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**ACCEPTABILITY AND FUNCTIONALITY OF  
STANDARD AND SMALLER LATEX  
CONDOMS DURING HUMAN USE:  
PHILIPPINES**

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## TABLE OF CONTENTS

|       |   |    |
|-------|---|----|
| I.    | Executive Summary .....                               | i  |
| II.   | Introduction .....                                    | 1  |
| III.  | Study Objectives .....                                | 2  |
| IV.   | Study Products .....                                  | 2  |
| V.    | Study Subjects .....                                  | 2  |
| VI.   | Study Design .....                                    | 3  |
| VII.  | Data Analysis .....                                   | 4  |
| VIII. | Results   |    |
|       | A. Sociodemographic Characteristics .....             | 4  |
|       | B. Past Condom Use Experience .....                   | 4  |
|       | C. Comparison of Condom Failure By Size .....         | 5  |
|       | D. Details of Condom Use, Breakage and Slippage ..... | 5  |
|       | E. Acceptability .....                                | 5  |
|       | F. Previous Condom Use and Future Preference .....    | 6  |
| IX.   | Discussion .....                                      | 7  |
| X.    | References .....                                      | 11 |
| XI.   | Tables .....  | 13 |
| XII.  | Appendix I: Study Questionnaires .....                | 21 |

## **I. EXECUTIVE SUMMARY**

The purpose of this study was to compare the breakage and slippage rates in actual use of standard versus smaller latex condoms (layflat widths 52mm and 49mm). Consumer preference was also evaluated. The results are intended to encourage distribution of reliable and acceptable condoms to the Philippines, as well as other Asian countries.

One-hundred and fifty men tested 744 smaller and 750 standard condoms. Breakage rates were very low (smaller=0.5%, standard=0.1%) and none of the condoms reportedly slipped off. The difference between these two rates is not statistically significant ( $p=0.5$ ).

Participants reported that both condoms were fairly acceptable. Based on a scale ranging from "liked very well" to "strongly disliked", ratings were favorable and very similar for the two condoms. Almost equal proportions of participants chose smaller or standard condoms with respect to which they generally "liked better", which "stayed on better", and which was "more comfortable to wear". For these measures of preference, 14% to 27% of the participants reported that both condoms were the same. Interestingly, 91% of the participants indicated that the standard condom "felt bigger". Slightly more participants reported that they would prefer to use standard condoms in the future.

Some caution should be used when interpreting these results. Participants were self selected and from only one site (Olongapo). They were fairly experienced condom users and many were part of a program with a strong education component. Furthermore, some participants reported that the study condoms were better lubricated and "fresher" than condoms they normally receive. Consequently, it is not known how well these participants represent condom recipients in the Philippines, or how similar the study condoms are to condoms distributed in this country.

FHI studies with the same design were also conducted in sites in Nepal and Sri Lanka. Similar to the Philippines, the functionality and acceptability results do not suggest that smaller condoms are preferable to standard condoms among participants from these two sites.

## II. INTRODUCTION

Although condoms have been a means of contraception and disease prevention for centuries, they have been given an elevated role in recent years. While continuing to serve as a valuable method of family planning, in large part this renewed interest in condoms is due to the crucial role they play in reducing the spread of sexually transmitted disease (STD), in particular the human immunodeficiency virus (HIV).

Researchers estimate that when used consistently and correctly during vaginal intercourse, condoms are up to 98% effective as a contraceptive and highly effective as a barrier against STD as well.

Nevertheless, as Contraceptive Technology 1990-1992 explains, "The condom's effectiveness depends heavily on how consistently it is used. The most common patient error is failure to use the condom".<sup>1</sup>

Thus, in the effort to increase the consistency of use, there is a crucial need to provide condoms that users will find most acceptable, both in terms of their reliability and their user-specific characteristics. In particular, many have speculated that the size of a condom may be an important characteristic related to comfort, sensitivity, breakage and retention.

The United States Agency for International Development (A.I.D.) currently provides smaller (49mm) latex condoms to several Asian countries, including the Philippines. An article which appeared in the Philippine popular press in 1992 summarized results of a survey of condom users commissioned by the Philippine Department of Health.<sup>2</sup> According to the article, the study found that among typical condom users, the most common complaints were that condoms are oversized, painful for women, not effective, and easily torn. Among the 2477 commercial and public outlets in three cities included in the study, 10% reported that they received complaints from the condom recipients.

Prior to recent FHI studies conducted in Nepal and Sri Lanka, to our knowledge, prospective studies have not been conducted to assess the performance and acceptability of smaller condoms in actual use.

1

5

Consequently, it has been unclear whether men in some Asian populations find that smaller condoms perform better than standard condoms (52mm) with respect to breakage, slippage, and acceptability.

### **III. STUDY OBJECTIVES**

The primary objective of this human use study was to determine if there were statistically significant differences in breakage and slippage rates between the standard and smaller A.I.D. latex condoms (52mm and 49mm layflat width, respectively). Furthermore, this study was designed to compare acceptability of the two sizes of condoms, focusing on preference, comfort and fit. In an effort to provide reliable and acceptable condoms to the Philippines and other Asian countries, the results of this study are intended to assist A.I.D. when considering future procurement of condoms for these countries.

### **IV. STUDY PRODUCTS**

This study tested two types of pre-lubricated latex condoms. The first is the standard latex condom manufactured by Ansell Inc., and distributed worldwide by A.I.D. This condom is 52mm in layflat width. The second, or smaller condom, is 49mm in layflat width, also manufactured by Ansell and distributed by A.I.D. Both condoms were packaged in white cellophane film and lubricated with silicone. Prior to human testing, the condom lots were sampled by FHI's Material Technology Division and met criteria set by the American Society for Testing and Materials (ASTM) Standard D-3492. The condom lots were also sampled to ensure that the respective layflat widths (52mm or 49mm) met the appropriate specifications.

### **V. STUDY SUBJECTS**

This study was conducted by the Olongapo City Health Department, which has one of the largest family planning/STD prevention clinics in this Philippine city of approximately 345,000 inhabitants. The 150 participants who made up the study cohort were recruited from the client base of the City Health Department and the City Population Office.

