

ORIGINAL RESEARCH ARTICLE

Potential for Revitalisation of the Diaphragm for Family Planning in Uganda: A Rapid Assessment of the Feasibility of Introducing the SILCS Diaphragm

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Abstract

This health systems assessment evaluated the feasibility of introducing a new contraceptive device, the SILCS single-size diaphragm, into the existing family planning method mix in Uganda. A total of 26 focus group discussions with 201 female and 77 male potential users and 98 key informant interviews with policymakers and providers were conducted between June and August 2010. Potential users, providers, and policymakers recognised that the SILCS Diaphragm could fill a gap in the method mix and expressed eagerness to make the SILCS Diaphragm available, particularly because it is nonhormonal and woman initiated. The diaphragm was viewed by all stakeholders as a method that would increase choice and could improve women's reproductive health in Uganda. Like many countries, Uganda's family planning programme is financially stretched, and clear support for the SILCS Diaphragm by end-users will need to be demonstrated before the product will be considered for public-sector introduction. *Afr J Reprod Health 2014; 18[2]: 77-86*.

Keywords: Diaphragm, family planning, Uganda, SILCS, introduction

Résumé

Cette étude des systèmes de santé a évalué la faisabilité de l'introduction d'un nouveau dispositif contraceptif, le diaphragme SILCS à taille unique, dans la planification familiale qui existent en Ouganda. Un total de 26 groupes de discussion y compris 201 femmes et 77 usagers potentiels masculins et 98 entrevues avec des informateurs clés avec les décideurs et les fournisseurs ont été menés entre juin et août 2010. Les usagers potentiels, les fournisseurs et les responsables politiques ont reconnu que le diaphragme SILCS pourrait combler une lacune dans le mélange de méthodes et d'empressement manifesté pour rendre disponible la diaphragme SILCS, en particulier parce qu'il est non hormonale et initié par les femmes. Le diaphragme a été considéré par toutes les parties prenantes comme une méthode qui permettrait d'accroître le choix et pourrait améliorer la santé génésique des femmes en Ouganda. Comme de nombreux pays, le programme de planification familiale de l'Ouganda est financièrement contraint et les usagers du diaphragme SILCS être démontrée avant que le produit sera considéré pour l'introduction dans le secteur public. *Afr J Reprod Health 2014; 18[2]: 77-86*.

Mots-clés: diaphragme, planification familiale, Ouganda, SILCS, introduction

Introduction

In Uganda, fertility has remained high for quite some time with a marked discrepancy between observed fertility and desired fertility. According to the Uganda Demographic and Health Surveys, total fertility rate stood at 7.1 live births per woman in 1995¹ and 6.7 in 2006². Yet the ideal number of children women reported wanting was 5.3 and 5.0, respectively. This implies that many women in Uganda are having children they do not

want. Pregnancies which are unplanned or mistimed are likely to result in significant infant and maternal morbidity due to frequent childbearing and unsafely induced abortions. Uganda's maternal mortality ratio is estimated to be 453 deaths per 100 000 live births, and unsafe abortions contribute about 13% of this mortality³.

The high fertility can be explained by early childbearing, which prolongs the period for reproductive exposure, and low contraceptive use. Surveys show that sexual activity and childbearing

in Uganda start very early. The median age for sexual initiation is 16.6 years, and one in four women are likely to begin childbearing between ages 15 and 19 years².

Uganda's population is currently estimated at 32 million people with one of the highest growth rates (3.2%) in the world, and this population is demographically very young⁴.

Unwanted childbearing persists because of low contraceptive use due to cultural factors, lack of supplies, and inadequate choice of methods. Although political support for family planning is viewed as weak⁵, Uganda's family planning managers are interested in increasing family planning use through increased access, promotion of choice, and adolescent-friendly services. According to National Development Plan 2010/11 - 2014/15, Uganda's strategy is to improve access to reproductive health services through health centres and to make family planning services affordable with a consistent and sustainable supply⁶.

