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Photo: PATH/Mike Wang.

A HealthTech report

Desktop review of the policy, research, and regulatory environment in South Africa relating to future introduction of the SILCS diaphragm as a nonhormonal barrier contraceptive and reusable delivery system for microbicide gel for HIV prevention

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CONTENTS

1.	ABBREVIATIONS AND ACRONYMS	1
2.	EXECUTIVE SUMMARY	2
3.	INTRODUCTION AND BACKGROUND	4
3.1	Looking to the future: combination products	6
4.	POLICIES AND GUIDELINES	7
4.2	Policies and guidelines relating to sexual and reproductive health services.....	11
4.3	Policies and guidelines relating to HIV and STI prevention	14
4.4	Policies and guidelines relating to monitoring and evaluation	16
4.5	Policies and guidelines: summary and conclusion	17
5.	PUBLISHED ARTICLES AND CONFERENCE ABSTRACTS.....	18
5.1	Access to SRH and contraception services in SA	18
5.2	Lessons from previous clinical trials investigating diaphragm and gel use.....	21
5.3	Publications: summary and conclusions	25
6.	REGULATORY FRAMEWORK	26
7.	INTRODUCTORY STRATEGIES	28
7.1	The female condom programme.....	28
7.2	Medical male circumcision rollout	30
7.3	Introductory strategies: summary and conclusion	31
8.	SUMMARY AND CONCLUSION	32
	REFERENCES.....	34

1. ABBREVIATIONS AND ACRONYMS

AIDS	Acquired immunodeficiency syndrome
ANC	Antenatal care
ARV	Antiretroviral
CARMMA	Campaign for Accelerated Reduction of Maternal Mortality in Africa
CHW	Community health worker
CPD	Continuing Professional Development
DHMIS	District Health Management Information System
DHS	District health system
GCP	Good Clinical Practice
FC	Female condom
FDA	US Food and Drug Administration
FP	Family planning
HAART	Highly active antiretroviral therapy
HCP	Health care provider
HCT	HIV counselling and testing
HIV	Human immunodeficiency virus
IEC	Information, education and communication
IUD	Intra-uterine device
KZN	KwaZulu-Natal
LNG-IUS	Levonorgestrel releasing intra-uterine system
MDGs	Millennium Development Goals
M&E	Monitoring and evaluation
MIRA	Methods for Improving Reproductive Health in Africa
MMC	Medical male circumcision
MNCWH	Maternal, newborn, child and women's health
MPT	Multi-purpose prevention technology
NDoH	National Department of Health
NGO	Non-governmental organisation
NHI	National Health Insurance
NSDA	Negotiated Service Delivery Agreement
PHC	Primary health care
PrEP	Pre-exposure prophylaxis
SA	South Africa
SABS	South African Bureau of Standards
SADHS	South African Demographic and Health Survey
SAHPRA	South African Health Products Regulatory Authority
SANAC	South African National AIDS Council
SRH	Sexual and reproductive health
STI	Sexually transmitted infection
TOP	Termination of pregnancy
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

2. EXECUTIVE SUMMARY

In South Africa, a large proportion of pregnancies are unplanned, and teenage pregnancy and unsafe abortion are major health concerns. In addition, women are at high risk of HIV infection from unprotected sex. In 2011, the prevalence of HIV among pregnant women attending public clinics was nearly 30%.

There is a clear need to improve methods of contraception and HIV prevention in South Africa. Because a large proportion of women are unable to negotiate condom use, it is especially important to increase access to methods that are female-initiated and that may potentially prevent both pregnancy and HIV infection.

PATH and research partners developed the SILCS diaphragm to expand women's options for short-term, reversible contraception. Unlike other diaphragms, SILCS comes in a single size, which fits most women, and does not require a pelvic exam, which can be difficult to obtain in low-resource settings. SILCS may be especially appropriate for adolescent and young women who do not want to use hormonal contraception or intrauterine devices. When used with a microbicide (when one receives regulatory approval), this diaphragm may help to prevent both pregnancy and HIV transmission.

This report describes an initial desk review to evaluate prospects for the successful introduction of the SILCS diaphragm in South Africa. It highlights existing policies and guidelines that may help or hinder SILCS introduction, published articles and abstracts with especially useful information, and regulatory issues related to the introduction of products for contraception and HIV prevention in South Africa. It also outlines several evidence-based strategies that may be effective for introducing SILCS. This review represents the preliminary stage of a more comprehensive assessment.

Our review found that policies and guidelines are generally conducive to introduction. The current political prominence of issues related to sexual and reproductive health, the drive toward improved access to rights-based services, and the call to expand contraceptive options all provide an enabling environment for the introduction of SILCS. In addition, published articles and abstracts suggest that work to address critical social, cultural, and health system factors can effectively increase the likelihood of successful introduction.

The regulatory environment for the introduction of SILCS is more complex and challenging. The statutory body (the Medicines Control Council) that controls the registration process and oversees registration of new medications and medical devices is soon to be replaced by a new body, the South Africa Health Products Regulatory Authority, resulting in uncertainty about future registration requirements and processes for devices like SILCS diaphragm. Further, the timing and type of registration awarded to microbicide gels and to SILCS as a contraceptive or as a delivery system for microbicide gels will influence possible introduction strategies and service delivery pathways.

Results of ongoing clinical research and additional information from stakeholders will help to determine the feasibility of and pathways for introducing and marketing SILCS in South Africa. Findings from our desk review point to the following initial set of seven recommendations for advancing potential introduction of the SILCS diaphragm:

1. *Consult early with a broad range of stakeholders and maintain clear lines of communication.* Key informants will identify primary stakeholders (clients) and secondary stakeholders, such as policymakers, provincial implementers, managers, health care providers, and clinic staff. Consultations with stakeholders will ensure product acceptability and help to guide introductory strategies, management, logistics, and monitoring and evaluation.

2. *Integrate new methods into the existing service-delivery framework.* A horizontal approach will improve eventual availability of SILCS, with or without microbicide gel, at a broad range of health care settings. It will also be consistent with the general policy direction, thus ensuring sustainability.
3. *Provide comprehensive training and support at all levels.* Training of trainers is an effective, efficient approach for introduction. Monitoring should ensure that all frontline staff members are adequately trained and have access to regular refresher courses.
4. *Provide comprehensive sexual risk-reduction counseling to all clients and identify those most at risk.* Risk-compensation behavior is common with any new HIV-prevention method and often occurs in the most at-risk groups. Counseling and communications materials should include clear messages on the importance of adherence, the relative protective effect of SILCS, and behavioral strategies to help women negotiate effective product use.
5. *Include men.* Involving men in work to research and introduce new contraceptive or HIV-prevention methods, increasing communication between partners, and securing male-partner approval are all effective for increasing uptake of new products by women. Key informants will help clarify the feasibility of involving men in family planning consultations and counseling during SILCS introduction.
6. *Use social marketing.* Social marketing has contributed to the success of programs to introduce female condoms and medical male circumcision. Specific strategies for introducing SILCS should be explored with key informants.
7. *Maintain reliable logistics for procurement and supply and measure progress.* Continuous commodity supply appears to be crucial for sustained uptake. Data collection by clinic staff will be necessary to accomplish this and should be integrated with existing systems, if possible. Methods to ensure accessibility of contraceptive or microbicide gels for use with SILCS in the long term will require careful consideration.

3. INTRODUCTION AND BACKGROUND

Women of reproductive age make up 27% of South Africa's population.¹ The most recent data on contraceptive prevalence and use in South Africa (SA) come from the 2003 South African Demographic and Health Survey (SADHS). This found a relatively high contraceptive prevalence in SA, with 64.6% of all sexually active women using a modern contraceptive method.² Nonetheless, a large proportion of pregnancies are unplanned, and teenage pregnancy and unsafe termination of pregnancy (TOP) remain major public health concerns.^{3,4} Unsafe sex is recognised internationally as the second-most important risk factor relating to disability, disease, or death in developing countries.⁵

The necessity of female-initiated protective methods is becoming increasingly recognised, in light of the feminisation of HIV and the fact that, despite strong counselling, a large proportion of women are still unable to negotiate condom use.⁶ Furthermore, there is evidence that the huge burden placed on the SA health system by the HIV epidemic has overshadowed family planning (FP) services, whilst additional attention is now required for the fertility needs of HIV-positive individuals and those at risk of infection. In 2011, the HIV prevalence in pregnant women attending public clinics was 29.5%.⁷ The need to integrate currently fragmented HIV and sexual and reproductive health (SRH) services is widely recognised.^{8,9}

64.6% of sexually active SA women reportedly use contraceptives, yet a large proportion of pregnancies are unplanned. Teenage pregnancy and unsafe TOP remain major public health concerns.

Historically, FP services in SA have been provided free of charge, since the apartheid government introduced a strong vertical FP service in 1974; this provided mainly long-acting hormonal contraceptives to even the most remote populations via clinics and mobile units. The aim was to stem the growing black population; services were therefore provided in a very paternalistic fashion, largely disregarding women's own preferences.² In 1994, FP services were reorganised during an overhaul of the health system and integrated into the primary health care (PHC) system, with a view to guarantee reproductive rights. In 2001, a progressive contraception policy was launched, which focused on quality of care and the client's right to choose.¹⁰

Contraceptive methods currently available at no cost in the public sector	
Male condoms	Widely available at public health facilities and non-traditional outlets.
Female condoms	Introduced in 1998. Limited availability at public facilities and non-traditional outlets.
Oral Contraception (combined or progesterone only)	Widely available at FP and PHC facilities.
Progesterone-only contraceptive injection (depot-medroxyprogesterone acetate, norethisterone enanthate)	Widely available at FP and PHC facilities.
Emergency contraception	Usually available at FP and PHC facilities. Limited awareness.
Intrauterine contraceptive device	Increasing availability in line with the revised National Contraception and Fertility Planning Policy and Service Delivery Guidelines, 2012.
Progesterone implant	Introduced in 2014.
Tubal ligation	Limited service points. Usually accessed by referral.
Vasectomy	Limited service points. Usually accessed by referral.

