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METHODS OF IDENTIFYING CONDOM USERS AT RISK OF BREAKAGE AND SLIPPAGE

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TABLE OF CONTENTS

Executive Summary i

I. Introduction 1

II. Study Objectives 2

III. Methods 2

A. Study Subjects 2

B. Study Product 3

C. Procedures 3

D. Definitions 4

E. Data Analysis 4

IV. Results 5

A. Admission Data 5

B. Condom Use Prior to Study 5

C. Prospective Condom Use & Failure 6

D. Predictive Strength of Past Condom Failure 6

E. Condom Use Behaviors 7

F. Behaviors Associated With Condom Failure 7

G. Background Characteristics and Failure 9

V. Discussion 9

A. Factors Associated with Condom Failure 9

B. Prevalence of Behaviors 12

VI. Conclusion 13

References 15

Tables 17

Appendix: Study Questionnaire 25

Executive Summary

Objectives: Human use studies suggest that condom failure is not a random event. While the majority of condom users experience failure infrequently or not at all, research suggests that a minority of condom users experience a disproportionate amount of failure. Secondary analysis done by Family Health International suggests that higher rates of failure are associated with past condom failure and also with specific misuse behaviors. The objectives of this study were to test the hypothesis that past condom failure can predict condom failure during prospective human use and to evaluate the association of behaviors with condom failure.

Methods: At each of three international sites (Mexico, Philippines, Dominican Republic), approximately 130 male family planning clients who used condoms were asked to participate in the study. Background information was collected and participants were categorized as being at "increased risk" of condom failure (those who reported having experienced at least one condom break and/or slip off completely prior to the study), or "low risk" (those who reported no condom failure before the study). Each participant was given five condoms to be used for vaginal intercourse. The men were interviewed about breakage, slippage and behaviors during condom use. The associations between prospective condom failure, past failure, and behaviors were evaluated.

Results: The primary hypothesis was confirmed. In all three sites, those groups of participants identified a priori as being at increased risk of failure reported twice as many condom failures as the corresponding low risk groups ($p \leq 0.03$). Trend analysis also showed condom failure increased with the number of adverse behaviors relating to condom use reported per participant ($p < 0.01$). Based on univariate analysis, using methods other than fingers to open the condom packages or unrolling the condoms before putting them on were both associated with breakage ($p \leq 0.02$). Unrolling the condoms before putting them on, reporting that intercourse lasted for at least 20 minutes or that intercourse was especially intense were all associated with slippage ($p \leq 0.03$). At the country level, loss of erection before withdrawal was associated with slippage in the Philippines ($p < 0.01$).

Conclusions: Two keys to reducing condom failure may include identifying condom users at increased risk of condom failure and cautioning them about behaviors that may lead to failure. Data from this study suggest that a history of condom failure is a good predictor of future failure and can be used for targeted intervention. Further research is needed to determine if this type of intervention could effectively reduce condom failure.

I. Introduction

In the effort to reduce unwanted pregnancies and the spread of sexually transmitted diseases (STD), including the human immunodeficiency virus (HIV), the male condom has been recognized by the public health community as one of the best methods available. Researchers estimate that when used correctly and consistently for vaginal sex, condoms are up to 97% effective as a contraceptive and also highly effective as a barrier against STD.[1]

However, among recent condom studies, breakage has been reported with less than 1% to about 12% of the condoms used.[2] Although there are less data regarding condoms slipping off, studies suggest that slippage occurs with comparable frequency.[3] Moreover, condom failure (defined as breaking or slipping completely off the penis) is not a random event.[4] While failure for the majority of condom users is rare, there appears to be a minority of condom users who experience a disproportionate amount of failure. Thus, condom failure seems to be strongly associated with the individual or couple using condoms.

Research done by Family Health International (FHI) suggests that the variability of condom failure among different individuals is related to differing characteristics and behaviors. Secondary analysis of a convenience sample of 177 couples who used 11 condoms each during a prospective study found that condom failure was almost twice as high among couples who had not used any condoms during the year before the study as compared to those who had used at least one.[4] Among couples who had used condoms in the year prior to the study, those who reported condom breakage during this time also reported study failure rates that were more than twice as high as reported by those participants who had not experienced breakage during the year prior to the study. The subset of participants who had used but not broken any condoms during the year before the study was analyzed for relationships between sociodemographic characteristics and condom failure during the prospective study. Two factors were found to be associated with increased condom failure: 1) not living with the sexual partner; and 2) not having attained more than a high school education. In addition to background characteristics, qualitative data from FHI studies also suggest there are four

categories of behaviors which may lead to condom failure including: 1) improper donning techniques; 2) use of oil-based lubricants; 3) reuse of condoms; and 4) lengthy or intense coitus.[5,6] An FHI prospective condom study has also shown that use of oil-based lubrication is associated with condom failure.[7]

Thus, when reporting results of condom studies, simply presenting percentages of condoms that fail without additional information including participant characteristics and reported behaviors can be misleading.[8] Moreover, a better understanding of how background characteristics and behaviors are related to condom failure would be useful for clinicians for the purpose of targeting condom users who are at increased risk of condom failure. Similarly, additional knowledge of this type would also contribute to more effective information, education and counseling on correct condom use.

II. Study Objectives

The primary objective of this study was to test the hypothesis that past condom failure will predict condom failure during prospective human use. A secondary objective was to collect additional information on the association between specific behaviors and condom failure.

III. Methods

A. Study Subjects At each of three international sites, a convenience sample of approximately 130 male family planning clients were enrolled. The study was conducted in collaboration with the Instituto de Investigación Científica (IIC) in Durango, Mexico; the Comprehensive Family Planning Center at the Jose Fabella Memorial Hospital in Manila, Philippines; and the Asociación Dominicana Pro Bienestar de la Familia (PROFAMILIA) in Santo Domingo, Dominican Republic (D.R.).

