Feasibility and Effectiveness of Integrating HIV Prevention and Testing into Family Planning Services in North West Province, South Africa
A cluster randomised trial

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AUTHORS DECLARATION

I, Saiqa Mullick, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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ABSTRACT

Background

South Africa has one of the highest HIV prevalence rates in the world and high contraceptive use among women aged 15–49 (65.3%). Family planning (FP) services remain a missed opportunity to integrate services for HIV. Recent reviews highlighted the lack of rigorously conducted studies of the effectiveness of integrated services. A cluster randomised trial (CRT) was conducted to evaluate the effectiveness of a model of integrating HIV into FP services compared with standard practice. The study sought to measure the effect of integrated services (Balanced Counselling Strategy Plus) on HIV testing in the previous year; use of dual protection and quality of HIV and FP care.

Methods

A CRT was conducted in 12 clinics in North West province, South Africa. Structured client-provider observations (CPOs) and client exit interviews (EIs) were conducted pre-intervention and one year later with FP clients aged >=18 years. Primary outcomes were condom use at last sex and testing for HIV in last year. The quality of care scores were constructed to assess HIV and FP quality of care. Analysis of effectiveness used statistical methods for CRTs.

Findings

A total of 1,111 CPOs and 1,111 EIs were completed at baseline and 1,223 CPOs and 1,264 EIs at follow-up. At follow-up 33.2% of women in the intervention arm had tested for HIV in the last year compared with 21.4% in the control arm; RR=1.56 (95%CI: 1.13– 2.15; p=0.01). Condom use at last sex was 43.7% in the intervention arm and 39.4% in the control arm; RR=1.10 (95%CI: 0.85–1.43; p=0.14).

Interpretation

There was strong evidence of higher frequency of HIV testing among FP clients at intervention clinics. However, condom use at last sex was similar across intervention and control arms. All QOC scores were higher in intervention clinics, but there was substantial variation across clinics and these differences were not significant.

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LIST OF ABBREVIATIONS AND ACRONYMS

ANC	Antenatal Care
ARV	Antiretroviral
BCS	Balanced Counselling Strategy
C&T	Counselling and Testing
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
CRT	Cluster Randomised Trial
DOH	Department of Health
DP	Dual Protection
EN	Enrolled Nurse
ENA	Enrolled Nurse Assistants
FGD	Focus Group Discussions
FP	Family Planning
HSRC	Health Sciences Research Council
ICPD	International Conference on Population and Development
IEC	Information, Education, Communication
IPPF	International Planned Parenthood Federation
IUD	Intra Uterine Device
KZN	KwaZulu-Natal
LRT	Likelihood Ratio Test
MCH	Maternal and Child Health
MCH-FP	Maternal and Child Health and Family Planning Programmes
MDG	Millennium Development Goals
MTCT	Mother to Child Transmission
NDOH	National Department of Health
NWP	North West Province
OR	Odds Ratio
PHC	Primary Health Care
PLHIV	People Living with HIV
PMTCT	Prevention of Mother to Child Transmission of HIV
RH	Reproductive Health
RR	Risk Ratio

RTI	Reproductive Tract Infections
SADHS	South African Demographic and Health Survey
SRH	Sexual and Reproductive Health
STI	Sexually Transmitted Infection
UCSF	University of California, San Francisco
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
WHO	World Health Organization

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Chapter 1: INTRODUCTION

South Africa has one of the highest HIV prevalence rates in the world. The annual antenatal sentinel surveillance survey 2010 estimated that 28% of all pregnant women were HIV positive (National Department of Health (NDoH, 2010). A national survey showed that prevalence of HIV infection in the general population has begun to stabilise at roughly 11% (Shisana et al., 2015). However, the survey also reported that HIV prevalence remains disproportionately high amongst young females as compared to males and peaks in the 25-29 year age group with almost 33% testing HIV positive.

The prevalence of contraceptive use among women of reproductive age (15-49) is also high and reported to be 65.3% (SADHS, 2003). Family planning (FP) services are the most frequently used public sector service. The majority of FP clients use hormonal contraception, either pills or injectables (SADHS, 2003) and therefore attend FP facilities every two to three months for new supplies. Data on the prevalence of HIV and sexually transmitted infections (STIs) specifically amongst FP clients are sparse but information from selected studies suggests that STIs are common in this group, that as many as 40% of women attending FP facilities in South Africa have an STI (excluding HIV) (Coetzee D, 1996, Wilkinson D, 1999) and that on any given day a quarter of women in the general population in a rural district of Kwa Zulu Natal province in South Africa are infected with at least one STI (Wilkinson D, 1999).

In response to the HIV epidemic, the National Department of Health (NDOH) in South Africa has rolled out a number of vertical HIV services, but uptake of services has been mixed. New policies such as the HIV & AIDS & STI National Strategic Plan (2012-2017) and the Policy and Guidelines for PMTCT support integration of HIV and Reproductive Health (RH) services as a key component of the NDOH strategy (SADHS, 2003). Nevertheless, despite supportive policies and guidelines, guidance and experience with programme implementation remain a challenge and FP services remain a missed opportunity to integrate information and services for other reproductive health issues.

1.1 Rationale for the research

A systematic review conducted in 2000 reported that past contributions by FP services to the fight against HIV/AIDS had been limited to education on risk reduction, education about STIs, and encouraging the use of condoms. However, although evaluations of these integrated services were able to demonstrate improved client satisfaction and that integrated services did not result in a decline in FP client load, they were not able to show any changes in STI risk behaviour, condom use or STI care coverage (Dehne KL, 2000). Further, this review highlighted that many of the studies showed a lack of documentation, a lack of a clear definition of integration, and a lack of documentation on the type and content of counselling. More recent reviews (Church and Mayhew, 2009, UNAIDS, 2009) confirm that rigorous evaluations of the impact of integrating HIV services into FP have not been conducted. FP services have been very successful over the past decade and there is a great deal of potential for RH services such as FP to contribute to STI/HIV control. *"As these services are directly concerned with outcomes of sexual relationships it is logical to expect them to be at the forefront of efforts to prevent sexual transmission of HIV"* (Askew and Berer, 2003).

With the current availability of cheap, easily administered and rapid diagnostic tests for HIV infection there are missed opportunities for offering HIV prevention counselling as well as counselling and testing (C&T) within the context of FP services, which could potentially increase the opportunity for this sexually active population to better understand how to protect themselves from possible infection and to know their status. In South Africa, care and support and antiretroviral (ARV) treatment for individuals infected with HIV is widely available within the public sector. However, counselling and testing for HIV (C&T) is primarily provided routinely through antenatal care (ANC) settings and vertical services. Even within the ANC setting where C&T is systematically offered to clients for the prevention of mother to child transmission of HIV (PMTCT) uptake is varied. Providing the test primarily in antenatal care means that women may not know their HIV status until they fall pregnant. C&T services have yet to be integrated into other reproductive health services. While providing C&T services within family planning (FP) services may not be effective in every context, in South Africa FP services are well utilised and the Government is seeking opportunities to expand access to and use of C&T services through other well-utilised services. This

integration strategy requires the reorientation of FP services to not only integrate C&T but also to strengthen education and screening on STI risks and information on dual protection. The degree of linkage or integration may affect the quality of existing services and information is also needed to determine whether integrating services leads to increased uptake of FP or C&T.

There is international recognition that the Millenium Development Goals will not be achieved without ensuring universal access to Sexual and Reproductive Health (SRH) services, including HIV prevention, treatment, care and support. However internationally, there is no clear understanding of the effectiveness, optimal circumstances and best practices for strengthening linkages between HIV and SRH services.

A recent review aimed at identifying the linkages that are currently being evaluated, outcomes, effectiveness and research gaps, identified peer-reviewed and rigorous evaluation studies as well as "promising practices" (IPPF/WHO/UNAIDS/UNFPA, 2008). Fifty eight studies were identified of which 35 were peer-reviewed studies and 23 promising practices. Only six of the 58 studies were conducted in FP facilities and aimed to add HIV services. None of these were peer-reviewed studies, none obtained data on a cohort of FP clients and the only behavioural outcome measured was condom use.

The cluster randomised trial reported in this thesis constitutes the second phase of a two-phased study and will provide important information on the effectiveness of integrating HIV prevention and C&T into FP services in terms of its impact on both quality of care as well as condom use, dual protection uptake and HIV testing. The first phase of this study assessed the feasibility, acceptability and effects of two alternative models of integration of HIV prevention and testing into FP services and is one of the promising practices reported in the review cited above. Based on the findings of the Phase 1 study, the second phase intervention was developed and a cluster randomised trial conducted for effectiveness in improving several service delivery and behavioural outcomes. The second phase of this study is the main subject of this thesis, the aims and objectives of which are described below.

1.2 Study aims and objectives

1.2.1 General aim

The general aim of the study is to evaluate the effectiveness of an acceptable and feasible model of integrating HIV into FP services compared with standard practice.

1.2.2 Specific aims

1) To compare the model of integrated services with the standard FP service in terms of the quality of both family planning services and HIV related services.
2) To evaluate the effectiveness of this model with respect to the following primary outcomes:
    - HIV testing in the previous year
    - Condom use at last sex

    And the following secondary outcomes:
    - Quality of integrated services measured through a series of quality of care scores

1.3 Outline of work to be presented and role of author

The thesis will report selected Phase 1 study findings but will focus primarily on the results of the second phase of the study and will be presented as follows. Chapter 2 will present a literature review on past and current experiences with the integration of FP and STI/HIV services including lessons learnt and current international perspectives. Chapter 3 will describe the key findings of the Phase 1 study and their influence on the intervention tested in Phase 2. Data from facilities and describing the target population will be used to present a rationale for the relevance and feasibility of the intervention tested. Chapter 4 will describe the methods used for the Phase 2 trial in detail, including the study setting, the policy and programmatic context and the study objectives, design and data collection methods. Chapter 5 will discuss the baseline results and Chapter 6 will discuss the key effectiveness results of the trial in improving the quality of services and impact on client behavioural outcomes at follow up respectively. The final chapter of the thesis, Chapter 7, will discuss and interpret results and discuss the implications of these findings in terms of broader programme and service delivery relevance as well as identify future research issues.

This study was supported financially by the United States Agency for International Development (USAID) through its South African Mission with funding from the President's Emergency Plan for AIDS Relief (PEPFAR). The author of this thesis was an Associate with the Population Council at the time this concept was initiated and a Senior Associate and Country Director for the South Africa office at the time of submission of the thesis. The author was responsible for preparing the original concept note to obtain initial donor support for the study and to obtain approval to proceed to the full proposal development stage. Following donor approval, she worked with two senior colleagues within the Reproductive Health Programme at the Population Council to define the study questions and review literature which identified the need for a rigorous study design to evaluate effectiveness. At this point she obtained guidance from her PhD supervisor in deciding on a potential cluster randomised study design. It was decided to conduct the study in two phases - a smaller Phase 1 study comparing feasibility and acceptability of two interventions against standard of care and then a Phase 2 study testing the best model against standard of care in a cluster randomised trial. She led the writing of the full study proposal, and solicited and incorporated inputs from senior colleagues at the Population Council and USAID, South Africa. She went on to lead the development of the study data collection instruments with regular inputs from colleagues and experts and led the writing of the study protocol and its submission to the local and Population Council ethical review committees in her role as Principal Investigator for the study. As this study was funded through PEPFAR, the author provided regular updates to the USAID South Africa mission technical staff through face to face meetings and though the routine partner reporting system. At the outset of the study the approximate level of funding available from USAID for the project was indicated and this was taken into consideration when developing the study protocol for the evaluation.

The author was responsible for developing the study budget, planning the staffing requirements for the study, developing job descriptions and hiring of the Study Coordinator and other members of the study team. She provided oversight of all administrative, human resource, financial and technical aspects of the study including direct supervision of the Study Coordinator. The Study Coordinator was responsible for ensuring day-to-day implementation of study activities, hiring of field workers, managing field work schedules, oversight of data management and field-level trouble

shooting. Administrative support (communications, payroll, logistics and financial reporting) for the study was provided by the Population Council (South Africa) Office Manager and a Programme Administrative Assistant. The author was responsible for obtaining buy-in and inputs from relevant Department of Health programme managers in order to keep them updated on study progress and managed consultation with stakeholders at national, provincial and district level with the assistance of the Study Coordinator. National Department of Health officials provided input on potential study sites, facilitated introductions to the provincial managers responsible for the provision of health services in North West Province and participated in the buy-in meetings with clinic staff to introduce the project. Department of Health officials also provided inputs to guide the adaptation of the intervention materials. The author worked with the study team to lead the development of the training materials and adaptation of job aides and participated in all training sessions for the clinic staff. Study monitoring visits and supervision of the data collectors were carried out by the Study Coordinator with regular feedback and supervision from the author.

Data management was supervised by the Study Coordinator including field quality checks, and oversight of data entry. The author took the lead on all data analyses presented in the thesis. Support and guidance on the statistical analyses and write up of the methodology and results and interpretation were provided by Dr Katherine Fielding and Prof. Richard Hayes, both of the London School of Hygiene and Tropical Medicine.

Chapter 2: Literature Review

This chapter will be presented in six sections reviewing relevant past and current literature and describing the South African context within which the study described in the thesis was conducted. The first section will provide an introduction and rationale for integration of HIV and FP services. The second section describes historical events and the resulting changes in the donor funding landscape. The third section will discuss the evolution of a number of terms to describe integrated service delivery models. The fourth section will discuss the evaluation methods and tools for integrated service delivery models. The fifth section will present the findings of a systematic review of literature specifically on experiences with facility level integration of HIV services into FP services since 2002. The chapter will conclude with a section on the South African context highlighting the rationale for integrating HIV into FP services specifically in the South African setting and describing how testing and FP services are currently delivered through the public sector services.

2.1 Introduction and rationale for integrating HIV and FP services

The fields of family planning (FP) and HIV intersect in a number of crucial ways. Many women are at risk of both unwanted pregnancy and HIV infection. However, for many years rather than being integrated, services for FP and HIV have remained largely vertically implemented in practice. HIV services provide an opportunity to reach women and men at risk of and living with HIV with FP information and services. And conversely, FP services, particularly in generalised epidemics, provide an opportunity to increase access to a range of HIV services (Wilcher et al., 2009).

Family planning (FP) is one aspect of RH where linkages with HIV programmes are especially important. Access to voluntary contraception, including natural methods, is consistent with the right of all women, regardless of HIV status, "to decide freely and responsibly on the number and spacing of their children and to have access to the information, education and means to enable them to exercise these rights (Teachnor, 1987, UNAIDS, 2008)". FP can improve the health of women by delaying first births, lengthening birth intervals, and reducing high-risk and unintended pregnancies that may lead to abortion.

Integration of services also needs to be thought about in terms of its directionality. For example, for women with HIV who do not wish to become pregnant, FP is a proven cost-effective strategy and one of the four cornerstones of a comprehensive approach to preventing mother-to-child transmission (MTCT) of HIV and, therefore reducing the number of children needing HIV treatment, care and support (Reynolds H, 2006, Reynolds HW, 2008, Sweat MD, 2004). Conversely, FP services, particularly in generalised HIV epidemics provide an opportunity to increase access to HIV services. Contraception, in the form of correct and consistent condom use, can also prevent the sexual transmission of HIV and other infections. Integrating FP and HIV services has the potential to draw on the strengths and resources of both HIV and FP programmes in order to increase access to services, improve health outcomes for the mother and infant, and contribute to HIV prevention, care, and treatment goals. There are a range of strategies for program planners to consider implementing in order to enhance the linkages between FP and HIV policies, programmes, and services. However, it is worth acknowledging that integrating FP and HIV services may not be appropriate in every circumstance.

Family planning use is low in many parts of Africa, and in some countries where the HIV burden is greatest. High rates of HIV can often coexist with high unmet need for contraception. Unmet need for family planning is defined as the percentage of married women who are sexually active and do not want to have a child or another child in the next two years, but are not using any method of contraception (Sedgh et al., 2007, UNAIDS, 2008).

A review by Askew and Berer in 2003 assessed contributions made by sexual and reproductive health services to HIV/AIDS prevention and treatment, mainly by services for family planning, sexually transmitted infections and antenatal and delivery care. The review highlighted that sexual and reproductive health programmes had the potential to make an important contribution to HIV prevention and treatment, and that STI control is important both for sexual and reproductive health and HIV/AIDS control. It further concluded that more integrated programmes of sexual and reproductive health care and STI/HIV/AIDS control should be developed which jointly offer certain services, and create well-functioning referral links to optimise the outreach and impact of what were essentially vertical programmes (Askew and Berer, 2003).

2.2 History and Donor Landscape

At the 1994 International Conference on Population and Development (ICPD), 180 governments committed themselves to providing a comprehensive set of reproductive health services for women, men and adolescents. They also agreed that reproductive health should be an integral part of primary health care and available to all. The programme of action recommended that six areas of reproductive health including FP counselling, information and services as well as treatment for reproductive tract infections, and sexually transmitted infections be provided in a holistic manner. Many countries tried to integrate services such as FP, sexually transmitted infections (STI), maternal and child health (MCH) in response to the ICPD call but were faced with many challenges in implementation (Askew and Maggwa, 2002a, Lush, 2002a). Against a backdrop of rising prevalence of STIs and HIV and calls for effective service integration and policies supporting integration, this was seen as a way to address multiple needs of FP clients and to address the missed opportunities resulting from "vertical" or stand-alone FP programmes. However, progress was poor and there were challenges in expanding service focus (Lush, 2002b, Caldwell and Caldwell, 2002, Foreit et al., 2002b, Askew and Maggwa, 2002b).

Although there were attempts to integrate maternal and child health and family planning programmes (MCH-FP) as early as the mid 1970's it was not until the mid-1980's with the start of the HIV epidemic and concurrent rise in STIs that it was recommended that HIV/STI prevention activities be integrated into MCH-FP services (Berer, 2003). Strategies to achieve integration of HIV/STI prevention were met with mixed success.

The high prevalence of sexually transmitted infections (STIs) and their role in HIV transmission made integrating STI prevention and management into existing family planning and antenatal care programmes a goal in most resource-poor countries, especially in Sub-Saharan Africa. However, little was known about how integrated services could best be configured, and what impact they have on prevention of infection and unwanted pregnancy (Askew and Maggwa, 2002b).

Several years after the ICPD declaration, the World Health Organization (WHO) conducted a review to document experiences with integration of STI management into FP services to clarify the public health benefit of integration. This review examined published and unpublished reports to draw empirical evidence from programmes worldwide (Dehne KL, 2000). The report concluded that studies had been conducted in a number of developing countries in Africa, Asia and Latin America and a number of programmes had attempted integration of STI into FP services with an emphasis on "prevention" of STIs. Integration efforts had generally improved the quality of services, provider attitudes and communication skills of providers. Evidence regarding the further extension of integration to include testing for STIs was inconclusive and could not be recommended due to the lack of cheap and rapid tests for STIs. This review was the first comprehensive review of experiences with STI and FP service integration. Dehne highlighted several problematic issues including a lack of documentation describing the integration models tested, a lack of clear definitions of integration and a lack of documentation on the type and content of counselling. The most common model of integration was STI/HIV prevention specifically incorporating service elements such as information, education, communication and male condom promotion. Early models of integration involved training providers who were used to providing one type of service to provide additional services or information to clients. The review did not discuss the impact of implementing these integrated services on health care providers as the concept of "task shifting" or other models of operationalising integrated services for the client had not been popularised at the time. However, the review reported a positive impact on client satisfaction, no evidence in decline of number of clients attending FP services but no evidence of change in STI risk behaviour, condom use or improvements in coverage for STI services. Cost effectiveness of integration approaches was also found to be context specific and most initiatives did not succeed in scaling up access (Dehne KL, 2000).

Mati reported in 1996 that the Integration of sexually transmitted disease (STD) and HIV/AIDS control efforts into family planning programmes in sub-Saharan Africa offered the potential to reach women of childbearing age when the risk of exposure to STDs and HIV is greatest particularly at the time when the epidemics in sub-Saharan Africa were beginning to become more generalised. A key component of the integration strategy was the need to promote the concept of "dual protection" to

provide protection against both STDs and pregnancy. Integration of these services also would permit maximisation of the limited resources available in developing countries. An obvious disadvantage of this strategy was that these services would not reach men directly, necessitating family planning program reorientation to permit more interaction with men (Mati, 1996).

A literature review conducted in 2002 (Askew and Maggwa, 2002a) examined what was then current knowledge about integration and aimed to identify priority areas to be addressed through research. At the time the feasibility and effectiveness of strategies that focused on the addition of either STI prevention services or detection and treatment activities into maternal health services was uncertain. The authors pointed to an urgent need for research in three areas. The first was the development and testing of strategies that, instead of adding STI-related activities to existing family planning and antenatal care programmes, sought to reorient the goals of routine consultations toward protection against the dual risks of unwanted pregnancy and infection and involvement of clients in deciding the outcome of the consultation. Second, they proposed that strategies should be developed and tested to reach male partners and facilitate access by adolescents to sexual and reproductive health services. Finally, they concluded that prospective, preferably randomised studies needed to be carried out to test and compare the impact of alternative integration strategies on population-level indicators of behavior and health. The authors further stressed the need for rigorous testing of strategies for integration of services to ensure that they are both feasible and effective before they are implemented.

Several years after these reviews the landscape had changed, and HIV prevalence had already begun to rise explosively in many parts of the world particularly in sub-Saharan Africa. In response, donors and governments rolled out vertical HIV related services (C&T, PMTCT, ART, Care & Support). Large investments from bilateral donors into HIV related services coincided with a decline or negligible increase in resources for FP and strengthened parallel programming (Pai and Klein, 2009). With these changes in donor priorities came a new opportunity for integrated services aimed at using the well-established maternal health service delivery platforms to improve access to and uptake of HIV services. However, large differentials in funding

for HIV and FP programmes resulted in the focus for service providers being shifted to HIV.

For example, in Kenya, where U.S. HIV/AIDS funding increased from $5 million in 1998 to an expected $500 million in 2008, making it the second-largest PEPFAR budget on the continent. Over the same time period, however, family planning and population funding had seen only minimal increases of about 3 percent. This was set against a sobering background. For many years, Kenya was rightly seen as a reproductive health and family planning success story, linked in part to the work of the U.S. Agency for International Development (USAID). But the 2003 Kenyan Demographic and Health Survey (DHS) was a wake-up call; it showed that total fertility rates and under-five mortality rates had increased between 1998 and 2003. This vast increase in HIV funding was a great opportunity to strengthen services, but it also conferred a responsibility to use the resources as creatively as possible ensuring that other services could also benefit rather than be compromised (Fleischman, 2008).

Despite the funding setbacks for FP programmes relative to the increased support for HIV programmes, evidence began to emerge highlighting contraception as an effective PMTCT strategy (Sweat et al., 2004, Stover et al., 2003, Reynolds et al., 2006). The contributions that contraception has made to reducing mother-to-child transmission have subsequently been well documented (Baek and Rutenberg, 2005, Mahendra et al., 2007, Quiterio et al., 2008, Rutenberg and Baek, 2005, Vartapetova and Karpushkina, Hladik et al., 2009) and recommended by WHO as a key, albeit neglected, strategy for the prevention of HIV infection in infants (WHO, 2003).

As the initial evidence on the links between PMTCT and FP emerged, major international organisations began to issue statements calling for stronger links between reproductive health and HIV and AIDS. In 2004 the “Glion Call to Action on Family Planning and HIV/AIDS in Women and Children” (World Health Organization, 2004) and “The New York Call to Commitment: Linking HIV/AIDS and Sexual and Reproductive Health” reinforced the ICPD resolutions and acknowledged that these links were important to meet the Millennium Development Goals (MDGs) (WHO. and UNFPA., 2004, UNFPA/UNAIDS/FCI, 2004). Four other international statements

followed (UNAIDS/WHO, 2005, UNGAS, 2001, WHO, 2007, African Union Commission, 2006).

In sub-Saharan Africa a wide range of approaches were used by FP associations in response to the HIV/AIDS epidemic including participation in developing national policies and plans for HIV/AIDS and sexually transmitted diseases (STDs); promotion of HIV/AIDS and STD prevention; condom distribution through alternative service delivery approaches; integration of HIV/AIDS- and STD-related services into family planning and sexual/reproductive health services; linkages with other nongovernmental organisations and key institutions; male involvement and participation in family planning integration of HIV/AIDS and STD prevention into adolescent health services; home care services for HIV carriers and AIDS patients; and promoting sexual health through community participation (Barry, 1998). In general, the involvement of men in sexual and reproductive health services was limited to small scale projects and was not implemented successfully at scale.

2.2.1 Definition and Terms

Integration in the health sector can be understood as both a process (the action of integrat*ing*) as well as an outcome in itself (integrate*d* services) (Church, 2011). Service integration has varying definitions and interpretations, and involves actions at both policy and service-delivery levels (Druce and Nolan, 2007). Integration of health services implies the coordination or blending of two or more services partially or fully into one unified service ("*horizontal*") previously provided separately or "*vertically*" through specialised or stand-alone programmes. These integrated services are aimed at strengthening access to relevant services as well as the reduction of missed opportunities. Integration also implies organisational changes to service provision (Briggs and Garner, 2006). Integration of services is considered most effective when the target groups for the separate services are the same. The decision about whether or not to offer services as part of an integrated package and to whom must be based on epidemiological data (Foreit et al., 2002a) and cannot be achieved without consideration of the changes, realignment of priorities, programmatic responsibilities, budgets and other resources. These factors need to be considered not only at the policy and programmatic level but also at all other levels of health service delivery.

Vertical programmes allow for central technical supervision, dedicated resources and direct supervision to assure delivery of services. However, vertical programmes have disadvantages that can cause inefficiencies and fragmentation resulting in poor communication and duplication of training, supervision, supply and reporting systems (Dudley and Garner, 2011). There has been a long-standing debate on the advantages and disadvantages of vertical versus horizontal service delivery with proponents of integration arguing that integration is important to improve health service efficiency and quality of care (Dudley and Garner, 2011). Since integration models need to be considered in light of epidemiologic and policy and service delivery contexts, a wide range of potential strategies and models can potentially be used in different contexts. It therefore follows that desired outcomes of integrated programmes might also be varied and may be measured at various levels including policy, health service or client level. These may be as widely ranging from assessing uptake of specific services by selected populations, to health outcomes, stigma, efficiencies and cost-effectiveness.

The large donor investment in funding HIV programmes and relative paucity of funding for SRH and FP programmes catalysed the need to explore alternative models of integration that would still address comprehensive needs of clients as well as overcome the systemic health systems and implementation challenges documented in the 1990s. This influenced policy makers to advocate a number of broader alternative and overlapping strategies including "*linkages*" between the fields of SRH and HIV (UNFPA/UNAIDS/FCI, 2004, Druce et al., 2006, WHO, 2008b). This approach implied joint programming, integration and cross-referrals, minimising missed opportunities as well as "*convergence*" defined as "*a very wide range of activities or processes, which are undertaken with an objective to provide a complete package to enable people to access services for HIV and Sexual and reproductive health (SRH) which overlap. It entails mutual referrals and communication activities between these two services, enabling communication on HIV issues and relevant referrals within SRH settings and vice-versa*" (Saha et al., 2007) in addition to the traditional approach to integration (Fleischman, 2006, Farrell, 2007, WHO, 2006). This also allowed flexibility and recognition that vertical and horizontal approaches may be complementary rather than competitive in a continuum of care within a complex health care delivery environment requiring planning, coordination and management (Unger et al., 2003, Kerber, 2007, WHO, 2005). A policy brief from WHO and other multilateral donors

advocated linkages in sexual and reproductive health (UNAIDS, 2009, WHO, 2008a) and concluded that linkages lead to a reduction in HIV-related stigma and a better understanding and protection of human rights. A more recent review highlights that although existing evidence supports linkages, there is still a need for rigorous evaluation of SRH and HIV linkages (Kennedy et al., 2010). As these integrated and linked models can be implemented in a diverse manner depending on the context evaluation of outcomes may be complex. Perhaps because of this there remains a lack of consensus on how to define integration of health services in general and specifically for SRH and HIV services (Atun et al., 2010).

2.3 Evaluation methods and tools

Health care, even at the first contact level is complicated, outputs diverse, dependent on specific health needs and on the inputs of different groups of providers (Dudley and Garner, 2011). Integration aims to improve services in terms of efficiency and access to health services, improved satisfaction with care and better health status (Dudley and Garner, 2011). However, the broad range of desired results introduces complexity in how to evaluate integrated programmes in the absence of a set of agreed upon indicators. Further, given the multiple types of linkages possible each integrated model could potentially result in a wide range of anticipated outcomes. Studies report on a wide range of outcomes in a number of health care settings including access, uptake of services, knowledge and behavioural outcomes such as condom use (WHO, 2008b). However, cost outcomes, health outcomes and impact of these integrated models on stigma as well as health systems outcomes have been insufficiently reported. Further, a number of interventions were inadequately studied, including integrated models targeting men, adolescents, interventions addressing gender-based violence prevention and management and comprehensive services for people living with HIV (WHO, 2008b).

Desired outcomes of integrated service delivery can vary widely and can include programme outputs such as range of services and quality of services delivered to outcomes such as improved uptake of HIV testing and condom use, efficiencies, cost-effectiveness and stigma. Studies reviewed (see Table 2.1) showed that a wide range of both qualitative and quantitative methodologies used to evaluate integrated service

delivery ranging from the use of routine data and process evaluation, check lists and inventories, interviews with clients and providers, costs and other program data particularly on service uptake.

In the absence of a standard set of indicators for integrated services and with sceptics raising concerns about overburdening first line health care providers with additional tasks it is important to demonstrate that integration does not compromise the quality of care for the services within which new or additional services are integrated. Ideally, integrated services should be synergistic, resulting in gains for both (or several) services which are provided in an integrated manner.

2.3.1 Quality of Care

While most people feel that improving quality of services is important, health specialists do not always agree about which components should be included in the definition of quality. Quality of care is particularly relevant to integration of services as the addition of new services may lead to increased work responsibilities for health care providers who may be overstretched and working in resource constrained settings. These increased responsibilities could, in turn, compromise quality of care for both new and existing services. Historically, quality has been defined at a clinical level and involves offering technically competent, effective and safe care which results in client well-being. However, quality of care itself is multi-dimensional and can be defined in a number of ways.

The Bruce-Jain framework, developed in 1990, is often considered the central paradigm for quality in international family planning. Judith Bruce and Anrudh Jain, researchers for the Population Council, have defined quality as “the way individuals and clients are treated by the system providing services” (Bruce, 1990, Jain, 1989). The framework identifies a number of elements, which apply mainly to clinical services, relevant to improving the quality of care in family planning programmes including choice of contraceptive methods, information given to clients, provider skills, client provider relationship and the appropriate constellation of services. Since the development of the Bruce-Jain framework, health care specialists have suggested several changes to broaden or modify the definition of quality of care, including extending the framework to other aspects of reproductive health services, such as

prevention and treatment of sexually transmitted infections (STIs); provision of maternal health services, including post-abortion care; and screening, counselling, and referral services for victims of violence (Mora and Villarreal, 1993); adding formal standards for quality of care, such as treatment protocols and clinical practice guidelines developed by ministries of health, professional organisations, or the facility itself (Brown, 2000). These modifications supplement the basic Bruce-Jain framework, placing the client at the centre of the concept of quality of care, while also emphasising the importance of technical standards and increasing access to information.

A range of both qualitative and quantitative methods has been used to evaluate aspects of quality of care for FP services. Quantitative tools include the Service Availability Module (SAM) a tool that was added to DHS surveys to assess population access and barriers to reproductive health services. The Situation Analysis (SA), developed by the Population Council in 1989, created widespread awareness about the importance of facility-based surveys in evaluating the availability, functioning, and quality of family planning and reproductive health. Situational Analysis studies have since been conducted in nearly 40 countries. The Quick Investigation of Quality (QIQ) was developed in 1999 by the MEASURE *Evaluation* project, in collaboration using a list of 25 indicators to monitor quality of care in clinic-based family planning programmes. MAQ considers indicators, which have been culled from over 100 possible choices as the most important to achieving quality of care outcomes (see Box 1). The QIQ survey was developed to meet the needs of all stakeholders while remaining low-cost and easy to use. Data are measured using a variety of tools, including interviews with providers, observations of client-provider interactions (CPI), exit interviews with clients, and facility audits. QIQ recommends using all three of these instruments to obtain the most complete picture of a group of health facilities. These and other tools used in measuring quality from both the client's and provider's perspectives are listed in Box 1.

Box 1. Methodologies to assess quality of care

Improving Provider Knowledge and Skills
_ Pre- and post-tests; follow-up "post-post-tests"
_ Provider observations
_ Provider surveys
_ "Mystery clients"
_ Reviews of records

Increasing Client Satisfaction
_ Client exit interviews
_ Household interviews
_ Focus group discussions
_ Service statistics

Improving Facilities' Capability or Readiness to Provide Quality Services
_ Facility audits or assessments
_ Provider surveys/focus group discussions
_ Mystery clients
_ Reviews of records
_ Client flow analyses

Understanding Why Clients Do Not Use Services
_ Focus group discussions with potential users or dropouts
_ Household interviews with potential users or dropouts

SOURCE: Family Planning Service Expansion and Technical Support/John Snow,Inc., *Mainstreaming Quality Improvement in Family Planning and Reproductive Health Services Delivery* (2000).

Qualitative approaches and tools such as Continuous Quality Improvement (CQI) a management technique encouraging staff members from all levels to collaborate, Client-Oriented Provider-Efficient services (COPE), and Performance Improvement (PI), include data collection as well as quality improvement components and have also been used widely (EngenderHealth, 2005, MSH, 1993).

The study reported in this thesis used a composite quality of care score extracted from structured client provider observations (Appendix 3). The creation of these scores and rationale are presented in chapter 4.

Similarly, Darney et al, utilised a five-point score outcome of quality of care based on technical and interpersonal criteria extracted from client interviews regarding the FP visit. The responses were grouped into technical and interpersonal. Technical questions related to information provided on the method, side effects and when to return in the case of side effects and interpersonal related to provision of adequate time to provide information and to address doubts (Darney et al., 2016)

Liambila et al 2009, used a similar methodology and measured quality of care using a composite index that consists of 26 indicators. The data were collected using a client-

provider observation checklist administered by a trained nurse and used to observe the family planning client–provider interactions. The checklist was completed based on the information and services during the consultation (Liambila et al., 2009).

The CDC define a broader range of parameters for defining quality of care for FP including accessibility, client-centeredness, effectiveness, equity, structure of health systems and timeliness (Gavin et al., 2014)

At the programmatic level (Weinberger and Ross, 2015) developed a survey administered in 86 developing countries to measure levels and types of effort for a range of reproductive health indicators termed the NCIFP (National Composite Index for Family Planning). The survey also utilised a score for the NCIFP, which is the average of the 35 individual scores for each country. These were organised under the five dimensions of Strategy, Data, Quality, Equity, and Accountability.

A recent review of methodologies and indicators to measure quality of FP services conducted by the Population Council (Population Council, 2016) concluded that there is great diversity in how quality is defined and which elements of quality are considered most important. The review highlighted the lack of a set of agreed indicators and variable definitions. Indices were reported as being used frequently but this was seen to create challenges for interventions geared at quality improvement.

The authors of the report state that few countries collect facility data, and even fewer observe clients' interactions with their health care providers to verify data from exit and provider interviews. The simulated client method could provide additional helpful information but is not frequently used, nor has a standardised tool been developed. Further discussion within the research community must ensure appropriate, feasible, and efficient strategies for measuring quality, to reduce quality-related barriers to optimal FP use.

2.4 Review of current evidence

2.4.1 Evidence from reviews of integrated services between Sexual and Reproductive Health (SRH) and HIV services

A review that specifically addressed the breadth of linkages between sexual and reproductive health services and HIV was published in 2008 (IPPF/WHO/UNAIDS/UNFPA, 2008). The review aimed to gain a clearer understanding of the effectiveness, optimal circumstances, and best practices of strengthening SRH and HIV integration. The review identified which linkages are being evaluated, the outcomes and effect, current gaps and recommendations for policies and programmes.

The review included integrated models in a range of SRH services, including FP, maternal and child health, gender-based violence, STI prevention and management as well as other SRH services. Both peer-reviewed publications as well as promising practices were reviewed. Peer-reviewed studies included articles published between 1990 and 2007, had a rigorous evaluation design (pre-post or control group) and were included if they had been conducted in any setting. Promising practices defined as those reported in the grey literature (non-peer reviewed literature) between 1990 and 2007 and conducted in resource limited settings only were included. A large number of citations were found through database and online searches (50,797) of which the majority did not meet the inclusion criteria (50,570). Two hundred and twenty seven citations were screened out of which a further 169 were excluded as they were studies evaluating linkages between HIV prevention, education and condoms only with SRH services were excluded (Foss et al.). Fifty eight studies were included in the analysis, 35 being peer-reviewed and 23 defined as “promising practices” defined as studies from “grey” literature and reporting some evaluation results. Of the studies assessing linkages between FP and HIV services, there were no peer reviewed studies identified. However, six promising practices were identified, of which four were conducted in Africa. Findings showed that integration of HIV services into FP services was feasible and improved outcomes. Integration was not found to increase waiting times or decrease quality of FP services. Only one study presented basic cost information on the cost per client to provide ARV drugs. None of these studies assessed health outcomes. The only behavioural outcome reported was condom use. None of the

studies was designed to compare integrated services to the same services offered separately, no studies measured stigma.

2.4.2 Evidence from reviews with a focus on integration of FP and HIV services

In 2009 Spaulding et al (Spaulding et al., 2009) published a systematic review of the literature to examine the effectiveness, optimal circumstances, and best practices for strengthening linkages specifically between FP and HIV interventions. Both peer reviewed articles and unpublished programme reports were included. Peer reviewed studies were included if they were published in a peer reviewed journal between 1 January 1990 and 31st December 2007, presented post intervention evaluation data of an FP-HIV linkage intervention and utilised a pre-post or multi-arm comparison of individuals receiving an intervention versus those who did not to assess quantitative outcomes of interest (biological, behavioural or process). Promising practices were defined as published or presented in some form (peer reviewed or otherwise) during the same time period, presented evaluation data either quantitative or qualitative and presented lessons learnt from a programme or implemented in a low income or middle income country.

Sixteen studies met the criteria for inclusion; 10 peer reviewed and 6 promising practices. Eight studies involved adding HIV services to FP with 7 studies adding FP to HIV services. One study reported simultaneous implementation. Several FP/HIV integration models were described:

- Integrating C&T or adding C&T as part of a package of new STI services into FP services
- Integrating C&T and provision of ARV drugs into FP services
- Integration of C&T into FP services comparing direct provision of C&T services versus referral for testing.

The authors found that study design was varied with the majority of studies being serial cross sectional and overall scientific rigour was low. Of the 16 studies only 3 studies used a randomised controlled study design and all three trials were designed to assess integration of FP services into HIV services. None of the eight studies involving the addition of HIV services to FP used a randomised controlled study design (Creanga et al., 2007, Rasch et al., 2006, Xu et al., 2002, Chege et al., 2005, Mullick et al., 2006,

Adams and Kraushaar, 2005, IPPF-WHR, PATH, 2009), and 3 of these did not report on key outcomes or results. Of the eight studies, two described community based programmes (Creanga et al., 2007, Adams and Kraushaar, 2005). Of the remaining 6 studies, 2 studies specifically addressed the provision of HIV testing and promotion of condom use amongst FP clients (Xu et al., 2002, Mullick et al., 2006). One of these studies was conducted in Thailand (Xu et al., 2002), and one study (Mullick et al., 2006) reported on the experience of integrating C&T into FP services in an African setting. This study was the Phase 1 study preceding the trial described in this thesis and which is summarised in Chapter 3.

Church et al (Church and Mayhew, 2009) more recently updated this review by examining evidence of the impact of integrating any component of STI or HIV prevention, care, and treatment into a family planning setting in developing countries. Forty-four reports were identified from a comprehensive search of published databases and "grey literature". The authors concluded that presenting solid evidence on the most effective models of service integration or the best modalities for delivering a comprehensive range of SRH services is difficult because of the context-specific nature of the effectiveness of health systems and because of limitations within and across studies. The authors called for well designed operational research evaluating and comparing different approaches to and models of care in specific contexts. Moreover, the lack of well-designed studies provides only weak evidence concerning whether the integration of additional components reduces the quality of clinical care. The trial reported in this thesis addresses this gap through implementing a programmatic intervention assessed through a randomised controlled study design.

2.5 Systematic Literature Review

This systematic review was informed by a number of reviews that have been conducted to date that have focused on the integration of FP/SRH services to HIV/VCT and/or HIV/VCT to FP/SRH (Spaulding et al., 2009, Church and Mayhew, 2009, Lindegren et al., 2012). In particular, to update the 2009 literature review that was conducted by Church and Mayhew on the integration of STI and HIV Prevention, Care, and Treatment into Family Planning Services. For the purpose of this review only unidirectional integration of HIV services into FP services were considered.

2.5.1 Search Strategy

The review considered quantitative and qualitative studies evaluating the integration of HIV or STI services (prevention, testing, treatment, care and support) into FP services. A systematic review of literature to identify relevant studies was conducted. The aim was to identify studies reporting any process or outcome evaluations of HIV transmission prevention, care or treatment or STI into family planning services (including those provided through reproductive health services and the primary care structure). Interventions that integrated HIV services exclusively directed to maternal and child health care including mother-to-child transmission of HIV [PMTCT] were also included. In addition, studies reporting health care processes and health-related outcomes of integrated care, and cost–effectiveness, efficiency of service integration were also examined.

The review included only studies that reported original findings published in English between January 2002 and August 2016. Database searches were conducted on the following five databases MEDLINE, CINAHL, PubMed, Science Direct, and POPLINE. MEDLINE, CINAHL, and PubMed, were searched using the following MeSH terms: ("HIV" OR "acquired immunodeficiency syndrome" OR "sexually transmitted diseases") AND ("family planning services" OR "contraception" OR "reproductive health services" OR "maternal health services" OR “PMTCT” OR "primary health care"). Science direct was searched using the following key words: (“HIV” OR “STI”) AND (Family planning, Contraception, contraceptives OR maternal health services OR PMTCT) AND ("integration models"). POPLINE was searched using the following terms: ("HIV" OR "HIV infections" OR "HIV prevention" OR "HIV testing" OR sexually transmitted diseases") AND ("family planning" OR "contraception") AND ("integration models"). In addition, websites of the following organisations were searched: UN agencies (World Health Organization, IPFF, UNFPA), international Non-governmental organisations (Population Council, International Planned Parenthood Federation, Program for Appropriate Technologies in Health and Family Health International), and the following academic institutions; University of Witwatersrand and University of California. Additional studies were identified in grey literature and through reference lists from other relevant publications.

2.5.2 Assessment of the studies

The list of titles and abstracts identified were screened. Studies were only included if they reported on the integration of HIV/STI/AIDS into FP/SRH services. Studies that reported on the integration of FP/SRH into HIV care treatment and prevention were excluded.

2.5.3 Data extraction and analysis

Abstracts were reviewed first to establish eligibility with the standardised eligibility criteria. Any incongruities were resolved through discussion with colleagues. Data recorded were as follows: model of integration or linkages, of HIV into FP services, study design, evaluation, intervention description, outcomes/results. Data were extracted and presented in a table (see figure 2.1).

2.5.4 Results

The flow chart depicts the number of citations that were identified, included and excluded in the review. The initial search yielded 148 771 hits. After refining the key words based on the study outcomes, 2258 citations were generated, of these 2148 did not assess the integration of HIV into FP were excluded. A total of 110 relevant citations were identified for possible inclusion and assessed for eligibility, methodological quality and models of integration, of which 89 papers did not meet the inclusion criteria. The integration models of the 21 studies that were identified as potentially meeting the inclusion criteria were evaluated and nine were excluded because the direction of the integration model used was not clear. Ultimately, 12 studies published between 2005 and 2016 which reported on the integration of HIV/VCT to FP/SRH were considered and included for the review (Maharaj and Cleland, 2005a, Liambila et al., 2009, Tran et al., 2010, Criniti et al., 2011, Mutemwa et al., 2013, Ngo et al., 2013, Parker and Scott, 2013, Kimani et al., 2015, Obure et al., 2015, Brunie et al., 2016, Hewett et al., 2016, Mullick et al., 2006). The majority of the studies included in the review were conducted in Sub-Saharan Africa (n=9) (Maharaj and Cleland, 2005a, Liambila et al., 2009, Criniti et al., 2011, Parker and Scott, 2013, Kimani et al., 2015, Obure et al., 2015, Brunie et al., 2016, Hewett et al., 2016, Mullick et al., 2006), with two studies conducted in the USA and one in Vietnam respectively (Tran et al., 2010, Ngo et al., 2013) A synthesis of the outcomes on the integration models will be discussed in detail below.

Figure 2.1: Literature search summary

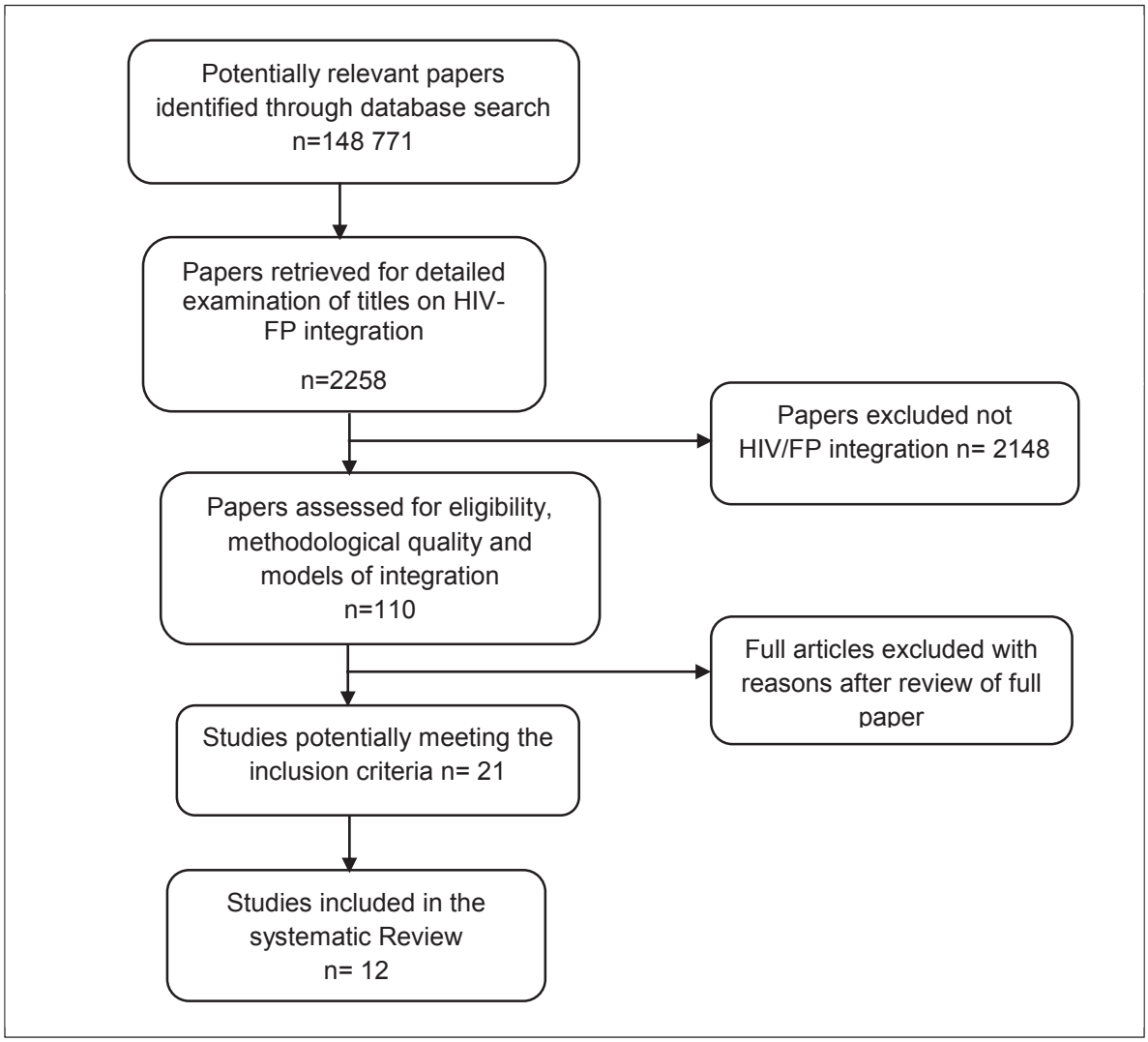


Table 2. 1: Summary of service integration studies reviewed

	Author(s) (Year)	Country	Service-integration	Evaluation type	Service integration results reported	Limitations
1	Maharaj & Cleland 2005	South Africa	STI/HIV-FP/MCH	Descriptive process evaluation. An inventory, key informant interviews Semi-structured interviews, Focus Group Discussions, and semi-structured interviews.	Quality of care Uptake of services Organisational effectiveness Provider-related Issues	Study relied only on subjective data collection methods.
2	Mullick et al 2008	South Africa	SRH/HIV-FP	Cluster randomised trial with two intervention arms and one control arm – client provider observations and client exit interviews	Quality of care Feasibility Cost	Phase I study assessing feasibility
3	Liambila et al 2009	Kenya	HIV/STI-FP	Pre and post intervention design without control	Client satisfaction, service uptake. Quality of Care, Acceptability and quality of service Population coverage	The sample size used for facilities compromised the validity of the results.
4	Tran et al 2010	USA	HIV -FP	Programme evaluation	Organisation effectiveness, Uptake of services	Heterogeneity of the sites led to differences in the observed intervention effects.
5	Criniti et al 2011	USA	HIV-FP	Process evaluation document review, and survey 6 months post the full integration.	Client satisfaction Population coverage, Organisational effectiveness Provider-related Issues	Study relied on data collected from the HIV testing documents, which may be unreliable and subjective.
6	Ngo et al 2013	Vietnam	VCT-SRH	Process evaluation using a pre-test/post-test, non-experimental evaluation design	Population coverage, Uptake of services	Samples were not entirely comparable, incomplete measurement of respondents' exposure to the interventions.
7	Parker et al 2013	South Africa	HIV-SRH	Descriptive cross-sectional design. Data collected using structured interviews; a facility-based checklist; and a patient record review.	Client satisfaction Service uptake Organisational effectiveness	Assessment of quality and integration of care dependent on record review. Subset of HIV-positive clients was too small to make conclusive inference.
8	Mutemwa et al 2013	Kenya	HIV-PNC HIV-FP	Semi structured, in-depth interviews.	Client satisfaction, organisational effectiveness, service uptake	The study only utilised subjective methods to assess the integration model.

	Author(s) (Year)	Country	Service-integration	Evaluation type	Service integration results reported	Limitations
9	Kimani et al 2015	Kenya and Swaziland	HIV-PNC	Prospective cohort study, follow-up for 15 months.	Quality of care, uptake of services Provider-related Issues	Although the study used a cohort design it was unable to control for extraneous variables and contamination. The study did not randomise facilities to intervention or control arms.
10	Obure et al 2015	Kenya and Swaziland	HIV and SRH	Quadratic cost function using data obtained from 40 health facilities, over a 2-year period.	Cost effectiveness, uptake of services Organisation effectiveness	An experimental design was not used therefore causality of the cost effectiveness cannot established. Sample size was too small to infer statistical evidence of organisational effectiveness.
11	Hewett et al 2016	Zambia	VTC-FP	Randomised evaluation of two interventions	Quality of care, uptake of services. Provider-related Issues	It is difficult to establish which of the two interventions evaluated had an impact. Thus the study failed to draw conclusive conclusions about the uptake of service and quality of care
12	Brunie et al 2016	Uganda	HTC-FP	RCT: eight health centres from matched pairs were randomly allocated to intervention or control.	Uptake of services Organisational capacity, Client satisfaction	Due to the presence of subject bias and lack of external validity the results from the study cannot be generalised to other contexts.

Maharaj et al (Maharaj P et al, 2005) conducted a study in a rural and urban area of KwaZulu-Natal in South Africa in four government health facilities and assessed availability and quality of services. Information was obtained through inventory, key informant interviews, FGDs and semi-structured interviews with providers and exit interviews with 300 clients. The purpose of these interviews was to assess the extent to which existing services offered integrated reproductive health and sexual and reproductive health services. FP clients were asked about whether they received information on STIs and HIV. The study found that providers were more likely to discuss condoms with new FP clients rather than re-visit clients. Less than a third of clients reported that the provider had mentioned condoms for dual protection. The topic of STIs and HIV was raised by providers in only 11% of FP consultations, behavioural risk assessment was only attempted in 5% of consultations and only 6% of FP clients were asked about vaginal discharge. The study highlights not only the need for the type of intervention developed and tested in this thesis but also an evaluation of the existing service delivery showing missed opportunities to strengthen integrated HIV and FP services.

In Kenya, an intervention for increasing access to and use of HIV testing amongst FP clients through provider-initiated testing and counselling for HIV was assessed using a prospective pre- post-intervention design with no control group in 23 public-sector hospitals, health centres and dispensaries in two purposively selected districts (Liambila et al., 2009). Two models, one in which FP providers were trained to provide HIV counselling and testing to FP clients requesting a test during the consultation and another where FP providers were referring FP clients for HIV testing were evaluated. The proportion of consultations in which HIV prevention counselling was provided and HIV testing offered increased significantly post-intervention. The proportion of clients requesting an HIV test increased from 1 to 26%; approximately one third of these clients had never tested previously. Overall, improvements in discussion of STIs and HIV, counselling and provision of condoms and discussion of HIV testing and counselling improved in both models post-intervention.

In the US, Tran et al (Tran T et al, 2011) evaluated the results of a broader initiative to integrate HIV prevention services into FP services. Grants were awarded in cycles to a range of existing FP providers operating nationally. Thirty three projects were

supported in round one, 63 projects in the second round and 77 projects in the third round of funding. Funding projects fell into two main categories, those that requested funds to initiate HIV activities beyond HIV prevention, and those that requested funds to supplement or enhance existing HIV prevention as part of their FP package of services. Grantees received training on the delivery of HIV/AIDS prevention education and the administration of CT. Data were collected using data reporting forms completed at regular intervals throughout the initiative. Key outcomes included increased institutional capacity for delivery of HIV prevention services, successful implementation of HIV prevention services and the identification of more than 1,500 HIV positive individuals through expanded CT.

(Criniti et al., 2011) integrated routine rapid HIV screening in a single urban family planning clinic in the US. HIV testing had been previously provided by a single counsellor to clients at high risk. The new integrated model expanded testing to become routine for all clients and segmented various tasks amongst a range of health care providers. Testing was also provided through point-of-care tests rather than being sent away to an external laboratory. Providers were trained to provide HIV testing within the existing clinic flow. A pre-post cross sectional study design was used with no control facilities. Data were extracted from medical charts and patient testing rates were reported. The study found that two years after the transition to the integrated model, the proportion of patients with an HIV test documented in the medical chart within the last 12 months increased 25.5%, HIV testing acceptance increased 17%. The authors concluded that routine offer of HIV testing can be offered successfully as standard of care in a high-volume, urban, reproductive health care setting. This was a single clinic study with no control, the paper did not discuss how representative this clinic was, whether other interventions, contextual factors or better routine reporting by providers as a result of training may have resulted in improved testing acceptance rates. It is unclear how many of the total number of tests were repeat tests on the same individuals as the results were reported for the previous 12 months. The only two outcomes, testing acceptance rate which may not be indicative of those who actually tested and proportion of clients with a documented HIV test result in the last 12 months.

Ngo et al (Ngo et al., 2013) evaluated a project that employed peer-based education strategies and integration of CT and SRH services for young people ages 15-24 in 5 provinces. These services were provided by a non-governmental organisation by Marie Stopes, Vietnam. A pre and post-test, non-experimental design was used and cross sectional data were collected using client exit interviews. Changes in behavioural outcomes were compared pre and post intervention. Training on CT was conducted for service providers along with upgrading facilities and the provision of HIV test kits. Peer educators were recruited and provided with refresher training on outreach and communication skills to encourage clients to come to health facilities for CT. There was a significant increase in the percentage of youth who wanted an HIV test, those who had ever had a test and those who had a repeat test in the last year. Exit interviews also found an almost five fold increase in the percentage of clients tested at their current visit. The authors recommended experimental studies to assess health outcomes and the uptake of HIV testing services.

