

# Feasibility of SILCS Introduction in Uganda



## Background

PATH designed the SILCS diaphragm to expand women's options for nonhormonal contraception. Its single-size design makes it easy to use and provide, thus reducing barriers that have limited use of traditional diaphragms, which require a fitting by a health care provider. Like other diaphragms, however, SILCS is intended to be used with a contraceptive gel. Since diaphragms have not been available in developing countries in recent decades, PATH and its partners implemented health systems assessments and market research to explore the feasibility and opportunities for SILCS diaphragm introduction in low-resource settings and to identify likely target audience and strategies for introduction.

This brief summarizes the results of a health systems assessment conducted in Uganda in 2010 that explored the perceived need for this method, how it could be integrated into the family planning (FP) system, and challenges that would need to be addressed prior to introduction. The Uganda assessment was the first of three health systems assessments implemented between 2010 and 2013; the other assessments and market research were conducted in India and South Africa (separate briefs are available for these countries). Information from this assessment is intended to inform strategies for future introduction. The full report can be accessed [here](#).

The SILCS diaphragm has been evaluated in 14 clinical studies in five countries to build evidence of its safety, acceptability, ease of use, and effectiveness. In 2010, PATH licensed the SILCS technology to Kessel medintim GmbH for manufacturing and marketing. In 2013, Kessel launched the Caya<sup>®</sup> contoured diaphragm after gaining European regulatory approval. Since then the Caya diaphragm has been approved in Australia, Canada, and the United States. As of 2016, the Caya diaphragm is available in more than 25 developed and middle-income countries and is poised for introduction in developing countries. Kessel also markets Caya<sup>®</sup> Gel/Contragel<sup>®</sup>, a contraceptive gel that contains lactic acid that is used with the Caya diaphragm.



## Family planning in Uganda

In Uganda, the fertility rate is high, as is the need for contraceptive options. According to the 2006 Uganda Demographic and Health Survey (UDHS), the total fertility rate was 6.7, with high incidence of maternal mortality. During the time of this assessment, the country's unmet need for family planning was pegged at 41 percent. Need was highest among married women living in northern Uganda and rural areas, where cultural and religious beliefs and misconceptions and myths contribute to low rates of contraceptive use and high discontinuation. According to the 2006 UDHS, 46 percent of married women said they could not ask their husbands to use a condom and 21 percent could not refuse sex.

In fact, only 23 percent of married women reported current use of a contraceptive method, and 58 percent of family planning users said they discontinued use within the first year because of side effects, inability to find supplies, and limited options. The Depot medroxyprogesterone acetate (DMPA) injectable contraceptive, Depo-Provera®, is the most widely used contraceptive in Uganda. However, persistent stockouts occur. The diaphragm was introduced into Uganda's family planning method mix in the 1980s, but it was never widely promoted and is no longer available.

**Figure 1.** Districts where FGDs and interviews were conducted.



## Methodology

With funding from the US Agency for International Development through the HealthTech IV program, PATH and its partners conducted an assessment, using a “whole systems approach,” to explore stakeholder perceptions and evaluate regulatory, policy, and programmatic factors that could determine potential strategies for SILCS introduction in Uganda.

Methods for the assessment included a document review as well as interviews and focus group discussions (FGDs) with FP stakeholders. Stakeholder groups (Table 1) included policymakers, government and nongovernmental organization (NGO) planners at both national and district levels, FP logistics and supply chain managers, 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). The team conducted 98 key informant interviews and 26 FGDs in the districts of Kampala, Mbarara, and Mbale (Figure 1), representing diverse regions of the country with varying cultures and levels of unmet need. The assessment was implemented from June to August 2010 by Dr. Kyamwanga Imelda Tamwesigire and Ms. Eleanor Turyakira, MSc, of Mbarara University of Science and Technology, Mbarara, Uganda, with assistance from PATH.



The research team interviewed providers and clients at a family planning clinic in Kampala to explore feasibility of SILCS introduction. Photo: PATH/Maggie Kilbourne-Brook

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**Table 1.** Participant categories, by district and sample size

District	Women	Men	Providers*	Policymakers**
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 KI)	25 (3 FGD; 2 KI)	35	4
<b>Total</b>	<b>201</b>	<b>77</b>	<b>59</b>	<b>39</b>

FGD = focus group discussion; KI = key informant interview.

\*Provider category includes staff from governmental and nongovernmental organizations and commercial outlets such as pharmacies, drug shops, and supermarkets.

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

## Key findings

### Is SILCS introduction feasible from a policy, regulatory, and program perspective?

Yes. Potential users, service providers, and members of training institutions were eager to see SILCS included as a FP option in Uganda. Stakeholders believed that a significant number of women would adopt the method, especially those with unmet need for birth spacing and those who have discontinued an FP method due to side effects.

