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EVALUATION OF TWO CONDOM DESIGNS:  
A COMPARISON OF STANDARD AND LARGER CONDOMS  
IN GHANA, KENYA, AND MALI

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## INTRODUCTION

Heightened concern about the prevention of sexually transmitted diseases, especially the prevention of Acquired Immune Deficiency Syndrome (AIDS), has led to increased interest in condoms in recent years. One issue regarding condom usage centers on adequate fit and its relationship to comfort and breakage. There has been speculation that in some populations men may find a larger condom more comfortable. By adding a larger size to condom styles offered, breakage might be decreased and acceptability increased. Conversely, a larger condom could adversely affect retention of the condoms during use. The Agency for International Development (A.I.D.) currently distributes the standard (52mm) and smaller (49mm) sizes only.

## Study Objectives

This study compared the acceptability and functionality of two sizes (52mm and 55mm layflat width) of Ansell latex condoms in three African countries (Ghana, Kenya, and Mali). The focus of the study was on the issues of preference, comfort, fit, breakage and retention. Participants' ability to correctly identify the differences between the two designs was also examined.

## METHODS

### Study Products

The study products were Ansell lubricated latex condoms that differed only in width. The standard condom was 52mm layflat width and the larger condom was 55mm layflat width. Both condoms were sealed in square white polyethylene (cello) packages. The condoms were randomly sampled and tested in the laboratory at Family Health International and passed all of the required American Society for Testing Materials (ASTM) specifications for elongation and tensile strength (Appendix 1). Although at the time of manufacture condoms were not required to meet International Standards Organization (ISO) airburst tests, these tests were performed and the condoms met these specifications as well. The test condoms were manufactured four months before the study took place.

### Study Subjects

The study was conducted with current condom users in Ghana, Kenya, and Mali. Subjects were men recruited from age groups and social classes typical of A.I.D. condom users at the selected sites. The sources for recruiting volunteers were a pharmacy in Ghana, an industrial clinic in a General Motors factory in Kenya, and a family planning clinic in Mali. Condoms distributed by A.I.D. are distributed at the Kenya and Ghana sites. One hundred subjects were recruited from both Ghana and

Mali, and 75 from Kenya. All study participants were informed about techniques of proper condom use.

### Study Design

Each participant received a study packet containing two condoms, one standard and one larger. In Mali and Kenya, the larger condom was marked with a blue dot and was to be used first by the participants, while the standard condom was unmarked and was to be used second. In Ghana, the standard condom was marked with a blue dot and was to be used first while the larger condom was unmarked and was to be used second. Both condoms were to be used within a two week period. The participants were not told that the condoms differed in any respect. They were instructed to return to the test center after using the condoms to answer questions about the fit and comfort of the test condoms, their preferences, and whether the test condoms slipped or broke during use (Appendix 2). Participants that returned for the follow-up interview were paid a small stipend and given their choice of a strip of three of either of the test condoms as further incentive. This selection of one of the test condoms was included in the study design to reconfirm preferences revealed during the interview.

### Data Analysis

Interview responses were evaluated through the use of frequencies, cross tabulations, and stratified analyses. Qualitative data in the form of open-ended questions were coded and incorporated into the analyses. The elements of acceptability were assessed by comparing participant satisfaction and comments concerning positive and negative aspects of the two test condoms. The proportions of condoms breaking and slipping off in each country were compared using McNemar's chi square. The preference for one or the other of the test condoms in each country was tested using the Z test for significance. The ability to correctly identify the difference in size of the test condoms was analyzed using the one-sided Z test for significance.

## RESULTS

The results among countries were not similar enough to group together; therefore, each country will be reported on separately.

### Ghana

#### Demographic Data

Ninety-eight subjects completed the study in Ghana. The mean age of subjects was 29, the median age was 27, and the range was 19 to 51 years old. All of the subjects were circumcised. A total of 95% of the men had used condoms in the last year; 72% had used condoms more

than half the time in the last year. One quarter of the subjects used the test condoms with their wives, 70% with their girlfriends, and 3% used them with prostitutes.

### Preference

Over half (58%) of the study subjects in Ghana preferred the standard condom ( $p=0.16$ ), while slightly less than a third (30%) preferred the larger condom, and 12% had no preference (Table 1). One quarter (25%) of the men reported that their partners preferred the standard condom and 13% reported that their partners had preferred the larger condom. Over half (62%) of the subjects stated that their partner either had no preference or that their preference was unknown.

### Comfort

Equal numbers of participants thought that the larger condom was more comfortable (38%) as those that thought the standard condom was more comfortable (38%), while 24% reported that there was no difference (Table 2). Forty-three percent thought the larger condom was easier to put on, 25% thought the standard condom was easier to put on, and 32% reported no difference in the donning of the two test condoms (Table 3). Forty-one percent thought the larger condom felt thinner, 37% thought the standard condom felt thinner, and 22% found no difference in the sensitivity of the test condoms (Table 4).

### Perception of Size

Fully two thirds (67%) of the subjects were able to correctly identify the larger condom as being larger ( $p<0.001$ ). Only 15% of the subjects thought the standard condom felt larger, while 19% felt there was no difference in size (Table 5).

