# AN EVALUATION OF A PROVIDER-INITIATED HIV TESTING AND COUNSELLING (PITC) INTERVENTION FOR PATIENTS WITH SEXUALLY TRANSMITTED INFECTIONS IN CAPE TOWN, SOUTH AFRICA

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B. Soc.Sci. (UCT), Psych. Hons. (UCT), MA Clin. Psych (UCT), MPH (UCT)



**Thesis Presented for the Degree of**

**DOCTOR OF PHILOSOPHY**

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# ABSTRACT

**An evaluation of a provider-initiated HIV testing and counselling (PITC) intervention for patients with sexually transmitted infections in Cape Town, South Africa**

## Background

The majority of people infected with HIV do not know their status and there is growing recognition that HIV testing and counselling is a critical component in managing the HIV epidemic. This situation is of particular concern in high HIV prevalence settings such as South Africa. Provider-initiated HIV testing and counselling (PITC) with all patients attending health care facilities is a streamlined approach to HIV testing that is recommended for routine implementation and aims to increase test uptake and earlier linkage to HIV care, treatment, and prevention. Questions have been raised, however, over how effectively and feasibly PITC can be implemented in resource-constrained settings. There have also been serious concerns over the ability of health systems to accommodate those newly diagnosed and the ability of healthcare providers to deliver PITC in an ethical manner that does not become coercive.

## Aim and Objectives

This study is an evaluation of a PITC intervention to increase HIV testing rates of new STI patients in Cape Town, South Africa. The objectives of the study were to assess the impact of a PITC intervention on HIV test uptake rates and on access to HIV care, to evaluate the extent to which ethical principles were upheld in its implementation, and to examine the influence of implementation factors on the intervention.

## Methods

Four sub-studies were conducted as part of an impact and process evaluation using a mixed method approach. Study one was a pragmatic, cluster-controlled trial with seven intervention and 14 control clinics in Cape Town. The trial was registered as a controlled trial; trial registration number ISRCTN93692532. The primary outcome was the proportion of new STI patients who took an HIV test in the PITC sites as compared to the control sites which offered VCT only. Outcomes were analysed using the t-test and multinomial regression analysis for the

main outcomes. Study two was an observational study whose primary outcomes compared access to CD4 and viral load testing in a sub-sample of 930 HIV-positive patients from the controlled trial. For sub-studies one and two, univariate and multivariate logistic regression was performed to analyse the difference between arms. Study three was a qualitative investigation of patient perceptions and provider practices of informed consent, based on 20 patient interviews and 13 observations of clinical consultations. Data were analysed using thematic content analysis and the Interactive Decision-Making (IDM) framework. Study four was a qualitative investigation of the factors underlying the implementation of the intervention using focus groups with staff and management as well as participant observation. Data were analysed using thematic content analysis and interpreted using the constructs of the Normalisation Process Model (NPM).



**Findings**

The main finding on the impact of PITC on testing rates was that PITC had three successes: it significantly increased the offer of testing (77% in intervention sites vs. 51% in controls, p=0.0029), the uptake of testing (56% in intervention sites vs. 43% in controls, p=0.037), and the consistency of clinic performance with respect to testing uptake (range of HIV testing rates for intervention clinics: 39% - 71% vs. 8% - 81% for controls, p=0.033). The study found no differences between PITC and VCT sites in the proportions of HIV-positive STI patients who accessed follow-up care for HIV (CD4 test records found for 70% of patients at intervention sites vs. 65% at controls, p=0.507) or in the stage of HIV at diagnosis (median CD4 at diagnosis was 386 cells/$mm^3$ at intervention sites vs. 364 cells/$mm^3$ at controls, p=0.446). There was also no difference between arms in the proportions of ART-eligible patients with viral load tests (14.9% in intervention sites vs. 10.9% in controls, p=0.064). The study found that ART-eligible patients in the PITC arm had a significantly shorter time between their CD4 and viral load measurement. PITC in this setting may therefore have a potential advantage for patients to initiate ART quicker, though this finding would need to be confirmed by larger studies.

The study found that providers met the requirements for obtaining informed consent in terms of conveying information and the voluntariness of testing. However, there were challenges to the effective integration of informed consent into standard practice. Using the IDM, the study was able to identify a range of patient and contextual factors that shaped the patients' positive appraisal of informed decision-making, including familiarity and positive attitudes to HIV testing and the motivational role played by the provider and the clinical context. Successful normalising

of the intervention was facilitated by appropriate adaptation of the PITC design and task re-allocation. Also important were high levels of accountability that, in turn, were facilitated by strong leadership, participative planning, operational support, continuous monitoring, and organisational support through appropriate resourcing of the intervention.

## Conclusion

PITC appears to be an effective and a feasible intervention for increasing HIV test uptake in a busy primary health care setting in Cape Town. It did not negatively affect access to follow-up care for HIV-positive patients and it was implemented ethically. Uptake of testing with PITC may not be as large as required to effectively manage the epidemic in LMICs and a variety of strategies for expanding testing may be required. Efforts are needed to improve linkage to HIV care alongside expanded testing approaches. Successful and ethical up-scaling of PITC in LMIC settings may be dependent on how well the intervention can be integrated into standard care and on broader health systems support mechanisms. It will also depend on how well the balance is struck between exceptionalising and normalising imperatives in HIV testing strategies. The research makes practical recommendations for how this balance might be achieved.

# TABLE OF CONTENTS

# LIST OF TABLES AND FIGURES

# LIST OF ACRONYMS

| | |
|---|---|
| AIDS | Acquired Immune Deficiency Syndrome |
| ART | Antiretroviral Treatment |
| CDC | Centers for Disease Control and Prevention |
| CT | Counselling and Testing Register |
| HCT | HIV Counselling and Testing |
| HIV | Human Immunodeficiency Virus |
| HREC | Human Research Ethics Committee |
| ICC | Intra-class Correlation Coefficient |
| IDM | Interactive Decision-Making framework |
| IQR | Inter-quartile Range |
| LC | Lay Counsellor |
| LMIC | Low and Middle Income Country |
| NHLS | National Health Laboratory Service |
| NPM | Normalisation Process Model |
| OI | Opportunistic Infection |
| PICT | Provider-initiated HIV Counselling and Testing |
| PITC | Provider-initiated HIV Testing and Counselling |
| PMTCT | Prevention of Mother-To-Child Transmission |
| PSC | Project Steering Committee |
| RCT | Randomised controlled trial |
| RMR | Routine Monthly Report |
| ROT | Routine Offer of HIV Testing |
| STI | Sexually Transmitted Infection |
| TB | Tuberculosis |
| UCT | University of Cape Town |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| UNICEF | United Nations Childrens Fund |
| USPSTF | US Preventive Task Force |
| VCT | Voluntary Counselling and Testing |
| WHO | World Health Organisation |

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# CHAPTER 1: INTRODUCTION

## Background

State of HIV testing globally

There is widespread recognition that HIV testing and counselling is a critical component in managing the HIV epidemic. There are individual and public health benefits associated with knowledge of HIV status such as being able to have early access to HIV treatment, care and prevention services (Nieburg et al. 2005; WHO/UNAIDS 2007). Screening tests for HIV, including rapid HIV tests, are extremely accurate at predicting the true infection status of the person tested, with positive and negative predictive values of over 99% (Chou et al. 2005a) although these tests may be less accurate in the field (Wolpaw et al. 2010). Nevertheless, the majority of people globally do not know their HIV status and there are many missed opportunities for diagnosing HIV testing in health facilities (UNAIDS/WHO/UNICEF 2010). This situation is particularly heightened in high HIV prevalence countries in Africa where, despite substantial increases in testing rates in recent years, it is estimated that in 2009, a median of only 39% of HIV positive people were aware of their HIV status (UNAIDS/WHO/UNICEF 2010).

HIV testing rates have remained below what is required to effectively manage the HIV epidemic which has prompted international institutions such as the World Health Organisation (WHO) and Centers for Disease Control and Prevention (CDC) to call for ways to expand the uptake of HIV testing. Data from 22 low- and middle-income countries (LMICs) (16 from sub-Saharan Africa) indicate that a median of only 10% of respondents reported ever having had an HIV test, and of these only 4% of women and 5% of men had received the HIV test in the 12 months prior to the survey (UNAIDS/WHO/UNICEF 2010). In seven sub-Saharan countries (excluding South Africa), the average percentage of respondents who been tested in the past 12 months was 19% for women and 10% for men, while only 30% of women and 17% of men had ever been tested (UNAIDS/WHO/UNICEF 2010). Nevertheless, access to HIV testing services in low- and middle-income countries have increased substantially in recent years. Demographic surveys of 17 countries in Africa and Asia show that the number of facilities providing HIV testing and counselling services had more than doubled between 2006 and 2008 with associated increases in HIV test uptake (WHO 2008). Whilst there may be progress with access to testing services, evidence indicates that late diagnosis of HIV (at the point of showing HIV-related symptoms) is

common. Delay in identification of HIV and in presentation for treatment increases the risks of morbidity and mortality, but also the risk of ongoing transmission of HIV (Braitstein et al. 2006; CDC 2003; Lawn et al. 2008).

Numerous studies also indicate that there are missed opportunities for identifying HIV among patients visiting health facilities (CDC 2009; Day et al. 2004; Nieburg et al. 2005; Van der Bij et al. 2008; Weinstock et al. 2002). There are indications that the missed opportunities for diagnosis and treatment of HIV are greater in sub-Saharan Africa, where high HIV prevalence, poverty, and health systems resource constraints pose unique challenges to dealing effectively with the epidemic (Braitstein et al. 2006; Lawn et al. 2008; Pilcher et al. 2004; Uphold & Mkanta 2005). Globally, therefore, there is agreement on the need to increase access to HIV testing and HIV test uptake in order to increase access to care and prevention (Bartlett et al. 2008; CDC 2006; Jürgens 2006; Nieburg et al. 2005; UNAIDS 2001; WHO 2002; 2007; WHO/UNAIDS/UNICEF 2007; World Health Organisation 2003; World Health Organisation/UNAIDS 2004).

Despite this agreement, however, there is an ongoing dispute about how HIV testing can be effectively and ethically expanded (Bayer & Edington 2009; Bayer & Fairchild 2006; Bayer & Jones 1991; Rennie & Behets 2006). Since the advent of HIV/AIDS in the mid 1980s, there have been disagreements in particular about the ethics of HIV testing. When HIV testing first became available in 1985, many argued for a public health response to the HIV epidemic that would include routine screening for HIV for early identification and prevention of HIV transmission (Frieden et al. 2005; Koo et al. 2006). Others, however, argued that HIV was an exceptional epidemic and required exceptional ways of dealing with the disease (Bayer & Jones 1991; Canadian HIV/AIDS Legal Network 2005; Crewe & Viljoen 2005).

The proponents for viewing HIV as exceptional argued that the following characteristics set HIV apart from other epidemics: (1) that it is not contagious, (2) the absence of a cure, (3) the mainly sexual route of transmission, (4) the stigma and discrimination associated with the illness, and (5) marginalised communities were mostly affected (Bayer & Jones 1991). These characteristics were the foundation for a human rights-based approach to managing the epidemic and HIV testing, an approach that later came to be known as HIV exceptionalism. The predominant voluntary counselling and testing (VCT) approach that was subsequently adopted by WHO and other international bodies required that HIV testing be treated differently from routine health screenings for other diseases and included stringent requirements for privacy, confidentiality,

counselling, and consent with an emphasis on testing being client-initiated (Bayer & Fairchild 2006; Bayer & Jones 1991; Canadian HIV/AIDS Legal Network 2005; Casarett & Lantos 1998; Jürgens 2006; Rennie & Behets 2006; WHO 2003)

With the development of antiretroviral treatment (ART) for HIV in the mid 1990s, the relevance of HIV exceptionalism was questioned and there was a shift towards 'HIV normalisation' (Bayer & Edington 2009; Bayer & Fairchild 2006; Casarett & Lantos 1998; De Cock & Johnson 1998; Koo et al. 2006; Rennie & Behets 2006). World leaders made commitments to increase access to antiretroviral treatment, especially in LMICs. The WHO and The Joint United Nations Programme on HIV/AIDS (UNAIDS) developed their '3 by 5' strategy to provide 3 million people with access to antiretroviral treatment by 2005 (Global Business Coalition on HIV/AIDS 2004; WHO/UNAIDS 2003).

Within this new attention to treatment, HIV testing was regarded as the 'critical gateway' to accessing HIV care, treatment and prevention and there was a renewed impetus to find ways to expand HIV testing (CDC 2006; Jürgens 2006; Nieburg et al. 2005; WHO 2002; 2003; 2004; WHO/UNAIDS 2007). The exclusive use of the VCT approach was considered by many to be a barrier to increasing testing access, mainly because of the counselling and written informed consent requirements are considered too labour intensive to implement widely. VCT also depends on individuals identifying themselves as at risk and risk perception is often found to be inaccurate (De Cock et al. 2003; De Cock et al. 2006; Frieden et al. 2005; Jürgens 2006; Koo et al. 2006; Nieburg et al. 2005; Obermeyer & Osborn 2007; Rennie & Behets 2006).

Experts within the WHO who had initially supported the need for HIV exceptionalism in the 1980s now suggested that the exceptional requirements for VCT (such as pre-test counselling) may ironically have perpetuated stigma and created barriers to access. They argued that HIV exceptionalism sent the message that HIV was indeed exceptional and should be conceived of and treated outside of standard medical care. Not normalising HIV testing as part of standard practice could also have created the impression that only targeted groups were considered high risk (Bayer & Edington 2009; De Cock et al. 2003; De Cock et al. 2002; Jürgens 2006; Obermeyer & Osborn 2007). There is a tension in the VCT approach to HIV testing, between the need for protecting individual rights to privacy and autonomy through client–centred counselling and the need for public health goals such as high levels of awareness of HIV status and thus the need for high HIV testing uptake (Buskens & Jaffe 2008; Silverman 1997; Strode et al. 2005; van Rooyen et

al. 2011). This tension has become heightened in debates about the ethics of expanded testing approaches, as will be shown later in this chapter. This tension is also discussed in detail in the Chapters 4 and 5 where it provides the rationale for the focus on evaluating informed consent in the PITC intervention.

Against the background of increasingly available antiretroviral treatment, a growing epidemic, low HIV testing rates, and missed opportunities for HIV diagnosis, WHO/UNAIDS recommended in 2003 that HIV testing be expanded beyond VCT (World Health Organisation 2003). The suggested strategies for expanding HIV testing included routine provider-initiated or 'opt-out' HIV testing and counselling in health facilities as well as broad-based testing approaches (such as community-wide testing and home-based testing).

Routine provider-initiated HIV testing and counselling (PITC) was recommended as a strategy to be implemented in health facilities to sharply increase the number of people who know their status and improve detection, prevention, and treatment.

> *"Provider-initiated HIV testing and counselling should be implemented with the objective of maximising the health and well-being of individuals through the timely detection of HIV, prevention of HIV transmission and subsequent access to appropriate HIV prevention, treatment, care and support services" (WHO/UNAIDS 2007:30).*

PITC is a more streamlined approach to HIV testing in that counselling and written consent are not prerequisites and the offer of testing is made to all patients in health facilities, irrespective of their presenting complaint (WHO/UNAIDS 2007). The approach was supported by the CDC which issued similar guidelines in November 2006 that recommended a streamlining of the HIV testing process. These guidelines included a reduction in counselling and consent requirements for HIV testing to bring them in line with those required for other health screening tests (CDC 2006). Routine HIV screening has also been found to be cost effective in settings with an HIV prevalence above 1% which has added to support for the approach from WHO and CDC (Paltiel et al. 2006; Walensky et al. 2005). There have also been claims that expanded testing approaches such as PITC could lead to positive change in the risk behaviour of HIV positive individuals and that it could contribute to a reduction of stigma, but such claims are still to be substantiated (Strode et al. 2005).

The new PITC guidelines, however, elicited a range of concerns about the implementation of PITC. In particular, there were concerns regarding its feasibility, acceptability, and ethics. The main concern was whether routine HIV screening in health settings could result in coercive and mandatory testing practices. Some felt that routine testing may increase stigma and discrimination and make high risk groups more vulnerable. There was also a concern about expanding HIV testing in the absence of universal access to ART. Critics felt that these concerns might be even greater in LMICs where patient rights are often less well protected and where access to care may be more limited (Becker et al. 2009; Crewe & Viljoen 2005; Jürgens 2006; Nieburg et al. 2005; Obermeyer & Osborn 2007; Rennie & Behets 2006; Strode et al. 2005).

The most recent WHO PITC guideline (May 2007) appears to have addressed some of the concerns raised by the draft document. It expanded the range of pre-test HIV information that should be shared with the client as part of the HIV test offer and it emphasised the importance of a rights-based approach that includes non-coercive consent and the need for a protective legal and policy environment.

Nevertheless, a range of critics (including human rights advocates, ethicists, and public health officials) continued to express concern about routine opt-out HIV testing and the PITC guidelines for what they perceived as an unwarranted departure from the rights-based approach to HIV testing (Bayer & Edington 2009; Bayer & Fairchild 2006; Bayer & Jones 1991; Becker et al. 2009; Buchanan 2005; Canadian HIV/AIDS Legal Network 2005; Crewe & Viljoen 2005; Csete et al. 2004; Gruskin et al. 2008; Rajkumar 2006; Rennie & Behets 2006; Richter 2006; Strode et al. 2005; UNAIDS Reference Group on HIV and Human Rights 2007).

The debate about routine opt-out HIV testing came to be framed as a human rights vs. public health rights issue. On one hand, critics of PITC argued for retaining heightened ethical requirements such as counselling and written consent in order to maintain a strong human rights approach and protection of individual autonomy and privacy. On the other hand, supporters of the public health rights approach argued for the individual and public health benefits of streamlined testing procedures that could increase detection, treatment, and prevention of HIV (Bayer & Edington 2009; Bayer & Fairchild 2006; De Cock & Johnson 1998; De Cock et al. 2003; De Cock et al. 2006; Frieden et al. 2005; Koo et al. 2006; Obermeyer & Osborn 2007; Rajkumar 2006; Rennie & Behets 2006).

These concerns about routine HIV testing form the background to this thesis' examination of the implementation of a demonstration PITC intervention. In April 2006, the City of Cape Town health authority (in conjunction with their provincial health department counterparts) implemented a PITC intervention with the aim of increasing HIV testing among patients with sexually transmitted infections at primary health care clinics. The intervention also aimed to determine the feasibility and acceptability of PITC in a real-life operational setting, where there was a high prevalence of HIV but resource constraints to expanding HIV testing services. This was done against the background of a national HIV testing policy that still advocated the exclusive use of VCT, a testing approach that required a separate infrastructure for HIV testing geared towards ensuring the protection of individual rights.

In the next three sub-sections, a brief summary is supplied of the WHO guidelines on PITC that informed the Cape Town PITC intervention, followed by a description of the South African setting in which the intervention was implemented, and a brief description of the PITC trial in Cape Town. A fuller description of the particular PITC intervention implemented in Cape Town can be found in Chapter 2.



The WHO/UNAIDS guidelines on Provider-Initiated HIV Testing and Counselling (PITC)

WHO and UNAIDS suggest that health care providers should recommend HIV testing to all adults and adolescents attending all health facilities (WHO/UNAIDS 2007). The guidelines indicate that this would be particularly important in settings where the epidemic is firmly established in the general population and where HIV prevalence is consistently above 1% for pregnant women. For settings with health system capacity constraints, the guidelines suggest phasing in this service according to a recommended priority list, starting with outpatients, TB patients, and patients seeking reproductive health services. The document also proposes streamlining HIV testing to make it easier to integrate into standard clinical care. Furthermore, the guidelines drop the requirement for pre-test counselling while still retaining elements such as pre-test information and informed consent. Pre-test information could be presented in groups or individually and verbal consent is considered sufficient (and would, the document notes, be encouraged as the norm). Box 1 below shows the range of HIV information that the guidelines recommend be covered when the HIV test offer is made (WHO/UNAIDS 2007:36).

