Assessment of opportunities and challenges for potential introduction of the SILCS diaphragm in South Africa

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Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ART	antiretroviral therapy
CE	Conformité Européenne (European Conformity)
CHW	community health worker
DHIS	District Health Information System
FGD	focus group discussion
FP	family planning
HCT	HIV counselling and testing
HIV	human immunodeficiency virus
IUD	intrauterine device
MatCH Research	Maternal, Adolescent and Child Health Research
MIRA	Methods for Improving Reproductive Health in Africa
NDoH	National Department of Health
NGO	nongovernmental organisation
SABS	South African Bureau of Standards
SADHS	South Africa Demographic and Health Survey
SRH	sexual and reproductive health
STI	sexually transmitted infection
UNFPA	United Nations Population Fund
US	United States
USAID	United States Agency for International Development
USFDA	United States Food and Drug Administration
WHO	World Health Organization

Executive summary

South Africa's sexual and reproductive health challenges

South Africa faces a number of challenges related to family planning and sexual and reproductive health (SRH), including high rates of unplanned pregnancy (including amongst teenagers) and one of the highest rates of HIV prevalence in the world, with the infection focused amongst young people.

Despite a relatively high reported use of modern contraceptives (64.6%) amongst sexually active women in South Africa, the high rates of unintended pregnancy and HIV and other sexually transmitted infections (STIs) suggest there is a gap in meeting their reproductive health needs. South Africa's leaders have recently made increasing access to high-quality family planning (FP) services and expanding the contraceptive method mix a national health priority.

The new single-size SILCS diaphragm aligns with this goal and can provide women with expanded access to a safe and effective nonhormonal option for preventing pregnancy. Injectable contraceptives are currently the most commonly used method amongst women in South Africa. The only nonhormonal options available are the male condom and, to a much lesser extent, female condoms.

PATH and its partners developed the SILCS diaphragm through a user-centred process that included feedback from women, partners, and providers in multiple countries, including South Africa. The device has an innovative shape and spring that allows a single size to fit most women and is designed to be easy to insert and comfortable to wear. The single-size design makes supply and provision less burdensome since no pelvic exam is required to determine the correct size. Whilst the SILCS diaphragm was developed initially as a contraceptive, it is also being evaluated as a reusable delivery device for microbicide gel, which would allow it to serve as a multipurpose prevention technology that could protect users from HIV as well as unintended pregnancy.

Study methods

The assessment described in this report evaluated opportunities and challenges related to the introduction of SILCS in South Africa as a FP option and as a potential microbicide delivery device once a microbicide gel is approved. The report also explores SILCS' potential role and impact within South Africa's SRH landscape, including regulation, procurement, service delivery, and provider and user perspectives. The Maternal, Adolescent and Child Health Research (MatCH Research) group at the University of the Witwatersrand implemented this assessment.

This report is comprised of findings from a review of national policies relevant to SILCS introduction (full report available as a separate document); interviews with more than 30 stakeholders (e.g., policymakers, regulatory experts, FP service providers, HIV prevention experts), seven facility assessments of potential service delivery sites, and three focus group discussions with potential users.

MatCH Research convened a stakeholder meeting in November 2013 where they summarised key findings from this assessment and obtained stakeholder feedback and recommendations for next steps.

Key findings

Overall, findings suggest that South Africa's policy and FP service delivery environments are likely to support the introduction of SILCS as a FP method. Interest in SILCS amongst government stakeholders, FP providers, and potential consumers (both women and their partners) was quite high; they viewed SILCS as a method that would expand the contraceptive mix and provide a woman-initiated, nonhormonal FP method. There also was significant interest in using SILCS as a reusable delivery device for microbicide gel, which would allow the diaphragm to protect from both unintended pregnancy and HIV. The regulatory process for SILCS approval would be straightforward and was not considered problematic since diaphragms are considered an inert medical device with a long record of safety and worldwide use.

The regulatory strategy for approval of a contraceptive gel for use with the diaphragm needs further exploration. Currently, there are no contraceptive gel products available in South Africa, and regulatory experts were not able to comment on the prospect of having a contraceptive gel approved for use only with the diaphragm, not as a standalone product (as is the case with ContraGel®/Caya® Gel, the lactic acid-based contraceptive gel approved in Europe for use with diaphragms). Even less clear is the level of data required for SILCS to be approved in South Africa as a delivery device for microbicide gels, since microbicides are still being evaluated and no microbicide gel has yet been approved.

Throughout the assessment, stakeholders contributed a broad range of insights and also some concerns. Although not all of these opinions aligned, they provided an overview of the South African context, creating a foundation for targeted, effective, and sustainable introduction of SILCS.

In discussions on the **policy environment and procurement**, stakeholders noted that South Africa's policy environment for family planning, SRH, and HIV prevention is likely to support introduction of the SILCS diaphragm. Interviews provided insight into existing public-sector purchasing and procurement systems (including funding mechanisms, costs, and taxation) and pointed to the value of registering SILCS with the South African Bureau of Standards. Although participants did not identify appropriate pricing or burden of cost for the SILCS diaphragm or microbicide gels, they did suggest that the government is prepared to fund microbicides and is therefore likely to fund SILCS. They also noted that the level of use, effectiveness, product lifespan, comparison with other methods, and packaging may affect cost and procurement. No supply chain management issues specific to SILCS were mentioned.

Discussions of **regulatory pathways** highlighted that the distinction between "devices" (SILCS) and "medicines" (microbicides) could affect regulation, taxation, and other factors involved in introduction.

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Stakeholders also noted that the South African regulatory environment for devices is in flux and that regulatory requirements for the use of SILCS with a microbicide gel are unclear.

The study explored **platforms for service delivery and education** through facility assessments and discussions with health service providers. Stakeholders noted that higher socioeconomic groups tended to access health care through the private sector, whereas lower socioeconomic groups typically used the public health care system, usually free of charge. They recommended broad distribution of the SILCS diaphragm through a range of outlets, including public health facilities, nongovernmental organisations, private health care providers (including pharmacies), tertiary education institutions, and retail stores. In general, stakeholders felt that SILCS introduction should be part of an integrated approach to service delivery (HIV, family planning, antenatal care, and maternal health and postnatal care) and should involve health care providers at every level, as well as community members.

Stakeholders suggested that FP workers would welcome additional **training**, and that there is a clear need for updated materials to train both new and more experienced providers about this "new-generation" diaphragm. The South African Nursing Council, which oversees health care worker training curricula, would need to approve the materials. Stakeholders also provided suggestions on the appropriate format, length, and content of trainings and highlighted potential issues, including the overlap between counselling clients on SILCS and condom use, how male clients may react to the product, and user compliance. Suggestions were also offered on which cadres of health care workers would be qualified to dispense SILCS and microbicides.

The study team also **assessed selected facilities** to explore their capacity to introduce SILCS and microbicides. These included public and private clinics, nongovernmental organisations, and schools. Evaluation factors ranged from whether facilities had adequate space and privacy for women to practise using the diaphragm to staffing levels, storage space, and hours of operation. Findings suggest that each venue has unique strengths and challenges and that a combination of delivery options would help reach the most users. Schools, for example, are uniquely positioned to deliver crucial information to adolescents but may not be able to deliver products. Facilities of all types would likely need staffing support to introduce SILCS, and stakeholders identified community health workers, nurses, and counsellors as particularly well suited to introduction.