### Breakage and Slippage

The rates of condoms breaking were 13% (13/98) for the standard condom and 7% (7/98) for the larger condom (Table 6). The combined breakage rate was 10% (20/196).

Fifteen percent (15/98) of the subjects experienced the larger condom slipping off (Table 7). For five of these men the condom slipped off during intercourse and for nine of them this occurred during withdrawal. Only one subject reported the standard size condom slipping off. Two of the subjects who reported a condom slipping off failed to identify which condom.

## Choice of Condom

When offered three free condoms of either test product type at the conclusion of the interview, over half (54%) chose to receive the standard condom, while 34% chose the larger condom, and 12% indicated that they had no preference (Table 8).

The condom the participants chose to receive corresponded with their responses to which condoms they had expressed liking best in the interview for 93% of those who preferred the larger condom and 88% of those who preferred the standard condom. Four subjects who preferred the standard condom chose to receive the larger condom. When asked why, three of them stated that it was because the standard condom broke, and the other stated that the larger provided better sensitivity.

The reasons given for selecting the standard condom were that it was tighter or held more firmly (13 subjects), it was best (13), it offered better sensitivity or had a more natural feel (9), it was more comfortable (7), it fit well or was the correct size (4), it did not break (4), and other (3) (Table 9). Reasons for choosing the larger condom were that it did not break (10 subjects), it offered better sensitivity or had a more natural feel (7), it was more comfortable (6), it was easier to don (3), it was best (3), and other (4) (Table 10).

Three fourths (75%) of the 53 subjects who chose the standard condom, correctly identified the other test condom as being larger. Sixty-three percent of the 33 men choosing the larger condom correctly identified it as the larger condom.

## Kenya

### Demographic Data

Seventy-five men completed the study in Kenya. The age of subjects in Kenya was slightly older than in both Ghana and Mali, with a mean age of 31 years, a median age of 30, and a range of 21 to 51 years old. Fifteen of the subjects were not circumcised and two subjects did not report whether they were circumcised or not. Ninety-five percent of the subjects reported using condoms in the last year; however, only 41% had used condoms more than half the time in the last year. One quarter (25%) of the subjects used the test condoms with their wives, 69% used them with their girlfriends, and 4% reported using them with prostitutes.

### Preference

Nearly two thirds (63%) of the study subjects in Kenya preferred the standard condom ( $p=0.04$ ), 31% preferred the larger condom, and 7% had

no preference (Table 1). Of those subjects who stated which condom they thought their partners preferred, 43% of the partners were said to have preferred the standard condom, 24% were said to have preferred the larger condom. One third of participants were either not aware of partner preference or did not respond to the question.

#### Comfort

Half (52%) of the participants thought the standard condom was more comfortable than the larger condom, while 44% found the larger condom to be more comfortable than the standard, and 4% reported no difference in comfort (Table 2). Nearly equal numbers of participants thought either of the test condoms was easier to don (44% for the larger condom, 47% for the standard condom, and 9% finding no difference (Table 3)). Sixty-four percent of the subjects thought the standard condom felt thinner, 28% thought the larger condom felt thinner, while only 8% found no difference in the sensitivity of the test condoms (Table 4).

#### Perception of Size

Two thirds (68%) of the participants were able to correctly identify the larger condom as being larger ( $p < 0.001$ ) (Table 5). Twenty-three percent of the subjects thought the standard condom felt larger, and 8% of the subjects felt there was no difference in size.

#### Breakage and Slippage

The breakage rates were 4% (3/75) for the standard condom, 9% (7/75) for the larger condom, and 6.7% (10/150) for the combined breakage rate (Table 6).

Nine percent (7/75) of the subjects experienced slippage while using the larger condom (Table 7). Two subjects experienced the larger condom slipping off during intercourse, two during withdrawal, and three failed to specify when the slippage occurred. Eleven percent (8/75) of the subjects experienced slippage while using the standard condom, three men reported it occurring during intercourse, two during withdrawal, and three did not report when it occurred. Two of the subjects who reported a test condom slipping off failed to specify which condom had slipped off.

#### Choice of Condom

When participants were offered three free condoms of either test product type at the conclusion of the interview, 63% chose to receive the standard condom, 36% chose the larger condom, and 1% indicated that they had no preference (Table 8).

The participants' choice of free condoms corresponded with the response to which condoms they preferred in 96% of the cases.

The reasons given for selecting the standard condom were that it offered greater sensitivity or felt more natural (16 subjects), it fit well or was the correct size (13), it was tighter or held more firmly (9), it was more comfortable (3), it did not break (3), and other (3) (Table 9). The reasons given for selecting the larger condom were that it offered greater sensitivity or felt more natural (6 subjects), it was best (5), it was tighter or held more firmly (5), it fit well or was the correct size (3), it was comfortable (3), it was thicker (3), and other (2) (Table 10).

Two-thirds of the 15 uncircumcised subjects in Kenya chose to receive the larger condom, noting that it was more comfortable (3), it was better (3), it was larger (1), it seemed thicker (1), it had a more natural feel (1), and it held more firmly (1). One-third of these uncircumcised men chose the standard condom indicating that it seemed tighter and held more firmly (2), it felt more natural (1), it fit well (1), and it seemed larger (1).

