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**Consumer Preference Study of the Female Condom  
in a Sexually Active Population at Risk of  
Contracting AIDS**

**Khon Kaen, Thailand**

**FINAL REPORT**

**August, 1989**

***Principal Investigator:***

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Department of Ob-Gyn  
Faculty of Medicine  
Khon Kaen University**

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Consumer Preference Study of the Female Condom  
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## ABSTRACT

The prevalence of HIV infection in Thailand is increasing rapidly. Changes in behavior and barrier methods of contraception remain the only ways of slowing the sexual transmission of HIV. The female condom represents a new and potentially important addition to the existing choices. Because the female condom is made of polyurethane, a material more durable than rubber, and covers a larger surface area, it may provide better protection than a standard latex condom.

During February 1989, the US-made WPC-333 female condom was tested in Khon Kaen, Thailand, to determine if the female condom might be an acceptable method of protection from STDs for high-risk women. Twenty at-risk women in Khon Kaen were trained by nurses to use the female condom and supplied with 20 unlubricated devices each. They also were provided with a supply of spermicidal lubricant and their regular supply of male condoms. The participants were instructed about the risk of AIDS and advised that they could use the female condom as an alternative method of protection to the male condom. The decision of which device to use, if any, was left to the participant.

Participants were interviewed two weeks later. They reported using the female condom alone in a total of 78 (32%) of 247 episodes of vaginal intercourse, of which eight episodes were in conjunction with the male condom. The male condom was used in 90 (35%) of the episodes and none in 87 (34%) episodes. Two-thirds of the volunteers reported no aversion to the female condom while one-third disliked it. Mechanically, the female condom performed well. No rips or tears were reported during intercourse, and no woman reported severe pain. The most common objection to the 17cm device for these Thai women was that it was too big. Also, the need to lubricate the condoms made their use messy and inconvenient. Nineteen participants said the female condom was less convenient to use than the male condom, and six said it was less comfortable. Most of these problems can be overcome by shortening and pre-lubricating the condoms. One other objection was difficulty inserting (15%), a problem which may have been due to lack of experience with inserting the condoms.

While the participants' own general assessment of the condom was fairly positive, most discontinued using the device because of male partner objection. Ten respondents reported that all partners with whom they used the female condoms objected to their use; eight said reactions were mixed; and two said all partners with whom they tried them reacted positively. Eighteen of 20 participants said they would advise other sex workers to try these female condoms.

Based on these results, we decided to repeat this study in Khon Kaen with a shorter (15mm), pre-lubricated version of the female condom.

## ACKNOWLEDGMENTS

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This project was funded by Family Health International under a Cooperative Agreement with the U.S. Agency for International Development. FHI is an international not-for-profit organization which conducts research and provides technical assistance in health, family planning, STDs, and AIDS. It is based in Research Triangle Park, NC. USA. Dr. Linda Potter was FHI's project director for this study; Jim McMahan was project monitor.

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## INTRODUCTION

When the proposal for this study was written one year ago, HIV infection in Thailand was increasing most rapidly among intravenous drug users in Bangkok. Now it appears that AIDS is finally beginning to spread rapidly among the female commercial sex workers who populate every province in Thailand. In a recent random, anonymous blood screening of high-risk groups in the Chiang Mai area of north Thailand, 200 individuals were found to have antibodies to the AIDS virus. Of these, 140 or 70 percent were female prostitutes.<sup>1</sup> A more recent report describes the increased prevalence of AIDS among prostitutes under age 20.<sup>2</sup>

This study was conducted in anticipation of the eventual spread of AIDS into the large population of commercial sex workers (CSW). The need for a method to help the woman protect herself from AIDS infection was clearly indicated by a previous study conducted by the author in 1987.<sup>3</sup> In that study it was found that only half of the customers of female CSWs in the Khon Kaen used condoms during vaginal intercourse. All the women in the study wanted complete protection from contracting AIDS and other sexually transmitted diseases (STD) but were not always able to convince their partners to wear a condom.

Thus the author requested assistance from Family Health International (FHI) to fund a small study of a female method to prevent STDs. A vaginal sponge to prevent STD (and contraception) had already been tested in a Bangkok high risk population with limited success.<sup>4</sup> However, to prevent STD and HIV infection it was clear that a more comprehensive barrier method was needed. The invention of the female condom by a Danish gynecologist offered the first opportunity to place effective STD prevention in the hands of women themselves.<sup>6</sup>

The manufacture of this condom was adapted by Wisconsin Pharmacial in the U.S. Through FHI, a supply of 400 female condoms were shipped to Khon Kaen, Thailand in February, 1989 for a study among twenty, highly sexually active women with multiple partners.

The following sections describe the objectives, methodology, results and conclusions of this study.

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## OBJECTIVES

The study had the following objectives:

- (1) To train a selection of sexually active Thai women in the use of the female condom.
- (2) To provide a supply of female condoms to these women for use during a two-week period.
- (3) To determine whether the condoms were used (if not, why); whether they were used correctly; and whether their use interfered with intercourse in any way.
- (4) To assess the budget requirement for wide scale introduction and orientation in use of the female condom among groups at risk of AIDS infection.

The goal of the study is to help the development of a greater variety of methods that can be used to prevent the contraception and spread of AIDS. Only through a variety of well-designed, rapid turn-around studies can the most suitable methods be discovered for the different high-risk populations.

## METHODOLOGY

Twenty highly sexually active women who have multiple sexual partners were the subjects of this study of the female condom. These women were selected because they are at high risk of contracting STD's and because their promiscuity enables the collection of data on a variety of male partner reactions to the female condom in a short period of time. Only women currently using contraception were eligible to participate.

As a pre-test, four women who were not part of the 20 subjects were trained in the use of female condom and given a supply of ten pieces plus two bottles of lubricant each and told to try using the condom for one week. The purpose of this pre-test was to gather practical information to enhance the content of the training instructions. In addition the pre-test was an exploratory step to determine that, in fact, the female condom could be used by this high-risk group at all.

The 20 subjects all worked in the same establishment and were selected randomly from among 60 peers to voluntarily participate in a two-week study of the female condom. Their employer gave full support and cooperation for the study.