To be eligible for the study, a participant had to meet the following selection criteria:

1. be at least 18 years of age;
2. be a sexually active male;
3. be a current or past condom user;
4. be willing to use ten condoms during vaginal intercourse during a two month period;
5. be willing to return for two follow-up visits during the study period;
6. be willing to answer questions about the use of the study condoms; and
7. be willing to sign an informed consent form.

Prior to study initiation, the study protocol was reviewed and approved by FHI's Protection of Human Subjects Committee.

## **VI. STUDY DESIGN**

Prior to admission, the purpose of the study and any associated benefits and risks were explained to potential participants. If they chose to participate, they were required to sign a written informed consent form. Once admitted, each participant was administered a background interview to gather information on sociodemographic characteristics, as well as prior use of condoms.

A single blind study design was used to test the condoms. Each participant was first given a set of five smaller condoms (49mm), provided with information on the correct use of the study products, and was requested to use all five condoms over a one month study phase. After using the first product, the participants were administered a follow-up questionnaire to assess breakage, slippage and acceptability of the smaller condoms. The same procedure was followed with the second set of five standard condoms (52mm). Upon completion of using both size condoms, a final questionnaire was administered to assess consumer preference and acceptability, as well as preference for future use. Active enrollment of participants lasted for approximately two months.

## **VII. DATA ANALYSIS**

The data set was analyzed by FHI staff. SURVEY was used to enter the data and Epi Info version 5.01b was used to produce the frequencies and cross tabulations presented in this report. The test of marginal homogeneity for ordered data (an extension of McNemar's test) was used for pairwise comparisons of breakage and slippage between the two condom types. Slippage, for the purpose of this study, was defined as the condom completely slipping off the penis before, during or after ejaculation. If a condom reportedly both broke and slipped off, only breakage was counted. This convention is based on the assumption that in these cases, breakage often leads to the condom slipping off. Condom failure was defined as the sum of breakage and slippage.

The test of marginal homogeneity for ordered data was also used to assess preferences of one condom size over the other. Two tailed z-tests were employed to evaluate if there were statistically significant differences in participant perceptions of, and future preference for, the two types of condoms. Significance was set at a level of alpha equal to 0.05.

## **VIII. RESULTS**

### **A. Sociodemographic Characteristics**

A total of 150 men from Olongapo were recruited and completed the study (Table 1). The median age of the participants was 36 years and the range was 19 to 65 years. Almost one third of the men were 40+ years of age, while only 9% were less than 25 years old. The median reported number of years of education was 10. Only 1% of the men reported that they had no education, while 35% reported having 11 or more years of education. Almost all of the men reported that they were married and/or in union at admission. All of the men reported that they considered themselves to be of Malay ethnicity.

### **B. Past Condom Use Experience**

Reported prevalence of past condom use was fairly high, both in terms of lifetime use and use in the past year (Table 2). More than half (55%) of the men reported using 26-100 condoms in their



lifetime. Just over one fourth (26%) of the men reported having used fewer than 26 condoms in their lifetime. In terms of condom use in the past year, 43% of the men reported having used between 26 and 100 condoms.

### **C. Comparison of Condom Failure By Size**

In this study, 744 smaller and 750 standard condoms were tested (Table 3). Reported breakage and slippage among the smaller and standard condoms was very low. According to participants, only four smaller condoms (0.5%) broke and one standard condom (0.1%) broke. None of the smaller or standard condoms reportedly slipped off. Consequently, condom failure (the sum of breakage and slippage) for the smaller and standard condoms in this study was also low (0.5% and 0.1%, respectively). There were no statistically significant differences when comparing the proportions of smaller versus standard condoms that broke, slipped off, or failed ( $p=0.5$ ).

### **D. Details of Condom Use, Breakage and Slippage**

According to the participants, they almost always tested the study condoms with their wives or regular partners (Table 4). Condom use with another partner or a prostitute was infrequent. Only six smaller condoms and no standard condoms were reportedly used with additional lubricant.

Participants reported that breakage happened along the tip or the opening of the condoms (Table 5). Among the four smaller condoms that broke, two broke while opening the package, while timing of breakage for the other two was not specified. The one standard condom that failed, reportedly broke at the opening of the condom during intercourse. According to the participants, all breakage took place while the condoms were being used with the men's wife or regular partner (Table 5). No additional lubrication was used with any of the condoms that failed.

### **E. Acceptability**

The majority of men indicated that they liked both the smaller and standard condoms (Table 6). Based on a scale, where 1="liked very much" and 5="strongly disliked", the mean ratings for the

smaller and standard condoms were very similar (2.1 and 2.0, respectively). Two thirds of the men reported that they liked the smaller and standard condoms either very or fairly well. Approximately one third of the men neither liked nor disliked the smaller and standard condoms. The test of marginal homogeneity for ordered data showed no significant difference in these ratings of the smaller and standard condoms.

Preferences for smaller or standard condoms, based on several acceptability parameters, are summarized in Table 7. There were no statistically significant differences in preference with respect to which of the two study condoms men "liked better", which was "easier to put on", which "stayed on better" and which was "more comfortable to wear". Interestingly, most men (91%) did indicate that they thought the standard condom "felt bigger" ( $p < 0.001$ ), and a larger proportion of men indicated that the standard condom was "easier to put on" (approached significance,  $p = 0.095$ ).

#### **F. Previous Condom Use and Future Preference**

Just over half of the men (53%) reported that prior to the study, they had used A.I.D. brand condoms, including Sultan and Tahiti (Table 8). About one third of the men (31%) reported that they had used a non-A.I.D. brand, including Prime, Trust, Lifestyles, Sensation and Trojan. Twenty-three men (15%) reported that they were not sure what brand of condom they had used prior to the study.

Future preference was slightly in favor of standard condoms, but not statistically significant (Table 8). When combining reported preference for the standard condoms used in the study with preference for the brands of 52mm condoms used prior to the study, 54% of the men indicated that they would like to use standard condoms in the future. Combining all reported preference for smaller condoms, 42% of the men favored the smaller condoms for future use. Very few expressed no preference or did not know. There was no association between size of condoms used prior to the study and reported future preference.

## IX. DISCUSSION

The findings of this report should be of use to the Agency for International Development (A.I.D.) when considering future procurement and distribution of standard and smaller condoms for the Philippines. Some caution should be used when interpreting the results due to uncertainty as to how well the participants in this study represent the population of condom recipients in the Philippines. Participants were self selected and from only one site in the Philippines. Furthermore, the men were fairly experienced at using condoms prior to the study, and many received their condoms through a program with a strong education component.