Currently, contraceptive methods are generally available at all PHC clinics in SA, and 83% of women access FP services from the public sector.² Although the range of methods available in the public sector is expanding, the contraceptive profile is still heavily skewed towards hormonal injectable contraceptives, which are associated with poor adherence and high rates of discontinuation and method switching.¹¹ The association between long-term hormonal contraceptives and HIV remains unclear, although some studies suggest that they may increase the risk of HIV transmission.^{12,13}

Other long-acting methods, such as the intrauterine contraceptive device (IUD), tubal ligation and vasectomy, are much less available in the public sector.^{2,14} However, the IUD is currently being re-introduced and promoted, in line with the revised 2012 National Contraception and Fertility Planning Policy and Service Delivery Guidelines.¹⁵ The levonorgestrel-releasing intrauterine system (LNG-IUS) is currently only available to clients in the private sector and some secondary and tertiary institutions.¹⁵

Although the range of contraceptive methods available in the public sector is expanding, the current method mix is skewed towards injectable contraceptives, which are associated with poor adherence and high rates of discontinuation and method switching.

The diaphragm is no longer available via SA's public health system since discontinuation in the 1980s, and has limited use in the private sector. Although high HIV prevalence increasingly necessitates use of dual methods to protect women from sexually transmitted infections (STIs) and unintended pregnancy, concurrent use of barrier and hormonal methods remains very low.^{16,17} Meanwhile, condoms are often promoted for STI prevention rather than as a method of contraception.¹⁸

The SILCS diaphragm is a single-sized cervical barrier developed to expand women's options for nonhormonal contraception, by addressing issues that have limited the use of traditional diaphragms. The single-size SILCS device reduces the need for a pelvic exam to determine which diaphragm size a woman needs, and has features designed to make it easy to use and comfortable for both partners. It could eventually be supplied outside the clinic setting, where permitted by regulatory guidelines. For example, SILCS is approved as an over-the-counter device in Canada and Europe. The SILCS diaphragm addresses key factors women cite for non-use of existing family planning methods, including wanting a method with few side effects and one that is initiated by the woman herself.¹⁹ Traditional diaphragms have reported efficacy of 84% and 94% with typical and perfect use respectively in clinical studies, when used with spermicidal cream or jelly.²⁰ A recent contraceptive effectiveness study of SILCS plus contraceptive gel (Nonoxynol-9 or BufferGel) conducted in the United States has reported 82% and 86% effectiveness, with typical and perfect use respectively.²¹ In an acceptability study in South Africa, women reported that SILCS was easy to handle and comfortable to insert and wear. Furthermore, male partners found it acceptable with and without condom use and most couples felt comfortable about reuse of the device.²²

3.1 Looking to the future: combination products

Current clinical guidelines recommend using diaphragms with spermicide or contraceptive gel, despite little clinical evidence of the impact of the gel on overall effectiveness.²³ Given that diaphragms are regularly used with a contraceptive gel, there is increasing interest in the potential use of a diaphragm as a delivery system for a future microbicide gel, so they could

protect from both unintended pregnancy and HIV/STIs. Therefore, clinical studies are underway to assess the safety and drug delivery of the SILCS diaphragm when used as a delivery system for Tenofovir gel. Other combination strategies also are in development for multipurpose prevention technologies (MPTs) which are products that could protect from both unintended pregnancy and HIV/STIs. For example, *in vitro* testing of a modified SILCS diaphragm with Dapivirine (another ARV compound) loaded into the spring has demonstrated proof of concept as a controlled release ARV drug delivery system.²⁴ Other studies are investigating the potential use of vaginal rings that combine both microbicide and contraceptive drugs.^{25,26} Results of these trials will influence future feasibility and regulatory pathway for MPTs, including use of SILCS as a reusable delivery system for microbicide gels.

This desk review was undertaken prior to data collection to inform a study investigating the opportunities, challenges, and lessons learned for future introduction of the SILCS diaphragm in SA, for contraception or dual protection. First, existing policies and guidelines are reviewed to identify gaps or features that may help or hinder SILCS introduction. Published articles and conference extracts relating to SRH services and previous local clinical trials are then reviewed for additional insights. The regulatory framework for FP and HIV-prevention methods is then examined in terms of requirements for in-country testing, registration, and prescribing. Finally, introductory strategies are discussed, including examples of two recent additions to HIV-prevention and FP services in SA. This review aims to gather as much evidence as possible from a range of sources; however, limited availability of published information means that as many questions may be asked as are answered. It therefore represents only the preliminary stage of a more comprehensive investigation.

4. POLICIES AND GUIDELINES

The 2010 Negotiated Service Delivery Agreement (NSDA) for the President's Programme of Action Outcome 2: *A Long and Healthy Life for All South Africans*, recognises that despite recent investments in health services, health outcomes in SA remain poor.²⁷ The country is unlikely to meet any of the health-related Millennium Development Goals (MDGs), particularly those relating to the health and well-being of women, mothers, and children. Reductions in maternal and child mortality are therefore identified as one of four key strategic outcomes for the health sector and, as such, SRH remains relatively prominent on the policy agenda. A number of policies and guidelines relate directly and indirectly to the introduction of SILCS for contraception or dual protection against pregnancy and STIs, when used as a reusable delivery system for microbicide gel. These can be divided broadly into documents relating to contraception, SRH services, HIV/ STI prevention, and monitoring and evaluation (M&E).

Policies and guidelines relating to SILCS introduction with or without microbicide gel
Campaign for Accelerated Reduction of Maternal Mortality in Africa (CARMMA)
Children's Act (Act 38 of 2005)
Choice on Termination of Pregnancy Act (Act 92 of 1996)
District Health Management Information System (DHMIS) Policy (2011)
Integrated School Health Policy (2012)
KwaZulu-Natal Provincial 5-point Contraceptive Strategy 2011–2016
National Condom Policy and Management Guidelines (2011)
National Contraception and Fertility Planning Policy and Service Delivery Guidelines (2012)
National Contraception Policy Guidelines (2001)
National Department of Health Strategic Plan 2010/2011–2012/2013
National Health Act (Act 61 of 2003)
National Strategic Plan on HIV, STIs and TB. 2012–2016
The Negotiated Service Delivery Agreement for the Health Sector for Outcome 2: A Long and Healthy Life for All South Africans (2010)
Policy and Guidelines for the Implementation of the PMTCT Programme (2008)
Policy Guidelines for Youth and Adolescent Health (2001)
The Primary Health Care Package for South Africa (2000)
Sexual and Reproductive Health and Rights: Fulfilling Our Commitments 2011–2021 and beyond (Final Draft 2011)
The Strategic Plan for Maternal, Newborn, Child and Women's Health (MNCWH) and Nutrition in South Africa 2012–2016
National Contraception and Fertility Planning Policy and Service Delivery Guidelines (2012)
National Contraception Clinical Guidelines (2012)
National Contraception Service Delivery Guidelines (2003)
Primary Health Care Standard Treatment Guidelines and Essential Medicines List for South Africa (2008)
Primary Health Care Supervision Manual: A Guide to Primary Health Care Facility Supervision (2009)
Southern African HIV Clinicians Society: Guideline on Safer Conception in Fertile HIV-infected Individuals and Couples (2011)
WHO Medical Eligibility Criteria for Contraceptive Use (2009)

4.1 Policies and guidelines relating to contraception

Until February 2013, the most up-to-date national documents relating to contraception were the **National Contraception Policy Guidelines (2001)** and **National Contraception Service Delivery Guidelines (2003)**.^{10,28} These were developed by a group of technical experts from government, academia, and non-governmental organisations (NGOs), based on World Health Organization (WHO) Medical Eligibility Criteria adapted to the SA context and using a rights-based framework and emphasis on informed choice. Core contraceptive methods required at all FP facilities include male condoms, combined or progesterone-only oral contraceptives, and progesterone-only injectable contraceptives; referral mechanisms are required for IUD insertion, tubal ligation, and vasectomy. Availability of the female condom (FC) has not been mandatory and there has been no requirement to stock or provide counselling on the use of diaphragms or microbicides/ spermicides.

In view of the availability of new technologies, the HIV/AIDS epidemic and the need to ensure linkages with other national and international policies, the National Department of Health (NDoH) has recently revised outdated contraceptive policy and guidance with input from an expert group, as well as a broader consultative forum. The new **National Contraception and Fertility Planning Policy and Service Delivery Guidelines (2012)**¹⁵ and accompanying **National Contraception Clinical Guidelines**,²⁹ 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 SRH package'*. These documents recognise a continuum between prevention of and planning for pregnancy and integrate this into a new definition of FP. Revised WHO Medical Eligibility Criteria²⁰ form the clinical basis, and there are clear linkages with the NSDA, the NDoH's framework for SRH and rights and MDGs 4, 5, and 6.

Key areas of focus are the need to make available and promote a wider contraceptive choice, to facilitate integration of FP and a broad range of SRH services, including HIV services, and to provide special considerations for vulnerable groups to ensure equitable access. Six key objectives and accompanying indicators are described: expanded choice, service integration, training and capacity-building, enabling legislative framework, communication strategies, and M&E and research.

In view of the availability of new technologies, the HIV/AIDS epidemic and the need to ensure linkages with other national and international policies, the NDoH has recently revised outdated contraception policy and guidance.

In addition to continued provision of existing methods, the policy promises to promote awareness and availability of emergency contraception; to strengthen access to the IUD; to undertake phased introduction of hormonal implants, the LNG-IUS and combined oestrogen and progesterone injectable contraceptives; and to strengthen referral systems for tubal ligation and vasectomy.

A re-training programme for IUD insertion is already underway. The policy requires the NDoH to consider new contraceptive methods, not currently available in SA, but which have been found to be safe and acceptable in other low- and middle-income countries. Such

methods will undergo cost-effectiveness analyses and fast-track registration with the Medicines Control Council (MCC) and National Essential Medicines List for SA. The policy also contains a section on the potential future use of PrEP and post-exposure prophylaxis to prevent HIV transmission between serodiscordant partners. Potential indications and current research findings are explained; it is also clearly stated that such technologies reduce, rather than eliminate, the risk of transmission during unprotected intercourse with an HIV-infected partner.