**Box 1: WHO/UNAIDS recommendations regarding pre-test information for provider-initiated HIV testing and counselling in health facilities.**

**6. 1 Pre-test information and Informed consent**

- The reasons why HIV testing and counselling are being recommended.
- The clinical and prevention benefits of HIV testing and the potential risks, such as discrimination, abandonment or violence.
- The services that are available in the case of either an HIV-negative or an HIV-positive test result including whether antiretroviral treatment is available.
- The fact that the test result will be treated confidentially and will not be shared with anyone other than health care providers directly involved in providing services to the patient.
- The fact that the patient has the right to decline the test and that testing will be performed unless the patient exercises that right.
- The fact that declining an HIV test will not affect the patient's access to services that do not depend upon knowledge of HIV status.
- In the event of an HIV-positive test result, encouragement of disclosure to other persons who may be at risk of exposure to HIV.
- An opportunity to ask the health care provider questions.

Post-test counselling is retained as an integral part of the HIV testing process but this component is also streamlined in the guidelines. Changes are geared towards increasing the focus on linking HIV-positive patients to follow-up medical care. A set of minimum information is recommended for HIV-negative and HIV-positive patients along with an assessment of whether further counselling is required. This set includes explanation of the test result, basic advice on methods to prevent HIV transmission, and the provision of male and female condoms. For HIV-positive patients, the post-test counselling should include support to help them cope with their emotional reaction, information on and links to follow-up care, prevention messages, discussion of possible disclosure of the result, and an assessment of their support needs and resources (WHO/UNAIDS 2007).

The WHO guidelines acknowledge that the implementation of PITC will need to be adapted to different epidemiological and social contexts and that it will be influenced by available resources. The guidelines call for an enabling environment to be in place that includes a supportive social, policy, and legal framework to "maximize positive outcomes and minimize potential harm to patients" (WHO/UNAIDS 2007:32). Although the availability of ART is not regarded as a prerequisite within the guidelines, there should be an HIV-related package of care for prevention, care, and support. Other requirements include community mobilisation, adequate resources and infrastructure, health care training and codes of conduct as well as

methods for redress where there are ethical transgressions. The document recommends close monitoring of practice to ensure efficient and ethical implementation and reiterates the importance of informed and voluntary decision-making:

> *"Careful monitoring and evaluation will allow best use of available resources and help avoid negative outcomes, including stigma, discrimination, violence, breaches of confidentiality, coercion or unmet demand for treatment and other HIV services" (WHO/UNAIDS 2007:17).*

The measures to ensure ethical implementation are specified:

> *"This requires giving individuals sufficient information to make an informed and voluntary decision to be tested, maintaining patient confidentiality, performing post-test counselling and making referrals to appropriate services" (WHO/UNAIDS 2007:17).*

Opponents of the PITC approach, however, are not satisfied that the guidelines allay sufficiently their fundamental concerns around protection of individual patient rights, especially in their specific concerns regarding the use of PITC in LMICs (Bayer & Edington 2009; Becker et al. 2009; Canadian HIV/AIDS Legal Network 2005; Rennie & Behets 2006; UNAIDS Reference Group on HIV and Human Rights 2007). These ethical concerns are detailed in the literature review in Chapter 4 and findings on the ethical implementation of PITC in this study are reviewed in Chapter 5.



HIV/AIDS and HIV testing in the South African setting

Sub-Saharan Africa is considered the epicentre of the HIV epidemic and is estimated to account for more than two thirds of the approximately 33 million people living with HIV globally. Out of the 2.7 million HIV infections worldwide in 2007, it is estimated that 1.9 million occurred in this region (UNAIDS/WHO/UNICEF 2008). South Africa has the largest epidemic in the world with an estimated 5.2 million people living with HIV. Whilst there are early indications that the growth of the epidemic is slowing, the 2008 population-based survey indicated that HIV prevalence remains high at an estimated 10.9% for the total population (aged over 2 years), 16.9% for the reproductive age group 15-49 years, and 29.3% for pregnant women. The majority of these infections (85%) occur through heterosexual sex in the general population (Shisana et al. 2009).

HIV prevalence varies substantially across gender and age groups as well as between different provinces in the country. Females, for example, bear a disproportionate burden of the epidemic. This is most notable in late adolescent females aged 15-19 years, who, in 2008, were 2.7 times more likely to be infected than their male peers (Shisana et al. 2009). The average national HIV prevalence figure of 16.9% (for ages 15-49 yrs) also obscures the substantial differences in HIV prevalence across and within provinces. For example, the provinces with the highest HIV prevalence, Kwazulu-Natal and Mpumalanga, have rates of 25.8% and 23.1%, respectively, while the provinces with the lowest prevalence, Northern Cape and Western Cape, have rates of 9% and 5.3%, respectively (Shisana et al. 2009).

The South African population has among the highest levels of HIV awareness and knowledge of HIV status in the world (UNAIDS/WHO/UNICEF 2008). In 2008, the percentage of respondents aged 15-49 years who had received an HIV test result in the last 12 months was 28.7% for women and 19.9% for men, compared to 13.3% and 10.2% respectively in 2005. Those who reported ever having had an HIV test also increased from 20% of respondents in 2005 to 50% in 2008, with women being more likely to have been tested (56.7% vs. 43% for males) (UNAIDS/WHO/UNICEF 2010). Nevertheless, given the extent of the epidemic, there is still a need for increased HIV testing, especially since the majority of people who are HIV infected are not aware of their status and may be unknowingly spreading the disease (UNAIDS/WHO/UNICEF 2010). A survey of South African youth aged 15-24 years done in 2003 found that 67% of HIV-positive respondents had not been tested and did not know their HIV status. In this study, nearly two thirds (62%) of HIV-positive participants had perceived themselves to be at no or low risk of contracting HIV at the time of the survey (Pettifor et al. 2004).

The HIV epidemic is also amplified by STI prevalence. Both these conditions are contracted and spread through a common route of unprotected sexual intercourse and the presence of an STI increases the likelihood of HIV transmission (CDC 1998; Chersich & Rees 2008; Sangani et al. 2004). The association between HIV and STIs makes improving HIV detection and treatment amongst STI patients an important area of focus in the fight against HIV. A Cochrane systematic review found that although the evidence was limited, improved STI treatment services can reduce HIV prevalence in conditions where there is an emerging HIV epidemic, where STIs are highly prevalent, and where STI treatment services are poor. The review also indicated that strengthening STI treatment could have other benefits for HIV prevention such as increased condom use (Sangani et al. 2004).

The annual incidence of new episodes of STIs in South Africa, 4.6% in 2008/09, remains high compared to high-income countries although there appears to have been a steady decline since 2000/01 when the figure was 6.8% (Day et al. 2010; Matjila et al. 2008). The prevalence of syphilis among antenatal clinic attendees in the public sector was 2.9% in 2007 and also showed a steady decline from 11.2% in 1997 (National Department of Health 2008).

At the time that the research for this thesis was started, national guidelines for HIV testing in public and private sector health and community-based services were published in the 2003 'South African National Voluntary Counselling and Testing (VCT): HIV Prevention and Care Strategy' (National Department of Health 2003). A revised HIV testing policy became available in 2010 at the end of writing this thesis. The most recent 'National Strategic Plan for HIV, AIDS and STI for 2007-2011 (NSP)' acknowledged that awareness of HIV status is central to the two main goals of the NSP, that of halving the incidence of HIV infections and ensuring access to ART for 80% of HIV positive people by 2011 (National Department of Health 2007).

From the time HIV testing became available in South Africa in the 1980s up to the time of the introduction of the 2010 National HIV Counselling and Testing (HCT) policy, VCT was the only recommended approach. VCT services are not integrated into clinical consultations but are offered in parallel with clinical services. The counselling components of VCT services are largely provided by 8,000 trained lay health workers known as HIV lay counsellors (LCs) who are paid a stipend by the government but who are managed by non-governmental organisations. Although nurses throughout the country may also be performing this service, HIV counselling is considered to be main responsibility of HIV lay counsellors. Until recently, this cadre of lay health workers was not allowed to perform the rapid HIV test itself so nurses were required to do the rapid test in between their other duties. A policy change is anticipated that will allow lay health workers to perform the rapid test under supervision of a professional health worker (National Department of Health 2010a).

The tension between the dual goals of VCT that was referred to earlier, to provide protection for individual patient rights and to achieve high test uptake, is also evident in the policy shifts around HIV testing in South Africa. There has been a recent policy shift towards expanding HIV testing through provider-initiated testing approaches (National Department of Health 2010a), following on from the WHO policy on PITC. However, there appears to be a tension in how the

WHO policy should be applied in South Africa. In practice, the new PICT recommendation in the South African policy continues to emphasise the need for pre-test counselling which makes it difficult to distinguish from the VCT approach. This emphasis on counselling is also reflected in the naming of the new recommendation which is called provider–initiated *counselling* and testing (PICT) and not provider–initiated *testing* and counselling (PITC) as in the WHO policy.

Provision of HIV testing services has increased rapidly each year and as of 2010, HIV pre- and post-test counselling were provided at 4,500 health facilities and non-medical sites throughout the country. The 2010 National HIV Counselling and Testing policy promotes a provider-initiated HIV testing approach as part of efforts to expand access to HIV testing, with the aim to increase the proportion of people ever having had a HIV test to 70% (National Department of Health 2010a).



Setting for the Cape Town PITC trial

The PITC intervention reviewed in this thesis was implemented with STI patients in Cape Town, the capital of the Western Cape Province and a city with a total population of 3.5 million. Like most of South Africa, Cape Town is characterised by dramatic socio-economic inequalities between different communities, with the majority of poor communities (previously classified as Black and Coloured during the apartheid era) living in impoverished township areas. Wealth inequalities are linked strongly to health status outcomes. HIV prevalence in the wealthier communities are the lowest in the city and in the country and HIV prevalence for most poor black communities is on par with the highest in the country. For instance, in Cape Town, at the time of this study in 2005/06, the average HIV prevalence for pregnant women in the city was 12.7% (Barron et al. 2006) while some of the poorest sub-districts had rates of over 30%, among the highest in the country (Department of Health Western Cape 2006).

South Africa has a public sector health system that delivers services to the majority of the population, with the wealthier minority and those with health insurance using private health care. In Cape Town, as in the rest of South Africa, both STI and HIV testing services are delivered free of charge at primary health care clinics in the public sector. The PITC intervention was implemented in the public sector, primary health care services in Cape Town. Both the provincial and municipal (local) health authorities deliver primary care services with a degree of overlap in their responsibilities. Adult curative health services are provided largely by provincial health authorities in larger community health centres where medical doctors provide the main clinical

service. STI services are provided largely by the municipal authority health clinics where nurses provide the bulk of the clinical services. The implementation of the PITC intervention was done collaboratively between the two health authorities.

The PITC intervention was adapted to address local service needs and resource availability and was implemented by the health authority as a demonstration project to test its impact, feasibility, and acceptability in a real-life operational setting. It was implemented in seven STI clinics throughout the Cape Metro health district starting in 2006. It required STI nurses to integrate the HIV testing service into their standard STI treatment (a full description of the intervention can be found in Chapter 2). In South Africa, a special cadre of lay health worker was created, called HIV lay counsellors, to deliver HIV counselling and testing services. Although nurses throughout the country also deliver HIV counselling and testing services, in the Western Cape Province, which is the setting for this study, the HIV counselling service is predominantly provided by the HIV lay counsellors. In this setting, this meant that the PITC intervention involved 'upward' task-shifting from lay health workers to professional staff, unlike much of the 'downward' task shifting for HIV-related services that is recommended by the WHO (World Health Organisation 2007).



**Study rationale and objectives of the thesis**

This study is comprised of impact and process evaluations of a PITC intervention with new STI patients in Cape Town. Against the background of the large HIV epidemic where the majority of people with HIV are still not aware of their HIV status, any intervention that promises to increase HIV testing and access to care and treatment should be evaluated to establish if the expected benefits are realised. This is particularly so for a new intervention such as PITC where there is little systematic evidence of its impact in the South African setting. As mentioned earlier, WHO acknowledged the need for countries to adapt the PITC guidelines to their local conditions; however, it does not specify how this should be done. Given the concerns that have been raised about the ethical implementation of PITC and given the high HIV prevalence and the continued emphasis on the importance of counselling in the South African HIV testing policy, it becomes even more important to evaluate PITC in the South African context.

In studies of new interventions, however, understanding process can be as important as understanding impact. Process evaluations aim to understand how an intervention operates,

identify what factors influence its operation and outcomes, and isolate the strengths and weaknesses of its implementation (Calnan & Ferlie 2003). This study thus also examines the process of implementing PITC with a view to identifying barriers and enablers to effective and ethical implementation.

An important rationale for undertaking these process and impact evaluations in this specific setting is that the intervention was initiated and implemented by the local health authority. This provided an opportunity for assessing impacts and examining aspects of PITC delivery and implementation in a real-life operational setting, thereby increasing the relevance of the study outcomes to policymakers and practitioners on the ground.

The study objectives were:

1. To determine the effectiveness of the PITC intervention compared to the Voluntary Counselling and Testing (VCT) approach with respect to increasing HIV testing uptake.
2. To assess the effect of the PITC approach on the extent to which people diagnosed HIV positive accessed follow-up HIV medical care (CD4 screening and where appropriate, initiation of antiretroviral treatment).
3. To evaluate the extent to which PITC was implemented ethically with respect to obtaining informed consent.
4. To evaluate the implementation process of the PITC intervention to increase understanding of study outcomes and of the factors that influenced the implementation.



**Structure and description of the thesis**

This section describes how each of the above objectives is addressed and outlines the structure of the thesis. Each objective is examined as a separate sub-study of the thesis and reported on in its own stand-alone chapter containing its own literature review, methods, results, discussion and conclusion. Objectives 1 and 2 are addressed in Chapters 2 and 3, Objective 3 in Chapters 4 and 5, and Objective 4 in Chapter 6.

Chapter 2: The impact of provider-initiated HIV testing and counselling on test uptake: a controlled trial

Although there is evidence that PITC increases HIV testing rates, the evidence from LMICs and especially for STI patients in these countries is limited. There is globally a high prevalence of HIV among STI patients and HIV screening for STI patients has been recommended as important for HIV prevention. However, in both high-income and LMIC settings, opportunities for identifying HIV among STI patients are being missed. The high HIV burden and STI incidence in South Africa make intervention with this high risk group particularly important.

This study evaluated whether the PITC approach increased HIV testing among patients with a new episode of STI as compared to standard VCT in primary care, public sector clinics. The study design was a pragmatic, cluster-controlled trial with seven intervention and 14 control clinics in Cape Town. The primary outcome of the evaluation was the proportion of new STI patients who took an HIV test. The secondary outcome was the proportion of patients who were offered an HIV test and who declined.

This study contributes evidence about the effectiveness of the PITC intervention with STI patients – a high-risk target group – in a LMIC setting. It also contributes to a broader body of knowledge about the applicability of the PITC approach in high prevalence and resource-constrained settings.

Chapter 3: The impact of provider-initiated HIV testing and counselling on access to HIV care

As noted earlier, one of the concerns in the debate about the ethics of the PITC approach relates to access to HIV care for those who are diagnosed HIV positive. The health system's ability to respond to the health care needs of newly-diagnosed HIV patients is important irrespective of the approach to HIV testing. However, concerns have increased about lack of access to HIV care for the increased numbers of people who would be diagnosed through expanded HIV testing, especially in LMICs where ART availability is limited. Little is known about how the PITC approach impacts on access to HIV care for patients diagnosed positive through this method.

This chapter investigates whether the PITC approach to HIV testing had any effect on access to HIV follow-up care for those diagnosed HIV positive as compared to those diagnosed through the VCT approach. It is an observational study using clustered data from the controlled trial in Chapter 2. The indicators of follow-up care were laboratory record evidence of having accessed

CD4 testing and viral load testing (with the latter used as an indicator that treatment-eligible patients initiated ART). The study examines therefore a sub-sample of the patients (those who were HIV positive) in the effectiveness trial described in Chapter 2. The primary outcomes were the proportion of HIV-positive patients who had a record of CD4 testing and the proportion of ART-eligible patients who had a record of viral load testing. Secondary outcomes were the time between HIV diagnosis and CD4 and viral load testing.

Evidence on access to HIV care in the context of PITC will help to inform debates, policy, and practice regarding the implementation of PITC, especially in high prevalence and resource-constrained settings.



Chapters 4-5: Informed consent and provider-initiated HIV testing and counselling

Most of the debate regarding the ethics of PITC has centred on the issue of informed consent and, in particular, the concern that PITC would compromise informed consent and result in coercive and mandatory testing practices. These concerns are heightened for LMICs where it is thought that the resource constraints and power imbalances between providers and patients could increase the risk of coercive practices among providers. In addition, there is a general gap in knowledge about how HIV testing processes are implemented in practice and how patients make decisions regarding testing – information considered important for evaluating informed consent.

This chapter evaluated the ethical implementation of the PITC intervention from a patient and external perspective, focusing on the level of informed decision-making. A qualitative approach was used, drawing on patient interviews and observations of clinical consultations and a patient decision-making conceptual framework to evaluate informed consent.

The study was split into two chapters: Chapter 4 reviews the literature and methods while Chapter 5 includes the findings, discussion, and conclusion. The study findings contribute to increasing understanding of the practice and experience of informed consent procedures within PITC in a real-life, operational setting. This information is important to informing debates on the ethics and practice of the PITC approach in LMICs.

Chapter 6: A process evaluation of the PITC intervention using the Normalisation Process Model

This sub-study is a process evaluation aimed at understanding the factors influencing the implementation of the PITC intervention and its outcomes. The gaps between research evidence, policy, planning, and actual implementation in health systems is widely acknowledged and a better understanding of the factors underlying implementation of change in health care delivery is required. Studies have identified a range of factors that inhibit or promote the implementation of successful change in health care but there is a need for more systematic analysis of implementation processes.

The Normalisation Process Model (NPM), an evidence-based conceptual framework, is used to examine the implementation processes (May 2006). This model focuses attention on the ways in which complex interventions are made 'workable' and are 'integrated' into everyday practice in health care settings.

The study used multiple qualitative methods including focus group and participant observation techniques. It described the implementation process of the PITC intervention, identified the factors that contributed to the normalising of the intervention in practice, and increased understanding of the reasons for the trial outcomes. This information is useful for identifying the factors that may strengthen or hinder the implementation of PITC in other settings. This is the second application of the NPM in a LMIC and the study also illustrates the usefulness of the model.



Chapter 7: Conclusions and Recommendations

This chapter provides an overview of the findings of the impact and process evaluations that comprise this study. The chapter discusses three key themes that emerged across the various studies and their policy, practice, and research implications. These themes relate to how HIV testing and access to care can be expanded in South Africa, how contextual factors may have shaped patient informed consent in this setting, and what may be required for effective, efficient, and ethical testing in South Africa and other LMIC settings. The chapter concludes with a review of the strengths and limitations of the study.

## Study Ethics

Ethical approval was obtained from the University of Cape Town's Health Sciences Faculty Human Research Ethics Committee (HREC, REC# 295/2007). The City of Cape Town and the provincial health services gave permission for this study. A standard operating procedure for the research process was drawn up to guarantee that confidentiality protection was in place for the different stages of data management (see Appendix 1). To further ensure the confidentiality of data, a confidentiality agreement was signed between the health authorities and the research team to ensure additional protection of data with patient identifying information. The paper copies of the clinic HIV counselling registers that were used for data extraction were kept under lock and key of the HIV manager of the local health authority, who was also the team leader for the implementation of the intervention. The register was only made available to the researcher and the data manager for data entry purposes and returned to the team leader for safe keeping.

