Twenty years of the female condom programme in South Africa: past, present, and future

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The female condom (FC) was introduced in South Africa in 1998, marking a parallel anniversary to this 20th edition of the South African Health Review. The FC programme has grown rapidly from a pilot phase to a national programme that is one of the largest government-funded FC programmes worldwide. Twenty-seven million FCs were distributed in South Africa in 2015/2016, exceeding the country’s National Strategic Plan (NSP) target of 25 million annually by 2016.

The primary objective of this evaluation, conducted in 2014–2016, was to evaluate the national FC programme and identify determinants of FC uptake and continued use among couples. The study aimed to provide an evidence base for the future direction of South Africa’s FC programme, and to identify health system, provider and client barriers and facilitators to FC uptake and continued use.

The evaluation included four components: a national survey in the public and private sectors consisting of interviews with providers and clients and an anonymous client survey; a cohort of new FC acceptors and their male partners; key informant interviews with policy and programme managers; and a unit-cost analysis of total programme costs.

Results indicated that nearly 90% of men and women interviewed had heard of the FC, and approximately 20% had used it. Although FCs were available at almost all sites surveyed, only two-thirds of clients knew that FCs were available at their healthcare facility. Female condom distribution has doubled since 2008, but there are marked differences across provinces. Provider interviews indicated that three-quarters of providers had been trained in FC provision, but most sites lacked information, education and communication (IEC) materials and demonstration models. Findings underscore the need to promote awareness of FC availability in South Africa for HIV, sexually transmitted infection (STI) and pregnancy prevention and also to demonstrate the pivotal role of the provider in delivering FCs to potential users.
Introduction

The female condom (FC) is one of several under-used reproductive health technologies.\textsuperscript{1} It has the potential to expand choice in reproductive health and family-planning programmes, add value to the method mix, and meet the diverse needs of clients.\textsuperscript{2,3} It is key to increasing HIV protection options for women and men, and is the only woman-initiated HIV prevention barrier method. However, despite increased FC distribution globally, distribution remains significantly low compared with male condoms (MCs), accounting for only 0.19\% of global condom procurement.\textsuperscript{1}

South Africa has one of the largest, best-established, government-funded, public-sector male and female condom programmes worldwide. Launched in 1998, the pilot FC programme targeted a small number of sites in each province.\textsuperscript{4,5} In the context of high HIV and unintended pregnancy rates, the programme was scaled up in phases; by 2014 the National Department of Health (NDoH) had made FCs available to all public-sector sites, expanded distribution to non-public sites, and added two new FC products. According to South Africa’s National Strategic Plan (NSP),\textsuperscript{6} 25 million FCs were to be distributed yearly by 2016, a goal that was exceeded by 2 million in 2016.

South Africa is one of many countries globally that are scaling up FC distribution; however, key knowledge gaps in programming remain, including limited data on public-sector programmes; lack of consensus regarding how FC success is operationalised; paucity of research on substitution of FCs for MCs; and limited, inconsistent and sporadic information about programmatic costs. A review of the progress and challenges to the MC and FC programme and condom research conducted in South Africa was published in 2012.\textsuperscript{7}

The primary objective of this study was to evaluate the national FC programme and determinants of uptake, and continued use of FCs among couples. The study aimed to provide an evidence base for the future direction of South Africa’s programme, and identify health system, provider and client barriers and facilitators to FC uptake and continued use. Knowledge gaps explored included variation of FC uptake across sites, gender dynamics of FC use, perspectives of long-term users, consistency of use, service-delivery challenges, a unit-cost analysis of total programme costs, and socio-cultural barriers to FC use. In addition, the availability of new FC products in South Africa provided the potential to assess the impact of parallel programming of more than one FC product. This was the first FC programme globally to undergo a comprehensive national evaluation and as such could help to maximise the effectiveness, efficiency and impact of scaling up FC delivery nationally, regionally and globally.

Evaluation design

The South African National FC Evaluation comprised four complementary, interrelated components, and used a mixed-methods approach.

Component 1 consisted of a telephone survey and review of distribution statistics from the District Health Information Software (DHIS). A sub-sample of sites participated in on-site assessments, client interviews (up to eight per site), provider interviews (two–three per site), and an anonymous client survey. Programmatic costing was conducted at selected sites in one province. Although the focus of the evaluation was on FCs, less detailed data on MCs were also collected in all components of the evaluation.

