study showed lack of realization of the disadvantages of HPT kits among the respondents.

The consumers' preference for HPT kits as it is evident from the reply to the questionnaire, stems from the factors including speed of obtaining results, privacy and convenience of the test. A report in the literature confirms similar reasons for preference of the HPT kits (Cole *et al.*, 2004). Furthermore, it is very convenient to obtain the kits, they are available in any pharmacy at low cost as easy as condoms and the test does not involve the exposure of the user who prefers privacy. The results are virtually immediate in addition to privacy. The test is known to provide accurate diagnosis and an opportunity to start prenatal care (Cole *et al.*, 2004).

Manufacturers of HPT kits are continually introducing new products and modifying current products to more user friendly versions (Munroe, 1994). In this process of changing and updating, there have been a number of commercial products introduced into the market. As of now, the different brands of the kits have

increased to >20 in Saudi markets. All the manufacturers continue to report their kit as being >99% accurate (Butler *et al.*, 2001). Nevertheless, studies conducted on accuracy of the available brands showed the accuracy to be between 45.7-89.1% (Doshi, 1986; Anonymous, 2003). This confirms the variability in accuracy of different brands. The results of present study showed that the consumers depend on pharmacists for the knowledge of superiority of brands of kits.

The questionnaire on confidence of the respondents for use of the HPT kits revealed very few to be confident about the technique and interpretation. The respondents were found to have less knowledge about the accurate use of the kits. In a review of five studies from 1997 that reviewed 16 HPT kits, Bastian *et al.* (1998) illustrated that the accuracy of HPTs is affected by the users' technique and interpretation. The deficiency of knowledge and expertise could be the major reasons for the lack of confidence among the users.

The HPT kits may be convenient and economical but have limitations. Since most of the participants were laywomen, they needed adequate education and training to appropriately conduct the test. Most of the respondents were found to be ignorant of the selection of a proper kit, conduct of the test, confirmation of the result, timing of pregnancy recognition and the timing of prenatal care. The intervention by pharmacist can increase utilization of HPT kits among women. Pharmacists can help educate consumers and clinicians.

### CONCLUSION

The results obtained in this study revealed that majority of the respondents were ignorant about importance of the kits for early detection of pregnancy, appropriate use, scientific know how and disadvantages. The response to questionnaires has clarified the views of the respondents on status, utility and probable improvement of these kits. The role of the pharmacists is stressed to improve the utilization of HPT kits. Since, there is gross variation between the claims of the manufacturers and the accuracy of the results, it is suggested that the HPT kits should be subjected to rigorous analytical controls and evaluated by a panel of potential users before being released on the market. The manufacturers should be requested to emphasize the vast sources of errors in product literature.

### ACKNOWLEDGEMENT

The efforts of Ms. Sarah A. Salah, Pharmacist are acknowledged in data collection.

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