PATH/Siri Wood

Assessing opportunities and challenges for potential introduction of the SILCS diaphragm in India

A HealthTech report

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Acronyms

ARC	Advocating for Reproductive Choices
ASHA	accredited social health activist
DCGI	Drug Controller General of India
FGD	focus group discussion
FP	family planning
FPAI	Family Planning Association of India
FSW	female sex worker
HLFPPT	Hindustan Latex Family Planning Promotion Trust
IC	injectable contraceptive
ICMR	Indian Council of Medical Research
INR	Indian rupees
IUD	intrauterine device
NFHS	National Family Health Survey
NGO	nongovernmental organization
SRH	sexual and reproductive health
STI	sexually transmitted infection
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
WHO	World Health Organization

Executive summary

The population of India has reached 1.2 billion and is growing rapidly. To help manage population growth and meet the needs of young people, the Government of India has committed to expanding the mix of contraceptive methods available to women to include more reversible methods for delaying and spacing births, especially among younger women.

According to the most recent National Family Health Survey (NFHS-3), the contraceptive prevalence rate among currently married women aged 15 to 49 years in India is about 56%. Female sterilization is widely promoted and available in India, and 37% of women (nearly two-thirds of all contraceptive users) are sterilized. Birth-spacing methods have not been widely promoted and represent only about 10% of total contraceptive method use. Given that 40% to 50% of girls are married before age 18 years, and use of reversible methods is quite low, there is significant need for promotion of and access to birth-spacing methods.

PATH and our research partners developed the SILCS diaphragm to expand women's options for nonhormonal barrier contraception, especially in countries where traditional diaphragms are not available. Unlike traditional diaphragms, SILCS comes in a single size that fits most women, simplifying supply and service delivery. There is no need for a fitting exam to determine what diaphragm size a woman can wear—an obstacle in many settings where resources are limited and providers have not been trained for this exam.

Although not all women will be interested in a user-initiated barrier method, SILCS is an appropriate option for women who cannot or do not want to use hormonal contraception or intrauterine devices, and whose partner will not use a condom. Recent analysis on unmet need for family planning suggests that a user-initiated, nonhormonal method could address the reproductive health needs of many women in India and elsewhere.

With funding from the US Agency for International Development through the HealthTech program, PATH collaborated with Ashodaya Samithi, an Indian nongovernmental organization (NGO) in Mysore dedicated to supporting the sexual and reproductive health of sex workers and other vulnerable populations, and Katherine Shapiro, a reproductive health consultant, to conduct a health systems assessment exploring opportunities and challenges related to the potential future introduction of the SILCS diaphragm in India. This assessment included key informant interviews with national-level stakeholders in Delhi, interviews with key stakeholders at the state and district levels, and focus group discussions with prospective users in two geographically diverse states in India.

Both stakeholders and users expressed strong interest in the introduction of SILCS to expand the contraceptive method mix in India. Because there is little awareness of diaphragms among potential users and family planning providers, stakeholders and users stressed that awareness raising and educational counseling would be needed to generate demand and address questions. Stakeholders recommended that SILCS introduction should be undertaken in a phased approach, starting with introduction through the private, not-for-profit sector to build awareness around this method and confirm acceptability among Indian women rather than attempting initial entry through the national family planning program.

Achieving regulatory approval for the SILCS diaphragm in India seems relatively straightforward because diaphragms are recognized as having a record of safe use globally and have been registered in India previously. Regulatory approval of a contraceptive gel to be used in conjunction with the diaphragm is more problematic because the gel would be considered a drug (rather than an adjunct to the medical device) and as such 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.

This report summarizes findings gleaned from the interviews and the focus group discussions. It concludes with a set of recommended steps for advancing the introduction of SILCS in India, such as:

- **Expedite approval of a contraceptive gel or build evidence for use of SILCS without gel.** Given that diaphragms are recommended for use with a contraceptive gel, and no gel is approved in India, SILCS introduction cannot move forward until this challenge is addressed. Gel approval could likely be expedited in several ways:
  - A contraceptive gel is manufactured in India (licensing and technology transfer).
  - A contraceptive gel with contraceptive-effectiveness dossier is submitted for Indian regulatory approval (for example, Amphora® gel via the Expanding Effective Contraceptive Options project) and imported into India.
- **Introduce the SILCS diaphragm in a phased approach, using private-not-for-profit and NGO sector clinics to test uptake of this new method.** Many women access family planning services through these channels. Introduction in the not-for-profit and NGO sectors can generate awareness and confidence about this method and develop best practices for service delivery. If uptake in the private-not-for-profit/NGO sectors is successful over time, then feasibility of future introduction through the national family planning program can be assessed, which would also require planning for technology transfer and local manufacture of the SILCS diaphragm per Government of India requirements.
- **Identify key organization(s) to lead and implement introduction.** While multiple NGOs and stakeholders expressed interest in SILCS introduction, a key organization/institution should be identified to coordinate strategy and planning. Several stakeholders suggested PATH as an organization that could lead SILCS introduction because of PATH's history with this product and its presence in the health community in India. Alternatively, having SILCS introduction led through Advocating for Reproductive Choices (ARC—a coalition of sexual and reproductive health organizations), the Family Planning Association of India, or Hindustan Latex Family Planning Promotion Trust (HLFPPT) could leverage existing relationships and build support across sectors since they are connected to both advocacy and service delivery channels. Social marketing organizations such as DKT International, Population Services International, and clinics such as Marie Stopes International could also be involved.
- **Build support for SILCS among women's health activists and parliamentarians.** These audiences are important and influential groups in India and will be key to future introduction. They seem interested and ready to support SILCS, partly because they are interested in expanding the contraceptive method mix, and they see SILCS as a method that can help address unmet need for family planning.
- Further recommendations for research, training, and promotion are also identified in this report.

Amphora is a registered trademark of Evofem, Inc. More information available at: http://www.evofem.com/products/.

Introduction

Family planning in India

India is home to more than 1.2 billion people, half of whom are of reproductive age. Each day, more than 70,000 babies are born.[1] India's population increases by 17 million people annually—equivalent to adding a country the size of the Netherlands, Niger, or Chile each year.

According to the most recent Indian National Family Health Survey (NFHS-3), about 44% of married women in India do not use any method and have an unmet need for contraception. Of the 56% of married Indian women of reproductive age who use a contraceptive method,[2] two-thirds rely on female sterilization, with more than half of women having the operation before they reach 26 years of age. By contrast, relatively few married women use reversible birth-spacing methods. Male condoms (5%), oral contraceptive pills (3%), and intrauterine devices (IUDs) (2%) are used by only 10% of married women in India. Among traditional methods, rhythm and withdrawal are used by 5% and 3% of married women, respectively. Injectable contraceptives (ICs)—which are available through retail clinics and pharmacies, but are not yet available through the national family planning program[†]—are used by less than 2% of married women (Table 1). A recent analysis of data from young married women (ages 15 to 24) in six Indian states found a high of demand for contraception to delay first births (51%), with only 10% of couples practicing contraception.[3]

Table 1. Contraceptive use among married women in India (NFHS-3, 2005–2006).[a]

Contraceptive method	Percent use
Not using any method	44%
Female sterilization	38%
Male condom	5%
Rhythm	5%
Withdrawal	3%
Pill	3%
Intrauterine device (IUD)	2%
Male sterilization	1.9%
Injectables	1.7%

[a] Adapted from the 2005–2006 National Family Health Survey (NFHS-3).[2]

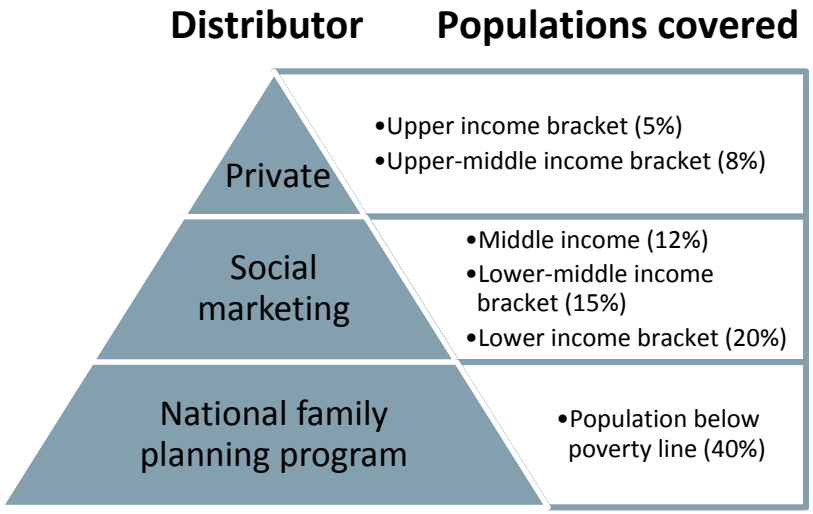
Family planning services are provided across diverse channels involving the public, social marketing, and commercial sectors, as well as by national and international nongovernmental organizations (NGOs). The national family planning program is intended to address the needs of the Indian population living below the poverty line by offering free access to products and services. The national family planning program of India currently offers five contraception choices free of charge to all couples: the IUD, oral contraceptive pills (including emergency contraceptive pills), condoms, and female and male sterilization. According to

