

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

A HealthTech report

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## Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ART	antiretroviral therapy
CCG	community caregiver
CE	Conformité Européenne (European Conformity)
CHW	community health worker
DHIS	District Health Information System
DoH	Department of Health
EC	emergency contraception
FGD	focus group discussion
FP	family planning
HCT	HIV counselling and testing
HIV	human immunodeficiency virus
IEC	Information, education, and communication
IUD	intrauterine device
KZN	KwaZulu-Natal
MatCH Research	Maternal, Adolescent and Child Health Research
MCC	Medicines Control Council
MIRA	Methods for Improving Reproductive Health in Africa
NDoH	National Department of Health
NGO	nongovernmental organisation
NHIS	National Health Information System
PHC	primary health care
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

## Key findings

Overall, findings suggest that South Africa’s policy and family planning (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, sexual and reproductive health, 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 to 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.<sup>1</sup> 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.<sup>2</sup>

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.<sup>2</sup> 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.<sup>1</sup> 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.<sup>3,4</sup> In addition, in 2011, the HIV prevalence amongst pregnant women attending public clinics was 29.5%.<sup>5</sup>

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),<sup>6</sup> as well as the accompanying National Contraception Clinical Guidelines,<sup>7</sup> 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.<sup>8</sup> The 2003 SADHS showed that KwaZulu-Natal had the highest recorded prevalence of contraceptive use in South Africa,<sup>1</sup> 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.<sup>9</sup>

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.<sup>10</sup> 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.<sup>10,11</sup>

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.<sup>12,13</sup> 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.<sup>12</sup> In addition, the gel was found to be popular because of its effect of enhancing sexual pleasure.<sup>12</sup>

## A. 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<sup>®</sup> 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).



**Figure 1.** The SILCS diaphragm.

In addition to being a contraceptive, the SILCS diaphragm could also be used as a reusable delivery device 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.<sup>13</sup>

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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## B. 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:**

- Identify policies relevant to the introduction and scale-up of SILCS as a barrier contraceptive and determine whether any of these differ if SILCS is considered a delivery device for a microbicide gel.
- Determine potential product procurement and the purchase and import process for SILCS, gels, and/or microbicides, and explore the possible purchase price of these products.

### 2. **The regulatory pathway:**

- Identify regulatory pathways relevant to the introduction and scale-up of SILCS as a nonhormonal barrier method.
- Determine what additional regulatory approvals are required if the SILCS diaphragm is considered a delivery device for a microbicide gel.

### 3. **Service delivery, training, and health management information systems:**

- Assess service delivery options (including logistics and supplies) for SILCS according to different service delivery scenarios (and by use as a contraceptive method or microbicide delivery device).
- Assess training required for future SILCS introduction as either a contraceptive method or microbicide delivery device.
- Assess the potential health management information system (data collection tools and data transmission system) for SILCS according to different service delivery scenarios (and by use as a contraceptive and/or microbicide delivery device).

### 4. **User/stakeholder feedback on SILCS:**

- Assess levels of general knowledge about and attitudes toward diaphragms.
- Determine acceptability of and interest in SILCS, either for family planning or as a microbicide delivery device, from a potential user perspective.

### 5. **Communication and advocacy with key target audiences:**

- Assess existing channels and systems for communicating with key target audiences, such as FP/reproductive health providers and women, about contraceptive and dual protection products.
- Identify advocacy needs for the introduction of SILCS as a contraceptive and as a microbicide delivery device.

## 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 the following groups:
  - Policymakers (working in the field of SRH and family planning).
  - Programme managers with expertise in family planning, HIV, and SRH in the public and private health sectors (including nongovernmental organisations [NGOs], pharmacies, and an educational institution).
  - Representatives of regulatory authorities/bodies at the national and provincial levels.
- In-depth interviews with public- and private-sector service providers, NGOs, pharmacists, HIV prevention clinical trial experts, training managers, tertiary education health centre staff, the National Health Information System (NHIS), 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 (PHC) clinic in eThekweni 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. All fieldwork was conducted between June and November 2013.

In November 2013, a meeting was held with key stakeholders in the contraceptive, HIV prevention, and reproductive health fields in South Africa (some stakeholders 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. (See Appendix A for the draft meeting proceedings.)

## A. Analysis

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.

## B. Participant profile

Tables 1 through 3 describe the participants. There were 31 key informant and stakeholder interviews and three FGDs with potential SILCS users (comprising 17 females and 7 males). In addition, a facility assessment was conducted at seven facilities that could be possible SILCS distribution sites in the future.

**Table 1. Key informant/stakeholder interview participant profile.**

Type of participant	N
Policymakers	5
Service providers (private, public sector, nongovernmental organisations)	13
Programme managers	4
Advocacy groups	2
Logistics managers	1
Training sites	2
HIV prevention clinical trial sites	1
Regulatory authorities*	5
<b>Total</b>	<b>31</b>

\*Three total regulatory authority interview were conducted, however one interview consisted of three participants.

**Table 2. Profile of focus group discussion participants.**

Sex and age	N
Females aged 18–24 years	9
Females aged 25–49 years	8
Males aged 18 years and older	7
<b>Total</b>	<b>24</b>

**Table 3. Facility assessment profile.**

Type of facility	N
Nongovernmental organisations	3
Primary health care clinics	2
Health care educational institutions	1
District hospitals	1
<b>Total</b>	<b>7</b>

## C. Desk review

The desk review (submitted as a separate document) showed a need for new contraceptive and HIV prevention methods in South Africa, particularly female-initiated methods and potential multipurpose prevention technologies. This is clearly reflected in the current policy environment, which overall is enabling for SILCS introduction: the newly revised contraception policy and guidelines promote choice, and dual protection is encouraged in a number of policies.

There is overlap amongst policies regarding sexual health promotion, the need for improved provider training, and human resources mobilisation. For successful uptake and effective use of new FP/HIV prevention methods, it is important to consider the capacity of service providers and health care facilities, provider attitudes, and the sociocultural context.

# Policy environment and procurement

## A. Policy environment

The current South African policy environment was explored to identify policies relevant to the future introduction of SILCS as a FP and/or HIV prevention device. Both restrictive and enabling policies were discussed by stakeholders. A total of five policy stakeholders were interviewed. In addition, programme managers and regulatory experts provided insight into understanding the policy environment.

### 1. Current policies and possible amendments required

According to the policymakers interviewed, 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.

#### *SILCS as a contraceptive*

All policymakers interviewed agreed that the SILCS diaphragm could be included in the recently updated National Contraception and Fertility Planning Policy and Service Delivery Guidelines (2012),<sup>6</sup> 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.

*We just have the new updated [contraceptive] policy, and the diaphragm is not one of the method[s] that has been considered there. So it might be you now need to have an addendum there.*

(Policymaker)

#### *SILCS as a microbicide delivery device*

Most policymakers felt that microbicides could also be added as an update to existing HIV prevention policies.

*I think we need to update more than separate policies because everything that we do is about development. Otherwise, we have to wait every time when we have something that's coming on.*

(Policymaker)

However, one policymaker thought that microbicides would be different.

*Microbicide[s] would be different. It would have to be policy because it will be talking about something quite new. But then when you are developing your policy guidelines, then you mainstream it in different areas in HIV prevention, in your dual protection guideline, in your sexual reproductive health guideline. (Policymaker)*

## 2. Approval process

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)*

*I think it depends on the urgency and the interest around the policy and the stakeholder engagement...but I think within 12 months. (Policymaker)*

One policymaker cautioned that budget cycles need to be considered because they affect the timeline for implementation of policies.

*The other issue causing delays is the budget. The government budgeting cycle is already starting now for work through 2016 and by March we should be done with the current budgeting cycle. So if it's not part of the plan already, this means that it will get moved into the next budget cycle. (Policymaker)*

## B. Product procurement

Potential product procurement for SILCS, gels, and/or microbicides and the processes for purchasing and importing these products were discussed with stakeholders. In addition, possible purchase prices were explored with stakeholders and potential user groups.

Policymakers and programme managers 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)*

A few policymakers commented that procurement of the SILCS diaphragm would be complicated by the fact that only one product is available. This situation was compared to that of female condom procurement. Where this is the case, different suppliers can bid to supply the same product.

*I know in government procurement policy there is a preferential process where there is only one provider that can deliver a particular product. And in most cases even if it is the same product, you will find there are different providers that will be bidding, so there will be a sort of a middle-man type of arrangement...and that will be where they will create the competition. (Policymaker)*

Regulatory stakeholders noted that whilst there is currently no legal requirement within the procurement system for regulatory approval of medical devices, this may change with implementation of the new regulatory system (described in the regulatory section below).

One policymaker strongly recommended registering any new product with the South African Bureau of Standards (SABS, a statutory body established under the Standards Act of 1945 that is responsible for developing standards and testing mechanical contraceptive devices), alongside early engagement with government stakeholders, to build a supportive environment for the procurement and introduction of SILCS.

*But my advice on that is to engage with the appropriate people in government and say this is something that we are working on. The most important thing that they would require from you is to have it cleared by the South African Bureau of Standards. (Policymaker)*

At the peripheral level, public-sector programmers and providers confirmed that their stock of contraceptive commodities is procured through a central supply chain. There was little reason to suspect that there may be any supply chain management issues specific to SILCS.

Programmes and institutions must order stock from a central pharmacy and are responsible for ensuring continuous supply through forecasting and maintaining minimum stores to avoid stockouts. Because this process is documented at several levels for audit purposes, resupply can take some time.

*Within a bureaucratic institution, there are documents that you need to fill in and then they go to finance...when you order something [it takes] two weeks max to get your order. It's not like I can just go to the supplier and get something. For audit purposes, it needs to go via other people, and some signatures are needed to get it processed. (Programme manager)*

One policymaker highlighted the importance of ensuring programmes are capacitated (for example, through training of staff) prior to organising the peripheral supply of any new commodity.

*So first we would make sure that they are procured by the Department. Health care delivery systems would then have to go around and train staff, and then once we have trained them and capacitated them then this product could be dispensed as any of the other family planning methods. (Policymaker)*

## **1. Purchase process**

Policymakers reported that the Department of Health (DoH) 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.

*At a national level as soon as we agree that this is policy and that we need this commodity, then the national treasury gets involved. (Policymaker)*

However, one stakeholder noted that funds might be sourced through specific programmes.