At the policy level, no guidelines or policies would impede provision of SILCS as a contraceptive option. In fact, diaphragms are still included in the Ministry of Health's FP guidelines as a method of choice.

“ It will not be introduction of a new method, but just revitalization.”

– Policymaker, Kampala

Although national efforts have prioritized HIV prevention in recent decades, and political support for family planning is viewed as “weak,” Uganda's FP managers are interested in increasing family planning through increased access, promotion of choice, and adolescent-friendly services. This includes a growing awareness among policymakers for the need to consider a complete reproductive health (RH) package.

Among policymakers and other stakeholders, three concerns surfaced about potential introduction of



PATH staff in Kampala and researchers practice demonstration and handling the SILCS diaphragm in preparation for the health systems assessment. Photo: PATH/Clarissa Lord Brundage

SILCS. First, because the family planning program relies on donor funding, government stakeholders questioned which donor would support SILCS procurement and introduction. Second, stakeholders questioned what contraceptive gel would be supplied to take the place of nonoxynol-9 gel, which is no longer recommended or available. Third, they expressed concern about whether diaphragm introduction would reduce male condom use, which is promoted in the fight against HIV/AIDS.

“ 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, Ministry of Health

At the same time, stakeholders acknowledged that most women in Uganda who use family planning use the injectable contraceptive, DMPA, which also does not protect from HIV. Many conceded that lack of dual protection from HIV should not impede future introduction of the SILCS diaphragm. Stakeholders wanted more information about the product cost and service delivery, as well as the role of the diaphragm in preventing sexually transmitted infections other than HIV. Policymakers and procurement groups said they would need evidence of local consumer uptake in Uganda before the national FP program or NGO agencies and clinics would include SILCS in their procurement requests.

## Who is the proposed target audience?

While there was no consensus on the primary target audience for SILCS, the group of women commonly proposed as “early adopters” included young married or cohabiting women, particularly educated women, with a need for birth spacing.

“Target literate women, target young women and corporate women. I see rural women having problems. For older women we are marketing more permanent methods like the IUD [interuterine device] and implant.”

– Private provider, Mbarara

In particular, urban stakeholders in Kampala commonly stated that introduction in the rural areas would be difficult.

“Rural women will not be likely to use it. They will not be able to keep it clean. Imagine the water they use and where they will keep it.”

– RH planner, Kampala

However, this perception among urban stakeholders that rural women could not use and clean the diaphragm was disputed by rural women. In fact, rural women said they often have water in their houses for cleaning after intercourse.

“Every woman has a bucket or basin in the bedroom which has water.”

– Rural woman, Mbarara

Program planners emphasized the need to create awareness and demand as well as the need to provide training and sensitization before any product is introduced.

“FP introduction in the country was wrongly done. They did not prepare the population...so 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

“Cultural issues will always be there... even there are religious issues... but you just have to persistently sensitize the people.”

– Rural woman, Mbale

While some stakeholders mentioned that SILCS would be attractive for young girls worried about pregnancy, they also perceived that promoting this device to young women could be politically sensitive.

“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



Some expressed the need for caution in targeting one particular user group, since that approach could make it difficult to expand the market to other groups later.

“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 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 not side effects. You never know where there will be a good niche for it.”

– Researcher, Kampala

## How and where should SILCS be introduced?

Since SILCS requires no complicated procedures, providers felt the diaphragm could be handled by family planning or health workers at any level. There was broad recognition that there will need to be investment in training and supportive supervision. Provider attitudes and biases were seen as a barrier to revitalization of the diaphragm, and pre-service and in-service training for FP providers in Uganda was considered weak.

“You have to target the providers to deal with their attitudes. Women ask trusted providers in their environment. There is a need to get them on board early.”

– RH provider in NGO, Kampala

“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

Stakeholders also recommended that SILCS introduction start in the private not-for profit sector, particularly through NGO providers. These partners have networks throughout the country that provide FP services at a subsidized cost, and they are able to ensure reliable supplies and more training for providers than the public sector. Stakeholders felt this could be a solid strategy for increasing demand, which would have to be demonstrated before the government would procure SILCS for its public program.

## What will motivate Ugandan women to use SILCS?

Nearly all potential users appreciated that SILCS has minimal side effects, unlike hormonal FP methods, and that it is under the woman's control. Many women complained of side effects of hormonal methods, including bleeding, changes in menstrual flow, vaginal “dryness,” weight gain, and being sickly. They were enthusiastic that SILCS could be an antidote to those problems. Both women and men alike expressed eagerness to try using SILCS.



