Recently, there has been increased recognition that contraceptive methods must meet women’s needs and fit the circumstances of their lives to better address unmet need for family planning. The SILCS diaphragm (SILCS) was developed in this spirit and expands women’s options for nonhormonal, user-initiated contraception. Clinical studies have proven its acceptability, functionality, safety and contraceptive effectiveness. Moreover, research has shown the feasibility and acceptability of SILCS as a multipurpose prevention technology (MPT) that could protect against both pregnancy and HIV and other sexually transmitted infections (STIs) by delivering microbicide gel.

A cost-effectiveness analysis determined that SILCS introduction in the Gauteng public sector could prevent an estimated 10,482 unintended pregnancies at five years if 5 percent of women with an unmet need for modern contraception used SILCS. Research in South Africa suggests that SILCS could be successfully integrated into existing family planning and commercial channels.

SILCS has the potential to provide user-initiated protection to meet the reproductive health needs of a range of women, including those who are breastfeeding, who want a discreet, nonhormonal contraceptive method with no side effects, and should
be considered for inclusion in the contraceptive method mix. Since the diaphragm is inserted before sex, it does not interrupt sexual relations, thus SILCS may provide an option for women whose partners are unwilling or unable to use a condom.

Expanding contraceptive choice

Current estimates of unmet need for family planning in South Africa vary from 12 percent to 18 percent. Unmet need exists across all age groups, but is highest among adolescents and young women, of whom more than half are not using any form of contraceptive protection. HIV-positive women also experience high rates of unintended pregnancy.8

Diaphragms were a part of the family method mix in South Africa, but for multiple reasons, including promotion of hormonal contraceptives, diaphragm provision was discontinued by the end of the 1980s. In 2012, expanding the options for nonhormonal barrier contraceptives, and responding to women who become dissatisfied with or are unable to use other methods, became core principles of South Africa’s progressive National Contraception and Fertility Planning Policy.9

Since SILCS is used only when a woman has sex, it could appeal to women who have intermittent or infrequent sexual relations and are reluctant to use a method that provides continuous protection. SILCS is reusable for up to two years, so it could also be an important option for women who find it difficult to use a method requiring repeated visits to a family planning provider.7,10

A woman-centred design

World Health Organization (WHO) research findings in the 1990s identified that women wanted more contraceptive methods that were under their control, had few side effects and could protect from STIs.11

In response, PATH, an international health organization (www.path.org), developed the SILCS diaphragm with research partners in multiple countries. Employing a user-centred development process, PATH and partners worked with women, their partners and providers to develop a diaphragm that is easy to use, comfortable for both partners and easy to provide. From inception, women, their partners and providers were integral co-designers in the development of SILCS, providing the impetus for a design that is innovative and of high quality.

SILCS has a contoured shape and flexible spring that allow the single-size device to fit most women. This makes SILCS easier to supply and provide than traditional multi-sized diaphragms, which require a pelvic exam to determine the correct size. SILCS is made of medical-grade silicone, and can be reused for up to two years.

After design and clinical validation, PATH licensed the SILCS technology to KESSEL medintim GmbH (KESSEL) for manufacturing and commercialization. Since 2013, KESSEL has achieved regulatory approvals in Australia, Canada, Europe, Malaysia and the United States, and as of 2016 markets the device in more than 26 countries as the Caya® contoured diaphragm. In Australia, Canada and Europe, Caya is approved for use without a prescription; women can purchase it at clinics and pharmacies and through online stores.

KESSEL and PATH are currently working to bring Caya to developing and middle-income countries, where expanding the contraceptive method mix could help address unmet need for family planning. For example, a health advocacy organization began work toward registration in Uganda in 2016.

Clinical guidelines recommend diaphragms be used with a contraceptive gel.12 KESSEL markets a lactic acid-based contraceptive gel (Caya® Gel/ContraGel®*)

* Caya, Caya Gel, and Contragel are registered trademarks of Kessel medintim GmbH.
that is CE marked, approved for use with diaphragms, and is registered and distributed in 26 countries in multidose tubes (15 doses per tube). As an alternative, KESSEL is developing single-use sachets for markets where women would prefer a smaller unit dose that is more portable, discreet and less expensive.

Despite the clinical recommendation that diaphragms be used with a contraceptive gel, little clinical evidence exists of the added impact of gel on contraceptive effectiveness. According to a Cochrane review in 2002, additional evidence is needed to determine the relative effectiveness of diaphragms used with and without gel. In the meantime, WHO recommends that diaphragms be used with contraceptive gel until more data are available.

