

Feasibility and appropriateness of introducing the SILCS diaphragm in Uganda

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Acronyms

AIDS	Acquired Immune Deficiency Syndrome
CSO	civil society organization
DHMT	District Health Management Team
DMPA	depot medroxyprogesterone acetate
FGD	focus group discussion
FP	family planning
HIV	human immunodeficiency virus
HMIS	health management information system
IPPF	International Planned Parenthood Federation
IUD	intrauterine device
JMS	Joint Medical Stores
MCH	Maternal and Child Health (MOH cluster)
MOH	Ministry of Health
MSU	Marie Stopes Uganda
NDA	National Drug Authority
NGO	nongovernmental organization
NMS	National Medical Stores
PACE	Programme for Accessible Health Communication and Education
RH	reproductive health
RHU	Reproductive Health Uganda
UDHS	Uganda Demographic and Health Survey
UHMG	Uganda Health Marketing Group
UNFPA	United Nations Population Fund
UPMO	Uganda Private Midwives Organization
USAID	United States Agency for International Development
WHO	World Health Organization

Executive summary

Fertility levels in Uganda have remained high, dropping only slightly from an average of 7.1 children per woman in 1995 to 6.7 children per woman in 2006. Uganda continues to experience high maternal and child morbidity due to frequent childbearing and unsafe abortions. In 2007, maternal and infant mortality ratios were estimated at 435 deaths per 100,000 live births and 76 deaths per 1,000 live births, respectively. Only 15.4 percent of sexually active women aged 15-49 use modern methods of contraception. Low use of contraception is associated with cultural and religious beliefs, myths and misconceptions about family planning (FP) methods, side effects of methods, a limited method mix, and lack of supplies. Current unmet need for family planning is estimated at 41 percent.

During the past decade, PATH, together with its partners, has been working to develop a redesigned diaphragm as an alternative barrier contraceptive. PATH's new prototype, the single-size SILCS diaphragm (SILCS), is seen as an opportunity to increase women's options for contraceptive protection. SILCS is not yet on the market. In preparation for its introduction in developing countries, PATH conducted a rapid assessment of the feasibility and appropriateness of introducing SILCS into the FP method mix in Uganda.

The assessment focused on identifying and evaluating opportunities and potential challenges of introducing SILCS into Uganda's service delivery system. Stakeholders in FP service delivery and use were conveniently selected to participate. In total, 31 focus group discussions and 53 key informant interviews were conducted in the districts of Kampala, Mbale, and Mbarara.

Eagerness to add SILCS to contraceptive options available in Uganda was expressed by potential users, service providers, and members of training institutions. All stakeholders agreed that a significant number of women would use the method, especially those who have discontinued family planning because of side effects and women with unmet need for birth-spacing. Potential users expressed anxiety, mainly around the way the method is used, including the process of insertion and removal, interference with sexual pleasure, and device hygiene and maintenance.

Ministry of Health (MOH) policymakers and planners expressed reservations about funding to support the product and its possible preferred use over the male condom, which is being promoted in the fight against HIV/AIDS. It was recommended that SILCS introduction start in the private not-for-profit sector, as demand would have to be created before the diaphragm would be included in the MOH contraceptive procurement table. Some policymakers requested further research on acceptability, cost, delivery, market penetration, and the role of SILCS in the prevention of sexually transmitted infections.

SILCS, if introduced, would improve Uganda's FP method choice. Diaphragms were first introduced in Uganda in the 1980s; although their success was limited, the process of adding SILCS to the method mix would be one of "revitalization" rather than "introduction." However, Uganda's FP delivery system seems stretched, and there would be need for initial vertical funding to create demand for SILCS. The MOH will only support SILCS if convinced there is demand for it.

Background

Uganda's population is currently estimated at 32 million, and the country's growth rate is one of the highest in the world, at 3.2 percent.¹ Demographically, the population is very young; more than 50 percent of people are younger than 15 years.² Fertility has remained high for some time, with a marked discrepancy between observed and desired fertility. According to the Uganda Demographic and Health Survey (UDHS), the total fertility rate stood at 7.1 live births per woman in 1995 and 6.7 in 2006. Yet the ideal number of children women wanted was 5.3 and 5.0, respectively.^{3,4} This implies that many women are having more children than they would prefer.

Early sexual debut, which prolongs the reproductive period, and low contraceptive use are two reasons for Uganda's high fertility rates. The median age of sexual initiation is 16.6 years, and one in four women is likely to begin childbearing between the ages of 15 and 19 years. Only 15.4 percent of sexually active women aged 15-49 use modern methods of contraception.⁴

Unplanned or mistimed pregnancies are likely to result in significant maternal and infant morbidity due to frequent childbearing and unsafe abortions. Uganda's maternal mortality ratio is estimated to be 435 deaths per 100,000 live births and unsafe abortions contribute to about 13 percent of this mortality.⁵

Low contraceptive use is due to cultural factors, side effects, lack of supplies, and inadequate choice of methods. Although political support for family planning (FP) is viewed as weak,⁶ Uganda's FP managers are interested in increasing FP use through increased access, promotion of choice, and adolescent-friendly services. According to the National Development Plan 2010/11-2014/15,⁷ Uganda's strategy is to improve access to reproductive health (RH) services through health centers and to make FP services affordable and the supply of contraceptives consistent and sustainable.

During the past decade, PATH, together with its partners, has been working to develop a redesigned diaphragm as an alternative option for barrier contraception in developing countries. PATH is a US-based nonprofit organization that strives to "create sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health." This new prototype, the single-size SILCS diaphragm (SILCS), is a barrier contraceptive that can be especially appropriate for women who cannot or do not want to use hormonal contraception or an intrauterine device (IUD). Samples of SILCS are currently being tested for effectiveness in the United States. Acceptability studies in the Dominican Republic, South Africa, and Thailand have shown that women in low-resource settings are able to use SILCS easily. In one study, 19 of 20 women preferred SILCS to the traditional diaphragm.⁸

Barrier contraceptives are not new to Uganda, except they have not gained widespread acceptance. The diaphragm was first introduced into Uganda's FP method mix in the 1980s. Reasons why it did not become popular are not clear. The male condom, a barrier method that provides dual protection, has been heavily promoted solely as an HIV prevention tool. Its use is also low. The latest addition to barrier methods in Uganda is the female condom, which is being marketed among commercial sex workers in pilot districts.

Although SILCS is not yet on the market for use, there is interest in preparing for its introduction into the existing FP method mix in developing countries. In line with PATH's framework of product development, a rapid assessment was conducted to identify and evaluate opportunities and potential challenges of introducing SILCS into the existing service delivery system in Uganda. This study examined available service delivery scenarios/options for SILCS; potential support and barriers in the policy and regulatory pathways; financing, procurement, and delivery mechanisms for FP supplies; and training required for introduction and scale-up of SILCS distribution. Systems and channels for communicating with key target audiences such as FP/RH providers and women about contraceptive products as well as advocacy strategies for the introduction of SILCS were explored.