During a period of three hours before they began to work, the 20 volunteers were given an overview of AIDS and how it can be prevented by an experienced OB-GYN. Next the female condom was described to them. Then the 20 participants split into four groups of five to learn more about the female condom and practice inserting the condom by using a full scale pelvic model. Four nurses conducted these smaller group sessions.

At the end of the small group sessions, each participant was given a Thai-language pamphlet on how to insert and remove the condom, a supply of ten unlubricated, female condoms and two bottles of lubricant supplied by the condom manufacturer. The participants were informed that they would be interviewed on their experience after the first and second weeks. They were told how to obtain resupplies of condoms and lubricant and all women were instructed not to reuse the condoms and to return any unused supply.

To conserve time, the 20 women were interviewed at their place of employment by the same four nurses who conducted the group training. These nurses are skilled in conducting in-depth interviews, especially with high-risk population such as the 20 subjects.

The questionnaire was developed through collaboration with FHI and went through a number of revisions before attaining the final version which appears in Appendix A. Because of the small number of respondents and the use of some open-ended questions the data were hand-tabulated. The following section presents the results of the two-week study.

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## RESULTS

All tabular results are presented in Appendix A. A total of 17 of the 20 subjects were interviewed twice. Three were interviewed after one week but were not available at the end of two weeks. Similarly, three were not available at the end on one week but were interviewed at the end of week two. For the 17 women who were interviewed twice, the results of the second interview are presented.

### Patient Characteristics

The twenty volunteers in this study of the female condom have the following characteristics:

- Age Ranged from 16 to 35 with a mean of 27.2 years.
- Education Ranged from none to junior college; 14 have primary education (equivalent to sixth grade).
- Fertility 17 had been pregnant before, 11 have given live birth while 15 had a history of abortion. Mean gravida was 2.6 pregnancies, mean number of abortions was 2.3 and mean fertility is 0.7 live births.
- STD 13 have had gonorrhea while 6 have had syphilis.
- Contraception 18 were using the pill, two were using injectables.

### Product use and women's perceptions

During the two weeks of the study the 20 volunteers had 247 acts of vaginal intercourse. The female condom was used in 78 (31.6%) of episodes. All 20 participants tried the female condom at least once but not one continued using the condom throughout the two weeks of the study. The most common reason for discontinuing use of the condom was male partner objection. The general assessment of the condom from the female perspective was positive however. Two-thirds of the volunteers had no aversion to the female condom although one-third said they disliked it.

Mechanically, the female condom performed well. No rips or tears during intercourse were reported, and no woman reported severe pain. The most uniform woman's objection to the condom was its large size. The U.S. manufactured condom was reported to be too long and too wide for the Thai women in this study. Virtually all women felt they had received adequate training in the insertion of the female condom but more than one-third found the process of inserting the condom to be a nuisance (See item 31b).

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### Male partner's reaction

In contrast to the women in this study, the man's reaction to the condom was negative (as reported by the woman). No male partners were interviewed in this study however. Ten out of the twenty volunteers reported that all their partners disliked the condom. Eight said some of their partners disliked the condom, while some liked it. Two of the twenty women reported that all their partners liked the female condom (See item 39).

### Condoms and STDs

Whether a condom (male or female) is used or not depends on two factors: (1) level of fear of contracting STD, and (2) strength of belief that the condom will prevent STD. (Because all the women in this study were already using some form of contraception, it is assumed that the only motive for using a condom is to prevent STD.) Thus the questionnaire posed a number of questions on the women's perceptions of condoms and prevention of STDs to explore whether this study is based on erroneous assumptions about the women's motivations.

The responses to questionnaire items 40-42 and 49-51 indicate that 18 out of the 20 volunteers believe that either the male and female condom can prevent gonorrhoea, syphilis or AIDS.

Finally the women were asked who they thought should bear the responsibility for prevention of STD. The responses are summarized below:

#### Why the woman should take responsibility

- men are not afraid of catching or spreading STD
- we can't tell if the man has STD

#### Why both should take responsibility

- both are at risk
- both are afraid of contracting STD
- both should be clean
- using condoms (male or female) requires the cooperation of both partners

### Communications and general view of the female condom

The final two sections of the questionnaire consist largely of open-ended items on the volunteers' discussions with peers about the female condom and their general assessment of the study and prospects for such a condom in Thailand. The following presents a selection of the comments and opinions to these items in the words of the study participants themselves:

#### Reason would not advise others to use the condom

- we know the man won't like it
- we don't have enough facts yet (on the method)

Reason would advise others to use the female condom

- peace of mind when you know you're preventing STD
- better than using nothing
- it's new, others should try it
- want friends to learn about new methods

Reason spoke to others about the female condom

- wanted to tell them to try a new method
- they asked me about it
- told our boyfriends about it

Why other women probably won't use the condom

- too big and inconvenient

Why other women will use the female condom

- out of curiosity
- to protect self from STD

Most favorable aspects of the female condom

- STD prevention
- clean and easy to dispose of
- no skin rash or itching as with the male condom
- thick enough to prevent all STD
- new and interesting
- the woman is in control

Least favorable aspects of the female condom

- inner ring too hard
- outer ring too large (i.e., a turn-off)
- doesn't fit snugly
- moves around in the vagina
- takes time to insert
- inconvenient to carry around
- too long and wide
- hard to convince partner to agree to letting me use it

Recommendations to improve the female condom

- soften the inner ring
- need a female condom that the man cannot see
- it may be hard to find a market for this, therefore it should be sold cheaply, such as \$0.40 to \$0.80 each

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## DISCUSSION AND CONCLUSION

This study has demonstrated that high-risk women for AIDS and other STDs can be rapidly and effectively trained in the use of a female condom. All twenty volunteers in this two-week study are promiscuous and are compensated in proportion to their partner's sexual satisfaction. Yet all the women were able to convince some of their partners to allow them to wear the female condom which is visible to the man and takes several minutes for the women to insert.

The least surprising finding of this study of the female condom is the partner objection. The men objected on aesthetic and sensual grounds. It is more noteworthy perhaps that the women were able to use the condom at all and that some reported that all their partners liked the female condom. All female participants were of the attitude that if the partner did not object, they would gladly use the female condom during each episode of intercourse. The major constraint to female condom acceptable is clearly partner objection.