User feedback from Australia and Europe suggests that women who cannot access or do not want to use contraceptive gel use a diaphragm alone.**

### Consumer feedback confirms advantages of SILCS/Caya diaphragm

Consumer use data from European countries—where the Caya contoured diaphragm has been available since 2013—showed that women, the majority of whom had no previous experience with either a diaphragm or cervical cap, found the single-size diaphragm easy to use, comfortable to wear and acceptable. Women could visit a family planning provider to learn how to correctly use Caya, but most reported they learned to insert and check the position of the device after reviewing the user instructions. About 60 percent reported Caya did not interfere with sex, and almost 35 percent said it made sex better. Women reported two primary reasons for using Caya: because it is nonhormonal and has no side effects. Approximately 99 percent said they would recommend Caya to a friend.

SILCS has been evaluated in multiple clinical studies—including in South Africa—to validate product performance (fit, ease of use, acceptability, safety), as well as effectiveness, willingness to use and potential for SILCS as a microbicide delivery system (see Table 1). Across all studies, most women easily learned to insert and use SILCS, and reported it was acceptable for both partners. In a couples’ use study for design validation in South Africa, both women and men reported SILCS was comfortable during sex (100 percent; 71 percent), and did not interfere with sensation or pleasure for either partner. Women and their partners were particularly interested in using SILCS if it can be combined with a microbicide gel to protect from both pregnancy and HIV.

### Contraceptive efficacy

Efficacy of the SILCS diaphragm used with a contraceptive gel was evaluated among 450 women in the United States who used SILCS as their contraceptive method for six months. Effectiveness was found to be “non-inferior” (i.e., similar) to results from a recent study of the Ortho All-Flex diaphragm used with contraceptive gel. These data (see Table 2) were submitted to the United States Food and Drug Administration (FDA) and resulted in approval to market the Caya contoured diaphragm in the United States.

SILCS diaphragm effectiveness is similar to typical use effectiveness commonly reported for other barrier methods: traditional diaphragm with a spermicide (16 pregnancies per 100 women); female condom (21 pregnancies per 100 women); and male condom (15 pregnancies per 100 women).

### Potential health impact and estimated costs in South Africa

In 2013, KESSEL estimated the cost of the SILCS diaphragm delivered to South Africa would be US$5.19 (approximately ZAR 62.28) per diaphragm, including regulatory fees, shipping, taxes and customs. From this starting point, a model was built to estimate the impact and cost-effectiveness of introduction of the SILCS diaphragm in Gauteng among women with unmet need for contraception in terms of unintended and mistimed pregnancies averted, assuming that available contraceptives were not a satisfying option for these women.

** DiaphragmsAndCaps discussion board (women members only). Available at: https://groups.yahoo.com/neo/groups/DiaphragmsAndCaps/info.
Table 1. Selected findings from clinical studies.

<table>
<thead>
<tr>
<th>SUMMARY FINDINGS</th>
<th>COUNTRIES</th>
<th>DETAILED NOTES</th>
</tr>
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<tbody>
<tr>
<td>SILCS diaphragm is easy to use and acceptable in low-resource settings.</td>
<td>Dominican Republic, South Africa and Thailand</td>
<td>Women who had never used a diaphragm before found the SILCS diaphragm easy to use. Both women and men found it to be acceptable.16-18</td>
</tr>
<tr>
<td>In comparative studies, SILCS diaphragm is preferred over other diaphragms and cervical barriers.</td>
<td>Dominican Republic, United States and Zimbabwe</td>
<td>Women and their partners preferred the SILCS diaphragm compared to the Ortho All-Flex® diaphragm; young women preferred SILCS to the Ortho All-Flex and FemCap.19</td>
</tr>
<tr>
<td>Confidence and ease of use increase with experience.</td>
<td>South Africa</td>
<td>Women with no previous diaphragm experience were able to confidently insert the SILCS diaphragm after 2-3 uses.5,10</td>
</tr>
<tr>
<td>SILCS diaphragm does not interfere with sensation and pleasure during sex.</td>
<td>Dominican Republic and South Africa</td>
<td>Women reported good comfort and sensation in 83-86 percent of product uses; men reported good comfort and sensation in 64-90 percent of uses.36-38</td>
</tr>
<tr>
<td>Reuse of SILCS diaphragm is acceptable.</td>
<td>Dominican Republic, South Africa and Thailand</td>
<td>Women had no difficulty washing and reusing the diaphragm; women and their partners found doing so to be unproblematic.21</td>
</tr>
<tr>
<td>Insertion of SILCS diaphragm is acceptable, even to young women.</td>
<td>Zimbabwe</td>
<td>Young women (16-21 years) were not discouraged from inserting or removing the device and having to touch their genitalia.19</td>
</tr>
<tr>
<td>SILCS diaphragm fits most women, and is easy to learn to insert and use.</td>
<td>South Africa and United States</td>
<td>In the contraceptive effectiveness study, most women (76 percent) were able to insert and correctly position the diaphragm on the first attempt after looking at the written and pictorial instructions (no coaching). With coaching, 94 percent of women were able to insert, correctly position and remove the diaphragm, per clinician assessment.22</td>
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<td>In the South African studies, the SILCS diaphragm fits women representing a range of body mass and parity,5,16,17 and most women (nearly 70 percent) reported insertion was easy after just one use; ease of use and comfort improved with additional experience.5,17</td>
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</table>

Table 2. Typical and perfect use pregnancy probabilities for SILCS plus contraceptive gel at 6 months and extrapolated to 12 months.