Methodology

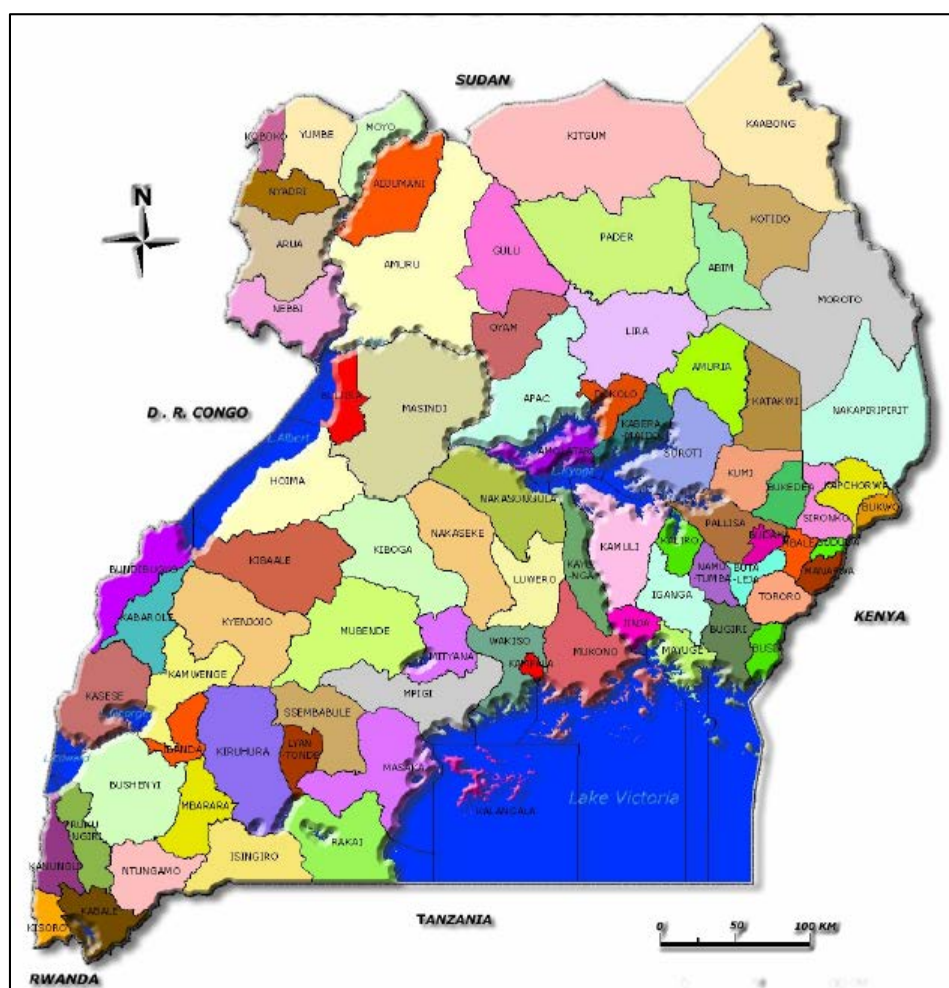
Stakeholders in FP service delivery and use in Uganda were conveniently selected and interviewed. Selected stakeholders included policymakers, government and nongovernmental organization (NGO) planners (at both national and district levels), FP logistics and supply chain managers, FP service providers (at government health facilities, NGO facilities, and commercial outlets), social marketing managers, community leaders, religious leader representatives, donors, and potential SILCS users (men and women). A total of 53 key informant interviews and 31 focus group discussions (FGDs) were conducted in the districts of Kampala, Mbarara, and Mbale, in the period June to August 2010. Participants were selected from both urban and rural areas.

Tools were designed separately for each stakeholder category (see Appendix A). The interview guides focused on collecting information on policy guidelines for FP service delivery and use experiences, financing, and procurement and distribution of FP products, as well as concerns and issues of providers and potential users. In addition, stakeholders were requested to suggest the best marketing strategies and positioning for SILCS. Information was also collected through review of relevant documents, training materials, and survey reports. All data collected from the different sources were transcribed verbatim, categorized, and analyzed according to themes that were derived from objectives of the assessment.

Family planning in Uganda

Uganda is situated in East Africa; its neighbors include Sudan to the north, Kenya to the east, Tanzania and Rwanda to the south, and the Democratic Republic of Congo to the west (see Figure 1 below). More than 80 percent of Uganda's 32 million people live in rural areas; only 12.3 percent of the population is urban.¹ Currently, the country is divided into at least 110 districts, a number that increases frequently.⁹ Table 1 details demographic indicators for Uganda. These indicators, which have remained stagnant for more than a decade, show a young population, high fertility, and high infant and maternal mortality. Contraceptive use, although acknowledged as one single RH strategy that can have impact on population structure, fertility, and maternal and infant mortality, is still low in Uganda.

Figure 1. Uganda districts and neighboring countries.



Source: Uganda Bureau of Statistics, 2010.¹

Table 1. Demographic indicators for Uganda.

Indicator	Value
Total population, 2002	24.4 million ^a
Projected population, 2010	32 million ^b
Population growth rate	3.3 percent ^a
Life expectancy at birth: men, women	50.4 years ^a
Population women 15-49 years	21 percent ^a
Population younger than 15 years	50 percent ^a
Urban population	12.3 percent ^a
Literacy levels: men, women (older than 15 years)	76.8 percent, 57.7 percent ^a
Sources of information: word of mouth, radio, print, television	49.2, 47.8, 0.7, and 0.6 percent ^a
Total fertility rate	6.7 children ^c
Contraceptive prevalence rate: married women	23 percent ^c
Maternal mortality ratio: deaths per 100,000 live births	435 ^c
Infant mortality rate per 1,000 live births	76 ^c
HIV/AIDS prevalence rate	6.4 percent ^d

Sources: ^a Uganda Population and Housing Census 2002; ^b Uganda Bureau of Statistics Statistical Abstract 2010; ^c Uganda Demographic and Health Survey 2006; ^d and ^e Uganda HIV/AIDS Sero-behavioural Survey 2004-2005.¹⁰

Contraceptive use

The contraceptive prevalence rate has remained low; in 2006, only 23 percent of married women reported using contraception (modern methods 18 percent; traditional methods 5 percent). While many women reported ever use of contraception, 58 percent of FP users were likely to discontinue using a method within a year of starting.⁴ As presented in Table 2, discontinuation rates (calculated as a percentage of episodes of contraceptive use discontinued within 12 months of initiation) differed by method. Reasons why women discontinued FP methods included side effects,¹¹ inability to find supplies, and misconceptions and myths,¹² including belief that FP methods interfere with future fertility, cause cancer, or may damage the uterus.¹³

Table 2. Contraceptive discontinuation rates within the first year of use.

Method	Pill	DMPA injection	Male condom	Rhythm method	Withdrawal	Other	All methods
Discontinuation rate (%)	61.4	46.6	71.0	64.5	67.9	54.3	57.8

Source: Uganda Demographic and Health Survey 2006.⁴

Surveys have shown that sometimes women who were not using any means of contraception would have liked to delay the next child or did not want any more children.^{12,14} This unmet need for contraception is high in Uganda, at 41 percent in 2007.⁴ Further, analysis of the 2008 UDHS report showed that unmet need was increasing for all groups of women, and was highest among currently married women, women in rural areas, and those in northern Uganda.¹¹ Most of the unmet need was for birth-spacing, which was higher among women who had three or more children.

In addition to cultural practices that favor large families, women's inability to negotiate use of contraception may explain the high unmet need. According to the 2006 UDHS, 46 percent of married women reported they could not ask their husbands to use a condom and 21 percent could not refuse sex.⁴

Availability of contraceptive methods

Theoretically, modern contraceptive methods are available at both government and private facilities. At the community level, they are available through community volunteers,¹⁵ traditional birth attendants, and small drug shops. However, at most service delivery points, methods are limited to temporary ones (condoms, pills, injectables). When women require a longacting or permanent method, they have to travel longer distances to higher-level health facilities. At lower levels of service delivery, providers are not adequately trained to provide sufficient counseling to handle side effects and there is very limited method choice.¹² It is not clear what women do when they do not find a method of choice at their preferred service delivery point. This is perhaps a significant explanatory factor for the high rates of method discontinuation.

Adolescents and unmarried women experience more challenges in accessing contraception. Societal norms and cultural expectations prohibit sexual activity outside of marriage.¹³ These groups of women

may not be able to seek services openly, as they would be questioned by parents and providers. Contraceptive use by such groups is linked to prostitution.

Although Ministry of Health (MOH) policies, guidelines, and strategic frameworks reflect support for FP service delivery, the country has gone through a period of reduced emphasis on family planning as an important strategy in achieving reproductive health for all (Millennium Development Goal 5). The past ten years have been characterized by a marked reduction in FP projects/programs, little or no in-service provider FP training, regular stockouts of the most used method—depot medroxyprogesterone acetate (DPMA) injection—and lack of young providers in the area of FP service provision. It is only recently that the MOH formed a FP revitalization group of public and private providers, NGOs, donors, and individuals responsible for coordination of FP service delivery activities, with efforts focused on advocacy, marketing, and reviving use of longacting (e.g., IUDs, implants) and permanent methods.¹⁴

Consumer family planning experience, attitudes, and concerns

Family planning experience

Most women have experience using a modern FP method, especially injections and pills, accessing them mainly through the private sector. Injection DPMA is the most prevalent contraceptive product used by women, mainly because it can be used discretely. However, at the time of this assessment, it had been out of stock in most facilities visited for almost three months. FP discontinuation rates seemed substantial, and may be attributed in part to irregular supply of products. Women reported frustration when they did not find their method of choice at a service delivery point, and FP providers concurred.

There are problems of stockouts especially Depo and women have to buy it from the pharmacy or risk becoming pregnant. (Public provider, Mbale)

Another contributor to FP discontinuation may be side effects. There seemed to be a substantial number of women who experienced side effects of hormonal methods of family planning. Of concern: bleeding, changes in menstrual flow, vaginal dryness, weight gain, and being sickly.