Confidentiality of data from the National Health Laboratory Service (NHLS) database was protected as the electronic search of the confidential data was done by two senior professionals based at the University of Cape Town who were officially in charge of managing the database for research purposes, on behalf of the Western Cape Department of Health. The electronic data generated were protected with a password and rendered anonymous using the unique patient identifier (Linked ID) that was created once the matching of CD4 and viral load records were completed. Confidentiality of data from interviews and clinical observations interview was maintained by the use of pseudonyms for patients and anonymous labels for staff and clinics (such as Clinic/Nurse A). Very few details are provided about staff and clinics to ensure individual clinics and staff cannot be identified. Access to transcripts of this data was restricted to the researcher and a professional transcribing and translation company (the company doing the transcribing and translation did not have access to patient and staff identifying details).

Written consent was obtained for patient interviews, staff focus groups and observation of clinical consultations. Providers obtained verbal consent from patients for the consultation to be observed and or digitally recorded. Nurses were provided with a standard script to use to recruit patients to get verbal consent, as described in Chapter 4 of this thesis. The written consent forms were contained the following elements: purpose of the study, participation and withdrawal, confidentiality, potential benefits, risks and discomforts, payment for participation, contact details of the chairperson on the Human Research Ethics Committee, identifying and

contact details of the investigator and a place for the name and signature of the patient. Copies of the three different consent forms are provided in Appendices 6, 7a, and 7b. The procedures for recruitment and obtaining written consent are described in the relevant chapters, Chapter 4 and Chapter 6. An important element of these processes was that patients and staff were re-assured about their anonymous participation and their right to decline participation without negative consequences.

Observations of clinical consultations took place in the privacy of the consultation rooms which assured the privacy of the staff member and the patient. Patients were interviewed at the clinic in rooms that were private for the most part. The rooms used included unoccupied consultation rooms and staff offices which meant that maintaining privacy was not always possible. On a few occasions, the interview process was interrupted by staff that needed to enter the room. In one case, the interview was suspended as the room was required for another purpose and an alternative room was arranged to continue with the interview.

Interviewing patients in the clinic has its limitations as it could create the impression that the researcher is a member of staff or aligned to the clinic. The researcher and translator wore name tags to distance themselves from being regarded as staff members and this distance was also emphasised at the start of the interview, but this remains a limitation in a clinical setting.

There were no adverse incidents associated with the patient interview process. Patients were asked about their experience of the STI consultation and were emotionally well contained in the interviews. In a few cases, patients expressed specific emotional vulnerability and this was handled in a supportive way. For instance, one patient became tearful when she revealed that she recently learned that her daughter was HIV positive. In another case, a young woman was fatalistic about her chances of getting HIV because her boyfriend was HIV positive and she was not, but she was almost resigned to becoming infected with HIV. She was encouraged to seek further counselling support at the clinic to deal with the anxiety and to find ways to protect herself. A young HIV-positive man made enquiries about the effect HIV might have his ability to have children. He was reassured, given basic information, and encouraged to discuss the issue with his health provider. Staff were on the whole open to being observed by the researcher as this method of research was negotiated with them beforehand and their participation was voluntary. One staff member declined to be observed or, for the consultation, to be digitally recorded.

The researcher was recruited by the team leader who was responsible for implementing the intervention and this decision was ratified by the Project Steering Committee where all the role-players were represented. The researcher in effect had dual roles, as an external evaluator and as a participant observer of the intervention project. The implications of this are reflected on in the final chapter of this thesis.

## Terminology

Various terms are used to describe expanded testing approaches such as the provider-initiated HIV testing and counselling approach recommended by WHO, and this is a source of confusion in both research and policy discussions. The different terms used for PITC sometimes reflect an underlying philosophical difference about expanded testing approaches. For instance, some might use a specific term to ensure that it reflects adequate focus on patient informed consent (Bayer & Edington 2009). The different understandings are reflected in the terminology and will be discussed in greater detail in Chapters 4 and 5 of this thesis. It is useful to briefly define the relevant terms in order to clarify the differences and similarities and to clarify the way in which specific terms are used in this research study.



Client-initiated HIV counselling and testing

This approach involves clients seeking HIV testing on their own initiative or they may be medically referred. Voluntary counselling and testing (VCT) is the traditional, client-initiated testing model where the emphasis is on first being counselled about the desirability and implications of an HIV test and then making the choice about accepting or declining the tests. In VCT, detailed pre- and post- test counselling is considered an essential component of the process. Pre-test counselling usually focuses on enabling an informed decision and includes a sexual health risk assessment, HIV information, discussion of the desirability of having an HIV test, and an assessment of test readiness. Post-test counselling focuses on giving the test result, helping the patient cope with an HIV-positive diagnosis, providing information about follow-up care, preventing infection, and developing individual risk reduction strategies. VCT is usually provided in various health and community-based settings (UNAIDS 2001; World Health Organisation/UNAIDS 2004).

Expanded HIV testing

This is a general term used by WHO and others to describe various strategies for increasing HIV testing more rapidly. It includes scaling up of VCT and provider-initiated approaches like PITC, as well as broader-based strategies such as workplace, mobile, community, and home-based testing and self-testing (Nieburg et al. 2005; WHO/UNAIDS 2007).

Provider-initiated HIV testing and counselling (PITC)

PITC refers to an approach that requires health providers to routinely offer HIV testing to all patients in health facilities as part of standard medical care. It is the term used in the WHO guidelines on PITC and it is an approach that aims to increase HIV testing uptake in clinical settings for all patients. It can, however, also be aimed at selected high-risk patient groups like STI patients. The main differences from VCT are that the offer of HIV testing is provider-initiated (and does not depend on the client to seek it out), it is aimed at all patients visiting the health facility (not only those self- or medically- identified), and it attempts to streamline the testing process to reduce barriers to its implementation and uptake in a clinical setting. Pre-test counselling is not a requirement but a minimum amount of HIV information should be provided and confidentiality and informed consent should be ensured. Verbal consent is considered sufficient. Individuals commonly would be informed that HIV testing was standard practice in the health facility and they would be asked to decline the HIV test explicitly if they did not wish it to be done. This method of offering and decision-making about HIV testing is described as an 'opt-out' approach to HIV testing (WHO/UNAIDS 2007). PITC is the term used in this monograph to indicate when referring to the HIV testing approach described in the 2007 WHO guidelines on PITC.

Routine offer of HIV testing and screening

The literature often uses the term 'routine offer of testing' (ROT) interchangeably with the term PITC. When the term ROT is used, this is usually to make it clear that it is only the *offer* of an HIV test that is routinely encouraged and that this does not mean the HIV test is actively recommended or that it is routinely performed. This distinction is made to reinforce for health providers the importance of ensuring informed consent and the voluntary nature of PITC-type approaches.

'Routine screening for HIV' or 'HIV-screening' is sometimes used in the place of ROT or PITC. Health screening usually refers to a traditional public health approach to HIV testing which is the pre-emptive investigation of health conditions with a view to early detection, diagnosis, treatment, and prevention. The use of the word 'screening' is considered by some to be controversial depending on their position regarding the debate around exceptionalism versus normalisation of HIV testing. The concept of 'screening tests' is considered by some as less voluntary and as having the potential to become compulsory and mandatory in practice (UNAIDS Reference Group on HIV and Human Rights 2007).

HIV Counselling and Testing (HCT)

This is a term used in the updated (2010) HIV testing policy guidelines of the National Department of Health of South Africa. It is used as an umbrella term to describe various types of HIV testing services. The policy outlines two types of HIV testing services: the traditional client-initiated VCT service (renamed in the policy as client-initiated counselling and testing, or CICT), which is distinguished from provider-initiated testing (named provider-initiated *counselling* and testing, or PICT) (National Department of Health 2010a). The definition of PICT is almost exactly that of PITC provided in the WHO/UNAIDS guidelines for PITC, although the name is different. As mentioned earlier, the HCT policy puts particular emphasis on the importance of a human rights and legal framework for HIV testing and the change in the name may be designed to highlight the continued emphasis on the importance of pre-test counselling.

'Opt-out' and 'opt-in' testing

In most cases, these terms refer to the process required for the patient to accept or decline testing. The method of obtaining the patient's permission for informed consent for HIV testing may differ depending on the standard practice of the health service (be it verbal or written consent). VCT is usually described as an 'opt-in' approach where the patient is required to explicitly request that the HIV test be conducted. In these cases, the test is client-initiated and then performed by health staff after discussion on the desirability of such a choice, and with informed consent requirements similar to special investigations or medical interventions. PITC is usually described as 'opt-out' where the HIV testing is considered the default position and the patient is required to decline the HIV test explicitly after having been informed that it is standard

practice. Informed consent procedure is similar to that for standard clinical investigations like blood tests or X-rays (WHO/UNAIDS 2007).

The use of these terms is sometimes confusing as it does not recognise that, within the PITC approach, methods for obtaining informed consent could be considered 'opt-in' or 'opt-out'. For instance, in some instances where general consent is obtained for all standard blood tests, patients may need to 'opt-out' of HIV testing being part of the standard testing. In other settings, HIV testing may be considered part of standard care but may require that special consent be obtained (over and above the standard blood tests). This could be viewed as an 'opt-in' method of obtaining informed consent, within the context of provider-initiated HIV testing and counselling (Jürgens 2006).



Compulsory testing

The term is used to refer to involuntary testing where there is no informed consent. The person is tested for HIV without their permission or sometimes without their knowledge and/or without the result being communicated to the person tested (Canadian HIV/AIDS Legal Network 2005; Jürgens 2006).

Mandatory HIV testing

Mandatory testing occurs when an HIV test is required as a prerequisite to accessing some other procedure or benefit, such as donating blood or organs, immigrating to certain countries, getting married, joining the military, or as a pre-condition to other kinds of employment. Often the terms 'compulsory' and 'mandatory' are incorrectly used as synonymous when it comes to describing some form of testing without consent (Jürgens 2006:3). Most international agencies reject mandatory testing as unethical except for screening blood products and organ donations (Richter 2006). The WHO guidelines on PITC stress that it is neither compulsory nor mandatory HIV testing (WHO/UNAIDS 2007).

# CHAPTER 2: THE IMPACT OF PROVIDER-INITIATED HIV TESTING AND COUNSELLING (PITC) ON TEST UPTAKE: A CONTROLLED TRIAL

This chapter describes a controlled trial to investigate the impact of the provider-initiated testing and counselling (PITC) intervention on HIV test uptake. The chapter also includes a detailed overview of the PITC intervention as it was designed to be implemented in Cape Town STI clinics. Aspects of this description will be referred to throughout the other chapters in the thesis.

## Background

The aim of PITC is to decrease barriers to HIV testing in order to facilitate earlier access to HIV treatment and prevention. Early access to treatment has been shown to reduce morbidity and mortality (CDC 1998; 2006; Chou et al. 2005a; WHO/UNAIDS 2007). There is also evidence that knowledge of HIV-positive status can reduce risk behaviour and transmission rates, especially among sero-discordant couples (Crepaz et al. 2006; Marks et al. 2005; Weinhardt et al. 1999).

Evidence from both low and high income countries indicates that the direct offer of HIV testing by health providers, using an 'opt-out' approach, can result in significant improvements in test uptake. Percentage improvements may range from absolute increases as low as 5% (Stringer et al. 2001) to over 50% (Wanyenze et al. 2008) while baseline testing rates can vary from 6% to 75%, depending on the setting (Chou et al. 2005a; Chou et al. 2005b; Jürgens 2006; Obermeyer & Osborn 2007; WHO/UNAIDS 2007). There appear to be no clear reasons for this wide variability in improvement. One suggestion for the high uptake in African countries is that it could be due to additional training, staff and resources dedicated to the study process (including making free ART services available) (Obermeyer & Osborn 2007).

HIV testing terminology is not used consistently in the literature and this, together with vague descriptions of the actual intervention make comparison difficult (April 2006). Nevertheless, evidence from various settings and with various target groups points to the success of routine provision of HIV testing with the option to opt-out in increasing HIV test uptake. A review of evidence on PITC showed that these studies are conducted mainly with antenatal patients and use quasi-experimental and observational methods (Chou et al. 2005b; Obermeyer & Osborn 2007; Weinstock et al. 2002).

A recent three-armed RCT at 2 Veteran Affairs health care sites in the US compared three intervention models: model A (traditional counselling/testing); model B (nurse-initiated screening, traditional counselling/testing); model C (nurse-initiated screening, streamlined counselling/rapid testing) (Anaya et al. 2008). The study found that both nurse-initiated approaches had significantly higher test uptake compared to the traditional VCT approach. Testing rates were 40.2% (model A), 84.5% (model B), and 89.3% (model C; p=<.01). Of interest was that there was no difference in the level of post-test risk knowledge or reported risk reduction behaviour between three arms, indicating that streamlined counselling did not negatively affect these outcomes.

Most studies of 'opt-out' testing, however, have been conducted with antenatal patients. The implementation of 'opt-out' testing for this patient group has been around for a number of years. Recommendations for opt-out screening of pregnant women in settings with HIV prevalence above 1% were issued by the US Preventive Task Force (USPSTF) as early as 1996 (Chou et al. 2005b). A cohort study with antenatal patients in Alabama, USA showed an increase from 75% to 80% after changing to an 'opt-out' policy in 1999. In Canada, the antenatal HIV testing rates increased from a baseline range of 25-83% to test uptake levels of 71-98% and appeared to be higher in provinces with 'opt-out' policies (Walmsley 2003). Stronger evidence from a randomised controlled trial (RCT) in 1996/97 in Britain that compared different opt-out HIV testing approaches with VCT showed significantly higher prenatal testing rates (from 6% to 35%) with the direct offer of HIV testing (Simpson et al. 1998). This increase was independent of whether comprehensive or minimal pre-test counselling was used but it was found that test uptake varied widely between individual providers offering the test.

Evidence indicates that PITC increases testing uptake in antenatal settings in Africa as well. For example, a before and after study in Zimbabwe in 2005 with patients from 4 antenatal clinics showed an increase from 65% to 99% (p<0.001) within the 6 months following the introduction of opt-out testing (Chandisarewa et al. 2007). The study identified a corresponding significant increase in the number of HIV-positive women identified (from 513 to 926, p<0.001). The study also found that the majority of patients expressed satisfaction with opt-out services and that HIV-positive women reported low levels of adverse social consequences (like spousal abuse), findings that are supported by other studies (Chandisarewa et al. 2007; Chou et al. 2005a; Creek et al. 2007; Obermeyer & Osborn 2007; Simpson et al. 1998; Wanyenze et al. 2008).

PITC has been researched in several European, Asian, African and other countries including Norway, Thailand, Hong Kong, Singapore, and Haiti. It has been credited with high test uptake rates for a range of patient groups, including TB, paediatric, and STI patients as well as hospital and emergency care patients (Chou et al. 2005a; Jürgens 2006; Obermeyer & Osborn 2007; Phanduphak 2011). Studies in African countries like Botswana, Malawi, Kenya, Uganda, Cameroon, Democratic Republic of Congo, Tanzania, Cote d'Ivoire, Zimbabwe, and Lesotho all reported HIV testing increases after the introduction of routine 'opt-out' testing in antenatal and other settings (Chandisarewa et al. 2007; Corbett et al. 2006; Creek et al. 2007; Jürgens 2006; Kalamya et al. 2006; Obermeyer & Osborn 2007; Perez et al. 2006). For example, in Kenya, the proportion of TB patients offered HIV testing over a one-year period of routine opt-out HIV testing in 2005 increased from 31.5% at the beginning of the period to 59% at the end (Chakaya et al. 2008). In Botswana, in 2004, a record review before and after introducing routine testing at four clinics in Francistown showed a significant increase from 76% to 95% ($p<0.001$) in the portion of antenatal attendees who tested for HIV with a corresponding increase in the proportions of women who received their test results (from 72% - 82%) (Creek et al. 2007).

Studies in South Africa have also shown increases with the introduction of routine HIV screening for antenatal patients though the size of the increases have been modest compared to those in other African settings (Coetzee et al. 2005). A cluster randomised trial in 2005 with newly registered TB patients in 20 study clinics in the Eastern Cape province of South Africa showed an absolute increase of 13.7% (from 6.5% to 20.2%, $p=0.009$) within 6 months of implementing PITC compared to the standard VCT approach (Pope et al. 2008). A quasi-experimental study on hospital outpatients in a semi-private facility in Durban, South Africa also reported a significant increase in testing rates with a routine, direct offer of HIV testing—48.6% as compared to 31.5% when patients were medically referred for VCT (Bassett et al. 2007). The authors of these studies suggested that their findings point to missed opportunities for HIV testing in medical settings that may not be captured by the client-initiated VCT approach.

Patients with STIs, another important high-risk group, have been less well studied, particularly in high-prevalence settings, perhaps because of the relative newness of the PITC approach. Studies indicate that having an STI was associated with high prevalence and with increased risk for contracting and transmitting HIV (CDC 1998). An anonymous, unlinked survey of HIV prevalence conducted in 28 STD clinics in 14 US cities in 1997 showed that the HIV prevalence was 50-100%

higher than the general population (and that 40% of HIV-positive patients did not know their HIV status) (Weinstock et al. 2002). More recently, systematic reviews of heterosexual risk of HIV infection showed that HIV infectivity per sexual act can be increased more than five-fold if one member of a couple has genital ulcers (Boily et al. 2009) and that the treatment of STIs can significantly reduce HIV viral shedding in the genital tract (Johnson & Lewis 2008). Recent information on HIV and STI co-infection in South Africa is limited to two studies: one indicated that, of HIV-positive patients attending a wellness health clinic, 10% of men and 16% of women were experiencing STI symptoms (Lurie et al. 2008) and another indicated that 12% of STI patients attending a clinic reported a HIV-positive test result (Kalichman et al. 2009). Given the strong association between STIs and the risk of acquiring and transmitting HIV (CDC 1998; Chersich & Rees 2008; Weinstock et al. 2002), improving HIV detection and treatment among STI patients is a pressing issue.

Despite the important connections between HIV infection and other STIs, the health service often misses opportunities to address issues of HIV with STI patients. Studies have found that an estimated 70% of HIV infections remained undiagnosed among STI patients visiting health facilities (CDC 1998; Day et al. 2004; Groseclose et al. 1994; Munro et al. 2008; Van der Bij et al. 2008; Weinstock et al. 2002). A cross-sectional study of male patients at two outpatient clinics at Lilongwe Hospital in Malawi in 2000/01 also showed that an alarming number of acute HIV infections had been missed among patients attending STI clinics (Pilcher et al. 2004).

Fewer studies have assessed the effectiveness of PITC for STI patients but evidence indicates that PITC can increase testing rates for STI patients as well. A UK study of STI patients attending a genitourinary clinic in 2001 found a significant increase in HIV testing rates from 35% before to 65% after the introduction of routine HIV screening (Stanley et al. 2003). In the Netherlands, a review of routine data showed there was a significant increase in HIV testing of STI patients after the introduction of routine opt-out HIV testing in 1999—from 13% in 1996 to 56% in 2004 (overall odds ratio=5.7), though surveys showed that the proportion of HIV-positive patients who knew their HIV positive status remained low at around 19% over this time (Van der Bij et al. 2008). Similarly, a before and after audit of clinic records of patients attending a genitourinary clinic at a hospital in London showed a significant increase in HIV testing from 18% in 1999 to 53% in 2002, after the introduction of an 'opt-out' HIV testing policy (Day et al. 2004).

There are a few studies on PITC with STI patients in sub-Saharan Africa but the limited evidence does point to increased testing uptake with a routine opt-out approach. A controlled trial in Botswana showed a significant absolute increase in HIV testing for STI patients in clinics with PITC (33% in intervention clinics as compared to 14%, $p < 0.001$) (Weaver et al. 2008). However, PITC was one of four clinical interventions that made up the training intervention in this study, making it difficult to isolate the impact of PITC alone. No randomised controlled trials of PITC for STI patients have been reported.

It cannot be assumed, however, that the broader success with PITC in antenatal and TB patients will translate to increased uptake in STI patients as there are other factors that may act as incentives to test among the former group (such as concern about the well-being of the unborn infant for pregnant women and the need for effective treatment of one's TB illness). The acute, non-recurring nature of STI services also means there are limited opportunities to offer HIV testing and thus to increase testing rates (Obermeyer & Osborn 2007).