Under the new policy, all PHC clinics and mobile units must provide male and female condoms, injectable contraceptives, emergency contraception, oral contraceptives, and the IUD (the latter is only required at expanded mobile units). Referral to secondary-level care must be available for IUD and implant insertion, tubal ligation, and vasectomy. District hospitals must supply all of the above, along with infertility management services and referral of specialist cases to tertiary centres. In addition to condoms, oral and injectable hormonal methods may be available in the community, schools, and workplaces; the IUD and implants may also be available from occupational health services where appropriately trained staff members are available. In order to facilitate service integration, the policy recommends inclusion of contraceptive guidelines in other policies and guidelines such as HIV, education and school health, social development, correctional services, police services, youth, and defence forces policies. Furthermore, contraception and fertility management must be available within SRH services (STI, breast and cervical cancer, sexual violence/sexual assault and TOP), maternal health, integrated management of childhood illnesses and expanded programme of immunisation, chronic conditions, and disability services. The policy also calls for partnerships with other government sectors, the private sector, development partners and NGOs. In line with a human rights focus, there is special consideration for adolescents, migrants, sex workers, and lesbian, gay, transgender, and intersex (LGBTI) persons. Clear guidance is given regarding the contraception and fertility management options for HIV-positive men and women.

The new contraception policy also reviews service-delivery outlets for FP, and includes requirements for the enhanced training of health care providers (HCPs) and task shifting. Service-delivery guidelines give details of which cadres of HCPs are required to provide each method, where additional training is needed, and service provision changes require legislative change (for example, for community health workers (CHWs) to provide oral contraceptives). According to the policy, a NDoH-appointed expert panel will maintain an agreed-upon core contraception curriculum for all institutions providing SRH training, which must be updated every five years and addenda made between updates as necessary. Furthermore, an agreed-upon package of in-service and post-qualification training will be developed for different cadres of health workers, in collaboration with regional training centres, attendance at which will earn Continuing Professional Development (CPD) points. To monitor changes that the policy intends, data based on nine data indicators, including 'method mix' and 'dual method use', will be collected within existing systems, at sentinel sites or within special studies.

WHO guidance (2009) states that diaphragms are safe and effective in preventing pregnancy in the majority of women, including those affected by a variety of medical conditions. The only stated exemptions are for women who have a high risk of contracting HIV (where there is an unacceptable health risk if the contraceptive method is used) and for women who are HIV-infected or whose condition has progressed to AIDS, who are advised to use diaphragms for

contraception only if alternative methods are neither acceptable nor available. This caution however is due to the risk of HIV acquisition associated with repeated and high-dose use of Nonoxynol-9—which was the only contraceptive gel available at the time the guidance was reviewed—rather than the risk associated with using the diaphragm itself. The safety and efficacy of diaphragms is discussed in the new contraception clinical guidelines, but there is no formally stated intention to re-introduce this method into the public sector. However, the new contraceptive policy does appear to be sufficiently broad, so as not to require amendment prior to SILCS introduction. Moreover, there is clearly space in the policy agenda for SILCS—first in view of a heavy focus on rights, since the diaphragm is female initiated and therefore facilitates female empowerment, and second in view of the drive towards promoting informed choice and dual protection. As a potential MPT, SILCS may make dual protection possible, even for women who find hormonal contraceptives unacceptable.

According to the **Children’s Act of 2005**, which came into full operation in 2010, no person may refuse to sell or provide condoms to a child who is over the age of 12, and contraceptives other than condoms may be provided without the consent of the parent or care-giver, as long as the child is at least 12 years old and has had a proper medical examination and advice. Full confidentiality should be observed, except in the case of suspected physical or sexual abuse, or deliberate neglect of a child, which must be reported to the relevant authorities.³⁰ Despite these clear regulations, the government is not consistent in the legal definition of a child’s capacity to give informed consent across a range of health-related interventions, including medical research.³¹

TOP legislation in South Africa is highly progressive: the **Choice on Termination of Pregnancy Act of 1996** promotes reproductive rights and freedom of choice by legalising TOP for pregnant women of any age in the first 12 weeks of gestation; from 13 to 20 weeks if a medical practitioner deems necessary; or over 20 weeks if two medical practitioners or registered midwives agree that the continued pregnancy is harmful to woman or foetus.³²

National Condom Policy and Management Guidelines (2011) are at the final draft stage of revision,³³ and relate to the national condom procurement and distribution programme which the NDoH began implementing in the early 1990s. Male, and to a lesser extent female, condoms are now widely available at health facilities, and the programme has secured a strong network of partnerships between government, NGOs and the private sector. The new policy plans to extend distribution of both male and female condoms to NGO establishments, workplaces, taverns, hotels, clubs, transport hubs and spaza shops, among others, and to strengthen recording and monitoring. Although schools would be an ideal venue for increasing condom access, few have taken the opportunity to distribute condoms, despite endorsement by the Department of Basic Education, for the fear that this will encourage sexual activity in children.³⁴ The South African National AIDS Council (SANAC) has recently recommended that the department revise their policy, making condom availability in schools mandatory in line with other SRH policies. Although the National Condom Policy aims for alignment with other policies and legislation, the main objective is to promote condom use to reduce sexual transmission of HIV and STIs. The ability of condoms also to prevent pregnancy is cited, but there is no mention of alternative or additional contraceptive methods. There is, however, reference to sustained commitment to FP at the policy level, with the suggestion that this should be incorporated into social/health insurance and basic health care programmes.

The National Condom Policy also includes strategies to remove logistical and sociocultural barriers that restrict condom access and use, such as better social marketing of condoms, training of HCPs to improve knowledge, attitudes and skills in SRH, and enhanced training of CHWs and peer educators in basic sexual health. This represents an additional drive towards more effective SRH service provision and therefore may increase demand for services with effective cross-departmental collaboration and policy implementation. It may be necessary to ensure that dual protection is adequately promoted within social marketing and training curricula, which will also need to be updated to include counselling on diaphragm use.

Provincial guidelines are often developed alongside national policy and guidelines in order to adapt to the local context; **the KwaZulu-Natal (KZN) Provincial 5-point Contraceptive Strategy 2011-2016**³⁵ is an example of this. The last SADHS in 2003 showed that KZN had the highest recorded prevalence of contraceptive use in the country, yet high rates of unplanned pregnancy and anecdotal reports of declining contraceptive prevalence do not support this claim. A desk review, stakeholder interviews and workshops were therefore held to identify priority areas for local action.³⁵ Within the strategy that was established as a result of this process, specific objectives that will support SILCS delivery include improved training and mentoring of staff using formal contraception curricula that will be updated regularly; enabling nurses and nursing assistants to provide certain contraceptive methods; and local strategies to promote awareness and education around FP options and sexual health, with emphasis on dual protection from an improved contraceptive method mix.

Contraception – key points	
The National Contraception Policy Guidelines (2001) and National Contraception Service Delivery Guidelines (2003)	<ul style="list-style-type: none"> • Informed choice from a range of contraceptive options should be available to all. • Diaphragms not available in the public sector.
National Contraception and Fertility Planning Policy and Service Delivery Guidelines (2012) and National Contraception Clinical Guidelines (2012)	<ul style="list-style-type: none"> • Aligned with policies on SRH and rights, the National Strategic Plan on HIV, STIs and TB and the NSDA • Need to expand method mix. • SRH service integration. • Vulnerable groups. • Enhanced training of HCPs and task-shifting. • Broad provision for introduction of new methods. • To be updated every five years, with addenda made to guidelines in between updates.
National Condom Policy and Management Guidelines (2011)	<ul style="list-style-type: none"> • Extend distribution of both male and female condoms. • Social marketing, HCP and peer-educator training. • Sustained commitment to FP. • No mention of alternative contraceptive methods.

4.2 Policies and guidelines relating to sexual and reproductive health services

A number of policies and guidelines relate to SRH services, including FP, through which SILCS would be provided. Officially, FP forms part of an integrated package at the PHC level, as outlined by the **Primary Health Care Package for South Africa**.³⁶ This document sets out norms and standards to ensure acceptable levels of health care at the provincial level, stating what—but not how—services should be provided (implementation is the responsibility of provincial and local governments). Agreed-upon SRH services include

contraceptive services (except tubal ligation and vasectomy); early diagnosis of pregnancy and delivery of normal pregnancy; antenatal care (ANC) and growth monitoring; child immunisation; nutrition education; TOP services; screening for breast and cervical cancer; the prevention and syndromic management of STIs; and, to some extent, HIV education and HIV counselling and testing (HCT). Standard treatment guidelines and an essential medicines list,³⁷ as well as a PHC supervision manual,³⁸ accompany this. The PHC package will soon be revised in the context of health system reorganisation (described below). Although little detail is provided, the NSDA promises various strategies to '*strengthen SRH to inter alia, ensure that contraceptives and other FP methods are readily available*'. Social mobilisation around SRH and FP is assured in partnership with NGOs and academic organisations, with '*basic public health education*' as the major community activity.

The NSDA links directly to the **National Department of Health Strategic Plan 2010/2011–2012/2013**, which sets out the medium term planned performance of the health sector in alignment with several policies and acts of parliament. The '10-point plan' forms the basis of the strategy: a 14-year project, which includes the introduction of National Health Insurance (NHI) and a PHC revitalisation initiative. Reorganisation of the health system to be community and household centred, using the district health system (DHS) as the platform of delivery, will involve establishing ward-based PHC outreach teams and district-based clinical specialist teams, and expanding and strengthening school health services. The plan promises to focus on training PHC personnel and mid-level HCPs, including a new curriculum and conditions of service for 60,000 CHWs assigned to a defined geographic area or number of households. Health promotion and community outreach programmes are to be intensified.

The strategic plan is largely focused on restructuring the health system as a whole, and despite sustained emphasis on improving women's and children's health, reference to SRH is largely in the context of HIV and STI prevention. Dramatic and on-going changes to the landscape of health service delivery are however alone highly significant for SILCS introduction, since new avenues for promotion, delivery and M&E may affect rollout. It will be important to stay up-to-date and adapt to this reorganisation during the period of introduction.

The NDoH's new framework for SRH and rights, **Sexual and Reproductive Health and Rights: Fulfilling Our Commitments 2011–2021 and beyond**,³⁹ defines a package of essential SRH services that the government has committed to provide within the new service framework. This evidence-based document brings together all existing laws, policies and guidelines in this area and states overall recommendations and government commitments, tailored to the goal of achieving SRH rights within the South African sociocultural context.⁴⁰

The new framework for SRH and rights defines a package of essential SRH services that the government has committed to provide, bringing together all existing laws, policies, and guidelines in this area.

Seven aspects of SRH and rights are defined, including sexuality, fertility, and STIs, and services are described in each area. Requirements from many government departments necessitate cross-departmental collaboration as well as with the private sector, civil society, and development agencies.