Pills affect urine flow and cause dizziness, injections cause changes in menstrual flow, you lose interest in the man, you dry up, it makes you grow fat,... [I]f you have not told him that you are on family planning you get into trouble. (Urban women, Mbarara)

The women are now very desperate...family planning makes them sick...a woman can experience ill health and you get tired...the women get weak, bleed continuously or gain weight...many are on injections...women would like to use family planning but they fear. (Rural men, Mbarara)

Women and providers reported that most men were not supportive of the birth control methods offered because they did not understand their purpose or because they wished to fulfill the cultural obligation of

producing many children. In all female focus group discussions, and most key informant interviews, it was reported that a significant number of women were on family planning without the knowledge of their husbands. This may pose a challenge for women who cannot afford family planning without the support of their husbands. It is also a barrier to methods that cannot be used discretely.

Some men...when you conceive they complain, but when you say let's go to the Family Planning Clinic they say they don't have time. (Urban women, Mbale)

Many women go for family planning stealthily....yet, sometimes there are stockouts at the government health facility and women have to buy family planning methods from the private clinics...some women may not have money. (Rural women, Mbale)

These findings concur with those of Khan et al.,¹¹ which indicated that a substantial proportion of women in Uganda did not use or intend to use contraception in the future due to fear of side effects and opposition from their husband or partner. Despite the poor level of male involvement in family planning, however, some women were determined to control their reproductive life and may benefit from methods with fewer side effects.

We have desperate women who would like to control pregnancy. For a woman who chooses abortion...why not this barrier? Many women do not like hormonal methods because of side effects. (NGO provider, Mbarara)

[W]e are not town women and we are not typical rural women. We are tired of having more children and yet we are still young. (Peri-urban, women, Mbarara)

This pregnancy I have I did not want. I already have six children. I tried the pills which made me sick. I have also tried the injection and had to get off. Now I am pregnant. I do not know what to use next. (Rural women, Mbarara)

Myths around family planning include the belief among many men that modern FP methods cause women to become sickly, birth defects, and low intelligence.

Some women have abnormal heads because of family planning. (Rural men, Mbale)

When we use those things, isn't it the reason we produce children with low intelligence. You should do more studies and come back with more 'science' about this method. (Male FGD, Kampala)

Men and women need reassurance that FP methods are safe and that they will deliver healthy babies after using FP methods for birth-spacing.

Consumer interest in the SILCS diaphragm

During the assessment, participants were shown the SILCS diaphragm and given samples to touch. The process of insertion and use of the diaphragm was explained. Nearly all participants appreciated that

SILCS had an advantage over hormonal methods given its minimal side effects. Participants' perceived benefits of SILCS included: "It has no side effects...you will have saved us." "That thing is good for everybody...it is better for married women." "It increases variety of female-controlled methods." "When there is a wide range of services, women can choose what is good for them."

Women and men expressed eagerness to try SILCS, asking to try the samples: "You are just exciting us without samples for us. When you come back please bring samples so that women can try." Heads of training institutions asked for samples for teaching aids.

Despite eagerness to try SILCS, however, both women and men expressed anxiety about use of the diaphragm. There were concerns related to fitting and maintenance of the device, sexual pleasure, HIV prevention, and cost.

Fitting and maintenance of the diaphragm

Insertion of the diaphragm was perceived as a difficult procedure. It was described as technical and elaborate. Respondents felt there would be need for a trained provider. Others said they would benefit from people who have tried it but would be comfortable doing the first insertion with a trained provider.

Inserting it will need technical expertise to put it properly. You have to put it where there are trained providers. (Urban men, Mbarara)

The cervix is very far, can the finger reach there. It is inconvenient. Insert-remove-insert every time. Isn't it difficult to remove? Can I keep it in for a month? (Urban women, Kampala)

Insertion of 'foreign' objects into the vagina was mentioned as a common practice in the communities visited. Some women inserted herbs for lubrication or to dry the vagina, depending on cultural preference for wet or dry sex. Traditional remedies for improving sexual pleasure included mixing and inserting herbs before sexual activity. Sometimes the herbs were mixed with Vaseline[®] petroleum jelly, or Vaseline[®] alone was smeared inside the vagina.

There was demonstrable lack of knowledge about vaginal anatomy. Both women and men expressed fear that the SILCS diaphragm may disappear into the uterus and possibly kill the woman. Respondents perceived a situation in which the device could be pushed into the uterus during sexual activity. Questions and issues were raised by nearly all respondents, including health care providers, regarding fit of the device in relation to vaginal anatomy.

How do you know it has reached and is holding? Suppose it fits badly. Does the whole of it fit? Will it not hurt the woman? It is hard, can't it cause wounds? It is too big? Are there smaller ones? Can one urinate with it? Can't it disappear inside?

Hygiene

Among elite urban respondents and health workers, rural and less educated women were perceived as unable to maintain and keep the diaphragm clean. It was felt that women in rural areas were unlikely to maintain the diaphragm in a hygienic manner.

Based on our experiences in [antenatal care] and during delivery, the hygiene of typical rural women is questionable. When they come in labor most of them are very dirty, so you tell them to go and bathe, so we are not sure if they can maintain the diaphragm. (Public provider, Mbale)

I would recommend it for the elite women. I do not see the rural women using it. They will not be able to keep it clean. Imagine the water they use and where they will keep it. (RH planner, Kampala)

This negative perception that rural women cannot maintain the diaphragm was disputed during discussions with women in rural areas. Rural women explained that they normally have water in their houses for purposes of cleaning after intercourse. This same water could be used to clean the diaphragm.

A woman who has no water to wash this diaphragm is just dirty. Maybe for those women who work outside home, water may be a challenge. If you are away from home you may have no water to wash. (Peri-urban women, Kampala)

Every woman has a bucket or basin in the bedroom which has water. When we wear herbs we wash otherwise you can smell. Those women who smell, it is not that they have not washed. It is because they have not washed their petties [undergarments]. (Rural women, Mbarara)

Women felt that the recommendation to keep the diaphragm in position six hours post coitus was problematic and may be adhered to only by housewives, who would not be worried about washing themselves and their diaphragm in the mid-morning if they had sex in the morning. Respondents wondered if this period could be shortened. They perceived discomfort, pain, and feelings of being dirty and messy for six hours.

Effect on sexual pleasure

Discussions generated interest around sexual pleasure. Respondents wanted to know the effect of SILCS on sexual pleasure. This concern was raised by both men and women. There was anxiety about interference with a 'natural' feeling, lubrication, and pain.

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 men, Mbale)

Does it affect the sex position? Can it hurt the man? Doesn't the man feel it? Does it affect vaginal lubrication? The contraceptive jelly may make things messy! Do you feel the woman?

On one hand, spermicides and lubricants were perceived as making the sexual encounter messy; on the other, as beneficial because of additional lubrication. For women who practice family planning without the consent of their partners, SILCS was viewed as not discrete enough, especially since it requires addition of another dose of contraceptive gel before engaging in a second or third round of sex. Also, some respondents felt the added gel would feel different from natural vaginal fluids.

HIV prevention

The fact that the diaphragm does not offer dual protection against both pregnancy and HIV infection was pointed out at all interviews. In a country like Uganda, where HIV rates continue to be high, recommending a barrier method that does not protect against HIV was perceived as wrong. Policymakers even perceived a possibility of the diaphragm encouraging the spread of HIV. This could be a potential challenge for SILCS uptake.

There are many people who do not know their HIV sero status. How do we provide a method that does not ensure dual protection? We have just re-launched the female condom and uptake has been slow, why would you like to take us backwards? (Planner, MOH)

However, it was also noted that many women on contraceptives were using methods that do not offer protection against HIV infection, including DPMA, pills, IUDs, and implants.

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)

Although there is a significant level of condom (especially male condom) promotion in the country, condom use continues to be low. Both men and women acknowledged that men have refused to use condoms. 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 and long-term partnerships. Partners do not like to raise any trust questions.