Almost three fourths (72%) of the 47 subjects who chose to receive the standard condoms correctly identified the other test condom as being larger. Sixty-five percent of the 27 men choosing the larger condom correctly identified it as being larger.

## Mali

### Demographic Data

There were 99 subjects who completed the study in Mali. The mean age was 28 years old, the median age was 27, and the range was 20 to 55 years old. All of the subjects were circumcised. Eighty-seven percent of the men reported using condoms in the last year, but only 35% had used condoms more than half the time in the last year. About half (52%) of the subjects used the condoms with their girlfriends, one quarter (25%) used the test condoms with prostitutes, and 19% used the condoms with their wives. Four percent of participants did not specify partner type.

### Preference

In contrast to the other two countries, the majority (60%,  $p=0.09$ ) of the subjects in Mali stated that they preferred the larger condom (Table 1). Just over a quarter (28%) of the men preferred the standard condom, and 12% had no preference. Of those participants who reported their partners' preference, 20% of the partners were reported to have preferred the larger condom, while only 7% of the partners were reported to have preferred the standard condom.

### Comfort

Almost two thirds (64%) of the subjects thought the larger condom was more comfortable, while only 25% thought the standard condom was more comfortable, and 11% thought there was no difference in comfort (Table 2). A larger proportion of the men (57%) thought the larger condom was easier to put on (Table 3) than the proportion reporting this in Ghana or Kenya (43% and 44% respectively). Just over a fourth (27%) of the men thought the standard condom was easier to put on, and 16% found no difference in donning the test condoms. Over half (56%) of the subjects thought the larger condom felt thinner, 35% thought the standard condom was thinner, and 9% felt there was no difference in the thickness of the test condoms (Table 4).

### Perception of Size

Though the proportion was slightly less than for the other two countries, the majority (56%,  $p=0.11$ ) of the subjects were able to correctly identify the larger test condom as being larger (Table 5). Just over a fourth (28%) thought the standard condom was larger, and 16% thought there was no difference in the size of the test condoms.

### Breakage and Slippage

Only one percent (1/99) of the test subjects reported having a larger test condom break, 4% (4/99) reported having the standard condom break, and one subject who reported a test condom breaking failed to report which condom it was that broke. The combined breakage rate for Mali was only 3.0% (6/198) (Table 6).

Only two percent (2/99) of the subjects reported having a larger condom slip off (Table 7), for one subject this occurred during intercourse and for the other during withdrawal. Eight percent (8/99) noted having the standard test condom slip off; seven subjects reported this happening during intercourse and one subject stated it occurred during withdrawal. One subject who reported a condom slipping off failed to report which condom it was.

### Choice of Condom

When offered three free condoms of either test product at the conclusion of the interview, well over half (61%) of the subjects chose to receive the larger test condom, while less than a third (32%) chose the standard condom and 6% indicated that they had no preference (Table 8).

Almost all (93%) of the study participants who had indicated a preference for the larger condom chose to receive it as the free

incentive at the conclusion of the study; 96% of those who had preferred the standard condom chose to receive it.

Those who chose to receive the standard condom stated that it fit well or was the correct size (5 subjects), it was best (4), it offered greater sensitivity or had a more natural feel (5), it was tighter or held more firmly (3), it was more comfortable (3), it was easier to put on (3), it seemed to have more lubrication (3), and other (4) (Table 9). The reasons given for selecting the larger condom were that it was more comfortable (17 subjects), it offered greater sensitivity or felt more natural (15), it was larger (10), it was best (5), it held more firmly (3), it was easier to put on (3), and other (6) (Table 10).

The majority (58%) of those choosing the larger condom correctly identified it as being larger, and two thirds (67%) of those who chose to receive the standard condom correctly identified the other test condom as being larger.

## DISCUSSION

The following conclusions may be drawn from the results of this study:

- the majority of men in each of these countries did have a preference for one or the other of the two condom sizes, however, these preferences were different among countries;
- the majority of men were able to accurately distinguish the difference in the size of the standard (52mm) and larger (55mm) test condoms;
- the actual failure rates for both test condoms were greater than the rates predicted by the laboratory test data.

### Preference

A majority of participants from each country preferred one or the other of the two test condoms; however, the preference was different among countries. The standard (52mm) size was preferred in Ghana and Kenya, while the larger (55mm) size was preferred in Mali. It is noteworthy that approximately a third of the subjects in each country did not prefer or choose the condom that the majority of their countrymen chose.

It is not possible to determine whether the differences in preference are attributable to culture specific or anatomic differences, however, it may be noted that the differences in the demographic characteristics as measured are slight. All of the subjects were condom users, and probably used A.I.D. condoms primarily. The ages of study subjects were similar across countries. Although the level of experience with

condoms was different among countries (use of condoms more than half the time in the last year was reported to be 72%, 41% and 35%, for Ghana, Kenya, and Mali, respectively) the preferences expressed across the different levels of experience were not different. While there were differences in proportions of the categories of partner the test condoms were used with (with greater use with prostitutes in Mali), there were no differences in the preferences across the different categories of partners within each country.