The national site evaluation sample included public- and non-public-sector sites. The public-sector health facilities sample comprised the existing national sexually transmitted infection (STI) sentinel surveillance sites, namely 30 sites per province (n = 270).\textsuperscript{8} All sites were contacted to participate in the telephonic survey using a structured questionnaire, which was completed by the operational manager or his/her designee. We anticipated that approximately 75–80\% of the 270 public-sector sites would be distributing FCs, and that approximately 50\% of these sites would be sampled for the on-site assessment. The on-site assessment sample comprised of 12–13 sites per province. These were selected randomly according to the following categories:

➢ Location (rural, urban, peri-urban)
➢ Level of care (community health centre, primary health care (PHC) clinic)
➢ Well-established long-term distribution (>5 years) and newer sites (<2 years)
➢ Sites distributing different types of FC products; between 12 and 13 sites were selected per province.

The aim for the non-public-sector site target sample (n = 36) was to include one non-governmental organisation (NGO), one tertiary education institution, one social-marketing outlet, and one private-sector site in each province, randomly selected from a list of FC-distributing sites identified in every province. All sites were additionally asked to participate in the on-site assessment. Providers were selected for interview on the day of on-site assessment in the public and non-public sector. In addition to the operational manager, one to two providers were randomly selected depending on the total staff complement. Clients were purposively selected on the basis of current or previous FC use.

Component 2, represented by a cohort study of 598 females who were new FC acceptors and a sub-sample of their male partners (n = 60) permitted longitudinal assessment of key outcomes related to FC and MC use, HIV-related behaviours, and relationship characteristics. New acceptors of the FC (including those who had ‘ever used’ FCs, but not used them in the last six months) in four facilities in KwaZulu-Natal (KZN) were identified by facility providers and asked if they would be interested in participating in the cohort study. Semi-structured in-person interviews were conducted at baseline, and follow-up interviews were conducted at one, six and 12 months for women and at one and 12 months for men.

Component 3 consisted of key informant (KI) interviews with policymakers and programme managers who identified critical issues, such as overall programme leadership and co-ordination, training, supply and commodity security, advocacy, monitoring, and integration with other programmes. We purposively selected policy and programme managers at provincial and national level to ensure representation of a range of views on the FC.

In Component 4, a unit-cost analysis was conducted at eight sites in order to establish FC programme costs.\textsuperscript{9} a

\textsuperscript{a} Data not presented in this chapter due to space limitations.
Figure 1 shows the number of sites and participants in each component of the South African National FC Evaluation Study.

Figure 1: National FC evaluation study components, 2014–2016

<table>
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<th>COMPONENT 1</th>
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| National Telephone Survey and Review of Distribution Statistics in FC Distribution Sites  
(n=256 public sector, 28 non-public sector) | Cohort of New FC Acceptors  
(n=598 at four sites in KwaZulu-Natal)  
Semi-structured interviews conducted at:  
Baseline (n=500)  
1 month (n=543)  
6 months (n=509)  
12 months (n=549) |
| In-depth Assessment of Sub-Sample of Survey Sites  
(n=114 public sector, 19 non-public sector sites from National Survey) | Male Partners of New FC Acceptors  
(n=60 partners of female participants)  
Semi-structured interviews conducted at:  
Baseline (n=60)  
12 months (n=58) |
| Client Interviews (n=427 across sites)  
Provider Interviews (n=278 across sites) |Anonymous Client Survey (n=4 442) |
| COMPONENT 3                                                                                                                                 |
| Key Informant Interviews with Policy-makers and Programme Managers (n=26) |
| COMPONENT 4                                                                                                                                 |
| Programmatic Costing (n=8 sites from In-depth assessment) |

Study approvals

The study protocol, recruitment materials and instruments were approved by the Human Research Ethics Committee (HREC) at the University of the Witwatersrand. Permission was received from national, provincial and district Departments of Health and from individual sites participating in the evaluation. Written informed consent was obtained from all participants (aside from the anonymous survey). Consents and client interviews were conducted in participants’ language of choice.