*The most important thing is that they must agree that this is something that would be able to meet a gap in the market for them. If it can meet needs for a specific group, then I'm sure that that allocation will have to come from that specific programme. (Policymaker)*

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

*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 whilst 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.

*Donor support helps, but what I've seen is that when it comes to commodities, the South African government really does it on its own. Where partners can be much more useful is to help meet the gap in terms of health care workers who need to be trained. (Policymaker)*

This support may also be used to prepare programmes in advance, whilst the process of securing budget funds for commodities is still under way.

*There's this new method that's there, that they have wait for the next year, the next budget allocation. But with funds available through development partners, you are able to put something together to help train the health care workers. (Policymaker)*

Current budget allocation decisions reportedly consider commodity prices, inflation, human resources, other programming costs, budgetary constraints, and current and future demand. One policymaker also reported that the decision to fund a new 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 diaphragm better than other diaphragms? (Policymaker)*

Two policymakers highlighted that there is currently no standardised costing procedure within the process of programme rollout, making it very difficult to accurately predict budget requirements or appropriately allocate funds. As one policymaker noted, "We do a budget, but whether you will get it is another story, because we don't know how much it costs. Sometimes we put the numbers there, and then we are told there's no funding". Technical assistance to implement a costing system is currently being delivered, which may result in a change in procurement procedures by the time of SILCS introduction.

*We are just now looking at costing of programmes. So going forward from 2014, we would have a costing method in place so we would know how much it is actually costing the Government. (Policymaker)*

One 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.

*There is a feeling that [family planning] has been kind of overtaken by the huge epidemic we are dealing with in terms of HIV and AIDS, so I think it's something that can be considered. 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)*

## **2. Import costs and duties**

Stakeholders were unclear about whether FP commodities were subject to duties, import taxes, or other fees and whether this would change in the future.

*There are [import costs/duties]. In December [2012], we had a donation of female condoms by UNFPA, and government had to pay some taxes and clearance fees even though they were donated. (Policymaker)*

*Little is actually manufactured here, except condoms,<sup>†</sup> so I think there would be some importation tax, though I am not sure how much. I'm not sure. (Policymaker)*

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 will be subject to charges within the new regulatory system, although it is not clear exactly how this will manifest.

*I don't know what the situation is with medical devices; I've never seen data on that. But in terms of medicines there are no import taxes. (Regulatory authority representative)*

*It depends whether in which side of the fence it falls. If it falls on the device side, I don't know. If it falls on the medicine side, then import tax is not an issue. (Regulatory authority representative)*

Another regulatory authority representative commented that although condoms usually are not subject to import taxes, some of the materials required for in-country manufacturing of the device itself or its packaging are taxed. This inconsistency in tax law has previously been raised with the Department of Trade and Industry.

## **3. Procurement cost**

Programmers and policymakers found it challenging to identify an appropriate price for procurement of SILCS in large quantities by the government. For many, the fact that SILCS is an unfamiliar product that is reusable for up to two years makes it difficult to estimate cost-effectiveness in comparison to other contraceptive or HIV prevention methods.

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<sup>†</sup> The majority of male condoms are imported from Asia; however, one local manufacturer manufactures and supplies to the Department of Health.

*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)*

*For most of the contraceptive products we are using, initially there is a cost, but over time it will benefit. If they are going to use it for two years, the cost might be high initially, but over time it can be cost-effective. (Policymaker)*

Several programme managers commented on their lack of awareness around costs in general, which made it difficult to estimate an appropriate price for SILCS.

*I really don't have an idea [of an appropriate price for SILCS] because we do not get costing information from the central supply on items such as condoms. (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. Two programme managers specifically cited the importance of monitoring and evaluation to determine cost-effectiveness following rollout.

*I think we need to look at the usage and the control. If I've issued the SILCS to my client who is attending family planning in my facility, this needs to be recorded, and I know that the lifespan is two years. Then there is no way I will have one client coming for the SILCS four times [in two years] or whatever. Because that's going to impact negatively on the cost. (Programme manager)*

Several stakeholders (advocates, programme managers, policymakers, and trainers) expressed concerns around cost to the DoH and issues of uptake and sustainability.

*I think the issue will be pricing...how much will it cost, and will the public sector be able to afford it. (Policymaker)*

One policymaker suggested that it might be necessary to investigate the effectiveness of SILCS without contraceptive gel before determining a procurement price.

*If there is evidence that we could use this without the gel, then it could mean saving money by not procuring the gel. (Policymaker)*

Most stakeholders reported no insight into discussions around potential government procurement prices for microbicide gels, should they become available. They felt unable to comment on an appropriate procurement price for either contraceptive or microbicide gels.

## **Assessment of the regulatory pathway**

To identify regulatory pathways for the introduction and scale-up of SILCS as a nonhormonal barrier method, and to determine what additional regulatory approvals may be required if SILCS is considered a

delivery device for microbicide gel, key informant interviews were held with two organisations that would play a major role in this process. Key informants included a representative from the Medicines Control Council (MCC), a statutory body established under the Medicines and Related Substances Control Act (Act 101 of 1965) to oversee the regulation of medicines in South Africa; a representative from a company that manufactures and imports contraceptive barrier devices; and three representatives of the SABS.

These interviews focused on existing legislation and procedures required for regulatory approval related to drug delivery and testing related to contraceptive use. Other key informants and stakeholders provided input into regulatory requirements related to the potential introduction of SILCS.

## A. SILCS—as a medical device

Currently, there is 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 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.

## B. SILCS plus gel—as a medicine

Although two policymakers felt that devices and gels together would currently need to go through SABS testing for procurement or registration in South Africa, other policymakers and the regulatory authorities interviewed 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, although not necessary for regulatory approval.

*Generally, we would look at FDA approval, the [European Union] CE mark, or WHO prequalification. Those are the three that are generally relied on by the government when buying devices. But there's no legal requirement for them to do that. (Regulatory authority)*

*The most important thing that they would require from you is to have it cleared by the South African Bureau of Standards. Although it might come with an internationally endorsed standard, such as the*

*FDA in the United States, it doesn't mean anything in South Africa until it has gone through the SABS approval standards. Then you've got their attention. (Policymaker)*

One regulatory representative 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 MCC 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 it will “have to go through the full MCC application as a new chemical entity” and be registered as a medicine. This individual believed that this would require proof of efficacy through clinical trials.

If a microbicide is found to be effective and is to be used with the SILCS diaphragm as a delivery device, there may be a need for a confirmatory bridging study (phase 3) to confirm that the microbicide works with the diaphragm, and details of how they work together.

## C. Other

### 1. Changing regulatory environment

One regulatory representative 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)*

### 2. Cost of approval process

Regulatory authorities noted that currently there is no cost for approval of a device because there is no system for device approval. However, SABS members noted that there may be a cost for them to test batches of the device, although there was no knowledge on how this would be costed.

### 3. Over the counter versus prescription

Stakeholders 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 different types of facilities identified as potential channels for SILCS delivery. This assessment included both individual interviews with service providers and seven facility assessments. A delivery channel was defined as a type of service through which SILCS could be delivered to beneficiaries. In choosing the potential delivery channels, the research team considered the current delivery of both contraception and HIV prevention services in South Africa.

The service delivery channel assessment was conducted in KwaZulu-Natal, one of South Africa’s nine provinces and home to roughly 20% of the country’s population. The following types of delivery channels, where most women would likely be able to access SILCS (if it were available), were explored:

- Public health sector, including PHC 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.

Interviews focused on issues related to the potential introduction of SILCS as a contraceptive and/or a microbicide delivery device. The assessment focused on (1) service delivery, (2) logistics, (3) pricing, (4) training, and (4) health management information systems.

### A. Potential service delivery channels

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

#### 1. Public health sector

Stakeholders commonly described the public health sector as a suitable place for delivering the SILCS diaphragm. Some described the first point of entry as PHC clinics, followed by hospitals. Mobile clinics were also viewed as a good point of entry. One policymaker noted that in these settings, the health care

providers and community health workers (CHWs) would need “good social mobilisation strategies with good training” to reach the community in need.

### ***SILCS as part of integrated service delivery***

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)*

Most service providers and programme managers discussed the usefulness of introducing SILCS as both a FP tool and microbicide delivery device in the public sector. Some providers specifically mentioned FP and HIV prevention programmes as preferred sites for SILCS introduction. Some stakeholders also highlighted the importance of including SILCS in a comprehensive package of services.

*If you give patients more options, you will improve compliance on any contraceptive, and then that might in turn improve our uptake in our population. (Service provider)*

*The package should include HIV screening and cervical cancer screening. All reproductive health care services should be part of this. (Service provider)*

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 youth and to reduce stigma associated with accessing reproductive health services.

### ***Strengths and weaknesses of the public health sector for delivery of SILCS***

Stakeholders commented on the strengths and weaknesses of the public health sector as a service delivery channel. One policymaker stressed the importance of the integrated services in the public health care system for diaphragm delivery. Programme managers and service providers also described some of the strengths of their facilities to offer the diaphragm. For example, a tertiary-level educational facility has a good peer education programme and good systems for reaching students, which could facilitate distribution.

The challenges most often mentioned by all stakeholders for health care facilities were training and buy-in of relevant health care providers.

*For me the biggest challenge is just making sure that you are educating the health care providers and getting their buy-in so that they can be comfortable and feel comfortable to share this information with their clients. (Policymaker)*

In addition, health care facilities would have limited access times for delivery of the diaphragm as a result of their working hours. 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)*

## **2. Nongovernmental organisations**

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. One described the success of NGOs in HIV prevention and how this would be useful for the introduction of SILCS.

*With HIV prevention we have seen NGOs playing quite a big role and closing the gap in terms of accessibility of health services for our communities. NGOs will tackle your rural areas because that is where there is a need and that's where NGOs have maximum capacity to deliver health services. (Policymaker)*

*So for me the best approach to deliver this would be through the nongovernmental organisations that can take it through to the community mainly using mobile services, because it's an issue of access to go to health facilities. (Policymaker)*

A programme manager and service provider based in NGO settings noted that their facilities had short client waiting times, which would be an advantage for delivering the SILCS diaphragm.

## **3. Private health sector**

Although one programme manager said he was “hesitant that the private sector will take to [the SILCS diaphragm]”, a trial site representative noted that once a product is registered, “the typical scenario in South Africa is that the private sector gets to use it first”. The trial site representative also suggested that gynaecologists operating in the private sector could be a “good place for women to get access to those kind of products”.