Participants from different countries who expressed a preference for a particular size test condom gave similar reasons for their preference. Aside from general expressions of superiority, the reasons given for preferring the standard condom were that it fit better and more snugly, and thus seemed to provide better sensitivity as well as a feeling of better security. For those subjects who preferred the larger condom, fit was less of an expressed issue and the larger size appeared to confer better sensitivity and comfort. A number of subjects preferring the larger size were influenced by adverse experiences with the standard condom; 10% of them chose the larger condom because it did not break and 9% chose it because it was larger.

The standard size condom seems to be preferable to many men, even though it may be more uncomfortable or more difficult to put on. In Ghana, where 58% of the subjects preferred the standard size, the proportion of subjects who thought that the standard condom was more comfortable, thinner, or easier to put on was less than half for each variable. In fact, the larger condom was rated higher on two of these characteristics (thinness and ease of donning), and received the same level of approval for the other comfort characteristic. In Kenya, where the majority of subjects not only preferred the standard condom but also thought that the standard size was more comfortable and thinner, a substantial proportion of those who thought the larger condom was more comfortable and easier to don preferred the standard condom, indicating that a snugger fit was preferable.

Those men who prefer larger size condoms either find adequate security and sensitivity from a less tight design, or the issues are not as important to them. Whether this is due to differing penile sizes or differing tastes is not clear. The discrepancy between the preference for condom size and measures of acceptability was not as evident in Mali, where the majority of participants indicated that the larger condom was not only preferable but also more comfortable, easier to don and seemed to be thinner.

There were only 15 subjects in the study who were not circumcised, all of whom were in Kenya. Ten of these uncircumcised men (66%) preferred the larger condom, even though 63% of the total sample from Kenya preferred the standard size. It may well be that the larger condom would be preferred by the majority of men in countries with large proportions of uncircumcised men. Reports from native medical practitioners indicate that almost all Christian males, who constitute two-thirds of the population of Ghana, and almost all Muslim males,

who account for 80-90% of the population of Mali, are circumcised. The prevalence of circumcision among men in these countries who do not belong to these religious groups, and the proportions of men in Kenya who are circumcised are unclear.

#### Perception of Condom Size

It has been proposed that condom users may not be able to discern between different sizes of condoms accurately, and, given the elasticity of latex condoms, that one standard size is adequate for all men. This study found that men could indeed tell the difference. A majority of participants in this study were able to discern between the two sizes correctly, with just over two-thirds in Ghana and Kenya, and 56% in Mali, identifying the larger condom as being bigger. There were no differences in the preference of those subjects who were able to correctly identify the size differential and those who could not.

#### Breakage and Slippage Rates

There were differences among countries in the overall rates of test condoms breaking. This overall rate for both condoms combined was 10.2% for Ghana, 6.7% for Kenya, and 3.0% for Mali. These rates are higher than those that would be expected for new condoms, especially in light of the satisfactory laboratory test data. There were not significant differences across the different levels of prior experience with condoms, nor was there a significant difference in the breakage rates when examined by partner type, although the lowest rates were present when the test condoms were used with wives and the highest with girlfriends.

Due to the small numbers of test participants and the consequent lack of statistical power, there was not a significant difference in the breakage rates between the two different test condoms, either within individual countries or for all three countries combined. For Ghana and Mali, the proportion of standard condoms breaking was greater than that of the larger size, as might be expected if the standard size condoms were too small or tight. However, in Kenya, the breakage rate for the larger condoms was twice as great as the rate for the standard size. This reversal of the proportions of the two sizes breaking was not explained by differences in age, partner, experience with condom use, or circumcision status. As noted above, the numbers are small, and whether they represent a reflection of true differences is unknown. It is possible that behavioral characteristics not included in this study may influence the breakage rates. In general it is evident that the rates are higher than expected from analysis of laboratory test data, and that they are also influenced by factors or practices not yet elucidated.

The larger test condoms had a greater propensity to slip off during intercourse in Ghana. However, in both Kenya and Mali, a greater

proportion of standard condoms slipped off . The causes of this apparently paradoxical finding may also be related to behavioral factors not examined in this study; there was not a significant difference among the different levels of prior experience with condoms nor among participants with regard to who they used the test condoms with.

The true failure rate of condoms may be more accurately indicated by combining the breakage rates and the rates of condoms slipping off during or after coitus, since both put couples at risk of pregnancy and infection. While the risks of pregnancy or transmission of agents of infection are certainly greater if the slippage occurs during intercourse, they are by no means absent if it occurs during withdrawal. When these rates are combined, the composite rates of failure are almost one in five (18%) for Ghana, 14% for Kenya, and 8% for Mali. This may be an indication of the limitations of the effectiveness of latex condoms in these populations. The implications for the use of condoms to prevent the spread of Acquired Immune Deficiency Syndrome (AIDS) and other sexually transmitted diseases, and to prevent unwanted pregnancy are evident.

#### Recommendations

Additional studies utilizing other sample populations within the countries used in this study and sample populations from other countries would help define similarities, differences and trends in preferences for condom size. Uncircumcised men represent a subset that needs to be included in the sample population. Other issues in the design and packaging of condoms need to be examined, to gain further insight into geographical, cultural and individual components of preference.

High failure rates with new condoms that passed both ASTM and ISO standards were observed in this study. This enigma needs further examination, to search for determinants of breakage and slippage. The discrepancy between the laboratory test data and the failure rates from the field suggests that either the laboratory testing standards and procedures need to be modified, or the interpretation of the laboratory data needs to be examined. Restriction of test subjects to those not engaged in behaviors that would put them at risk for sexually transmitted diseases or unwanted pregnancy needs to be considered, even though this may not target the population for whom the data are needed most.