SRH and rights services are now required to be fully integrated into all levels of the PHC/DHS system, which is important given the history of service fragmentation in the context of multiple vertical programmes intended to tackle HIV/AIDS. Within the social framework, the NDoH promises to collaborate with partners to provide social outreach interventions in schools, clinics, communities, and workplaces. (The Integrated School Health Policy⁴¹ supports this through the requirement for all schools to provide 'Life Orientation' classes, covering SRH and contraception counselling). Within the health framework, a full range of contraceptive methods and advice must be provided at the primary care to tertiary hospital levels, where relevant, including within HIV services. At the community level, CHWs will be responsible for screening and facilitating access to contraception and promoting dual protection during home visits. They will also provide information and education in communities, schools and early childhood centres. Clinics and mobile units must provide contraceptive methods as per national guidelines, and the policy promises to incorporate all drugs and supplies necessary to deliver the package of essential SRH services into the Essential Primary Care and Hospital Drugs lists. Health education and counselling, including fertility planning, should also be available, with a particular focus on vulnerable populations such as sex workers, adolescents and people living with HIV and AIDS. Health centres have the additional responsibility to provide tubal ligation and vasectomy, and district hospitals will provide specialised contraceptive services for women with specific medical conditions. Furthermore, it is stated that the Health Professions Council of South Africa and the South African Nursing Council will ensure that curricula for HCPs incorporates all aspects of the policy in pre- and in-service training; clinical and supervision guidelines will be required to be kept up-to-date with WHO eligibility criteria; and M&E should be completed at every level.

These measures, which focus on health promotion, task-shifting, and uniform provision of quality services, will hopefully improve access to FP services and increase demand for new and alternative forms of contraception and MPTs. This could be highly beneficial for SILCS introduction; provided product information is effectively disseminated and high-quality training given at all levels. Vulnerable groups will need to be accounted for in SILCS guidance so that HCPs can provide counselling in line with national policy.

If SILCS is incorporated into contraceptive policy, future status as an 'essential drug' may facilitate availability in remote areas. The SRH services framework requires political and health service leaders to articulate their commitment to SRH and rights and build it into all platforms. It also commits the NDoH to support on-going applied research into social and cultural understandings of SRH. This may help raise the political profile of FP, and therefore attract attention to and funding for contraceptive services in the public, private, and not-for-profit sectors, which could be used to promote more widespread awareness and use of SILCS.

The last significant policy influencing SRH services, and therefore SILCS, is the **Strategic Plan for Maternal, Newborn, Child and Women's Health (MNCWH) and Nutrition in South Africa 2012-2016**,⁴² through which the government promises to mobilise the necessary financial and human resources to reduce maternal, neonatal, infant and child mortality by 10% by 2016. The policy reiterates the move towards community-based health care, where MNCWH services are fully integrated with PHC and HIV services, potentiating wider availability of FP services. It also promises to tackle social determinants of health by targeting under-resourced districts. Teenage pregnancy—a priority area within Policy Guidelines for

Youth and Adolescent Health⁴³—will be tackled by empowering users with relevant information on SRH and contraceptive use within accredited ‘youth-friendly’ clinics.

There is a sub-section on access to contraceptive services, which states that ‘*all PHC facilities and hospitals are required to provide a full range of contraceptive services and methods, and promote the use of dual methods (contraceptive and condom use)*’. This policy incorporates the strategy of the Campaign for Accelerated Reduction of Maternal Mortality in Africa (CARMMA), an African Union Commission and UNFPA initiative to reduce maternal mortality in the Africa region. This was recently officially launched in SA and is internationally recognised, thus drawing widespread attention to this cause and existing policy objectives.

SRH services – key points	
Primary Health Care Package for South Africa (2000)	<ul style="list-style-type: none"> • Norms and standards for PHC services – does not dictate delivery. • Includes FP package. • Shortly to be revised.
National Service Delivery Agreement and The National Department of Health Strategic Plan 2010/2011–2012/2013	<ul style="list-style-type: none"> • NHI. • PHC revitalisation. • Promises strategies to ensure contraceptives are accessible.
Sexual and Reproductive Health and Rights: Fulfilling Our Commitments 2011–2021 and Beyond (Final Draft 2011)	<ul style="list-style-type: none"> • Commits to a package of essential SRH services. • SRH service integration. • Clinics and mobile units must provide FP counselling and contraceptive methods as per national guidelines. • Social outreach. • Mandatory to include policy in HCP training. • Clinical and supervision guidelines must be up-to-date with WHO eligibility criteria. • Commits to on-going applied research. • May improve access to FP and increase demand for MPTs. • Need to ensure SILCS information effectively disseminated and included in training curricula.
Strategic Plan for Maternal, Newborn, Child and Women’s Health (MNCWH) and Nutrition (2012–2016)	<ul style="list-style-type: none"> • Integration of MNCWH with PHC and HIV services. • Promises to tackle social determinants of health by targeting under-resourced districts. • ‘All PHC facilities and hospitals are required to provide a full range of contraceptive services and methods, and promote the use of dual methods’.

4.3 Policies and guidelines relating to HIV and STI prevention

The primary policy in this area is the **National Strategic Plan on HIV, STIs and TB 2012–2016** (updated every five years),⁴⁴ which informs stakeholders at national, provincial, district, and community levels on related strategic directions, and provides a framework to coordinate and monitor implementation. Of four key objectives, ‘*preventing new HIV, STI, and TB Infections*’ relates most directly to SILCS introduction. This objective covers structural, social, behavioural, and biomedical interventions; acknowledges the importance of integrating HIV and STI prevention into the SRH framework; and supports a comprehensive package of services that includes fertility management (TOP, contraception counselling and dual-contraceptive method use), with a focus on vulnerable populations such as adolescents. It also recommends a wider range of contraceptive methods, and that HIV- positive men and women should be offered contraception at ‘*every opportunity*’, including within highly active antiretroviral therapy (HAART) services.

Although no policy currently exists regarding the promotion or distribution of microbicide gels for use as topical PrEP for women at high risk of HIV infection, the necessity to prepare for market availability of such new technologies is recognised, for example, through the commitment to conducting feasibility studies. This creates enabling policy space for SILCS as a delivery system for microbicide gel; it would therefore be helpful to maintain policymakers' attention in this area.

Although no policy currently exists regarding the promotion or distribution of microbicide gels, the necessity to prepare for market availability of such new technologies is recognised.

A second important document is the **Policy and Guidelines for the Implementation of the Prevention of Mother to Child Transmission (PMTCT) Programme**,⁴⁵ which aims to decrease the number of HIV-infected babies born to HIV-positive mothers. Its four main elements include primary prevention of HIV, especially among women of childbearing age, and prevention of unintended pregnancies among women living with HIV. Although the policy states that all women at enrolment should be counselled on safer sex and provided with condoms, 'contraception' is not mentioned anywhere in the document, nor does it describe other methods which would be appropriate for HIV-positive women. Given the drive towards expanding the method mix available to all women and the impending availability of new technologies such as diaphragms and PrEP, this area may need to be addressed.

In light of the fact that that 29% of SA's 1 million annual births occur in women living with HIV, a majority of which are unplanned, the Southern African HIV Clinicians Society recently published a **Guideline on Safer Conception in Fertile HIV-Infected Individuals and Couples (2011)**.⁴⁶ Importantly, the authors recognise that reproduction is a human right; a clinician therefore has a duty to identify patients' fertility desires and to provide safe and effective contraception or conception guidance to a presumed fertile couple where one or more partners are HIV positive. It is stressed that, even when accounting for local resource constraints as well as international norms, a number of safe contraceptive methods are available for HIV-positive women. Dual protection is also strongly recommended for those who are able to negotiate condom use. In the advent of SILCS introduction and availability of PrEP, it would be useful for the Society or the NDoH to provide clear and updated guidance in this area.

HIV and STI prevention – key points	
National Strategic Plan on HIV, STIs and TB 2012–2016	<ul style="list-style-type: none"> • Integration of HIV /STI and SRH services. • Fertility management. • Recommends expanded range of contraceptive methods. • Recognises importance of preparing for market availability of PrEP.
Policy and Guidelines for the Implementation of the Prevention of Mother-to-Child Transmission (PMTCT) Programme (2008)	<ul style="list-style-type: none"> • Prevention of unintended pregnancies among HIV-positive women is a key area. • Omission of contraceptive options may need review.
Southern African HIV Clinicians Society: Guideline on Safer Conception in Fertile HIV-infected Individuals and Couples (2011)	<ul style="list-style-type: none"> • All HIV positive individuals have a right to fertility • Recommends safe and effective contraceptive methods for HIV positive individuals • Update when SILCS/microbicides become available would be useful

4.4 Policies and guidelines relating to monitoring and evaluation

A number of policies discussed refer to enhanced M&E in procurement and logistics, service provision and ultimately health outcomes in their relevant areas. The District Health Management Information System (DHMIS) provides a medium for the majority of these activities, which are mandated by the Health Act of 2003⁴⁷ at all levels within the public and private sector. An updated **District Health Management Information System (DHMIS) Policy (2011)**⁴⁸ aims formally to standardise implementation of the DHMIS, to promote uniformity countrywide and to clarify roles and responsibilities at each level. There are planned improvements in human resources and training, and synchronisation and hierarchical organisation with other departmental information systems. The NDoH is responsible for revising the National Indicator Data Set every two years, whilst provinces may add further indicators relevant to the local context. It has been commented that *'information on the performance of the health care system in relation to SRH and rights is limited to a few routinely collected indicators, which are of suboptimal quality and not easily available'*.⁴⁰ Review of national and provincial data sets for FP, at least to include numbers of diaphragm acceptors, will be necessary to inform successful introduction and continued provision of SILCS diaphragm and microbicide gel.

M&E – key points

District Health Management Information System (DHMIS) Policy (2011)

- Aims formally to standardise implementation of the DHMIS.
- May need to review national/provincial indicator data sets.