Men do not care about women...no concern. We have even failed to use condoms. I tell you condoms, me I cannot use them. You will not get the same enjoyment. (Rural men, Mbale)

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 women, Mbarara)

Our men do not use condoms. They do not have concern about us. They can make holes in the condom. They want us pregnant so when I have something I can be sure of myself I will be safer. Preventing AIDS is not easy for us who are married. A man will say that he cannot use a condom on you and when you insists it means that you are the one who is promiscuous. (Urban women, Mbarara)

Cost and supply of the contraceptive gel

Although the SILCS diaphragm is a reusable method that can last up to five years, contraceptive gel needs to be refilled much more often. The issue of cost of the gel cut across all potential users, implementers, planners, and policymakers. MOH stakeholders were not sure they would support the gel: “Who will support this product. Can we sustain its supply?” The product was perceived as too expensive for poor women, who have the highest unmet need for family planning. Without gel, women were likely to lubricate using a petroleum-based product.

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. (Women, Mbale University)

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 women, Mbale)

Approaches for introduction of SILCS

Family planning service delivery scenarios

Available service delivery options

Uganda has a wide variety of FP service delivery options. The MOH recognizes FP service provision through public health facilities, private not-for-profit and private for-profit facilities, commercial outlets, village health teams, and community resource persons.¹⁶ The FP methods offered at each outlet depend on the level of training of service providers and grading of the facility. Health facilities are graded as health center II, III, and IV, then district and referral hospitals. It is theoretically possible to provide condoms, pills, and DMPA at all levels of care. IUDs, implants, and female and male sterilization require high-level skilled providers so are available only at the health center IV level or higher. Catholic-funded facilities, as per doctrine, provide only natural family planning (rhythm/moon beads). One Catholic hospital, visited in Kampala, provides information and refers clients.

Public facilities provide FP services free of charge; non-public facilities charge a fee depending on the location of the facility. Contraceptive prices vary depending on method and location of the service provider. Providers in more elite communities charge higher fees. Table 3 shows the range of costs per method. Women reported similar costs; however, added that removal of an IUD or implant could cost an additional shillings 50,000 (US\$25). SILCS was compared to moon beads, as similarly long-lasting and priced (not to exceed shillings 5,000 [US\$2.50]). While some women were willing to pay only shillings 300 (US\$0.15), others were motivated to prevent pregnancy and willing to pay more than shillings 10,000 (US\$5).

Table 3. Family planning method costs.

Method	Cost (range)	
	Uganda shillings	US\$
Male condom (package of three)	300-10,000	0.15-5.00
Female condom (package of three)	600-800	0.30-0.40
Pills (three cycles)	500-2,500	0.25-1.25
Three-month DMPA injection	1000-2,000	0.50-1.00
Implant	20,000	10.00
IUD	6,000-20,000	3.00-10.00
Contraceptive foam tablets	1,000	0.50
Moon beads	3,000-5,000	1.50-2.50
Emergency pill	2,000-5,000	1.00-2.50

Service delivery options for SILCS

Integrating SILCS into the existing service delivery system should not be difficult since the diaphragm traditionally existed in the method mix. As one policymaker put it, “It will not be introduction of a new method but just revitalization.” It was pointed out that there would be no need to integrate it using SILCS as a brand name, since many young people and potential users are unfamiliar with diaphragms.

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 a hormonal method.

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. I have clients who have used the foam tablet, all their reproductive life, and have been able to space and stop childbirth. (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)

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 women, Mbarara)

Since it is a female controlled method, many women who are having problems with FP will use it. All women can use it. There are many young girls worried about getting pregnant. (Rural men, Mbarara)

With no side effects or complicated procedures, the diaphragm can be handled by providers at any level. Stakeholders noted, however, that providers should be trained in counseling and assurance skills. Although women in Mbarara reported purchasing DMPA at drug shops and self-injecting, providers were concerned about commercial outlets (pharmacies, drug shops, and supermarkets) as an entry point for FP

methods. For example, providers at commercial outlets are unlikely to instruct women on use and side effects of DMPA injection. And women who purchase the injection from a drug shop report altering the recommended dosage and injecting based on their bleeding patterns.

These days I buy and give myself the injection. If I take an injection today and my periods disappear, I will not get another one till my periods return. If you get too many of these injections you may get problems. (Women, Mbarara)

Integrating SILCS through NGO partners was suggested, namely Reproductive Health Uganda (RHU), Programme for Accessible Health Communication and Education (PACE), and Marie Stopes Uganda (MSU). These partners have a network of providers throughout the country who provide FP services for a fee, and run vertical activities to ensure more reliable supply and provider skills development. However, the community perceived them as providers for elite women. Women in peri-urban and more rural communities preferred obtaining FP supplies from a public health facility because they are less expensive, stating that “private providers will over charge us.” This may be because public facilities continue to provide services free of charge.

Provider attitudes, skills, and training needs

Many of the providers visited, even planners (for RH services), knew of the traditional diaphragm, had been trained on its use, and yet had not initiated clients on it. Some expressed strong views regarding its value as a contraceptive and its potential to spread infection.

I do not know who would use it, maybe young people. Even then for the young ones we have to consider protection against HIV/AIDS. Older people like you and me will choose better methods where they are sure of protection. Like the IUD, Injection and Norplant. Imagine the women in the community, what facilities do they have to keep it clean, the dirty water and lack of soap will encourage introduction of infection related to hygiene. Think of vaginal warts, for example. (RH trainer, Kampala)

There will be need to invest in provider training and supportive supervision. Planners and providers themselves see provider attitudes and biases as a barrier to revitalization of the diaphragm. The need to convince them to advocate for the method was pointed out.

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 RH provider, Kampala)

You know people come with fixed ideas about FP methods, some methods die in the hands of health workers. The health workers are sometimes rigid, have bias. Also many trainers are old women with biases against some methods and do not promote them. (RH planner, Kampala)

Weak pre-service and in-service provider training in family planning as a whole was noted. In the last ten years, very few providers have been equipped with FP skills (method use, counseling, and handling of side effects).

The last time we had orientation in family planning was 1997. Nurses used to get 2 to 3 weeks training in family planning methods and counseling. These training activities are no more. (Provider, Mbarara)

Introduce this in training schools. When introduction is done in training schools, knowledge dissemination will be much faster. When you teach only those who are already working, that is the end. (Women trainees, Mbale)

Most FP 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.

Contraceptive procurement, supply, and financing

Although shortages and stockouts continue to exist, FP supplies are reported to have significant donor attention; planners estimate that the United Nations Population Fund (UNFPA) and United States Agency for International Development (USAID) contribute 95 percent toward FP supplies. Procurement of contraceptives is based on multi-stakeholder forecasting that is done centrally. Forecasting is based on volume of services provided historically. If a product has not been used before, there is no chance it will be included in contraceptive procurement.

Medical supplies, including contraceptives, are normally distributed through the National Medical Stores (NMS), which charges a handling fee equal to 10 percent of the total consignment. Direct distribution to health facilities is done using a push system. All funds for drugs and supplies, including contraceptives, are allocated to NMS. Any product that has not been supplied or purchased by NMS will not be available at public facilities. Public facilities do not have the budget to purchase supplies from elsewhere. Private-sector facilities had been obtaining supplies from NMS, but a change in policy now directs them to get their supplies from district authorities; however, providers interviewed were not sure the new system would work. Information from District health Management Teams (DHMTs) and visits to clinics in Mbarara and Mbale revealed that NGO clinics were experiencing stockouts of pills and DMPA.

We have been getting our supplies through NMS. Our logistics officer makes orders and monitors stock. However, there has been a change in policy and in the new policy our clinics all over the country should get supplies through the district. I think it is ok, if the policy can work. (NGO Stakeholder, Kampala)

The Catholic-operated alternative, Joint Medical Stores (JMS), which provides private providers with drugs and other supplies, does not handle contraceptives. Sometimes NGOs and private facilities obtain

supplies directly from their parent organizations (e.g., International Planned Parenthood Federation/IPPF) or purchase from importing pharmacies.

Contraceptive stockouts affect almost all facilities, public and private. Reasons given included insufficient deliveries to NMS, irregular deliveries to health facilities, and providers issuing incomplete orders. Sometimes supplies, especially condoms, were reported to be stuck at higher-level facilities.

Procurement and supply of SILCS

At the start, the MOH is unlikely to procure the SILCS diaphragm, as currently there is no demand for it at the health facility level. Stakeholders said demand will have to be generated first. In all facilities visited (public and private), not even a sample of the traditional diaphragm was found. Providers did not remember the last time they had seen one. To create satisfied users and demand, perhaps an initial donation will have to be placed with NMS for supply to public facilities. This could be augmented by vertical distribution to training institutions, pilot project sites, and NGOs (e.g., PACE, RHU, MSU). Once there is demand, local importers (usually wholesale pharmacies) may make SILCS available in the private market.