A few of the study outcomes were particularly surprising. Incidence of breakage and slippage of the study condoms was almost nonexistent (smaller=0.5%, standard=0.1%). Also somewhat unanticipated, none of the 150 participants were lost to follow-up.

The interviewers who conducted much of the field work for this study speculated that there were several factors which contributed to infrequent breakage and slippage, and no participant drop out during the study. According to the interviewers, many of the participants received condoms through a door-to-door distribution/outreach program. The study condoms were delivered in a similar manner. Consistent with data from the background interview, interviewers also emphasized that the participants were fairly experienced and regular condom users. Reportedly, some participants found the study condoms to be better lubricated and "fresher" than condoms they normally received. Even after completion of the study, some participants specifically asked for additional study condoms. Moreover, at the time of the study, there were shortages in the regular condom supplies and participants were remunerated based on how many condoms they used, increasing the likelihood that participants would use all of the study condoms. Although participant/interviewer relationships can inhibit participants from being critical of study products, the interviewers did not think the men in this study withheld information concerning problems experienced during the study.

Despite possible limitations, in terms of functionality and acceptability, the results of this study suggest that there are no clear advantages of one condom size over the other among Filipino condom recipients. Differences in breakage, slippage and failure rates between the two types of condoms were not statistically significant. Acceptability was frequently split between the two condoms. When the two condoms were rated on a scale where 1="liked very well" and 5="strongly disliked", the distributions of ratings were almost identical and very favorable.

Moreover, with the exception of future preference, a sizable proportion of participants indicated that they perceived both condoms to be the same. After testing both types of condoms, almost equal proportions of participants chose smaller or standard condoms with respect to which condom they generally "liked better", which "stayed on better", and which was "more comfortable to wear". For these same measures of preference, from 14% to 27% of the participants reported that they thought both condoms were the same. In cases where the results seem to suggest preference for one of the condoms, they generally favor the standard condoms.

Interestingly, even though the study was designed such that the participants would not have known that the two study condoms were of different sizes, 91% of the participants indicated that they thought the standard condom "felt bigger". Thus, although a clear majority of participants did not indicate a preference for one condom over the other, the participants were apparently able to distinguish the difference in size between the two condoms.

The final measure of acceptability, future preference, was also fairly evenly divided between the two condoms. Only a marginally larger proportion of men expressed a preference for the standard condoms. As mentioned earlier, there does not appear to be an association between the type of condom used prior to the study and future preference. The participants were not specifically asked if they would be willing to use either condom type if they had no choice. However, given that many participants reportedly perceived both the smaller and standard condoms to be the same in several

12

respects, and both condoms were liked "fairly well" or "very well" by over two thirds of the participants, the results suggest that the participants would be willing to use either of the condom types if only one were available.

FHI studies with the same design and purpose were recently completed in two other Asian sites, in Nepal and Sri Lanka<sup>3</sup>. In the Nepalese site, the reported proportions of smaller versus standard condoms that broke were not statistically different (3.2% and 4.0%, respectively). However, the proportion of 49mm condoms that reportedly slipped off was significantly lower than that of the 52mm condoms (0.4% and 3.5%, respectively;  $p=0.003$ ). Preference for the smaller condom in terms of comfort, and preference for the standard condom with respect to ease of donning, were both statistically significant ( $p=0.001$  and  $p<0.001$ , respectively). However, based on the five point scale ranging from "strongly liked" to "strongly disliked", more than three fourths of the Nepalese men responded positively to the smaller condoms and almost two thirds of the Nepalese men responded positively to the standard condoms. Even more indicative of how similarly the two types of condoms were perceived, almost half of the Nepalese men thought the smaller condoms were "bigger" and more than half of these participants indicated no preference for one condom over the other for future use.

Consistent with results from the Philippines and Nepal, functionality and acceptability results from the site in Sri Lanka generally did not favor one condom type over the other. When comparing the 49mm with the 52mm condoms, neither reported breakage nor slippage was significantly different (breakage: 2.2% and 2.7%, slippage: 2.3% and 1.2%, respectively). Similar to Nepal and the Philippines, over three fourths of the participants in Sri Lanka indicated that they liked the smaller or standard condoms "fairly well" or "very well". Depending on the particular question, 27% to 63% of the men reported that they found both condoms to be the same in terms of which condom they "liked better", which condom was "easier to put on", which "felt bigger", which "stayed on better" and which was "more comfortable to wear". Interestingly, a significantly larger proportion of men in Sri Lanka reported that they would prefer standard condoms for future use ( $p<0.001$ ).

When considered separately, the results from these three Asian sites are, in some respects, inconclusive. Nevertheless, a few important trends seem to be common among all three sites. From the stand point of functionality, the results from these sites generally suggest there is little advantage to using one size condom instead of the other. The proportion of smaller versus standard condoms that broke was not statistically significantly different for any of the three sites. Similarly, there was no significant difference in the proportion of smaller versus standard condoms that slipped off in the Philippines and Sri Lanka. However, in Nepal, a significantly larger proportion of standard condoms slipped off. For effective protection against unwanted pregnancy and STD, slippage is believed to be as detrimental as breakage. Thus, although breakage was not significantly different based on condom size, some caution should be used when choosing one condom over the other based on functionality alone.

Perhaps with greater certainty, the acceptability results from these three sites suggest that the smaller condom would not be preferable to the standard condom. In all three sites, the majority of participants rated both condoms highly, based on the five point scale ranging from "strongly liked" to "strongly disliked". Future preference, an important indicator of acceptability, ranged from being very similar for both condoms in the Philippines and Nepal, to significantly favoring the standard condoms in Sri Lanka.

## X. References

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2. **Condoms are too big, city users complain.** PHILIPPINE DAILY INQUIRER 1992 Feb 25:11.
3. Neupane S, Abeywickrema S, Martinez K, et al. **Acceptability and Actual Use Breakage and Slippage Rates of Standard and Smaller Latex Condoms: Nepal and Sri Lanka.** VRG/FPASL/FHI Final Report, Durham, North Carolina, September 1992.

