ORIGINAL RESEARCH ARTICLE

Notes on the female condom: experiences in Brazil

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Summary: A nationwide effort to introduce the female condom (FC) into public health services was undertaken in Brazil in 1998–99. To this end, the Ministry of Health sponsored a national research group of public health professionals, aided by local field workers and supervisors, to conduct a preparatory study at 20 sites in six cities. Clinic health workers were trained to conduct the study. Following an educational session, 2382 women volunteered to use the FC and to report their experiences at follow-up. Among those seen at 15 days, 1782 had used the FC at least once; among those seen at the 90-day follow-up, 1453 women had used it at least once, while 1296 of them liked it and wished to continue its use. Among these 1296 women, barrier use at last intercourse (either with a male or a female condom) was more than double at 90 days what it had been at baseline: 70% compared with 33%. Clinics providing active health-education activities achieved higher rates of follow-up and of FC acceptability.

These findings suggest that in Brazil, the introduction of the FC at public health centres could lead to high initial adoption rates and that continued use would be effective in encouraging safer sex. The level of health education and type of clinic are likely to influence the effectiveness of a future programme.

Keywords: female condom, acceptability, dual protection

INTRODUCTION

The female condom (FC) is gaining recognition for its potential role in the prevention of HIV and other sexually transmitted infections. Increasingly, it is being realized that we cannot stand by, applauding progress in vaccine and microbicide development, without attending to women's immediate needs.[1] Effective vaccines and microbicides remain on the horizon of the future, but the plight of women at risk is here and now. As a currently available device that women might use to protect themselves against HIV, the FC stands alone.

Two recent reviews of reported experiences with the FC[2,3] point out the dearth of published studies on introducing the device. In this paper, we describe the steps taken in Brazil where one of the largest and most systematic efforts to introduce the FC was undertaken in 1998–99 by the Ministry of Health, in collaboration with the Center for Population Studies at the State University of Campinas and Brazilian Center for Analysis and Planning.

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The study was commissioned primarily to address the issue of whether promoting the FC in the public sector would increase uptake of the device, or whether it could only be distributed in a limited way, as was occurring at the time through non-governmental organizations, outlets and settings. Lessons learned from the Brazil experience might be information for other health departments in Brazil and elsewhere.

METHODS

Outline

The design of the study was to select a number of clinics from different parts of the country, all in urban areas, then gain the interest, understanding and support of clinic staff, who would be trained in the use and demonstration of FC. Each clinic would hold information sessions for clients about FCs, and then call for volunteers to participate. Participants would receive a set of FCs free, try them out at home, and return, first at 15 days, then at 90 days, to report success. These innovations would take place during the clinic's routine sessions, with minimal additional staff or arrangements. Evaluation forms and questionnaires were administered by trained interviewers. This study, which could be described as operations research, involved more than 2000 women and 20 clinics, the latter continuing with their routine activities.

Planning and preparation

A research group was set up, comprising an overall coordinating team, which identified local coordinators and supervisors at each site. In all, 90 professionally-trained personnel took part. These team members generated educational and training materials for use in the clinics. The study was publicized intensively in the media, and folders were distributed to ensure high coverage within each town.

Site selection

Twenty sites were selected for the trial in six cities, all of which had implemented not only regular preventive and curative services but also a women's health programme offering family planning, prenatal care and gynaecological consultations.

The six cities from (São Vincente, Rio de Janeiro, Belo Horizonte, Goiânia, Cabo de Santo Agostinho and Porto Alegre) reflected the sociodemographic and health differences among inhabitants of the various cities as well as the variety of models of health care. In addition to socio-cultural distinctions, a particular effort was made to represent the different HIV/AIDS epidemics in Brazil and variations in the use of contraceptive methods. Other factors that determined site selection were:

(1) existence of fully functioning women's health and sexually transmitted disease (STD)/AIDS programmes; (2) health units' ability to incorporate the FC into the range of services already being offered; (3) staff interest in the study and (4) availability and appropriateness of local facilities in the units to sustain the research (staff, infrastructure, number and type of health-related services offered). All the chosen clinics were judged to have these qualities.

Health education and clinic type

It was assumed that some health education would be offered at each site. The extent and level of health education differed considerably by site. The researchers, therefore, distinguished three types of site: Type 1 included clinics with incipient health education programmes; Type 2 included clinics with a strong health education programme but virtually no outreach in the community and Type 3 had both clinic and health education outreach programmes.

Training of health-care workers

A preliminary step was to familiarize health-care workers with the FC and instruct them in its use, and demonstrate how to explain insertion of the device to clients. Members of the coordinating team conducted a standardized 48-hour training programme for health workers three times at each clinic.