Stakeholders representing private pharmacies thought that SILCS could be provided as part of the services and/or products made available in private pharmacies. A service provider based in a PHC clinic at a private pharmacy felt that SILCS could be provided in a pharmacy together with optional counselling (and information leaflets) for first-time users.

Other stakeholders (including service providers, programme managers, a few policymakers, and one training manager) agreed that the SILCS diaphragm should be available in 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. Issues around affordability, and the need for a clinician and/or counselling support, were also raised.

*Pharmacies are accessible by many people...and if the price is reasonable, people will definitely buy it. (Service provider)*

*A lot of people who are employed have difficulty where the employer doesn't want them to go to a clinic because of time. To make a product accessible, we need to pull out all the stops. Another thing is that the clinics are busy and filled with people who are sick. If I am just coming for a diaphragm, I don't want to sit and wait with everybody else who is sick. (Service provider)*

One stakeholder also suggested that the private sector would be a good service delivery channel because “people prefer to buy, and they believe in commodities that they pay for”. (Policymaker)

One pharmacy manager noted that his staff are well trained in currently available FP methods, which would be an advantage for SILCS delivery.

#### **4. Schools**

Given the early sexual debut of youth in South Africa, some stakeholders (including an advocacy representative, training manager, programme manager, and service provider) 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 family planning and HIV prevention.

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

*There is an increasing rate of teenage pregnancy, and you go into schools and you no longer can talk about abstinence. Before they enter into high school, they are already sexually active. (Advocacy representative)*

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 delivery of the diaphragm.

*We've got the tools to show them how to use it. Once we have the tools and the material, there's nothing stopping us from giving it to women. (Programme manager)*

#### ***Strengths and weaknesses of delivery through schools***

At primary and secondary schools, the biggest perceived barrier to the introduction of the SILCS diaphragm was that school policies would not allow its introduction. When stakeholders were asked whether schools (primary and secondary levels) would be appropriate sites for delivery of the diaphragm,

only one policymaker agreed. Although stakeholders thought that these schools would be appropriate for distribution of information, most expressed concern about schools as a delivery channel. Parents and the school governing bodies were believed to play a major role in decision-making around such issues and have even been resistant to condom distribution in schools.

*Knowing the challenge we have in terms of implementing sexual reproductive health activities, even educational ones in the school context, I know it would be met by a level of resistance within the communities themselves. It's dependent on the endorsement of the parents themselves, and most often the first reaction you get is that you are...promoting promiscuity. (Policymaker)*

One policymaker said that it may be possible in time to use schools as a delivery channel.

*With the [new] integrated school health programme, perhaps we are going to see things unfolding in terms of schools being open to using contraception, including the diaphragm. If the move that I'm seeing towards accepting condom use within the schools [actually occurs], then perhaps it will be easier for the diaphragm to be introduced in schools. (Policymaker)*

## **5. Facility assessments**

Appendix B summarises the results of the facility assessment.

The purpose of the facility assessment was to assess the appropriateness and capacity of these types of facilities as future distribution channels for the SILCS diaphragm. Different types of facilities were included in the assessment (see Table 3), including NGOs and PHC facilities (at the clinic and hospital levels as well as an educational institution). All offered ART, HCT, and/or FP services.

All facilities assessed had some capacity for the introduction of the SILCS diaphragm to complement existing SRH services, 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 CHWs, nurses, and counsellors. Because stakeholders perceive counsellors and CHWs to be the appropriate level of staff for introducing the diaphragm to clients, staffing shortages could place a strain on existing services and already overburdened staff. This could affect the quality of the counselling/training provided with the diaphragm.

All facilities surveyed had access to separate/private counselling rooms, which could be beneficial for SILCS counselling and assistance with insertion if necessary. Only two facilities surveyed had access to a pelvic model, which was perceived as a useful tool for SILCS counselling for both providers and clients.

All facilities surveyed had experience with HCT and dispensing FP products. Although not all facilities provided both ART and FP services (five provided antiretroviral medications and six provided 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 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.

A larger-scale survey would be necessary to determine whether these findings would be similar across other potential SILCS delivery sites.

## B. Logistics

### 1. Impact of SILCS on service delivery

There was limited concern that the introduction of the SILCS diaphragm would affect current service delivery in any of the delivery settings assessed.

*I don't think [provider workload] will increase that much because the demand in the beginning will not be great. Eventually, you will have to monitor it and find out from the health care providers exactly how they feel and that kind of thing, but I don't think there is going to be a flood of people.* (Service provider)

*It will be part of the package of service that we are actually providing.* (Programme manager)

A few respondents felt that there may be added work for some health care providers, and some mentioned that more staff may be required.

*Work load is going to be big because you can never just give a person [this diaphragm]. You will need someone who is trained, who will be able to teach women and have time with them and teach them how to insert it.* (Service provider)

Most felt that initial demand for the device would be small and workload would increase gradually.

## 2. Dispensing and delivering the lubricant

Stakeholders were generally supportive of a lubricant being used together with the SILCS diaphragm. However, drawing on experience supplying lubricants for use with condoms, they expressed concerns about the logistics of dispensing and delivering the lubricant.

*Within the Department of Health, we trying to battle with the concept of being able to deliver lubricants as well as condoms. We need to devise strategies for delivering two commodities.*

(Policymaker)

A key lesson from this experience is the importance of involving and engaging all levels of health care providers as well as community members. Knowing the target audience and their preferences is key to uptake and delivery to meet the needs of the community. Another important point that stakeholders mentioned is the challenge of dispensing two commodities that rely on one another for correct usage. Managing the logistics or stock and delivery could be challenging, and planning would be required, especially since the frequency and quantity of dispensing each product would differ over time and require monitoring to correctly assess distribution needs.

## 3. Lubricant delivery options

ContraGel<sup>®</sup>/Caya<sup>®</sup> Gel is the contraceptive gel (or lubricant) that is currently recommended for use with the SILCS diaphragm. Stakeholders were asked for feedback on two different delivery scenarios for the lubricant—a multi-dose tube and a single-dose sachet. Stakeholders raised several logistical issues around the two delivery scenarios—including ease of use, dispensing protocols (for example, the number of sachets that could be dispensed at a single visit), and logistics (and associated costs) of dispensing and delivery.

*How much gel would you issue at one time? What control mechanism are we going to put in place? Are we going to allow 30 sachets per person, per month? 15 per month? (Service provider)*

Most stakeholders preferred sachets over tubes for lubricant delivery for several reasons. Sachets were seen as removing the possibility of human error when applying a single dose of the gel. There was also some concern around the safety of exceeding the required amount of gel when dispensing from a tube. In addition, lubricants for condoms are dispensed in sachets, so sachets are both a costed and tested method within the current health care system.

*A single dose would be a lot better. (Advocacy representative)*

Stakeholders raised several issues related to use of tubes for gel delivery. These included dosing accuracy, proper storage, product expiration, and the need for user counselling and training. The primary concerns of service providers related to the need for adequate training for themselves to correctly counsel and advise clients.

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*If it's in a tube, it's going to stay unused if that client is not active. Maybe she will be worried, "What if it is expired" or "where can I keep it".* (Service provider)

*Would there be some way of measuring out the correct amount of gel, and would the gel stay good at temperatures over 40 degrees Celsius in a shack? For example, if you can get 20 applications of gel with one of the tubes, would it last for three months at over 40 degrees Celsius and still be effective?* (Service provider)

Although there was a preference for sachets, stakeholders noted that the best method for gel delivery would depend on the end-user's preference, and that both options should be provided. In addition, cost was seen as a key factor in determining choice.

## C. Pricing

### 1. Price and public-sector availability

Stakeholders were asked about what prices they felt users would be prepared/able to pay for the SILCS diaphragm and a contraceptive and/or microbicide gel.

When discussing the potential price to consumers, many stakeholders (particularly advocates, service providers, and programme managers) expressed a strong opinion that SILCS should be available within the public sector at no cost to all women who need it. This 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)

*I would prefer it to be coming via the public sector so that it's going to be free. Because once there are costs involved, it might not reach everyone because it's not like everyone can afford to pay for it.* (Programme manager)

One advocacy representative discussed an appropriate price for the SILCS diaphragm by comparing it to the costs of obtaining other FP methods via the private sector, but then by describing public-sector access at no cost.

*It [an appropriate price] is comparative to what I'm using at the moment...I could be on a pill, could be paying a R120<sup>§</sup> per month. But first and foremost, you are saying to me these are the benefits, and everyone would want accessibility at no cost.* (Advocacy representative)

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<sup>§</sup> About US\$12.

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

*Only those who are at an advantage would be able to purchase this.* (Programme manager)

*If [you're targeting] working women, they might be okay with paying for the microbicide, but with the rest of population, I don't, think so. From the perspective of a student, if you ask them to pay for it when other contraceptives are freely available, then that might pose a challenge.* (Programme manager)

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. Meantime, it's stuff that hasn't been tested, it's rubbish.* (Regulatory authority)

*Most people don't like free things. With condoms, they prefer buying.* (Service provider)

Programme managers and service providers also highlighted potential problems associated with providing the device at no cost but then charging for microbicide or contraceptive gel.

*I think of cost issues especially when we think of the gel. And then it becomes a very huge challenge.* (Programme manager)

## **2. Not-for-profit sector and pricing**

Most stakeholders found it equally challenging to indicate a price that might be acceptable to women accessing SILCS in the not-for-profit sector, such as through services provided by FP NGOs or not-for-profit clinics. Again, an appropriate price was considered alongside the requirement to buy gel, and relative to other methods available in this sector.

*And is it the same price or less [than the pill]? Because if it's more, I can't see them taking it. But then once you have the device, it's just the cost of spermicidal gel every month.* (Service provider)

One programme manager commented that although some women may be willing to pay a subsidised price for SILCS through a not-for-profit clinic, this strategy would likely result in missed opportunities in terms of uptake, in comparison to a policy of free public-sector availability.

*I mean there's a niche market, but it's not going to reach the main market.* (Programme manager)

## **3. Private sector—commercial pharmacies**

An appropriate price for SILCS in the commercial sector was not widely discussed. A programme manager commented that whilst the market price of the SILCS device may represent a standard markup above wholesale, the cost to the consumer of a gel would be subject to regulation.