4.5 Policies and guidelines: summary and conclusion

The current political prominence of SRH, the drive towards improved access to rights-based services, and a call to widen the contraceptive method mix all provide an enabling policy environment for the introduction of SILCS as a non-hormonal contraceptive method or for dual protection against pregnancy and STIs. There is significant overlap/alignment between policies, in terms of sexual health promotion, improved HCP training, and human resources mobilisation, which act as facilitating factors. Newly issued contraception policy and guidelines represent a positive step towards expansion of choice and make broad provision for new methods such as SILCS. There is increasing availability of guidance on fertility management and HIV, although a number of policy documents may need updating in the future to clarify the role of PrEP. Dual protection is encouraged in a number of policies, and this could be capitalised on. Conversely, the absence of clear guidance on dual protection or prevention of unintended pregnancy in national condom and PMTCT policies, although not obstructive, could be reviewed. Health system restructuring may act as a facilitator for SILCS introduction, yet it is also important to stay up-to-date in such a dynamic environment, to maintain the profile of FP and to ensure that opportunities are not missed. This review does not account for provincial variation in local policy, which may require evaluation. Review of national and provincial indicators for M&E will also be necessary. Establishment of a contraception expert committee is promising in terms of more regular updates of policy and guidance in this area. The panel would also provide a consultation pathway to include SILCS in policy and may facilitate timely registration and effective dissemination of information. SANAC is another key body to consult with at the introductory stage.

5. PUBLISHED ARTICLES AND CONFERENCE ABSTRACTS

A significant amount of research has been conducted in recent years related to SRH service provision in SA, and to FP services in particular. This section considers the published literature on SRH policy and service delivery that would affect introduction of SILCS for contraception or dual protection, and the literature more directly related to diaphragm use, to identify areas for consideration in policy and guidance when introducing SILCS. This is not an exhaustive literature review, but briefly considers key themes of access to services and lessons from previous clinical trials investigating diaphragm and gel use.

5.1 Access to SRH and contraception services in SA

Given the current policy discourse on improved SRH service integration, the success of SILCS will depend on the nature and extent of its incorporation into developing SRH structures. Numerous aspects of access to contraceptive services could be considered; discussed here are commonly cited challenges and opportunities in equitable service delivery that may impact SILCS introduction.

As previously mentioned, FP services have formally been integrated into PHC in South Africa since 1994, and theoretically should be available to all women at PHC facilities. It is argued that this system has greatly improved access to contraception and continuity of care, thus contributing to a falling total fertility rate.⁴⁹ However, additional challenges such as simultaneous vertical programming, health system decentralisation and human resource shortages have detracted from full integration of services. Evidence suggests that policy rhetoric is therefore seldom fully realised in practice.⁵⁰

A 2001 qualitative study showed that, despite high levels of interest from clients and providers in integrated care, clients attending rural and urban PHC facilities providing women's health services in KZN were rarely offered counselling on a comprehensive range of contraceptive options.⁵¹ Furthermore, despite the emphasis on informed choice in contraceptive policy, evidence shows that use of a particular type of contraceptive is heavily influenced by the provider, with little concern for the woman's own preferences.⁴⁸ Dual method counselling is inadequate, leading to very low uptake;^{9,16,17} FC availability and uptake is limited; and there is very little awareness of EC, which should be universally available. In some facilities where IUDs are reportedly available, HCPs either have no knowledge of such devices, or are not trained to use them.⁵² Lack of knowledge and provider promotion clearly limits uptake of new methods of potential importance. For example, one study in Cape Town showed that amongst 277 HIV positive women attending a PHC clinic, only 37% were aware of the IUD, yet following an information session, 86% showed interest in using the device.⁵³ Access is also unequal between urban, peri-urban and rural communities; in KZN, for example, despite consistent availability of male condoms, many more clients receive STI, FP, ANC and HCT in urban as opposed to rural and peri-urban facilities.⁵⁴

Maharaj and Cleland (2005) found that major obstacles to 'active' SRH service provision (whereby the HCP initiates assessment of unmet need in addition to the presenting problem) include inadequate training, time constraints, health system logistics and dissatisfaction with salaries.⁵¹ Importantly, many providers reported a lack of clear guidance as to what services should be offered within the 'one stop shop' model.⁵¹ Integration of new methods into the existing

health system needs careful consideration: in recent study in Cape Town, a provider training intervention on IUD insertion failed to increase women's knowledge about the device. Qualitative participant insights revealed that the four-day training was too short to ensure that providers were confident in recommending and inserting the device. Providers also felt that women would benefit from better access to FP education and simultaneous community awareness campaigns.⁵⁵ Several studies have commented on provider resistance to integration of FP into PHC, in the context of their previous role as 'specialists' in a field, or the historical provision of certain services on certain days. Many however, recognise the importance in reducing stigma for unmarried women accessing FP services and those attending for STI services, as a result of the 'one queue' system.^{50, 51}

Many obstacles to service integration and efforts to increase access to FP have been attributed to the manner in which health system decentralisation has been implemented in SA. Parallel processes of devolution and deconcentration have occurred at different levels, blurring the organisational lines of accountability in a system already fragmented by vertical programming. This has resulted in lack of clarity over responsibilities at different levels and contestations over political power and financing between levels.⁵⁰ When introducing new services, capacity issues are most commonly overlooked, resulting in both failure to implement new policies due to lack of resources and significant disparities between provinces.⁴⁹ Some managers and HCPs see policy-making as a very 'top-down' process, and communication to implementers has been very poor, resulting in low staff morale and negative attitudes towards change. Unfortunately, the impact of the lack of consultation and communication appears to have been particularly heavy on reproductive and women's health services (e.g., provision of free and safe TOP), which undoubtedly affects availability and accessibility.⁵⁰ Indeed, it has been shown that offering HCPs mechanisms to report and address problems, and to reflect on their roles and behaviour, is key to establishing an enabling environment to implement new reproductive health policies.⁵⁰

More recently the integration discourse has included more specific aspects of SRH to improve access; namely FP, ANC, STI services, HCT, HAART and PMTCT. The rapid scale-up of vertical HIV services since the 1990s has contributed to a situation where HIV-positive patients attending tertiary treatment centres frequently miss out on more 'general' FP services. Integration of HIV with other SRH services is now widely regarded as essential for meeting the needs of both men and women.⁸ Steps have therefore been taken at a policy level to establish a mandate for integration via PHC re-engineering,³⁹ although the exact model of integration that will develop in coming years remains unclear.

The importance of providing quality SRH services within the HIV framework has gained attention in terms of the impact on maternal and child health and the rights of HIV-positive individuals. Studies show that HIV-positive women generally report significantly lower levels of childbearing intention in comparison to HIV-negative individuals, whilst HAART initiation is strongly associated with increased intention to have children.^{9, 56} Evidence also shows, however, that HIV-positive women in SA frequently lack information regarding HIV, contraceptive options, fertility and pregnancy.^{8, 57} A 2009 study found that a minority of HIV-positive women in Cape Town had ever discussed their reproductive intentions with a HCP.⁹ Equally, there is evidence of missed opportunities for HIV and STI prevention within FP and ANC services.⁵¹ HIV-positive women also experience negative attitudes towards childbearing and difficulties in accessing safe legal TOP. Key informants interviewed in 2002 felt that HCP attitudes towards HIV and pregnancy had not changed, or were only slightly influenced, towards approving of pregnancy in HIV-positive women since the introduction of HAART for

PMTCT.⁵⁷ One study of women's contraceptive preferences in Soweto demonstrated a positive effect of HAART services on increasing contraceptive prevalence and dual protection in comparison with HIV-negative women and, to a lesser extent, HIV-positive HAART-naïve women.⁵⁸ This highlights the importance of improved integration of HCT, HAART and FP services, and therefore the availability of a full range of contraceptive options within HIV services.

Smit et al. (2012) examined the policy and service-delivery environment for HIV and SRH service integration, finding that key informants frequently reported a lack of national policy guidance on integrated care, and felt that clinical service guidelines in particular remain too specialised. Separation of HIV and SRH under different directorates appears to exacerbate the problem by preventing coordinated planning, whilst vertical programming and poor coordination between facilities contribute to inefficient referral systems. At a service-delivery level, it was felt that staff shortages, high client load, resistance to change and negative attitudes all contributed to poor-quality care. Suggested solutions included strengthened management, integrated training courses for SRH and HIV, partial integration of services provided within the same physical space, task-shifting and greater emphasis on cross-departmental policies such as the National Strategic Plan on HIV, STIs and TB.⁸

Young people represent another social group, frequently cited in the literature, which experiences poor access to contraception and high levels of unintended pregnancy. One 2007 study of a nationally representative sample of 15- to 24-year-old SA women showed that over two-thirds were sexually experienced and 50% had ever been pregnant, yet only 50% reported using contraception. A majority (66%) of the contraception users favoured hormonal injectable contraceptives, and only 6.7% were using dual protection (barrier and hormonal methods).⁵⁹ An estimated two-thirds of pregnancies in young people are unintended,⁴ and many young people only start using contraception when accessing post-natal care following an unintended pregnancy.⁴⁹

Barriers to young people accessing contraception services include concerns over lack of privacy, inconvenient clinic opening times, and hostile attitudes from staff members, who disapprove of their sexual activity.⁴⁹ Alli et al. (2012) found that, although the majority of youth respondents to exit interviews from SRH services in KZN reported that they were happy with the service, one third felt they did not get all the information they needed and some felt judged or disrespected by clinic staff. HCPs in the same facility felt that time constraints required them to prioritise curative treatment over health promotion, and commonly cited cultural factors as barriers to effective communication with youth.⁶⁰ Holt et al. (2012) examined HCPs' attitudes to young people accessing SRH services in Soweto in 2009: providers commonly felt that young women should not be having sex before marriage and reported feeling frustrated that education and awareness campaigns were ignored. Provider contraceptive preference leaned heavily towards injectable methods, followed by abstinence, and many HCPs stated that TOP was a sin. In contradiction to national policy, some services were restricted to women over the age of 18 and none of three facilities assessed had policies for or provided training on youth-friendly service provision. The researchers felt that these findings were more than likely to impact service accessibility and recommended contraception refresher courses and further research into interventions for youth-friendly service provision.⁵² It has been found that the strongest predictor of dual-protection use in young people is reporting having talked about condoms with their last partner, highlighting the importance of relationship communication strategies in contraceptive counselling.⁶¹

In response to promising results from recent PrEP trials, studies have begun to investigate whether and how PrEP can be delivered outside of clinical trials. In South Africa, a qualitative study⁶² of the physical deliverability of PrEP was undertaken in 2011–2012 to identify and assess possible delivery channels, to evaluate the impact on existing services and determine the level of additional capacity required, and to identify potential delivery models. Overall, it was felt that public PHC clinics and FP clinics were the most appropriate channels for possible service delivery. Existing systems for ARV procurement and client tracking could be utilised, as could opportunities for dissemination of information as well as PrEP sensitisation and mobilisation. Several inputs to existing services would, however, be required, including position-specific staff training, improvements to counselling, outreach, increased physical space and integration with other services.