**Table 1**

| <b>Distribution of Participants According to Sociodemographic Characteristics<sup>1</sup></b>   |            |            |
|---|------------|------------|
| <b>Sociodemographic characteristics</b>   | <b>n</b>   | <b>%</b>   |
| <b>Age:</b>   |            |            |
| < 25  | 13         | 9          |
| 25-29   | 27         | 18         |
| 30-34   | 28         | 19         |
| 35-39   | 39         | 26         |
| 40+   | 43         | 29         |
| Median:   | 36         |            |
| Range:  | 19-65      |            |
| <b>Education<sup>2</sup>:</b>   |            |            |
| None  | 1          | 1          |
| Primary 1-6   | 22         | 15         |
| Secondary 7-10  | 75         | 50         |
| University 11+  | 52         | 35         |
| Median:   | 10         |            |
| <b>Marital status:</b>  |            |            |
| Married/in union  | 136        | 91         |
| Single  | 9          | 6          |
| Not specified   | 5          | 3          |
| <b>Total</b>  | <b>150</b> | <b>100</b> |
| <sup>1</sup> percentages in this and subsequent tables may not equal 100 due to rounding.<br><sup>2</sup> due to a limitation in the questionnaire, caution should be used when interpreting data regarding level of education. |            |            |

16



**Table 2**

| <b>Distribution of Participants According to Condom Experience Prior to Study</b> |            |            |
|---|------------|------------|
| <b>Condom experience</b>  | <b>n</b>   | <b>%</b>   |
| <b>Number of condoms used in lifetime:</b>  |            |            |
| <10   | 3          | 2          |
| 10-25   | 36         | 24         |
| 26-100  | 83         | 55         |
| >100  | 28         | 19         |
| <b>Number of condoms used in past year:</b>                                       |            |            |
| None  | 8          | 5          |
| <10   | 14         | 9          |
| 10-25   | 55         | 37         |
| 26-100  | 65         | 43         |
| >100  | 8          | 5          |
| <b>Total</b>  | <b>150</b> | <b>100</b> |

17

**Table 3**

| <b>Distribution Condom Failure (breakage and slippage)<br/>According to Condom Size</b> |                |          |                 |          |
|---|----------------|----------|-----------------|----------|
| <b>Condom failure</b>   | <b>Smaller</b> |          | <b>Standard</b> |          |
|   | <b>n</b>       | <b>%</b> | <b>n</b>        | <b>%</b> |
| Total number of condoms used  | 744            | 100.0    | 750             | 100.0    |
| Breaks  | 4              | 0.5      | 1               | 0.1      |
| Slips <sup>1</sup>  | -              | -        | -               | -        |
| Total failures  | 4              | 0.5      | 1               | 0.1      |

<sup>1</sup> when condoms reportedly slipped off and broke, only breakage was counted. This convention is based on the assumption that in these cases, breakage leads to the condom slipping off.

18

**Table 4**

| <b>Details of Condom Use According to Condom Size</b> |                |                 |
|---|----------------|-----------------|
|   | <b>Smaller</b> | <b>Standard</b> |
|   | <b>n</b>       | <b>n</b>        |
| <b>Total used:</b>                                    | 744            | 750             |
| <b>Partner at time of use:</b>                        |                |                 |
| Wife/regular partner                                  | 709            | 710             |
| Other partner   | 28             | 33              |
| Prostitute  | 7              | 7               |
| <b>Use of additional lubricant:</b>                   |                |                 |
| Oil based (Baby Oil)                                  | 5              | -               |
| Water based (Surgilube)                               | 1              | -               |

19

**Table 5**

| <b>Details of Condom Breakage According to Condom Size</b> |                |                 |
|--|----------------|-----------------|
|  | <b>Smaller</b> | <b>Standard</b> |
|  | <b>n</b>       | <b>n</b>        |
| <b>Total breaks</b>  | 4              | 1               |
| <b>Location of break:</b>                                  |                |                 |
| Opening  | 2              | 1               |
| Shaft  | -              | -               |
| Tip  | 2              | -               |
| <b>When did condom break:</b>                              |                |                 |
| Opening package  | 2              | -               |
| While putting condom on                                    | -              | -               |
| During intercourse   | -              | 1               |
| Withdrawal   | -              | -               |
| Taking off   | -              | -               |
| Not specified/missing                                      | 2              | -               |
| <b>Partner at time of break:</b>                           |                |                 |
| Wife/regular partner                                       | 4              | 1               |
| Other partner  | -              | -               |
| Prostitute   | -              | -               |
| <b>Used additional lubricant:</b>                          | -              | -               |

**Table 6**

| <b>Distribution of Participant Ratings of Study Condoms According to Condom Size</b> |                |          |                 |          |
|--|----------------|----------|-----------------|----------|
|  | <b>Smaller</b> |          | <b>Standard</b> |          |
|  | <b>n</b>       | <b>%</b> | <b>n</b>        | <b>%</b> |
| Liked very well or fairly well   | 101            | 67       | 101             | 67       |
| Neutral  | 42             | 28       | 44              | 29       |
| Somewhat or strongly disliked  | 7              | 5        | 3               | 2        |
| Not specified  | -              | -        | 2               | 1        |
| Total  | 150            | 100      | 150             | 100      |
| Mean <sup>1</sup>  | 2.1            |          | 2.0             |          |

<sup>1</sup> Based on a scale of 1 to 5 where 1=liked very well, 2=liked fairly well, 3=neutral, 4=somewhat disliked and 5=strongly disliked

21

**Table 7**

| <b>Distribution of Participants' Perceptions of the Study Condoms by Condom Size</b> |                |          |                 |          |                      |          |                      |          |
|--|----------------|----------|-----------------|----------|----------------------|----------|----------------------|----------|
|  | <b>Smaller</b> |          | <b>Standard</b> |          | <b>Both the same</b> |          | <b>Not specified</b> |          |
|  | <b>n</b>       | <b>%</b> | <b>n</b>        | <b>%</b> | <b>n</b>             | <b>%</b> | <b>n</b>             | <b>%</b> |
| Liked better   | 53             | 35       | 62              | 41       | 34                   | 23       | 1                    | 1        |
| Easier to put on <sup>1</sup>  | 46             | 31       | 64              | 43       | 40                   | 27       | -                    | -        |
| Bigger <sup>2</sup>  | 1              | 1        | 137             | 91       | 10                   | 7        | 2                    | 1        |
| Stayed on better   | 60             | 40       | 66              | 44       | 24                   | 16       | -                    | -        |
| More comfortable   | 60             | 40       | 68              | 45       | 22                   | 15       | -                    | -        |