Discussions on **monitoring** suggested that South Africa's National Health Information System could be easily revised or updated to track information on SILCS and microbicide distribution and use.

Focus group discussions with potential consumers (two groups of women, one group of male partners) identified perceptions and concerns related to the use of SILCS for family planning and for HIV prevention with the use of microbicides. All groups stressed the value of SILCS as a nonhormonal, female-controlled FP method that may ultimately enable dual protection against pregnancy and HIV.

Stakeholders also noted that the current gap in the market for nonhormonal contraceptive methods is of particular concern in South Africa, where high HIV prevalence means that many clients are on treatment regimens that can interact negatively with hormonal FP methods. They suggested that demand for both

SILCS as a contraceptive and SILCS with microbicide as a multipurpose prevention technology is likely to be high, especially for people living with HIV or other health concerns, younger and older women who may not want to be on a long-acting method, and women who do not want to take hormones because of potential or actual side effects. Many noted that high early uptake amongst these groups is likely to spark wider interest. Concerns were primarily associated with a presumed lack of knowledge about the product amongst women (about issues such as fit, ease of use, efficacy, cleaning, and storage of SILCS, as well as partner response and impact during sexual encounters) and a poor understanding of vaginal anatomy. However, most felt that these concerns could be addressed through proper introduction strategies and training.

End-users also thought that SILCS' unique attributes would contribute to high demand. Concerns included ease of use and comfort, safety (especially for male partners), and cleaning and storage. Response to the use of SILCS with a microbicide gel was mixed. Some noted that the gel would ease diaphragm use, but others were concerned about its safety. Some also worried that use of the combination might make it more difficult to convince men to use a condom as well.

In discussions on **marketing channels and messages**, participants from every group felt that SILCS would appeal, and should be marketed to, all South African women. They identified several channels to promote SILCS, including public health clinics; mass media, especially television, radio, newspapers, posters, and magazines; social media; chemists or pharmacists; schools; churches; traditional leaders; supermarkets; peer networks; health promotion projects; and social security offices. Hospitals, mobile health services, and community health workers and caregivers may also be appropriate sources of information. Engaging SILCS users and political leaders as **champions** to promote SILCS would be necessary to raise awareness and share knowledge and experiences. In general, the groups did not differentiate between the advantages and disadvantages of promoting SILCS for family planning or HIV prevention.

Conclusion and recommendations

Overall, stakeholders thought it would be easy to introduce SILCS because some women would embrace the opportunity to increase control over their contraceptive options. Whilst some said it could be useful to introduce the SILCS diaphragm for family planning and as a microbicide delivery device simultaneously, others recommended introducing SILCS as an FP method first. This would allow women and providers to gain familiarity with this new method and build confidence whilst researchers generate the additional data required for microbicide gel regulatory submissions. Since the SILCS diaphragm is already approved and being marketed in multiple countries as a contraceptive, it is reasonable for it be introduced in South Africa as a contraceptive once questions around the steps for approval for the contraceptive gel are addressed.

Although all groups suggested that introduction generally include all women, opinions varied on the value of SILCS or SILCS with gel for particular groups. Some suggested that women in stable relationships

were an ideal target group. Perceptions on the suitability for rural women were mixed; although some thought these women would struggle to align traditional beliefs with use, others felt that training could overcome this concern. Participants also had mixed opinions about younger users, suggesting that young women may be more open to new or nonhormonal approaches to family planning but that adherence could be an issue. They further noted that SILCS used with microbicide is likely to appeal to women who want a self-initiated way to protect themselves from HIV, including those with male partners who are abusive, resistant to new methods or condoms, or untrustworthy.

Based on the findings, the study team compiled a list of specific, actionable recommendations to support SILCS introduction for family planning or HIV prevention in South Africa. Because of the breadth of the study design, the recommendations provide evidence-based insight for every stage of the introduction process and take into account a broad range of health system concerns and policies.

The results of this comprehensive assessment can support successful introduction of the SILCS diaphragm in South Africa, whether used only for family planning or, in the future, as multipurpose prevention to protect from both unintended pregnancy and HIV/STIs. By giving women and couples throughout South Africa a greater range of appealing, effective, and affordable options, SILCS has the potential to support national health goals by empowering thousands of people to protect their own health and that of their families and communities.

Background

Sexually transmitted infections (STIs), including HIV, are a major public health burden in South Africa. According to the most recent South Africa Demographic and Health Survey (SADHS), 7.7% of women who had ever had sex reported an STI, vaginal discharge, or genital ulcer in the past 12 months.[1] South Africa has one of the highest rates of HIV in the world, with an overall population prevalence of 12.3% in 2012. HIV prevalence peaks amongst women aged 30–34 years, at 36.8%; in men, the peak is 24.2% and occurs in the 35–39 year age group.[2]

There are some positive signs that the infection rate is stabilising, however. A National HIV and Communication Survey conducted in 2005, 2008, and 2012 showed gradually declining HIV prevalence amongst youth, from 10.3% to 8.6% to 7.3%, respectively.[2] The 2012 survey findings also indicated an increase in condom use, HIV testing, and uptake of medical male circumcision.

Although regular surveys continue to update the status and changes in HIV prevalence and HIV prevention behaviours, we have less recent information on contraceptive indicators. The most recent national data on contraceptive prevalence and use in South Africa come from the 2003 SADHS, which found a relatively high contraceptive prevalence of 64.6% amongst all sexually active women.[1] Nonetheless, anecdotal reports suggest fewer people are seeking and using family planning (FP) services, a large proportion of pregnancies are unplanned, and teenage pregnancy and unsafe termination of pregnancy remain major public health concerns.[3,4] In addition, in 2011, the HIV prevalence amongst pregnant women attending public clinics was 29.5%.[5]

In view of the availability of new technologies, the HIV/AIDS epidemic, and the need to ensure linkages with other national and international policies, in December 2012, the National Department of Health (NDoH) published its revised contraceptive policy and guidance with input from an expert group and a broader consultative forum. The new National Contraception and Fertility Planning Policy and Service Delivery Guidelines (2012),[6] as well as the accompanying National Contraception Clinical Guidelines,[7] aim to ensure that "comprehensive quality contraception and fertility management services are available and accessible for all people in South Africa as part of a broader sexual and reproductive health package". These documents recognise a continuum between prevention of and planning for pregnancy and integrate this into a definition of family planning. Revised World Health Organization (WHO) Medical Eligibility Criteria form the clinical basis, and there are clear linkages with the NDoH's framework for sexual and reproductive health (SRH) and rights, as well as Millennium Development Goals 4, 5, and 6 (reduce child mortality, improve maternal health, and combat HIV/AIDS, malaria, and other diseases, respectively).

Key areas of focus are the need to make available and promote wider contraceptive choice; to facilitate the integration of FP and a broad range of SRH services, including HIV services; and to make adjustments for vulnerable groups and key populations to ensure equitable access to these services. The new policy and guidelines describe six key objectives and accompanying indicators: (1) expanded choice; (2) service integration; (3) training and capacity-building; (4) enabling legislative framework; (5)

communication strategies; and (6) monitoring and evaluation and research. Importantly, the policy requires the NDoH to consider contraceptive methods that are not currently available in South Africa. To advance these objectives, the policy has addressed broadening the scope of practice or "task-shifting" of health care providers to enable wider access to contraceptives. This would enable different (and additional) levels of staff to dispense contraceptives, increasing the availability of these products to the general population.