Hewett et al (Hewett et al., 2016) assessed whether improved service delivery models increased uptake and cost-effectiveness of HIV and SRH services in Zambia. Clients accessing three types of service, FP services, CT services and male circumcision services were enrolled and individually randomised to one of three study arms, standard of care at the entry point, enhanced counselling and referral to an additional service with follow up and the latter strategy with the addition of an escort. Interviews were conducted at baseline, six weeks and six months to assess uptake of services for HIV, FP, male circumcision and cervical cancer screening at a mixture of public health and NGO-managed sites. Clients in the intervention arms received enhanced counselling with referrals for additional services and telephonic follow up if they failed to access the service within seven days. Motivational interview techniques and a standardised needs assessment was used to identify need for additional services and address barriers to service uptake. A strength of this model was that referrals were provided not only to the client but also to spouse and children where appropriate. The second intervention arm provided for an immediate escort at the time of referral. Although a range of entry points and services were evaluated CT amongst FP clients was also assessed. The study found limited effects on HIV care and treatment outcomes and no effects on increasing FP uptake. Although clients were randomised the study design did not allow for an exposure analysis making it impossible to see

which intervention components contributed to results. This study also incorporated an economic analysis which showed higher cost efficiencies for CT and medical circumcision services at integrated sites.

Parker et al, (Parker and Scott, 2013) conducted a cross-sectional study using structured interviews with facility managers, facility checklists and patient records to describe how current provision of government-provided reproductive health services are integrating HIV prevention and care and to assess quality and coverage of integrated services at six clinics in Cape Town, South Africa. The study showed that although facilities are equipped to provide integrated services, there is poor coverage of services with only a half (54%) of FP clients knowing their HIV status and 55% being offered HIV CT services and receiving condoms.

Mutemwa et al, (Mutemwa et al., 2013) conducted a qualitative study using in-depth interviews with various cadres of health care provider in two provinces in Kenya. The study was conducted in facilities already providing integrated HIV and reproductive health services and aimed at exploring provider experiences with integration to ascertain their significance to performance of the integrated health facilities. At the operational level, providers reported increased service uptake, increased willingness of clients to have an HIV test and reduced loss of clients.

Kimani et al, (Kimani et al., 2015) compared effectiveness of integrating HIV and FP services into postnatal care with stand-alone services on postpartum women's use of HIV CT and FP services in purposively selected public health facilities in Kenya. Women assigned to intervention and control groups were interviewed at baseline and 15 months later. A closed ended questionnaire was used to collect data on a range of factors including HIV testing and FP use. The study found that 47% and 30% of women in intervention and comparison sites respectively were offered CT. Uptake of CT was associated higher in the intervention clinics with an adjusted OR of 1.6 which was statistically significant. Having a partner tested for HIV was also positively associated with uptake of CT, highlighting the need to encourage male partners to test.

Obure et al, (Obure et al., 2016) investigated the determinants of technical efficiency of a range of integrated HIV and sexual and reproductive health services using data

collected from 40 health facilities in Kenya and Swaziland. Technical efficiency was defined as the ability of the health facility to produce maximum outputs from a given level of inputs. Statistical modelling techniques were used to identify determinants of efficiency and quality. The results showed low efficiency across all models of integration suggesting a high level of inefficiency across integrated HIV and SRH services in the 40 health facilities. The results also showed a weak effect on the extent of the integration on efficiency of HIV and SRH services. These findings highlight a complex relationship between availability and actual delivery of services. A further paper by Obure et al (Obure et al., 2016) used the data from these 40 health facilities over two years for estimating economies of scale and scope using a quadratic cost function. Only HIV CT services were characterised by service-specific economies of scale with no economies of scale demonstrated as outputs were increased. The results showed cost complementarities between FP and STI treatment services.

As a result of vertical funding for HIV services and as a way to address skewed resource allocation allowing clients access to services irrespective of HIV status Odeny et al, (Odeny et al., 2013) tested the effect of integration of HIV services into primary health care clinic on patient satisfaction and perceived stigma in rural Kenya. Integration was defined as colocation and sharing of services and resources for HIV care and primary care including clinic space, clinicians and other services such as laboratory and pharmacy. The study took place at three health facilities one sub-district hospital and two health centres. Both male and female clients were assessed. A baseline survey was administered to clients aged 18 years or older attending the clinic. The survey was administered to a sample of clients at 3 months and 12 months after the introduction of services. Clients were interviewed about satisfaction with various components of the services received and stigma measured through questions on privacy, equitable treatment and discomfort receiving care. Although satisfaction levels remained high, this study did not report on HIV integration into FP services specifically. This study did not have a control group, had small numbers of health facilities and clients assessed.

(Bradley et al., 2008) conducted a review of 30,257 client records from Ethiopian non-governmental, non-profit reproductive health clinics and examined associations between HIV and FP integration modality and CT client composition and client initiated

HIV testing and client HIV status. This study was a cross-sectional multivariate analysis of CT and RH service-use data for a 21 -month period, taken from CT clinic log books. The authors concluded that relative to facilities co-locating services in the same compound, those offering FP and HIV services in the same rooms saw higher proportions of clients defined as a typical-seeing (2-13 times) (categorised as single women less than 25 years of age) than older ever married women. Facilities where counsellors jointly offered HIV and FP services and served many repeat FP clients were significantly less likely to serve single clients. Younger, single men and older, married women were most likely to self-initiate HIV testing (78.2% and 80.6% respectively). Compared with facilities offering co-located services, those integrating services at room and counsellor levels were 1.9-7.2 times more likely to serve clients initiating HIV testing. The analysis suggested that client types may be differentially attracted to these facilities depending on service integration modality.

Brunie et al (Brunie et al., 2016) conducted a cluster randomised matched pair design study in eight health facilities in Uganda. Village health teams linked to health facilities provided CT in addition to FP services in the intervention group and only FP services in the control group. A survey amongst the village health teams and their clients was conducted 10 months after the intervention. Eighty percent of the family planning clients surveyed in the intervention group received an HIV test during the intervention; 27% of those were first-time testers. More clients had ever tested for HIV in the intervention group compared with the control; clients also retested more often. Findings indicate that this model is feasible and acceptable for expanding quality HTC into communities.

The final study conducted in South Africa, is featured in the “grey” literature (Mullick et al., 2008) aimed at assessing the feasibility, acceptability and preliminary evidence of effectiveness of an intervention aimed at integrating HIV prevention and testing into FP services. This study was the only one that used a cluster randomised controlled design with the collection of pre and post intervention data to evaluate two interventions. This study is described in detail in Chapter 3 of the thesis and formed the Phase 1 study informing the intervention tested in the CRT described in the thesis.

With the exception of the Phase I study leading to this thesis (Mullick et al., 2008), only two studies reported used a cluster randomised study design (Hewett et al., 2016, Brunie et al., 2016). These studies were conducted in Zambia and Uganda respectievely. The study conducted in Zambia (Hewett et al., 2016) failed to establish which of the interventions had an impact on service uptake and quality of care. The Ugandan study lacked generaliseability. Most studies used a descriptive approach incorporating pre and post intervention data collection without controls. The Phase 2 study described in this thesis is the first CRT assessing the effect of integrating HIV prevention and testing into FP services and the first study assessing integration of HIV into FP in the South African context. Further, none of the studies reported, with the exception of the Phase I study sought (Mullick et al., 2008) to establish the effect of integrated servcies on the quality of the existing FP services.

2.6 South African Context

The lack of a rigorous evaluation of the integration of HIV into FP services has been highlighted in the sections above. This section will describe the relevance of integrating HIV prevention and testing into FP services in the South African context.

2.6.1 Accessibility of FP services

The South African Department of Health's "National Framework and Guidelines for Contraceptive Services" establishes guidelines for providing contraceptives in family planning services and these have made contraceptive services widely available. The 2003 Demographic and Health Survey (SADHS, 2003) showed high rates of access to and utilisation of family planning services. Ever use of contraception by sexually active women and women in unions (married and cohabiting) is high (85% and 83% respectively). Current use of contraception was reported at 65% an increase from 62% reported in the 1998 SADHS (SADHS, 2003).

A province-wide situational analysis study in KwaZulu Natal (KZN) province conducted in 2002, in which a representative sample of 98 facilities were visited, found that the FP programme is well established with all except one health care facility surveyed offering FP services. Most FP facilities had adequate infrastructure, availability of contraceptives, equipment, logistics and other supplies required to provide services

(Ndhlovu et al., 2003). Eighty-four percent of all staff working at these clinics had been involved in providing FP services in the last three months. Almost all facilities had oral contraceptives and supplies of the two and three monthly injectables. Five percent did not, however, supply male condoms, while female condoms were available in only 11% of facilities (Ndhlovu et al., 2003).

Data from the South African Demographic and Health Survey (SADHS, 2003) shows that over half of sexually active women (56 percent) have ever used injectables and almost a third (29 percent) have ever used the pill. The male condom has ever been used by 38 percent of sexually active women but this figure falls to 28 percent in women in a current union. This figure is however considerably higher than found among women in a union in 1998 when 19 percent of women had ever used a male condom.

The majority (83 percent) of contraceptive users obtain their methods from the public health sector. Contraceptive services in the public sector are free to clients and they are an essential component of PHC services. Within the public health sector the most commonly mentioned source is the government primary health care centre (41 percent). Women also get contraceptives from hospitals and family planning clinics. The family planning clinics are normally based within a government health centre. Although family planning services have been integrated into PHC services, they often remain as stand-alone services within a health centre. The private health sector is less utilised as a source of contraceptives (13 percent) (SADHS, 2003).

2.6.2 HIV and other Reproductive Tract Infections (RTI) in FP Populations

In South Africa, it is estimated that 11 million new STI infections occur every year (Centre for Health Policy). A recent national survey shows that prevalence of HIV infection in the population has begun to stabilise at roughly 11% (Shisana et al., 2015). However the survey also reported that HIV prevalence remains disproportionately high amongst females as compared to males and peaks in the 25-29 year age group with almost 33% testing positive.

Surveillance or screening for STIs including HIV is not routinely conducted in family planning clients. However, it is not unreasonable to assume that a significant

proportion of antenatal women will go on to seek FP services and HIV prevalence is known to be high among ANC women (NDOH, 2013).

Although not many studies have been conducted on HIV and other RTIs in FP clients, the small body of existing data suggests that prevalence of these infections is high. It is estimated that 40 percent of women attending FP clinics in South Africa have an STI (excluding HIV) (Coetzee and Schneider, 1996) and that on any given day 24.9 percent of women in the general population in a rural district of KwaZulu Natal province in South Africa are infected with at least one STI (Wilkinson et al., 1999). A study in this rural area found that of 198 consecutive women attending a family planning clinic, 22 percent reported having an STI treated in the preceding 12 months and 63 percent had at least one STI/RTI at the time of the visit: gonorrhoea 8 percent, chlamydia 8 percent, trichomonas 14 percent, candidiasis 30 percent, active syphilis 8 percent, HIV 24 percent and bacterial vaginosis 15 percent. More than a quarter of these women (26%) had multiple infections (Wilkinson et al., 1997).

A literature review published in 1996 that examined publications since 1980, historical reports and salient unpublished literature concluded that with the possible exception of HIV systematic surveillance, data for STIs are lacking. This review found that Chlamydia and vaginal infections were detected in 20-49 percent of family planning clients, ulcerative infections were present in 5-15 percent of asymptomatic clinic attenders, whilst prevalence rates of gonorrhoea averaged 8 percent (Pham-Kanter et al., 1996). A cross sectional study of 249 rural women attending a family planning service in South Africa found the following prevalences of RTIs: Chlamydia 12 percent, gonorrhoea 3 percent, trichomonas 18 percent, and bacterial vaginosis 29 percent (Schneider et al., 1998). An earlier urban study in new asymptomatic family planning attenders in Soweto Township found a culture positive gonorrhoea prevalence of 10.2 percent (Hall and Whitcomb, 1978).

A study was undertaken to assess the etiological distribution of RTI's among routine family planning (FP) and antenatal clinic (ANC) attendees in two rural clinics in Vulindlela in KwaZulu Natal province in South Africa (Table 2.2). This cross-sectional study was undertaken from September to November 2002. All first-time ANC and FP clinic attendees during this period were eligible to participate in this study. Vulvo-

vaginal swabs were obtained using a self-administered tampon method. The presence of *N gonorrhoea, C trachomatis*, and *T vaginalis* were determined by polymerase chain reaction (PCR). Blood for syphilis and HIV testing was collected in the context of pre- and post-test counselling. A total of 92 percent of attendees consented to participate in this study. The mean age of participants was 23 years (ANC) and 24 years (FP).

Table 2.2: Prevalence of RTIs among antenatal and family planning clients in rural South Africa (2003)

Reproductive Tract Infection Etiology	Prevalence ANC (n=48) %	Prevalence FP (n=224) %
N gonorrhoea	4.2	6.7
C trachomatis	8.3	8.9
T vaginalis	22.2	24.3
Syphilis	2.6	2.3
HIV	34.1	45.5
At least two STIs present	14.5	17.9

***Source**: J.Frolich, SS Abdool Karim, Q Abdool Karim. South African AIDS Conference 2003. ICC Durban 3-6 August.*

A review of studies of STI prevalence in South Africa between 1985 and 2003 showed that high STI prevalence rates have been measured, particularly in the case of HSV-2, trichomoniasis, bacterial vaginosis and candidiasis. The prevalence of gonorrhoea and syphilis is highest in “high risk” groups such as sex workers and attenders of STI clinics, but chlamydia and trichomoniasis prevalence levels are not significantly higher in these groups than in women attending antenatal and FP clinics. The authors concluded that the prevalence of STIs in South Africa is high, although there is extensive variability between regions. There is a need for STI prevalence data that are more nationally representative and that can be used to monitor prevalence trends more reliably (Johnson et al., 2005).

The results highlight the high burden of STIs in FP attendees. Particularly of note are the high rates of HIV in both family planning and antenatal clients. The existing data suggest the importance of considering models of integration of RTI and HIV care within existing services that target women of reproductive age. Although the integration of RTI care into FP services is currently recommended, in practice this is not well implemented, and clients are not routinely asked about RTI symptoms, offered

condoms or offered C&T for HIV. Of 90 client provider interactions observed in a situational analysis study only 26 percent of clients were asked about history of STI symptoms, 33 percent were asked about HIV risk, 11 percent were informed about C&T, and dual protection was discussed with less than half (46%) of the clients (Ndhlovu et al., 2003).

Although not specifically conducted amongst FP clients, a more recent study to examine the relationships among changes in self-reported HIV and sexually transmitted infection (STI) and exposure to the national loveLife youth HIV prevention programmes used a cross-sectional population-based household survey was conducted using a multistage stratified cluster sampling approach. The total sample included 3123 participants, aged 18-24, 54.6% men and 45.4% women, from four provinces in South Africa (Eastern Cape, Gauteng, KwaZulu-Natal and Mpumalanga). Results indicate a self-reported STI past-year prevalence of 2.6%, experienced genital sores or ulcers in the past year prevalence of 3.9% and an HIV self-reported prevalence of 7.4% (Peltzer et al., 2012).

2.6.3 Dual protection

Dual protection (DP) is the simultaneous prevention of STIs, and unintended pregnancy. This can be achieved through abstinence, non-penetrative sex practices, consistent and correct use of the male or female condom, or a combination of condoms and non-barrier contraceptive methods (the latter is also defined as dual method use). Women seeking FP services are assumed to be sexually active and the vast majority use hormonal methods which, when used alone do not protect against STIs including HIV. Given the high rates of STI in South Africa, the rationale for promoting dual protection in FP programmes is clear. Condoms protect against STIs and pregnancy if used alone and can also be used in conjunction with hormonal contraceptives. Sexually active women such as family planning users, and sometimes men, attend health facilities for contraceptive services and can easily be accessed. In the long run it is expected that dual protection strategies could have a bearing on the HIV/STI epidemic and the ability of women to achieve their reproductive health goals. In South Africa, uptake of dual protection is low, and barriers to uptake and long-term use are not well identified. The DHS data show high rates of injectable and oral contraceptive

use amongst FP clients and low rates of condom use; 1.9 percent of all women currently using a contraceptive method are using a condom (SADHS, 2003).

The concept of dual protection is not widely implemented in South Africa and demonstrating successful integration of this concept into family planning services is important. There is, however, a lack of programmatic experience on the ways in which dual protection should be promoted and provided, and little knowledge on the factors and/or services that most influence self-perceived risk and the uptake of dual protection and its continued use.

Low provider knowledge of dual protection and negative attitudes may account for failure to promote the service. Inadequate training of providers may also account for poor uptake. Clients may also not be aware that they can achieve their reproductive goals by using a combination of methods that offer dual protection. Discussion of STI risk, HIV status, routine pre-test counselling or being tested could all potentially impact on clients' decisions to take up and continue to consistently use dual protection methods, but the interplay and relative contribution of these factors are not well understood. It is now well documented that HIV status does have a significant impact on fertility desires (Johnson et al., 2009).

2.6.4 HIV Counselling and Testing (C&T) services in South Africa

Greater attention needs to be given to creating a demand for and being able to provide adequate quality C&T and HIV services particularly in the light of the UNAIDS 90-90-90 goals that South Africa has adopted (Joint United Nations Programme on HIV/AIDS, 2014). This remains particularly relevant with the release of South Africas recent HIV testing policy (Department of Health, 2016) but was already a priority prior at the start of the study reported in this thesis. At that time and the South African government had moved towards making C&T services available at all public sector clinics and had announced the national roll out of anti-retroviral treatment in the public sector. Currently, efforts are being made to expand testing for all groups with a particular focus on adolescent girls and young women.

Overall, the infrastructure and equipment at facilities offering C&T appears to be fairly strong with PEPFAR having supported infrastructure and partners over many years to

conduct both facility-based and non-facility based testing. Current research priorities articulated in the consultations around the new National Strategic Plan (NSP) include the need for further evidence on approaches to effectively increase uptake of testing and availability at all levels of health service delivery throughout the country. However, with reference to FP clientele specifically, the effect of offering HIV counselling and testing on contraceptive choices, including the use of condoms, is unknown.

Referral of FP clients for C&T remains low. For those that test negative, there is little focus on ensuring that they remain negative. Knowledge of availability of treatment for infected individuals may in itself improve willingness to be tested as an entry point for treatment which may be seen by clients as a much more direct benefit of undergoing testing. In a country with the highest number of HIV positive people in the world, increasing access to and use of C&T services is vitally important for helping to control the epidemic through prevention as well as care and support activities.

Historically, contributions by FP services to the fight against HIV/AIDS have been limited to education on risk reduction, education about STIs, encouraging use of condoms and providing FP choices to infected individuals to avoid unwanted pregnancies. However, FP services have a great deal of potential to be able to offer a wider spectrum of HIV related services. “As these services are directly concerned with outcomes of sexual relationships it is logical to expect them to be at the forefront of efforts to prevent sexual transmission of HIV” (Askew and Berer, 2003). The large proportion of sexually active women using FP provides an opportunity for providers to integrate information about other services, though this is currently a missed opportunity.

Counselling and testing for HIV in South Africa needs to be expanded significantly and is not routinely offered in FP settings although ARVs and care for infected individuals is available through the public sector. Despite recent work integrating HIV voluntary counselling and testing services into reproductive health settings evidence of what works in providing C&T in FP settings remains extremely limited and further testing and evaluation is needed.

It is clear that integration may not always be the answer in every context. However, in South Africa, where FP services are well utilised and the Government is seeking to expand access to and use of C&T/HIV services, it is reasonable to suggest that integrating C&T for HIV (with appropriate referral for medical treatment of opportunistic infections and prophylaxis and antiretroviral therapy (ART)) into family planning services may be effective.

This strategy would require the reorientation of family planning services that would not only integrate C&T services for HIV, but would also strengthen the provision of information on STI risk and contraception to ensure dual protection. The degree of linkage or integration may affect quality of existing services and care and this needs to be documented. Information is also needed to determine whether integrating services leads to improved uptake of FP or C&T, and efficacy and cost effectiveness studies are required.

Given the rationale for integrating HIV services into FP services in this context, the lack of strong evidence on the effect of models of care, and the fact that many health care workers complain of staff shortages and overload, it would be important to assess both the feasibility of such models and their effect on outcomes such as HIV testing, dual protection and quality of FP and HIV care.

The provision of HIV Counselling and Testing is an important aspect of HIV prevention. The South African policy on voluntary counselling and tested was more recently expanded to include additional components. Initially it required providers to offer HIV testing and counselling to any patients visiting a health facility for any ailments other than HIV. The expansion requires not only that health providers offer counselling and testing to all patients but also requires that health care workers explain the importance of testing and knowing one's HIV status as a normal health seeking behaviour (Secretariat, 2010).

2.6.5 Gender issues related to HIV testing

Family planning is often regarded as the woman's responsibility, but there is growing recognition of the need to involve men in family planning programmes. Strategies include couple counselling, outreach activities that encouraged men to participate in

family planning and integration of family planning into traditionally male programmes. Integration of other critical sexual and reproductive health topics, including intimate partner violence, HIV, sexuality and partner communication are important (Lundgren et al., 2012)

HIV testing is known to promote knowledge and awareness of HIV, thus in certain cases prompt individuals to change their sexual behaviour and adopt safer practices, it also informs the initial steps for HIV positive individuals in accessing antiretroviral treatment. The South African government has taken various steps in promoting the importance of testing in various sectors of the South African society, however, with all the knowledge that the South African population has about testing, many people remain reluctant to know their HIV status. (Luseno and Wechsberg, 2009) mention various barriers to seeking HIV testing; some include very low risk perception – many individuals believe that they are have little to no risk of acquiring HIV. Maman, Mwambo, Hogan and Sweat (2001) found that significant barriers to testing were the possible problems that may ensue as a result of disclosure. Many women fear that their partners will reject, threaten or use physical violence towards them if their HIV status is not desirable. In this instance women are faced with two fears, the initial fear of the testing itself and the other being one concerning disclosure (Maman et al., 2001). Barriers to testing found in a study conducted by Luseno & Wechsberg (2009), included an unwillingness to test for HIV from various participants concerned about isolation, violence from spouses and rejection. Luseno & Wechsberg (2009), found that education as a socio-economic factor impacted testing behaviour amongst women. Women who are considerably more educated than others within the study tested more than those that were slightly less educated. The study also found that users of alcohol and cannabis were more likely to take HIV tests than those that had not used any of the substances within the past year. Those that had previously experienced some form of physical abuse were more likely to test for HIV; on the other hand there was no relationship between sexual abuse and testing. Luseno & Wechsberg (2009) found that although alcohol and drug abuse placed many of the participants at risk of acquiring HIV, it also enables HIV testing (Luseno and Wechsberg, 2009).

To ensure universal access to HIV treatment, expanding coverage of HIV testing and counselling for women is needed, both within and outside of antenatal care settings. Obermeyer and Osborn (2007), state that different countries have various socio-demographic determinants for HIV testing. In the Northern Hemisphere men who have sex with men have grabbed the most attention, however in the Southern Hemisphere HIV Testing and Counselling programmes have been targeted mostly at pregnant women. Most women access HIV testing within maternal health services (Obermeyer and Osborn, 2007). The emphasis on counselling and testing for pregnant women means that most women are not tested regularly for HIV as they are not often in contact with the health system.

Few HIV testing programmes that are not part of PMTCT services are designed to meet the needs of women. A study in South Africa conducted by (Mullick et al., 2008) found that men were not open to discussions with their partners for HIV testing and often relied on their partners HIV results to determine their own results. Research indicates that men usually underestimate their HIV risk potential in comparison to women; this is the case even though men have more high risk behaviours than women. The fears of disclosure is more frequently documented for women, and this fits with the evidence that outside of prenatal care programmes, women are tested less frequently than men (Obermeyer and Osborn, 2007).

In summary, evidence of FP services reaching men and adolescents and of their impact on health outcomes is inconclusive (Church and Mayhew, 2009).

The study presented in this thesis is one of twelve identified in the literature over the last fourteen years. This study adds to the scarce literature around the integration of HIV services into FP services with the vast majority of studies in the literature reporting on testing models of integrating FP services for HIV positive clients. The lack of rigorous studies and well documented models to integrate HIV into FP services in the context of busy primary health care facilities is a gap in the literature with most studies using descriptive study designs and with no controls. The evolution of funding over the years has contributed to a bias towards studying FP integration only for HIV positive individuals. These models exclude the need to demonstrate the effect of uptake of HIV testing as an entry point to HIV testing and prevention services for this highly

vulnerable population (adolescent girls and young women). In light of the availability of new prevention technologies such as PrEP it is imperative to demonstrate through well conducted studies whether FP services which reach large numbers of sexually active women have the potential to act as entry points for both prevention and treatment services. The study is one of three randomised studies conducted to address this topic in the last 14 years and the only one of its kind monitoring the effect on quality of existing FP services and conducted in South Africa in primary health care (PHC) facilities representative of PHC settings in other parts of the Africa region. The study therefore plays an important role in contributing to filling this gap in the literature.

2.6.6 Male engagement

Evaluation of some outcomes such as HIV testing amongst FP clients and condom use can be challenging to interpret as both uptake of FP services and testing and condom use may be influenced by many factors including male involvement in reproductive health, issues around disclosure to partners and risk of subsequent violence knowledge of partner status and factors such as intimate partner violence.. The correct and consistent use of condoms may also be influenced by a host of factors beyond the provision of a quality service as this form of prevention requires negotiation and partner cooperation which may be challenging for many women particularly those experiencing intimate partner violence (IPV). Indeed, in some settings partner consent are significant also in accessing FP services at all (Adongo et al., 2013) and there is still a need to implement and evaluate strategies to involve men in reproductive health services.

Sexual violence experienced by women, and girls in particular, remains a huge and daunting problem facing public health in South Africa, perceived to have one of the worst rates of sexual and gender-based violence (SGBV) in the world (Dunkle et al., 2004, Jewkes et al., 2006, Jewkes et al., 2009). The term sexual violence describes a broad range of behaviours that include physical violence, sexual violence, emotional violence and intimate partner violence (also called domestic violence). Sexual violence is gender-based and embedded in pre-existing social, cultural and economic inequalities between men and women (Mullick et al., 2010).

The true magnitude of intimate partner violence in South Africa remains unknown and there are great disparities with respect to reported cases of sexual violence. However, most studies point to gross under-reporting of cases. Added to this, is the poor use of health services by sexual violence victims with only an estimated one in six women who have experienced rape seeking health services (Mullick et al., 2010). Intimate partner violence is often also sexual and emotional, usually occurring in a broader context of relationships marked by controlling behaviours by men and a pervasive sense of fear among women, limiting freedom of choice and access to services. Over 40% of men reported in research interviews having been physically violent to a partner (Dunkle et al., 2004, Jewkes et al., 2006, Jewkes et al., 2009). Male sexual violence directed at women including intimate partners is well documented. A study in Cape Town showed that 15% of men participating in a survey reported having perpetrated sexual violence against an intimate partner in the last ten years (Mullick et al., 2010). Such violence was seen to be associated with factors such as alcohol abuse, conflict outside the home, having more than one current partner and conflict which resulted in the men feeling that their authority had been undermined.

There is also evidence that women experiencing IPV may be less likely to access FP services or to use contraception, further highlighting the need to involve men as IPV is highly prevalent in many parts of the world including South Africa. A survey conducted in KwaZulu Natal South Africa found that a high proportion of men (71%) were willing to accompany partners to FP services. This study showed that it was indeed acceptable and feasible to involve men in the reproductive health care of their partners. Both men and women were interested in men's involvement during maternity care. However, the study highlighted a number of health service delivery challenges including provider attitudes and infrastructural issues that need to be addressed within the South African context before reproductive health services become more male friendly (Mullick et al., 2010).

In India, it is reported that the youngest and most newly married wives are least likely to use contraception and most likely to report husband's exclusive family planning decision-making control, suggesting that male engagement and family planning support is important for this group (Yore et al., 2016). In Nigeria, men's awareness of, and support for, use of modern contraceptives were markedly associated with their

spouses' desire to use contraception (Ezeanolou et al., 2014) Previous studies conducted in Ghana and Nigeria suggest that spousal communication predicts contraceptive use and available evidence shows that women whose partners disapprove of modern contraceptive practice are unlikely to use them (Odimegwu, 1999). In Ethiopia, barriers to women's unmet need for contraception include their husbands' opposition, religion, poor knowledge, and lack of communication between spouses (Tilahun et al., 2014, Ezeanolue et al., 2015). In addition to evidence highlighting IPV as a barrier to seeking FP services, there is also evidence that IPV is common amongst women attending FP services and this needs to be addressed in terms of clinical and psychosocial support as well as issues around condom use and test disclosure (Decker et al., 2011, Decker et al., 2014, Delamou et al., 2015, McCauley et al., 2015, Miller et al., 2011, Raj et al., 2016).

HIV status of women and their partners may also play a role in the use of contraception and condom use, studies from USA and Nigeria showed that discordant couples didn't use condom during sexual intercourse due to their desire to maintain primary relationship, establish trust and increase intimacy (Hailemariam et al., 2012)

In addition to partner and contextual issues influencing access to services and use of FP and HIV prevention methods, user characteristics such as client motivation to avoid unintended pregnancy, ability to plan, comfort with sexuality, and previous contraceptive use, stage of sexual career, relationship characteristics, and physical and sexual abuse are important situational influences that influence condom use.

In addition to contextual, partner and client characteristics other health system factors including health care providers have an extremely important role in promoting effective and consistent method use and therefore assessing actions and advice given by providers is an important aspect of evaluation to include (Beckman and Harvey, 1996).

Chapter 3: DEVELOPMENT AND PRELIMINARY EVALUATION OF THE INTERVENTION

3.1 Chapter Overview

This chapter describes the development and the preliminary evaluation of the intervention that was further tested using a randomised controlled study design and described in this thesis. The first section of the chapter describes the rationale and design of the intervention, the adaptation of a generic version of the Balanced Counselling Strategy (BCS) to suit high HIV and STI prevalence settings and the two models of integrated services tested in the Phase 1 study. The second section of this chapter will provide a description of the Phase 1 study which was aimed at evaluating the feasibility and acceptability of the two models. The methods, results and conclusions will be summarised. The third section of this chapter will describe the development of the Phase 2 intervention, taking account of lessons learnt from the Phase 1 study and feedback from key stakeholders. This intervention was subsequently tested in the Phase 2 study and results are reported in later chapters of this thesis.

3.2 Rationale and design of the Phase 1 intervention

In order to address quality of care and standardisation of family planning services, the Population Council developed and tested a practical and interactive strategy for improving counselling during family planning consultations. This strategy was called the Balanced Counselling Strategy (León, 1999, León et al., 2003). The Balanced Counselling Strategy (BCS) process was designed for the provider to undertake a series of steps to determine the contraceptive method that best suits the client according to their preferences and needs. During the process the provider uses three key job aids (visual memory aids) for counselling clients about family planning: an algorithm (decision-tree) outlining all the steps, a set of counselling cards on different contraceptive methods, and corresponding brochures on each of the methods.

Results of operational research studies testing the BCS in Peru and Guatemala indicated that using the BCS strategy improved the quality of the provider's counselling and allowed the client to take ownership of the decision (León et al., 2003). The

approach was considered practical, low cost, and easy to adapt to local contexts. *The Balanced Counselling Strategy: A Toolkit for Family Planning Service Providers* was published to provide the information and tools needed for health care facility directors, supervisors, and service providers to implement the Balanced Counselling Strategy in their family planning services (León et al., 2008). The BCS had not been used in Africa.

In 2004 the South African government acknowledged that South Africa had high rates of STIs, including HIV, and had high coverage of contraceptive use for the region. This situation provided opportunities to reach a substantial proportion of the sexually active population (albeit predominantly female) seeking to prevent pregnancy and that may also be at some risk of exposure to HIV or other STIs. As in most countries, the South African family planning and HIV programmes were implemented separately, although the government was actively seeking ways to integrate services. Thus, the Department of Health was keen to develop practical tools for increasing the quality of services and numbers of clients receiving integrated services.

In response to the need to incorporate counselling, screening and services for STIs, including HIV, within routine family planning consultations in settings characterised by high prevalence of these infections, the original version of the BCS tool was shared by the author with relevant national and provincial level programme managers at the Department of Health (DOH). As there were no similar job aids existing for FP services, the BCS offered an opportunity to adapt a validated methodology and existing tools for a high HIV and STI prevalence context. DOH staff were keen to capitalise on the opportunity to adapt and test an existing tool rather than “reinvent the wheel”. The author and Study Coordinator coordinated discussion with programme managers through electronic inputs and face-to-face meetings. Discussions were also held with trainers experienced in sexual and reproductive health at the Reproductive Health and HIV Research Unit in Johannesburg. Following discussions it was agreed that the adaptations of the BCS would involve the integration of HIV prevention counselling, risk assessment, and counselling and testing (C&T). The adaptations to the BCS were undertaken by Population Council staff with inputs from a range of programme managers and providers as described above. The algorithm, method cards and client brochures were all adapted to include relevant steps in the consultation and

information relating to STI/HIV. Additional cards on STI/HIV risk were also developed. Client brochures were translated into local languages.

Adaptation of the BCS involved the inclusion of additional information on STI/HIV:

- The three key behaviour change messages were stressed: A B C (abstain, being faithful and using a condom correctly and consistently). Abstaining refers to secondary abstinence in this case as family planning users are assumed to be sexually active. In South Africa, because a quarter of FP clients are under 19, it is especially important to explain that secondary abstinence is still an option.
- Promotion of dual protection by providing information on the concept of dual protection, strengthened promotion of the condom, highlighting that hormonal methods and sterilisation do not protect against STIs, and stressing correct and consistent condom use.
- During the consultation, risk of STI/HIV was explored on an individual basis and dual method use and the correct and consistent use of condoms were to be stressed. The STI/HIV and dual protection messages were also reinforced during pre-test counselling for HIV testing.
- This approach to FP was adapted to ensure that clients are given a choice of FP methods and to ensure that standardised FP messages and integration of STI/HIV risk information are provided. This was also done to minimise provider bias in the promotion of contraceptive methods.

The resulting version was called the Balanced Counselling Strategy Plus (BCS Plus/BCS+). These tools were developed not only to improve the quality of the family planning service but also to enable providers to address clients' needs related to STIs and HIV during the same consultation.

In addition to the concerns raised by Department of Health programme managers regarding the lack of tools and models for providing integrated services, discussions had revealed that FP providers in South Africa did not use any form of brochures or leaflets during FP consultations. This meant that they had to rely on their memory, and also failed to discuss their clients' wishes, or gave either too much or too little

information about a certain FP method. The BCS Plus tool potentially addressed these limitations since the strategy allowed providers to focus only on those contraceptive methods relevant to the client. The brochures could also be translated into local languages for clients to take away with them after a consultation.

Further to the need to incorporate information on HIV and STI prevention, the South African government expressed a need to expand the availability and use of C&T for HIV. One option considered was to integrate C&T into well-attended services, such as family planning (FP). However, at the time this approach had not been evaluated for feasibility or acceptability amongst service providers or clients. Further, there was no consensus or evidence on whether the provision of HIV testing in FP services should be conducted by the same professional nurse or through referrals to a lay counsellor based at the facility. After discussion with stakeholders, the author with support from senior Population Council staff took a decision to test the feasibility and acceptability of two models of integrating C&T for HIV into family planning services, in order to identify which model would be taken forward to test effectiveness. A concept note was prepared by the author and shared internally at the Population Council, with USAID and DOH managers. Following their endorsement, this concept note was further developed by the author into the study protocol.

3.2.1 Description of the BCS Plus intervention

The modified BCS Plus toolkit consists of a set of counselling job aids: (a) an algorithm, (b) a set of method cards, and (c) corresponding brochures for clients on each FP method. The algorithm summarises the steps an FP service provider should take to implement the BCS Plus during a counselling session. There are 18 counselling cards in the toolkit. The first card contains six questions that the service provider will ask to rule out if a client is pregnant and the second card outlines contraindications for contraceptive use. There are 12 method cards, used to help narrow down the appropriate method for the client. Three cards focus on HIV and STI risk and testing for HIV and one card emphasises dual protection. Each method card has a photograph of the method on the front side of the card. The reverse side of the card contains a description of four basic attributes or characteristics of the method. This allows the client to get a rough idea of each method. Lastly, the toolkit contains 13 brochures or IEC (information, education, communication) materials—one for each FP method

represented by a method card and one on condoms. A brochure on the method that the client has been provided with is given to each client to take away and read at their leisure (brochures were translated into the local language Tswana). As part of the adaptation of the BCS Plus the HIV issues were added to the algorithm, but new IEC materials were not developed for the contraceptive methods. However, the content was adapted to include statements saying (where appropriate) that the current method of choice does not protect against STIs including HIV and that condom use in conjunction with the contraceptive method of choice was advised. All clients were provided with the IEC brochure on condoms in addition to the brochure on their chosen method in order to reinforce information on condom use and dual protection. Each brochure contains general information on the specific FP method, a list of contraindications, how to use the method, side effects, other benefits, key points for follow-up, and warning signs for when to seek medical attention. The provider uses these job aids during the FP counselling session to provide better quality FP services and to integrate HIV counselling and testing into FP services.

The BCS Plus is divided into four counselling stages. Each stage contains a sequence of steps to follow. The BCS Plus assumes that the motive of a client's visit is family planning but serves to also offer the client additional counselling and services in the same facility or through referral. Information on the cards guides providers through the steps of conducting an STI/HIV risk assessment, discussing dual protection and discussing and offering the client HIV counselling and testing. Below is a summary of the four stages of a consultation using the BCS Plus:

(i) **Pre-Choice Stage:** During this stage, the provider creates the conditions that help a client select a family planning method. The provider cordially greets the client. The provider emphasises to the client that, during the consultation, other reproductive health issues will be addressed depending on her/his individual circumstances. The provider reviews the client's fertility intentions and counsels her on healthy timing and spacing of pregnancy. Pregnancy is ruled out using the counselling card with the checklist of questions. If the client is not pregnant, the provider displays all the method cards and asks questions described in the algorithm. As the client responds to each question, the provider sets aside the cards of the methods that are not appropriate for the client. Setting aside these cards helps to avoid giving information

on methods that are not relevant to the client's needs.

(ii) **Method Choice Stage:** During this stage, the provider offers more extensive information about the methods that have not been set aside, including their effectiveness. This helps the client select a method suited to her/his reproductive needs. Following the steps in the BCS Plus algorithm, the provider continues to narrow down the number of counselling method cards until a method is chosen.

(iii) **Post-Choice Stage:** During this stage, the provider uses the method brochure to give the client complete information about the method that she has chosen. If the client has conditions where the method is not advised or is not satisfied with the method, the provider returns to the Method Choice Stage to help the client select another method. The provider also encourages the client to involve her partner(s) in decisions about contraception, either through discussion or visit to the clinic.

(iv) **HIV and STI risk assessment and information:** During this stage, the provider uses information collected previously and targeted questions to determine additional health services and counselling that the family planning client may need. Using the remaining 4 counselling cards (job aid cards), the provider may review important information related to STI/HIV transmission and prevention; conduct a risk assessment; discuss dual protection and positive health; and offer the client HIV counselling and testing. The provider offers HIV testing to the client following national protocols, and encourages the client to disclose her STI/HIV status to her partner(s), letting the client know both the benefits and risks of disclosure.

Upon completion of the counselling session, the provider gives follow-up instructions on the chosen contraceptive method, the method brochure, and a condom brochure. The provider and client also fix a date for a follow-up visit. First visit and repeat clients are handled similarly in this process. This is because clients may have experienced problems and may want to change methods, or clients may not have adhered to their method or defaulted and fallen pregnant and clients may also have changed fertility intentions, changed partners and therefore risk since the last visit.

3.2.2 Referral and Testing Models

In 2004, in an effort to generate evidence for using the new approach, the Population Council began a study with the Department of Health (DOH) in North West Province led by the author at the Population Council, with funding obtained from USAID and the endorsement of the DOH at national, provincial and district levels. Two models were developed and assessed in a randomised study, referred to as Phase 1, in response to the expressed interest of the NDOH to offer two levels of integration of C&T into family planning. Both models included common components of a strengthened FP consultation using the BCS Plus and routine STI/HIV education and risk assessment. The Testing Model educated FP clients about HIV C&T and offered C&T during the FP consultation by the FP provider, while the Referral Model educated FP clients about C&T and referred interested clients for testing and post-test counselling to a specialised C&T service. The differences in the two models related to how the testing was conducted, i.e. either by an FP provider within the consultation (Testing) or through referral to a lay counsellor (Referral). Both models were compared with facilities offering the existing standard of care for FP.

3.2.3 Developing training objectives, content and methods

A training audit questionnaire was developed by the study team to identify training needs prior to the development of training materials as well as to ascertain numbers of potentially eligible nurses and their cadre in order to arrange training logistics. The self-administered questionnaire was sent to 21 clinics through district managers in the three sub districts of the North West Province. These clinics included all 18 clinics that would eventually take part in the Phase I study. All health care professionals were requested to complete the questionnaire. Responses were received from 263 nurses.

Table 3.1: Results of training audit collected by self-administered questionnaire (N=263)

Topic	Received pre service training (%)	Received in service training (%)	Felt confident in providing services (%)	Expressed a need for training (%)
Pre-test counselling	17.9	47.3	49.3	39.8
Post-test counselling for HIV	17.3	45.9	47.6	39.8
HIV testing	14.5	45.7	31.3	34.9
ARV	2.3	2.9	5.5	63.7
STI diagnosis and management	41	53.8	49.4	29.2
Family Planning	41	53.8	49.4	29.2
PMTCT	4	18.2	22.3	56.1

**Note that providers could have received both pre-service and in-service training*

All nurses providing FP care were asked to complete the training questionnaire and this included both professional nurses and non-professional categories (enrolled nurses). As expected, a larger proportion of nurses had received training in the more "traditional" services such as FP and STI diagnosis and management. A third of providers expressed a need for additional training and only half felt confident in providing these services. A greater proportion of nurses expressed a need for training in the newer HIV related services with PMTCT and ARVs being the services the providers felt least confident about.

Based on the results of this short survey it was felt that there was a need for strengthened training covering FP, STI and HIV counselling and testing and it was decided to tailor the BCS Plus training to address these needs.

Based on the discussions with stakeholders a five module programme of training covering 4 days was developed for all providers. A sixth module delivered on an additional day of training (5th day) was delivered only to those providers implementing the Testing model. Module 1 covered the rationale for the study and the role of the family planning nurse within the study. Module 2 covered values clarification to ensure that nurses explored their values relevant to the study and recognised that there can

be a difference between personal values and those required to complete professional activities. Module 3 sought to introduce the concept of integration to allow participants to understand what integration means in terms of their role as FP nurses and understanding the multiple needs of FP clients, identifying areas which nurses are personally uncomfortable with and developing an understanding of how to engage in an integrated consultation. Module 4 covered STIs, contraception, HIV and HIV counselling and testing to increase providers' understanding of STIs and how to manage them syndromically, the relationship between STIs and HIV, the WHO medical eligibility criteria for the provision of contraception, the importance of dual protection and HIV transmission and pathogenesis. This module also covered the goals of HIV counselling and testing and the importance of pre and post-test counselling for HIV testing. The module also covered implications of HIV positive and negative test results, and risk reduction through behaviour change. Module 5 utilised the BCS Plus tool to cover the practical integration of STI diagnosis and management, dual protection and HIV counselling and testing. This was so that participants could break down the components of the integration algorithm and describe the communication required in each component. This would include being able to provide information on HIV and STIs and discuss the benefits of dual protection with clients, demonstrate condom use, and use the BCS algorithm and cards to conduct a complete consultation integrating all of the above. The sixth module focused only on the practical aspects of being able to provide HIV counselling and testing including an understanding of the Rapid and Elisa tests and how the results are presented, the ability to distinguish between good and poor pre and post-test counselling, an understanding of the components of pre and post-test counselling and the communication styles involved, the ability to perform pre and post-test counselling, the ability to provide a positive result and appropriate referrals. Training methods included didactic sessions, participatory exercises, practical sessions and demonstrations. Training was evaluated through a pre and post-test administered to ensure that all providers were competent in the provision of the Testing or Referral model of integration depending on the clinics they worked in.

3.2.4 Strengthened supervision for quality assurance

Continuous support and mentoring were provided by the Study Coordinator and/or author at regular intervals after the training to ensure that providers adapted to these

new practices at their facilities until competency was gained. A supervisory tool was developed and used to regularly monitor practice and to facilitate follow-up and supportive supervision by facility heads. The intervention clinics were visited on alternate months for the three-month period of introduction. Observation of the clinic structure, availability of supplies and equipment, FP consultation and the progress of the intervention, and challenges were discussed with clinic staff. On the spot training was conducted where there were gaps. Regular supplies of the IEC materials on the different methods of contraception were delivered to all twelve clinics. The research team also attended lay counsellors' monthly meetings to ensure on-going support and communication.

At intervention facilities in both models all cadres of nurses involved in various aspects of delivery of FP services were trained in the use of the BCS Plus tools. Local area service managers were also included in trainings so that they would be supportive of the interventions at the sites. The training for the Testing model included conducting a rapid HIV test and interpreting the results as nurses needed to be equipped with the skills and knowledge to be able to conduct the HIV tests after offering them. In the Referral Model in addition to the nurses, lay counsellors were also included in the training. In this model nurses were not trained on HIV testing but lay counsellors were included in some sections of the training and received training on how to conduct an HIV test and interpret results. As this was mainly a refresher training for lay counsellors the training for this model was a day shorter than that for the Testing Model. The duration of provider training varied by model: three days training was conducted with 56 providers who implemented the Referral Model and four days training, including HIVC&T, was conducted with 73 providers who implemented the Testing Model. Training focused on service integration but also included updates in FP method effectiveness, WHO medical eligibility criteria, reproductive tract infections (RTIs) and HIV, reproductive rights, informed choice and consent, safe sex and dual protection, values clarification, risk assessment and reduction of risk, record keeping, logistics management and referral. These training workshops were held between April and June 2005.

3.3 Description of the Phase 1 Study

The overall aim of the Phase 1 study was to test the acceptability and feasibility of two models of integration of C&T for HIV into family planning services in South Africa in order to guide the choice of which intervention strategy to take forward for formal evaluation in Phase 2 and to provide preliminary evidence of effectiveness compared with existing standard of care for FP.

3.3.1 Objectives of the Phase 1 study were:

3.3.1.1 To develop and implement two models of integration that educate FP clients about HIV prevention, dual protection and C&T and

(i) offers clients counselling and testing for HIV within the routine visit by a FP provider (subsequently referred to as the "Testing" model)

(ii) refers interested clients for testing and post-test counselling to a specialised C&T service (subsequently referred to as the "Referral" model)

3.3.1.2 To describe the feasibility of implementing each of the models as well as provider perspectives on their implementation.

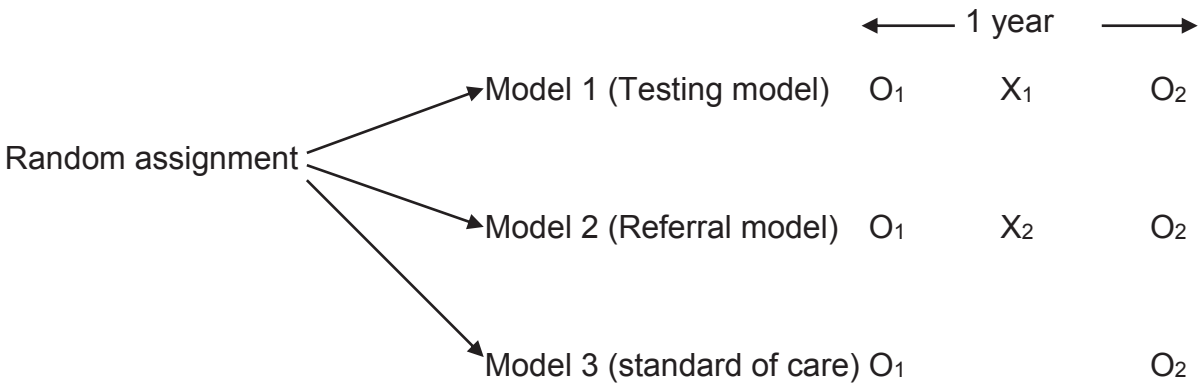
3.3.1.3 To assess implementation of the two models of integration in a number of health care delivery settings in terms of their acceptability to clients and effectiveness in increasing C&T uptake compared with existing standard of care.

3.3.1.4 To assess the effect of integrating C&T on the quality of FP services received.

3.3.2 Study design

A three arm cluster randomised study design was used to conduct this evaluation. Clinics (health facilities) were considered clusters and randomly assigned to receive one of the two intervention models (Referral or Testing) or to the control arm which continued to provide services as they were. No BCS materials were provided at control facilities. Cross sectional surveys were used to collect data at baseline and again post intervention to evaluate the interventions. Separate samples of women were interviewed at baseline and post-intervention a year later.

Phase 1



O_1 – Baseline observations and exit interview

O_2 – Follow up observations and exit interview

X_1-Intervention (Testing model)

X_2-Intervention (Referral model)

3.3.3 Site eligibility and selection

The study was conducted in 18 facilities (6 Urban, 5 Peri Urban and 7 Rural) in the Bojanala region in North West Province. These facilities fulfilled the following criteria which made them eligible for inclusion in the study:

- Clinics which provide HIV testing
- Clinics which provide family planning services
- High volume of FP clients (≥ 100 per month)
- Clinics providing STI treatment
- Clinics with more than one professional nurse.

3.3.4 Randomisation process

As staff to client load and the level of existing C&T activity were expected to influence the uptake of the intervention, data from a clinic inventory (described below) were used to carry out the randomisation. From March-August 2004 data to be used in the randomisation were collected. Total FP load per month, rather than total clinic load per month was collected. Data on the total number of providers involved in FP services

were also collected. The following indices were used to calculate % testing and staff to client load:

Percent tested = 100*(average # tested from Mar-Aug 04/total FP client load in May04)

Staff to client load = 1000*total FP staff number/total FP client load in May 2004

Table 3. 2: List and characteristics of facilities for Phase 1

Clinic number and district	Clinic name	Type of facility	Location	Percent tested	Staff to client load	Model
Moretele						
1	Kutlwanong	2	2	.41	5.7	Referral
2	Kekanastad	2	3	.25	3.0	Control
3	Mathibestad	1	3	.47	3.2	Referral
4	Makapanstad	2	3	.41	4.7	Control
5	Temba	2	1	.18	1.6	Testing
6	Refentse	2	3	.30	1.6	Referral
7	Moretele	2	3	1.06	7.3	Testing
Odi						
8	Kgabo	2	1	.54	2.6	Control
9	Sedilega	1	1	1.14	2.3	Referral
10	Phedisong 1	1	1	.26	5.3	Control
11	Winterveldt	1	3	.85	1.9	Testing
12	Tlamelong	1	1	.93	2.4	Referral
13	Bokenhout	1	1	.33	2.5	Testing
Rustenburg						
14	Luka	1	2	.33	1.2	Referral
15	Boitekong	1	2	.18	0.6	Testing
16	Mfidikwe	1	3	1.41	2.2	Control
17	Wonderkop	1	2	1.91	3.3	Testing
18	Haartbeesfontein	1	2	.45	1.9	Control

type of facility: 1= clinic, 2=CHC

location: 1= urban, 2=peri-urban, 3=rural

Stratification was conducted accordingly to testing levels at the facility measured by percent tested (number tested/total clinic load) as this was anticipated to affect the outcome. Two groups of 9 facilities each were categorised into high percentage tested and low percentage tested based on a median of 0.43. In each of the groups 3 facilities were randomised to receive intervention A, intervention B and intervention C respectively.

There are a total of 2,822,400 ways of randomising 18 facilities which are stratified into 2 groups, both of size 9, to three study arms (A, B and C).

This is calculated by: $({}^{9}C_{3} \times {}^{6}C_{3}) \times ({}^{9}C_{3} \times {}^{6}C_{3})$

$= (84 \times 20) \times (84 \times 20))$

$= 1{,}680 \times 1{,}680$

$= 2{,}822{,}400$

The total number of random allocations (2,822,400) were then restricted to ones that achieve “balance” for factors listed below.

- Sub-district
- Staff to client ratio*1000;
- And achieve further balance on number HIV tested /total clinic load

A total of n=647,280 (22.93%) random allocations achieved balance on the above criteria. A list of allocations was generated using STATA and from the first 20 allocations listing in each row 18 facility numbers randomly allocated to three intervention groups A, B and C the first allocation in the generated list was selected. Please refer to Appendix 1 for the full randomisation process.

Next the choice of what the interventions A, B & C represent was made based on 6 possibilities.

	A	B	C
1	Model 1	Model 2	Model 3
2	Model 1	Model 3	Model 2
3	Model 2	Model 1	Model 3
4	Model 2	Model 3	Model 1
5	Model 3	Model 2	Model 1
6	Model 3	Model 1	Model 2

Where:

Model 1: high degree of integration: C&T administered by FP providers

Model 2: low degree of integration: clients are given "routine pre-test counselling" during their regular FP planning visits and referred for C&T

Model 3: standard of care

3.3.5 Outcomes

Feasibility was assessed through documenting:

- Availability of supplies and equipment to provide integrated services
- Availability of staff that could provide integrated services
- Preliminary evidence of the effects of the intervention on quality of care

Acceptability was assessed through documenting:

- Attitudes of clients towards receiving integrated services
- Attitudes of providers towards providing integrated services

Preliminary evidence of effect of the interventions was assessed through documenting:

- Condom use
- HIV test uptake
- Provider discussion on STI/HIV issues
- Provider counselling on condoms
- Provider counselling on HIV testing
- Family planning counselling

3.3.6 Data collection methods

- **Inventory of supplies to provide FP services and C&T**

A structured inventory of supplies and equipment for provision of FP and C&T services including staffing was completed at the start of the study to document availability of resources needed to provide integrated services.

- **Structured observations of client-provider interactions**

Consecutively selected clients in each clinic were approached for consent to be observed during their interactions with providers pre- (baseline) and post- (follow-up) intervention. Separate surveys were conducted at baseline and follow up, one year after the intervention. Consecutive first visit and repeat FP clients aged 18 and above were approached and provided with information on the study, and informed consent was sought. Written informed consent was obtained from participating clients and verbal consent obtained from the facility manager and providers who were going to be observed as part of the research. All FP clients who expressed willingness to be involved in the study and provided informed consent forms before participating were included. As part of the informed consent process it was explained to them that they were free to terminate their participation at any point if they wished to do so with no adverse effect on the level or quality of services provided for clients or supervisory sanctions for providers. A trained retired nurse observed interactions and noted all actions and information provided using a structured checklist.

- **Client exit interviews**

Client exit interviews were conducted with all clients for whom the client-provider interaction was observed. These interviews were conducted both pre and post intervention. These interviews were conducted by trained field workers using a questionnaire which included closed and open ended questions on socio-demographics, services received and information on uptake of testing.

3.3.7 Sample size

The planned sample sizes for pre and post intervention measures were 540 client-provider observations and client exit interviews, that is, 30 client-provider observations and 30 client exit interviews per facility.

This sample size which was based on available resources to conduct data collection over a two-week period was considered feasible based on routine health facility statistics and given the time and resource constraints. Since this study was designed to assess feasibility and acceptability a formal sample size calculation was not done. Although data collectors were placed in the low client volume sites for a few additional days, resource constraints did not allow for them to be placed at facilities until the total target sample size was reached and so the achieved sample size was less than 30 in some clusters. During the data collection period at each facility all clients attending study facilities seeking FP services were targeted for recruitment

3.3.8 Data analysis

Data entry screens for all quantitative data were set up in Epidata and data were double entered. Analysis was done using STATA version 8. At baseline, client characteristics were compared across study arms and baseline comparisons were also made between pre intervention and post intervention results. As this study was regarded as a pilot study designed to assess feasibility and acceptability and preliminary evidence of effect the quantitative data were not analysed using methods for cluster randomised trials, that is, data were analysed ignoring the effect of cluster.