In summary, evidence on PITC shows that PITC generally increases HIV test uptake across settings but there is wide variability in the size of this increase. The quality of the evidence is also variable, with the majority of studies being quasi-experimental and observational. The main target group in PITC studies are antenatal patients with fewer studies on PITC with STI patients. In the Sub-Saharan African setting, there no studies focussing exclusively on evaluating the impact of PITC on test uptake of STI patients. This sub-study will address these gaps by evaluating the impact of PITC on STI patients in a LMIC setting using a controlled trial methodology. The aim of this controlled trial was to assess PITC's impact on increasing HIV test uptake as compared to the VCT approach.



## The Cape Town PITC intervention

This intervention was an adapted version of the 'ACTS' approach which includes four brief steps: **A**ssess, get **C**onsent, **T**est and provide **S**upportive services (Futterman et al. 2004). In this intervention, the STI nurse offered HIV testing as a standard part of STI care for all STI clients and the client had to decline or 'opt-out' of this testing. According to policy in South Africa, written consent was required (although the WHO guidelines for PITC allow for verbal consent only). Abbreviated pre-test counselling consisted of informing patients that HIV is an STI and recommending that they test for HIV at this consultation. If they agreed, the nurse would do a

brief test readiness assessment, obtain written informed consent and perform the HIV rapid test along with other routine blood tests such as those for syphilis.

By using clinical staff to deliver the intervention as an integrated part of the STI consultation, the intervention departed significantly from the standard approach in South Africa where VCT is predominantly provided by lay counsellors. The shift required a reconfiguration of roles for nurses and lay counsellors with nurses taking on some of the tasks previously performed by lay counsellors. It was anticipated that more patients would be tested because the clinical care setting provided the opportunity to offer HIV testing to all patients and might also increase patients' willingness to test.

As this was a demonstration project to evaluate the feasibility and acceptability of using clinical staff for HIV screening, the intervention needed to address concerns about the possible overloading of nurses. To save time, nurses were allowed to refer the patient to the clinic lay counsellor for the test result and post-test counselling once they had completed the STI consult and HIV testing. The implementation of PITC in this study is therefore not the full PITC protocol (that includes abbreviated post-test counselling by the same health care provider). The adapted PITC protocol focuses on the pre-test encounter and the HIV testing procedure performed by the nurses as part of their clinical consultation.

The differences between the VCT and the PITC approach to HIV testing (as implemented in this setting) are detailed in Table 1 below.



**Table 1: Differences between the VCT and the PITC interventions for STI patients in Cape Town**
Table adapted from Table 1 in (Bock et al. 2008)

| | **Voluntary Counselling and Testing** | **Provider–Initiated Testing and Counselling for STI patients** |
|---|---|---|
| Patient access | Client-initiated: patients come on their own initiative or are medically referred for HIV testing.<br><br>Patients anticipate being tested for HIV at their clinic visit. | Provider-initiated: patients come to the clinic because they are seeking treatment for STI-related symptoms.<br><br>The STI nurse offers all STI patients an HIV test, irrespective of their presenting complaint.<br><br>Patients do not anticipate being offered an HIV test at their clinic visit. |
| Providers | Usually trained lay counsellors.<br><br>Basic counselling training can be lengthy (10 | Health care providers (STI nurses) trained to provide PITC. |

| | | |
|---|---|---|
| | -20 days). | Training is short (2 days) and focuses on how to offer the test and how to get informed consent. |
| Primary purpose | Primary focus is diagnosis of HIV but the emphasis differs between the two approaches.<br><br>Focus is meant to be more on being neutral about HIV testing and not promoting the option to take the test, as a way of ensuring complete informed consent. Counselling focuses on the psychosocial aspects of increasing HIV awareness, ensuring patient readiness for HIV testing, coping with the news of an HIV diagnosis, and promoting prevention behaviour. | The focus is diagnosis of HIV.<br><br>Aim is to increase the total number of people who know their status and linking them to medical care and prevention. HIV testing can be promoted by the provider as a medically recommended option (as part of comprehensive STI and HIV management). |
| Pre-test encounter | Detailed counselling includes basic HIV information, risk assessment, test-readiness, and risk reduction messages.<br><br>Written informed consent.<br><br>Can take up to 25 minutes. | Brief counselling includes a message about the rationale for HIV testing, HIV information, and the need for informed consent, getting written consent, and doing a brief assessment of test readiness.<br><br>Risk assessment and risk reduction is already part of the STI consultation.<br><br>Written informed consent is required in South Africa, though the WHO PITC guidelines recommend verbal consent.<br><br>Can take less than 5 minutes. |
| HIV testing procedure | Nurse asked to do the rapid test due to limits in the scope of practice of lay health workers. | Nurse does the rapid test along with other blood tests in the STI consultation. |
| Post-test and follow-up care | Lay counsellor gives the test result and post-test support.<br><br>As important for HIV-negative as for HIV-positive clients to receive post-test counselling, including risk-reduction messages.<br><br>HIV-positive patients linked to follow-up care. | Nurse refers patient to lay counsellor for result and post-test support (but with the option of doing this him/herself). In the WHO guidelines, it is suggested that a single provider performs the whole process.<br><br>Primary focus is on follow-up medical care, support, and secondary prevention for those who test positive, with less focus on HIV-negative patients. |



As shown in this table, the PITC intervention differs from VCT in terms how the service is accessed (provider-initiated versus client-initiated and routine versus as needed) and who delivers the service (nurses versus lay counsellors). The pre- and post-test counselling and consent procedures also differ (with PITC, pre-test counselling, and written consent not being required). There is also a different emphasis on motivating for HIV testing although this is not explicitly stated in the PITC guideline. For instance, with PITC, HIV testing is in effect framed as beneficial for medical reasons whereas with VCT, the counsellor is meant to remain neutral

about the option of HIV testing (though it is unclear if this is practiced in VCT). Finally, with post-test counselling in PITC, the emphasis is meant to be on ensuring linkage to HIV care and prevention services for HIV-positive patients (with less emphasis on prevention counselling for HIV-negative patients).

The following section will describe the various components of the implementation of the PITC intervention in the study setting, including the training, the organisation of patient flow, the supervision and the monitoring and evaluation. In the Cape Town PITC intervention, STI nurses from each of the intervention sites received a two-day training course on PITC on how to implement it. Lay counsellors received a 5-day training course that focussed on extending their role in providing follow-up support for HIV-positive clients. The intervention required HIV patients to return for at least 2 more consultations with the lay counsellor to receive support with prevention, disclosure, and follow-up medical care. This was in addition to the standard single post-test session immediately after doing the rapid test. The nurse training provided information on the PITC intervention, increased HIV knowledge of nurses, and practice in giving the offer of HIV testing in a role-play setting. A copy of all the training programmes can be found in Appendix 2. The counselling and consent clinical guideline used by lay counsellors when providing VCT was adapted for use by nurses implementing PITC. A copy of this adapted counselling and consent guideline called 'Standard of care HIV testing record' can be found in Appendix 3. In this thesis, the adapted clinical guideline will be referred to as the PITC clinical guideline or clinical guideline.

The PITC clinical guideline included the activities that were normally required as part of the standard treatment of STI (such as assessment of risk behaviour, providing health education, assessing and diagnosing symptoms, and providing health screening tests). It provided the nurse with guidance on how to introduce the offer of HIV testing at the start of the STI consultation and how to assess the patient's test readiness. The following script was suggested for introducing the test offer (extracted from the PITC clinical guideline):

> ***"Explain:*** *Role of the nurse is to provide treatment for the condition [STI/other]. HIV testing is a routine part of treating this condition. Nurse will take informed consent and do the HIV test. HIV test result will be provided by the counsellor."*

The guideline included a series of five open-ended questions to determine the patient's test readiness and to prepare them for the possibility of an HIV-positive test result. Some of the questions in the guideline were: 'How do you feel about having an HIV test?', 'How would you feel if the HIV test result is positive?' and 'Who would you tell if you are HIV positive?' Nurses had to explain that the test was confidential, that consent was required, and that the patient can refuse the test.

The PITC intervention required a change in the patient flow for HIV testing from the usual way of accessing VCT. Patients accessing VCT do not normally access clinical services on the day of their clinic visit. A patient-flow diagram was developed to help clinics with implementing the change in patient-flow and the sequencing of tasks with the new PITC intervention. A copy of this patient flow diagram can be found in Appendix 4.

The implementation of PITC was standardised in terms of the main components (such as the nurse integrating the offer of HIV testing into the STI consultation) but other components could be adapted by clinics to best suit their patient flow arrangements. For instance, the flow diagram shows that patients would be provided with group education about HIV testing while waiting for their STI consultation but this depended on the availability of staff. In some clinics, the STI nurse would get consent for HIV testing but the actual finger-prick test would be performed with other blood tests in the neighbouring treatment area by another nurse. In most cases, the patient would receive the test result from the lay counsellor, sometimes immediately after the STI consultation, or as soon as a counsellor was available, which meant that STI patients sometimes had to wait their turn along with other patients who came for VCT. Occasionally, STI nurses provided the test result themselves, mainly with HIV-negative patients and usually in response to a shortage of lay counsellors.

No additional nursing resources were provided to implement the intervention at clinic level but a part-time project manager from within the health service allocated 30% of her time to oversee the implementation, supervision, and monitoring of the intervention. Intervention clinics also received quarterly feedback about their performance and there were quarterly group meetings for supervision and support.

In control sites, the routine VCT service continued as normal, as well as the standard supervision and monitoring activities, including sub-district quarterly meetings. VCT was available at the

same site as the STI clinics and any person could access HIV testing through the VCT service. The majority of patients using VCT would be required to initiate testing themselves while some would be medically referred if they had HIV-related symptoms or were considered high risk**.** Managers identified low HIV testing rates among STI patients as a problem in this setting. Studies have indicated that low perceived risk and poor perception of testing services by patients and poor accessibility of testing services are factors that influence low HIV test uptake (Jürgens 2006; Matovu & Makumbi 2007; Obermeyer & Osborn 2007; Van Dyk & Van Dyk 2003). In addition, with VCT, lengthy pre-and post-test counselling and shortages of counsellors can lead to long waiting times or the need for a return clinic visit, factors thought to be relevant in the Cape Town setting as well .

In the standard VCT service, lay counsellors provided pre- and post-test counselling that lasted an average of 45 minutes per patient (Magongo et al. 2002). This excludes waiting time which can be considerable in public sector clinics. Pre-test counselling usually lasts between 10 and 20 minutes. In the South African setting, there are limits in the scope of practice of lay workers with regard to performing tests. This means that a nurse has to perform the finger prick needed for the rapid and confirmatory test and he/she is required to read the HIV test result once it is processed. This not only fragments the VCT service but also adds to the duration of the VCT session and the patients' waiting time (especially as nurses are not always easily accessible to do the finger prick test).

Not all patients who access the VCT service agree to take the HIV test. Some may, after pre-test counselling with the lay counsellor, reconsider their decision and decline the actual HIV test. In the Counselling and Testing (CT) register, these patients would be recorded as having been offered HIV testing which provides a useful indicator of the coverage of the HIV testing service (how widely available it is). The difference between those offered HIV testing and those who accepted the test, also provides useful information on patient testing behaviour and the functioning of the testing service. It should be noted that, to compare the rates of patients who were offered HIV testing in this study (irrespective of whether they accepted testing), the VCT pre-test counselling session (offered by the lay counsellor) and the abbreviated pre-test information (offered by the nurse in the PITC intervention) are both captured by the outcome 'Offered HIV testing' in the results of this study.

A standard tool for documenting HIV counselling and patient consent was used by all lay counsellors providing HIV testing services in Cape Town. This counselling and consent form (referred to as a clinical protocol in this study) was adapted for use by STI nurses in the PITC intervention. A copy of this adapted clinical protocol can be found in Appendix 3. The clinical protocol outlines the steps and information nurses were required to follow when implementing HIV testing as part of the STI consultation. Nurses used this clinical protocol as a script to remind them to record the relevant information and to obtain written consent from patients. The back of the clinical protocol was used by lay counsellors to record their post-test counselling and any follow-up counselling.

## Methods

Study design

The design was a pragmatic, cluster non-randomised controlled trial in which 7 clinics were selected to receive the intervention and 14 clinics served as controls. The trial was registered as a controlled trial; trial registration number ISRCTN93692532. The trial aimed to test the effect of the intervention under normal operational and management conditions. Randomisation was not feasible because the intervention clinics were selected before the evaluation was planned. The assessment of the intervention was facilitated by the health management team, which also made it impractical to blind the implementers and the assessors.



The primary outcome was the HIV testing rate among new STI clients. Secondary outcomes were the proportion of STI clients offered HIV testing (irrespective of whether they accepted or not) and the proportion that declined testing once offered. Participants' gender, age, and proportion diagnosed with HIV are also described.

Study setting

As mentioned in the brief description of the study setting in Chapter 1, STI services and HIV testing services are provided by local health authorities free of charge at most primary health care sites in Cape Town. STI services are usually delivered by trained nurses who diagnose and

prescribe medication for STI. HIV testing services are provided by trained lay health counsellors who provide pre- and post-test counselling.

Clinics deal with large caseloads and STI, HIV, and TB rates are high. At the start of the intervention in 2006, the total new STI caseload for Cape Town was more than 5,000 patients per month (across 146 clinics). As of 2007, HIV testing rates of pregnant women have reached a level of over 90% in Cape Town due to a dedicated prevention of mother-to-child transmission (PMTCT) programme (Barron et al. 2007) but other high-risk groups lag behind, with testing rates for STI patients being estimated at less than 30% in 2005 (personal communication, HIV manager, P. Naidoo, January 2006).

In the Cape Town setting, a shortage of lay counsellors meant there has been little room to increase HIV testing for STI patients by expanding the existing VCT approach. Integrating HIV testing into standard STI care was considered a viable option to expand HIV testing services; hence a provider-initiated HIV testing approach (using STI nurses) was designed, implemented, and evaluated. This decision meant that, in effect, nurses would be providing a service that was previously delivered by lower-skilled cadre of workers, an unusual shift given the WHO recommendations for HIV-related tasks to be shifted downwards to lower cadres (World Health Organisation 2007). Nevertheless, in the Cape Town setting, this was considered a feasible option because the PITC intervention would be more streamlined and therefore easier to integrate into an STI consultation. It was also in line with the health services' efforts to provide a more integrated service for treating STI, HIV, and TB infections (Scott et al. 2010). Integration of HIV testing into the STI consultation was therefore thought to address both the bottleneck created by a shortage of counsellors and to increase opportunities for HIV test uptake (Naidoo 2006).



Study population and sampling

A pool of 24 clinics was identified by the health services as eligible to participate, based on criteria of geographical representation (at least one clinic from each of the health sub-districts), nurse-patient ratio, and a minimum STI caseload of 30 new STI patients per month. A project steering committee, in consultation with local district managers, selected one representative clinic from each district. Nine intervention sites were selected initially, but 2 clinics declined participation shortly before implementation, citing operational difficulties. One control clinic opted out, citing similar reasons. The remaining 14 eligible clinics became the comparison group.

There was no matching of clinics but statistical comparison of clinics at baseline was conducted using general routine administrative data that were collected retrospectively.

A sample size validation was done given that the intervention arm would consist of seven intervention clinics. With this restriction, the study would be able to show an increase of 20% in testing rate from an estimated baseline of 30% with 80% power at a 5% significance level and using an intra-class correlation coefficient (ICC) of 0.08 and a cluster size of 90. In a recent review of ICCs in 188 health systems research studies, the median ICC used was 0.051 (inter-quartile range (IQR): 0.011 to 0.094). The ICC of 0.08 in this study is closer to the conservative end of this range. We doubled the control group to 14 clinics to increase the power of the study. Based on available data, we assumed a cluster size of 90 new STI patients per quarter per clinic.



Data collection and analysis

*Data sources and data management*

Baseline data for 2005, the year prior to the intervention, were collated for intervention and control clinics to determine how the two groups compared on clinic demographics and health service delivery for STI and HIV testing services. The baseline data summary (Table 2 below) describes the intervention and control groups according to characteristics that might have had an influence on the outcomes. TB treatment outcomes and STI and HIV service outcomes are likely to be related since these are considered priority programmes in the service and in South Africa, 73% of TB patients are HIV positive (WHO 2009). TB treatment outcomes were thus included as a proxy indicator of how well clinics were functioning in other priority service areas like HIV and STIs.

The intervention was evaluated approximately one year after the start of implementation using six months of routine data from January to June 2007. Although the health management was able to do ongoing monitoring of the progress of the intervention from the start, the research evaluation (on which this study is based) aimed to assess the impact when the intervention was already well established, hence the delay in evaluation. The Routine Monthly Report (RMR) collated by the health services provided data on the numbers of new STI patients. HIV testing data were collated from the Counselling and Testing (CT) Register that included the patient demographics of new STI patients offered HIV testing and whether they accepted the test and

received the HIV test result. The CT register was adapted to record STI patients as a separate category.

Data from the CT register were entered into an Excel database. The data were linked to patient identifiers and for this part of the study, patient record numbers were recorded but not patient names. Data quality checks were done in stages. This involved checking the RMR data, paper copies of the CT registers, and the electronic dataset for completeness and accuracy. Problems such as incomplete and inaccurate CT registers (including missing patient identifiers and missing or inconsistent testing information) were queried and corrected by clinic staff through checking patient records. Following a 10% random sample audit of the database, data entry errors (mainly incorrect sex and age) were corrected. This did not require a re-checking and re-entry of the whole dataset.

*Statistical methods*

The proportion of patients offered testing, tested, and declined per clinic was calculated. For the variables 'HIV Tested', 'Not tested', and 'Offered HIV Testing', the denominator was the total number of new STI patients treated in these clinics. For the variable 'Declined HIV testing', the denominator was the total number of new STI patients who were *offered* HIV testing, i.e. a subgroup of the total new STI population.

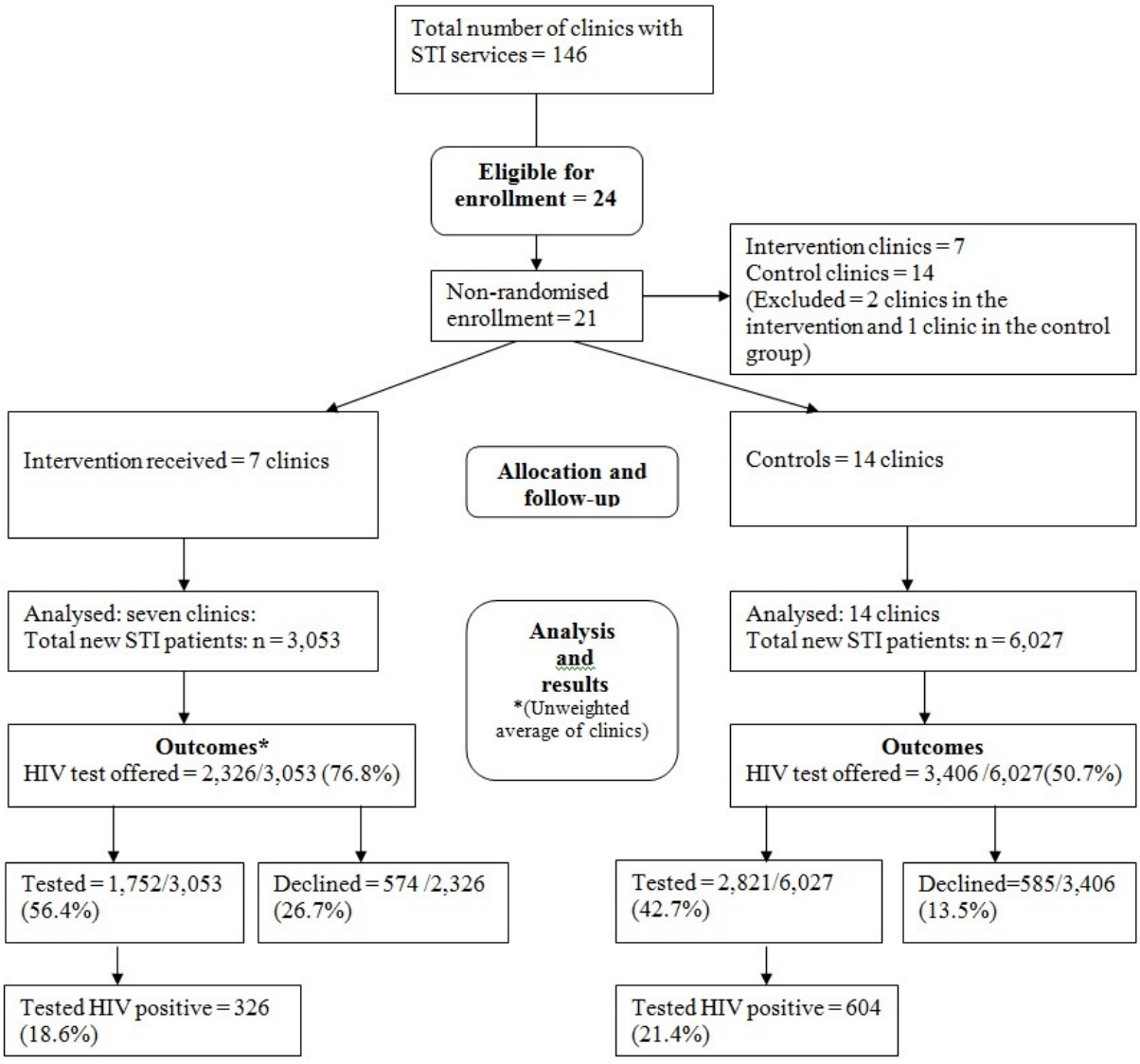
A two-sample t-test was used for the comparison of the study outcome and baseline data between the intervention and control group. We checked the normality assumption of the t-test. A formal test for the equality of variances in the two groups was done using the F-test. The appropriate t-test was subsequently performed based on the homogeneity status of the variances. Multinomial logistic regression analysis with adjustment for clustering was done on the composite testing outcome ('tested', 'offered' and 'not tested') to confirm the results of the analysis. Only the clinics that were operationally able to implement the protocol and provide outcome data to the trial were included in the analysis because we wanted to know the effectiveness of the PITC intervention in clinics that actually implemented the intervention. For the variable 'declined HIV testing', the denominator was the total number of new STI patients who were offered HIV testing, in other words, a subgroup of the total new STI population. These proportions were calculated at the clinic level and in aggregate for each arm and compared across the two arms. This analysis accounted for clustering between clinics in the two arms

(Donner & Klar 2000). A statistical adjustment for baseline differences was also conducted to explore the impact of baseline differences in the two arms.

## Results

The flow chart in Figure 1 provides a profile of the enrolment, analysis, and results of the trial. It includes total raw numbers across all clinics along with the appropriate denominator for each outcome. The proportions in parentheses are an un-weighted average over the clinics and are thus not the same as the proportions for the raw numbers presented.

**Figure 1: Flow chart for the PITC controlled trial**



Baseline comparison

Baseline data on clinic demographics and service delivery from before the start of the intervention in 2005 are provided in Table 2 below. There were no significant differences between the intervention and control groups for either their STI and HIV testing service delivery characteristics or their TB treatment outcomes except for the HIV test acceptance rate variable (Variable #8, 93% vs. 85%, p = 0.03). The HIV test acceptance variable refers to the proportion of general clinic patients who were tested as a proportion of those who received pre-test counselling by lay counsellors. It is not considered to be directly associated with the outcome variable of the proportion of STI patients tested, as assessed in this study, as it was nurses and not lay counsellors who offered the testing in the new intervention (and it was STI patients and not the general patient population, who were tested in the trial).

However, given the lack of baseline data on the main outcome, it was felt that this 'HIV test acceptance rate' variable should be examined. This variable may be an indirect measure of improved clinic monitoring and support systems. These, in turn, could have resulted in increased lay counsellor efficiency in getting patients to accept testing—a factor that could also differentially affect nurse performance in intervention clinics. Discussion with local health managers suggested that the high HIV testing acceptance rates of over 80% in both groups make this difference less meaningful in practice (Dr K. Jennings, HIV manager, personal communication, December 2007). Nevertheless, a baseline adjusted analysis was done and the results are reported on in Table 2 below.

**Table 2: Baseline comparison of intervention and control clinic demographics and service profile: annual data for 2005**

| Characteristics | Intervention clinics (N = 7) | Control clinics (N = 14) | P value *p < 0.05 |
|---|---|---|---|
| **Caseload** | | | |
| 1. Average caseload per clinic: annual number of patients treated in 2005 (total annual for all clinics) | 72,097 (504,679) | 58,741 (822,395) | 0.40 |
| 2. Average adult caseload: annual number of patients who were 5 yrs and older (total annual number for all clinics) | 47,823 (334,758) | 42,687 (600,142) | 0.66 |
| **STI services** | | | |
| 3. Average number of STI-new: number of patients treated who presented with a new episode of STI (total STI-new) | 1,209 (8,466) | 884 (12,377) | 0.26 |
| 4. STI load as a proportion of total adult caseload | 3% | 2% | 0.17 |
| **HIV testing services** | | | |
| 5. Average VCT Total: number of patients who received voluntary counselling and testing (VCT) (Total VCT) | 1,896 (13,275) | 1,388 (19,426) | 0.33 |
| 6. VCT load as a proportion of total adult caseload | 4% | 2% | 0.94 |
| 7. Proportion of VCT patients who were female | 56% | 54% | 0.33 |
| 8. HIV test acceptance: proportion of VCT patients who were tested for HIV | 93% | 85% | 0.03* |
| 9. HIV positive rate amongst patients who tested for HIV | 29% | 28% | 0.82 |
| 10. Lay Counsellor workload: the average number of VCT patients counselled per lay counsellor per day | 4.3 patients | 4.7 patients | 0.59 |
| **TB treatment outcomes** | | | |
| 11. VCT for TB: proportion of New Smear Positive TB patients who received VCT | 79% | 77% | 0.63 |
| 12. TB success rate: proportion of New Smear Positive TB patients who were successfully treated (combined TB cure and TB completion rates) | 79% | 77% | 0.97 |

*Data sources for variables numbered: 1-4 = Routine Monthly Report (RMR); 5, 7, 8, 9, and 11 = Voluntary Counselling and Testing quarterly reports; 10 = Quarterly lay counsellor statistics report, 2005; 12 = TB quarterly reports.*



Proportion tested and offered testing

Clinic-level raw data and proportions for the main outcomes are shown in Table 3 below along with the total raw numbers and proportions for the main outcomes in each arm. Note that the main outcomes in each arm are calculated using an un-weighted average of the individual clinic-

level outcomes. A total of 9,080 new STI patients were treated during the study period; 3,053 in the intervention and 6,027 in the control group.

**Table 3: Comparison of outcomes for the intervention and controls per clinic 'Offered HIV testing', 'HIV tested', 'Not tested' and 'Declined HIV Testing'**

| | STI Total | Offered HIV testing (%) (Total offered/ Total STI) | HIV tested (%) (Total tested/Total STI) | Not tested for HIV (%) (Total declined/ Total STI) | Declined HIV testing (%) (Total declined/ Total offered) |
|---|---|---|---|---|---|
| **Intervention** | | | | | |
| 1 | 451 | 363 (80.5) | 256 (56.8) | 107 (23.7) | 107 (29.5) |
| 2 | 520 | 400 (76.9) | 306 (58.8) | 94 (18.1) | 94 (23.5) |
| 3 | 412 | 346 (84.0) | 236 (57.3) | 110 (26.7) | 110 (31.8) |
| 4 | 850 | 572 (67.3) | 492 (57.9) | 80 (9.4) | 80 (14.0) |
| 5 | 425 | 338 (79.5) | 228 (53.6) | 110 (25.9) | 110 (32.5) |
| 6 | 249 | 215 (86.3) | 177 (71.1) | 38 (15.3) | 38 (17.7) |
| 7 | 146 | 92 (63.0) | 57 (39.0) | 35 (24.0) | 35 (38.0) |
| **Total*** | **3 053** | **2 326 (76.8)** | **1 752 (56.4)** | **574 (20.4)** | **574 (26.7)** |
| **Control** | | | | | |
| 8 | 421 | 87 (20.7) | 86 (20.4) | 1 (0.2) | 1 (1.1) |
| 9 | 174 | 119 (68.4) | 105 (60.3) | 14 (8.0) | 14 (11.8) |
| 10 | 388 | 129 (33.2) | 120 (30.9) | 9 (2.3) | 9 (7.0) |
| 11 | 166 | 51 (30.7) | 47 (28.3) | 4 (2.4%) | 4 (7.8) |
| 12 | 593 | 197 (33.2) | 165 (27.8) | 32 (5.4) | 32 (16.2) |
| 13 | 789 | 669 (84.8) | 636 (80.6) | 33 (4.2) | 33 (4.9) |
| 14 | 837 | 684 (81.7) | 534 (63.8) | 150 (17.9) | 150 (21.9) |
| 15 | 626 | 333 (53.2) | 221 (35.3) | 112 (17.9) | 112( 33.6) |
| 16 | 320 | 25 (7.8) | 24 (7.5) | 1 (0.3) | 1 (4.0) |
| 17 | 373 | 135 (36.2) | 103 (27.6) | 32 (8.6) | 32 (23.7) |
| 18 | 164 | 27 (16.5) | 27 (16.5) | 0 (0.0) | 0 (0) |
| 19 | 285 | 211 (74.0) | 182 (63.9) | 29 (10.2) | 29 (13.7) |
| 20 | 576 | 449 (78.0) | 327 (56.8) | 122 (21.2) | 122 (27.2) |
| 21 | 315 | 290 (92.1) | 244 (77.5) | 46 (14.6) | 46 (15.9) |
| **Total*** | **6 027** | **3 406 (50.7)** | **2 821 (42.7)** | **585 (8.10)** | **585 (13.5)** |

**Un-weighted clinic averages*

Some of the key findings from Table 3 above are summarised in Figure 2. The two bars in Figure 2 represent 100% of the new STI patients seen in the period January to June 2007 in both intervention and control clinics. A significantly greater proportion of new STI patients were tested for HIV in the intervention compared to the control group (56.4% vs. 42.7%, p = 0.037).

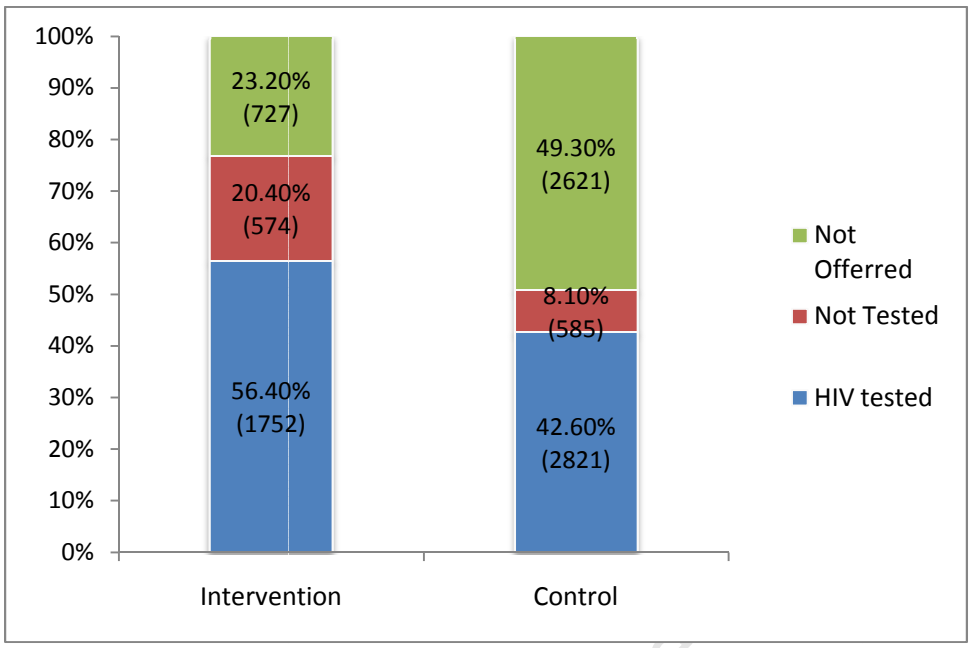
The increase of 13.7% in test uptake with the intervention means that for every seven new STI patients treated, one additional HIV test was achieved (NNT = 7.3).

Patients were also more likely to be offered HIV testing in the intervention clinics; intervention clinics offered the HIV test to 2,326 or 76.8% of new STI patients versus 3,406 or 50.7% of the control group (p = 0.0029). Note that in Figure 2, the proportion of patients *offered* testing is made up of a combination of the blue ('HIV tested') and red ('Not tested') sections of the graph. The 'Not tested' variable in Figure 2 represents the patients in the CT register who were offered but *declined* testing. The denominator for this proportion, however, is all new STI patients (rather than only those who were offered testing).

Another way to measure those who declined testing is the number of patients who declined testing as a proportion of all patients offered testing (a smaller denominator). This alternative calculation represents test declines within the context of those offered the test rather than all new STI patients and is reflected by the variable 'Declined HIV testing' (Figure 1 and last column of Table 3). Of those patients offered HIV testing, a significantly greater proportion (26.7%) declined testing in the intervention group than in the control group (13.5%, p = 0.0086).

In a multinomial regression (adjusted for clustering) on the composite testing outcome (tested, offered, not tested), the odds ratio for being tested was 2.24 (95% CI: 1.12 to 4.46, p = 0.022) for the intervention group compared to the control group. The odds ratio is 3.35 (95% CI: 1.42 to 8.79, p = 0.007) for 'not tested' in the intervention group compared to the control group. These results confirm the outcome specific comparisons reported above and in Figure 2 and Table 3.

**Figure 2: Comparison of outcomes for the intervention and controls per clinic 'HIV tested, 'not tested' and 'not offered'.**



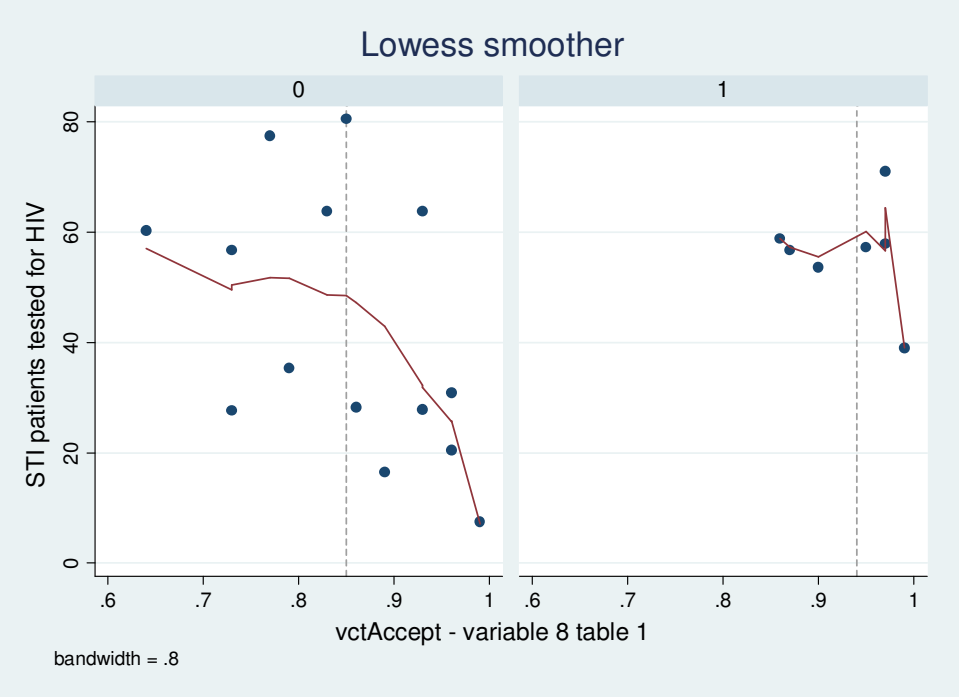



Baseline adjustment for proportion HIV tested

At baseline, HIV test acceptance in the context of VCT with general patients (Variable 8, Table 2) differed significantly between the two arms, with intervention clinics having higher rates than control clinics. A baseline adjustment was done in order to model how the 'HIV tested' outcomes in the two arms would be different for STI patients if this baseline difference were removed. The adjusted estimated intervention effect was a 22.2% increase in testing HIV test uptake (p = 0.03, 95% CI: 2.4% to 42.0%). This is bigger than the non-adjusted estimated intervention effect of 13.7% (95%CI: 1.2% to 26.3%). This increase in estimated effect size appears to be the result of an inversely proportional relationship among the clinics between VCT acceptance rates at baseline and HIV test acceptance during the intervention. That is, the higher the baseline VCT acceptance rate at a particular clinic, the lower the eventual HIV testing rate at that clinic during the trial for both arms. This relationship is captured in Figure 3 below where the two rates—HIV test acceptance at baseline (on the x-axis) and HIV tested during intervention (on the y-axis)—are plotted for intervention and control clinics separately (intervention clinics= 1, are on the right, controls=0, on the left). The Lowess smoother was used to estimate a regression line that models this inverse relationship. The increased effect size after the baseline adjustment was therefore assumed to be the result of this underlying trend—by lowering the baseline rates for intervention clinics (in order to match the controls at baseline), the estimated

HIV test acceptance rates during the intervention were significantly increased for intervention clinics. The researcher did not collect data that would help to account for the reasons behind this trend. Unadjusted outcome measures are therefore presented as a more conservative estimate of the intervention's effect.

**Figure 3: The association between baseline VCT acceptance rates of general patients and HIV testing rates of STI patients in control and intervention clinics.**






Variance in clinic performance

Although not a pre-specified outcome measure, the data suggested wide variability in range for outcomes measured in the clinics and this was compared statistically using the F test. As reported in Table 4, there was significantly less variation in clinic performance in the intervention group for both 'HIV tested' (intervention: 39% - 71%; control: 8% - 81%; p = 0.033) and 'HIV test offered' rates (intervention: 63 - 84%; control: 7.8 - 92%; p = 0.0076). Of note is that two control clinics (numbers 13 and 22) achieved higher testing rates than the intervention sites (80.6% and 77.5% respectively, as compared to the highest rate of 71% in the interventions clinics). Table 4 below summarises both the average across clinics for these three variables (with 95% confidence intervals) along with the 'clinic range' (in italics) of these variables in each arm.

**Table 4: Proportion of new STI patients who were 'HIV tested', 'offered HIV testing" and 'declined HIV testing' in the intervention and control groups**

| Outcome variables | Intervention N = 7 | Control N = 14 | P value (p < 0.05) |
|---|---|---|---|
| HIV tested (% of total STI patients tested for HIV) | 56.4% (CI: 49.4-63.2) | 42.7% (CI: 31.4-53.8) | 0.037* |
| *Clinic range* | *39% - 71.1%* | *7.5% - 80.6%* | 0.033** |
| Offered HIV testing (% of total STI patients offered HIV testing) | 76.8% (CI: 68.8-84.0) | 50.7% (CI: 34.3- 72) | 0.0029* |
| *Clinic range* | *63% - 84%* | *7.8% - 92.1%* | 0.0076** |
| Declined HIV testing (% of STI patients offered, but declined testing) | 26.7% (CI: 18.7-4.7) | 13.5% (CI: 7.6-19.4) | 0.0086*** |
| *Clinic range* | *Range: 14% - 38%* | *Range: 0% - 33%* | 0.71** |

** Two-sample t-test with unequal variance*
*** Test for equality of variances (F-test)*
**** Two-sided t-test since no direction was hypothesised.*



Gender profile, age and HIV diagnosis of study participants

There were no significant differences in the male-to-female ratio between the intervention and control groups in any of the outcomes examined (see Table 5 below). Of those who tested, a similar proportion was male (43%) in both groups. There was also no significant difference between intervention and control clinics in the proportion of patients who tested HIV positive (18.6% in the intervention, 21.4% in the control group, p = 0.147).

**Table 5: Gender, age and HIV diagnosis for study participants in the intervention and control groups**

| | Intervention | Control |
|---|---|---|
| Proportion tested (male) | 42.8% (n = 751) | 42.5% (n = 1200) |
| Proportion offered testing (male) | 43.9% (n = 1,012) | 43.7% (n = 1490) |
| Proportion who declined testing (male) | 47% (n = 270) | 49.6% (n = 290) |
| Mean age of patients tested for HIV | 26 yrs | 28 yrs |
| HIV positive diagnosis for tested patients | 18.6% (n = 326) | 21.4% (n = 604) |

## Discussion

There was a significant increase in the proportion of new STI patients who tested for HIV in the PITC intervention sites, as hypothesised. There was also a significantly higher proportion of patients who were being offered HIV testing by providers in these sites. The proportion of patients who declined HIV testing once offered was significantly higher in the intervention sites, as compared to control sites. There was wide variation in the performance of clinics in both intervention and control sites. However, there was significantly less variation in the main outcomes across the intervention clinics, suggesting that the PITC intervention also facilitated more consistent performance.

The absolute increase in HIV testing rate of 13.7 % is smaller than the difference of 20% anticipated prior to the study. Studies on antenatal and TB patients have shown absolute effect sizes of higher than 50% (Jürgens 2006; Wanyenze et al. 2008). As mentioned in the introduction to this study, the variation in the study settings and methodology, as well as the lack of clarity on the nature of the PITC intervention used in these other studies limit comparisons. Nevertheless, from available evidence, studies in high-income countries with STI patients had absolute effect sizes ranging from 30% (Stanley et al. 2003) to as high as 43% (Van der Bij et al. 2008), though the latter increase was achieved over a period of 8 years. The effect size in this sub-study is similar to that reported in prior studies on PITC in South Africa (13.8% increase for TB patients) (Pope et al. 2008) and Botswana (19% increase for STI patients) (Weaver et al. 2008), though in the latter, the effect of PITC could not be isolated from other interventions used to improve the management of STIs.

Part of the reason for the high uptake of HIV testing in other studies could be due to the difference in settings. For example, hospital patients represent a captive audience and return visits for TB and antenatal patients present multiple opportunities for HIV testing. Antenatal patients may also have increased incentives to test—concern for the welfare of their baby has been cited as the predominant reason for them considering HIV testing (Cartoux et al. 1998; de Paoli et al. 2002). Another reason suggested for high uptake of HIV testing in other studies is that the interventions are implemented with additional staff and resources associated with national initiatives and the study of the PITC strategy (Evans & Ndirangu 2009; Obermeyer & Osborn 2007).

This sub-study may also have underestimated the impact of the PITC intervention in this setting as two changes in practice during the trial could have narrowed the difference between control and intervention clinic outcomes. Firstly, following revisions to the CT register, all clinics were able to record the testing of new STI patients and it is possible that merely making provision for recording HIV treatment for STI patients could have incentivised staff at control sites to increase the HIV testing of STI patients. Secondly, midway through the intervention period, the health authority set a 50% HIV testing target for new STI patients across the city which could have provided an additional incentive, especially for control sites, to increase their HIV testing rates of STI patients. Both of these changes might have improved the performance of control sites and thus reduce the effect size of the PITC intervention. However, this suggestion remains speculative due to the lack of data on baseline testing rates for STI patients. It is worth investigating further the possible underlying reasons for the size of the increase in this sub-study (as has been done in Chapter 6 of this thesis) as this could improve efforts to increase the impact of future PITC interventions.

There are at least two areas where the impact of the PITC intervention in this sub-study could have been improved. For instance, the increase in testing rate was achieved even though only 76% of all STI patients in the intervention clinics were offered testing (against a target of 100%). Increasing the coverage of the offer of testing to 100% of new STI patients could potentially further increase the impact of the PITC intervention. Another area for increasing the impact of the PITC intervention may be to reduce the proportion that decline the offer of testing. More than one-quarter of patients offered testing in the intervention group declined to test (twice the proportion in the control group), a result that is not favourable to the intervention. This larger decline rate is understandable given that patients did not self-initiate testing or anticipate being offered HIV testing, as in the VCT approach. In addition, it may be possible that the high refusal rate could be due to staff being less confident about motivating for testing (perhaps due to the short training) or because staff were being cautious about not pressurising patients.

Higher rates of refusal, though, may also indicate a desirable degree of patient autonomy and efforts to increase acceptance of testing should not be done at the expense of reducing patient autonomy. As mentioned in the introduction to this thesis, concerns have been raised about the ethical implementation of PITC, especially with respect to patient informed consent. The issue is examined in Chapters 4 and 5 where the level of patient autonomy in the implementation of PITC is evaluated. Nevertheless, staff could be trained to use more effective motivation

strategies to encourage patients to test and the proportion declining HIV testing could be reduced to at least match that found with the VCT approach.

As a pragmatic trial, this intervention was implemented using existing management and clinical staff resources and with only some additional project management support from within the health authority. This approach, where service managers initiate and run the intervention and where there are few new resources added, is an ideal context for an effectiveness evaluation as it reflects the reality of implementation in resource-constrained settings (Calnan & Ferlie 2003; Zwarenstein & Treweek 2009). It also may make it more difficult, however, to control the implementation environment. There may be other unidentified factors that could also be influencing staff performance and that may account for the effects on the trial results. It is interesting to note that two control clinics achieved higher testing rates with the VCT approach than the intervention sites. Further enquiry suggested that their success was due to the close supervision and monitoring of the VCT staff team in those particular clinics. This might be an indication that with better management and supervision, there is room for increasing HIV testing rates in the VCT service as well. Of interest is that the study found a wide variation in performance amongst both intervention and control clinics, but this variation was less in the intervention arm. The reduced variation among intervention clinics could be interpreted as a further indication that increased management and supervision could lead to more consistent improvement in clinic performance.

Another unexpected finding that points to the influence of other institutional factors in clinic performance in HIV testing is that those clinics that had, at baseline, a lower VCT acceptance rate had a higher proportion of STI patients tested for HIV during the study period. This inverse association held for both intervention and control sites. A baseline adjustment resulted in an inflated difference between arms in HIV testing rates (22% adjusted difference as opposed to 13.7% unadjusted). One could speculate that the reason for this association could be that those clinics with lower baseline VCT acceptance rates may have been managing and supervising the VCT service more poorly, and that when better management and supervision was put in place, those clinics had a better response and showed greater improvements in HIV testing. This sub-study, however, did not collect quantitative data on these health systems factors and so this must remain speculative. As explained in the results section, this sub-study therefore uses the smaller effect size (13.6%) as it is considered a more conservative estimate of the impact of the intervention.

The findings have important operational implications beyond the testing rate itself and relate to the management of staff resources. In this study, STI nurses integrated HIV screening into their STI consultations, taking on a task previously performed by lay health workers. This is unlike the most common type of task shifting recommended by WHO where tasks are referred down to less skilled workers to free up clinical time for treatment and care of HIV (Type III task shifting) (Sanjana et al. 2009; World Health Organisation 2007). There were constraints to using the existing cadre of lay workers for expanding HIV testing to a broader base of patients so in this setting, using clinical staff was more a case of task optimisation, i.e. trying to ensure that tasks are undertaken by the most appropriate cadre rather than the lowest possible cadre or the least costly cadre. This approach also had the added advantage of promoting integrated services for HIV and STI, which was in line with national policy (Naidoo 2006; Scott et al. 2010).

The change in nursing roles was achieved with relatively short training and it was anticipated that the intervention would marginally extend their consultation time (by an estimated 5 minutes on average, excluding post-test session). However, as was evident from the less than 100% offer of HIV testing, nurses were not able to implement the intervention in full with all their STI clients and tended to drop the offer of testing during busy periods. Findings from the sub-studies reported in Chapter 5 and 6 indicate that the intervention may have taken longer than anticipated. The impact of this PITC intervention may have been influenced by how efficiently staff were able deliver the HIV testing in the context of a busy primary health care clinic.

Where nursing resources are very limited, it may be less feasible to use only clinical staff for PITC and lay providers could be used in such settings (Chandisarewa et al. 2007; Evans & Ndirangu 2008; 2009). In neighbouring Botswana and Lesotho, the two countries at the forefront of PITC in Africa, logistical and resource constraints to implementing PITC have already emerged and there are associated concerns about compromising patient informed consent (Matovu & Makumbi 2007). It is possible that these problems with implementation and the quality of consent may increase as the intervention is taken to scale and supervision and support is reduced. In Chapter 5, the quality of the informed consent practices in this study is investigated in depth.

Finally, there is evidence that many patients in the sub-Saharan region are willing to test if provided with an opportunity that is accessible in terms of cost and time (Pettifor et al. 2005;

Shisana et al. 2005; Shisana et al. 2009). Of interest in this study, is the similarly high levels of HIV prevalence found amongst STI patients in both arms. The high level of HIV prevalence in the PITC arm could be a reflection of the high level of HIV amongst the general STI patient population. Even so, in South Africa, the health facility-based PITC approach on its own may not be able to deliver testing to the large numbers that need it. Strategies for expanding testing may need to consider a combination of multiple strategies, including optimising existing VCT services and investigating other creative testing strategies that show promise such as mobile, community-based, workplace, home-based, and self- testing (April 2006; Jürgens 2006; Matovu & Makumbi 2007; Obermeyer & Osborn 2007; Richter 2006).

Strengths and limitations of this sub-study

The lack of randomisation of clinics to intervention and control groups introduces a risk of bias for the study outcomes. A limitation is that we were not able to obtain baseline measures for the main outcome (i.e. HIV testing rates for STI patients). While the baseline comparison on other variables showed few differences between intervention and control sites, other unknown sources of selection bias cannot be excluded. In the absence of blinding, factors such as staff enthusiasm and increased monitoring could have had a modifying effect. As mentioned earlier, it is uncertain how the unforeseen parallel management efforts to increase the HIV testing rate across all STI clinics, intervention and control, may have affected the study results. The study was also not able to determine whether the variations in implementation (described on page 31), had any effect on the results. Another potential limitation of this study is that it did not use an intention to treat analysis as the analysis excluded results from the two clinics that declined to participate prior to implementation of the intervention, as was explained earlier. An intention to treat analysis would most probably have reduced the effect size. The likely effect size may lie between an intention to treat analysis and the per protocol analysis used in this study.

The generally higher level of resources in the public health sector in Cape Town might also limit how generalisable these findings are to significantly more resource-constrained contexts. The estimated baseline HIV testing rate for STI patients of 30% in this study might be higher than in other low-resource settings and the staff configurations for HIV service delivery may also differ. These factors could influence the magnitude of the intervention effects in other settings.

## Conclusion

To our knowledge, this is only the second study, the first being in Botswana (Weaver et al. 2008), on the impact of the PITC approach for STI patients in a high-prevalence African country and the first where the study design was able to isolate the effect of the PITC intervention. The study demonstrates that PITC, integrated into STI care and delivered by nurses in an urban, primary health care setting, had three successes: it increased the availability of HIV testing opportunities (coverage), it increased testing rates, and it delivered more consistent performance across clinics. PITC can be effective in a resource-constrained setting but this approach alone may not deliver the large-scale increases in testing rates required in high-prevalence countries and other creative strategies should be investigated for their impact and acceptability.

The success of expanded testing strategies cannot only be measured by increased test uptake. These strategies should aim to link the increased numbers of HIV-positive patients identified to follow-up care (Rennie & Behets 2006). The next chapter will examine the levels of follow-up care of patients who were diagnosed HIV positive in this trial.

# CHAPTER 3: THE IMPACT OF PROVIDER-INITIATED HIV TESTING AND COUNSELLING (PITC) ON ACCESS TO HIV CARE

The aim of the provider-initiated HIV testing and counselling (PITC) approach is to increase test uptake and the previous chapter examined whether this aim was achieved in this controlled trial. The ultimate aim of increasing test uptake is to allow for earlier diagnosis of HIV and increased opportunities to access follow-up HIV care, treatment, and prevention services (WHO/UNAIDS 2007) and this chapter examines the impact of PITC on the follow-up care of those who were diagnosed HIV positive in the controlled trial.



## Background

Most people who are infected with HIV will progress to acquired immune deficiency syndrome (AIDS) within approximately 10 years (CDC 2009). Antiretroviral treatment (ART) for HIV-positive patients is associated with reduction of illness and increased lifespan and accessing ART at an earlier stage of HIV infection is associated with greater survival. In the US alone, an estimated 3 million life-years have been saved in the first decade of ART availability. Starting ART at a CD4 count of 320 cells/$mm^3$ versus 87 cells/$mm^3$ results in an average survival rate that is about 11 years longer (Bartlett et al. 2008). HIV testing is considered the 'critical gateway' to accessing HIV care and expanded testing strategies are aimed at increasing the numbers who could benefit from treatment and also at achieving earlier diagnosis of HIV and thus optimising the potential medical and prevention benefits (CDC 2006; Nieburg et al. 2005; WHO/UNAIDS 2007). Nevertheless, there are few studies that examine how the approach to HIV testing, such as the VCT or PITC approaches, may be impacting on the level of access to follow-up care.

HIV care includes a range of interventions including CD4 testing and clinical assessment to determine the stage of the disease, monitoring of disease progression, prevention and treatment of opportunistic infections and, for those eligible, initiation of ART. Comprehensive HIV care also involves psychosocial support to manage the disease and to prevent transmission to others. Clinical guidelines recommend that a person newly diagnosed with HIV should be linked to care immediately to determine the stage of the disease through CD4 testing and clinical examination (UNAIDS/WHO/UNICEF 2010). The South African NDOH guideline is for CD4 testing and clinical staging at baseline for all patients and 6-monthly CD4 testing to monitor health in

the pre-ART stage. ART-eligible patients require a CD4 test and/or clinical staging (WHO clinical disease stage III and IV) at initiation of ART and 6-9 monthly monitoring of viral load suppression (National Department of Health 2010b).

While most people agree on the medical benefits associated with knowledge of HIV-positive status and access to ART, not all agree that expanded testing strategies like PITC can achieve these benefits (Jürgens 2006; Obermeyer & Osborn 2007). Critics of expanded 'opt-out' routine screening in health settings have argued that PITC could be considered unethical in situations where there is limited access to ART, especially in LMICs. (Canadian HIV/AIDS Legal Network 2005; Crewe & Viljoen 2005; Rajkumar 2006; Rennie & Behets 2006). They question the value of an HIV diagnosis for patients who are not able to access the survival gains associated with ART and argue that it might expose more vulnerable and marginalised people to stigma and discrimination. A further concern raised by critics is whether health systems in LMICs are able to respond to the needs of increased numbers of people who test positive given the limited resources (Becker et al. 2009; Crewe & Viljoen 2005; Nieburg et al. 2005; Obermeyer & Osborn 2007; Rennie & Behets 2006; Strode et al. 2005).

Proponents of HIV testing in general, and of PITC in particular, have argued for the medical and prevention benefits of PITC even in the absence of universal access to ART. This includes treatment with cotrimoxazole prophylaxis, treatment of opportunistic infections, and opportunities to reduce transmission to partners and unborn children (April 2010; Chou et al. 2005a; De Cock et al. 2003; De Cock et al. 2006; Marks et al. 2005; Matovu & Makumbi 2007; Richter 2006). Knowledge of HIV-positive status has also shown to reduce HIV risk behaviour in the US (Marks et al. 2005) and in a studies with sero-discordant couples in Zambia, Kenya, Tanzania, and Trinidad (Allen et al. 2003; Voluntary HIV-1 Counseling and Testing Efficacy Study Group 2000). Expanded testing may therefore lead to epidemic control. Finally, proponents note that routine 'opt-out' HIV testing has been shown to be cost effective in settings with an HIV prevalence greater than 1%, including in LMICs (Paltiel et al. 2006; Walensky et al. 2005; WHO/UNAIDS 2007). These and other ethical concerns about PITC, especially concerns around patient informed consent, are discussed further in Chapter 4.

Although the benefits of early diagnosis and early access to care are known, there is increasing evidence of substantial gaps in access to care for those newly diagnosed with HIV (Braitstein et al. 2006; Uphold & Mkanta 2005). Loss to follow up can occur at different stages in the

continuum of HIV care. This includes not returning for CD4 testing, for the CD4 result, or for a clinical examination to determine the stage of HIV illness. It also occurs when those who are ART-eligible are not initiated onto ART or when those on ART drop-out of treatment. In addition to being diagnosed late, indications are that once diagnosed, patients may delay medical care or not receive care at all (Chou et al. 2005b).

Late diagnosis (as indicated by a low CD4 count and/or onset of AIDS) is common across low-, middle-, and high-income settings. The CDC defines late diagnoses as persons who receive an AIDS diagnosis concurrently or soon after receiving an HIV diagnosis (CDC 2009). Late diagnosis often occurs despite multiple prior visits to health care settings and is considered an indicator of missed opportunities for earlier diagnosis of HIV and for earlier access to prevention and treatment (Bartlett et al. 2008; CDC 2009).

From across country settings, figures for late diagnosis range from around 20% to over 50% of patients being eligible for ART at the time of diagnosis (Althoff et al. 2010; Bartlett et al. 2008; CDC 2003; 2009; Connelly et al. 2007; Fairall et al. 2008; Mandala et al. 2009) In the United States, evidence from routine data in a confidential name-based register of HIV-positive patients in 34 states in the USA between 1996 and 2005 show that 38.5% of patients had an AIDS diagnosis within 1 year of their HIV diagnosis and 45% within 3 years (CDC 2009). A review of CD4 levels at diagnosis of a cohort of nearly 50,000 North American patients diagnosed between 1997 and 2009 reported similarly that 54% of those testing positive had a CD4 count under 350 cells/$mm^3$. The mean cell count at diagnosis increased only marginally, from 256 to 317 cells/$mm^3$, over the ten year period.

The problem of late diagnosis of HIV in LMICs is similar or worse (Braitstein et al. 2006). For example, a South African study of a large cohort of over 14,000 HIV-positive patients referred to HIV care public sector clinics between May 2004 and December 2004 reported that nearly half (48%) were eligible for ART (Fairall et al. 2008). The health systems' ability to respond to the health care needs of newly diagnosed HIV patients is important irrespective of the approach to HIV testing to ensure that individual and public health benefits of HIV treatment are being realised (CDC 2003).

But the availability of ART is not an either/or question. Large-scale ART programmes in high-prevalence LMICs have only been initiated in the last 6 to 7 years. Nonetheless, in recent years

there have been substantial advances in the roll-out of ART. Estimates show that the biggest annual increase in ART coverage in LMICs, from 42% to 52%, occurred between 2008 and 2009 (WHO 2010). When using WHO 2010 criteria for higher CD4 count initiation of ART, the figures for coverage are 28% and 36%, respectively. The estimated figure for ART coverage for South Africa in 2008 was 40.2% (Adam & Johnson 2009).

Despite these increases in ART coverage for ART-eligible patients, there is evidence of loss to follow-up care soon after HIV diagnosis in terms of accessing CD4 screening tests and in terms of initiation of ART once eligible. Once found to be ART eligible (based on low CD4 count and or clinical disease staging) and referred for ART, the loss to follow-up prior to initiation of ART can be substantial. In Malawi and Kenya, a retrospective analysis of retention in care of nearly 15,000 patients in two *Medicins sans Frontieres* (MSF) programmes found that 33% and 23% respectively were lost during the pre-ART period (Zachariah et al. 2010) and a South African study of two HIV testing and treatment sites in Durban reported that nearly half failed to have CD4 counts done within 8 weeks of HIV diagnosis (Losina et al. 2010).

High loss to follow up and delays in ART initiation contribute to high mortality in both high- and low-income countries but more so in low-income settings (Bassett et al. 2009; Braitstein et al. 2006; Fairall et al. 2008; Lawn et al. 2008). A comparative review in 2006 showed that patients starting ART in low-income countries had lower CD4 counts (median 108 cells/$mm^3$ vs. 234 cells/$mm^3$) and higher mortality in the first 6 months of ART initiation compared to high-income countries (Braitstein et al. 2006). Another review, focussing on sub-Saharan countries, showed loss to follow-up of patients on ART ranged from 20% at 6 months to 38% at 24 months (Rosen et al. 2007).

Mortality figures in sub-Saharan Africa are also particularly high, as reported in a review of 18 cohort studies where from 8-23% of patients were estimated to have died in the first year of ART (Lawn et al. 2008). There is also wide variation in retention of patients on ART. A systematic review of patients retained in care in sub-Saharan Africa shows retention in care from 46% to 85%, after two years on ART (Rosen et al. 2007). Nevertheless, for those retained in care, studies in South Africa have shown excellent clinical outcomes including reduced mortality (Boulle et al. 2008; Cornell et al. 2010; Fairall et al. 2008; Fatti et al.; Rosen et al. 2007).

There is also wide variation in the extent to which CD4 screening levels are done and in the levels of those accessing ART. Indications are that in high-income countries like the US, the majority of pregnant women who are diagnosed HIV positive are able to access short-course ART shortly after being diagnosed HIV positive (Chou et al. 2005b). A retrospective cohort study of approximately 2,000 patients diagnosed HIV positive in New York City in 2003 examined risk factors for delayed initiation of medical care and found that the majority (82%) had accessed care (defined as CD4 and viral load testing) within 48 months with most (63.7%) having done so within 3 months (Torian et al. 2008). The study found, however, that for 17% of patients, there was no record of initiating care three years later, with similar figures for loss to follow-up being reported in the UK (Gerver 2008).

Table 6 below reports on sub-Saharan countries with findings on proportions of those eligible for ART at HIV diagnosis and low median CD4 levels for cohorts of newly diagnosed HIV-positive patients. It reveals numerous gaps in access for CD4 screening and ART initiation. In Zambia, for example, despite the high (73%) ART coverage of identified ART-eligible antenatal patients for whom CD4 counts were performed, the low CD4 screening coverage following testing (17%) meant that a small minority of the total number of ART-eligible pregnant women were identified (Mandala et al. 2009). In Cape Town, a study on ART referral in four antenatal clinics in 2005 showed the opposite, where the majority of pregnant women had a CD4 test done (97%) (Stinson et al. 2008). In this study, 15% of those with CD4 tests were ART-eligible, but only 60% of this group were referred for ART. Of the 15% who were initially eligible for ART, only half (51%) were found to be on ART by the time they gave birth (Stinson et al. 2008). Another Cape Town study (which excluded pregnant women accessing ante-natal services) showed that in 2006, for a cohort of 375 HIV-positive patients at two health centres, 62% had a CD4 test done within 6 month of diagnosis, of whom 20% were immediately eligible for ART and 68% of those received ART within 6 months (April et al. 2009). Finally, access to HIV care was better in a semi-private hospital out-patient setting in Durban, South Africa where 81% of ART eligible patients initiated ART within 3 months of referral (Bassett et al. 2009).

Reasons for loss to follow-up care for HIV patients vary from setting to setting but generally include individual-level factors (such as advanced stage of disease and death, patient health-seeking behaviour, fear of stigma, patient perceptions of the health services); structural factors (such as poverty, cost of accessing care); and health systems factors (such as accessibility, the capacity to provide CD4 screening and ARV services, user fees for ART, and problems with

referral and navigating the health system) (Chou et al. 2005a; Chou et al. 2005b; Kumar et al. 2008; Louis et al. 2007; Obermeyer & Osborn 2007; Uphold & Mkanta 2005). Structural and health systems factors were identified in two South African studies investigating low ART coverage. One found that in 2008 in an impoverished rural South African area, distance from the health facility was the single most limiting factor for accessing ART (Cooke et al. 2010) and another identified implementation level differences (other than financing and human resource capacity) as the reason for the differential uptake of ARV treatment at sites in three different provinces (Schneider et al. 2010).

PITC and access to care

Although the aim of expanded testing is earlier diagnosis of HIV and earlier access to HIV care, claims that PITC may increase access to care are still unsubstantiated (UNAIDS Reference Group on HIV and Human Rights 2007). The relationship between expanded HIV testing and access to HIV follow-up care is also not well understood (Nieburg et al. 2005)and the mechanisms for how PITC would achieve increased linkage to care are not spelled out in the WHO guidelines for PITC or anywhere else. Some have speculated that patients who test via 'opt-out' testing approaches like PITC may be less ready to test and thus be less able to deal with an HIV-positive diagnosis and to access follow-up care (Rennie & Behets 2006). As mentioned earlier, there are also concerns about whether the health services in LMICs would be able to respond to the HIV care needs of the increased numbers of HIV-positive patients diagnosed through PITC (Becker et al. 2009; Crewe & Viljoen 2005; Rennie & Behets 2006).

There are few published studies where the aim was to examine the impact of PITC on linking HIV-positive patients to care. Most studies focussed on evaluating the impact on testing rates (as was the case in Chapter 2 of this study) and a few have reported on access to care as a secondary outcome. The limited evidence available does not appear to bear out the concerns about reduced access for patients diagnosed HIV positive via the PITC approach. Evidence from antenatal settings in Zimbabwe (Chandisarewa et al. 2007) and Botswana (Creek et al. 2007) indicate that there was no difference in terms of the level of access to short-course ART between PITC and client-initiated testing approaches. A South African cluster randomised controlled study of PITC for TB patients in South Africa also found no difference in follow-up medical care compared to VCT, with equally low access across arms in terms of patient referral for HIV care or prescribed cotrimoxazole prophylaxis (Pope et al. 2008).

It is also not clear whether PITC is able to diagnose patients at an earlier stage of the disease. A Ugandan study reviewed routine data from before and after the introduction of PITC and found that the proportion of patients with low CD4 counts (CD4 <200 cells/mm3) dropped from 65% to 45%, with a corresponding drop in the number of patients who were HIV symptomatic (Andia 2006). A South African study conducted in 2005 with outpatients at a semi-private hospital found no difference in the median CD4 cell counts for those tested based on physician referral (123 cells/$mm^3$) and those tested by routine testing (140 cells/$mm^3$) (Bassett et al. 2007).

A recent Cape Town study compared the routine records of 885 randomly selected adult patients who tested HIV positive at 3 different testing sites between January 2004 and March 2009 (Kranzer et al.). Although this study did not compare PITC patients, the findings showed that individuals who tested on their own initiative (through the VCT service) had the worst linkage to care and individuals testing through antenatal and STI services had the best linkage to care as defined by accessing a CD4 test within 6 months of HIV diagnosis and having repeat CD4 testing. The study also found that linkage to ART care was best for antenatal patients compared to those who accessed VCT, TB, and STI services. These findings point to a possible relationship between accessing follow-up care and the way that HIV testing services are accessed and indicate that in this setting, the client-initiated HIV testing approach does not necessarily produce the best follow-up care as some might have proposed.

Several studies, across high and LMIC settings, have highlighted the need to pay closer attention to monitoring linkage to follow-up care immediately after HIV testing and especially for eligible patients prior to accessing ART (April et al. 2009; Bartlett et al. 2008; CDC 2009; Kranzer et al.; Obermeyer & Osborn 2007; Pope et al. 2008; 2000). Nevertheless, as mentioned above, there is little evidence on whether the PITC approach to HIV testing increases access to HIV care, compared to other HIV testing approaches.

This sub-study investigates this gap in knowledge on the impact of PITC on access to HIV care in the context of a high-prevalence LMIC setting. The aim is to determine if the PITC intervention increases access to follow-up HIV care as measured by CD4 and viral load screening, compared to patients diagnosed HIV positive in the VCT approach. This knowledge will provide insight into the level of access to HIV follow-up care for the increased numbers of patients who were diagnosed HIV positive through the PITC method, an issue that has been raised as an ethical concern in the debate about the feasibility and acceptability of PITC.

**Table 6: Summary of studies from sub-Saharan Africa on access to HIV care following an HIV-positive diagnosis**

| Studies | Study focus | Key findings |
|---|---|---|
| (April et al. 2009) | Examining trends in HIV testing rates and outcomes during 2001-2006 in Cape Town, South Africa | • The estimated HIV prevalence for the community was 23% in 2005 and the population HIV testing rates rose from 4% in 2001 to 20% in 2006<br>• The proportion of HIV-positive diagnoses was 28% in 2006<br>• In 2006, 62% of those diagnosed HIV positive received a CD4 test within 6 months of diagnosis, with a median CD4 count of 288 cells/$mm^3$<br>• About 20% of those with CD4 cell counts were immediately eligible for ART<br>• The majority (92%) had a documented WHO clinical staging assessment<br>• The majority (68%) of the 20% who were ART eligible received ART within 6 months of becoming ART eligible |
| (Fairall et al. 2008) | Examining the effectiveness of ART in a cohort of HIV-positive patients in the Free State Province, South Africa (May 2004-December 2005) | • A cohort of 14,267 HIV-positive patients were followed up for up to 20 months<br>• 48% of the cohort were ART eligible (CD4 counts of ≤200 cells/$mm^3$)<br>• Of the ART-eligible patients, 45.3% had been enrolled for ART during the follow-up period of up to 20 months<br>• Over half (53%) of a sub-total of 4,570 patients followed-up for at least 1 year were known to have died, 87% before they were initiated on ART |
| (Mandala et al. 2009) | Evaluating HIV follow-up care of a cohort of HIV-positive pregnant women at PHC clinics in Zambia (2007-2008) | • Of the 14,815 HIV positive pregnant women registered in 60 primary health care clinics, 2,528 (17.1%) had their blood sample collected to request CD4 testing<br>• Of those with laboratory record of CD4 testing, only 1,680 (66.5%) had a record of a CD4 test result at the PHC clinic<br>• The median CD4 count was 366/$mm^3$ for the available CD4 results<br>• Of those with available CD4 results, 796 (47.4%) were ART-eligible (count ≤ 350 cells/$mm^3$)<br>• A high proportion (73%, n = 581) of ART-eligible patients were initiated on ART during the 12 month observation period |
| (Stinson et al. 2008) | Evaluating different approaches to ART initiation for HIV-positive pregnant women in four antenatal public sector clinics in Cape Town, South Africa (2005) | • Of the 26% of pregnant women who tested HIV positive at 4 antenatal clinics in Cape Town, 97% had a CD4 blood test done<br>• 15% of those with CD4 tests were ART eligible (CD4 counts of ≤200 cells/$mm^3$)<br>• Of the ART-eligible patients, 60% had a documented referral to a HIV clinic (and 51% had initiated treatment by the time they gave birth)<br>• ART initiation rates did not vary according to the proximity to the HIV treatment centre |
| (Pope et al. 2008) | A randomised controlled trial of a PITC approach to increase HIV testing uptake among TB patients in the Eastern Cape, South Africa | • The proportion of tested patients with positive HIV test results was similar in the intervention and control arms (36% versus 43%)<br>• Follow-up medical care did not differ and was equally low across intervention and control arms, with less than 40% of HIV-positive patients being referred for HIV care or prescribed cotrimoxazole prophylaxis as per the clinical protocol |

## Methods

Study setting

This sub-study was conducted with STI patients in the context of a PITC intervention in primary health care clinics in Cape Town. The study setting and intervention has been described in detail in Chapter 2. This chapter reports on the impact of PITC on follow-up care for patients diagnosed HIV positive during the trial.

Clinical guidelines for the management of HIV in South Africa require CD4 count blood testing for all HIV-positive patients. If the CD4 count is ≤200 cells/$mm^3$ (and/or if the patient has a clinical diagnosis of WHO Stage IV AIDS), the patient should be referred for initiation of ART. In 2010, the South African government changed the recommendation to allow for earlier ART initiation at higher CD4 levels of ≤350 cells/$mm^3$. ART initiation usually requires a baseline clinical assessment and a 3-week period of preparing the patient for ART aimed at improving adherence. The requirement for a baseline viral load test was dropped during the trial period and the protocol now requires viral load testing after 6 months of ART initiation (usually between 6 and 9 months) and viral load testing at 6-12 month intervals to monitor treatment. This means that the sample of those with viral load tests in this study will be a mix of those with baseline tests (before ART initiation) and those with viral load tests done some months after having been initiated on ART. This change in protocol affects both arms of the trial and therefore should not have an effect on the impact of the PITC intervention. It does make interpretation of the findings on viral load testing, however, more difficult.

Staff in all clinics in Cape Town have the capacity to draw blood samples and request CD4 testing from the National Health Laboratory Service (NHLS). Not all participating clinics provide HIV care on site but refer patients with low CD4 counts to nearby facilities where ART preparation, ART initiation, and viral load testing are done.

Study design

This comparative, observational sub-study examines a subset of the study population in the pragmatic cluster controlled trial that evaluated the impact of PITC on HIV testing rates. The PITC intervention and the study design for the trial was described in detail in Chapter 2. The 930 patients who tested HIV positive in the controlled trial (in the period January to June 2007) form

the sample for investigating access to HIV follow-up care in this study. The study reviewed retrospective laboratory records of CD4 and viral load tests as indicators for access to HIV care.

The study examined whether patients who tested for HIV in the PITC intervention clinics had increased access to HIV care as compared to patients who tested for HIV in the VCT clinics. The study compared access to care between the intervention and control arms by examining:

1. The proportion of HIV-positive patients who had a record of CD4 testing;
2. The CD4 blood count levels of those with records of CD4 testing;
3. The proportion of ART-eligible patients with a record of viral load testing;
4. For those with records of CD4 testing, the time from HIV testing to CD4 testing, and for those with viral load test records, the time from CD4 testing to viral load testing.

The primary outcomes were the proportion of HIV-positive patients with a record of CD4 blood testing and the proportion of ART-eligible patients with a record of viral load testing. These were used as indicators of access to HIV care for STI patients who were newly diagnosed HIV positive. In this study, patients with a CD4 count ≤200 cells/$mm^3$ were defined as being ART eligible according to the criteria of the NDOH at the time of the research. Ensuring access to HIV care for this group should be considered a priority given the high morbidity and mortality associated with low CD4 levels (Braitstein et al. 2006). Secondary outcomes included assessing the levels of CD4 counts between arms to determine if there were differences between the testing approaches in terms of how early or late HIV was being diagnosed. The time between test measures was also assessed to determine if there is a difference between arms in terms of how long it took to progress through different stages of care.



Data collection and analysis

In South Africa, all blood testing in the publicly funded health sector is done by the National Health Laboratory Service (NHLS) of South Africa (www.nhls.ac.za), including CD4 and viral load testing for HIV. The NHLS has a national information system with individual patient names linked to laboratory results. In this study, laboratory records of CD4 and viral load testing are used as indicators for access to HIV follow-up care because these tests can only be requested by a nurse or doctor. Laboratory records represent a centralised and comprehensive source of information about CD4 and viral load testing across all primary health facilities which makes it a more efficient way of extracting data than, for instance, reviewing individual patient folders.

The Excel database used for the controlled trial study on impact of PITC had individual patient information on the total numbers of patients who tested for HIV in the 21 clinics that participated in the controlled trial. The compiling of that database was described in detail in Chapter 2. A subset of that database was used for this study. All the entries with an HIV-positive result were extracted into a separate database of HIV-positive patients. Using linked information from the Counselling and Testing (CT) register from where the data originated, the names and surnames of the 930 HIV-positive patients were added to the original Excel database. Six HIV-positive entries originally in the CT register were excluded, 5 due to missing data on the HIV confirmatory test and one entry without a name that may have been entered in error. Eleven records in the CT register had incomplete or missing data on date of HIV testing but these records were retained as the main outcome of interest (tested HIV positive) was not affected by the missing data.

The CT database was then converted to an Access database and used to search electronically for CD4 records and viral load records in the NHLS database that could be matched to the names of the HIV-positive patients. Using the patient names (in combination with other variables such as age and gender), the NHLS electronic register database was searched for CD4 records for a 12-month period between January 2007 and December 2007. The search for viral load test records was done a year later which meant that viral records could be searched for a 24-month period between January 2007 and December 2008. Follow-up periods were not standardised for each patient but there was a minimum follow up time of 6 months for CD4 records and of 12 months for viral load records.

To search for HIV-positive patients who had a record of a CD4 test or a viral load test in the NHLS database required that the identifying details of a HIV-positive patient in the CT register database be matched exactly with the identifying details of the same patient in the NHLS database. The patient variables from the CT register were used to search the NHLS database. The variables included the patient's name and surname, gender, age, patient folder number, the location of the clinic, and dates of HIV tests. The NHLS database also recorded the location of the clinic that requested the test, date on which the CD4 and viral load tests were done, and the result of the tests. The search for matching HIV-positive names with CD4 records was complicated by the fact that no single unique patient identifier (such as, for instance, a unique patient identity number) was used in these registers and that there were inconsistencies and

errors in the way data were entered. Examples include misspelling of names, transposing of the first name and surname, incorrect age or gender, and missing patient folder numbers (or different folder numbers from those in the CT register). A unique patient identifier (linked ID) was created in the CT database to assist with tracking and matching patients across the two databases.

The NHLS electronic register database for the Western Cape that was searched comprised close to 150,000 laboratory records of CD4 tests done for the period January to December 2007. Various search strategies were used to optimise the yield of names that might match those of the 930 HIV-positive names from the CT register. The search strategies had various combinations of the following variables: patient name and surname, transposing the name and surname, gender, age, and patient folder number. The Access software was not able to determine the probability of potential matches and as a result, multiple NHLS entries were selected as possible matches for one HIV-positive name. Also, to maximise the yield, a 'sounds like' algorithm (using the 'Soundex' protocol) was used in the search for matching names and this generated a much broader pool of possible names to match against. This is a search parameter that matches names based on a combination of letters that sound alike even if the spelling is not exactly the same. The search of the NHLS database generated a list of 3,679 names of patients with CD4 test records that represented possible matches for the 930 HIV-positive patients in the CT database. This NHLS search list of multiple names was then searched manually to determine exact matches. The steps of the manual search are summarised below.



The manual searching of the NHLS list was done in three phases with each phase moving to a higher level of certainty in matching CD4 records to the HIV-positive names. The researcher was blind to the allocation of names to intervention or control clinics. The 'clinic' variable was included in the electronic searching but was removed for the purposes of the manual search for matches.

- The first phase involved the researcher manually reviewing the electronic database of 3,679 names and comparing a range of variables (such as name, gender, age). Matches were identified using a colour coding system that rated the probability of a name being a true match: green for highly probable, yellow for potential matches, grey for improbable and white for highly improbable matches. This step was repeated using additional variables such as folder numbers to increase the accuracy of the first round of

colour coding. During this first phase, it was established (using the unique ID created for the CT register database) that no potential matches were generated for 157 (of the 930) HIV-positive names. The assumption was that there were no possible matched CD4 records found for these missing names. This assumption was checked for accuracy (see description of quality control below) to ensure these names were not excluded in error.

- In the second phase of matching, a basic quantitative system was designed to assist with further narrowing the search for probable matches. The five main variables that appeared to be good predictors of exact matches were each allocated a point and this was used to score each probable match. For each entry identified as a potential match, one point would be allocated for a match on any of the following variables: surname and name (or a close version of these two), gender, age (within a 2 year bracket), patient folder number (where available) and date of CD4 testing (if the HIV testing date preceded the CD4 blood test request date). Ideally, a perfect match would mean that a name entered into the CT register of HIV-positive patients would have achieved a score of 5 points, meaning that they were matched on all 5 of the variables mentioned above. In most cases, a match was assumed when three variables matched: the patient's surname and name, the age and patient folder number where available. Surname and name matches appeared to provide the strongest predictor of a match.
- Using these three main variables as the focus (patient's surname and name; age; and patient folder number), a third and final phase of matching was done where entries were classified into three categories: category 3 identified definite or exact matches (3 main variables matched exactly or closely enough), category 2 identified possible matches (matched on a few variables, but not necessarily on 3 main ones) and category 0 was for improbable or non-matches (no main variables matched). This step was repeated to increase the accuracy of the classification of category 3 and 2 matches.