Provincial guidelines are often developed to adapt national policy and guidelines to the local context. In 2011, Maternal, Adolescent and Child Health Research of the University of the Witwatersrand, Durban, South Africa, was tasked by the Provincial Department of Health for KwaZulu-Natal and the United Nations Population Fund (UNFPA) to develop the KwaZulu-Natal Provincial 5-point Contraceptive Strategy 2011–2016.[8] The 2003 SADHS showed that KwaZulu-Natal had the highest recorded prevalence of contraceptive use in South Africa,[1] yet high rates of unplanned pregnancy, especially amongst teenagers (leading to high dropout rates from school), are inconsistent with the survey results. Based on a desk review and stakeholder interviews and workshops, the Contraceptive Strategy identified five high-priority areas for local action: (1) improving contraceptive awareness and access at health facilities and in the community; (2) improving the contraceptive method mix; (3) promoting the integration of contraceptive services with other services; (4) improving training and mentoring of health care workers (using formal contraception curricula that will be updated regularly); and (5) improving recordkeeping and monitoring and evaluation at facilities.

The huge burden placed on the South African health system by the HIV epidemic has not only overshadowed FP services but also required that attention be paid to the contraceptive needs of people with HIV infection or at risk of infection. The need for integration of FP and HIV services in South Africa is widely recognised. In particular, maximising opportunities to provide contraception services at routine HIV visits is called for (rather than requiring a separate visit or referral), as is counselling about HIV and appropriate methods within FP services.[9]

The profile of contraceptive use in South Africa is skewed heavily toward injectable hormonal methods. Other long-acting, reliable methods, such as the intrauterine device (IUD) and female and male sterilisation, are less available. The high prevalence of HIV in South Africa has increased the need for emphasis on dual protection from unwanted pregnancy and STIs.[10] However, limited data are available on use of methods for dual protection, and evidence shows that in some facilities condoms are primarily promoted for STI prevention only, rather than as a method of contraception.[10,11]

Diaphragms are currently unavailable in the public health sector in South Africa and have limited use in the private sector. They were available in the 1980s but were discontinued with the promotion of hormonal contraceptives. However, several clinical trials in South Africa determined that users find different types of diaphragms both comfortable and easy to use.[12,13] In the MIRA (Methods for Improving Reproductive Health in Africa) trial, both a traditional multi-sized diaphragm and lubricant gel were found to be highly acceptable in South Africa. Convenience, ease of use, dual-use potential, and being

female initiated were some of the important product attributes influencing user acceptability.[12] In addition, the gel was found to be popular because of its effect of enhancing sexual pleasure.[12]

The SILCS diaphragm

Figure 1. The SILCS diaphragm.

The SILCS diaphragm was designed and developed by PATH and CONRAD to improve protection options for women. Although traditional diaphragms come in a range of sizes and must be fitted by a trained provider, the single-size SILCS device allows it to fit a wide range of women and to be easy to use. In 2010, PATH licensed the SILCS technology to Kessel medintim GmbH (http://www.medintim.de/) for manufacturing and marketing. Kessel is a privately held German company that manufactures and distributes SRH 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 FP providers, pharmacies, and online shops. In August 2014, Caya received market clearance from the United States Food and Drug Administration (USFDA).

In addition to being a contraceptive, the SILCS diaphragm could also be used as a reusable delivery system for microbicide gels when they become available (such as 1% tenofovir gel or other microbicide gels in development). In a small study (21 South African couples) that assessed the short-term acceptability of the SILCS diaphragm in South Africa, couples reported that SILCS was easy to use and provided good comfort and sensation.[13]

There is a need to expand the existing contraceptive method mix in South Africa. The new South African contraceptive policy promises to promote awareness and availability of emergency contraception; to strengthen access to the IUD; to undertake phased introduction of hormonal implants, the levonorgestrel-releasing intrauterine system, and combined oestrogen and progesterone injectable contraceptives; and to strengthen referral systems for tubal ligation and vasectomy. Although the diaphragm is not specifically mentioned as a method for future introduction, the opening up of a range of methods presents a window of opportunity for a radical shift in the contraceptive method mix and training of providers in new methods. This policy, coupled with potential future availability of a microbicide product, presents an opportunity for SILCS introduction as a nonhormonal dual protection method.

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Goal and objectives

The goal of this study was to evaluate South Africa country readiness for introduction of the SILCS diaphragm as a contraceptive and/or a microbicide delivery device, identify opportunities and challenges for the potential introduction of SILCS, and develop recommendations for next steps and future introduction. Key objectives were organised around five themes:

1. Policy environment and procurement.
2. The regulatory pathway.
3. Service delivery, training, and health management information systems.
4. User/stakeholder feedback on SILCS.
5. Communication and advocacy with key target audiences.

Methodology

The researchers conducted a desk review of South African policies to understand the existing regulatory environment. For the field work, the team requested and received approval from the Human Research Ethics Committee of the University of the Witwatersrand, and permission was obtained from local health authorities at the provincial, district, and facility levels.

The methodology for field work in South Africa was as follows:

- Key informant in-depth interviews with policymakers, programme managers, and regulatory experts.
- In-depth interviews with service providers, nongovernmental organisation (NGO) representatives, pharmacists, HIV prevention clinical trial experts, training managers, tertiary education health centre staff, the National Health Information System, and advocacy groups.
- Facility assessments in the public health care sector, with NGOs, and at a tertiary education health centre at the provincial and district levels.
- Focus group discussions (FGDs) with potential users/attendees at a primary health care clinic in eThekwini District (two groups of women and one of men).

Participants and facilities were selected via purposive and snowball sampling for all except the FGDs, for which purposive and convenience methods were used. Researchers conducted a total of 31 key informant and stakeholder interviews and three FGDs with potential SILCS users (17 females and 7 males). In addition, seven facilities were assessed for potential as SILCS distribution sites. All fieldwork was conducted between June and November 2013.

Interviews and FGDs were transcribed and translated into English as necessary. Two researchers independently developed codes based on key themes identified from key questions asked, and from information emerging from the data. A qualitative data analysis software programme, NVivo (version 10, QSR International), was used to organise, code, and analyse the qualitative data. The data were coded and

results organised according to these themes. A subset of the interviews (n=5) and FGDs (n=3) were double-coded to strengthen the reliability of the coding. Facility assessment data were entered into SPSS and the data descriptively analysed.

In November 2013, a meeting was held with key stakeholders in the contraceptive, HIV prevention, and reproductive health fields in South Africa (and included some stakeholders who had participated in the in-depth interviews). The purpose was to present preliminary findings of the assessment and obtain additional input on the way forward for introducing the SILCS diaphragm in South Africa.

Policy environment and procurement

According to interviewed policymakers, no existing policies or guidelines deal with either diaphragms or microbicide use. The NDoH would be the institution responsible for revising or amending policies related to introducing SILCS.

All policymakers agreed that the SILCS diaphragm could be included in the recently updated National Contraception and Fertility Planning Policy and Service Delivery Guidelines as an update or addendum, with guidelines specifically developed for the diaphragm. An update would entail revising the existing text (if appropriate) and adding details about the SILCS diaphragm as a separate document, or addendum. Most policymakers felt that microbicides could also be added as an update to existing HIV prevention policies.