Key findings

Data were collected between 2014 and 2016. After verification of the sentinel surveillance sample within each province, we learnt that five sites were no longer functioning; an additional nine elected not to participate. Twenty-eight non-public-sector sites were included. Although an NGO distributing FCs was identified in each province, not all provinces had one of the other three categories that distributed FCs (tertiary education institution, social-marketing outlet, and private-sector site).

Government and donor commitment

The national condom programme has various sources of funding. Key informants reported that at national level the programme is funded primarily by national government, with additional support from international funders such as the US President’s Emergency Plan for AIDS Relief (PEPFAR) and the United States Agency for International Development (USAID). At provincial level, participants reported that the programme is funded through a conditional grant. Non-governmental organisations also received international funding.

Distribution and commodity management

Key informants indicated that condom distribution targets are set at national level, and that these are divided into provincial and district targets. Population-distribution statistics and logistics-management systems are used to determine quantities of condoms required for distribution and storage per district, sub-district and facility.

Review of DHIS FC distribution data (which have only been collected since 2013) showed large increases in distribution over the three-year period (2013/14–2015/16), with many provinces doubling distribution over this time (Figure 2). This increase was also reported in the Ki interviews, with targets exceeded in many areas. Overall, between 2015 and 2016, there was a 28% increase in distribution nationally, which was the largest increase of any contraceptive method available in South Africa in this time period.

By comparison, MC distribution data from the DHIS showed increases in eight of the nine provinces between 2013/14 and 2014/15 (Figure 3). The Western Cape (WC) noted a small decline, also seen in the third year (2015/16), whereas four other provinces (KZN, Mpumalanga [MP], Northern Cape [NC], and North West [NW]) showed no change or small decreases in distribution between 2014/15 and 2015/16.

b A conditional grant is a system of allocation of funds from national level to a decentralised level (in this case provinces), set aside for support and encouragement of projects or specific and clearly defined expenditure.
The telephonic site survey indicated that all public-sector sites had distributed FCs – 53.8% had distributed for more than five years, while 18.8% had commenced distribution within the last two years. Only a small proportion of sites (2.8%) had stock expire in the last year. Fourteen (4.9%) of the 284 sites reported stock-outs due to the following:

➢ depleted FC supply (n = 7);
➢ late ordering of FCs (n = 2);
➢ no demand for FCs and so staff did not re-order (n = 2);
➢ rumours that FCs were not being used for what they were intended, so staff did not re-order (n = 2); and
➢ one site identified itself as a non-designated FC distribution site.

Five of the 14 sites discontinued ordering and supplying FCs to clients, despite NDoH guidelines that FCs should be available at all sites.

Each site was asked to report its distribution figures for the same three-month period (February–April 2014). These data were then confirmed at the site visit and also checked on the DHIS. With 68 (57%) of the 114 public-sector sites participating in the on-site assessment, there was no agreement among the three data sources (telephone survey, site visit and DHIS) in at least one of the three months. Reasons for the discrepancy were mainly unknown or were assumed to be due to missing records. During data collection, some sites reported distribution box units rather than actual FC numbers, and they often did not report distribution if a box had not been emptied. Condom boxes are bulky and some sites did not have storerooms to accommodate condoms. Storage was noted as a challenge by almost half (49%) of the sites.

The most commonly distributed FC was FC2 (99%), followed by Cupid (34%) and Pleasure More (2%). Of the 23 sites experienced in distributing newly introduced FCs, only one site had all three FCs in stock on the day of the site assessment; 17 had two FC products, and five had one product in stock. Sites reporting only one FC product indicated that they had received a new product that replaced the one previously distributed.
Role of the provider in the female condom programme

Condom counselling and demonstration

Two-thirds (65.5%) of the 278 providers who completed the provider interview had been trained in FC counselling and demonstration compared with four-fifths (79.1%) who received MC training (Figure 4).

Figure 4: Provider training in FC/MC counselling and demonstration, and values clarification, National FC Evaluation Study, 2014–2016

In the last year, 66.7% of providers reported that they had never or rarely counselled/given FCs to men. In the last month, 39% of providers discussed FC use in one-on-one interactions with female clients compared with 61% who discussed MC use.

Thirty-seven percent of providers had ever used a FC. Provider technical knowledge on FCs was good; however, attitudes varied; 38% of providers thought FCs were ‘weird’, 28% thought they were inconvenient, and 42% thought they were messy.

