The Egyptian Fertility Care Foundation

And

Family Health International

Validation of the Pregnancy Checklist
In Selected Egyptian Family Planning Centers

Final Report

June 2005

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Acknowledgment

The Egyptian Fertility Care Foundation (EFCF) and Family Health International (FHI) would like to extend sincere thanks to Dr. Yehia El-Hadidy, Undersecretary and Head of the Population Sector, Ministry of Health and Population for his support, assistance, and approval to conduct the study.

Thanks are also due to USAID for providing Financial Support to conduct the study.

Lastly, the Foundation would like to thank its Technical team, the researchers and the clients for their collaboration and efforts in conducing the study.

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Key to Abbreviations

COCs	Combined oral contraceptives
EFCF	Egyptian Fertility Care Foundation
FHI	Family Health International
FP	Family Planning
FP/RH	Family Planning / Reproductive Health
HCG	Human Chorionic Gonadotrophin
IUD	Intra Uterine Device
MOHP	Ministry of Health and Population
SPSS	Statistical Package for Social Sciences
USAID	United States Agency for International Development

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Executive Summary

Family planning providers have a responsibility to ensure – with a reasonable degree of certainty -- that FP clients are not pregnant before prescribing a contraceptive. In an attempt to reduce medical barriers for starting contraceptives, The Egyptian Fertility Care Foundation conducted a descriptive study to validate the pregnancy checklist developed by Family Health International. The checklist is based on WHO "selected practice recommendations for contraceptive use" stating that service providers may be reasonably certain that clients are not pregnant by responding to a series of six questions and consideration of symptoms and signs suggestive of pregnancy.

The study was carried in one Teaching Hospital in Cairo Governorate, four primary health care centers in Giza Governorrate and two University Hospital FP clinics in Dakahlia and Menya Governorates. One thousand and thirteen FP clients were recruited nearly equally distributed between the seven centers. An exit interview was conducted with consenting women during which, a questionnaire was filled that provided information about their socio-demographic characteristics and answers to the checklist questions translated to the Arabic language. After that, a sensitive immunochromatographic pregnancy test was performed for each client.

Data were analyzed to compare the results of the checklist with those of the pregnancy test for the purpose of ruling out pregnancy. One shortcoming of the study is that the pregnancy test was carried out at the time of filling the checklist irrespective of the time since last menstruation. It was not repeated later so as to diagnose possible already existing pregnancy too early to be diagnosed by the first pregnancy test.

The main results providing information to help validation of the checklist varied slightly whether they were based on answers to the six questions or after addition of those of symptoms suggestive of pregnancy:

	Without considering symptoms suggestive of pregnancy	Considering symptoms suggestive of pregnancy
Sensitivity	88%	96%
Specificity	83.2%	59.4%
Positive predictive value	11.7%	5.6%
Negative predictive value	99.6%	99.8%
False negative results	0.4%	0.1%
False positive results	88.3%	94.3%

Adding the results of symptoms suggestive of pregnancy to the six checklist items increased the checklist sensitivity and the false positive results, decreased specificity, positive predictive value and false negative results but did not change the negative predictive value.

Overall, the validity of the checklist was high as measured by high sensitivity (88%) and high specificity (83.2%). It performed well for ruling out pregnancy as in 99.6% of cases, the checklist was correct when it suggested that the woman was not pregnant.

In low resource settings, where pregnancy tests are not available, and where women should not leave a family planning clinic without an effective method, the programmatic effectiveness of the checklist will be high, given that providers can be reasonably sure a women is not pregnant, if the checklist so indicates.

Institutional Profiles

The Egyptian Fertility Care Foundation is a non-profit non-governmental organization, registered in the Ministry of Social Affairs in the year 2003. Its mission is to promote women's health in general and Reproductive Health in particular. The Egyptian Fertility Care Foundation has close ties with all the Egyptian Universities, Teaching Hospitals and research institutes and work closely with the Egyptian Society of Gynecology and Obstetrics.

The Foundation responds to the research needs of The Ministry of Health and Population, The National Population Council, and to all National and International Research Organizations, assisting in both formulation of policy plans and upgrading Reproductive Health services in the country.

The Egyptian Fertility Care Foundation remains loyal to the belief that it can contribute to the future that is encapsulated in this vision and will continue to do so in the challenging years ahead.