*With devices, there are no regulations. I'm not sure what our head office would ask as a markup, but I imagine it would probably be about 30%. By contrast, the gels will be regulated in terms of the cost.* (Programme manager)

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. One key informant cited a price for both contraceptive and microbicide gels of R10–20\*\* per sachet but stressed that microbicide gels should also be available at no cost within the public sector.

Another commercial pharmacist commented that smaller pharmacies might find it difficult to supply SILCS at an affordable price, if they lack economies of scale.

*[Large commercial pharmacies] buy wholesale because they can, but the smaller pharmacies aren't given that same sort of discount because they are not ordering such big bulk. The cost of the diaphragm may vary from pharmacy to pharmacy.* (Service provider)

#### **4. Potential user perspectives**

Women in the younger age group (18–24 years) cited a maximum acceptable price of R50–100,†† whereas older women (25–49 years) reported they would only pay up to around R20,‡‡ comparing this to the cost of other contraceptive methods.

*Yes, if you can pay R25 for the injection, then you can pay for [the diaphragm].* (Female FGD participant, 25–49 years old)

Men participating in FGDs also commented that the price of contraceptive gel should be kept to a minimum.

*If the gel is sold, [the cost] should be almost the same as condoms that we buy at shops. The price should not be too high.* (Male FGD participant)

Young women participating in FGDs recognised the value of SILCS as a dual protection method, suggesting that the price they are willing to pay may reflect this. However, potential users generally expressed that SILCS should be available to women either at no cost or low cost.

*It should not be expensive because most people are not working and they would like to use it.* (Female FGD participant, 18–24 years old)

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\*\* About US\$1–\$2.

†† About US\$5–\$10.

‡‡ About US\$2.

## D. Training

Regardless of the service delivery channel, 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 (CCGs). Although one policymaker stressed that buy-in would be necessary from top-level managers in health care facilities, it was agreed that counsellors, CHWs, and CCGs would be most likely to introduce the SILCS diaphragm to the population. NGO staff, pharmacists, and peer educators were also suggested as people to distribute the diaphragm.

### 1. Health care worker training requirements

Stakeholders provided information regarding the requirements for designing and implementing a sustainable training programme for SILCS as either a contraceptive or microbicide delivery device. In particular, the training curriculum would need to be approved by the South African Nursing Council, as the regulatory body that provides certified training to health care practitioners.

*Whatever curriculum we develop, it has got to be according to the South African Nursing Council directive for the type of training we are going to offer, and it has to be approved by the Council before it is actually implemented. (Training manager)*

Most stakeholders thought that trainers should be supervised by the provincial and district Departments of Health and that training should not be completely outsourced to a third party. Stakeholders also felt that trainers should be capable, experienced, knowledgeable, and, preferably, medical professionals. Some stakeholders suggested that NGOs with research-based information and understanding of the SILCS diaphragm should be involved in designing and providing the training.

*The training would be conducted and supervised by the provincial department of health, and then we would take it down to the district level. Right now, what we are trying to do is to capacitate and empower district trainers so at the end of the day we will have sustainability if they are owning these programmes. (Policymaker)*

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)*

Most stakeholders expressed a willingness to participate in training sessions and were eager to learn about the SILCS device in greater detail. Some stakeholders even stated that training could be viewed as a form of health care practitioner empowerment. There did not seem to be a concern that participating in training sessions would strain the current health care system. The need for ongoing or refresher training was also addressed.

*All of us would need training, not just once, but also regular updates. There needs to be close contact, and monitoring and evaluation, with whomever is supplying us the method. (Service provider)*

Stakeholders anticipated that through regular training they would improve their knowledge, address any issues or gaps that arose during consultations, and have a forum for sharing experiences, all of which could improve providers' confidence when dispensing the diaphragm. With regard to the content of the training, stakeholders suggested a range of topics, such as caring for the material, cost, insertion of the product, and infection control.

*I will need to know everything about the product. I cannot talk about something that I won't have the answers to when my clients are asking me. So all my staff will need to know everything there is to know about the product, both as a contraceptive device and as a microbicide delivery device. (Service provider)*

## **2. Training logistics for SILCS**

Stakeholders involved in training addressed specific training needs regarding SILCS. In particular, they identified the need to update training; the need for approvals to update the training curriculum; and the need for information, education, and communication (IEC) materials.

### ***Updated training***

One training manager noted that information about diaphragms is outdated, and a new training manual would need to be developed. In addition, the training would need to include both theoretical and practical information about diaphragm use.

*You would have to develop a new training manual because the manuals that we have now are outdated. (Training manager)*

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.

### ***Including SILCS in the training curriculum***

A training manager noted that at academic institutions, updating the training curriculum would require consideration and approval by various structures, such as the faculty Senate, which discusses academic issues and changes, and the Council, which ratifies changes passed by the Senate.

Whilst one training stakeholder noted that some providers would be curious and most likely motivated to advance the use of SILCS, given the prevalence of injectables and oral contraceptives, hard work would be required to bring family planning back to the attention of some providers.

*Family planning has never been at the forefront, so they would really have to work very hard to bring family planning back to the health provider's mind again, to change their mind set. At this moment, they are just giving the injection or oral contraceptive, and those are the two methods that are being used in all the clinics. (Training manager)*

### ***Information, education, and communication***

The need for adequate funding—especially to provide IEC materials—was also highlighted. Trainers discussed specific IEC materials that could be used to assist with introduction of the SILCS diaphragm, including posters and pamphlets. One training manager felt strongly that trainers should have access to pelvic models with which to practise and demonstrate techniques to students. In addition, she felt that diagrams could be helpful for training. Finally, she mentioned that electronic media such as DVDs could be useful for training of both providers and clients.

### **3. Specific issues related to the SILCS**

#### ***SILCS as a contraceptive—counselling on SILCS plus condom use***

Following South African guidelines, women who decide to use SILCS as a barrier contraceptive will also be counselled to use male condoms for HIV protection. Service providers were asked for their feedback on whether this would be a concern for health care providers; how they thought women and their partners would react; and whether this message would be confusing.

Stakeholders expressed mixed opinions as to whether health care providers would be willing to counsel clients to use the SILCS diaphragm together with a condom. Whilst it was agreed that they would understand the need to provide HIV prevention counselling along with contraception, some thought that health care providers in the public sector may have a negative attitude toward this counselling practice (likely to be brought on by having to change their counselling messages and thus do additional work).

Most policymakers and health service providers thought that potential users would understand the concept of using the diaphragm and condom together—especially if it was introduced with training and education on why and how to do this, to pre-empt any misconceptions that may arise.

*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. We were saying we are introducing circumcision because of the research findings [on HIV prevention], the benefits that were found. However, it doesn't take the condom away. (Policymaker)*

Some stakeholders also suggested involving partners in introduction or communication about the diaphragm to increase understanding of both parties. The issues of male partner buy-in, relationship dynamics, and willingness to use dual protection were also raised.

*If you give the education over and over and over, the message will be there. But how they choose to take that message and if they will use the information is another story altogether. (Service provider)*

*It's the preference. It's the partner's prescriptions about the way the sexual encounter should happen.*  
(Advocacy representative)

#### ***SILCS as a microbicide delivery device—counselling on SILCS plus condom plus gel use***

Service providers were asked about the use of condoms if SILCS were used as a microbicide delivery device. Most service providers and advocacy representatives said that health care providers would be able to counsel clients on using the diaphragm, condom, and gel together.

*They are already counselling on the barrier method, which is the condom, so it's just an additional piece we could talk about. You know this is something new but you have to use A and B.*

(Policymaker)

Concerns were raised about user compliance—related to the use of multiple products (the complexity of the regimen), understanding around product efficacy, and personal preference around product use.

*When you tell patients that a regimen is going to be complicated, then the compliance drops. So for the health care provider, it might be simpler for them to just say use a condom. You might have a challenge convincing the health care provider to tell patients to use the diaphragm as well as the condom. But if you counsel them adequately and if the microbicide is added, then the provider might be more successful with promoting the use of the diaphragm.* (Service provider)

*People will think it offers total protection, but then you are saying that you also need to use a condom. Because it offers only partial protection, that's why you still need to use a condom.*

(Programme manager)

Some service providers 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)

#### **4. Client and community training**

The discussion of training and counselling of potential users on the use of SILCS (either as a contraceptive or as a microbicide delivery device) raised interesting perspectives on how to access potential users of the SILCS diaphragm in communities. To access the broader community and expose non-attendees of health facilities to relevant FP training, stakeholders (including a policymaker and training manager) and potential user groups felt that outreach workers and CHWs could utilise community centres to conduct workshops and other training programmes.

Bearing in mind resource limitations, some stakeholders believed that with the correct training, the individual dispensing the diaphragm to clients did not necessarily need a medical qualification.

*So if you can tell them how this works, not everybody has to have a qualification to do that [dispense the diaphragm]. If they are trained, they have the skill, and once they have the skill, they can then pass it on to someone else. They can always do the thing because they know the steps. (Training manager)*

Stakeholders listed a variety of training materials that would be necessary to engage with clients when counselling (see Table 4). One female focus group participant also highlighted the importance of making different types of materials available: “Other people understand more when they read than when they see”.

**Table 4. Suggested training materials needed for introduction of SILCS.**

Suggested training materials	Supporting quotes
Movies or skits on DVD (Electronic media)	<p><i>If there’s a little DVD or a thing just to show you on a live patient actually how to do it—for me that visual, seeing how to insert it properly, would make a big difference. (Service provider)</i></p> <p><i>If you’ve got DVDs on these things and then you talk about it, you know people tend to concentrate on what is on a video, and they tend to have interest. (Programme manager)</i></p>
Pelvic models (or visual aids for client demonstrations)	<p><i>You have to show the patient what it looks like: a model, which shows the uterus and the vagina, and how this [diaphragm] will need to be inserted into the vagina. It will be much clearer than you giving a verbal, or written, instruction. (Service provider)</i></p>
Posters or pamphlets	<p><i>Well it’s obviously a novel method that the patients are not too aware of, so you would need time, and we might need colourful posters. (Service provider)</i></p> <p><i>They always like to have something to take home to read. It may be a good idea to have on a small sort of A5 sized paper, quick instructions on how to use it. Just as a back-up to what they’ve discussed with a health worker or pharmacist. (Programme manager)</i></p>

***Male partner buy-in***

Concerns were also raised regarding SILCS and condom negotiation, SILCS and condom and microbicide negotiation, and male partners as barriers to use.