An unexpected finding of the study is that the U.S. manufactured condoms are too large for the Thai women in this study. The oversize length and diameter cause problems of insertion, lack of snug fit, too much mobility of the condom and slippage.

Thai high-risk women in this study fear venereal disease and fear AIDS the most among STDs. The women also recognize the importance and effectiveness of the condom in STD prevention. However, they are prevented from protecting themselves and their partners because the nature of their sexual relationships dictates that the man's pleasure and desires take priority over their own health.

When one volunteer was asked if she would agree to have unprotected intercourse with a man she knew had gonorrhoea, she said she would not. Thus, when the danger of contracting STD is visible and immediate the woman makes a rapid cost-benefit decision and becomes the assertive partner. Although the woman might fear AIDS most, and realize that it can be spread by someone without symptoms, the threat of AIDS may still be too remote to motivate them to insist on condoms or no sex. Thus, another volunteer suggested that the female condom should be promoted for prevention of syphilis and not AIDS because syphilis is a disease which they fear and which 6 out of the 20 volunteers have contracted before.

It is the conclusion of the investigator that the female condom will only become a viable alternative to high-risk women when their proximity to AIDS increases or if the male partners can be motivated to accept the female condom. Steps toward promoting increased acceptability of the condom would be (1) prelubrication of the condom to reduce insertion time and nuisance, (2) redesign of the condom to suit the Thai female anatomy and, ideally, (3) development of a new barrier technology for females that cannot be seen or felt by the man.

To achieve its fourth objective:

To estimate the cost implications of a wide-scale replication of the training and distribution of the female condom more data need to be gathered from different groups of women. Subject to FHI approval, the author proposes to use the condoms that are left over from this study to conduct a locally funded replication in Bangkok to see if the results are similar to the Khon Kaen findings. The employment status of the volunteers and the trainings method will be held constant to improve the comparison. The small replication will take only one month but should provide valuable information on the potential for replication without any modifications to the female condom.

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## REFERENCES

- 1 Tunsarawuth, Sinfah. "AIDS spread in Chiang Mai draws concern." The Nation, February 25, 1989.
- 2 "More young prostitutes test positive for AIDS." Bangkok Post, March 23, 1989.
- 3 Chuanchom Sakondhavat. Study of AIDS prevention Strategies in a High-risk Population. Khon Kaen. 1989. (Unpublished monograph)
- 4 Rosenberg, M.J., P.J. Feldblum, W. Rojanapithayakorn and W. Sawasdivorn. "The Contraceptive sponge's protection against Chlamydia Trachomatis and Neisseria Gonorrhoeae." Sexually Transmitted Disease. 14(3):147, 1987.
- 5 International Herald Tribune. April 24, 1988.
- 6 Bangkok Post. February 27, 1988.

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APPENDIX A.

Distribution of Responses by Question

ADMISSION QUESTIONNAIRE

ITEM i-iii: (Volunteer Identification.)

iv. Age:

	N
16-20	3
21-25	5
26-30	6
31-35	6
Total	20

mean age = 27.2 years

v. Education:

	N
none	1
primary	14
secondary	4
junior college	1
Total	20

vi. Number of previous pregnancies:

	N
0	3
1	4
2	3
3	3
4	3
5	2
6	2
Total	20

Number of previous live births:

	N
0	9
1	8
2	3
Total	20

Number of previous abortions:

	N
0	5
1	3
2	5
3	3
4	3
5	1
Total	20

vii. Ever had gonorrhea:

	N
yes	13
no	7
Total	20

viii. Ever had syphilis:

	N
yes	6
no	14
Total	20

ix. Ever had other STD:

	N
yes	10
no	10
Total	20

x. Method of contraception currently used:

	N
pill	18
injectable	2
Total	20

#### FOLLOW-UP QUESTIONNAIRE

##### PRODUCT USE

5. How many times have you had vaginal intercourse since receiving the female condoms?  
247 times (n = 20 respondents)

6. Did you ever use the female condom?

	N
no	0
yes	20
Total	20

7. a) How many times did you use the female condom only: N (range)  
b) How many times did you use the male condom only: 70 (1-25)  
c) How many times did you use the male and female condoms together: 82  
d) How many times did you use no condom at all: 8  
Total 247

8. Did you use the female condoms throughout the weeks or did you stop using them at some point?

	N
discontinued	20
used for entire two weeks	0
Total	20

9. If you stopped using it, what were the main reasons?

	N
caused discomfort to me	6
caused discomfort to my partner(s)	10
inconvenient	11
decreased sexual satisfaction	6
partner(s) objected	15
out of supplies	0
other reason:	13
- menstruation	
- sticky	
- prefers male condom	

10. Did you use these condoms during your period?

	N
no	18
yes	2
Total	20

11. Did you douche after use of these condoms?

	N
no	2
yes	18
Total	20

12. Did you reuse any of these condoms?

	N
no	20
yes	0
Total	20

#### WOMEN'S PERCEPTION OF PRODUCT

13. In general, how did you like the female condoms?

	N
no opinion	3
a great deal	2
a little	8
disliked	7
Total	20

14. Did the female condom provide lubrication?

	N
no	0
yes, a little	1
yes, too much	19
Total	20

15. Did the female condom have a noticeable odor?

	N
no	19
yes, pleasant	0
yes, unpleasant	1
Total	20

16. Was it hard to insert properly?
- |                |    |
|----------------|----|
| no             | N  |
| yes, sometimes | 10 |
| yes, often     | 7  |
| Total          | 3  |
|                | 20 |
17. Did you feel the inner ring during intercourse?
- |              |    |
|--------------|----|
| no           | N  |
| somewhat     | 7  |
| continuously | 8  |
| Total        | 5  |
|              | 20 |
18. If you felt the inner ring, did it interfere with intercourse?
- |                 |    |
|-----------------|----|
| no              | N  |
| yes             | 7  |
| did not feel it | 6  |
| Total           | 7  |
|                 | 20 |
19. Did the female condom stay in place?
- |       |    |
|-------|----|
| no    | N  |
| yes   | 6  |
| Total | 14 |
|       | 20 |
20. Did you feel the outer ring?
- |       |    |
|-------|----|
| no    | N  |
| yes   | 9  |
| Total | 11 |
|       | 20 |
21. Did it interfere with intercourse?
- |                 |    |
|-----------------|----|
| no              | N  |
| yes             | 4  |
| did not feel it | 7  |
| Total           | 9  |
|                 | 20 |
22. Did the outer ring of the condom get pushed up into your vagina?
- |                     |    |
|---------------------|----|
| no                  | N  |
| yes, once           | 13 |
| yes, more than once | 6  |
| Total               | 1  |
|                     | 20 |
23. Did the partner ever insert the penis between the outer ring and your vagina?
- |       |    |
|-------|----|
| no    | N  |
| yes   | 20 |
| Total | 0  |
|       | 20 |