Quantitative data from client provider observations and exit interviews were analysed at individual level using Stata 8.

3.4 Results

The intervention was implemented at facility level. Baseline data were collected through facility inventory (N=18), client exit interviews (N=338) and client provider observations (N= 374) in December 2004. The differences in the numbers of client provider observations and exit interviews could be because the field workers conducting the observations and the exit interviews were working at varying speed. It

is thus possible that because some of the consultations were short, that the exit interviewers were not able to exit interview as many clients. The same data collection methods were repeated post-intervention, with the exception of clinic inventories in December 2005 (N=366 for both methodologies). Due to the varying FP client loads, the desired sample size of 540 could not be reached as some facilities did not have enough FP clients during the 2 week data collection period.

3.4.1 Facility inventory at baseline

Prior to the pre-intervention surveys and as a measure of feasibility to guide the development of the integrated models of services a trained field worker visited all 18 facilities in the Phase 1 study and collected data on supplies and equipment, staffing, client load, and current procedures for provision of care using a structured inventory tool. Data were collected by observing whether supplies and equipment were present at the facility, interview with the facility manager and the review of routine statistics. Table 3.2 shows that most facilities had the necessary commodities and supplies to provide integrated HIV and FP services. As the intervention did not include purchasing of supplies or equipment these data were shared with programme managers.

Table 3.3: Availability of supplies and equipment to provide FP and HIV services at baseline

Number of facilities with Commodities and Equipment available (Yes/No):		Testing Model (N=6)	Referral Model (N=6)	Control (N=6)
(1)	Penis model (dildo)	6	4	5
(2)	Gynecological exam table	5	4	5
(3)	Speculum	6	6	6
(4)	Thermometer	6	5	6
(5)	Stethoscope	6	6	6
(6)	Blood Pressure gauge	6	6	6
(7)	Combined Pills	6	6	6
(8)	Progestin only Pills	6	6	6
(9)	Emergency Contraception	5	3	5
(10)	2 Month Injectable	6	6	6
(11)	3 Month Injectable	6	6	6
(12)	Female Condoms	3	1	3
(13)	Male Condoms	6	6	6
(14)	HIV rapid test kits	6	6	6
(15)	Disposable syringes	5	6	4
(16)	Re-usable syringes	2	0	0
(17)	Disposable gloves	4	6	5
Mean total score (0-17)		15.00	13.83	14.50

A score of 1 was given for each of the 17 items of commodities and equipment and a mean composite score calculated for the 6 facilities in each study arm.

There were no substantial differences between the three groups of facilities in terms of supplies and equipment, although the facilities in the Referral model were less well supplied in terms of emergency contraception, female condoms, and re-usable syringes, where fewer of the facilities had these supplies compared to facilities in the other study arms.

Table 3.4: Staff Availability and Client Load at baseline

	Testing	Referral	Control
Mean number of staff by category	(N=6)	(N=6)	(N=6)
Registered Nurses (RNs)	7.3	5.5	8.5
RNs providing FP	4.8	5.5	3.8
Enrolled Nurses (ENs)	1.2	0.8	1.2
ENs providing FP	1	0.8	0.3
Enrolled Nurse Assistants (ENAs)	2.5	3	2.2
ENAs providing FP	0	0.5	0.2
Number of Lay Counsellors	2.3	1	2.3
*Mean client load per month**			
FP Clients	410.2	706.2	323.6
C&T	51.6	35.6	41.1

*(Data source: facility inventory) *(Data source for FP and C&T client load: routine facility statistics)*

As illustrated in Table 3.4, family planning services are delivered largely by registered nurses (from 5 to 8 in each site), of which between 4 and 5 reported that they do provide FP services. There was approximately one enrolled nurse (EN) per site; most reported being involved in the provision of FP services in the two intervention arms and fewer in the control arm. Enrolled nurse assistants (ENAs) were about 2-3 per site; however, most seemed not to be involved in the provision of FP services. However, in some facilities, enrolled nurses or enrolled nursing assistants provide FP services under the supervision of the professional registered nurse. ENs often provide assistance with taking vital measurements and filling in clinic cards. C&T is a vertical programme within the facilities that is mainly provided by lay counsellors who sit in separate rooms at the facility. Under normal circumstances, clients may be referred internally from other services provided at the clinic or may come only for testing. In the Referral Model arm there was, on average, one fewer lay counsellor than in the Testing Model arm which may have posed a potential problem in terms of facility capacity to conduct an increased number of HIV tests.

The client load of the facilities varied considerably, with a mean of 448 FP clients per month (range 151 – 1245), and an average of 43 C&T clients per clinic per month (range 8 – 120). The Referral Model arm had more FP clients overall but fewer C&T clients at the outset of the intervention. Despite using randomisation to try to create equivalent groups, the differential staff numbers and client load certainly had the

potential to affect the implementation and eventual effectiveness of the model interventions.

Table 3.5: Descriptive Statistics of Target Population at Baseline by Model

General Socio-economic indicators:	N	Pooled Sample (N=333) %	Testing Model (N=104 %	Referral Model (N=115) %	Control Model (N=120) %
Age:					
Age ≤ 20 years	48	14.4	15.6	15.0	12.7
Age 21 - 30 years	165	49.5	51.9	51.3	45.7
Age 31 - 40 years	88	26.4	24.5	23.8	30.5
Age ≥ 41 years	32	9.6	7.8	9.7	11.0
Education:					
Incomplete Primary or less	100	30.0	35.2	28.3	27.1
Complete Primary	214	64.2	58.8	63.7	69.4
Secondary and above	16	4.8	4.9	6.1	3.3
Marital Status:					
Married	94	28.2	29.4	25.6	29.6
Cohabiting	92	27.6	23.5	20.3	38.1
Other relationship status	143	42.9	46.0	52.2	31.3
Number of Pregnancies:					
None	59	17.7	24.5	11.5	17.8
One	114	34.2	28.4	41.5	32.2
Two	86	25.8	26.4	23.8	27.1
Three	45	13.5	9.8	14.1	16.1
Four or more	29	8.71	10.7	8.8	6.7
FP Related Indicators:					
Purpose of Visit:					
New user of FP method	45	13.3	8.6	19.3	11.6
Repeat user of FP method	286	84.6	88.4	79.8	85.8
Switching FP method	7	2.0	2.8	.8	2.5
Method use:					
Using method when arrived at clinic	241	72.3	82.3	69.9	66.1
Percentage using injectable	198	59.4	73.5	53.9	52.5
Percentage using pill	41	12.3	7.8	15.9	12.7
Percentage using other method (IUCD, implant)	1	.3	.9	0	0
Percentage using condom	23	6.9	4.9	9.7	5.7
Using contraceptive method during last conception	135	40.5	37.2	45.1	38.9
Risk Indicators					
Ever tested for HIV	96	28.8	25.4	28.3	32.2
Condom use at last sex	129	38.7	27.4	41.5	45.7
Use condom with method	137	7.6	5.8	10.7	5.8
Reported more than one partner	34	10.2	7.8	15.9	6.7
Intend to have another child	112	33.6	47.0	26.5	28.8

Table 3.5 shows the client socio-demographic and risk characteristics of the 338 FP clients interviewed at baseline.

The majority of women completed primary schooling or above while 30% reported not completing primary school. Seventy two percent of women reported using short term hormonal contraception, either pills or 2/3 monthly injectables. Less than half of the women (38.7%) reported using a condom at last sex. Thirty three percent of women said they would like to have another child indicating an intention to have unprotected sex in the future. Less than a third of women (29%) had ever had an HIV test. Ten percent of women reported having more than one sexual partner. These data suggest that FP clients attending these facilities are at risk of STIs and HIV and would benefit from an intervention integrating STI/HIV prevention and C&T for HIV into their regular FP services. Reasonable balance was achieved by study arm.

Table 3.6: Effects of intervention on condom use and HIV testing

Percentage clients reporting:		Testing		Referral		Control	
		Baseline	Follow up	Baseline	Follow up	Baseline	Follow up
		(N=104)	(N=124)	(N=115)	(N=123)	(N=120)	(N=119)
1)	Used condom at last sex	27	35	41	45	45	39
2)	Used condom in last month	13	24	23	27	30	20
3)	Using condom with contraceptive method	5	35	10	50	5	40
4)	Ever had HIV test	25	29	28	39	32	27
5)	Client tested for HIV at the same facility	14	15	7	17	13	15

Table 3.6 highlights findings from the client exit interviews concerning their self-reported behaviours. The table indicates that condom use at last sex and condom use in the last month showed increases in both intervention groups although increases in the Referral Model were small. The proportions declined post intervention in the control group. The only behaviour that increased markedly in all groups was the proportion of clients who reported currently using a condom with another contraceptive method, which increased dramatically from 5-10% at baseline to 35-50% at follow up. Self-reported condom use with a contraceptive method also increased in the control group from 5-40%. This may have been due to contamination or to respondents

providing responses they felt were acceptable. However, it is unclear why this particular variable might have been affected as this should have affected other responses as well.

At follow up the proportion “using condom in last month” was less than those reporting “using condom with contraceptive method”. This could have been due to a proportion of clients not having sex in the last month. Condom use at last sex was consistently higher than condom use in the last month further supporting this explanation. As these data were collected using client exit interviews those reporting ever having had an HIV test could also include those that were tested on the day of the clinic visit.

One item of programmatic importance is that for the Referral model, the proportion indicating that they had been tested for HIV at the same facility increased from 7% to 17% whereas those reporting testing at the same facility remained stable in the other arms. This may suggest that there may be a preference by clients to have a referral within the same facility rather than have the same provider do the testing.

As can be seen in Table 3.7, although the proportion of consultations in which providers mentioned C&T increased in the control group (perhaps due to some contamination between facilities), the increase was much greater in the two intervention groups; by the time of the follow up survey, 79-97 percent of clients in the intervention facilities heard about C&T. This also translated into an increase in the proportion of clients being offered an HIV test, especially by the providers in the referral facilities.

Table 3.7: Proportion of clients offered and deciding to have an HIV test

Percentage of consultations when:	Testing		Referral		Control	
	Baseline	Follow-up	Baseline	Follow up	Baseline	Follow up
	(n=104)	(n=124)	(n=114)	(n=123)	(n=120)	(n=119)
Provider mentioned C&T	40	79	47	97	32	45
Provider offered C&T	14	20	16	29	5	6
Client decided to have C&T	9	19	7	25	1	5

(data source: client exit interview)

The proportion of clients offered C&T increased over time, so that by the follow up survey 19-25% of clients in the intervention facilities had decided to have an HIV test, compared with 7-9 percent at baseline. It is important to note that there was also an increase in control facilities, albeit from one to five percent. Both the Testing and Referral models seem to show improvements, therefore, in increasing the proportion of FP clients who have an HIV test. One important limitation of this study, however, was that it was not possible to confirm whether or not the clients deciding to be tested actually had a test.

3.4.2 Client provider observations - baseline and follow-up

At baseline, STIs, HIV and AIDS were already being discussed in over half of all consultations and there was little improvement after the intervention. There was little change across all three arms in those discussing STI/HIV and AIDS.

Table 3.8: Discussions of STI/HIV issues with family planning clients

Percentage of consultations in which provider:		Testing		Referral		Control	
		Baseline	Follow up	Baseline	Follow up	Baseline	Follow up
		(N=104)	(N=124)	(N=115)	(N=123)	(N=120)	(N=119)
(1)	Discussed client history of STI symptoms	27	29	46	78	46	51
(2)	Discussed number of sexual partners	22	21	33	60	27	47
(3)	Discussed STI/HIV/AIDS	65	60	80	87	55	57
(4)	Discussed STI/HIV/AIDS risk factors	43	52	56	96	51	52
(5)	Tells client STI increase risk of HIV	18	37	38	67	50	44
Mean total score (0-5):		**1.74**	**2.00**	**2.54**	**3.91**	**2.32**	**2.52**

A composite score out of a maximum of 5 points with a value of 1 for each answer "yes" for the above behavioural questions was calculated and a mean score for each study arm at baseline and follow up calculated. The discussion of client history of STI symptoms improved dramatically in the Referral arm and remained unchanged in the Testing arm. Discussion of number of sexual partners also improved in the Referral arm and the Control arm but remained unchanged in the Testing arm. Discussion of STI/HIV/AIDS risk factors improved in both intervention arms and remained

unchanged in the control group. Information provision on STIs increasing risk of HIV improved in both intervention arms although the largest improvement was seen in the Referral arm. Overall, the Referral model showed the largest improvements in counselling and information provision on STIs and HIV.

There were improvements in virtually all items concerning dual protection and condom use for all groups of observations (Table 3.9). Improvements in the control group may reflect the national campaigns to promote condom use, and there appeared to be little additional value gained from exposure to the intervention in the two experimental groups. However, it was surprising to see a notable decline in the provision of information on how to use a condom in the Testing arm.

Table 3.9: Counselling and provision of condoms

Percentage of consultations in which provider:		**Testing**		**Referral**		**Control**	
		Baseline	**Follow up**	**Baseline**	**Follow up**	**Baseline**	**Follow up**
		(N=104)	(N=124)	(N=115)	(N=123)	(N=120)	(N=119)
(1)	Explains condoms protect against STIs/HIV and pregnancy	17	37	26	75	49	61
(2)	Give information on how to use a condom	92	35	29	64	32	49
(3)	Emphasise correct/consistent condom use	22	37	29	63	35	52
(4)	Explains how to negotiate condom use	1	40	12	47	3	48
Mean total score (0-4):		**0.61**	**1.50**	**0.98**	**2.50**	**1.20**	**2.11**

The strong emphasis on HIV C&T did lead to improvements during counselling of FP clients, for both models. Most impressive were the large increases in discussing the client's HIV serostatus (from 5 to 62% in the Testing arm; 6% to 81% in the Referral arm), although there was also a notable increase, albeit smaller, in the control group (16% to 25%).

Table 3.10: C&T information for family planning clients

Percentage of consultations in which provider:		Testing		Referral		Control	
		Baseline	Follow up	Baseline	Follow up	Baseline	Follow up
		(N=104)	(N=124)	(N=115)	(N=123)	(N=120)	(N=119)
(1)	Discuss HIV serostatus	5	62	6	81	16	25
(2)	Mentions C&T	39	79	47	97	32	45
(3)	Discuss what the test tells client	27	54	24	85	32	43
(4)	Explain about the window period	9	38	1	78	29	27
Mean total score (0-4):		**0.81**	**2.35**	**0.78**	**3.42**	**1.11**	**1.42**

Although the proportion of consultations in which providers mentioned C&T increased in the control group, it increased much more in the two intervention groups. This was possibly due to some contamination between facilities as some staff may have rotated to control facilities or district supervisors may have provided support for integrated services in other facilities in the district. This also translated into an increase in the proportion of providers offering an HIV test especially by the providers in the Referral Model facilities.

One concern frequently expressed about integrating services is that adding further components to the FP service may reduce the quality of FP counselling. As can be seen in Tables 3.7-3.11 there were no notable differences at follow-up in the quality of care scores for either intervention group which may suggest that adding the HIV services had not adversely affected the FP services. No intervention was introduced in the control facilities but since district staff were involved in on-going discussions and staff may have rotated from intervention to control facilities there was potential for contamination. Discussion about previous use of FP and, for the Referral group, providing clients with a choice, did decrease but this was balanced by improvements in some other items. A notable improvement was in discussion of reproductive intentions, which increased in both experimental groups but declined in the control group. Although the quality of care indicators related to condom use, dual protection, HIV testing and discussion of STI/HIV and AIDS generally improved in the intervention

arm, indicators of general FP services did not improve as expected with the exception of discussion of reproductive intentions which is a specific entry level step in the BCS Plus algorithm.

Table 3.11: Percentage of consultations in which family planning issues were covered

Percentage of consultations in which provider:		Testing		Referral		Control	
		Baseline	Follow up	Baseline	Follow up	Baseline	Follow up
		(N=104)	(N=124)	(N=115)	(N=123)	(N=120)	(N=119)
(1)	Discussed reproductive intentions	15	29	26	60	38	20
(2)	Discussed previous use of FP	66	47	86	61	55	77
(3)	Discussed 2 or more methods	11	8	12	15	11	10
(4)	Provided with choice regarding preferred method	79	77	95	73	83	83
(5)	Discussed how chosen method works	49	53	48	64	61	68
(6)	Explained advantages/ disadvantages of chosen method	45	47	42	60	57	67
Mean total score (0-6):		**2.67**	**2.63**	**3.12**	**3.34**	**3.07**	**3.27**

The mean consultation time in the control group remained constant at 22 minutes for both baseline and follow up surveys, whereas for the testing group it increased from 16 to 18 minutes and for the referral group from 21 to 25 minutes.

Focus group discussions were held with providers and clients prior to the baseline survey and again a year after implementation to obtain data on the acceptability to the health facility and to clients of integrating provision of FP and C&T services. FGDs were facilitated by trained researchers and recorded. Provider FGDs were conducted in English and client FGDs in Tswana. Transcripts were translated from Tswana to English. At baseline, in each of the three sub-districts one clinic was randomly selected, and at each clinic six to ten FP clients were asked to participate in a FGD. Clients were asked to comment on the current perceived challenges in the provision of FP care from their perspective, their perception of the quality of care, access to C&T services, factors affecting their C&T uptake and access, and the feasibility and

acceptability of providing HIV and FP services at the same visit and by the same provider. The post-intervention client FGDs were conducted in four facilities that had implemented the interventions. Four of the 12 intervention facilities, two from each arm, were selected randomly for the post intervention FGDs. The questions addressed similar issues as in the pre-intervention FGDs in order to gauge the effect of the interventions from a client perspective.

In addition, pre- and post-intervention FGDs were conducted with providers at the same facilities to assess the acceptability of the interventions in the three sub-districts. Providers were asked to comment on the current challenges to provision of FP care, their perception on the quality of care, current provision of services, contribution of FP services in combating HIV and STIs, attitudes towards people with HIV or with AIDS, and the acceptability and experiences with the provision of integrated services.

At baseline, discussions with clients revealed that they were generally supportive of the idea of being offered more than one service at their FP visit. However, these discussions were hypothetical as clients had not experienced the services first hand. Post intervention discussions highlighted that clients liked the fact that they were offered C&T during their FP consultation. Most FP clients said that they liked the integration of C&T in their FP service because it got them thinking about HIV. Even though they were sexually active and were accessing contraceptives, they had not thought about taking the HIV test. Clients reported that C&T was good for them because it gave them the opportunity to know their HIV status. Furthermore clients felt that counselling on STI/HIV, C&T, risk assessment and dual protection during the consultation helped them address misconceptions about HIV/AIDS and condoms. They also emphasised that counselling on dual protection gave them a better understanding of the importance of condom use while using another contraceptive.

Discussions with FP providers at intervention sites revealed that they felt energised and equipped by the intervention enabling them to do STI/HIV risk assessment and to discuss client sexual behaviour. They mentioned that their clients opened up freely when discussing sexual behaviour irrespective of their age. Some FP providers, however, raised challenges they experienced discussing condom use with their

clients. One provider highlighted that condoms are socially unacceptable for married couples in the community they serve.

Generally, FP providers felt strongly that on-going counselling of FP clients about HIV and the importance of C&T would increase the uptake of HIV testing. Most providers from the intervention sites mentioned that the discussions about counselling and testing elicited many questions about HIV. Although some clients had not consented to take the HIV test, they had started talking about it.

FP providers also expressed the need for a values clarification workshop that would help them address their attitudes towards clients who do not want to use dual protection. They confessed that sometimes they became irritated when clients refused to comply with their reproductive health advice.

3.4.4 Focus group discussions with providers at follow-up

In conclusion, the results of the Phase 1 study showed that facilities were equipped to provide integrated services and that both providers and clients thought that integrated services had value. Although results from client provider observations showed some improvements in the quality of services provided, improvements were also seen in the control facilities. There may have been a number of explanations for this including other national activities as well as the possibility of contamination between facilities. It was noted that quality of care did not appear to decline as a result of integrating additional services. Client exit interviews also revealed large improvements in the reported use of dual protection and smaller increases in those ever tested or reporting that they had decided to have an HIV test. These findings were discussed with the Department of Health, where it was concluded that there was evidence of acceptability as clients and providers were supportive of integrated services on the whole. Quality of care data and the data collected from inventories provided evidence of feasibility and the improvements in self-reported dual protection uptake and HIV testing showed promise and should be further rigorously evaluated.

3.5 Limitations of the Phase 1 study

According to the study protocol, the target sample size for both client-provider observations and client exit interviews was 540, but due to the varying FP client load and the timing of data collection, this target could not be met. Another limitation was that the control facilities were in the same sub-districts as the intervention facilities, which meant that the rotation of staff from intervention to control facilities could not be prevented and the control facilities had the same DOH supervisors as the intervention facilities. Data on staff rotation were not collected throughout the study period although study staff were aware that staff rotations had taken place. Furthermore, in all sub-districts there were monthly meetings at which all clinic service providers meet to discuss progress, obtain updates from their managers and address challenges. There is a possibility that during these meetings information about the intervention activities could have been shared.

Rotation and relocation of FP providers who had received training on integration created an important gap in terms of the implementation in the intervention sites. Furthermore the placement of new untrained providers at the intervention sites contributed towards an uneven process of implementation. Staff shortages played a major role in providers' decisions on providing integrated services.

As this study was a pilot study carried out on a small scale, data were not analysed using methods for cluster randomised trials. While general patterns in the findings have been described, formal assessment of statistical significance was not attempted at this stage.

3.6 Developing the Phase 2 Intervention

Considering the policy context and the evidence from the Phase 1 study, a meeting was held with Department of Health (DOH) managers at the provincial, district and facility levels, clinic supervisors, facility managers, nurses, lay counsellors and field workers to discuss the implications and experiences and to make recommendations on the Phase 2 intervention. This meeting was arranged and facilitated by the author. In terms of a decision regarding which model to take forward, the following

considerations regarding the rights of clients to information and choice were taken into account:

- Counselling of all FP clients about STI/HIV/AIDS risk behaviours and prevention should be provided to address common misconceptions, and provides the opportunity to engage with clients about their sexual behaviour and interest in HIV testing.
- Client preference for location of HIV testing should be respected and clients should be able to access services in the facility where they receive FP services either through their FP provider or referral. It was decided that FP providers at all facilities should be able to provide testing should it be requested. Clients should also be able to opt for referral should they wish.
- Some providers indicated that they needed enough flexibility to be able to implement either of the two models from day to day depending on client load or other factors such as availability of providers and client preferences. Models of integrated care need to allow flexibility at facility level.
- Programme managers also felt that both FP providers as well as lay counsellors should be able to competently provide counselling and testing to FP clients.

Based on the comments it was agreed that there was no compelling evidence to conclude that either model was superior and that the content of the intervention was relevant and showed potential for effectiveness as quality of care indicators had shown improvement. Further, the concerns about limiting clients' rights to choose where to go to for HIV testing by rolling out a single model were raised. Instead of one of the two models being taken forward as the preferred model to test for effectiveness, it was recommended that the intervention should be a hybrid model enabling either HIV testing within the FP service or referral for HIV testing. This model would be assessed for effectiveness in (i) improving testing for HIV amongst FP clients and (ii) dual protection uptake, compared with standard of care. In addition, quality of care would also be more rigorously evaluated.

3.6.1 Development of training materials for Phase 2

This study was designed as an operations research study involving evaluation of an intervention intended primarily for implementation under the control of government programme managers. The author therefore held several meetings with the National Department of Health, Maternal and Child Women's Health (MCWH) directorate to discuss and obtain continued buy-in and input. The North West Province was identified by the NDOH as a potential site for the Phase 2 study and further buy-in meetings were held between the study team and the provincial MCWH, as well as the regional and district directorates. During these meetings, members of the provincial and district teams discussed the current number of C&T sites, strengths and opportunities for the proposed project, challenges, potential solutions and their expected roles and responsibilities.

Several working groups were tasked to review and finalise the training curriculum, the training strategy, adaptation of the proposed intervention tools, and the translation of pamphlets into the local language. The intervention consisted of four components: 1) strengthening FP services across all public primary health care settings; 2) introducing STI and HIV risk assessment; 3) promotion of dual protection; and 4) increased access to C&T.

3.6.2 The Phase 2 intervention

The Phase 2 intervention utilised the same algorithm and job aids described earlier. However in order to ensure that facilities could provide either the Testing or Referral model the most significant change in the Phase 2 model was the targeting of both professional nurses and lay counsellors for training in the intervention. This required training of both professional nurses and lay counsellors at facilities in conducting and interpreting a rapid test for HIV and providing pre and post-test information. The BCS Plus tools for use by FP providers were revised to include additional provider cards on topics such as PMTCT as many providers said that clients had asked them about what would happen if they were to find out they were HIV positive and wanted to have more children. Cards were also added to the provider job aid on HIV pre and post-test counselling so that nurses conducting the testing could refer to these should they wish to conduct the testing. Appendices 4–15 show the BCS Plus materials that were subsequently tested in the Phase 2 trial.

The following chapter (Chapter 4) describes the study methods for the Phase 2 trial which comprised a cluster randomised study of the effectiveness of the Phase 2 intervention in increasing HIV testing and dual protection. Secondary outcomes to be tested were quality of delivery of FP and HIV service delivery components.

Chapter 4: METHODS FOR THE TRIAL

This chapter describes the study methods for the trial in detail. The following will be described; study setting, background to study methodology, study objectives, study design, selection and randomisation of facilities, data collection methods, statistical methods, sample size and ethical considerations. Study cluster identification and participant flow, dates defining periods of recruitment and follow up and the numbers analysed are described in Chapter 5 as are the baseline findings. Chapter 6 describes the study results comparing endpoints in the two study arms at follow-up.

4.1 Study Setting and Methodology

The study was undertaken in North West Province (NWP) in South Africa. The province consists of four districts and 19 sub-districts and is largely rural with mining as a key activity. The province has a population of approximately 3.4 million people, and is the sixth most populated province in South Africa. Ninety-one percent of the population is of African descent, mainly Tswana. Whites make up 7% of the population, coloureds 1% and Asians less than 1%. The province has the lowest proportion of people aged 20 years and older who have received a higher education (6%). The literacy rate in the region is 57% which is well below the national rate of 85%. The 2010 national HIV survey among antenatal attendees indicated that 29.6% (95% CI 27.3–31.9) of pregnant women in the North West Province were HIV-positive (NDOH, 2010a).

4.1.1 Background to study methodology

Operations Research (OR) in public health interventions and programmes is aimed at answering questions to constantly guide public health programme implementation to achieve best results. OR studies the modulation of inputs and processes involved in the programme cycle and strives to produce optimal gains in achieving programme targets and goals (Malhotra and Zodpey, 2010). OR uses a wide range of qualitative and quantitative methods to study factors under the control of programme managers (Population Council, 2008). OR uses research techniques to choose among alternative uses of resources to meet programme objectives and supports programmatic decisions with empirical evidence. It also assists in identifying problems

and understanding bottlenecks, arrives at “best practices” by comparison of different models, and tests service delivery innovations and alternative strategies.

Implementation Science (IS) is a new and emerging field. However, there is currently lack of consistency in terms and methods. The most narrow interpretation of IS addresses the level to which health interventions which are already proven to be effective can fit within real-world public health and clinical service systems. In this context IS has been described as the use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within specific settings. Other broader definitions of IS encompass what was traditionally covered under OR to include:

– **investigating and addressing major bottlenecks** (e.g. social, behavioural, economic, management) that impede effective implementation,

– **testing new approaches to improve health programming**,

– determining a causal relationship between the **intervention and its impact**

Donors such as USAID have extended this definition to encompass not only the generation of new knowledge of what works and how it can work at scale but also the use of knowledge, specifically how evidence can be integrated into programmes and learning about challenges and facilitating factors and also the management and utilisation of knowledge to effectively reach stakeholders.

“Application of systematic learning, research and evaluation to improve health practice, policy and programs in developing countries” (USAID, GH, n.d.)

“Improving programming through the translation of evidence into practice” (PEPFAR, n.d.)

This study tests a new strategy for improving uptake of C&T, through integrating interventions that have been proven effective when offered separately, and therefore could be considered to fall within the scope of both OR and IS.

4.2 Study objectives

4.2.1 General aim

The overall aim of this study was to conduct a cluster randomised controlled trial to compare a model of HIV prevention and routine provider initiated offer of testing integrated within family planning services with the existing standard of care for family planning services. The integration model was determined in the Phase 1 study described in Chapter 3.

4.2.2 Specific objectives

To evaluate the effectiveness of the integration model compared to standard practice with respect to the following primary and secondary outcomes:

Primary outcomes

- To compare the uptake of HIV testing by FP clients measured by clients reporting to have tested for HIV in the previous year in intervention and control arms
- To compare the use of dual protection by FP clients measured by clients reporting condom use at last sex in intervention and control arms.

Secondary outcomes

- To compare quality of care (measured through a series of quality of care scores) in intervention and control arms.

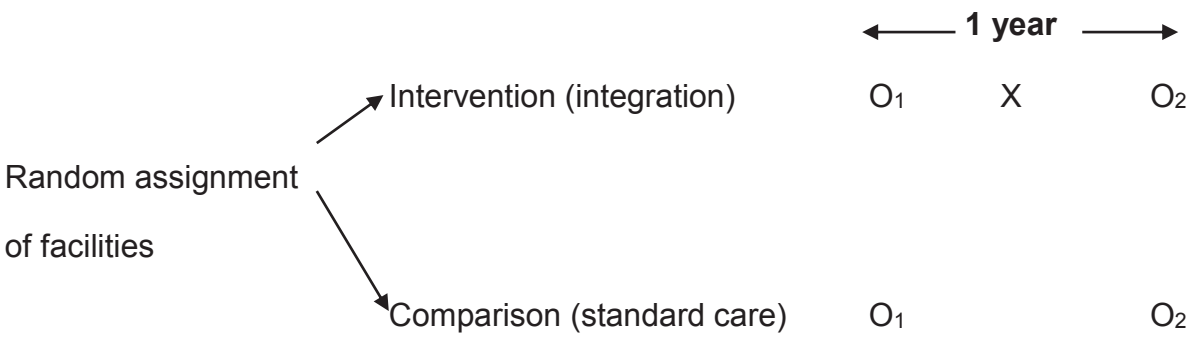
4.3 Study design

The study design was a two arm cluster randomised controlled trial with one intervention arm and the other a control arm, and with a primary health clinic being the unit of randomisation. The comparison arm clusters continued to provide services following the practices and guidelines recommended by the Department of Health at the time. Two cross-sectional surveys using client exit interview and client provider observations were conducted to collect data at baseline and at follow up (one year after the intervention was put in place). The purpose of the baseline survey was to assess clinic attendees pre-intervention in terms of their socio-demographics and

quality of care provided at baseline in order to establish whether randomisation was successful in avoiding any imbalances across study arms. Identified imbalances could subsequently be adjusted for in the analysis of outcomes at follow up. The follow up survey was used to measure primary and secondary outcomes for comparison across study arms. Primary outcomes were measured on women attending the facilities using a client exit interview and secondary outcomes were measured through client provider observations.

A randomised trial design was justified as there was no information on how integrated services would perform in comparison to standard practice in South Africa. For logistic and administrative reasons it was decided to implement the study at clinic level, rather than at the individual level. This was done as it would have required more complex procedures to randomise individuals to receive the intervention or not at facility level. This approach also minimised the risk of contamination which could occur if the randomisation was conducted at the individual level as both control and intervention clients would have to be seen by providers at the same health facility. It was assumed that all clients attending facilities where providers have been trained are exposed to the intervention. Finally, two cross-sectional surveys at baseline and follow-up were used as the available resources for the trial would not allow for the establishment and follow up of a cohort. However, a number of women interviewed at follow up were also seen at baseline and these formed the retrospective cohort referred to in Chapters 5 and 6.

Figure 4.1: Study design



O1= observations and client exit interviews at baseline
O2 = observations and client exit interviews at follow up
X = intervention

4.4 Facility eligibility and selection

Clinics fulfilling the following criteria were considered to be eligible for inclusion:

1. Clinics which provide HIV testing
2. Clinics which provide family planning services
3. High volume of FP clients (>=100 per month according to routine statistics)
4. Clinics providing STI treatment
5. Clinics with more than one professional nurse.

During the previously conducted Phase 1 study described in Chapter 3, facilities in three sub-districts in NWP, Odi, Moretele and Rustenburg, were involved. Due to the time and resource-intensive buy-in process that would be required (with provincial, district and facility management) to include new sub-districts in the Phase 2 study and to gain access to facilities, it was decided that the Phase 2 facilities be selected from the same sub-districts. However, all facilities that had participated in the Phase 1 study, including control sites, were excluded from those eligible for inclusion in Phase 2 to avoid any distortion in outcomes due to previous participation in Phase 1. On further discussion with the study team it was decided that Odi sub-district would not be included due to challenges obtaining sub-district level information and feedback during the Phase 1 study and additionally because of a national re-demarcation process which resulted in Odi sub-district no longer falling under NWP but under Gauteng Province. Facilities in the remaining two sub-districts which met the inclusion criteria but were not part of the Phase 1 study were available for potential selection. A list of public sector facilities meeting the criteria listed above was requested from Moretele and Rustenburg sub-district management.

Table 4.1: Eligibility and selection of facilities by district

Districts	Number of Facilities in the sub-district	Number of facilities excluded	Number of facilities NOT meeting selection criteria	Number of facilities meeting the criteria	Number of facilities selected for the Phase 2 study
Moretele	31	7 participated in Phase 1 3 No longer in Moretele district	5 did not meet selection criteria due to low client volumes	16	6
Rustenburg	21	5 participated in Phase 1	All met selection criteria	16	6

4.5 Randomisation of clusters

The randomisation process was carried out in the presence of the DOH sub-district managers from each of the two sub-districts. Table 4.1 shows the facility eligibility and numbers selected in the two sub-districts. After exclusion of ineligible clusters a total of 16 facilities in each of the two sub-districts remained available for potential selection. Each of the facilities was assigned a number from 1 to 32. Each manager took alternate turns to select 12 numbers from a bowl containing slips of paper numbered 1 to 32. During this selection process the facility numbers on the slips were not revealed to the audience. As the slips were selected they were placed in two groups, A and B, in alternating sequence, resulting at the end of the selection process in six slips in group A and six slips in group B. A coin was then assigned heads “intervention” and tails “control” by the study team. The sub-district manager for Moretele was asked to select a group, A or B, and to toss the coin. She selected group B and tossed the coin which landed on “heads” thus determining that group B facilities would receive the intervention and group A facilities would act as comparison facilities. The slips were then opened in front of the district managers to reveal which clinic numbers had been assigned to the two study arms. The procedure ensured that concealment of randomisation was achieved in this trial. Restricted randomisation was not conducted.

Clinics were not stratified by sub-district as these sub-districts were considered similar in terms of socio-demographics and health facility infrastructure.

4.6 Intervention

Chapter 3, Section 3.2, describes the intervention in detail, which consisted of training of FP providers and lay counsellors to use the BCS Plus tools aimed at integrating the discussion of STIs and HIV and discussion of testing for HIV and dual protection routinely into the FP consultation. Providers were trained to use the BCS Plus algorithm and job aids and to provide HIV testing if requested. Post training visits were conducted at the health facilities to provide support and to ensure that the tools were available at the health facilities.

Although study staff ensured that as many nurses as possible from intervention facilities were trained in the intervention, an assumption was made that all clients receiving FP services at an intervention clinic were considered exposed to the intervention regardless of whether the specific provider had participated in the study training.

Three, five-day intervention training courses took place in August, September and October 2007. Participants consisted of 26 lay counsellors, 29 nurses, one trainer and one data capturer resulting in 57 participants in total from six intervention facilities in two sub-districts. All participants were present for the full five days training.

The groups varied in size with 10 participants in the first workshop, 39 in the second and eight in the final workshop. During training, nurses and sub-district managers were instructed to ensure that any new or untrained providers be subjected to in-service training by managers or professional nurses who had received training. Due to the high cost of training it was not cost effective for study staff to provide the training for individuals or small groups. However, a further one-day in-service training was organised in November 2007 for intervention facilities to ensure that as many staff as possible from intervention sites were exposed to training in the integrated model. This training was specifically targeted at those providers who were not able to attend earlier training sessions.

4.7 Site Description

Appendix 1 shows a summary of all twelve intervention and control facilities, showing that most facilities were rural and located in poorly developed areas.

4.8 Study population

At the 12 selected study sites the following clients were eligible for inclusion in the baseline and follow-up surveys (client exit interview and client provider observations):

- Female clients accessing FP services for the first time and those coming to the facility for a repeat visit
- Clients able and willing to provide informed consent.

Clients under the age of 18 years were excluded.

4.9 Data collection methods

4.9.1 Screening clients for eligibility

At both baseline and follow up approximately 6–8 consecutive clients per day coming to a clinic for FP services between 7 am and 4 pm on a weekday were given a sequential number as they came in to the clinic and every client screened for eligibility using a screening checklist. The number of clients recruited varied in practice from day to day due to varying client volume.

At baseline and follow up a team of three field workers was deployed at each facility for a period of two and a half weeks (13–14 working days). This was considered adequate time to achieve the desired sample size of 110 per cluster. After two weeks if facilities had fallen short of the target the data collection period was extended for a week. At the end of this period data collection was stopped regardless of sample size due to limited resources available to retain data teams in the field. Each team consisted of two field workers and one retired nurse. One field worker was responsible for screening and informed consent procedures, another for conducting exit interviews and a third, a retired nurse, responsible for conducting the client provider observations. Clients who were eligible were told about the study and their informed consent to

participate was sought. If clients were not eligible or did not give informed consent, the next consecutive client was approached.

For the baseline survey all clients observed with the provider were also interviewed following exit from consultation. The baseline survey was not conducted blind to the random allocation meaning that the randomisation process had already taken place before the baseline survey was done. However, field workers were not part of the randomisation process and training for the field workers did not include identification of which sites were intervention and control sites. All clients who were consented and observed were subsequently led to the field worker responsible for conducting the exit interview for the interview to be conducted.

At the one-year follow-up, the surveys were conducted differently. As we were not comparing information and services given by providers to client knowledge and reporting of services it was felt that at follow up it would not be essential to carry out observations and exit interviews on the same client. It was also felt that the potential for more positive provider behaviour, due to having an observer present, may positively bias the knowledge and behaviours reported in the exit interviews. Therefore in the follow up survey a mix of clients were exit interviewed, some of whom had been observed and some not. At a facility level this simply meant not linking up all observed clients with an interviewer. Blank questionnaires were coded with a colour coded sticker which indicated whether or not the client would be asked for consent for both client exit interview and client provider observations, client provider observation only or exit interview only. The blank questionnaires were arranged to consecutively have the series of the three colours so that consecutive clients were sequentially consented either to being observed and exit interviewed, exit interviewed only or observed only.

At the follow up surveys, first visit clients at intervention facilities were considered to have received services from a trained provider at intervention facilities and would have thus had some exposure to the intervention. This assumption was made as clients were seen by a trained provider during the client provider observations and interviewed on exit from the facility and would therefore have already received information and services from a provider assumed to have received training.

4.9.2 Client-provider interactions

Providers at each facility provided verbal consent to be observed; and were informed that they were not being individually evaluated. Providers were not told the nature of the information that was being collected. Client-provider observations were carried out by a trained nurse, who used a structured checklist (see Appendix 4) to document the components of the FP consultation and the elements of HIV and STI management and counselling that were covered. Retired nurses from other sub-districts were trained to conduct these observations as it was necessary to have a clinically trained observer and it was felt that engaging nurses from the same district or the same facilities may bias the observations. The trained nurse observed the provider providing FP services and used a checklist to note which actions were taken and what information was provided during each consultation. The observer was instructed not to interfere with the consultation and to complete the documentation during and immediately after the consultation.

4.9.3 Exit interviews

Exit interviews were conducted with each client by a trained interviewer to ascertain socio demographic data, client knowledge, risk behaviour, HIV testing behaviour and their perceptions of the service received.

Through the client exit interview, data on the two primary outcomes were collected. In addition information was collected on method of contraception, use of dual protection, number of times tested for HIV, their risk behaviour during the period, experience of the service, risk perception and partner notification and testing. A one-year follow up period was felt to be adequate time to allow the intervention to settle and for clients to decide whether or not to get tested and to allow exposure of clients to the intervention through more than one visit. Bearing in mind that most FP clients use injectables or oral contraceptive pills, the majority of women recruited into the study were expected to make a visit to the clinic every two to three months for resupply of contraceptives so that typically over the period of a year, a client attending regularly would have attended three to six times depending on their contraceptive method.

4.9.4 A structured inventory of supplies and equipment

An inventory of supplies and equipment for provision of integrated services was completed at baseline using a structured tool. This was to ensure that uptake levels and quality of care factors were not influenced by availability of supplies and equipment but differences attributed to the intervention itself. The study staff did not procure any supplies or equipment. However, field workers were asked to document, monitor and facilitate routine procedures to address shortages. The DOH was responsible for buying supplies and equipment. This inventory was linked to supervisory visits by project staff.

4.10 Sample size calculations

The sample size calculations for Phase 2 of the study took into account that the unit of randomisation of the intervention was the clinic. A formula for calculating the number of facilities required for comparing unmatched proportions of clusters (i.e. facilities) as described by Hayes and Bennett (Hayes and Bennett, 1999) was used:

The number of clusters per model, *c*, is given by:

$$c = 1 + f\left[\left(\frac{\pi_0(1-\pi_0)}{m}\right) + \left(\frac{\pi_1(1-\pi_1)}{m}\right) + k^2(\pi_0^2 + \pi_1^2)\right] / (\pi_0 - \pi_1)^2$$

where π_0 is the proportion with the outcome in the control arm and π_1 is the proportion with the outcome in the intervention arm, *m* is the number of individuals in each cluster (assumed equal in all clusters), and *f* is the factor depending on the required study power and type 1 error. *k* is the coefficient of variation in the true proportions between the clusters in each model.

Sample size calculations are presented for the following main outcome measures:

- Tested for HIV in the last year as reported during the exit interview
- Condom use at last sex as reported during the exit interview

A two-sided type 1 error of 0.05 is assumed throughout and a power of 80 percent has been assumed, though for some scenarios the comparison is powered at greater than 80 percent. The coefficient of variation (k) was assumed to be 0.25.

4.10.1 Primary outcome: Testing for HIV in the previous year

In the standard of care model we expected the percentage uptake of testing for HIV to range from 20 to 30 percent. Uptake of testing was estimated at 11–14 percent for antenatal populations at the time of the inception of the study – HIV testing had begun to be systematically offered to pregnant women. We thus expected that this figure would be much lower in FP populations where there was no programme currently aimed at systematically offering HIV testing to FP clients. However, baseline data from the Phase 1 study showed testing varied from 25 to 32% at baseline across the 18 facilities. We assumed at least a two-fold increase between the standard of care arm and the intervention arm, that is to 40–60%. The number of clusters in each model required for comparing the control arm versus the intervention arm, assuming 80% power and 100 women per facility was calculated as follows (note that it was planned that an extra 10 women per cluster be recruited in order to compensate for any damaged or incomplete questionnaires).

Confidence level	power	π_0	RR	π_1	Number of women/ clinic	k	# facilities per arm
0.95	**0.8**	**0.2**	**2**	0.4	**100**	**0.25**	4.24
0.95	**0.8**	**0.3**	**2**	0.6	**100**	**0.25**	3.85

** π_0 and $\pi_1$represent the expected proportion tested for HIV in the previous year in the intervention and control arms respectively. RR represents the ratio of the proportions in the two study arms; k coefficient of variation*

According to Hayes and Moulton (Hayes and Moulton, 2009), a useful rule of thumb is to regard four clusters per arm as an absolute minimum. This is because the t-test based on cluster level responses is generally the preferred method of analysis for CRTs with small numbers of clusters. However, with as few as four clusters per arm, we would not have been able to rely on parametric methods such as the t-test that require assumption of normality of cluster-level responses.

Condom use at last sex: In the standard of care model, we expected the percentage using condoms at last sex by the one-year post recruitment visit to be approximately 20% as a conservative estimate. Baseline data from the Phase 1 study showed that condom use at last sex varied from 27–45% in the three study arms. We assumed a

75% increase from the standard of care model to the intervention model, to 35%. The number of clusters in each model required for comparing the standard of care model versus the intervention model, assuming 80 percent power and ever use of condoms at a level of 20–40% was as follows:

Confidence level	power	π_0	RR	π_1	Number of women/clinic	k	# facilities/arm
0.95	**0.8**	**0.2**	**1.75**	0.35	**100**	**0.25**	5.89
0.95	**0.8**	**0.3**	**1.75**	0.525	**100**	**0.25**	5.26
0.95	**0.8**	**0.4**	**1.75**	0.7	**100**	**0.25**	4.94

** π_0 and $\pi_1$represent the expected proportion ever using condoms in the intervention and control arms respectively. RR represents the ratio of the proportions in the two study arms; k coefficient of variation*

Allocating six facilities to each study arm with a total sample size of 1 200 women for Phase 2 of the study (approximately 100 per clinic) was considered adequate to provide sufficient power to detect differences considered important in the primary outcomes.

4.10.2 Secondary outcome: Creation of quality of care scores

The BCS Plus tools (see appendices 5–16) were designed not only to improve and standardise the quality of FP services but also to ensure that HIV and STI issues are integrated into the consultation. Through discussions with programme managers and Population Council staff involved in strengthening FP services, a number of elements of the consultation were identified to incorporate into a set of scores used to determine whether key components of a consultation were provided. Client provider rapport and the provision of information on a range of methods were also considered important elements of quality and highlighted as critical elements of quality of FP services. The BCS

Plus was also designed to improve the integration of STIs and HIV information and services and scores were developed to assess STI/HIV history taking in order to identify risk behaviours as well as information provided on STIs, condom use and HIV testing. The components of these scores are described below.

These elements were included in the client provider observation tool (see Appendix 4), which was developed as a checklist that aimed to assess whether or not specific information and services relating to both FP and HIV were delivered. The data from this tool predominantly consisted of binary responses for each action or piece of information recorded as completed. Missing data were coded as “not done” as it was assumed that the observer would have recorded an action if indeed it was observed. These binary responses were added together, assuming equal weight for each question, to produce a series of scores providing a more comprehensive assessment of the quality of care provided. This approach was selected as it was agreed that this would provide a fuller picture of the quality of care as compared to selection of a few variables.

Table 4.2: Construction of quality of care scores

Name of Score:	Component: Did the provider ask about/ mention the following?
General FP (range 0-4)	• Pre-existing medical conditions • Reproductive intentions • Previous use of FP • Partner cooperation with FP
Client provider rapport (range 0-4)	• Greeted the client • Use the client's name when speaking to her • Asked the client if she understood information • Encourage the client to ask question
Number of methods (range 0-7)	• Combined pill • Progestin only pill • Injectables • Condom (male or female) • Intrauterine contraceptive device • Permanent methods • Emergency contraception
STI/HIV history taking (range 0-3)	• Current or previous history of signs and symptoms of STI • Number of sex partners • HIV sero-status
STI information (range 0-4)	• Discussion of STI • Discussion of STI risk factors • Whether the client was told to seek treatment for symptoms • STI can be asymptomatic
Dual protection and condom counselling (range 0-7)	• Correct and consistent use of condoms • Negotiation of condoms use • Condoms protects against STIs/HIV and pregnancy • Information on how to use condom • Demonstration of condom use • Information on where to get condoms • If the client was given male condoms
HIV test counselling (range 0-4) Total quality score (range 0-33)	• Mentioned HIV testing • Explain what the test can tell • Explain about the window period • Offered HIV testing to the client

4.11 Data management and analysis

Data were collected on structured forms that were pre-tested. During data collection a team of three field workers was assigned to each study clinic. Within each team one member was assigned to being the lead and ensuring that questionnaires were completed, labelled and handed over to the field supervisor who provided oversight to all study facilities for data collection. The field supervisor was based at the Population Council office in Johannesburg and would travel regularly to study facilities to provide supervision, quality checks and to return all completed questionnaires to the office. These were handed to the data manager who was responsible for setting up data entry screens for all methodologies and for supervising data entry and cleaning. Data were entered in Epi info and exported to STATA. Data were double entered and inconsistencies clarified by reviewing hard copies of questionnaires. Data cleaning was done through a combination of reviewing ranges for variables, running frequencies and descriptive tables for variables and eyeballing data. Data were analysed in STATA 11.0 (StataCorp, College Station, Texas USA) by the principal investigator (author of this thesis).

4.12 Ethical Considerations

Eligible women attending study facilities for FP services were asked for their informed consent to participate in the study and were asked if they would participate in the client exit interview and client provider observations (if relevant). In all cases potential study participants were approached and consent obtained by trained field workers. Field workers were selected if they had a matriculation certificate, were fluent in the local language and were prepared to receive a three day training prior to being deployed for data collection. All field workers completed the training which included the principles of research ethics, informed consent, confidentiality, interview techniques and the study tools. Field workers collecting data for client-provider observations were retired nurses. Written informed consent was also requested from all providers interviewed during the study. The study protocol was submitted to and approved by the University of Witwatersrand Human Research Ethics Committee (HREC) Protocol Ref M070255 (see Appendix 16)

4.12.2 Informed consent

Eligible clients were provided with the following information in the local language as part of informed consent:

- Objective of the study
- Study requirements: completion of questionnaire and observation during consultation
- Explanation that:
  - Study participation is entirely voluntary and withdrawal is possible at any time without having to give a reason.
  - Refusal to participate will not affect the services they receive at the health facility in any way
  - Sensitive questions regarding sexual behaviour, partners and condom use will be asked, though they may choose not to answer any questions
  - Questionnaire administration will increase time at clinic
  - All research records will be kept confidential and that only the study team will have access to this information.
  - Their names will not be used to identify them in any report of the study findings
  - No information will be divulged to partners or other third parties
  - No monetary compensation will be provided
- Contact details of the study coordinator for any questions or concerns

It was recognised that some of the information collected and discussed during the client exit interview would be of a personal and sensitive nature. As part of the procedure for ensuring the respondent's informed consent, each respondent was informed that issues on sexual partners and behaviour, and diagnosis of STIs, would be discussed during the interview and asked if they may be concerned that this might put them at risk. In addition, each respondent was informed that they need not answer all questions and that all answers would be treated with the strictest confidentiality. During training, interviewers were provided with skills on handling sensitive topics. Their training included a strong emphasis on putting the client at ease when asking sensitive questions and the need to maintain confidentiality. Particular attention was paid to ensuring that translations of questions into the local language took into account the need for accurate yet sensitive language.

4.12.3 Informed consent for C&T

When providing training to heath care providers as part of the study intervention the Department of Health HIV/AIDS policy guidelines on HIV testing were used and provided the following guidance on informed consent for pre-test and post-test counselling:

Testing for HIV at all health care facilities will be carried out with informed consent, which includes pre-test counselling. The information regarding the result of the test must remain fully confidential, and may be disclosed in the absence of an overriding legal or ethical duty only with the individual's fully informed consent.

In the context of HIV/AIDS, testing with informed consent means that the individual has been made aware of and understands the implications of the test. Consent in this context means the giving of express agreement to HIV testing in a situation devoid of coercion in which the individual should feel equally free to grant or withhold consent. Written consent should be obtained where possible.

4.12.4 Confidentiality

Once enrolled into the study clients were given a study number, which identified them. The names and corresponding study numbers were linked in one file. This file was only accessible to the study team. Names and study numbers only appeared together on the first sheet of the questionnaire. This sheet was detached from the rest of the questionnaire and entered in a separate password protected data set. All the remaining pages of the questionnaire only indicated the participant study number. Field workers did not ask clients to disclose their HIV sero-status.

Study questionnaires were kept in a locked cabinet at the Population Council offices in Johannesburg.

4.12.5 Compensation

Women participating in the study were not offered monetary compensation.

4.12.6 Risks and benefits

Participants were informed that the questions asked may be of a sensitive nature and that there may be a risk of discomfort or distress as a result. Women testing positive for HIV as part of the study intervention were referred for ARV assessment and treated according to the then current standards of care for primary level facilities according to clinical staging (Modi, 2008).

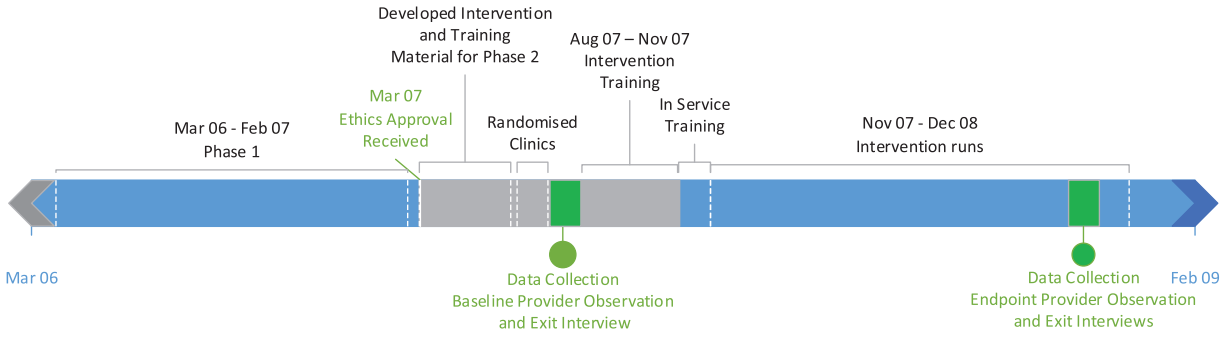
Those found positive or negative for HIV were counselled on safer sex practices, and provided with condoms and information on the implications of both positive and negative HIV results in terms of the need for retesting. All clients testing HIV positive were still exposed to safer sex information at the FP visit.

4.13 Statistical analysis plan

4.13.1 Description of the participant flow, timelines

Numbers of eligible and participating clusters, and sample sizes for the Phase 2 baseline and follow up surveys for each methodology were described to provide an overview of the study design and number of participants. The participant flow was described using a schematic diagram in line with CONSORT guidelines (Campbell et al., 2012) recruitment dates, training to implement intervention and sample sizes were also highlighted on the diagram. Sample sizes for both methodologies used (client provider observations and client exit interviews) were also presented by facility at baseline and at follow up to show the contribution of each facility to the total sample size.

Figure 4.2: Study Phase 2 Timeline



4.13.2 Describing the baseline characteristics of study population

In order to assess comparability of the study population in the two study arms at baseline, characteristics of individuals in the intervention and control groups were described using the data from the baseline client exit interviews. Client socio-demographic characteristics (age group, education, relationship status, number of pregnancies) were described. Fertility intentions, purpose of the visit (new FP user, repeat user, switching methods), risk indicators (such as multiple sexual partners and condom use) as well as experience of testing (ever tested for HIV) were also compared in the two study arms. These data were presented by study arm and pooled. Data were examined to identify large imbalances and no statistical tests for differences were conducted in line with good practice for the analysis of clinical trials.

4.13.3 Comparing primary endpoints at baseline

Baseline data on the primary endpoints of testing for HIV and condom use at last sex, measured using the client exit interview data, were compared across the two study arms. Data were tabulated showing proportions including raw data by cluster, overall proportions within the two study arms and the means of the cluster proportions. It should be noted that for HIV testing the baseline data on “ever tested for HIV” was used as data on the actual primary outcome of testing for HIV in the previous year were only collected during the follow up survey. All characteristics were compared by arm of the trial to ensure comparability. This assessment was *not* based on the results of significance tests, and p-values were not reported.

4.13.4 Comparing secondary endpoints at baseline

As described earlier in this chapter, a number of ‘quality of care’ scores were developed to assess key aspects of the services provided. Using data from the client provider observations at baseline, the mean scores for each of the seven individual scores (general history taking, client provider rapport, number of methods discussed, STI/HIV history taking, STI information provided, dual protection and condom counselling and HIV test counselling) and the total quality score combining the seven individual scores were presented for the intervention and control arms. As with the baseline data on primary outcomes this assessment was *not* based on the results of significance tests, and p-values were not reported.

In order to compare facilities and assess variability between facilities the total quality score combining all scores was presented by cluster and by study arm. The total sample size for each cluster, mean score and standard deviation for each facility (cluster) were also presented as was the mean score and mean of cluster means with standard deviation by intervention and control arms.