[†] In late 2015, the Indian Ministry of Health announced that injectable contraceptives are approved "in principle" for use in the Indian national family planning program. This announcement was reconfirmed at the International Conference on Family Planning in Nusa Dua, Indonesia, January 2016. This marks a significant expansion of birth spacing option for women who access services at national family planning clinics; however, it does not address the needs of women who cannot or do not want to use hormonal contraceptives.

the NFHS-3, the public sector provides 85% of sterilizations. The private and social marketing sectors are the stronger provider of short-term spacing methods such as pills and condoms.

Other methods are available at a cost through the private sector and the not-for-profit and social marketing sectors. These include seven brands of ICs and the Standard Days Method.[‡] IUD provision is split nearly equally between the public and commercial sectors. Overall, social marketing is focused on the lower, lower-middle, and middle income brackets, and the commercial markets are aimed at the upper-middle and upper income brackets (see Figure 1).

Figure 1. Distribution channel segments and relative size of market.



Note: There is overlap between distribution through social marketing and through the national family planning program.[4]

Contraceptive method use in India is influenced by awareness, availability, and cost (see Table 2). For example, consumers who are able to pay frequently access services through private-sector clinics, pharmacies, not-for-profit clinics, and NGOs. These sectors provide health products and services to women representing a wide range of socioeconomic categories.

Table 2. Availability and cost of contraceptives in India in 2012–2013.

Method	Where available	Cost
Female sterilization	Public sector, camp settings	Free in public sector
No-scalpel vasectomy	Public sector	Free in public sector
Oral contraceptive pills	Public sector, medical stores	Free in public sector
Emergency contraceptive pill	Public sector, accredited social health activists (ASHAs) at village level, medical stores, social marketing organizations	Free in public sector; 32 to 50 Indian rupees (INR) in private sector
Intrauterine device (IUD)	Public sector, private sector, nongovernmental organizations (NGOs)	Free in public sector; 300 to 750 INR in private sector

[‡] The Standard Days Method is a method of natural family planning developed by the Institute for Reproductive Health at Georgetown University. More information can be found at: http://www.natural-family-planning.info/standard-days-method.htm.

Method	Where available	Cost
Postpartum IUD	Public and private institutions (following institutional delivery)	Free in public sector
Male condom	Public, private, social marketing	Free in public sector; sold at range of prices through social marketing and retail channels
Female condom	Limited availability through medical stores, and through government and NGO targeted interventions	30 to 90 INR per condom in stores; 5 INR through targeted interventions supported by government and NGOs
Injectable contraceptives	Multiple products available through private sector, NGOs	90 INR for 3 months; 150 INR for 6 months
NuvaRing®[a] vaginal ring	Family Planning Association of India (FPAI) clinics in select cities	Free on limited-pilot basis through FPAI
Progesterone vaginal ring (for breastfeeding women)	Phase III clinical trial of safety and effectiveness (completed in 2015); sponsored by Population Council and the Indian Council of Medical Research (ICMR)	Only available in research setting

[a] NuvaRing is a registered trademark of Merck Sharp & Dohme B.V., a subsidiary of Merck & Co., Inc.

Although India was one of the first countries in the 1950s to establish a national family planning program, policies in the 1960s and after strongly promoted male and female sterilization. Negative reaction to these policies has resulted in a strong movement against birth control among some segments of the population. In recent decades, this legacy has contributed to suspicion of some contraceptive methods, such as ICs, which has stalled their acceptance into the national family planning program.

At the London Summit on Family Planning in July 2012, the Government of India committed to shifting from a focus on permanent contraceptive methods to expanding access to birth-spacing methods.[5] This shift is consistent with the recognition that at least 40% of young women in India marry before the age of 18 years and that the unmet need for contraception is highest among these women, who are not yet candidates for sterilization. The Government of India's current objective is to postpone the birth of the first child until age 20 and the second child to three years later. Only 6.9% of girls/women between 15 and 19 years of age use a modern spacing method,[6] yet 40% to 50% of them are married before age 18 and are in greatest need of delaying pregnancy. Maternal mortality rates are also highest for women in this age group.

Despite the commitment to increase use of spacing methods, the Government of India and other stakeholders in India have identified a number of challenges to implementing this new policy. These include:

- *Lack of broad accessibility* to birth-spacing methods. Short-term methods are available through the private sector and so are less accessible to most Indian women living in poverty and/or rural areas.
- *Underutilization* of available short-term birth-spacing methods.
- *Health worker and provider bias* against short-term methods.
- *Public opposition* by women's health activists to ICs.
- *Poor quality of counseling* on proper use and side effects of different contraceptive methods.

The SILCS diaphragm

PATH/Patrick McKern

The contraceptive diaphragm has a long history of safe use globally. Developed in Europe in the early 19th century and widely available until recent decades, diaphragms can be used by almost all women, according to World Health Organization (WHO) Medical Eligibility Criteria. Although promotion of diaphragms declined as hormonal contraception and IUDs became widely available, nonhormonal barrier contraceptive methods have recently garnered renewed interest as an option to address unmet needs for family planning. For example, the diaphragm may be an excellent option for women who are not using an available method due to concerns about side effects or health consequences, or women who have infrequent sex and need protection only intermittently. In addition to protection from unintended pregnancy, diaphragms provide partial protection from sexually transmitted infections (STIs) that involve the cervix, such as gonorrhea, chlamydia, trichomoniasis, pelvic inflammatory disease, and human papillomavirus.[7–9] This added benefit strengthens the potential appeal and value proposition for the SILCS diaphragm.

In India, diaphragms were available on a limited basis in the 1950s and 1960s, and then again in the 1990s. Although diaphragms were included in the Indian national family planning program, they were never widely promoted, in part because of pervasive cultural assumptions that Indian women would not find using diaphragms acceptable because they were considered messy and women preferred not to touch their genitals.[10] There have been only two studies in India that have actually assessed diaphragm acceptability and willingness to use. One study among married women in Tamil Nadu found that, when introduced with training and a supportive environment, low-income women found the diaphragm acceptable; were highly motivated to use the diaphragm; and were able to overcome perceived obstacles to successful use such as difficulty with insertion, lack of privacy, and limited access to water.[11] In the second study, which evaluated uptake of several birth-spacing methods at several family planning clinics, diaphragm uptake was so low that the diaphragm arm of the study was stopped.[10] However, it is not clear what level of information or counseling accompanied introduction of the diaphragm in this study. Finally, according to some stakeholders interviewed as part of this assessment (gynecologists who had dispensed diaphragms), Indian women used and liked the diaphragm when it was available.

Traditional diaphragms come in multiple sizes and require a health care provider to conduct a pelvic exam to determine the correct size for each woman. This requirement is one of the obstacles that have limited the use of diaphragms, especially in low-resource settings where trained providers and clinic resources are in short supply. PATH and its partners developed the SILCS diaphragm so that a single size fits most women, thus eliminating the need for a pelvic exam to determine diaphragm size. Simple instructions help the woman understand how to correctly insert the device and how to protect themselves from unintended pregnancy. PATH employed a user-centered development process that incorporated feedback from women, men, and health care providers from four countries. User feedback helped ensure that the single-size SILCS device was both easy to use and comfortable for both partners. The SILCS diaphragm has been validated in clinical studies for safety, acceptability, and contraceptive effectiveness.[12–16]

In 2010, PATH licensed the SILCS technology to Kessel medintim GmbH (Kessel) (http://www.medintim.de/) for manufacturing and marketing. Kessel is a privately held German company that manufactures and distributes sexual and reproductive health products. After gaining regulatory

approval in Europe, Kessel launched SILCS as the Caya® contoured diaphragm in April 2013. By early 2014, it was being marketed in 14 European countries and Canada via family planning providers, pharmacies, and online shops. In late 2014, Caya received market clearance from the US Food and Drug Administration, and launched in the United States in 2015. By early 2016, the Caya diaphragm was introduced and being marketed in more than 25 developed and middle income countries.