<sup>1</sup> p=0.095 2 tailed z-test  
<sup>2</sup> p<0.001, 2 tailed z-test

22

**Table 8**

| <b>Distribution of Participants' Previous Condom Use and Future Condom Preference</b> |            |            |
|---|------------|------------|
|   | <b>n</b>   | <b>%</b>   |
| <b>Condom use prior to study:</b>   |            |            |
| <b>A.I.D. brand</b>   | <b>80</b>  | <b>53</b>  |
| Sultan  | 64         | 43         |
| Tahiti  | 16         | 11         |
| <b>Non A.I.D. brand</b>   | <b>47</b>  | <b>31</b>  |
| Prime   | 38         | 25         |
| Trust   | 3          | 2          |
| Lifestyles  | 3          | 2          |
| Sensation   | 2          | 1          |
| Trojan  | 1          | 1          |
| <b>Not sure/don't remember</b>  | <b>23</b>  | <b>15</b>  |
| <b>Future condom preference:</b>  |            |            |
| <b>Total smaller</b>  | <b>63</b>  | <b>42</b>  |
| Smaller study condoms   | 62         | 41         |
| Previous brand (smaller)  | 1          | 1          |
| <b>Total standard</b>   | <b>81</b>  | <b>54</b>  |
| Standard study condoms  | 79         | 53         |
| Previous brand (standard)   | 2          | 1          |
| <b>No preference</b>  | <b>5</b>   | <b>3</b>   |
| missing   | 1          | 1          |
| <b>Total</b>  | <b>150</b> | <b>100</b> |



**XII. Appendix I**  
**Study Questionnaires**



# Family Health International

## Comparative Study of the Acceptability and Actual Use Breakage Rates of Two Condoms

Study Number: 6316

### Philippines

#### INSTRUCTIONS:

1. When a potential participant enters the clinic or pharmacy, briefly inform him about the condom study.
2. If he shows interest in participating in the study, review the Fact Sheet and the Selection Criteria with him.
3. If he passes all the requirements stated in the Selection Criteria and still wants to participate, have him sign the Informed Consent Form.
4. Enter his name and address in the Participant Log and begin the interview with the Background Questionnaire.

#### BACKGROUND QUESTIONNAIRE:

Screening Site: \_\_\_\_\_

Today's Date:         
Day Month Year

Interviewer:  
Name: \_\_\_\_\_  
Signature: \_\_\_\_\_

Participant Identification Number:

1. How old were you on your last birthday?

2. What is the highest level of schooling you have completed?

|            |    |    |    |    |     |    |  |
|------------|----|----|----|----|-----|----|--|
| None       | 0  |    |    |    |     |    |  |
| Primary    | 1  | 2  | 3  | 4  | 5   | 6  |  |
| Secondary  | 7  | 8  | 9  | 10 | 11  | 12 |  |
| University | 13 | 14 | 15 | 16 | 17+ |    |  |

3. What is your marital status?  
1. Single (divorced, widowed, separated)  
2. In union (married or in a consensual union)

4. What ethnic group do consider yourself to be a part of?  
1. Malay  
2. Chinese  
8. Other, specify: \_\_\_\_\_

5. How many condoms have you used in YOUR LIFETIME?  
1. Less than 10  
2. Between 10 and 25  
3. Between 26 and 100  
4. More than 100

6. How many condoms have you used in THE PAST 12 MONTHS?  
1. Have not used condoms in the past year  
2. Less than 10  
3. Between 10 and 25  
4. Between 26 and 100  
5. More than 100

Give the participant a packet of 5 condoms marked with **RED DOTS**. Ask him to use these condoms during the next 4 weeks and return to the clinic/pharmacy as soon as he has used all 5 condoms.

Follow-up Date (4 weeks from today):      
Day Month Year

If 4 weeks have passed and the participant has not returned for his follow-up interview, attempt to contact him at home or at work. If after 3 attempts the participant cannot be located, drop him from the study. Give the First Follow-up Interview on the follow-up date scheduled above or upon his return to the clinic/pharmacy.

# First Follow-up Interview - Philippines

Site: \_\_\_\_\_

Today's Date:        
Day Month Year

Interviewer Name: \_\_\_\_\_

Interviewer Signature: \_\_\_\_\_

Participant Identification Number:

1. How many of the study condoms did you use? (maximum 5 condoms)   
2. If all 5 study condoms were not used, why weren't they used? \_\_\_\_\_

3. How did you like these study condoms?  
1. Liked them very much      3. Neutral (neither liked nor disliked them)  
2. Liked them fairly well      4. Somewhat disliked them      5. Strongly disliked them

4. How many of the study condoms slipped off completely? (maximum 5 condoms)

5. How many of the study condoms broke? (maximum 5 condoms)

6. If one or more of the condoms slipped off, how many of these also broke? (maximum 5 condoms)

7. How many condoms did you use with: (maximum 5 condoms)

Your wife/regular partner?   
Another partner?   
A prostitute?

8. Did you use an additional lubricant or saliva?  
1. Yes  
2. No → **GO TO INSTRUCTIONS ON BACK OF THIS PAGE**

9. With how many condoms did you use: (maximum 5 condoms)  
An additional **water-based** lubricant? Specify brand: \_\_\_\_\_   
An additional **oil-based** lubricant? Specify brand: \_\_\_\_\_   
Saliva?