4.13.5 Assessing factors associated with baseline measures of primary outcomes

A number of variables that may be associated with testing for HIV and with condom use at last sex were cross-tabulated with these outcomes (measured at baseline) and analysed by logistic regression. The variable for facility (cluster) was included in all models, as a fixed effect, to adjust for this variable. Variables giving a p-value of less than 0.05 using the likelihood ratio test (LRT) were considered significantly associated with the outcome. Crude and age adjusted ORs for the association of each variable with the two primary endpoints were tabulated. For each primary endpoint a table showing the associated factors, raw data, crude and age adjusted odds ratios with 95% confidence intervals and p values was reported. Where relevant, tests for trend were also presented. For each endpoint, a final model was obtained by including age, facility and all variables showing a statistically significant association in the age-adjusted analysis.

4.13.6 Assessing baseline characteristics of a retrospectively identified cohort

The retrospectively identified cohort consisted of women who were interviewed during the follow up survey and who had also been interviewed at baseline. The socio-demographic baseline characteristics of the retrospectively identified cohort were presented and compared to the overall study population to identify whether clients known to have been attending FP services during the baseline and follow up surveys were representative of the overall study population or had differentiating characteristics. As with the baseline comparison of client socio demographic characteristics a similar table showing age group, education, relationship status, and number of pregnancies was presented. Fertility intentions, purpose of the visit (new FP user, repeat user, switching methods), risk indicators (such as multiple sexual partners and condom use) as well as experience of testing (ever tested for HIV) were

also compared in the two study arms. These data were presented by study arm and pooled.

4.13.7 Comparing primary outcomes at follow up across study arms

This was the main analysis of the study results and data from client exit interviews at follow up were used for this analysis. Overall proportions in the intervention and control arms were presented for the two primary endpoints (testing for HIV in the previous year and condom use at last sex). Data were collapsed to calculate cluster proportions and the unpaired t-test was used to obtain a p-value for the comparison between study arms. The means of the cluster proportions in the intervention and control arms were used to estimate the relative risk (*RR*) and an approximate 95% confidence interval for the RR was calculated as follows:

$$RR = \frac{\overline{p_1}}{\overline{p_0}}$$

Where $\overline{p}_1$ and $\overline{p}_0$ are the means of the cluster proportions for the intervention and control arms, respectively.

$$V = \frac{{s_1}^2}{6\overline{p_1}^2} + \frac{{s_0}^2}{6\overline{p_0}^2}$$

The variance of the log (*RR*) is calculated using the above formula where s_1 and s_0 are the sample standard deviations of the cluster proportions in the intervention and control arms, respectively and 6 is the number of clusters in each study arm.

Then the 95% confidence interval was calculated using:

$$\log(RR) \pm t_{10,0.025} \times \sqrt{V}$$

An adjusted cluster level analysis was conducted for HIV testing in the previous year and adjusting for baseline cluster means for “ever tested for HIV”. A two-stage method was used.

In the first stage, we carried out a standard logistic regression analysis of the outcome of interest, at the individual level, which incorporated all covariates except the intervention effect. After fitting the regression model, we compared the fitted and

observed values by computing a residual for each cluster using the ratio of observed to predicted. In the second stage of analysis, we compared the residuals between treatment arms.

A point-estimate of the intervention effect was calculated:

Adjusted risk ratio = $\frac{\bar{R}_{r1}}{\bar{R}_{r0}}$

Where $\bar{R}_{ri}$ is the arithmetic mean of the ratio-residuals for the clusters in the ith treatment arm. The unpaired t test was applied to the cluster-level residuals, R_{rij} to test the significance of the difference between treatment arms. An approximate 95% confidence interval for the adjusted risk ratio was obtained using the error factor:

EF = $\exp(t_{v,0.025} \times \sqrt{V})$

Where

$$V = \frac{{s_1}^2}{c_1 \overline{R_{r1}}^2} + \frac{{s_0}^2}{c_0 \overline{R_{r0}}^2}$$

In this equation, s_i^2 is the empirical variance of the observed cluster-level residuals in the ith treatment arm.

Cluster proportions of each of the two primary endpoints were displayed by study arm graphically by plotting the proportions for each of the twelve facilities in both study arms.

4.13.8 Comparing secondary outcomes at follow up

This analysis utilised data from the client provider observations at follow up. Quality of care scores for each of the seven scores and total quality score were presented. Mean intervention and control scores with standard deviation and mean differences between each of the scores in the intervention and control arms were presented with 95% confidence intervals and p values. Cluster proportions for total quality score by study arm were also represented graphically by plotting the proportions for each of the twelve facilities in both study arms.

4.13.9. Analysis for effect modification

In order to examine whether the effect of the intervention differed between subgroups we examined the effect of the intervention by age group, educational status and relationship status. We then tested if these variables were effect modifiers by testing whether there is an interaction between the intervention effect and the covariate. We converted each of the three variables (age, educational status and relationship status) into binary variables and used the following:

Suppose the proportion with the outcome in the kth subgroup (k=0 or 1) in the jth cluster in the ith treatment arm is denoted as p_{ijk}. The interaction effect can be estimated by:

$$\sum \frac{\log (p_{1j1}) - \log (p_{1j0})}{6} - \sum \frac{\log (p_{0j1}) - \log (p_{0j0})}{6}$$

We perform a test for interaction using a t-test on the cluster level differences. This also provided a confidence interval for the interaction effect.

For these analyses age, relationship status and educational status were re-categorised as dichotomous variables. Age was divided into those aged 30 and younger and those aged greater than 30 years. Relationship status was divided into married and not married, and educational status into those who had completed primary education and those not having completed. For each primary endpoint cluster means for the re-categorised groups of age, relationship and educational status were compared in the intervention and control arms. Overall proportions and raw data were presented as were risk ratios with 95% confidence intervals and p values for interaction.

4.13.10 Sub group analysis of nested cohort

Sub group analysis on the cohort of clients retrospectively identified was conducted. Analyses outlined earlier for the comparison of primary endpoints were replicated for the retrospectively identified cohort of FP clients interviewed as part of both the baseline and follow up surveys. This analysis was conducted because it was expected that these FP clients would have had the opportunity for repeated exposure to the intervention during the year and therefore the opportunity for larger behaviour change

outcomes. There is no reason to expect that these clients would have received better quality of care and therefore the subgroup analysis on the cohort of clients was only conducted for primary study endpoints. All of these clients are by definition repeat clients.

4.13.11 Assessing the effect of the intervention tools on quality of care

Exposure analyses to assess the effect of use of the intervention tools on the quality of care were presented using data from the six intervention facilities. A cluster level analysis of the degree of observed use of the BCS Plus tools was regressed against individual quality of care scores and against total quality of care score. The regression analysis was conducted with a single independent variable, the observed level of utilisation of the BCS Plus tools. The r^2 statistic (square of the correlation coefficient) for each score was calculated. This statistic is a measure of the proportion of variation in the dependent variable (in this case each quality of care score) that is explained by variation in the observed use of the intervention tools. Regression coefficients with 95% confidence intervals and p value were also calculated.

4.13.12 Assessing the relationship between use of intervention tools and primary outcomes

Relationship between use of the tools (exposure analysis) and primary outcomes was explored through a similar regression analysis with cluster level data described above using data from all six intervention facilities.

4.13.13 Assessing the relationship between total quality of care and primary outcomes

For this regression analysis data on the total quality of care score for all 12 study facilities was regressed against the two primary outcomes. R squared, regression coefficients with 95% confidence intervals and p values were presented.

4.13.14 Assessing factors associated with primary outcomes at follow up

Similar to the process described above for assessing factors associated with primary endpoints at baseline, a number of variables that may be associated with testing for HIV and with condom use at last sex were listed and analysed by logistic regression. The variable for facility (cluster) was included in all models to adjust for this variable.

Variables giving a p-value of less than 0.05 using the likelihood ratio test (LRT) were considered significantly associated with the outcome. Crude and age adjusted factors associated with the two primary endpoints were tabulated. For each primary endpoint a table showing the associated factors, raw data, crude and age adjusted odds ratios with 95% confidence intervals and p values was reported. Where relevant, trend analyses were also presented. For each endpoint, a final model was obtained by including age, facility and all variables showing a statistically significant association in the age-adjusted analysis.

Chapter 5: RESULTS: OVERVIEW AND BASELINE RESULTS

5.1 Chapter overview

This chapter will provide an overview of the study cluster identification and participant flow, dates defining periods of recruitment and follow up and the numbers analysed, using the CONSORT guidelines for reporting of cluster randomised trials (CRT) (Campbell M. Et al; 2004). The details of study methodologies and sampling have been presented in Chapter 4. This will be followed by a second section which provides a description of the baseline characteristics of the study population specifically comparing baseline characteristics between the intervention and control arms. This chapter will also include the description and baseline comparison of the two primary outcomes. Several quality of care scores created to assess FP and HIV quality of care will also be compared at baseline. In order to identify factors associated with the two primary endpoints for this study a crude and age-adjusted risk factor analysis for two outcomes (Ever testing for HIV and condom use at last sex) will be presented. Since data on testing in the preceding year were not collected during the baseline survey, factors associated with previous testing for HIV irrespective of time frame were considered. Results at follow-up examining the impact of the intervention will be presented in Chapter 6.

5.2 Cluster selection

The study was carried out in 12 facilities in two sub-districts as described in Chapter 4, section 4.3. A summary table describing selected characteristic of the study facilities including access, location, population served and distances from urban centres is provided in Appendix 1.

5.3 Data collection from individuals attending facilities

Between 4th April and 18th May 2007 all consecutive individuals attending intervention and control facilities to receive FP services and fulfilling the study inclusion criteria for recruitment were provided with information on the study and provided informed consent to participate in the study. Training was conducted between 9th July and 3rd August 2007 and a follow up survey was conducted between 18th February and 3rd

May 2007 using the same approach as for the baseline survey. Details on the study methods and data collection methodologies have been described in Chapter 4.

Figure 5.4: Flow diagram of progress of clusters and individuals through the study

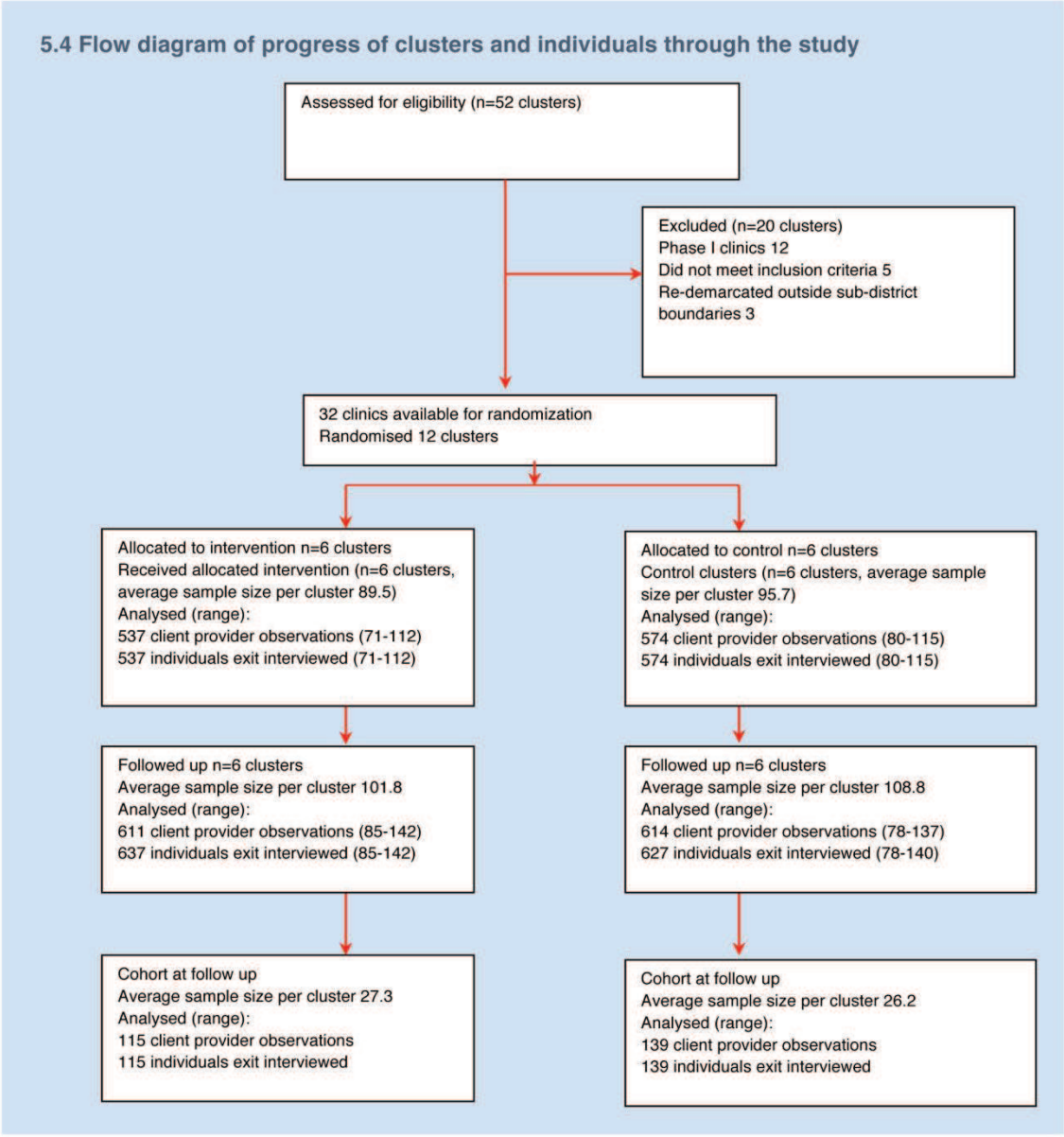


Figure 5.4 shows the numbers of participants for each of the two methodologies (client provider observations and client exit interviews) at baseline and follow up as well as the number of clusters, all 12 of which were included up to the end of the study. Given this study design, the majority of clients in the baseline and follow up surveys were not the same individuals. However, a proportion of clients (approximately 20% of the total sample at follow up) who were included in the baseline survey were also captured in

the follow up survey. These clients formed a retrospectively identified nested cohort within the main study and are analysed as a sub group.

A sample size of 1200, that is, 100 clients per clinic had been calculated for the follow up surveys (see Chapter 4). However, due to difficulties in recruitment of clients in some of the smaller facilities this sample size was not reached for all clusters. Table 5.1 summarises the sample sizes for each of the study components at baseline and follow-up by clinic.

Table 5.1: Sample sizes for client provider observations and exit interviews by clinic at baseline and follow up

	Client Provider Observations		Exit Interviews	
Facility	**Baseline**	**Follow up**	**Baseline**	**Follow up**
Intervention				
Lebotloane	112	115	112	116
Maubane	110	142	110	142
Bosplaas	98	87	98	87
Tlaseng	64	74	64	74
Thekwana	82	107	82	107
Chaneng	71	85	71	85
Total	***537***	***610***	***537***	***610***
				Control
Mogogelo	115	98	115	98
Leseding	103	137	103	138
Ngobi	110	78	110	78
Rankelenyane	78	95	78	95
Karlien Park	88	104	88	104
Monakato	80	101	80	140
Total	***574***	***524***	***574***	***653***

**CPO – client provider observations EI-exit interviews*

In general, the client provider observation and exit interview numbers for each facility were very similar at follow-up as the vast majority of clients who were observed were also invited for exit interview on the days where data collection took place. However, the only exception was Monokato clinic where a significantly higher number of clients were exit interviewed compared to those observed.

5.4 Comparison of baseline characteristics for the study population

Table 5.2 below compares baseline data in the two study arms from client exit interviews. The table shows that, in general, the women in the intervention and control arms were very similar in terms of their socio-demographic, fertility and HIV risk indicators. A higher proportion of women under the age of 20 were seen in the control facilities. A lower proportion of women in the control arm reported more than one partner in the preceding year. Of concern, was the high proportion of women (approximately half the group) who reported that their last pregnancy was unwanted, a large proportion of whom reported being on a contraceptive method at the time which raises questions regarding compliance with their chosen method of contraception. However, questions on compliance were not asked during the exit interviews. Previous testing for HIV was reported by approximately half of the women. A larger proportion of women in the control facilities had previously tested for HIV (58%) compared to intervention facilities (49%). Considering that many of these women had previous pregnancies it is possible that some of the testing could have taken place through Prevention of Mother to Child (PMTCT) programmes which were introduced in the public sector in 2001 in South Africa.

Table 5.2: Baseline client Socio-demographic and risk factors by study arm and collapsed by cluster

General Socio-economic indicators:	*N*	Pooled % (N=1,111)	Intervention % (N=537)	Control % (N=574)
Age				
< 20	58	5.3	4.9	6.9
20 - 29	535	54.7	54.2	55.0
30 - 39	256	26.1	27.5	24.8
≥ 40	130	13.3	13.3	13.3
Education				
Incomplete Primary	225	20.7	21.0	20.4
Complete Primary	762	70.0	68.9	71.0
Secondary and above	102	9.4	10.1	8.7
Marital Status				
Married	273	21.5	25.5	24.6
Cohabiting	348	31.9	34.3	29.7
Other	469	43	40.2	45.7
Number of Pregnancies				
None	111	10.0	8.5	11.3
One	405	36.5	34.8	38.0
Two	288	25.9	26.1	25.8

Three	164	14.8	17.1	12.5
Four or more	143	12.9	13.4	12.4
FP Related Indicators:				
Purpose of Visit:				
New client	136	12.6	10.3	14.7
Repeat client	819	75.6	76.2	75.0
Switching client	73	6.7	7.2	6.3
Defaulter client	55	5.1	6.3	4.0
Method use:				
Pill	*356*	33.3	33.1	33.4
Injectable	556	51.5	53.3	49.8
IUCD	0	0	0	0
Condom	0	0	0	0
Last pregnancy unwanted	556	51.5	53.9	49.1
Contraceptive during last conception	324	29.2	31.8	26.6
Risk indicators				
Ever tested for HIV	596	53.7	49.0	58.0
Condom use at last sex	379	34.1	32.2	35.9
Use condom with method	542	48.8	47.7	49.8
Reported more than one partner	119	10.7	13.0	8.5
Intends to have another child	458	41.2	40.0	42.3

5.4.1 Baseline comparison of behavioural indicators defining the primary outcomes of the study

Baseline comparisons of the two primary behavioural outcomes are presented below. Previous testing for HIV was overall 49% in the intervention arm and 58% in the control arm. There was a large degree of variation by cluster in each of the study arms ranging from 35.9% to 58.9% in the intervention arm and 46.6% to as high as 70% in the control arm at baseline.

Table 5.3: Summary of reporting ever tested for HIV at baseline, by cluster and intervention arm (n=1,111)

Intervention			Control		
Site	%	n/N	Site	%	n/N
Tlaseng	35.9	23/64	Leseding	46.6	48/103
Chaneng	42.3	30/71	Karlien Park	54.6	48/88
Bosplass	40.8	40/98	Mogogelo	68.7	79/115
Lebotlwane	58.9	66/112	Ngobi	70.0	77/110
Maubane	50.9	56/110	Rankelenyane	53.9	42/78

Thekwane	58.5	48/82	Monokato	48.8	39/80
Overall %	49.0 (263/537)			58.0 (333/574)	
Mean cluster* (sd) %	47.9 (9.7)			57.1 (10.0)	

*(Data Source: Follow up client exit interviews)*arithmetic mean of cluster proportions sd standard deviation; CI confidence interval*

Condom use at last sex was also compared by cluster and also showed large variation by facility although overall proportions were very similar in the two study arms, 32.2% in the intervention arm compared to 35.9% in the control arm.

Table 5.4: Summary of reporting condom use at last sex at baseline by cluster and intervention arm (n=1,111)

Intervention			Control		
Site	%	n/N	Site	%	N
Tlaseng	39.1	25/64	Leseding	34.0	35/103
Chaneng	32.4	23/71	Karlien Park	19.3	17/88
Bosplass	24.5	24/98	Mogogelo	42.6	49/115
Lebotlwane	27.7	31/112	Ngobi	33.6	37/110
Maubane	39.1	43/110	Rankelenyane	35.9	28/78
Thekwane	32.9	27/82	Monokato	50.0	40/80
Overall %	32.2 (173/537)			35.9 (206/574)	
Mean Cluster* (sd) %	32.6 (5.9)			35.9 (10.3)	

*(Data Source: Follow up client exit interviews)*arithmetic mean of cluster proportions; sd standard deviation; CI confidence interval*

5.4.2 Baseline comparison of quality of care scores

The creation of the quality of care scores has been described in Chapter 4. The following table shows the comparison of scores at baseline by each type of score and the total quality score.

Table 5.5: Summary of quality of care scores at baseline by study arm

Quality of care scores (range of score)	**Mean* Intervention (sd) (n=537)**	**Mean Control (sd) (n=574)**
General FP History Taking (0-4)	1.78 (0.81)	1.50 (1.25)
Client Provider Rapport (0-4)	2.89 (0.87)	2.78 (0.92)
Number of FP Methods (0-7)	1.99 (1.07)	2.30 (1.69)
STI/HIV History Taking(0-3)	1.09 (0.79)	0.72 (1.10)
STI Information Score (0-4)	1.73 (1.12)	1.23 (1.42)
DP and Condom Counselling (0-7)	1.99 (2.13)	2.25 (2.44)
HIV Test Counselling (0-4)	1.41 (1.01)	1.29 (1.49)
Total quality (0-33)	12.90 (8.65)	12.1 (9.63)

*(Data source: Follow up client provider observations) sd-standard deviation *arithmethic mean of cluster means*

Table 5.5 above shows that quality of care was generally low and highly variable across all scores for both FP and HIV related services at baseline. Individual scores were generally low and similar across both study arms.

Table 5.6: Total quality score by cluster at baseline

Intervention				Control			
Facility	N	Mean Score	sd	Facility	N	Mean Score	sd
Bosplass	96	3.6	(2.4)	Monokato	80	4.79	(2.47)
Thekwane	82	17.8	(3.7)	Karlien Park	86	5.13	(2.18)
Maubane	106	17.3	(3.3)	Ngobi	110	29.22	(4.18)
Chaneng	70	8.1	(4.8)	Rankelenyane	75	14.36	(6.74)
Tlaseng	64	10.0	(2.4)	Mogogelo	110	4.8	(1.37)
Lebotloane	111	20.6	(3.5)	Leseding	101	14.31	(3.62)
Mean of cluster means	12.9 (6.7)			12.1(9.6)			

(Data source: Follow up client provider observations)

Total quality score showed a large degree of variability both within facilities as shown by the large standard deviations and between facilities within each study arm. Overall, total quality of care was similar in the two groups.

5.5 Baseline factors associated at baseline with reported condom use at last sex and ever tested for HIV

All factors considered to be potentially associated with the two primary endpoints were entered into a logistic regression model to identify which of these factors was associated with condom use at last sex and ever tested for HIV at baseline. Variables giving a likelihood ratio test (LRT) p value of less than 0.05 were considered to be significantly associated with the outcome. Cluster (facility) was included as a factor in each model.

5.5.1 Condom use at last sex

Table 5.7 shows the risk factor analysis for condom use at last sex at baseline. Age was significantly associated with condom use, with older women less likely to report condom use. Women 20-29 years had the highest likelihood of using a condom at their

last sexual encounter compared to those aged under 20. Those aged 30-39 years were 0.76 times as likely to report condom use at last sex compared to those aged under 20 while those above the age of 40 were least likely (OR 0.37)($p<0.001$). The test for trend was significant showing decreasing condom use with increasing age.

After adjustment for age, relationship status, partner testing for HIV, number of pregnancies, number of partners in the last year and self-perceived risk of STI/HIV remained significantly associated with condom use at last sex. Married women were least likely to report condom use at last sex. Cohabiting women were 1.53 times more likely than married women to report using a condom at last sex and single women were the most likely to report condom use at last sex being 2.15 times more likely than married women to report using condoms. Women who reported that their partner had tested for HIV were 1.61 times more likely than women who reported that their partners had not tested to report condom use at last sex. Women who had not been pregnant before were more likely to report condom use at last sex, women with one pregnancy were 0.72 times as likely to report condom use and women with two and three pregnancies were 0.49 times as likely to report condom use at last sex. The test for trend was significant with condom use being less likely to be reported with increasing pregnancies. This could suggest that (as expected) low condom use is associated with an increased number of pregnancies.

It was encouraging to see that women who reported higher numbers of sexual partners were increasingly more likely to have used a condom at last sex. Those that reported one partner were more than double (OR 2.48), and those that reported two (OR 4.79) and three or more partners (OR 4.32) were more than four times more likely to use a condom at their last sexual encounter compared to those with no partners. Conversely, however, high self-perceived risk of HIV was significantly associated with a decreasing likelihood of condom use at last sex with those reporting high self-perceived risk of STI/HIV 0.70 times as likely to report condom use at last sex.

Number of times tested and number of partners in the last year showed significant trends (see table 5.7). Increasing number of times tested and increasing number of sexual partners reported in the last year were associated with increased reporting of condom use at last sex.

The final adjusted model including only those variables significantly associated with condom use after adjustment for age showed that married women were least likely to report condom use at last sex: cohabiting women were 1.58 times more likely than married women to report condom use at last sex and single women were twice as likely to report condom use at last sex (OR 2.03) as compared to married women. Those reporting that their partners tested for HIV were 1.71 times more likely to report using condoms at last sex. Number of pregnancies also remained significantly associated with condom use at last sex with increasing number of pregnancies being associated with lower self-reported condom use at last sex. Number of partners in the last year did not remain significantly associated with condom use at last sex in the adjusted model (p=0.07). Self-perceived high risk of STI/HIV remained significantly associated with lower condom use at last sex (OR 0.66) suggesting that the high self-perceived risk may be as a result of low condom use.

Table 5.7: Risk factor analysis of factors associated with condom use at last sex at baseline

Condom use at last sex	**No/Total**	**%**	**Crude OR**	**Age Adjusted OR**	**95% CI**	**Adjusted OR**	**95% CI**
Relationships							
Married	64/273	23.44	1.00	1.00	p<0.00	1.00	p=0.02
Cohabit	121/348	34.77	1.70	1.53	(1.03-2.25)	1.58	(1.06-2.34)
Single, Div, Wid	194/469	41.36	2.54	2.15	(1.45-3.19)	2.03	(1.36-3.04)
Age Group							
<20	51/124	41.13	1.00				
20-29	224/585	38.29	1.11				
30-39	80/272	29.41	0.76				
>40	24/130	18.46	0.37				
			*pT = p<0.001				
Education Status							
Incomp	59/225	26.22	1.00	1.00	p=0.16		
Primary	281/762	36.88	1.67	1.38	(0.96-1.98)		
Complete Primary	38/102	37.25	1.84	1.54	(0.89-2.64)		
Sec & Above							
Intention to have more children							
No	212/653	32.47	1.00	1.00	p= 0.59		
Yes	167/458	36.46	1.20	0.23	(0.07-1.22)		

Condom use at last sex	No/Total	%	Crude OR	Age Adjusted OR	95% CI	Adjusted OR	95% CI
Previous testing for HIV							
No	157/515	30.49	1.00	1.00	p= 0.16		
Yes	222/596	37.25	1.36	1.21	(0.93-1.58)		
No of times tested							
None	157/514	30.54	1.00	1.00	p=0.13		
One	127/360	35.28	1.24	1.10	(0.82-1.49)		
Two	59/160	36.88	1.32	1.18	(0.80-1.74)		
Three or more	36/77	46.75	2.06	1.83	(1.11-3.04)		
			*pT = 0.00				
Partner tested for HIV							
No	237/774	30.62	1.00	1.00	p= 0.00	1.00	p<0.00
Yes	142/337	42.14	1.71	1.61	(1.22-2.14)	1.71	(1.28-2.29)
No of pregnancies							
None	49/111	44.14	1.00	1.00	p= 0.03	1.00	p=0.05
One	161/405	39.75	0.88	0.72	(0.46-1.15)	0.60	(0.36-0.99)
Two	85/288	29.51	0.54	0.49	(0.29-0.81)	0.41	(0.24-0.70)
Three	44/164	26.83	0.47	0.49	(0.28-0.88)	0.39	(0.12-0.72)
Four or more	40/143	27.97	0.51	0.72	(0.39,1.35)	0.47	(0.25-0.88)
			*pT = p=0.00				
No of partners in last year							
None	4/20	20.00	1.00	1.00	p= 0.01	1.00	p=0.07
One	317/972	32.61	2.26	2.48	(0.79-7.79)	2.89	(0.91-9.14)
Two	42/86	48.84	4.89	4.79	(1.42-16.22)	5.33	(1.57-18.11)
Three or more	16/33	48.48	4.52	4.32	(1.13-16.50)	5.93	(1.53-22.97)
			*pT = p=0.00				
Self-perceived high risk of STI/HIV	278/754	36.87	1.00	1.00	p= 0.02	1.00	p=0.01
No	101/357	28.29	0.74	0.70	(0.52-0.94)	0.66	(0.49-0.89)
Yes							
Contraceptive Category							
None	46/158	29.11	1.00	1.00	p=0.74		
Injectable	187/532	35.15	1.20	1.18	(0.78-1.76)		
Oral	119/344	34.59	1.22	1.14	(0.74-1.74)		

*Test for trend p-value

5.5.2 Previous testing for HIV

Table 5.8 shows the risk factor analysis previous testing for HIV at baseline. Age was significantly associated with previous testing for HIV. Increasing age was associated with lower self-reported testing for HIV. After adjusting for age, educational status, condom use in the last month, partner testing for HIV and number of pregnancies remained significantly associated with having previously tested for HIV.

With increasing levels of education women were more likely to have been previously tested for HIV. Those with primary education were 1.38 times and those with secondary or higher were 1.95 more times more likely than women with no education to have tested for HIV (p=0.03). Those reporting condom use in the last month were also more likely to have tested for HIV (OR 1.30, p=0.05).

The more pregnancies a woman reported the significantly more likely she was to have been previously tested for HIV than those who had no pregnancies, both before and after adjusting for age (p<0.001) There was clearly strong confounding between number of pregnancies and age. After age adjustment there was a strong relationship between pregnancies and HIV testing, with HIV testing increasing with number of pregnancies. This may be as a result of testing during pregnancy within the PMTCT programme. Partner testing was also associated with a greater likelihood of previous testing of HIV. Those whose partners tested were almost four times more likely to have tested previously (OR 3.85, P<0.001). Although this may be due to reverse causality as it is unknown whether the partner tested before or after the woman.

Educational category and number of pregnancies showed significant trends (see Table 5.8) with increasing educational attainment and increasing number of pregnancies both associated with a higher likelihood of having previously tested for HIV.

In the final adjusted model which included educational status, condom use in the last month, partner testing for HIV and number of pregnancies. Only partner testing (p<0.001) and number of pregnancies (p<0.001) remained significantly associated with having previously tested for HIV.

Table 5.8: Baseline analysis of factors associated with previous testing for HIV

Previous HIV testing	No	%	Crude OR	Age Adjusted OR (95% CI)	Adjusted OR (95% CI)
Relationships					
Married	141/273	51.65	1.00	1.00 p=0.45	
Cohabit	184/348	52.87	1.09	0.85 (0.59-1.22)	
Single, Div, Wid	271/469	57.78	1.15	0.80 (0.55-1.15)	
Age Group					
<20	72/124	58.06	1.00		
20-29	351/585	60.00	1.08		
30-39	138/272	50.74	0.32		
>40	35/130	26.92	0.47		
			*pT = p<0.00		
Education Status					
Incomp Primary	98/225	43.56	1.00	1.00 p= 0.03	1.00 p=0.09
Complete Primary	431/762	56.56	1.73	1.38 (0.99-1.93)	1.37 (0.95-1.97)
Sec & Above	67/102	65.69	2.54	1.95 (1.15-3.32)	1.73 (0.97-3.10)
			*pT = p<0.001		
Intention to have more children					
No	328/653	50.23	1.00	1.00 p=0.89	
Yes	268/458	58.52	1.34	1.02 (0.78-1.34)	
Condom use at last sex					
No	374/732	51.09	1.00	1.00 p=0.15	
Yes	222/379	58.58	1.36	1.22 (0.93,1.59)	
Condom use last month					
No	325/652	49.85	1.00	1.00 p= 0.05	1.00 p=0.08
Yes	271/459	59.04	1.46	1.30 (1.01-1.68)	1.28 (0.97-1.68)
Use of condom with contraceptive					
No	279/569	49.03	1.00	1.00 p= 0.14	
Yes	317/542	58.49	1.40	1.21 (0.94-1.57)	

Previous HIV testing	No	%	Crude OR	Age Adjusted OR (95% CI)	Adjusted OR (95% CI)
Ever use of condom					
No	194/387	50.13	1.00	1.00 p= 0.17	
Yes	402/703	57.18	1.36	1.21 (0.92-1.58)	
Partner tested for HIV					
No	346/774	44.70	1.00	1.00 p <0.001	1.00 p<0.00
Yes	250/337	74.18	4.15	3.85 (2.84-5.24)	3.86 (2.82-5.29)
No of pregnancies					
None	26/111	21.62	1.00	1.00 p < 0.001	1.00 p<0.00
One	257/405	63.46	5.87	5.39 (3.16-9.08)	4.96 (2.89-8.54)
Two	159/288	55.21	4.38	5.13 (2.90-9.07)	3.94 (2.26-6.90)
Three	92/164	56.09	4.54	7.22 (3.82-	4.19 (2.29-7.68)
Four or more	62/143	43.36	2.67	6.19 13.67) (3.13- 12.27)	2.96 (1.56-5.62)
				*pT = p<0.001	
No of partners in last year					
None	7/20	35.00	1.00	1.00 p= 0.11	
One	526/972	54.12	2.45	2.40 (0.90-6.37)	
Two	49/86	56.98	2.83	2.35 (0.81-6.82)	
Three or more	14/33	42.42	1.61	1.27 (3.13-12.27)	
Self-perceived high risk of STI/HIV					
No	391/754	51.86	1.00	1.00 p= 0.08	
Yes	205/357	57.42	1.37	1.29 (0.97-1.71)	
Contraceptive Category					
None	89/158	56.33	1.00	1.00 p= 0.06	
Injectable	260/532	48.87	0.98	0.91 (0.62-1.34)	
Oral	167/344	48.55	0.76	0.67 (0.45-1.00)	

5.6 Description of retrospectively identified cohort at baseline

A retrospectively identified cohort of FP attendees assumed to have been receiving services regularly during the study period is described in the table 5.9 below.

Table 5.9: Cohort: Baseline client socio-demographic characteristics by study arm

Variable	Pooled Study Population (N=1,111) %	Pooled (N=254) %	Intervention (N=115) %	Control (n=139) %
Age(yrs)				
<20	5.3	5.0	3.7	6.6
20-39	54.7	45.9	43.5	50.0
30-49	26.1	29.0	32.6	26.5
>40	13.3	20.1	20.3	16.9
Education				
Incomplete Primary	20.7	19.1	15.3	23.1
Complete Primary	70.0	73.0	73.0	73.1
Secondary and above	9.4	7.8	11.7	3.9
Relationship Status				
Married	21.5	24.8	25.2	24.4
Cohabiting	31.9	34.2	36.2	32.1
Other	43	41.1	38.7	43.6
Number of pregnancies				
None	10.0	6.3	4.9	7.7
One	36.5	36.1	35.6	36.5
Two	25.9	31.4	31.9	30.8
Three	14.8	12.9	11.7	14.1
Four or more	12.9	13.5	16.0	10.9
FP Related				
Purpose of visit				
New client	12.6	2.5	2.9	2.1
Repeat client	75.6	90.5	92.8	87.9
Switching client	6.7	4.2	2.2	6.4
Defaulter	5.1	2.8	2.2	3.6
Method use:				
Pill	33.3	37.0	34.7	39.7
Injectable	51.5	48.9	50.9	46.8
IUCD	0	0	0	0
Condom	0	0	0	0
Last pregnancy unwanted	51.5	28.2	32.5	23.7
Risk indicators				
Ever tested for HIV	53.7	56.7	54.6	59.0
Condom use at last sex	34.1	33.5	29.4	37.8
Reports current use of condom with method	48.8	49.2	50.3	48.1
Reported more than one partner in last year	10.7	12.9	13.5	12.2
Intends to have another child	41.2	39.8	41.1	38.5

The characteristics of the women in the retrospective cohort were compared to the overall study population. There were more women in the 20-39 year age group in the pooled study population (54.7%) compared to the cohort (45.9%). However, the proportion of women over 40 years of age was higher in the cohort (20.1%) compared to 13.3% in the overall study population. Educational status, relationship status and number of pregnancies and type of method were also similar between the cohort and overall study population. However, there were large differences in terms of reporting that the last pregnancy was unwanted. The women in the cohort reported much lower rates of their last pregnancy being unwanted (28.2%) compared to 51.5% amongst the broader study population. This may be due to the fact that the women in the cohort attend FP services more regularly and are thus less likely to have an unplanned pregnancy. This finding seems to support the assumption of more regular attendance at FP facilities and perhaps better compliance with the contraceptive method.

Other risk factors including ever testing for HIV were similar in the cohort and study population. Proportions of those tested for HIV (53.7% and 56.7%) and condom use at last sex (34.1% and 33.5%) were similar in the broader study population and the cohort. As expected a larger proportion of women in the retrospective cohort reported being repeat clients.

When comparing the intervention and control group within the cohort, the two groups were similar in terms of all socio-demographic and risk variables.

5.7 Summary of chapter

The baseline comparisons of individual and clinic level data presented in this chapter suggest that the intervention and control arms of the study were generally comparable with regard to socio-demographic characteristics. The two primary outcomes and secondary outcomes were balanced across both arms overall but showed a large degree of variability from facility to facility within study arms. An imbalance (9% difference) at baseline for previous testing for HIV was seen between the two study arms and therefore cluster level measures for previous testing at baseline were used to adjust for the primary outcome analysis for HIV testing in the previous year (Chapter 6).

Family planning clients are generally thought to be at “low risk” for STIs and HIV. However, on examining the baseline characteristics of this population there are a number of factors that indicate a need to consider these women at higher risk of STIs and HIV such as low condom use, unknown HIV status and intention to have more children (requiring the need to have unprotected sex). The majority of FP clients were young with 64% of the sample between 18 and 30 years of age. This proportion is expected to be higher in practice as the under 18 year old clients were not recruited into the study. In South Africa clients 14 years and above are able to seek FP services without the presence of a parent or guardian. The majority of women 75% are not in married relationships. However, condom use was found to be higher in those not reporting to be married. Approximately half of the women reported that their last pregnancy was unwanted showing that they were unable for unknown reasons to take protective measures against unwanted pregnancy. Fifty four percent of women had never tested for HIV despite only one third (34.1%) reporting condom use at last sex. No clients reported condom use as a contraceptive method. Eleven percent also reported more than one sexual partner in the last year.

The finding that only a minority of clients were captured as the retrospectively identified cohort at the follow up survey a year is also of concern indicating that FP clients may not be as stable a population as initially thought in terms of health seeking behaviour and reproductive intentions. However, since the data collection at follow up took place over a shorter period than 3 months it is possible that a larger cohort of women could have been captured. As discussed in the study limitations, the study did not set out to follow up those clients not returning to the facilities for FP methods and therefore we do not know if clients migrated, fell pregnant, received services elsewhere, changed reproductive intentions or simply defaulted from their method.

Logistic regression analysis showed that a number of factors beyond the scope of a clinic based intervention such as relationship status, age, education were significantly associated with each of the two primary outcomes, condom use at last sex and having previously had a test for HIV after adjustment for facility and age. However, although many of these variables are difficult for an intervention to change directly, the analyses presented here highlight sub-groups of the population on which interventions may need to be targeted such as encouraging condom use amongst older women and

married women. There are some factors that may have the potential to be influenced by community or health facility based interventions that may have an impact for example after adjusting for age, partner testing for HIV, number of pregnancies, number of sexual partners and high self-perceived risk for HIV remained significantly associated with condom use at last sex. However, as discussed in Chapter 7 our study is not able to tell if these relationships are causal or there is reverse causality.

The contraceptive method mix was highly skewed towards the great majority of client using short term contraceptives (pills or injectables) despite 60% of clients reporting not intending to have another child. This raises broader programmatic issues about access to a broad range of methods particularly the absence of IUDs in the method mix in South Africa.

The characteristics of the study population do reinforce the need for an intervention to integrate STI/HIV related services within FP services offered to these clients.

Chapter 6: STUDY RESULTS

6.1 Chapter overview

This chapter will report on the follow up data from both the client provider observations and exit interviews. The results of the study will be presented in five sub-sections. The first sub-section will describe the effect of the intervention on the two primary behavioural endpoints, condom use at last sex and testing for HIV in the last year, and the secondary endpoints of quality of care scores. Secondly, further sub analyses of the two primary endpoints assessing for effect modification by age, marital status and educational status will be presented. The third section of the chapter will present an analysis of a retrospectively identified cohort consisting of women seen at both baseline and follow up surveys. The fourth section will present an exposure analysis examining the associations between observed use of the intervention tools, quality of care scores and the primary behavioural outcomes. This chapter will conclude with a fifth and final section describing the risk factors associated with the two primary outcomes.

6.2 Study results

6.2.1 Primary outcomes: Behavioural

As discussed in the previous chapter, with the exception of one variable - previous testing for HIV (49% intervention and 58% control group at baseline) – the randomisation process was largely effective with no large imbalances found in terms of the behavioural and socio-demographic characteristics of the women in the intervention and control groups at baseline (see Chapter 5 Table 5.2) and therefore an unadjusted analysis for the primary outcomes was undertaken as initially stated in the study protocol.

Table 6.1: Cluster level comparison of the primary behavioural outcomes at follow up

	Mean* % Intervention (sd)	Mean % Control (sd)	Unadjusted Risk Ratio	95% CI	P value
Tested for HIV in the previous year	33.2 (6.9)	21.4 (6.1)	1.56	(1.13,2.15)	0.01
Condom use at last sex	43.4 (7.1)	39.4 (9.5)	1.10	(0.85,1.43)	0.14

*(Data source: Follow up client exit interviews) * mean of cluster proportions sd standard deviation; CI confidence interval*

Table 6.1 shows the means of the cluster-level proportions of clients in the intervention facilities (6) and control facilities (6) reporting the two primary behavioural outcomes. The proportion of women reporting use of a condom at last sex was higher in the intervention group as compared to the control group (RR 1.1; (0.85,1.43)) but this difference was not statistically significant (p = 0.14). However, there was strong evidence that HIV testing in the year preceding the follow up survey was higher in the intervention group, with women in the intervention group 56% more likely to have tested in the previous year (RR 1.56; (1.13-2.15 p = 0.01)).

Table 6.1 shows testing for HIV in the previous year by cluster. Testing varied considerably from 25.6% to 42.2% in the intervention group and from 16.4% to 33.3% in the control group. The overall rate of testing in the previous year was 33.8% (215/637) in the intervention group compared to 20.7% (130/627) in the control group.

Table 6.2: Summary of reporting tested for HIV in the previous year at follow up, by cluster and study arm (n=1,264)

Intervention			Control		
Site	%	n/N	Site	%	n/N
Tlaseng	30.4	24/79	Leseding	18.8	26/138
Chaneng	37.8	34/90	Karlien Park	20.4	22/108
Bosplass	25.8	24/93	Mogogelo	18.0	18/100
Lebotlwane	25.6	31/121	Ngobi	33.3	26/78
Maubane	42.2	62/147	Rankelenyane	21.2	21/99
Thekwane	37.4	40/107	Monokato	16.4	17/104
Overall %	33.8	215/637		20.7 (130/627)	
Mean cluster* (sd) %	33.2 (6.9)			21.4 (6.1)	
Risk Ratio (95% CI)	1.56 (1.13,2.15)				

*(Data Source: Follow up client exit interviews)*arithmetic mean of cluster proportions sd standard deviation; CI confidence interval*

Table 6.3 shows self-reported condom use at last sex by cluster. Again these showed a large degree of variability from 37.2% to 56.2% in the intervention group and 24.0% to 50.0% in the control group. Overall 44.1% reported condom use at last sex in the intervention facilities compared to 38.9% in the control facilities.

Table 6.3: Summary of reporting condom use at last sex at follow up, by cluster and study arm (n=1,259)

Intervention			Control		
Site	%	N	Site	%	N
Tlaseng	40.5	32/79	Leseding	34.1	47/138
Chaneng	46.7	42/90	Karlien Park	39.8	43/108
Bosplass	41.3	38/92	Mogogelo	41.0	41/100
Lebotlwane	37.2	45/121	Ngobi	47.4	37/78
Maubane	56.2	82/146	Rankelenyane	24.0	23/96
Thekwane	38.3	41/107	Monokato	50.0	52/104
Overall %	44.1	280/635		38.9	243/624
Mean Cluster (sd) %	43.4 (8.7)			39.4 (10.3)	
Risk Ratio (95% CI)	1.10 (0.85,1.43)				

*(Data Source: Follow up client exit interviews)*arithmetic mean of cluster proportions sd standard deviation; CI confidence interval*

- **Adjusted analysis**

Despite self-reported previous testing for HIV measured at baseline being approximately 9% lower in the intervention group compared to the control group, women in the intervention arm were still 56% more likely to have tested in the previous year at follow up in an unadjusted analysis. However, despite a higher proportion of women reporting having tested in the previous year an unadjusted analysis may have either under- or over-estimated the true impact of the intervention on testing for HIV since women who may have tested at baseline may be more or less likely to test again. An adjusted cluster level analysis controlling for previous testing at baseline was conducted. Data on testing for HIV in the past year were not collected at baseline and therefore information on baseline levels of previous testing (ever tested for HIV) were used for adjustment. Adjusting for cluster level testing was also necessary as the study collected cross sectional data at baseline and follow up and therefore baseline data for the individual women seen at follow-up were unavailable.

Table 6.4: Adjusted Analysis: Testing for HIV in previous year (adjusted for baseline cluster levels for ever tested for HIV)

	Mean* % Intervention (sd)	Mean % Control (sd)	Risk Ratio	95% CI	P value
Tested for HIV in the previous year	1.20 (0.26)	0.80 (0.25)	1.51	(1.07,2.13)	0.02

*(data source: follow up client exit interviews) *Mean represents means of observed/expected residuals*

The adjusted analysis compares a ratio of means of observed over expected residuals at follow up adjusted for baseline cluster means for ever testing for HIV.

The adjusted analysis did not result in large changes in the estimate (1.51) as compared to the unadjusted (1.56) suggesting that previous testing for HIV did not markedly influence testing in the previous year. This finding remained statistically significant (p=0.02). The adjusted risk ratio was slightly lower than the unadjusted suggesting a negative association between having tested previously and testing in the previous year, meaning those who have tested before are less likely to test again. However, since the individuals surveyed at baseline and follow up were not the same individuals this association cannot be examined directly. Although adjustment for individual levels of previous testing is possible for the nested cohort, baseline levels of previous testing were very similar in control and intervention groups 54.6% in the intervention group compared to 59% in the control group and therefore this analysis was not conducted.

6.2.2 Secondary outcomes: Quality of care

The creation of quality of care scores assessing various components of the care provided to clients and measured through structured client provider observations is described in Chapter 4. The same data collection tool (client-provider observation checklist) was used to collect data at follow up in order to assess quality of care post intervention. Data were collected from 1,264 clients at follow up.

Table 6.5: Quality of care scores at follow up (N=1,264)

Quality of care scores (range of score)	Mean* Intervention (sd) (n=637)	Mean Control (sd) (n=627)	Mean Difference	95% CI	P value
General FP History Taking (0-4)	2.23 (1.11)	1.03 (1.41)	1.20	(-0.43, 2.83)	0.13
Client Provider Rapport (0-4)	2.89 (1.06)	2.41 (0.94)	0.48	(-0.81, 1.77)	0.42
Number of FP Methods (0-7)	2.41 (1.45)	1.58 (1.70)	0.83	(-1.21, 2.86)	0.39
STI/HIV History Taking(0-3)	1.37 (0.95)	0.33 (0.71)	1.05	(-0.03, 2.12)	0.06
STI Information Score (0-4)	2.17 (1.09)	0.87 (1.25)	1.30	(-0.21, 2.81)	0.08
DP and Condom Counselling (0-7)	3.02 (2.10)	1.61 (2.66)	1.41	(-1.67, 4.50)	0.33
HIV Test Counselling (0-4)	1.93 (1.35)	1.01 (1.51)	0.92	(-0.93, 2.76)	0.29
Total quality (0-33)	16.02 (8.65)	8.82 (9.63)	7.19	(-4.59, 18.98)	0.20

*(Data source: Follow up client provider observations) sd-standard deviation CI-95% confidence interval *mean of cluster proportions*

The table above shows that although the mean scores for quality of care were consistently higher in the intervention group post intervention indicating a trend towards better quality of care, and demonstrating an overall doubling of the mean total quality of care scores in the intervention group, these differences were not statistically significant. This is likely to be due to the large variability observed between facilities. The largest improvements in scores were seen in dual protection and condom counselling and STI information scores. Although the strongest evidence of an effect was for STI/HIV history taking and STI information score.

Figure 6.1: Cluster proportions of those testing for HIV in past year by study arm

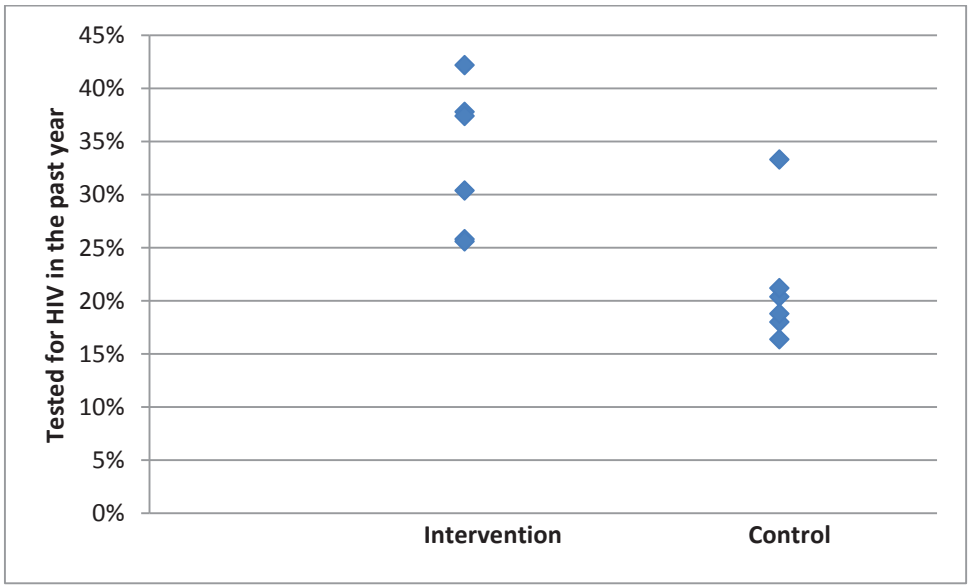


Figure 6.2: Cluster proportions of those using condom at last sex by study arm

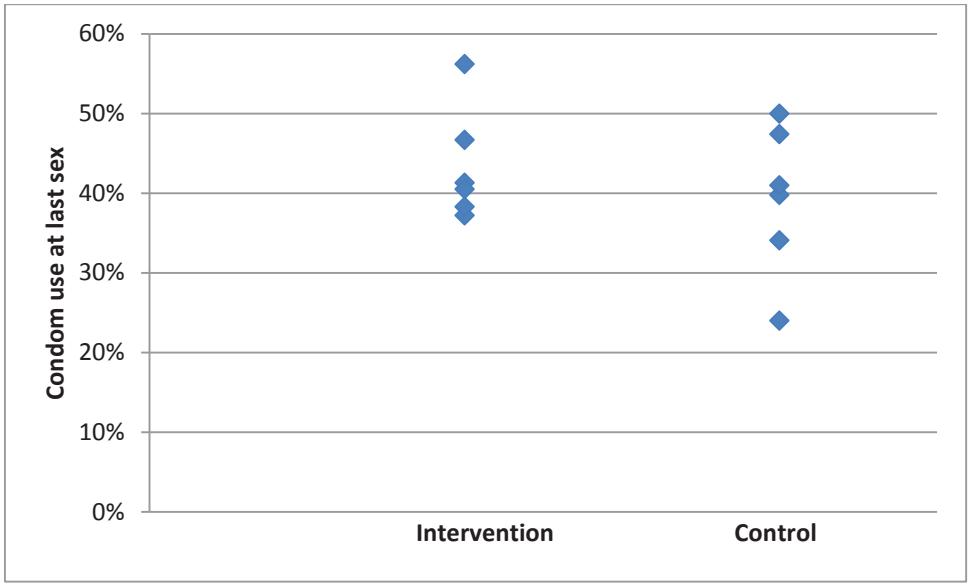


Figure 6.3: Total quality score for clusters by study arm

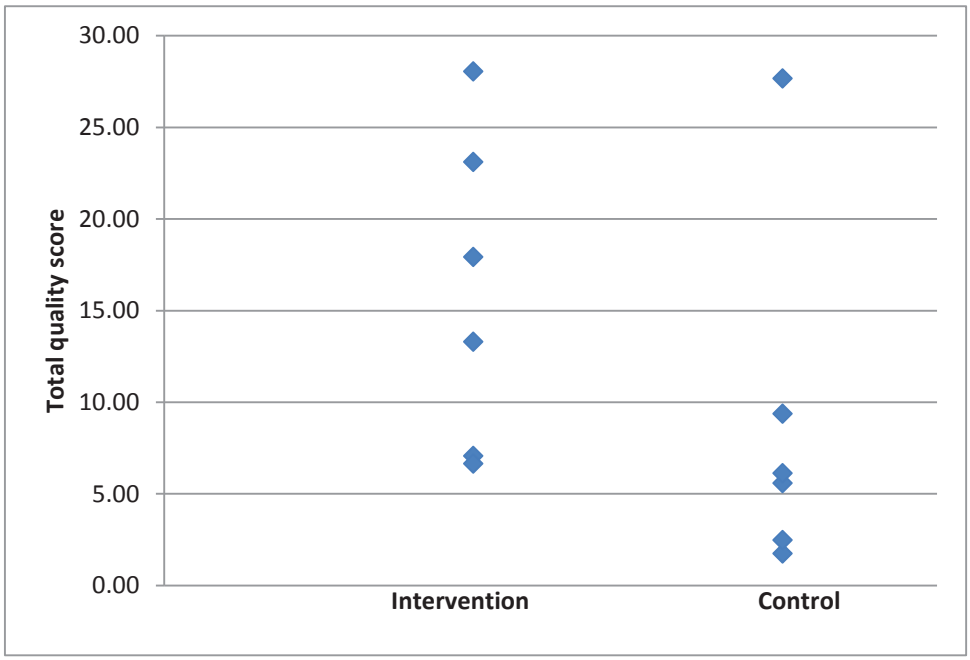


Table 6.6: Summary of observed total quality score by cluster and study arm (N=1,264)

Intervention				Control			
Facility	N	Mean Score	sd	Facility	N	Mean Score	sd
Bosplass	86	6.65	3.46	Monokato	101	2.47	1.54
Thekwane	93	28.05	3.45	Karlien Park	104	1.74	1.39
Maubane	137	23.11	2.84	Ngobi	75	27.67	1.66
Chaneng	82	7.07	3.83	Rankelenyane	95	5.59	3.57
Tlaseng	73	13.29	6.40	Mogogelo	94	6.12	2.84
Lebotloane	114	17.92	5.23	Leseding	136	9.37	2.74
Mean Score*	16.02				8.83		
Mean of cluster means (sd)	16.02 (8.7)				8.82 (9.6)		
Mean Difference	7.19 (95% CI: -4.59, 18.98)						

(Data source: Follow up client provider observations) arithmetic mean sd standard deviation CI confidence interval)*

The table 6.6 shows the total quality score by facility in the intervention and control arms of the study. This shows the degree of variability in scores with a wide range from 6.65 to 28.05 in intervention facilities and 1.74 to 27.67 in the control facilities. Four of the six intervention facilities had scores >=10 as compared to only one of the six facilities in the control arm. This particular clinic (Ngobi) also had a high total quality of care score at baseline.