Addressing challenges of health service structure and accessibility is clearly beyond the scope of SILCS introduction, yet it is important to bear these issues in mind as the context in which introduction strategies must operate. Much of this evidence will be accounted for in proposed developments to SRH service provision, which SILCS may benefit from, as long as an adequate profile is maintained. One key message is the importance of consultation and communication, not only with policymakers, but also with managers and HCPs in the introductory phase. This may increase access to SILCS by ensuring a positive experience of the process of change and avoiding negative attitudes towards SILCS. It is also clear that HIV and ANC services should be included in service-delivery pathways in addition to FP clinics at the PHC level; clinical guidance on contraception and training curricula should also therefore be updated in these areas. Training on SILCS should emphasise informed consent and the benefits of dual protection. At-risk groups such as youth should be given special attention in training, and clinics should be encouraged to implement youth-friendly policies and training for staff in line with the government's plans for accreditation of youth-friendly facilities. Finally, future service-delivery pathways for PrEP will be highly relevant to SILCS in coming years, and developments in research and policy in this area should be monitored.

Access to FP and contraception services – key points

- Rural FP clients, HIV patients and young people experience poor access.
- Provider attitudes and beliefs influence contraceptive options.
- Insufficient promotion of dual protection.
- Contributing factors to mismatch between policy and reality include inadequate training, time constraints, logistics and dissatisfaction with salaries.
- Top-down policy-making results in negative attitudes towards change.
- Stakeholders aware of need for integrated SRH and HIV services.
- Steps are being taken to prepare for PrEP.
- Early and on-going consultation and communication with providers is vital in the introductory phase.

5.2 Lessons from previous clinical trials investigating diaphragm and gel use

There is increasing awareness of the need to improve access to female-initiated methods that are safe, easy to use, acceptable and effective in preventing unintended pregnancy

and/or protecting women against HIV, STIs or other reproductive-tract infections.¹² The diaphragm has been used worldwide as a contraceptive method for decades, but has seen limited use in SA. This is largely because of the recommendation to use conventional diaphragms with Nonoxyl-9 spermicide gel, which has been shown in SA to increase the risk of HIV acquisition with frequent use, with no significant effect on the incidence of Gonorrhoea or Chlamydia infections.⁶³ However, there is renewed interest in the diaphragm's potential as an MPT and numerous trials and studies conducted both in SA and elsewhere have implications for successful introduction of both SILCS and microbicide gels in SA.

The SILCS diaphragm is an example of a 'one size fits most' device that does not require a "fitting examination" by a trained provider to assess appropriate diaphragm size. Testing by 21 South African couples in a short-term acceptability study demonstrated that the device, when used with lubricant gel, was easy to use and provided good comfort and sensation to women representing a range of diaphragm sizes, parity and body mass index. Couples used condoms concurrently in 50% of product uses, which did not appear to affect comfort, sensation or device stability.²² South African women also demonstrated the ability to wear and care for SILCS.⁶⁴ U.S. studies have assessed feasibility and acceptability of the SILCS diaphragm as a delivery system for microbicide gel. A study using magnetic resonance imaging found vaginal gel coverage from SILCS diaphragm (both single- and double-sided gel delivery) was comparable to that delivered via a vaginal applicator.⁶⁵ In a subsequent U.S. study, couples' preferred the vaginal applicator for gel delivery primarily for ease of use; researchers suggest this finding may be influenced by low familiarity with the diaphragm and low perceived need for dual protection.⁶⁶ Participants in a study in SA, which compared gel delivery via a cervical cap to gel delivery via a vaginal applicator reported preference for the cervical cap device, because it reduced the amount of gel leakage. Importantly, the use of the cervical cap enhanced adherence with Tenofovir gel use in comparison to the applicator.⁶⁷ A study in SA to evaluate the acceptability of SILCS as a gel delivery system is planned for the second quarter of 2014. CONRAD also is scheduled to implement two clinical studies of SILCS used with Tenofovir gel to assess pharmacokinetics/pharmacodynamics and safety, as well as barrier properties when SILCS is used with TFV gel.⁶⁸

Only one study has evaluated diaphragm for HIV protection. The Methods for Improving Reproductive Health in Africa (MIRA) trial was a multi-site, open-label randomised controlled trial conducted between 2003 and 2006 to determine the effectiveness of a traditional multi-sized diaphragm and lubricant gel in preventing heterosexual acquisition of HIV and other STI infections in Zimbabwean and South African women. Women in the intervention arm were counselled to use diaphragm with lubricant gel and condoms and followed up for 24 months, whereas women in the control arm were counselled to use male condoms only. The MIRA trial demonstrated high acceptability of the diaphragm and gel, based on convenience, ease of use, dual use potential, being female-initiated, and enhancement of sexual pleasure as a result of lubrication.⁶⁹ Approximately half the control arm participants accepted a diaphragm at trial exit, and a minority were using several months after completing the trial, compared to most accepting and half still using in the intervention arm, despite equal counselling at the exit interview.⁷⁰ Although MIRA did not produce enough evidence to demonstrate efficacy of the diaphragm in protecting women against HIV, Chlamydia, Gonorrhoea or HSV-2 acquisition,^{71,72} a number of quantitative and qualitative sub-studies conducted simultaneously provide useful insights into other aspects of potential diaphragm use in SA.

Okal et al. (2008) state that *'the perspectives of diaphragm users and population-level uptake are likely to be context specific, as trade-offs between positive and negative attributes are shaped by social and cultural practices'*.⁷³ Poor adherence posed a significant problem to the MIRA team, and may have caused a reduction in power sufficient to prevent detection of a protective effect of the intervention. Despite regular counselling on sexual health and study design, only 36.3% of last sex acts at interview were protected by both a male condom and diaphragm, and 22.4% of participants reported product substitution at every visit (ever using a diaphragm instead of a condom in the previous three months).⁷⁴ Other so-called risk-compensation behaviours are described elsewhere, such as increased frequency of sex acts after enrolment in a contraceptive/HIV-prevention trial.⁷⁵ In a qualitative study exploring obstacles to diaphragm and condom use, some couples reported alternating between methods depending on availability and mood. Both female participants and male partners frequently reported lack of awareness of study recommendations, or a belief that diaphragms alone protect against pregnancy and disease, which was reinforced by repeated negative HIV tests in the intervention arm.⁷⁶

In the CAPRISA 004 study, high adherence with pericoital use of Tenofovir 1% gel achieved a 54% reduction in HIV seroconversion compared to placebo, demonstrating proof of concept for use of topical microbicides as PrEP. Similar to the MIRA trial, product acceptability was very high; 97.4% of the participants found Tenofovir gel acceptable and 97.9% stated that they would use it if they knew it prevented HIV. However, low adherence was equally problematic; overall, participants used the gel before and after sex only 59.2% of the time during the two-year study period (based on an objective count of used and unused applicators returned each month in addition to self-reporting). HIV incidence reduction in low adherers was only 28%.⁷⁷ Adherence also declined over time, which may explain the apparent decline in product efficacy.⁷⁸

Despite subsequent implementation of an intensive adherence-support programme, 40% of women had less than 50% gel adherence. This is highly significant given that population level adherence patterns to oral and topical PrEP may be as important as product efficiency, in terms of the public health benefit.⁷⁹ Mathematical modelling has shown that if Tenofovir gel is used by South African women in at least 80% of sexual encounters, 2 million new HIV infections and 1 million deaths could be prevented over the next 20 years. Cost-effectiveness would occur with gel use in as few as 25% of sexual encounters.⁸⁰ Furthermore, CAPRISA authors point out that, although substantially lower than in the placebo arm, seroconversion was unacceptably frequent, even in PrEP high-adherers, highlighting the need to improve adherence and effectiveness of Tenofovir gel or to develop new prevention strategies for combination use.⁷⁷

Women in the MIRA trial were frequently unable to negotiate condom use, sometimes due to intimate partner violence or the effects of alcohol, or if a male partner used diaphragm wear as an excuse not to condomise.⁷⁶ Disclosure to and approval of male partners was strongly associated with consistent diaphragm use in Zimbabwe, supporting existing evidence that male-partner involvement is an important aspect of successful uptake of any female-initiated HIV-prevention strategy.⁸¹ Many authors comment on potential covert use as an important attribute of diaphragms that may benefit women who have limited opportunity for sexual negotiation.⁷³ In the MIRA trial, 9% of women never disclosed to their primary partners that they were using the diaphragm; these women were more likely to be older, to not co-habit with their partner, and to have a partner who did not use condoms.⁸² Covert use was a common strategy used by

women to encourage men to wear a condom.⁷⁶ Another study found that disclosure is often very difficult, especially for those in stable, rather than casual or commercial, relationships. Disclosure tends to be a process rather than an event, the nature and timing of which dictated its success. Unfortunately, the social context that necessitates covert use of contraceptive methods or microbicides may also lead to adverse consequences for women in the event of accidental disclosure.⁷³

MIRA also qualitatively examined the association between diaphragm plus gel use and vaginal practices, such as washing, wiping and insertion of dry or absorbent materials.⁸³ Such practices are of specific cultural significance within local contraception/HIV-prevention trials, since interference with the effectiveness of female-initiated methods is unknown. Vaginal practices were consistently associated with poor adherence with the intervention product. Although counselling, which encouraged non-use, resulted in lower frequency during the trial, vaginal practices were more frequent post-trial for those who chose to continue using the diaphragm. Hypothesised causes include a perceived need to reduce excess discharge caused by gels, perceived cleansing properties of the gel, or reduced condom use due to product substitution.