Family Health International (FHI) is dedicated to improving lives, knowledge and understanding worldwide through a highly diversified program of research, education and services in family health. Since 1971, FHI has worked with governments and communities to meet the public health needs of some of the world's most vulnerable people. FHI has offices in 38 countries and manages research and field activities in more than 70 countries. Working with a wide variety of partners such as EFCF, FHI helps countries and communities to:

- Improve people's access to quality reproductive health services, especially safe, effective, and affordable family planning methods
- Prevent the spread of HIV/AIDS and sexually transmitted infections and care for those affected by them
- Improve the health of women and children, especially those who live in resource-constrained settings

INTRODUCTION

This study was carried out by the Egyptian Fertility Care Foundation and FHI in an attempt to reduce medical barriers for contraceptive use. Its aim is to validate the pregnancy checklist developed by Family Health International to help service providers be reasonably sure that FP clients are not pregnant before starting a contraceptive method.

Family planning service providers have a responsibility to ensure - with a reasonable degree of certainty - that family planning clients are not pregnant before they receive the chosen contraceptive method. The reason, of course, is the fear that contraceptives might harm an unrecognized pregnancy or that the pregnancy may be considered as a contraceptive failure.[1]

The current standards of practice for FP/RH services in Egypt allow for starting contraceptive methods only to women while they are menstruating. Starting a contraceptive after the end of menstruation is allowed only under special conditions or exceptional circumstances. Many providers consider that menstrual bleeding is the only sure way to know that a woman is not pregnant. Thus, they advise clients who present for family planning services when they are not bleeding to wait for the occurrence of menstruation before being prescribed a contraceptive. Other providers will trust the results of a pregnancy test (or sometimes two pregnancy tests), and still others will attempt to induce menstrual bleeding by the administration of oral contraceptive pills or hormone combinations. Finally, some providers may rule out pregnancy simply by history taking and clinical examination.

Because some women may seek contraceptive services during the postpartum period, during lactation amenorrhea, or sometimes in the interval between

[1] Inserting an IUD during pregnancy may terminate the pregnancy. However, there is no evidence, that accidentally providing a hormonal method to a pregnant woman will harm the fetus.

normal menstrual periods, ruling out pregnancy is often difficult. Clients who are sent home to await menses, those required to return for a second pregnancy test, or those who have their menstruation induced may not be adequately protected from pregnancy before returning to the clinic. As well, for some clients, visiting the clinic again presents financial, logistic, or other hardships.

The World Health Organization " Selected Practice Recommendations For Contraceptive Use " states that the diagnosis of pregnancy is important. However, the ability to make this diagnosis early in pregnancy will vary depending on the resources and settings. Highly reliable biological pregnancy tests are often extremely useful, but not available in many areas. Pelvic examination, where feasible, is reliable at approximately 8-10 weeks since the first day of the last menstrual period. It adds that the provider can be reasonably certain that the woman is not pregnant if she has no symptoms or signs of pregnancy and meets any of the following criteria:

- Has not had intercourse since last normal menses.
- Has been correctly and consistently using a reliable method of contraception.
- Is within the first 7 days after normal menses.
- Is within 4 weeks postpartum for non-lactating women.
- Is within the first 7 days postabortion or miscarriage.
- Is fully or nearly fully breast feeding, amenorrhoeic and less than six months postpartum.

Family Health International had translated this statement into a checklist to be used by service providers.

The aim of the present study is to test the validity of the checklist developed by Family Health International.

METHODOLOGY

Study design

This is a descriptive study that was conducted over a period of six months.

First, EFCF obtained the approval of the Undersecretary for Population and Family Planning, MOHP for the conduct of the study. Selection of study sites ensured representation of Upper and Lower Egypt governorates. Four governorates were selected in coordination with MOHP officials namely; Cairo, Giza, Dakahlia, and Menya. Within these governorates, seven sites were included to represent MOHP primary health care centers, Teaching Hospitals, as well as University Hospitals. These clinics were selected according to the highest caseload of family planning clients as guided by the Ministry of Health and Population records and the findings of the previous study conducted to estimate the Caseload of family planning clients who were denied a contraceptive method due to absence of menstruation in selected Egyptian health centers

Study sites

- Cairo governorate: El-Galaa Teaching Hospital
- Giza governorate: Embaba, MCH Center
  Warrak, Primary health care center
  South Giza, MCH Center
  Saft El-Laban Primary health care Center
- Dakahlia Governorate: Mansoura University hospital, Family Planning Clinic
- El-Menya Governorate: Menya University Hospital, Family Planning Clinic

Data collection tool

A questionnaire was prepared (Appendix 1) to record selected socio-demographic characteristics, menstrual status, the checklist questions, symptoms suggestive of pregnancy, the service received by non-menstruating clients and the result of the pregnancy test.