All policymakers said that revising or updating the guidelines (if necessary) would take some time.

> *We work in a very bureaucratic system and things take a long time within the Department…so I really would not be able to tell you definitely how long it will take.* (Policymaker)

Policymakers and programme managers also indicated that procurement of all government-sector contraceptives involves a national process.

> *With South African government procurements, whether it's for condoms, implants or whatever, they have tenders. They put a budget aside for it, and then service providers bid, and they select the successful provider.* (Policymaker)

Regulatory stakeholders further noted that although there is currently no legal requirement within the procurement system for regulatory approval of medical devices, this may change with implementation of a new regulatory system. One policymaker strongly recommended registering any new product with the South African Bureau of Standards (SABS), alongside early engagement with government stakeholders, to build a supportive environment for the procurement and introduction of SILCS.

Policymakers reported that the NDoH allocates money to health programmes but were unable to describe the process of specific budget allocation to meet individual FP requirements (such as funds dedicated to the supply of oral versus injectable contraceptives). Such decisions reportedly occur at the national level.

South Africa's unique economic status in the region means that the budgeting process and timing may differ from that of its neighbors.

> *The South African programme differs from those of many other countries, where they're reliant on donor support to provide those commodities. The South African government just needs to make an allocation as the budget is developed.* (Policymaker)

Policymakers agreed that although donors have been known to fund some contraceptive methods in South Africa (for example, partial funding of female condom procurement by UNFPA), the government is keen to remain "self-sustainable" when it comes to commodity supply, especially for items on the Essential Drugs List (for example, if the contraceptive gel is registered as a drug). Therefore, donor funding usually comes in the form of technical or programmatic support.

One policymaker also reported that the decision to fund a new contraceptive method depends on a cost-effectiveness analysis to show that the method is not only effective and acceptable but also economically viable.

> *We have to gather as much evidence as possible about acceptability in terms of costing and how many unwanted pregnancies we are preventing if we introduce this. Any why is this diaphragm better than other diaphragms?* (Policymaker)

Another policymaker commented that since the government was preparing to fund microbicides, it was likely that it would also consider funding SILCS procurement. Another specifically commented on the strength of local innovation in relation to securing budget funds for new contraceptive methods.

> *South Africa likes to invest in what is seen as a locally grown kind of initiative. You have studies that are taking place within the country. That's a selling point for government.* (Policymaker)

Stakeholders were unclear about whether FP commodities were currently subject to duties, import taxes, or other fees. From a regulatory point of view, the definition of SILCS as a medicine or a device appears to be a key factor in determining whether the product would be subject to charges within the new regulatory system, although it is not clear exactly how this will manifest.

Programmers and policymakers found it challenging to identify an appropriate price for procurement of SILCS in large quantities by the government.

> *I'd want to know more about the device, how long it lasts, how easily it is damaged, how often we anticipate having to replace it. [Without knowing this information] it's almost impossible to come up with a cost.* (Programme manager)

Suggested considerations for price estimation included the level of use by those who own SILCS, effectiveness in terms of preventing unintended pregnancies and STIs, product lifespan, comparison with other methods over time, and the cost of packaging.

Assessment of the regulatory pathway

Regulatory experts indicated that there is currently no regulatory process or legal requirement for registering medical devices in South Africa. The SABS has not tested diaphragms, and does not currently test personal lubricants or contraceptive gels.

> *If it is purely a device, and it is considered a device at the moment, it is free just to enter the market. There's no regulatory approval at all.* (Regulatory authority)

According to current regulations, SILCS alone could be sold without registration (similar to a condom) because it is an inert device and has no active ingredient. If SILCS is effective for family planning without a contraceptive gel and is used with a lubricant (i.e., a gel that does not claim to be a contraceptive or change the efficacy of the diaphragm), it does not currently require registration. However, if SILCS is sold together with a spermicide or contraceptive gel, it could be considered either as part of the device or as a medicine.

Although two policymakers felt that devices and gels together would need to go through SABS testing for procurement or registration in South Africa, other policymakers and regulatory experts felt that international approvals (such as WHO prequalification, USFDA registration, and the European Union CE Mark) would be sufficient as a guide for government procurement. One regulatory expert suggested that the example of the CE Mark could be used as the basis for an argument that SILCS plus gel should be treated as a device rather than a medicine.

> *So we could bring an argument and say, in Europe, both the diaphragm and the gel do not require medicines registration, and we want the same approval process in this country. In other words, we sidestep [the Medicines Control Council] completely. Also, when the new South African Health Products Regulatory Authority is brought in to effect, there will be another process, and we don't know how long that will take. So there's an opportunity here to move fast. If you delay, the system will become more complicated.* (Regulatory authority)

Nevertheless, if the two products together (SILCS plus gel) are considered a medicine, a regulatory authority representative said they "will have to go through the full [Medicines Control Council] application as a new chemical entity" and be registered as a medicine. This could require proof of efficacy through clinical trials.

One regulatory expert noted that guidelines concerning medical device registration are expected to change.

> *There is an intention to include medical devices in the Medicines Act, and a bill to amend Act 101 of 1965, the Medicines and Related Substances Act, is expected to be tabled in parliament before the end of this year. That regulatory process will be risk based. Low risk would, perhaps, just require a notification process and an identification of where manufacturing occurs. At the highest risk, products would not be allowed to be marketed until there's authorisation. What exactly the data will*

be that have to be submitted, and how those data have to be generated, in terms of regulated clinical trials, is unclear at the moment. (Regulatory authority)

Stakeholders also noted that SILCS on its own could be bought or sold over the counter because it does not have a schedule attached to it. But if it is to be used with a gel or lubricant that is scheduled, then it may require a prescription.

Service delivery assessment

To confirm and validate the data collected from policymakers and programme managers, a "rapid service delivery channel assessment" was conducted at various types of facilities identified as potential channels for SILCS delivery. This assessment included both individual interviews with service providers and seven facility assessments. The following types of delivery were explored:

- Public health sector, including primary health care facilities (in hospitals/clinics) with standard FP services and/or antiretroviral therapy and HIV counselling and testing (ART/HCT) services.
- Private sector, including general practitioners and pharmacies.
- NGOs providing FP and/or HIV prevention/treatment services.
- Schools (secondary and tertiary levels). These were assessed as a potential service delivery channel for girls/young women.

The assessment focused on (1) service delivery, (2) logistics, (3) pricing, (4) training, and (5) health management information systems.

Potential service delivery channels

Many stakeholders felt that the SILCS diaphragm could be made available through multiple service delivery centres. Possible sites mentioned included the public health sector, mobile clinics, tertiary-level educational institutions, shops, taverns, pharmacies, and NGOs.

In general, stakeholders felt that SILCS introduction should be part of an integrated approach to service delivery, including services related to HIV, family planning, antenatal care, and maternal health/postnatal care.

Whatever we are doing, we should be integrating it in all of the service delivery points. So if I came to get my [antiretroviral medications], or if I came for my [tuberculosis] treatment, or I came to you because I have a chronic ailment, I will be able to get whatever products I need as far family planning from any of those settings. (Policymaker)

Many felt that SILCS would need to be introduced with counselling—through health education to all clients, potentially in waiting rooms, or as part of comprehensive counselling for FP and HIV services.

One policymaker and several providers discussed the importance of introducing SILCS at youth-friendly clinics to increase availability to young people and to reduce stigma associated with accessing reproductive health services.

