Feasibility of SILCS Introduction **in India**

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Background

PATH designed the SILCS diaphragm to expand women's options for nonhormonal contraception. Its single-size design reduces barriers that have limited use of traditional diaphragms, which require a fitting by a health care provider. SILCS was developed through a user-centered process to be easy to use—especially for new users—and easy to provide. Like other diaphragms, it 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 of SILCS diaphragm introduction in low-resource settings and identify likely target audiences for introduction.

This brief summarizes the results of a health systems assessment conducted in India that explored the perceived need for this method, how it could be integrated into the family planning system, and challenges that need to be addressed prior to introduction. The full report can be accessed **here**. A separate brief summarizes key findings from market research assessing acceptability among potential target audiences in India. Information from the health systems assessment and market research can inform strategies for future introduction. Additional assessments were implemented in Uganda and South Africa.

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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® 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 markets CayaGel®/Contragel®, a contraceptive gel that contains lactic acid that is used with the Caya diaphragm.

Photo: PATH/Patrick McKern

Family planning in India

The unmet need for contraception in India is high, with most women marrying young, and nearly half (44 percent) of women in India not using contraception. India's National Family Planning Program provides a range of family planning methods, including female and male sterilization, male condoms, oral contraceptive pills, and intrauterine devices (IUDs). At the time of this assessment in 2012–2013, injectable contraceptives were available only through the private and social marketing sectors, but in 2015 the Government of India indicated that injectables would be included in the National Family Planning Program. Female sterilization is the most widely used contraceptive method, accounting for 77 percent of all women using a modern contraceptive. Birth-spacing methods have not been widely promoted and represent only about 10 percent of contraceptive users in total. In the past, the diaphragm was available in India, but few providers or young women now are aware of its existence or benefits.

Figure 1. Areas in which focus group discussions and interviews were conducted.

Methodology

With funding from the US Agency for International Development through the HealthTech V program, PATH and its partners conducted an assessment, using a "whole systems approach," to explore stakeholder perceptions and evaluate regulatory, policy, and programmatic factors influencing strategies for SILCS introduction in India. Key informant interviews with national-level stakeholders and stakeholders at the state and district levels of Karnataka in the south and Rajasthan in the north, and focus group discussions (FGDs) with prospective users in these two geographically diverse states, provided the basis for the findings. Researchers conducted 22 interviews with national-level stakeholders (government agencies, national and international nongovernmental organizations [NGOs]) in Delhi and seven interviews with district-level stakeholders in Karnataka (government agencies, health institutions, and private practitioners). Perceptions among potential end users were explored during nine FGDs in Karnataka and Rajasthan with urban and rural women who were either married or in a relationship, female sex workers (FSWs), and their partners and clients (see Table 1). This assessment was implemented by Ms. Katharine Shapiro, an independent reproductive health consultant, in collaboration with Ashodaya Samathi, a sex worker–led community-based organization in Karnataka that conducts community-led research and advocates for policies and health services to make sex work safe in India.

Female participants were between the ages of 18 and 35 years and male participants were between the ages of 25 and 50 years. None of the FGD participants reported sterilization as their family planning method. A FGD was also conducted with a group of FSW community leaders in Mysore to gain additional perspective on the potential acceptability of the SILCS diaphragm among female sex workers.

Table 1. Number and type of focus group discussions in each state

Participant type	Karnataka (Mysore)	Rajasthan (Ajmer and Jaipur)
Women from general population	1 (urban), 1 (rural)	1 (Jaipur)
Female sex workers (FSWs)	1 (urban), 1 (rural)	1 (Ajmer)
Men (partners or clients)	1 (partners),1 (FSW male partners and clients)	1 (Jaipur, partners)
Total number of focus groups	**6**	**3**

Key Findings

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

Yes. National-level stakeholders in Delhi agreed that the SILCS diaphragm could help address the needs of women who cannot or do not want to use hormonal methods and whose partners will not use condoms. Many of these stakeholders reported "openness" on the part of the Ministry of Health and Family Welfare (MOHFW) to introduction of new methods, especially those that are nonhormonal, which women's groups are more likely to support. Some stakeholders remembered the diaphragm used to be part of the family planning program and felt it played an important—if small—role then, and could play a larger role in the future.