To participate, the clinic attenders were required to have used at least one condom during the twelve months prior to the study, be at least 18 years old, agree to answer in-depth questions regarding use of the study condoms, and sign an informed consent form. Prior to initiation of

6

the study, the Study Protocol was approved by the Protection for Human Subjects Committee of FHI. Participant compensation (for travel expenses, etc.) was determined by the principal investigator at each site.

B. Study Product The men were supplied with standard (52mm) silicone lubricated, latex condoms manufactured by Ansell Inc. and distributed throughout the developing world by the United States Agency for International Development (USAID). Condoms for all three sites came from the same lot, and were used within a year of their manufacture date (Feb. 1992). Prior to use, the study condoms were tested in the FHI laboratory in accordance with methods of the American Standard Testing Materials (ASTM document 3492) and the International Standards Organization (ISO document 4074).

C. Procedures The men were administered a background questionnaire to collect information on past condom use as well as sociodemographic characteristics. Participants were considered to be in one of two categories:

- increased risk: men who reported having experienced failure (at least one condom broke and/or slipped off completely during vaginal intercourse) prior to the study.
- low risk: men who reported NOT having experienced condom failure before the study.

Recruitment among the three countries varied slightly. In the Dominican Republic, the participant's risk was categorized based on condom failure during the twelve months prior to the study, while the other two countries based this categorization on the men's condom failure throughout their lifetime. Although not followed with respect to recruitment, the study protocol called for all three sites to base the risk categorization on condom failure during the twelve months prior to the study. In each site, approximately equal numbers of men were recruited for each of the two risk categories described above.

The men were given five condoms each and asked to use them for vaginal intercourse over a three-week study period. Since one objective of this study was to gather data on typical

7

behaviors that lead to condom breakage and slippage, men were not given special instructions on proper condom use beyond standard procedures of the clinics. After using all five condoms, the men returned to the clinics and were interviewed about their experiences with the condoms. Specific questions were asked about any condoms which broke or slipped off. All participants, regardless of whether they experienced any failure, were asked to describe how the five study condoms were used. Issues such as opening the package, donning the condom, use of additional lubricants, re-use of condoms, length and intensity of coitus, and other specific behaviors relevant to condom use were discussed in detail.

D. Definitions Definitions of condom failure in this study are consistent with those used in prior FHI condom trials.[8] Total breakage is defined as the number of condoms that reportedly broke divided by the total number of condoms participants attempted to use. Clinical slippage is defined as the condom slipping all the way off the penis during intercourse or withdrawal, and is calculated as the number of condoms that completely slipped off divided by the number of condoms that were used for intercourse. When the same condom both broke and slipped off, only breakage is counted, based on the belief that breakage in most instances leads to slippage. Clinical breakage excludes condom breakage before intercourse or after withdrawal, which is termed non-clinical breakage. Non-clinical breakage is so named due to minimal risk of conception or disease transmission from breakage prior to penetration or after withdrawal. Clinical failure is the sum of clinical breakage and clinical slippage.

E. Data Analysis The study protocol called for recruitment of 130 participants per site to use five condoms each, allowing for 15% non-response due to loss to follow-up or use of less than five condoms. The Wilcoxon Rank Sum Test (1-tailed exact), stratified by country and number of study condoms tested, was used to evaluate the primary hypothesis. The Binomial Trend Test, stratified by country, was used to evaluate the relationship between the number of adverse behaviors reported and condom failure. For univariate analysis of specific behaviors and condom failure, country level results were tested for significance with 1-tailed Fisher's Exact tests and combined results were tested with 1-tailed Cochran-Mantel-Haenszel (CMH)

8

analysis, stratified by country. Multivariable regression models were used to simultaneously evaluate several behaviors and their association with breakage and slippage. Similar analysis was used to assess background characteristics and condom failure. Fisher's Exact tests (1-tailed) and CMH analysis (controlling for country) were used to evaluate possible associations between background characteristics and condom failure, as well as background characteristics and risk status (all variables dichotomous). For all tests, results were considered significant at alpha=0.05. No adjustments were made for multiple testing. Actual exact p-values are reported.

IV. Results

A. Sociodemographic Characteristics A total of 130 participants each in Mexico and the Philippines, and 126 in the Dominican Republic completed the study (Table 1). All field work was completed by March 1993. The median age of the men was lowest in the D.R. (25) and highest in the Philippines (33). The median years of education completed was lowest in the D.R. (11) and highest in Mexico (13). The proportion of men reportedly in non-stable relationships was highest in the D.R. (48%) and lowest in the Philippines (15%).

B. Condom Use Prior to Study At admission, a majority of Filipino men (60%) reported use of condoms for family planning purposes only (Table 1). Conversely, in the D.R. a majority of men (64%) reported condom use specifically to protect themselves from STD and relatively few reported condom use for family planning exclusively. Men in the Philippines were less experienced with condoms than men in the other two sites. Just less than half of the Filipinos reported that they had used no more than 25 condoms during their lifetimes. Among the three sites, the D.R. had the largest proportion of men (27%) who reported having used more than 100 condoms. Not surprisingly, the highest proportion of men who reported that more than six condoms had failed prior to the study (25%) were from the D.R. In contrast, only 5% of the Filipinos reported that more than six condoms failed prior to the study.

9

C. Prospective Condom Use & Failure All participants at each of the three sites reportedly completed the admission and follow-up interview. Despite no loss to follow-up, some participants did not use all five study condoms. Use of all five condoms was most frequent in the Philippines and least frequent in the D.R. (Table 2).

Total breakage during the study was highest in the D.R. (4.7% of all condoms used) and lowest in the Philippines (0.8%). Clinical slippage occurred most frequently in Mexico (1.9%) and least often in the D.R. (0.8%). Total failure rates, the sum of total breakage and clinical slippage, were relatively low for all three countries (from 2.0% in the Philippines to 5.5% in the D.R.).

