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SPERMICIDE ACCEPTABILITY AMONG CLIENTS OF AN STD CLINIC: ZAMBIA

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I. INTRODUCTION

Barrier contraceptives are the focus of increasing interest among health care providers and policy makers worldwide. In large part, this is due to the potential of barrier methods to provide both contraception and protection against sexually transmitted diseases (STD). Among the various barrier methods, spermicides have been identified as having several notable advantages. These advantages include: female control, availability over the counter, few side effects, and ease of use. Given the advantages of spermicides and the need for alternatives among contraceptives which also provide STD prevention, staff of the Zambian National STD Control Programme were interested in studying the feasibility of providing spermicidal contraceptives to clients of their STD clinics.

II. STUDY OBJECTIVES

To assist the Zambian National STD Programme in their consideration of distributing spermicides, the primary objective of this study was to assess whether spermicidal products would be generally acceptable among men and women at above average risk of contracting STD. Further, the study was designed to determine which of three spermicidal products tested would be most acceptable and why. A secondary study objective was to learn whether spermicides could be distributed to, and used by, male clinic attenders. This study did not assess the prophylactic efficacy of the three study products.

III. STUDY SUBJECTS

Female and male participants were recruited from the STD clinic in the Dermato-venereology Department at the University Teaching Hospital (UTH) in Lusaka, the capital of Zambia. Eligibility criteria for this study included the following:

age 16-50;
currently sexually active;
not currently using a spermicide;
not pregnant within the last 42 days (by self report);
willing to use two spermicidal products for two weeks each;
willing to take part in an admission, two follow-up, and one post-study interview;
willing to provide candid opinions about study products; and
willing to sign a Consent Form.

IV. STUDY PRODUCTS

Vaginal spermicides come in several forms, including foams, creams, gels, suppositories, tablets and film. Spermicides are typically made of two basic components: a spermicidal chemical which immobilizes the sperm and a base to stabilize the chemical component during storage and serve as a delivery mechanism during use. The most widely used spermicidal ingredient is nonoxynol-9 (N-9).

The acceptability of three different types of spermicides was compared in this study. The three products, all containing N-9, are manufactured by Ortho Pharmaceutical Corporation. The first product, Delfen^R foam, comes in an aerosol container with an applicator, and contains N-9 (100mg per application, 12.5%) in a base including benzoic acid and cetyl alcohol. This product is similar to contraceptive foam available in pharmacies in Lusaka. Also included in the study were Intercept^R melting suppositories, containing N-9 (100mg, 5.56%) in white pellets made up of ingredients including citric acid and polyethylene glycol. This spermicidal suppository was commercially available in the U.S. at the time of the study. The third spermicide tested, Conceptrol^R vaginal foaming tablets (N-9, 100mg), comes in the form of a fairly hard sodium bicarbonate tablet. Foaming

tablets are subsidized and distributed by the U.S. Agency for International Development (USAID) in several developing countries.

V. STUDY DESIGN

The study was conducted in an STD clinic which is the referral clinic for the capital city of Lusaka. The study was designed to include 150 women and 150 men. Prior to admission, the purpose of the study and any associated benefits and risks were explained to potential participants. In order to be enrolled into the study, participants were required to sign a written consent form.

Once admitted, each participant was administered an interview to gather information on sociodemographic characteristics, as well as knowledge and use experience of specific contraceptive methods. At admission, each participant was also given a medical examination to determine if they had any STD and/or genital infection.

Each participant tested two of the three spermicidal products (described earlier) in a specific order. Participants received a two-week supply of their first spermicide and were instructed in its use. They were requested to have at least four episodes of intercourse and use the product during each act. After using the first product, participants returned to the clinic and the same procedure was followed for use of the second product.

The two products the participants received and the order in which they were used was determined according to a random allocation list generated by FHI. The participants were divided into six study groups, depending on which of the two products they used and in which order they used these two products. This design controlled for both time and product effects.

After using the first product for two weeks, participants returned to the clinic and were administered a follow-up questionnaire to assess acceptability of this product. The same procedure was followed with the second spermicidal product. Participants were also asked about any preference for one of the two products they used, as well as potential for future use. Active enrollment of participants lasted for approximately three months.

Upon completion of the second follow-up interview, participants were told which of the five pharmacies in Lusaka sold the same or similar products they used in the study. Approximately three months after active participation in the study, each participant was interviewed to determine if s/he had continued to use a spermicide, and if so, why.

VI. DATA ANALYSIS

The data set was analyzed by FHI staff. SAS versions 6.06 and 6.07 were used to enter the data and to produce the frequencies and cross tabulations presented in this report. Pearson chi-squared exact tests were employed to evaluate if there were statistically significant differences in demographic characteristics between the study groups. Wilcoxon sign ranked matched pairs comparison tests were calculated to assess mean preferences of one spermicide over another (or specific characteristics of one over another). McNemar's chi-squared tests were used for comparing reported proportions of other outcome variables (i.e. reported proportions of participants who reported irritation associated with spermicide use). Significance was set at a level of alpha equal to 0.05.

VII. RESULTS

A total of 114 women and 150 men signed a consent form and were enrolled into the study. Among this initial group of participants, 28 women and 22 men were lost to follow up. One female was

dropped from the analysis due to inconsistent information on her data forms. In all, 85 women and 128 men completed the study and provided data acceptable for analysis.

A. Sociodemographic Characteristics

The median ages of the women and men were 30 years and 27 years, respectively (Table 1). The level of education reported by the women ranged from primary to university, with 42% having completed primary school. Among the men, education ranged from none to university, and 43% reported they had completed vocational school. At admission, more than two thirds of the women reported that they were married or in a consensual union, while just over half of the men indicated that they were of similar status.

B. Pregnancy History and Level of Sexual Activity

The range of reported lifetime pregnancies was from zero to more than nine and the median was three (Table 2). Twelve percent of the female participants reported that they had never been pregnant in their lifetime, while just more than half said they had been pregnant between one and four times. The median reported coital frequency during the month prior to the study was nine among women and ten among men (range: 4-18 and 3-28, respectively).