24. Did any of these female condoms tear or rip during insertion?

	N
no	19
yes, how many	1 (1 piece)
Total	20

25. Did any of these female condoms tear or rip during intercourse?

	N
no	20
yes, how many	0
Total	20

26. Was it easy to remove?

	N
no	0
yes	20
Total	20

27. Did you have enough education/information to use this condom correctly?

	N
no	1
yes	19
Total	20

28. Did the female condom cause you any inconvenience or discomfort?

	N
no	14
yes	6
Total	20

29. a) Did it cause you any pain or burning?

	N
no	13
minor but able to ignore it	2
moderate and interfered with sex	5
severe and so unable to have sex	0
Total	20

b) If yes, how long did the pain last?

	N
briefly; disappeared when intercourse began	1
throughout intercourse, ending after intercourse	5
continued after intercourse ended	1
Total	20

30. Did it bother you to insert the condom by yourself?

	N
no	8
yes	12
Total	20

31. a) How convenient is the female condom compared to the male condom?

	N
less convenient	.19
about the same	0
more convenient	1
Total	20

b) in what ways?.....

The following are verbatim comments on the women's perception of the female versus the male condom:

**Female condom versus male condom:**

- can prevent STDs as well as a male condom
- harder to put on
- makes a noise during intercourse
- more steps to follow (e.g., applying lubricant, inserting)
- must inspect the condom first to see if condition is good
- partner must be careful not to insert outside the condom
- must put on the condom myself and hold on the ring during intercourse and this spoils the mood
- feel tight inside after intercourse
- too large to carry conveniently (in purse)
- sticky, greasy
- pain during intercourse
- partner objection

**Male condom versus female condom:**

- easy to put on
- easy to carry around
- better sexual feeling

**PARTNER'S REACTION**

32. Did your partner(s) know that you were using the female condom?

	N
no	0
some did	0
all did	20
don't know	0
Total	20

33. Did you tell your partner(s) you were wearing a condom?

	N
no	0
yes, some	0
yes, all	20
Total	20

34. Did they like or dislike the condom?

	N
all liked	2
some disliked, some liked	8
all disliked	10
don't know	0
Total	20

35. Did the female condom affect your partners' overall sexual satisfaction?

	N
no	1
yes, all increased	0
some increased, some decreased	5
all decreased	14
don't know	0
Total	20

36. Did the spermicide cause them any pain or burning?

	N
no	19
yes, some of them	1
yes, all of them	0
don't know	0
Total	20

37. Did your partner(s) ever feel the inner ring?

	N
no	10
some did	7
all did	3
Total	20

38. Was this condom long enough?

	N
no	0
yes	20
Total	20

39. Did they mention any other difference in sexual intercourse caused by the female condom?

	N
no	2
yes, specify	18.....
Total	20

The following are comments made by male partners in reaction to the female condom:

Partner's perception of the difference in sexual intercourse when a female condom is used.

- good for preventing STD
- same as usual
- reduces sexual feeling
- moves around too much
- unnatural
- inner ring causes pain
- unattractive, too large, not Thai size
- too thick, delays ejaculation too long

When interpreting these comments, it should be kept in mind that they are based on the women's report of the partner's reaction and not on a direct interview with the partner himself.

#### CONDOMS AND STDS

40. Do you think the female condom prevents gonorrhoea?

	N
no	2
yes	18
Total	20

41. Do you think the female condom prevents syphilis?

	N
no	2
yes	18
Total	20

42. Do you think the female condom prevents AIDS?

	N
no	2
yes	18
Total	20

43. Do you think oral sex prevents gonorrhoea?

	N
no	20
yes	0
Total	20

44. Do you think oral sex prevents syphilis?

	N
no	20
yes	0
Total	20

45. Do you think oral sex prevents AIDS?

	N
no	20
yes	0
Total	20

46. Can you tell if a man has gonorrhoea?

	N
no	6
yes	14
Total	20

47. Can you tell if a man has syphilis?

	N
no	20
yes	0
Total	20

48. Can you tell if a man has AIDS?

	N
no	20
yes	0
Total	20

49. Can the male condom prevent gonorrhoea?

	N
no	2
yes	18
Total	20

50. Can the male condom prevent syphilis?

	N
no	2
yes	18
Total	20

51. Can the male condom prevent AIDS?

	N
no	3
yes	17
Total	20

52. Which STD are you afraid of most?

	N
AIDS	20
syphilis	0
gonorrhoea	0
other (specify)	0.....
Total	20

53. What do you do to prevent STD?  
 Actions include .....
- Use male or female condom
  - Avoid oral sex
  - Not promiscuous
  - Douche
  - Visit doctors to check up
  - Use antiseptic solution

54. a) Is prevention of STD the responsibility of the man or the woman?

	N
man	0
woman	5
both	15
Total	20

b) Why .....

- Why the woman alone should take responsibility
- men are not afraid of catching or spreading STD
  - we can't tell if the man has STD

- Why both should take responsibility
- both are at risk
  - both are afraid of contracting STD
  - both should be clean
  - using condoms (male or female) requires the cooperation of both partners

#### COMMUNICATIONS

55. a) Would you advise others to use the female condom?

	N
no	2
yes	18
Total	20

b) Why?.....

- Reason would not advise others to use the condom include ...
- we know the man won't like it
  - we don't have enough facts yet (on the method)

- Reason would advise others to use the female condom include ...
- peace of mind when you know you're preventing STD
  - better than using nothing
  - it's new, others should try it
  - want friends to learn about new methods

56. a) Have you ever spoken to others about the female condom?

	N
no	.0
yes	20
Total	20

b) Why?.....

Reason spoke to others about the female condom include ...