10. When and where did you add the lubricant or saliva? (Mark all that apply.)  
1. Onto penis prior to putting on condom   
2. In vagina prior to sex   
3. Inside condom   
4. On condom before sex   
5. On condom during sex

If none of the condoms broke or slipped off, go to the instructions at the bottom of this page. FOR EACH CONDOM THAT BROKE OR SLIPPED OFF, FILL OUT ONE OF THE SECTIONS BELOW.

|   |   |   |   |   |
|---|---|---|---|---|
| <p>1. How did the condom fail?<br/>1. Broke<br/>2. Slipped<br/>3. Both</p>  | <p>1. How did the condom fail?<br/>1. Broke<br/>2. Slipped<br/>3. Both</p>  | <p>1. How did the condom fail?<br/>1. Broke<br/>2. Slipped<br/>3. Both</p>  | <p>1. How did the condom fail?<br/>1. Broke<br/>2. Slipped<br/>3. Both</p>  | <p>1. How did the condom fail?<br/>1. Broke<br/>2. Slipped<br/>3. Both</p>  |
| <p>2. With whom did you use it?<br/>1. Wife/regular partner<br/>2. Other partner<br/>3. Prostitute</p>  | <p>2. With whom did you use it?<br/>1. Wife/regular partner<br/>2. Other partner<br/>3. Prostitute</p>  | <p>2. With whom did you use it?<br/>1. Wife/regular partner<br/>2. Other partner<br/>3. Prostitute</p>  | <p>2. With whom did you use it?<br/>1. Wife/regular partner<br/>2. Other partner<br/>3. Prostitute</p>  | <p>2. With whom did you use it?<br/>1. Wife/regular partner<br/>2. Other partner<br/>3. Prostitute</p>  |
| <p>3. Did you use an additional lubricant or saliva?<br/>0. No → GO TO # 6<br/>1. Yes</p>   | <p>3. Did you use an additional lubricant or saliva?<br/>0. No → GO TO # 6<br/>1. Yes</p>   | <p>3. Did you use an additional lubricant or saliva?<br/>0. No → GO TO # 6<br/>1. Yes</p>   | <p>3. Did you use an additional lubricant or saliva?<br/>0. No → GO TO # 6<br/>1. Yes</p>   | <p>3. Did you use an additional lubricant or saliva?<br/>0. No → GO TO # 6<br/>1. Yes</p>   |
| <p>4. What type of lubricant?<br/>Brand: _____<br/>1. Water-based<br/>2. Oil-based<br/>3. Saliva</p>  | <p>4. What type of lubricant?<br/>Brand: _____<br/>1. Water-based<br/>2. Oil-based<br/>3. Saliva</p>  | <p>4. What type of lubricant?<br/>Brand: _____<br/>1. Water-based<br/>2. Oil-based<br/>3. Saliva</p>  | <p>4. What type of lubricant?<br/>Brand: _____<br/>1. Water-based<br/>2. Oil-based<br/>3. Saliva</p>  | <p>4. What type of lubricant?<br/>Brand: _____<br/>1. Water-based<br/>2. Oil-based<br/>3. Saliva</p>  |
| <p>5. When and where did you add the lubricant or saliva?<br/>1. Onto penis before putting on condom<br/>2. In vagina before sex<br/>3. Inside condom<br/>4. On condom before sex<br/>5. On condom during sex</p> | <p>5. When and where did you add the lubricant or saliva?<br/>1. Onto penis before putting on condom<br/>2. In vagina before sex<br/>3. Inside condom<br/>4. On condom before sex<br/>5. On condom during sex</p> | <p>5. When and where did you add the lubricant or saliva?<br/>1. Onto penis before putting on condom<br/>2. In vagina before sex<br/>3. Inside condom<br/>4. On condom before sex<br/>5. On condom during sex</p> | <p>5. When and where did you add the lubricant or saliva?<br/>1. Onto penis before putting on condom<br/>2. In vagina before sex<br/>3. Inside condom<br/>4. On condom before sex<br/>5. On condom during sex</p> | <p>5. When and where did you add the lubricant or saliva?<br/>1. Onto penis before putting on condom<br/>2. In vagina before sex<br/>3. Inside condom<br/>4. On condom before sex<br/>5. On condom during sex</p> |
| <p>6. Where did it break?<br/>1. Opening<br/>2. Shaft<br/>3. Tip<br/>4. Not sure/doesn't know<br/>5. Condom did not break</p>   | <p>6. Where did it break?<br/>1. Opening<br/>2. Shaft<br/>3. Tip<br/>4. Not sure/doesn't know<br/>5. Condom did not break</p>   | <p>6. Where did it break?<br/>1. Opening<br/>2. Shaft<br/>3. Tip<br/>4. Not sure/doesn't know<br/>5. Condom did not break</p>   | <p>6. Where did it break?<br/>1. Opening<br/>2. Shaft<br/>3. Tip<br/>4. Not sure/doesn't know<br/>5. Condom did not break</p>   | <p>6. Where did it break?<br/>1. Opening<br/>2. Shaft<br/>3. Tip<br/>4. Not sure/doesn't know<br/>5. Condom did not break</p>   |
| <p>7. If condom broke, when?<br/>1. Opening the package<br/>2. Putting the condom on<br/>3. During sex<br/>4. During withdrawal<br/>5. Taking the condom off<br/>6. Not sure/doesn't know</p>                     | <p>7. If condom broke, when?<br/>1. Opening the package<br/>2. Putting the condom on<br/>3. During sex<br/>4. During withdrawal<br/>5. Taking the condom off<br/>6. Not sure/doesn't know</p>                     | <p>7. If condom broke, when?<br/>1. Opening the package<br/>2. Putting the condom on<br/>3. During sex<br/>4. During withdrawal<br/>5. Taking the condom off<br/>6. Not sure/doesn't know</p>                     | <p>7. If condom broke, when?<br/>1. Opening the package<br/>2. Putting the condom on<br/>3. During sex<br/>4. During withdrawal<br/>5. Taking the condom off<br/>6. Not sure/doesn't know</p>                     | <p>7. If condom broke, when?<br/>1. Opening the package<br/>2. Putting the condom on<br/>3. During sex<br/>4. During withdrawal<br/>5. Taking the condom off<br/>6. Not sure/doesn't know</p>                     |
| <p>8. When did it slip off?<br/>1. During sex<br/>2. During withdrawal<br/>3. Not sure/doesn't know<br/>4. Condom did not slip off</p>  | <p>8. When did it slip off?<br/>1. During sex<br/>2. During withdrawal<br/>3. Not sure/doesn't know<br/>4. Condom did not slip off</p>  | <p>8. When did it slip off?<br/>1. During sex<br/>2. During withdrawal<br/>3. Not sure/doesn't know<br/>4. Condom did not slip off</p>  | <p>8. When did it slip off?<br/>1. During sex<br/>2. During withdrawal<br/>3. Not sure/doesn't know<br/>4. Condom did not slip off</p>  | <p>8. When did it slip off?<br/>1. During sex<br/>2. During withdrawal<br/>3. Not sure/doesn't know<br/>4. Condom did not slip off</p>  |
| <p>9. Why do you think it broke or slipped off?<br/>_____<br/>_____<br/>_____</p>   | <p>9. Why do you think it broke or slipped off?<br/>_____<br/>_____<br/>_____</p>   | <p>9. Why do you think it broke or slipped off?<br/>_____<br/>_____<br/>_____</p>   | <p>9. Why do you think it broke or slipped off?<br/>_____<br/>_____<br/>_____</p>   | <p>9. Why do you think it broke or slipped off?<br/>_____<br/>_____<br/>_____</p>   |

Give the participant a packet of 5 condoms marked with **BLUE DOTS**. Ask him to use these condoms during the next 4 weeks and return to the clinic/pharmacy as soon as he has used all 5 condoms.