Male condom availability was much higher than FC availability at all site distribution points, particularly in areas outside of consultation rooms, such as waiting areas (MC availability 80%, FC availability 62%). This means that FC uptake requires provider promotion and willingness to counsel and offer FCs to clients.

In the early years of the programme, FCs were primarily distributed from consulting rooms to ensure that new users were given counselling on use, and because of concerns about limited stock and that wider distribution would lead to stock-outs. This mode of distribution is now shifting, with FCs being distributed at more accessible points at sites; however, some improvements are still required to mirror MC availability at sites.

Female condom promotion strategies: Availability and use of information, education and communication material

Ninety per cent of providers reported that clients were informed verbally about the availability of FCs and MCs. This may be due to lack of availability of IEC material, which was limited for both MCs and FCs (Figure 5). Although providers talked about FC leaflets and pamphlets, these were the manufacturers’ instructions in the condom boxes.

Experience with new female condoms

Nearly all providers (96.3%) with experience in providing more than one FC thought it was important to increase FC choice. However, two-thirds of providers (66.0%) were concerned that if one type was more popular, they might run out of stock. Twenty-seven per cent worried that having different FCs available may confuse clients.

‘It’s better to have two types of FCs for people to have choice and take the one they like most.

Providers requested more product-specific training and IEC material for both themselves and the community. Key informants reported a shortage of MC and FC training manuals, and although most facilities (78%) had access to MC demonstration models (dildos), few had pelvic models for FC demonstration (22%).
Client perspectives

Client anonymous survey

Of the 4,442 anonymous surveys completed, similar proportions of women (84%) and men (79%) had ever heard of FCs (Figure 6), and overall, 19.3% had ever used a FC; of these, two-thirds (65.5%) had used them for dual protection (pregnancy and STI/HIV prevention). Awareness of FCs has been increasing gradually and is now higher than reported in past national population-based surveys. In 2003, just over half of the women and men interviewed (53% and 56%, respectively) had heard of the FC.10 Five years later, the National Human Sciences Research Council (HSRC) Communication Survey reported that 78% of women and 72% of men had heard of the FC.11

The level of FC ‘ever used’ was found to be considerably lower than the level of awareness, with wide variation in ‘ever used’ across the provinces, ranging from 10.6% in KZN to 28.3% in MP (Figure 6). These data can be compared with data collected in the 2008 National Communication Survey11 which also found that ‘ever used’ FCs was the lowest in KZN at 3.3%. Two of the three best-performing provinces in 2008, Limpopo (LP) (11.4%) and MP (9.8%),12 continued to lead FC ‘ever used’, while the third best-performing province in 2008, namely the NC (12.8%), had not gained as much ground over the same period.

Figure 6 also shows the proportion of clients who reported ever being offered a FC by a provider. The provinces with the lowest ‘ever offered’ score, namely KZN and the Eastern Cape (EC), also showed the lowest levels of ‘ever used’. The data on overall distribution of FCs and MCs (Figures 2 and 3) show that KZN was the second-highest distributor of both condoms. These data may seem at odds with client data indicating that KZN appears to have the lowest reported ‘ever used’ and ‘ever offered’ rates by provider. This may be related to variations in district distribution. Data on MC coverage at district level indicate wide differences in coverage in KZN – uMgungundlovu distributed 153.4 condoms to every male 15 years and older in 2013/14, whereas eThekwini reported distributing 14.6 condoms per male.13 Female condom coverage per adult male or female is not currently reported in the District Health Barometer.

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Figure 7 shows FC ‘ever users’ by age and clearly indicates the disparity among the age groups, with the youngest group, which should be a key target for condom use, showing the lowest levels of ‘ever used’ for both men and women.

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**Figure 6:** ‘Ever heard of’ FC, ‘ever offered’ FC and ‘ever used’ FC, by province, National FC Evaluation Study, 2014-2016

**Figure 7:** Ever used female condoms by age and sex, National FC Evaluation Study, 2014-2016
Although awareness of FCs may be high and FCs are available at sites, as confirmed in the national site assessment, clients need to know that they are available in order to access them. In seven provinces, at least three-quarters of anonymous survey clients were aware that FCs were available at the site where they were interviewed, compared with 60.7% in KZN and 67.9% in Gauteng (GP) (Figure 8). One of the main reasons given for not ever using FCs was that clients did not know where to obtain them. This highlights the importance of developing IEC materials to promote FC awareness, and of healthcare providers routinely discussing and offering FCs to their clients at clinics and other sites where FCs are available. The other main reasons for not using the FC were partner reluctance and fear of trying it.