The timing of breakage among the 13 condoms that broke in Mexico was fairly evenly distributed across all stages of condom use (Table 3). In the D.R. about two thirds of the breakage occurred while rolling the condom onto the penis. In Mexico and the Philippines slippage most often occurred during withdrawal.

Condom failure was a fairly rare event and it was generally concentrated among a minority of men (Table 4). In Mexico, for example, 112 men (86%) reported no failure, while three men (2%) experienced 40% of all failure. Similarly, in the D.R. 105 men (83%) did not experience any failure, and four men (3%) were responsible for 41% of the failure. In the Philippines failure was infrequent and was not concentrated among a few individuals.

D. Predictive Strength of Past Condom Failure Data from this study strongly support the primary study hypothesis (Table 5). Based on condom experience during the 12 months prior to the study, prospective failure among the group of men considered at increased risk occurred approximately twice as often as among the lower risk group. In Mexico, for example, the group of men for whom at least one condom had broken or slipped off during the 12 months before the study, reported failure with 7.1% of the study condoms. In contrast, among those who had not experienced any failure within 12 months of the study initiation, only 3.0% of the study condoms reportedly failed. Similarly, in the D.R. the proportions of

condoms that failed among these two groups of men are 7.1% and 3.6%, respectively. This trend is consistent across all three sites and the difference between the rates is statistically significant (p=0.01, Wilcoxon Rank Sum Test, 1-tailed exact, stratified by country and number of condoms used). As shown in Table 5, this trend also holds true for alternative criteria based on reported condom failure during other time periods prior to the study (e.g. lifetime p=0.03, six months p=0.02).

E. Condom Use Behaviors The men reported a wide range of behaviors during condom use (Table 6). Varying by country, 10% to 39% of the condom packages were opened with methods other than fingers (e.g. teeth, scissors, knives, pencils). In the Philippines, one fifth of the condoms were reportedly unrolled before donning and 7% were filled with air or water before use. With less frequency, 4% of the condoms were reportedly inside-out as they were rolled on to the penis in the D.R.

Use of additional lubrication or removal of lubrication (e.g. for "dry sex") was reported fairly infrequently (≤3% of condoms). Because of the infrequent use of additional lubrication, no distinction is made between use of oil-based and non-oil-based lubricants. In the D.R. coitus reportedly lasted for at least 20 minutes with 8% of the condoms and 41% of the condoms were used during particularly intense intercourse.

Men in the D.R. also reported with greatest frequency that condoms were withdrawn after loss of erection (56%). In the Philippines, 44% of the condoms were reportedly not held during withdrawal. According to the men in the study, almost none of the condoms were reused.

F. Behaviors and Condom Failure Table 7 presents the level of condom failure by the number of adverse behaviors reported per participant. This analysis is based on ten behaviors: 1) opening condom packages with methods other than fingers; 2) unrolling condoms before donning; 3) filling condoms with air or water before use; 4) using additional lubrication; 5) removing lubrication from condoms before or during use; 6) particularly

11

intense coitus; 7) lengthy coitus; 8) losing an erection before withdrawal; 9) not holding on to the base of the condom during withdrawal; and 10) reusing condoms for more than one act of coitus. As shown, the proportion of condoms that failed increases significantly with the number of these behaviors reported (exact $p<0.01$, Binomial Trend Test stratified by country). For example, among the group of men who reported none of these behaviors, less than 3% of the 401 condoms used failed. In contrast, among the group that reported from four to seven behaviors, almost 10% of the 194 condoms failed. To ensure fair comparison, only participants who used all five condoms were included in this analysis (316 men who used a total of 1,580 condoms). When this analysis is repeated for all condoms used by study participants, results are almost identical.

Through univariate analysis of the combined sample (with the condom as the unit of observation) some behaviors were found to be significantly associated with breakage or slippage (Table 8, 1-tailed CMH analysis stratified by country). Both using methods other than fingers (e.g. teeth, scissors, knives, pencils) to open the condom packages and unrolling the condoms before putting them on were associated with breakage ($p=0.02$, $p=0.01$, respectively). Unrolling condoms before putting them on, intercourse that lasted for at least 20 minutes and intercourse that was especially intense, were all associated with slippage ($p=0.03$, $p=0.01$, $p=0.01$, respectively). At the country level, loss of erection before withdrawal was associated with slippage in the Philippines ($p<0.01$), whereas in Mexico and the D.R. there was no association between loss of erection before withdrawal and slippage ($p=0.81$, $p=0.78$, respectively).

Potential correlates of condom breakage and slippage were also examined through multivariable analysis (data not shown). When independent variables which were found to be significant during univariate analysis were evaluated simultaneously, neither the model for breakage nor slippage was significant.

12

G. Background Characteristics and Failure As described in the introduction, secondary analysis from another FHI study found that certain background characteristics were associated with condom failure.[4] Data from the present study were analyzed to determine if there were similar relationships (data not shown). Background characteristics included in this analysis were the number of condoms used during one's lifetime, age, education and relationship status. Among these variables, lower education attainment was found to be associated with condom failure ($p<0.01$, linear regression model controlling for country). In all three sites lower education was also associated with condom failure during the year prior to the study and this relationship was statistically significant in Mexico ($p<0.01$, 1-tailed Fisher's exact test). Similarly, for combined data lower education was statistically significantly associated with a history of condom failure ($p<0.01$, CMH Statistic, controlling for country).

V. Discussion

A. Factors Associated with Condom Failure Building on FHI research to date, the results of this study strongly support the primary study hypothesis. Basic information concerning past condom failure can accurately identify condom users at increased risk of further condom failure. In all three sites, those groups of participants identified as being at increased risk of failure reported failure approximately twice as frequently during the study as reported by the corresponding low risk groups.