Follow-up Date (4 weeks from today):        
Day Month Year

If 4 weeks have passed and the participant has not returned for his follow-up interview, attempt to contact him at home or at work. If after 3 attempts the participant cannot be located, drop him from the study.

# Second Follow-up Interview - Philippines

Site: \_\_\_\_\_

Today's Date:        
Day Month Year

Interviewer Name: \_\_\_\_\_

Interviewer Signature: \_\_\_\_\_

Participant Identification Number:

1. How many of the study condoms did you use? (maximum 5 condoms)

2. If all 5 study condoms were not used, why weren't they used? \_\_\_\_\_

3. How did you like these study condoms?

- 1. Liked them very much
- 2. Liked them fairly well
- 3. Neutral (neither liked nor disliked them)
- 4. Somewhat disliked them
- 5. Strongly disliked them

4. How many of the study condoms slipped off completely? (maximum 5 condoms)

5. How many of the study condoms broke? (maximum 5 condoms)

5. If one or more of the condoms slipped off, how many of these also broke? (maximum 5 condoms)

7. How many condoms did you use with: (maximum 5 condoms)

- Your wife/regular partner?
- Another partner?
- A prostitute?

3. Did you use an additional lubricant or saliva?

- 1. Yes
- 2. No → **GO TO INSTRUCTIONS ON BACK OF THIS PAGE**

9. With how many condoms did you use: (maximum 5 condoms)

- An additional **water-based** lubricant? Specify brand: \_\_\_\_\_
- An additional **oil-based** lubricant? Specify brand: \_\_\_\_\_
- Saliva?

10. When and where did you add the lubricant or saliva? (Mark all that apply.)

- 1. Onto penis prior to putting on condom
- 2. In vagina prior to sex
- 3. Inside condom
- 4. On condom before sex
- 5. On condom during sex

If none of the condoms broke or slipped off, go to the instructions at the bottom of this page. FOR EACH CONDOM THAT BROKE OR SLIPPED OFF, FILL OUT ONE OF THE SECTIONS BELOW.