Finally, previous diaphragm trials shed light on issues relating to high-risk groups. For example, a few studies in sub-Saharan Africa, although not in SA, have investigated diaphragm use by female sex workers. High levels of acceptability were found in Kenya⁸⁴ and Madagascar,⁸⁵ with comparable levels of adherence to women in the general population, often increasing over the study period. For this group, lack of coital interruption and covert use were particularly beneficial.^{73,86} The MIRA team used trajectory analyses to predict adherence patterns based on baseline characteristics; finding that high-risk behaviour at baseline was strongly associated with poor adherence. In addition to more frequent reporting of risky sexual behaviours by young women, young age (less than 24 years) independently predicted poor adherence.⁸⁷

Findings from these trials demonstrate that on-going support, rather than simply providing access and teaching basic skills, is required to ensure successful uptake and continued use of new contraceptive products. Although it is shown that broadening the method mix increases overall contraceptive coverage by increasing use of any barrier method,⁷⁰ it is also crucial that future clinical guidelines and provider training for SILCS accounts for the cultural and social context. This will help HCPs identify high-risk individuals and give appropriately tailored counselling to minimise risk-compensation behaviours, without limiting the range of methods offered. It is significant that concurrent condom use does not impact SILCS acceptability, since providers may feel that marketing of SILCS plus condoms may be important initially, given the sociocultural background in SA and political emphasis on condomising.

HCPs need to ensure that clients understand that contraceptive effectiveness of SILCS alone is lower than male or female condoms; likewise, when available, the relative effectiveness of SILCS plus microbicide gel should be made explicit. It is also important that SILCS is truly offered as an additional method, rather than a replacement for existing barrier methods. The influence of gender power dynamics on capacity to benefit from a new method should receive specific attention; including introducing training for counselling on strategies for beneficial disclosure and negotiating condom use, although further research in this area specific to SILCS may be helpful. Young people may also require more intensive counselling if SILCS is to be

available to them at introduction. Finally, larger local acceptability studies may be useful prior to commercial availability of microbicides for use with SILCS, although initial studies show promising results in terms of improved microbicide adherence in comparison with vaginal applicators.

Previous clinical trials – key points

- A study using a small sample of participants has shown SILCS to be highly acceptable to SA women, unaffected by concurrent condom use.
- Previous diaphragm and gel trials in SA have demonstrated high acceptability but low adherence.
- SA women are still frequently unable to negotiate condom use and disclosure of diaphragm use may be problematic.
- High-risk sexual behaviour is often associated with poor product adherence.
- Effective counselling and support will therefore be crucial to ensure effective use in SA.

5.3 Publications: summary and conclusions

This section has highlighted some important considerations in terms of impact of the social and cultural context in SA on health service provision and on introduction of new products. Awareness of specific gaps between policy and reality is helpful in terms of designing strategies for successful population uptake and sustained use of new contraceptive/HIV-prevention methods. Key messages include the importance of early consultation with and on-going support for key stakeholders to provide an enabling environment. SILCS introduction should build on the consensus for service integration, to improve equity in health service provision, by targeting a range of SRH and HIV services during the introduction phase, and by ensuring that SILCS is included in guidelines and training across all aspects of SRH. Finally, training and counselling needs to be carefully designed to enable identification of at-risk groups and minimise risk-compensation behaviours.

6. REGULATORY FRAMEWORK

The regulatory framework relating to new FP and HIV-prevention methods is important to consider in terms of registration of new products for legal availability in both the public and private sector, in-country testing of products for quality assurance, and prescribing by medical and nursing practitioners.

The **Medicines and Related Substances Act of 1965**⁸⁸ is the primary piece of legislation relating to introduction of new FP methods to SA. It sets out regulations for registration of medicines and medical devices to ensure safety, quality and efficacy and for transparency in the pricing of medicines. The MCC is the statutory body that controls these regulations, which apply both to new products and new indications for existing products. All clinical trials undertaken in SA must be registered with the MCC and must be compliant with SA Good Clinical Practice (GCP) requirements. The MCC is also responsible for licensing professionals to dispense and manufacture medicines, and decides whether a drug or device should be available on prescription only or available 'over the counter'. Because of the urgency of tackling the HIV/AIDS epidemic, sponsors may apply to the MCC for fast-track registration of microbicides to receive a decision within nine months.⁸⁹

The South African Bureau of Standards (SABS) is a statutory body that operates in terms of the latest edition of the **Standards Act of 2008**⁹⁰ for the promotion and maintenance of standardisation and quality of commodities and services. SABS develops technical regulations (compulsory specifications), which are based on national standards, and tests products to provide certification of compliance with regulations. While a 'standard' specifies the minimum requirements for key properties that ensure safety and effectiveness of a product, the 'specification' is a statement of the buyer's requirements and covers all attributes of a product that may not be fully specified in a standard (including safety, efficacy, performance, design, packaging and labelling). Testing is often done by SABS, but may be contracted out to universities or other establishments. Relating to the diaphragm, the current relevant standard in SA, based on the international ISO standard, is: *Mechanical contraceptives - Reusable natural and silicone rubber contraceptive diaphragms - Requirements and tests SANS 8009:2007/ISO 8009:2004, approved 23/02/2007.*

In 2008, the **Medicines and Related Substances Amendment Act** was passed, creating the South African Health Products Regulatory Authority (SAHPRA).⁹¹ Once the act is formally declared, SAHPRA will replace the MCC as the formal decision-making body on medicines regulation, adopting a role similar to that of the US Food and Drug Administration (FDA) that will include regulation of medical devices.

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In 2011, **draft regulations proposing a new regulatory system for assessment of medical devices** were issued.⁹² A risk-based classification approach was designed with eight categories of devices; C7 comprises 'medical devices used for contraception or the prevention of the transmission of sexually transmitted diseases'. A notification process will be set-up for devices already on the market; and provision is made for devices 'already registered by a regulatory authority outside of the Republic' in order to undergo

'abbreviated assessment'. The five-year re-licensing system for drugs will also apply to contraceptive devices. Depending on the time frame of SILCS introduction, it is possible that abbreviated assessment under SAHPRA will be required if FDA approval is already obtained. Further, registration as a microbicide delivery system will also be required, since this constitutes a change in indication from contraceptive device to HIV-prevention method.

SA law states that all FP methods (except condoms) should be prescribed by a licensed practitioner. In addition to registered medical doctors, professional nurses with dispensing licenses can prescribe and manage treatment up to schedule 4 drugs. In recent years the human resource crisis has prompted discussions around task-shifting to improve access to certain products, but with no significant change to prescribing legislation.⁹³ In 2001, the South African Pharmacy Council requested a new category of pharmacist prescribers, but this too remains controversial. The eventual type of registration with the FDA and MCC will determine the points of access to SILCS with or without microbicide gel. As in the case of the FC, SILCS is unlikely to require prescription and may therefore be available 'over the counter'. However, because effective microbicides are likely to be ARV-based, they will be registered as schedule 4 or above medications, available therefore only on prescription. Introductory strategies need to consider these possibilities in terms of feasibility of delivery outside the clinic setting, and training of lay counsellors to ensure safe and effective use.

Key informant issues will provide better insight into the steps that will be required by SABS and SAHPRA within the new system. The timing and type of registration awarded to microbicide gels and to SILCS as a contraceptive or MPT method will affect possible service-delivery pathways and introductory strategies.

Regulatory framework – key points

- The MCC regulates registration of all new medications and medical devices in SA, although a new body, SAHPRA, is soon to take over this role
- Technical regulations are developed by SABS – the existing national standard for diaphragms is based on the international ISO standard
- 'Abbreviated assessment' may be applicable to future registration of SILCS
- Microbicides are likely to be registered as schedule 4 drugs, requiring prescription

7. INTRODUCTORY STRATEGIES

The success of SILCS introduction may be measured in terms of uptake, equal access and effective and continued use. Previous programmes introducing new methods of contraception and HIV prevention to SA provide important insights to achieving positive outcomes in the local context. This section examines lessons learned from SA's FC programme and the rollout of MMC.

7.1 The female condom programme

The most recent addition to the contraceptive mix in SA was the FC, via a national programme initiated in June 1998 by the NDoH. In accordance with the national contraception policy, the FC is promoted for dual protection. This is also the only new method for reducing HIV transmission approved and introduced since the start of the epidemic and, being female-controlled, is of particular relevance. After provincial programme introduction meetings, clinic baseline assessments and provider training, distribution began in 30 FP clinics within the public and NGO sectors and two commercial sex-worker sites. Social marketing was conducted by an independent not-for-profit organisation at 590 sites. In the first 18 months, the programme achieved relative success, with FCs being distributed to 10,787 clients and 13 to 15% of users returning for re-supply; 75% of women felt ready to try the FC based on information given by the provider. Dual-protection rates were high, and the majority of clients and providers felt that the FC was suitable for all women and a necessary addition to the method mix. Importantly, over two-thirds of participants said that it would be easier to convince partners to use the female than the male condom, as the responsibility lies with the woman; conversely, partner resistance was the main reason for once ever or never use.⁹⁴

The performance report emphasised some key issues that emerged during implementation: first, identification of provincial coordinators through consultation was critical for integration of the FC into clinic activities. It was noted that 'buy-in' was necessary for all stakeholders to ensure personal commitment; variability in this area may explain distribution differences between sites. Careful planning and setting up of logistics management and M&E systems was necessary to minimise stock-outs, one of the major barriers to integrating FC provision into daily clinic activities.⁹⁴

A cascade approach to provider training helped maximise capacity whereby initial training of trainers ensured broad dissemination of information. Despite resource constraints, regular monitoring meant that the need for further and refresher training was identified and addressed at an early stage. Follow-up with providers and clients at 18 months identified a need for counselling to include both technical and behavioural aspects of FC use, in order to provide clients with strategies to negotiate successful use. Adequate user support in the initial period was associated with a significant reduction in method problems experienced by the user.⁹⁵ In spite of these measures, many providers reported feeling that they lacked the skills to explain and provide solutions for common problems, and it emerged that only one-third of providers had formal training on FC use, due to staff rotation and mobility. Data collection was seen as a burden by some providers, which may contribute to underestimated distribution.

In relation to introducing new methods or skills, the report recommended that: data collection is integrated into existing systems to avoid creating work; on-going training of trainers is provided alongside dissemination of information, education and communication (IEC) materials; potential technical and behavioural problems and solutions are covered in training curricula; continuous commodity supply is ensured; regular support and supervision is provided to clinics especially in the initial stages of introduction; and that research into men's perceptions of female-initiated methods is undertaken.⁹⁴ An independent report has cited SA as one of four international success stories for FC introduction, along with Brazil, Ghana and Zimbabwe.⁹⁶ According to the authors, the main predictor of success was consultation with multiple stakeholders to ensure full integration into existing public SRH structures. Horizontal rollout also helped to minimise stigma that might be attached to the FC as a disease-prevention method.