Of similar importance, the data suggests a strong link between reported behaviors and condom failure. Trend analysis shows condom failure increased significantly with the number of condom misuse behaviors reported per participant. Among the group of men who reported none of these behaviors, less than 3% of the condoms failed, while, among the group that reported from four to seven behaviors, almost 10% of the condoms failed.

Univariate analysis suggests that specific behaviors were associated with breakage and slippage among this study population. These results should be interpreted with some caution. Analyzing specific behaviors without controlling for the impact of other behaviors ignores

possible confounding and interaction between the different behaviors. Nevertheless, future research which attempts to further understand the relationship between specific behaviors and condom failure should consider behaviors identified through univariate analysis in the present study.

Multivariable analysis did not single out specific behaviors which were associated with condom failure. This may have been due to two limitations in particular. First, the outcomes of interest, breakage and slippage, were rare events; less than 4% of the 1,810 condoms tested failed. Secondly, we could not conduct multivariable analysis with the condom as the unit of observation. Alternatively, for each behavior reported per participant, a percentage was calculated based on the proportion of condoms with which the participant reportedly exhibited the behavior in question. Evaluation based on the individual instead of the condom as the unit of analysis compounded limitations on statistical power and prohibited meaningful evaluation of simultaneous effect of different behaviors reported on condom failure.

Future research designed to examine the relationship between specific behaviors with breakage and slippage will benefit from increasing the probability of sufficient cases of condom failure. One strategy would be to oversample (to a greater extent than in this study) condom users who have experienced condom failure in the past. As outlined earlier in the Methods section, recruitment procedures varied slightly among the three countries in this study. During recruitment in Mexico and the Philippines, participants were placed in the increased risk category if they had experienced condom failure anytime during their lifetime, while in the D.R. only men who had experienced condom failure during the twelve months prior to the study were considered as being at increased risk. Much of the analysis was stratified by country, thus this inconsistency was controlled for. Nevertheless, it is interesting to note that overall frequencies of condom failure and adverse behaviors reported were generally lower in the two sites that recruited proportionately less participants who were at increased risk.

Future research which includes multivariable analysis (e.g. logistic regression) with the condom as the unit of observation will necessitate collecting detailed behavior data on each condom used, regardless of whether failure occurred. In this study condom specific data were collected only for condoms that failed. Inferences on how condoms were used (Table 6 and 7) were drawn from responses concerning all condoms each participant used. When using data from both sources, some inconsistencies were found (Table 8). Collecting data on each condom used in future studies will prevent this problem.

Although this study was well controlled and designed to gather in-depth information on many potential causes of condom failure, we can only speculate what the primary causes of condom failure were. In addition to information collected in this study, some researchers feel it is important to collect data on penis size, sexual positions and other variables which may contribute to condom failure. No doubt some behaviors and user characteristics do play an important role in condom failure, especially when potential failure due to manufacturing defects, age of condoms, and improper storage are minimized, as in this study. Nevertheless, few behaviors or user characteristics consistently cause condom failure and, as this study demonstrates, they can be difficult to accurately measure. Moreover, among the numerous variables which may contribute to condom failure, most likely there is significant overlap and interaction.

Perhaps the most important results of the present study regarding behaviors and condom failure are in terms of the frequency of behaviors. These results suggest that engaging in multiple adverse behaviors is more strongly associated with failure (and consequently be a better predictor of failure) than any one adverse behavior in particular. Moreover, engaging in multiple behaviors may be associated with, and therefore capture other factors which contribute to condom failure that were not measured.

Consistent with results of secondary analysis of other FHI data, the present study evaluated specific background characteristics of condom users including the number of condoms used during one's lifetime, age, education and relationship status. Only lower educational

15

attainment was found to be associated with increased condom failure. Less education was also associated with a history of condom failure and so needs to be considered as a potential confounder in studies of condom failure.

B. Prevalence of Behaviors If future research does provide sufficient reason to try to rank causes of condom failure, two equally important factors should be kept in mind. One is how strongly a specific behavior seems to be related to breakage and slippage and the other is how frequently condom users engage in the behavior. If a given behavior is likely to result in condom failure, but almost never occurs, it will have a minor impact on failure rates. Conversely, if a behavior is only mildly associated with failure, but is very common among condom users, efforts to curb the behavior may have a significant impact on overall condom failure. Moreover, it is important to keep in mind that specific behaviors may vary significantly from one country or region to another.

To date, anecdotal evidence from FHI research has implicated four categories of behavior with respect to condom failure. These include putting condoms on incorrectly, use of additional oil-based lubrication, lengthy or intense intercourse, and reuse of condoms. To our knowledge, this is the first prospective condom study that has systematically evaluated the prevalence of several behaviors which have been suggested as potential causes of condom failure. Based on the prevalence of behaviors reported in this study, the behavior categories should be expanded to include improper methods of opening condom packages and incorrect withdrawal of condoms.

In one site, 39% of the participants reported opening one or more condom packages with methods other than fingers, including teeth, knives, scissors and pencils. Using a sharp object to open the package could clearly result in damaging the condom before use. In fact, univariate analysis suggests that this behavior was associated with breakage. With respect to withdrawal, 56% of men in one site reported losing their erection before withdrawal and 44% of the men in another site indicated that they did not hold the base of the condom to prevent slippage during withdrawal. Given that research suggests that slippage is as prevalent as

breakage,[3] and may be as detrimental to contraceptive and STD protection, reducing behaviors that lead to slippage could help reduce condom failure significantly.

In contrast, very few men indicated that they used additional lubrication and even less reported reuse of condoms. Research has clearly established a link between use of additional lubrication (oil- and non-oil-based) and increased slippage.[7] Moreover, laboratory data and human use research has shown that use of oil-based lubrication can cause condom breakage.[7,9] Nevertheless, it appears that use of additional lubrication may vary by region, thus condom failure associated with use of additional lubrication may be limited to certain areas.