Stakeholders also noted that limited resources at health care facilities—including lack of space and privacy to assist with insertion and already overburdened staff—would complicate distribution of the diaphragm.

> *We will have to see that there is enough space and privacy, a couch, an angle-poised lamp, speculums—all those things that one would need.* (Policymaker)

Two policymakers and two service providers said that NGOs had more time and resources to allocate to service delivery, enabling increased access to services for clients, especially in rural areas. An NGO programme manager and service provider noted that their facilities had a short client waiting time, which would be an advantage for delivering the SILCS diaphragm.

Some stakeholders noted that "the typical scenario in South Africa is that the private sector gets to use it first". One said that gynaecologists operating in the private sector could be a "good place for women to get access to those kind of products". Others suggested that the SILCS diaphragm should be available from private-sector pharmacies. Pharmacies were seen as having the potential for increasing availability of SILCS because of more flexible hours and accessibility in rural areas. A pharmacy manager noted that his staff are well trained in currently available FP methods.

Given the early sexual debut of youth in South Africa, some stakeholders suggested using primary and secondary schools to access youth. The school curriculum was described as potentially being a good place for delivering *information* about the SILCS diaphragm for FP and HIV prevention.

> *Schools, schools. I mean we know the sexual debut is very early now. So, that is the best place.* (Service provider)

In addition, a programme manager and service provider at a tertiary-level educational institution agreed that higher-level educational institutions would be appropriate sites for the delivery of the diaphragm.

All facilities assessed had some capacity for the introduction of the SILCS diaphragm to complement existing SRH services. Their current capacity could support introduction, although there may be a need for additional resources in some centres.

All facilities (except one that was open 24 hours a day, seven days a week) had limited operating hours, which could affect the deliverability and accessibility of the SILCS. However, there was flexibility in access via some facilities, including one that operated 11 hours a day during the week and another that was open on Saturday mornings. Although each facility employed a range of health care workers, the main challenge identified was a shortage in some staffing categories, such as community health workers (CHWs), nurses, and counsellors.

All facilities surveyed had experience with HCT and dispensing FP products. Although not all facilities provided both ART and FP services, they provided one or the other and therefore could deliver the SILCS diaphragm as part of their current service package. All facilities reported functioning referral processes (both from and to their facilities), most of which were in written format. This could be useful in ensuring appropriate referrals for SILCS access. However, it would be optimal to maximise opportunities to provide SILCS for family planning at routine HIV visits (rather than requiring a separate visit or referral) and counselling on SILCS for HIV prevention within FP services.

Each facility had a dispensary on site, and all but one felt that there would be sufficient storage space for the SILCS diaphragm and a contraceptive gel in their dispensary. Only three facilities reported that there would be sufficient staff to dispense microbicides. Although existing pharmacy services appeared sufficient for the introduction of SILCS, there was concern that introduction of a microbicide would place strain on these.

Logistics

There was some concern that the introduction of the SILCS diaphragm would adversely affect current service delivery. Most felt that initial demand for the device would be small and workload would increase gradually.

Stakeholders were generally supportive of a lubricant being used together with the SILCS diaphragm. However, drawing on experience in supplying lubricants for use with condoms, they expressed concerns about the logistics of dispensing and delivering lubricants, including issues such as whether to use a multi-dose tube or single-dose sachet.

Pricing

Many stakeholders expressed a strong opinion that SILCS should be available within the public sector at no cost to all women who need it. This opinion was also extended to contraceptive gels and microbicides, if these are recommended for use alongside SILCS. Some stakeholders highlighted the impact of poverty on women's contraceptive and HIV prevention choices in relation to these products.

> *Really, the device should be available at no cost because there are many such families that do not have money to buy bread.* (Advocacy representative)

Several stakeholders said that if SILCS (plus contraceptive or microbicide gel) came at a cost, it would be accessible to only the relatively affluent.

Conversely, a regulatory authority representative and service provider highlighted the potential challenges of providing products at no cost, including perceptions of quality and desirability.

> *With the government system, everybody believes it's an inferior product if it's free-ish. They would sooner go and pay even if it's a small price because they believe it's superior to the government.* (Service provider)

Most stakeholders found it challenging to indicate a price that might be acceptable to women accessing SILCS through services provided by NGOs or not-for-profit clinics. Although some women may be willing to pay a subsidised price, this strategy would likely result in missed opportunities for uptake in comparison to a policy of free public-sector availability.

An appropriate price for SILCS in the commercial sector was not widely discussed. The commercial price of SILCS would likely be determined based on cost-effectiveness in relation to other commercially available methods, such as the IUD and oral contraceptive pills, but it may also take into account the favourable side effect profile that will appeal to some people.

Younger women (18–24 years) cited a maximum acceptable price of R50-R100 (about US$5-10), whereas older women (25–49 years) reported that they would pay only up to around R20 (about $2), comparing this to the cost of other contraceptive methods. Men participating in FGDs also commented that the price of contraceptive gel should be kept to a minimum.

Training

Most stakeholders agreed that health care workers would be the most appropriate people to promote and distribute the SILCS diaphragm. Identified cadres of health care workers included general practitioners, nurses, nursing assistants, counsellors, CHWs, and community caregivers. NGO staff, pharmacists, and peer educators were also suggested as options for distributing the diaphragm.

Stakeholders noted that the training curriculum would need to be approved by the South African Nursing Council, the regulatory body that provides certified training to health care practitioners. Most thought that trainers should be supervised by provincial and district Department of Health staff and that training should not be completely outsourced to a third party.

Some stakeholders indicated that more intensive and thorough training would be needed if SILCS were to be used for microbicide delivery.

> *When you are a health care provider, you can't just do something that you have not trained for. They need to know about the microbicide; they must know how it works.* (Service provider)

One training manager noted that available information about diaphragms is outdated, and a new training manual would need to be developed.

The introduction of IUDs was cited as a model for how training on a new method could be integrated into the health care system. In each of the nine provinces, trainers were trained, and these people then became mentors and trained others at the district level. The training included theory as well as insertion of the

IUD. After about ten insertions, health care workers were accepted as trained ("a safe practitioner"). The training was captured in a log book. In this model, master trainers would "train the trainers", and training on SILCS would cascade down from the provincial to the district level.

The need for adequate funding for training—especially to provide information, education, and communication materials—was also highlighted. Trainers discussed specific materials that could be used to assist with introduction of the SILCS diaphragm, including posters, pamphlets, and pelvic models.

One area of concern amongst stakeholders was training on how to counsel clients on use of the SILCS diaphragm together with a condom. Some thought that health care providers in the public sector may have a negative attitude toward this counselling, though most policymakers and service providers thought that potential users would understand the concept of using the diaphragm and condom together.

> *I think we need to strongly say the introduction of the diaphragm does not take the issue of the condom away. Like we were saying when we were introducing male medical circumcision….it doesn't take the condom away.* (Policymaker)

Most service providers and advocacy representatives said they believed that health care providers could effectively counsel clients on using the diaphragm, a condom, and gel together. Concerns were raised, however, about user compliance with concurrent use of multiple products.

Some service providers also had concerns about the impact of introducing SILCS (or any other new product) on current workload, and whether they would have sufficient staff and time to do this.