During the past decade, PATH, together with its research partners in several countries, redesigned the diaphragm to make it easier to use. PATH's mission is to improve the health of people

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around the world by advancing technologies, strengthening systems, and encouraging healthy behaviours. This technology, the SILCS Diaphragm (SILCS) (Figure 1), is designed to expand women's options for contraceptive protection. It is a barrier contraceptive method that can be especially appropriate for women who want a birth-spacing method but cannot or do not want hormonal contraception or intrauterine devices (IUDs). SILCS has several unique features designed to address issues that have limited use of traditional diaphragms. For example, it is a single-size device that should simplify supply and service provision. It was designed through a user-centred product development process to be easy to use and comfortable for both partners. Acceptability studies in the Dominican Republic, South Africa, and Thailand have shown that women in low-resource settings are able to use SILCS easily, and in one study 19 in 20 women preferred SILCS to the traditional diaphragm^{7,8}. In a recently completed contraceptive effectiveness study in the United States, the SILCS single-size diaphragm was shown to have effectiveness similar to a traditional diaphragm that comes in multiple sizes⁹.

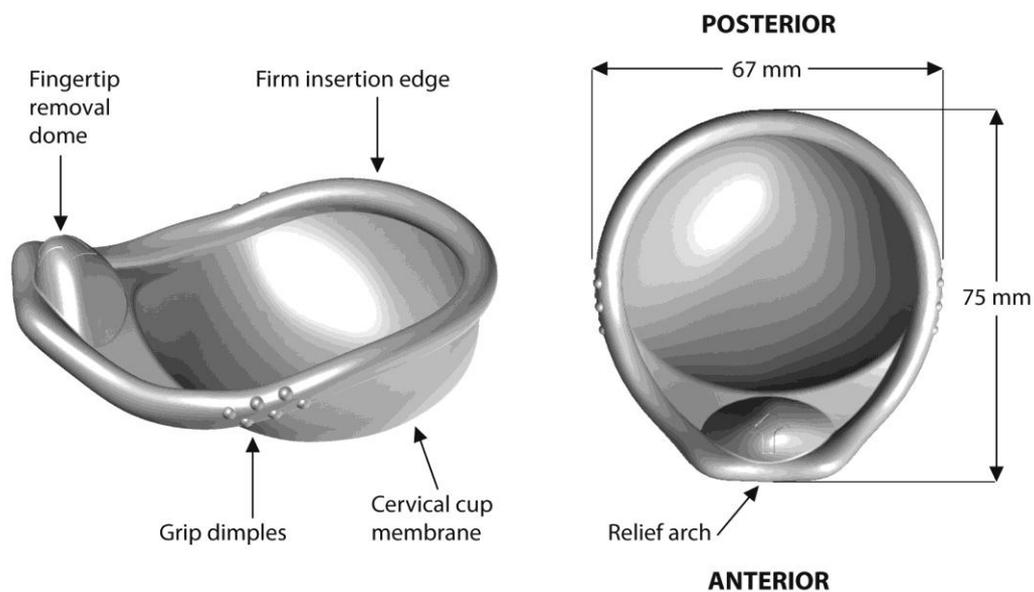


Figure 1: The SILCS Diaphragm

Although diaphragms have not been included as part of family planning programs in developing countries in recent years, several studies show that

women in a range of countries can learn to use the diaphragm and find this method acceptable¹⁰⁻¹⁴. In addition, a study that assessed diaphragm

introduction in three countries found discontinuation rates of the diaphragm were similar to those of other barrier methods¹⁵.

Barrier contraceptives are not new to Uganda. The diaphragm was first introduced in Uganda's family planning method mix in the 1980s, but they were never widely promoted and did not gain widespread acceptance. Reasons why they did not become popular are not clear. Since the 1980s, the male condom, a barrier method that provides dual protection, has been heavily promoted solely as an HIV-prevention tool. Despite these efforts, male condom use is still low. The most recent addition to the barrier methods in Uganda is the female condom, which is being marketed among commercial sex workers in pilot districts.

SILCS regulatory applications are under way in several countries, and the product was approved in Europe in 2013. Where it marketed as the CAYA™ contoured diaphragm. There is interest in evaluating the feasibility of introducing SILCS into the existing family planning method mix of developing countries. Uganda was selected as the first country for this feasibility assessment since there is an unmet need for family planning, coupled with a limited contraceptive method mix, and a limited choice of nonhormonal methods. Given this scenario, expanding the contraceptive method mix to include a single-size diaphragm could improve women's family planning options. As part of the PATH product introduction methodology, a rapid assessment to evaluate opportunities and potential challenges of introducing SILCS into the existing service delivery system in Uganda was conducted. This study examined potential support and barriers in the policy and regulatory pathways; financing, procurement, and delivery mechanisms for family planning supplies; service delivery scenarios; and training required for SILCS introduction and scale-up. Channels for communicating with key target audiences such as family planning/reproductive health providers and women about contraceptive products as well as advocacy strategies for the introduction of SILCS were also identified. This article focuses on interests and concerns of potential users as well as opportunities and challenges that were identified by service providers and policymakers in relation to

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introduction of the SILCS Diaphragm into Uganda.

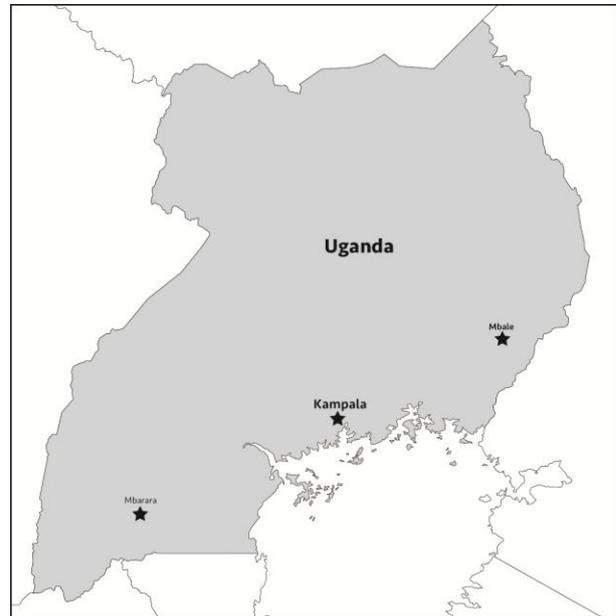


Figure 2: Districts involved in the rapid assessment

Methods

Focus group discussions with potential consumer groups (both women and men) were held to explore their attitudes about a contraceptive diaphragm and identify questions and concerns that would need to be addressed if introduction is deemed feasible. A total of 26 focus group discussions with 201 female and 77 male potential users and 98 key informant interviews with policymakers and providers were conducted between June and August 2010. Convenience sampling was used to identify and select stakeholders in three districts of Uganda (Kampala, the national capital; Mbale in the east; and Mbarara in the southwest) (Figure 2). These three districts represent diverse regions of the country with varying cultures and levels of unmet need. Stakeholders included women and men (as partners of potential users), reproductive health service providers, policymakers, regulatory authorities, and donors, among others (Table 1) in both rural and urban areas. Women of reproductive health age and men were recruited to

participate in the focus group discussions to share perspectives on family planning methods and to identify interest/concerns with the SILCS Diaphragm. Female focus group discussion participants were recruited from clientele of health facilities, consumers at markets, secondary school staff, and university students. Male focus group

discussion participants were recruited from local Rotary groups, sports clubs, secondary school staff, and university students. Each focus group discussion took approximately one hour. Participants were not paid for their participation; they received a beverage and a snack during the session.

Table 1: Participant categories, by district and sample size

District	Potential users		Providers*	Policy-makers**
	Women	Men		
Kampala	38 (4 FGD, 1 KI)	14 (1 FGD)	13	28
Mbarara	59 (4 FGD, 1 KI)	38 (4 FGD)	11	7
Mbale	104 (10 FGD, 3 KIs)	25 (3 FGD, 2 KIs)	35	4
Total =376	201	77	59	39

Key: FGD=focus group discussions; KI=key informant interviews.

*Provider category includes staff from government and nongovernmental organisation (NGO) facilities and commercial outlets such as pharmacies, drug shops, and supermarkets.

**Policymaker category includes district/Ministry of Health (MOH)/NGO planners, religious leaders, regulatory experts, procurement and logistics experts, and donors.

Separate interview guides were designed for each category of stakeholder. During the assessment, participants were shown the SILCS Diaphragm and given samples to touch. The process of insertion and use of the diaphragm were explained.

Additional information was obtained through review of relevant documents, training materials, and survey reports. All data collected from the different sources were transcribed verbatim, categorised, and analysed according to themes that were derived from the objectives of the assessment. This qualitative assessment was reviewed and approved by the Institutional Ethics Review Committee at the Mbarara University of Science and Technology.

Results

Perspectives of potential users (women and men)

Nearly all participants appreciated that SILCS had an advantage over hormonal methods given the minimal side effects with this method.

Respondents described shared examples of dissatisfaction with side effects from hormonal contraceptives.

'This one will be good, if it has no side effects. You will have saved us. We are tired of having children and yet we are young. The women here are desperate. Is there a woman who does not want family planning? Except it makes them sick.' (rural woman, Mbarara)

'Since it is a female controlled method, many women who are having problems with FP [family planning] will use it. All women can use it. There are many young girls worried about getting pregnant.' (rural man, Mbarara)

Participants also described additional advantages that SILCS introduction might bring:

'That thing is good for everybody...it is better for married women'(public provider, Kampala);

'It increases variety of female-controlled methods and when there is a wide range of services, women

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can choose what is good for them.' (donor, Kampala)

'Me I have like it. If it can fit properly, it better than other methods. Other methods have side effects like bleeding. I see that if a woman learns how to use it well, she cannot go back to pills.' (urban woman, Kampala)

Women and men expressed eagerness to try using SILCS and wanted to take SILCS samples and try them.

'You are just exciting us without samples for us...when you come back please bring samples so that women can try.' (urban woman, Kampala)

Heads of training institutions asked for samples for teaching aids. Women were enthusiastic about using the diaphragm, and both women and men asked questions about ease of use, cost, and sexual pleasure as noted below.

'If it has no side effects, you will have saved the women. Women like to use family planning but they fear.' (rural man, Mbarara)

Ease of use

Women were concerned about ease of use, particularly with how to learn to insert and check placement of the device. Both women and men shared concerns based on misconceptions and limited knowledge of vaginal anatomy, such as fear that the SILCS Diaphragm may disappear into the uterus and possibly kill the woman. Respondents also wondered if the device could be pushed into the uterus during sexual activity. Discussion about inserting/checking correct placement of the device in the vagina raised questions from almost all respondents, including health providers, such as:

'How do you know it has reached and is holding? Suppose it fits badly. ...does the man know you have it?' (rural woman, Mbarara)

'Doesn't it enter inside? Won't a man push it further in. But removing it...it is short, doesn't it dislodge?' (urban man, Kampala)

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'Isn't it painful? Can't the man push it into the uterus? Can't the man dislodge it? Can you urinate with it? Isn't it big?' (urban woman, Kampala)

'Does the whole of it fit? Will it not hurt the woman? Doesn't the man feel it? Isn't there a possibility of a woman wearing it badly and sperms pass through?' (rural man, Mbarara)

'It is hard. I hope it does not cause wounds for women. It is too big.' (rural man, Mbale)

'Isn't it hard and doesn't it make the woman uncomfortable? If she is wearing it does she walk comfortably? Women who are short does it fit? Can't it be pushed beyond the cervix and it goes inside?' (urban man, Mbarara)

'Can't it disappear inside?' (service provider, Mbale)

'The ring seems hard. Will it not be uncomfortable or cause pain? I hope it does not make noise like the female condom. Will it not hurt the man?' (public provider, Kampala)

Although women reported insertion of 'foreign things' in the vagina as a common practice in the communities visited, some women perceived insertion and removal of the diaphragm as a difficult procedure when it was described to them and demonstrated by the researchers using their hands. Respondents felt they would need instruction from a trained provider. Others said they would benefit from talking to women who had tried it before.

'It is inconvenient—insert-remove-insert every time. Isn't it difficult to remove it? I see that it is bothersome. You might forget to remove it. Can I keep it in for a month?' (urban woman, Kampala)

'This is for women who have time. Imagine insert and remove. How do I know I have inserted it properly? Sperms may escape and go up.' (urban woman, Kampala)

'When you are alone you fear that it will not fit properly. We shall need support from the health providers to help us make sure we insert it properly.' (urban woman, Kampala)

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'Inserting it will need technical expertise to put it properly...you have to put it where there are trained providers.' (urban man, Mbarara)

Product accessibility

Concern about cost of the diaphragm and contraceptive gel was a crosscutting issue across all potential users, implementers, planners, and policymakers. Since the product is not yet commercially available and the sales price is not determined, researchers asked women what they thought it should cost and what they would be willing to pay. The product was perceived as too expensive for poor women who have the highest unmet need for family planning. Women stated they were willing to pay from Uganda shillings 300 to 15,000 (0.12–6.00 USD). The modal price they were willing to pay was about shillings 5,000 (2.00 USD). Most women, however, expressed that they would prefer to receive the diaphragm free of charge, mirroring the manner in which public-sector family planning services are currently being delivered.

Although the SILCS is a reusable method that can be used for two years and perhaps longer before replacing, it is recommended for use with contraceptive gel to increase its effectiveness. The gel is a recurring cost since it must be resupplied. The frequency of resupply depends on the frequency of sex. Women said that if they lacked access to contraceptive jelly, they would likely use petroleum-based products (like samona, a type of petroleum jelly used by many women) as lubricant since these are readily available.

'I am thinking about my ordinary sister in Kapchorwa, ...you talk about jelly and she is going to use 'Samona,' thinking that it will make the diaphragm slide easily.' (university woman, Mbale)

'If the contraceptive jelly is finished and I do not yet have money, can I use ordinary Vaseline for lubrication...can I use cooking oil...can I use the diaphragm without the jelly?' (rural woman, Mbale)

'What about the jelly? How long does it last and how much does it cost? Suppose we use 'samona?' (rural woman, Mbarara)

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Women agreed that some type of lubricant is necessary to help in the insertion of the diaphragm.

In Uganda, there are cultural practices where women use herbs to enhance vaginal lubrication, especially in central and western Uganda. In other places (such as northern Uganda), the vagina is dried to enhance pleasure for the man. So, use of the lubricant may not be equally acceptable across the different regions of Uganda.

Contraceptive gel/spermicide gel products were not readily available in pharmacies in Uganda when surveyed as part of the rapid assessment. KY[®] Brand Jelly is used in clinics but is perceived as a medical product not a lubricant to be used during sex. This lubricant was described by women as very 'cold.' A 'warm' lubricant, which would make sex more attractive and appealing, would be preferable.

Effect on sexual pleasure

Concerns about the effect of SILCS on sexual pleasure were raised by both men and women. There was anxiety about interference with 'natural' feeling, lubrication, and possibly experiencing pain with intercourse.

'What are the chances of appetite when you use the diaphragm...sometimes the reason people do not use some methods is that they want to enjoy sex as it is naturally.' (rural man, Mbale)

'Doesn't it affect enjoyment? Doesn't the man hit it?' (urban man, Kampala)

'Doesn't it affect the enjoyment of sex? Does the man feel the woman's vaginal walls? You know we are different; some people get their enjoyment on the walls.' (urban woman, Mbale)

Participants expressed a variety of attitudes about the use of spermicides and lubricants. On one hand, some perceived spermicides and lubricants as making the sexual encounter messy. On the other, some felt they can be beneficial because of additional lubrication. For the women who practice family planning without the consent of their partners, SILCS was viewed as not discreet enough, especially since it required addition of another dose of contraceptive jelly before going into a second or third round of sex.

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Some respondents were of the view that the added gel would feel different from the natural vaginal fluids.

Risk of HIV infection

The fact that the diaphragm used with contraceptive gel does not provide dual protection against both pregnancy and HIV infection was discussed as a part of all focus group discussions. The need for additional methods that offer dual protection was recognised by many participants. The male condom, which does provide dual protection, has been heavily promoted for HIV prevention, but its use is still low. Both men and women acknowledge that men have 'refused' to use the condom.

Women were quick to acknowledge that their men were not using condoms.

'Our men do not use condoms...they want us pregnant...Preventing AIDS is not easy for us who are married.' (urban woman, Mbarara)

'My husband threw the box of condoms that I had brought into a pit latrine. He says sex is not natural and he will not use condoms.' (rural woman, Mbarara)

Condoms are perceived as devices that make sex unnatural and should be used only when there are questions of trust. Trust issues are very sensitive in regular or long-term partnerships. Partners would not like to raise any trust questions.

Perspectives of health providers

Although some family planning trainers remembered diaphragms as a safe and effective method and had been trained on their use, few had ever fitted a traditional diaphragm or provided this method. Also, few health workers were aware of the method. However, since the diaphragm is still in family planning guidelines, providers viewed any effort to introduce the SILCS Diaphragm as a 'revitalisation' effort rather than introduction of a new method. Reproductive health planners and some of the providers themselves identified the need to invest in training for family planning providers and health workers to provide accurate information and address biases that could undermine revitalisation of this method.

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'You know people come with fixed ideas about FP methods. Some methods die in the hands of health workers.' (reproductive health planner, Kampala)
'You have to target the providers to deal with their attitudes. Women ask trusted providers in their environment. There is need to get them on board early.' (NGO provider, Kampala)

'You will need to sensitise service providers. It is the service providers that can kill methods.' (private provider, Kampala)

'You will have to train providers. The current providers will not be able to market it. Most of the providers I have come across are not informed. They do not know how to deal with clients, how to counsel clients. For example, there is a lot of method discontinuation because providers do not explain side effects and what to expect.' (researcher, Mbarara)

Several key informant interviews noted that pre-service and in-service provider training for family planning has been weak for over the past ten years. Training will be needed for health care providers on how to counsel about method use. Further, most of the family planning service points visited were run by relatively older providers. These providers may be unable to relate to younger clients and may not adequately market 'new' products like male and female condoms, emergency contraception, and SILCS.

With few side effects or no complicated procedures, providers felt the diaphragm could be handled by family planning or health workers at any level.

Perspectives of policymakers and planners

Policymakers and planners raised three questions of note: 1) funding, 2) concern about nonoxynol-9 (N-9) spermicide, and 3) HIV prevention.

Funding

While there is no policy or guideline that impedes introduction of SILCS, policymakers and planners expressed concern about funding for the device. They stated that family planning in Uganda depends heavily on donor funding which is already stretched. They felt strongly that SILCS would

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need donor support to purchase and introduce. Policymakers and planners suggested a new source of funding for this product would need to be identified.

'Who is going to support this product...can we sustain its supply?...there is need for demonstration models, pictographic teaching aids...' (policymaker/planner, MOH)

Nonoxynol-9 spermicide

Policymakers and planners were aware that N-9 is no longer recommended for use for those at high risk of HIV¹⁶. Clinical trials evaluating N-9 gel for HIV prevention found that commercial sex workers who used the product multiple times daily were at increased risk of HIV rather than being protected from HIV¹⁷. Policymakers and planners stated that an alternative contraceptive gel to N-9 will be needed before SILCS could be introduced, or alternatively, evidence of SILCS effectiveness when used without a contraceptive gel should be provided. They also noted that any new contraceptive gel would need to undergo a review process before it would be accepted into the MOH service guidelines.

HIV prevention

Policymakers and some family planning/reproductive health providers expressed concern that SILCS does not protect from HIV. They felt that recommending a barrier method that does not protect against HIV/AIDS was wrong in a country like Uganda where HIV rates continue to be high.

'There are many people who do not know their HIV sero status...how do we provide a method that does not offer dual protection?' (policymaker/planner, MOH)

They cited recent data¹⁸ that suggest HIV infection rates in Uganda are highest among women in long-term partnerships. They noted that these are the type of couples who might also be potential users of the SILCS.

After further discussion, this group acknowledged that the MOH family planning program provides several methods that do not protect against HIV.

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'Ok it does not prevent HIV/AIDS but what about the Depo, IUD and pills we are providing...that should not prevent the introduction of the method.' (public provider, Mbarara)

Eventually they agreed that lack of dual protection should not be used as a reason for not supporting this method.

Generally, the diaphragm was viewed by all stakeholders interviewed as a method that would increase choice, an opportunity to provide a female-initiated method that would help women who do not want to use or have discontinued use of hormonal methods.

'Do open targeting. Many people have different needs. Different products work for women at different stages of their life cycle.' (NGO planner, Kampala)

'Let us not assume that we know what women out there want. Let us not allow our biases to block means to increase alternatives for women. There are women out there who do not use methods for fear of side effects. This one has no side effects. You never know there will be a good niche for it.' (researcher, Kampala)

'I see a lot of advantages with this diaphragm. First of all women will be able to control it themselves. Women will be happy to be the ones to take care unlike for the male condom.' (NGO provider, Mbarara)

Stakeholders perceived the only requirement for providing the SILCS is a trusted provider with counselling and assurance skills.

Discussion

This assessment found that the single-size SILCS Diaphragm could increase contraceptive choice and reduce the gap of unmet need for family planning in Uganda. Women and men expressed eagerness to try an alternative nonhormonal method of contraception. The assessment identified the types of information and counselling messages that would need to be developed when implementing introduction programs. A high degree of misinformation about family planning

and limited awareness about method side effects and reproductive anatomy were evident even among more educated groups. This finding is also reported by those who found that myths and side effects are significant barriers to use of contraception in Uganda¹⁹. Given this, it is likely that women would need training in sexual health and body awareness as well as how to insert and use SILCS.

Women who experience problems with existing methods, such as side effects from injectables, do not have many alternative options. Uganda's family planning clinics have a limited method mix and experience regular method stockouts. SILCS could be a good back-up method for women if other methods are unavailable.

Family planning is one of the many health practices that operates in multilevel interactions between individuals and social contexts²⁰. Although the SILCS Diaphragm offers discreet protection and can be used by a woman without her partner's knowledge, it perhaps should not always be considered a woman's affair only. Its introduction will benefit from creating awareness among the husbands.

Evidence suggests that regular use of N-9 gel could increase the risk of HIV infection among women¹⁷. The Uganda MOH was, therefore, concerned about use of N-9-based contraceptive gel with the SILCS Diaphragm. The MOH recommended identification of an alternative contraceptive gel or provision of evidence of effectiveness of SILCS without a contraceptive gel. Further research is needed to demonstrate country-level acceptability and optimum service delivery channels, evidence that is crucial for decision-making to promote and introduce SILCS into the family planning method mix. Since the diaphragm is still in the MOH guidelines, the primary policy debate will most likely centre around recommended use of gel. Research on the effectiveness of SILCS used without a contraceptive gel would be extremely valuable.

Conclusion

The diaphragm was viewed by all stakeholders as a method that would increase choice and could serve a role to improve women's reproductive health in Uganda. Like many countries, Uganda's

family planning program is financially stretched, and clear support for the SILCS Diaphragm by end-users will need to be demonstrated before the product will be considered for public-sector introduction.

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Contributions of the authors

Maggie Kilbourne-Brook and Patricia S. Coffey conceived and designed the study; Imelda T. Kyamwanga and Eleanor Turyakira collected and analysed the data; and Patricia S. Coffey prepared the manuscript. All authors mentioned in the article reviewed and approved the manuscript.

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