Researchers introduce the SILCS diaphragm to a woman who had distributed diaphragms decades ago. Photo: PATH/Maggie Kilbourne-Brook

“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...”

– Urban woman, 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 man, Mbarara

“[SILCS] has no side effects... you will have saved us!”

– Rural woman, Mbarara

## What is needed to raise awareness and build confidence in this new method?

This assessment identified a high degree of misinformation about family planning—even among urban, educated respondents. Women and men also had many questions about how to use SILCS, ranging from understanding how to insert and remove the diaphragm, to whether SILCS would affect sexual pleasure, to how to clean and care for SILCS. Many of these issues can be addressed through education, training for providers, and counseling for consumers. And while the cost of SILCS itself is low because it can be reused for up to two years, consumers and other stakeholders questioned the cost and ease of obtaining the contraceptive gel.

## Recommendations

Based on findings, the following recommendations emerged from the assessment and could pave the way toward introduction of the SILCS diaphragm in Uganda:

- **Identify alternative contraceptive gel.** Because the World Health Organization recommends that products containing nonoxynol-9 not be used in countries where couples are at risk of HIV infection, an alternative contraceptive gel must be identified and registered before SILCS introduction can move forward, or evidence of effectiveness and acceptability of diaphragm use without a contraceptive gel is needed.
- **Provide the Ministry of Health with additional evidence on local need and potential uptake for the SILCS diaphragm.** This evidence might consist of market research, acceptability studies, and evidence about the role of the diaphragm in the prevention of sexually transmitted infections. Policymakers also need detailed information about product cost, provider training and service delivery requirements, and evidence that donors support SILCS introduction.
- **Generate awareness and support from FP providers.** Building awareness and knowledge among FP providers will be critical for building provider confidence in this method and generating demand among users over the long term. This should include pre-service and in-service training; it should also address biases that providers might have toward the method.
- **Provide gender-based education and sensitization on female anatomy and SILCS use to increase awareness and eventually demand.** Many women in Uganda lack awareness of sexual anatomy. Providing basic education in vaginal anatomy is necessary for a woman to understand how to use SILCS properly and could improve women’s ability to care for their reproductive health.
- **Complete product registration and market clearance.** While diaphragms were once part of Uganda’s FP program, SILCS is not yet registered. The certification and registration process will require a certificate of conformity from the Uganda Food and Drug Administration, a certificate of Good Manufacturing Practice, and a visit to the manufacturer.

- **Introduce SILCS initially through private not-for-profit sector.** Introducing SILCS first through the private not-for-profit sector has advantages, including creating initial evidence of demand among women, piloting training for health care providers, and utilizing a strong network of providers throughout the country while ensuring supply.

## Conclusion

This assessment found that the single-size SILCS diaphragm could help address unmet need for family planning in Uganda and expand contraceptive choice through a nonhormonal, user-initiated option for women who experience problems with existing methods. SILCS also could serve as a back-up method, if other methods are unavailable due to stockouts. Many potential users were enthusiastic about trying SILCS, and stakeholders also welcomed the benefits that SILCS could bring to Uganda's FP program. The diaphragm was previously offered in Uganda and the process of adding SILCS to the contraceptive method mix could be relatively straightforward from a regulatory perspective.

Before introduction can proceed, several steps must be addressed. These include identifying an alternative to nonoxynol-9 gel, raising awareness about this method through education and training for both FP providers and potential users, and finding partners from the private not-for-profit/NGO sectors to build evidence of uptake and acceptability.

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<sup>†</sup> Kyamwanga IT, Turyakira E, Kilbourne-Brook M, Coffey PS. Potential for revitalisation of the diaphragm for family planning in Uganda: a rapid assessment of the feasibility of introducing the SILCS Diaphragm. *African Journal of Reproductive Health*. 2014;18(2):77–86.

## Updates since this assessment

In 2010, the SILCS diaphragm had not yet received regulatory approval for marketing. Since then, Kessel medintim GmbH has achieved regulatory approvals in both Europe and the United States for the Caya contoured diaphragm. As of 2016, Caya is marketed in more than 25 developed and middle-income countries. PATH and our partners shared findings from this assessment at conferences and in a peer-reviewed journal article to raise awareness about the feasibility of SILCS introduction in Uganda.<sup>†</sup> PATH and CONRAD also implemented two clinical studies assessing Contragel (Caya Gel), the lactic acid-based contraceptive gel, to provide data on Contragel safety and barrier effectiveness when used with SILCS. Kessel continues to explore partnerships for Caya introduction in low-resource settings to expand contraceptive method choice and help address women's unmet need for family planning.



Kessel developed an array of marketing materials to support Caya introduction, now available in 14 languages.  
Photo: PATH/Patrick McKern



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