With funding from the United States Agency for International Development (USAID), PATH is working with research partners in multiple countries to assess opportunities for future introduction in low- and middle-income countries. PATH is focused on countries that have limited contraceptive options and a high unmet need for birth-spacing methods, and where the addition of SILCS as a nonhormonal barrier method could help address women's reproductive health needs. This report summarizes findings from a health systems assessment that explored whether the SILCS diaphragm could help address women's reproductive health needs in India and evaluated issues and attitudes that will influence the success of any future introduction. Information from this health systems assessment, along with results from the market research conducted by IMRB International in 2013 and 2014,[17,18] will inform strategies/opportunities for future introduction in India.

Assessment methods

Using a systems approach, this assessment explored stakeholder perceptions and evaluated regulatory, policy, and programmatic factors that will influence strategies for SILCS introduction. Between November 2012 and April 2013, project staff conducted 22 interviews with national-level stakeholders in Delhi (see appendix) and seven interviews with district-level stakeholders in Karnataka (see map, Figure 2). National stakeholders represented government agencies, national and international NGOs involved in family planning, reproductive health research and training institutions, regulatory authorities, and women's reproductive health activists. At the district level, stakeholders represented government agencies, health institutions, and private practitioners in Mysore with responsibilities and insights into family planning service delivery at the state level. Interview guides for various categories of stakeholders

Figure 2. Indian states in which focus groups were conducted.

Caya is a registered trademark of Kessel medintim GmbH.

were adapted from interview guides and assessment tools developed for a similar SILCS health assessment conducted in Uganda in 2010.[19]

This assessment also explored perceptions among potential end users. A total of nine focus group discussions (FGDs)—with between 8 and 13 participants each—were conducted in Karnataka and Rajasthan. FGD participants included urban and rural women who were either married or in a relationship, female sex workers (FSWs), male partners, and FSW male partners and clients (see Table 3).

Table 3. 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

All female participants were between the ages of 18 and 35 years, and none of the participants had undergone sterilization. Male participants were between the ages of 25 and 50 years, and, for male partners, neither they nor their partner had undergone sterilization. To get additional perspective on the potential acceptability of the SILCS diaphragm among FSWs, a FGD was also conducted with a group of FSW community leaders in Mysore. The protocol, FGD guides, and interview guides were reviewed and approved by the Asha Kirhana Institutional Ethics Committee in Mysore in 2013.

Focus group discussion participants were shown the SILCS diaphragm and told how it is used. Participants were able to handle the device, but they did not insert or use it. Group discussions were recorded, transcribed, and then translated from the local language into English for categorization according to themes derived from the assessment's objectives.

Stakeholder feedback on SILCS

Support for SILCS introduction

Policymakers expressed support for bringing SILCS to India. Many stakeholders recalled that the diaphragm played a small but important role in family planning programs in the 1960s and 1970s and felt that diaphragms could play a larger role in the future. A sense of urgency at high levels of the Government of India to expand contraceptive choices has opened a window of opportunity that stakeholders agreed should be acted upon as soon as possible (since a concern was also expressed that this window may be short-lived). Stakeholders also expressed a need for methods that will be supported by women rather than be subject to intense opposition by civil society groups, as has been the case with IC.

Stakeholders, including policymakers, family planning program managers, researchers, and reproductive health advocates, voiced three key reasons for supporting introduction of SILCS in India:

1. **India's young population and focus on adolescent health (the unmet need for contraception among 15 to 19 year olds is 27%).**

   "India has a large young population. The government has a major objective to postpone childbearing until age 20 and delay the second child for three years. But 40% of Indian

women still marry before age 18."
— Representative, United Nations Population Fund (UNFPA)

2. **The public commitment to expand family planning and contraceptive choices made at the London Summit in 2012.**

   "The contraceptive prevalence rate will increase if there are more choices."
   — Researcher, Delhi

3. **The lack of existing contraceptive choices.**

   "The IUD and pill are not popular, and they're all women have for spacing."
   — Spokesperson, Indian Council of Medical Research

Stakeholder issues to be addressed

Stakeholders identified key issues that would affect support for SILCS introduction. These included availability of a contraceptive gel; provider bias toward long-acting, permanent methods; concern about impact on condom use; and even mixed stakeholder perception about the need for expanding the contraceptive method mix at all. Aside from the gel issue, most of these issues are similar concerns for introduction of any new birth-spacing method being considered for India.

- **Lack of an approved contraceptive gel:** The current lack of an approved contraceptive gel in India that can be used with SILCS is a barrier to SILCS introduction. It would take significant resources to implement a contraceptive effectiveness study, if this is what will be required for approval of a new contraceptive gel. Some stakeholders questioned how Indian women would feel about the need to use contraceptive gel since use of vaginal lubricants or gels is not common. However, stakeholders could not recall any objections to gel use when the traditional diaphragm and nonoxynol-9 were available in previous decades. One stakeholder in Mysore expressed negative feedback about the length of the plastic applicator used to apply the gel and felt this might be a concern for women unused to using a vaginal applicator.
- **Provider bias:** Stakeholders acknowledged there is potential opposition and bias from gynecologists against a user-initiated (rather than provider-controlled) method and also against a method that is perceived as less effective.

  "…gynecologists control the field of family planning and they have strong government influence." — Senior researcher and clinician, Delhi

- **HIV and condom migration:** Stakeholders raised concerns that SILCS introduction would have a negative impact on condom use, especially among high-risk populations. They expressed little concern about SILCS displacing condom use among the general population, which is perceived as a low-risk population for HIV and STIs, but stakeholders implementing HIV prevention programs among high-risk women wondered if women would begin using SILCS rather than relying on male condoms during sexual encounters, thus increasing potential risk for HIV infection. Ultimately, most stakeholders agreed that since few contraceptive methods protect from STIs, SILCS introduction should not be opposed simply on that regard.

Some stakeholders recommended SILCS introduction should emphasize the diaphragm's ability to *protect from some STIs*, such as pelvic inflammatory disease, which can affect future fertility, since this would add to its health value for some couples.

> *"Since there's only moderate pregnancy protection, the protection from some STIs will build its value. But don't focus on the FSW population or this will stigmatize it."* — Stakeholder, international NGO, Delhi

Stakeholders also acknowledged the value of SILCS as a back-up method for sex workers when their partners refuse condoms, especially common among intimate compared to transactional partner sex. They also agreed that its potential use in the future as a microbicide delivery system would be a plus since this would provide protection from unintended pregnancy and HIV or other STIs.

- **Cost:** Stakeholders cited concern about cost as a key issue for future introduction and access to SILCS. Although many stakeholders voiced that SILCS should be in the national family planning program and, therefore, be available for free to all women, government representatives said cost would be a critical issue that the Government of India would consider. At the time of this health systems assessment, the research team was not able to provide an estimate of the SILCS cost in India because multiple factors that influence product cost were not yet established. For example, production was not yet scaled up; costs associated with Indian regulatory approval and associated import fees were not known; and costs associated with introduction through public-, social marketing-, and private-sector distribution channels were not identified. Since these factors all influence "product cost," it was too early to estimate whether SILCS could achieve a cost structure that would make it appropriate for the public sector.

  While stakeholders were supportive of a reusable diaphragm that can be used for up to two years, they expressed concern about the recurring cost of the contraceptive gel used with the diaphragm. They suggested local production of the contraceptive gel as a strategy for reducing the manufacturing cost of gel and avoiding import fees, as well as exploring feasibility of packaging the gel in single-use sachets rather than current packaging in a multi-dose tube. Some stakeholders also were interested in the feasibility and acceptability of the diaphragm used without gel, since this would eliminate the recurring cost of gel and sidestep the hurdle of not having a contraceptive gel available in India. Stakeholders emphasized that a high price would make government distribution impossible. For example, the government does not distribute female condoms because of the cost. Instead, female condoms are made available through social marketing groups.