We should first provide this diaphragm free of charge, so that people can first appreciate it, then when they know the goodness of it we attach a price. (Community health workers, Mbale)

Additional resources for SILCS introduction

An appropriate contraceptive gel

RH stakeholders will not support the use of nonoxynol-9 in Uganda, which was shown in a controlled trial in South Africa to be associated with an increased risk of HIV infection among microbicide users.¹⁷ There is need, therefore, for an alternative to contraceptive gel and/or evidence of contraceptive effectiveness of SILCS without a spermicide. Further, the gel will need to be added to the MOH service guidelines.

Some type of lubricant is perceived as necessary to help in the insertion of the diaphragm. There are cultural practices where women use herbs to enhance vaginal lubrication, especially in central and western Uganda; in northern Uganda, the vagina is dried to enhance pleasure for the man. Use of the lubricant may not be appreciated universally.

Lubricant products are not available in pharmacies in Uganda. One type of K-Y[®] jelly is considered a medical product and is used in clinics. This lubricant was described by women as very ‘cold.’ A “warm” lubricant, which would make sex more appealing, would be preferable. Further, the gel will need to remain in supply to be considered, in order to ensure availability for use with SILCS. Women recommended provision of the gel in smaller, less expensive quantities. Women considered use of Vaseline[®], which is not recommended.

Monitoring and evaluation

Like other FP methods, SILCS would be monitored within the existing health management information system (HMIS). This would not happen immediately, as existing forms used to monitor service delivery do not include diaphragms. Forms are revised every five years. Monitoring would require initial use of a parallel mechanism to track supplies and use.

Policy and regulatory environment

Family planning policies and guidelines

There is no policy or guideline that would impede provision of SILCS as a contraceptive in Uganda. The diaphragm is included in the MOH FP guidelines as a method of choice. Approval of SILCS would fall under the MOH Maternal and Child Health (MCH) Cluster, a policy arm chaired by the commissioner of community health.

To pilot this diaphragm you have to be endorsed by the MCH Cluster or MOH top management. The MCH Cluster is a policy structure. If the product is not yet approved by [the National Drug Authority], the MCH Cluster may assist with clearance. (RH Planner. Kampala)

The diaphragm was recently removed from MOH FP flipcharts and HMIS Form 5. However, most facilities still use the old training materials; among the public and private facilities visited, the new chart was found only in Kampala facilities. The MOH has been distributing a FP handbook¹⁸ to providers and training institutions, which includes the diaphragm as a FP method.

Level of support from policymakers and planners

Policymakers and planners were concerned about the risk of HIV infection among couples who choose the diaphragm as a FP method. Stakeholders believed that HIV infection rates are increasing among couples in long-term partnerships, who may be potential users of SILCS.

We are now promoting condoms (male and female) for HIV prevention... now this diaphragm for people who are only concerned about contraception. Diaphragm uptake will be a problem. In my opinion we would rather put more money in the female condom than the diaphragm. (HIV prevention stakeholder)

However, providers and some women acknowledged condom use remains low despite knowledge about HIV. Many women, even young people, continue to use other methods (e.g., pills, DPMA, IUDs, and implants), which do not provide HIV protection. Condom use is said to be very low in stable relationships because it raises trust issues. Condoms continue to be used mainly in casual relationships.

While many programs targeting young people emphasize HIV prevention, many stakeholders feared use of SILCS by this group, which may be more interested in preventing pregnancy than HIV. Planners mentioned potential objection from advocates for youth, like First Lady Janet Museveni and the World Health Organization (WHO).

I see this method is not for young girls not even University students. You know that WHO and the First Lady are against promoting family planning methods among young people, even the condom. They are emphasizing abstinence even though promoting abstinence is a big challenge. You should focus on married women in stable monogamous relationships. Do not market to young people/youth due to the HIV risk. Dual protection is a must for the youth! (Marketing stakeholder, Kampala)

Stakeholders also voiced funding concerns. Family planning is heavily dependent on donor funding. The device will need donor support for purchase and introduction.

Who is going to support this product? Can we sustain its supply? There is need for demonstration models, pictographic teaching aids.... (Policymaker, MOH)

MOH stakeholders were likely to support SILCS if there were significant demand. They requested more evidence of local support of the product in the form of further research on acceptability, cost of the product and product delivery, market penetration, and the role of the diaphragm in the prevention of sexually transmitted infections.

Despite these concerns, there is growing support for FP programs in Uganda, and recognition of their role in achieving the Millennium Development Goals. Policymakers are more aware of the need to consider the total RH package, not just HIV/AIDS. Current efforts of the MOH FP revitalization group include improving supplies and skills to revitalize longacting FP methods: the IUD and hormonal implant. This group may be a good entry point, at the policy level, to introduce SILCS.

Regulatory requirements

Uganda's National Drug Authority (NDA) is the regulatory body for importation and use of medicines and medical devices. The certification and registration process for a new product like SILCS requires a certificate of conformity regulated by the Food and Drug Administration, a certificate of Good Manufacturing Practice, and sometimes a visit to the manufacturer. NDA stakeholders advised that SILCS could be introduced first as an investigational product and tested in Uganda so that it is evaluated using local protocol. Such a trial could bridge studies being conducted in the United States and assess effectiveness, adherence, acceptability, and other relevant issues.

Stakeholder analysis

Table 4 lists different stakeholders identified and categorized as beneficiaries, actors, supporters, opponents, and critics. This list is not exhaustive. SILCS was perceived as a diaphragm that would benefit all women who are sexually active.

Table 4. Stakeholders for SILCS diaphragm introduction in Uganda.

Groups	Community	Government sector	NGOs	Commercial sector	International organizations
Beneficiaries	All married women, sexually active single women				
Actors	Women leaders, Mothers' Union, <i>senga</i> (paternal aunts)	Service providers, health facilities, training institutions (medical and nursing)	Service providers, health facilities, training institutions (medical and nursing)	Pharmacies, drug shops, supermarkets, training institutions (medical and nursing)	
Supporting institutions	Researchers, media, civil society organizations (CSOs; e.g., Association of Obstetricians and Gynaecologists of Uganda, Uganda Private Midwives Organization/ UPMO)	MOH, MCH Cluster, FP revitalization group, Population Secretariat, NMS, National Drug Authority, DHMTs	RH projects (e.g., RHU, STRIDES for Family Health, EngenderHealth), marketing groups (e.g., Uganda Health Marketing Group/ UHMG, PACE, MSU)		USAID, UNFPA, IPPF, WHO
Opponents/ critics	Women older than 40 years, men, politicians		Religious groups (Catholic, Muslim), JMS		
Competitors	Condom promoters	HIV prevention projects	HIV prevention projects		

Older women in the community as well as older providers were critical of the method. Other possible opposition will likely come from individuals and organizations committed to prevention of HIV. The HIV epidemic is generalized in Uganda, and there are marked efforts to promote female and male condoms. HIV prevention stakeholders perceive the diaphragm as a method that will reduce condom use.

Table 5 places the stakeholders on a power/interest (influence) grid. MOH planners, donors, public providers, HIV/AIDS stakeholders, and religious groups may have reservations about revitalization of the diaphragm. Stakeholders interviewed had concerns about promoting a method that does not prevent HIV; i.e., promoting a diaphragm at a time when they are trying to market condoms to prevent HIV and revitalize more permanent methods. Some perceived the process as taking the country backward.

Table 5. Power/interest grid for stakeholders in Table 4, above.

High			MOH				
			UNFPA USAID	FP revitalization group			
		Public providers	WHO	DHMTs	Population Secretariat		
		Politicians	HIV prevention groups	Religious groups	RHU, UPMO	Media, CSOs	Researchers, training institutions
Power		Men	Women older than 40		UHMG, MSU	PACE	Women leaders
						Mothers' Union	
Low					Senga		
							Young women
		Low		Interest		High	

These stakeholders require more information and convincing on the value of the diaphragm. On the other hand, the FP revitalization group, composed of private and public stakeholders, perceived opportunity and potential for the diaphragm. Others who showed potential for positive support included researchers, training institutions, NGO providers, and the Population Secretariat. The Population Secretariat, an independent policymaking body within Uganda's Ministry of Planning, advocates for and promotes increased choice in FP service delivery. Civil society organizations, like the Mothers' Union and *senga* (paternal aunts), may have no power to affect integration of the SILCs diaphragm but may be good entry points as advocates for the diaphragm as a method to increase faithfulness among married women. Traditionally, *senga* were responsible for teaching young girls about sex and sexuality; however, this tradition is dying out. Women who call themselves *senga* teach classes for girls and women about sex.