Client exit interviews

A total of 427 women, all of whom were current or ex-users of FCs, completed an exit interview during the in-depth assessment. Their mean age was 31 years (18–49 years), with only 2.8% under 20 years; 42% were HIV-positive and 20.8% reported having an STI in the last year. The three main reasons cited for initially trying a FC were, “to protect against HIV/STIs” (39.4%), “to protect against pregnancy” (40.9%), and “just wanted to try one” (28%). Almost all clients (96%) felt it was important to increase the choice of FCs. Most women reported acquiring their first FCs directly from providers (76%) and fewer women first obtained them from dispensers (18%). Two-thirds (65.9%) reported that they were offered FCs by providers, while 31.1% had requested FCs. Providers explained how to use FCs to 92% of women, 84.2% were shown a FC, 67.2% were given a hand demonstration, and 67.2% received advice on how to introduce the FC into their relationship. Two-thirds of FC users (67.9%) said they would prefer to use the FC, compared with 21.7% who preferred MCs, and 10.4% who liked both equally. Of the current FC users, 73.4% reported using condoms more often than before they started using FCs, while 24.5% used condoms at about the same frequency as previously.

Cohort of new female condom users

Women enrolled in the cohort (n = 598) had a mean age of 28 years, with 3.7% under 20 years; 50% were unemployed; the majority (80%) had regular visiting partners, and 11% had at least two regular and/or casual partners. Thirty per cent of the women reported that they were HIV-positive and 36% believed that they would ‘probably or definitely become infected’. Almost all the women (91%) had used FCs by the one-month interview; those who had not used them stated that ‘partner refused to use the FC’ and ‘FC was difficult to use’ as their main reasons for non-use.

At their one-month interview, most women (87%) reported that their partners were supportive of using the FC, and at six months this rose to 97%. Eighty per cent of women at one month felt that FC use placed the woman in charge. The level of unprotected sex (no MC or FC use) declined from 43.3% at baseline to 8.4% at 12 months.

At the 12-month interview, over half (53%) of the male partners reported that they were interested in and willing to try FCs when initially introduced to them by their partners and just over half (57%) said that FCs did not change their sexual experience. At their one-month interview, 58% of men said that the FC was ‘better or much better’ than the MC, and at 12 months this rose to 74%.

New developments in male and female condom programmes

The Max male condom

Re-branding has been shown to be an effective demand-creation strategy for the MC. For more than 10 years, the South African government promoted, freely distributed, and branded MCs as ‘Choice’. However, the quality of the condom was questioned, along with its appeal to young people.14 The re-branding of ‘Choice’ as ‘Max’, available in four different scents, was based on market research confirming that potential condom users wanted something new and more desirable. Deputy-President Cyril Ramaphosa and Health Minister Dr Aaron Motsoaledi highlighted the importance of condom use at the 2016 launch of the Max condom as part of the wider launch of the national HIV campaign.15
New female condom products in the condom programme

Between 1999 and 2013, only one FC product design was procured by the South African NDoH. The polyurethane FC1 was available until 2009 when it was replaced by the FC2 which was the same design but made of synthetic latex. At the end of 2013, two other FC products were added to the programme, namely Cupid and Pleasure More. In 2014, following training of some healthcare providers, the new products were gradually introduced into the public and non-public sector (NGOs, private sector and tertiary education) as sites ordered new FC stock.

Conclusions

The FC programme introduced 20 years ago is now well established and embedded in the healthcare system; in particular, systems for MC and FC distribution are complementary, with similar ordering and reporting processes. The proportion of FC distribution relative to MC remains low. The low level of uptake despite availability is reflective of FC uptake worldwide, including in the African region. This low level of use has been attributed to limited availability (often due to higher cost compared with MC), lack of male acceptance, and difficulties in use. The literature stresses that although female-initiated, male involvement is key for successful programming.