India has created strong family planning policies focused on increasing family planning and contraceptive choice. The National Population Policy (NPP), enacted in 2000, emphasizes the need to reduce India's birthrate and stabilize the population by 2045. This policy is implemented through two national programs: the Reproductive and Child Health Project (RCH II) and the National Rural Health Mission (NRHM). RCH II focuses on increasing contraceptive use by eligible couples and is an integral part of the NRHM, which is India's over-arching public health program that aims to expand the quality of public and private health facilities at all levels.

India's robust set of family planning guidelines are widely distributed and utilized. The guidelines are intended to be responsive to a changing contraceptive landscape, and updating them as new methods emerge is relatively straightforward. Recently, for example, emergency contraception pills were included after a two-day consultation that established the guidelines and outlined required training.

Ms. Katharine Shapiro (center) led the health systems assessment, with support from Dr. Nisha Gupta (left). Dr. Saroj Pachuri, Population Council Country Director, shared perspectives through stakeholder interviews. Photo: PATH/Maggie Kilbourne-Brook

> "The contraceptive prevalence rate will increase if there are more choices."
>
> – National-level stakeholder, Delhi

The regulatory pathway for SILCS approval in India is straightforward. Diaphragms are recognized as a safe contraceptive device used for decades and previously available in India. According to the Deputy Drug Controller General of India (DCGI), the SILCS clinical studies and regulatory approvals from Europe and the United States are sufficient to confirm the safety of SILCS. A small study will

be needed to generate acceptability data among Indian women; this is a requirement for approval of all medical products in India.

While a regulatory pathway for SILCS approval is clearly mapped out, the path for approval of a contraceptive gel that is used with the diaphragm seems less clear. Currently, no contraceptive gel is available in India, so there is no recent experience evaluating this type of product. And the Indian regulatory system does not seem to include a provision—as the European medical device regulations does—that allows a contraceptive gel intended to be used only with a diaphragm to be approved as an adjunct to the medical device. This is how the Contragel/CayaGel products are approved in Europe. These products are intended for use with the diaphragm and not to be used as stand-alone contraceptive products. The DCGI advised that a contraceptive gel would be considered a drug and would likely need to be evaluated as a stand-alone product in a contraceptive effectiveness study in India.

Who is the likely target audience—women in urban or rural areas?

While stakeholders felt that SILCS could be an option for any woman desiring a user-initiated nonhormonal method, young married women, especially educated urban women, emerged as a likely primary target audience. Features likely to appeal to these potential users were: SILCS is used only when needed, is woman-initiated, and has no systemic side effects (including the bleeding or pain sometimes experienced with other methods).

Perceptions were mixed among stakeholders and FGD participants about the appropriateness of SILCS for women in rural areas. While some stakeholders thought SILCS would be more difficult to introduce to women in rural areas, this perspective was not supported by the women themselves. For example, one woman compared SILCS to learning to use condoms.

> “In the beginning when you spoke to us about condoms, we were amused as to how to put this on the male and have sex. But when we started using it and discussing, we realized the importance. So, in the same way, if we can discuss among ourselves, we can start using this too.”
>
> – FSW community leader FGD, Mysore)

> “If you train us, we can properly insert SILCS after practice.”
>
> – Female, Mysore

Some stakeholders also believed that SILCS could be appropriate for women in rural settings as well as urban:

> “Urban women are shy about these things, but rural women are not.”
>
> – Delhi, provider, researcher, and advocate

Women and their partners were enthusiastic about a method that would be safe, with no systemic side effects, and woman initiated. Sex workers and those working in HIV prevention programs thought that SILCS could play an important role for contraception and protection in intimate partner relationships, where condom use is limited.