Although there is evidence of condom reuse for more than one act of coitus,[10] the men in this study most likely had little reason to reuse any of the five study condoms they were given. The condoms were to be used in a short amount of time and participants had access to free supplies if they needed additional condoms before the study period ended. Thus, the results of this study with respect to reuse may not accurately reflect both the prevalence and the importance of reuse with respect to condom failure. In a more general sense, caution should be used in terms of generalizing results since participants were specifically selected in order to test the primary hypothesis. Thus, recruitment was not designed to provide a representative sample of condom users for the other analyses.

VI. Conclusion

As with other barrier methods that require a high degree of user involvement and compliance, effectiveness of condoms decreases significantly as imperfect use increases. Particularly in light of the elevated role condoms are expected to play in providing protection from both unwanted pregnancy and STD, it is incumbent upon health care providers to help clients maximize the effectiveness of condom use. Important keys to reducing failure rates may include identifying condom recipients at increased risk of condom failure and encouraging them not to engage in behaviors associated with condom failure. Results from this study suggest that baseline information collected on history of condom failure is a good predictor of

future failure and can be used for targeted intervention. Results from this study also suggest that engaging in multiple adverse behaviors during condom use is linked with failure. Further research is needed to determine if condom failure can indeed be reduced by cautioning condom acceptors who are at increased risk against engaging in behaviors that may lead to failure.

18

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Table 1: Background Characteristics

	Mexico n=130	Philippines n=130	Dom. Rep. n=126
Age (in years)			
median	29	33	25
(range)	(18-53)	(18-64)	(18-58)
Education (in years)			
median	13	12	11
(range)	(3-13+)	(2-13+)	(0-13+)
Relationship Status			
non-stable	25%	15%	48%
stable	75%	85%	52%
Purpose for Condom Use[2]			
family planning only	48%	60%	19%
protection from STD only	8%	10%	64%
family planning & STD protection	43%	29%	15%
Number of Condoms Used (lifetime)			
1 - 25	32%	49%	31%
26 - 100	46%	33%	42%
> 100	22%	18%	27%
Number of Condoms that Broke or Slipped Off (lifetime)[3]			
none	50%	52%	42%
1 - 3	23%	34%	23%
4 - 6	12%	9%	10%
> 6	15%	5%	25%

[1]Percents on this and subsequent tables may not add to 100 due to rounding.
[2]In the D.R., 2 responses are missing.
[3]Condoms that reportedly broke and slipped off were only counted once as breakage.

20

Table 2: Condom Breakage and Slippage by Site

	Mexico	Philippines	Dom. Rep.
Condom use per participant			
1	--	--	1
2	1	--	11
3	3	--	20
4	11	2	21
5	115	128	73
Total condoms used	630	648	532
Total breakage[1]	2.1%	0.8%	4.7%
Clinical slippage[2]	1.9%	1.2%	0.8%
Total failure[1]	4.0%	2.0%	5.5%
Clinical failure[3]	2.4%	1.7%	2.3%

[1]Includes all condoms used.
[2]Condoms that reportedly slipped off and broke do not count towards slippage.
[3]Excludes condoms reportedly broken before intercourse.

24

Table 3: Details of Condom Failure

	Mexico n=25	Philippines n=13	Dom. Rep. n=29
Total broke	13	5	25
When did condom break:			
opening package	3	--	--
putting condom on	3	--	17
intercourse	2	3	8
withdrawal	1	--	--
taking off	4	2	--
Location of break:			
opening	6	--	7
shaft	5	2	7
tip	2	3	11
Total slipped off[1]	12	8	4
When did condom slip:			
intercourse	1	2	2
withdrawal	11	6	2

[1]When the same condom both broke and slipped off, it is only counted as a break, based on the belief that breakage often leads to slippage.

22

Table 4: Distribution of Number of Condom Failures per Participant

	Mexico n=130	Philippines n=130	Dom. Rep. n=126
Total failed condoms	25	13	29
No. participants reporting failure	18	13	21
Failures per individual			
0	112	117	105
1	15	13	17
2	1	--	2
3	1	--	1
4	--	--	--
5	1	--	1

23

Table 5: Prospective Condom Failure by Risk Group

(Increased Risk: ≥1 condom failed during time period)

Time Period	Mexico n=130		Philippines n=130		Dom. Rep. n=126		p-value[1]
	Increased Risk	Low Risk	Increased Risk	Low Risk	Increased Risk	Low Risk	
Lifetime:							
study condoms used	318	312	314	334	316	216	
proportion failed	5.0%	2.9%	2.2%	1.8%	7.6%	2.3%	0.03
Past Year:							
study condoms used	156	474	190	458	281	251	
proportion failed	7.1%	3.0%	3.7%	1.3%	7.1%	3.6%	0.01
Past Six Months:							
study condoms used	88	451	40	513	194	298	
proportion failed	9.1%	2.7%	2.5%	2.1%	9.3%	3.0%	0.02

[1]Wilcoxon Rank Sum Test, 1-tailed exact, stratified by country and number of condoms used.

29

Table 6: Prevalence of Behaviors

	Mexico n=630	Philippines n=648	Dom. Rep. n=532
Putting Condom On:			
Not opening with fingers	11%	10%	39%
Unrolling before donning[1]	7%	20%	12%
Filling condom (air, water)[1]	2%	7%	2%
Donning cond. inside-out[1]	2%	1%	4%
Lubrication:[1]			
Adding lubrication	3%	1%	1%
Removing lubrication	<1%	--	3%
Intercourse:[2]			
Lasting more than 20 min.	2%	4%	8%
Especially intense	12%	11%	41%
Withdrawal:[2]			
Losing erection before	33%	15%	56%
Not holding cond. during	42%	44%	38%
Reuse:[3]	--	<1%	<1%

[1]Excluding condoms which broke while opening package.
[2]Excluding condoms which broke while opening package or while putting on.
[3]Excluding condoms which broke.