- **Mixed support for expanding contraceptive choice:** Despite public statements about India's commitment to expanding choice, some stakeholders noted that the Minister of Health stated in 2012 that "no new spacing methods will be added to the national program." Some stakeholders identified that the Government of India has decided to focus on the postpartum IUD as the primary way to increase use of birth-spacing methods. This postpartum IUD strategy builds on successful efforts to increase the number of institutional deliveries where the postpartum IUD is offered. As one stakeholder noted, however, this strategy does not increase the choices available for women who do not want the IUD:

  > *"But do women have a real choice? The question on the delivery table is, 'Do you want an IUD or sterilization?'"* — National-level reproductive health researcher and women's health advocate

  One senior-level stakeholder took a strongly contrarian view concerning the need for access to additional birth-spacing methods at all, maintaining that they are not needed in India because women marry young, have their children at a young age, and then are sterilized, and spacing is achieved through breastfeeding (and the lactational amenorrhea method):

"Money is being poured down the drain to push reversible family planning, but there is no interest in India—the fact that less than 5% of family planning is reversible reflects what Indian women want." — Senior representative, National Institute of Health and Family Welfare

- **Stakeholder perceptions about women's potential comfort with SILCS:** The issue of whether women in India would be comfortable inserting and removing a diaphragm was raised as a key issue by some stakeholders who noted that Indian women are not accustomed to putting anything into the vagina and that this could be a problem for the uptake of SILCS (or any other female barrier method). For example, women in India do not use tampons for menstruation, and these products cannot be found in medical stores.

  "Women do not touch themselves. They may be afraid of infection. After an episiotomy, if a woman is given a salve to put on sutures, she will ask her mother to apply it instead of doing it herself." — Auxiliary nurse midwife, primary health center, Mysore

  However, some health care worker stakeholders differed in their opinions about whether women would have problems inserting and removing the diaphragm and noted that women often use vaginal tablets and creams for infections.

  "Women will use vaginal tablets for treatment of vaginitis, and this is no problem. They also apply gel for herpes to the labia, vulva, no problem. Women would use a spermicide but not with 'that long thing' [she showed a plastic applicator], which would frighten them off." — Family planning clinic manager, Mysore

  A prominent gynecologist with experience fitting diaphragms also noted that acceptability might vary between urban and rural areas and, contrary to some opinions, said that "urban women are shy about these things, but rural women are not."

Target populations and approaches to introduction

Health care providers both in Delhi and in Mysore noted that demand for greater choice in birth-spacing methods is high among their clients. Providers said that their patients frequently ask about the availability of other methods:

"Many people nowadays are asking, is there anything else available elsewhere [other than the methods offered by the government]? And some would pay for other choices." — Auxiliary nurse and midwife, maternity center, Mysore

Most stakeholders agreed that young married women, especially better-educated urban women, would be a key target population for SILCS. The fact that SILCS needs to be used only when sex is expected (rather than daily use); that SILCS does not cause systemic side effects (like hormonal methods) or lead to pain and bleeding problems (associated with IUDs); and that SILCS is within women's control would be motivating factors for many women. Therefore, SILCS could be promoted as a potential option for any woman desiring contraception.

Others felt that including messages about the diaphragm's ability to provide partial protection from some STIs—even though this is considered to be only partial protection and only for STIs that infect the

cervix—is important and would build its value, especially if there is protection against pelvic inflammatory disease and infertility as well.[7,8]

All stakeholders interviewed strongly recommended that SILCS be positioned as a contraceptive method and presented to all women in the general population who may be interested in new birth-spacing methods.

> *"[SILCS should be offered to] married women who need methods for spacing. Also women who don't want oral contraceptives or the IUD. There is a huge need for spacing methods, and the government should and will want them even though the market may not be large."* — Practicing gynecologist, researcher, and activist

Several stakeholders (especially those involved with the promotion of the female condom) strongly advised not targeting FSWs specifically as part of the early introduction because SILCS could then become stigmatized, as happened with the female condom promotion in India. Sex workers should be included in the population of women who receive information about SILCS but should not specifically be targeted. It was also discussed that sex workers may use SILCS differently than women from the general population since they are strongly committed to condom use for STI/HIV protection within transactional relationships and report a high degree of use of condoms during sex work.

Although some stakeholders expressed support for the potential future use of SILCS as a multipurpose prevention technology if used with a microbicide gel to protect from unintended pregnancy and also from HIV or other STIs, most also emphasized that SILCS should be promoted first and foremost as a family planning method since this is the primary role it was designed for. They said that talking about using SILCS as a potential future multipurpose prevention technology—especially during early stages of introduction and market development—could cause confusion and lead to stigma regarding the product. There is a high degree of stigma around HIV in India and even concern around using the word "contraceptive gel" because it could be confused with microbicide gel. Stakeholders emphasized that many more women in India are in need of contraceptive protection than are at risk of HIV. Stakeholders recommended that introduction in India should focus on SILCS as a barrier contraceptive to avoid confusion.

The role of women's health advocates in the introduction of SILCS was also addressed by some stakeholders. According to the report from a stakeholder consultation on underutilized methods in 2012, "the biggest challenge to introduction of currently available yet under-utilized methods (e.g., injectables) has been the opposition from women's health advocates."[20] However, stakeholders thought most women's health activists would support the introduction of SILCS because it is without side effects and puts contraception into women's hands. Building on the potential support from women's health activists would be an important strategy for introducing SILCS in India and would give credibility to the government's efforts to meet women's needs. Finding the appropriate country-level advocates who link to these activist groups and can enlist their support for SILCS introduction will be important for any future introduction effort.

SILCS service delivery options

Stakeholders felt that the SILCS diaphragm should be broadly available but expressed mixed opinions about including SILCS in the national family planning program as an initial introduction strategy. While many Indian women access family planning through the national family planning clinics, and stakeholders agreed that adding a woman-initiated, nonhormonal method would benefit the method mix,

most stakeholders agreed it would be easier to introduce SILCS first through not-for-profit, NGO clinics. Stakeholders said the process for getting SILCS accepted into the national program would be long and arduous and that NGO-sector clinics may be better situated to take on introduction since they may have resources for service delivery research. Launching first through the not-for-profit NGO sector could generate evidence of uptake and acceptability among Indian women and establish best practices for providing this method, which could jump-start scaling to the national level in the future, if warranted.

Also, contraceptives included in the national family planning program are required to be manufactured in India, so the Government of India would need a Memorandum of Understanding transferring rights to the SILCS technology to India for local production. This is because the government needs to control supply and pricing for products in their national family planning program. However, this requirement could be a stumbling block, especially during early-stage introduction when it is unknown whether the market size justifies the investment required to transfer and establish local production. It may make more sense to explore feasibility of local production after there is experience with the contoured diaphragm in India and more is known about the potential market size. Until SILCS has shown uptake and market acceptability, there does not seem to be a strong business case for local production of the single-size diaphragm in India, and distribution channels not requiring a local production commitment should be considered.

Many stakeholders interviewed suggested introduction through private, not-for-profit organizations should be considered for initial introduction. For example, SILCS could be introduced through Marie Stopes International and DKT clinics that operate on a social marketing model that reaches middle and lower income clients (as with female condoms and injectables), the private sector and private gynecologists (as with emergency contraceptive pills), and clinics such as those of the Family Planning Association of India. Introduction through this sector was seen as providing opportunities for raising awareness and testing delivery options on a smaller scale that would provide evidence for scale-up to the national level in future if uptake and acceptability warrant.

Regardless of which service delivery channel is used, stakeholders acknowledged that the SILCS diaphragm will be easier to provide than traditional diaphragms because the single size fits most women and it does not require a pelvic exam to determine which size diaphragm a woman can wear. This will make it less cumbersome to supply and frees up the provider to focus on counseling the woman and ensuring she knows how to use the diaphragm successfully. This also means the SILCS could be provided outside of the clinic system— over-the-counter or through peer-to-peer counseling, according to regulatory approval and the local standard of care.

> *"Get it out for self-use, over-the-counter, as soon as possible. A provider interface can cause major problems in access, so get it to the lowest levels."* — Stakeholder, NGO

Although some stakeholders were interested in the concept of over-the-counter provision as a strategy for increased access, others were cautious about this approach for India. They stressed that over-the-counter distribution could be fraught with problems, since most women have limited knowledge of their anatomy and no prior experience with diaphragms. These stakeholders cautioned that introduction should be taken slowly to build evidence of success before expanding more broadly, including outside a clinic setting. Some stakeholders felt that providing a pelvic examination could empower women by providing them with greater awareness of their own anatomy and also uncovering potential problems. Stakeholders all agreed that women need to learn about their vaginal anatomy to use SILCS. They need to know where their cervix is located and how to position the diaphragm, and they need to be coached in how to insert, use, and remove the diaphragm correctly.