Many stakeholders cautioned against introducing SILCS specifically to sex workers, saying that this could lead to stigmatization of the product, as occurred when the female condom was introduced. They suggested that sex workers should be included in outreach to the general population of women at risk of unintended pregnancy but should not be specifically targeted.

How and where should SILCS be introduced?

Stakeholders held mixed opinions about how SILCS should be introduced in the national family planning program. Since the majority of Indian women access family planning through the public sector, adding another free birth-spacing method could be a benefit. The route for getting a new product into the national program after regulatory approval, however, is long and arduous. Instead, a number of stakeholders recommended that introducing SILCS initially through private, not-for-profit organizations could accelerate access through multiple service-delivery channels such as social marketing, commercial marketing, and NGO family planning clinics. This smaller-scale approach might also pave the way for introduction into the national program.

> "It should be started as a one-to-one effort with one committed doctor providing it in the beginning and giving plenty of information. Provision should be started slow[ly] and with adequate counseling. This is very important. It could be combined with the Safe Days Method and other methods, like condoms."
>
> – Private gynecologist, Mysore

Providers were enthusiastic about SILCS since it would allow them to provide an additional birth-spacing method without side effects. While there was some disagreement about what level of health care provider, from accredited social health activists (ASHAs) to doctors, should provide SILCS, providers agreed that word-of-mouth testimony by experienced users was the most powerful promotion tool.

> "Education would not be a problem once there is real-life experiences. Providing women's testimony is the most important."
>
> – Staff nurse, Maternity Center

All agreed that SILCS introduction would require efforts prior to introduction to raise awareness about the method, including education and counseling for how to use this method correctly. A researcher with previous experience assessing diaphragm acceptability in India emphasized that women would need support to learn how to use this new method, saying:

> "It would be hard for women on their own as they have limited pictorial literacy to follow line drawings and insufficient knowledge of their own anatomy."
>
> – Sexual and reproductive health researcher

Because of its single size, in some countries women can obtain SILCS over the counter and without visiting a health care provider. However, Indian stakeholders had mixed views about whether this would be feasible in India. Some liked the concept that the method's distribution and promotion could transcend the clinical setting. Ultimately the decision about where to provide SILCS should be guided by women's preferences and comfort with the device, as well as insights from providers.

> "Get it out for self-use, over-the-counter, as soon as possible. A provider interface can cause major problem with getting access out to the lowest levels."
>
> – NGO director, Delhi

Photo: PATH/Gabe Bienczycki

Should SILCS be introduced as a future multipurpose prevention technology?

No. National and state-level stakeholders had strong, consistent views that SILCS should be introduced primarily as a contraceptive, not as a potential future multipurpose prevention technology (MPT) that could protect from both unintended pregnancy and HIV when used with a microbicide gel. They felt that discussing the potential of SILCS as an MPT, especially before a microbicide gel is available, would confuse audiences and potentially turn off potential users, since HIV is highly stigmatized in India. Stakeholders also emphasized that more women in the country are at risk of unintended pregnancy than HIV, so more women would see value in a new birth-spacing method—especially a nonhormonal option. In the future, once a microbicide gel is approved, then it might be possible to discuss using the two products together, especially if the gel could protect from other sexually transmitted infections (STIs) and not just HIV alone.

Recommendations

Based on findings from the health systems assessment, the following recommendations emerged that could pave the way toward introduction of SILCS in India:

- Seek partnerships and funding for the small, short-term study of SILCS' acceptability and safety in India. This study will be required as part of the regulatory submission.
- Introduce the SILCS diaphragm in a phased approach, using private-not-for-profit and NGO sector clinics to test uptake. Many women access family planning services through not-for-profits and NGOs; introduction through these sectors could generate awareness and confidence about this method and develop best practices for service delivery. If uptake is successful, future introduction through the national family planning program could be assessed.
- Identify key organization(s) to lead and implement introduction. While several NGOs and stakeholders expressed interest in SILCS introduction, a key organization/institution should be identified to lead the strategy and coordinate planning. The groups suggested included PATH, Advocating for Reproductive Choices (ARC—a coalition of sexual and reproductive health organizations), the Family Planning Association of India, and Hindustan Latex Family Planning Promotion Trust (HLFPPT). Funding would need to be identified to support introduction efforts.
- Build support for SILCS among women's health activists and parliamentarians. These are two influential groups who are key to introduction of any method. They seem interested and ready to support SILCS, partly because they are interested in expanding the contraceptive method mix, especially with a method that has no systemic side effects, and can be used intermittently whenever sex is expected. They see SILCS as a method that can help address this unmet need for family planning.
- Develop training and information materials for health care providers. Health care providers need education and training on SILCS. This should be included as part of in-service trainings for providers at all levels, including clinicians who provide family planning services, as well as health workers with community-based organizations, ASHAs, Anganwadi workers, and peer educators. Training should be coordinated with the overall introduction strategy.
- Include materials for low literacy consumers as a part of any widespread education campaign. All women need a basic understanding of their vaginal anatomy to use the SILCS diaphragm. SILCS' educational materials are needed for a range of audiences, including low-literacy groups. This knowledge can add to women's ability to understand and care for their bodies.
- Expedite approval of a contraceptive gel for use with the diaphragm, and/or explore use of SILCS without gel. Until a feasible regulatory pathway for contraceptive gel approval in India is identified, SILCS introduction will not move forward. Gel

approval could be facilitated if the gel was manufactured in India (requires licensing and technology transfer) and/or if a contraceptive gel (such as Amphora® gel[1]) that has been evaluated for contraceptive-effectiveness is submitted for Indian regulatory review. A third option is to explore acceptability of the Caya diaphragm used without contraceptive gel, since evidence about the added value of the gel when used with the diaphragm is limited.[2]

Note: Recent developments within the Indian regulatory system could simplify the necessary steps for gel approval with the diaphragm. Proposed amendments to India's medical device and pharmaceutical laws submitted for approval in 2015 are intended to align India's regulations with the European Medical Device Directives. If approved, this could allow contraceptive gel to be approved in the same way it is CE Mark–approved in Europe.[3]

Conclusion

Strong support exists, among both stakeholders and potential users, for introduction of SILCS in India. While access to birth-spacing methods has been limited, the Government's pledge at the FP2020 London Summit to improve contraceptive choice creates an opportunity for SILCS. A strong NGO and not-for-profit sector provide alternate distribution opportunities to the national family planning program. And since diaphragms are recognized as having a record of safe use globally and have been registered in India in the past, achieving regulatory approval for the SILCS diaphragm in India seems relatively straightforward. Once this happens, India-based organizations will be best placed to lead the introduction effort.

However, work remains to overcome challenges prior to introduction. Awareness is currently low among both health care providers and users. Women's health activists have a history of opposing certain forms of contraception, so messages and education targeting civil society and policymakers will be critical. Regulatory approval of a contraceptive gel to be used with the diaphragm would require a contraceptive effectiveness study before approval. This is an obstacle for SILCS introduction, which will be delayed until a contraceptive gel that meets Indian regulatory guidelines is available, or unless the SILCS diaphragm can be approved for use without a contraceptive gel. For women across India, work is needed by all partners and stakeholders to ensure that SILCS meets the final challenges to introduction in India.

Photo: Kessel medintim GmbH

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[1] Amphora® is a registered trademark of Evofem, Inc. http://www.evofem.com/products/.

[2] A Phase I post coital study implemented by CONRAD in the United States is evaluating the barrier effectiveness of the SILCS diaphragm when used with Contragel/CayaGel and also SILCS used with no gel compared to SILCS used with nonoxynol-9-based contraceptive gel. Results expected in late 2016.

[3] More information can be found at: http://www.meddeviceonline.com/doc/india-s-medical-device-regulations-may-change-in-0001.


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