The checklist questions were translated to Arabic, (Appendix 2) field tested to ensure that the questions are clearly understood, then the questions were translated back to English by another translator to ensure accurate translation before being included in the questionnaire. Again, the questionnaire was pre-tested before finalization, to obtain feedback from a sample of Family Planning clients and service providers about:

- Whether clients clearly understand the questions and the wording
- Acceptability of clients to answer the stated questions
- Time needed to fill the form

During field-testing, difficulty was encountered in understanding the question about “having sexual relations since last menstruation” because it is put in a negative format. Thus, a question was added in an affirmative way to validate the response to that question. As well, some difficulties were encountered in answering and recording the composite question on “having a child delivered since less than 6 months”. However this was overcome by intensive training of data collectors.

Inclusion Criteria

(1) Clients not using a contraceptive method and presenting to the family planning center requesting a method for family planning.
(2) Free from menstrual bleeding.
(3) Whether lactating or not.
(4) At any time post partum or post abortion.

An exit interview was conducted with each client after receiving the service. The questionnaire was filled and a pregnancy test was performed for those who consented to participate in the study (Appendix 3).

The pregnancy test used is a simple rapid test based on an immunochromatographic technique with sensitivity down to 20 HCG units per liter.

Choice and training of data collectors

Data collectors were physicians and nurses working in the selected family planning clinics. A total of fourteen were identified, one physician and one nurse from each clinic. In addition, one field supervisor was assigned to each center to facilitate data collection activity and to ensure day-to-day monitoring.

A one-day training course was conducted for data collectors at EFCF headquarters (Appendix 4). The didactic and the practical training was attended by all data collectors and supervisors. Participants were introduced to the study and its objectives followed by a presentation on ethical considerations in research. The trainers explained the data collection tool in details after which a role-play on filling of forms was conducted. Participants were also trained on performing and interpretation of the pregnancy test. An Arabic data collection guide was prepared for the training and distributed to researchers involved in the data collection activity. This guide explained the process of filling the forms, as well as the job description for data collectors and supervisors.

Data collection

Over a period of three months 15th January to 15th April 2005, 1013 consenting clients meeting the inclusion criteria were enrolled in the study. The questionnaire was filled and a pregnancy test was performed for each client.

The research sites were visited on a weekly basis by the principal investigator and the project officer to monitor the quality of data collection. During these visits, all forms were reviewed and checked for accuracy and completeness. Forms were regularly sent to EFCF on weekly basis where they were checked by the data management staff before data entry.

Data Management and analysis

Forms received at EFCF were manually cleaned and double entered on SPSS (version 11) software in two separate files by two different persons. Data were later checked using the VALIDATE program of EPI - INFO version 3.3.

Further data cleaning was carried out before starting data analysis.

Results were reported approximated to the nearest first decimal.

Study limitation

The pregnancy test was carried out at the time of filling the form that included the checklist questions irrespective of the time since last menstruation. It was not repeated after sometime so as to diagnose possible already existing pregnancies that may have not been detected by the first test.

FINDINGS

(Table 1): Distribution of the study population by center

Center	Number	Percent
Cairo Governorate		
El Galaa Teaching Hospital	129	12.7
Giza Governorate (Total)	**577**	**57.0**
Warrak (MOHP) FP Center	135	13.3
Saft El Laban (MOHP) FP Center	148	14.6
South Giza (MOHP) FP Center	148	14.6
Embaba (MOHP) FP Center	146	14.4
Dakahlia Governorate		
Mansoura University Hospital	172	17.0
Menya Governorate		
Menya University Hospital	135	13.3
Total	**1013**	**100.0**

The study was conducted in seven centers located in four governorates, namely Cairo and Giza representing greater Cairo, Dakahlia representing Lower Egypt, and Menya to represent Upper Egypt. The family planning clinics included in the study centers serve clients from both urban and rural populations. Over the three months period of data collection, a total of 1013 family planning clients were included in the study.