|  |  |  |  |  |
|--|--|--|--|--|
| <p>1. How did the condom fail?<br/>         1. Broke<br/>         2. Slipped<br/>         3. Both</p>  | <p>1. How did the condom fail?<br/>         1. Broke<br/>         2. Slipped<br/>         3. Both</p>  | <p>1. How did the condom fail?<br/>         1. Broke<br/>         2. Slipped<br/>         3. Both</p>  | <p>1. How did the condom fail?<br/>         1. Broke<br/>         2. Slipped<br/>         3. Both</p>  | <p>1. How did the condom fail?<br/>         1. Broke<br/>         2. Slipped<br/>         3. Both</p>  |
| <p>2. With whom did you use it?<br/>         1. Wife/regular partner<br/>         2. Other partner<br/>         3. Prostitute</p>  | <p>2. With whom did you use it?<br/>         1. Wife/regular partner<br/>         2. Other partner<br/>         3. Prostitute</p>  | <p>2. With whom did you use it?<br/>         1. Wife/regular partner<br/>         2. Other partner<br/>         3. Prostitute</p>  | <p>2. With whom did you use it?<br/>         1. Wife/regular partner<br/>         2. Other partner<br/>         3. Prostitute</p>  | <p>2. With whom did you use it?<br/>         1. Wife/regular partner<br/>         2. Other partner<br/>         3. Prostitute</p>  |
| <p>3. Did you use an additional lubricant or saliva?<br/>         0. No → GO TO # 6<br/>         1. Yes</p>  | <p>3. Did you use an additional lubricant or saliva?<br/>         0. No → GO TO # 6<br/>         1. Yes</p>  | <p>3. Did you use an additional lubricant or saliva?<br/>         0. No → GO TO # 6<br/>         1. Yes</p>  | <p>3. Did you use an additional lubricant or saliva?<br/>         0. No → GO TO # 6<br/>         1. Yes</p>  | <p>3. Did you use an additional lubricant or saliva?<br/>         0. No → GO TO # 6<br/>         1. Yes</p>  |
| <p>4. What type of lubricant?<br/>         Brand: _____<br/>         1. Water-based<br/>         2. Oil-based<br/>         3. Saliva</p>   | <p>4. What type of lubricant?<br/>         Brand: _____<br/>         1. Water-based<br/>         2. Oil-based<br/>         3. Saliva</p>   | <p>4. What type of lubricant?<br/>         Brand: _____<br/>         1. Water-based<br/>         2. Oil-based<br/>         3. Saliva</p>   | <p>4. What type of lubricant?<br/>         Brand: _____<br/>         1. Water-based<br/>         2. Oil-based<br/>         3. Saliva</p>   | <p>4. What type of lubricant?<br/>         Brand: _____<br/>         1. Water-based<br/>         2. Oil-based<br/>         3. Saliva</p>   |
| <p>5. When and where did you add the lubricant or saliva?<br/>         1. Onto penis before putting on condom<br/>         2. In vagina before sex<br/>         3. Inside condom<br/>         4. On condom before sex<br/>         5. On condom during sex</p> | <p>5. When and where did you add the lubricant or saliva?<br/>         1. Onto penis before putting on condom<br/>         2. In vagina before sex<br/>         3. Inside condom<br/>         4. On condom before sex<br/>         5. On condom during sex</p> | <p>5. When and where did you add the lubricant or saliva?<br/>         1. Onto penis before putting on condom<br/>         2. In vagina before sex<br/>         3. Inside condom<br/>         4. On condom before sex<br/>         5. On condom during sex</p> | <p>5. When and where did you add the lubricant or saliva?<br/>         1. Onto penis before putting on condom<br/>         2. In vagina before sex<br/>         3. Inside condom<br/>         4. On condom before sex<br/>         5. On condom during sex</p> | <p>5. When and where did you add the lubricant or saliva?<br/>         1. Onto penis before putting on condom<br/>         2. In vagina before sex<br/>         3. Inside condom<br/>         4. On condom before sex<br/>         5. On condom during sex</p> |
| <p>6. Where did it break?<br/>         1. Opening<br/>         2. Shaft<br/>         3. Tip<br/>         4. Not sure/doesn't know<br/>         5. Condom did not break</p>   | <p>6. Where did it break?<br/>         1. Opening<br/>         2. Shaft<br/>         3. Tip<br/>         4. Not sure/doesn't know<br/>         5. Condom did not break</p>   | <p>6. Where did it break?<br/>         1. Opening<br/>         2. Shaft<br/>         3. Tip<br/>         4. Not sure/doesn't know<br/>         5. Condom did not break</p>   | <p>6. Where did it break?<br/>         1. Opening<br/>         2. Shaft<br/>         3. Tip<br/>         4. Not sure/doesn't know<br/>         5. Condom did not break</p>   | <p>6. Where did it break?<br/>         1. Opening<br/>         2. Shaft<br/>         3. Tip<br/>         4. Not sure/doesn't know<br/>         5. Condom did not break</p>   |
| <p>7. If condom broke, when?<br/>         1. Opening the package<br/>         2. Putting the condom on<br/>         3. During sex<br/>         4. During withdrawal<br/>         5. Taking the condom off<br/>         6. Not sure/doesn't know</p>            | <p>7. If condom broke, when?<br/>         1. Opening the package<br/>         2. Putting the condom on<br/>         3. During sex<br/>         4. During withdrawal<br/>         5. Taking the condom off<br/>         6. Not sure/doesn't know</p>            | <p>7. If condom broke, when?<br/>         1. Opening the package<br/>         2. Putting the condom on<br/>         3. During sex<br/>         4. During withdrawal<br/>         5. Taking the condom off<br/>         6. Not sure/doesn't know</p>            | <p>7. If condom broke, when?<br/>         1. Opening the package<br/>         2. Putting the condom on<br/>         3. During sex<br/>         4. During withdrawal<br/>         5. Taking the condom off<br/>         6. Not sure/doesn't know</p>            | <p>7. If condom broke, when?<br/>         1. Opening the package<br/>         2. Putting the condom on<br/>         3. During sex<br/>         4. During withdrawal<br/>         5. Taking the condom off<br/>         6. Not sure/doesn't know</p>            |
| <p>8. When did it slip off?<br/>         1. During sex<br/>         2. During withdrawal<br/>         3. Not sure/doesn't know<br/>         4. Condom did not slip off</p>   | <p>8. When did it slip off?<br/>         1. During sex<br/>         2. During withdrawal<br/>         3. Not sure/doesn't know<br/>         4. Condom did not slip off</p>   | <p>8. When did it slip off?<br/>         1. During sex<br/>         2. During withdrawal<br/>         3. Not sure/doesn't know<br/>         4. Condom did not slip off</p>   | <p>8. When did it slip off?<br/>         1. During sex<br/>         2. During withdrawal<br/>         3. Not sure/doesn't know<br/>         4. Condom did not slip off</p>   | <p>8. When did it slip off?<br/>         1. During sex<br/>         2. During withdrawal<br/>         3. Not sure/doesn't know<br/>         4. Condom did not slip off</p>   |
| <p>9. Why do you think it broke or slipped off?<br/>         _____<br/>         _____<br/>         _____</p>   | <p>9. Why do you think it broke or slipped off?<br/>         _____<br/>         _____<br/>         _____</p>   | <p>9. Why do you think it broke or slipped off?<br/>         _____<br/>         _____<br/>         _____</p>   | <p>9. Why do you think it broke or slipped off?<br/>         _____<br/>         _____<br/>         _____</p>   | <p>9. Why do you think it broke or slipped off?<br/>         _____<br/>         _____<br/>         _____</p>   |

GO TO THE NEXT PAGE. Fill out the last section of the second follow-up interview with the COMPARISON OF THE TWO CONDOMS questionnaire.

29

# Family Health International

## Comparative Study of the Acceptability and Actual Use Breakage Rates of Two Condoms

Study Number: 6316

### Philippines

#### COMPARISON OF THE TWO CONDOMS:

Participant Identification Number:

|  |  |  |
|--|--|--|
|  |  |  |
|--|--|--|

Now I will ask you some questions comparing the condoms you tested first with the condoms you tested second.

1. Which study condoms did you **LIKE BETTER?**
  1. Red dots (*First study condoms*)
  2. Blue dots (*Second study condoms*)
  3. Both were the same
  4. Not sure/doesn't remember
2. Which study condoms were **EASIER TO PUT ON?**
  1. Red dots (*First study condoms*)
  2. Blue dots (*Second study condoms*)
  3. Both were the same
  4. Not sure/doesn't remember
3. Which study condoms **FELT BIGGER?**
  1. Red dots (*First study condoms*)
  2. Blue dots (*Second study condoms*)
  3. Both were the same
  4. Not sure/doesn't remember

4. Which study condoms **STAYED ON BETTER?**
  1. Red dots (*First study condoms*)
  2. Blue dots (*Second study condoms*)
  3. Both were the same
  4. Not sure/doesn't remember
5. Which study condoms were **MORE COMFORTABLE TO WEAR?**
  1. Red dots (*First study condoms*)
  2. Blue dots (*Second study condoms*)
  3. Both were the same
  4. Not sure/doesn't remember
6. Prior to this study, which brand of condom did you prefer to use?
  1. USAID brand, specify: \_\_\_\_\_
  2. Private sector, specify: \_\_\_\_\_
  8. Other, specify: \_\_\_\_\_
  4. Not sure/doesn't remember
7. Which type of condom would you like to use in the future?
  1. Red dots (*First study condoms*)
  2. Blue dots (*Second study condoms*)
  3. Preferred/previous/favorite brand (specified in question #6)
  4. No preference/all condoms are the same/not sure/doesn't know which one would like to use
  5. Doesn't intend to use condoms in the future
8. Why do you want to use the type of condom specified in question #7 in the future? **(Interviewer: Write in the response exactly as it is stated by the participant.)**  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**THANK YOU FOR BEING IN THIS STUDY!!**