This study presents arguments for the provision of more than one standard size of condom. Preference may well be a predictor of use, and in the interest of attaining the highest possible levels of use to prevent the spread of AIDS, other STDs, and unwanted pregnancies, the varied preferences of potential users should be accommodated through the provision of different condom sizes.

**Table 1: Condom Preference**

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Country	Preferred Condom					
	Standard %* (N)	Larger %* (N)	No Preference %* (N)			
Ghana (N=98)	58 (57)	30 (29)	12 (12)			
Kenya (N=75)	63** (47)	31 (23)	7 (5)			
Mali (N=99)	28 (28)	60 (59)	12 (12)			

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\*percentages may not equal 100 due to rounding

\*\*p<0.05

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**Table 2: Evaluation of Condom**

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Country	Condom Reported as Most Comfortable					
	Standard %* (N)	Larger %* (N)	No Difference %* (N)			
Ghana (N=98)	38 (37)	38 (37)	24 (23)			
Kenya (N=75)	52 (39)	44 (33)	4 (3)			
Mali (N=99)	25 (25)	64 (63)	11 (11)			

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\*percentages may not equal 100 due to rounding

**Table 3: Donning**

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Condom Reported as Easiest to Put On

Country	Standard		Larger		No Difference	
	%*	(N)	%*	(N)	%*	(N)
Ghana (N=98)	25	(25)	43	(42)	32	(31)
Kenya (N=75)	47	(35)	44	(33)	9	(7)
Mali (N=99)	27	(27)	57	(56)	16	(16)

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\*percentages may not equal 100 due to rounding

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**Table 4: Perceptions of Sensitivity**

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Condom Reported as Being Thinner

Country	Standard		Larger		No Difference	
	%*	(N)	%*	(N)	%*	(N)
Ghana (N=98)	37	(36)	41	(40)	22	(22)
Kenya (N=75)	64	(48)	28	(21)	8	(6)
Mali (N=99)	35	(35)	56	(55)	9	(9)

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\*percentages may not equal 100 due to rounding

**Table 5: Perception of Condom Size**

Condom Reported as Being Larger						
Country	Standard		Larger		No Difference	
	%*	(N)	%*	(N)	%*	(N)
Ghana (N=98)	15	(14)	67**	(64)	19	(18)
Kenya (N=75)	23	(17)	68**	(50)	8	(6)
Mali (N=99)	28	(27)	56***	(55)	16	(16)

\*percentages may not equal 100 due to rounding

\*\*p<0.001

\*\*\*p=0.11

**Table 6: Breakage Rates**

Condom Breaking						
Country	Standard		Larger		Combined	
	%	(N)	%	(N)	%	(N)
Ghana (N=98)	13	(13/98)	7	(7/98)	10.2	(20/196)
Kenya (N=75)	4	(3/75)	9	(7/75)	6.7	(10/150)
Mali (N=99)	4	(4/99)	1	(1/99)	3.0	(6*/198)
Total	5.5	(15/272)	7.4	(20/272)	6.6	(36/544)

\*one break not specified

**Table 7: Slippage Rates**

Country	Condom Slippage							
	Standard %	(N)	Larger %	(N)	Unspecified %	(N)	Combined %	(N)
Ghana (N=98)	1	(1/98)	15	(15/98)	2	(2/98)	9.2	(18/196)
Kenya (N=75)	11	(8/75)	9	(7/75)	3	(2/75)	11.3	(17/150)
Mali (N=99)	8	(8/99)	2	(2/99)	1	(1/99)	5.6	(11/198)
Total	5.9	(16/272)	8.5	(23/272)	1.8	(5/272)	8.5	(46/544)

**Table 8: Choice of Free Incentive Condoms**

Country	Condom Chosen							
	Standard %*	(N)	Larger %*	(N)	No Preference %*	(N)	Neither %*	(N)
Ghana (N=98)	54	(53)	34	(33)	12	(12)	0	(0)
Kenya (N=75)	63	(47)	36	(27)	1	(1)	0	(0)
Mali (N=99)	32	(31)	61	(60)	6	(6)	1	(1)

\*percentages may not equal 100 due to rounding

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**Table 9: Reasons for Choosing Standard Size**

Reason	Country			Total (N=130)
	Ghana (N=53)	Kenya (N=47)	Mali (N=30)	
Better sensitivity	9	16	5	30
It was tighter, held more firmly	13	9	3	25
It fit well, was my size	4	13	5	22
It was best	13	1	4	18
It was more comfortable	7	3	3	13
It did not break	4	3	0	7
It has better lubrication	1	0	3	4
It was easier to put on	0	0	3	3
Other	2	2	4	8

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**Table 10: Reasons for Choosing Larger Size**

Reason	Country			Total (N=119)
	Ghana (N=33)	Kenya (N=27)	Mali (N=59)	
Better sensitivity	7	6	15	28
More comfortable	6	3	17	26
It was best	3	5	5	13
It did not break	10	0	2	12
It was larger	0	1	10	11
It was tighter, held more firmly	0	5	3	8
It felt well, was my size	2	3	1	6
It was easier to put on	3	0	3	6
It was thicker	1	3	0	4
Other	1	1	3	5

APPENDIX 1

## APPENDIX 1

### I. METHODOLOGY

#### a. Laboratory Testing

The condoms were randomly sampled, per Mil-Std.-105D, and tested in September, 1990 in accordance with procedures set forth in ASTM Standard D-3492 - 83, Standard Specification for Rubber Contraceptives (Condoms), and ISO Standard 4074/6, Rubber condoms - Part 6: Determination of Bursting Volume and Pressure.