6.3 Analyses for effect modification

Subgroup analyses were conducted for effect modification by age, relationship status and educational status for the two primary study outcomes. For these analyses age, relationship status and educational status were re-categorised as dichotomous variables. Age was divided into those aged 30 years and younger and those aged greater than 30 years, relationship status into those who were married and those not married (single, divorced and widowed), and educational status was divided into those who had not completed primary education and those who had completed primary education and above.

6.3.1 Testing for HIV in the last year

Table 6.7: Effect Modification: HIV Testing in Previous year

	Intervention Mean* (Overall n/N)	Control Mean* (Overall n/N)	Risk Ratio (95% CI)	P value Interaction
Age Group				
<= 30 yrs	35.6(150/412)	22.8(92/411)	1.56(1.04,2.33)	0.86
> 30 yrs	28.5(64/221)	17.1(38/211)	1.67(0.99,2.80)	
Relationship Status				
Married	32.8(65/190)	20.1(26/142)	1.57(0.95,2.61)	0.86
All non Married	33.2(150/446)	21.9(104/481)	1.52(1.13,2.04)	
Educational Status				
Not Completed primary	24.8(39/145)	18.1(15/89)	1.37(0.83,2.27)	0.20
Completed Primary	35.6(176/492)	22.4(115/535)	1.59(1.14,2.22)	

(Data Source: Follow up client exit interviews) sd-standard deviation; CI-confidence interval mean of cluster proportions*

Testing for HIV in the previous year was higher in younger women and in women who had higher levels of education. A comparison of cluster means in the two age groups showed that in both old and young age groups a larger proportion of women in the intervention group had tested in the previous year. Testing for effect modification by age showed that there was no evidence that age group was an effect modifier for HIV testing during the last year. A comparison of cluster means by relationship status showed that in both the married and the unmarried group there were higher levels of testing for HIV in the previous year. A test for effect modification showed no evidence of effect modification by relationship status. Finally, comparing cluster means by educational category showed that a higher proportion of women reported having tested for HIV in the previous year in the intervention group in both educational categories. A test for effect modification showed no evidence of effect modification by educational status.

6.3.2 Condom use at last sex

Table 6.8: Effect Modification: Condom Use at last sex

	Intervention Mean* (Overall n/N))	Control Mean* (Overall n/N)	Risk Ratio (95% CI)	P value Interaction
Age Group				
<= 30 yrs	48.4(193/399)	44.3(188/424)	1.09(0.39,3.09)	0.26
>30 yrs	37.2(80/208)	25.5(57/224)	1.49(1.01,2.21)	
Relationship Status				
Married	35.1(59/175)	26.5(30/157)	1.32(0.95,1.84)	0.70
All non Married	57.1(216/436)	46.3(215/496)	1.23(0.97,1.57)	
Educational Status				
Not Completed Primary	35.5(46/132)	26.3(25/102)	1.35(0.92,1.98)	0.81
Completed Primary	47.1(229/479)	39.4(220/551)	1.20(0.94,1.52)	

*(Data Source: Follow up client exit interviews) *arithmetic mean CI confidence interval*

The cluster means showed that there were large differences in reporting condom use between the subgroups of women. Older women, married women and women who had not completed primary education were less likely to report condom use at last sex.

The table above examines the effect of the intervention in the two age groups 30 and younger and older than 30. The relative risk (comparing intervention and control group) for condom use in the younger age age group was 1.09 and this was 1.49 in the older age group. In the older age group a t-test comparing means showed higher levels of condom use at last sex in the intervention group (p=0.04). However, a test for effect modification showed that there was no evidence of effect modification by age. Similar analyses were conducted to assess the role of relationship status. Although condom use was higher in both the married and unmarried groups in the intervention group compared to control, these differences were not significant. Comparing cluster means in the intervention and control groups in both married and unmarried women revealed no evidence for effect modification by relationship status (p=0.7). As described earlier, educational status was divided into two categories, those

without complete primary education and those with completed primary education and above. A comparison of cluster means showed higher condom use in the intervention arm compared to the control arm in both the high and low education categories, though the 95% confidence intervals for the risk ratios included one. As with age group and relationship status, there was no evidence of effect modification by educational status.

6.4 Cohort analysis

A cohort was retrospectively identified based on women who were interviewed at follow up and who had also been part of the baseline survey. These women were analysed separately from the main analysis reported in Chapter 6.2, as they would have been expected to have made multiple visits to receive family planning services over the intervention period and therefore were more likely to have been exposed to the intervention. A further advantage of the cohort is that it is possible to adjust the analysis for the baseline data at individual rather than cluster level.

Table 6.9: Sample sizes for retrospectively identified cohort (N=254)

Facility	Intervention (n)	Facility	Control (n)
Tlaseng	18	Leseding	33
Chaneng	5	Karlien Park	16
Bosplass	12	Mogogelo	30
Lebotloane	23	Ngobi	16
Maubane	32	Rankelenyane	23
Thekwane	25	Monokato	21
Total	115		139

The table above shows that 254 such clients were identified and the numbers were similar across the intervention and control arms of the study. At baseline a total of 1,111 women were included in the study 537 in the intervention group and 574 in the control group. Thus, 21.4% of the intervention group and 24.2% of the control group were interviewed again at follow up a year later. At baseline, previous testing for HIV was similar in the intervention and control arms in this subgroup of 254 women (65 % intervention and 60% in the control group, though percentages were higher than for the overall sample.

There is no rationale for better quality of care being provided to repeat clients and therefore the cohort was only analysed for behavioural outcomes.

Table 6.10: Cohort: cluster level comparison of key behavioural outcomes at follow up

	Mean* % Intervention (sd)	Mean % Control (sd)	Risk Ratio	95% CI	P value
Tested for HIV in the previous year	57.4 (10)	56.4 (6)	1.02	(0.83,1.20)	0.82
Condom use at last sex	45.3 (13)	36.8 (17)	1.23	(0.61,1.64)	0.35

*(Data source: Cohort: Follow up client exit interviews) *arithmetic mean sd standard deviation CI confidence interval*

Table 6.11 shows cluster level comparisons of testing for HIV in the previous year and condom use at last sex in the cohort. Testing for HIV was reported at much higher levels than in the total group of study participants. This may be because this group of women are regular attenders for FP services and may have more positive health seeking behaviour than the general group of FP clients. Testing levels were similar in both intervention and control groups with over a half of women in both groups reporting that they had tested for HIV in the past year. Self-reported condom use at last sex was higher in the intervention group but this difference was not significant.

Table 6.11: Cohort: Comparison of behavioural outcomes at follow up (N=254)

Cohort analysis: Summary of reported testing for HIV in previous year at follow up, by cluster and study arm (N=254)

Facility	Intervention % (n/N)	Facility	Control % (n/N)
Tlaseng	50.0 9/18	Leseding	48.5 16/33
Chaneng	60.0 3/5	Karlien Park	56.3 9/16
Bosplass	50.0 6/12	Mogogelo	63.3 19/30
Lebotloane	47.8 11/23	Ngobi	56.2 9/16
Maubane	68.8 22/32	Rankelenyane	52.2 12/23
Thekwane	68.0 17/25	Monokato	61.9 13/21
Overall %	59.1 68/115		56.1 78/139
Mean Cluster* (sd) %	57.4 (10)		56.4 (6)
Relative Risk (95%CI)	1.02 (0.83,1.20)		

*(Data Source: Follow up client exit interviews)*arithmetic mean sd standard deviation CI confidence interval*

The proportion of cohort clients who tested in the last year showed variability between facilities. Proportions of those who tested in the previous year varied from 47.8% to 68.8% in intervention facilities and from 48.5% to 63.3% in control facilities. However, in comparing these proportions to the proportions tested in the overall sample a consistent pattern emerged in terms of low and higher performing facilities.

Cohort analysis: Summary of reported condom use at last sex at follow up, by cluster and study arm (N=254)

Facility	Intervention % (n)	Facility	Control % (n)
Tlaseng	22.2 4/18	Leseding	30.3 10/33
Chaneng	40.0 2/5	Karlien Park	37.5 6/16
Bosplass	50.0 6/12	Mogogelo	30.0 9/30
Lebotlwane	56.5 13/23	Ngobi	62.5 10/16
Maubane	46.9 15/32	Rankelenyane	13.0 3/23
Thekwane	56.0 14/25	Monokato	47.6 10/21
Overall %	47.0 54/115		34.5 48/139
Mean Cluster (sd) %	45.3 (13)		36.8 (17)
Relative Risk (95%CI)	1.23 (0.61,1.64)		

(Data Source: Follow up client exit interviews)

Condom use at last sex also varied considerably from 22.2% to 56.5% in the intervention facilities and from 13.0% to 62.5% in the control facilities. However, most facilities had small sample sizes making these estimates unstable.

6.5 Exposure Analysis

To assess the effect of use of the BCS Plus tool on quality of care and more specifically to assess the impact of the BCS Plus tool on HIV and FP related services and on overall quality of care provided an exposure analysis was conducted limiting the analysis to the six intervention facilities in which the intervention tools were used.

6.5.1 Exposure analysis: Effect of use of tools on quality of care scores

The following graphs show quality of care scores and the total quality score plotted against the proportion of client provider observations at each intervention clinic in which a provider was observed using the BCS Plus tools. A regression analysis was conducted with a single independent variable the observed level of utilisation of the

BCS Plus within the client provider consultations. The r square statistic (square of the correlation coefficient) for each score was also calculated.

Figure 6.4: Exposure analysis: History Taking Score by observed use of BCS Plus

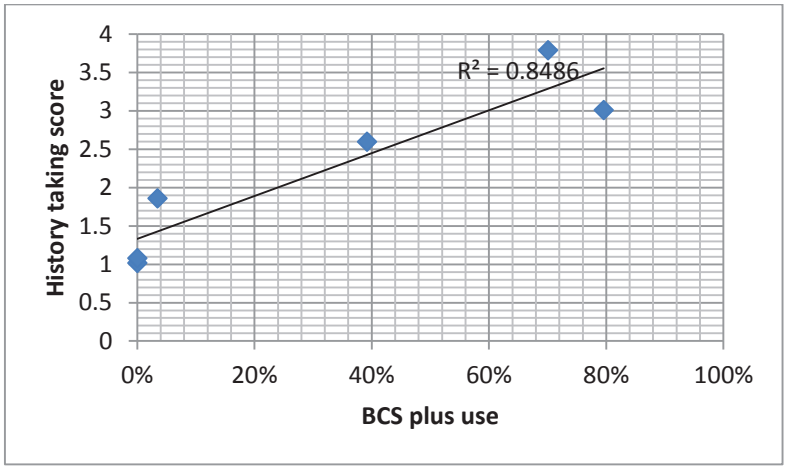


Figure 6.5: Exposure analysis: Client Provider Rapport Score by observed use of BCS Plus

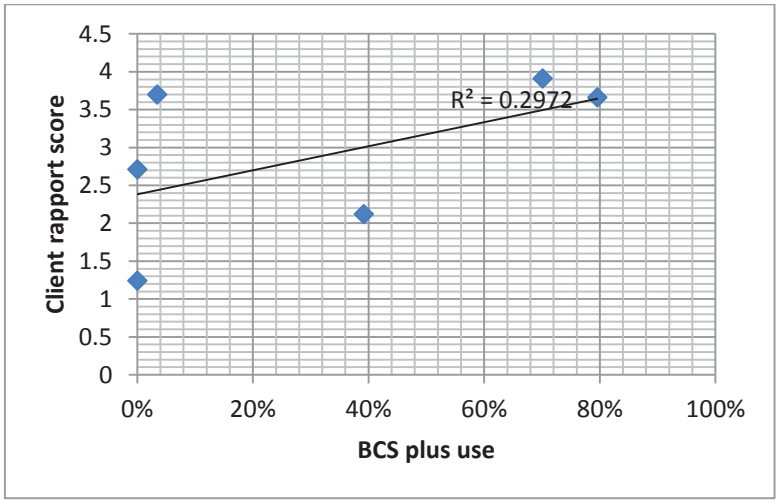


Figure 6.6: Exposure analysis: Number of Methods Score by observed use of BCS Plus

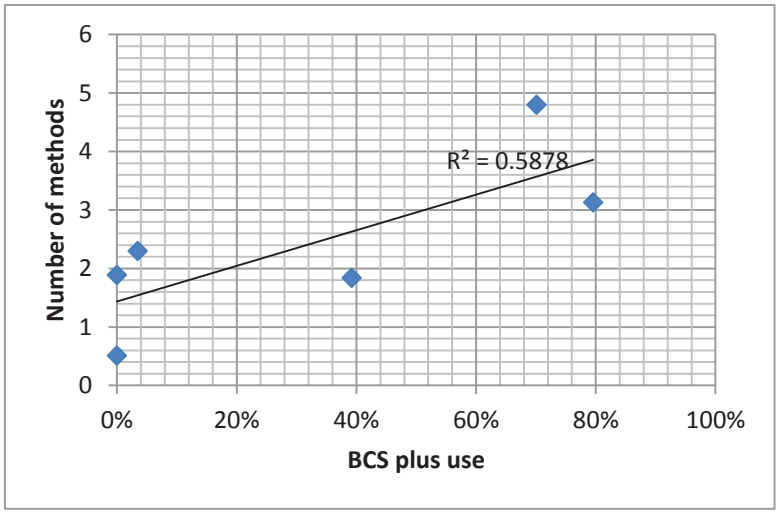


Figure 6.7: Exposure analysis: STI History Taking Score by observed use of BCS Plus

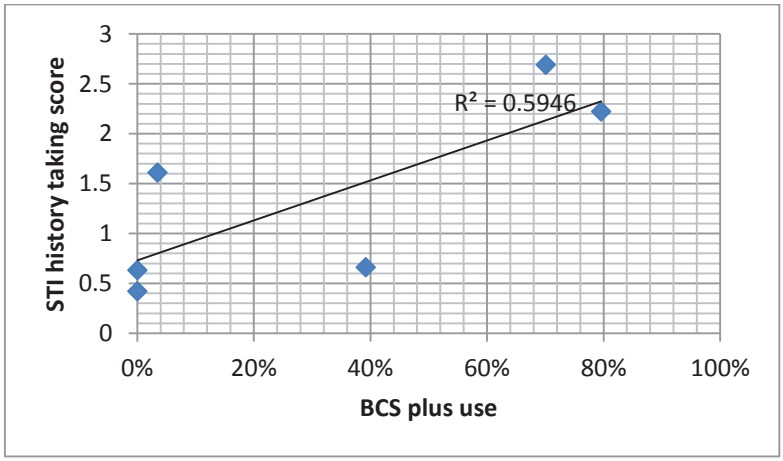


Figure 6.8: Exposure analysis: Dual protection score by observed use of BCS Plus

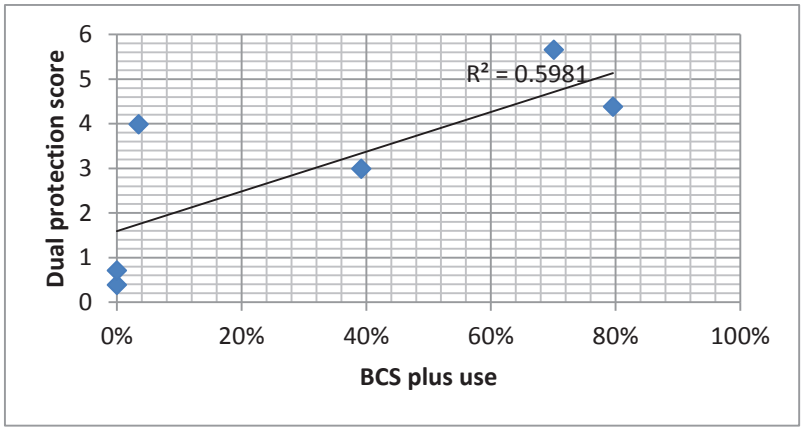


Figure 6.9: Exposure analysis: STI Information Score by observed use of BCS Plus

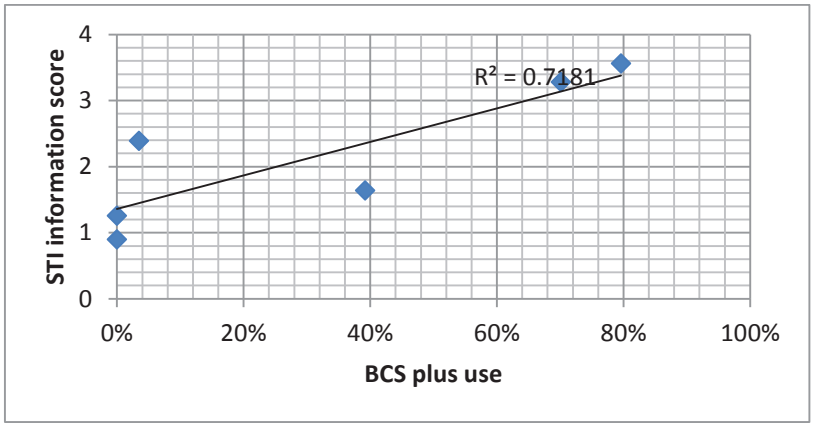


Figure 6.10: Exposure analysis: C&T Counselling Score by observed use of BCS Plus

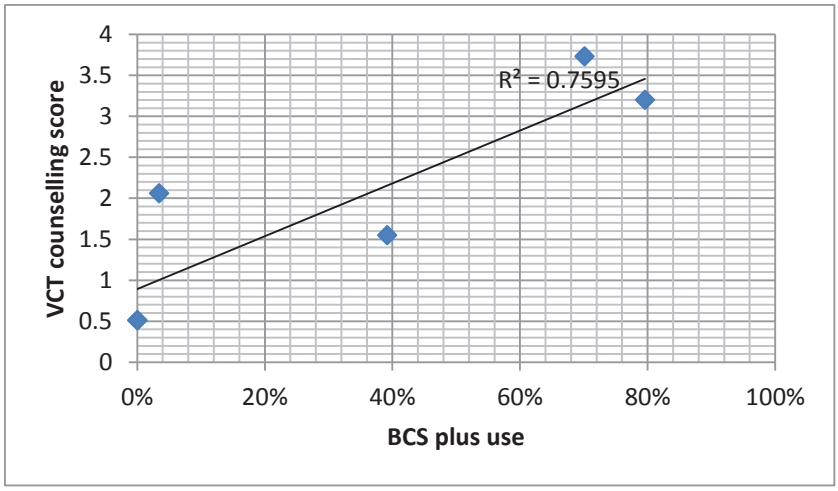
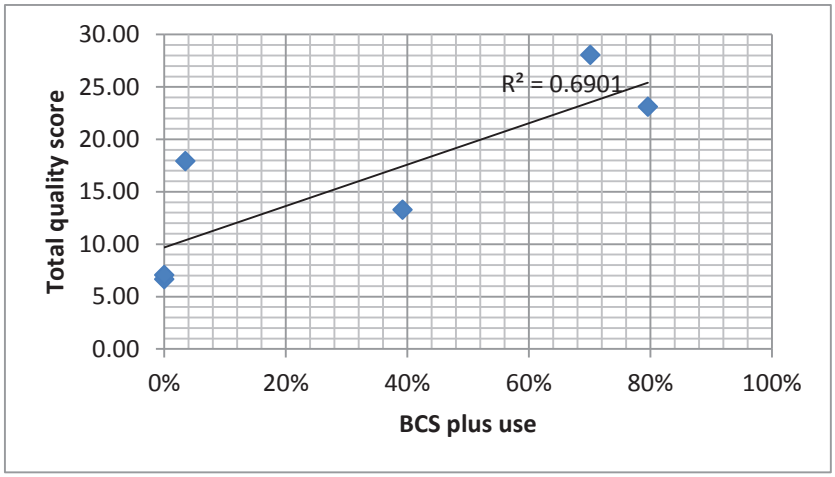


Figure 6.11: Exposure analysis: Total Quality Score by observed use of BCS Plus



The r square measures the proportion of the variation in the dependent variable (quality score) that is explained by variations in the independent variable (proportion of client provider observations in which the BCS Plus tools were used). This measure quantifies how much of the variation in the *mean* quality score for each cluster is accounted for by the use of the intervention tools. The interpretation of the r and its values show that for all variables there was a positive trend in the score with increased use of the BCS Plus. Overall, 69% of the variation of total quality of care was explained by use of the BCS Plus tools. For history taking score (85%), STI information score (72%), STI history taking score (59%), dual protection score (60%) and C&T counselling score (76%) and number of methods discussed (59%) high proportions of the variations in score were explained by the use of the BCS Plus tool. Increases in client provider rapport (30%) were explained to a lesser degree by use of the BCS Plus tools.

Table 6.12: Table summarising the relationship between quality of care scores and BCS Plus observed use

Name of score	r	r^2	Regression co efficient	95% CI	P value
History Taking Score	0.92	0.85	0.30	(0.13,0.48)	0.01
STI Information Score	0.85	0.72	0.28	(0.04,0.53)	0.03
Client Rapport Score	0.55	0.30	0.19	(-0.21,0.59)	0.26
Dual Protection Score	0.77	0.60	0.13	(-0.02,0.29)	0.07
C&T Counselling Score	0.87	0.76	0.24	(0.05,0.42)	0.02
STI History taking Score	0.77	0.59	0.19	(0.03,0.42)	0.07
Number of methods Score	0.77	0.59	0.19	(-0.03,0.42)	0.08
Total Quality Score	0.83	0.69	0.03	(0.00,0.06)	0.04

The table above summarises the relationship between the use of the BCS Plus tools and the quality of care scores and behavioural outcomes. Strong evidence for improvements in the quality of care with use of the BCS Plus tools was found for total quality, general history taking, the provision of STI information and C&T counselling.

Overall, positive trends in both FP and HIV related quality of care were seen with increasing observed usage of the BCS Plus tools. General client provider rapport was less influenced by the use of the BCS but 6 of the 7 quality of care scores were explained to a large degree by use of the tools. Although in two intervention facilities the BCS Plus tools were not seen to be used in a consultation they were still included in the analysis as the intervention was considered to have been implemented at these sites since providers had been trained. The client provider observations at follow up were conducted one year after the training and some providers mentioned that they were familiar with the tools and did not have to refer to them. The providers observed in the sample may or may not have participated in the training on the tools. Trained providers were asked to cascade training to their colleagues and this may have either not been done or training may have been provided in a less intensive manner. A cluster level analysis was done as the intervention was considered to have been implemented

at the clinic level. The level of utilisation of the intervention tools was extremely variable across all six intervention facilities and ranged from 0%-80%.

6.5.2 Exposure analysis for primary outcomes

An exposure analysis was also conducted on primary outcomes which were plotted against the proportion of client provider observations at each intervention clinic in which a provider was observed using the BCS Plus tools.

Table 6.13: Exposure analysis for primary outcomes

	R	r²	Regression co efficient	95% CI	P value
Testing for HIV	0.69	0.48	3.64	(-1.62,8.90)	0.12
Condom use	0.38	0.15	1.72	(-4.06,7.49)	0.46

Figure 6.12: Exposure analysis: Testing for HIV in last year by observed use of BCS Plus

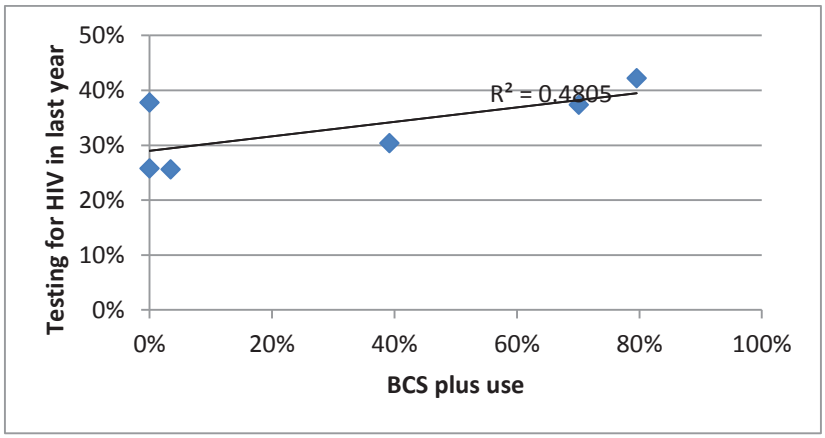
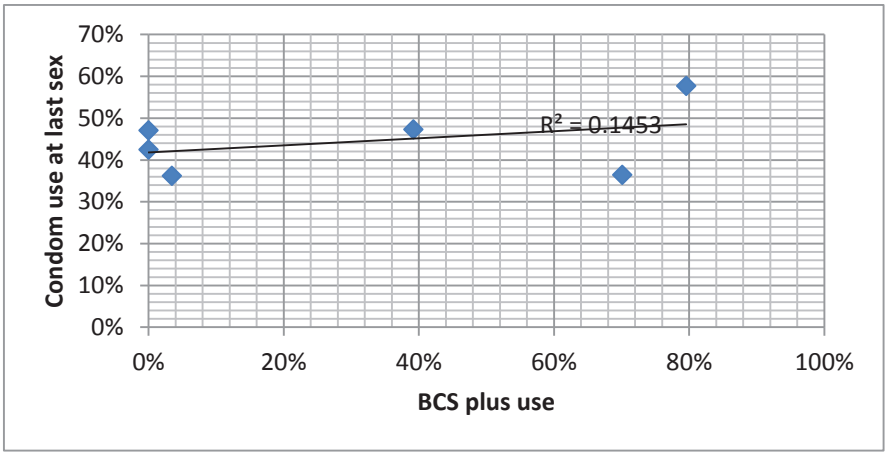


Figure 6.13: Exposure analysis: Condom use at last sex by observed use of BCS Plus



Although use of the tools showed a positive effect on quality of care, the tools did not explain much of the variation in condom use at last sex, explaining only 15% of the variation. However, a greater degree of variation was explained (48%) by the use of the tools on testing for HIV in the previous year but this association was not statistically significant.

Relationship between total quality of care and primary outcomes (N=12)

The association between total quality of care and the primary outcomes was also assessed using data from all 12 clusters.

Table 6.14: Relationship between total quality of care and primary outcomes

	r	r^2	Regression co efficient	95% CI	P value
Testing for HIV in last year	0.72	0.52	0.78	(0.26,1.31)	0.007
Condom use at last sex	0.24	0.06	26.83	(-50.07,103.73)	0.45

There was strong evidence that total quality of care influenced testing for HIV in the previous year. However, this was not the case for condom use at last sex.

Figure 6.14: Tested for HIV in the past year by total quality score

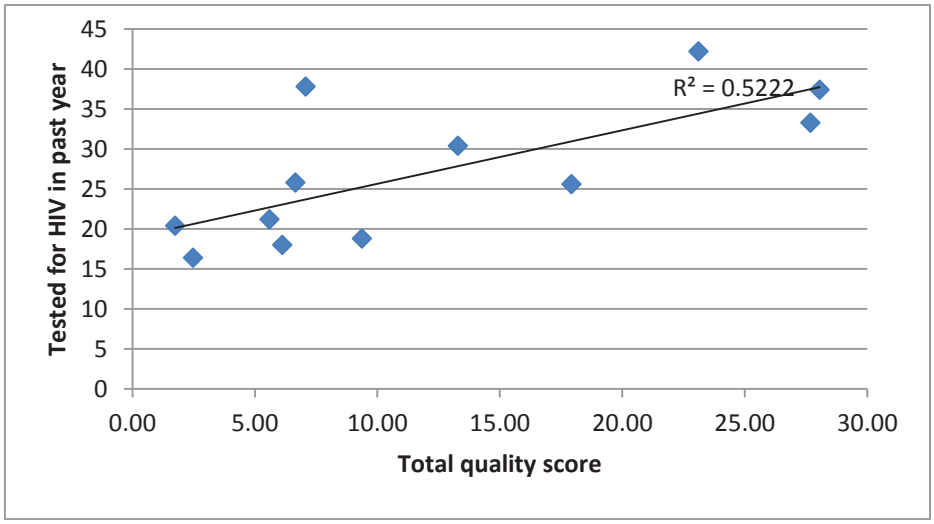
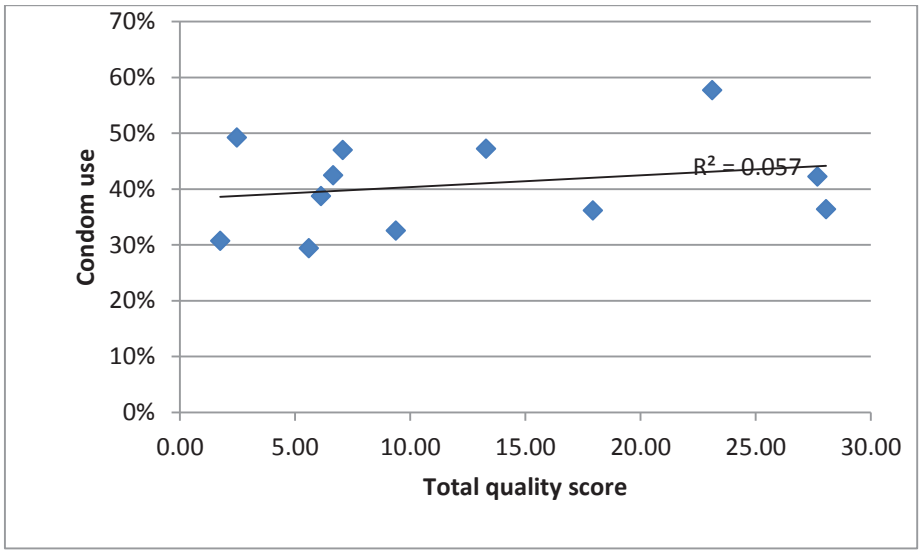


Figure 6.15: Condom use at last sex and total quality score



6.6 Risk Factor Analysis

A risk factor analysis was conducted for both primary behavioural outcomes at follow up. This analysis was conducted across both study arms allowing for cluster.

6.6.1 Risk factors for condom use at last sex

Table 6.15 shows the risk factor analysis for condom use at last sex at follow up. Age was significantly associated with whether women used a condom the last time they had sexual intercourse. Women aged less than 20 years had the highest likelihood of

using a condom at their last sexual encounter, while those above the age of 40 were least likely ($p<0.001$).

After adjustment for age, relationship status, previous testing for HIV, number of times tested, partner testing for HIV, number of pregnancies, number of partners in the last year and self-perceived risk of STI/HIV remained significantly associated with condom use at last sex. As in the baseline risk factor analysis, married women were least likely to report condom use at last sex. Cohabiting women were 1.62 times more likely than married women to report using a condom at last sex and single women were most likely to report using condoms at last sex (OR 2.60). Those having tested for HIV previously were 1.46 times more likely to report condom use ($p=0.01$). As found in the baseline survey, the more often women had reported testing for HIV in the past, the higher the odds of reporting condom use at last sex ($p<0.001$). Women who had tested three or more times for HIV were 2.31 times more likely than those who had not tested for HIV to report using a condom at last sex. Partner testing for HIV was associated with increased odds of condom use (OR 1.41). As with the baseline data increasing number of pregnancies were associated with decreasing odds of condom use at last sex with those who had four or more pregnancies 0.23 times as likely to use condoms at last sex. Increasing number of sexual partners reported in the past year were also associated with increasing odds of condom use. Those reporting three or more partners in the last year were more than seven times (OR 7.14) more likely to use condoms at last sex. As with the baseline findings high self-perceived risk was associated with lower odds of condom use (OR 0.22).

These findings suggest that (as expected) low condom use is associated with an increased number of pregnancies. On the other hand, it was encouraging to see that women who reported higher numbers of sexual partners were increasingly more likely to have used a condom at last sex.

In the final adjusted model only relationship status, number of pregnancies and self-perceived risk of STI/HIV were associated with condom use at last sex.

Table 6.15: Factors associated with condom use at last sex at follow up

Condom use at last sex	No/Total	%	Crude OR 95% CI	Age Adjusted OR 95% CI		Adjusted OR 95% CI*	
Relationships							
Married	89/332	26.81	1.00	1.00	p<0.00	1.00	p=0.01
Cohabit	102/275	37.09	1.62	1.62	(1.10-2.38)	1.63	(1.12-2.39)
Single	329/652	50.46	2.98	2.60	(1.83-3.69)	2.71	(1.89-3.87)
Age Group							
<20	73/147	49.66	1.00				
20-29	300/552	54.35	0.85				
30-39	176/263	66.92	0.49				
>40	103/143	72.02	0.39				
Education Status							
Incomp Primary	6/19	31.58	1.00	1.00	p= 0.28		
Complete Primary	65/215	30.23	0.91	0.99	(0.32-3.08)		
Sec & Above	449/1030	43.59	1.60	1.33	(0.44-4.01)		
Intention to have more children							
No	313/828	37.80	1.00	1.00	p=0.24		
Yes	207/436	47.48	1.44	1.19	(0.89-1.58)		
Previous testing for HIV							
No	151/435	34.71	1.00	1.00	p=0.01		
Yes	369/829	44.51	1.48	1.46	(1.11-1.91)		
No of times tested							
None	157/446	35.20	1.00	1.00	p<0.00	1.00	p=0.08
One	163/411	39.66	1.19	1.16	(0.85-1.59)	1.32	(0.96-1.82)
Two	125/274	45.62	1.50	1.48	(1.05-2.08)	1.80	(1.27-2.56)
Three or more	75/133	56.39	2.31	2.48	(1.60-3.83)	2.84	(1.82-4.41)
Partner tested for HIV							
No	308/813	37.88	1.00	1.00	p=0.011		
Yes	212/451	47.01	1.44	1.41	(1.08-1.84)		
No of pregnancies							
None	72/109	66.06	1.00	1.00	p =0.00	1.00	p<0.00
One	211/470	44.89	0.40	0.41	(0.25-0.69)	0.37	(0.23-0.62)
Two	141/359	39.28	0.31	0.32	(0.18-0.55)	0.37	(0.22-0.63)
Three	57/182	31.32	0.23	0.24	(0.12-0.44)	0.35	(0.19-0.64)
Four or more	39/144	27.08	0.19	0.23	(0.11-0.45)	0.31	(0.16-0.58)
No of partners in last year							
None	6/23	26.09	1.00	1.00	p= 0.01		
One	470/1157	40.62	1.88	2.43	(0.80-7.44)		
Two	29/62	46.77	2.76	3.36	(0.97-11.69)		
Three or more	15/22	68.18	7.14	8.88	(2.03-38.90)		

Self-perceived high risk of STI/HIV							
No	458/925	49.51	1.00	1.00	p<0.00	1.00	p<0.00
Yes	62/339	18.29	0.21	0.22	(0.16-0.32)	0.20	(0.15-0.28)
Contraceptive Category							
Injectable	249/606	41.09	1.00	1.00	p=0.41		
Oral	203/521	38.96	0.92	0.89	(0.67-1.18)		
Condom	0/0	-	-	-	-		

6.6.2 Testing for HIV in the previous year

Table 6.16 shows the risk factor analysis for HIV testing in the previous year at follow up. As with condom use, age was significantly associated with whether women had tested for HIV during the past year. After adjusting for age, intention to have more children, condom use at last sex, use of condom with contraceptive method, ever use of condom, number of pregnancies and contraceptive category were associated with testing for HIV in the previous year. Women intending to have more children were less likely to have tested in the previous year (OR 0.67, p=0.01). Those women who reported condom use at last sex (OR 1.46), condom use with a contraceptive method (OR 1.56) and ever use of condoms (OR 1.87) were more likely to have tested for HIV in the previous year. Partner testing for HIV was associated with increased odds of testing (OR 3.21) as were increasing numbers of previous pregnancies (p=0.001). Interestingly, self-perceived risk of STI/HIV and number of sexual partners in the previous year were not associated with increased odds of testing for HIV in the previous year.

Women using oral contraceptives were also less likely to test for HIV in the previous year (OR 0.65) than women using injectable contraceptives.

In the final adjusted model ever use of condoms, partner testing for HIV and number of pregnancies were associated with HIV testing in the previous year. Ever use of condom was associated with increased odds of HIV testing in the previous year (OR 1.97). Those women who reported that their partners had tested for HIV were more than three times more likely to have tested for HIV in the previous year (OR 3.17). As

with the baseline findings women who reported having had a previous pregnancy were more likely to have tested for HIV in the previous year.

Table 6.16: Factors associated with testing for HIV in previous year

Testing for HIV in previous year	No/Total	%	Crude OR 95% CI	Age Adjusted OR 95% CI	Adjusted OR 95% CI*
Relationships					
Married	202/332	60.84	1.00	1.00 p=0.31	
Cohabit	182/275	66.18	1.22	1.03 (0.71-1.50)	
Single	444/652	68.10	1.41	1.27 (0.90-1.80)	
Age Group					
<20	87/147	59.18	1.00		
20-29	403/552	73.01	2.18		
30-39	164/263	62.35	1.44		
>40	69/143	48.25	1.75		
Education Status					
Incomp Primary	10/19	52.63	1.00	1.00 p=0.21	
Complete Primary	121/215	56.28	0.99	0.96 (0.34-2.68)	
Sec & Above	698/1030	67.77	1.80	1.32 (0.48-3.60)	
Intention to have more children					
No	544/828	65.70	1.00	1.00 p=0.01	
Yes	285/436	65.37	0.94	0.67 (0.50-0.91)	
Condom use at last sex					
No	460/744	61.83	1.00	1.00 p= 0.01	
Yes	369/520	70.96	1.48	1.46 (1.11-1.91)	
Use of condom with contraceptive					
No	352/587	59.97	1.00	1.00 p=0.00	1.00 p=0.41
Yes	477/677	70.46	1.59	1.56 (1.20-2.04)	1.17 (0.81-1.68)
Ever use of condom					
No	174/328	53.05	1.00	1.00 p<0.00	1.00 p=0.00
Yes	654/931	70.25	2.04	1.87 (1.40-2.51)	1.97 (1.32-2.94)
Partner tested for HIV					
No	466/813	57.32	1.00	1.00 P<0.00	1.00 p<0.00
Yes	363/451	80.49	3.28	3.21 (2.37-4.37)	3.17 (2.33-4.32)
No of pregnancies					
None	31/109	28.44	1.00	1.00 P<0.00	1.00 p<0.00
One	348/470	74.04	7.71	7.76 (4.50-13.38)	9.13 (5.37-15.54)
Two	246/359	68.52	5.81	7.18 (3.96-13.01)	6.88 (3.99-11.88)
Three	117/182	64.29	4.74	7.16 (3.67-13.98)	5.75 (3.18-10.38)
Four or more	87/144	60.42	4.01	8.90 (4.34-18.25)	5.31 (2.83-9.96)

Testing for HIV in previous year	No/Total	%	Crude OR 95% CI	Age Adjusted OR 95% CI		Adjusted OR 95% CI*	
No of partners in last year							
None	15/23	65.22	1.00	1.00	p=0.86		
One	761/1157	65.77	0.99	0.89	(0.36-2.24)		
Two	40/62	64.52	0.95	0.72	(0.25-2.13)		
Three or more	13/22	59.09	0.77	0.69	(0.19-2.51)		
Self-perceived high risk of STI/HIV							
No	607/925	65.62	1.00	1.00	p=0.84		
Yes	222/339	65.49	1.01	0.97	(0.72-1.30)		
Contraceptive Category							
Injectable	410/606	67.66	1.00	1.00	p=0.00	1.00	p=0.09
Oral	312/521	59.88	0.71	0.65	(0.49-0.87)	0.78	(0.58-1.04)
Condom	0/0	-	-	-	-	-	-

Chapter 7: DISCUSSION

7.1 Chapter Overview

This chapter is the final chapter in the thesis and will be presented in four sections. The first section will aim to review and summarise the main study findings. This will be followed by a discussion of the limitations and implications of the study findings. Finally, areas for further research will be discussed.

7.2 Summary of main findings

7.2.1 Relevance of the intervention tested

Adolescent girls and young women are a population at risk of HIV in eastern and southern Africa and young women are eight times more likely than their male counterparts to be living with HIV (UNAIDS, 2013). Expanded access to antiretroviral treatment (ART) has led to declines in AIDS-related mortality meaning that the number of people living with HIV continues to increase. This means that health systems need to cater for increasing number of people on treatment as well as provide expanded access to testing and prevention for all requiring more innovative ways of integrating services to meet multiple needs.

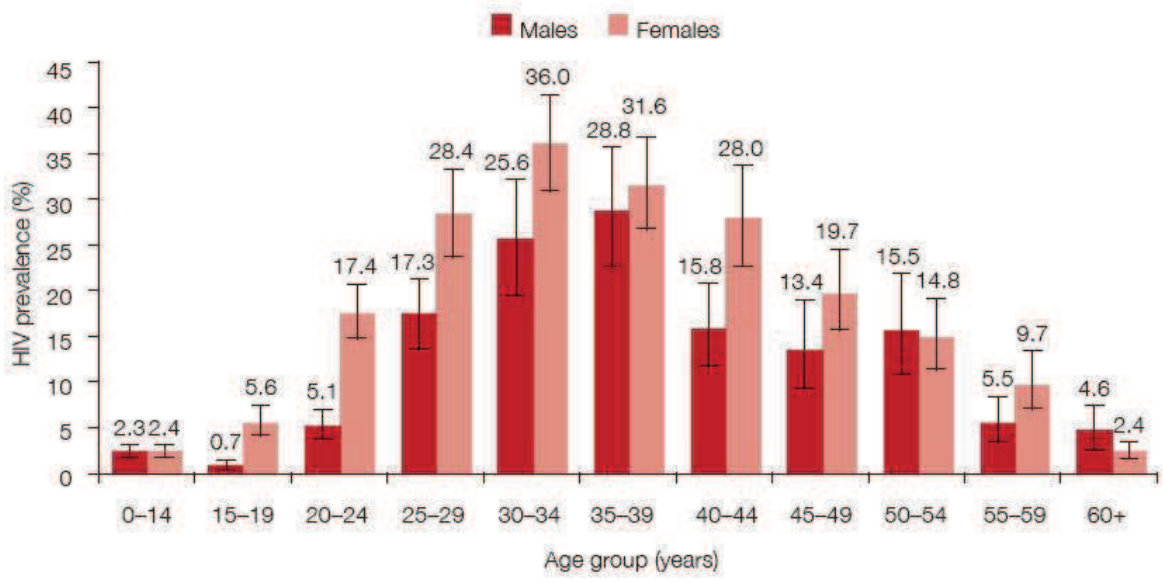
New HIV infections have declined but not abated and strategies to prevent new infections are still needed (UNAIDS, 2013). In east and southern Africa approximately 7,000 new infections occur every week amongst young women, and a third of these new infections occur in South Africa which contributes disproportionately to these new infections despite a doubling of the proportion of HIV-positive people on ART from 16% in 2008 to 31% in 2012 (UNAIDS, 2013). HIV prevention amongst young women has thus become a priority.

Recent guidelines recommending universal testing for HIV and immediate treatment and Pre-exposure prophylaxis provision for populations at significant risk of HIV (World Health Organisation, 2016) have also required thinking about where best to position these services for young women. HIV testing is an entry point for both prevention as well as early initiation for treatment.

Recent breakthroughs in HIV prevention research have created new opportunities to curb new HIV infections, save lives and reduce the global investment required for the HIV response. The HIV epidemic is already being impacted by using existing prevention tools (especially expanded HIV testing and early antiretroviral (ARV) treatment, voluntary medical male circumcision (VMMC), and Option B+ for pregnant women). In addition, activity is continuing in the biomedical prevention research arena, and the availability of oral PrEP is now a potential reality, with further potential prevention technologies at various stages in the development pipeline. Despite enthusiasm for biomedical tools, there is still a lack of a clear framework for defining optimal, context-specific packages of combination prevention. There are real challenges in sustaining support for research and timely introduction of new strategies in the future including how best to provide HIV testing as an entry point for both prevention technologies and early treatment for those testing HIV positive.

The trial reported in this thesis provides evidence of an effective integration strategy for offering testing to sexually active women in South Africa, a country with high HIV prevalence amongst young women and high contraceptive uptake. South Africa recently announced that universal testing for HIV and immediate treatment, as well as oral PrEP for sex workers will be made available through the national department of health.

Figure 7.1: HIV Seroprevalence by age group in South Africa (Shisana et al., 2015)



Family planning services are a highly utilised public sector service in South Africa catering to women who access the services, are sexually active and requiring both contraception services as well as HIV prevention and treatment. A qualitative study (Gates Foundation et al., 2012) assessing potential service delivery channels for PrEP specifically highlighted FP services as a delivery channel for young women. The report stated reasons such as high utilisation of FP services and accessibility of the service, potential reduction of stigma associated with PrEP provision and being able to leverage existing staff, facilities and client management systems (Gates Foundation et al., 2012). The baseline characteristics of the women participating in the trial showed that the integration of STI and HIV services and information was a relevant intervention for this relatively young, sexually active population with low condom use, half of whom had not tested for HIV previously. Almost two thirds of the women were 30 years old or younger. This is the group with the highest HIV prevalence and incidence in South Africa (NDOH, 2012). None of the women reported using condoms as a contraceptive method and under a third of women reported using a condom at last sex. Most women (90%) reported having had at least one previous pregnancy and for many of those women HIV testing may have been offered as part of antenatal care services. However, it is important that women are able to know their HIV status early prior to getting pregnant, for example through FP services, so that appropriate measures can be taken to minimise the risk of transmission to the infant. In South Africa, the National Contraceptive and Fertility Policy (Department of Health, 2012) makes provision for safer conception services for sero-discordant couples. The study did not address improving uptake of HIV testing amongst male partners of FP clients. However, HIV testing for women already accessing services would be an important entry point to prevention and treatment services for herself as well as potentially her male partner. As we did not follow up a cohort of women nor did we ask women to disclose their HIV status, our study design did not allow us to determine the number of women who intended to have children in future and who were detected as HIV positive early through this approach.

As the only cluster randomised study assessing the integration of HIV testing into FP services, this study provides empirical evidence of the feasibility and effectiveness of an intervention to improve testing uptake amongst FP clients as an entry point to prevention and treatment services for HIV. In the South African context this study also

provides an effective model to operationalise existing policy and guidelines. There are relatively few studies examining outcomes of integrating HIV services into FP as the majority of studies address FP integration for HIV positive individuals. Of the studies identified in the systematic literature review in Chapter 2, the study reported in this thesis is one of two RCTs conducted on integrating testing into FP services, with the majority employing study designs with no control group. Liambila et al (Liambila et al, 2009) evaluated a similar intervention using the BCS plus materials in Kenya through a pre and post intervention design without a control group. The study reported in this thesis therefore adds empirical evidence to the literature on the effectiveness of interventions to integrate HIV testing into FP services through a gold-standard study design.

7.2.2 Comparison of primary outcomes between intervention and control arms

There were two primary outcomes of the trial – HIV testing in the previous year and condom use at last sex. Information on both of these outcomes was collected through client exit interviews. Follow up comparison between study arms showed that testing for HIV in the previous year was significantly higher amongst women attending the intervention facilities (unadjusted RR 1.56 (1.13,2.15) p=0.01). After adjustment for cluster level previous testing for HIV, women in the intervention facilities were still more than 50% more likely to have tested in the previous year (adjusted RR 1.51 (1.07,2.13) p=0.02). However, condom use at last sex was similar across the two groups (RR 1.10 (0.85,1.43) p=0.14) at follow up. At baseline, cluster means for condom use were 32.6% and 35.9% in intervention and control groups respectively. At follow up these figures were 43.4% in the intervention arm and 39.4% respectively showing an increase of over 10% in the intervention facilities and approximately 7% in the control facilities. However, there were wide confidence intervals around these estimates and the comparison at follow up did not show significant differences in condom use at last sex at follow up.

Thus the intervention did show an effect on one of the primary outcomes, self-reported HIV testing in the previous year. Since we did not ask about HIV status we are unable to ascertain what proportion of clients would have required retesting.

7.2.3 Comparison of secondary outcomes (quality of care scores) between intervention and control arms

Integrating additional services such as the offer and provision of HIV testing as part of the routine FP visit may improve uptake of HIV testing amongst FP clients but if this occurs whilst diminishing the quality of FP services this would not be a desirable outcome. Thus it was important to measure the effect of the intervention on both the HIV test uptake as well as the effect on the quality of the FP service.

Secondary outcomes of the trial were a set of quality of care scores to ascertain the provision of aspects of both FP and HIV service provision. Although quality of care scores would not traditionally be assessed as part of a trial, given that this is a trial testing the effect of integrating new services into an existing service, it was felt that it would not only be appropriate but important to demonstrate the effect of adding a new service to the existing one. A set of seven scores and a total quality score adding up the scores of the seven component scores were assessed. The total quality of care scores in intervention facilities were double those in the control facilities (16.02/33 versus 8.82/33) at follow up but the wide confidence intervals around estimates due to the high level of variability between facilities resulted in these differences at follow up not being statistically significant.

Despite some measurable improvements in the quality of care, there remained much room for improvement even at the intervention facilities. This may have been accomplished by a more intensified intervention promoting more adherence with the use of the intervention tools as some providers were not observed to be using them and the exposure analysis showed a correlation between observed use of the tools by providers and quality of care scores.

Sub-group analyses for the two primary outcomes sub-group analyses were conducted for effect modification by age, relationship status and educational status. Testing for HIV in the previous year was more likely in the intervention group (RR 1.56) in those 30 years and younger as well as in the over 30 year age group (RR1.67). Similarly women in all educational categories were more likely to have tested for HIV in the previous year in the intervention facilities. Tests for interaction showed that neither age, relationship status nor educational status were effect modifiers.

A similar analysis for effect modification by age group, relationship status and educational status for condom use at last sex showed that condom use was similar in both intervention and control groups in young women <=30 years (RR 1.09). In the older age group condom use at last sex was higher (RR 1.49) in intervention versus control group. Women in both high and low educational categories were more likely to report condom use at last sex in the intervention group. Older women, married women and women who had not completed primary education were less likely to report condom use. There was no evidence of effect modification by age, relationship status or educational status on reported condom use at last sex.

7.2.4 Retrospectively identified cohort

An analysis for effect of the intervention on the two primary outcomes was repeated on a cohort of retrospectively identified women who were interviewed at the study facilities during the baseline and follow up surveys. A total of 254 such women were identified during the follow up survey. There were no effects of the intervention seen on testing for HIV in the previous year (RR 1.02 (0.83,1.20) p=0.82). Condom use at last sex was also not significantly higher in the intervention group (RR 1.23 (0.61,1.64) p=0.35). However, proportions of women testing for HIV were higher in this group 57.4% and 56.4% of women reporting testing in the last year in the intervention and control arms respectively.

7.2.5 Analyses of associations between use of BCS Plus tools and quality of care

Regression analyses were conducted to ascertain the association between observed use of the intervention tools and quality of care scores as well as total quality of care. This analysis was conducted at cluster level and limited to the six intervention facilities. Positive trends in all scores were seen with increasing observed use of the BCS Plus tools and with the exception of client provider rapport score changes in all the other scores were explained to a large degree by usage of the BCS Plus tools. Total quality score was significantly explained by the use of the tools accounting for 69% of the variation in quality of care overall (p=0.04). Although total quality of care was not found to be significantly higher in intervention as compared to control facilities the exposure analysis shows that the use of the tools was associated with better quality of care. Positive trends were also seen for other component scores with a significant proportion

of history taking score, STI information score, C&T counselling score and total quality score being explained by the use of the BCS Plus tools.

When assessing the relationship between the total quality of care and the two primary outcomes there was strong evidence that improved total quality of care was associated with improved testing for HIV in the previous year (p=0.007) showing a dose-response effect further strengthening the case for the effectiveness of the intervention on HIV test uptake. Unfortunately this association was not seen for condom use at last sex (p=0.45) suggesting that the decision to use condoms is not so much influenced by information and counselling provided through health providers but driven by other factors not amenable to a health service delivery based intervention. These factors influencing condom use are discussed in Chapter 2. However the opposite seemed true for HIV testing suggesting that provision of information and offer of testing was likely to influence clients to test. Perhaps this is because a woman is able to take an HIV test without informing her partner and this can be done relatively independently as opposed to condom use which relies heavily on partner cooperation. A weakness of the intervention was the lack of emphasis on partner engagement and in particular encouraging FP clients to ask their male partners to test for HIV or use condoms.

7.2.6 Key results of risk factor analyses

7.2.6.1 Condom use at last sex

The adjusted risk factor model for condom use at last sex at follow up showed that number of pregnancies, self-perceived risk of STI/HIV and relationship status were associated with condom use at last sex. Condom use decreased with increasing age group. Those women with secondary or higher education were more likely than women with no education to use a condom the last time they had sex (p=0.002). This finding is consistent with other studies in South Africa (Maharaj and Cleland, 2004). Women who had previously been tested for HIV were more likely to report having used a condom at last sex than those who had not previously tested for HIV. This may be because these women may have more positive health behaviours which include getting tested and using condoms or could be a result of effective promotion of condoms during HIV test counselling. However, high self-perceived risk of HIV was significantly associated with a decreasing likelihood of condom use at last sex, suggesting that the high self-perceived risk might be due to an inability to negotiate

condom use with a partner. Other studies in South Africa found that high self-perceived risk of HIV from her partner was a strong predictor of condom use (Maharaj and Cleland, 2005b). It would have been useful to explore why these women who clearly expressed their high risk were not using condoms and whether the lack of use was related to inability to negotiate condom use with the partner or other factors, for example gender based violence.

7.2.6.2 Testing for HIV in the previous year

The final adjusted risk factor analysis showed that ever use of condom, partner testing for HIV and number of pregnancies were associated with testing for HIV in the previous year. Partner testing was also associated with a greater likelihood of previous testing of HIV. Those whose partners tested were around three times more likely to have tested previously ($P<0.001$) although this may be due to reverse causality as it is unknown whether the partner tested before or after the woman. Women that were using oral contraceptives were less likely to have been previously tested for HIV than those using the injection, both before and after adjusting for age ($p=0.01$ and $p=0.003$ respectively). However, in the final adjusted model this association did not remain significant.

7.3 Limitations of the study

7.3.1 Study design

Despite using a randomised controlled trial design, regarded as the gold standard for the evaluation of health interventions, there were a number of limitations of this study design. Two cross sectional surveys were conducted pre and post intervention as it was assumed that family planning clients are a fairly stable population attending the same health facility at two to three month intervals for a re-supply or re-administration of their contraceptive method. Only a small number of clients captured in the baseline survey were interviewed at follow up suggesting that FP clients may not be as stable a population as previously thought. One explanation for this could be that the data collection period of less than three months could have meant that some clients who were still accessing FP services at the facility were missed. Other possible explanations for this finding may be that clients may have changed fertility intentions either as a result of testing for HIV or other factors and they may have subsequently

decided not to use contraception; fallen pregnant or tested and been referred for other HIV related services in which case they would be attending other antenatal, wellness or treatment services; or migrated out of the area and sought FP services elsewhere. Some providers in a few (not all) clinics reported that once FP clients tested positive that they would not return for FP as they would have to attend other services and some would seek advice from traditional healers who may advise them to discontinue their contraceptive methods. Unfortunately, combined with the lack of a unique client identifier used routinely in health facilities we were unable to track individual clients and their utilisation of additional services.

Ideally, follow up of a cohort of women in the control and intervention clusters could have provided stronger data on testing, utilisation of other services, risk behaviour including condom use and changes in fertility intentions or pregnancies and provided baseline data at individual level (rather than aggregate for cluster) and more accurate data on exposure to the intervention. Further, a cohort study would have allowed a better understanding of the number of FP visits before clients tested for HIV, and other HIV related services provided both through the formal sector and through traditional channels. However, the resources available for the study did not allow the follow up of a large cohort of women.

Data on testing in the previous year (primary outcome) were not collected during baseline and for this reason the baseline comparisons were made on the variable ever tested for HIV. Thus, it is unknown whether recent testing in the previous year was comparable at baseline.

The evaluation outcomes should have included an assessment of the effect of the intervention on HIV testing for male partners and a detailed understanding of partner dynamics and negotiation including experience of GBV. This data would have assisted in interpreting the data on primary outcomes.

7.3.2 Methodology

Client provider observations may overestimate the quality of care provided due to the presence of an observer in the room. However, this effect is anticipated to be similar in both intervention and control arms. Client exit interviews were conducted at health

facilities that may have increased the chances of reporting of positive health behaviours. Again, this effect is assumed to be similar in intervention and control groups but the possibility that the use of these methodologies may have biased the estimated difference between arms cannot be ruled out.