25

Table 7: Condom Failure by No. of Risk Behaviors Reported per Participant

No. of Risk Behaviors	0	1	2	3	4-7	Total
Percent failed	2.7%	1.7%	4.0%	4.0%	9.8%	3.7%
$CI_{95\%\ exact}$	(1.4, 4.9)	(0.7, 3.2)	(2.4, 6.1)	(1.9, 7.2)	(6.0, 14.9)	(2.9, 4.7)
Condoms used	401	482	481	252	194	1,810

CI=confidence interval. Binomial Trend Test, exact **$p<0.01$**, stratified by country, includes only participants who tested 5 condoms (n=1,580 condoms).

Table 8: Univariate Analysis of Behavior & Condom Failure

	Mexico n=630		Philippines n=648		Dom. Rep. n=532		Combined[1] n=1,810	
	Break-age	Slip-page	Break-age	Slip-page	Break-age	Slip-page	Break-age	Slip-page
Putting Condom On:								
Not opening with fingers	0.15	--	1.00	--	0.06	--	0.02	--
Unrolling before donning[2]	0.17	1.00	0.27	0.06	0.08	0.07	0.01	0.03
Intercourse:[3]								
Lasting > 20 min.[4]	1.00	1.00	0.17	0.03	1.00	0.23	0.45	0.01
Especially intense[5]	0.21	0.05	0.10	0.56	0.90	0.18	0.23	0.01
Withdrawal:[6]								
Losing erection before[7]	--	0.81	--	<0.01	--	0.78	--	--

-- not applicable

[1]P-values for individual countries were derived from 1-tailed Fisher Exact tests. P-values for combined sample were derived from 1-tailed CMH analysis stratified by country. P-values for combined sample were not reported where strong interaction was present.
[2]Calculations for breakage exclude condoms which broke while opening package. Calculations for slippage exclude condoms which broke.
[3]Calculations for breakage exclude condoms which broke while opening package or while putting on. Calculations for slippage exclude condoms which broke.
[4]Participants with inconsistent responses were excluded (Mex n=1, D.R. n=2).
[5]Participants with inconsistent responses were excluded (Phil n=1).
[6]Excludes all condoms which broke.
[7]Participants with inconsistent responses were excluded (Phil n=2, D.R. n=1).

27

Appendix: Study Questionnaire

Latex Condom Study: 6004 R / NR
(site specific)/FHI
BACKGROUND QUESTIONNAIRE

Interview site _____ Today's date ___ _____ ____
day month year

Participant ID number___/___/___ Interviewer name _____

****

. How old were you on your last birthday? _____ years

. How many years of education have you completed? (circle highest completed)

0 1 2 3 4 5 6 7 8 1 2 3 4 13+
primary secondary university/technical

. Are you in a stable relationship?
1 - no (single, no regular partner)
2 - yes (married, living together, regular partner)

. What is your religion?
1 - Christian
2 - Muslim
3 - other:_____
4 - none
(the religions included here will vary depending on the country and will be coded differently)

he following questions may seem similar. However, each question is slightly ifferent, so please think about each question carefully before answering.

. For what purpose do you usually use condoms? (circle all that apply)
1 - to prevent pregnancy, for family planning
2 - for protection against STD's
3 - other:_____

. Do you have problems with condoms breaking or slipping off completely during intercourse or withdrawal?
0 - no
1 - yes

How many condoms have you used in your lifetime?
0 - never used condoms---->terminate interview
1 - less than 10
2 - between 10 and 25
3 - between 26 and 50
4 - between 51 and 100
5 - more than 100

. How many condoms have you had break in your lifetime? ____

. How many condoms have you had slip off completely during intercourse or withdrawal in your lifetime? ____
-->if one or more slipped off, how many of these condoms also broke? ___

). *How many condoms have you used in the past 12 months?
0 - did not use condoms in the past 12 months ---->terminate interview
1 - less than 10
2 - between 10 and 25
3 - between 26 and 50
4 - between 51 and 100
5 - more than 100

29

11. *How many condoms have you had break in the past 12 months? ___

12. *How many condoms have you had slip off completely during intercourse or withdrawal in the past 12 months? ____
-->if one or more slipped off, how many of these condoms also broke? ___

13. How many condoms have you used in the past six months?
0 - did not use condoms in past six months---->skip to question #19
1 - less than 5
2 - between 5 and 12
3 - between 13 and 25
4 - between 26 and 50
5 - more than 50

14. How many condoms have you had break in past six months? ____

15. How many condoms have you had slip off completely during intercourse or withdrawal in the past six months? ____
-->if one or more slipped off, how many of these condoms also broke? ___

16. How many condoms have you used in the past month?
0 - did not use condoms in past month---->skip to question #19
1 - less than 5
2 - between 5 and 10
3 - between 11 and 25
4 - more than 25

17. How many condoms have you had break in past month? ____

18. How many condoms have you had slip off completely during intercourse or withdrawal in the past month? ____
-->if one or more slipped off, how many of these condoms also broke? ___

19. Have you used 10 or more condoms in your life?
1 - yes
2 - no --->skip to bottom of this page

20. Out of the last 10 condoms you used, how many broke? _____

21. Out of the last 10 condoms you used, how many slipped off completely during intercourse or withdrawal? ____
-->if one or more slipped off, how many of these condoms also broke? ___

22. What brand(s) were the last 10 condoms that you used?
1 - they were all Sultans, or other USAID brand(s): _____
2 - they were all private sector condoms; specify brand: _____
3 - they were different brands; specify brands: _____
4 - I cannot remember the brand(s)

****

Give participant five condoms. Ask him to use these condoms over the next three weeks and return or call for a follow-up interview as soon as he has used all five condoms.

The date three weeks from today will be: ___ _____ ____
day month year

If the participant has not returned nor called by the date specified above, attempt to contact him. If the participant cannot be reached after three attempts, drop him from the study.