<table>
<thead>
<tr>
<th>Estimated number of pregnancies per 100 women during time period</th>
<th>6 MONTHS</th>
<th>12 MONTHS (EXTRAPOLATED)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TYPICAL USE</td>
<td>10.4</td>
<td>17.8</td>
</tr>
<tr>
<td>PERFECT USE</td>
<td>7.9</td>
<td>13.7</td>
</tr>
</tbody>
</table>

* Ortho All-Flex diaphragm is a registered trademark of Janssen Pharmaceuticals, Inc.
Results showed that at five years, the SILCS diaphragm could avert a total of 10,482 unintended pregnancies, including 2,217 abortions and 8,270 pregnancies that would have resulted in birth.6

Full costs were estimated from both a provider’s and a user’s perspective. SILCS diaphragm introduction could be cost-effective compared to other interventions for reducing unintended pregnancy. When considering full costs associated with SILCS introduction, the recurring cost of the contraceptive gel was the largest factor. Suggestions were made about ways to reduce the cost of contraceptive gel, such as packaging in a smaller dosage (single-use sachets) and assessing potential cost-savings with local production of gel in the future if diaphragm/gel uptake warrants this.

KESSEL is also looking at ways to reduce the cost of the Caya contoured diaphragm for developing and middle-income countries to ensure that cost is not a barrier to access, such as packaging for bulk procurement and creating lower-cost options for the packaging and training materials. A second cost-effectiveness/health impact analysis is underway to look at SILCS plus an effective microbicide gel as an MPT compared to other HIV prevention strategies. This model should be available to be shared in late 2016.

Expanding options for dual protection: multipurpose prevention technology

Many women in South Africa experience overlapping needs for both contraception and HIV protection. Currently, female condoms are the only woman-initiated prevention option available. The SILCS diaphragm is being evaluated as a delivery system for microbicide gel. This has the potential to offer women a low-cost, reusable delivery system for microbicide gel, once an effective gel is approved. Offering the SILCS diaphragm as a way to deliver microbicide gel would strengthen the current dual protection strategy of the South Africa Department of Health by being able to both prevent the high number of unintended pregnancies and reduce the burden of HIV infection, particularly among adolescents.

There are several potential advantages to using the SILCS diaphragm compared to an applicator for microbicide gel delivery: (1) the diaphragm ‘the diaphragm holds the gel high in the vagina, near the cervix, which is a vulnerable site for infection; (2) using the diaphragm could be less messy than using a vaginal applicator for delivery; (3) the environmental impact would be less; (4) the diaphragm would be less costly than applicators since it is reusable; and (5) possibly less gel would be needed with SILCS than for delivery from a vaginal applicator. Also, since the SILCS diaphragm would be introduced first as a contraceptive, there could be less stigma associated with its use than with other HIV prevention strategies, including male and female condoms, which may make it more acceptable in long-term relationships.

Exploratory clinical studies in the United States suggest that using the SILCS diaphragm as a gel delivery system is feasible and acceptable to some couples. One study using magnetic resonance imaging found that gel delivered by SILCS covered the upper vagina similar to gel delivered by vaginal applicators.3 A study that compared acceptability of SILCS versus vaginal applicators for gel delivery found that most participants preferred applicators for gel delivery due to ease of use and familiarity, but they thought SILCS plus gel would provide better protection from pregnancy and STIs than gel alone from an applicator, and they preferred SILCS for
being less messy and having less gel leakage than the vaginal applicator.4

Data from a recent study implemented in South Africa of the SILCS diaphragm for microbicide gel delivery found strong support from both women and men for the SILCS diaphragm with microbicide gel for dual protection.5 Couples indicated that the SILCS diaphragm, as a microbicide delivery system, was easy to use, acceptable and they would be willing to use this method to protect from unintended pregnancy and HIV if it were available. Even without use of microbicide gel, diaphragms provide a physical barrier which protects the cervix and could reduce the risk of STIs such as gonorrhoea, chlamydia, trichomoniasis and pelvic inflammatory disease.25

Regulatory considerations: SILCS as a contraceptive and as a multipurpose prevention technology

Diaphragms have a long-established record of safety and SILCS has been well studied; approval for use in South Africa is not anticipated to be problematic. Based on an assessment of current South African regulatory guidelines and meetings with regulatory experts, registration of the SILCS diaphragm as a contraceptive has a clear regulatory pathway.