*It’s difficult enough to get them to use the condom. So now you’re asking them to use the condom plus the gel plus the diaphragm. It’s a very very big order. (Policymaker)*

Most stakeholders stated that condom use would be difficult because of male partners’ dislike of condoms, a dislike that is associated with the desire to have unprotected sex.

*Men don’t want to use condoms at all. They want to touch somebody’s flesh. (Service provider)*

Stakeholders (including a programme manager, training manager, and service providers) also 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)*

## E. 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 were asked whether it would be useful to monitor SILCS introduction and distribution via this system.

The NHIS representative, almost all policymakers, and service providers agreed that it would be useful to monitor SILCS introduction and distribution, whether used as a contraceptive or a microbicide delivery device. In particular, they felt this was important for monitoring distribution, planning service delivery support resources, and understanding impacts on clients.

*Any new programme needs to be part of the DHIS. It makes life easier for us because if it's non-DHIS we have to drill on how to get that information to report to the province. DHIS is the software that helps us monitor how new programmes are doing. (Service provider)*

*We need data so we can learn about adverse effects and complications and know what works. Creating databases is absolutely important. (Service provider)*

The NHIS stakeholder and other policymakers had differing opinions regarding the difficulty of including additional categories in the data capture system to facilitate monitoring of the SILCS diaphragm.

*It would be just one new data element. (Policymaker)*

*It's not difficult because it's a daily thing. (Service provider)*

*It's going to be challenging because it is going to be an added task on top. (Service provider)*

The NHIS representative described the process of updating the system. In particular, the importance of clearly defining the necessary data elements and collection frequency was emphasised.

*If a programme comes up with a new data element that they want to be [monitored], we want them to give us the data element and definitions and tell us where it should be collected, how often, and all those things so that when we go to the facilities or to the people we can tell them that this is how it will [be]. (NHIS representative)*

The NHIS representative also noted that there would be no additional resource requirements to add it to the national management system. It would be part of the normal process.

# Stakeholder and user feedback on SILCS

Stakeholders were asked about their personal perspectives concerning diaphragms in general and SILCS in particular. And FGDs with potential user groups (both women and men) were conducted to obtain feedback on acceptability of and interest in SILCS.

## A. Stakeholder perspective

### 1. General knowledge and attitudes about diaphragms

Stakeholders reported varying degrees of knowledge about diaphragms in general. More than half, including service providers, policymakers, an NHIS representative, and trainers, stated that they had received training on diaphragms, had heard of diaphragms, or had some personal experience or knowledge of diaphragms. Of those service providers and trainers who had been trained on diaphragms, many had received training in the late 1970s or early 1980s. This group reported variable levels of knowledge.

Most stakeholders (including some service providers and training managers) who had undergone formal training on the diaphragm did not have any experience dispensing it, and they had not attended any follow-up training. They believed that their knowledge may be 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)*

*When I started in family planning, I think that was in 1987, we knew about it. I didn't see it, but I knew it was available. (Service provider)*

A few stakeholders reported hearing about the diaphragm only recently because of recent government-led activity on policy updates and expansion of FP methods. Also, stakeholders who had recent diaphragm knowledge did not have specific or in-depth knowledge.

*I think there hasn't been a lot of information in South Africa around diaphragms as a family method. (Policymaker)*

Very few stakeholders reported personal experiences with diaphragms, but those who did had positive attitudes toward the diaphragm. One policymaker had personally used a diaphragm, and a training manager reported having second-hand knowledge of the diaphragm, due to having known someone who had used the diaphragm for family planning.

*I used it during my reproductive years, and I did very well in managing it to space and time my pregnancies. So it's a method that I really endorse. (Policymaker)*

Stakeholders with limited knowledge about diaphragms tended to report negative attitudes toward them, 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 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)*

*The diaphragm is an old tool that was used for family planning. They used to say, "Now every time I want to enjoy my sexual relationship, I've got to put this thing in". And even the sight of it was not nice. (Programme manager)*

Some stakeholders (largely service providers) likened diaphragms to condoms, describing them as latex-based devices that required insertion or use at every sex act. They felt diaphragms were available before condoms and that when condoms and other FP methods became available and more popular, use of diaphragms was largely discontinued.

*But we were told [about the diaphragm] in 1986. The diaphragm was used because there were no condoms available then. (Service provider)*

*It was discontinued a long time ago. The other methods were given more preference, because it is easy to inject or to give people tablets to swallow every day. (Service provider)*

Although some stakeholders described the diaphragm as "old fashioned", they also noted that it was a popular and reliable method amongst users. These stakeholders noted that diaphragms possess several advantages for women: they are a nonhormonal method and are met with little resistance from religious groups. Stakeholders who held positive beliefs about traditional diaphragms thought the SILCS was an improvement on the traditional version, describing it as aesthetically pleasing and easy to fit, store, and use.

*I mean this [SILCS diaphragm] is far, far superior to the old ones. It is a good method for those who are motivated to use a diaphragm because it does not include any hormonal aspect. There are people who are not keen on using hormones because of the side effects, overweight, etc. (Training manager)*

## **2. Attributes of the SILCS diaphragm**

Stakeholders highlighted three attributes of SILCS as being of interest in South Africa: it is a nonhormonal contraceptive; it is female controlled; and it has potential for dual prevention.

### ***Nonhormonal contraceptive option***

Stakeholders felt there is a gap in the market for nonhormonal contraceptive methods and a definite need for these methods within South Africa's unique 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 being 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 and that these methods are not suitable for all women, including those with breast cancer.

*There are some women who react to the hormonal methods, maybe by being overweight, and they would welcome anything that is going to prevent that. (Training manager)*

*Women know the dangers of hormonal contraceptives, and modernised women do not want to introduce a lot of substances in their bodies, especially hormones. They want to try something new. (Advocacy representative)*

Stakeholders suggested that the strongest demand and uptake would initially be amongst this group of women who are not good candidates for hormonal contraception, and then, if these women have positive experiences, word of mouth would generate interest amongst other women.

### ***Controlled by women***

Several stakeholders believed there would be definite demand for and interest in SILCS, both as a contraceptive method and a microbicide delivery device, because it is a female-controlled method. One advocacy representative noted that the current options are limited or scant and essentially 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)*

### ***Dual protection***

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 on 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)*

Stakeholders felt that combining HIV and pregnancy prevention through the use of the SILCS diaphragm and a microbicide would clearly convey the notion of dual protection to clients.

*I think [the introduction of SILCS with a microbicide] would provide a good example of what we mean by dual protection because we will be preventing HIV and unwanted pregnancy within the same device. (Policymaker)*

### ***Other positive attributes***

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.

*If you keep [the diaphragm] in your bag, at any time you've got it, no matter where you go. With tablets, it's the issue of swallowing: people do not like to swallow. (Programme manager)*

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.

### **3. Questions and concerns regarding the SILCS diaphragm**

Stakeholders raised some questions and concerns about the SILCS diaphragm—including ease of use, durability, cleaning and storage, and the impact on the male partner. These concerns were mirrored by potential users (see discussion below).

#### ***Ease of use and durability***

Some stakeholders expressed a concern that potential users would be worried about inserting and using the diaphragm. Other stakeholders were initially concerned about women's ability to remove the device, although once removal was explained, they thought that women would really like it.

*I think they might be worried about whether it could cause them any damage. They might be worried about the size. (Service provider)*

Some stakeholders were also concerned that the diaphragm might burst or tear.

*What if it bursts? They won't come here and say the diaphragm burst? (Service provider)*

#### ***Cleaning and storage***

Stakeholders had concerns about storage and the possibility of infection, especially if women did not clean and store SILCS properly. They suggested that women should be counselled on correct cleaning and storage to prevent infection and damage to the device that might compromise efficacy.

*They need to know how to take care of it, how it should be stored. They need to know about infection and infection control. Washing of hands before even touching the genitalia. All those kind of things.* (Service provider)

*The issue of hygiene needs to be emphasised. How do you clean it so that you can use it again?* (Programme manager)

### ***Impact on men and covert use***

Other concerns expressed by service providers focused on the potential for the device to harm or hurt male users.

*I think men are mainly interested in how it's going to affect their sexual experience. So is it going to prick them, poke them, hurt them, inhibit them sexually? That's important for them.* (Service provider)

One service provider suggested that men would complain of discomfort or pain even if they did not experience any. This individual suggested that the best approach would be for women to not disclose everything about the SILCS device to their sexual partners. Hiding the device (or covert use) was discussed, though this was not seen as the best approach for the long term.

*Never tell a man what you have done, because he will say, when you are using an injectable, 'you are wet'; when you are using the loop, 'the strings are poking me in my private parts'; when you use a diaphragm, 'I don't feel comfortable with this cup of yours'. So you must just tell women not to disclose too much to their partners.* (Service provider)

## **4. Acceptability—factors impacting potential use of SILCS**

Stakeholders felt that SILCS, like the female condom, would be acceptable to women. However, they also described a cultural norm around the lack of discourse about both male and, more particularly, 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, would 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. Stakeholders felt that younger women would be more receptive to discussions and education around this topic and that education could start at the primary school level.

Stakeholders discussed some vaginal insertion practices, but many did not know how common or rare these practices were. Practices that were discussed included the use of tampons and other menstrual

management products, as well as douching. Stakeholders noted that many women were comfortable inserting and using tampons, that some women use other FP methods that require insertion, and that some women insert foreign objects for sexual pleasure or other reasons.

Almost all stakeholders felt that despite insertion concerns, there would be no cultural barriers to using SILCS as a microbicide delivery device.

## B. Potential end-user perspective

Three FGDs were conducted with potential end-users: young women aged 18–24, older women aged 25–49, and men older than 18 years. Participants provided feedback on SILCS as both a contraceptive and microbicide delivery device. (Appendix C provides demographic and other information about participants.)

### 1. Key attributes of SILCS

Potential end-users highlighted two attributes of SILCS as being of special interest: that it is female controlled and has potential for dual protection.

#### *Female control*

Both female and male FGD participants liked the fact that SILCS is female controlled and said it would probably be in high demand amongst women because they could control its use and it seemed to be easy to use.