### II. RESULTS

#### Laboratory Testing

Samples selected for testing are randomly pulled from a unique population. The number of samples to be tested for each characteristic is determined by using Mil-Std-105D. The standard is a statistical sampling plan which is based on the number of units in a given population. Based on additional factors, the standard allows for a prediction of population quality, percent defective, based on the number of samples tested.

Since the exact number of condoms in the original lot population was unknown, a total of 20 and 125 55 mm condoms were tested for tensile and airburst testing. At this sampling level, the original lot population would be greater than of 500,000 condoms. Only one-hundred (100) 52 mm condoms were available for testing. Twenty (20) were tensile tested and 50 were airburst tested. At this sampling level, the original lot population would have an approximate population of 35,000 condoms. These sampling levels were used to test the 52 and 55 mm condoms. See Table 1 for test results.

A sample of the condoms were tested against the ASTM and ISO standards. In order to show that the study condoms passed ASTM and ISO testing, based on a Mil-Std-105D sample size, the first 8 or 13 test results from the original testing were evaluated. The laboratory test results for both the 52 and 55 mm condoms are shown in Table 2.

The condoms passed all required ASTM specifications. At the time of manufacture, condoms were not required to meet airburst standards as set forth in ISO 4074/6. Airburst results indicated that the condoms met airburst specifications.

**TABLE 1**

**Physical Tests Performed on 55 mm Condoms**

<b><u>Test Performed</u></b>	<b><u>Number Tested</u></b>	<b><u>Mean Test Results</u></b>	<b><u>Minimum Specifications</u></b>	<b><u>Number of Failures Needed To Reject Lot</u></b>	<b><u>Number of Failures Observed</u></b>
<b><u>Tensile</u></b>	20				
Breaking Force		110.3	20.4	2	0
Tensile, MPa		39.2	17.0	2	0
% Elongation		848.0	675.0	2	0
<b><u>Airburst</u></b>	125				
Volume, L		27.6	16.5	6	2
Pressure, kPa		1.5	0.9	6	0
<b><u>Condom Quality Index</u></b>		82.0			

**Physical Tests Performed on 52 mm Condoms**

<b><u>Test Performed</u></b>	<b><u>Number Tested</u></b>	<b><u>Mean Test Results</u></b>	<b><u>Minimum Specifications</u></b>	<b><u>Number of Failures Needed To Reject Lot</u></b>	<b><u>Number of Failures Observed</u></b>
<b><u>Tensile</u></b>	20				
Breaking Force		69.5	20.4	2	0
Tensile, MPa		25.7	17.0	2	1
% Elongation		857.0	675.0	2	0
<b><u>Airburst</u></b>	50				
Volume, L		30.6	15.0	3	2
Pressure, kPa		1.5	0.9	3	0
<b><u>Condom Quality Index</u></b>		96.0			

TABLE 2

Physical Tests Performed on 55 mm Condoms

<u>Test Performed</u>	<u>Number Tested</u>	<u>Mean Test Results</u>	<u>Minimum Specifications</u>	<u>Number of Failures Needed To Reject Lot</u>	<u>Number of Failures Observed</u>
<u>Tensile</u>	8				
Breaking Force		112.8	20.4	1	0
Tensile, MPa		39.5	17.0	1	0
% Elongation		853.8	675.0	1	0
<u>Airburst</u>	13				
Volume, L		26.8	16.5	1	0
Pressure, kPa		1.5	0.9	1	0
<u>Condom Quality Index</u>		100.0			

Physical Tests Performed on 52 mm Condoms

<u>Test Performed</u>	<u>Number Tested</u>	<u>Mean Test Results</u>	<u>Minimum Specifications</u>	<u>Number of Failures Needed To Reject Lot</u>	<u>Number of Failures Observed</u>
<u>Tensile</u>	8				
Breaking Force		70.3	20.4	1	0
Tensile, MPa		26.7	17.0	1	0
% Elongation		860.0	675.0	1	0
<u>Airburst</u>	13				
Volume, L		30.2	15.0	1	0
Pressure, kPa		1.5	0.9	1	0
<u>Condom Quality Index</u>		100.0			

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Family Health International  
 Materials Technology Division - Testing Laboratory  
 Airburst Data Report

Country: ZIMBABWE  
 FHI Lot: ZW2  
 Mfg. Date: 11/89  
 Mfg. Lot: UNK.  
 Brand: SULTAN  
 Size: 52  
 Test Location: FHI  
 Test Date: 09/11/90

Average Burst Volume: 30.6 L  
 Standard Deviation: 3.6  
 Condom Quality Index: 96  
 Volume Rejects: 0  
 Average Burst Pressure: 1.5 kPa  
 Standard Deviation: 0.1  
 Pressure Rejects: 0