- wanted to tell them to try a new method
- they asked me about it
- told our boyfriends about it

57. Do you think women need to have someone train them to insert the condom or can they understand from the leaflet like the one we gave you?

	N
need training	10
can learn from leaflet	10
Total	20

58. Do you think you know enough to train others how to use it?

	N
no	2
yes	18
Total	20

59. Do you think other women will use it?

	N
no	2
yes, a few	17
yes, many	1
Total	20

Why?.....

Why other women probably won't use the condom

- too big and inconvenient

Why other women will use the female condom

- out of curiosity
- to protect self from STD

60. Why do you think other women will not want to use it?

- not easy to use
- male partner(s) object
- too large
- they are not interested in a new method

GENERAL VIEW OF FEMALE CONDOM

61. Would you like to use the female condom in the future?

	N
no	7
yes	13
Total	20

62. Please tell me the things you liked best about these female condoms:

Most favorable aspects of the female condom include ...

- STD prevention
- clean and easy to dispose of
- no skin rash or itching as with the female condom
- thick enough to prevent all STD
- new and interesting
- the woman is in control

63. Now please tell me the two things you liked least about these female condoms:

Least favorable aspect of the female condom include...

- inner ring too hard
- outer ring too large (i.e., a turn-off)
- doesn't fit snugly
- moves around in the vagina
- takes time to insert
- inconvenient to carry around
- too long and wide
- hard to convince partner to agree to letting me use it

64. Is there anything else you would like to say about your experience using the female condom?

Recommendations to improve the female condom include ...

- soften the inner ring
- need a female condom that the man cannot see
- it may be hard to find a market for this, therefore it should be sold cheaply, such as \$0.40 to \$0.80 each

APPENDIX B.  
PROTOCOL

CONSUMER PREFERENCE STUDY OF A FEMALE CONDOM  
IN A SEXUALLY ACTIVE POPULATION AT RISK OF CONTRACTING AIDS

August 26, 1988

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Khon Kaen University  
Khon Kaen, Thailand

Family Health International  
Research Triangle Park  
Durham, North Carolina 27709 USA

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## I. Introduction

It is now well-established that AIDS is a threat to Thailand. The number of cases of HIV infection is increasing dramatically. The epidemiology of the spread of AIDS is generally following the Western model. The first cases, diagnosed in 1984, were male homosexuals. These were followed several years later by AIDS cases infected by blood transfusion. Now, intravenous drug addicts in poor urban areas are the highest risk group and the infection is expected to spread from these groups into the general heterosexual population.

Thailand is noted for its success in family planning. Contraceptive prevalence currently stands at 70% of eligible couples. This high rate has been achieved almost entirely through the use of female methods of contraception which, in order of popularity are female sterilization, the pill, the injectable and the IUD. Male contraceptive methods have never accounted for more than a few percent of eligible couples.

The Ministry of Public Health of Thailand (MOPH) currently has a policy to contain the spread of AIDS through the promotion and use of condoms in high-risk groups of the population or those who have sexual contact with individuals at risk of contracting AIDS. The use of condoms can greatly reduce the risk of AIDS infection. A recent report calculated that, in the U.S.A. a single act of unprotected intercourse with an infected partner carries a risk of 1 in 500 of contracting HIV. If male condoms are used with a low-risk partner the risk of being infected decreases to 1 in five billion.

However, if Thai men have failed to take the initiative in preventive reproductive behavior, they may not take the initiative in AIDS prevention. If Thai women are allowed the means to prevent STD through the use of a female condom, the AIDS-prevention program of the MOPH is more likely to succeed.

The female condom has been developed by a Danish obstetrician and is assumed to be an effective barrier to the AIDS virus. This device has not yet been tested among Thai couples although samples have been brought into the country on an individual basis. Before any female condom distribution and education program can take place, it is essential to first study the acceptability of the condom among high-risk women and their partners.

In a recent AIDS-prevention study conducted by the proposed principal investigator, male condom use was increased from 50% to 70% of episodes of sexual intercourse through intensive education of highly sexually active women. Among the same group, levels of syphilis infection did not decrease significantly indicating that a higher level of protection is needed to reduce the risk of STD (and AIDS) infection. This document is a proposal to conduct a small feasibility trial of the female condom among the same population of high risk women and their partners. The ultimate

goal is increased AIDS-preventive behavior, in this case, through a female barrier method.

## II. Study Objectives

This protocol describes a small study to test the short-term acceptability of a female condom in a population of high risk women. Issues of fit, comfort, slippage, breakage and acceptability to both the user and her partners will be examined. Also, the decision to use any condom, and if so whether to use the standard male condom or female condom, will be examined.

The effectiveness of this condom is not being tested at this time.

## III. Length of Study

The study will take a maximum of eight months to complete, from initiation through data analysis and reporting. The first two months will be for designing and pretesting the interview schedule and instruction sheet. The next ten weeks will be for the actual field work, training and interviewing the participants for the two-week trial as well as doing the STD testing. A fifth and sixth month are needed for data analysis and a seventh month for writing the report, with the eighth month for any revisions, printing and dissemination.

## IV. Number of Participants

Twenty highly sexually active women will be randomly selected from among women working in a single massage parlor. We expect that women will be interested in trying the new barrier methods because of the unwillingness of some of their partners to use standard condoms. Volunteers will be examined by a physician before initiating the study to insure that they are not pregnant or that they do not have any STDs.

The study subjects are already fully informed about standard condom usage as part of on-going counseling. As part of this study, they will be trained in the use of the female condom by the study investigators. They will be protected by an effective method of contraception and will be using spermicidal lubrication as backup protection against STDs when using the female condom.

Subjects who wish to terminate the study prematurely will be asked to inform the investigator of the reason(s).

Confidentiality will be protected at all times and informed consent will be obtained.

## V. Institutional Review

This study is pending approval from the Protection of Human Subjects Committee of Family Health International (FHI). Prior to shipment of any study supplies, the Principal Investigator will provide FHI with written documentation that the study protocol has been approved by the appropriate local institutional review committee.