FC users less than 20 years of age were poorly represented across all three data-collection methods for female clients in this evaluation, a pattern that has been noted previously in national surveys. Client reasons for not using FCs were similar across all data-collection methodologies. One of the main reasons cited in the anonymous survey was that clients did not know where to get FCs, confirming data that many clients were unaware that the FC was available at the site where they completed the survey. For those who had tried to use a FC, a common reason for non-use across all data-collection methods was that the male partner had refused use, or that the woman had practical difficulties in using the FC.

Data highlight the role of providers as gatekeepers to FC access; thus they hold the key to the improved uptake of the FC in public and non-public sectors. Promotion by providers is variable, with different attitudes about FCs influencing what providers offer and how they counsel.

Evaluation findings provide solid support for further programme expansion in South Africa and more widely, generating crucial information to ensure that programme responses consider the realities of system, provider and client concerns. Years of limited distribution may have conveyed to both providers and clients that FCs are not available at all sites, and that providers do not need to stock and promote the product. With new HIV prevention options on the horizon, there are opportunities to learn and apply lessons learnt from evaluated national FC programmes.

Recommendations and study utilisation

A national dissemination meeting was held in Johannesburg on 27 January 2017 to present key findings of the evaluation to the NDoH and other key stakeholders. Following an overview of study findings, the following specific recommendations were made.

Policy and programmatic considerations

➢ The FC should be re-branded to make it more appealing, as was done for the Max male condom, including different colours and scents, and it should be branded to appeal to both men and women.

➢ Available of more than one product will ensure that female and male clients are offered a choice; sites should be offered all FC types when they order.

➢ Storage of large bulky FC/MC boxes is a reported challenge. Mpumalanga has a good model of warehouse storage with dedicated staff, which reduces stock-outs.

➢ There is a need to standardise acceptable FC distribution points (e.g. waiting areas) and to inform sites of recommendations.

➢ Containers specific to FCs are needed to accommodate the packaging of FCs. Condom containers that health facilities use for MCs are an inappropriate fit for FCs.

➢ All sites should have a FC demonstration model.

➢ Some providers still hold negative views about the FC; this should be addressed in future condom training.

➢ With the introduction of new HIV-prevention technologies such as pre-exposure prophylaxis (PrEP), condom messaging must be consistently linked with sexual and reproductive health and HIV, that is, the three-in-one package must be reinforced (HIV/STI/pregnancy prevention). Condoms should be integrated into new prevention services in a similar way to medical male circumcision.

➢ Free FCs should continue to be provided to private companies and this could be expanded to increase awareness among employed populations who may purchase FCs in the commercial sector in the future.

Health provider issues

➢ Since FCs are available in healthcare facilities, clients and communities should be advised that they can obtain FCs there.

➢ Provider training should focus on ongoing myths and problems related to FC use and include values-clarification exercises that address provider attitudes.

➢ If more than one FC product is available at the site, clients should be given a choice.

➢ The decision about whether or not to stock FCs should not be made by the site.

➢ Female condoms should be available in at least one private area at each site so that clients do not have to obtain them from a provider.
➢ As young people are the least likely group to be using FCs, sites should focus on counselling young people to try FCs.

Demand creation
➢ There should be expanded promotion of FCs among men. Sites that serve male populations should be targeted, and providers should be encouraged to promote FCs to men.
➢ As female condoms are acceptable to HIV-positive women, FC provision should be ensured in HIV clinics and to people living with HIV.
➢ In some provinces, higher-education institutions have not started FC distribution; support is needed to help these institutions to launch FC programming.

Further research
➢ Research priorities should include acceptability studies involving men, youth and under-represented user groups such as men who have sex with men, and sex workers.

Acknowledgements
Support for the national FC evaluation was made possible by the generous support of the American people through PEPFAR and the United States Agency for International Development (USAID) under the terms of the CoAg number AID-OAA-A-13-00069 to MatCH Research Unit (MRU), a unit of the Wits Health Consortium (Pty) Ltd. The contents are the responsibility of authors and do not necessarily reflect the views of USAID or the US government. Additional research support was provided to Dr Joanne Mantell by a center grant from the National Institutes of Mental Health, US (Center Grant NIMH P30 MH43520; Principal Investigator: Robert H. Remien, Ph.D.). We thank the South African Department of Health (national, provincial, district) and participating facilities for support and assistance with project planning and logistics. We also thank all participants for their time and contribution, and the non-public sector sites for their willingness to take part in our evaluation.
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