30

Latex Condom Study: 6004
(site specific)/FHI
FOLLOW-UP QUESTIONNAIRE

Interview site _____ Today's date ___ ____ ____
day month year

Participant ID number ___/___/___ Interviewer name _____

********** SECTION I **********

For the following questions, we will only be talking about the five study condoms you were given to use during the past three weeks.

. How many of the condoms did you use? _____ (0 - 5 condoms)

. How did you like the study condoms as compared to other condoms you have used?
1 - liked study condoms more
2 - neutral/same
3 - liked study condoms less

. How many of the five condoms did you use with each of the following people?
wife or regular partner _____
other (or occasional) partner _____
prostitute _____
(numbers in question #3 should equal total in question #1)

. How many of the study condoms broke? _____

. How many of the study condoms slipped off completely during intercourse or withdrawal? _____
-->if one or more slipped off, how many of these condoms also broke? ___

********** SECTION II **********

For each condom that broke and/or slipped off, please answer the following set of questions. Ask questions # 6-30 for the first condom that failed and then repeat this procedure for the second condom that failed, third condom...etc. If none of the five study condoms broke OR slipped off, skip to SECTION III.

FAILED CONDOM:	1'st	2'nd	3'rd	4'th	5'th
. With whom did you use this condom?					
1 - wife or regular partner	1	1	1	1	1
2 - other (or occasional) partner	2	2	2	2	2
3 - prostitute	3	3	3	3	3
4 - other	4	4	4	4	4
. How was the condom package opened?					
1 - with fingers	1	1	1	1	1
2 - with teeth	2	2	2	2	2
3 - with sharp object	3	3	3	3	3
4 - other	4	4	4	4	4
if other, specify:	____	____	____	____	____
. Was it difficult to open the condom package?					
0 - no	0	0	0	0	0
1 - yes	1	1	1	1	1

31

	1'st	2'nd	3'rd	4'th	5'th
9. Did the condom seem to be defective, damaged or of poor quality before you used it?					
0 - no	0	0	0	0	0
1 - yes,	1	1	1	1	1
if yes, specify:	____	____	____	____	____
10. Did you use additional lubricant or saliva with the condom?					
0 - no --->skip to question #13	0	0	0	0	0
1 - yes	1	1	1	1	1
11. What brand or type of lubricant did you use? (specify exactly)	____	____	____	____	____
-->question for the interviewer to answer: What type is this?					
1 - water based	1	1	1	1	1
2 - oil based	2	2	2	2	2
3 - do not know	3	3	3	3	3
4 - other,	4	4	4	4	4
if other, specify:	____	____	____	____	____
12. When and where did you add the lubricant?					
1 - on penis prior to putting on condom	1	1	1	1	1
2 - in vagina prior to intercourse	2	2	2	2	2
3 - inside condom	3	3	3	3	3
4 - on condom before intercourse	4	4	4	4	4
5 - on condom during intercourse	5	5	5	5	5
6 - other	6	6	6	6	6
if other, specify:	____	____	____	____	____
13. Did you unroll the condom before putting it on?					
0 - no	0	0	0	0	0
1 - yes	1	1	1	1	1
14. Did you fill the condom up with air or water before putting it on?					
0 - no	0	0	0	0	0
1 - yes	1	1	1	1	1
15. Did you have difficulty putting condom on because it was inside out?					
0 - no	0	0	0	0	0
1 - yes	1	1	1	1	1
16. Did you pinch the tip of the condom to remove the air?					
0 - no	0	0	0	0	0
1 - yes	1	1	1	1	1
17. Did you do anything to reduce the amount of lubrication before or during intercourse?					
0 - no	0	0	0	0	0
1 - yes,	1	1	1	1	1
if yes, specify:	____	____	____	____	____

32

	1'st	2'nd	3'rd	4'th	5'th
18. Once you put on the condom, how long did it take you to reach orgasm?					
1 - less than 1 minute	1	1	1	1	1
2 - between 1 and 20 minutes	2	2	2	2	2
3 - more than 20 minutes	3	3	3	3	3
19. Was intercourse especially intense or vigorous?					
0 - no	0	0	0	0	0
1 - yes	1	1	1	1	1
0. Did you wait until the penis became soft before withdrawing?					
0 - no	0	0	0	0	0
1 - yes	1	1	1	1	1
1. Did you hold onto the base of the condom during withdrawal?					
0 - no	0	0	0	0	0
1 - yes	1	1	1	1	1
2. Did you reuse the condom (more than one ejaculation)?					
0 - no -->skip to question #25	0	0	0	0	0
1 - yes	1	1	1	1	1
3. How long did you wait before reusing condom?					
1 - less than an hour	1	1	1	1	1
2 - between an hour and a day	2	2	2	2	2
3 - more than a day	3	3	3	3	3
'. Did you clean the condom before using it again?					
0 - no	0	0	0	0	0
1 - yes,	1	1	1	1	1

if yes, describe how you cleaned and stored condom before using it again:

1'st failed condom:_____

2'nd failed condom:_____

3'rd failed condom:_____

4'th failed condom:_____

5'th failed condom:_____

5. How did the condom fail?					
1 - broke	1	1	1	1	1
2 - slipped off completely	2	2	2	2	2
3 - broke and slipped off completely	3	3	3	3	3

----->if condom only slipped off, skip to question #29

'. Where did the condom break?					
1 - tip	1	1	1	1	1
2 - shaft	2	2	2	2	2
3 - open end	3	3	3	3	3
4 - do not know/remember	4	4	4	4	4

33

27. When did the condom break?

1 - while opening package	1	1	1	1	1
2 - while putting condom on	2	2	2	2	2
3 - during intercourse	3	3	3	3	3
4 - during withdrawal	4	4	4	4	4
5 - while taking condom off	5	5	5	5	5
6 - other, specify:	6 ____	6 ____	6 ____	6 ____	6 ____

