CENTRE FOR SEXUAL & REPRODUCTIVE HEALTH

INVESTIGATION OF CONDOM QUALITY

CONTRACEPTIVE SOCIAL MARKETING
PROGRAMME, NIGERIA
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Susan Beckerleg

John Gerofi

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Contents

Acronyms

ASTM	American Society for Testing and Materials
CQI	Condom Quality Index
CSW	Commercial sex workers
FGM	Female genital mutilation
FHI	Family Health International
IEC	Information Education Communication
ISO	Organisation for International Standardisation
LIG	London International Group (now known as SSL)
LLD	Long distance drivers
MSM	Men-who-have-sex-with-men
NASCP	National AIDS-STD Control Programme
PATH	Program for Appropriate Technology in Health
PMS	Patent medicine store
PPFN	Planned Parenthood Federation of nigeria
SFH	Society for Family Health
SWAA	Society for Women against AIDS in Africa –Nigeria Chapter
STD	Sexually transmitted diseases
UNFPA	United Nations Fund for Population Activities
USAID	United States Agency for International Development
WHO	World Health Organisation

Executive Summary

Technical and Distribution Issues

Based on NASCP results, some USAID products tested prior to packing did not compare well with the requirements in the current international standards for condoms. Many lots had low burst volumes, and the standard deviations of burst properties were high in some lots. Some testers at the NASCP laboratory may be getting median burst volumes which are about 6 to 10% below those obtained elsewhere. Nonetheless, there is a very consistent difference in test results between the Aladan condoms and those purchased recently from Seohung.

Low burst volumes and high standard deviations mean that there will be relatively many condoms which cannot stretch very far, and these seem likely to break in use. This appears to be the case in Nigeria, and similar results were shown in the FHI study of 1991. While no causal connection has been proven between clinical breakage and the inflation properties, there is a very strong circumstantial link that has been established over many years.

The time taken for condoms to get from the factory to the point where they are to be packed by SFH has been between 9 months and 35 months. More recently, the times have been at the lower end of the range.

Storage conditions at the Lagos warehouse are adequate, but could be improved.

The criterion used to accept the condoms (the CQI) was based on condoms from a particular donor, and related considerations. As a result, some lots of condoms which probably did not comply with international standard 4074 were packed and released by SFH. The bad experiences of Gold Circle condom users in Sagamu appear to correlate with the release of condoms with low CQI.

Laboratory Report and Test Results

The laboratory equipment is still operational, but needs replacement or at least re-furbishing.

The testing being conducted gives a reasonably consistent indication of the physical properties, but burst volumes appear 6% to 10% below international consensus values.

Methodology for Qualitative Research

Data were collected using a range of qualitative research techniques. Using a questionnaire, in-depth, one- to- one interviews were carried out with CSW and men identified as condom users. Natural group interviews were conducted with adolescents, students, long distance drivers and associates, and peer educators.

Key informant interviews were also carried out, along with informal visits to pharmacies and patent medicine stores. This range of data enabled the cross-checking of information, most of which was of a highly sensitive nature.

Community Perceptions

In all areas visited reports of condom breakage were widespread.

Gold Circle condoms were as popular, or unpopular, as any other condoms in areas where unbranded condoms were not being promoted.

Cool Aladan condoms, which have been withdrawn from the market, were reported to have been popular in most areas visited. Some people said they were stronger than Gold Circle. However, they are the same product in different packages.

In Sagamu and Otukpu, where the DFID HIV/STD Management project is implemented, Pathfinder International, is working with CSW, long distance drivers and adolescents, there was a strong preference for UNFPA unbranded condoms. This preference can be attributed largely to Pathfinder's advice to condom users that they should not purchase or use Gold Circle.

Reported Condom Breakage

Accurate measurement of reported rates of condom breakage amongst those interviewed was not possible in this study.

Respondents were asked to recall the number of condoms used in the past month, and the number of breakages by brand. However, a range of factors, including the limitations of memory and enumeration, calculation of time off for menstruation and recall of brands used, made responses unreliable.

It was impossible to tell if reported breakage of Gold Circle concerned Aladan condoms or the new Seohung product.

Condom Negotiation/Usage Issues

Many clients of CSW are reported to be drunk so that intercourse is prolonged, causing dryness of the vagina. Lengthy and forceful penetration is a commonly reported cause of condom breakage.

The use of double condoms was reportedly widespread and appeared to be associated particularly with Gold Circle. Large penis size or prior knowledge that a client will be rough are reported to be the main reasons for CSW insisting on double condom use. Triple condom use was also reported.

Large penis size was reported to be a major cause of condom breakage.

In the majority of transactions it appears that the CSW provides the condom. Sometimes the man brings a condom and insists on its use. In most cases the condom brought is Gold Circle.

It is usually the CSW who opens the condom package and puts in on the man. When asked to demonstrate putting a condom on a model, many CSW opened the packet with their teeth. One reason that CSW may prefer to put the condoms on their clients is that there were frequent reports of men breaking condoms on purpose. Some men who are coerced into condom use retaliate by tearing the condom with their finger nails as they take it out of the packet or put it on.

Most sex workers reported that one of the main problems leading to condom breakage was rough sex. This entailed a lack of any foreplay, sudden and rough entry and forceful thrusting by men.

Rough sex contributes to the need for extra lubricants to be used. The vast majority CSW reported using oil based lubricants such as Vaseline, Apple Hair Food and baby oil. Many women reported applying a small amount of oil or Vaseline to the 'mouth' of their vagina to facilitate easy entry.

Some women considered that they had particularly tight vaginas and that their anatomy might contribute to condom breakage. A few women said that a tight vagina might be associated with female genital mutilation (FGM).

The vast majority of clients of CSW were reported to take three to five minutes to reach ejaculation. However, a minority, mostly those who had been drinking, were said to take much longer. Those men who took a long time and thrust hard were considered most likely to break condoms.

Men reported that condoms sometimes slipped off or broke because they were used for more than one 'round' of sex. Condoms were also reported to break as they were being put on, upon entry, during intercourse and at the point of ejaculation. The most common site of the breakage was reported to be at the tip.

Cultural Factors

During the research a number of culturally specific sexual practices were investigated in relation to condom breakage. Respondents were asked about anal and oral sex and other positions besides the 'missionary' position. Anal sex was found to be occurring in brothels. CSW were also asked about a range of other topics which might be relevant to condom breakage, including FGM, shaving of public hair and whether they worked when they were menstruating. However, from the findings it appears unlikely that any of these factors have a significant bearing on condom breakage.

The research was carried out almost exclusively amongst southern Nigerians. However, it is likely that Northern Nigerians may have different cultural/sexual patterns.

Major Recommendations

1. An aqueous lubricant should be made available to sex-workers through SFH.

2. The criterion for acceptance for packing should be upgraded to ISO 4074 or the WHO Specification.

3. SFH should continue to use only the Seohung condoms until the present stocks and those on order are running out.

A double blind cross-over study should be conducted soon in another country where Aladan condoms are still readily available, to compare the breakage rates and acceptability of the two products. Additional in-depth studies should be conducted with people from the double-blind study who break a lot of condoms. With the results of this study, a rational decision about future product sourcing can be made. Examination of all Aladan's and FHI's test results over an extended period may also assist.

4. A technical expert and a senior DFID official should visit the headquarters of SSL to discuss the problems encountered in Nigeria.

5. The inflation equipment should be replaced, or, if that is not possible, refurbished. At the time of replacement (or refurbishment) the existing staff, plus about three SFH staff should be trained in its use. The trained staff should do at least one test per fortnight to maintain their skills.

6. The distribution system and its management should be upgraded to minimise transit times and dwell times between the factory and the consumer, consideration should be given to improving storage conditions at the Lagos warehouse, and measures should be implemented to improve the lot traceability through the distribution system.

7. A full study should be done on the applicability of a larger condom in Nigeria.

1. Technical and Distribution Issues

1.1 The Condoms

1.1.1 Until 1998, most of the condoms supplied to SFH were donated by USAID. In recent years, they were manufactured by Aladan Corp, now a part of LIG, recently merged with Seton-Scholl Healthcare. Similar condoms were previously supplied to USAID by Ansell International. They were packed in a polyethylene foil until 1996, when the packing was changed to aluminium foil. Apparently, the first of these were distributed around the beginning of 1998.

1.1.2 In 1995-6, 42 million Aladan condoms were purchased using DFID funds, directly by PSI. The condoms were similar to the ones supplied by USAID. About 120 million condoms have been received from USAID since 1994.

1.1.3 In 1998, PSI purchased 60 million condoms packed in aluminium foil from Seohung. Although they were purchased to a PSI specification, Seohung condoms usually meet the WHO requirements. Seohung is currently producing an additional 90 million condoms for delivery by May 2000.

1.1.4 The condoms supplied by USAID have generally been characterised by their variability between lots, and sometimes relatively high standard deviations of burst properties. Tests by Enersol on samples from Nigeria suggest that for condoms made in mid 1998, the median burst volume can vary from about 24 to about 35 L, and the median pressure can vary from about 2.2 to 3.25 kPa.

1.1.5 Initially, these condoms were purchased according to the US GSA specification, but in the early 1990s, an inflation test requirement was added.

1.1.6 USAID purchases the condoms from Aladan, and they are sent to a USAID warehouse, from which they are later dispatched to recipient countries. USAID has a quality assurance scheme that is believed to involve independent testing by FHI of 10% of the lots produced. If many lots are rejected, the level of surveillance is increased.