## VI. Informed Consent

The purpose of this study will be fully explained to each potential subject prior to entering the study. Women electing to participate in the study will read or will have read to them a copy of the Fact Sheet (Appendix A), which explains the reasons for the study, the way in which it will be conducted and potential side effects that they may encounter during the study. Each volunteer will be required to give informed consent by signing the Volunteer Agreement (Appendix B), acknowledging that the study has been explained to her and that she has been offered a copy of the Fact Sheet and Volunteer Agreement. The signed Volunteer Agreement will be retained by the Principal Investigator.

Subjects will be asked to describe any adverse reactions experienced when using the study product. Serious adverse reactions experienced by the subjects or their partners during the study must be reported immediately to FHI's Protection of Human Subjects Committee.

## VII. Study Product

The WPC 333 female condom is a loose-fitting polyurethane sheath, 15 cm long with a soft polyurethane ring attached to the open end to keep the condom from being displaced. A firmer polyurethane ring is inside the sheath to facilitate insertion into the vagina and to ensure that the female condom remains in place during intercourse. The inner ring need not rest against the cervix but may be placed in the fornices. The act of coitus will seat the inner ring in the proper position. The inner ring should be left in the female condom during intercourse. The condoms will be lubricated with Nonoxynol-9 and extra spermicidal lubricant will be provided.

This female condom differs from the male condom in three respects:

1. It is not skin tight, but covers the surface of the vagina allowing the penis to move freely inside the female condom.
2. It can be inserted or put on well in advance of coitus, thus reducing interference in the actual act of intercourse.

3. It protects the entrance to the vagina and urethra as well as the vagina itself, and also the base of the partner's penis.

The materials used to make this condom have been approved by the FDA for certain biomedical applications. Nevertheless, they may cause some irritation in a small number of users, as may the Nonoxynol-9 in the lubricant.

Specific instructions will be prepared for the female condom, and tailored to the participants. The participants will be trained in the use of the female condom and educated about AIDS prevention by the study staff.

#### VIII. Study Supplies

The female condoms will be provided by FHI free of charge after joint approval of this study by the Principal Investigator in each country and the Contracts Administrator of FHI.

The Principal Investigator is responsible for assuring proper storage conditions for the female condoms, as recommended by the manufacturer's guidelines. The Principal Investigator is also responsible for keeping an accurate inventory of the condoms supplied by FHI and the number supplied to participants.

#### IX. Study Procedures

Twenty subjects will be trained in the use of the female condom by the study investigators. They will then be given 25 female condoms to use during the next two weeks, along with the spermicidal lubricant. They may obtain more if needed. After two weeks of use, they will be asked to demonstrate application of the condom, and will be interviewed about how many female and standard condoms they used during the two week period, when and why; any slipping or breaking; and their own satisfaction and their partners' satisfaction. Both structured and unstructured questions will be asked. (Note: This group of high risk women averages 10 episodes of vaginal intercourse per week).

- A. Data Analysis: The functional aspects of the female condom will be assessed by comparing subject satisfaction and comments concerning its positive and/or negative aspects. Particular attention will be given to reports of slipping, breaking or tearing during use. Analysis of the data will be performed in Thailand by the Principal Investigator with technical assistance from FHI.
2. Reporting: A preliminary report will be issued after the interview schedule has been designed and the cases recruited into the study. A final report written with technical

assistance from Family Health International (FHI) will present the full results of the study plus recommendations to the Ministry of Public Health.

As an incentive to participate, subjects will be offered free blood screening for HIV and syphilis at the start and end of the study. They already receive regular counseling and education by the medical staff that will conduct this study. Previous research with the target population has shown that the free blood screening helps to increase cooperation and reduce loss to follow-up.

#### X. Study Termination

If participants decide to discontinue use of the method for any reason before completing two weeks of use, reasons for discontinuation should be fully documented on the follow-up form. FHI may terminate the study at any time should sufficient evidence become available that shows the condoms to be associated with any major complication, or other unanticipated or undesirable effects. At this point, there is no reason to expect that study participants will be put at any risk.

#### XI. Investigator Responsibility

The Principal Investigator will be responsible for carrying out the following tasks or for delegating them to appropriate study personnel and supervising their performance:

1. Inform each participant about the study, and any risks and benefits of her participation using a fact sheet (Appendix A) and obtain a properly executed, signed, witnessed "Volunteer Agreement" form for each study participant.
2. Provide STD check-ups and counseling as needed, before and after participation.
3. Train women in use of female condom.
4. Train interviewers (if PI doesn't do all interviews), etc.
5. Develop final questionnaire, have it reviewed by FHI.
6. Insure interviews are conducted in friendly fashion.
7. Provide appropriate care on referral for the participant after her enrollment in the study if problems relating to the study products occur.
8. Complete data collection forms as required at designated times.

9. Data analysis/report writing.
10. Maintain a master log of study participants and establish a filing system to alert interviewers to scheduled follow-up contacts; establish procedures to locate and interview those women who miss their scheduled follow-up interview.
11. Provide the original copies of all completed screening and follow-up forms to FHI at the end of the study; maintain study files (including "Volunteer Agreements"), for this study for three years after the study is complete.
12. Respond to data queries initiated by FHI project staff.
13. Make available for review participant or other records which relate to this study for FHI study monitors or other authorized individuals.
14. Notify FHI immediately by telephone or telex of any serious or unanticipated adverse experience, and by submitting a completed follow-up form on anyone with an adverse experience related to the study.
15. Sign all data collection forms.
16. Provide a C.V. for the Principal Investigator to FHI.

#### XII. Data Analysis

Initial data analysis will be done by the Principal Investigator and staff. A copy of all completed data collection forms will be sent to FHI as soon as the data collection is completed. On-site monitoring of the study, including a review of participants and study records, may be conducted during the course of the study by FHI. All site visits will be arranged at the mutual convenience of the study investigator(s) and FHI.

The analysis will be primarily descriptive and will consist of the characteristics of the participants, their opinions about the study condoms in and of themselves and in comparison with other forms of protection against STDs. The draft report will be sent to FHI by the Principal Investigator after completion of the study and will be reviewed and edited at FHI and then sent to the PI for final approval.

#### XII. Benefits of Study

This study will provide important information on acceptability of this female condom in a population at high risk of AIDS and other STDs, whose partners may not agree to use a standard male condom.