Baseline comparisons of the socio-demographic and risk characteristics of family planning clients showed that the intervention and control groups were generally very similar suggesting that the randomisation was effective. However, the experience of previous testing for HIV was higher at baseline in the control group (58% versus 49%) necessitating an adjusted analysis on the primary outcome testing for HIV in the previous year.

7.3.3 Implementation of the intervention

Implementation of the intervention was provided through training providers from intervention sites that attended training. It was expected that trained providers would have gone back to their facilities and provided training to others unable to attend. There was no verification of whether this training was provided and no observation of the quality of this cascaded training. It is possible that the intervention could have been further intensified by doing direct training with all eligible staff at all intervention sites. This potential “dilution” of the intervention could have resulted in an overall underestimate of the possible effect of the intervention at facility level. Pre and post-tests were also not conducted as part of the training of providers to explain differences between sites in terms of implementation. However, a great deal of variation in quality of care was explained by the observed use of the intervention tools. Further, the research team learnt that some staff rotated out of facilities. There was no further information available as to how many trained staff rotated out of facilities and whether they were posted to control facilities. Staff moving between intervention and control facilities would have diluted the effect of the intervention by reducing differences between study arms thus further underestimating the true impact of the intervention tools. Staff rotation and cascaded training are nevertheless common events at health facilities all over the country and therefore the results of the study may be a good reflection of effectiveness of the interventions in “real life” circumstances.

There was also a large degree of variation in observed use of the BCS Plus intervention tools at follow up. In fact, in two intervention clinics none of the providers were observed to be using the intervention tools. The utilisation of tools observed ranged widely from 0–60% but they were not used universally in any of the intervention clinics. This would have also resulted in an underestimate of the true potential of the tools and the use of the intervention tools could have been reinforced during supervisory visits. Again, the results may be reflective of the intervention under operational circumstances and of effectiveness rather than efficacy if applied under optimal conditions. During supervisory visits where the tool was not observed to be used, providers were asked about why they were not using the tools. Some reported that they were already conversant with the content and therefore did not need to keep referring to the tools. However, barriers to the use of tools were not documented and addressed systematically further potentially diluting the potential effect of the intervention. The exposure analysis presented in Chapter 6 does illustrate that observed use of tools was positively associated with improved quality and therefore this explanation provided is unlikely to be valid. Understanding of provider issues is a critical aspect to understand and address. Whilst shortage of financial resources, particularly as reflected in shortage of staff, is frequently assumed to be the biggest constraint in South Africa, a study found that most health managers identified other issues, particularly staff morale, as greater barriers to the delivery of high quality health services. The authors concluded that it is the complexity of experience and feelings described by health managers that may determine the extent and quality of service delivery (McIntyre and Klugman, 2003). We did not attempt to measure staff morale and management capacity at facilities.

At both baseline and follow up a large degree of variation was seen between facilities in terms of quality of care. Although the large degree of variation did not allow significant changes in quality of care to be detected the differences in total quality scores was large. It was interesting to note that the quality of care in all control facilities declined post intervention.

One aspect of the integrated service that was not observed during client provider interactions in an attempt to preserve confidentiality was the provision of testing for HIV. The pre-test counselling may have impacted significantly on client decisions to

have an HIV test. Thus, we are unable to report on the quality of the pre and post-test counselling for the HIV test and whether or not the quality of pre-test counselling was associated with uptake of the HIV test.

7.3.4 Outcomes

The primary outcomes (HIV testing and condom use) in the study were both self-reported and assessed through client exit interview at health facilities and may have been subject to over reporting. In addition to the problem of social desirability responses regarding risk behaviours, for logistic reasons it was not possible to verify whether or not clients had tested for HIV in the past year, for example using health facility registers or other means, however quality of routine clinic data is notorious for its poor quality and this was not done. Actual condom use would have been impossible to verify and was therefore only self-reported. An additional problem with choosing condom use at last sex as an indicator of dual protection is that it reflects one time point and may not be a measure of consistent condom use. Also condom use may be determined by other factors such as availability, type of partnership, circumstances of sex (forced or consensual). We did not explore all of these factors this in the client exit interviews.

The complexity of the trial would have been significantly increased if we had attempted to monitor clients testing at other clinics and HIV testing registers being paper based and therefore this was not done. Also, due to confidentiality reasons we did not ask clients to disclose their HIV status to field workers and were therefore not able to assess who may have already tested positive and therefore been ineligible to test for HIV. However, a large proportion of clients had not tested at baseline and therefore testing for HIV was an appropriate outcome for the large proportion of clients who had not previously tested and those who may have tested negative for HIV on a previous test and would therefore be eligible for retesting. Ideally, the proportion of clients taking up testing should have been assessed with a denominator that excluded clients who had tested positive for HIV on a previous test.

The lack of effect observed on condom use may have been due to factors uptake of services that were insufficiently explored during the client exit interview; for example, a women's ability to negotiate condom use may have been affected by her experience

or fear of gender-based violence (GBV). Women experience high levels of intimate partner violence (IPV) in their lifetime with a prevalence of 30%, although there is significant heterogeneity within regions. In a study conducted in 6 cities including Johannesburg experience of IPV ranged from 10-36% amongst 15-19 year olds and was highest in Johannesburg (Decker et al., 2014, Heise and Fulu, 2014). In a study of 1099 women aged 15-26 years from the Eastern Cape in South Africa, 23% experienced physical or sexual IPV whilst 5% reported rape by a non-partner over a two-year period. In addition to the strong association between IPV and HIV, this study also showed a relationship between levels of inequality within partnerships and HIV. Women who reported low relationship power equity had a higher risk of HIV infection (Jewkes, 2010). Women who experienced low gender equity were also more likely to experience IPV. Interestingly, risk of incident HIV was not associated with rape by a non-partner. These data suggest that sexual violence may not be the most important risk factor and that physical violence, verbal abuse, and male controlling behaviours are potentially more important (Durevall and Lindskog, 2014, Kouyoumdjian et al., 2013). Studies amongst pregnant women show that anticipated IPV is associated with refusing HIV testing due to stigma and fear of disclosure to the partner (Hatcher et al., 2013).

The limitations related to self-reporting of primary outcomes could have been addressed in the study design with the use of additional data on biological markers such as STI and HIV testing. This had been discussed at the study design phase but the cost of including this data was prohibitive. Other studies have shown that condom use is considerably higher in couples where one or both partners were thought to be HIV positive but remained low in married couples (Maharaj et al., 2012).The influence of HIV sero-status on condom use and testing would have been a useful aspect to have explored further.

As discussed in Chapter 2 of the thesis, quality of care has multiple dimensions including provider knowledge, skills and attitudes, client satisfaction, facility level readiness and addressing barriers to access. For this trial, client provider observations were chosen as the methodology as this allowed observation and measurement of actual services and advice provided to the client. As improvements in provider knowledge may not always translate into improved services provided to clients this

was considered a more direct measure. It may have also been desirable to evaluate client understanding of provider messages. However, due to the length of the client exit questionnaire this channel of enquiry was not included. It is possible that client provider observations may positively influence quality of care due to the presence of an observer. However, this effect would have been seen in both intervention and control clinics equally and therefore differences in quality of care could still be attributed to improved provider skills as a result of the training provided.

7.4 Implications of the findings

The study shows that the intervention did impact on HIV testing in the previous year but did not show any effect on condom use at last sex. The exposure analysis presented in Chapter 6, section 6.5 shows that the relationship between dual protection score and use of the BCS plus tools was not significant. Condom use at last sex was also not associated with total quality score. Further, the risk factor analysis showed that relationship status, number of pregnancies and self-perceived risk were significantly associated with condom use. These findings imply that although there is a need to strengthen the dual protection component of the BCS plus intervention, this may not influence condom use and in fact other factors play a stronger role in decisions around condom use. Findings show the need to target older women and married women to promote condom use. At the time this study was conducted there was an interest in models of integrated services that would improve uptake of testing. However, in the more recent context of the release of the WHO guidelines on Universal Test and Treat (World Health Organisation, 2016) as well as oral pre-exposure prophylaxis (PrEP) the findings of this study have more current relevance.

South Africa has only recently rolled out PrEP to sex workers (National Department of Health, 2016). Although no policy currently exists regarding the promotion or distribution of ARV-based prophylaxis (PreP) for young women, the necessity to prepare for availability of such new technologies and the understanding that testing for HIV is an entry point to both prevention and treatment services is widely accepted. For example, the new National Contraception and Fertility Planning Policy and Service Delivery Guidelines (DOH, 2012) and accompanying National Contraception Clinical Guidelines, contain a section on the potential future use of PrEP and Post-

exposure prophylaxis (PEP) to prevent HIV transmission in sero-discordant couples. Potential indications and current research findings are explained, including that these products reduce, not eliminate, the risk of transmission during unprotected intercourse with an HIV-infected partner.

7.4.1 Generalisability

The location of the study sites in North West Province as well as the inclusion criteria for the health facilities which the majority of primary health facilities in South Africa meet allow the conclusion that the results of this study can be generalised to other rural/peri-urban facilities in the country. Despite clinics meeting the same inclusion criteria, there was a large degree of variability between the study clinics resulting in a loss of power particularly when comparing the quality of care across study arms.

7.4.2 Implications for scale up

There are currently no published randomised controlled trials assessing the effect of integration of HIV services into FP. Further this is one of the few studies that provide a validation of intervention tools to strengthen integrated FP and HIV services in terms of improved quality of care. The data presented in this thesis further demonstrate the association of total quality of care with improved testing for HIV in the previous year. The use of a rigorous study design and the exposure analysis showing the effect of the intervention tools supports the promotion of wider use of the BCS Plus tools as an evidence-based practice in high HIV/STI prevalence settings. Implementation of the tools would require an investment in printing of materials and training as a recurrent cost due to high staff turnover at facilities. The costs of developing the tools including consultations with stakeholders were covered through this project and would not be considered as costs related to scale up.

A recent paper published in the Lancet reporting on the relationship between use of hormonal contraception and HIV acquisition (Morrison et al., 2012) has led to much international discussion and a need to review evidence. In February 2012 the World Health Organization (WHO) brought together global experts to review existing evidence. WHO subsequently recommended that women living with HIV, or at high risk of HIV, continue to use hormonal contraceptives to prevent pregnancy, but emphasised the need to also promote the use condoms to prevent HIV acquisition and

transmission and the importance of offering a wider choice of contraceptive options. These recommendations have been upheld by the WHOs Guidelines Review Committee, the body responsible for ensuring that all WHO recommendations are based on the best available scientific evidence. There is a pressing global need to ensure that appropriate HIV prevention messages and services coupled with expanding the choice of contraceptive methods available to women form a routine part of family planning (FP) services, particularly in high HIV prevalence settings. However, despite the development of tools aimed at better integrating HIV services into FP services there is little empirical evidence on whether these tools improve quality of integrated care.

The publication of the Morrison paper (Morrison et al., 2012) led to the South African Government convening a team of national experts in 2012 to review the current South African National Contraceptive Guidelines (National Department of Health); a revision of the guidelines has been conducted in line with WHOs recommendations and are about to be launched. The findings on the BCS Plus as a potential tool to implement the recommendations are thus timely. Based on presentation of preliminary findings from the study the Provincial Department of Health in KwaZulu-Natal has requested copies of the BCS Plus materials with a request for technical assistance to train providers in the province.

7.5 Areas for further research

The study results demonstrate the potential for FP services to improve the uptake of HIV testing as part of these services. A valuable area for further research in the context of providing comprehensive integrated services would be to document whether the testing led to effective referrals for HIV services and also to explore the potential for further HIV related services to be offered to FP clients known to be HIV positive. Given the challenges with early detection of HIV infected individuals and with poor retention in care the potential of FP services to diagnose early and retain HIV positive women in care should be explored.

In addition to exploring the impact of integrated services on HIV positive women it would be important to address HIV negative FP clients. As the majority of FP clients, even in high prevalence settings, are HIV negative the potential effect of repeated

discussion of HIV risk and prevention on keeping women negative would be important to document. PrEP has now become an available prevention option. However, there is a lack of evidence on how to target women at most risk and how best to deliver PrEP to young women and through which service delivery models. In a recent study assessing the practical delivery of PrEP in South Africa (van der Straten et al., 2014) women did not express a clear preference for any one PrEP formulation, but identified benefits and limitations associated with each specific formulation. The regulatory requirements, and health system infrastructure, led stakeholder to identify public sector primary health care clinics (PHC) as a key programmatic entry point for most women. Given the PHC sector has implemented HCT, PMTCT and ARV services, the provision of PrEP could be seen as a good fit within this basket of services. In addition to PHC, family planning clinics were also recommended as key entry points, given that family planning use is high among women in KZN and clinics are widely available and accessible. Providing PrEP through the PHC setting reduces potential stigma associated with PrEP, provides a convenient opportunity for integrated health care, and takes advantage of existing staff, facilities and client management systems

A related issue of the timing and intervals for repeat testing as well as the feasibility and uptake of repeat testing would be crucial to provide evidence-based guidance on testing frequency and recommendations.

It is unclear why women decide to undergo testing for HIV, and how positive and negative test results impact their sexual behavior (Exner et al., 2002). A study offering an intervention aimed at reducing sexual risk showed that the predominant reason for not being tested for HIV was anxiety about the result. Regardless of their testing status at baseline, more than 40% of the 340 women in the study believed that getting tested is a good way to prevent acquiring HIV. Women in this study (Exner et al. 2002) who had been tested multiple times or had last been tested more than six months ago were more likely than women in the control group to initiate HIV testing by the one-month follow-up (relative risk, 2.9 and 6.1, respectively). Rates of mutual testing (being tested at the same time as one's partner) were significantly greater among women who participated in an intervention than among controls at the one-month and six-month interviews (Exner et al., 2002). A study amongst HIV positive women in Zimbabwe found prejudices that HIV positive women should not be sexually active or have

children meant women did not disclose their status to health workers, making it difficult for their needs to be acknowledged or addressed. In this study, condom use was also considered inappropriate in marriage (Feldman and Maposhere, 2003). Understanding what motivates women to test and factors influencing repeat testing is a critical issue to consider in the current discussion on the availability of an increasing array of biomedical prevention technologies for women including microbicides, and pre-exposure prophylaxis. The impact of such interventions on male HIV testing should also be further investigated.

As mentioned above, the resources for the study did not allow the follow up of a cohort or the measurement of the effect of integrated services on the incidence or prevalence of HIV in the two study arms or on the rates of unwanted pregnancy as a result of strengthened FP services. The impact of this integrated intervention on biological outcomes should be investigated.

High proportions of women reporting that their last pregnancy was unwanted (almost 50%) were reported in both intervention and control groups at baseline and follow up. About a third of women reported that they were on a contraceptive method when they fell pregnant. Questions were not asked regarding intermittent use and compliance with the method. Further research should be conducted as to why these reported rates were so high amongst FP users and whether unwanted pregnancies prompted the use of FP services or whether inconsistent use, irregular attendance at FP services, poor understanding of the method or poor compliance with FP methods play a role in the high rates reported. It was interesting to note that amongst the retrospective cohort of clients identified at follow up the rates of unwanted pregnancy were only about half as high as in other women, possibly reflecting more positive health behaviours including continued attendance for FP services in this group.

A broader issue of programmatic importance is the low uptake and provision of long acting and permanent methods of contraception reported at all services and the extremely low use of condoms as a contraceptive. This is a generalised issue in South Africa and the need for reintroduction of a broader contraceptive method mix and the perception of condoms purely as an STI/HIV prevention method needs to be addressed. The lower likelihood of using condoms reported by married couples is also

consistent with other studies but on a broader level requires further research on how prevention programmes can better meet the needs of married couples (Maharaj et al., 2012).

Despite the promotion of condom use and dual protection as part of the intervention there was a lack of substantial effect on condom use. It is noteworthy that reported condom use at last sex did not seem as strongly influenced by quality of care as HIV testing. There is further research required into the reasons for low condom use as well as an understanding of how to "reposition" the condom to be seen as a contraceptive option. Integrating dual-protection counselling and female condom provision into family planning services appears feasible, as is service providers' acceptance of dual-protection objectives. While providers and clients are key to transforming family planning to dual-protection services, the attitudes and behaviors of clients' male partners were not addressed in this study but must be considered in gauging the success of dual-protection interventions (Adeokun et al., 2002). Further, women experience difficulties in divulging their HIV infection to their partners and then negotiating the adoption of new practices which proves to be a major obstacle to behavioural change. The success of future prevention programmes will depend on their ability to take the relationship between man and woman in the couple into account (Loû and Coleman, 2005). However, factors affecting the uptake of dual protection are more complex and seem to be influenced by other non-provider related issues. A study examining the use of dual-protection strategies in a sample of 15–49-year-old men and women in Botswana showed that only 2.5% of respondents reported dual-method use. Multiple logistic regression analyses showed that urban residence, less than a ten-year age difference between partners, discussing HIV and contraception with one's partner, not intending to have a child in the next year, having no children, being in a relationship where one or both partners have additional concurrent partners, and supportive condom norms were associated with dual protection (Kraft et al., 2009)

As this intervention has been found to have a positive impact on HIV testing further costing information on cost effectiveness as well as unit costs per person tested through an integrated approach as opposed to vertical services would be useful for policy makers to make decisions on whether to prioritise further investments in integrated models or continue to support vertical C&T services. There are no studies

in the published literature that compare the cost effectiveness of integrated FP/HIV services versus vertical services.

The strategy of testing for HIV within FP services and the potential for early detection of HIV status with integrated long term follow up for those tested HIV positive within FP services has not been tested. Most contraceptive methods are safe and effective for HIV positive women and men (Delvaux and Nöstlinger, 2007) and therefore this might be a feasible integrated model to test. The existing range of contraceptive options should be available to people living with HIV, along with more information about and access to emergency contraception. How to promote condoms and dual protection and how to make them acceptable in long term-relationships remains a challenge. Simple and cost-effective procedures to reduce risk of vertical transmission should be part of counselling for women and men living with HIV who intend to have children. However, more operations research on best practices is needed. Recently nurses in South Africa have begun to initiate and manage antiretroviral therapy (ART) and therefore a more integrated approach for HIV management within the FP services might be feasible and should be tested. A recent systematic review on integration of FP with other services reported that the evidence supporting the integration of family planning with other health services remains weak, and well-designed evaluation research is still needed (Kuhlmann, Gavin et al., 2010). Future research should report outcomes for all health areas being integrated and should investigate in more detail the perspectives of providers, clients and community members and assess the cost-effectiveness of integration (Kuhlmann et al., 2010).

Finally, evidence of FP services reaching men and adolescents and of their impact on health outcomes is inconclusive. Several studies have found that providers frequently miss opportunities to integrate care and that the capacity to maintain the quality of care is also influenced by many programmatic challenges. The range of experiences indicates that managers need to determine appropriate health-care service-delivery models based on a consideration of epidemiological, structural, and health-systems factors (Church and Mayhew, 2009).

REFERENCES

ADAMS, I. & KRAUSHAAR, H. 2005. Expanded Community Based Distribution project: impact analysis report Zimbabwe. Arlington: Advanced Africa.

ADEOKUN, L., MANTELL, J. E., WEISS, E., DELANO, G. E., JAGHA, T., OLATOREGUN, J., UDO, D., AKINSO, S. & WEISS, E. 2002. Promoting Dual Protection in Family Planning Clinics in Ibadan, Nigeria. *International Family Planning Perspectives,* 28**,** 87-95.

ADONGO, P. B., TAPSOBA, P., PHILLIPS, J. F., TABONG, P. T.-N., STONE, A., KUFFOUR, E., ESANTSI, S. F. & AKWEONGO, P. 2013. The role of community-based health planning and services strategy in involving males in the provision of family planning services: a qualitative study in Southern Ghana. *Reproductive health,* 10**,** 1.

AFRICAN UNION COMMISSION 2006. *Maputo Plan of Action for the Operationalization of the Continental Policy Framework for Sexual and Reproductive Health and Rights: 2007–2010,* The African Union Commission: Maputo: Special Session of the Africa Union Conference of Ministers of Health. Maputo, 18–22 September 2006.

ASKEW, I. & BERER, M. 2003. The contribution of sexual and reproductive health services to the fight against HIV/AIDS: a review. *Reproductive health matters,* 11**,** 51-73.

ASKEW, I. & MAGGWA, N. B. 2002a. Integration of STI Prevention and Management with Family Planning and Antenatal Care in Sub-Saharan Africa: What More Do We Need to Know? *International Family Planning Perspectives,* 28**,** 77-86.

ASKEW, I. & MAGGWA, N. B. 2002b. Integration of STI prevention and management with family planning and antenatal care in sub-Saharan Africa: What more do we need to know? *International Family Planning Perspectives***,** 77-86.

ATUN, R., DE JONGH, T., SECCI, F., OHIRI, K. & ADEYI, O. 2010. A systematic review of the evidence on integration of targeted health interventions into health systems. *Health policy and planning,* 25**,** 1-14.

BAEK, C. & RUTENBERG, N. 2005. Addressing the family planning needs of HIV-positive PMTCT clients: baseline findings from an operations research study.

BARRY, T. M. 1998. Family planning associations (FPAs) respond to the HIV / AIDS epidemic. *Africa Link: A Publication Of The Africa Region***,** 8-9.

BECKMAN, L. J. & HARVEY, S. M. 1996. Factors affecting the consistent use of barrier methods of contraception. *Obstetrics & Gynecology,* 88**,** 65S-71S.

BERER, M. 2003. HIV/AIDS, sexual and reproductive health: intimately related. *Reproductive Health Matters***,** 6-11.

BRADLEY, H., BEDADA, A., TSUI, A., BRAHMBHATT, H., GILLESPIE, D. & KIDANU, A. 2008. HIV and family planning service integration and voluntary HIV counselling and testing client composition in Ethiopia. *AIDS care,* 20**,** 61-71.

BRIGGS, C. J. & GARNER, P. 2006. Strategies for integrating primary health services in middle-and low-income countries at the point of delivery. *The Cochrane Library*.

BROWN, A. 2000. Current issues in sector-wide approaches for health development. *Overseas Development Institute, London, Strategies for Cooperation and*

PArtnership, Global PRogramme on Evidence and Health Policy Report WHO/GPE/00.4.
BRUCE, J. 1990. Fundamental elements of the quality of care: a simple framework. *Studies in family planning*, 61-91.
BRUNIE, A., WAMALA-MUCHERI, P., AKOL, A., MERCER, S. & CHEN, M. 2016. Expanding HIV testing and counselling into communities: Feasibility, acceptability, and effects of an integrated family planning/HTC service delivery model by Village Health Teams in Uganda. *Health policy and planning*, czw035.
CALDWELL, J. C. & CALDWELL, P. The fertility transition in sub-Saharan Africa. Conference on Fertility and the Current South African Issues of Poverty, HIV/AIDS and Youth, Pretoria, South Africa, 2002.
CAMPBELL, M. K., PIAGGIO, G., ELBOURNE, D. R. & ALTMAN, D. G. 2012. Consort 2010 statement: extension to cluster randomised trials. *Bmj,* 345, e5661.
CHEGE, J. N., ASKEW, I., MOSERY, N., NDUBE-NXUMALO, M. & KUNENE, B. 2005. Feasibility of introducing a comprehensive integrated package of antenatal care services in rural public clinics in South Africa.
CHURCH, K. 2011. *Meeting the sexual and reproductive health needs of HIV care and treatment clients in Swaziland: A comparative case study of integrated and stand-alone models of care.* London School of Hygiene and Tropical Medicine.
CHURCH, K. & MAYHEW, S. H. 2009. Integration of STI and HIV Prevention, Care, and Treatment into Family Planning Services: A Review of the Literature. *Studies in Family Planning,* 40, 171-186.
COETZEE, D. & SCHNEIDER, H. 1996. Urbanisation and the epidemic of sexually transmitted diseases in South Africa. *Urbanisation and health newsletter*, 36.
COETZEE D, S. H. 1996. Urbanization and the epidemic of sexually transmitted diseases in South Africa. . *Urban Health News*, 36-41.
CREANGA, A. A., BRADLEY, H. M., KIDANU, A., MELKAMU, Y. & TSUI, A. O. 2007. Does the delivery of integrated family planning and HIV/AIDS services influence community-based workers' client loads in Ethiopia? *Health policy and planning,* 22, 404-414.
CRINITI, S. M., AARON, E., HILLEY, A. & WOLF, S. 2011. Integration of routine rapid HIV screening in an urban family planning clinic. *Journal of Midwifery & Women's Health,* 56, 395-399.
DARNEY, B. G., SAAVEDRA-AVENDANO, B., SOSA-RUBI, S. G., LOZANO, R. & RODRIGUEZ, M. I. 2016. Comparison of family-planning service quality reported by adolescents and young adult women in Mexico. *International Journal of Gynecology & Obstetrics*.
DECKER, M. R., MILLER, E., MCCAULEY, H. L., TANCREDI, D. J., LEVENSON, R. R., WALDMAN, J., SCHOENWALD, P. & SILVERMAN, J. G. 2011. Intimate partner violence and partner notification of sexually transmitted infections among adolescent and young adult family planning clinic patients. *Int J STD AIDS,* 22, 345-7.
DECKER, M. R., PEITZMEIER, S., OLUMIDE, A., ACHARYA, R., OJENGBEDE, O., COVARRUBIAS, L., GAO, E., CHENG, Y., DELANY-MORETLWE, S. & BRAHMBHATT, H. 2014. Prevalence and health impact of intimate partner violence and non-partner sexual violence among female adolescents aged

15–19 years in vulnerable urban environments: a multi-country study. *Journal of Adolescent Health,* 55**,** S58-S67.
DEHNE KL, S. R., O'REILLY KR 2000. Integration of prevention and care of sexually transmitted infections with family planning services: what is the evidence for public health benefits? . *Bull World Health Organ,* 78**,** 628-39.
DELAMOU, A., SAMANDARI, G., CAMARA, B. S., TRAORE, P., DIALLO, F. G., MILLIMONO, S., WANE, D., TOLIVER, M., LAFFE, K. & VERANI, F. 2015. Prevalence and correlates of intimate partner violence among family planning clients in Conakry, Guinea. *BMC Res Notes,* 8**,** 814.
DELVAUX, T. & NÖSTLINGER, C. 2007. Reproductive choice for women and men living with HIV: contraception, abortion and fertility. *Reproductive health matters,* 15**,** 46-66.
DEPARTMENT OF HEALTH 2012. National Contraception and Fertility Planning Policy and Service Delivery Guidelines. Pretoria.
DEPARTMENT OF HEALTH 2016. National HIV Testing Services Policy. South Africa.
DOH 2012. National Contraception and Fertility Planning Policy and Service Delivery Guidelines A companion to the National Contraception Clinical Guidelines. Department of Health, Rupublic of South Africa.
DRUCE, N., DICKINSON, C., ATTAWELL, K., CAMPBELL WHITE, A. & STANDING, H. 2006. Strengthening linkages for sexual and reproductive health, HIV and AIDS: progress, barriers and opportunities for scaling up. *London: DFID Health Resource Centre*.
DRUCE, N. & NOLAN, A. 2007. Seizing the big missed opportunity: link HIV and maternity care services in sub-Saharan Africa. *Reproductive Health Matters,* 15**,** 190-201.
DUDLEY, L. & GARNER, P. 2011. Strategies for integrating primary health services in low-and middle-income countries at the point of delivery. *The Cochrane Library*.
DUNKLE, K. L., JEWKES, R. K., BROWN, H. C., GRAY, G. E., MCINTRYRE, J. A. & HARLOW, S. D. 2004. Gender-based violence, relationship power, and risk of HIV infection in women attending antenatal clinics in South Africa. *Lancet,* 363**,** 1415-21.
DUREVALL, D. & LINDSKOG, A. 2014. Violence in relationships with HIV in Africa in the Sub Saharan Africa. *Ekonomisk Debatt***,** 44-52.
ENGENDERHEALTH 2005. *A Process for Improving Quality in Health Services,* New York, USA, EngenderHealth.
EXNER, T. M., HOFFMAN, S., PARIKH, K., LEU, C.-S. & EHRHARDT, A. A. 2002. HIV Counseling and Testing: Women's Experiences and the Perceived Role of Testing as a Prevention Strategy. *Perspectives on Sexual and Reproductive Health,* 34**,** 76-83.
EZEANOLUE, E. E., IWELUNMOR, J., ASAOLU, I., OBIEFUNE, M. C., EZEANOLUE, C. O., OSUJI, A., OGIDI, A. G., HUNT, A. T., PATEL, D. & YANG, W. 2015. Impact of male partner's awareness and support for contraceptives on female intent to use contraceptives in southeast Nigeria. *BMC public health,* 15**,** 1.
FARRELL, M. 2007. From EU model to external policy? Promoting regional integration in the rest of the world. *Making history: European integration and institutional change at fifty,* 8**,** 299.

FELDMAN, R. & MAPOSHERE, C. 2003. Safer Sex and Reproductive Choice: Findings from "Positive Women: Voices and Choices" in Zimbabwe. *Reproductive Health Matters,* 11**,** 162-173.
FLEISCHMAN, J. 2006. Integrating reproductive health and HIV/AIDS programs: strategic opportunities for PEPFAR. A report of the CSIS Task Force on HIV/AIDS.
FLEISCHMAN, J. 2008. Voices from the field. The role of integrated reproductive health and HIV/AIDS programs in strengthening US policy. A report of the CSIS Task Force on HIV/AIDS.
FOREIT, K. G. F., HARDEE, K. & AGARWAL, K. 2002a. When Does It Make Sense to Consider Integrating STI and HIV Services with Family Planning Services? *International Family Planning Perspectives,* 28**,** 105-107.
FOREIT, K. G. F., HARDEE, K. & AGARWAL, K. 2002b. When does it make sense to consider integrating STI and HIV services with family planning services? *International Family Planning Perspectives***,** 105-107.
FOSS, A. M., VICKERMAN, P. T., ALARY, M., WATTS, C. H. & FOSS, A. How much could a microbicide's STI-efficacy contribute to reducing HIV-risk and the level of condom use needed to lower risk? Model estimates.
GATES FOUNDATION, FHI360, MATCH & DOH 2012. Assessing Physical Delivery of PrEP in Support of Proof of Deliverability. Bill and Melinda Gates Foundation.
GAVIN, L., MOSKOSKY, S., CARTER, M., CURTIS, K., GLASS, E., GODFREY, E., MARCELL, A., MAUTONE-SMITH, N., PAZOL, K., TEPPER, N. & ZAPATA, L. 2014. Providing quality family planning services: recommendations of CDC and the US Office of Population Affairs. *MMWR.* USA: CDC.
HAILEMARIAM, T. G., KASSIE, G. M. & SISAY, M. M. 2012. Sexual life and fertility desire in long-term HIV serodiscordant couples in Addis Ababa, Ethiopia: a grounded theory study. *BMC public health,* 12**,** 1.
HALL, S. M. & WHITCOMB, M. 1978. Screening for geonorrhoea in family planning acceptors in a developing community. *Public health,* 92**,** 121-124.
HATCHER, A. M., ROMITO, P., ODERO, M., BUKUSI, E. A., ONONO, M. & TURAN, J. M. 2013. Social context and drivers of intimate partner violence in rural Kenya: implications for the health of pregnant women. *Culture, health & sexuality,* 15**,** 404-419.
HAYES, R. & BENNETT, S. 1999. Simple sample size calculation for cluster-randomized trials. *International journal of epidemiology,* 28**,** 319-326.
HAYES, R. & MOULTON, L. 2009. Analysis based on cluster-level summaries. *Cluster Randomised Trials***,** 163-197.
HEISE, L. & FULU, E. 2014. What works to prevent violence against women and girls?
HEWETT, P. C., NALUBAMBA, M., BOZZANI, F., DIGITALE, J., VU, L., YAM, E. & NAMBAO, M. 2016. Randomized evaluation and cost-effectiveness of HIV and sexual and reproductive health service referral and linkage models in Zambia. *BMC Public Health,* 16**,** 785.
HLADIK, W., STOVER, J., ESIRU, G., HARPER, M. & TAPPERO, J. 2009. The contribution of family planning towards the prevention of vertical HIV transmission in Uganda. *PloS one,* 4**,** e7691.
IPPF-WHR Integrating HIV/AIDS treatment and care services into a family planning setting. London: IPPF.

IPPF/WHO/UNAIDS/UNFPA 2008. Sexual and Reproductive Health and HIV Linkages: Evidence Review and Recommendations.
JAIN, A. K. 1989. Fertility reduction and the quality of family planning services. *Studies in family planning*, 1-16.
JEWKES, R. 2010. Gender inequities must be addressed in HIV prevention. *Science,* 329, 145-147.
JEWKES, R., DUNKLE, K., KOSS, M. P., LEVIN, J. B., NDUNA, M., JAMA, N. & SIKWEYIYA, Y. 2006. Rape perpetration by young, rural South African men: Prevalence, patterns and risk factors. *Social science & medicine,* 63, 2949-2961.
JEWKES, R., SIKWEYIYA, Y., MORRELL, R. & DUNKLE, K. 2009. Understanding men's health and use of violence: interface of rape and HIV in South Africa. *Cell,* 82, 3655.
JOHNSON, L., COETZEE, D. & DORRINGTON, R. 2005. Sentinel surveillance of sexually transmitted infections in South Africa: a review. *Sexually transmitted infections,* 81, 287-293.
JOHNSON, L. F., DORRINGTON, R. E., BRADSHAW, D., PILLAY-VAN WYK, V. & REHLE, T. M. 2009. DEMOGRAPHIC RESEARCH VOLUME 21, ARTICLE 11, PAGES 289-340 PUBLISHED 10 SEPTEMBER 2009.
JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS 2014. 90-90-90: an ambitious treatment target to help end the AIDS epidemic. *Geneva: UNAIDS*.
KENNEDY, C. E., SPAULDING, A. B., BRICKLEY, D. B., ALMERS, L., MIRJAHANGIR, J., PACKEL, L., KENNEDY, G. E., MBIZVO, M., COLLINS, L. & OSBORNE, K. 2010. Linking sexual and reproductive health and HIV interventions: a systematic review. *Journal of the International AIDS Society,* 13, 26.
KERBER, K. J. 2007. The continuum of care of maternal, newborn and child health: coverage, co-coverage and equity analysis from demographic and health surveys.
KIMANI, J., WARREN, C. E., ABUYA, T., NDWIGA, C., MAYHEW, S., VASSALL, A., MUTEMWA, R. & ASKEW, I. 2015. Use of HIV counseling and testing and family planning services among postpartum women in Kenya: a multicentre, non-randomised trial. *BMC women's health,* 15, 1.
KOUYOUMDJIAN, F. G., FINDLAY, N., SCHWANDT, M. & CALZAVARA, L. M. 2013. A systematic review of the relationships between intimate partner violence and HIV/AIDS.
KRAFT, J. M., GALAVOTTI, C., MARION, C., JAMIESON, D. J., BUSANG, L., FLEMING, D. & KILMARX, P. H. 2009. Use of Dual Protection in Botswana. *Studies in Family Planning,* 40, 319-328.
KUHLMANN, A. S., GAVIN, L. & GALAVOTTI, C. 2010. The Integration of Family Planning with Other Health Services: A Literature Review. *International Perspectives on Sexual and Reproductive Health,* 36, 189-196.
LEÓN, F. R. 1999. *Peru: providers' compliance with quality of care norms*, Frontiers in Reproductive Health, Population Council.
LEÓN, F. R., RÍOS, A., ZUMARÁN, A., DE LA CRUZ, Z., BRAMBILA, C. & BRATT, J. H. 2003. *Enhancing quality for clients: the balanced counseling strategy*, Population council. Frontiers in reproductive health program (FRONTIERS).
LEÓN, F. R., VERNON, R., MARTIN, A. & BRUCE, L. 2008. The Balanced Counseling Strategy: A toolkit for family planning service providers. *New York: Population Council*.

LIAMBILA, W., ASKEW, I., MWANGI, J., AYISI, R., KIBARU, J. & MULLICK, S. 2009. Feasibility and effectiveness of integrating provider-initiated testing and counselling within family planning services in Kenya. *AIDS,* 23**,** S115-S121.
LINDEGREN, M. L., KENNEDY, C. E., BAIN-BRICKLEY, D., AZMAN, H., CREANGA, A. A., BUTLER, L. M., SPAULDING, A. B., HORVATH, T. & KENNEDY, G. E. 2012. Integration of HIV/AIDS services with maternal, neonatal and child health, nutrition, and family planning services. *The Cochrane Library*.
LOÛ, A. D. D. & COLEMAN, H. 2005. The Couple and HIV/AIDS in Sub-Saharan Africa: Telling the Partner, Sexual Activity and Childbearing. *Population (English Edition, 2002-),* 60**,** 179-198.
LUNDGREN, R., CACHAN, J. & JENNINGS, V. 2012. Engaging men in family planning services delivery: experiences introducing the Standard Days Method® in four countries. *World Health & Population,* 14**,** 44-51.
LUSENO, W. K. & WECHSBERG, W. M. 2009. Correlates of HIV testing among South African women with high sexual and substance-use risk behaviours. *AIDS care,* 21**,** 178-184.
LUSH, L. 2002a. Service Integration: An Overview of Policy Developments. *International Family Planning Perspectives,* 28**,** 71-76.
LUSH, L. 2002b. Service integration: an overview of policy developments. *International Family Planning Perspectives***,** 71-76.
MAHARAJ, P. & CLELAND, J. 2004. Condom Use Within Marital and Cohabiting Partnerships in KwaZulu-Natal, South Africa. *Studies in family planning,* 35**,** 116-124.
MAHARAJ, P. & CLELAND, J. 2005a. Integration of sexual and reproductive health services in KwaZulu-Natal, South Africa. *Health Policy and Planning,* 20**,** 310-318.
MAHARAJ, P. & CLELAND, J. 2005b. Risk perception and condom use among married or cohabiting couples in KwaZulu-Natal, South Africa. *International family planning perspectives***,** 24-29.
MAHARAJ, P., NEEMA, S., CLELAND, J., BUSZA, J. & SHAH, I. 2012. Condom use within marriage: an assessment of changes in South Africa and Uganda. *AIDS care,* 24**,** 444-450.
MAHENDRA, V., MUDOI, R., OINAM, A., PAKKELA, V. & SARNA, A. 2007. Continuum of care for HIV-positive women accessing programs to prevent parent-to-child transmission: findings from India.
MALHOTRA, S. & ZODPEY, S. P. 2010. Operations research in public health. *Indian journal of public health,* 54**,** 145.
MAMAN, S., MBWAMBO, J., HOGAN, N., KILONZO, G. & SWEAT, M. 2001. Women's barriers to HIV-1 testing and disclosure: challenges for HIV-1 voluntary counselling and testing. *AIDS care,* 13**,** 595-603.
MATI, J. K. 1996. Family planning, sexually transmitted diseases and AIDS. *African Journal Of Fertility, Sexuality, And Reproductive Health,* 1**,** 101-108.
MCCAULEY, H. L., SILVERMAN, J. G., DECKER, M. R., AGENOR, M., BORRERO, S., TANCREDI, D. J., ZELAZNY, S. & MILLER, E. 2015. Sexual and Reproductive Health Indicators and Intimate Partner Violence Victimization Among Female Family Planning Clinic Patients Who Have Sex with Women and Men. *J Womens Health (Larchmt),* 24**,** 621-8.

MCINTYRE, D. & KLUGMAN, B. 2003. The human face of decentralisation and integration of health services: experience from South Africa. *Reproductive health matters,* 11**,** 108-119.
MILLER, E., DECKER, M. R., MCCAULEY, H. L., TANCREDI, D. J., LEVENSON, R. R., WALDMAN, J., SCHOENWALD, P. & SILVERMAN, J. G. 2011. A family planning clinic partner violence intervention to reduce risk associated with reproductive coercion. *Contraception,* 83**,** 274-80.
MODI, S. 2008. Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents.
MORA, M. & VILLARREAL, J. 1993. Unwanted pregnancy and abortion: Bogota, Colombia. *Reproductive Health Matters,* 1**,** 11-20.
MORRISON, C. S., SKOLER-KARPOFF, S., KWOK, C., CHEN, P. L., VAN DE WIJGERT, J., GEHRET-PLAGIANOS, M., PATEL, S., AHMED, K., RAMJEE, G., FRIEDLAND, B. & LAHTEENMAKI, P. 2012. Hormonal contraception and the risk of HIV acquisition among women in South Africa. *AIDS,* 26**,** 497-504.
MSH 1993. Management Sceinces for Health. Family Planning Management Development Using CQI to strengthen family planning programs. *Family planning manager,* 2.
MULLICK, S., ASKEW, I., MALUKA, T., KHOZA, D. & MENZIWA, M. Integrating counselling and testing into family planning services: What happens to the existing quality of family planning when HIV services are integrated in South Africa? conference on Linking Reproductive Health, Family Planning and HIV/AIDS in Africa, Addis Ababa, 2006. 9-10.
MULLICK, S., MENZIWA, M., MOSERY, N., KHOZA, D. & MAROGA, E. 2008. Feasibility, acceptability, effectiveness and cost of models of integrating HIV prevention and counseling and testing for HIV within family planning services in North West Province, South Africa. *FRONTIERS final report. Washington (DC): Population Council*.
MULLICK, S., TEFFO-MENZIWA, M., WILLIAMS, E. & JINA, R. 2010. Women and sexual violence. *South African Health Review.*
MUTEMWA, R., MAYHEW, S., COLOMBINI, M., BUSZA, J., KIVUNAGA, J. & NDWIGA, C. 2013. Experiences of health care providers with integrated HIV and reproductive health services in Kenya: a qualitative study. *BMC health services research,* 13**,** 18.
NATIONAL DEPARTMENT OF HEALTH 2016. Pre-Exposure Prophylaxis (PrEP) - Test and Treat to be provided to Sex Workers starting. National Department of Health.
NDHLOVU, L., SEARLE, C., MILLER, R., FISHER, A. & SNYMAN, E. 2003. Reproductive health services in KwaZulu Natal South Africa: a situation analysis study focusing on HIV/AIDS services.
NDOH 2010a. The National Antenatal Sentinel HIV and Syphilis Prevalence Survey. South Africa.
NDOH 2010b. New EPI Vaccines Guidelines. South Africa: National Department of Health.
NDOH 2012. The 2012 National Antenatal Sentinel HIV & Herpes Simplex Type-2 Prevalence Survey in South Africa. . Pretoria, South Africa.
NDOH 2013. The 2013 National Antenatal Sentinel HIV Prevalence Survey South Africa. *In:* SURVEILLANCE, E. A. (ed.). South Africa: National Departmnt of Health.

NGO, A. D., HA, T. H., RULE, J. & DANG, C. V. 2013. Peer-based education and the integration of HIV and Sexual and Reproductive Health services for young people in Vietnam: evidence from a project evaluation. *PloS one,* 8**,** e80951.
OBERMEYER, C. M. & OSBORN, M. 2007. The utilization of testing and counseling for HIV: a review of the social and behavioral evidence. *American journal of public health,* 97**,** 1762-1774.
OBURE, C. D., GUINNESS, L., SWEENEY, S., VASSALL, A. & INITIATIVE, I. 2015. Does integration of HIV and SRH services achieve economies of scale and scope in practice? A cost function analysis of the Integra Initiative. *Sexually transmitted infections***,** sextrans-2015-052039.
OBURE, C. D., JACOBS, R., GUINNESS, L., MAYHEW, S., VASSALL, A. & INITIATIVE, I. 2016. Does integration of HIV and sexual and reproductive health services improve technical efficiency in Kenya and Swaziland? An application of a two-stage semi parametric approach incorporating quality measures. *Social Science & Medicine,* 151**,** 147-156.
ODENY, T. A., PENNER, J., LEWIS-KULZER, J., LESLIE, H. H., SHADE, S. B., ADERO, W., KIOKO, J., COHEN, C. R. & BUKUSI, E. A. 2013. Integration of HIV care with primary health care services: effect on patient satisfaction and stigma in rural Kenya. *AIDS research and treatment,* 2013.
ODIMEGWU, C. O. 1999. Family planning attitudes and use in Nigeria: a factor analysis. *International Family Planning Perspectives***,** 86-91.
PAI, N. P. & KLEIN, M. B. 2009. Rapid testing at labor and delivery to prevent mother-to-child HIV transmission in developing settings: issues and challenges. *Womens Health (Lond Engl),* 5**,** 55-62.
PARKER, S. & SCOTT, V. 2013. Integration of HIV prevention into sexual and reproductive health services in an urban setting in South Africa. *African journal of primary health care & family medicine,* 5.
PATH 2009. Preventing mother-to-child HIV transmission: Ukraine project increases access to prevention interventions. Seattle: PATH.
PELTZER, K., RAMLAGAN, S., CHIRINDA, W., MLAMBO, G. & MCHUNU, G. 2012. A community-based study to examine the effect of a youth HIV prevention programme in South Africa. *International journal of STD & AIDS,* 23**,** 653-658.
PHAM-KANTER, G., STEINBERG, M. & BALLARD, R. 1996. Sexually transmitted diseases in South Africa. *Genitourinary medicine,* 72**,** 160-171.
POPULATION COUNCIL 2008. Operations Research Handbook for Managers of Reproductive Health Programmes. Population Council.
POPULATION COUNCIL 2016. Measuring the Quality of Care: A review of methodologies and indicators. *In:* COUNCIL, P. (ed.) *popcouncil.org.*
QUITERIO, G., MOLINA, M., MIRIC, M., VERNON, R. & RIVERO-FUENTES, M. E. 2008. Situation Analysis of the Integration of Family Planning Services in Postpartum, Postabortion and Prevention of Mother to Child Transmission Programs in the Dominican Republic. *Population Council: Frontiers in Reproductive Health/USAID*.
RAJ, A., GHULE, M., RITTER, J., BATTALA, M., GAJANAN, V., NAIR, S., DASGUPTA, A., SILVERMAN, J. G., BALAIAH, D. & SAGGURTI, N. 2016. Cluster Randomized Controlled Trial Evaluation of a Gender Equity and Family Planning Intervention for Married Men and Couples in Rural India. *PLoS One,* 11**,** e0153190.
RASCH, V., YAMBESI, F. & MASSAWE, S. 2006. Post-abortion care and voluntary HIV counselling and testing–an example of integrating HIV prevention into

reproductive health services. *Tropical Medicine & International Health,* 11**,** 697-704.
REYNOLDS H, J. B., HAMON R, JOHNSON L 2006. The value of contraception to prevent perinatal HIV transmission. . *Sex transm Dis,* 33**,** 350-356.
REYNOLDS, H. W., JANOWITZ, B., HOMAN, R. & JOHNSON, L. 2006. The value of contraception to prevent perinatal HIV transmission. *Sexually transmitted diseases,* 33**,** 350-356.
REYNOLDS HW, J. B., WILCHER R, CATES W 2008. Contraception to prevent HIV positive births: current contribution and potential cost-savings in PEPFAR countries. . *Sex Transm Info* 84**,** ii49-ii53.
RUTENBERG, N. & BAEK, C. 2005. Field Experiences Integrating Family Planning into Programs to Prevent Mother-to-Child Transmission of HIV. *Studies in family planning,* 36**,** 235-245.
SADHS 2003. South African Demographic and Health Survey. Pretoria: Medical Research Council.
SAHA, A., SELLERS, T., PANDA, M., BIDLA, R. & KHAN, I. 2007. Options and challenges for converging HIV and sexual and reproductive health services in India. Findings from an assessment in Andhra Pradesh Bihar Maharashtra and Uttar Pradesh.
SCHNEIDER, H., COETZEE, D., FEHLER, H. & BELLINGAN, A. 1998. Screening for sexually transmitted diseases in rural South African women. *Sexually Transmitted Infections,* 74**,** S147.
SECRETARIAT, S. 2010. The national HIV counselling and testing campaign strategy. *South African National AIDS Council*.
SEDGH, G., HUSSAIN, R., BANKOLE, A. & SINGH, S. 2007. *Women with an unmet need for contraception in developing countries and their reasons for not using a method*, Alan Guttmacher Institute.
SHISANA, O., ZUNGU, N., NWANYANWU, O., SIMBAYI, L., PARKER, W., DINH, T., ZUMA, K., NGOGO, N., PEZI, S. & PILLAY-VAN WYK, V. 2015. South African National HIV Prevalence, Incidence and Behaviour Survey 2012.
SPAULDING, A. B., BRICKLEY, D. B., KENNEDY, C., ALMERS, L., PACKEL, L., MIRJAHANGIR, J., KENNEDY, G., COLLINS, L., OSBORNE, K. & MBIZVO, M. 2009. Linking family planning with HIV/AIDS interventions: a systematic review of the evidence. *Aids,* 23**,** S79-S88.
STOVER, J., FUCHS, N., HALPERIN, D., GIBBONS, A. & GILLESPIE, D. 2003. Costs and benefits of adding family planning to services to prevent mother-to-child transmission of HIV (PMTCT). *Washington, DC: The Futures Group*.
SWEAT, M. D., O'REILLY, K. R., SCHMID, G. P., DENISON, J. & DE ZOYSA, I. 2004. Cost-effectiveness of nevirapine to prevent mother-to-child HIV transmission in eight African countries. *Aids,* 18**,** 1661-1671.
SWEAT MD, O. R. K., SCHIMID GP, DENISON J, DE ZOYSA 2004. Cost-effectiveness of nevirapine to prevent mother-to-child HIV transmission in eight African countries. *AIDS,* 18**,** 1661-1671.
TEACHNOR, S. 1987. UN Convention on the Elimination of All Forms of Discrimination against Women: An Effective Tool to Combat Discrimination in the 20th Century, The. *Whittier Law Review,* 9**,** 419.
TILAHUN, T., COENE, G., TEMMERMAN, M. & DEGOMME, O. 2014. Spousal discordance on fertility preference and its effect on contraceptive practice among married couples in Jimma zone, Ethiopia. *Reproductive health,* 11**,** 1.

TRAN, N. T., HALLERDIN, J. M., FLOWERS-MAPLE, C. & MOSKOSKY, S. B. 2010. Collaboration for the integration of HIV prevention at Title X family planning service delivery sites. *Public Health Reports*, 47-54.
UNAIDS. 2008. *Report on the global AIDS epidemic* [Online]. Available: http://www.amarc.org/documents/manuals/JC1510_2008GlobalReport_en.pdf [Accessed].
UNAIDS 2013. Global Report: UNAIDS Report on the Global AIDS Epidemic 2013. Geneva: UNAIDS, 2013.
UNAIDS, W. 2009. AIDS epidemic update 2009. Geneva: Joint United Nations Programme on HIV. *AIDS*.
UNAIDS/WHO 2005. Joint United Nations Programme on HIV/AIDS
UNFPA/UNAIDS/FCI 2004. The New York call to commitment: linking HIV/AIDS and sexual reproductive health.
UNGAS 2001. Declaration of Commitment on United Nations General Assembly *26th Special Session.* New York
UNGER, J. P., DE PAEPE, P. & GREEN, A. 2003. A code of best practice for disease control programmes to avoid damaging health care services in developing countries. *The International journal of health planning and management,* 18, S27-S39.
VAN DER STRATEN, A., STADLER, J., MONTGOMERY, E., HARTMANN, M., MAGAZI, B., MATHEBULA, F., SCHWARTZ, K., LABORDE, N. & SOTO-TORRES, L. 2014. Women's experiences with oral and vaginal pre-exposure prophylaxis: the VOICE-C qualitative study in Johannesburg, South Africa. *PLoS One,* 9, e89118.
VARTAPETOVA, N. & KARPUSHKINA, A. Prevention of mother-to-child transmission of HIV and family planning practices in HIV-infected women facility survey. Report of main findings.
WEINBERGER, M. & ROSS, J. 2015. The National Composite Index for Family Planning. Avenir Health.
WHO 2003. Strategic approaches to the prevention of HIV infection in infants: report of WHO meeting. Morges, Switzerland: World Health Organization.
WHO 2005. The World health report: 2005: make every mother and child count: overview. World Health Organization.
WHO 2006. The world health report: 2006: working together for health.
WHO. 2007. Inter-Agency Task Team on Prevention of HIV infection in Pregnant Women, Mothers and their Children. Available: http://www.unicef.org/aids/files/PMTCT_enWEBNov26.pdf.
WHO 2008a. The World Health Report 2008: Primary health care (now more than ever). World Health Organization.
WHO, U., UNICEF 2008b. Scaling up priority HIV/AIDS interventions in the health sector: progress report. *Towards universal access.* Geneva: World Health Organization.
WHO. & UNFPA. 2004. Glion consultation on strengthening the linkages between reproductive health and HIV/AIDS: Family planning and HIV/AIDS in women and children. *WHO HIV,* 2006.
WILCHER, R., CATES JR, W. & GREGSON, S. 2009. Family planning and HIV: strange bedfellows no longer. *AIDS (London, England),* 23, S1.
WILKINSON D, A. K. S., HARRISON A, LURIE M, COLVIN M, CONOLLY C, STURM AW. 1999. Unrecognized sexually transmitted infections in rural South African women: a hidden epidemic. *Bull World Health Organ,* 77, 22-28.

WILKINSON, D., KARIM, S. A., HARRISON, A., LURIE, M., COLVIN, M., CONNOLLY, C. & STURM, A. 1999. Unrecognized sexually transmitted infections in rural South African women: a hidden epidemic. *Bulletin of the World health Organization,* 77**,** 22-28.

WILKINSON, D., NDOVELA, N., HARRISON, A., LURIE, M., CONNOLLY, C. & STURM, A. W. 1997. Family planning services in developing countries: an opportunity to treat asymptomatic and unrecognised genital tract infections? *Genitourinary medicine,* 73**,** 558-560.

WORLD HEALTH ORGANISATION 2016. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection

Recommendations for a public health approach - Second edition.

WORLD HEALTH ORGANIZATION 2004. The Glion Call to Action on family planning and HIV/AIDS in women and children. *WHO: Geneva*.

XU, F., KILMARX, P. H., SUPAWITKUL, S., MANOPAIBOON, C., YANPAISARN, S., LIMPAKARNJANARAT, K., CHAIKUMMAO, S., MOCK, P. A., YOUNG, N. L. & MASTRO, T. D. 2002. Incidence of HIV-1 infection and effects of clinic-based counseling on HIV preventive behaviors among married women in northern Thailand. *Journal of acquired immune deficiency syndromes (1999),* 29**,** 284-288.

YORE, J., DASGUPTA, A., GHULE, M., BATTALA, M., NAIR, S., SILVERMAN, J., SAGGURTI, N., BALAIAH, D. & RAJ, A. 2016. CHARM, a gender equity and family planning intervention for men and couples in rural India: protocol for the cluster randomized controlled trial evaluation. *Reproductive health,* 13**,** 1.