Strategies for education and communication

Primary stakeholders

Responses regarding the most appropriate target beneficiary for SILCS were mixed. Young married or cohabiting women, particularly elite women, with a need for birth-spacing, and women with three or four children, were frequently proposed as early adopters for the SILCS diaphragm.

Target literate women, target young cooperate women, bankers, UN staff. I see rural women having problems. For older women we are marketing more permanent methods like the IUD and implant. (Private provider, Mbarara)

It will be for women who have failed on the other methods especially the injection. Since it has a failure rate of 20 percent, it is for women who want to space not those who want to stop. (Public provider, Kampala)

Although the need for family planning is greatest among rural women, who are served by the public sector, it will be very difficult to start with the rural public sector. Planners emphasized the need for demand creation before a free product is supplied to public health facilities. Private-sector clients, on the other hand, are able to pay for the service.

Stakeholders mentioned that SILCS would be attractive to young girls who are worried about pregnancy. However, they perceived marketing this device to young people as politically sensitive and perhaps unethical because of the associated HIV risk.

A steady couple who know their sero-status and are HIV free. Sex workers and the young age group like students? It may be tricky for those who are single. (Planner, Mbarara)

I see it being use by young couples who have had a few children and for old ones at the end of childbearing. People involved in casual sex and in unstable relationships will prefer a method for double protection. (Male policymaker, Kampala)

One idea was to target all women of reproductive age: “Let [all women] try it and make a choice.” The need to be careful about targeting a particular user group was acknowledged. If a method is targeted for a particular group at the start, it may be difficult to expand the market to different women later on.

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

Secondary stakeholders (implementers)

Reaching out to providers, both public and private (doctors, midwives, nurses, community workers), and the need to gain their confidence, was perceived as critical. Even if women get the diaphragm from a pharmacy, they will need a reference person in case of questions. Service providers were also seen as the ones that would market the method.

A method will work if the local service providers promote/speak for it. Midwives have to be given skills. (Marketing stakeholder, Kampala)

You have to target providers and demystify this method. (NGO RH planner, Kampala)

Providers at pharmacies could also be involved in the initial orientation and training activities, as pharmacies were perceived as important points for marketing and distribution of the device.

Key stakeholders

Key stakeholders frequently mentioned as likely to be influential and supportive of the revitalization of the diaphragm were women leaders, women's groups, marketing groups, training institutions, and donors. Women leaders and women's groups were viewed as a means to access women. Women suggested mobilization through their *nabakyala* (local female leader). With their *nabakyala*, they would be able to try out the device and share experiences.

Training schools were recommended since they provide opportunities for quick mass demonstration of the use of the product to future and current health workers. Students were also mentioned as potential users of SILCS. Heads of all training schools visited were very positive and interested in samples for demonstration.

I hope you are leaving some here....consider giving samples to teaching schools. [S]tudents are interested in FP methods, some are using the methods, and they are keen to listen when you talk about family planning. (Academic researcher, Kampala)

Education and sensitization messages

Findings of the assessment revealed a high degree of misinformation about family planning, even among educated groups, with the exception of those trained in obstetrics and gynecology. There were myths and misconceptions about methods and limited awareness about method side effects and vaginal anatomy. Education and sensitization will be required to deal with this gap. Misconceptions about diaphragm use included the belief of some potential users and service providers that using a diaphragm and spermicide can cause cervical cancer.

FP introduction in the country was wrongly done. They did not prepare the population....so the people conceived distorted messages. By the time they came to correct the messages it was too late. The people need to be prepared. Once people have misconceptions, it is finished. (NGO planner, Mbale)

The need for sensitization was underscored by women community leaders.

Indeed cultural issues will always be there...even there are religious issues...but you just have to persistently sensitize the people. (Rural women, Mbale)

Women need information on vaginal anatomy and demonstrations on insertion of the device. Messages need to be developed to address anxiety about discomfort while wearing it, keeping it in place for six hours after contact, cleaning, storage, and infection prevention. It was suggested that promotional

information should focus on the value and benefits of the method, clarification of method use, and application of appropriate contraceptive gels or vaginal lubricants.

The diaphragm, although still in the policy guidelines of the MOH, has been removed from FP flipcharts and other training materials. Relevant materials will have to be developed. The usual print materials were perceived as inadequate and video demonstrations were recommended. Cartoon animations showing how the product is inserted and removed and how it fits in a woman's body were considered appropriate.

Communication channels

Clearly, there is need to have a pool of satisfied users who can market the product through woman-to-woman communication. This could help build women's confidence so they use the device correctly.

We have learnt that big campaigns using mass media (TV, radio, billboards) does not work. We are using private midwives association, private providers and community messages. We depend on mouth to mouth marketing. We use satisfied users, community forum discussions and women group discussions. This is slow and expensive but since FP is a household issue, women have to hear it from their peers, someone who has used the method and a local provider they trust. (NGO RH planner)

Changing the mindset of the people is so difficult. You will need a lot of interpersonal social communication to change their behaviors. You need intensive communication. You have to create demand for the product. Research should inform the communication strategy/messages. (Marketing stakeholder, Kampala)

Stakeholders recommended peer-to-peer education through *nabakyalas* and the Mothers' Union as an important model for the SILCS product. The use of brochures alone would not be enough. During activities of the groups (above), there would be opportunity to demonstrate insertion and to sensitize women on family planning. Specifically for single, sexually active women, income generation groups were identified.

There is a group of single women who are sexually active. The community does not expect them to use FP. These cannot be accessed through mother's union. You could access them through income generating groups or use of voucher system. People do not have to know the product they are accessing. (Marketing stakeholder, Kampala)

Policymakers and planners also felt there was need to bring more formal providers on board. Nurses, midwives, and obstetricians/gynecologists need sensitization to believe in the method and advocate for it; therefore, market it. Some stakeholders advised that promotion of SILCS could be approached with a comprehensive strategy. Supplies could be made available, providers trained, and the media used to tell users where to find the product. This recommendation could work for the more elite women.

You have to approach it systematically. Provide supplies at a few outlets to create demand. Use the media to tell women where to find it. Then later it can even be put elsewhere even at commercial outlets. (NGO provider, Mbarara)

Further awareness creation was recommended at forums such as general meetings of obstetricians and gynecologists and research dissemination conferences.

Advocacy strategies

Advocacy for family planning must continue and there is need to get more people involved. This should include both family planning and reproductive health. There is need for increased funding for reproductive health beyond HIV/AIDS. For SILCS, the current catch word may be “revitalization,” not “introduction.” Emphasis should focus on benefits of the method, promoting faithfulness in long-term partnerships, giving women choices, and male involvement. Specifically, there is need to raise awareness among policymakers about the safety and effectiveness of diaphragms in low-resource settings.

Highlight advantages of the method

Promote the method as nonhormonal, with no side effects. This will be attractive to women who have had challenges with hormonal methods, a substantial population. SILCS could be perceived as a spacing method, which would help women space their children without affecting return of fertility. For those stakeholders who are concerned about HIV prevention in marriage, SILCS could be a tool to help the Mothers’ Union and Catholic associations promote faithfulness by marketing it alongside the ‘be faithful’ campaign.

Empower women to take responsibility for their reproductive health

Through this strategy, women could take personal responsibility to make choices without depending on their spouse. SILCS, a female-initiated method, could be marketed as something every woman must own. Every woman could use it any time she chooses, or as a backup method (e.g., alongside moon beads, or during stockouts of her primary method). Stakeholders agreed that at every stage of the reproductive cycle, there is a time when a woman is at risk and needs something to fall back on.

Increase male participation in family planning

Male involvement and support is key for the successful introduction of SILCS. Women were concerned that the method was not discrete enough and would require discussion with their partners. Fortunately, some men already recognize the need to plan their families, a few men support their wives in family planning, and there are men who do not want to have many children and could mobilize other men. Some men and women recommended that FP sensitizations should be moved out of health facilities to community meetings, where men and women would hear the same messages. This would mean that women would not have to explain to their partners when they need a method.

You could come and teach us in the community. We have men who are willing to listen. We now see a lot of improvement in the community. There are those who are still rigid but slowly they will learn.
(Rural men, Mbarara)

Come to our villages and invite our men at the same time with us. The men do not accept to come to the health centre. Mother's union teaches men and women together, about marriage and sex. What about something like this? (Rural women, Mbarara)

Identify potential champions

The Mothers' Union and *senga* were suggested as potential champions. *Senga* were, however, recommended with some caution, as some *senga* are only out to make money.