C. Contraceptive Use

Almost three fourths of the women and more than half of the men reported that they were not using any form of birth control at the time of the admission interview (Table 3). Among all women, the most prevalent method was oral contraceptives (used by 13% of the women). Among the men, 37% reported use of condoms. When asked about past use of contraceptives, one third of the women and one fourth of the men reported they had never used any method of birth control.

D. STD and Genital Infection Status

At admission, all participants received a physical examination to determine their STD/genital infection status (Table 4). Eighty percent of the women and 98% of the men were diagnosed with one or more STD/genital infections. This cohort of participants clearly fits the desired study criteria of being at increased risk of STD. Among all female participants, the most prevalent STD/infections were trichomoniasis (40%), candidiasis (29%) and mucopurulent cervicitis/nongonococcal urethritis (19%). The men were most frequently diagnosed for gonorrhea (34%), trichomoniasis (17%) and genital herpes (16%).

E. Consistency Across Study Groups

Based on the product assignment, as described earlier, female and male participants were subdivided into three different groups. Using admission characteristics such as age, education, religion, marital status, coital frequency, use of contraception and STD/genital infection status, chi square tests were carried out to evaluate if there were statistically significant differences between these three groups. No significant association between any of these background characteristics and the study groups as described above were found.

F. Spermicide Use During Study

Of the 85 female and 128 male participants who contributed data for analysis, 56 women and 86 men tested the Delfen^R foam, 53 women and 84 men used the Intercept^R suppositories, and 61 women and 86 men tested the Conceptrol^R tablets (Tables 5a and 5b).

The proportion of women that did not use the study products throughout each of the two week study phases was fairly high (from 41% to 47%). Approximately half of these women, regardless of

spermicide type, reportedly stopped use for personal reasons unrelated to acceptability (e.g. "partner went away" or illness unrelated to spermicide use). Among women who discontinued use of foam, the second most frequent reported reason was "messiness". The second most frequent explanation for discontinued use of suppositories and tablets was "out of supplies". Proportionately fewer men than women, about one fifth of the men in each of the three product groups discontinued use of the spermicide before the end of the study period (Table 5b). These men most often reported that they discontinued because of personal reasons (unrelated to acceptability).

On average, women who used foam reported the highest proportion of coital episodes not using the spermicide (22%). The proportion of coital episodes without spermicide use among women who tested suppositories and tablets was 12% and 5% percent, respectively. In general, male participants reported fewer coital episodes without use of the study products.

At least one fifth of women and men, depending on the particular spermicide, reported use of another method during the study. The participants were not specifically asked what methods they used, or if the additional methods were used simultaneously with the study products. From 8% to 16% of the women, and about twice this proportion of men (17%-30%), reported that they had more than one partner during the study period.

G. Spermicide Preference

Since each participant used only two of the three products, preference results are shown for each of the three product comparison groups (Table 6). The order in which the participants used the products did not appear to affect preference. Among women, there was not a strong preference for one spermicide over the other in any of the three product groups.

Foam and Suppositories: Reported preference was slightly higher for foam among the women who tested foam and suppositories. Preference for suppositories was consistently attributed to less vaginal lubrication than with foam. Among the men, preference was evenly divided. Reported preference for foam was largely based on it being convenient, quick and not too messy, as compared to suppositories.

Foam and Tablets: Among the women who compared foam with tablets, slightly more women liked tablets. Again, preference was largely based on less lubrication, when compared to foam. Reported preference for foam was strong among the men who compared foam with tablets (70% vs. 27%). Most often this preference was based on foam reportedly being convenient, quick and not too messy.

Suppositories and Tablets: In this group, women reported a slight preference for tablets. The reason most often cited for this preference was because of less lubrication, compared to suppositories. The men who tested these two products also marginally preferred tablets over suppositories, most frequently reporting improved sexual satisfaction with tablets.

H. Spermicide Acceptability: Best and Worst Features

When female and male participants were asked what they thought were the "best" features of the spermicides they tested, more than three fourths to almost all of the participants reported specific characteristics they liked (Table 7). Conversely, when participants were asked to report what they thought were the "worst" features, more than one third to almost two thirds indicated that there was no characteristic in particular they did not like.

Improved sexual satisfaction was the most frequently reported best feature (women: range 30%-38%, men: range 44%-65%, depending on product). According to women who tested foam, the worst

feature was that it was messy and/or caused vaginal discharge (43%). Women who used suppositories or tablets most frequently responded that there was nothing in particular that they did not like (42% and 61%, respectively). From 40% to 44% of all of the men reported that there was nothing in particular that they did not like about the spermicides. A large proportion of the men who tested foam (30%) also indicated that there was too much lubrication. Thirty percent of the men who used tablets reported that the worst feature was irritation, pain or itch experienced while using this product.

I. Mean Ratings of Spermicide Characteristics

Table 8a and 8b present participants' mean ratings of several outcomes and characteristics of spermicide use. For each question, participants rated each of the two spermicides they tested on either a three or five point scale. P-values, based on Wilcoxon sign ranked comparison tests for paired data, help indicate whether one product was rated more favorably than another. When reviewing these results, it should be noted that the mean values are derived from every participant who rated the product, while the p-values are based on matched pairs (i.e. include only participants who used and rated both spermicides they were given). For ease of presentation, only p-values of $p \leq 0.05$ are shown in the tables. The reader is cautioned that multiple testing increases the likelihood of finding differences that may appear to be significant, but are actually due to chance.

When asked how they liked the spermicide in general, the female mean ratings for all three spermicides were neutral or better (Table 8a). Tablets received the most favorable rating with respect to "sexual satisfaction" (Suppositories vs. Tablets: $p=0.042$). All three spermicides received favorable ratings in terms of packaging and ease of insertion. The women who tested foam and tablets indicated there was more lubrication with use of foam ($p=0.016$).

Fewer women reported irritation with tablets (11%) than with foam (16%) or suppositories (23%). Among those who experienced irritation, most reported that it was minor and brief. In terms of spermicide leaking from the vagina, reportedly this occurred more often with foam than with tablets ($p=0.007$).

Most women reported that their partners were aware that they were using a spermicide (86% - 94%). Among these women, the mean ratings for partner's general reaction and sexual satisfaction were consistently better than neutral. Partner irritation was fairly infrequent and typically mild when reported.