Appendix 1 Table Describing Study Facilities

Intervention clinics

Characteristics	**Moretele**			**Rustenburg**		
	Lebotlwane	Maubane	Bosplas	Thekwane	Tlaseng	Chaneng
Rural/Urban	Rural	Rural	Rural	Rural	Rural	Rural
Size of the Clinic	Clinic under construction to increase size of rooms	Small	Small	Small	Well sized, newly constructed clinic	Large clinic
Consultation Room	2 consulting rooms 1 counseling room,	3 Consulting rooms	2 Consulting Room	3 consulting rooms, 1 counseling room	3 consulting rooms 1 counseling room	3 consulting rooms
Road Conditions	Long gravel to Clinic, main road also gravel	Gravel road, very close to the tarred main road	Tarred road	Tarred roads close to main road (and sun city)	Tarred road not close to the main road	Tarred roads close to main road
Public transport	Not easily accessible	Not easily accessible	Not easily accessible	Public transport is easily accessible during peak hour	Accessible during peak hours	Able to access public transport
Houses	Surrounded by houses	Surrounds the clinic	Scattered	Nearby the clinic	Close to a high school, and a mine	Surrounded by houses and mines
Proximity to Central Business	Very far (about 80km) away from	Close to Moretele Central	Close to Moretele Central	At a distance from central	About 75km to CBD	At a distance from central

Ditrsict	Moretele central. Close to a community hall and post office			Rustenburg	Rustenburg	Rustenburg
Staffing	5 Prof nurses 3 Nursing assistants nurse that supported intervention was moved to another clinic. New people have been trained but no evaluation has been done	4 Prof Nurse 1 Retired Prof Nurse 3 Nursing Assistants	1 Prof Nurse 1 Assistant Nurse	4 Prof Nurses, 1 nursing assistant	4 Prof Nurses, 2 nursing assistant	12 Prof nurses 3 assistant nurses
Staff Supportin to integration	The nurses support integration	Yes	Sister in charge does not support integration	The facility manager supports integration	The staff support integration	Staff generally supportive
Availability of VCT Room	Yes	Yes	Yes	Yes	Yes	Yes
Deals with deliveries	No	No	No	Yes	Yes	Yes
Opening and Closing times	7.00 – 17.00 (7 days a week)	7:00 to 16:30	8:00 to 16:30	7.30 – 16.00	6:00 to 18:00	24 hours
Who does it serve	The local community in the village	Local community of Maubane	Local community and migrants	Local community and migrants	Predominantly migrants	Both migrants and locals

Comments	Staff movement created challenges for implementation. As with some other facilities staff were moved to other facilities and the managers of those facilities were not aware of the integration therefore they did not support the use of BCS+. Some were transferred to facilities that were not part of the integration making it difficult to track.	Staff members showed support of the integration	Trained staff was on leave during end line data collection	2 trained staff went on study leave during implementation	During the intervention the facility has not reported any staff shortages	Staff rotation created a challenge with implementation

Control clinics

Characteristics	Moretele			Rustenburg		
	Ngobi	Mogogelo	Leseding	Monakato	Rankelenyane	Karlien Park
Rural/Urban	Rural	Rural	Rural	Rural	Rural	Urban
Consultation Room	2 consulting rooms 1 counseling room	3 consulting rooms, 1 counseling room,	2 consulting rooms 1 counseling room,	Well sized 3 consulting rooms, 1 counseling room,	Well sized 2 consulting rooms, 1 counseling	Well built and neat 3 consulting rooms, 1 counseling room
Road Conditions	Roads are tarred. Far from main roads	Gravel road to clinic but close to main road which is tarred	Gravel road but close to main road which is tarred	Tarred road close to main road	Tarred road close to main road	Tarred roads
Public transport	Close to taxi rank but the taxis do not run locally. Therefore transport can still be a problem	Public transport for locals is not easily accessible	Public transport is difficult to access for locals	Public transport a challenge – but available during peak hours	Public transport not easily accessible	Public transport easily accessible
Houses	Surrounded by houses	Surrounded by houses	Surrounded by houses	Surrounding community is small	Surrounded by houses	In a suburb
Proximity to Central Business	Far from Moretele central	Close to Moretele central	Close to Moretele, about	Far from Rustenburg	Far from shopping	Close to Rustenburg

District			25kms	central	centres	central, about 8kms
Staffing	2 Prof nurses 1 nursing assistant	2 Prof nurses 2 assistant nurses	2 Prof nurses, 1 nursing assistant	6 Prof nurses 1 enrolled Nurse 2 assistant nurses	3 Prof nurses, 1 nursing assistant	3 Prof nurses, 1 assistant nurse
Availability of VCT Room	Yes	Yes	Yes	Yes	Yes	Yes
Deals with Deliveries	No	No	No	Yes	Maternity during the day	No
Opening and Closing times	07.30 – 16.00 (5 days a week)	7.00 – 16.00 (5 days a week)	7.00 -16.00 (5 days a week)	7.00 – 19.00 (7 days a week)	7.00 – 16.00 (5 days a week)	7.00 – 16.00 (5 days a week)
Who does it serve?	Community of Ngobi	Local community and the surrounding villages	Local community	Local population	Local population	Local population

Appendix 2 Client Exit Interview Questionnaire

DATE:	dd	mm	yyyy	STUDY NO.										
TITLE (MRS, MS)				CLIENT'S NUMBER										
SURNAME														
FIRST NAME IN FULL														
SECOND NAME IN FULL														
PHYSICAL ADDRESS														
														POST CODE
HOME TELEPHONE NUMBER														
CELLULAR NUMBER														
FRIEND OR RELATIVE'S NAME														
HOME TELEPHONE NUMBER														
CELLULAR NUMBER														

DATE OF NEXT CLINIC VISIT	

Study ID number:

THE VOLUNTARY COUNSELLING AND TESTING/FAMILY PLANNING INTEGRATION STUDY

(Setswana)

EXIT INTERVIEW QUESTIONNAIRE

PHASE II ENDLINE

COVER

Field Edit _____(initial) Study ID Checked: _____ (initial)

50 YEARS 1952–2002 Population Council

Frontiers IN REPRODUCTIVE HEALTH

National Department of Health
Northwest Department of Health

Visit Number	[4]
Interviewer name	
Date of interview	__ __ /__ __/ 2007 D D M M YY
Facility/Clinic cluster number:	
Moretele district	
Rustenburg	
Start Time of Interview	Hr[ ] [ ] Min[ ] [ ] (24 hr clock)

PLEASE DO NOT FILL IN THE FOLLOWING TABLE. GO TO SECTION ONE NOW.

For Data Entry:

First Entry: __ __ /__ __ / __ Y _____ Initials

Second Entry: __ __ /__ __ /__ Y _____ Initials

Notes and Queries:

SECTION ONE:
SOCIODEMOGRAPHICS AND REPRODUCTIVE INTENTIONS

Thank you very much for agreeing to participate in the study. We would like to ask you some questions about your experience when seeking family planning, and particularly about your visit today. We would also like to ask you some questions that may be of a sensitive nature for example about whether you have ever sought testing for HIV and your sexual behaviour as well as questions about your partner. Please try and relax, and remember that there are no right or wrong answers. You have the right to refuse to answer any question that you do not feel comfortable answering. You also have the right to stop the interview at any time. This will not affect any services that you receive at this clinic or other clinics. Remember that everything you tell me will be kept confidential and your name will not appear in any report or document arising from this study.
My first set of questions is about you, who you are and any children that you might have. This information will not be used for identifying people, but we are just interested in knowing the types of women who seek family planning.

NO.	QUESTIONS AND FILTERS	CODING CATEGORIES	SKIP
V101	Which year were you born? *O belegwe ka ngwaga ofe?*	DD / MM / YYYY [ ] / [ ]/ [ ]	
V102	Are you currently studying? *A o sa ithuta?*	YES……..01 NO…….00	
V103	Are you working? *A o a dira?*	YES……..01 NO……00	
V104	What is the highest education level that you have passed? *Ke mophato ofe o o kwa go dimo oo falotseng?*	No schooling……....01 1 to grade 7……..……..……..02 8 to grade 12……..…..……03 Education beyond Matric (grade 12_)….04	
V105	Have you ever been pregnant? *A o kile wa nna moimane ?*	YES…….01 NO……...……00	→201
V107	How many living children do you have? *Ba bakae baba phelang?*	[ ] [ ] number **If zero, skip to 106**	
V108	How old is your youngest child? *Go fejane o na le dingwaga tse kae?* **If less than a 2 years, put months.**	[ ] [ ] Days [ ] [ ] months [ ] [ ] years	
V106	Has any of your children passed away? *A o kile wa tlhokofallwa ke bana?*	YES…….01 NO……...……00	→107
V106(a)	How many children passed away? *Ba ba kae?*	[ ] [ ]	
V106 (b)	How old was the last child when he/she passed away? *Re bua ka ngwana wagothlokofala labofelo - One a nale dingwaga tsekae ge athlokofala?*	[ ] [ ] Days [ ] [ ] months [ ] [ ] years	

V106(c)	When did he/she pass away Othlokofetse neng?	[ ] [ ] Days [ ] [ ] Months [ ] [ ] Years	
V106(d)	What was the cause of death? *O bolailwe ke eng?*		
V109	Did you want to fall pregnant when you fell pregnant the last time?? *Ka nako e o neng o imile a mpa eo ene e rulagantswe ?*	YES……..01 NO…….……00 Don't know…….……99	
V110	Were you using a contraceptive method when you fell pregnant with your last child? *A one o dirisa thibela pelegi fa otla ima ngwana wa gago wa bofelo?*	YES……..01 NO……...……..…00	→201
V111	If yes, which method were you using? *Fa o dumela, ke mofuta o feng o oneng o o dirisa?* **(Circle only one hormonal method)**	1. Nur-Isterate ……..…1 2. Depo……..2 3. Ovral……..3 4. Triphasil……....4 5. Nordett …… ….5 6. Microval…… … ….. 6 7. IUCD/Loop …… …..7 8. Condom …… ……8	

SECTION 2:
FAMILY PLANNING COUNSELLING-METHOD CHOICE

Now I would like us to move on and talk about the family planning service that you received today.

V201	What method are you currently using? *Ke mofuta o fe o o neng o o dirisa?* (***Circle only one hormonal method***)	Nur-Isterate……1 Depo……..2 Ovral……..3 Triphasil……4 Nordett……5 Microval……..6 Loop……7 Condom……..8 Emergency contraception…….9			
V202	In the last six months how many times have you been to the clinic to receive your contraceptive method? *O tlile gakae mo dikgweding tse tshelela tse difetileng gotlo tsaya mofuta wagago wa thibela pelegi?*	None……0 Once……1 Twice……...2 Three times…..3 Other (specify) _____			
V203	Are you using a condom together with this method? *A one o dirisa Condom ga mmogo le mofuta wa thibela-pelegi?*	YES ……01 NO……...…….00			→205
			YES	NO	
V204	Why are (were) you using a condom with your method? *Goreng o dirisa kgotlopo ga mmogo mofuta wa gago wa thibela pelegi?* **(write all reasons given)**	To protect against HIV/STIs…... To prevent pregnancy……. I'm on treatment……. Other (Specify)_____ _____ ____	1 1 1 1	0 0 0 0	
V205	How long have you been using this method? *Ke lebaka le lekanakang o dirisa sethibela se?* (**Specify the method stated in 201. Tlhalosa mofuta o o mo go 201)**	Days[ ] [ ] Months [ ] [ ] Years [ ] [ ]			
CHK	**PLEASE NOTE: THE NEXT SET OF QUESTIONS IS ABOUT TODAY'S VISIT.**				

V206(a)	Did you get a method of contraception today? ***A o amogetse thibela pelegi*** *gompieno?*		**Y** 1	**N** 0→207	
V206	What method did you get today? *O a mogetse mofuta o feng gompieno?* **(*if dual method, circle Yes to both the method and the condom*)**	Nur-Isterate…… Depo……... Ovral…….. Triphasil…… Nordett…….. Microval…… Condom…… Emergency contraceptive……..	**Y** 1 1 1 1 1 1 1 1	**N** 0 0 0 0 0 0 0 0	
V207	Which methods did the nurse tell you about today? *A mmoki o go boleletse ka mefuta efe gompieno ?* **(Circle all that were mentioned)**	Nur-Isterate……..…… Depo…….……... Ovral……... Triphasil…… Nordett…… Microval……..…..…. Loop/IUD……..….. Condom…….. Sterilisation…….… No method mentioned……..…. Emergency Contraceptives……	1 1 1 1 1 1 1 1 1 1 1	0 0 0 0 0 0 0 0 0 0 0	
V207(a)	Total number of method discussed during consultation	[ ] [ ] **[Check] Q207 COUNT THE NUMBER OF METHOD DISCUSSED**			
CHK	**PLEASE NOTE: THE NEXT SET OF QUESTIONS IS ABOUT REPRODUCTIVE INTENTIONS.**				
V112	Are you planning to have child/children in the future? *A o rulaganya go nna le bana (ba bangwe) mo isagong?*	YES……01 NO……..……00 Don't know……99		→301 →301	
V113	When do you plan to have your (next) child? *O rulaganya go nna le ngwana yo mongwe leng?*	Within the next year……1 Between 1-3 years from now… ……..2 After 3-5 years from now…… ….3 More than 5 years from now… … …..4 Don't know……...5			

SECTION 3.
CONDOM USE

Please remind the client that some of the questions are sensitive in nature. Remind the client that the interview is confidential and her name will not be linked in any way to the responses she is giving.

V301	Have you ever used a condom? *A o kile wa dirisa condom?*	YES ……01 NO……..……00	→302

V 301(a)	What are the reasons you have never used a condom before? Ke fa tlase ga mabaka afe osa dirisi kgotlopo? *Other Specify:*_____ _____ _____ _____ __		Y	N	
		I have never had sex ….1	1	0	
		I don't know how……...2	1	0	
		I`m married/Faithful partner ……..3	1	0	
		Afraid it will burst……..4	1	0	
		I do not like it ……....5	1	0	
		Partner Doesn't like it…6	1	0	
		Other ……..7	1	0	
V302	In the last month how often would you say you use condoms when you have sex? *Mo kgweding ya go feta o dirisa condom ga kae fa idira thobalano?*	Never..……..01 Sometimes……02 Always…… 03			
V303	The last time you had sex, did you use a condom? *La bofelo fa o robalana, a o dirisitse kgotlopo?*	YES ……01 NO……..……00			

SECTION 4.
CLIENT'S FEELINGS ABOUT THE QUALITY OF FP COUNSELLING

Now I would like to ask you some questions about your views about today's consultation.

V401	Do you feel that you received the information you wanted today? *A o ikutlwa fa o fitlhetse kitso e o e batlileng gompieno?*	Yes……..…01 No…… ..…..…...00 Did not need information….02			
V402	Did you feel that the consultation was too short, too long or about the right amount of time? *A o ikutlwa fa kopano e nnile khutswane, e telle, kgotsa e itekanetse?*	Too short…… ….01 Too long…… ……..02 Just about the right amount of time (specify) _____.03			
V403	In your opinion, did you have enough privacy during the consultation apart from the fact that the observer was there? *Go ya ka wena a o bone tshireletsego ya sephiri (ka ntle le taba ya gore mookamedi o ne dutse foo)?*	Yes……..…01 No……..….00			→405
			Y	N	
V404	Why do you think you had privacy? *Goreng o nagana gore o nnile le tshireletsego ya sephiri?*	No body could hear…… No body could see…… There were no interruptions during consultation…… Other (Specify) _____ _____	1 1 1 1	0 0 0 0	**→go to Section 5**

V405	Why do you think you didn't have privacy? *Go reng o nagana gore ga wa nna le tshireletsego ya sephiri*? ***(Circle all that are mentioned***)	People could hear…… Others could see……..… Interruptions by persons during consultation…… Other(probe)_____ _____ _____	1 1 1 1	0 0 0 0	**→go to Section 5**

SECTION 5.
KNOWLEDGE OF SEXUALLY TRANSMITTED INFECTIONS AND HIV.

***We are going to ask you question around VCT but at no point are you going to be asked to reveal your HIV status*.**

V501	As far as you know, are there any diseases that can be transmitted through sexual intercourse? *Go ya ka kitso ya gago,a go na le malwetsi a a ka fitisiwang ka thobalano?*	Yes…… …01 No……..00			
V502	If a woman has an STI what signs and symptoms might she have? *Fa mosadi a na le tshwaetso ya thobalano, ke matshawao a fe a a ka nnang nao?* **(Circle all that are mentioned)**	Vaginal discharge……. Sores in the genital area…… Lower abdominal pain…….. Don't know……. Other (Specify)_____ _____	Y 1 1 1 1 1	N 0 0 0 0 0	
V503	If a man has an STI what signs and symptoms might he have? *Fa monna a na le tshwaetso ya thobalano, ke matshawao a fe a a ka nnang nao?* **(Circle all that are mentioned)**	Burning urine…… Discharge from the penis….. Sores in the genital area…… Don't know……. Other (Specify)_____ _____	**Y** 1 1 1 1 1	**N** 0 0 0 0 0	

V504	Is it possible to have a sexually transmitted infection, including HIV/AIDS, and look healthy? *A go na le kgonagalo ya go nna le tshwaetso ka thobalano go akaretsa le HIV/AIDS mme o lebege o itekanetse?*	Yes……01 No……..00 Don't know……99	
V505	Can a pregnant woman transmit an STI, including HIV/AIDS, to her baby? *A mosadi yo o a imileng o kgona go fetisetsa tshwaetsano ya thobalano go akaretsa le HIV/AIDS ko leseeng la gagwe?*	Yes…… …01 No……..00 Don't know……99	→505© →505©
V505 (a)	What are the ways that a woman can transmit HIV to her baby?	During pregnancy……01 During delivery ……02 Breast feeding……03 Don't know……04	
V505 (b)	Is there medicine that can help to prevent mother to child transmission?	Yes (specify) _____ _____ …… …01 No……..00 Don't know……99	
V505 (c)	If you were HIV positive would you still want to have children?	Yes…… …01 No……..00 Don't know……99	
V506	If a person tested HIV negative should she test again? *Ge motho a sena tshwaetso ya HIV, a motho oo o tlamegile go ya ditekong gape?*	Yes……01 No……..…….. ..00 Don't know……99	→508 →508
V507	After how long? *Morago ga sebaka se se kanakang?*	Days [ ][ ] Weeks [ ][ ] Months [ ][ ] Years [ ][ ] Don't know	
V508	What do you think are the chances that you may become infected with a sexually transmitted infection including HIV/AIDS? Would you say there is no chance, some chance, or a high chance? *Fa o akanya ke monyetla efeng e o o nang nayo fa o ka tshwaediwa ka thobalano go akaretsa le HIV/AIDS?* *A o ka re ga ona monyetla, monyetla o monyane kgotsa, monyetla o mogolo?*	No chance……01 Some chance……02 High chance……..03	→509 →510 →511

V509	Why do you think that you have no chance of getting a sexually transmitted infection, including HIV/AIDS? *Goreng o nagana gore ga o na monyetla wa go tsenwa ke tshwaetso ya thobalano go akaretsa le HIV/AIDS?* **(Circle all mentioned)**	1.Believe partners are uninfected… 2. Abstain from sex…… 3. Always use condoms……. 4. Use condoms with partners I don't now/trust…….. 5. Have only one sex partner…… 6. Neither I nor my partner have other partners…… Don't know……..….	**Y** 1 1 1 1 1 1 1	**N** 0 0 0 0 0 0 0	**Go to Sec 6**
V510	Why do you think you have some chance? *Go reng o nagana gore o na le monyetla o monnye?* **(Circle all mentioned)**	1.Do not use condoms…… 2. I have other sex partners…… 3. Suspects/knows partner has other sex partners…… 4. Other……..….. 5. Have one partner…… 6. Don't know…… 7. Don't always use a condom…….	**Y** 1 1 1 1 1 1 1	**N** 0 0 0 0 0 0 0	**Go to sec 6**
V511	Why do you think you have a high chance? *Go reng o nagana gore o na le monyetla o mogolo?* **(Circle all mentioned)**	1.Do not use condoms……. 2.I have other sex partners…….. 3.Suspects/knows partner has other sex partners…… 4.Don't know……. 5. Other specify_____	1 1 1 1 1	0 0 0 0 0	**Go to sec 6**

SECTION 6
COUNSELLING AND TESTING FOR HIV

Now I am going to ask you some questions on voluntary counselling and testing. I will ask you about your experiences with testing but at no time will I ask you to reveal your status. **WE ARE NOT ASKING YOUR STATUS.**

V601	Where could someone in your community go to get a test to find out if they are infected with HIV? *Ke ko kae kwa mongwe mo sechaba sa gago a ka yang go dira teko go tlhola fa a tshwaeditswe ke HIV/AIDS?*	1.Clinic ……..1 2. Hopsital…… 2 3. Doctor……..3 4. NGO's……4 5. Don't know……5 6. Other …… 6	
V601(a)	Before today have you ever been offered HIV counselling and testing? *Pele ga gompieno, A o kile wa fiwa tetla go dira teko ya HIV?*	Yes ……01 No……00	
V602	Have you ever been tested for HIV? *A o kile wa dira teko ya HIV?*	Yes ……01 No……00	→619
V603	If yes how many times have you been tested?	[ ] [ ]	

V604	When did you last have the test? *O dirile leng diteko la bofelo?*	----/---------- Mm/yyyy	
V605	Were you pregnant at the time when you took the test? *A one o le moimane ga one o dira diteko?*	Yes ……01 No……00	
V606	Did you get your results? *A o bone dipoelo?*	Yes……01 No……..00	→609
V607	After how long did you go back to get your results? *O amogetse dipoelo moraga ga sebaka se se ka na kang?*	Days [ ] [ ]…… …01 Weeks [[[ ]…… …02 Months [ ] [ ]…… ..03	
V608	Did you inform any of your partners of your test results? *A o boleletse molekane ka ga dipoelo tseo?*	Yes……01 No……..00	
V609	Where did you go to get tested ? *O dirile diteko kae?* ***If other clinic please specify*** **Clinic name :** _____	This clinic……..01 Other clinic……02 Hospital……03 Doctor……04 Other (specify)_____ _____….05 _____	
V610	Who influenced you to decide to take the test? *Ke mang yo a go rutluweditseng go dira diteko?* **Circle all mentioned**	Health care nurse……..……01 Relative……02 Friend/boyfriend……..03 Media……...04 Other ……...……07	
V611	Would you say that the information that you were given before testing was informative to you? *A okare kitso eo o e amogetseng(go tswa go mogomotsi) pele ga diteko e go file kitso naa?*	Yes……01 No…… … ….00	
V612	Would you say the results were explained in a way that you understood. *A okare dipoelo di tlhalositswe ka tsela e leng gore o di tlhalogantse?* ***CHK IF NO TO Q606***	Yes……01 No…… …….00	
V613	If you were to get tested again would you go back to the same place for testing? *Fa o ka ya ditekong gape, a o ne o a ka ya go dira diteko kwa o dirileng teng lantlha*?	Yes……01 No…… …….00 Don't know……99	→614 →615 →615
V614	If yes, Why? *Fa ore eng, goreng?*	I trust the nurses here (there)… …01 To keep confidentiality…… …..02 Other (Specify) _____ _____.03	

V615	If no, why not? *Ga ele gore ore nya, goreng?*	Lack of confidentiality……..01 Other (Specify) _____ _____02	
V616	Would you say your overall experience of testing was good, bad or just/okay? *A maitemogelo a gago a diteko, a ne a itumedisa, magareng kgotsa a sa itumedise?*	Good……01 Just/okay……02 Bad……..03	
V617	Who would you have preferred to offer you HIV counselling? *One oratile go memwa kemang godira HIV counselling?*	Nurse……..01 Counselor …….02 Other (Specify) _____ _____03	
V618	Should you have required further counselling (post-counselling) who would you have preferred	Nurse……..01 Counselor …….02 Other (Specify) _____ _____03	
V619	Has any of your sexual partner(s) gone for HIV testing? *A molekane wa gago o dirile diteko?*	Yes ……01 No……..00 Don't know……99	 →623 →623
V620	Where did he go for testing? *O dirile diteko ko kae?*	This clinic……01 Other clinic……..…02 Hospital……03 Doctor……..05 Work……06 Other (specify)……..…04 Don't know……99	
V622	Was it the same place that you were tested? *A e ne e le lefelo le o tswang kwa go lone?*	Yes……...01 No……00 Don't know……02	
V621	Did he tell you his results? *A o go bolleletse dipoele tsa gagwe?*	Yes……..01 No……00	
THIS NEXT SECTION ASKS QUESTIONS ABOUT TODAY ONLY. IT DOES NOT MATTER IF SHE HAS TESTED BEFORE THESE QUESTIONS SHOULD BE ASKED TO ALL.			
V623	Were you offered HIV testing today? *A o memetswe go dira teko ya HIV gompieno?*	Yes……...01 No……00	→626
V624	Who offered you HIV testing today? *Ke mang ogo memileng?*	Nurse……..01 Counselor …….02 Other (Specify) _____ _____.03	
V625	Who would you have preferred to offer you HIV testing? *One oratile gomemwa kemang?*	Nurse……..01 Counselor …….02 Other (Specify) _____ _____.03	
V626	Do you intend to go for HIV testing? *A o ikaelela go dira teko ya HIV?*	Yes……01 No……..02 Not Sure……03.	→629 →629

V627	Where do you intend to go for testing? *O ikaelela go dira diteko kae?* ***If other clinic please specify*** ***Clinic name :*** _____	This clinic……01 Other clinic……02 Hospital……..03 Other (Specify) _____ _____04	
V628	Why do you intend to go to this place for HIV testing? *Goreng o ikaelela go dira diteko kwa lefelong le?*	This is the nearest clinic……..01 No transport costs involved……02 Other (Specify) _____ _____03	**Skip to Q 630**
V629	Why won't you go for an HIV test? *Go reng o sa batle go dira teko ya HIV?*	Not ready/prepared……01 Fear to be injected with infected blood..02 Afraid of knowing status------……03 I don't want to lose hope because of stress…… .04 I stick to one partner…… …05 Already tested/know status…… …...06 Other (Specify) _____ _____07	
V630	Do you intend to ask your sexual partner(s) to go for a test? *A o ikaelela go bolelela molekane go dira teko?*	Yes……01 No……00 Don't know……99	→632 →632
V631	If no, Why not? _____ *Fa ore nyaa, goreng ore nyaa?* _____		
V632	Were you tested today? *A o dirilwe diteko gompieno?*	Yes……01 No……..02	
V633	Did you feel comfortable discussing sexual health issues with your FP nurse? *A o ne o gololosegile fa o bua matshwenyego a gago a thobalano le mooki*?	Yes……..01 No……02 There was no discussion of sexual issues……..03 Don't know……04	

SECTION7.
SEXUAL PARTNERS

Now I am going to ask you about your sexual partners. The questions are very personal but your name will not be connected with any of your answers.

V701	Are you married or have a partner? *A o nyetswe kgotsa kgotsa o nale molekani?*	Married……01 Partner/boyfriend……..02 No current partner…….03	→705
V702	Are you currently living with your partner? *O nna le molekane?*	Yes ……01 No…….00	
V703	How long have you been in this relationship? *O nale sebaka se se kanakang mo kgolaganong e?*	Days [ ] [ ] Weeks [ ] [ ] Months [ ] [ ] Years [ ] [ ]	
V704	How often do you see this partner? *Le bonana ga kae le molekane wa gago?*	Everyday……01 Weekly……02 Monthly ……03 Yearly……04 other_____……05	
V705	How many other partners (excluding your main partners) have you had in the last 12 months? *Ke balekane ba ba kae (ntle le balekani ba leruri) ba o ba boneng modikgeding tse 12 tse difetileng?*	[ ] [ ]	
V706	How many sexual partners have you had in the last 12 months? *Ke balekane ba ba kae ba leruri ba o ba boneng modikgweding tse 12 tse difetileng?*	Main [ ] [ ] Casual [ ] [ ]	
V707	With which partner(s) do you use a condom when you have sex? *Ke molekane o feng yo o dirisana Condom le ena?* **(CIRCLE ALL that are mentioned)** **[Check] q301 if ever use a condom**	None……01 All……02 Main……03 Casual/other……..04 Other (Specify) _____ _____05	→801
V708	How often do you use a condom with your main partner(s)? *O dirisa condom ga kae le molekane wa gago wa leruri?* .	Not at all……01 Sometimes……02 Always ……03	
V709	How often do you use a condom with your casual or other partner (s)? *O dirisa condom ga kae le molekane/balekane ba gago ba e seng ba leruri?*	Not at all……01 Sometimes……02 Always ……03	

SECTION 8. **WAITING PERIOD**			
V801	What time did you arrive at the clinic today? *O fitlhile nako mang mo kliniking?*	Hour [ ][ ] Minutes [ ][ ] Don't know…….99	
V802	Did you feel the waiting period between the time you first arrived and the time you received services was okay? *A o bone kemo ya gago magareng ga nako e o fitlhileng ka yona le nako e fumanego ditirelo ka yona e ne e siame?*	Yes……..…01 No……..00	
V803	Overall, would you say that you were satisfied with your visit or dissatisfied with your visit? *Go tsotlhe a okabua gore o kgotsofetse ka ketelo yo gago kgotsa one osa kgotsofala?*	Satisfied……01 Dissatisfied……...02	

FINISH

I would like to thank you very much for helping us. We have talked about some very difficult things today. I appreciate the time you have taken. I realise that some of these questions may have been difficult for you to answer, but we have to ask them if we are to really understand how to provide better services at the clinic. We really appreciate your participation in this study. By sharing this personal information with us you are helping us with our research and that will ultimately help many other people in the country.

End Time of Interview: Hours[ ] [ ] Minutes[ ] [ ]

Study ID number ☐☐☐☐☐☐☐

Integration of CT for HIV within FP Services in South Africa

FP CLIENT OBSERVATION

A. FACILITY IDENTIFICATION

01	**NAME OF FACILITY**_____ **CODE:** ____ ____		
PLEASE DO NOT FILL IN THE SHADED SECTIONS. GO TO QO6			
02	**DISTRICT** _____ **CODE** _____		
03	**RURAL/URBAN**	URBAN	1
		PERI URBAN	2
		RURAL	3
04	**TYPE OF FACILITY**	CLINIC	1
		COMMUNITY HEALTH CENTER	2
05	**NAFCI ACCREDITED**	YES	1
		NO	2
06	**POSITION OF PROVIDER OBSERVED**	PROFESSIONAL NURSE	1
		ENROLLED NURSING ASSISTANT	2
		ENROLLED NURSE/AUXILLIARY NURSE	3
		OTHER _____	4
07	**SEX OF PROVIDER**	FEMALE	1
		MALE	2
00	**NAME OF OBSERVER** _____**CODE:** _____ _____ _____**DATE**_____		
00	**FIELD EDIT** _____ **DATE** _____		

INTRODUCTION

OBSERVER INSTRUCTIONS: OBTAIN PERMISSION FROM THE CLIENT AS WELL AS THE HEALTH PROVIDER BEFORE BEGINNING TO ASSESS THE INTERACTION BETWEEN THEM. BE AS DISCREET AS POSSIBLE DURING THE ASSESSMENT AND DO NOT TAKE PART IN THE INTERACTION IN ANY WAY. MAKE SURE THAT THE HEALTH PROVIDER KNOWS THAT YOU ARE NOT THERE TO EVALUATE HER/ HIM AND THAT YOU ARE NOT AN EXPERT TO CONSULT DURING THE SESSION. TRY TO SIT BEHIND THE CLIENT, BUT IN A POSITION NOT DIRECTLY IN FRONT OF THE HEALTH PROVIDER. FOR EACH OF THE QUESTIONS LISTED BELOW, CIRCLE THE ANSWER THAT MOST APPROPRIATELY REFLECTS YOUR ASSESSMENT OF WHAT HAPPENED DURING THE INTERACTION.

READ TO HEALTH PROVIDER: HELLO, MY NAME IS _____. I AM REPRESENTING POPULATION COUNCIL AND THE NORTH WEST DEPARTMENT OF HEALTH. WE ARE CARRYING OUT A SURVEY OF HEALTH FACILITIES THAT PROVIDE REPRODUCTIVE HEALTH SERVICES WITH THE GOAL OF FINDING WAYS TO IMPROVE SERVICE DELIVERY. I WOULD LIKE TO OBSERVE YOUR CONSULTATION IN ORDER TO BETTER UNDERSTAND HOW HEALTH CARE IS PROVIDED IN THIS PROVINCE. THIS INFORMATION IS COMPLETELY CONFIDENTIAL AND NO NAMES WILL BE TAKEN. YOU MAY CHOOSE TO STOP THE OBSERVATION AT ANY TIME. MAY I BE PRESENT AT THIS CONSULTATION?

08	**MAY I CONTINUE?**	YES	1
		NO	0 **STOP**

READ TO CLIENT: HELLO, MY NAME IS _____. I AM REPRESENTING POPULATION COUNCIL AND THE NORTH WEST DEPARTMENT OF HEALTH. WE ARE CARRYING OUT A SURVEY OF HEALTH FACILITIES THAT PROVIDE REPRODUCTIVE HEALTH SERVICES. I WOULD LIKE TO OBSERVE YOUR CONSULTATION WITH THIS HEALTH PROVIDER IN ORDER TO BETTER UNDERSTAND HOW HEALTH CARE IS PROVIDED. THIS INFORMATION IS COMPLETELY CONFIDENTIAL AND WILL NOT AFFECT THE LEVEL OF CARE YOU RECEIVE HERE NOW OR IN THE FUTURE. NO NAMES WILL BE TAKEN. AFTER THE CONSULTATION, ANOTHER RESEARCHER FROM POPULATION COUNCIL WOULD LIKE TO TALK WITH YOU ABOUT YOUR EXPERIENCES HERE TODAY. YOU MAY TELL ME TO STOP THE OBSERVATION AT ANY TIME. MAY I STAY?

09	**MAY I CONTINUE?**	YES	1
		NO	0 **STOP**

B. GREETING AND ASSESSING CLIENT

TIME CONSULTATION STARTED: HOUR ☐☐ **MINUTE** ☐☐

10	**DID THE PROVIDER GREET THE CLIENT IN A FRIENDLY/ RESPECTFUL MANNER?**	**YES**	**NO**	**DID NOT GREET**
		1	0	3

11	**WHAT WAS THE MAIN PURPOSE OF THE VISIT AS INITIALLY INDICATED BY THE CLIENT?**	NEW USER	1
		REPEAT CLIENT	2
		SWITCHING	3
		DEFAULTER	4

12	**ARE THE FOLLOWING AREAS DISCUSSED/MENTIONED DURING THE CONSULTATION (OBSERVE AND CIRCLE IF MENTIONED):**	**YES**	**NO**	
a)	CLIENT'S AGE	1	0	
b)	MARITAL STATUS	1	0	
c)	MEDICAL HISTORY (GENERAL)	1	0	
d)	OBSTETRICS HISTORY	1	0	
e)	NUMBER OF CHILDREN ALIVE	1	0	
f)	DESIRED NUMBER OF CHILDREN	1	0	
g)	AGE OF YOUNGEST CHILD	1	0	
h)	CURRENTLY BREASTFEEDING	1	0	
i)	TIMING OF NEXT BIRTH	1	0	
j)	DATE OF LAST MENSES	1	0	
k)	INTERCOURSE SINCE LAST MENSES	1	0	
l)	SIGNS AND SYMPTOMS OF PREGNANCY (TENDER BREASTS OR NAUSEA)	1	0	
m)	HISTORY/SIGNS/SYMPTOMS OF RTIs/STIs	1	0	
n)	NUMBER OF SEXUAL PARTNERS	1	0	
o)	PARTNER'S NUMBER OF SEXUAL PARTNERS	1	0	
p)	PREVIOUS USE OF FP	1	0	
q)	DISCUSSED FAMILY PLANNING WITH SPOUSE/PARTNER	1	0	
r)	PARTNER COOPERATION	1	0	
s)	HIV RISK	1	0	
t)	HIV SEROSTATUS	1	0	
u)	USE OF VAGINAL INSERTS/CLEANING/DRY SEX	1	0	
v)	OTHER _____	1	0	

C. CLIENT COUNSELING

13	**WHICH INFORMATION, EDUCATION, AND COMMUNICATION (IEC) MATERIALS ARE USED DURING THE CONSULTATION?**	**USED**	**NOT USED**	
a)	FLIP CHART	1	0	
b)	BROCHURES/LEAFLET	1	0	
c)	CONTRACEPTIVE SAMPLES (PILLS, CONDOM, ETC)	1	0	
d)	POSTERS	1	0	
e)	ANATOMICAL MODELS	1	0	
f)	BALANCED COUNSELING STRATEGY TOOLS	1	0	
g)	OTHER _____	1	0	
h)	NONE	1	0	
14	**WHICH METHODS ARE DISCUSSED DURING THE CONSULTATION**	**YES**	**NO**	
a)	COMBINED PILL (OVRAL, TRIPHASIL, NORDETT)	1	0	
b)	PROGESTIN ONLY PILL (MICROVAL)	1	0	
c)	PILL (TYPE UNSPECIFIED)	1	0	
d)	IUCD	1	0	
e)	CONDOM (MALE OR FEMALE)	1	0	
f)	INJECTABLES (DEPO OR NURISTERATE)	1	0	
g)	FEMALE STERILIZATION	1	0	
h)	EMERGENCY CONTRACEPTION	1	0	
i)	OTHER _____	1	0	
15	**DOES THE PROVIDER PROMOTE OR EMPHASIZE ONE METHOD IN PARTICULAR?**	**YES**	**NO**	
	[IF A REPEAT USER SKIP TO QUESTION 17]	1	0 →**17**	
16	**(IF YES) WHICH METHOD DOES THE PROVIDER EMPHASIZE?**	**EMPHASIZED**	**NOT EMPHASIZED**	
a)	COMBINED PILL (OVRAL, TRIPHASIL, NORDETT)	1	0	
b)	PROGESTIN-ONLY PILL (MICROVAL)	1	0	
c)	IUCD	1	0	
d)	CONDOM (MALE OR FEMALE)	1	0	
e)	INJECTABLE 2 MONTH (NURISTERATE)	1	0	
f)	INJECTABLE 3 MONTH (DEPO)	1	0	
g)	FEMALE STERILIZATION	1	0	
h)	OTHER _____	1	0	
17	**DOES THE PROVIDER DISCUSS STI/HIV/AIDS WITH THE CLIENT?**	**YES**	**NO**	
		1	0	
18	**DOES THE CLIENT MENTION ANY MISINFORMATION ON HIV/AIDS?**	**YES**	**NO**	

		1	0 →20	
19	**DOES THE PROVIDER CORRECT ANY MISINFORMATION ON STI/HIV/AIDS?**	1	0	
20	**DOES THE CLIENT HAVE GAPS IN KNOWLEDGE ABOUT STI/HIV/AIDS?**	1	0 →22	
21	**DOES THE PROVIDER FILL IN GAPS IN INFORMATION ON STI/HIV/AIDS?**	1	0	
22	**DOES THE PROVIDER DISCUSS STI AND/OR HIV RISK FACTORS WITH THE CLIENT?**	1	0 →24	
23	**IF YES, WHAT RISK FACTORS DOES THE PROVIDER DISCUSS?**	**YES**	**NO**	
a)	MULTIPLE PARTNERS	1	0	
b)	STIS	1	0	
c)	UNPROTECTED SEXUAL INTERCOURSE	1	0	
d)	OTHER _____	1	0	
24	**IS THE CLIENT GIVEN INFORMATION ON SYMPTOMS OF AN STI?**	1	0	
25	**IS THE CLIENT TOLD TO SEEK MEDICAL TREATMENT IF THEY NOTICE ANY SYMPTOMS OF AN STI?**	1	0	
26	**IS THE CLIENT TOLD THAT AN STI MAY BE ASYMPTOMATIC?**	1	0	
27	**IS THE CLIENT TOLD THAT AN STI CAN INCREASE TRANSMISSION OF HIV?**	1	0	
28	**DOES THE PROVIDER MENTION CONDOMS?**	1	0 →36	
29	**DOES THE PROVIDER MENTION EXPLICITLY THAT CONDOMS PROTECT AGAINST STI AND/OR HIV?**	1	0	
30	**DOES THE PROVIDER MENTION EXPLICITLY THAT CONDOMS PROTECT AGAINST PREGNANCY?**	1	0	
31	**DOES THE PROVIDER ENCOURAGE THE USE OF CONDOMS FOR STI/HIV PREVENTION ALONG WITH THE USE OF ANOTHER METHOD?**	YES, MALE CONDOMS		
		YES, FEMALE CONDOMS		
		YES, CONDOMS UNSPECIFIED		
		YES, BOTH		
		NO		
32	**DOES THE PROVIDER MENTION ANYTHING NEGATIVE ABOUT MALE CONDOMS?**	**YES**	**NO**	
		1	0 →33	
32B	**IF YES, WHAT DID THE PROVIDER SAY?** _____ _____			
33	**DOES THE PROVIDER MENTION ANYTHING NEGATIVE ABOUT FEMALE**	**YES**	**NO**	

	CONDOMS?			
		1	0 →34	

33B	**(IF YES) WHAT DID THE PROVIDER SAY?** _____ _____		
34	**DOES THE PROVIDER GIVE INFORMATION ON HOW TO USE A CONDOM?**	**YES** 1	**NO** 0
35	**DOES THE PROVIDER EMPHASIZE CORRECT AND CONSISTENT USE OF A CONDOM?**	1	0
36	**DOES THE PROVIDER DISCUSS OTHER STI/HIV PREVENTION METHODS OTHER THAN THE CONDOM?**	1	0 →38

37	**(IF YES) WHICH METHODS?**	**YES**	**NO**
a)	ABSTINENCE	1	0
b)	MONOGAMY	1	0
c)	PARTNER MONOGAMY	1	0
d)	KNOWING YOUR PARTNER'S STATUS	1	0
e)	OTHER _____	1	0
38	**Does the provider ask the client the following?**	**YES**	**NO**
a	Ever tested for HIV?	1	0→41
b	When last tested?	1	0
c	Knowing own status?	1	0
d	If she is willing to disclose her HIV status to the provider?	1	0
		POSITIVE	**NEGATIVE**
e	**What is the status of the client**	1→40	0
39	**If Negative or unknown**	**YES**	**NO**
a	Is HIV testing offered?	1	0
b	Does the provider talk about what the test can tell?	1	0
c	Does the provider mention dual protection?	1	0
d	Does the provider mention the availability of treatment?	1	0
e	Does the client accept the test?	1	0
f	**Is the client referred for testing?**	**YES**	**NO**
		1	0

g	**Does the provider test the client?**	**YES**	**NO**
		1	0
40	**If Positive Does the provider check or ask about the following?**	**YES**	**NO**
a	Screen for symptoms of TB (chronic cough, weight loss and night sweats)?	1	0
b	If TB negative have they started prophylaxis?	1	0
c	If TB positive have they been referred to a TB clinic?	1	0
d	Have they been for CD 4 count?	1	0 →K
e	When was the last CD 4 count done?	1	0
f	If they are on ARV treatment?	1	0 →K
g	If they are taking medications regularly?	1	0
h	When last did they receive their medication?	1	0
i	If they are experiencing any problems with medication?	1	0
j	If they are attending at ARV treatment site?	1	0
k	If they are attending wellness clinic or support group?	1	0

41	**DOES THE PROVIDER MENTION VCT?**	**YES**	**NO**	
		1	0 →48	
42	**DOES THE PROVIDER DISCUSS WHAT THE TEST CAN TELL THE CLIENT?**	1	0	
43	**DOES THE PROVIDER EXPLAIN ABOUT THE WINDOW PERIOD?**	1	0	
44	**DOES THE PROVIDER GIVE THE CLIENT INFORMATION ON WHERE TO GET VCT?**	1	0	
45	**DOES THE PROVIDER OFFER THE CLIENT VCT?**	1	0 →47a	
46	**DOES THE CLIENT ACCEPT VCT?**	1	0	
47a	**Does the provider refer client for testing?**	**YES**	**NO**	
		1	0	
47 b	**Does the provider test the client?**	**YES**	**NO**	
		1	0	

D. FP METHOD SELECTION

48	**DOES THE CLIENT MENTION A PREFERENCE FOR A PARTICULAR METHOD WITHOUT BEING ASKED?**	**YES**	**NO**	
		1	0	
49	**DID THE PROVIDER ASK THE CLIENT WHICH METHOD SHE WOULD PREFER TO USE?**	1	0	
50	**DOES THE CLIENT RECEIVE HER PREFERRED METHOD (LEAVE WITH METHOD IN HAND OR A PRESCRIPTION)?**	1	0	
51	**DOES THE CLIENT DECIDE TO USE A CONTRACEPTIVE METHOD DURING THE CONSULTATION?**	1	0 **→57**	
52	**WHICH METHOD DOES THE CLIENT DECIDE TO USE?**		**YES**	
a)	COMBINED PILL		1 **→METHOD**	
b)	PROGESTIN ONLY PILL		1 **→METHOD**	
c)	INJECTABLES		1 **→METHOD**	
d)	MALE CONDOM		1 **→57**	
f)	IUD		1 **→METHOD**	
g)	FEMALE STERILIZATION		1 **→57**	
h)	OTHER _____		1 **→57**	

PILL CLIENTS GO TO Q53 (PAGE 9)
INJECTABLE CLIENTS GO TO Q55 (PAGE 10)
CONDOM CLIENTS GO TO Q57 (PAGE11)
IF NO METHOD GO TO Q57 (PAGE 11)

E. OBSERVATION OF SPECIFIC METHODS

PILL (COMBINED OR PROGESTIN-ONLY PILL)

53	DOES THE PROVIDER?	MENTIONED	NOT MENTIONED	
a)	CHECK/ASK ABOUT HEART/LIVER DISEASES/HIGH BLOOD PRESSURE	1	0	
b)	ASK ABOUT SMOKING	1	0	
c)	EXPLAIN HOW METHOD WORKS	1	0	
d)	EXPLAIN ADVANTAGES/BENEFITS	1	0	
e)	EXPLAIN DISADVANTAGES	1	0	
f)	EXPLAIN HOW TO USE METHOD	1	0	
g)	EXPLAIN WHAT TO DO IF CLIENT FORGETS A PILL	1	0	
h)	EXPLAIN WHAT TO DO IF CLIENT FORGETS TWO PILLS	1	0	
i)	DISCUSS PRACTICES AFFECTING EFFECTIVENESS	1	0	
j)	DISCUSS POSSIBLE SIDE EFFECTS	1	0	
k)	DISCUSS MANAGEMENT OF SIDE EFFECTS	1	0	
l)	DISCUSS RETURN TO CLINIC IF SHE HAS COMPLICATIONS	1	0	
m)	DISCUSS POSSIBILITY OF CHANGING METHOD	1	0	
n)	DISCUSS EMERGENCY CONTRACEPTION	1	0	
o)	EXPLAIN NEED FOR STI/HIV/AIDS PROTECTION/ DUAL PROTECTION	1	0	
p)	DISCUSS CONDOM USE IN ADDITION TO THE METHOD	1	0	
q)	ADVISE CLIENT WHEN TO RETURN FOR RESUPPLY	1	0	
r)	GIVE ORAL OR WRITTEN FOLLOW-UP INSTRUCTIONS	1	0	
s)	OTHER (SPECIFY) _____	1	0	
54	**HOW MANY PACKETS OF PILLS DOES THE CLIENT RECEIVE?**	_____		

GO TO Q57 (PAGE 11)

INJECTABLE (2 OR 3 MONTH)				
55	**DOES THE PROVIDER?**	**OBSERVED**	**NOT OBSERVED**	
a)	CHECK/ASK ABOUT HEART/LIVER DISEASES/HIGH BLOOD PRESSURE	1	0	
b)	ASK ABOUT SMOKING	1	0	
c)	ASK CLIENT HOW THE METHOD IS TREATING HER	1	0	
v)	EXPLAIN HOW METHOD WORKS	1	0	
d)	EXPLAIN ADVANTAGES/BENEFITS	1	0	
e)	EXPLAIN DISADVANTAGES	1	0	
f)	DISCUSS CHANGES IN MENSTRUAL CYCLE	1	0	
g)	DISCUSS DELAYED RETURN TO FERTILITY	1	0	
h)	DISCUSS POSSIBILITY OF CHANGING METHOD	1	0	
i)	SHAKE THE VIAL/AMPULE	1	0	
j)	WARM THE VIAL/AMPULE	1	0	
k)	WIPE THE TOP OF THE VIAL WITH DISINFECTANT	1	0	
l)	USE A STERILE SYRINGE AND NEEDLE	1	0	
m)	DISINFECT THE INJECTION SITE USING LOCAL ANTISEPTIC	1	0	
n)	MASSAGE INJECTION SITE	1	0	
o)	REASSURE THE CLIENT AFTER THE INJECTION	1	0	
p)	EXPLAIN WHEN THE CLIENT SHOULD COME BACK FOR RESUPPLY	1	0	
q)	AFTER COMPLETING THE INJECTION, DISPOSE OF THE SYRINGE AND NEEDLE INTO SHARPS CONTAINER	1	0	
r)	EXPLAIN NEED FOR STI/HIV/AIDS PROTECTION/ DUAL PROTECTION	1	0	
s)	DISCUSS USE OF CONDOMS IN ADDITION TO THE METHOD	1	0	
t)	GIVE ORAL OR WRITTEN FOLLOW-UP INSTRUCTIONS	1	0	
u)	OTHER (SPECIFY) _____	1	0	
56	**WHICH INJECTABLE DISPENSED?**	2 MONTH		1
		3 MONTH		2

GO TO Q57 (PAGE 11)

MALE CONDOMS				
57	**DOES THE PROVIDER?**	**YES**	**NO**	
a)	MENTION USE OF THE MALE CONDOM	1	0	
b)	ASK IF THE CLIENT HAS AN ALLERGY TO LATEX	1	0	
c)	EXPLAIN HOW TO UNROLL THE CONDOM OVER THE ERECT PENIS	1	0	
d)	DEMONSTRATE HOW TO UNROLL THE CONDOM OVER THE ERECT PENIS	1	0	
e)	EXPLAIN HOW TO REMOVE AND DISPOSE OF CONDOM	1	0	
f)	EXPLAIN THE NECESSITY OF USING A NEW CONDOM FOR EACH ACT OF INTERCOURSE	1	0	
g)	EXPLAIN PROPER STORAGE AND CARE OF CONDOMS	1	0	
h)	CHECK THE EXPIRY DATE OF CONDOMS	1	0	
i)	DISCUSS HOW TO NEGOTIATE USE WITH PARTNER	1	0	
j)	MENTION EMERGENCY CONTRACEPTION	1	0	
k)	GIVE THE CLIENT ORAL OR WRITTEN FOLLOW-UP INSTRUCTIONS	1	0	
l)	OTHER (SPECIFY) _____	1	0	
58	**DOES THE PROVIDER GIVE THE CLIENT MALE CONDOMS?**	1	0	
59	**HOW MANY MALE CONDOMS ARE GIVEN TO THE CLIENT?**	_____		

F. CONCLUDING ISSUES FOR ALL FP CLIENTS				
60	**DOES THE CLIENT RECEIVE A CONTRACEPTIVE METHOD DURING THE VISIT?**	**YES**	**NO**	
		1 →**62**	0	
61	**(IF NO) WHY NOT**		**YES**	**NO**
a)	NOT APPROPRIATE METHOD/CONTRAINDICATIONS		1	0
b)	METHOD NOT AVAILABLE		1	0
c)	TOLD TO RETURN DURING/AFTER MENSES		1	0
d)	CHANGED MIND AFTER LISTENING TO PROVIDER		1	0
e)	NO APPROPRIATE PROVIDER AVAILABLE THAT DAY		1	0
f)	LACK OF NECESSARY EQUIPMENT		1	0

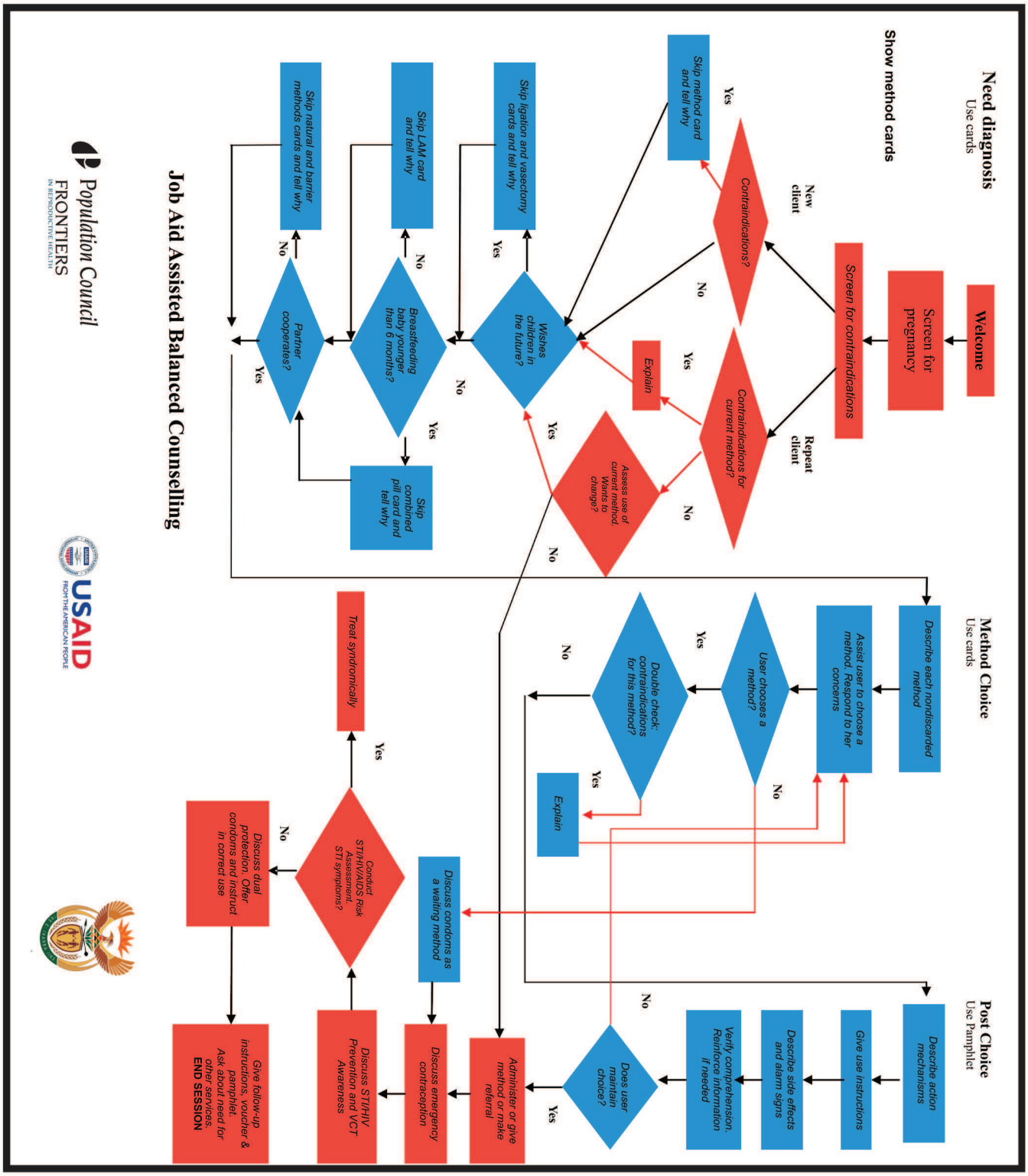
g)	OUT OF PROFESSIONAL CAPACITY		1	0
h)	NO OBVIOUS REASON		1	0
i)	SUSPECT PREGNANCY		1	0
j)	OTHER (SPECIFY) _____		1	0
62	**DOES THE HEALTH WORKER GIVE THE CLIENT A REMINDER, IN WRITING, OF WHEN TO RETURN?**	**YES**	**NO**	
		1	0	
63	**WHAT OTHER HEALTH ISSUES ARE MENTIONED/ DISCUSSED WITH THE CLIENT DURING THE CONSULTATION?**	**MENTIONED**	**NOT MENTIONED**	
a)	GYNECOLOGICAL EXAM/PAP SMEAR	1	0	
b)	HIV/AIDS	1	0	
c)	PREGNANCY TEST	1	0	
d)	MTCT	1	0	
e)	GENDER BASED VIOLENCE/ABUSE	1	0	
f)	TOP	1	0	
g)	OTHER _____	1	0	

G. SUMMARY IMPRESSIONS FROM OBSERVER

64	**DOES THE CLIENT ASK THE PROVIDER QUESTIONS**	**YES**	**NO**	
		1	0	
65	**DOES THE PROVIDER:**	**YES**	**NO**	
a)	USE CLIENT'S NAME WHEN TALKING TO HER	1	0	
b)	USE KIND AND INVITING TONE OF VOICE	1	0	
c)	LISTEN TO THE CLIENT	1	0	
d)	ASK QUESTIONS	1	0	
e)	HELP IN DECISION MAKING	1	0	
f)	ASK IF CLIENT UNDERSTOOD THE INFORMTION	1	0	
g)	ENCOURAGE CLIENT TO ASK QUESTIONS	1	0	
h)	SEE CLIENT IN PRIVATE	1	0	
i)	USE CLIENT RECORD	1	0	

66	**ANY OTHER COMMENTS/IMPRESSIONS (WRITE OVERLEAF IF NECESSARY)** _____ _____ _____ _____		
	TIME CONSULTATION ENDED: HOUR ☐☐ **MINUTE** ☐☐		
67	**REFER THIS CLIENT TO THE EXIT NTERVIEWER. DID YOU REFER THIS CLIENT?**	**YES**	**NO**
		1	0

Appendix 4 Balanced Counselling Strategy Plus - Algorithm



Appendix 5 Balanced Counselling Strategy Plus - counselling cards for Providers

BALANCED COUNSELING STRATEGY

Population Council
FRONTIERS

USAID
FROM THE AMERICAN PEOPLE

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Checklist to rule-out pregnancy for women who are notmenstruating

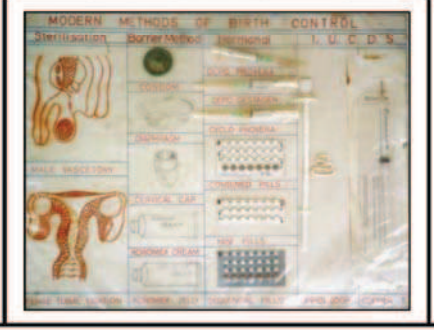
Checklist to rule out pregnancy for women who are not menstruating

- ? have you given birth during the last four weeks?
- did you give birth during the last six months, are breastfeeding exclusively and have not had a menstruation since childbirth?
- did your last period start within the last 7 days?
- have you had a miscarriage or abortion within the last 7 days?
- have you stayed away from sex since your last menstrual period
- have you been using a reliable contraceptive method consistently and correctly?