28. Why do you think the condom broke? (interviewer: please write down exactly what the participant says)
1'st failed condom:_____
2'nd failed condom:_____
3'rd failed condom:_____
4'th failed condom:_____
5'th failed condom:_____

---->IF NO CONDOMS SLIPPED OFF, SKIP TO SECTION III

CONDOMS SLIPPED OFF:	1'st	2'nd	3'rd	4'th	5'th
29. When did the condom slip off completely?					
1 - during intercourse	1	1	1	1	1
2 - during withdrawal	2	2	2	2	2
3 - other specify:	3 ____	3 ____	3 ____	3 ____	3 ____

30. Why do you think the condom slipped off completely? (interviewer: please write down exactly what the participant says)
1'st failed condom:_____
2'nd failed condom:_____
3'rd failed condom:_____
4'th failed condom:_____
5'th failed condom:_____

********** SECTION III **********

IN-DEPTH INTERVIEW: For this final part of the interview, we want to learn more about how you used the five condoms in this study, REGARDLESS OF WHETHER ANY OF THESE CONDOMS BROKE OR SLIPPED OFF. We will discuss in detail the different stages of using a condom.

NOTE TO INTERVIEWER: WITHOUT PROMPTING THE PARTICIPANT, BEGIN BY HAVING A CONVERSATION ABOUT EACH STAGE OF USING A CONDOM (OPENING PACKAGE, PUTTING ON CONDOM, INTERCOURSE, WITHDRAWAL). HAVE THE PARTICIPANT TELL YOU IN DETAIL HO' HE OR HIS PARTNER CARRIED OUT THE DIFFERENT STEPS. IF NONE OF THE BEHAVIORS LISTED BELOW ARE VOLUNTEERED DURING THE CONVERSATION, USE THE QUESTIONS STATED BELOW TO TRY TO GET A PROMPTED RESPONSE. BE SURE TO COVER ALL THE POINTS LISTED. BE CAREFUL THAT THE PARTICIPANT IS NOT FORCED INTO GIVING A RESPONSE. RECORD ALL THE RESPONSES HE PROVIDES, EITHER PROMPTED OR UNPROMPTEL

---------- OPENING THE PACKAGE ----------

1 - used method other than fingers to open the package? if yes, specify:
other method:_____ with how many condoms:___
other method:_____ with how many condoms:___

2 - was it difficult to open the condom package?
if yes, with how many condoms:___

3 - none of the answers above

34

---------- PUTTING ON CONDOM ----------

- unrolled condom before putting it on?
  if yes, with how many condoms:___

- filled condom up with air or water before donning?
  if yes, with how many condoms:___

- put lubricant inside the condom or on penis before donning?
  if yes, with how many condoms:___

- had difficulty putting condom on because it was inside out?
  if yes, with how many condoms:___

- did not pinch tip of condom to remove air?
  if no, with how many condoms was air not removed:___

- other behaviors that interviewer thinks could cause condom failure
  (causing condom to break or to slip off during intercourse or withdrawal)
  specify:_____ with how many condoms:___
  specify:_____ with how many condoms:___

0 - none of the answers above

---------- INTERCOURSE ----------

1 - had especially long intercourse? if yes, specify:
  how long:_____ with how many condoms:___
  how long:_____ with how many condoms:___

2 - had especially vigorous intercourse?
  if yes, with how many condoms:___

3 - reduced the amount of lubrication before or during intercourse?
  specify:_____ with how many condoms:___
  specify:_____ with how many condoms:___

4 - other behaviors that interviewer thinks could cause condom failure
  (causing condom to break or to slip off during intercourse)
  specify:_____ with how many condoms:___
  specify:_____ with how many condoms:___

5 - none of the answers above provided

---------- WITHDRAWAL ----------

6 - waited until penis was soft before withdrawing?
  if yes, with how many condoms:___

7 - did not hold onto base of the condom while withdrawing?
  if no, with how many condoms was base not held:___

- other behaviors that interviewer thinks could cause condom failure
  (causing condom to break or to slip off during withdrawal)
  specify:_____ with how many condoms:___
  specify:_____ with how many condoms:___

9 - none of the answers above provided

Finally, we will discuss a few additional aspects of condom use.

---------- USE OF LUBRICANT ----------

20. Did you use additional lubricant or saliva with any of the five condoms?
    0 - no --->skip to question #22
    1 - yes

21. What brand(s) or type(s) of lubricant did you use?

specify exactly:	_____	_____	_____
with how many condoms?:	___	___	___
(interviewer: what type of lubricant is this?)	1-water based 2-oil based 3-do not know 4-other_____	1-water based 2-oil based 3-do not know 4-other_____	1-water based 2-oil based 3-do not know 4-other_____

---------- REUSE ----------

22. Did you reuse any of the condoms (more than one ejaculation)?
    0 - no --->skip to question #25
    1 - yes,
        if yes, how many:___

23. How long did you wait before using the condom(s) again?
    1 - less than an hour --->with how many condoms:___
    2 - between an hour and a day --->with how many condoms:___
    3 - more than a day --->with how many condoms:___

24. Did you clean any of the condoms before using them again?
    0 - no
    1 - yes -->if yes, how did you clean and store them?:
    specify:_____ with how many condoms:___
    specify:_____ with how many condoms:___

---------- OTHER ----------

25. Did any of the condoms seem to be defective, damaged or of poor quality before you used them? If yes,
    specify:_____ with how many condoms:___
    specify:_____ with how many condoms:___

26. Overall, do you think condom breakage is a major problem with condoms?
    0 - no
    1 - yes

27. Overall, what do think is the most important cause of condom breakage?
    specify:_____

28. Overall, do you think condom slippage is a major problem with condoms?
    0 - no
    1 - yes

29. Overall, what do think is the most important cause of condoms slipping off? specify:_____

30. Interviewer: Please write down any additional comments that may be of interest (write on back or attach an additional page if necessary):

36