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

*Women can do it. It is women who can like it most because [the men] will be running away from wearing a condom.* (Female FGD participant, 25–49 years)

#### *Dual protection*

End-users were interested in the potential of SILCS to provide dual prevention. FGD participants thought this potential would greatly increase uptake of and demand for SILCS.

*[The diaphragm will keep] you safe from two things. You will not become pregnant and you will not get [STIs and HIV].* (Female FGD participant, 25–49 years)

### 2. Questions and potential concerns

Because most participants were unfamiliar with diaphragms, that had questions and concerns about using SILCS. Questions were raised around ease of use and comfort, safety (especially impact on the male partner) and efficacy, and cleaning and storage.

### ***Ease of use and comfort***

Potential users (both women and men) expressed concerns regarding ease of insertion and possible pain and discomfort when using SILCS. They noted that if SILCS were accompanied by a lubricant, it would be easier to insert. There was also a concern that the diaphragm would either move or get dislodged during use.

*Another thing is that there are women who get extremely dry in the vagina. I think that the gel is really all right to be there. Imagine if you insert it while you are already dry in the vagina. It means that you will get hurt.* (Female FGD participant, 25–49 years)

*Will it not disappear here inside?* (Female FGD participant, 25–49 years)

### ***Safety and efficacy***

Some end-users questioned the durability of SILCS and expressed concerns that it would burst or tear. There was also a concern about potential spillage during removal and use during multiple rounds of sex.

*Is there a problem of bursting with the diaphragm, like in the case of a condom?* (Male FGD participant)

*When you have sex, you must have the first round and take it out. I am afraid it is going to spill if I am going to have the second one.* (Female FGD participant, 25–49 years)

### ***Impact on the male partner***

FGD participants were concerned about the potential for SILCS to harm or hurt male users.

*Is it safe for males?* (Female FGD participant, 25–49 years)

*When you use it with your partner when you are having sex, does he not get hurt? Does he not feel any pain because you have inserted this thing? Will it not touch him?* (Female FGD participant, 18–24 years)

### ***Cleaning and storage***

FGD participants had several queries and concerns about cleaning and storing a device that is intended for such long-term use. Some participants suggested that cleaning SILCS would be a challenge for some women, who might re-use the device without cleaning it. Participants were aware of the potential for infection from use of unsanitary practices and stated that if women were infected they would blame the device rather than their unhygienic practices.

*How do you protect it from germs while you are holding it in your hands?* (Female FGD participant, 18–24 years)

*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, 25–49 years)

### 3. Feedback on scenarios of use

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

#### *SILCS plus lubricant*

There was mixed feedback on the use of SILCS plus lubricant. Whilst 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.

*It is like rubber. It will not be easy to insert it as it is; maybe it can hurt you somehow. But if it has gel, you will not feel any pain.* (Female FGD participant, 25–49 years)

*Does the gel cause infection here underneath? Is it safe?* (Female FGD participant, 25–49 years)

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 the 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.

*You said that when you have another round there is no problem; you do not have to take it out. So you have to add the gel. How do you add the gel when it is inside you?* (Female FGD participant, 25–49 years)

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

*Others may choose the one in a tube. They do not want to buy often. If you need it now and the stores are closed, it is always there.* (Male FGD participant)

*Maybe they will have a problem with the one in the tube. After you have opened it, how long will it remain before it expires?* (Female FGD participant, 18–24 years)

#### *SILCS plus condom use*

There were mixed opinions in the FGDs about willingness to use the SILCS diaphragm and a condom together. In the older female and male groups, some said that people would not be willing to use a condom and diaphragm together, as there may be an understanding that SILCS should be offering them full protection against STIs.

*I do not think that men will continue using condoms. They will say ‘Okay, use that thing of yours’.* (Female FGD participant, 25–29 years)

*The diaphragm is good for us men because we sometimes do not want to wear a condom. (Male FGD participant)*

Some FGD participants felt that wearing both would be preferred because it would offer additional protection against diseases and pregnancy.

*They will like [using both a condom and diaphragm]. They will not get a baby, they will not get HIV, and they will not get STIs. (Female FGD participant, 25–49 years)*

*It is better to use both so that I am safe. (Male FGD participant)*

The younger female group was divided; they felt that some users would not use the diaphragm and a condom together, but this was related to individual preferences related to use of condoms. However, some suggested that with proper counselling the partner would understand the importance of using both products, and he would agree to this.

### ***SILCS plus condom plus microbicide gel***

Concerns were raised about using multiple products and resistance to using condoms by male partners. 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.

*Is there a problem of bursting with the diaphragm, like in the case of a condom? If it is not [a problem], it would be better for the diaphragm to be in use and the condom should not be there because there is no direct skin contact. You set it [the diaphragm in the woman] with its gel. (Male FGD participant)*

Although female participants thought that men would be difficult to sway and create challenges to using condoms plus the diaphragm, they also noted that in an ideal situation, they would want their male partners to support their use of the SILCS device and condoms and/or gel.

*If we are going to have sex, he should remind me to insert it; or he should ask if I have inserted it. (Female FGD participant, 18–24 years)*

## **Communication and advocacy**

### **A. Promotion, marketing, and advocacy**

Communication strategies for promoting the SILCS diaphragm for family planning or HIV prevention were explored from the perspectives of both stakeholders and potential users.

## 1. Promotion and communication

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

*Our workshops are specifically with sex workers. When we brought in this topic of family planning, we didn't expect to get their amazing questions and the response that we did, so there's a definite need. It's about accessibility, and it's about knowledge, so we can then advocate in a way that empowers women and transfers knowledge. (Advocacy representative)*

*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)*

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)*

## 2. SILCS as a contraceptive and/or multipurpose prevention technology

### *Stakeholder perspectives*

The advantages and disadvantages of promoting SILCS as either a FP and/or HIV prevention method were not extensively differentiated in the stakeholder interviews. One policymaker highlighted the risk of poor uptake if the device gains a reputation as primarily an HIV prevention method, especially given the existing skew in the South African contraceptive profile toward injectable methods.

*This is something that's new, and when you look at it in the media, it was mainly used in trials for HIV prevention. People will automatically think 'oh that may take away the pleasure' when thinking about commodities that are positioned as more of an HIV prevention device. So that's the first point for me, to educate about this and speak about the functional benefits to make sure you break the barriers, in terms of the perceptions of people out there. (Policymaker)*

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)*

*With the education in terms of the microbicide together with SILCS, you need to highlight that...whatever partner you have—whether it’s your husband or someone else—you need to know that whilst you are at home or at work you don’t know what he is doing. (Programme manager)*

*One thing that you’d need to be very clear about in the training of providers and patients is that one is a contraceptive and one is [HIV] prevention. And I think that’s where the confusion arises in partners as well. It’s like, are you trying to prevent pregnancy, or are you trying to prevent HIV? And that distinction has to be very clear. (Programme manager)*

### ***User perspective***

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

*If they talk about it and include the fact that it prevents HIV, women will be more interested in it than if it is considered a family planning method. She will just say ‘I have my own family planning, so what is the difference?’ (Female FGD participant, 25–49 years)*

## **3. Sources of information about SILCS**

### ***Stakeholder feedback***

Stakeholders suggested a wide range of possible sources of information regarding the SILCS diaphragm. Overall, stakeholders did not distinguish between appropriate sources of information regarding SILCS for contraception or HIV prevention.

Advocacy representatives, policymakers, and providers cited the following as appropriate sources of information: 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. As one service provider stated, information should be available “anywhere and everywhere”.

*Having worked with [sex worker] peer educators so extensively, I know they can play a key role. If we can train them and build their capacity, they are the key because of the kind of relationships they have with the hard-to-reach population we want to reach. (Advocacy representative)*

*The media play an important role. Whenever there's bad news about contraception, they hear about it very quickly [through] the media so I think even when there's good news about contraception it should also be from the media, from the health care provider, and even from other family members.* (Service provider)

*Within the institution where we've got students teaching other students, those are the people we can use. We can train them on how to educate other students on how the diaphragm can be inserted. In that way you are not only giving the responsibility to the health care provider but also taking it down to other people at a lower level.* (Programme manager)

Within the health service, stakeholders suggested that information should be available not only at FP and HIV/ART clinics but also within wider PHC and child and maternal health services, where information could be delivered via individual counselling, waiting room talks and demonstrations, posters, pamphlets, and videos.

*So it must be incorporated into health talks. In clinics we wait for hours on end, and often we are looking at a blank wall. So media would reach a targeted population.* (Advocacy representative)

*Even if you're talking to men, why shouldn't they know? They have female partners.* (Service provider)

Stakeholders also cited hospitals, mobile health services, CHWs, and CCGs as appropriate sources of information about SILCS. Advocacy representatives, providers, and policymakers positioned 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)

### ***End-user feedback***

Potential users suggested a wide range of possible sources of information regarding the SILCS diaphragm. For example, FGD participants suggested that information could be delivered via mass media, and in community settings such as client homes, workplaces, shops, and garages. Overall, participants did not distinguish between appropriate sources of information regarding SILCS for contraception or HIV prevention.

*I am saying that [SILCS information] should be shown on TVs, talked about on radios, and publicised in newspapers. People should be encouraged go to the clinic to learn more. You understand something better if you hear it from a person face-to-face.* (Female FGD participant, 18–24 years)

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.

*There are nurses who are trained and who have enough information about it. (Female FGD participant, 18–24 years)*

*It is at the clinics [that men can feel comfortable about getting information about the diaphragm]. At the clinic many things are discussed concerning people's lives...and you get full information. (Male FGD participant)*

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 education, especially for 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)*

Finally, potential users highlighted several key questions about SILCS that they felt should be addressed in promotional materials, including regarding how it works, how it is used, how long it can stay inside the woman, how to clean it, how much it costs, how the device itself or its efficacy might be affected by menstrual blood, and how it is different from the female condom.

## B. SILCS introduction

Stakeholders provided feedback on the potential introduction of SILCS in South Africa as well as recommendations and thoughts on introduction strategies and target user groups. 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 centered 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)*

### 1. Timing of introduction

Several stakeholders felt that it would be useful to introduce the SILCS diaphragm for family planning and as a microbicide delivery device simultaneously. In addition, one stakeholder recommended that if SILCS were to be introduced for family planning first, clients should also be made aware of its future role as a microbicide delivery device. Another stakeholder expressed concern that if SILCS were first introduced as a microbicide delivery device, there might be issues of stigma if women later wanted to use the diaphragm for family planning.