> *They are already overloaded. I've been to clinics, and I can see that they are frustrated. And now if they have to go through the counselling that we want them to do, spend maybe 30 to 45 minutes with one client, that will not happen. I don't think it will work unless you acknowledge the workload.* (Advocacy representative)

To provide information on the diaphragm to the broader community, stakeholders and potential user groups felt that outreach workers and CHWs could utilise community centres to conduct workshops and other training programmes.

Concerns were also raised about male partners as potential barriers to use. Stakeholders stressed the importance of including men in the FP training process.

> *We can use a [pelvic] model to show him how it is inserted. This should be available.* (Service provider)

Health management information systems

The District Health Information System (DHIS) is used to collect statistics from all health facilities at the district, provincial, and national levels. Stakeholders agreed that it would be useful to use this system to

monitor the introduction and distribution of SILCS, whether used as a contraceptive or a microbicide delivery device. In particular, they felt this was important for planning service delivery support resources and for understanding impacts on clients.

> *Any new programme needs to be part of the DHIS. DHIS is the software that helps us monitor how new programmes are doing.* (Service provider)

Stakeholder and user feedback on SILCS

Stakeholder perspective

Stakeholders reported varying degrees of knowledge about diaphragms. Most said they had received some training on diaphragms, had heard of diaphragms, or had some personal experience or knowledge of diaphragms. However, most who had received formal training did not have any experience dispensing diaphragms, and they had not attended any follow-up training. They believed that their knowledge was likely outdated.

> *That [the training on the diaphragm] was part of the family planning course, and I did that in 1984. That's such a long time ago.* (Service provider)

The few stakeholders who reported personal experience with diaphragms reported positive attitudes toward them. In contrast, stakeholders with limited knowledge about diaphragms tended to report negative attitudes, and some held incorrect beliefs about diaphragms. These stakeholders described the traditional diaphragm as unattractive and (reportedly) uncomfortable, as well as difficult to fit or insert. Also, they believed that clients were reluctant to insert diaphragms before sex. They thought that these issues may have contributed to the discontinuation of the method.

> *I've always seen them as an old-fashioned option that people didn't use any more.* (Regulatory authority)

Stakeholders also noted, however, that the SILCS diaphragm offers several potential advantages for women in South Africa: it is a nonhormonal method; it is female-controlled; and it has potential for dual prevention.

Stakeholders felt that there is a definite need for greater access to nonhormonal contraceptive options within South Africa's context of high HIV prevalence because many clients are on complicated and burdensome treatment regimens that interact negatively with a range of hormonal contraceptive methods. SILCS was seen as potentially beneficial for women, providing an alternative to condoms, and (possibly) supporting safer sex behaviours.

You need a method that a woman who is already taking piles of medication [for HIV] can use so there will be no interaction with the medication. Because we live in a high HIV and [tuberculosis] prevalence area, anything that is nonhormonal would be very helpful for clients. (Policymaker)

Most stakeholders noted that there is a dominance of hormonal contraceptive methods in South Africa but that these methods are not suitable for all women because of potential side effects.

Several stakeholders believed that there would be definite demand for SILCS, both as a contraceptive method and microbicide delivery device, because it is a female-controlled method. One advocacy representative noted that the current options are limited and largely controlled by men, and that women constantly struggle to negotiate condom use.

I think many women will want to use it. Except for the female condom, there is nothing else that they can use that they can control. In fact it's a lie that women can control use of the female condom. It's controlled by men because you cannot use it unless the man says yes. (Advocacy representative)

Potential dual protection and expansion of the current FP method mix were important discussion points amongst stakeholders. They noted that with the current method mix, there are challenges conveying the message of dual protection to clients, who are often more focused on pregnancy prevention than both STI/HIV and pregnancy prevention.

[Existing] methods do not offer you the opportunity to emphasise the need for dual protection. Most people are much more concerned with the immediate impacts, or outcomes of a pregnancy, rather than even thinking of HIV infection. (Policymaker)

Most stakeholders noted that women could easily and discreetly insert and remove the device and that they could easily carry it around so it would be available when needed. One programme manager thought that SILCS could be more acceptable than oral contraceptives for some women, noting that some women did not like swallowing tablets and often forgot to do so.

There was a strong sentiment that the SILCS device would be a welcome, client-friendly method for inclusion in the South African market and would increase the range of contraceptive choices for women. Some stakeholders raised questions and concerns, however, about ease of use, durability, cleaning, and storage, and the impact on the male partner's sexual experience.

Stakeholders felt that SILCS would be acceptable to women. However, they also described a cultural norm around the lack of discourse about both the male and, more particularly, the female anatomy. Many stakeholders noted that, in a conservative society, a woman's vagina is not talked about and thought that this could affect SILCS use.

You're dealing with something new, and you're dealing with something that deals with a private part of the women's body, the genital tract. Still, with counselling and education, you can overcome these challenges. (Service provider)

In addition, the secrecy around the female anatomy, and specifically the vagina, could make it difficult for some women to understand how to insert the device, and how it protects against pregnancy and/or HIV infection. Some service providers thought this concern would be more pervasive amongst older women, who would be reluctant to engage with others on these topics.

Potential end-user perspective

Potential end-users highlighted two attributes of SILCS as being of special interest: that it is female controlled and that is has potential for dual protection. Both female and male FGD participants agreed that SILCS would probably be in high demand amongst women because they could control its use, it seemed easy to use, and it might provide dual protection.

> *Women are able to insert it and they are protected.* (Male FGD participant)

Because most participants were unfamiliar with diaphragms, participants had questions and concerns about ease of use and comfort, safety (especially for the male partner), efficacy, and cleaning and storage. Some said that cleaning the SILCS diaphragm would be a challenge for some women, who might reuse the device without cleaning it. Participants were aware of the potential for infection as the result of unsanitary practices and stated that if women were infected they would blame the device rather than their unhygienic practices.

> *Some women will just grab it without even washing their hands. They will take it and insert it and then it will make them sick. They will then blame it and not blame herself because she was not clean when she took it.* (Female FGD participant)

Potential end-users also provided feedback on various scenarios of use—SILCS plus lubricant, SILCS plus condom, and SILCS plus condom plus microbicide gel.

There was mixed feedback on the use of SILCS plus lubricant. Although some potential users felt that using the gel would reduce or remove the potential for harm or pain when inserting the diaphragm, others were concerned about the safety of the gel, and potential for infections caused by use of the lubricant.

Potential users were also unsure about the logistics of inserting the diaphragm; applying and reapplying the lubricant; the timing between microbicide application and consecutive sex acts; and subsequent removal and cleaning. However, when these issues were discussed and their questions were answered, participants reported feeling at ease, and some said that they felt capable of implementing these steps in practice.

FGD participants also provided feedback on two different scenarios of gel application. Depending on the situation, both single-dose sachets and multi-dose tubes were seen as having potential advantages, including ease of use (for example, ensuring the correct dose) and access.

There were mixed opinions in the FGDs about willingness to use the SILCS diaphragm and a condom together. Some participants said that although women might be open to using condoms as well as the SILCS device and/or gel, men would definitely be resistant.

> *I do not think that men will continue using condoms. They will say 'Okay, use that thing of yours'.* (Female FGD participant)

Others suggested that with proper counselling, the male partner would understand the importance of using both products and would agree to this.

Communication and advocacy

Promotion, marketing, and advocacy

Advocacy representatives, programme managers, and service providers acknowledged that promotional messages would need to be tailored to the requirements of different groups.