Following the initial introductory phase, the NDoH used a model of national government leadership together with comprehensive and large-scale provider training for horizontal, clinic-based programming to expand access to the FC. Since condom training is essential for FCs, IEC leaflets and pelvic models for demonstration were made available to all sites, in order to counsel clients and promote continued use. Although the majority of initial FC promotion occurred in FP clinics, NGOs and other non-traditional outlets were subsequently trained to distribute FCs in other sites, including truck stops, universities and workplaces.⁹⁶ In 2003, the FC was added to the list of methods asked about in the contraception section of the SADHS; over half of the male and female respondents had heard of the FC, whilst 'ever use' peaked at 4.8% in the 25 to 29 age group.² The SA FC public-sector programme is now one of the largest in the world; there is at least one FC promotion and distribution site in every sub-district, totalling more than 400 in 2011, with additional sites operating as a result of sub-secondary distribution mechanisms and referrals.⁹⁷ The programme has encountered some challenges, however, with demand lower than supply in some sites due to limited social marketing. This was addressed by devolving the programme to provinces and providing direct support to each provincial Department of Health together with the manufacturers of the FC.

In 2009, a new second-generation condom, the FC2, replaced the original FC1 for general distribution in SA. Using training of trainers and networking of partner organisations and professionals, in less than 18 months over 1,500 providers of all categories had participated in training events that included values, beliefs and attitudes discussion. This resulted in higher demand than ever for the FC, which, despite logistical challenges, has largely been met by closely monitoring availability down to a local level.⁹⁷ Plans to bring social marketing and widespread distribution of FCs in public and private settings into line with male condoms have been set out in the new National Condom Policy.³³ Although regulatory issues and high unit costs remain major obstacles to market expansion,⁹⁸ on-going acceptability research⁹⁹ into less expensive FC options will help facilitate this, thereby increasing choice and improving uptake of the FC.¹⁰⁰ Future local medical device regulation will potentially allow new FC products currently in the pipeline to be made available in SA in a timely fashion.

7.2 Medical male circumcision rollout

MMC was introduced in SA in 2010 as a new HIV-prevention strategy. This followed publication of three major trials in SA, Kenya and Uganda, which demonstrated a 60% reduction in the risk of contracting HIV following the procedure.¹⁰¹⁻¹⁰³ One of these trials was the 2005 ANRS 1265 Trial undertaken in Orange Farm Township, Gauteng Province.⁹⁶ Within the same community, the Bophelo Pele project successfully rolled out free MMC based on WHO/UNAIDS recommendations, alongside HCT, condom distribution, and community education. After one year, 14,011 MMCs had been performed, representing 39% of clinically uncircumcised men over 15 years of age in Orange Farm.¹⁰⁴ A follow-up study showed that, without MMC, HIV incidence among men aged 15 to 34 in the study group would have been 61% higher. Significantly, no effect on sexual behaviour was demonstrated.¹⁰⁵

It is thought that the main factors contributing to successful rollout included high levels of community consultation, via workshops and a community advisory board, which increased support for the project and client willingness to undergo MMC. Multiple communication channels were used to educate residents about MMC as well as broader HIV-prevention strategies and sexual health, thus creating a political and sociocultural environment that enabled increased uptake. Low rates of uptake for HCT and poor follow-up rates were identified as challenges to larger-scale service provision.¹⁰⁴ Following the success at Orange Farm, national rollout began in April 2010. The number of clinics at which MMC was available was expanded within the public sector, and by July 2011 the NDoH reported that over 140,000 men were medically circumcised as a result of the initiative. Implementation guidelines are now available for medical practitioners and, although the national policy for MMC is still in development, there are clear plans to expand the programme.⁴⁴

Despite successes there are still practical and medico-legal concerns in health and political communities regarding widespread implementation of MMC.¹⁰⁶ A commonly cited concern, relating also to SILCS and microbicides, is behavioural risk compensation; some studies have demonstrated more risky sexual behaviours in populations at high risk for behavioural disinhibition following MMC, because of perceived protection against HIV.¹⁰⁷ Other studies, however, show a reduction of this effect, at least in the short-term, by relatively brief and focused HIV risk-reduction counselling.¹⁰⁸ Modelling also suggests that it is possible to establish a synergistic relationship with other interventions in order to have a more dramatic effect on incidence.¹⁰⁹ This may explain lack of effect on sexual behaviour at Orange Farm and also supports the drive towards complete integration of SRH services.

An evaluation of MMC rollout in sub-Saharan Africa to date substantiates many of the above findings and cites the following features as central to successful introduction and expansion of MMC in this particular setting: early and on-going leadership at national, provincial, district and community levels; partnerships and stakeholder engagement with government, NGOs, the private sector, professional associations, religious groups, the media and funders; clear strategies for advocacy and communications; demand creation and community outreach; assurance of minimum standards for service delivery; and sustained technical and financial support.¹¹⁰

7.3 Introductory strategies: summary and conclusion

These two examples show how horizontal approaches to introductory strategies can help maximise organisational and adaptive capacity within the health sector for positive outcomes. This also supports the previously discussed policy drive towards better integration of services. Additional factors consistently associated with success are consultation and communication with a broad range of stakeholders; comprehensive training and support mechanisms; reliable systems for logistics and M&E; and effective social marketing. Learning from the FC, SILCS initial service delivery may be most appropriate within a relatively small number of health facilities that already provide FP services. However, if possible, delivery outlets should cover a range of services related to SRH, such as PHC clinics, ANC clinics and HAART services. Once initial capacity and uptake is established, this network may be expanded to pharmacies and commercial outlets. If microbicide gels become available after successful introduction of SILCS, the strategy used for the transition from FC1 to FC2 may be simulated and adapted to promote SILCS as an MPT.

Introductory Strategies – key points

Successful strategies common to both FC and MMC introduction include:

- Consultation with primary, secondary and tertiary stakeholders.
- Capacity building by training of trainers at introduction and roll-out.
- Effective M&E and logistics systems.
- On-going support to providers and clients.
- Integration into existing frameworks.
- Political leadership.
- Effective social marketing.

8. SUMMARY AND CONCLUSION

There is a clear need for new methods of contraception and HIV prevention in SA, particularly those which are female-initiated and/or are potential MPTs. The policy environment relating to contraception, SRH services, HIV and STI prevention is correspondingly enabling, with few modifications potentially required to facilitate SILCS introduction. Key relevant policymakers are those at SANAC and the NDoH expert panel on contraception (or contraception policy expert working group if the panel is not yet in operation). It may also be helpful to contact provincial Departments of Health to discuss implications for local policy and data collection. In terms of the regulatory framework, key informants will help clarify requirements for testing and registration of new medical devices under new statutory bodies and regulations. During the introductory phase, it is important to remember that reality rarely mirrors policy when it comes to SRH service provision in SA; multiple gaps resulting from capacity issues, provider attitudes and the sociocultural context could potentially impede successful uptake and effective use of new FP/HIV- prevention methods. Conversely, awareness of potential pitfalls may facilitate success. Finally, the fact that SILCS has a range of potential indications with varying effectiveness, when provided with or without contraceptive or microbicide gel, has implications that cannot be fully explored in this review. Both on-going clinical research and key informant input will help determine the feasibility of marketing and providing SILCS under each indication within the SA context, in terms of the impact on regulation, procurement, distribution, training, etc.

The following headings summarise areas for consideration in introductory strategies for SILCS, based on findings from this review. These include both initial recommendations and aspects requiring clarification during the course of the study.

1. *Consult early with a broad range of stakeholders and maintain clear and open lines of communication.*

Stakeholders will be identified by key informants, and can be primary (clients) as well as secondary, including national and provincial policymakers, provincial implementers, managers, HCPs and clinic staff. This will ensure acceptability of the product as well as introductory strategies, management, logistics and M&E.

2. *Integrate new methods into the existing service-delivery framework.*

A horizontal approach will improve eventual availability of SILCS, with or without microbicide gel, at a broad range of health care settings and would be consistent with the general policy direction, thus ensuring sustainability. Introductory strategies could help strengthen links between services and departments and improve general knowledge and awareness relating to contraception and MPTs in a range of service providers. Training curricula and clinical guidelines will need updating accordingly. It is crucial to guarantee a high level of support to a small number of health facilities initially. Yet with increased training of trainers over time, distribution outlets could be expanded to include NGO partners, pharmacies and the private market. The potential to integrate SILCS into policies and programmes beyond the scope of FP may be further explored.

3. *Provide comprehensive training and support at all levels.*

Training of trainers was a highly successful strategy at introduction and post-introduction phases of the FC programme, using a cascade approach to maximise limited human resources. This could be tailored for different cadres of health workers, but should address knowledge, attitudes, practices and behaviours at all levels. Any technical or logistical issue should be addressed quickly to maintain staff satisfaction and continued engagement with the programme. Monitoring should ensure that all frontline staff members are adequately trained and regular refresher courses should be provided if necessary.

4. *Provide comprehensive sexual risk-reduction counselling to all clients and identify those most at risk.*

Evidence shows that risk-compensation behaviour is common with any new HIV-prevention method, often occurring in the most at-risk groups, which has been repeatedly demonstrated in SA. External influences and gender power imbalances may limit the extent to which women themselves can control this, even with female-initiated products. Counselling should include clear messages on the importance of adherence, the relative protective effect of SILCS, and behavioural strategies to help women negotiate effective product use and avoid product substitution. A range of IEC materials should be carefully designed, which all staff should be familiar with.

5. *Include men.*

Including men in research into, and when introducing, new contraceptive or HIV-prevention methods; better communication between partners, and male-partner approval are all proven to be effective in increasing uptake of and adherence with new products. Bearing in mind the importance of female agency in sexual relationships, involving men in FP consultations and counselling during SILCS introduction may be beneficial. Again, key informants will help clarify the feasibility of this.

6. *Social marketing.*

Social marketing is cited as a factor of success in both FC and MMC programmes, and is frequently mentioned in a number of policies. Specific strategies could be explored with key informants.

7. *Maintain reliable logistics for procurement and supply and measure progress.*

Continuous commodity supply appears to be crucial for sustained uptake. Data collection by clinic staff will be necessary to facilitate this, but should be integrated with existing systems, if possible, to avoid creating extra work, which may risk staff disengagement. Methods of ensuring accessibility of contraceptive or microbicide gels for use with SILCS in the long term may need careful consideration.

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