SILCS would be submitted for approval as a medical device, following one of two regulatory pathways. At present, international approval by the FDA in the United States and by the European Union (CE mark) would prequalify the SILCS diaphragm for approval as a medical device.26 However, should procurement be made after the amended Medicines and Related Substances Act (Act 101 of 1965) is promulgated and the regulations finalized, then it is likely that a simplified procedure assessing the device for risk to patient or to public health would apply.27 In either case, conformity of the SILCS diaphragm to international regulatory standards will facilitate the registration and approval process.27

The European regulatory authority for medical devices approved Caya Gel/ContraGel as an adjunct to the diaphragm, since it is intended for use only with the diaphragm and not as a standalone contraceptive. Regulatory approvals in Australia and Canada followed a similar process, and Caya Gel/ContraGel is approved in these countries as a gel for use with the diaphragm. This is a relevant strategy for South Africa to consider, as it is the most straightforward way to proceed with regulatory approval of the contraceptive gel.

SILCS as a multipurpose prevention technology (diaphragm + microbicide gel)

Although several microbicide gels have been evaluated in clinical studies, so far none have demonstrated effectiveness strong enough to lead to a regulatory submission. The lack of effectiveness seems to be related to poor adherence and women’s inability to use the gel product as directed during the clinical trials.28

However, additional microbicide gel products are in development.28 Using the diaphragm as a reusable gel delivery system is promising because of multiple advantages, including lower cost and potentially higher motivation for women to use a product that provides protection from both unintended pregnancy and HIV over HIV protection alone, as well as the potential for less stigma.

Once a microbicide gel is shown to be effective in clinical trials, and clinical evidence confirms the SILCS diaphragm is a safe and effective way to deliver the gel, this could pave the way for a new
MPT for South Africa. KESSEL and PATH are working with developers of microbicide gels to build SILCS evaluations into the development pathway early in the process.

Conclusion

The SILCS diaphragm is a new contraceptive developed to overcome obstacles that limited use of traditional diaphragms, especially for women in low-resource settings. The user-centred development process led to design innovations that make this product easy to supply, provide and use. Since 2013, SILCS has been launched in more than 26 countries as the Caya contoured diaphragm. This has reinvigorated interest in nonhormonal barrier methods as a relevant option for women with an unmet need for family planning, and for women who are dissatisfied with their current method. In Europe, where Caya has been available since 2013, surveys over the past two years showed that women who purchased Caya represented a range of ages, parity, reproductive history, education and socioeconomic status.

The SILCS/Caya method is relevant for South Africa and responds to many of the complex issues facing women’s need for contraceptive protection and conception planning and as a future dual protection method and MPT.

Current systems in the health sector in South Africa are in place to facilitate introduction of the SILCS diaphragm with a comprehensive package of services to be offered by providers to first-time users, including how to use the method, insertion instructions, ensuring good fit, and care of the diaphragm, as well as follow-up support for women who have questions.

Next steps

Constructive engagement between researchers and key policymakers is needed to align expectations and provide a cogent appraisal of the process and implications for inclusion of the method in the National Contraception and Fertility Planning Policy. Gaining support from policymakers is critical to creating a supportive environment for SILCS introduction in South Africa.

Proposed next steps include:

1. Engage the Department of Health and align inclusion of the SILCS diaphragm into policy with the budget process.
2. Identify existing programmes for pilot introduction, integration and training.
3. Adapt existing instructions and counselling materials and integrate Caya training into pre-service and in-service curricula for health care providers.
4. Identify best practices for Caya counselling, including on insertion, checking fit and care of the diaphragm, as well as follow-up support for women who have questions.
5. Explore procurement strategies and costing, including the possibility of subsidizing the diaphragm to ensure equal access.
6. Strategize an advocacy and information dissemination campaign to raise awareness among providers and consumers about this new method, especially among women who are at risk of unintended pregnancy and HIV/STIs or are dissatisfied with their existing method.

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REFERENCES


10. Bekinska M, Greener R, Smit J, Maphumulo B, Mpili N, Kilbourne-Brook M, Coffey PS. A randomized crossover study evaluating the use and acceptability of the SILCS diaphragm compared to vaginal applicators for vaginal gel delivery. [To be published, 2016.]


20. CONRAD. A Phase I Comparative Postcoital Testing and Safety Study of the SILCS Diaphragm vs. the Ortho All-Flex® Diaphragm. 2002 [unpublished].


27. Gray A. Medical device regulation in flux [satellite session]. 7th SA AIDS Conference, 2015, Durban, South Africa.