Other champions suggested included individuals in training and marketing institutions, who are already involved in promotion of reproductive health. These advocates could be involved from the start.

Community leaders/people of influence in the community should be involved. You need a lot of sensitization. You should have champions who will market the product. You need to bring out clearly the strengths of the diaphragm over other methods. (NGO planner, Kampala)

Conclusions and the way forward

All sexually active women of reproductive age need a contraceptive method. Both men and women are interested in an effective contraceptive method without side effects that can be applied with ease without interfering with their sexual pleasure. The SILCS diaphragm has potential to meet these needs. Further, these users need a reference point, a trained service provider whom they trust in case there is a problem or they have questions.

Users will need to be sensitized about insertion of SILCS. Education sessions with demonstrations would help women better understand their vaginal anatomy. Messages should be clear about the risk of HIV when using SILCS and overall care to prevent other sexually transmitted infections.

Experience with family planning in Uganda shows that stockouts of supplies are not rare; supply of SILCS could face a similar challenge. The FP program is supported primarily by donors; therefore, the government may not add a new product to the contraceptive method mix without donor support when it cannot support existing methods. Most FP methods are provided free of charge at government health facilities, and it is safe to presume clients will want to receive SILCS free of charge as well. Policymakers and planners will insist that demand be created first, before the product is supplied to government facilities through the usual channels. However, there are women who are independent and would be able to purchase the product from a private provider.

SILCS could be introduced slowly, through training institutions, pilot projects, or a product for use through RH NGOs and later the commercial sector. The public sector is likely to be brought on board only after demand has been created.

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Appendix A. Data collection tools

ASSESSMENT OF THE FEASIBILITY AND APPROPRIATENESS OF INTRODUCING SILCS DIAPHRAGM

INTRODUCTORY REMARKS

We/I am here on behalf of PATH, an international non-profit organization whose mission is to improve the health of people by advancing technologies, strengthening systems, and encouraging healthy behaviors. PATH together with its partners have worked for more than 15 years to develop a new family planning method for women. The SILCS diaphragm is a new single-size device designed to improve women's options for contraceptive protection. This is a barrier contraceptive method that can be especially appropriate for women who cannot or do not want hormonal contraception or IUDs.

Traditional contraceptive diaphragms have been used for about 100 years. They used to be quite popular in many countries. Traditional diaphragms come in several sizes, and require a trained health care provider to assess the correct size for each woman. This has limited the use and availability of diaphragms, especially in low-resource countries.

PATH and their partners developed the SILCS device so a single size fits almost all women. It has been designed to be easy to use and comfortable for both partners. PATH and its partners tested the SILCS diaphragm in clinical studies in several countries to ensure it is safe. Groups of women from several countries worked with PATH to ensure the design is easy to use and acceptable. A study is being completed in the United States to determine the contraceptive efficacy. The SILCS diaphragm is not yet on the market for use. PATH anticipates this new device will be approved for use in developed countries first (US and Europe), since diaphragms are still part of the family planning program in some of those countries.

Even though SILCS may not be available in low resource countries for several years, we want to start now to understand issues and attitudes that will help us determine whether SILCS may be acceptable and help improve women's reproductive health in a country like Uganda.

We would like to look at Uganda's family planning program and identify opportunities and challenges for future introduction. With us we have samples of this diaphragm (take a few moments to introduce the SILCS diaphragm and talk about the features).

During the next few months, we will conduct interviews and focus group discussions to the assess feasibility and acceptability in Uganda for this new method. This will help create a plan to prepare for future introduction of SILCS.

You have been identified as a key resource person in relation to the family planning program in this country. The objective of this visit is to discuss family planning service delivery in Uganda and preparations needed before introduction of a new family planning method.

DESK REVIEW GUIDE: FP Situation analysis

The aim is to document the current status of family planning service delivery and use.

1. Background information on Uganda. Demographics, social economic status, donor trends in relation to RH
2. FP knowledge & awareness, FP level of use, unmet need, supports and barriers to FP use
3. FP Stakeholder Analysis. Identification of important key players in family planning.
 - a. Policy makers
 - b. Donors
 - c. Politicians –pro / against
 - d. Religious leaders
 - e. Key ministries
 - f. NGOs promoting reproductive health programmes
 - g. Service providers
 - h. Information, communication and marketing groups
 - i. Users/consumers
4. FP service methods and delivery options
 - a. Available methods, source of methods, supplies – volume, regularity of supplies.
Are spermicide products available in Uganda?
 - b. Integration and coordination of FP services within the existing health care system
5. Policy environment
 - a. Level of political support and involvement in FP service delivery
 - b. Policies and guidelines affecting FP service delivery and FP use
 - c. Policies relevant to FP product introduction
6. Regulatory pathways
 - a. Procedures and processes that guide introduction and registration of a new medical product/ device in the country
7. Supply chain and logistics system
 - a. Procurement options and experiences in relation to FP products
 - b. Service delivery supplies for different options – amount of supplies & source of supplies
 - c. Supply chain management
8. Ongoing FP related training activities
 - a. Training of service providers – pre-service and in-service
 - b. Consumer education and sensitisation
9. Communication and advocacy
 - a. Existing FP communication strategies (implementers, channels, target groups, source of funding)
10. Monitoring and evaluation
 - a. Monitoring of FP service delivery through the health management information system

A. KI GUIDE FOR POLICY MAKERS/(FP RH)PLANNERS

The objective is to understand reproductive health policymakers and planners' perspective regarding potential future introduction of a new contraceptive method (pros/cons/opportunities/challenges). What can we learn from past experience to influence future introduction of SILCS.

1. FP service delivery scenarios (public sector, private-not-for-profit sector, social marketing, commercial sector)
 - a. Key stakeholders(Donors, promoters, suppliers, marketing groups, providers)
 - b. Different FP service delivery options in our health care system? (Health units, clinics, pharmacies, shops, hotels, workplaces etc.)
 - c. How these options for FP service delivery performed, especially for barrier methods like the male & female condom
 - d. Opportunities, challenges/weakness/gaps present for each scenario
 - e. Service delivery scenarios would be most appropriate for introduction of a new female initiated barrier method, SILCS
 - f. Identification of programs and areas where SILCS could be introduced.
2. Existing policies and guidelines concerning FP service delivery
 - a. Policies are relevant to introduction & scale up of SILCS
 - b. Need for policy amendment before introduction of SILCS
 - c. Identification of diaphragms identified in FP guidelines
 - d. Inclusion of diaphragms in training documents/standards of care. What it takes to include them
 - e. In addition to being listed in policies and guidelines, what else is needed to bring a new contraceptive into the FP program? (what is the process/who are the key decision makers)
 - f. Existence of a committee that works on introduction of FP products
3. Feasibility of integration of SILCS into the existing FP service delivery system
 - a. What is the most recent product added to the FP mix? What is your experience with product introduction?
 - b. What key changes/additions should be made to the existing health delivery system/infrastructure in preparation for SILCS?
 - c. What are the training needs and resource requirements (for service providers, health educators, consumers)?
 - d. Monitoring and evaluation tools: ease of integration or challenges of integrating SILCS M&E into current HMIS?
 - e. What impact will SILCS distribution and use have on the existing FP service delivery system?
4. Communication and advocacy needs: How have different FP methods been promoted?
 - a. What are the key information needs and concerns? (pros/cons)
5. Stakeholder interest/eagerness to participate
 - a. Which stakeholders are likely to quickly embrace SILCS?
 - b. Where is resistance likely to be met?

6. Consumer issues/concerns

- a. What have been the common concerns of consumers towards; new FP methods? Barrier methods? Female initiated methods?
- b. Who are the likely early adapters of SILCS?
- c. Are there other products that women in Uganda insert in the vagina? Will this be comfortable/familiar or a challenge?
- d. Women need to have a basic understanding of their anatomy (and cervix and pubic bone) in order to insert and confirm position of SILCS. What is the level of awareness of vaginal anatomy? How can this type of body awareness teaching be incorporated into planning for preparedness?
- e. Are there any cultural inhibitions or prohibitions that would affect acceptability of the SILCS?
- f. How can we include men in the promotion of SILCS?

7. Personal questions and concerns about SILCS

- i. Would you kindly share your opinion towards this new product: Do you have any questions or concerns which you feel should be addressed before introduction of SILCS?
- ii. Would you recommend the SILCS Diaphragm to a couple you know is in need of a FP method or would you and your partner use it?

B. REGULATORY AUTHORITY (NDA) GUIDE

The objective is to understand the regulatory pathways for introduction of a new medical device (SILCS).

1. What procedures and processes have to be followed when introducing a new FP method?
2. Is there an existing committee that works on introduction of FP products?
3. Does Uganda look more favorably on CE marking of FDA approval?
4. Would you kindly share your opinion towards this new product: Do you have any questions or concerns which you feel should be addressed before introduction of SILCS?
5. Would you recommend the SILCS Diaphragm to a couple you know is in need of a FP method or would you and your partner use it?

C. LOGISTIC AND SUPPLY CHAIN (MOH Logistics Unit, NMS,JMS) GUIDE

The objective is to appreciate service delivery logistics and supply chain management for family planning products.

1. What is the current structure of the supply chain for FP methods?
2. Costs of supply, cost for consumers under each service delivery scenario (gov't/NGO health facilities, private clinics, pharmacies etc.). Does the cost of FP products vary based on where services are delivered? What is included in that “cost” Is it just the product? Or program costs, promotion, counseling, etc?
3. Current FP Supply chain management- what are the challenges or issues?
4. In your opinion, which service delivery options would be most appropriate for the introduction of the SILCS Diaphragm?
5. What other additional logistics are required for the introduction of SILCS?
6. Would you kindly share your opinion towards this new product: Do you have any questions or concerns which you feel should be addressed before introduction of SILCS?
7. Would you recommend the SILCS Diaphragm to a couple you know is in need of a FP method or would you and your partner use it?

D. MARKETING GROUPS GUIDE

The objective is to assess promotion channels, messages and appropriate target groups for the introduction of a new female initiated contraceptive (SILCS).

1. Experience in the promotion of family planning products
 - a. Have you been involved in the introduction of a new family planning product? What is your experience with new product promotion?
 - b. Who are major stakeholders in FP social marketing/promotion?
 - c. Have there been any memorable advertising or promotion campaigns that we can learn from?
 - d. What can we learn from past promotions? What worked well? What didn't work at all?
2. Communication and advocacy needs/strategy: How have different FP methods been promoted?
 - a. Who is involved in FP information/messages communication/education?
 - b. What kind of information is disseminated? What are the key information needs and concerns? (pros/cons)
 - c. Which communication media are popular?
 - d. Who are the common target audiences for FP promotion?
 - e. Which communication strategies will be relevant for SILCS? Information dissemination channels? Target audiences?
 - f. Who are community stakeholders who may influence decision making and norms around sexuality, reproductive health, and family planning?
 - g. Any possibility to find friendly reception from religious leaders (non-catholic), or other key community influencers?
3. Consumer issues/concerns
 - a. What have been the common concerns of consumers towards; new FP methods? Barrier methods? Female initiated methods?
 - b. Who are the likely early adapters of SILCS?
 - c. Likely level of participation/ enthusiasm of different groups. Which stakeholders are likely to quickly embrace SILCS?
 - d. Where is resistance likely to be met?
 - e. How do we get men involved in promotion and use of female initiated FP methods? What is the likely reception/reaction from men/spouses?
 - f. Are there other products that women in Uganda insert in the vagina? Will this be comfortable/familiar or a challenge?
 - g. Women need to have a basic understanding of vagina (and cervix and pubic bone) in order to insert and confirm position of SILCS. What is the level of awareness of vaginal anatomy? How can this type of body awareness teaching be incorporated into planning for preparedness?
 - h. Are there any cultural inhibitions or prohibitions that would affect acceptability of the SILCS?
4. Personal questions and concerns about SILCS
 - a. Would you kindly share your opinion towards this new product: Do you have any questions or concerns which you feel should be addressed before introduction of SILCS?

- b. Would you recommend the SILCS diaphragm to a couple you know is in need of a FP method or would you and your partner use it?

E. GUIDE FOR SERVICE PROVIDERS

The objective is to understand service providers' perspective about the SILCS diaphragm. Identify types of training and other resources that would be needed to incorporate SILCS into existing FP service delivery. Assess strategies for service delivery channels and pros/cons of these. Identify opportunities and challenges for future introduction of SILCS.

1. Experience with current FP services delivery
 - a. Available family planning methods.
 - b. Source of family planning supplies
 - c. Other family planning providers in the locality
 - d. Barriers to family planning service delivery and FP use.
2. Information dissemination messages & channels
 - a. What are the current channels and target audiences for FP messages?
 - b. Have there been any memorable advertising or promotion campaigns that we can learn from? What worked well? What didn't work at all?
 - c. What would be the information needs of the potential users of SILCS?
 - d. What would be the appropriate messages and channels of communication?
 - e. Who would be the early adopters of SILCS?
3. Introduction of a new FP method? The SILCS
 - a. Are there other products that women in Uganda insert in the vagina? Will this be comfortable/familiar or a challenge?
 - b. Women need to have a basic understanding of vagina (and cervix and pubic bone) in order to insert and confirm position of SILCS. What is the level of awareness of vaginal anatomy? How can this type of body awareness teaching be incorporated into planning for preparedness?
 - c. Are there any cultural inhibitions or prohibitions that would affect acceptability of the SILCS?
 - d. How can we interest men in the SILCS diaphragm promotion and use?
4. Integration into existing system
 - a. How do we integrate SILCS into the existing service delivery system? In view of introduction of a new FP method, what are the strengths of the current system?
 - b. What are examples of other methods that have been integrated into existing systems? How did that work?
 - c. What would be the easiest entry point? Target group, service delivery scenario?
 - d. What challenges are likely to be faced with the introduction of SILCS? What are the FP service delivery gaps that must be addressed?
5. Monitoring and evaluation tools: ease of integration or challenges of integrating SILCS service delivery information into current HMIS?
6. Provider questions and concerns about SILCS
 - a. Are you familiar with other FP products that have been introduced into the method mix?
 - b. What training needs and other resources may be required for the introduction of SILCS?
 - c. Would you kindly share your opinion towards this new product: Do you have any questions or concerns which you feel should be addressed before introduction of SILCS?

- d. Would you recommend the SILCS diaphragm to a couple you know is in need of a FP method or would you and your partner use it?

e.

[During these questions it will be helpful to collect the words that respondents use to describe the SILCS device, and its features and how it is used. Also, what attracts them, and what concerns they have]

F. FGD GUIDE FOR CONSUMERS/POTENTIAL USERS

The objective is to explore potential consumers' perspective and interest in a female initiated cervical barrier contraceptive method. Identify interest and concerns about this new method.

1. FP service mapping
 - a. Who are the FP service providers in your locality (lets draw a map)?
 - b. Identify communication strategies/messages and channels for FP promotion that you are aware of.
2. Experience with FP service delivery
 - a. What methods of family planning have you used/ currently using?
 - b. What influenced your choice about the method you use? Are you satisfied with your method?
 - c. What improvements would you like to see in family planning methods you are using?
3. Introduction of a new FP method? The SILCS (*the consultant describes and demonstrates the SILCS diaphragm*)
 - a. Are there other products that women in Uganda insert in the vagina? Will this be comfortable/familiar or a challenge?
 - b. Women need to have a basic understanding of their bodies (and cervix and pubic bone) in order to insert and confirm position of SILCS. How can this type of body awareness teaching be incorporated into planning for preparedness?
 - c. What do you think would be the most appropriate role for men/spouses to play if this method is to be introduced smoothly? How are they likely to respond/react?
 - d. How can we build interest and gain support from men/spouses?
4. Appropriate communication strategy for introduction of SILCS
 - a. Where would women like to get information about a new method like this one?
 - b. What type of information would they need to feel comfortable and confident to use?
5. SILCS Distribution/Supply
 - a. If women were interested to use SILCS, where would they like to get the SILCS? At clinic? From Social marketer or pharmacy? From women's health advocate? From a Community Based Distributor?
6. Accepting/adopting SILCS
 - a. What are the likely barriers to introduction of SILCS?
 - b. Are there any cultural inhibitions or prohibitions that would affect acceptability of the SILCS?
 - c. What would you recommend that would enable us to achieve smooth introduction of SILCS?
 - d. Do you have any questions or concerns which you feel should be addressed before introduction of SILCS?
 - e. Would you recommend the SILCS diaphragm to a couple you know is in need of a FP method or would you and your partner use it?