1.1.7 An extensive stability study conducted by PATH in the early 1990s shows that condoms of the type being purchased by USAID had physical properties that decayed relatively rapidly with time when stored at elevated temperatures. Another study conducted by FHI shows increasing breakage rate as these condoms aged and their burst properties declined.

1.1.8 It is most probable that all latex condoms will decay more rapidly at elevated temperatures than at cool temperatures, but some are more stable than others. On the basis of the limited data available from Nigeria, it does appear that the condoms presently being supplied may not decay as fast as the ones in the PATH study.

1.2 The Quality Requirements and Indicators

1.2.1 USAID purchases its condoms according to its own specification. This is similar to the ISO standard, but a little less stringent. The two principal tests are the inflation test and the freedom from holes test.

1.2.2 Other condoms purchased by international agencies are usually purchased to the ISO standard (ISO 4074) or the WHO specification, which is an extension of it (although slightly more stringent).

Table 1
Comparison of Condom Burst Requirements
For 52 mm Condoms

	ISO 1990	WHO 1991	WHO 1995-8	ISO 1996 & USAID	ASTM 1997
Volume	15 L	16 L	18 L	16 L	16 L
Pressure	0.9 kPa	1.0 kPa	1.0 kPa	1.0 kPa	1.0 kPa
AQL	1.5	1.5	1.0	1.0	1.5

1.2.3 For a sample of 125 condoms , an AQL of 1.5 allows 5 defective condoms, while an AQL of 1.0 allows 3 defectives.

1.2.4 The freedom from holes test involves filling the condom with water and visually examining it for holes. The inflation test involves inflating the condom with air until it bursts. The inflation testing process yields individual burst volumes and pressures, which are then processed to yield the following:

- Pressure and volume histograms
- Median and modal volumes and pressures
- CQI

1.2.5 The approach used in the international standards is to constrain the number of condoms falling below certain limits of volume and pressure.

1.2.6 The CQI was developed around 1990, specifically to monitor the quality of condoms being distributed in developing countries. These tended to come from one factory, and were bought by a large international aid agency. These products were often found to be deteriorated when tested in the recipient country. The quality of the products was such that one was unsure that the products would meet international standards after some time in-country.

1.2.7 The index, ranging from 0 to 100 was intended to be used to produce a measure of quality as a function of time. Tests were to be done every 6 to 12 months, to produce a graph of quality vs. time. In fact, this is not done by the laboratory in Nigeria. Generally, the laboratory uses the CQI to determine fitness for packing of the products. For products being supplied by the donor concerned, the CQI produces a useful measure of the way in which the physical properties of the product deteriorate. In view of the size of the donations and the inability to obtain supplies elsewhere, it was decided to make the recommendations on the fate of tested lots such that many which no longer complied with ISO or WHO acceptance criteria would still be deemed suitable for distribution.

1.2.8 PATH's Condom Testing Handbook recommends full acceptance for CQIs of 60 or greater, acceptance for immediate distribution for CQIs between 36 and 59, acceptance for emergency use between 20 and 35, and destruction for CQIs under 20. SFH has modified this, and accepts products with CQI above 50 only.

1.2.9 Current international thinking is that the products should continue to comply with ISO requirements until the expiry date. This may not be the case with lots distributed according to the CQI criterion.

1.2.10 For example, a lot with a CQI of 60 (limit of full acceptability) could have 6 out of 125 condoms bursting at 10 litres or below, or 11 bursting at 14 litres. A lot with a CQI of 50 could have 8 out of 125 condoms bursting at 10 litres or below, or 22 bursting at 16 litres. The ISO requirements introduced in 1990 allowed 5 out of 125 to burst below 15 litres. This has since been tightened to 3 bursting under 16 litres. Some other examples are shown in Table 2.

Table 2
Examples of relationship between CQI and numbers of condoms with specified burst volumes (Sample size, 125)

CQI	No < 11	No at 14
30	14	25
35	12	22
40	10	19
45	9	17
50	8	14
55	7	12
60	6	11
65	5	9
70	4	7
75	3	6
80	3	5
85	2	3
90	1	2
95	1	1

1.2.11 It would be useful to change to an approach in which condoms arriving in Nigeria were assessed according to the WHO or ISO requirements. Later, it would be appropriate to require compliance with these requirements for at least most of the stated shelf life. These tests could be done using similar reduced sample sizes to those currently used. If the test results did not comply with requirements, they could be compared with lot by lot acceptance results, and received samples could be referred for re-testing.

1.2.12 As an interim measure, the CQI for acceptance could be raised, for example, to 65 or 70.

1.2.13 In other countries, the CQI is no longer widely used.

1.2.14 It must be understood that there is no direct equivalence between the ISO/WHO/ASTM acceptance criteria and the CQI. The former simply count the number of burst results below a certain limit, acceptance is based the proportion of condoms falling below the limit. There is an inherent benefit of the doubt built into the decision, using the ISO 2859-1 (MIL STD 105-D) sampling tables.

1.2.15 The CQI is based on a larger portion of the low end of the distribution of results, and an index is constructed by penalising those condoms bursting below 10 L the most, and condoms bursting below 11 and 20 litres on a sliding scale.

1.2.16 In PATH's handbook, the possibility of combining manufacturing lots into "rational lots" for testing is mentioned. This concept was introduced because USAID did not ship condoms by complete manufacturing lots, and because storage conditions in warehouses often made it difficult to keep what remained of the manufacturing lots segregated. The "rational lots" were supposed to be made up in some rational way, for example, of condoms made in the same month, or of condoms stored in the same way. However this process intrinsically destroyed any link to the product as originally manufactured. It is a process of last resort, and not one to be promoted.

1.3 Assessment of Test Results

1.3.1 For the purpose of an independent comparison, small samples (27 to 50 condoms each) of 10 lots of recently-manufactured Aladan condoms were inflation tested at Enersol. Although none the lots tested appeared to be of poor quality, there was a large and alarming variation amongst the lots. Mean burst volumes were between 23 and 35 L and mean burst pressures were between 2.3 and 3.25 kPa. This suggests strongly that the process is not in control in the factory. In view of that, one must question the homogeneity within the lots produced. If that homogeneity is compromised, then the validity of the sampling techniques used for any tests is in doubt. In general, larger samples may be needed to get a reliable impression of the quality of each lot.

1.3.2 In addition, the high burst pressures and low burst volumes obtained for some of the lots suggest a high rubber modulus product, reminiscent of the one in the 1991 FHI and PATH tests. These latter products demonstrated increasing breakage rates in use as the burst volume decreased.

1.3.3 The laboratory in Lagos does a check inflation test on a small sample (80 to 125 condoms). No test for holes is done. The sample sizes normally used for lots like the ones being delivered by USAID are 315 (or 200 for inflation testing of smaller lots). Testing is sometimes done on individual lots, but often it is done on rational lots.

1.3.4 Examination of the 47 lots of Aladan condoms tested for SFH between January 1999 and June 3, 1999 shows that 10 of these had a CQI less than 70. By comparison, only 2 out of 73 Seohung lots had a CQI less than 70. These conclusions are based on the volumes obtained by the NASCP lab.

1.3.5 Based on NASCP results of 44 lots of Aladan condoms tested between January 1999 and June 3 1999 it appears that 5 lots would have failed the 1990 ISO requirements, and 31 would have failed the WHO 1995 requirements. If the volume results were slightly low, as suggested by the comparisons with Enersol's tests, then many of the CQIs should be a little higher than the NASCP results suggest, and the number of lots that would have failed ISO and WHO requirements would be a little lower. Nonetheless, the results indicate that lots leaving the Lagos warehouse probably did not all comply with international standards.

1.3.6 Tests done by the NASCP laboratory in Lagos on Aladan condoms show that there have been several lots of low CQI released over the last two years, for want of other supply.

1.3.7 Contrary to the practice of other major public sector purchasers, USAID does not do independent testing of each lot. Instead, 10% of the lots offered are checked independently, until significant indications of non-compliance are obtained. When that happens, the level of surveillance is increased in steps, depending on the severity of the situation.

1.3.8 Information relayed to the consultants from USAID through SFH states that Aladan had had quality problems between June 1998 and January 1999. These are said to have been resolved. However, in view of the history illustrated by the NASCP test records, it appears likely that there have been many other occasions when there were problems with the Aladan product in the past. While such things happen with other suppliers too, the full independent lot by lot testing implemented by other purchasers provides a much safer screen.

1.3.9 Accordingly, one must be less confident about the quality of products delivered through the USAID system than that obtained through, say, PSI, WHO or UNFPA.

1.4 The Distribution System

1.4.1 The condoms enter Nigeria through Lagos port. In the past, extensive delays have been experienced at the port, but now, a diplomatic exemption agreement has been arranged, and since then, the condoms have been cleared through the port relatively quickly.

1.4.2 They are then taken to the SFH warehouse in Lagos, adjacent to the SFH office. There they are packed and transferred to the finished product store adjacent to the packing area, or to one of seven run by Manufacturers Delivery Services in the country, from which condoms are distributed to 40 different wholesalers. Gold Circle condoms are packed in retail packs of four, which are stamped on the inside with an expiry date. These are packed into dispenser packs of 96 condoms, which are in turn packed into cartons. It is intended that the dispenser packs and cartons contain only one lot, but it appears that this is not always the case.

1.4.3 The wholesalers buy the condoms from SFH and from that point they may go directly to retailers, or through one or more sub-wholesalers.

1.4.4 In the past, there have been extensive dwell times in the main warehouse, prior to packing. This resulted in packing occurring up to almost three years after manufacture. The reasons for the long delays included a supply that was donor-driven rather than demand-driven, the port delays mentioned above, erroneous estimates of future demand and suspension of the promotion campaign.

1.4.5 In the last year, the demand level has been better established, and it is to be hoped that future estimates will be more realistic.

1.4.6 SFH now sells only for cash, so wholesalers have a financial incentive not to hoard product. While some old product (expiring in March to September 2000) was found on the retail market outside Lagos, the cash sale system is expected to minimise the dwell time in the distribution system in the future.

1.4.7 In general, the most likely source of possible damage to the condoms is the wharf. Data provided by PATH suggests that in the middle of a hot day, the temperature in the container could rise to around 40C, although it would cool below 30C at night. A few weeks of such conditions should not affect the product unduly, but several months could damage the less stable products.

1.4.8 The SFH Lagos warehouse is a concrete block structure with a high, sloping aluminium roof. The roof tends to develop small holes, which are generally fixed by the landlord. However, leaks do wet the stock from time to time. There are no windows, but there are ventilation fans in the end walls. Warehouse staff regularly monitored the temperatures for some time, but the temperature was found to be so stable that the procedure was discontinued. The functioning of one the warehouse thermometers was checked against the lab thermometer during the mission and it appeared to be correct. If there is any doubt about its accuracy (to the nearest 1 to 2 C) of the other one that was used, then the monitoring should be repeated.

Measures that could be taken to reduce the temperature in the warehouses include:

- Installing roof insulation or a ceiling throughout the warehouses. This is an expensive option.

- Managing airflow through the warehouses. This would involve keeping the warehouses closed while the outside shade temperature was above the inside temperature, and running the fans when the situation is inverted (eg in the evening and early morning). Careful management or automatic control would be required. The fans may need to be reconfigured to ensure that the airflow through the warehouse was maximised, and that the flows from each end did not fight each other.

- Roof insulation reduces the rate of temperature rise during the day, but it also reduces the rate of cooling at night. Therefore, the full benefit of insulation would only be available with the use of ventilation at appropriate times, as described above.

1.4.9 As the warehouse is rented, and the roof is not in good condition, some guarantees about tenure, rent and roof condition would be desirable before any decision to spend money on insulation were made.

1.4.10 It appears difficult to ensure that the roof does not develop leaks which are only found after they have caused some rain damage. A programme of monitoring the walls and floor, plus examination of the tops of the cartons (maybe with binoculars) whenever it rains, should be instituted. In addition, consideration should be given to putting plastic drop sheets over all the stock in the warehouse.

1.4.11 As a result of the recent nationwide shortage of condoms in Nigeria, the distribution pipeline was empty. Currently, it is improbable that the condoms would stay in the central warehouse longer than about three months. Under these circumstances, it seems unlikely that stable condoms would deteriorate significantly over this period.

1.4.12 As the distribution system is based on cash payments, there is little incentive for anyone to keep big stocks. Trucking from Lagos to most areas in Nigeria should not take longer than about two days.

1.4.13 The most important precaution to be taken is the need to limit the dwell time on the wharf. Maintaining the present diplomatic customs exemption is essential.

1.4.14 Despite the apparent stock-out, many PMS outlets visited during this study still had stock manufactured in 1995 or 1996. Clearly, there are areas of high turnover (eg outlets near brothels) and those with low turnover.

1.5 Relationship Between Test Results and Clinical Use

1.5.1 Condom breakage can be caused by the original quality of the condom itself, its transport and storage conditions, and the way it is used. It is impossible without a major epidemiological study to quantify the relative magnitudes of these factors. Because of the situation in which condoms are used, and the many anatomical and behavioural variables that may come into play, it is very difficult to establish a causal link between laboratory results and breakage in use. Relatively few studies have addressed this matter.

1.5.2 In 1987, PATH began a detailed study of the physical stability of condoms under tropical conditions. Much of the data obtained was for condoms being supplied by USAID at the time. Although those condoms were made in a different factory to the present one, their physical characteristics are in some ways similar, especially in regard to the high burst pressures and low burst volumes obtained in some cases. A number of personnel involved with the first factory transferred to the present one.

1.5.3 The PATH study showed that there was a significant decline in burst volume during storage, and the results are published in Contraception (Free MJ, Srisamang V, Vail J, Mercer D, Kotz R and Marlowe D. Latex rubber condoms: Predicting and extending shelf life. Contraception 53: 1996, 221-229).

1.5.4 A clinical study also concentrated on the condoms being supplied by USAID. Volunteers used samples from various lots of condoms, with different ages and CQIs. The breakage rates were correlated against various physical properties of the condoms. Breakage rate showed a very strong correlation with decreasing CQI, decreasing mean burst volume, and increasing number of non-compliers on burst volume. This correlation was further improved when the three lots made by other manufacturers were removed from the analysis. This study is described in: Steiner M, Foldesy R and Cole D, Study to Determine the Correlation between Condom Breakage in Human Use and Laboratory Test Results, FHI, December, 1991.

1.5.5 However, thorough comparisons of breakage rates between two other types of condom, both of which had higher mean volumes, lower mean pressures and more consistent distributions than those used in the above study showed no benefit in vaginal use from increased burst volumes above a mean of about 33 L. Also, the breakage rates were lower than those in the 1991 study. (See Benton KWK, Jolley D, Smith AMA, Gerofi J and Moodie, R, An actual use comparison of condoms meeting Australian and Swiss standards: results of a double-blind crossover trial, Int Journal of STD and AIDS, 8, 1997, 427-431)

1.5.6 Clinical trials managed by Enersol, in which users compared two types of condom, also yielded statistical correlations between various parameters and causes for breakage. This study showed that men with larger penises were significantly more likely to break condoms. (See Smith AMA, Jolley D, Hocking J, Benton K and Gerofi, J. Does penis size influence condom slippage and breakage? Int Journal of STD and AIDS, 9 1998, 444-447.)

1.5.7 Numerous studies have demonstrated the deleterious effect of oil-based lubricants and medications on condom physical properties. A 1992 study (Piedrahita C, Foldesy R, Spruyt A and Joanis C, Assessing the Impact of Oil-based and Aqueous Lubricants on the Breakage and Slippage of Latex Condoms: PILOT STUDY, FHI, April, 1992) compared the effect of no additional lubricant, an aqueous lubricant and baby oil on condom breakage rate. The conclusion was that use of baby oil more than doubled breakage rates. Vaseline, widely used by CSW in Nigeria, is likely to have a slower effect on rubber than baby oil, because of its higher molecular weight and viscosity. It is difficult to say whether Vaseline gives a lower breakage rate in commercial sex than no lubricant at all, but it is certain that use of an aqueous lubricant instead of Vaseline would be better than either option.

1.5.8 On the other hand, the benefits of additional lubricant in non-commercial vaginal sex are not clear (See Smith AMA, Jolley D, Hocking J, Benton K and Gerofi, J. Does additional lubricant influence condom slippage and breakage? Int Journal of STD and AIDS, 9 1998, 330-335.) Therefore, the lubricant would need to be targeted at specific users.

1.5.9 It should be noted that sex workers in developed countries experience very low breakage rates. One Australian study found an overall perceived breakage rate of about 0.7% (Richters J, Donovan B, Gerofi J and Watson L, Low Condom Breakage Rate in Commercial Sex, The Lancet, 24/31, December 1988). The real breakage rate was lower, at 0.5%.

2. Laboratory Report and Test Results

2.1 History and Current Status of the Laboratory

2.1.1 The laboratory was established in the premises of the Nigerian NASCP, Yaba, circa 1990. In 1994, it was moved to SFH, but continues to be operated by the NASCP. Effectively, the laboratory tests only condoms supplied by SFH, since that is the only approved importer of condoms in Nigeria. Other condoms are available in pharmacies and markets, but these are apparently imported "informally".

2.1.2 The equipment was supplied by PATH, and originally commissioned by the author of this report. The equipment supplied includes, principally:

- 1 leaks tester
- 1 inflation tester
- 1 length tester
- 1 ruler
- 1 thickness gauge
- 1 flowmeter
- 1 barometer
- 1 thermometer
- 1 water-tube manometer, with rubber bulb attachment (for pressure calibration)
- 1 compressor
- 1 stopwatch
- 1 calculator
- 1 package seal tester
- Various tools and minor parts.

2.1.3 The original inflation tester required manual timing of the inflation of each condom with the stopwatch, and only one could test one condom at a time. In 1996, the inflation tester was replaced by a machine which displayed the burst time and pressure directly, and which allowed two condoms to be inflated simultaneously.

2.1.4 The laboratory basically follows the recommendations for testing as outlined in PATH's handbook. Only the inflation test and the package seal test are currently performed. Primarily, these tests are conducted on lots received from a supplier. Occasionally, the tests are done on stock from the distribution system.

2.2 State of the Equipment

2.2.1 At the time of the inspection, the state of the equipment was:

a: Inflation tester

The machine was giving a bimodal distribution of pressures, and the head giving the higher pressures was not switching off after the condom burst. The machine was dismantled and it was found that the pneumatic system was filled with water. The inlet filter and moisture trap was upside down, and was therefore not functioning. The system was drained and the filter cleaned and rearranged to the correct configuration. This corrected the problem. The laboratory manager reported that the two heads had been behaving differently since the beginning of 1999.

The liquid crystal displays on the inflation tester had become very pale over its life, and are now very difficult to read.

The output of pressure transducers used in this design of tester is known to drift over time.

The tester has no sound insulation, and the room in which it is installed is small, with hard walls and ceiling. As a result, the noise from bursting condoms reaches over 110 dB peak, and is disturbing to the people in the room. Similarly, the compressor located immediately adjacent to the testing room is also noisy.

The standards require that 150 ± 3 mm of the condoms be inflated. The clamp system used lifts the condom slightly when the airflow starts, and effectively, the length inflated could be 153 to 156 mm.

The water-tube manometer in the lab had insufficient fluid in it to allow convenient pressure measurement, and hence checking of the pressure transducers in the inflation tester. A rough check was performed on one head after it was repaired, and the results appeared plausible. An attempt was made to add water to the manometer, but the water did not mix with the fluid in the manometer, indicating that the fluid was probably an oil, with a density that did not match the calibration instructions. Therefore, the fluid was replaced with drinking water. When connected to the pressure transducers, the system did not hold pressure. There was insufficient time to solve this problem.

There appears to be no full manual for the inflation tester available in the lab itself, although there are extracts in the lab, and others in the SFH files.

The air compressor appeared to be functioning in accordance with its specifications, and does supply sufficient air, but it had originally been supplied to run the older inflation tester, which can only inflate one condom at a time. The amount of moisture reaching the tester may be due to the compressor being heavily taxed, with little settling time in the reservoir.

b: Other equipment

The package seal tester was functioning satisfactorily.

The length mandrel was in good condition.

The thickness gauge needed some adjustment to bring it into working condition. This was done.

The leaks tester was not examined, since it was not used.

2.3 Laboratory Operation

2.3.1 The laboratory tests only SFH condoms. The tests performed are the inflation test and the package seal test. The inflation test involves 80 or 125 condoms, and the actual test takes one to two hours. A similar amount of time is taken up in doing the calculations and producing the report. The lab generally tests one to two lots per day. The package seal test takes only a few minutes.

2.3.2 The laboratory is operated by the NASCP. It is managed by Mrs M. A. O. John, and the actual testing is done by up to four other people. Mrs John does the calculations and prepares the reports. She also sets up the inflation machine for the testers.

2.3.3 In general, the results obtained by the lab appeared to be a reasonable indicator of the quality of the condoms being tested. However, there were a number of details of procedure that were not being followed, or were being done incorrectly. While these are unlikely to have given an incorrect decision on most of the lots that were tested, they could well have caused some values to be incorrect.

2.3.4 The presence of water in the inflation tester caused a shift in burst pressures on one head. This problem had persisted for some months. There was apparently insufficient local knowledge of the consequences of the problem, or how to deal with it. There was also no backup information that could be accessed to give help under these circumstances. There was no effect of this on the decisions made, since the indicator used, the CQI, depends only on the burst volumes.

2.3.5 The atmospheric pressure and ambient temperature are essential inputs to the calculations. The barometer supplied needs calibration every few months. The staff were not aware of how to do this. The temperature recorded for one test that was observed was different from that indicated on the thermometer at the end of the test.

2.3.6 It was noted that testers were not wearing gloves when doing the inflation test. As many lots have CQIs less than desirable, and do not meet ISO or WHO requirements, it is highly desirable that the testers wear gloves, to avoid allegations that the condoms were damaged by the tester. Rubber examination gloves or thin cotton gloves are suitable.

2.3.7 The laboratory has participated in two inter-laboratory comparisons conducted by PATH, one in 1995 and one in 1999. In the 1995 trial, the burst volumes obtained compared reasonably well with those of PATH, but the pressures were a little low in all three cases. In 1999, two samples were tested. For one sample, agreement on one sample was good, while on the other one, the mean burst volume for the NASCP lab was about 7% below the PATH value. For this sample, there were many burst values that were about 20% low, for both volume and pressure. These were principally in the range 20 to 30 L, and the corresponding pressures of 1 to 1.5 kPa.

2.3.8 Some returned samples were sent to the Enersol laboratory for testing. Two of these, 0068821 and 0050821, had been tested as single lots by the NASCP laboratory in May, 1999. In addition, Seohung lot 8K09 was tested by both laboratories. Comparison of the two laboratories' results is shown below:

Comparison of Enersol and NASCP Results

	8K09		0050821			
	Enersol	NASCP	Enersol	NASCP	Enersol	NASCP
Mean Vol	33.45	32.05	33.11		32.11	
Vol SD	3.95	3.61	7.23		2.60	
Median Vol	34.5	32	35.00	33	32.00	29
Mean Press	2.01	1.88	2.20		2.31	
Press SD	0.20	0.25	0.30		0.19	
Median Press	2.05	1.9	2.30	2.3	2.30	2.4

2.3.9 The differences in burst volume are more significant than the pressure differences.

2.3.10 Although no obvious mishandling of the condoms was observed during the visit, it could be that one of the testers who was not present at the time may be unrolling the condoms incorrectly. Periodic re-training in this matter is desirable. Use of gloves is also important.

2.3.11 Mrs John and the other testing staff are employees of the Ministry of Public Health, and may have other duties. They are not always able to be present. SFH staff are neither trained nor allowed by the NASCP to use the equipment. Accordingly, SFH sometimes has trouble getting tests done in time for orderly distribution of product.

2.3.12 In the interests of continuity and turn-around time, it is clearly necessary to have more than person able to do the testing and it would be wise to provide SFH with the capacity to test the product in the event that NASCP staff cannot meet the demand. However, it would be best if those people who had been trained remained in practice, by doing at least one test per fortnight.

2.4 Possible New Inflation Testing Equipment

2.4.1 There are a few experienced suppliers of inflation testing equipment, including Enersol, Doka and CPR. Selection of a suitable equipment supplier should be based on the equipment itself and on the supplier's experience in developing countries.

2.4.2 Three relevant options are available from Enersol:

1. Two Head "Monitoring" inflation tester, intended for low volume use. This is usually configured so the operator writes down the results from each head as they are recorded. It is more advanced than the PATH tester, as it reads directly in volume and pressure, the results obtained can also be viewed after the test is complete, and it has sound insulation. With an optional extra, it can also download the results to a computer, but, at present, the analysis would have to be done in a commercial spreadsheet program. The unit can also be calibrated properly.

Without the computer connection, this tester is faster than the one presently in use, since it does not require calculation of individual volume results. (Budget price $US 20,000 without computer link, and $US 23,000 with computer link and computer.)

2. Two Head "Classic" inflation tester. This is connected directly to a computer, and produces statistical information on each batch tested, as well as control chart information, automatically. It has a capacity of about 70 condoms per hour. (Budget price $US 29,000 including computer link and computer)

3. Four Head "Classic" inflation tester. This is like the two head unit above, but with a capacity of 140 condoms per hour. (Budget price $US 44,000 including computer link and computer)

2.4.3 All budget prices are ex-works, but include commissioning and staff training, subject to availability of in-country facilitation by DFID.

2.4.4 The present compressor may be suitable for the two head machines, but is inadequate for the four-head machine. It could be retained as a backup machine, which would allow two head testing to continue if the main compressor failed. (Budget price $US 1,600 for two heads or $US 2200 for four heads.)

2.4.5 Additional equipment to prevent moisture from entering the testing equipment should be considered. The simplest would be a centrifugal dryer (budget price $US 500).

2.4.6 If new equipment were purchased, the four-head tester would provide the ability to test many lots per day, and, if necessary to enlarge samples to the size used in compliance testing.

3. Methodology for Qualitative Research

3.1 In order to supplement the technical quality assessment of Gold Circle condoms, a range of qualitative research methods was employed. The collection of data from different sources allowed the cross-checking of findings, or triangulation.

3.2 A combined questionnaire and tool for the collection of in-depth information through personal narratives from individual condom users was drawn up (See Annex). This was tested on respondents and based on their responses some questions were dropped or added and the order of questioning adjusted. Efforts were also made to ensure that the researchers were asking the questions in a similar manner, using the same language.

3.3 The questionnaire/in-depth interview was administered primarily to brothel-based CSW and any customers or other men encountered in brothels. Due to the sensitivity of many of the questions it was necessary to conduct the interviews on a one-to-one basis. No names were taken, confidentiality was assured by the researchers and the interviews were conducted out of earshot of other people.

3.4 In order to reduce bias and encourage the collection of detailed information, care was taken in the giving of introductions and explanations when entering a brothel. SFH or Pathfinder staff introduced the team in some places, while in others the researchers negotiated entry by asking to speak to the barman or manager. Often this person referred the team to the chair-lady. Once approval to ask questions about condom breakage in order to improve people's sexual health had been gained, the CSW were called to hear about the research. The researchers stressed that interviews were being held on a voluntary basis. As well as avoiding the coercion of a group enjoying very limited power and autonomy, this approach meant that those who agreed to talk were more likely to be forthcoming, as they had a choice in the matter. 93 such questionnaires/in-depth interviews were carried out with CSW.

3.5 A topic guide for natural group interviews, whereby people who know each other and already constitute a group discuss a given subject, was also drawn up. The questions were designed for use with groups of people who may or may not be condom users. The rationale was that any condom users in the group might feel free to disclose their personal experience. 16 group interviews were held with long distance drivers and others working in lorry parks, transport union officials, adolescents, peer educators, police cadets, public health students and female university students. A more or less direct approach to asking about condom use and breakage was adopted depending on the nature of the group.

3.6 Three additional group interviews were held with CSW where particular issues such as condom size and lubrication were probed. The women were also asked to demonstrate how to put a condom on a model penis. This practical exercise was both revealing to the researchers and fun for the participants.

3.7 In addition, data were collected by informal interviews with pharmacy and patent medicine shop staff and key informant interviews were held with relevant project staff. In Sagamu the Nigerian researchers carried out informal interviews while observing business in a busy brothel bar.

3.8 Most interviews were conducted in pidgin or English. Even when the researchers and the CSW respondents spoke the same language, it was considered better to avoid Yoruba, as women might be reluctant to talk to somebody from the same ethnic group or location due to the stigma attached to their work. At the conclusion of the interviews respondents and 'gatekeepers', such as barmen or transport union officials, were given gifts of Gold Circle condoms, calendars, key holders or biros, as appropriate.

4. Community Perceptions

4.1 There had been a number of informal reports that Gold Circle products broke frequently, and that sex workers preferred other brands, particularly those supplied by UNFPA.

In Lagos, this was confirmed by the Executive Director of the PPFN and the Action Health Incorporated.

4.2 Condom users in Lagos, at the Benin border and in Ibadan had a better image of Gold Circle and overall did not perceive it to be inferior to any other condom brand. In Lagos and at the Benin border the researchers were introduced by SFH staff to CSW and customers in brothels, and it is therefore possible that respondents might have been a little reluctant to criticise Gold Circle. However, in Ibadan where the researchers negotiated entry to brothels themselves, it is unlikely that they would have been associated with the Gold Circle brand.

4.3 In Sagamu, amongst the staff and beneficiaries of the DFID funded project the perceived difference between Gold Circle and unbranded condoms was greater than the real one, because sex workers were given training sessions by the Pathfinder project, telling them not to use Gold Circle, or to buy condoms in pharmacies or PMS stores. The project itself sold UNFPA condoms.

4.4 The staff of the Sagamu Community Centre project explained that in 1997, they had received a bad shipment of Gold Circle condoms, which was subsequently returned. Since then, they had advocated using the UNFPA condoms. The timing correlates with the release by SFH of several lots with CQIs between 50 and 60.

4.5 In Sagamu, although CSW expressed great dislike of Gold Circle saying that most of them broke, other respondents, who had less close, or no, association with Pathfinder had more mixed opinions, some preferring Gold Circle and some unbranded condoms.

4.6 The situation in Otukpo was similar to that found in Sagamu. Pathfinder International, which is DFID funded through the same initiative as in Sagamu are active in the town. They also support projects run by PPFN and SWAAN. Pathfinder, SWAAN and PPFN staff expressed a strong dislike of Gold Circle, while Cool was consider a superior product. They did not seem aware that a particular bad shipment might account for frequent reports that Gold Circle breaks. On the other hand, the marking on the Gold Circle cartons indicating that the product was ‘not for sale outside Nigeria’ had aroused suspicion amongst Pathfinder that an inferior product was being dumped in the country.

4.7 By contrast, the project workers spoke of the superior nature of UNFPA unbranded condoms which they referred to as London Rubber. SWAAN work in five brothels in the town, as well as with peer educators working with motorcyclists and drivers. PPFN work with peer educators of adolescents. All these groups are told, as part of their training, that Gold Circle is inferior and 'normally breaks'.

4.8 SWAAN sell unbranded condoms direct to brothels. CSW reported that the price of a box of 144 unbranded condoms had recently dropped from Naira 200 to Naira 150. Unbranded condoms were also being sold by other people in brothels, in some pharmacies and reported by one pharmacist to be available in the wholesale drug market. Pharmacy staff, where both unbranded and Gold Circle were sold, reported that customers, who were mostly or exclusively men, preferred Gold Circle.

4.9 White PPFN condoms are available in Otukpo where they are referred to as 'Aladan'. These are perceived to be better than Gold Circle. However, in fact Gold Circle (Aladan) and the PPFN condoms are the same product in different packaging.

4.10 In one group interview with CSW in a brothel in Otukpo, respondents reported that the advantages of unbranded condoms were that, unlike Gold Circle, they did not break or smell bad. However, unbranded condoms were hard and caused greater pain than Gold Circle during sex. They explained that men preferred Gold Circle because of the greater sensitivity during sex, as compared with unbranded condoms.

4.11 In Kaduna, UNFPA unbranded condoms were sold in PMS and in brothels. In addition, PPFN had been selling white unmarked Aladan condoms of the same kind encountered in Otukpu. These were now expired and the clinic had withdrawn them from sale. Expired PPFN condoms were observed on display next to Gold Circle in one pharmacy. These PPFN condoms were used by some sex workers. Both condoms were referred to as the 'white ones' Therefore, it is likely that confusion over whether UNFPA or PPFN condoms were being referred could confound the issue of preferred brands. Gold Circle was sold in all PMS visited and used exclusively in the Hausa run brothel visited. A wide range of other condoms is reported to be available in Kaduna, notably, Durex, Prudence (a PSI product from Benin) and Protect (a PSI product from Cameroon).

4.12 In group interviews with police cadets and public health students in Kaduna, frequent breakage of Gold Circle condoms were reported. These groups had been recently exposed to SFH IEC initiative.

5. Reported Condom Breakage

5.1 CSW and other condom users were asked to report the number of condoms breaking and/or slipping off, by brand during the last month. They were also asked to estimate the number of condoms used during the last month, so that a rate of condom breakage/slippage could be calculated. It was decided to ask about condom use during the last month and not, for example, the last day or week, as a month is a period where CSW could reasonably be expected to have used a large number of condoms, even if they had not worked throughout the period.

5.2 However, data on the number of condoms used were difficult to collect, amongst sex workers. Factors confounding measurement included the issue of whether a condom was used every time and reluctance in many brothels to report the non use of condoms, particularly where SFH or Pathfinder and associates had been active. Recall covering a whole month was also problematic. In addition, some women took time off during menstruation, while others did not. Given that women were already finding the process of calculating days and numbers difficult it was not possible to establish how many days they had 'rested'. However, many CSW estimated condom usage of between about 40 and 120 times in a month.

5.3 Given the unreliability of the numbers of condoms used and breaking/slipping, it is not possible to calculate a breakage rate. In order to collect quantitative data on condom breakage, a large scale study, with rigorous sampling procedures would be necessary. The reports of condom breakage outlined here are certainly confounded by a range of factors, including overall community perceptions of different condom brands and the level of recent IEC activity in the various brothels visited.

5.4 Another factor complicating the analysis is the impossibility of knowing whether respondents are reporting on the breakage of Gold Circle Aladan condoms or the new Gold Circle. Those recalling past experiences of breakage are more likely to have used Aladan condoms than those reporting on breakage during the last month. However, both Gold Circle Aladan and Seohung condoms were found on sale in Otukpu.

5.5 Reports of the number and brand of condoms that had broken were very varied, mostly by town. Hence, most of the CSW interviewed, who worked in several different brothels in Sagamu, reported that unbranded condoms 'never' break, while expressing great distaste for Gold Circle. Only one respondent reported that an unbranded condom had broken during the last month, while reports of Gold Circle breaking were more frequent, although they reported using the brand less. The situation, as reported by CSW, was similar in Otukpu.

5.6 By contrast in Ibadan, Kaduna and Lagos, breakage reports concerning both unbranded and Gold Circle were less frequent.

5.7 The consultants had been directed to visit areas where reports of frequent Gold Circle condom breakage emanated. Accordingly Sagamu and Otukpu, where DFID supports Pathfinder projects, were visited. Hence, the consultants did not set out to interview a representative sample of condom users. It should be noted that the views expressed by the CSW, LDD and others interviewed differ from those of the SFH commissioned condom user survey. According to the SFH survey 27% of respondents agreed that Gold Circle break regularly, while 36% of respondents agreed that Cool break regularly; 39% agreed that Durex break regularly and 30% agreed that other brands regularly break. Hence, Gold Circle was perceived as breaking less often than other brands. Yet, only 65% of condom users said that they preferred Gold Circle because of its 'good quality', compared with 78% who preferred Cool because of its god quality, and 86% who preferred unbranded condoms. The SFH survey and the results of this study are inconclusive in terms of determining whether most consumers believe that Gold Circle is as reliable, or more or less reliable than other condom brands to which they have access. Nevertheless, it is striking that, when asked to give suggestions for improvements to the product, most respondents said that Gold Circle condoms should be made stronger.

6. Condom Negotiation/Usage Issues

6.1 Both the in-depth interviews and the group interviews probed for information concerning the ways that condoms are used and the circumstances under which they were most reported to break. By repeating the same questions and following up emerging issues around breakage, a clearer picture of usage issues contributing to condom breakage emerged.

6.2 Alcohol Use by Clients

Many clients of CSW are reported to be drunk. This means that sex is prolonged, causing the woman to become dry. Lengthy and forceful penetration is a commonly reported cause of condom breakage.

6.3 Alcohol Use by Sex Workers

Some CSW clearly drink alcohol before and during work. However, they are less likely to be drunk than their clients as they must remain alert. One sex worker in Kaduna explained that she could not afford to drink while working because it would make her aggressive towards her clients, who would in turn be provoked towards violence. If she became drunk during working hours she would go any lie down on her bed.

6.4 Negotiation/Iinitiation of Condom Use

Some CSW reported that they only used condoms if the client requested it. Conversely, some establishments operated a non condom- no sex policy.

6.5 Double Condom Use

6.5.1 The use of double condoms was widespread and appeared to be associated particularly with Gold Circle. In some commercial sex transactions the client reportedly insisted on using more than one condom, while in other cases the CSW may have imposed double condom use as a condition for agreeing to sex with the customer. Large penis size or prior knowledge that a client will be rough are reported to be the main reasons for insisting on double condom use. Triple condom use was also reported.

6.5.2 Those discussing non-commercial condom use, for example women university students, also reported the common use of more than one condom.

6.6 Examination for Disease

In many cases the negotiation of condom use is linked to the examination by the CSW of the client's genitals. The man is touched and examined by the woman for sores and his penis squeezed to see if there is a discharge of blood or white fluid. If the man is deemed healthy, many CSW agree to sex without a condom. Men who appear to have a STD are usually refused sex. One CSW explained that she would not refund the money if a man had a disease, because he should be penalised for seeking to infect her.

6.7 Penis size

The examination of the man for disease allows CSW to assess the size of his penis, which usually becomes erect through handling of the genitals. Large penis size, both in terms of length and diameter, was reported to be problematic by many CSW, and a major cause of condom breakage. One woman said that she would refuse a man altogether if his penis were too big. Other CSW reported that they insisted on double condom use or applied extra lubricant.

6.8 Penis Size Measurement

In general CSW suggested big penises, lack of lubrication and rough sex as possible reasons for condom breakage. A preliminary self-measurement study of penis size was done in the SFH office, and it indicates that the mean length and circumference is approximately 3 mm greater than for Australian men. However, the sample size was very small, not representative of ethnic groupings and not done with the same control as the Australian study. A full study of this type would yield more information. Enersol is able to design and manage such studies.

6.9 Povision of Condom

In the majority of transactions it appears that the condom used is the one she provides. Some CSW said that they preferred to use their own condoms so that they could ensure use of their favourite brand. However, sometimes the man brings a condom himself and insists on its use. In most cases the condom brought is Gold Circle, the most easily available condom in Nigeria.

6.10 Putting on the Condom

Once condom use has been negotiated, it is usually the CSW who opens the package and puts in on the man. When CSW were asked to demonstrate putting a condom on a model, many opened the packet with their teeth. Most women carefully squeezed the tip of the condom to expel air when applying it to the model. Some women had trouble in 'fixing' the condom on, particularly when the model was large.

6.11 Male Sabotage

6.11.1 One reason that CSW may prefer to put the condoms on their clients is that there were frequent reports of men breaking condoms on purpose. Some men who are coerced into condom use retaliate by tearing the condom with their finger nails as they take it out of the packet or put it on.

6.11.2 Some men said that other men are known to 'sabotage' condom usage in this way. The reasoning behind such action appears to be that the man may be using a condom, but the woman is not protected, so has not got her way. One man, a reluctant and irregular condom user, acknowledged that his only breakage was caused when, forced to use a condom, he became angry and was particularly rough with his partner.

6.12 Rough Sex

Most sex workers reported that one of the main problems leading to condom breakage was rough sex. This entailed a lack of any foreplay, sudden and rough entry and forceful thrusting by men.

6.13 Lubrication

6.13.1 Rough sex contributes to the need for extra lubricants to be used. The vast majority CSW reported using oil based lubricants such as Vaseline, Apple Hair Food and baby oil. A few women who had been exposed to SFH, Pathfinder or SWAAN said that they now used only water as a lubricant.

6.13.2 There was considerable variation in the products used for lubrication and the method of application. It was clear that women in the same brothel shared tips on lubrication and initiated new sex workers into its use. Many women reported applying a small amount of oil or Vaseline to the 'mouth' of their vagina in order to facilitate easy entry. Some CSW smeared lubricant around their 'private parts' or inserted it into their vagina. Others said that they put Vaseline/oil on the tip of the condom after it had been put on the man.

6.13.3 There were varied reports as to whether clients consented to or even knew about the use of lubricants. Some women reported using it secretly, while others said they used it only if the clients agreed.

6.13.4 Some CSW said that if the client was taking too long and she was becoming dry, she would ask him to stop so that she could apply lubricant, or extra lubricant, to her vagina.

6.14 Problems Getting an Erection

One older, experienced CSW said that condoms often broke during use with men experienced difficulty in getting or maintaining an erection. Manual stimulation to assist in erection was reported to be unacceptable to clients.

6.15 Tight Vagina/FGM

Some women considered that they had particularly tight vaginas and that their anatomy might contribute to condom breakage. A few women said that a tight vagina might be associated with female genital mutilation (FGM). However, few women could describe the extent to which they had been circumcised. One woman suggested that a clitoretomy had made her vagina bigger. Several other CSW thought that FGM might have made her vagina tight.

6.16 Dry Sex

All but one of the 93 CSW interviewed, were southerners working in brothel/bars. None reported the use of any substance to dry the vagina. However, one woman working from a discreet Hausa-run lodging, a Fulani, said that she drank herbal remedies mixed with milk to tighten her vagina and fumigated her genital area with incense for the same reason. Unlike many of the brothel/bar based CSW who made use of lubricants, she reported that she did not find sex painful. However, it appeared that she did not see as many clients as the bar/brothel workers.

6.17 Length of Time of Sex

The vast majority of clients of CSW were reported to take three to five minutes to reach ejaculation. However, a minority, mostly those who had been drinking, were said to take much longer. Those men who took a long time and thrust hard were considered most likely to break condoms.

6.18 Slippage

Some women reported condoms slipping off, during sex or when the man withdrew after ejaculation. Such slippage was associated with small penis size. Men, on the other hand, reported that condoms sometimes slipped off because they were used for more than one ‘round’ of sex.

6.19 Stage At Which Condom Broke

Condoms were reported to break as they were being put on, upon entry, during intercourse and at the point of ejaculation. Some women said that could feel when a condom broke, while others said that the breakage was discovered only when the man withdrew.

6.20 Fragments Remaining in the Vagina

6.20.1 Women, both CSW and other condom users, had experienced the problem of a part of a condom breaking off and remaining inside her vagina. The fragment of the condom would only be discovered during careful washing of the genital area. One sex worker reported that such an incident had affected a colleague, resulting in a visit to hospital, surgical removal, and payment of high fees.

6.20.2 Men also reported that women sometimes refused condom use because they were afraid of fragments breaking off in the vagina.

6.21 Where On The Condom the Breakage Occurred

The most common site of the breakage was reported to be at the tip. However, splits along the length of the condom, including large tears, were also mentioned by respondents.

6.22 Reaction To Breakages

There was wide variation reported in ways of dealing with a breakage.

If the condom broke early in the sexual transaction:

take off the broken condom, put another and resume sex;

remove the broken condom and continue, encouraging the man to withdraw before ejaculation;

remove the broken condom and continue;

put a second condom on top of the broken one and resume sex;

take off the broken condom and replace it with two new ones.

If the breakage was discovered after ejaculation:

carefully wash the genital area;

wash genital area and seek drugs to treat STD.

7. Cultural Factors

7.1 Brothel based sexual activity appears to follow a pattern. Many men are drunk and may become violent, there is no foreplay, intercourse is often forceful and 'rough'. Many men were reported to reach ejaculation quickly, an outcome considered desirable. Sex was often spoken of as a 'release' and a visit to a sex worker may fulfil the same function as masturbation does for many 'western' men.

7.2 Although, some women reported that customers were rough and hurt them, there seemed to be little evidence of extreme violence. CSW often spoke of ejecting potential customers because they had a visible STD or because their penis was too big. However, violence within sex work was not probed in any depth and may be hidden.

7.3 One striking cultural issue is that of sexual position or 'styles'. The 'missionary' position is termed 'normal', while all other positions are considered against the cultural norm. Talking about 'styles' provokes embarrassment and denial amongst most CSW and men. There is also an assumption that practising 'styles' contributes to condom breakage, which was linked to the assumption that condoms were designed for use in the 'normal' position. Nevertheless, CSW reported that many men ask for 'styles', and some acknowledge that they offer this service. Many CSW and men interviewed said that other people performed 'styles' but would not admit it. One CSW in Ibadan said that she agreed to 'styles' and that these were requested mostly by university students, rather than older men.

7.4 The 'style' most frequently mentioned was intercourse whereby the woman lies on her stomach and the man enters her vagina from behind. However, some expressed concern that such a position would damage the womb.

7.5 When CSW were asked if customers asked for anal sex, all agreed that it was sometimes requested. Most sex workers said they refused anal intercourse, but several CSW said that they agreed to it, but that they might charge extra.

7.6 No CSW reported agreeing to performing oral sex on clients, although it is occasionally requested. One CSW said that she engaged in fellatio only with her boyfriend. But, in general, CSW appeared to find the idea of performing oral sex repugnant.

7.7 Although most commercial intercourse appears to consist of penetration, one CSW reported that some men wanted only to touch her breasts and body. She agrees to this but charges more, apparently because this is more intimate, and therefore more distasteful, than penetrative sex. Her last condom breakage had occurred as the client ejaculated between her thighs, after fondling her.

7.8 Some of the CSW reported working through out the month, even when they were menstruating. Others said that they stopped work during menstruation.

7.9 As well as probing about the possible effects of FGM on condom breakage, CSW were asked if they shaved their pubic hair. The majority who reported that they did, were asked if this might have a bearing on condom breakage. Only one sex worker said that her public hair, which was reportedly wiry, might be causing condoms to break.

7.10 All the findings were about heterosexual sex. Given the scope of the research, the TOR and the hidden nature of homosexuality and /or the existence of men-who-have-sex with-men (MSM) in Nigeria this is unsurprising. Yet, MSM was reported anecdotally to be occurring particularly amongst Northerners. Indeed, one of the researchers was propositioned for sex by a young Hausa man in Kaduna, and an extremely effeminate man was observed in the adjacent brothel. Many respondents and key informants who discussed MSM associated it with the Hausa. Although the subject is highly sensitive, given the high risk of all anal sex, be it between men or with women, information about condom use as a protective measure should be disseminated.

7.11 Apart from information from one Hausa run establishment in Kaduna, all the findings presented in this report refer to commercial sex activity in bar/brothels staffed by southern CSW and run by southerners. Hence, the cultural and sexual issues explored during the research apply only to parts of the country. It is probable that other sexual patterns exist amongst different cultural groups within Nigeria. For example, dry sex, using herbal preparations or other substances, is reported anecdotally to be a northern custom. Only one CSW interviewed, a Fulani, said she practised dry sex.

7.12 The majority of CSW, by contrast, said they regularly used lubricant. The extent of FGM, and particularly the practice of infibulation, is likely to vary by region and ethnic group. It is possible that women who have very tight vaginas due to circumcision or infibulation may have difficulties in using condoms. Although this did not appear to be an issue amongst the sex workers interviewed, it may be a cause for concern amongst Hausa or other Northerners.

Conclusions

Technical

1. Based on NASCP results, some USAID products tested prior to packing did not compare well with the requirements in the current international standards for condoms. Many lots had low burst volumes, and the standard deviations of burst properties were high in some lots. There are grounds to believe that some testers at the NASCP lab may be getting median burst volumes which are about 6 to 10% below those obtained elsewhere. Nonetheless, there is a very consistent difference in test results between the Aladan condoms and those purchased recently from Seohung.

2. Low burst volumes and high standard deviations mean that there will be relatively many condoms which cannot stretch very far, and these seem likely to break in use. This appears to be the case in Nigeria, and similar results were shown in the FHI study of 1991. While no causal connection has been proven between clinical breakage and the inflation properties, there is a very strong circumstantial link that has been established over many years, and the inflation test is now one of the most important tests in international standards.

3. The time taken for condoms to get from the factory to the point where they are to be packed by SFH has been between 9 months and 35 months. More recently, the times have been at the lower end of the range.

4. Storage conditions at the Lagos warehouse are adequate, but could be improved, as outlined in the text.

5. The criterion used to accept the condoms (the CQI) was based on condoms from a particular donor, and related considerations.

6. As a result, some lots of condoms which probably did not comply with international standard 4074 were packed and released by SFH.

In a developed country with strong medical device regulations, such a practice would not be acceptable.

8. Since the CQI was initiated, condom standards have been tightened and it is now generally becoming accepted that they should comply with acceptance standards for their entire shelf life

9. The bad experiences of Gold Circle condom users in Sagamu appear to correlate with the release of condoms with low CQI.

10. It is probable that condoms from these lots, and indeed weaker condoms from other lots, resulted in many of the breakage incidents.

11. As even the best condom manufacturers cannot achieve 100% perfect product, and there are big differences amongst users and user practices, no brand of condom is entirely free of breakage. The reports obtained in this mission indicate that Gold Circle condoms break considerably more often than good quality brands in developed countries.

12. It is impossible to quantify the difference between different brands of condoms from the data available, and the reports from users are confounded by many factors. Accordingly, to get more conclusive information, a double-blind cross-over study would need to be conducted. Participants with high breakage rates could then be asked to give further information, in an attempt to identify causes of breakage. It would be in the interests of all suppliers and users of condoms for such a study to be done. As the last supplies of the Aladan condom are already well into the distribution pipeline, it will very soon be difficult to find Nigerian users of that product. It may therefore be necessary to conduct such a study in a country where Aladan condoms are still in common use. Enersol is able to design and manage such a study.

13. Other significant causes of breakage identified by sex-workers include large penises, lack of suitable additional lubrication and "rough sex". A preliminary study of penis size in Lagos suggests further work is needed, including a more rigorous determination of the distribution of penis sizes, as well as a user trial of larger condoms. Enersol is able to design and manage such studies.

14. The laboratory equipment is still operational, but needs replacement or at least re-furbishing.

15. The testing being conducted gives a reasonably consistent indication of the physical properties, but burst volumes appear 6% to 10% below international consensus values.

Community Perceptions

SFH is in the unusual position of trying to operate as a quasi-commercial venture and also promote contraception and sexual health. Its condom sales of 55 million a year put it among the larger condom packers and distributors, world-wide. The name Gold Circle is almost synonymous with condoms in Nigeria, since Gold Circle tends to be the only product available to most of the population. SFH is also very prominent in the education campaign on HIV. Therefore, the image and efficacy of Gold Circle condoms has wide ramifications.

Condom breakage reports were frequent in all areas visited and amongst all groups of people interviewed. However, reported levels of satisfaction with Gold Circle varied depending on the area. For example in Ibadan and Lagos Gold Circle was perceived as being as reliable as any other condom.

Pathfinder International and SWAAN have no confidence in Gold Circle, but report that Cool condoms are better. Despite the fact that they are the same product in different packaging. Accordingly, they advocate the use of unbranded condoms which they sell in brothels and through peer educators. Condom users are instructed not to buy Gold Circle.

In Sagamu and Otukpo, where Pathfinder are working, the influence of the organisation has led to an exaggerated regard for unbranded condoms and an intense dislike of Gold Circle.

In Kaduna, where a wide range of condom brands is available, there were varied reports on the reliability of Gold Circle compared to other brands. Pharmacy staff reported that customers preferred Gold Circle to unbranded condoms.

There is a tendency for men to prefer Gold Circle, as opposed to unbranded condoms, as the product reportedly allows more sensitivity during sex. Conversely, many CSW say they prefer unbranded because they break less easily.

User Reports

The main causes of breakage identified by sex-workers are large penises, lack of suitable additional lubrication and “rough sex”.

Much commercial sex takes place in brothels that also operate as bars. Many of the clients are drunk during sex. Some CSW link alcohol consumption to condom breakage. They report that drunkenness in clients delays ejaculation, causing dryness in the vagina as the lubricant on the condom dissipates.

Many clients of sex workers are reluctant to use condoms. Many CSW reported that men sometimes purposely tear condoms with their finger nails so as to maliciously thwart the woman’s attempt to have safer sex. Some men interviewed collaborated this.

Some condom breakage is associated with re-use of condoms, with men using one condom for more than one ‘round’ of sex with either the same partner or with another woman.

Reports from women of condoms slipping off were not widespread.

Reported use of double, or even triple, condom use were common, with Gold Circle most frequently mentioned as the brand that might easily break. However, some CSW also reported doubling up unbranded condoms.

Anal sex is occurring in some brothels. This is a highly sensitive subject as anal sex is 'taboo'. The women who acknowledged that they allowed anal sex said that they used condoms. However, as many CSW do not use condoms with up to half of their clients, it is possible that unprotected anal sex may be fairly widespread. Anal sex between men is also reported to occur.

Major Recommendations

1. Sex-workers generally use Vaseline or some other oil-based lubricant, and such lubricants cause clinically demonstrated increases in breakage rate and decreases in condom physical properties. Therefore, an aqueous lubricant should be made available to sex-workers through SFH.

2. The current release criterion is not as stringent as equivalent requirements applied in developed countries, or those applied to condom purchases by other international agencies. Therefore, the criterion for acceptance for packing should be upgraded to ISO 4074 or the WHO Specification.

3. There have been many complaints about breakage of Aladan condoms, and some of these seemed to be correlated with the release of product with poor CQI. A new image is needed. The results of tests conducted by the NASCP show that condoms from Seohung have physical properties superior to and more consistent than the Aladan condoms. The Aladan product's variability from lot to lot indicates that the production process is not well controlled. SFH has or has ordered supplies of Seohung condoms that will last for more than two years from the time of this study. Distribution of these has recently begun. Therefore, for the time being, SFH should continue to use only the Seohung condoms until the present stocks and those on order are running out. A double blind cross-over study should be conducted soon in another country where Aladan condoms are still readily available, to compare the breakage rates and acceptability of the two products. Additional in-depth studies should be conducted with people from the double-blind study who break a lot of condoms. With the results of this study, a rational decision about future product sourcing can be made. Examination of all Aladan's and FHI's test results over an extended period may also assist.

4. The Aladan factory is owned by SSL (previously LIG), a company that operates condom factories in several countries. The products from SSL's other factories has completely different physical characteristics from the Aladan condoms, and has a very high reputation. Therefore, a technical expert and a senior DFID official should visit the headquarters of SSL to discuss the problems encountered in Nigeria.

5. The testing laboratory has been functioning for some years without the benefit of staff re-training or external calibration or maintenance of the testing equipment. The inflation equipment is difficult and noisy to use, and requires considerable manual calculations and transfer of data. There are indications that some of the operators may be mounting the condoms on the inflation tester in a way that decreases the burst volume results. Therefore, the inflation equipment should be replaced, or, if that is not possible, refurbished. At the time of replacement (or refurbishment) the existing staff, plus about three SFH staff should be trained in its use. The trained staff should do at least one test per fortnight to maintain their skills.

6. The supply chain has in the past been responsible for relatively old condoms reaching the consumer. Recent changes have reduced the likelihood of this happening in the future, but condoms may decay if stored for long periods in hot conditions. They are a life-saving medical device. Therefore the distribution system and its management should be upgraded to minimise transit times and dwell times between the factory and the consumer, consideration should be given to improving storage conditions at the Lagos warehouse, and measures should be implemented to improve the lot traceability through the distribution system.

7. The major causes for condom breakage suggested by sex workers were large penises, lack of lubrication and rough sex. Therefore, a full study should be done on the applicability of a larger condom in Nigeria.

Detailed Recommendations (NOT in order of priority)

Acceptance, Release and Distribution

1. The criterion for release of condoms for distribution should be upgraded to the ISO standard or the WHO specification as soon as practicable. As an interim measure, the minimum acceptable CQI could be raised to 65 or 70.

2. Times in the pipeline from factory to distribution from the Lagos warehouse should as far as possible, be less than 18 months.

3. The society should manage its ordering of condoms to ensure that stocks are kept in the Lagos warehouse and elsewhere in the pipeline for as short a time as possible. While difficulties at the port may make it impossible to reduce this time to the optimum, the demand pattern has now recovered from a number of "shocks" and it should be possible to plan ahead more effectively.

4. If it is desired to improve storage conditions at the Lagos warehouse, the goods should be protected from roof leaks, and the airflow through the warehouse could be managed using the fans and doors already installed, to reduce the temperature. Roof insulation would further cool the warehouse, but this option is expensive.

5. In order to improve lot traceability, the consumer package should be altered when practicable to provide a white blank panel on one edge, and this should be used to stamp the expiry date and lot number.

6. Procedures to ensure that each carton contains condoms from one and only one lot should be strengthened.

7. A sample of one gross of condoms from each lot tested should be retained at the SFH for future comparison with field data.

8. The use of rational lots for testing should be avoided as far as possible.

9. If the CQI continues to be used, it should be for tracing the product through its life in the storage and distribution system.

The condom design

10. SFH should continue to use exclusively the Seohung condoms it has or has ordered until these are running out. A user trial as outlined below should be conducted to determine options for future orders.

11. Discussions should be held with SSL (LIG) in the UK regarding the quality and characteristics of the Aladan product, and the possibility of making them identical with other SSL condoms. This discussion should involve a technical expert and a senior DFID official. Experts could also be sent to inspect the Aladan factory and quality system, and the overall performance of the factory should be assessed on the basis of aggregated test results over all lots produced over the last few months, or longer.

12. A double blind user trial, comparing the Aladan condoms (especially lots with low median burst volume) with those that are purchased according to WHO specifications (eg Seohung or TTK-LIG) should be conducted as soon as possible, in the interests of resolving the situation. Participants who break many condoms in this trial should be asked to cooperate in supplementary studies to identify possible causes of breakage. This trial should be managed by a small team of experts experienced in conducting such trials. Enersol is capable of managing this trial.

13. A study should be done on the benefits of supplying a larger condom for the Nigerian market, possibly under a different name. This study should involve penis measurements and a comparison trial managed by a small team of experts experienced in such trials. Enersol is capable of managing this trial.

Ancillary services

14. Supply of additional lubricant at an affordable price for use by sex workers is essential.

The Laboratory

15. The inflation tester needs to be either replaced or refurbished.

The present laboratory facilities, although slightly updated, are based on designs that are at least 15 years old. The updated inflation tester currently being used could be re-furbished and could continue to function. However, the machine has some inherent limitations:

It is slow

It is noisy

Its accuracy is less than that of more modern machines

As all the calculations must be done by hand, there is considerable scope for human error in the production of the results.

The compressor is operating close to its capacity limit, and that may be the cause of the excessive moisture in the tester. Consideration should be given to the installation of an additional drying device, such as a small centrifugal dryer.

As the equipment appears to be in daily use, there is good reason to replace it if funds are available.

16. Additional means of drying the air, such as a centrifugal dryer, should be installed as part of the air supply for the inflation tester.

17. The package seal tester appears in good condition and can continue to be used.

18. Currently, the equipment to do the other tests is not used. If it were desired to do frequent leaks testing, it would be advisable to replace the equipment with more sophisticated equipment.

19. If width and thickness measurement were desired, then new equipment should be obtained.

20. Training:

It became clear that the staff is very isolated from other condom testing expertise. Staff turnover, and low levels of use in the past have resulted in a decline in expertise in some areas, including maintenance, principles of operation, standards, and use of ancillary equipment. In order to remedy this, the following is recommended:

Technical manuals for all significant equipment must be available in the laboratory

Duplicate copies of these documents should be kept by SFH
A person with experience in condom testing should be sent to the lab to do re-training as soon as practicable. If new inflation equipment is to be provided, then the training should be done immediately after the new equipment is installed.

Any purchase of equipment should be integrated with commissioning and training by the equipment supplier.

The training should include staff from the Society for Family Health, who should be able to use the lab themselves, to check on the state of their own products.

Approximately three people from the NASCP and three people from SFH should be trained, and these people should then use the equipment at least once a fortnight, to keep up their techniques

The training should be repeated approximately 12 months after it is first done.

21. In the interests of orderly record-keeping, the name of the person actually doing the test should appear on the form, rather than the name of the supervisor.

22. The laboratory should participate each year in one of the interlaboratory trials run by PATH or Enersol.

Community/ Cultural Issues

SFH senior staff members should visit Pathfinder to discuss the project's perceptions of Gold Circle and to provide reassurance that the product is actually different and improved.

This research gathered data from CSW of southern origins working in bar/brothels, consideration should be given to carrying out additional research into sexual networks and patterns of commercial sex in Northern Nigeria, particularly amongst the Hausa.

DFID should also consider commissioning a literature review of the nature and incidence of FGM amongst various ethnic groups in Nigeria. This would enable an initial assessment of the likelihood that tight vaginas, due to cutting and sewing the genital area, is contributing to condom breakage.

The feasibility of 'sex craft' education for sex workers should be investigated. The objective of such an approach would be to enable women to gently persuade or seduce men into condom use. Increased 'sex craft' would also give CSW greater control over the transaction, thus allowing them to work in a fashion that is conducive to their overall sexual health and personal well-being.

APPENDICES

Appendix 1

Data by Source

LAGOS
16 interviews with CSW
4 interviews with men

BENIN BORDER
8 Interviews with CSW
3 interviews with men
1 group interview with 6 men in brothel
1 PMS visit

SAGAMU
12 interviews with CSW
3 interviews with men
observation of brothel during evening
1 group interview with adolescents in community centre
1 group interview with 15 men in oil depot lorry park
1 group discussion, trial of GC over-night and follow up in one brothel
4 key informant interviews with Pathfinder staff
3 PMS visits

KADUNA
3 group interviews with police trainees
1 group interview with community health college students
19 interviews with CSW
3 interviews with men
1 group interview with 9 'mobile' sex workers in bar where work is organised
4 PMS/pharmacy visits
1 key informant interview with PPFN provider

ABUJA
2 group interviews with LDD at Zuba lorry park

OTUKPO
4 Key informant interviews with staff of SWAAN, PPFN and Pathfinder
14 interviews with CSW
3 interviews with men
1 interview with female peer educator
1 Group interviews – peer educators for out of school adolescents
1 group with motor cyclists/peer educators
1 group interview with drivers/lorry park officials
2 group interviews with CSW

5 pharmacies/PMS

GBOKO
11 interviews with CSW
1 group interview with over 20 youth in an open- air bar

MARKURDI
1 group interview with lorry drivers/union officials

IBADAN
13 interviews with CSW
2 interviews with men
1 group interview with women university students
1 group interview with LDD
2 visits to pharmacies

Appendix 2

Interviews with CSW/Men

DATE: TOWN: PLACE:

INTERVIEW NO: ETHNIC GROUP: YEARS OF SCHOOL:

How long have you been a CSW?

Occupation: How long:

Since when have you been using condoms?

Which brands of condoms have you ever used?

Which brand(s) have you used in last month?

How many condoms have you used in last month? (Or no/day and days worked/month)

Which brand did you use most?

Do you usually use double condoms?

How many condoms broke in the last month?

How many of each brand broke?

How many condoms slipped off in the last month?

How many of each brand slipped?

What did you do about the break/slip?

DETAILED LAST BREAKAGE STORY AS TOLD BY RESPONDENT

INFORMATION ABOUT OTHER BREAKAGES?

What are your suggestions to improve Gold Circle?

TIPS FOR DETAILED STORIES

man was drunk/stoned

were you drunk/stoned

violent

use of alum/vaseline/other substances beforehand?

Tight vagina?

Negotiation/initiation of condom use

Who opened package?

Who put condom on?

Could you see when the condom was being put on?

Any problems putting on the condom?

lubricant

size/shape of man's penis

position

anal sex

oral sex

FGM

length of time

withdrawal

At what stage did condom break or slip off?

Did it break or did it slip off?

What happened then?

Where on the condom was the break?

What do they think the reason for breakage was?

GROUP INTERVIEWS

1. Occupations
2. Ages
3. What kinds of people should use condoms?
4. What is good about condom use?
5. What is bad about condom use?
6. Are some brands of condom are better than others?
7. What do people around here say about the different types of condom?
8. Do you think this is true?
9. What do they say about Gold Circle?
10. What are your suggestions to improve Gold Circle?

Appendix 3

Terms of Reference