> *It depends on the age group that we are dealing with. If the mother is still in the child-bearing age group, she is going to look more for a contraceptive method. But if people are finished with having children or they've had ligations, then they are going to look more at the prevention of infections. I think it will depend on what group we are going to address.* (Service provider)

A few stakeholders suggested that SILCS marketing should be limited to specific groups, such as rural women or young women who might be more likely to try new methods. Most suggested broader marketing efforts.

> *Marketing [should highlight] that you are in charge of your body, you know you can choose. Do you want to stay with oral contraception, or do you want to use this?* (Service provider)

Stakeholders compared promotion of the SILCS diaphragm to that of male or female condoms, suggesting that lessons can be learnt from previous experience, in terms of ensuring that women feel confident in trying the device.

> *From the beginning, you need to make it seem normal. You insert it like a female condom, this is how you do it, this the pamphlet that will explain the procedure. We need to avoid this thing of saying it's very difficult to insert because then people become resistant.* (Programme manager)

The advantages and disadvantages of promoting SILCS as either a FP and/or HIV prevention method were not extensively differentiated in the stakeholder interviews. Several programme managers expressed an opinion that the device's dual protection properties should be explicitly described in education and promotion materials, both to derive maximum benefit and to reduce personal risk exposure.

The benefits of using the SILCS need to be clearly explained, both in terms of preventing pregnancies and possible prevention of HIV. (Programme manager)

Although most potential users saw no harm in promoting SILCS for dual protection, some suggested that positioning SILCS as a contraceptive method would limit the attraction for women who do not perceive a need for alternative FP methods.

Stakeholders suggested a wide range of possible sources of information regarding the SILCS diaphragm, including public health clinics, mass media, social media, chemists or pharmacists, schools, churches, traditional leaders, supermarkets, peer networks, health promotion projects, and social security offices. They also cited hospitals, mobile health services, and community caregivers. Advocacy representatives, providers, and policymakers highlighted CHWs as an untapped resource.

We must not underestimate the role of the community health workers. They are everywhere. They are known in the community. The community can easily go to their homes. If you give them enough information…I think we can go places. (Advocacy representative)

Potential users suggested a range of possible information sources, including mass media and community settings such as client homes, workplaces, shops, and garages. Both female and male potential users most often cited clinics as the most appropriate source of information, where it would be possible to see the diaphragm, observe a demonstration (for example, using a pelvic model), and get counselling.

Some participants emphasised the importance of one-on-one counselling.

I think the two-way communication like this [is important]. You are able to explain it to me, and I am able to ask you questions. (Female FGD participant, 18–24 years)

Schools were suggested as a good location for informing young women.

I would like them to educate at schools because…there are young mothers. [With education] the rate of pregnancy and HIV will decrease. (Female FGD participant, 18–24 years)

SILCS introduction

Overall, stakeholders felt that the diaphragm would not be problematic to introduce because women would feel greater self-efficacy by controlling their choice of contraceptive method and messages would be centred on promoting women's skills and knowledge.

I don't see problems. I think they will be willing to try it, especially because it's going to be a message about female control [of contraception]. (Programme manager)

Several stakeholders felt that it would be useful to introduce the SILCS diaphragm for family planning and as a microbicide delivery device simultaneously. Likewise, potential users typically felt that SILCS should be introduced for *both* purposes. However, older women felt that SILCS should be introduced first

as a FP method and that its potential as a microbicide delivery device could then be discussed with users to increase demand for SILCS.

> *It should be introduced as a family planning method, but it should also be explained that as time goes on it may also protect them from HIV.* (Female FGD participant, 25–49 years)

Although stakeholders felt that "all women" may be interested in using the SILCS diaphragm, they gave specific examples of potential target groups, including women who either cannot use currently available contraceptive methods or want to avoid hormonal contraceptives, rural women, and female sex workers and other groups at high risk for HIV infection.

Some stakeholders noted that there are women with "personal preferences" who would not support SILCS use. For example, women who are uncomfortable with inserting products such as tampons or female condoms may be averse to inserting a diaphragm.

Stakeholders said that middle-class, mature mothers in long-term relationships were likely to be the most consistent SILCS users. Many felt that urban, older women would be well informed and would want to either space their pregnancies or prevent pregnancy at this point in their lives.

> *I would say [your best target is] a more stable couple, so women who are in a long-term partnership, probably with children, who want to space fertility, or who don't want more children.* (Programme manager)

A few stakeholders, however, felt that older women may not be interested in using SILCS because they have settled on another FP method. Older women were also thought to be more cautious and methodical when selecting a method.

There was mixed feedback on rural women as a potential user group. Some stakeholders felt that rural women should not be considered potential users, primarily due to perceptions that they are not educated enough or able to access or understand the diaphragm in conjunction with traditional beliefs. Other stakeholders, however, felt that rural women or women with low education levels could be potential users if given information about their anatomy and SILCS use.

Service providers and policymakers felt that long-term use of the diaphragm could be beneficial to rural people with limited access to clinics, and that rural women may prefer a FP method that does not require frequent visits to a health care facility.

Stakeholders and potential users were divided in their opinions about youth as a potential target group. A few service providers were concerned about adherence amongst this group. Some stakeholders and potential users stressed that young women are new to contraception and open to different approaches and possibilities.

> *The young women who are not experienced with other methods are highly possible users.* (Service provider)

A few stakeholders and potential users felt that women on either extreme—young women and older women—would be potential users. Both groups might engage in infrequent or erratic sexual activity, possibly with multiple partners, and might not require a constant method.

Stakeholders noted that consistent use could be influenced by the subsequent support received at access points such as health care facilities.

> *But it also depends on the support. If you are going to go to [a local] clinic and they say 'I will see you in January', surely they will know that there is no support, so they may not try it. But if the support is always there, I think it's simpler.* (Advocacy representative)

Stakeholders felt that a variety of women would be interested in using SILCS as a microbicide delivery device. Some felt that women would be motivated to use SILCS if it empowered them to protect themselves against HIV infection within a range of conceivable relationship scenarios—namely, abusive partners, partners resistant to new methods or condoms, and untrustworthy or cheating partners.

Advocacy needs and strategy

Stakeholders noted that advocacy strategies should be targeted so that appropriate messages could be disseminated to potential SILCS users. One way of targeting communications is through champions. Advocacy representatives described who could serve as champions for the SILCS diaphragm—from Department of Health officials to people who have bought into the concept, are vocal, and are potential users.

> *Your key is your Department of Health. But you also need somebody these people identify with, like a role model, who has bought into the concept who has used the concept. People may say, 'You are promoting this to me, but have you experienced it?'* (Advocacy representative)

Training and trial site representatives agreed that the best people to act as champions for potential users would be current SILCS users.

Conclusions and recommendations

The South African **policy** and service delivery environment regarding contraception, SRH services, and HIV and STI prevention is enabling for SILCS introduction as a contraceptive method and/or microbicide delivery device. However, the South African **regulatory** environment regarding devices is in flux, and regulatory requirements for use of SILCS with a microbicide gel are unclear.

South African health care features both private and public options. Higher socioeconomic groups tend to access health care at a cost through the private sector, and lower socioeconomic groups access services through the public health care system, usually free of charge. Stakeholders recommended broad

distribution of the SILCS diaphragm through public health facilities, NGOs, the private sector (including pharmacies), tertiary education institutions, and even shops. Therefore, both the public and private health care sectors could be targeted for SILCS introduction.