SPL NO.	PRES (kPa)	VOL (L)	SPL NO.	PRES (kPa)	VOL (L)	SPL NO.	PRES (kPa)	VOL (L)	SPL NO.	PRES (kPa)	VOL (L)
1	1.50	29.1	14	1.60	30.9	27	1.60	28.5	40	1.50	30.1
2	1.50	30.1	15	1.60	33.1	28	1.60	34.1	41	1.50	29.6
3	1.50	30.8	16	1.50	31.8	29	1.60	33.2	42	1.50	30.7
4	1.30	20.1	17	1.50	30.1	30	1.40	28.6	43	1.40	27.2
5	1.60	36.0	18	1.70	34.1	31	1.60	32.9	44	1.60	31.4
6	1.50	35.5	19	1.50	30.3	32	1.50	31.9	45	1.40	31.0
7	1.50	29.5	20	1.50	30.6	33	1.50	29.8	46	1.60	29.2
8	1.60	33.1	21	1.50	31.7	34	1.20	18.3	47	1.60	34.5
9	1.50	33.6	22	1.50	31.7	35	1.40	29.3	48	1.40	29.9
10	1.40	28.6	23	1.60	31.2	36	1.50	30.8	49	1.60	34.2
11	1.60	31.0	24	1.40	26.9	37	1.70	34.2	50	1.60	35.1
12	1.20	21.5	25	1.40	25.7	38	1.60	34.3			
13	1.60	33.9	26	1.50	28.6	39	1.50	30.0			

Family Health International  
 Materials Technology Division - Testing Laboratory  
 Tensile and Elongation Data Report

Country: ZIMBABWE  
 FHI Lot: ZW2  
 Mfg. Date: 11/89  
 Mfg. Lot: UNK.  
 Brand: SULTAN  
 Size: 52 mm  
 Test Location: FHI  
 Test Date: 09/11/90

Average Tensile: 25.7 MPa  
 Standard Deviation: 5.0  
 Tensile Rejects: 1  
 Average Elongation: 857%  
 Standard Deviation: 39.8  
 Elongation Rejects: 0

PL NO.	NEWT	PCT ELNG	TENS. (MPa)	SPL NO.	NEWT	PCT ELNG	TENS. (MPa)	SPL NO.	NEWT	PCT ELNG	TENS. (MPa)
1	76.0	873	26.4	8	58.5	815	20.8	15	86.8	911	31.9
2	70.5	859	26.2	9	78.0	887	29.0	16	64.3	852	25.8
3	57.7	814	21.4	10	52.0	788	18.5	17	72.0	868	29.5
4	67.4	853	25.5	11	77.3	880	27.6	18	66.2	847	22.3
5	83.1	917	35.4	12	76.6	873	26.5	19	84.8	903	30.3
6	80.3	896	32.4	13	60.6	836	21.0	20	42.4	763	15.7*
7	68.8	855	25.7	14	66.2	849	22.7				

Family Health International  
Materials Technology Division - Testing Laboratory  
Airburst Data Report

Country: ZIMBABWE  
FHI Lot: ZW1  
Mfg. Date: 11/89  
Mfg. Lot: UNK.  
Brand: SULTAN  
Size: 55  
Test Location: FHI  
Test Date: 09/10/90

Average Burst Volume: 27.6 L  
Standard Deviation: 4.6  
Condom Quality Index: 82  
Volume Rejects: 2  
Average Burst Pressure: 1.5 kPa  
Standard Deviation: 0.2  
Pressure Rejects: 0

PL NO.	PRES (kPa)	VOL (L)	SPL NO.	PRES (kPa)	VOL (L)	SPL NO.	PRES (kPa)	VOL (L)	SPL NO.	PRES (kPa)	VOL (L)
1	1.50	27.9	33	2.00	26.6	65	1.60	27.7	97	1.70	32.6
2	1.50	28.5	34	1.30	35.3	66	1.50	31.2	98	1.20	23.7
3	1.50	25.6	35	1.50	30.7	67	1.40	26.7	99	1.40	26.7
4	1.60	29.0	36	1.30	26.2	68	1.50	30.6	100	1.50	28.1
5	1.30	23.6	37	1.80	31.8	69	1.40	21.2	101	1.50	26.6
6	1.60	28.1	38	1.40	33.1	70	1.60	24.9	102	1.50	31.4
7	1.50	25.6	39	1.60	28.8	71	1.90	34.4	103	0.90	2.2*
8	1.50	24.2	40	1.30	32.1	72	1.50	29.4	104	1.50	29.4
9	1.80	29.4	41	1.50	29.3	73	1.50	27.5	105	1.40	26.6
10	1.40	27.5	42	1.50	28.7	74	1.80	28.4	106	1.30	22.0
11	1.70	31.6	43	1.60	28.4	75	1.50	34.6	107	1.30	24.2
12	1.10	24.9	44	1.40	38.5	76	1.50	27.4	108	1.70	35.0
13	1.40	22.7	45	1.80	29.3	77	1.60	27.9	109	1.30	23.5
14	1.70	29.6	46	1.50	28.0	78	1.60	26.6	110	1.30	21.2
15	1.80	27.7	47	1.20	18.6	79	1.60	27.9	111	1.50	29.6
16	1.00	8.1*	48	1.90	29.5	80	2.10	32.1	112	1.40	36.3
17	1.50	29.9	49	1.50	25.6	81	1.40	27.7	113	1.60	28.2
18	1.50	25.3	50	1.90	32.6	82	1.50	27.9	114	1.50	28.0
19	1.20	20.3	51	1.60	30.4	83	1.40	21.4	115	1.50	29.9
20	2.10	31.9	52	1.60	28.6	84	1.50	27.1	116	1.50	26.0
21	1.70	31.0	53	1.30	24.6	85	1.30	21.8	117	1.50	28.1
22	1.50	24.8	54	1.80	30.1	86	1.70	29.7	118	1.20	25.8
23	1.90	29.5	55	1.50	24.3	87	1.50	25.9	119	1.50	26.4
24	1.60	26.1	56	1.40	27.7	88	1.70	29.1	120	1.50	25.5
25	1.70	29.5	57	1.10	25.7	89	1.40	22.9	121	1.80	28.3
26	1.40	19.7	58	1.30	25.8	90	1.70	27.5	122	1.50	38.9
27	1.50	27.8	59	1.60	28.8	91	1.20	35.4	123	1.50	27.3
28	1.70	29.2	60	1.60	27.1	92	1.50	28.3	124	1.10	29.6
29	1.80	28.7	61	1.30	29.6	93	1.90	28.9	125	1.50	27.0
30	1.70	29.3	62	1.60	29.7	94	1.40	25.8			
31	1.40	26.7	63	1.50	25.9	95	1.50	26.2			
32	2.00	31.8	64	1.50	30.2	96	1.30	24.9			

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Family Health International  
 Materials Technology Division - Testing Laboratory  
 Tensile and Elongation Data Report

Country: ZIMBABWE  
 FHI Lot: ZW1  
 Mfg. Date: 11/89  
 Mfg. Lot: UNK.  
 Brand: SULTAN  
 Size: 55 mm  
 Test Location: FHI  
 Test Date: 09/11/90

Average Tensile: 39.2 MPa  
 Standard Deviation: 3.9  
 Tensile Rejects: 0  
 Average Elongation: 848%  
 Standard Deviation: 38.2  
 Elongation Rejects: 0

PL NO.	NEWT	PCT ELNG	TENS. (MPa)	SPL NO.	NEWT	PCT ELNG	TENS. (MPa)	SPL NO.	NEWT	PCT ELNG	TENS. (MPa)
1	123.3	850	43.6	8	111.8	913	41.9	15	113.7	859	42.6
2	103.6	806	40.9	9	107.2	826	38.3	16	111.7	854	41.9
3	88.7	786	31.1	10	126.2	840	41.2	17	125.6	851	35.8
4	101.7	920	37.9	11	76.9	763	29.1	18	114.1	840	40.2
5	131.9	854	40.5	12	96.0	886	40.9	19	111.4	813	37.6
6	134.5	861	40.2	13	94.9	882	35.8	20	107.8	846	39.2
7	106.5	840	40.1	14	118.1	872	45.2				

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APPENDIX 2

FAMILY HEALTH INTERNATIONAL

EVALUATION OF TWO CONDOM DESIGNS

Project 3376-1

Country \_\_\_\_\_ Date Condoms Issued \_\_\_\_\_  
day/month/year

Site \_\_\_\_\_ Interview Date \_\_\_\_\_  
day/month/year

\_\_\_\_\_  
Investigator Signature

GENERAL INFORMATION:

1. Participant Address \_\_\_\_\_  
\_\_\_\_\_
2. Participant ID Number: \_\_\_\_\_
3. Age: \_\_\_\_\_
4. Marital Status: 1 = Married 2 = Not Married
5. Average Number of Condoms Used Per Week: \_\_\_\_\_
6. Interval (days) between use of Condom 1 and Condom 2 (date of condom issue is Day 1) \_\_\_\_\_

PLEASE ANSWER THE FOLLOWING QUESTIONS ABOUT THE STUDY CONDOMS.

7. Which condom did you like better? 1 = First  
2 = Second  
3 = No Preference
8. Which condom did your partner like better? 1 = First  
2 = Second  
3 = No Preference  
4 = Do not know
9. Which condom was thinner? 1 = First  
2 = Second  
3 = No Difference

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10. Did any of the condoms break? YES \_\_\_\_\_ NO \_\_\_\_\_ If NO, proceed to question 12.

11. Which condom(s) broke? 1 = First  
2 = Second  
3 = Both

12. Which condom was bigger? 1 = First  
2 = Second  
3 = No difference

13. Which condom was more comfortable to wear? 1 = First  
2 = Second  
3 = No difference

14. Which condom was easier to put on? 1 = First  
2 = Second  
3 = No difference

15. Did the condoms slip off during use? YES \_\_\_\_\_ NO \_\_\_\_\_ If NO, proceed to question 17.

16. Which condom(s) slipped off during use? 1 = First  
2 = Second  
3 = Both

17. You may have three free condoms. Which would you like to have?  
1 = First type  
2 = Second type  
3 = Neither, specify reason \_\_\_\_\_

18. General Remarks \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_