Table (1) describes the distribution of those clients recruited from the seven study centers in the four governerates. It shows that 57.0% of the sample was from the four centers in Giza governorate while the rest were nearly equally distributed between Cairo, Dakahlia, and Menya (12.7%, 17.0%, and 13.3% respectively).

Table (2): Socio – Demographic characteristics of study sample

Characteristic	Cairo		Giza		Dakahlia		Menya		Total	
	N	%	N	%		%	N	%	N	%
Residence										
Urban	107	82.9	531	92.0	79	45.9	85	63.0	802	79.2
Rural	22	17.1	46	8.0	93	54.1	50	37.0	211	20.8
Age group										
< 20	6	4.6	33	5.7	7	4.1	13	9.6	59	5.8
20-39	118	91.5	524	90.8	139	80.8	118	87.4	899	88.7
40+	5	3.9	20	3.5	26	15.1	4	3	55	5.4
Education										
Illiterate	19	14.7	156	27.0	44	25.6	40	29.6	259	25.6
Primary	19	14.7	83	14.4	34	19.8	19	14.1	155	15.3
Preparatory/ secondary	76	59	280	48.5	77	44.8	63	46.7	496	49.0
University	15	11.6	58	10.1	17	9.8	13	9.6	103	10.2
Occupation										
Housewife	111	86	529	91.7	134	77.9	99	73.3	873	86.2
Working for Cash	18	14	48	8.3	38	22.1	36	26.7	140	13.8
Number of living Children										
0-3	87	68.2	392	67.9	98	57.0	75	55.6	653	64.5
> 3	41	31.2	185	32.1	74	43.0	60	44.4	360	35.5
Total	**129**	**100**	**577**	**100**	**172**	**100**	**135**	**100**	**1013**	**100**

Table (2) describes the socio-demographic characteristics of family planning clients in the different governorates.

Clients mostly reside in urban settings (79.2%). The majority (88.7%) was in the age group 20-39 years. However, the percentage of <20 years was higher among Menya population and that > 40 years was higher among Dakahlia population.

The illiteracy rate was (25.6%) among the study population. It was highest in Menya (29.6%) and lowest in Cairo (14.7%), About half (49%) of the study population had preparatory / secondary education, and 10.2% were university graduates.

Women were mostly housewives (86.2%). Unexpectedly, the highest percentage of women working for cash was in Menya (26. %7) followed by Dakahlia (22.1%).

Only one woman had no children and about one third of the clients (35.5%) had more than three children.

Table (3): Distribution of clients according to the desired family planning method

Desired Method	Cairo		Dakahlia		Menya		Giza		Total	
	N	%	N	%	N	%	N	%	N	%
I U D	89	69.0	102	59.3	49	36.3	318	55.1	558	55.1
Injectables	11	8.5	9	5.2	48	35.6	59	10.2	127	12.5
Ocs	13	10.1	13	7.6	18	13.3	47	8.2	91	9.0
Implants	13	10.1	12	7.0	6	4.4	3	0.5	34	3.4
No choice	3	2.3	36	20.9	14	10.4	150	26.0	203	20.0
Total	**129**	**100**	**172**	**100**	**135**	**100**	**577**	**100**	**1013**	**100**

Table (3) shows that more than half (55.1%) of the clients requested an IUD, followed by injectables (12.5%), oral contraceptive pills (9%) and 3.4% requested Implants. However, one fifth (20%), did not request a specific contraceptive.

Table (4): Distribution of Clients by lactation status.

Governorate	Lactating		Non lactating		Total	
	N	%	N	%	N	%
Cairo	123	95	6	5	**129**	**100**
Dakahlia	106	62	66	38	**172**	**100**
Menya	109	81	26	19	**135**	**100**
Giza	489	85	88	15	**577**	**100**
Total	**827**	**81.6**	**186**	**18.4**	**1013**	**-**

Table (4) shows that (81.6%) of clients were lactating. This percentage was highest (95%) among clients who attended the Cairo center (El-Galaa Hospital). About one Fourth (24%) of lactating clients delivered since 40 days or less.

Table (5): Distribution of clients according to their menstrual characteristics

Characteristic	Cairo		Dakahlia		Menya		Giza		Total	
	N	%	N	%	N	%	N	%	N	%
Intermenstrual	1	0.8	61	35.5	22	16.3	72	12.5	156	15.4
Breast feeding and Amenorrhea	112	86.8	55	32.0	86	63.7	363	62.9	616	60.8
Breast feeding and spotting / Bleeding	11	8.5	51	29.7	22	16.3	132	22.9	216	21.3
Recent Abortion	5	3.9	4	2.3	5	3.7	6	1.0	20	2.0
Not lactating and amenorrhoeic *	-	-	1	0.6	-	-	4	0.7	5	0.5
Total	**129**	**100**	**172**	**100**	**135**	**100**	**577**	**100**	**1013**	**100**

* Recent neonatal death and did not menstruate yet.

Table (5) demonstrates the distribution of family planning clients according to their menstrual characteristics. The majority (60.8%) were breast-feeding and amenorrhoeic. About one fifth of the clients (21.3%) were breastfeeding and encountering some spotting/bleeding. On the other hand, 15.4% were menstruating but presenting at a time other than the menstrual phase.

Four cases encountered recent neonatal death and did not menstruate yet. They were recorded as non-lactating and amenorrhoic.

An unusually large proportion (35.5%) of clients in the family planning clinic at Mansoura University Hospital presented for services between two normal periods (intermenstrual). Researchers attribute this finding to the lower percentage of breast feeding clients among their study population.

Table (6): Distribution of clients according to encountered symptoms suggestive of pregnancy

Symptoms*	Cairo		Dakahlia		Menya		Giza		Total	
	N	%	N	%	N	%	N	%	N	%
Nausea	3	2.3	5	2.9	00	00	80	13.9	88	8.7
Vomiting	5	3.9	1	0.6	00	00	20	3.5	26	2.6
Sleepy	3	2.3	4	2.3	1	0.7	56	9.7	64	6.3
Frequency of micturition	9	7.0	4	2.3	8	5.91	176	30.5	197	19.4
**Any symptom	19	6.0	10	3.1	9	3.8	280	88	318	31.4
No symptom	111	86.0	162	94.2	126	93.3	298	51.6	697	68.8

* Some had more than one symptom

** This row is not included in the total

Table (6) shows the incidence of symptoms suggestive of pregnancy among the studied population. About two thirds of the clients (68.8%) had no such symptoms, while 19.4% had frequency of micturition, 8.7% complained of nausea, 6.3% from feeling sleepy and 2.6% complained of vomiting. About one third of the studied population (31.4 %) complained of at least one symptom.

Table (7): Distribution of clients according to the result of the pregnancy test

Result of Pregnancy test	Cairo		Dakahlia		Menya		Giza		Total	
	N	%	N	%	N	%	N	%	N	%
Positive	1	0.8	7	4.1	00	00	17	2.9	25	2.5
Negative	128	99.2	165	95.9	135	100	560	97.1	988	97.5
Total	**129**	**100**	**172**	**100**	**135**	**100**	**577**	**100**	**1013**	**100**

Table (7) shows that the pregnancy test was positive in 2.5% of the studied population. The percentage was highest (4.1%) in Dakahlya and no test was positive in Menya governorate.

Table (8): Relation between symptoms suggestive of pregnancy and the presence of Pregnancy as determined by the pregnancy test

Signs and Symptoms*	n	% Who were pregnant
Sleepy	64	10.9
Vomiting	26	15.4
Nausea	88	9.1
Frequency of micturition	197	4.1
Any symptom	318	5.3
No symptoms	696	1.1

Table 8 shows that only 5.3%of women having any of the symptoms suggestive of pregnancy, turned to be pregnant as determined by the pregnancy test. The percentage was 15.4 for vomiting, 10.9 for feeling sleepy, 9.1 for nausea and 4.1 for frequency of micturition. Out of 696 women who had no such symptoms, only 1.1% turned to be pregnant.

It is of interest to note that those symptoms are not specific for pregnancy. Their prevalence may vary among different populations according to the "burden of disease" in different communities. It may also depend on how clients are interrogated and whether they are asked specifically about each symptom-as happened in the present study- with the possibility of false positive answers.

Table (9): Differential of selected client characteristics with a positive pregnancy test

Variable	Positive preg. tests	% of category	P. Value
Age			
> 20	2	3.4	
20-39	23	2.6	0.73
40+	0	0.0	
Residence			
Rural	4	1.9	0.509
Urban	21	2.6	
Number of Children			
< 3	16	2.5	0.964
3+	9	2.5	
Educational Status			
Educated	17	2.3	0.48
Illiterate	8	3.1	
Working Status			
House wife	22	2.5	0.777
Working for cash	3	2.1	
Lactation Status			
Lactating	11	1.3	0.002 **
Non -lactating	14	7.7	

** Statistically significant

The difference between the numbers having a positive or a negative pregnancy test in different categories was not significant except with lactation status.

Table (10): The percentage of clients having a positive pregnancy test among groups with different menstrual characteristics

Characteristic	Number	Number with positive pregnancy test	Percentage
Intermenstrual	156	11	7.1
Breast feeding and Amenorrhea	616	2	0.3
Breast feeding and spotting / Bleeding	216	9	4.2
Recent Abortion	20	2	1.0
Not lactating and amenorrhoic	5	1	20.0
Total	**1013**	**25**	**2.5**

Table (10) shows the percentage of women with a positive pregnancy test among groups with different menstrual characteristics.

The highest percentage was among the non-lactating amenorrhoeic group (20%), followed by the intermenstrual (7.1%), then among the group that encountered some sort of bleeding during lactation (4.2%). It was least among breast-feeding amenorrhoeic women (0.32%).

Comparing the intermenstrual with the breastfeeding and amenorrhoeic women, the difference was statistically significant (0.001).

Table (11): Comparison between the results of the checklist six questions and the pregnancy test [Not considering symptoms suggestive of pregnancy]

Check list	Pregnancy Test positive		Pregnancy Test negative		Total	
	N	%	N	%	N	%
Checklist suggests not being pregnant	3	* 0.4	822	99.6	**825**	**100**
Checklist suggests may be pregnant	22	11.7	166	** 88.3	**188**	**100**

* False negative

** False positive

Table (11) shows that the checklist has a very high negative predictive value as 99.6% of women diagnosed as not pregnant by the checklist had a negative pregnancy test. In other words, if the checklist suggests the woman is not pregnant, it is correct 99.6% of the time.

Table (12): Comparison between the results of the checklist and the pregnancy test

[After addition of symptoms suggestive of pregnancy]

Check list	Pregnancy Test positive		Pregnancy Test negative		Total	
	N	%	N	%	N	%
Checklist suggests not being pregnant	1	* 0.1	587	99.6	**588**	**100**
Checklist suggests may be pregnant	24	11.7	401	** 94.3	**425**	**100**

* False negative

** False positive

Table (12) shows that after addition of the presence of one or more pregnancy symptoms to the six items in the checklist, the false negative results were 0.1% and the false positive 94.3%.

Table (13): Validity of the checklist

Statistical value	Without symptoms suggestive of pregnancy	Adding symptoms suggestive of pregnancy
Sensitivity	88%	96%
Specificity	83.2%	59.4%
Positive predictive value	11.7%	5.6%
Negative predictive value	99.6%	99.8%
False negative results	0.4%	0.1%
False positive results	88.3%	94.3%

It can be seen from table 13 that addition of the symptoms suggestive of pregnancy to the six items of the checklist increased its sensitivity but reduced its specificity. It increased the positive predictive value but did not change the negative predictive value. Lastly, it reduced false negative results but increased the false positive results.

Table (14): Sensitivity and specificity of individual questions of the checklist

Checklist Questions	Sensitivity	Specificity	Positive predictive value	Negative predictive value
Did you have a baby less than 6 months ago, are you fully or nearly-fully breastfeeding, and had no menstrual period since then?	99.8% (99.6-100%)	6.8% (4.3-9.3%)	66% (63-69%)	96% (88-100)
Have you abstained from sexual intercourse since your last menstrual period?	99.4% (98.6-100%)	3.4% (2.1- 4.7%)	34.5% (31.5-37.5%)	92% (86.6-97.4%)
Did your last menstrual period start within the past 7 days?	100%	2.6% (24 -27.9%)	8.7% (6.94-20.2%)	100%
Have you had a baby in the last 4 weeks?	100%	2.5% (1.5-3.5%)	1.4% (0.6-2.2%)	100%
Have you had a miscarriage or abortion in the last 7 days?	100%	2.5% (1.4-3.6%)	0.3% (26.6-33.4%)	100%
Have you been using a reliable contraceptive method consistently and correctly?	100%	2.5% (1.5-3.5%)	1% (0.4-1.6%)	100%

Table (14) shows that individual questions had a high sensitivity and negative predictive values but low specificity. The first “composite question” had the highest positive predictive value.

Table (15): Comparison between Egypt and Kenya validation study

	* Egypt	** Kenya
Sample size	1013	1852
Post partum and lactating	24%	59%
Recent abortion	2%	4%
Intermenstrual clients	15.4%	37%
Checklist suggests not being pregnant	81.4%	88%
Pregnancy detected by the Pregnancy test	2.5%	1%
Sensitivity of the checklist	88%	64%
Specificity of the checklist	83.2%	89%
Positive predictive value of the checklist	11.7%	6%
Negative predictive value of the checklist	99.6%	>99.5%
False negative	0.4%	0.4%

* Without addition of symptoms suggestive of pregnancy.

** Kenya study used a dipstick pregnancy test, while Egypt study used an immunochromatographic test with sensitivity down to 20 HCG IU / liter.

Table (15) compares the results of a pregnancy checklist validation study conducted in Kenya and the present study. Inspite of some differences, the results of the two studies were identical as regards the negative predictive value and the false negative results.

CONCLUSION

- The Validity of the checklist even without considering symptoms suggestive of pregnancy is high as measured by high sensitivity (88%) and high specificity (83.2%).
- Taking into consideration the study limitation, the false negative results for the checklist is very low (0.4%) thus there is a 1/250 chance that relying on the checklist will result in providing a FP method to a pregnant woman.
- This chance is further reduced to 1/1000 if symptoms suggestive of pregnancy are also considered.
- In low-resource settings where pregnancy tests are not available and where women should not leave a family planning clinic without an effective method, the programmatic effectiveness of the checklist will be high, given that providers can be reasonably sure a woman is not pregnant, if the checklist so indicates.

Appendices

Appendix (1)

Ministry of Health and Population

The National Egyptian Fertility Care Foundation

Validation of Pregnancy Checklist

Serial Number To be recorded by the statistician
……

(1) Name of Center ☐ Galaa ☐ Mansoura ☐ Menia ☐ Warrak ☐ Saft El-Laban ☐ South Giza ☐ Embaba

(2) Form Serial Number ☐☐☐

Day Month Year

(3) Date of interview ☐☐ ☐☐ ☐☐

(4) Age (completed years) ☐☐

(5) Number of living children ☐

(6) Education ☐ Illiterate ☐ Read / Write or primary ☐ High school/Diploma ☐ University

(7) Occupation ☐ Housewife ☐ Work for cash

(8) Desired family planning method ☐ Pills ☐ IUD ☐ Injectables ☐ Implants ☐ Other (Specify) ……

If no desire for a specific method, record 9

(9) Do you breastfeed at the present time ☐ Yes ☐ No

(R) Did you have sexual intercourse after your last menses ☐ Yes ☐ No

(10) Menstruation (choose only one)		Day	Month	Year
☐	Menstruate, but not menstruating now … Date of Last menstruation	☐☐	☐☐	☐☐
☐	Breast feed and do not menstruate…Date of last labor	☐☐	☐☐	☐☐
☐	Breast feed and bleed → Date of last bleeding	☐☐	☐☐	☐☐
	Breast feed and bleed → Date of last live birth	☐☐	☐☐	☐☐
☐	Recent Abortion — Date of last abortion	☐☐	☐☐	☐☐

Pregnancy checklist

	Yes	No
(0) Do you think you may be pregnant now?	☐	☐
(11) You did not have sexual intercourse since your last menstruation?	☐	☐
(12) Did your last menstrual start within the past seven days?	☐	☐
(13) Have you had an abortion in the last seven days?	☐	☐
(14) Have you had a delivery within the last four weeks?	☐	☐
(15) Did you deliver a baby since less than six weeks? **And had no menstruation since delivery?** **And fully or nearly fully breast-feeding?**	☐	☐
(16) Have you been using a reliable contraceptive method consistently and Correctly?	☐	☐

(17) Do you feel any of the following symptoms:

☐ Nausea ☐ Vomiting ☐ Sleepy

☐ Frequency of micturition

(18) The service provided to the client

☐ Advised to return home and come back during menstruation

☐ Prescribed a temporary contraceptive method and advised to come back during menstruation

☐ Prescribed a method to induce menses ☐ Pills ☐ Injections

☐ Had a method ☐ Pills ☐ IUD ☐ Injections ☐ Other (specify)……

(19) Result of the pregnancy test ☐ Negative ☐ Positive

Appendix (2)

Arabic Translated Pregnancy checklist

استبيان تشخيص الحمل

	نعم	لا
(1) محصلش جماع مع جوزك من اخر مرة كانت عليكى العادة الشهرية ؟	☐	☐
(2) آخر عادة شهرية جات لك ابتدأت خلال السبعة أيام اللى فاتت؟	☐	☐
(3) انتى سقطتى (أجهضتى) خلال السبعة أيام اللى فاتت؟	☐	☐
(4) انتى ولدتى خلال الاربع اسابيع اللى فاتت؟	☐	☐
(5) • انتى ولدتى من اقل من 6 شهور؟	☐	☐
• والعاده الشهرية مجتلكيش من ساعة ما ولدتى ؟		
• وبترضعى رضاعة كاملة ؟		
(يعنى ما بتساعديش بأى لبن أو أكل من بره أو بتساعدى مرات قليله)		
(6) انتى بتستعملى وسيلة أكيدة لمنع الحمل بالطريقة الصحيحة وبانتظام؟	☐	☐

• والعاده الشهرية مجتلكيش من ساعة ما ولدتى ؟
• وبترضعى رضاعة كاملة ؟
• (يعنى ما بتساعديش بأى لبن أو أكل من بره أو بتساعدى مرات

Appendix (3)

Consent Form

دراسة استبيان تشخيص الحمل

إقرار للموافقة علي الاشتراك في الدراسة:

أنا اسمي..... وبأشتغل في الوحدة وبنعمل دراسة في العيادة دي وعدد من العيادات الثانية الهدف منه هو تحسين خدمات تنظيم الأسرة ومساعدة السيدات في معرفة إذا كانت حامل ولا لأ من غير عمل تحليل لاختبار الحمل وده عن طريق مجموعة من الأسئلة.
ولو وافقت علي الاشتراك في البحث ده حا اسألك مجموعة من الأسئلة الخاصة بصحتك الإنجابية .

وأحب ان أؤكد ليكي إن ما فيش أي ضرر واقع عليكي من اشتراكك معانا في البحث بالإضافة إلى إن كل البيانات اللي راح تقوليها في البحث سرية تماما ومفيش حد حايعرفها غير اللي اشتغلوا في الدراسة واسمك لن يتم ذكره أبدا في أي مرحلة من المراحل.

وأحب أؤكد إن اشتراكك في البحث ده اختياري ، ياعني ممكن توافقي أو ترفضي، بس مشاركتك معانا حاتساعد الأطباء في تقدير مدي كفاءة الطريقة الجديدة " استبيان تشخيص الحمل" وده حايساعد الكثير من السيدات اللي ماعليهمش الدورة وعايزين يستخدموا وسائل منع الحمل.

هل عندك أي استفسارات أخري؟

هل توافقين علي الاشتراك في هذا البحث؟

- **لا توافق علي المقابلة** ← **أشكر السيدة علي ما أخذته من وقتها وانهي المقابلة**
- **توافق علي المقابلة** ↓

- **هل نستطيع أن نبدأ الآن؟**
- **هل هذا المكان مناسب أو تحبي نروح مكان آخر؟**

الاسم: **الإمضاء:**

Appendix (4)

Validation of the pregnancy checklist

Training On Data Collection Activity

Site of training: Egyptian Fertility Care Foundation Headquarters
Duration: one day
Date: 10 January, 2005

Agenda:

10 :00– 10:30	Welcome and Introduction of participants	Prof. Ezzeldin Osman Dr. Hala Eldamanhoury
10:30 – 11:00	Introduction to study and objectives	Dr. Hala Eldamanhoury
11:00 – 12:00	Ethical considerations in conducting research	Prof. Ezzeldin Osman
	How to fill the consent form	Dr. Hala Eldamanhoury
12:00 – 1:00	Explanation of the data collection form	Dr. Hala Eldamanhoury
1:00- 1:30	Lunch Break	
1:30 – 2:00	Logistics and administrative aspects	Dr. Hala Eldamanhoury
2:00 – 3:00	Practical training on how to perform and interpret the pregnancy test	Prof.Mohamed Shaarawy
3:00 – 4:00	Role distribution and job description	Dr. Hala Eldamanhoury