The South African health care system is operating in an increasingly integrated fashion, with primary health care facilities often offering both HIV and FP services, creating a facilitative environment for introduction of SILCS. Stakeholders suggested that the SILCS diaphragm be introduced as part of a comprehensive **package of services**, at an integrated service delivery level (including HIV, family planning, antenatal care, and postnatal services). However, resources in the public sector may require some strengthening. This could include revising the scope of work of some staff to enable a wider variety of personnel to counsel on and dispense the diaphragm (and possibly gel). Furthermore, there would be a need to train health care workers on SILCS use as well as address staff attitudes toward counselling on new products in a busy work environment.

There is currently no standardised **costing** procedure for family planning in South Africa, so it would be difficult to predict budget requirements for the diaphragm. However, stakeholders felt that the government is prepared to fund microbicides, so they are likely to fund the SILCS diaphragm. Current FP procurement is managed by the national government. Stakeholders were unable to identify an appropriate procurement cost for the SILCS diaphragm, ContraGel®/Caya® Gel, and microbicides. However, suggested considerations for price estimation of SILCS included the level of use by those who own SILCS, effectiveness in preventing unintended pregnancies and STIs, product lifespan, comparison with other methods over time, and the cost of packaging. Comparisons could be made with earlier diaphragms, including the MIRA diaphragm. Stakeholders suggested that SILCS be registered with the SABS to build a supportive environment for procurement. Stakeholders and potential users felt that although some consumers should be able to access the diaphragm free of charge, others would be willing to pay a fee.

The South African health care worker **training** curriculum is drafted with the South African Nursing Council, and any changes to the curriculum would need to be approved by this body. Current training on diaphragms is outdated and would need to be revised to include theoretical and practical information about the SILCS diaphragm. Health care providers said they would welcome training.

South Africa has a National Health Information System for **monitoring** (the DHIS), which could be easily revised/updated to include SILCS (and microbicide) information. Stakeholders agreed that distribution of the SILCS diaphragm should and could be monitored by the National Health Information System. Although some stakeholders felt this may place additional burden on existing staff, others said it would not be much additional work.

Stakeholders felt that potential SILCS **users** could include all women, but uptake may be based on individual preferences and circumstances. Marketing and promotional strategies could be tailored to these individual circumstances.

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Stakeholders and potential SILCS users had a variety of **concerns** about the SILCS diaphragm. Most of the concerns were associated with lack of knowledge (such as fit, ease of use, efficacy, cleaning, and storage of SILCS, as well as partner response and impact during sexual encounters). Understanding of vaginal anatomy in the South African community was perceived to be poor. However, most of these concerns could be addressed through proper introduction strategies and training.

A variety of channels were identified for the **promotion** of SILCS in South Africa, including public health clinics, mass media (specifically television, radio, newspapers, posters, and magazines), social media, chemists or pharmacists, schools, churches, traditional leaders, supermarkets, peer networks, health promotion projects, and social security offices. Hospitals, mobile health services, and CHWs and community caregivers could also serve as appropriate sources of information. Visuals such as learning aids and flip charts could be used for one-on-one promotion. Making use of SILCS users and political leaders as **champions** to promote SILCS was also described as necessary and feasible.

A comprehensive health systems assessment such as this—implemented early in the planning process—is critical to identify opportunities and challenges related to the introduction of the SILCS diaphragm, whether used only for family planning or for both contraception and HIV prevention. Lessons learnt may be applied to the introduction of other multipurpose prevention technologies.

Based on the study findings, the research team has developed a number of recommendations for the introduction of the SILCS diaphragm for family planning and/or HIV prevention in South Africa:

- Facilitate an **enabling policy environment** by establishing relationships with regulatory personnel. The clarification of policy and regulatory issues should be sought urgently to prevent delays in introducing SILCS. This will help to optimise use of SILCS for both family planning and HIV prevention when a microbicide is available.
- **Register** SILCS with the SABS to facilitate procurement.
- Introduce the SILCS diaphragm as part of a **comprehensive package of services** at an integrated service delivery level. It should be introduced first as a FP tool. Once it is in health care facilities and pharmacies, the introduction of SILCS as a microbicide delivery device may be less complicated. A draft guideline should be developed to guide service delivery processes.
- Introduce SILCS through **broad-based distribution centres**, including public health facilities, private pharmacies, shops, tertiary education institutions, and NGOs. It should also be part of youth-friendly services. If SILCS introduction were to be implemented at schools, as part of the Integrated School Health Programme, community-based sessions could be conducted with teachers, parents, students, governing body members, and other school staff to facilitate its introduction.
- **Consider and update the scope of work** for various health care workers, especially for counsellors, community caregivers, and CHWs, who are perceived to be appropriate for introduction of the SILCS diaphragm to potential users. Training guidelines should include tools to develop the capacity of the workers who will introduce the diaphragm.
- Ensure appropriate **recordkeeping and monitoring** of distribution and use to assist with product adherence. This could be done by including components for the SILCS diaphragm in the DHIS. Adherence depends on resolving any issues that may arise, and this is achievable only if providers and clients are actively and positively engaging with each other. This is an important point of consideration for provider training and messaging for end-users.

- Include strategies for users to negotiate condom and gel use in **health care worker counselling tools** for the introduction of the SILCS diaphragm. Support mechanisms should be put in place with health workers/service providers to assist potential users with issues that they could have when negotiating diaphragm and condom use.
- Emphasise, within **marketing and advocacy**, that the SILCS diaphragm is a nonhormonal method, a device that can be used for dual protection against pregnancy and HIV, and a female-controlled method.
- Use marketing tools that are able to target multiple potential **user groups**. Potential diaphragm users may vary and be defined based on whether people use it for dual protection or as a female-controlled method. Future research should focus on who these potential users may be. However, the SILCS diaphragm may just be an additional FP and HIV prevention tool in the method mix, increasing opportunities for individual choice.
- Ensure **appropriate information dissemination**, education, and counselling of users and the general public. Information should address concerns associated with the SILCS diaphragm (including fit, ease of use, efficacy, cleaning, and storage). One component of this could be to improve understanding of vaginal anatomy: there needs to be a focus on education and discussions with younger women to better educate them about their anatomy and demystify their body. Younger women may be more receptive to discussions and education around this topic, and education could start as soon as primary school. Discussions and education should focus on every aspect of sexuality and the reproductive system. This may reduce negative vaginal practices and improve openness and uptake of contraceptive methods.
- Address concerns about partner response and impact during sexual encounters in individual circumstances through **health care provider availability and support**. Counselling and education with clear and consistent messaging wherever SILCS is available could increase buy-in and highlight the need to use condoms. This approach has been used with men during medical male circumcision campaigns.
- Subsidise the **cost** of the SILCS diaphragm. The cost of the diaphragm to consumers could vary according to where clients source it.
- Adjust the South African Nursing Council **training curriculum** to include both practical and theoretical information on the SILCS diaphragm. Frequently asked questions for providers and clients could be developed for use in training health workers and potential users. To familiarise users with the terminology and application process, participatory community forums and workshops could be held to provide basic levels of education and information.
- **Promote** the SILCS diaphragm via existing community networks to facilitate buy-in and create brand awareness. As suggested by stakeholders, SILCS promotion and awareness could be facilitated and supported by **champions** such as political leaders and product users.

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