## APPENDIX C.

### FACT SHEET

Name of Study: Consumer Preference Study of a Female Condom

Principal Investigator: Chuanchom Sakondhavat, MD  
Khon Kaen University Dept. of Ob/Gyn

#### Reasons for the Study

We would like you to be in a research study to find out if a female condom is acceptable to women who may be worried about getting AIDS. We want to learn if the female condom is comfortable and easy to use, if it stays in place, and if it breaks. We also want to know how much your partners notice the condom, and how you and they feel about using this female condom instead of a standard condom or no condom at all.

The study will last about two weeks. About 20 women will be in the study. If you agree to be in the study, you will be taught how to use the female condom and given 25 condoms to use. At the end of the two weeks, you will be asked about your reactions to that female condom and about the reactions of your partners.

You are asked to use the female condom as often as possible, but to let us know exactly how many times you use the female condom, how many times you use a standard (male) condom, and how many times you use neither condom.

#### Benefits and Risks

The materials used in these female condoms are generally safe and should not cause you any irritation. The spermicidal lubricant (Nonoxynol-9) is currently available in many condoms and other birth control products. However, we do not know yet how well the female condom prevents pregnancies or sexually transmissible diseases. We will give you the female condom at no cost while you are in the study, and we will check you for AIDS and syphilis at the beginning and end of the study, if you would like. What we learn from this study may not help you, but later it may help to improve the health of others.

#### Other Methods of Birth Control

We ask that you use another method of family planning while you are in the study.

#### Confidentiality

No one except Dr. Chuanchom and her staff will know that you are

In this study. Your name will not be put on the forms, and you will only be identified by number. If the results of this study are published in medical journals or somewhere else, your name will not be included.

### Compensation

You do not have to be in this study unless you agree to be. You will not be paid or rewarded in any way for being in the study. If you want, you can receive a free HIV test for AIDS and a test for syphilis at the beginning and end of this study, and you will be provided with the results of those tests. If you are found to have HIV or syphilis, you will be provided counseling, and will receive treatment for syphilis.

If you get sick, you should telephone Dr. Chaunchom Sakondhavat at the Department of Ob/Gyn at Khon Kaen University. If you are sick or have a medical problem because you are in this study, Dr. Chaunchom will provide medical attention free of charge. If you need more help, she will refer you to other services, which you may have to pay for. If you think you are infected at any time during the study, please contact Dr. Chaunchom right away.

### Contact for Questions

If you have any questions after the study has been explained to you, or after the study has begun, or if you have a medical problem which may be due to the study, please ask Dr. Chuanchom. Her telephone number is \_\_\_\_\_. We will also give you a card with her name and telephone number, and we will also give you a copy of this form.

### Right to Leave the Study

You will be in this study only if you want to volunteer. If you want to leave the study any time, or if the doctor asks you to leave the study, there will be no penalty. If you want to leave the study, please tell Dr. Chuanchom or her staff why you wish to leave. You will still be able to receive regular care and counseling from Dr. Chuanchom and her staff. If we get any new information about the female condom, we will tell you at once.

This study has been approved by the Protection of Human Subjects Committee of Family Health International, [and the ethics committee of Khon Kaen University Hospital.]

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APPENDIX D.

VOLUNTARY AGREEMENT FORM

Study: Consumer Preference Study of a Female Condom in a Sexually Active Population at Risk of Contracting AIDS

Principal Investigator: Chuanchom Sakondhavat, MD  
Khon Kaen University Dept. of Ob/Gyn

I have read and been given the Fact Sheet and agree to be in this study of a female condom.

\_\_\_\_\_  
Print name (Volunteer)

\_\_\_\_\_  
Sign name (Volunteer)

\_\_\_\_\_  
Date

-----  
WITNESS

I was present while the volunteer read the Fact Sheet about the study, had further explanation of the study and her questions answered, and when she signed the agreement.

\_\_\_\_\_  
Sign name (Witness)

\_\_\_\_\_  
Date

-----  
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**For Illiterate Volunteers Only:**

I certify that the Fact Sheet about this study and the Volunteer Consent Form have been read to the volunteer in her native language. The reasons for this study, the benefits and risks of the device and the way in which the study will be conducted have also been fully explained to her and she agrees to participate as a volunteer in this research project.

\_\_\_\_\_  
Sign name (Witness)

\_\_\_\_\_  
Date

APPENDIX E.

KHON KAEN  
FEMALE CONDOM ACCEPTABILITY STUDY  
ADMISSION QUESTIONNAIRE

IDENTIFICATION

1. Patient number:
2. Study number:
3. Date of admission visit (day, month, year): \_\_/\_\_/\_\_

PATIENT CHARACTERISTICS

4. What is your age? (completed years): \_ \_
5. What is the highest level of schooling you have completed?  
0) none 1) primary 2) secondary 3) post-secondary
6. How many pregnancies have you had? \_ \_
7. Have you ever had gonorrhoea?  
0) no 1) yes
8. Have you ever had syphilis?  
0) no 1) yes
9. Have you ever had any other STD?  
0) no 1) yes
10. Are you currently using a method of birth control?  
0) no (IF NO, INELIGIBLE)  
1) yes What method? \_\_\_\_\_

FOLLOW-UP

11. Date of scheduled follow-up visit (day, month, year): \_\_/\_\_/\_\_
- Card number:

\_\_\_\_\_  
Investigator's signature

\_\_\_\_\_  
Date

BEST AVAILABLE DOCUMENT

KHON KAEN UNIVERSITY  
FEMALE CONDOM ACCEPTABILITY STUDY  
FOLLOW-UP QUESTIONNAIRE

**IDENTIFICATION**

1. Patient number:
2. Study number:
3. Date of follow-up visit (day, month, year): \_ \_ / \_ \_ / \_ \_
4. Result of interview attempt: 1) completed 2) refused 3) could not locate