> *"It should be started as a one-to-one effort with a doctor providing it in the beginning and giving plenty of information. Provision should be started slowly and carefully with adequate counseling. This is very important. It could be combined with the Standard Days Method and other methods, like condoms."* — Private gynecologist, Mysore

Health care providers had various opinions about who should provide SILCS, ranging from accredited social health activists (ASHAs) to doctors. Providers said that more needs to be learned about women's knowledge, preferences, and awareness regarding use of a device that requires repeated insertion, removal, washing, and storage. Stakeholders' concern about women's ability to wash and reuse a diaphragm is an issue that has been raised in other diaphragm acceptability assessments. However, this concern is not born out by research. For example, a consumer use study of the SILCS diaphragm among couples in three countries with the SILCS diaphragm found that women in low-resource settings easily managed washing and re-using the SILCS diaphragm.[21] A study of the acceptability of the traditional diaphragm among rural women in India also reported that low-income women easily learned to use and care for the diaphragm.[11] Research studies in more than 14 countries have confirmed that women in a range of developing and middle-income countries find diaphragms acceptable and discover strategies for washing and reuse. Female FGD participants said they would like to get SILCS from medical stores (kiosks/pharmacies) and to have access through all levels of the government health system, including from Anganwadi (community health care center) workers. Many of these women said that door-to-door delivery by ASHAs, who already provide family planning information as well as birth control pills and emergency contraception, would be useful and convenient. Women who were part of the Ashodaya (Indian NGO and partner in this study) community said they would prefer to obtain SILCS at their clinics, where they feel comfortable accessing sexual and reproductive health services.

Most stakeholders said they felt that SILCS distribution should start small, with a phased approach beginning with private, not-for-profit clinics to build awareness and develop support.

A representative of a group involved in social franchising advocated giving women access to nongovernment methods using vouchers to increase access. He noted that the injectable DMPA (depot medroxyprogesterone acetate) did not get approval from doctors, but when the private sector took it on, use grew and cost has dropped.

> *"Forget the public sector, increase the market by working with private sector and letting them develop the market."* — Social marketing NGO stakeholder

Provider training

Stakeholders emphasized the need for information and training for providers to prepare for SILCS introduction. The integration of SILCS into training for public-sector providers would include in-service training for medical officers, nurses, and others who provide family planning services. This could be relatively simple, since there are already trainings organized for IUDs, female sterilization, and delivery care. This type of education is commonly done in short workshops, of one- to two-days duration, by the national, state, or local government in partnership with NGOs and other organizations that focus on training in maternal health and family planning. SILCS could easily be integrated into the curriculum just as other contraceptive methods have been.

Strengthening family planning training and counseling are areas that have been targeted by the government to improve the quality of care and continued use of contraceptive methods among public-

sector family planning programs. Incorporating SILCS training and counseling for providers into these training workshops would raise awareness and could build support among providers for this new method.

Some providers said that pelvic models would be useful for explaining to women how to use SILCS and show how it works by covering the cervix to prevent pregnancy. Others said the anatomical posters they already use would be sufficient to explain this new method. Still others said it is impossible to know what potential users will think before they have a chance to use the diaphragm, and they emphasized the importance of acceptability research or piloting to inform any future introduction.

Both providers and potential users agreed that SILCS users will need support from providers or peers who they can talk to if they have problems. Sex worker peer educators were confident that women could learn to use SILCS with minimal training and that they could easily train and support other women in their communities to use the SILCS diaphragm. These sexual and reproductive health educators said it would not be confusing to understand that SILCS does not replace male condoms for disease protection.

Education and counseling

Stakeholders and users suggested a number of messages to engage potential SILCS users. They recommended focusing on the following attributes: lack of side effects; woman-initiated and controlled; used only when needed (that is, does not require daily use); can be used with or serve as a back-up for other methods; reusable; and has the potential for protection from some STIs.

Providers generally said that word-of-mouth testimony by experienced users was essential and the best way to promote a new method.

> *"Education about it wouldn't be a problem once there is real life experience with the method here. Providing women's testimony here is the most important."* — Staff nurse, primary health center, maternity unit, Mysore

Stakeholders stressed the importance of market segmentation that uses different messages for different groups. For married men, communications might emphasize that SILCS may make it unnecessary to use a condom and that SILCS does not interfere with sexual pleasure.

> *"Stress the pleasure principle and find the positive aspects of SILCS to include."* — Reproductive health program implementer, international NGO, Delhi

For policymakers and providers, messages could emphasize that SILCS increases choice; the fact that, as a new method, SILCS has the potential to increase contraceptive prevalence; and that SILCS is reusable and thus potentially cost-effective. For reproductive health activists, communications might emphasize safety and women's control.

Advocates also stressed the need to position the diaphragm as a "modern method" for greater acceptability.

Feedback from focus group discussions with potential users

Experience with existing family planning methods

In all FGDs, participants (both women and men) noted that there has been increased awareness of modern methods—largely due to efforts of government health workers at all levels—and availability of multiple family planning methods. This perception is consistent with the Government of India's report that women's awareness of modern contraceptive methods is almost universal in India—97.7% in rural areas and 98.8% in urban areas.[6] Female participants reported hearing about family planning from a variety of sources, including the media; nurses, doctors, and other providers at clinics and hospitals; ASHA workers in their communities (these workers often go door-to-door); Anganwadi workers (a cadre of female community health workers in child development centers); and their elders. These sources focus on two key messages: (1) the need for *birth spacing* to preserve health and (2) the need to *limit family size* to two children. It is expected that women will go for sterilization after having their second child. This is widely—but not universally—practiced and accepted.

While some women described having positive experiences with birth-spacing methods, many expressed concerns about existing methods, ranging from side effects and safety to partner concerns and cost. For example, in regard to birth control pills (such as Mala D), women repeatedly mentioned side effects such as weakness, irregular bleeding, white discharge, and nausea. For IUDs (such as the Copper T), women noted side effects such as pain, excessive bleeding, and infection.

> *"There is a problem with Copper T. Some months there is too much bleeding, and sometimes it hurts men. It is difficult sometimes to take out, and it causes pain during journeys. It also hurts when we sit. Sometimes if we do not change it, it irritates and may lead to other infections."* — Female, general population FGD, Mysore

Some women reported their partners/husbands did not support their use of certain contraceptive methods because of concerns about adverse effects.

> *"My husband thinks that all these methods are useless and create health problems… That's why he won't use any methods and won't allow me to take [birth control] pills."* — Female, general population FGD, Rajasthan

Male participants also expressed concerns about the side effects of birth control pills, IUDs, and other methods. Many also acknowledged that they refuse to use condoms because of a decrease in sexual pleasure.

> *"But injection usually harms the female's body. It affects her period time."* — Male, partner FGD, Jaipur

> *"But sometimes the Copper T creates problems like pain and infections to women."* — Male, partner FGD, Mysore

Some women also reported not liking the fact that they have to take birth control pills at the same time every day. Women also mentioned reports of contraceptive failures with these methods—either based on their own experience or that of someone close to them.

Women's comments about condoms were generally more positive. Condoms were considered to work well if used properly, and without side effects.

> *"I feel tablets [pills] and Copper T are not safe. The safest is condoms. Pills have side effects. If we use properly, condoms are the safest."* — Female, general population FGD, Mysore

Cost was not mentioned as a concern because most FGD participants accessed contraception through government clinics where contraceptives are free. In addition, lack of access was not brought up as a problem. On the whole, women in both Mysore and Rajasthan had favorable opinions about using reversible methods, specifically mentioning condoms and the Standard Days Method because they do not cause systemic side effects. Thus, it seems that SILCS could provide another option for women seeking a method with no systemic side effects.

Gender dynamics around family planning decision-making

Despite advances in some areas, many women in the FGDs in Mysore and Rajasthan indicated that their male partners are typically the primary decision-makers especially around sexual and reproductive health issues. Male participants make decisions around family planning based on their own sexual pleasure, such as by refusing to use condoms. These perceptions were confirmed by focus group discussions with men.

> *"In the rural areas, still there is male dominance in the family; men are the decision-makers in the family… In villages male decides on everything."* — Male, partner FGD, Mysore

> *"In our society… men have the power… they make all the decisions. Never do women tell us not to have babies, so they do not ask us to use condoms. [A wife] has to have sex with [her husband] whenever he wants and listen to whatever he says."* — Male, partner FDG, Mysore

Economics was also identified as an issue men consider when thinking about family planning decisions.

> *"The majority of us including our partners would think of what would be economical. They think of their incomes and expenditure and what they can provide for the children. Then only they decide how many children they wish to have."* — Male, client of FSW FGD, Mysore

Other participants indicated that elders, especially the husband's mother, may have a strong influence on the timing of pregnancy as well as sterilization. This is particularly true in rural areas. However, some men and women, especially in Mysore, said that decisions about family planning and how many children to have are taken together by the couple.

> *"Nowadays, elders or parents do not interfere in these kinds of decisions. [The] husband and wife discuss and decide whatever they think is right. The mindset has changed."* — Male, partner FDG, Mysore

SILCS acceptability—perceived benefits

The key benefits of SILCS for FGD participants were that it has no side effects and can be used only when needed. Some women also said that SILCS may be preferable to condoms.

> *"The diaphragm can be used and removed when we feel like it. The Copper T [an IUD] is inside us from the day of insertion until it is removed."* — Female, general population FGD, Mysore

> *"The good thing about this product is that it will not harm the body. Now women can use this device because we don't have side effects; the only thing is that we need to remove it once in 24 hours and wash it."* — Urban FSW FGD, Ajmer

> *"With this device, women will feel free. It will be under her control."* — Female, general population FGD, Jaipur

Female FGD participants from the general population noted that SILCS may be preferred over condoms because condoms are often associated with sex work. Some participants also noted that condoms can be difficult to dispose of.

> *"Disposing of used condoms is very difficult. But the diaphragm can be easily washed when we go to the washrooms and reused."* — Female, general population FGD, Mysore

Male participants highlighted pleasure as a benefit and noted that they would not need to use a condom.

FGD responses from both women and men suggest confidence about using SILCS once they receive training:

"If you train us, we can properly insert SILCS after practice." (female)

"If you simply give this to the woman and ask them to use it they may not, but if you explain and make them understand it they may." (male)

"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 its importance. So in the same way if we can discuss among ourselves we can start using this, too." (female)

> *"When these methods are introduced, companies should talk more about pleasure, along with protection and prevention of pregnancy."* — Male, partner FGD, Mysore

Among FSWs, the ability to use SILCS for sex with their husbands or other regular partners, where condoms are not regularly used, was seen as a benefit. Some FSWs also suggested that SILCS would be useful as a back-up method to condoms.

> *"Normally, when we are with our partners or husbands, we do not use condoms, so SILCS may be important for us. With clients, condoms are a must and so we can use both then."* — FSW FGD, Mysore

> *"I think we should use both. What if condoms break?"* — FSW FGD, Mysore

Enabling women to use SILCS

Since none of the FGD participants had seen a diaphragm before, many female participants had questions about insertion and removal. These questions speak to the need for basic education to help women understand about their bodies and can be addressed through education and counseling.

> *"…Is it uncomfortable and difficult inserting this device?"*
>
> *"Can it harm our womb when inserting/removing it?"*
>
> *"If this device gets stuck at that place, then what will we do?"*

In addition to the questions about insertion and removal, female FGD participants also raised questions the following topics:

- Interference with urination.
- Comfort or interference during sex.
- Concern that the partner may be bothered by it.
- Fear of diaphragm falling out.

All of these types of user questions can be dealt with by means of provider training and appropriate educational/instructional materials, as well as coaching or counseling by a peer provider who has experience using the diaphragm herself. Responses from female FGD participants suggested that, while they had some questions and concerns about SILCS, women thought that, given adequate training and practice, they could use SILCS (see text box at right). In addition, current acceptability research on the progesterone vaginal ring has shown that women have no problem inserting and removing the device (personal communication, Dr. Suneeta Mittal and Dr. Saroj Pachauri).

Most women in the FGDs said that they would be willing to pay from 50 to 200 Indian rupees (INR) for a diaphragm that could be used for two years (US$0.93 to $3.71, USD exchange rate as of February 2013). Others said that since only a few women would be able to purchase SILCS, it should be provided free of charge at government clinics.

Regulatory and policy environment

Regulatory stakeholders agreed that registration of the SILCS diaphragm should be fairly straightforward. Traditional diaphragms previously were available in India and are recognized as having a long history of safe use. Also, SILCS has a substantial record of clinical data showing safety, effectiveness, and acceptability. Data from a small, short-term study among 50 to 100 Indian women will be required to provide local evidence of acceptability and safety. ICMR and the Family Planning Association of India could implement a study like this; since effectiveness is already established, the additional clinical study in

Regulatory bodies in the Indian government that are responsible for medical device registration in India:

- The **Central Drug Standards Control Organization (CDSCO)** is India's main regulatory body for pharmaceuticals and medical devices.
- **The Drug Controller General of India (DCGI**) is the key official within the CDSCO. The DCGI is responsible for the approval of the manufacturing of certain drugs (vaccines, specific medical devices [including **diaphragms], and new drugs).**
- Manufacturing, import, sale, and distribution of medical devices are regulated under **India's Drugs & Cosmetic Act and Rules (DCA).**

India should not be too burdensome. The Director General of ICMR expressed strong support in 2012 for identifying the research questions around SILCS and implementing the necessary bridging studies, saying, "Family planning is huge topic now, and we need to move."

Contragel (Caya Gel) has regulatory approval in Europe, Canada, and multiple other countries and has been marketed since the 1970s for use with diaphragms. It does not have a clinical dossier, but it has good safety and consumer acceptability. Phase I clinical studies in the United States for safety and barrier effectiveness when used with the SILCS diaphragm are scheduled to be completed in 2016. These data could be presented to the Indian regulatory authority, along with the consumer data and a request to determine what additional data would be needed to register Contragel for use with the diaphragm.

However, discussions with a DCGI representative revealed potential obstacles getting a contraceptive gel approved for use with the SILCS diaphragm in India. The Indian regulatory process for medical devices does not have a provision allowing a contraceptive gel to be approved as an adjunct used with the diaphragm, which is how Contragel®/Caya® Gel (the lactic acid-based contraceptive gel from Europe) is approved. In Europe the Contragel/Caya Gel is approved as a Class IIb device under the medical device guidelines for CE Mark; Kessel medintim GmbH has registered and marketed in 26 countries for use with the diaphragm (https://www.medintim.de/woman-contraception-diaphragm-gel-contragel-green/).

The DCGI advised that the contraceptive gel used would be considered a pharmaceutical, requiring a new drug application and a contraceptive effectiveness study of the gel before it could be approved. Since Contragel/Caya Gel is formulated for use only in conjunction with *diaphragms and cervical caps* and is not intended for use as a stand-alone product, data from a contraceptive effectiveness study on the use of the gel alone would not provide relevant data since this is not its intended use. Clinical data on the safety and barrier effectiveness to sperm of the SILCS diaphragm used with the Contragel are expected in late 2016, after two studies being implemented by CONRAD (www.CONRAD.org) are completed.

Thus, the absence of an approved contraceptive gel in India and lack of clarity about how to address the regulatory questions associated with approval of Contragel/Caya Gel are challenges for SILCS introduction in India.

In the absence of an approved contraceptive gel, one strategy to move forward is to evaluate SILCS for use *without* a contraceptive gel. This is a strategy that has been evaluated in clinical studies in multiple countries. While it is logical that a diaphragm used with a contraceptive gel would be more effective, little evidence exists of the added benefit from the contraceptive gel, and studies in Brazil,[22] Kenya, and Madagascar suggest good acceptability and effective use of the diaphragm without contraceptive gel.[23,24,25] Since Indian women are not accustomed to using vaginal lubricants, the exploration of using SILCS as a stand-alone product might be useful, even if this results in slightly reduced effectiveness compared to SILCS used with a contraceptive gel.

Another strategy that could benefit SILCS introduction in the future may come from the Expanding Effective Contraceptive Options project being implemented by WomanCare Global and Population Services International.[26] The Expanding Effective Contraceptive Options project (2015–2018) is working to register and introduce several women-initiated contraceptive methods in India. One of these will be Amphora® gel, which is a lactic acid–based contraceptive gel developed by Evofem. Amphora gel has been evaluated in a contraceptive effectiveness study, and Evofem has submitted an application in the United States for regulatory approval. Once Amphora achieves US Food and Drug Administration

Contragel is a registered trademark of Kessel medintim GmbH.
Caya Gel is a registered trademark of Kessel medintim GmbH.
Amphora is a registered trademark of Evofem, Inc. More information available at: http://www.evofem.com/products/.

regulatory approval as a contraceptive, this could facilitate a regulatory submission for Amphora gel in India as well. If Amphora gel is approved in India, it could be used with the SILCS diaphragm. This could facilitate SILCS introduction in India and could be an important strategy to consider moving forward.

Finally, recent developments within the Indian regulatory system could help simplify necessary steps for Contragel/Caya Gel approval for use with the SILCS diaphragm. In 2015 proposed amendments to India's medical device and pharmaceutical laws were submitted to parliament for approval.[§§] The legislation was developed to more closely align India's regulations with the European Medical Device Directives. If these changes are approved, the Contragel/Caya Gel could possibly be approved as an adjunct to the diaphragm, the same way this gel is CE Mark–approved in European countries.

Recommendations for introduction of SILCS in India

This health systems assessment found broad support for the SILCS diaphragm as a contraceptive method that could help address unmet need for family planning, especially among young married women. It also identified next steps to advance SILCS introduction in India:

- **Expedite approval of a contraceptive gel or build evidence for use of SILCS without gel.** Given that diaphragms are recommended for use with a contraceptive gel, and no gel is approved in India, SILCS introduction cannot move forward until this challenge is addressed. Gel approval could likely be expedited in several ways:
    - A contraceptive gel is manufactured in India (licensing and technology transfer).
    - A contraceptive gel with contraceptive-effectiveness dossier is submitted for Indian regulatory approval (for example, Amphora gel via the Expanding Effective Contraceptive Options project) and imported into India.
- **Introduce the SILCS diaphragm through a phased approach, using private-not-for-profit and NGO sector clinics to test uptake of this new method.** Many women access family planning services through these channels. Introduction in the not-for-profit and NGO sectors can generate awareness and confidence about this method and develop best practices for service delivery. If uptake in the private-not-for-profit/NGO sectors is successful over time, then feasibility of future introduction through the national family planning program can be assessed, which would also require planning for technology transfer and local manufacture of the SILCS diaphragm per Government of India requirements.
- **Identify key organization(s) to lead and implement introduction.** While multiple NGOs and stakeholders expressed interest in SILCS introduction, a key organization/institution should be identified to coordinate strategy and planning. Several stakeholders suggested PATH as an organization that could lead SILCS introduction because of PATH's history with this product and its presence in the health community in India. Having SILCS introduction led through Advocating for Reproductive Choices (ARC—the coalition of sexual and reproductive health organizations), the Family Planning Association of India, or Hindustan Latex Family Planning Promotion Trust (HLFPPT) could leverage existing relationships and build support across sectors since they are connected to both advocacy and service delivery channels. Social marketing organizations such as DKT International, Population Services International, and clinics such as Marie Stopes International could also be involved.

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

- **Build support for SILCS among women's health activists and parliamentarians. These** audiences are important and influential groups in India and will be key to future introduction. They seem interested and ready to support SILCS, partly because they are interested in expanding the contraceptive method mix, and they see SILCS as a method that can help address unmet need for family planning.

This assessment identified three key areas where additional research will benefit future introduction:

- **Data on user/provider acceptability of SILCS in India.** Stakeholders at the national and regional levels, and the regulatory authority, all agreed that generating data on acceptability of SILCS in India will be a required next step. Understanding women's/provider's questions, concerns, and willingness to use SILCS will help tailor instruction and counseling messages to the Indian context.
- **Assess feasibility of different distribution channels, including the private, not-for-profit clinics/NGO sector and government family planning clinics.** This will inform which distribution channels are best suited for early introduction and also ensure that the channels selected for product launch reach the consumers most likely to be early adopters. After some experience has been gained with SILCS in India, explore feasibility and acceptability of SILCS provision both in and outside of clinic settings, especially if there is interest in incorporating SILCS into the national family planning program**.** For example, door-to-door delivery by ASHAs or distribution through Anganwadi workers should be explored, as well as distribution through pharmacies or other medical stores.
- **Evaluate the acceptability and effectiveness of SILCS use without a contraceptive gel.** Little is known about the relative added value of the contraceptive gel to the overall effectiveness of the diaphragm. The need to use contraceptive gel will be a burden for the consumer both in terms of cost and ensuring supply. Using the diaphragm as a barrier method—even if used without the contraceptive gel—is better than using no method at all. Studies from several countries suggest use of the traditional diaphragm without contraceptive gel is acceptable and still offers protection. The feasibility of this strategy should be considered in the Indian context (*and globally)*, especially if no workable solution is found to expedite access to a contraceptive gel.

Since there is little experience with diaphragms in recent decades in India, training and education will be needed for both consumers *and* providers:

- **Address education about SILCS through appropriate instructional materials for low-literacy consumers.** To use the SILCS diaphragm, women need a basic understanding of their vaginal anatomy. This knowledge could be obtained from health workers using flip charts; from peer educators; from a package insert; or through other communication channels. This increased knowledge and awareness will add to women's ability to understand and care for their bodies and may empower them to take part in decisions that affect their reproductive health. Some issues, such as women's concern about comfort and fear of the diaphragm getting stuck or falling out, may be best addressed by experienced and trusted users.
- **Health care providers should receive information and training related to SILCS.** Even if introduction begins in the private, not-for-profit, NGO, and social marketing sectors, over time, education and training on SILCS should be included as part of in-service trainings for providers at all levels. This includes 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 an overall introduction strategy, so providers are trained first in those distribution channels and sectors where SILCS is being first introduced, and training is expanded as the method is scaled to reach women in different service delivery channels.

- **Incorporate clear messaging in advocacy and awareness-raising efforts to build a supportive environment for introduction by**:
    - **Emphasizing SILCS as a nonhormonal family planning method and highlighting benefits for different user groups.** For example, messages for young married women can emphasize that use of SILCS will help delay birth of their first child and protect future fertility (by reducing risk of cervical STIs). For couples who already have a child, communications may stress that SILCS can be used safely while breastfeeding. And for FSWs, messages may emphasize that SILCS can be used with intimate partners where condom use is low and as a back-up for use with transactional sex partners who refuse condom use.
    - **Positioning SILCS as woman-initiated method.** India remains a male-dominated society. Yet the large emerging middle class, the increasing education and awareness of girls, urbanization, and new patterns of socialization have opened up new opportunities for women to gain a measure of independence in their personal lives. SILCS can be positioned to women as a way for them to gain some control over their own bodies and reproductive futures.
    - **Including outreach to men when introducing SILCS.** Men are increasingly aware of the importance of family planning and are concerned about the effects of contraceptives on their partners/wives. Specific messages that address the needs and concerns of men as partners should be developed and included as part of SILCS introduction planning in each community, since women are consistently more able to use a contraceptive method when their partner is supportive.
    - **Engaging champions from multiple sectors to build support for introduction.** A number of diaphragm champions still exist in India, and these are and can be supporters of SILCS. They have already been involved in this assessment and will continue to advocate for the introduction of SILCS in their various spheres, but they also need an institution to take the lead. Other potential champions from the women's health activist community could be engaged as well; some of these have been a powerful mobilizing force *against* the use of hormonal contraceptives because of their systemic side effects but would likely support SILCS precisely because it offers a choice free of side effects.

Conclusion

Increasing options for reversible family planning methods, particularly for young married women, is a high priority for the Government of India. The SILCS diaphragm has the potential to help address unmet need for family planning, especially among young married couples, by offering Indian women a method that has no systemic side effects, is used only when needed, is reusable for up to two years, and is more discrete than male or female condoms. SILCS has been designed to be easy to supply and provide, thus reducing the burden on the clinic system. Special features are designed to make it easy to handle and use—especially for first-time users. Eventually, if allowed by regulatory approval and service delivery guidelines, SILCS could be provided both within clinics and outside

Advocacy is an important component of successful sexual and reproductive health (SRH) programs and is an especially important strategy when planning for introducing a new contraceptive method. The key SRH advocacy organization in India is Advocating for Reproductive Choices (ARC) (http://www.arccoalition.org/).

ARC supports introduction of the SILCS diaphragm to expand contraceptive method mix and to help address unmet need for family planning. ARC is a coalition of 36 member organizations, with member chapters in the five states in India with the highest total fertility rates. They focus primarily on advocacy at the national parliamentary level. ARC receives technical support from WHO, UNFPA, the Indian Council of Medical Research (ICMR), and the Ministry of Health and Family Welfare. The Family Planning Association of India, a nongovernmental provider of women's health services with 43 clinics across India, serves as the secretariat for ARC.

the clinic system by community health workers or over the counter, as it is being marketed now in Europe.

Almost all stakeholders and potential users interviewed and surveyed in this health systems assessment expressed support for introduction and use SILCS as a way to expand the method mix and address unmet need for contraception in India. Researchers, reproductive health advocates, and gynecologists and other clinicians all expressed that SILCS would be appropriate and should be made available as an alternative to the two birth-spacing methods currently promoted. Women and their partners were enthusiastic about a method that would be safe, with no systemic side effects, and within a woman's control. Sex workers and those working in HIV prevention programs felt that SILCS could play an important role for contraception and protection in intimate-partner relationships, where condom use is limited.

ARC and its member groups discussed the potential of SILCS diaphragm introduction at a Delhi meeting in September 2012 sponsored by FHI 360 and Management Sciences for Health titled "Expanding Contraceptive Choice in India: Focus on New and Underutilized Methods" and also at a meeting in December 2012 convened by Futures Group: Health Policy Project, ARC, and USAID. ARC has included SILCS introduction as part of its recommendations for the next 5-year goals.

The ARC coalition provides an important infrastructure for community-based advocacy that could be mobilized in support of SILCS introduction. ARC members and others who were interviewed suggested that PATH should take a leadership role in introducing SILCS in India given PATH's role in developing the diaphragm and PATH's initiatives to move this product toward developing-country introduction.

Stakeholders at the national and regional levels, and the regulatory authority, all confirmed that Indian data on acceptability of SILCS is required as a next step. Thus, research institutions—such as the Indian Council of Medical Research—and advocacy and service delivery organizations—such as the ARC coalition—will play important roles moving forward. SILCS introduction should be phased in slowly, with early introduction in the private, not-for-profit sector clinics and systems to assess patterns of use and address potential challenges. Stakeholders suggest that regulatory activities should be implemented in parallel with activities to expedite market access. Lack of a readily approvable contraceptive gel currently is the limiting factor stalling efforts toward future introduction of SILCS. Identifying a key institution or group of organizations to champion and coordinate SILCS introduction, as well as securing the necessary funding, are necessary steps before preparatory activities will proceed.

Since 2013, PATH and our research partners have shared these results at international conferences to raise awareness among donors, researchers, and other stakeholders about the opportunities and challenges for SILCS introduction in low-resource settings. PATH and the Indian market research firm IMRB also implemented market research in India to assess potential target markets and key messages for women who may be interested in using this method. Kessel medintim GmbH has moved forward developing partnerships for introduction of the Caya contoured diaphragm in countries where the diaphragm and the contraceptive gel are able to be registered. This single-sized contoured diaphragm is reinvigorating interest in the whole category of vaginal barrier methods, and a new generation of women are considering using this new nonhormonal barrier method. Results of this assessment and the market research confirm there is interest in the SILCS diaphragm in India, and this new method could help meet the needs of women who cannot or do not want to use existing methods.

Based on their experience advocating on behalf of other underutilized methods, the ARC coalition recommends including strategies to raise awareness and build a supportive environment for SILCS introduction by developing messages that highlight key benefits important to different audiences. For example, messages such as "a nonhormonal method that expands women's options for family planning" and "a woman-initiated method, used only when you need protection," used in promotion and awareness-raising campaigns, may appeal to specific potential user groups. A statement such as "a birth-spacing method that is easy to provide and can help address unmet need for family planning, especially among young married couples" may have more appeal for researchers, providers, and policymakers.

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Appendix. Key stakeholders interviewed, 2012

Stakeholder category	Organization or institution	Role
Government of India agencies		
Research institute	Indian Council of Medical Research (ICMR)	The national research institute in India for the formulation, coordination, and promotion of biomedical research. Any clinical study of SILCS designed to lead to regulatory approval would need to be implemented either by or in coordination with ICMR. ICMR can provide insight into the regulatory process.
Training institute	National Institute of Health and Family Welfare (NIHFW)	Responsible for national-level training in family planning for providers and trainers (clinical and didactic).
Regulatory authority	National Drug Controller General of India (DCGI)	All new drugs and devices must have DCGI approval before use in India is allowed.
International nongovernmental organizations		
	Population Council	Sexual and reproductive health (SRH) research, new family planning (FP) methods; researching progesterone vaginal ring, works closely with ICMR.
	FHI 360	Worked in India for two decades. Member of Advocating for Reproductive Choices (ARC). Activities encompass technical assistance, research, and implementation across a broad array of public health priorities, including HIV and AIDS; family planning and reproductive health; maternal and child health; health systems strengthening; integrated health and development; and infectious diseases.
	Futures	Coordinated meeting on joint advocacy strategy with ARC.
	International Planned Parenthood Federation	Direct service provision; diaphragm remains in international FP basket.
	Marie Stopes International	Direct SRH service provision; focus on social marketing in India.
United Nations agencies		
	UN Population Fund (UNFPA)	Strong player at national level; good relations; imported and procured female condom for Government of India; supports capacity-building for sex worker organizations; supports spacing methods.
National nongovernmental organizations		
	Population Foundation of India (PFI)	Some priorities are: delaying child marriage, promoting non-coercive programs, and FP; involved in 'expanding FP choices' taskforce.
	Hindustan Latex Family Planning Promotion Trust (HLFPPT)	Indian 'not for profit' organization, promoted by HLL Lifecare Ltd, a Mini Ratna Public Sector Enterprise (Government of India); founded in 1992. Known as a pioneer in promoting public health through social marketing and social franchising strategies. HLFPPT actively contributes toward the goals of the National

Stakeholder category	Organization or institution	Role
		Health Mission, FP2020, universal health coverage, and post-2015 Millennium Development Goals agenda.
	Family Planning Association of India (FPAI)	Service delivery, broad reach, and can deliver nongovernment as well as government methods; serves a broad population; does research with ICMR on FP methods.
Donor agencies		
	United State Agency for International Development (USAID)	Funding for FP being significantly decreased.
	Packard Foundation	Earlier, strong support for diaphragm. Funded a stakeholder meeting in 2008 on potential for reintroducing the diaphragm in India.
	United Kingdom Department for International Development (DFID)	Has funded FP/SRH social franchising programs but is largely withdrawing from this in India.
Professional bodies		
	Federation of Obstetric and Gynaecological Societies of India (FOGSI)	National organization of ob/gyns; leadership progressive but not rank and file; male gynecologists can be an obstacle.
Advocacy groups		
	Advocating for Reproductive Choices (ARC)	Expanding FP choices with focus on safe, effective, quality in public and private delivery points, affordable; support from World Health Organization (WHO), United Nations Population Fund (UNFPA), ICMR, Indian Ministry of Health and Family Welfare (MOHFW).
Advocates, individual		
	Dr. T.K. Sundari Ravindran	Professor at the Achutha Menon Centre for Health Science Studies. Activist/researcher on gender, health, and equity. Principal investigator of diaphragm acceptability study in the 1990s: "Is the Diaphragm a Suitable Method for Low-Income Women in India" http://www.rhmjournal.org.uk/publications/beyond-acceptability/078_Ravindran.pdf.
	Dr. Saroj Pachauri	Distinguished scholar and former country director of the Population Council in India.
	Dr. Suneeta Mittal	Director and head of obstetrics and gynecology at Fortis Memorial Research Institute. Influential at national level and in FOGSI; a champion of diaphragm; convened national meeting on guidelines for emergency contraceptive pills use.
	Suneeta Krishnan	Social epidemiologist working to promote gender and health equity. Works on women's empowerment issues. Colleague of Nomita Chandiok at ICMR; would be a champion.
	Kalpana Mehta (email conversations)	Involved with bringing Brazilian diaphragm to India—many problems with importing it; women were very positive but supplies limited.