*If it is used as a contraceptive first, then it makes usage more widely accepted. And then by the way you can also use this for other things [microbicide delivery], and I think it becomes much easier for people to adapt in that way. (Policymaker)*

## **2. User perspective**

Potential users had mixed feedback on introducing SILCS first as a FP method versus a microbicide delivery device. Both groups felt that SILCS should be introduced for both purposes. However, women in the older focus group 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)*

## **3. Target populations**

Stakeholders felt that SILCS would have a wide-ranging target market and the potential to empower all women because its use is controlled by women.

*We really need to move towards more female-controlled methods. The market is out there. The most important thing is for the manufacturers to identify which target market they want to go with. (Policymaker)*

In general, stakeholders felt that “all women” may be interested in using the SILCS diaphragm. However, stakeholders 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.

*Definitely the peri-menopausal women, and somebody who has just been diagnosed with breast cancer, I would definitely give them the option. (Service provider)*

*I think it is women maybe who have tried hormonal contraceptives and had issues, or it is the modernised women who do not want to introduce a lot of substances in their bodies. (Advocacy representative)*

Some stakeholders noted that there are women with personal preferences and practices that 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.

*I think it depends on your preference. I would be scared to insert this because I am even scared to insert a tampon. (Policymaker)*

Stakeholders also mentioned other women who would likely have no interest in SILCS, including menopausal and elderly women and women for whom it would hold no relevance.

### ***Potential users of SILCS for family planning***

**Women in stable relationships:** Although most stakeholders felt that the SILCS diaphragm could be used by many different groups of women, middle class, mature women in long-term relationships and with children were thought to be the most consistent, “trusted” 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)*

*I believe mature couples [are the best candidates]. I know that teenagers can borrow one from another, so you cannot trust them never mind how educated they can be. (NHIS representative)*

*Married people...because they can have sex whenever they want to, and they can be free and open about it. I think women in a married relationship would be the ones who would really respond. (Training 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.

*Maybe start with younger girls. Older women are entrenched in those ways already, but younger women are not. (Service provider)*

**Rural women:** 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 rural women 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.

*Once people are educated, even those from lower income group would use this. (Policymaker)*

Finally, 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.

*Rural women might opt for a diaphragm for different reasons. They might say now it allows them to stay away from the clinic for two years. It costs them money to go to that clinic and wait for their injection, and they can't do their farming or cooking or looking after their children in that time. So if we can offer them something that limits their visits to the clinic, then they might opt for that. (Service provider)*

**Youth:** Stakeholders and potential user groups were divided in their opinions about youth as potential users. Some saw a definite need in this group; however, a few service providers were concerned about adherence. Stakeholders and potential users felt that young women would be interested in using the SILCS diaphragm and that it could be used at any age. In particular, 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)*

**Other potential user groups:** A few stakeholders and potential users felt that women on either extreme—specifically, young women or 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.

*Maybe younger and older. You know those at the early stages of their sexual experiences who do not want to take something regularly, who don't have a regular partner. They might be into that. And then at the other end of the scale, those who are coming to the end of their reproductive years may want to use that, for the occasional thing, instead of relying on a daily tablet, which has risks the older you get. (Programme manager)*

Stakeholders recognised that some women may use SILCS inconsistently (e.g., whilst continuing to “shop around for a method”), which could have negative cost consequences for a method that is designed for long-term use and costed accordingly. Experimentation and curiosity were also seen as strong drivers for clients to try or consider using the SILCS diaphragm, but they were not seen as a predictor of consistent use.

Stakeholders noted that consistent use could also be determined by 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 highlighted the idea of educating women and improving access. Some stakeholders noted that with insertion instructions, information, and personalised counselling, anyone could be a potential user.

### ***Potential users of SILCS for microbicide delivery***

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 become users of SILCS if it were a microbicide delivery device because it would empower them to protect themselves against HIV infection in a range of conceivable relationship scenarios—namely, abusive partners, partners resistant to new methods or condoms, and untrustworthy or cheating partners.

*The women with long-distance relationships [would be interested in using the SILCS diaphragm for microbicide delivery]. Women in long-distance relationship will try anything to prevent themselves from getting HIV/AIDS or pregnant because they don't trust their partners since they are far away from them. (Service provider)*

*Those who are unable to negotiate condom use [would be good candidates for using SILCS]. That will be a plus for them because then they won't have to negotiate, and we know also that young people may be involved in multiple, concurrent partnerships so that will also provide something for them. (Programme manager)*

Whilst relationship issues, such as lack of partner trust, were identified as motivating factors for potential users of SILCS as a microbicide delivery device, they were rarely raised when discussing SILCS as a FP method.

## C. Advocacy needs and strategy

One stakeholder cautioned that advocacy strategies should be targeted, so that appropriate messages could be disseminated to potential SILCS users.

*There are too many assumptions in research. We assume that doctors and nurses know. We assume that politicians know. And they don't, and then they cause more harm than good. So these politicians must put this thing on everybody's agenda so that it is out there. It is supported by everyone. You don't want to promote microbicides and then have a senior politician come and say to you, you are using women as guinea pigs. Why are you not using other race groups? So unless you target all the structures, we will not succeed. Look where the women are and target those who will really use it. (Advocacy representative)*

### 1. Use of champions

One way of targeting communications is through champions. Advocacy representatives described who could be champions in advocating for the SILCS diaphragm—from DoH 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)*

*You need people who believe in what you're doing. You need people who know research. Start from there. And you need people who are passionate about women's problems. You need people who have been touched by the effect of HIV on communities. You need people who are out there who are bold, who are not afraid to be criticised. And you need people who are vocal. (Advocacy representative)*

It was also felt that SILCS training programmes should be supported by a champion, such as a minister of health or another person in power.

*It has to be a well-funded programme with a champion who has a direct linkage to someone like a minister of health. It has to be mandated by someone of power. It cannot be done in isolation.*

(Training manager)

Training and trial site representatives agreed that the best people to act as champions would be SILCS users. Although this group does not yet exist, they could be nurtured and developed through NGOs.

## 2. Stakeholder workshop

Appendix A summaries the results of a workshop for stakeholders.

## 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 PHC 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.

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 CCGs 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, CCGs, 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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## Appendix A. Stakeholder meeting report

### Health Systems and Opportunity Assessment: SILCS diaphragm as a microbicide delivery system in South Africa DISSEMINATION WORKSHOP: Summary of key points raised

**Date:** 27 November 2013

**Venue:** eMakhosini Conference Centre, Morningside

#### **Presentations:**

1. Update on multipurpose prevention technologies
2. Preliminary study findings

#### **Introduction**

A stakeholder meeting was held to disseminate the findings from the assessment and to obtain additional input from key stakeholders. Key informants and some of the participants of the in-depth interviews were invited along with other key stakeholders. Attendees included Department of Health representatives, programme managers, academic institution representatives, national family planning experts, and representatives from local and international nongovernmental organisations (NGOs) based in South Africa. There were 24 participants, eight of whom were MatCH (Maternal, Adolescent and Child Health) staff; seven apologies were received.

#### **Summary of general comments**

##### *Users*

- SILCS diaphragm gives people an additional choice.
- People are given choices, yet some do not accept that they are at risk; these people need to be considered in introduction.  
*Response: How the product is introduced, training, and counselling are important.*
- Is the product complicated to use/insert? Should it be marketed to a special/select group?
- There needs to be a lot of training and community information given. Community caregivers (CCGs) are ideally placed to disseminate this information in communities and at the household level.
- SILCS would be useful for sex workers, and would help prevent unwanted pregnancies. However, potentially it also could create some problems for them. They may try to use it for a purpose for which it is not intended (e.g., a menstrual cup, for intercourse during their menstrual cycle); or they may leave it in too long, especially if having multiple clients. They will need a lot of training.  
*Response: CCGs could provide sex worker training. Correct information to potential users is key.*

##### *Efficacy*

- Use of SILCS plus gel does not offer vaginal wall protection.
- What happens in terms of contraceptive efficacy if there is spillage of semen as the diaphragm is removed?

### ***SILCS plus other products***

- Can the SILCS diaphragm be used together with a ring (like the dapivirine ring being tested by the International Partnership for Microbicides)?  
*Response: It depends on the ring. If the ring has both contraception and [antiretroviral medications] in it, it is not necessary. The insertion of both together will need to be considered, as it is probably not possible.*
- Using contraceptive gel versus microbicide gel may create confusion as the two cannot be used together.

### ***Hygiene/cleanliness/diaphragm care***

- We must emphasise that personal hygiene must be of a high standard when using the diaphragm.
- Important to emphasise how to clean the diaphragm.
- Women must consult with a doctor if they have vaginal problems, before they use the diaphragm.

## **Recommendations or suggestions to facilitate the introduction of SILCS for family planning and HIV prevention**

### ***At the service delivery level***

Facilities where SILCS could be introduced:

- Any supplier; there should be no restrictions from the government.
- NGOs (can also be used to monitor introduction and train service providers).
- Schools (need to consider regulatory issues and parental concerns, but students are sexually active); school health services can be used.
- Primary health care clinics: The system is being re-engineered, nurses are multi-tasking, and services are integrated. All clinics should be involved. Introduction of SILCS should be implemented as part of a “one-stop shop”.
- Private companies: Should be subsidised by the government as clients cannot afford to pay.
- General practitioners/medical specialists.
- Pharmacies (including Clicks and Dischem).
- Mobile clinics.
- CCGs: They are being trained on how to talk to people about condoms, sex, etc.
- Indunas, traditional healers (important, as highly regarded, and, in some cases, certified).
- Traditional birth attendants.
- Churches (although some religious leaders are still not very open).
- Shopping centres (such as Shoprite).

Type of service: Should be comprehensive; national contraception and fertility programme are combined.

Service delivery concerns:

- Allergies (although not as common as latex allergies).
- Cost.
- Long-acting reversible contraceptives have good compliance; SILCS is timed, so compliance may not be as good (sex fits in anytime).
- Can it be used during acute episodes of sexually transmitted infection (STI)? Will it increase STI occurrence because of the manipulation of the cervix?
- Can it be used as a menstrual cup? Sex workers may use it for controlling menstruation.
- Stock and availability are critical (after hours availability is key).
- Having a DVD on its use is good; pamphlets are clear but people do not read.

### ***Policy and regulatory framework***

Policy:

- SILCS is covered in the current HIV prevention and family planning policies (family planning policy advocates choices for women; HIV policy advocates for dual protection).
- What is the feasibility of using the diaphragm to deliver microbicides during pregnancy? Pregnant women are at risk of HIV.
- Policy needs to consider role of CCGs in teaching communities about the diaphragm and CCG scope of work (now health is moving into the community).
- Policy needs to ensure there is no cost for obtaining SILCS, and that it is available and accessible.

Regulatory framework:

- The Medicines Control Council focuses on pharmaceuticals; the South African Bureau of Standards focuses on devices. SILCS cuts across the two regulatory bodies.
- Need collaboration and to develop guidelines as to how SILCS would be regulated in terms of going forward.
- Need regulation for use during pregnancy.
- Specifications for storage need to be considered.
- Dispensing licenses: Who has the authority to dispense?

### ***Communication and advocacy support required***

- The SILCS programme needs to be launched at the national level, either by the Minister of Health or the South African president.
- A task team at the national level must launch the SILCS programme at the national and provincial levels.
- Invite all provinces, and appoint provincial coordinators.

- Task teams must include all stakeholders (NGOs, Departments of Health and Education) so that all know about the diaphragm.

#### Promotion:

- Politicians should be involved so that the SILCS diaphragm is acceptable.
- The diaphragm should be free and accessible to all.
- Traditional and cultural leaders need to be involved so that marketers can understand the people they are trying to reach.
- Civil groups like the Treatment Action Campaign and gender groups should be involved.
- Need to develop clear messages about the product.
- Messages need to be disseminated to clinic patients.
- Promotion needs to be full blown, through social networks, television, radio, and workshops, in a language understood by the people.
- There needs to be a core team to gain buy-in at the health care facility level; hospital managers must buy in and support use of the product.
- Consider social harms and intimate partner violence. Will there need to be advocacy about this?
- If SILCS is going to be used with a microbicide, there will need to be a lot of buy-in with women, to raise awareness.
- FAQs are needed to answer questions/myths:  
*Can SILCS be used by gay people? Is there a time when SILCS cannot be used? Can it be used during menstruation? It can't be shared, it's not for oral sex or anal sex. Can it be inserted with other products? Does it need to be changed between rounds? (No, there's no need to kill the fun!)*
- Ensure that marketing is appropriate.
- There could be a competition to provide a catchy phrase or slogan to go with the product; this would create product awareness and involve the community before dissemination.

#### Where should SILCS be available?

- It must be accessible and available at health care facilities, as one-stop shops.
- In all services at clinics.
- Schools, higher learning institutions (universities, technicons).
- Medical male circumcision camps.
- Churches.

#### Who should make it available?

- Trainers of trainees exist, so should be involved in training the appropriate service providers.
- There should be core champions and CCGs to make it available (key family health team members).
- Health care workers need to be approachable.

## Appendix B. Facility assessment summary

Seven facility assessments were conducted in eThekweni District, KwaZulu-Natal, at facilities that offered sexual and reproductive health (SRH) and/or HIV and/or family planning (FP) services, and which could be potential sites for providing the SILCS diaphragm if it is introduced in South Africa. Table 1 provides a breakdown of the types of facilities, which included nongovernmental organisations and primary health care centres at the clinic, hospital, and educational facility levels. The purpose of the facility assessment was to assess the appropriateness and capacity of these types of facilities as future distribution channels for the SILCS diaphragm. The assessment may also provide an indication of the impact on facility operations of introducing the SILCS diaphragm as either a FP method and/or a reusable delivery device for microbicide gel. This appendix provides a summary of the capacity of the seven facilities.

**Table 1. Facility assessment profile.**

Type of facility	N
Nongovernmental organisations	3
Primary health care clinics	2
Health care educational institutions	1
District hospitals	1
<b>Total</b>	<b>7</b>

### Hours of operation

Hours of operation varied by facility. One facility operated for 24 hours a day, seven days a week. Another facility was open for 11 hours a day, Monday through Friday. Two facilities operated nine hours a day Monday through Friday. One operated nine hours a day Monday through Thursday, and was open for eight hours on Fridays. One facility was open for eight hours a day, Monday through Friday, and four hours on Saturdays.

### Key staff available

Table 2 summarises the mean number of staff employed at the facilities as well as the mean number of unfilled positions. Community health workers had the highest average number of unfilled positions, followed by all nursing staff categories.

**Table 2. Summary of staff employed and unfilled staff positions.**

Staff type	Mean employed	Range employed	Mean unfilled positions	Range unfilled positions
Directors/managers	2.6	1-12	0.4	0-3
Doctors/medical officers	1.7	0.1-5	0.3	0-1
Physician assistants/clinical managers	0.6	0-1	0.3	0-1
Professional nurses/chief or senior professional nurses	9.9	2-27	1.1	0-3

Staff type	Mean employed	Range employed	Mean unfilled positions	Range unfilled positions
Enrolled nurses/enrolled nursing assistants	4.4	1-10	1.1	0-5
Counsellors	4.1	0-10	0.1	0-1
Health educators	0.8	0-5	0.2	0-1
Community health workers	8.7	0-22	3.43	0-22
Laboratory technicians	1	0-6	0.2	0-1
Pharmacists	0.6	0-3	0.3	0-1
Pharmacist assistants	1.3	0-4	0	0

### Services offered

Table 3 summarises the relevant SRH services offered at the facilities and the average number of clients served on a typical day. All facilities offered HIV counselling and testing and sexually transmitted infection diagnosis and treatment services. The majority of services offered were free to the public. Only one facility offered medical male circumcision services; the remainder did not have capacity for this.

**Table 3. Summary of SRH services offered and clients served daily.**

Service offered	No. facilities offering service (N=7)	Mean no. males served on typical day (Range)	Mean no. females served on typical day (Range)	Services paid for or at no cost
HIV counselling and testing services	7	17.4 (4-40)	22.9 (6-60)	All free
HIV treatment/antiretroviral medications	5	63.6 (10-188)	135.2 (39-347)	All free
Mobile HIV testing services	4	20 (10-40)	28.7 (6-60)	All paid
Sexually transmitted infection diagnosis and treatment	7	9.8 (1-40)	17.5 (5-60)	6 free, 1 paid
Medical male circumcision	1	2	N/A	All paid

### Family planning methods offered

Table 4 summarises the FP methods offered at the seven facilities, and the average number of clients served on a typical day. The two- or three-month injection was the most common FP service, provided to the most number of clients (18.7 females) on a daily basis. Male condoms were widely distributed, with an average of 936 condoms distributed from the facilities daily. Most facilities offered FP methods free of charge.

**Table 4. Summary of FP methods offered and clients served daily.**

FP method offered	No. facilities offering service (N=7)	Mean no. males served on typical day (Range)	Mean no. females served on typical day (Range)	Services paid for or at no cost
Two-/three-month injections	6	N/A	18.7 (5-45)	5 free, 1 paid
Oral contraceptives	6	N/A	9 (2-20)	5 free, 1 paid
Intrauterine devices	4	N/A	8.7 (1-20)	2 free, 2 paid
Male condoms	7	936 condoms distributed (0-5000)		All free
Female condoms	7	30 female condoms distributed (0-120)		All free
Emergency contraception	7	N/A	1.5 (0-3)	6 free, 1 paid
Male sterilisation/vasectomies	2	1 (1-1)	N/A	1 free, 1 paid
Female sterilisation	1	N/A	5 (5-5)	All free

**Availability of counselling rooms**

All facilities interviewed had separate counselling rooms, and the average was 3.8 rooms per facility (range: 1–10).

**Availability and use of pelvic models**

Only two facilities had at least one pelvic model, but there was only sufficient stock of these models at one facility. One of these facilities used the model to train both providers and clients, whereas the other used it to train clients only.

**Referrals**

Facilities were asked to report on referrals from other organisations and whether these were written or oral. On average, there were three referrals per facility for both referrals from each facility (range: 1–4) and referrals to each facility (range: 1–5). The majority of both types of referrals were in written format (2.43 for referrals to each facility [range: 1–4], and 2.57 for referrals from each facility [range: 1–4]). Few referrals were oral (0.14; range: 0–1) and the remainder were unreported (0.14; range: 0–1), for both referrals to and from the facilities.

**Capacity of pharmacies/dispensaries**

All facilities had a dispensary on site. At the majority of the facilities (4/7), the professional nurse was responsible for dispensing medication. At the remaining facilities, medications were dispensed by the pharmacist, the pharmacy assistant, or the enrolled nurse.

Stock was monitored by the pharmacy assistant at three of the facilities. It was monitored by a nurse at two of the facilities and by a pharmacist or another individual at the remaining two facilities.

At the time of the assessment, only five of the facilities had sufficient storage space in the dispensary. All but one reported they would have sufficient storage space in the dispensary if the SILCS diaphragm becomes available as a microbicide delivery device. Similarly, all but one reported there would be sufficient storage space for lubricants or contraceptive gels. However, only three reported they would have sufficient staff to dispense additional drugs such as microbicides for HIV prevention.

## Appendix C. Focus group discussion participants

The following information summarises the demographic characteristics of the potential users who participated in the focus group discussions.

### Demographics/baseline information

- All participants were black African.
- Participants' ages ranged from 19 to 43 years (mean 29.5 years).
- One respondent had no formal education; just more than a quarter (n=8) had not completed high school; just more than half (n=13) had completed high school (matric); and two had some post school training.
- Half (n=12) were unemployed; almost a quarter (n=5) were employed full time; one was employed part time; and a quarter (n=6) were students.
- Just less than half (n=11) had a regular partner of more than one year who they did not live with, followed by about a quarter (n=6) who had a regular partner of less than one year who they did not live with. Three were living with a regular partner, and one was married. One was not currently in a relationship.

### Experience with contraceptive methods

- Only seven respondents or their partners were using hormonal contraceptives: three-month injection (n=5); two-month injection (n=1); progesterone-only pills (n=1).
- Just more than half (n=14) of respondents were reportedly using male condoms, and one was reportedly using female condoms.
- Two female respondents had been sterilised.
- Only two respondents had heard about diaphragms; none had ever used a diaphragm.

### Microbicide trial participation

- No participants (or their partners) had ever participated in a microbicide trial.