**PRODUCT USE**

5. How many times have you had vaginal intercourse since receiving the female condoms? \_ \_
6. Did you ever use the female condom?  
0) no 1) yes (IF NO, DISCONTINUE)
7. a) How many times did you use the female condom only? \_ \_  
b) How many times did you use a male condom only? \_ \_  
c) How many times did you use both male and female condoms? \_ \_  
d) How many times did you use no condom of either type? \_ \_
8. Did you use the female condoms throughout the two weeks, or did you stop using them at some point?  
1) discontinued 2) used for entire two weeks
9. If you stopped using it, what was the main reason? 1) caused discomfort to me 2) caused discomfort to my partner(s)  
3) inconvenient 4) messy 5) decreased sexual satisfaction  
6) partner(s) objected 7) out of supplies 8) other reason,  
specify \_\_\_\_\_
10. Did you use these condoms during your period? 0) no 1) yes
11. Did you douche after use of these condoms? 0) no 1) yes
12. Did you reuse any of these condoms? 0)no 1)yes

**WOMAN'S PERCEPTIONS OF PRODUCT**

13. In general, how did you like the female condoms?  
0) no opinion 1) a great deal 2) a little 4) disliked

14. Did the female condom provide lubrication?  
0) no 1) yes, a little 2) yes, 'too much
15. Did the female condom have a noticeable odor?  
0) no 1) yes, pleasant 2) yes, unpleasant
16. Was it hard to insert properly?  
0) no 1) yes, sometimes 2) yes, often
17. Did you feel inner ring during intercourse?  
0) no 1) somewhat 2) continuously
18. If you felt the inner ring, did it interfere with intercourse?  
0) no 1) yes
19. Did the female condom stay in place?  
0) no 1) yes
20. Did you feel the outer ring?  
0) no 1) yes
21. Did it interfere with intercourse?  
0) no 1) yes
22. Did the outer ring of the condom get pushed up into your vagina?  
0) no 1) yes, once 2) yes, more than once
23. Did partner ever insert penis between the outer ring and your vagina?  
0) no 1) yes
24. Did any of these female condoms tear or rip during insertion?  
0) no 1) yes, how many? \_\_\_\_\_
25. Did any of these female condoms tear or rip during intercourse?  
0) no 1) yes, how many? \_\_\_\_\_
26. Was it easy to remove?  
0) no 1) yes
27. Did you have enough education/information to use this condom correctly? 0) no 1) yes
28. Did the female condom cause you any discomfort?  
0) no 1) yes
29. a. Did it cause you any pain or burning?  
0) no 1) minor but able to ignore it 2) moderate and interfered with sex 3) severe and so unable to have sex  
 b. If yes to 1, 2, or 3, how long did the pain last? 1) briefly; disappeared when intercourse began 2) throughout intercourse, but ended when intercourse ended 3) continued after intercourse ended

30. Did it bother you to insert the condom by yourself?  
0) no 1) yes
31. a. How convenient is the female condom compared to the male condom?  
1) less convenient 2) about the same 3) more convenient
- b. In what way(s): \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**PARTNERS' REACTIONS**

32. Did your partner(s) know that you were using the female condom?  
0) no 1) some did, 2) all did 8) don't know
33. Did you tell your partner(s) you were wearing a condom?  
0) no 1) yes, some 2) yes, all
34. Did they like or dislike the condom? 1) all liked 2) some disliked, some liked, 3) all disliked 8) don't know
35. Did the female condom affect your partners' overall sexual satisfaction?  
0) no 1) yes, all increased 2) some increased, some decreased  
3) all decreased 8) don't know
36. Did the spermicide cause them any pain or burning?  
0) no 1) yes, some of them 2) yes, all of them 8) don't know
37. Did your partner(s) ever feel the inner ring?  
0) no 1) some did 2) all did
38. Was this condom long enough? 0) no 1) yes
39. Did they mention any other difference in sexual intercourse caused by the female condom?  
0) no 1) yes, specify \_\_\_\_\_

**CONDOMS AND STDS**

40. Do you think the female condom prevents gonorrhoea?  
0) no 1) yes
41. Do you think the female condom prevents syphilis?  
0) no 1) yes
42. Do you think the female condom prevents AIDS?  
0) no 1) yes
43. Do you think oral sex prevents gonorrhoea?  
0) no 1) yes

44. Do you think oral sex prevents syphilis?  
0) no 1) yes
45. Do you think oral sex prevents AIDS?  
0) no 1) yes
46. Can you tell if a man has gonorrhoea?  
0) no 1) yes
47. Can you tell if a man has syphilis?  
0) no 1) yes
48. Can you tell if a man has AIDS?  
0) no 1) yes
49. Can the male condom prevent gonorrhoea?  
0) no 1) yes
50. Can the male condom prevent syphilis?  
0) no 1) yes
51. Can the male condom prevent AIDS?  
- 0) no 1) yes
52. Which STD are you afraid of most?  
1) AIDS 2) syphilis 3) gonorrhoea 4) other (specify) \_\_\_\_\_
53. What do you do to prevent STD? \_\_\_\_\_  
\_\_\_\_\_
54. a. Is prevention of STD the responsibility of the man or the woman?  
1) man 2) woman 3) both  
b. Why? \_\_\_\_\_  
\_\_\_\_\_

#### COMMUNICATIONS

55. a. Would you advise others to use the female condom?  
0) no 1) yes  
b. Why? \_\_\_\_\_  
\_\_\_\_\_
56. a. Have you ever spoken to others about the female condom?  
0) no 1) yes  
b. Why? \_\_\_\_\_  
\_\_\_\_\_
57. Do you think women need to have someone train them to insert the condom or can they understand from the leaflet like the one we gave you?  
0) need training 1) can learn from leaflet
58. Do you think you know enough to train others how to use it?

0) no 1) yes

59. Do you think other women will use it?

0) no 1) yes, a few 2) yes, many

Why?

(If 1 or 2, skip to 61)

60. Why do you think other women will not want to use it?

#### GENERAL VIEW OF FEMALE CONDOMS

61. Would you like to use the female condom in the future?  
0) no 1) yes

62. Please tell me the two things you liked best about these female condoms:

a. \_\_\_\_\_

b. \_\_\_\_\_

63. Now please tell me the two things you liked least about these female condoms:

a. \_\_\_\_\_

b. \_\_\_\_\_

64. Is there anything else you would like to say about your experience using the female condom?

a. For yourself? \_\_\_\_\_

b. For your partner? \_\_\_\_\_

65. Do you have any final comments about the female condom or about the study? 0) no 1) yes What \_\_\_\_\_

Card number: \_\_\_\_\_

Investigator's signature \_\_\_\_\_

Date \_\_\_\_\_