Provide a method if an answer is YES to any of the questions.
If the answer is NO to all questions it means pregnancy cannot be ruled out, conduct a pregnancy test. Encourage condom use. Give the method and condoms, don't wait for the menstrual period.

1 of 18

Contraindications for contraception use



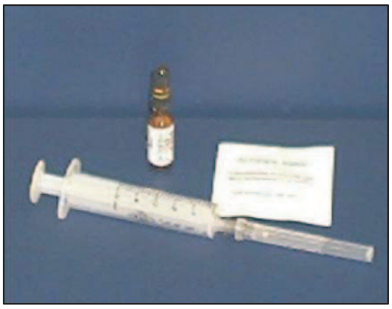
Contra-indications for contraception use

- are you taking any medications (prescription as well as over the counter products such as laxatives)?
- are you currently using any herbs?
- are you on a long-term/chronic illness treatment?
- do you have any other disease?
- are you on ARV's?

If answer is YES to any questions, investigate use of a method.

2 of 18

Nur-Isterate

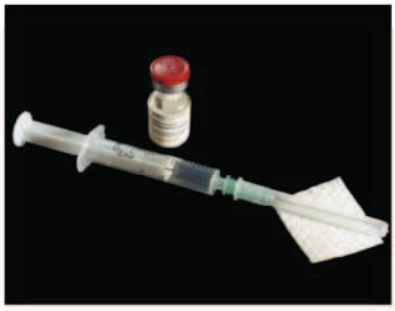


Nur-Isterate

- prevents pregnancy if given every two months
- may cause amenorrhea and other changes in menstrual bleeding
- may cause a delay in return to fertility
- is suitable for all age groups
- does not protect against STI and HIV infections

3 of 18

Depo-provera

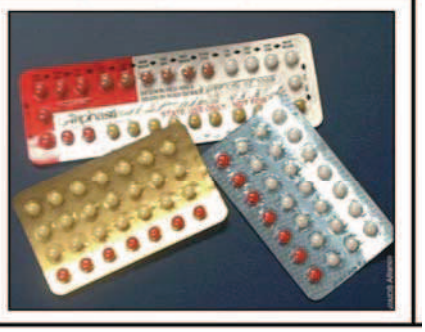


Depo-provera

- prevents pregnancy if given every three months
- may cause amenorrhea and other changes in menstrual bleeding
- may cause a delay in return to fertility
- it is suitable for all age groups
- does not protect against STI and HIV infections

4 of 18

Pills
Combined oral contraceptives
Triphasil, Nordett, Ovral



Pills
Combined oral contraceptives
Triphasil, Nordett, Ovral

- prevents pregnancy if the woman takes one pill every day, at about the same time, without forgetting
- no delay in return to fertility: can get pregnant as soon as she stops taking the pill
- may cause irregular bleeding and headaches which disappears in the first month
- does not protect against STI and HIV infections

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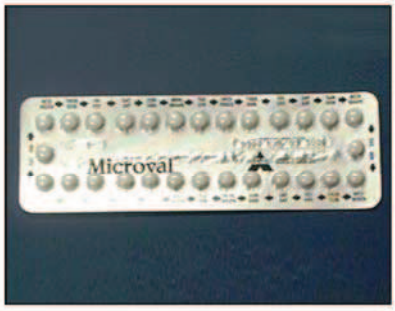
Mini Pill

Progestin-only oral contraceptive

Microval



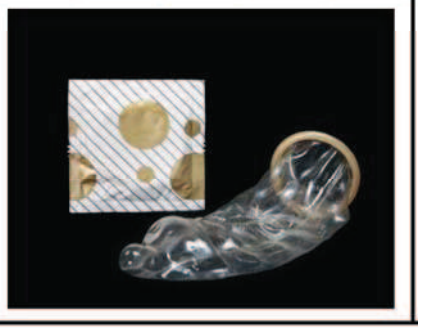
Progestin-only oral contraceptive

Microval

- this is a progestin only oral contraception
- can be used when a woman is breastfeeding
- prevents pregnancy if the woman takes one pill every day, at about the same time, without forgetting
- no delay in return to fertility: can get pregnant as soon as she stops taking the pill
- does not protect against STI and HIV infections

6 of 18

Male condom



Male condom

- is a thin sheath made of latex that a man places over his erect penis each time he has sex
- prevents pregnancy if used correctly at every intercourse
- a new condom must be used for each sexual intercourse
- must be placed before the penis enters the vagina and taken off before losing erection
- also protects against STI and HIV infection. Can be used during pregnancy to protect against STI and HIV infections

7 of 18

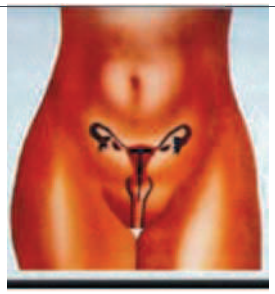
Female condom

Female condom

- prevents pregnancy if used correctly at every intercourse
- is suitable for all women
- a new condom must be used for each sexual intercourse
- can also be used by women who are allergic to latex
- can be inserted up to 8 hours before intercourse
- may not be used with a male condom at the same time
- also protects against STI and HIV infection. Can be used during pregnancy to protect against STI and HIV infection

I

Intrauterine Contraceptive Device
Loop/CopperT



T

IUCD/Loop

- is a small plastic and copper devise which is inserted in the uterus of the woman by a trained health provider
- provides contraception for 5 to 10 years
- should only be removed by a trained health care provider
- can be removed if a woman decides to get pregnant or has side effects
- can increase menstrual bleeding and have other side effects in some women
- does not cause a delay in return to fertility
- can also be used as emergency contraception
- does not protect against STI and HIV infections

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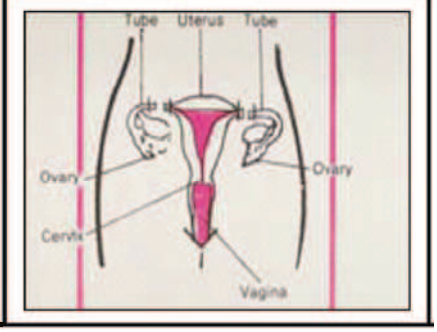
Sterilization
Tubal ligation
Voluntary Female Surgical Contraception



Sterilization

- should be considered a permanent method: will not be able to have more children after the surgery
- is a quick and simple surgical procedure and only requires few hours of hospital stay
- will not lose ability to have and enjoy sex
- will not affect menstruation
- must be certain do not want to have any more children
- does not protect against STI and HIV infections

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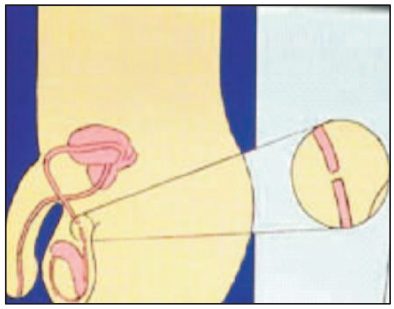
Vasectomy
Voluntary Male Surgical Contraception



Vasectomy

- is a permanent method: the man will not be able to have any more children after the surgery
- is a quick and simple surgical procedure and only requires few hours stay at the doctors office or hospital
- the man will not lose his ability or desire to have sex
- the man must be certain that he does not want to have any more children
- the man should use a condom for the first three months after the surgery
- does not protect against STI and HIV infections

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Natural methods
Periodic abstinence

Natural methods

- Periodic abstinence
- avoiding sex during the days when a woman may become pregnant (fertile time)
- must learn to identify fertile days. During this time the cervical secretions will be especially slippery and wet, and can be stretched. Avoid sex.
- requires partner collaboration
- can be stopped to switch to another method or to get pregnant
- fertile period can be affected by emotions and other medical conditions
- does not protect against STI and HIV infections

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LAM
Lactational Amenorrhea Method

Lactational Amenorrhea Method

- temporary method if have a baby less than 6 months old and are breastfeeding
- all of baby's feeding should be exclusively breastfeeding (no other food or liquid)
- works only if menstrual period has not returned since childbirth
- can be stopped to switch to another method or to get pregnant
- must be replaced by another method when infant reaches 6 months or sooner if baby begins taking other food or liquid or menstrual period returns
- does not protect against STI and HIV infections

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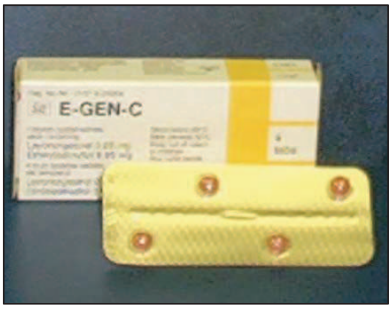
Emergency contraception

E-GEN-C,
Microval, Ovral, Nordett,
IUCD



Emergency contraception

- E-GEN-C, Ovral, Nordett, Microval should be taken as prescribed by the health care provider
- should be used within 72 hours of unprotected sexual intercourse
- IUCD should be inserted by a trained health care provider within five days of unprotected sex
- does not protect against STI and HIV infections

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STI/HIV Prevention and VCT Awareness Counseling

STI/HIV Transmission and Prevention information

STI/HIV Prevention and VCT Awareness Counseling

STI/HIV Transmission and Prevention information

- can be infected with a sexually transmitted infection (STI) through unsafe or unprotected sexual activity. STI are common. HIV is an STI.
- HIV can also be transmitted through blood and during pregnancy and breastfeeding
- some STI can be treated. Because the infection is sexually transmitted both partners must be treated to avoid re-infection
- an infected person may not show any symptoms. A person with an STI, including HIV, may look healthy
- common symptoms of STI are vaginal discharge/discharge from penis, sores in genital area, burning on urination for men, lower abdominal pain
- risk of infection can be reduced by using a condom, limiting the number of sex partners, periodic abstinence, alternatives to penetrative sex and delaying sex (adolescents)

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STI/HIV Prevention and VCT Awareness Counseling

VCT Awareness

STI/HIV Prevention and VCT Awareness Counseling

- a test is available to determine whether or not a person is infected with HIV. The test involves taking a sample of blood.
- when a person is infected it can take 3-6 months for the body to produce levels of antibodies that can be detected by the test (window period)
- knowing your status can help you make decisions about protecting yourself and your sexual partners, having children, etc.
- no one can force you to have the test. Taking an HIV test is voluntary
- results are confidential
- positive results mean you are infected and can transmit the virus to others
- negative results can mean you are not infected or that you are in the window period. Retest in three months. If still negative, it does not mean that you cannot get HIV at a later stage. Retest in future if you have had unprotected sex
- HIV is an STI. It is advisable to ask your sexual partners to be tested
- the test is free and available at clinics, hospitals, and other places

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STI/HIV/AIDS Risk
Assessment

STI/HIV/AIDS Risk Assessment

Find out how much client knows about STI/HIV and VCT. Correct misinformation, fill in gaps, answer questions.

Find out about the client's sexual and reproductive needs, risks and social context in order to assist the client to perceive and determine her risk for STI/HIV and plan to reduce risk:

- number of sexual partners currently and in the past
- knowledge of partner's sexual practices and other partners
- past and present condom use (include attitude and perception of partner's attitude)
- history of and current symptoms of STI/infections (for self and partner)
- sexual practices and behaviors
- HIV status (if known for self and partner)
- home life situation (partner violence, social supports, etc.)

Help client make a plan to reduce risk (including discussion of dual protection and condom use and whether or not to test)

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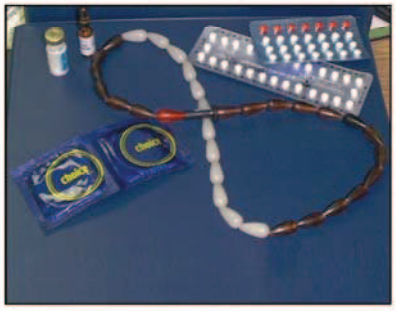
Dual Protection

Abstinence

Mutual monogamy w/uninfected partner plus correct and consistent contraceptive use

Correct, consistent condom use

Condom + injection/pill/loop



Dual Protection

- protects against both STI and HIV and prevents unwanted pregnancies
  - o abstinence from intercourse/all types of penetrative sex
  - o using contraception correctly and consistently in a mutually faithful relationship with an uninfected partner
  - o using correctly and at each intercourse the female or male condom
  - o using your chosen method and a male or female condom at the same time
- show how to correctly use condoms
- give information on where to get condoms

18 of 18

- Return at any time if you have questions or problems.
- You can switch methods if you experience severe allergies (itching or burning) or you can stop using it if you want to have children. Otherwise, you can keep using the condom for as long as you want, without interruptions.
- If you miss a period, you should return to see the nurse, since you might be pregnant.
- There are no other signs of danger for which you should return to the provider.

Emergency Contraception

If you suspect that you did not use the condom correctly or a condom broke or slipped off during sexual intercourse, please go to the clinic and get emergency contraception as soon as possible and not later than 5 days. Emergency contraception's effectiveness is reduced the longer the time between unprotected intercourse and taking the pills. Effectiveness is higher the sooner you take it, preferably within the first 3 days.

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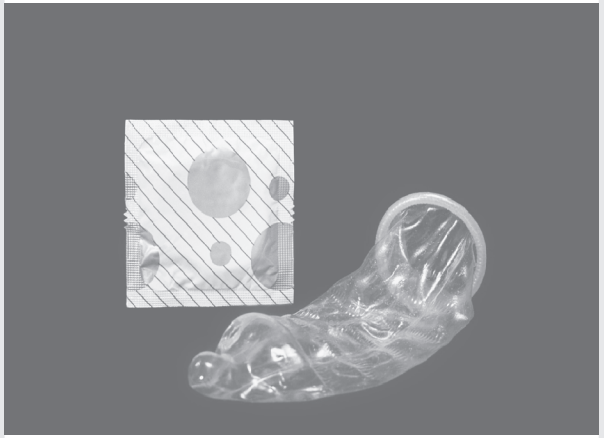
Appendix 6 IEC Leaflet for Clients

Condom



What is a condom and how does it work?

- A condom is a sheath, or covering, made to fit over a man's erect penis.
- Condoms are made of thin latex rubber, some are coated with a dry lubricant or with spermicide.
- The male condom catches the man's sperm and stops it from going into the woman's vagina.
- Used correctly, they keep sperm and any disease organisms in semen out of the vagina.
- Condoms also stop any disease organisms in the vagina from entering the penis.
- Condoms are effective for preventing pregnancy when used correctly every time.
- All public health facilities provide them free of charge.

How to use

- Put the condom on the erect penis before the penis touches the vagina or area outside and around it.
- Make sure the manufacturing date is within the last five years. Do not use a condom that is sticky, dried-out, or comes from a torn or open package.
- Open the package carefully, do not damage the condom with fingernails, teeth or scissors.
- Make sure the part of the condom that rolls down is on the outside.
- Squeeze the tip of the condom so that there is no air in it. Place the condom on the tip of the penis and unroll it all the way to the base of the penis, leaving space at the tip for the semen to be deposited in.
- Water or a water-based lubricant on the outside of the condom can help prevent breaks. Do not use creams, oil or petroleum jelly.
- After ejaculation, the man should hold the rim of the condom to the base of the penis and pull the penis out of the vagina before losing erection.
- Be careful not to spill semen when withdrawing the penis or taking off the condom.
- Tie a knot in the condom to stop fluid from leaking out and dispose of the used condom in a rubbish bin.
- Use a new one for every act of sexual intercourse.
- Store condoms in a cool, dry place if possible.

Can baby oil or other creams be used with a condom?

No. Don't use baby oil, hand creams, aqueous creams or petroleum jellies such as Vaseline for lubrication. These contain oils which can damage the latex and cause tears and breakages.

Can women and men enjoy sex when they use a condom?

- Yes. You can relax and enjoy sex without having to worry about pregnancy or disease. Although sex with a condom may feel different you can get used to it quite quickly. Many couples find that sex lasts longer with a condom and is less messy afterwards.

Side effects

- Rarely, men or women may be allergic to latex rubber. Condoms must not be used if one of the partners has a severe allergy to latex rubber.

Other benefits

- It is the only method that provides dual protection, from pregnancy and sexually transmitted diseases, including HIV/AIDS. Can be used along with other family planning methods to provide extra protection from pregnancy or STI and HIV/AIDS.
- Increases male participation and responsibility in family planning.
- Condoms work if used correctly every time.
- Has no important contraindications.

Following up

- The number of condoms provided by public health facilities varies. After an initial supply,return to the clinic at any time to get more condoms

wish to get pregnant.

- If you switch to another brand of injectable, make sure you get instructions on how to use it and information on contraindications, side effects and signs of alarm.

Return immediately to see the nurse if any of the following occur:

- Very bad headaches.
- Brief loss of vision, blurred vision, or if you see flashing lights or zigzag lines.
- Extremely heavy bleeding.
- Difficulty in breathing.
- Pain in your legs.
- More than 2 weeks late for your injection and have been sexually active.

Emergency Contraception

If you are more than two weeks late for your return date to the clinic and have had sex without a condom or the condom broke or slipped off during sexual intercourse, please go to the clinic and get emergency contraception as soon as possible and not later than 5 days. Emergency contraception's effectiveness is reduced the longer the time between unprotected intercourse and taking the pills. Effectiveness is higher the sooner you take it, preferably within the first 3 days.

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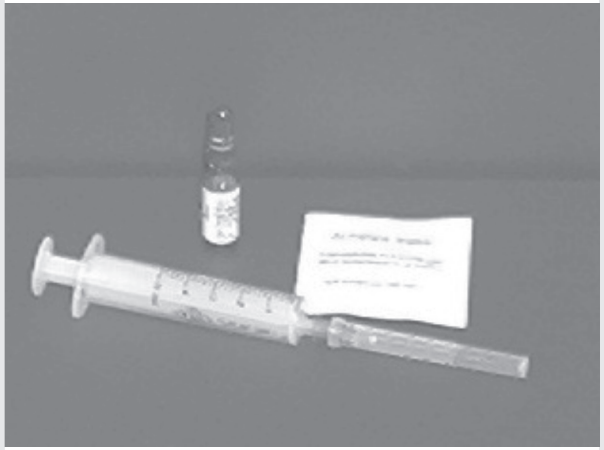
Appendix 7 IEC Leaflet for Clients

Injectable

Nur-Isterate



What is it and how does it work?

- A Hormonal long-term method providing protection for two months.
- Produces changes inside the uterus.
- Prevents ovulation (release of an egg) and thickens the cervical mucus.
- All public health centers provide Nur-Isterate free of charge.
- Does not protect against sexually transmitted diseases, including HIV/AIDS. A condom should be used together with the method.

Must not be used if you:

- Are pregnant.
- Have had a heart attack, had or have heart disease, stroke, blood clots.
- Have severe chest pain, severe high blood pressure, diabetes.
- Have cirrhosis, liver infection or tumor.
- Have unusual vaginal bleeding.
- Have or have had breast cancer.

How to use

- You receive injections every two months.
- You can start the injection during the first 7 days after menstrual bleeding starts, or any time if pregnancy can be ruled out.
- If you start any time other than in the first 7 days of the menstrual cycle, you should use condoms or avoid sex for the next 7 days.
- If you have recently given birth and are not breastfeeding you can receive the injection immediately. If you receive it 21 or more days after delivery you should use condoms or avoid sex for the next 7 days.
- If you are breastfeeding an infant 6 weeks or older, the injection can be given at any time. If your infant is 6 months or older or your menses have already returned, you should use condoms or avoid sex for the next 7 days if the injection is not given during your menses (or your menses have not yet returned).
- If you are breastfeeding, the injection is not recommended before 6 weeks but can be given if no better alternative is available.
- After an abortion, the injection can be given immediately or in the first 5 days. If it is given later, you must avoid sex or use condoms for 7 days.

Side effects

- Most common are changes in your menstrual bleeding and possibly weight gain.
- These changes include spotting between periods, irregular, heavy bleeding, or no bleeding at all. These changes are common, normal, and not harmful.
- After a long period using it, return of fertility may be delayed for 6 to 12 months.

Other benefits

- Can be used by women of any age, whether or not they have children.
- Can be used safely if you are breastfeeding
- It is private. No one else can tell you are using it.
- It provides long-term pregnancy prevention that is reversible.
- Helps prevent uterine cancer.
- Helps prevent infection of the reproductive organs
- May help reduce anemia.

Following up

- You must return every two months for medical check up and to receive the next injection.
- You can receive your injection up to two weeks early or two weeks late. If you do not get your injection at the right time and have sex without a condom, you could get pregnant even if menstruation has not returned.
- At your visit the health provider will check if you have developed some disease or medical condition that should prevent you from using the injection.
- You can return any time if you have questions or problems
- You can switch to another method if side effects are very uncomfortable or if you

use it and information on contraindications, side effects and signs of alarm.

Return immediately to see the nurse if any of the following occur:

- Very bad headaches.
- Brief loss of vision, blurred vision, or if you see flashing lights or zigzag lines.
- Extremely heavy bleeding.
- Difficulty in breathing.
- Pain in your legs.
- More than 2 weeks late for your injection and have been sexually active.

Emergency Contraception

If you missed your return date to the clinic and have had sex without a condom or the condom broke or slipped off during sexual intercourse, please go to the clinic and get emergency contraception as soon as possible and not later than 5 days. Emergency contraception's effectiveness is reduced the longer the time between unprotected intercourse and taking the pills. Effectiveness is higher the sooner you take it, preferably within the first 3 days.

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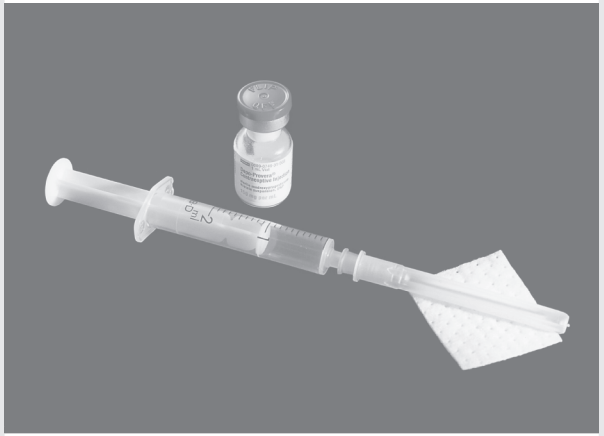
Appendix 8 IEC Leaflet for Clients

Injectable

Depo-Provera



- **What is it and how does it work?**
- A Hormonal long-term method providing protection for three months.
- Produces changes inside the uterus.
- Prevents ovulation (release of an egg) and thickens the cervical mucus.
- All public health centers provide Depo-Provera free of charge.
- Does not protect against sexually transmitted diseases, including HIV/AIDS. A condom should be used together with the method.

Must not be used if you:

- Are pregnant.
- Had a heart attack, had or have heart disease, stroke, or blood clots.
- Have severe chest pain, severe high blood pressure, or diabetes.
- Have cirrhosis, liver infection or tumor.
- Have unusual vaginal bleeding.
- Have or have had breast cancer.
- Can not support any changes to your menstrual cycle.

How to use

- You receive injections regularly every three months.
- You can start the first injection during the first 7 days after menstrual bleeding starts, or any time if pregnancy can be ruled out.
- If you start any time other than in the first 7 days of the menstrual cycle, you should use condoms or avoid sex for the next 7 days.
- If you have recently given birth and are not breastfeeding you can receive the injection immediately. If you receive it 21 or more days after delivery you should use condoms or avoid sex for the next 7 days.
- If you are breastfeeding an infant 6 weeks or older, the injection can be given at any time. If your infant is 6 months or older or your menses have already returned, you should use condoms or avoid sex for the next 7 days if you do not get the injection during your menses (or your menses have not yet returned).
- If you are breastfeeding, the injection is not recommended before 6 weeks but can be given if no better alternative is available.
- After an abortion, the injection can be given immediately or in the first 5 days. If it is given later, the user must avoid sex or use condoms for 7 days.

Side effects

- Most common are changes in menstrual bleeding and possibly weight gain.
- These include spotting between periods, irregular, heavy bleeding, or not bleeding at all. These changes are common, normal, and not harmful.
- May cause increased appetite.
- After a long period using it, return of fertility may be delayed for 6 to 12 months.

Other benefits

- Can be used by women of any age, whether or not they have children.
- Can be used safely if you are breastfeeding.
- It is private. No one else can tell that you are using it.
- It is long-term pregnancy prevention that is reversible.
- Helps prevent uterine cancer.
- Helps prevent infection of the reproductive organs
- May help reduce anemia.

Following up

- You must return every three months for medical check up and to receive the next injection. If you do not get your injection on the right day and have sex without a condom, you could get pregnant even if menstruation has not returned.
- At your visit, the health provider will check if you have developed some disease or medical condition that should prevent you from using the injection.
- You can return any time if you have questions or problems
- You can switch to another method if side effects are very uncomfortable or if you wish to get pregnant.
- If you switch to another brand of injectable, make sure you get instructions on how to

- If you want to have it removed, a trained health care provider should remove the IUCD.

Return immediately to see the nurse if you:

- Have pain after insertion (there is a small chance that the IUCD was not positioned properly)
- Experience any signs and symptoms of infections of the reproductive organs (bad cramps in lower abdomen or pain along with tenderness in the abdomen, fever or chills that you cannot explain, vaginal discharge that smells bad, etc.).
- Think you have an STI.
- Miss your menstrual period, have a late period or a very light period.
- Do not find the strings or can feel the hard part of the IUCD sticking out of your cervix (the IUCD may have spontaneously come out of the uterus).

Emergency Contraception

If you suspect that the device is no longer in place and you have had sex without a condom or the condom broke or slipped off, please go to the clinic and get emergency contraception as soon as possible and not later than 5 days. Emergency contraception's effectiveness is reduced the longer the time between unprotected intercourse and taking the pills. Effectiveness is higher the sooner you take it, preferably within the first 3 days.

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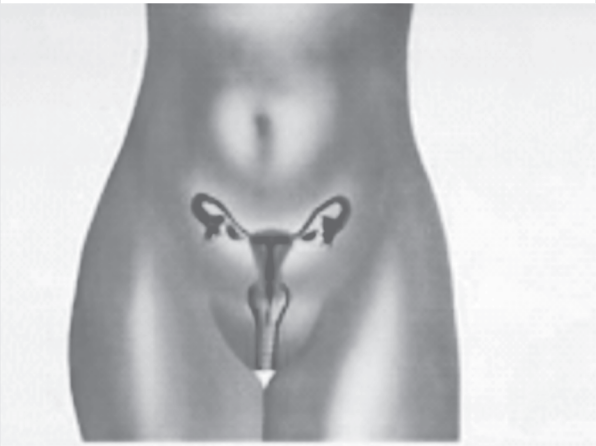
Appendix 9 IEC Leaflet for Clients

Intrauterine Device

IUCD / Loop / Copper T



What is it and how does it work?

- It is a small device made of plastic and copper that is inserted into your uterus through the vagina.
- It prevents sperm and egg from meeting.
- It can protect from pregnancy for 5-10 years.
- Selected public health institutions provide the IUCD for free.
- You may have it removed any time you want, either to switch to another method or to get pregnant.
- It does not protect against sexually transmitted diseases, including HIV/AIDS. A condom should be used together with the method.

How to use

- It can be inserted between the first and the fifth day of menstrual bleeding or at any other time during the menstrual cycle if reasonably certain you are not pregnant.
- It can be inserted immediately and up to the first two days after childbirth or four weeks or more after childbirth if reasonably certain you are not pregnant.
- It can be inserted during a caesarean section.
- It can be inserted immediately and up to 7 days after an abortion.
- It must be inserted by specially trained providers (physician or obstetric nurse) in the consulting room or clinic.
- It requires previous pelvic exam to rule out genital infections. If genital infection is suspected, treatment should be taken but the IUCD can still be inserted.
- Once inserted you should check the position of the IUCD strings from time to time.

Side effects

You may experience the following:

- slight bleeding after insertion
- menstrual changes during the first 3-6 months which usually decrease over time, such as
- Longer and heavier menstrual periods.
- Bleeding or spotting between periods
- More cramps or pain during periods.

Other benefits

- It is a good method if you want to prevent pregnancy for a number of years
- Can be used by women of any age, whether or not they have children.
- Prevents pregnancy immediately.
- Does not interfere with sex.
- Once it is removed, you may get pregnant immediately.
- IUCD can be used even if you have medical conditions such as breast cancer, high blood pressure, and heart disease.
- It can be safely used by women with HIV.
- Can be inserted within 5 days of unprotected intercourse as emergency contraception.

Must not be used if you:

- Are pregnant or think you might be pregnant.
- Have unusual vaginal bleeding that is not part of your period.
- Have had an infection in the female reproductive organs in the last 3 months.
- Have uterine disorders or benign tumors that deform the uterus (e.g. fibroids).
- Have any kind of cancer in the female organs.

Following up

- You must return within 3 to 6 weeks after IUCD insertion for medical follow up.

  Later, you must return for medical follow up every year.
- You can come back any time if you have questions or problems.
- You can use the IUCD for up to 10 years; no rest periods are required.
- IUCD does not cause discomfort to your partner; if he can feel the strings and bothers him, cutting the strings shorter should solve the problem.
- You can switch to another method if side effects are very severe or can stop using it if you want to get pregnant.

effectiveness is reduced the longer the time between unprotected intercourse and taking the pills. Effectiveness is higher the sooner you take it, preferably within the first 3 days.

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Appendix 10 IEC Leaflet for Clients

Lactational Amenorrhea Method

LAM

What is it and how does it work?

- LAM is the use of breastfeeding as a temporary family planning method.
- "Lactational" means related to breastfeeding and "Amenorrhea" means not having menstrual bleeding.
- It stops ovulation (release of eggs from ovaries) because breastfeeding changes the rate of release of natural hormones.
- Does not protect against sexually transmitted diseases, including HIV/AIDS. A condom should be used together with this method.

Should not be used if you:

- Cannot breastfeed your baby as a result of any given condition (examples: you have to go back to work, illness, baby unable to suck properly).

How to use

- You are naturally protected against pregnancy when ALL of the following conditions are present: (1) your baby is breastfeeding exclusively (2) you breastfeed your baby often, both day and night (3) your menstrual periods have not returned, and (4) your baby is less than 6 months old.
- You must not give your baby any water or other liquid other than breast milk and must breastfeed every time the baby demands it, day or night.

Side effects

- No side effects.

Other benefits

- Can be used by women of any age and with any number of children.
- Can be stopped at any time, either to switch to another method or to get pregnant.
- No requirement need be met other than the conditions for use mentioned before.
- No interference with sexual intercourse.
- Reduces bleeding after childbirth.
- Breastfeeding provides the healthiest food for the baby during the first months.
- Protects the baby from diseases that microorganisms from water or utensils might cause by passing the mother's protection to the baby.

Following up

You must return to the clinic:

- 40 days after childbirth for postpartum follow up.
- If you stop meeting one of the conditions for use of LAM as a contraceptive method. Use another method immediately to prevent pregnancy and continue to use a condom.
- Some time before six months postpartum, to choose another method.
- Any time, if you have questions or problems.

Emergency Contraception

If you no longer fit all of the conditions for this method and you have had sex without a condom, please go to the clinic and get emergency contraception as soon as possible and not later than 5 days. Emergency contraception's

- If you switch to another method, you should make sure you do not stop taking the pill until you start using the new method.
- You can keep using the method indefinitely, without interruptions.
- Serious complications of progestin-only pill use are rare. Still, you should see a health provider if you have questions or problems.
- You can stop using it any time to either switch to another method or to get pregnant.

You should return to see the nurse immediately if you have:

- Very bad headaches.
- Skin or eyes become unusually yellow.
- Brief loss of vision, blurred vision, or if you see flashing lights or zigzag lines.
- Absence of menstrual period for two months as you might be pregnant.
- Abdominal pain or tenderness, or faintness.
- Constant vomiting even when taking the pill along with food.

Emergency Contraception

If you ran out of pills or have been unable to take them at the same time every day and have had sex without a condom or the condom broke or slipped off during sexual intercourse, please go to the clinic and get emergency contraception as soon as possible and not later than 5 days.

Emergency contraception's effectiveness is reduced the longer the time between unprotected intercourse and taking the pills. Effectiveness is higher the sooner you take it, preferably within the first 3 days.

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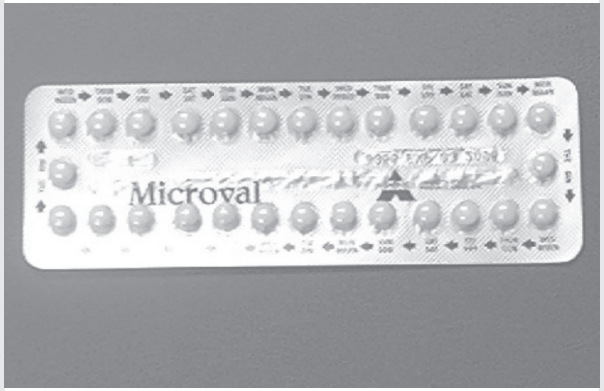
Appendix 11 IEC Leaflet for Clients

Minipills

Progestin-Only Oral Contraceptives



What is it and how does it work?

- A hormonal method taken daily as a pill.
- Prevents you from ovulating (releasing an egg) and thickens your cervical mucus.
- Most effective when taken at about the same time every day.
- Public health services provide these pills for free.
- Does not protect against sexually transmitted diseases, including HIV/AIDS, therefore you should use a condom every time you have sex.

Must not be used if you:

- Are pregnant.
- Have irregular vaginal bleeding that is not part of your period.
- Have or have had breast cancer.
- Have serious active liver disease.
- Are taking medicine for seizures or tuberculosis.

How to use

- One pill must be taken every day and at the same time.
- Start with the first pill of the packet and follow the arrows to take the rest of the pills. Progestin-only pills should be taken every day without any interruption.
- Taking a pill more than three hours late increases the risk of pregnancy. If you forget to take one or more pills by three hours, you should take a pill immediately and use condoms or avoid sex for 2 days. Continue taking pills every day at the same hour.
- Start taking them in the first five days of menstrual bleeding.
- If you do not start in the first 5 days of your menstrual period, you should avoid sex or use a condom for the next 2 days.
- If you have given birth but are not breastfeeding, you can start at any time. If it is more than 21 days after childbirth you should avoid sex or use a condom for the first two days.
- If you are breastfeeding, you can start 6 weeks after childbirth. It is not recommended to use them before 6 weeks if you are breastfeeding but if no better option is available, you can start immediately after childbirth.
- You can start in the first 5 days after an abortion.
- If taking the pill makes you vomit, take it with food.
- The pill may not be effective if you have severe vomiting or diarrhea for more than 24 hours or take your pill at a different time each day. If vomiting or diarrhea lasts more than two days avoid sex or use a condom until two days after the vomiting and diarrhea stop. If you vomit within 2 hours of taking a pill, take another pill.

Side effects

You may experience:

- Spotting between periods; irregular or heavy bleeding, or absence of menses.
- Weight changes.

Other benefits

- Can be used by women of any age, with or without children.
- Can be used if you are breastfeeding.
- Quick return of fertility. If you stop taking the pill, you can become pregnant immediately.
- May help prevent endometrial and ovarian cancer, benign breast disease, and infection of the reproductive organs.
- Has less contraindications and less side effects than combined oral contraceptives.

Following up

- You must return on your appointment date for follow up and to receive new packages of pills.
- Make sure you return to the clinic before you run out of pills. You should not stop taking them at the same hour each day, unless you want to get pregnant.
- You may come back any time if you have questions or problems.
- You should switch to another method if you constantly forget to take the pill at the same hour.

normal pattern of your secretions.

- Stress and emotions can also affect the length of your menstrual cycle.

Side effects

- No physical side effects, but requires full cooperation from your partner.

Other benefits

- Increases male participation in family planning.
- Allows early identification of some genital diseases.

Following up

- You should return to the clinic to verify if you are using the method correctly.
- Return for medical check up at least every year.
- You can come back at any time if you have questions or problems.
- If you miss a period, you should return to see the nurse, since you might be pregnant.

Emergency Contraception

If you are unsure that you correctly followed the recommendations for use and you have had unprotected sex or you had unprotected sex on day 8-21 or the condom broke or slipped, please go to the clinic and get emergency contraception as soon as possible and not later than 5 days. Emergency contraception's effectiveness is reduced the longer the time between unprotected intercourse and taking the pills. Effectiveness is higher the sooner you take it, preferably within the first 3 days.

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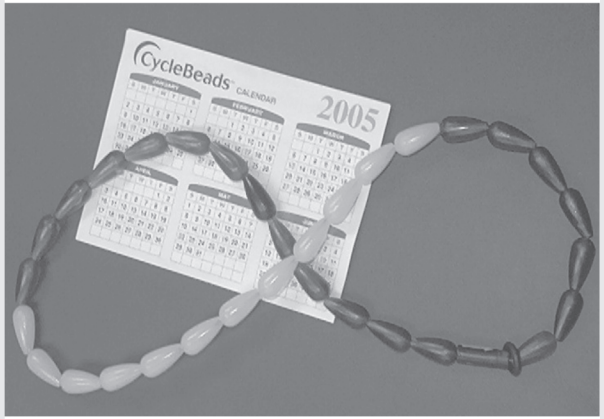
Appendix 12 IEC Leaflet for Clients

Natural Contraceptive Methods

Calendar and Cervical Secretions/Billings method



What is the Calendar method?

- You and your partner avoid sex or unprotected vaginal intercourse during your fertile time.
- Your fertile time is estimated according to the days of the menstrual cycle.
- Before relying on this method, you must record the number of days in each menstrual cycle for at least 6 months. The first day of menstrual bleeding is always counted as day 1.
- If your recorded cycles vary from 26 to 32 days, you can use this method. If more than 2 cycles per year are longer or shorter than this length, this is not a suitable method.

How to use

- You and your partner are told how to use the method and both must agree to use the method.
- You must record the first day of your menstruation on a calendar every month. This day is counted as day 1.
- You must either abstain from sex or use a condom (male or female) from day 8 through day 21 of your cycle (14 days of avoiding unprotected sex when you are most fertile).
- The method will be more effective if you avoid sex from day 8 to 21. You can have sex during your fertile days using a condom.

What is the Cervical Secretions/ Billings method?

- You and your partner avoid sex or unprotected vaginal intercourse during your fertile time.
- Your fertile time is estimated according to the consistency of your cervical mucus (pasty, sticky and crumbly, or slippery and stretchy).

How to use

- You check every day for any cervical secretions. You may feel wetness at the opening of your vagina or see secretions on your finger, underpants, or tissue paper.
- As soon as you notice any secretions, you avoid sex or use a condom (male or female).
- The secretions have a peak day, when they are most slippery, stretchy, and wet. You continue to avoid sex or use a condom until 4 days after the peak day.
- When your secretions become sticky, pasty, or crumbly, or when you have no secretions at all, you can have unprotected sex until menstrual bleeding begins again. Also, sex during menstruation will not lead to pregnancy.
- After menstrual bleeding stops, you may have several days without secretions. Sex is usually considered safe during this time.

All the natural methods discussed here:

- Can be used by women of any age, regardless of the number of children they have.
- Can be stopped at any time, either to switch to another method or to get pregnant.
- Do not protect against sexually transmitted diseases or against HIV/AIDS, therefore one should use a condom as well.
- Require partner participation.

Must not be used if you:

- Are unwilling or unable to abstain from sex or use a condom during fertile time.
- Have cycles outside of the 26-32 day range (for the calendar method).
- Do not know how or cannot identify changes of your cervical mucus or menstrual cycle (Billings method).
- Are a teenager whose menstrual cycles are not regular yet.
- Are an older women whose periods have become irregular or have stopped.
- Have irregular bleeding that is not part of their regular cycle.
- Are breastfeeding and have not had a menstruation since childbirth.

Other important information

- Douching, dry sex, spermicides, vaginal infections, and some drugs also affect the

first 6 months of use.

Other benefits

- Can be used by women of any age, whether or not they have had children.
- Quick return to fertility. After stopping, you can become pregnant almost immediately.
- Helps monthly periods become regular.
- Helps reduce menstrual cramps.
- May reduce benign breast cysts.
- Helps prevent ovarian and endometrial cancer.
- Helps prevent infection of the reproductive organs
- May decrease iron deficiency anemia.

Following up

- You have to return to the clinic when your nurse asks you to, for example in one month to see if you have problems and to obtain more pills.
- You can return at any time if you have questions or problems.
- You can switch methods or stop using the pill if side effects are severe or if you want to get pregnant. Otherwise, you can use them as long as you want; no rest period is needed.
- You must switch to another method if you often forget to take the pill.
- If you get your pills from a pharmacy, make sure you get instructions for the use of that pill.
- Make sure you have a new packet of pills before you finish your packets.

Return immediately to see the nurse if you experience:

- Very bad headaches that start or become worse after you begin to take combined oral contraceptives.
- Severe and constant pain in belly, chest or legs.
- Brief loss of vision, blurred vision, seeing lashing lights or zigzag lines; brief trouble speaking or moving arm or leg.
- Jaundice skin and eyes look yellow.

  Absence of menstrual period for two months. You might be pregnant.
- You must come back to the health facilities if side effects persist for more than 6 months.

Emergency Contraception

If you missed several pills or ran out of pills and had sex without a condom or the condom broke or slipped off during sexual intercourse, please go to the clinic and get emergency contraception as soon as possible and not later than 5 days. Emergency contraception's effectiveness is reduced the longer the time between unprotected intercourse and taking the pills. Effectiveness is higher the sooner you take it, preferably within the first 3 days.

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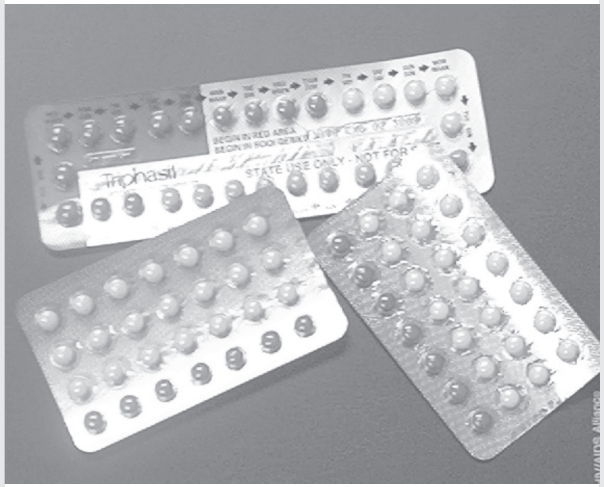
Appendix 13 IEC Leaflet for Clients

The Pill

Combined oral Contraceptives



What is it and how does it work?

- A hormonal method taken daily as a pill.
- They prevent ovulation (release of an egg) and thicken cervical mucus.
- Packets have 28 pills. The packet has 21 pills which contain hormones (yellow, white or brown pills), followed by 7 red pills that do not contain hormones.
- Does not protect against sexually transmitted infections (STI), including HIV/AIDS, therefore you should use a condom each time you have sex.

Must not be used by women who:

- Are pregnant.
- Have vaginal bleeding that is not the menses.
- Have high blood pressure.
- Have a known heart disease or have had a stroke.
- Are breastfeeding a baby less than 6 months old.
- Have or have had breast cancer or growths caused by tissue lining the uterus.
- Have severe liver disease or have had jaundice (skin and eyes look yellow) while taking the pill.
- Suffer bad headaches with blurred vision.
- Are taking medicine for seizures or tuberculosis.
- Smoke more than 15 cigarettes a day and are 35 years of age or older.
- Are within a two week period before or after having a major surgery, or if surgery will keep you from walking for a week or more.
- Gave birth in the past 21 days.
- Have a chronic disease such as diabetes.

How to use

- Must be taken every day.
- Taking the pill at the same hour each day is preferable and may help you remember, for example every night before going to bed.
- Begin taking the pills between the first and the fifth day of menstrual bleeding.
- If you start taking the pill any other day, you should avoid having sex or use condoms for seven days.
- If breastfeeding, wait until your infant is 6 months old before using the pill. Otherwise, you can start taking the pill 21 days or more after childbirth. If your menses have not returned you should avoid having sex or use condoms for seven days.
- You can begin pills between the first and the fifth day after an abortion or miscarriage. If more time has passed, avoid having sex or use condoms for seven days.
- Start with the first pill of the packet and follow the arrows to take the rest of the pills, one each day.
- When you finish a packet, start a new one the very next day.
- If you forgot to take one pill, take it immediately when you remember and take the next at the usual time. Do not stop taking them.
- If you forget to take the pill for 2 or more days (the white, yellow or brown pill), take a pill as soon as possible and continue taking pills daily. To avoid pregnancy, avoid sex or use a condom until you have taken the seventh white, yellow or brown pill in a row. If you had unprotected sex you may want to use emergency contraception. If you missed the pills in the third week, finish the white, yellow or brown pills in the pack and start a new pack the next day (do not take the red pills).
- If you missed a red pill, throw it away and take the rest as usual, one each day.
- If you vomit within the first half hour after taking the pill, take another one from a separate packet.
- If you experience diarrhea or vomiting for two or more days, avoid having sex or use a condom during the following seven days.
- Stop taking the pill if you will be in bed for more than a week due to illness, injury or surgery. When you resume taking the pill, avoid sex or use a condom for the first seven days if you are not starting during the first five days of your menses.

Side effects

Some women may experience:

- Nausea.
- Dizziness.
- Mild headaches.
- Moodiness.
- Breast tenderness.
- Spotting or bleeding between menstrual periods, irregular bleeding or amenorrhea.
- Slight weight gain.
- These side effects usually disappear after the

- Sterilization is a permanent method. It is important to discuss the option with your health provider and partner, if appropriate. You should only choose the method after thorough counseling on family planning and female voluntary surgical contraception (tubal ligation).
- You may be asked to sign a consent form before the procedure.
- You must understand fully the procedure you will be submitted to.
- You can decide against the procedure at any time before it takes place.

Following up

- After the procedure, you shall remain 4 hours in observation.
- If you live far away or in a rural area, you must remain 24 hours at the facility where the procedure took place.
- Follow-up within 7 days or at least within 2 weeks is strongly recommended, among other things, to remove stitches.
- You should rest for a few days and avoid heavy work for a week.
- Don't pick up children, lift heavy objects, do hard physical exercise, or play sport for the first week or until doctor advises.
- Don't have sex for three days after the procedure
- Take paracetamol in case of pain, but not aspirin or ibuprofen.
- You can return to see the doctor any time you want if you have questions or problems.

You should return immediately to the clinic or health facility if you experience:

- Pain lasting longer than a few days
- Strong pain, heat, swelling, or redness at or around the incision.
- Strong abdominal or lower abdominal pain.
- Bleeding from the wound.
- Fever that cannot be explained.

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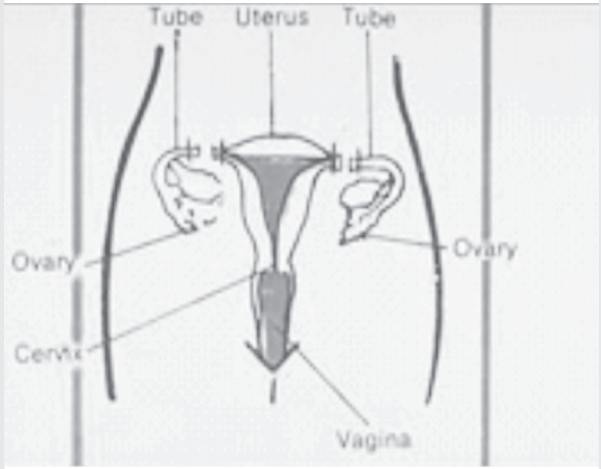
Appendix 14 IEC Leaflet for Clients

Tubal Ligation

Voluntary Female Surgical Contraception



What is it and how does it work?

- It is a safe and simple surgical procedure that provides permanent contraception if you will not want more children.
- Your fallopian tubes are blocked off or cut and tied.
- It can usually be done with local anesthesia and light sedation.
- With the tubes blocked, your egg cannot meet the man's sperm.
- The ovaries still release eggs but because the tubes are blocked the eggs are harmlessly absorbed by your body.
- You continue to have menstrual periods and normal sexual desire.
- Some public health institutions provide this service for free.
- Tubal ligation does not prevent sexually transmitted infections or HIV/AIDS, you should use a condom each time you have sex.

Must not be used if you:

- Are under 18 years of age.
- Are pregnant.
- Have not had all the children you want to have.
- Have an infection of the reproductive organs
- Currently have a sexually transmitted infection or cervical, endometrial, or ovarian cancer.
- Have serious postpartum or postabortion complications.
- Have unexplained vaginal bleeding that suggests a serious condition.
- Have acute heart disease, or blood clots in the deep veins or lungs.
- Severe anemia or diabetes for more than 20 years.
- Are not sure you will not want to have any more children.
- Have been forced to make the decision.

How to use

- It can be performed immediately and up to 7 days after childbirth, or 6 weeks or more after childbirth.
- It can be performed immediately postabortion or during a caesarian delivery.
- It can be performed at any time if you are not pregnant.
- Light sedation and local anesthetic is injected in your abdomen, you stay awake.
- The health provider makes a small incision in your abdomen and blocks off or cuts and ties the fallopian tubes.
- It only requires a few hours of hospital stay.
- It must be performed by a trained medical provider and requires a surgery room with the necessary equipment.

Risks/Side Effects

- General anesthesia may be needed in some cases, requiring referral to a center that can provide it.
- You may have some discomfort and pain that lasts for a few days.
- No known discomforts related to the method itself.

Consider that

In some cases, there may be regrets later, for example if you:

- Are young.
- Have no children.
- Have one child with poor health.
- Have an unstable partner relationship.
- Are single or widow.
- Are sterilized immediately after delivery or abortion and had no time to make up your mind about going through permanent sterilization.

Other benefits

- You can have sex without worrying about pregnancy.
- No long-term side effects.
- Protects immediately from pregnancy.
- Does not interfere with your ability to have sex.

Informed consent

- Sterilization is your choice. You do not need anyone else's consent to have the procedure.

in observation for at least one hour.

- If he lives far away or in a rural area, he must stay at the facility where the procedure took place for at least six hours.
- He must rest for 2 days and keep the incision clean and dry for 2 to 3 days
- He must avoid heavy work or vigorous exercise for a few days.
- He can take paracetamol or another safe, locally available pain relief medication as needed.
- The first follow-up visit must take place 7 days after the procedure or at least within the first two weeks.
- He can return to see the doctor any time you want if he has questions or problems.
- He can come back to have his semen examined to make sure it does not contain sperm.
- He can have sex within 2 or 3 days after the procedure if it is not uncomfortable, but he should use a condom or his partner should use another contraceptive method during the first three months after the procedure.

The vasectomy does not protect from pregnancy during the first three months.

He must return to the facility immediately if he has:

- High fever in the first 4 weeks, especially in the first week.
- Bleeding or pus from the wound.
- Pain, heat, swelling, or redness at an incision that becomes worse or does not stop.
- Discomforts during urination.

Emergency Contraception

If you and your partner have sex without a condom before three months have passed and you are not using another method of contraception or the condom broke or slipped, please go to the clinic and get emergency contraception as soon as possible and not later than 5 days. Emergency contraception's effectiveness is reduced the longer the time between unprotected intercourse and taking the pills. Effectiveness is higher the sooner you take it, preferably within the first 3 days.

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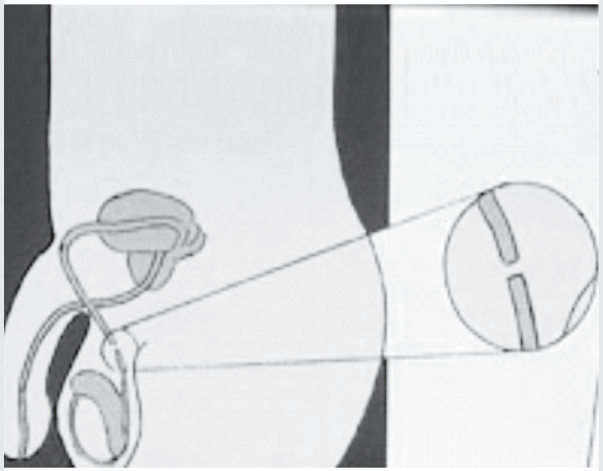
Appendix 15 IEC Leaflet for Clients

Vasectomy



What is it and how does it work?

- It is a safe and simple surgical procedure that provides permanent contraception if you and your partner will not want more children.
- The tubes that carry sperm to the man's semen will be blocked off.
- The man can still have erections and ejaculate semen, but his semen has no sperm in it.
- It does not harm the testicles, which produce male hormones, and does not affect a man's sexual desire.
- It does not prevent sexually transmitted diseases, including HIV/AIDS, therefore you should always use a condom each time you have sex.

Must not be used by men who:

- Have not had all the children they want.
- Have been forced to make the decision.
- Are not sure they will not want to have any more children.
- Are not sure their decision is "right."

Surgery may proceed with special precautions or be delayed until the following conditions are corrected:

- Infections, swelling, injuries or lumps in the penis or scrotum.
- Swollen veins or membranes in the spermatic cord or testes.
- Acute systemic infection.
- Active STI infection.
- Symptomatic heart disease.
- Hernia in the groin.
- Undescended testicles with proven fertility.
- Blood clotting disorders
- Diabetes.

How to use

- It is a safe, simple, and quick surgical procedure.
- The health care provider makes either 1 or 2 small openings in the man's scrotum (the sac of skin that holds the testicles) and closes off both the tubes that carry sperm to his semen.
- Only requires local anesthetic.
- It is performed by a trained medical provider with basic medications, supplies, instruments, and medical equipment and is done in a clinic or treatment room with proper infection prevention procedures.

Risks

- No known long-term side effects.
- Common minor short-term complications of surgery may be: discomfort for 2 or 3 days, pain, swelling or bruising in the scrotum, and brief feeling of faintness after the procedure.
- Reversal surgery is difficult and expensive.

Consider that

In some cases, there may be regrets later, for example when the man:

- Is young.
- Has no children.
- Has one child with poor health (especially the youngest).
- Has an unstable partner relationship.
- Is single or a widower.

Other benefits

- Increased sexual enjoyment because no need to worry about pregnancy.
- No long-term inconveniences.
- Does not interfere with the ability to have sex.

Informed consent

- Requires the man to be the one who chooses the method.
- Sterilization is a permanent method. It is important to discuss the option with the health provider. A man should only choose the method after thorough counseling on family planning and male voluntary surgical contraception (vasectomy).
- In some places the man has to sign a consent form before the procedure.
- He must understand fully the procedure he will be submitted to.
- The man can decide against the procedure at any time before it takes place.

Following up

- After the procedure, the man shall remain

Appendix 16 HREC Certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Mullick

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M070255**
PROJECT	Feasibility, Effectiveness and Cost of Models of Integrating Counseling and Testing for HIV within Family Planning Services in SA
INVESTIGATORS	Dr S Mullick
DEPARTMENT	Population Council
DATE CONSIDERED	07.03.02
DECISION OF THE COMMITTEE*	APPROVED UNCONDITIONALLY

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 07.03.20 **CHAIRPERSON** .....
(Professors PE Cleaton-Jones, A Dhai, M Vorster, C Feldman, A Woodiwiss)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor :

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10005, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES