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CONTRACEPTIVE FILM
ACCEPTABILITY STUDY

THE DOMINICAN REPUBLIC

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PROFAMILIA
SANTO DOMINGO
THE DOMINICAN REPUBLIC

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I. INTRODUCTION

Vaginal spermicides are playing an increasingly important part in the method mix of many family planning programs because they can serve the dual role of contraception and prevention of sexually transmitted diseases (STDs). An innovative spermicidal contraceptive method commonly referred to as contraceptive film has received clearance from the U.S. Food and Drug Administration (FDA) and was introduced into the U.S. market in 1987 under the trade name VCF_R. This spermicide is a water-soluble film containing nonoxynol-9, that works much like foaming tablets. The manufacturer claims that the advantages of contraceptive film over foaming tablets include less burning, easier insertion and a shorter wait before intercourse can be initiated. According to Contraceptive Technology Update/September 1992 "this highly effective barrier method just now is gaining wide acceptance in health departments and family planning clinics" in the United States (p. 146).

II. STUDY OBJECTIVES

The primary objective of this study was to assess whether the contraceptive film is preferred over foaming tablets among current acceptors of foaming tablets in the Dominican Republic. An additional objective was to see whether clients would use a spermicide in conjunction with condoms if they were provided with both methods. This study did not assess the clinical efficacy of the three methods.

III. STUDY SUBJECTS

The study was conducted with a convenience sample of 65 new and current acceptors of foaming tablets in Santo Domingo, the capital of the Dominican Republic. Most participants were recruited from the client population of two health clinics in Santo Domingo run by PROFAMILIA, a private, not for profit affiliate of International Planned Parenthood Federation (IPPF). The remaining participants are current or former clients of a community-based family planning program. The majority of the participants were from densely populated, lower income urban areas of the capital city. Contraceptive use among this type of population is fairly high. However, according to study staff in the Dominican Republic, foaming tablet use among PROFAMILIA clients has been fairly low during the past five years and currently constitutes about five percent of the contraceptive method mix.

IV. STUDY PRODUCTS

Three family planning methods were used in this acceptability study. The first method was the standard, lubricated (52mm) latex condom manufactured by Ansell Inc., and provided to developing country family planning programs by the U.S. Agency for International Development (USAID). The second product was a foaming tablet containing nonoxynol-9 (100 mg) manufactured by Ortho Pharmaceutical and distributed in the developing world by USAID under the trade name Conceptrol^R. The third product was a contraceptive film distributed by Apothecus, Inc. under the trade name VCF^R. VCF^R is a water-soluble, polyvinyl alcohol film containing 5% glycerin and 28% nonoxynol-9 (72 mg).

V. STUDY DESIGN

Prior to admission into the study, potential participants were informed of the purposes and procedures of the study. If they chose to participate, they provided the Principal Investigator with written informed consent. The study protocol and informed consent forms were approved by FHI's Protection of Human Subjects Committee prior to initiation of the study.

At admission into the study, each participant was administered a questionnaire to collect sociodemographic information and to assess the participant's knowledge and preferences regarding available methods of contraception. Each participant was provided with a supply of 15 condoms, 15 foaming tablets and 15 contraceptive films and asked to use condoms along with one of the spermicides during each act of intercourse over the three-week study period. Participants were required to use at least two foaming tablets and two contraceptive films during the three weeks. If the participant, or her partner, refused to use condoms, it was recommended that a spermicide be used alone. Participants were provided with a coital log to keep track of sexual episodes and the combination of contraceptive methods they used during the three-week study. Participants were administered a follow-up questionnaire after three weeks to assess the acceptability of the three methods.

VI. DATA ANALYSIS METHODS

The data set was analyzed by PROFAMILIA staff with technical assistance provided by FHI. EPI-INFO version 5.01 was used to enter the data and to produce the frequencies and cross tabulations presented in this report. Statistical tests were calculated using SAS-PC version 6.04.

Informal data collected by FHI staff in Kenya and Zambia prior to this study suggested that participants would have a strong

preference for the contraceptive film; thus one-tailed tests were employed to test for significance. A one-tailed z-test for paired data was calculated to assess whether there was a preference of contraceptive film over foaming tablets. Differences in ratings of the two spermicides on a three-point scale (1-liked, 2-neutral and 3-disliked) were assessed with a one-tailed Wilcoxon matched pairs signed rank test. Compliance with the requested use of condoms along with a spermicide was described but not tested statistically. Alpha of .05 was used for the tests of statistical significance.

VII. RESULTS

A. Sociodemographic Characteristics

Of the initial 65 participants who were administered the background questionnaire and enrolled into the study, 52 participants completed the study. These 52 participants were all female with a median age of 24 (range 16-45) and a median education of 10 years (range 0-13+) (Table 1). Ninety-four percent of the participants were in union and almost all (96%) were Catholic.

The 13 participants who did not complete the study had the same median age (24) and had less education (median education 7 years). Ninety-two percent were in union and they all were Catholic. Of these 13 participants, three did not return for the follow-up interview while ten participants had not used two spermicides of each type at the time of the follow-up interview and were dropped from the study. Of the ten participants who returned for the follow-up interview, four gave personal reasons for not completing the study while two participants said the foaming tablets were irritating. The remaining four participants did not provide reasons for not using the prescribed study products.

B. Contraceptive Use History

Prior to their current use of foaming tablets, most of the participants (92%) had used at least one method of contraception (Table 2). The most common method used were oral contraceptives (75%), followed by condoms (27%), vaginal foam (12%), IUD (6%) and finally foaming tablets (2%).

When asked to cite the most important characteristic of a contraceptive method, ninety percent said "effectiveness" in preventing pregnancy (Table 2). Other responses included "ease of use/convenience" (6%), "no side effects" (2%) and "price" (2%).

At the time of the study, over three-fourths of the participants (79%) reported being new acceptors of foaming tablets (Table 3). Only three participants (6%) said they had been using foaming

tablets more than six months. Well over half the participants (63%) said they intended to use foaming tablets as a temporary method before switching to another method. Almost a third (29%) said they planned to use foaming tablets as their regular method.

The most important reason cited for currently choosing foaming tablets was because its "effectiveness in preventing pregnancy" (71%), followed by "ease of use/convenience" (23%), "no side effects" (4%) and "use as a temporary method" (2%).

Of the eleven participants who said they had received foaming tablets in the past, none said they were ever provided condoms along with foaming tablets (Table 4). Only one participant (2%) reported having used foaming tablets in the past and having discontinued the method prior to their current use. The participant said she used foaming tablets less than one month and discontinued due to partner opposition.

C. Experience with Study Products

All participants were asked to keep a coital log for 21 consecutive days. One of the 52 coital logs (2%) did not agree with some of the responses provided during the follow-up interview and was dropped from the analysis presented in Tables 5 and 6. The 51 "presumed-accurate" coital logs recorded a total of 449 coital episodes (Table 5). Daily coital frequency ranged from zero to three. Of the 449 coital episodes recorded in the study, 443 episodes (99%) were reported to be protected by barrier contraception. Almost half (49%) of the protected episodes were reported to be protected by the contraceptive film alone, while 42 percent were said to be protected by foaming tablets alone. Condom use during this study was limited. Four percent of the protected coital acts were reported to be protected by the condom alone while the remaining five percent were protected by a combination of condom and spermicide.

Table 6 presents the level of contraceptive protection that each participant recorded during the three-week study period. The vast majority (94%) said all their coital episodes were protected by a contraceptive method, while only one person said she was protected less than seventy percent of the time. Of the three participants who said they had unprotected intercourse during the study period, two said it was because they forgot while the third said she did not use contraception during her safe period.

The majority of participants (92%) said they never used two methods together during the study. One participant said they used two methods 13 percent of the time while the remaining three participants said they used double protection between 26 and 50 percent of the time. The most frequently cited reason for not

using two methods was because the participants said they forgot (45%) followed by "partner opposition" (27%) and "too much trouble" (20%).

D. Acceptability of Foaming Tablets and Contraceptive Film

According to the study participants, contraceptive film and foaming tablets were perceived to be almost equally acceptable (Table 7). Slightly more participants said they "liked" contraceptive film than said they "liked" foaming tablets (60% vs. 46%).

When the mean score was calculated where 1-liked, 2-neutral and 3-disliked, contraceptive film received a mean score of 1.7 versus 1.8 for the foaming tablets. The difference in preference was not statistically significant ($p = 0.26$). According to the participants, their partners liked the two methods slightly less (foaming tablet mean score 2.3 vs. contraceptive film mean score 2.1). Again the difference in preference scores is not statistically significant ($p = 0.26$).

When asked to state one characteristic they liked most about foaming tablets, a little over one-third (36%) said "nothing," while twenty-three percent said they liked the "general feel/comfort" (Table 8). The most often cited reason for liking the contraceptive film was "general feel/comfort" (33%). Almost the same proportion (31%) said they liked "nothing" about the contraceptive film and twenty-seven percent felt the method was "easy to use".

The reason most frequently stated for disliking foaming tablets was "messy" (36%). A similar proportion (35%) said they disliked "nothing" about foaming tablets. Almost half the participants (48%) said they disliked "nothing" about the contraceptive film. One-third (33%) complained that the "spermicide stuck to finger". Ten percent of the participants felt that the contraceptive film was "too wet".

As shown in Table 9, foaming tablets were reported to be easier to insert than contraceptive film (56% vs. 33%). Since we predicted that the contraceptive film would be easier to insert, the null hypothesis was not rejected ($p = 0.96$). When asked about specific problems inserting foaming tablets, two participants reported "problems touching myself" while one participant said she had "problems because tablets are hard". Almost half the participants (48%) said they had problems with the contraceptive film because it "stuck to finger".

When asked which method they found less messy, 73 percent of respondents chose contraceptive film ($p < 0.01$). None of the participants said they could feel the contraceptive film during intercourse, while 85 percent reported that they did not feel the

foaming tablets. Of the eight participants who said they could feel the foaming tablets, four complained about "unpleasant lubrication", two said they felt "unpleasant burning" and two participants said they "felt undissolved tablet".

Eighty-one percent preferred the packaging of the contraceptive film ($p < 0.01$) although three-fourths of the participants (75%) found both types of packaging easy to open.

When asked which type of spermicide they would use in the future, assuming both were available, 52 percent ($n=27$) said contraceptive film while 46 percent ($n=24$) said foaming tablets (Table 10). There was not a statistically significant difference in preference of the two methods ($p = 0.36$). Of the twenty-four participants who preferred foaming tablets, over half (54%) would be willing to pay between 20 and 60 pesos (US\$ 1.60-4.80) for 20 units. Of the twenty-seven participants who preferred contraceptive film, fifty-nine percent would be willing to pay between 20 and 60 pesos (US\$ 1.60-4.80), while eleven percent would be willing to pay more than 60 pesos (US\$ 4.80) for 20 units.

VIII. LITERATURE REVIEW

There are many vaginal spermicides on the market today in developed countries, including foams, creams, gels, spermicidal suppositories and contraceptive film. The spermicides have two main components: a spermicidal chemical which immobilizes the sperm by disrupting its membrane and an inert base or carrier which holds the spermicide and helps vaginal dispersion. The scientific literature presents a wide range of efficacy rates for the various types of vaginal spermicides. According to Contraceptive Technology 1990-1992, "our best guess is that the initial-year failure rate among perfect users of spermicides would be about 3%. The first-year failure rate among typical users is about 21%. The most common patient error leading to an accidental pregnancy is failure to use the spermicide" (p. 183).

In the mid 1970's, two clinical trials were conducted on the contraceptive film manufactured by Potter and Clarke (United Kingdom) and marketed in Europe under the brand name C-FILM. The results of these clinical trials were hotly debated in a series of letter exchanges in the British Medical Journal. On November 2, 1974, the Family Planning Association U.K. presented the preliminary findings of their clinical trial. They included 45 subjects using C-FILM during a total of 185 months in their analysis. These participants recorded nine involuntary pregnancies for a pregnancy rate of 62 per 100 woman-years. The Family Planning Association terminated the clinical trial after this interim analysis due to the unacceptably high failure rate.

On November 1, 1975, N. Raabe and O. Frankman presented the findings from their clinical trial at three family planning clinics in Sweden. Two-hundred and thirty-seven women used C-FILM during 1866 months and reported a pregnancy rate of nine per 100 woman-years. Raabe and Frankman speculated that the high failure rate in the first clinical trial was due to inconsistent usage and improper instructions. In the final letter on December 20, 1975, the Family Planning Association asserted they did not believe the high pregnancy rate experienced in their clinical trial should be attributed to user failure.

A recent study presented in The Journal of the Society for the Study of Infertility of Japan 1980;25:2 found a surprisingly low pregnancy rate of 0.56 per 100 woman years for a sample of 168 women who had used the C-FILM during 2161 months.

Clearly, given this wide range of efficacy rates, there is a strong need to conduct more research to better document the efficacy rates of contraceptive film and other types of spermicides to help clients choose which method may be most appropriate for them.

IX. DISCUSSION

Based on the limited efficacy data available to date, the acceptability of the different vaginal spermicides may be the best predictor of the actual failure rate (method failure plus user failure) because of the clear link to non-use if a user finds a spermicide to be unacceptable. With the increased emphasis on vaginal spermicides for both family planning and disease prevention, research is being conducted to assess which delivery systems for spermicides are most acceptable.

The data presented in this report are from one of three sites in a multi-site acceptability study that compared foaming tablets with contraceptive film. The two other study sites were Mexico and Kenya. Data from Kenya have been presented in the final report "Acceptability Film Study: Kenya - December 1992". Caution must be taken when interpreting the results from these three sites because they are based on small, convenience samples. However, the results do suggest varying degrees of acceptability of the two methods and potential problems with their use.

In Kenya, this multi-site study evaluated a convenience sample of 51 current foaming tablet acceptors. This study population expressed a strong preference for contraceptive film over foaming tablets. An overwhelming majority (86%) would prefer to use contraceptive film in the future if they had a choice of both methods ($p < 0.01$). Only two participants complained that the contraceptive film stuck to the finger during insertion and over three-fourths (78%) thought the contraceptive film was easier to insert than foaming tablets ($p < 0.01$).

In the Dominican Republic, the 52 participants who completed the study reported a much lower preference for contraceptive film over foaming tablets. Slightly over half (52%) said they would choose contraceptive film if both methods were available. More participants found foaming tablets easier to insert than the contraceptive film (56% vs. 33%) with almost half (48%) complaining that the contraceptive film stuck to their finger during insertion.

A possible explanation is that the participants in Kenya may have received better instructions on how to insert the contraceptive film. In the Dominican Republic, formal interviews were conducted with 15 of the 25 participants who complained about the film sticking to their fingers during insertion in an attempt to understand why they were encountering this problem. All 15 participants said that study staff reviewed the written instructions with them and that they felt they understood how to use contraceptive film correctly. Nevertheless, five participants said they moistened the contraceptive film with saliva before insertion and eight participants said they failed to fold the contraceptive film in half before insertion. This data suggest that the current written instructions are not sufficiently clear to assure that contraceptive film is used properly. FHI has contacted Apothecus, Inc. and they are currently updating their written instructions.

It is interesting to note that the 27 participants who did not experience problems with the contraceptive film sticking to their fingers found the contraceptive film to be more acceptable than foaming tablets (70% vs. 25%). This suggests that the lower acceptability for the contraceptive film in the Dominican Republic may be caused by problems with the method sticking to fingers during insertion.

Once inserted, participants found the method to be less messy than foaming tablets (73% vs. 17%, $p < 0.01$). This study suggests that if problems with the contraceptive film sticking to the finger can be overcome, then this method may be an acceptable spermicide to be used by women in the Dominican Republic.

The secondary study objective was to assess whether clients would use a condom in conjunction with a spermicide if they were provided with both methods. In the Kenya study, almost half of all coital episodes were protected by a condom and spermicide. It is important to note that the study participants in Kenya were recruited from a family planning program that encourages its clients to use both condoms and spermicides.

In the present study, only five percent of coital episodes were protected by both condoms and a spermicide. Participants said they did not use two methods because they "forgot" (45%), "partner opposition" (27%) and "too much trouble" (20%). The PROFAMILIA program does not actively encourage the use of both condoms and

spermicides at the same time. It is unclear to what degree the study staff stressed the importance of having participants use two methods during the study.

Currently, many family planning programs recommend that clients should be encouraged to use both condoms and spermicides at all times. However, Contraceptive Technology 1990-1992 asserts that "use of latex condoms along with spermicides....for one week each month, beginning five days before ovulation is expected" (p. 186) is also a reasonable alternative.

If future studies show that improved instructions can minimize problems with the film sticking to the fingers during insertion, we would recommend that additional research be conducted to better document the efficacy of contraceptive film. A clinical trial should be conducted in various study populations and have a strong acceptability component. If the clinical trial shows the method failure rate of contraceptive film to be comparable to foaming tablets and further documents high acceptability of the method, we would recommend that contraceptive film replace foaming tablets in commodity distribution programs.

Table 1
Sociodemographic Characteristics
N=52

	N	(%) *
Site		
Santo Domingo	52	(100)
Age (years)		
16-20	14	(27)
21-25	16	(31)
26-30	15	(29)
31-45	7	(13)
	(median: 24 years)	
Sex		
female	52	(100)
male	0	(0)
Education (years)		
0	4	(8)
1-5	2	(4)
6-8	16	(31)
9-12	22	(42)
13+	8	(15)
	(median: 10 years)	
Marital Status		
single	3	(6)
in union	49	(94)
Religion		
Catholic	50	(96)
Protestant	1	(2)
none	1	(2)

*In this and all subsequent tables, percents may not equal 100 due to rounding.

Table 2
Use of Contraceptives
N=52

	N	(%)
Contraceptives Used in Past:*		
OCs	39	(75)
condoms	14	(27)
vaginal foam	6	(12)
IUD	3	(6)
vaginal foaming tablets	1	(2)
never used contraceptive in past	4	(8)
Most Important Characteristic of a Contraceptive:		
effectiveness	47	(90)
ease of use/convenience	3	(6)
no side effects	1	(2)
price	1	(2)
Second Most Important Characteristic of a Contraceptive:		
ease of use/convenience	39	(75)
effectiveness	3	(6)
price	3	(6)
no side effects	3	(6)
partner approves	1	(2)
did not give second response	3	(6)
*Multiple responses were allowed.		

Table 3
Current Foaming Tablet Use
N=52

	N	(%)
Length of Current Foaming Tablet Use:		
new acceptor	41	(79)
less than one month	3	(6)
two to six months	5	(10)
more than six months	3	(6)
Type of Current Foaming Tablet Use:		
for FP until a regular method can be adopted	33	(63)
regular FP method	15	(29)
for FP, sporadic use	4	(8)
Most Important Reason for Choosing Foaming Tablets:		
effectiveness in preventing pregnancy	37	(71)
ease of use/convenience	12	(23)
no side effects	2	(4)
use as a temporary method	1	(2)

Table 4
Past Foaming Tablet Use
N=52

	N	(%)
Have you ever received foaming tablets in the past?		
no (first time user)	41	(79)
yes	11	(21)
In the past, did you receive foaming tablets with condoms?		
always	-	
sometimes	-	
never	11	
Have you used foaming tablets in the past and stopped?		
no	10	
yes	1	
How long was your past use of foaming tablets?		
less than 1 month	1	
Why did you stop the past use of foaming tablets?		
partner opposition	1	

Table 5
Type of Contraceptive Protection of Total Coital Episodes
According to Coital Log
N=449*

	N	(%)
Total Coital Episodes	449	(100)
Unprotected Coital Episodes	6	(1)
Protected Coital Episodes	443	(99)
Type of Contraceptive Protection		
condom alone	19	(4)
foaming tablet alone	188	(42)
foaming tablet and condom	7	(2)
contraceptive film alone	217	(49)
contraceptive film and condom	12	(3)

*One participant was dropped from Tables 5 and 6 because of inconsistencies between their coital log and the follow-up interview.

Table 6
Level of Contraceptive Protection of Individual Clients
According to Coital Log
N=51*

	N	(%)
Percentage of Coital Episodes Protected by Contraception:		
100%	48	(94)
90-99%	-	-
80-89%	2	(4)
70-79%	-	-
< 70%	1	(2)
Reasons for having unprotected intercourse (n=3):		
I forgot	2	
safe period	1	
Percentage of Coital Episodes Protected by Two Methods:		
26-50%	3	(6)
1-25%	1	(2)
0%	47	(92)
Reason for not using two methods:		
partner opposition	15	(29)
too much trouble	10	(20)
I forgot	23	(45)
did not like to	1	(2)
missing	2	(5)
*One participant was dropped from Tables 5 and 6 because of inconsistencies between their coital log and the follow-up interview.		

Table 7
Acceptability of Foaming Tablets and Contraceptive Film
N=52

	TABLETS		FILM		p-value***
	N	(%)	N	(%)	
How did you like the method?					
liked	24	(46)	31	(60)	
neutral	10	(19)	5	(10)	
disliked	18	(35)	16	(31)	
mean score*	1.9		1.7		0.26
How did your partner like the method?					
liked	11	(21)	15	(29)	
neutral	6	(12)	4	(8)	
disliked	15	(29)	14	(27)	
don't know	20	(38)	19	(36)	
mean score**	2.3		2.1		0.26

*Scale based on 1-liked, 2-neutral and 3-disliked.

**Scale based on 1-liked, 2-neutral and 3-disliked; participants who said "don't know" were excluded from the mean score calculation.

***1-tailed Wilcoxon matched pairs signed rank test.

Table 8
Client Preferences for Foaming Tablets and Contraceptive Film
N=52

	TABLETS		FILM	
	N	(%)	N	(%)
What did you like most about the spermicide?				
nothing	19	(36)	16	(31)
general feel/comfort	12	(23)	17	(33)
easy to use	9	(17)	14	(27)
clears discharge	6	(12)	1	(2)
under my control	3	(6)	3	(6)
safe/no side effects	2	(4)	1	(2)
effectiveness	1	(2)	-	-
What did you dislike most about the spermicides				
messy	19	(36)	2	(4)
nothing	18	(35)	25	(48)
spermicide did not dissolve	4	(8)	-	-
touching private parts	3	(6)	-	-
burning sensation	3	(6)	1	(2)
waiting before sex	3	(6)	-	-
too wet	2	(4)	5	(10)
spermicide stuck to finger	-	-	17	(33)
do not trust method	-	-	1	(2)
partner opposition	-	-	1	(2)

Table 9
Problems with Foaming Tablets and Contraceptive Film
N=52

	N	(%)	P-value**
Which spermicide was easier to insert?			
foaming tablets	29	(56)	
contraceptive film	17	(33)	
both were easy	4	(8)	
both were difficult	1	(2)	
both were the same	1	(2)	0.96
Did you have specific problems inserting foaming tablets?*			
no	49	(94)	
yes, problem touching myself	2	(4)	
yes, problems because tablets are hard	1	(2)	
Did you have specific problems inserting contraceptive film?*			
no	27	(52)	
yes, stuck to finger	25	(48)	
What spermicide did you find less messy?			
foaming tablets	9	(17)	
contraceptive film	38	(73)	
disliked both	1	(2)	
liked both	4	(8)	< .01
Could you feel the foaming tablets during intercourse?			
no	44	(85)	
yes, unpleasant lubrication	4	(8)	
yes, unpleasant burning	2	(4)	
yes, felt undissolved tablet	2	(4)	
Could you feel the contraceptive film during intercourse?			
no	52	(100)	
Did you have problems opening the package of either of the spermicides?			
foaming tablets	7	(14)	
contraceptive film	4	(8)	
both were difficult to open	2	(4)	
both were easy to open	39	(75)	
Which packaging did you like better?			
foaming tablets	9	(17)	
contraceptive film	42	(81)	
liked both	1	(2)	< .01
*Multiple responses were allowed.			
**1-tailed Z-test			

Table 10
Future Preference of Foaming Tablets
and Contraceptive Film
N=52

	N	(%)	p-value*
What spermicide preferred in future:			
foaming tablets	24	(46)	
contraceptive film	27	(52)	
either, both are the same	1	(2)	.36
If foaming tablets preferred, how much willing to pay for 20 units? (N=24)			
not willing to pay	0	(0)	
less than 20 peso (US\$ 1.60)**	9	(38)	
20 to 60 peso (US\$ 1.60-4.80)	13	(54)	
more than 60 peso (US\$ 4.80)	1	(4)	
whatever price	1	(4)	
If contraceptive film preferred, how much willing to pay for 20 units? (N=27)			
not willing to pay extra	0	(0)	
less than 20 peso (US\$ 1.60)	8	(30)	
20 to 60 peso (US\$ 1.60-4.80)	16	(59)	
more than 60 peso (US\$ 4.80)	3	(11)	

*1-tailed Z-test

**Exchange rate at the time of the study.