With respect to how the men liked the spermicide, sexual satisfaction and sensitivity, mean ratings were better than neutral for all three products (Table 8b). Similarly, all three spermicides received favorable ratings in terms of packaging, ease of insertion and odor. Among men who used foam and suppositories, the mean ratings indicated more lubrication with the foam ($p=0.009$).

Slightly more frequently than the women, about one fifth to one fourth of the men reported irritation associated with use of the spermicides. As in the case of the women, severity and length of irritation were minor and brief. Among the men, the mean ratings of their partners' general reaction and sexual satisfaction were better than neutral for all three products. Partner irritation associated with use of one of the three spermicides was reported by 20% to 26% of the men, but the reported severity of irritation was usually mild.

J. Post Study Spermicide Use

A large proportion of participants reported continued use of a spermicide three months after the second follow-up interview (Table 9). Among the 85 women and 128 men who were interviewed, almost four fifths of both the women and men reported that they were currently using a spermicide.

These results should be interpreted with caution. Among the various spermicidal products, the only products which would have been available to the study participants (and only through pharmacies) included a type of foam similar to the Delfen, and to a lesser extent, Conceptrol foaming tablets, assuming that supplies of this product were diverted from the public sector and sold in some pharmacies. Furthermore, it is doubtful that participants would have had leftover supplies from the study three months after its completion.

Among those who reportedly knew the brand name of the spermicide they were using, most often women said they were using tablets. Most often men said they were using tablets, followed closely by foam and suppositories. A large proportion of women indicated that they did not remember the product name, but chose suppositories. The questionnaire did not distinguish between suppositories and tablets in this section, so this result should be interpreted with caution.

Approximately three fourths or more of the women and men reported use of spermicide during every act of coitus, and/or use of spermicide without another method, and/or purchasing the products they reportedly used.

Among the women, the reasons given for continued use of a spermicide were most frequently based on generally liking the spermicide, STD prevention, and pregnancy prevention. Men most often cited

STD prevention and pregnancy prevention as reasons for continued use. Personal reasons (unrelated to acceptability) were most frequently given by women and men for discontinuation.

VIII. DISCUSSION

Increasing emphasis is being placed on the need to offer methods that provide both protection against unplanned pregnancy and sexually transmitted diseases (STD), including human immunodeficiency virus (HIV). Particularly since the emergence of HIV, strategies to reduce the spread of STD have relied heavily on the provision of condoms. Research suggests, however, that effective use of condoms is often problematic due to lack of female control, and inconsistent or incorrect use. As condoms have become widely available and these problems have become more apparent, many in the public health community have suggested that female barrier methods should also be available, particularly for women whose male partners refuse to use condoms.

The public health community is becoming increasingly interested in the use of virucides, specifically spermicides, as a potentially effective complement or alternative to condoms for protection against STD. Vaginal spermicides on the market today include foams, creams, gels, suppositories, and films. Epidemiological studies have demonstrated that spermicides with nonoxynol-9 can reduce the incidence of STD (e.g. PID, gonococcal and chlamydial infections) in high-risk populations and are approximately as effective as condoms against bacterial STD.¹⁻³ Although the results are not conclusive, there is hope that N-9 may also reduce the transmission of HIV.⁴

Arguably, one of the most controversial issues concerning the relative value, and therefore the appropriate role, of vaginal spermicides, is the wide range of reported contraceptive efficacy rates for the various types of spermicides. According to Contraceptive Technology 1990-1992, "our best guess

is that the initial-year failure rate among perfect users of spermicides would be about 3%. The first-year failure rate among typical users is about 21%. The most common patient error leading to an accidental pregnancy is failure to use the spermicide."⁵

Similar to other barrier contraceptives, assuming that user failure is often due to inconsistent use, the acceptability of the different vaginal spermicides may be the best predictor of the actual failure rate (method failure plus user failure). Given this relationship, research is being conducted to assess which methods are the most acceptable, and therefore may be used most consistently.

To a significant extent, motivation for conducting the present study was based on the concerns outlined above. Condom distribution in Zambian STD clinics began in 1989⁶, and the National STD Control Programme has considered dispensing spermicide products as well. Programme managers wished to learn whether spermicide products would be broadly acceptable to those at high risk of STD, and if so, which product would be preferred and why.

Caution should be used when interpreting the results of this study. An appreciable proportion of participants were lost to follow-up and a larger proportion discontinued product use during at least one of the two-week study periods (Table 5a and 5b). The significance of this is not completely clear, given that most frequently discontinuation was attributed to personal reasons unrelated to acceptability (e.g. "partner went away" or illness unrelated to spermicide use). As discussed earlier, although a high proportion of participants reported continued spermicide use three months after the study (Table 9), these results are questionable given the lack of availability of the specific products the participants reported they were using.

Participants were encouraged to give objective feedback concerning the acceptability of the study products. Nevertheless, due to the participants' relationships with the interviewers, some may have felt obliged to give inaccurate, favorable responses rather than be critical of the study products. In part, this could explain some of the results summarized above as well as inconsistencies among other results.

Despite these possible limitations, similar to other recent short-term FHI acceptability studies⁷⁻¹⁰, this study suggests that spermicides may be acceptable among certain groups. To summarize some of the more encouraging findings, more participants identified positive rather than negative features of the spermicides (Table 7). Mean ratings of various product characteristics were also favorable along a wide range of acceptability parameters (Table 8a and 8b). Concerning acceptability among men in particular, the data suggests that men generally found the spermicides to be at least as acceptable as the women did.

This apparent success of distributing spermicides to male clinic attenders is particularly noteworthy. These men already have, or at least suspect they have, an STD. Consequently, they are more likely to be aware of, and interested in, strategies to prevent future infections. In light of their influence and often control over sexual decision-making, they may well be successful at encouraging their partners to use a spermicidal product. This may be an effective way in which to interrupt the transmission of STD, particularly in high-risk subgroups, and may be a promising direction for future research.

The findings of this report should be of use to the Zambian National STD Control Programme when considering inclusion of spermicides in the contraceptive method mix offered to their clients.

Nevertheless, studies to date, focusing either on the efficacy or acceptability of various spermicides,

have produced a wide range of results, making it difficult to formulate clear policy recommendations. Given the increasing importance of providing alternatives to condoms, particularly for STD prevention, methodologically-sound studies should continue to focus on acceptability of various spermicides to determine which types will be used with greatest consistency. Findings from this research will help identify spermicides most likely to have the lowest failure rates, and therefore help optimize the role of spermicides in local and international STD prevention and family planning strategies.

IX. References

1. Kelaghan J, Rubin GL, Ory HW, Layde PM. Barrier-method contraceptives and pelvic inflammatory disease. *JAMA* 1982; 248:184-7.
2. Austin H, Louv WC, Alexander WJ. A case-control study of spermicides and gonorrhea. *JAMA* 1984; 251:2822-4.
3. Niruthisard S, Roddy RE, Chutivongse S. Use of nonoxynol-9 and reduction in rate of gonococcal and chlamydial infections. *Lancet* 1992; 339:1371-5.
4. Zekeng L, Feldblum PJ, Oliver RM, Kaptue L, Barrier contraceptive use and HIV infection among high-risk women in Cameroon. *AIDS* 1993; 7:725-731.
5. Hatcher RA, Stewart F, Trussell J, et al. *Contraceptive Technology: 1990-1992*. Irvington Publishers, Inc., New York; 1990:167.
6. Hira S, Tembo G, Perine PL. Condom promotion through STD clinics in Zambia. Fifth International Conference on AIDS in Africa, Kinshasa, Zaire, 1990, abstract T.O.C.4.
7. Mariri G, Onoka C, Trangsrud R, et al. Vaginal Foaming Tablet User Dynamic Pilot Study. FPAK/FHI Final Report, Durham, North Carolina, October 1992.
8. Mariri G, Onoka C, Trangsrud R, et al. Contraceptive Film Acceptability Study: Kenya. FPAK/FHI Final Report, Durham, North Carolina, December 1992.
9. Alvarado G, Steiner M, Spruyt A, et al. Contraceptive Film Acceptability Study: Mexico. IIC/FHI Final Report, Durham, North Carolina, March 1993.
10. Cordero M, Steiner M, Spruyt A, et al. Contraceptive Film Acceptability Study: The Dominican Republic. PROFAMILIA/FHI Final Report, Durham, North Carolina, March 1993.

Table 1: Socio-demographic Characteristics

	Female n=85		Male n=128	
	n	(%)*	n	(%)*
Age (in years)				
17-25	28	(33)	44	(34)
26-30	20	(24)	52	(41)
31-35	19	(22)	19	(15)
36-40	13	(15)	7	(5)
41-45	5	(6)	6	(5)
Median	30		27	
Education				
none	--	--	2	(2)
primary	36	(42)	21	(16)
high school	28	(33)	44	(34)
vocational	11	(13)	55	(43)
university	9	(11)	6	(5)
missing	1	(1)	--	--
Marital Status				
married/living together	57	(67)	67	(52)
single	21	(25)	57	(45)
divorced/separated	5	(6)	2	(2)
widowed	2	(2)	2	(2)
Religion				
Protestant	35	(41)	68	(53)
Catholic	28	(33)	41	(32)
Muslim	--	--	6	(5)
Other	22	(26)	13	(10)

*Percents on this and subsequent tables may not add to 100 due to rounding.

Table 2: Pregnancy History and Level of Sexual Activity

	Female n=85		Male n=128	
	n	(%)	n	(%)
Pregnancies during lifetime				
0	10	(12)	--	--
1-4	45	(53)	--	--
5-8	24	(28)	--	--
9-13	6	(7)	--	--
Median	3			
Sexual Relationship Status				
stable	81	(95)	124	(97)
not stable	3	(4)	4	(3)
missing	1	(1)	--	--
Coital Frequency during Last Month				
3-11	69	(81)	69	(54)
12-20	16	(19)	55	(43)
21-28	--	--	4	(3)
Median	9		10	

Table 3: Birth Control Experience

	Female n=85		Male n=128	
	n	(%)	n	(%)
Current Method(s) of Birth Control				
None	63	(74)	74	(58)
Oral Contraceptives	11	(13)	6	(5)
Condom	4	(5)	47	(37)
IUD	3	(4)	--	--
Rhythm or Withdrawal	2	(2)	--	--
Sterilization	1	(1)	--	--
Other	--	--	1	(1)
missing	1	(1)	--	--
Past Method(s) of Birth Control*:				
None	29	(34)	32	(25)
Oral Contraceptives	40	(47)	25	(20)
Condom	14	(16)	84	(66)
IUD	10	(12)	5	(4)
Spermicide	4	(5)	7	(5)
Rhythm or Withdrawal	11	(13)	10	(8)
Other	3	(4)	3	(2)

*Multiple responses allowed.

Table 4: Current and Past STD/Genital Infection Status

	Female n=85		Male n=128	
	n	(%)	n	(%)
STD/Infections at Admission*				
None	17	(20)	2	(2)
Trichomoniasis	34	(40)	22	(17)
Candidiasis	25	(29)	9	(7)
Mucopurulent cervicitis/nongonococcal urethritis	16	(19)	8	(6)
Syphilis	12	(14)	16	(12)
Gonorrhea	8	(9)	44	(34)
Genital warts	4	(5)	12	(9)
Chancroid	4	(5)	9	(7)
Genital herpes	3	(4)	20	(16)
Bacterial vaginosis	2	(2)	--	--
Chlamydial infection	1	(1)	9	(7)
Genital ulcers	--	--	5	(4)
Lymphogranuloma venereum	--	--	3	(2)
Orchitis	--	--	3	(2)
HIV	2	(2)	1	(1)
Other	3	(4)	1	(1)
missing	--	--	1	(1)
Past STD/Infections*				
Genital discharge	38	(45)	59	(46)
Genital ulcer	26	(31)	55	(43)
Pelvic Inflammatory Disease	15	(18)	--	--
Genital growths	12	(14)	14	(11)
Genital buboes	4	(5)	20	(16)

*Multiple STD/infections were recorded.

**Table 5a: Spermicide Use During Study
by Females**

	Foam n=56		Suppositories n=53		Tablets n=61	
	n	(%)	n	(%)	n	(%)
Spermicide Discontinuation						
Used for full two weeks	33	(59)	27	(51)	36	(59)
missing	--	--	1	(2)	--	--
Discontinued	23	(41)	25	(47)	25	(41)
Why discontinued:						
personal reasons*	12		13		12	
messy	8		1		--	
partner objected	2		--		1	
out of supplies	1		8		9	
inconvenient	--		1		1	
caused me discomfort	--		1		--	
decreased sexual satisfaction	--		1		--	
caused partner discomfort	--		--		2	
Prevalence of spermicide use during study period						
Total coital episodes	488	(100)	511	(100)	699	(100)
Total acts w/out spermicide	109	(22)	60	(12)	34	(5)
Use of other method during study period						
No	41	(73)	43	(81)	44	(72)
Yes	15	(27)	10	(19)	17	(28)
Number of Partners						
1	49	(88)	48	(91)	48	(79)
>1	7	(12)	4	(8)	10	(16)
missing	--	--	1	(2)	3	(5)

*Unrelated to acceptability of product.

**Table 5b: Spermicide Use During Study
by Males**

	Foam n=86		Suppositories n=84		Tablets n=86	
	n	(%)	n	(%)	n	(%)
Spermicide Discontinuation						
Used for full two weeks	69	(80)	67	(80)	67	(78)
Discontinued	17	(20)	17	(20)	19	(22)
Why discontinued:						
personal reasons*	5		7		8	
messy	2		--		--	
partner objected	2		2		2	
out of supplies	--		1		1	
inconvenient	2		3		--	
caused me discomfort	1		3		3	
decreased sexual satisfaction	4		1		2	
caused partner discomfort	1		--		3	
Prevalence of spermicide use during study period						
Total coital episodes	637	(100)	648	(100)	670	(100)
Total acts w/out spermicide	54	(8)	41	(6)	50	(7)
Use of other method during study period						
No	74	(86)	61	(73)	64	(74)
Yes	12	(14)	22	(26)	22	(26)
missing	--	--	1	(1)	--	--
Number of Partners						
1	66	(77)	59	(70)	71	(82)
>1	20	(23)	25	(30)	15	(17)

*Unrelated to acceptability of product.

Table 6: Spermicide Preference

	FEMALES		MALES	
	Foam / Suppositories n=24		Foam / Suppositories n=42	
Spermicide preferred: percent	n=14 58%	n=10 42%	n=21 50%	n=21 50%
Why preferred:				
sexual satisfaction	2	--	2	7
convenient, quick, no mess	4	--	13	1
reduced lubrication	5	10	3	7
no irritation, pain	3	--	2	3
other	--	--	1	1
missing	--	--	--	2
	Foam / Tablets n=32*		Foam / Tablets n=44*	
Spermicide preferred: percent	n=13 41%	n=18 56%	n=31 70%	n=12 27%
Why preferred:				
sexual satisfaction	4	--	2	8
convenient, quick, no mess	5	3	15	--
reduced lubrication	4	12	2	1
no irritation, pain	--	1	8	2
other	--	1	2	1
missing	--	1	2	--
	Suppositories / Tablets n=29		Suppositories / Tablets n=42*	
Spermicide preferred: percent	n=13 45%	n=16 55%	n=19 45%	n=22 52%
Why preferred:				
sexual satisfaction	4	5	8	15
convenient, quick, no mess	--	--	1	--
reduced lubrication	4	7	2	2
no irritation, pain	1	3	3	4
other	1	1	4	1
missing	3	--	1	--

*One subject did not answer the question.

Table 7: Spermicide Acceptability

	Foam		Suppositories		Tablets	
Best Features of Spermicide:						
Female respondents*	n=56	(%)	n=53	(%)	n=61	(%)
sexual satisfaction	21	(38)	16	(30)	20	(33)
convenient, quick, no mess	16	(29)	11	(21)	15	(25)
pregnancy & STD prevention	8	(14)	13	(25)	6	(10)
no irritation, pain, itch	2	(4)	--	--	2	(3)
generally liked it	2	(4)	--	--	--	--
reduced vaginal lubrication	1	(2)	1	(2)	8	(13)
additional lubrication	1	(2)	--	--	2	(3)
other	1	(2)	--	--	1	(2)
nothing	4	(7)	12	(23)	7	(11)
Male respondents*	n=86	(%)	n=84	(%)	n=86	(%)
sexual satisfaction	38	(44)	55	(65)	52	(60)
scent	17	(20)	--	--	1	(1)
pregnancy & STD prevention	9	(10)	9	(11)	9	(10)
convenient, quick, no mess	7	(8)	--	--	--	--
additional lubrication	6	(7)	9	(11)	6	(7)
no irritation, pain, itch	1	(1)	3	(4)	5	(6)
generally liked it	1	(1)	1	(1)	1	(1)
reduced vaginal lubrication	--	--	1	(1)	--	--
nothing	7	(8)	6	(7)	12	(14)
Worst Features of Spermicide:						
Female respondents*	n=56	(%)	n=53	(%)	n=61	(%)
messy, vaginal discharge	24	(43)	5	(9)	5	(8)
too much lubrication	4	(7)	13	(25)	4	(7)
inconvenient, awkward	4	(7)	4	(8)	12	(20)
irritation, pain, itch	1	(2)	8	(15)	3	(5)
other	1	(2)	1	(2)	--	--
nothing	22	(39)	22	(42)	37	(61)
Male respondents*	n=86	(%)	n=84	(%)	n=86	(%)
too much lubrication	26	(30)	15	(18)	8	(9)
irritation, pain, itch	17	(20)	12	(14)	26	(30)
reduced sensitivity	3	(3)	2	(2)	1	(1)
inconvenient, awkward	2	(2)	14	(17)	11	(13)
messy, vaginal discharge	2	(2)	1	(1)	--	--
other	2	(2)	3	(4)	4	(5)
nothing	34	(40)	37	(44)	36	(42)

*Each participant was allowed to list two features, only the first response appears here.

Table 8a: Mean Ratings of Spermicides by Females¹

	Foam n=56	Supposit. n=53	Tablets n=61	Paired Comparison P-Value ²
How did you like method: (1=very well, 5=not at all)	2.2	1.9	1.6	
Sexual satisfaction was: (1=much better, 5=much worse)	2.5	2.1	1.6	S vs T=.042
Sensitivity: (1=increased, 5=decreased) missing	2.8 -	2.7 1	2.3 1	S vs T=.038
Opening package was: (1=very easy, 5=very difficult)	1.3	1.3	1.4	
Inserting spermicide was: (1=very easy, 5=very difficult)	1.4	1.3	1.5	
Spermicide lubrication: (1=none, 5=too much) missing	3.3 -	3.4 -	2.8 2	F vs T=.016
Spermicide Odor³: (1=very pleasant, 5=very bad) missing	2.2 18	2.9 21	2.8 31	
Percent reporting irritation:	16%	23%	11%	
Irritation was: (1=minor, 3=severe)	1.0	1.2	1.0	
Length of Irritation: (1=brief, 3=continued after coitus)	1.2	1.3	1.3	
Leaked out of vagina: (0=no, 2=a lot)	0.9	0.5	0.4	F vs T=.007
Vaginal discharge³: (1=decreased, 5=increased) missing	3.3 1	3.2 -	3.1 -	
Prevalence of partner awareness of spermicide:	86%	94%	89%	
Partner general reaction: (1=liked, 5=disliked)	2.6	2.4	1.9	
Partner sexual satisfaction³: (1=improved, 3=worsened) missing	1.7 15	1.6 18	1.1 21	
Prevalence of partner irritation:	12%	8%	10%	
Partner irritation was: (1=mild, 3=severe) missing	1.0 -	1.0 -	1.4 1	

¹Mean values are based on every participant who rated the product. ²P-values are based on matched pairs, include only couples who rated both products (all possible comparisons were tested, only p-values < 0.05 are shown). ³For consistency, scale was altered in direction from what appears on questionnaire.

Table 8b: Mean Ratings of Spermicides by Males¹

	Foam n=86	Supposit. n=84	Tablets n=86	Paired Comparison P-Value ²
How did you like method: (1=very well, 5=not at all) missing	2.2 2	2.1 -	2.2 1	F vs T=.015 ³
Sexual satisfaction was: (1=much better, 5=much worse)	2.3	2.1	2.1	F vs S=.010
Sensitivity: (1=increased, 5=decreased) missing	2.8 -	2.5 -	2.5 1	F vs S=.002
Opening package was: (1=very easy, 5=very difficult) missing	1.2 2	1.3 1	1.5 -	F vs T=.016
Inserting spermicide was: (1=very easy, 5=very difficult) missing	1.3 -	1.3 -	1.4 1	
Spermicide lubrication: (1=none, 5=too much) missing	3.3 -	3.0 1	2.9 1	F vs S=.009
Spermicide Odor⁴: (1=very pleasant, 5=very bad) missing	1.4 26	1.7 60	2.0 64	
Percent reporting irritation:	20%	26%	27%	
Irritation was: (1=minor, 3=severe)	1.3	1.1	1.2	
Length of Irritation: (1=brief, 3=continued after coitus)	1.4	1.1	1.6	
Partner's general reaction: (1=liked, 5=disliked) missing	2.5 -	2.3 -	2.4 1	
Partner sexual satisfaction⁴: (1=improved, 3=worsened) missing	1.8 35	1.5 39	1.4 32	F vs S=.008
Prevalence of partner irritation:	23%	20%	26%	
Partner's irritation was: (1=mild, 3=severe) missing	1.4 -	1.1 3	1.2 -	

¹Mean values are based on every participant who rated the product. ²P-values are based on matched pairs, include only couples who rated both products (all possible comparisons were tested, only p-values < 0.05 are shown). ³The mean ratings for Foam and Tablets were 2.19 and 2.20, respectively. ⁴For consistency, scale was altered in direction from what appears on questionnaire.

Table 9: Post Study Spermicide Use¹

	Female		Male	
Currently using a spermicide:	n=85	(%)	n=128	(%)
Yes	66	(78)	101	(79)
No	18	(21)	21	(16)
missing	1	(1)	6	(5)
Details of current spermicide use:	n=66	(%)	n=101	(%)
Product by name ² :				
Conceptrol ^R Tablets	22	(33)	41	(41)
Delfen ^R Foam	9	(14)	38	(38)
Intercept ^R Suppositories	8	(12)	23	(23)
if name not known, type:				
suppository ³	25	(38)	--	--
foam	4	(6)	--	--
gel	2	(3)	--	--
don't know/missing	1	(2)	2	(2)
Consistency of use:				
with every act of coitus	51	(77)	77	(76)
used inconsistently	15	(23)	24	(24)
Method of use:				
by itself	51	(77)	75	(74)
with other method	15	(23)	26	(26)
Method of distribution:				
purchased	48	(73)	88	(87)
free	18	(27)	13	(13)
Reasons for continued use:	n=66	(%)	n=101	(%)
generally like it	22	(33)	1	(1)
STD prevention	16	(24)	48	(48)
pregnancy prevention	15	(23)	26	(26)
pregnancy and/or STD prevention	9	(14)	13	(13)
reduces itching, discharge	2	(3)	--	--
improves sexual satisfaction	1	(2)	13	(13)
missing	1	(2)	--	--
Reasons for discontinuation:	n=18	(%)	n=21	(%)
personal reasons	14	(78)	11	(52)
out of supplies	3	(17)	2	(10)
partner opposition	1	(6)	7	(33)
side effects	--	--	1	(5)

¹The median time from second follow up interview to post study interview was 92 days. ²Some participants reported use of more than one type of spermicide. Percentages are based on females (n=66) and males (n=101) who were currently using a spermicide. ³The questionnaire did not distinguish between suppositories and tablets, thus caution should be used when interpreting this result.

XI. Appendix I

Study Questionnaires

**UNIVERSITY TEACHING HOSPITAL/FHI
SPERMICIDE ACCEPTABILITY STUDY
ADMISSION QUESTIONNAIRE**

IDENTIFICATION

- | | | |
|---|-----------------|-------|
| 1. Study number: | 3 2 6 9 | 1-4 |
| 2. Patient number: | _ _ _ | 5-7 |
| 3. Clinic chart number: | _ _ _ _ _ | 8-13 |
| 4. Study group assignment: 1) Delfen--->Conceptrol
2) Delfen--->Intercept 3) Intercept--->Delfen
4) Intercept--->Conceptrol 5) Conceptrol--->Delfen
6) Conceptrol--->Intercept | | _ 14 |
| 5. Study phase: 1) female 2) male | | _ 15 |
| 6. Date of admission visit (day, month, year): | _ _ / _ _ / _ _ | 16-21 |

PATIENT CHARACTERISTICS

- | | | |
|---|-----------------|-----------|
| 7. What is your age? (completed years)
(NOTE: if age is <16 or >50 person is ineligible) | | _ _ 22-23 |
| 8. Are you currently in school? 0) no 1) yes | | _ 24 |
| 9. What is the highest level of schooling you have completed?
0) none 1) primary 2) high school 3) vocational 4) university | | _ 25 |
| 10. What is your religion? 1) Protestant 2) Catholic 3) Muslim
8) other, specify _____ | | _ 26 |
| 11. What is your marital status? 1) single, not living together
2) single, living together 3) married 4) divorced or
separated 5) widowed | | _ 27 |
| 12. (For women) How many times have you been pregnant in
your life? | | _ _ 28-29 |
| 13. (For women) How many live births have you had? | | _ _ 30-31 |
| 14. (For women) What is the date of your last period?
(day, month, year) | _ _ / _ _ / _ _ | 32-37 |
| 15. (For women) Do you use tampons? 0) no 1) yes | | _ 38 |
| 16. Are you currently in a stable sexual relationship?
0) no 1) yes | | _ 39 |
| 17. How many times have you had sexual intercourse in the
past month? [NOTE: if less than 2, person is ineligible] | | _ _ 40-41 |

CONTRACEPTION AND STDs

18. Are you currently using a method of birth control? 0) no 1) yes 42

If yes, which method? 1) pill 2) IUD 3) condom 4) vaginal tablet or other spermicide 5) rhythm or withdrawal 6) sterilization 8) other, specify _____ [If '4', person is ineligible] 43

19. Have you ever used a method of birth control? 0) no 1) yes 44
If yes, which method(s)?

pill 0) no 1) yes 45

IUD 0) no 1) yes 46

condom 0) no 1) yes 47

vaginal tablet/jelly/foam/cream 0) no 1) yes 48

rhythm or withdrawal 0) no 1) yes 49

other, specify _____ 50

20. Have you heard of any health problems that may be associated with any of these methods of birth control? If yes, specify. If no, code 00.

pill _____ 51-52

IUD _____ 53-54

condom _____ 55-56

vaginal tablet, foam or jelly _____ 57-58

rhythm/withdrawal _____ 59-60

other, specify _____ 61-62

21. Have you heard of any health benefits that may be associated with any of these methods? If yes, specify. 00) no

pill _____ 63-64

IUD _____ 65-66

condom _____ 67-68

vaginal tablet, foam or jelly _____ 69-70

rhythm/withdrawal _____ 71-72

other, specify _____ 73-74

 80

22. Have you ever had any of the following diseases?
 [NOTE: use colloquial names when appropriate]

genital discharge	0) no 1) yes	—	16
genital ulcer disease	0) no 1) yes	—	17
genital growths	0) no 1) yes	—	18
pelvic inflammatory disease	0) no 1) yes	—	19
genital buboes	0) no 1) yes	—	20

FOLLOW-UP

23. Date of scheduled follow-up visit (day, month, year): — / — / — 21-26

24. May we come to your house to interview you? 0) no 1) yes — 27

If yes: address _____

contact person _____
 address _____

MEDICAL RECORD (current visit)

25. Was patient diagnosed with an STD? 0) no 1) yes — 28
 If yes, which one(s)?

gonorrhea	0) no 1) yes	—	29
chlamydia	0) no 1) yes	—	30
syphilis	0) no 1) yes	—	31
trichomoniasis	0) no 1) yes	—	32
genital herpes	0) no 1) yes	—	33
genital warts	0) no 1) yes	—	34
mucopurulent cervicitis/nongonococcal urethritis	0) no 1) yes	—	35
HIV infection	0) no 1) yes	—	36
other, specify _____		—	37

ard number: 2 80

UNIVERSITY TEACHING HOSPITAL/FHI
SPERMICIDE ACCEPTABILITY STUDY
SHORT-TERM FOLLOW-UP QUESTIONNAIRE

IDENTIFICATION

- | | | |
|---|-----------------|-------|
| 1. Study number: | 3 2 6 9 | 1-4 |
| 2. Patient number: | _ _ _ | 5-7 |
| 3. Clinic chart number: | _ _ _ _ _ | 8-13 |
| 4. Study group assignment: 1) Delfen--->Conceptrol
2) Delfen--->Intercept 3) Intercept--->Delfen
4) Intercept--->Conceptrol 5) Conceptrol--->Delfen
6) Conceptrol--->Intercept | | _ 14 |
| 5. Study phase: 1) female, first product 2) female, second product
3) male, first product 4) male, second product | | _ 15 |
| 6. Date of visit (day, month, year): | _ _ / _ _ / _ _ | 16-21 |
| 7. Result of interview attempt: 1) completed at clinic
2) completed at home 3) refused 4) lost to follow-up | | _ 22 |

PRODUCT USE

- | | | |
|---|-----|-------|
| 8. How many times have you had sexual intercourse since receiving the spermicide? | _ _ | 23-24 |
| 9. How many times did you <u>not</u> use the spermicide? | _ _ | 25-26 |
| 10. Can you please give me any spermicide that you did not use?
0) no 1) yes | _ | 27 |
| [For Intercept and Conceptrol users only] number returned | _ _ | 28-29 |
| 11. Since your last visit, have you had sex with more than one partner? 0) no 1) yes | _ | 30 |
| If yes, how many different partners have you had? (8 or more=8) | _ | 31 |
| 12. Did you use the product with all of your partners? 0) no 1) yes | _ | 32 |
| If not, why? _____ | _ _ | 33-34 |
| 13. Did you use the spermicide throughout the two weeks, or did you stop using it? 0) discontinued 1) used for full two weeks | _ | 35 |
| 14. If you stopped using it, what was the main reason? 1) caused discomfort to me 2) caused discomfort to my partner(s)
3) inconvenience 4) messiness 5) decreased sexual satisfaction
6) partner(s) objected 7) out of supplies 8) other reason, specify _____ | _ | 36 |

5. Did you use any other method of birth control in the past two weeks? 0) no 1) yes, specify _____ 37
16. (For women) Did you use the spermicide during your period? 0) no 1) yes 38
17. (For women) Did you douche after use of the spermicide? 0) no 1) yes 39
18. Did you mop the vagina for dry sex? 0) no 1) yes, sometimes 2) yes, most or all of the time 40

PERCEPTIONS OF PRODUCT

18. Please tell me the two best features of the spermicide:
- a. _____ 41-42
- b. _____ 43-44
19. Now please tell me the two worst features of the spermicide:
- a. _____ 45-46
- b. _____ 47-48
- J. In general, how did you like the spermicide? very well _____ not at all 49
21. Did the spermicide affect your overall sexual satisfaction? much better _____ much worse 50
22. Was the packaging easy to use? very easy _____ very difficult 51
23. Was the spermicide easy to insert? very easy _____ very difficult 52
24. Did the spermicide provide lubrication? no lubrication _____ too much lubrication 53
25. Did the spermicide have a noticeable odor? (not applicable=8) very bad _____ very pleasant 54
26. Did the spermicide have a noticeable taste? (not applicable=8) very bad _____ very pleasant 55
27. Did the spermicide affect your sensitivity? increased a lot _____ decreased a lot 56
28. (For women) Did the spermicide leak out of your vagina? 0) no 1) yes, a little 2) yes, a lot 57

29. Did the spermicide stain clothing or bed linens? 0) no 1) yes. _ 58
30. Did the spermicide cause you any irritation? 0) no 1) minor but able to ignore it 2) moderate and interfered with sex 3) severe and so unable to have sex _ 59
- If yes, how long did the irritation last? 1) briefly; disappeared when intercourse began 2) throughout intercourse, but ended when intercourse ended 3) continued after intercourse ended _ 60
31. (For women) Did the spermicide change the amount of your vaginal discharge?
increased a lot _ _ _ _ decreased a lot _ 61

PARTNER'S PERCEPTIONS OF PRODUCT

[NOTE: this section refers to the most frequent partner]

32. Was your partner aware that you were using the spermicide?
0) no 1) yes 8) unknown _ 62
33. Did s/he like or dislike the spermicide?
liked _ _ _ _ disliked _ 63
34. Did s/he mention any difference in sexual relations?
improved _ _ _ _ worse _ 64
35. Did the spermicide affect his/her overall sexual satisfaction?
0) no 1) yes, improved 2) yes, worsened 8) unknown _ 65
36. Did the spermicide cause him/her any irritation? 0) no 1) yes 8) unknown _ 66
37. If yes, how would you rate his/her irritation? 1) mild 2) moderate 3) severe 8) other, specify _____ _ 67
38. Do you have any additional comments about the spermicide?
0) no 1) yes, specify _____ _ 68

FUTURE USE OF SPERMICIDES

[NOTE: ask these questions only at second short-term follow-up]

39. These products are for birth control. But they also may protect against diseases transmitted by sex, including gonorrhea, chlamydia, syphilis, herpes and AIDS. Do you want to use a spermicidal product? 0) no 1) yes _ 69
40. If you are using a birth control method now, do you wish to use a spermicide: 1) in addition to your current method 2) instead of your current method? _ 70
41. Are you willing to pay for a spermicide? 0) no 1) yes _ 71

35

2. Of the two methods you received in this study, which one do you like better? 1) first 2) second

72

43. What is your main reason for that preference?

73-7

44. Do you have any final comments about the study? 0) no 1) yes, specify

75

Thank you very much for participating in this study.

Card number:

80

**UNIVERSITY TEACHING HOSPITAL/FHI
SPERMICIDE ACCEPTABILITY STUDY
THREE-MONTH FOLLOW-UP QUESTIONNAIRE**

IDENTIFICATION

- | | | |
|---|-------------------------------------|-------|
| 1. Study number: | <u>3</u> <u>2</u> <u>6</u> <u>9</u> | 1-4 |
| 2. Patient number: | _ _ _ | 5-7 |
| 3. Clinic chart number: | _ _ _ _ _ | 8-13 |
| 4. Study group assignment: 1) Delfen--->Conceptrol
2) Delfen--->Intercept 3) Intercept--->Delfen
4) Intercept--->Conceptrol 5) Conceptrol--->Delfen
6) Conceptrol--->Intercept | | _ 14 |
| 5. Study phase: 1) female 2) male | | _ 15 |
| 6. Date of contact (day, month, year): | _ _ / _ _ / _ _ | 16-21 |
| 7. Result of contact attempt: 1) reached by phone
2) reached by home visit 3) refused 4) lost to follow-up | | _ 22 |

PRODUCT USE

- | | | |
|--|----------|-----------|
| 8. Are you currently using a spermicidal product? 0) no 1) yes | | _ 23 |
| 9. If no, what is the main reason? _____ | | _ _ 24-25 |
| 10. If yes, what is the main reason? _____ | | _ _ 26-27 |
| 11. If yes, what is the name of the product? _____ | | _ _ 28-29 |
| 12. If you don't know the name, what type of product is it?
1) suppository 2) foam 3) gel 4) cream 5) sponge
8) other, specify _____ | | _ 30 |
| 13. Are you buying the product, or do you receive it free?
1) buying it 2) free supplies | | _ 31 |
| 14. Are you using it together with another contraceptive method,
or all by itself? 1) joint use 2) sole use | | _ 32 |
| 15. Do you use it every time you have sexual intercourse, or only
some of the time? 1) all of the time 2) some of the time | | _ 33 |
| Card number: | <u>5</u> | 80 |