Health education of potential users

Educational group sessions were conducted for all women clients at each site, explaining how the FC protects against both pregnancy, HIV and other sexually transmitted infections and how to use the device. The group sessions were designed to facilitate active discussion between health workers and clients, broaching issues, for example, of autonomy for women and dual protection. A total of 238 group sessions were held during the recruitment period.

Procedures and client eligibility

All interested women completed a baseline interview prior to attending the special educational sessions demonstrating the FC. Those wishing to join the study gave written informed consent, agreeing to try out the FC and return for re-interview 15 and 90 days later. Eligibility criteria for participation were: age 18 years and over, not wanting to become pregnant, being sexually active and consenting to be followed over 90 days. Since the study protocol called for women to try the device, each participant received three FCs initially, and upon return for the 15-day follow-up visit, she would be re-interviewed about her experiences and receive an additional 12 FCs. She would then be asked to return at 90 days. Male condoms and FCs were supplied as requested.

Ethical issues

Besides ethical approval of the protocol, the study coordinators signed cooperation agreements with the State and Municipal Health Departments of each of the cities involved to ensure assistance and educational support to the FC users, as well as FC availability after the end of the study. After discussing the protocol, all women involved in the study signed a letter of informed consent. The women were granted the right to interrupt their participation in the study at any stage and to be issued the condoms regardless, while not having to answer the study instrument questions for any reason whatsoever.

Measures

The baseline interview focused on participants' demographic background and current use of contraceptives. The 15-day and 90-day questionnaires explored the consistency of use of male and female condoms and participants' experiences with using the FC (incorrect use, reasons for non-use and interrupted use, slippage, difficulties, advantages and disadvantages) as well as partners' opinion. Questions addressing sexual behaviour and the use of other contraceptive methods were also asked. A direct question as to whether a condom (male or female) had been used on the most recent occasion of sexual intercourse was asked at baseline, and again at 15 days and 90 days.

The questionnaire was administered by a trained interviewer, and the responses were reviewed weekly for consistency by the local coordinator, supervised by the overall coordinators. Every two weeks, the overall coordinators conducted a new consistency analysis. Any inconsistencies, such as those relating to use of male or female condoms, were corrected by home visits. Information from each of the three interviews (at baseline, 15 and 90 days)

was also matched for consistency against the other two. The questionnaires were pre-tested to ensure appropriate language and sequencing of questions in such a way that the key response (use) was elicited at several points in the interview.

Evaluation

Three outcomes were used to evaluate the acceptability and use of the FC.

(1) Proportion of participants who had used the FC at least once: at 15 days and at 90 days ('Use of FC').
(2) The proportion who found the FC acceptable and wished to continue using it at 15 days and at 90 days ('Acceptability of FC').
(3) The proportion of participants who reported using a barrier (male or female condom) at the latest sexual encounter at baseline, 15 days and 90 days ('Safer sex').

Predictors

(1) We explored whether any of the items listed on the sociodemographic questionnaire predicted outcomes.
(2) We tested whether the type of clinic (1, 2 or 3) influenced study participation (e.g. by using home visits to enhance participation) and each of the three outcomes.

RESULTS

The educational sessions, demonstrating the FC, attracted 2453 women, all of whom responded to a questionnaire. From these, 2382 volunteered to try it out and were given three FCs.

Table 1 sets out the sociodemographic characteristics of the 2453 women who attended the educational sessions, and of the 2382 volunteers who were included in the study. No differences were found between the two groups. Socioeconomically, they described themselves as poor; less than half had completed more than eight years of schooling. Most were married, and most were contracepting.

Volunteers were asked to return at 15 days to report their experiences with use of the FC. Those who wished to continue were given a further 12 condoms and invited to return at 90 days. Table 2 shows the numbers who returned at 15 days and 90 days, and the numbers at each visit who reported 'use' (at least once) of the device, and 'acceptability' (had used it, had liked it and wished to continue). The numbers of those who were sexually active are also indicated. The return after 15 days (93%), and the rates of use (90%) and acceptability (80%) indicate strong interest in the innovation. By 90 days, just over two-third returned to the clinics, and interest remained high among them – 90% for use and 80% for acceptability. Overall, after 90 days, 1296 (70%) of the 1849 volunteers remained satisfied with their experience of the FC and wished to continue. For the

Table 1 **Female condoms in Brazil, 1998–99 (sociodemographic characteristics of participants)**

Selected characteristics at baseline	Women who attended educational group sessions % *n*=2453	Women included in the study % *n*=2382	Women who accepted the FC % *n*=1296
Age (years)			
18–24	28	28	26
25–34	38	38	39
35–44	24	24	25
45 or more	10	10	10
Schooling (years)			
0–4	29	29	29
5–8	36	36	36
9–11	27	27	26
12 or more	8	8	9
Stable partner			
Yes	89	89	93*
No	11	11	7
Contraceptive methods used			
Male condom plus other method	20	21	25*
Male condom alone	20	20	20
Pill or other reversible methods	27	26	25
Female or male sterilization	20	23	22
No method	13	10	8
Type of health-care service			
Type 1	17	15	9*
Type 2	52	52	51
Type 3	31	33	40

*$P < 0.000$

Table 2 **Use and acceptability of the FC among women sexually active over trial period, Brazil, 1998–99**

	Clinic attendance No. of women (%)	Sexually active No. of women (%)	Use at least once No. of sexually active (%)	Acceptability No. of sexually active (%)
Women included	2382 (100)	2382 (100)	n/a	n/a
Returned at 15 days	2207 (93)	1988 (90)	1782 (90)	1595 (80)
Returned at 90 days	1640 (69)	1568 (96)	1453 (93)	1296 (83)
Over total period (0–90 days)	1938 (81)	1849 (95)*	1715 (93)	1296 (70)

*These 1849 comprised all sexually active women within the period excluding those who dropped out from follow-up

original 2342 women included in the study, the acceptability rate is 54%.

The responses to the baseline interview administered to the 1296 women who at 90 days liked, and wished to continue using, the FC could be compared with those of the total (2382) included in the study (Table 1). The sociodemographic variables (age, schooling, stable partner) were very similar in the two groups, although the proportion of stable partners was slightly higher (93%) among women who liked the device. There were two other variables associated with the acceptability of the device: for the whole series, reported prior use of the male condom plus other method was 21%; among those who were satisfied with the FC, it had been 25%.

The last factor was the type of clinic attended. This is explored further in Table 3. Although much of the instruction and supervision was standardized across sites, the results vary considerably across clinics. The outcome results for Type 1, the clinics with least health education, are compared with Types 2 and 3 for percentage follow-up, and for use and acceptability of the FC at 15 days and 90 days. Type 1 clients fared worse on every count.

Across clinics, there were considerable differences in socioeconomic levels. For example, education level varied by city: in one city, one-third had no more than primary schooling, while in another, 13% had university education. The ratio of black to white women also varied by city. Nevertheless, these characteristics seemed not to vary between clients who did, and did not, take up the use of the FC.

It appeared that initial difficulties with insertion discouraged some women. This problem has been reported from other studies and, because it is readily overcome by trained clinic staff, it could be one explanation for the differences in acceptability across clinics.

The additional outcome, shown in Table 4, is the response to the question repeated at each encounter: 'At your last sexual encounter, what form of contraceptive did you use?' The table is based on the women who at 90 days were using the FC and wished to continue using it. There is no doubt that safer sex was a clear outcome in this group. Use of the male condom declines significantly to 81% of the original figures, whereas the proportion of protected sex more than doubles from the baseline to the 90th day follow-up.

The responses of the 187 sexually active women (10%) who at 15 days reported using the FC at least once, but preferred not to continue using it, are of some interest. In general, these women found the device aesthetically unpleasant, an opinion endorsed by one-quarter of their partners.

DISCUSSION

Brazil is the country that has most energetically confronted a major epidemic of HIV, present at every level among men who have sex with men, injection drug users, female and male sex workers, and single and married women in the general population. It is, therefore, not surprising that in Brazil both the diaphragm[4] and the FC have been tested and made available to women, as have other modalities of prevention and treatment.

The study showed that, following instruction in the use of the FC by trained clinic staff, there was considerable interest in its use among clients of public health services. About half of the clinic clients, followed at 90 days, found it acceptable and would like to continue using it. Sociodemographic characteristics of women, except for stable partnerships, did not predict condom use. Women who used the male condom for contraception, before the study was instituted, were more likely to adopt the FC. There were clear differences in the effectiveness of clinics in the introduction of the FC.

In the responses to questions of contraceptive use at last encounter, there was a doubling in reports of safer sex following implementation of the programme, at least among the 1296 women who accepted the FC.

Limitations

This study was clearly not a randomized control of an intervention, but more in the style of operations research.

The observations were made in the context of regular health services in public clinics, and the numbers of women successfully followed were large. However, they provide less than complete coverage of all of the women initially approached. Nor is a study of this kind representative of all women using public sector services, although it can claim to be generally descriptive of urban women who could be reached through these services in Brazil.

Lessons learnt

The strengths of the study was its multi-level approach: it was initiated and encouraged by the Government, planned and supervised by researchers working with the government, who devised and monitored specific training sessions for clinic workers, overseen by clinic team supervisors;

Table 3 **Female condoms in Brazil, 1998–99 (differences among clinic type by rates of follow-up, use and acceptability over total trial period)**

Clinic type	Returned for follow-up No. of women (%) *n*=2382	Returned for follow-up No. sexually active (%) *n*=1938	Use at least once No. sexually active (%) *n*=1849	Acceptability No. sexually active (%) *n*=1849
Type 1	235 (69)	218 (93)	189 (87)	114 (54)*
Type 2	1034 (83)	976 (94)	899 (92)	667 (68)†
Type 3	669 (84)	655 (98)	627 (96)	511 (78)
All	1938 (81)	1849 (95)	1715 (93)	1296 (70)

*Type 1 is significantly worse than Type 2 and Type 3 ($P<0.001$)
†Type 2 is significantly worse than Type 3 ($P<0.001$)

Table 4 **Safer sex (use of female and/or male condom) at most recent encounter (Brazil, 1998–99 (*n*=1288))***

	Use at baseline No. (%)	Use at 90 days No. (%)
Male condom used	432 (33)	349 (27)†
Female condom used	0	544 (42)‡
Protected	432 (33)	893 (69)§

*These 1288 were drawn from the 1296 women who accepted the FC, at 90 days: eight women were not included due to missing information (see Table 2)
†$P<0.001$; ‡n/a; §$P<0.000$

education for all clients, and in some cases other women in the community who used the services.

The results of this study show clearly that by introducing FCs into the general services of the clinic and by offering them with appropriate introductory education, instruction and encouragement, these programmes can add to the prevention options available to women.

The increase in the proportion of safer sex acts observed in this study has been repeatedly shown as an outcome in other studies.[5,6] Moreover, our results show that this increase was not confined to those who subsequently relied solely on the FC, as shown in Table 4. The advent of the FC substantially raised the proportion of sexual intercourse acts that were protected, and not only by substituting the FC for the male condom. The reasons for this beneficial response are not well understood, but may be due to dialogue between partners stimulated by introduction of the FC. Then again, couples may prefer to alternate the method of protection they use.

The third finding also is in line with findings from other studies. Introducing the FC to clinic staff, hence in turn to women clients, takes effort and commitment on the part of staff, not only at the outset, but continuously after training. Many studies have reported the difficulties faced by health workers who counsel women about contraceptive methods, especially the pill and injectables, in shifting the focus of their counseling messages, from pregnancy prevention only, to both disease and pregnancy prevention.[7–10] This entails promoting condoms and translating their new training into clinical practice.[11] At the same time, clients have to understand the basis of the needed partner negotiation skills. In this too, women can be supported by health workers with experience and contact with the community. The differences in results by type of site in Brazil support the inference that the philosophy and commitment of the clinic, including outreach to women in the community, influence the degree to which the site was able to introduce the FC and realize the benefits of introducing the FC.

The findings of this study are in accord with the recommendations of Warren and Morris.[2] They emphasize the requirement of training at the service level and of commitment to the programme at higher and lower echelons of the service. In addition, once FCs are introduced, supply must be assured. Those who carried out this extensive trial provided the Ministry of Health with adequate justification for large-scale implementation of a nation-wide programme. On the basis of results of the study, the Ministry of Health in Brazil decided, in 2000, to introduce the FC on a larger scale and purchased two million FCs to distribute to 20 states.

CONCLUSION

In general, study findings showed fairly high levels of use, continuity of use and acceptability of the FC in Brazil, indicating good initial and continued receptivity to the method. Highest levels were obtained in health services that possessed well-structured health programmes based on models that entailed community involvement or in those with a strong emphasis on health education in the health units. These results demonstrate that the type and quality of the health services have an important role to play in the promotion and acceptability of the FC.

On the other hand, because the FC can confer protection against sexually transmitted diseases and help women to be autonomous – two factors heavily emphasized by the participants in the study – it lends credence to the idea that access to an alternative to the male condom makes it possible to increase women's capacity to negotiate their protection from HIV and other sexually transmitted infections.

The commitment of the government of Brazil and the Ministry of Health to this trial was integral to its success. However, the task of implementation, expansion to other sites, promotion and supervision continues to be of central importance. Perhaps even more than with other public health programmes (notification, vaccination, monitoring the environment), work with female barrier programmes will call for persistence and continuous monitoring and encouragement. Given the widespread resistance to the use of condoms, added to existing prejudice against female barrier methods, this study, important as it is, is a beginning, not an end in itself.

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