A final list of 824 exact matches was generated. Some patients were found to have had more than one CD4 test done. The first CD4 test record after HIV testing was included in the analysis and subsequent records were removed from the dataset. After removing these multiple records, 622 exact matches (or category 3 matches) for CD4 records were found.

The database of 622 matched names for CD4 records was then used to search the NHLS register database for matching viral load records. By this time, new software was available which simplified the search and matching process considerably. The search was done using Link Plus

software developed at CDC's Division of Cancer Prevention and Control in support of CDC's National Program of Cancer Registries (NPCR). Link Plus is a probabilistic record linkage programme designed to detect duplicate cancer records and to link records in the cancer registry with external files and is now being used by researchers and organisations as a linkage tool for public health data (www.cdc.gov/cancer/npcr/tools/registryplus/lp.htm). The software was able to rate the probability of a match which meant that fewer possible matches were generated and each entry came with a probability rating which enabled the researcher to make quicker judgements on the exact matches during the manual matching process. The criteria for an exact match were similar to those used for the CD4 matching process. The final search yielded a total of 84 viral load records.

Quality control

Quality control of the data collection was aimed at ensuring the accuracy of the search and matching strategies (electronic and manual) for CD4 records. For the quality check of the electronic strategy, a repeat search was done on a random sample of 20 of the 157 missing records to determine if any possible matches existed that may have been excluded in error. This involved individualised searches of the entire NHLS database for each of the 20 names. This strategy yielded one definite match out of the 20 names, meaning there was an estimated probability that one out of 20 missing names (or 5%) of the 157 excluded names could have had a CD4 record that was not picked up by the search strategy used in this study. Given the time consuming nature of such individualised searching and the small margin of error, it was decided (based on the advice of a senior research colleague who performed the search and the quality check) to accept that there may be a 5% underestimate of the true number of CD4 records that were done.

The accuracy of the rest of the manual matching process was checked in two ways. The first was getting a second opinion from a senior research colleague (who conducted the NHLS electronic search) on 26 names where the researcher was uncertain about the accuracy of the matching. All the matches were confirmed as accurate by the senior colleague. The second quality check was for the same senior colleague to do an independent matching of a random sample of 20 names in the original search list (the one that generated over 3,000 potential names). This independent quality check did not identify any discrepancies that could affect the main outcomes. For instance, the independent check changed one entry that was categorised as a

'no–match' (category 0), to a category 2 (possible match) but this did not affect the main outcome since only category 3 matches were counted towards the outcome variable.

Data analysis

The sample size was determined by the numbers of patients who were diagnosed HIV positive in the controlled trial. The confidence intervals for this study, therefore, reflect the precision that was linked to the sample size that was obtained from the main study as described in Chapter 2. Data analysis was performed using STATA statistical software, Version 10. Analysis compared the study arms with respect to the proportion of HIV-positive patients with CD4 records, their CD4 levels, and the proportion of ART-eligible patients with viral load records, as well as the timing of CD4 and viral load testing. All analysis took clustering by clinic into account using generalised linear models with 95% confidence intervals. Univariate and multivariate logistic regression was performed to analyse the difference between arms with respect to the primary and secondary outcomes. Kruskal-Wallis, a non-parametric, one-way analysis of variance test, was used to test for the equality of population median CD4 values. Kaplan-Meier estimates and Cox proportional hazards regressions were used for the time-to-event analysis of CD4 and viral load testing for those with observed events.

## Results

Participants

A total of 930 patients (20.3%) who accepted HIV testing across both the intervention and control arms had an HIV-positive test result. As indicated in Figure 4 and Table 7 below, there was no significant difference in the proportion of patients who tested HIV positive between study arms (18.6% in the intervention clinics, 21.4% in the control sites, p = 0.147). (Please note that in Figure 4 (as in Figure 1 in Chapter 2), the percentages calculated for all the variables are un-weighted percentages calculated at the clinic level).

The median age of the patients was 28 years in intervention clinics and 26 years in control clinics. In both study arms, the majority (approximately two thirds) of the patients were female. The majority (91%) of females were 35 years or younger and the majority of males (83%) were 25 years and older. Table 7 and the flow diagram in Figure 4 present the results on access to care by study arm, for those patients who tested HIV positive.

**Figure 4: Flow chart for PITC controlled trial and observational study on access to HIV care**

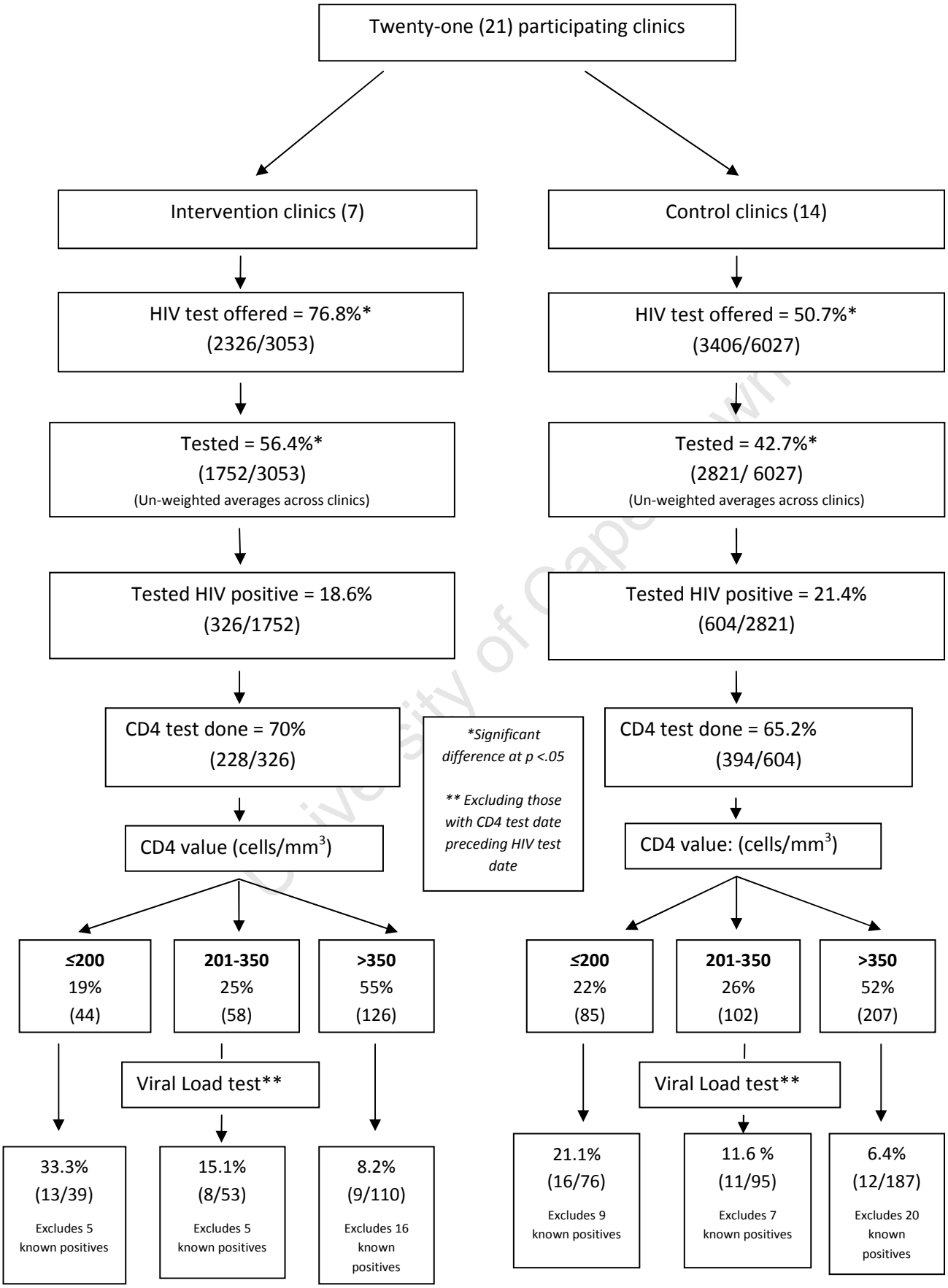


**Table 7: Demographic information and CD4 and viral load testing results for HIV-positive patients in the control trial, by study arm.**

| Participants enrolled | Intervention % (n) | Control % (n) | P value *p < 0.05 |
|---|---|---|---|
| **1. Numbers tested** | (1752) | (2821) | |
| **2. Tested HIV positive (as % of all tested)** | 18.6 (326) | 21.4 (604) | 0.147 |
| **3. Median age, years (Range)** | 28 (14-54) | 26 (3-70) | 0.162 |
| **4. Gender: women** | 62.9 (205) | 66.7 (403) | 0.423 |
| **5. CD4 test done (as % all HIV positive)** | 69.9 (228) | 65.2 (394) | 0.507 |
| **6. Median CD4 (cells/mm$^3$) (Range)** | 386 (17-1509) | 364 (11-1445) | 0.446 |
| **7. Viral load test done (as % of CD4 done)**** | 14.9 (30) | 10.9(39) | 0.071 |
| **8. Median time(days) from HIV testing to CD4 testing, days (IQ range)** | 3 (1 - 290) | 2 (1 - 337) | 0.646 |
| **9. Median time (days) from CD4 to viral load testing, days (IQ range)** | 245 (177 - 560) | 306 (195 - 550) | 0.622 |
| **10. Median time (days) from CD4 to viral load testing for ART eligible participants (CD4 ≤200) (IQ range)** | 214 (177 – 230) | 288 (195 – 492) | 0.007* |

**p < 0.05*
***Excluding those with CD4 test date preceding HIV test date.*

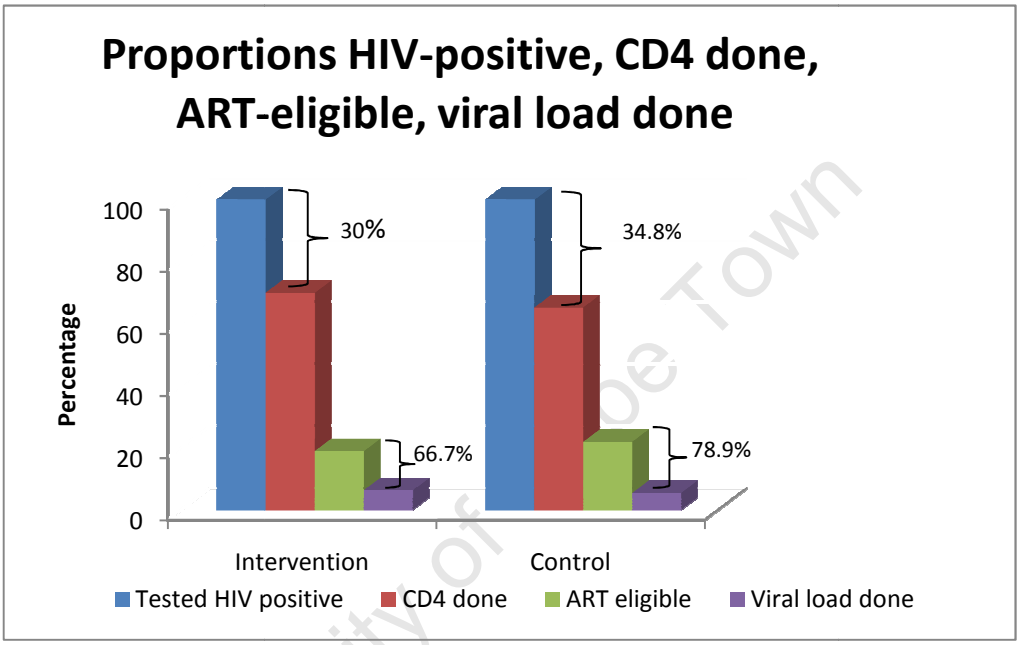


CD4 testing

PITC did not have a higher proportion of patients with CD4 testing done. As reported in Table 7 above, the difference between study arms in the proportion of HIV-positive patients with a record of CD4 testing was not significant: 69.9% or 228 patients in the intervention and 65.2% or 394 patients in the control sites (p = 0.507, z= -0.66). In Figure 5 below, this data is also presented as the percentage lost to follow-up, with 30% in the intervention and 34.8% in the

control arm of HIV-positive participants without any record of CD4 testing having been done. In the pooled analysis of both arms, the proportion with a record of a CD4 testing was 66.8% or 622 of the 930 HIV-positive patients.

**Figure 5: Proportion of people who tested HIV positive; proportion of HIV-positive patients with a record of CD4 testing; proportion of ART-eligible patients; and the proportion of ART-eligible patients with a record of viral load testing, by study arm**




In a small proportion of patients with CD4 test results (10% or 62 patients), the date of the CD4 test record preceded their HIV testing date. The most likely explanation for this is that these patients knew their status to be HIV positive but nevertheless re-tested for HIV during their STI consultation. There was no significant difference between intervention and control arms in the proportions of such 'known HIV positives' with 11.4% (26 patients) and 9.1% (36 patients) respectively ($p = 0.363$, Pearson $chi^2 = 0.8267$,). These 'known positive' patients were excluded from the analysis of the proportion with viral load testing and from timing of CD4 testing and timing of viral load testing because, in these cases, the patient's earlier CD4 testing may make them more likely to have accessed care by the time of the study than patients who did not know their status.

ART eligibility by CD4 value

The mean CD4 value of patients in the intervention arm was not higher than for those in the control arm. The difference between the median CD4 values (for those with CD4 records) in the two study arms was not significantly different, with similar median CD4 levels found in both arms (intervention = 386 cells/$mm^3$, IQ range 17–1509 and control = 364 cells/$mm^3$, IQ range 11–1445; p = 0.446, $chi^2$=0.581). In Figure 4, the proportions of patients with CD4 values in three categories from lowest to highest (≤200, 201-350 and >350 cells/$mm^3$) are shown by study arm. There was also no association between study arm and these CD4 categories**.** Using the highest CD4 category as a reference, there was no significant difference between arms for the lowest CD4 category (≤200 cells/$mm^3$, p = 0.578, z=0.56) and for the middle CD4 category (201-350 cells/$mm^3$, p = 0.672, z=0.42). Approximately 20% of patients in both arms had CD4 counts ≤200 cells/$mm^3$ and would have been considered eligible for initiation of ART according to the NDOH guidelines at the time of the study. When using the new WHO criteria adopted by the NDOH in 2010 (eligible if CD4 ≤350 cells/$mm^3$), close to half of STI patients in both study arms would be ART eligible (44% and 48% in intervention and control arms, respectively).

Viral load testing

Of the 622 HIV-positive patients with a record of a CD4 test, laboratory records for viral load testing were found for 13.5% or 84 patients, across both intervention and control sites. Of these 84 patients, 15 (17.5%) were identified as 'known HIV positives' and these patients are excluded from further analysis. There was no statistical difference between arms for the proportions of 'known HIV positives' (p = 0.822, Pearson $chi^2$ = 0.0508). The rest of the analysis is therefore based on the remaining 69 patients with viral load testing records.

In Figure 5 above, the proportion of ART-eligible patients with records of viral load testing is illustrated. The graph also indicates that this represents a substantial loss to follow-up of patients (66.7% in the intervention and 78.9% in the control sites) who did not have records of viral load testing after being found to be ART eligible.

For the pooled analysis (combining both arms), the proportion with a record of the viral load testing done (if CD4 test was done), was 12.3% for all CD4 categories combined. Across both arms, there was an association between CD4 category and having a record of a viral load test done. The higher the CD4 category, the less likely a patient was to have a record of viral load testing (p < 0.001, Pearson $chi^2$= 30.449).

There was a non-significant difference between the intervention arm and the control arm in the proportion of participants with a viral load record if all CD4 categories are considered (see Table 7, 14.9% in the intervention arm versus 10.9% in the control arm; crude OR = 1.43, p = 0.064, Z = 1.86). When only the ART-eligible category (CD4 ≤200 cells/mm$^3$) is considered, there was an absolute difference of 12% between arms in the proportion of patients who had a record of viral load test done (33.3% in intervention as compared to 21.1% in control). Two other CD4 categories (CD4 between 200 and 350 and CD4>350) did not show such large absolute differences (see Figure 4 for a breakdown of the numbers and percentages in each CD4 category with viral load records). The numbers in these three CD4 sub-groups, however, were too small to test for differences between arms statistically with confidence.

A multiple logistic regression analysis was run to assess the impact of the intervention while adjusting for confounders such as CD4 level, age, and gender. The analysis used a generalised linear models approach with adjustment for the clustering effect of clinics. To improve the simplicity and stability of the model, the CD4 categories (≤200, 201-350, >350) were collapsed into two groups (≤200, >200). The estimates of the regression models are presented in Table 8 below. Interaction effects between study arm and CD4 level (below and above 200) were investigated but found to be non-significant. Only the main effects model is reported below.



**Table 8: Logistic regression model of effect of study arm, CD4 level, age and gender on viral load record**

| Variable | Odds Ratio (95% CI) | p-value | Z test statistic |
|---|---|---|---|
| Intervention Arm | 1.45 (0.89 – 2.36) | 0.131 | 1.51 |
| ART-eligibility (CD4≤200) | 3.53 (2.13 – 5.87) | <0.001 | 4.88 |
| Age 25-35 (reference group: under 25) | 1.81 (1.25 – 2.62) | 0.002 | 3.12 |
| Age above 35 (reference group: under 25) | 3.27 (1.41 – 7.61) | 0.006 | 2.76 |
| Female | 2.32 (1.47 – 3.67) | <0.001 | 3.60 |

The regression analysis showed that the intervention was not associated with viral loads being done after adjusting for potential confounders of CD4 category, age and sex. ART eligibility

(CD4≤200) was significantly associated with more viral loads being done. These patients are sicker and should have been prioritised by health providers for ART initiation. Older patients also had significantly more viral loads done than younger patients. Those aged 25-35 had an odds ratio of 1.81 with respect to those under 25. Those aged above 35 had an odds ratio of 3.27 with respect to those under 25. This could be related to increased health-seeking behaviour of older people due to the progression of the disease. Finally, females had significantly more viral loads done than males. This could be related to the well-recognised increased utilisation of health services by women in this setting (Obermeyer & Osborn 2007).

Time to CD4 testing from HIV testing

The time from HIV testing to CD4 test measurement was not shorter for patients in the intervention arm. The difference between arms was not statistically significant, with a similar number of days found for both arms. The median time from HIV testing to CD4 testing in the intervention arm was 3 days (IQ range: 1–290 days) and 2 days in the control sites (IQ range: 1–337 days, HR: 0.907, CI: 0.599–1.373, p = 0.646).

As shown in Figure 6 below, the majority (up to 75%) in both arms (shown in the figure as initial numbers at risk, 159 and 239 patients) had a record of a CD4 test within 7 days of their date of HIV testing. This analysis only includes those patients who had a CD4 test done during the observation period. As mentioned earlier, the analysis excludes those whose CD4 testing record pre-dated their HIV testing.

Time to viral load testing from CD4 testing

When taking all CD4 categories into account, the patients in the intervention group did not have a shorter duration between the date of their CD4 measurement and the date of their viral load measurement. The difference between the study arms in the time from CD4 measurement to viral load measurement was not significant. The median time from date of CD4 testing to viral load testing in the intervention arm was 245 days (IQ range: 177–560 days) and 306 days in the control sites (IQ range: 195–550 days, HR: 0.892, CI: 0.566–1.403, p = 0.622). As shown in Figure 7 below, there was a steady progression over time in the proportions of patients with viral load tests done in both arms (initial numbers at risk: 30 in intervention and 39 in control).

However, when focussing on those patients who were ART-eligible based on low CD4 count (CD4 ≤200 cells/mm$^3$), the study found that patients in the intervention group had a significantly shorter duration between their date of CD4 measurement and their date of viral load measurement, as shown in Table 7 above (row 10) and Figure 8 below (initial numbers at risk: 13 in intervention and 16 in control). The median time in the intervention arm was 214 days (about 7 months) and 288 days in the control arm (about 9.4 months) with an absolute difference of approximately two and a half months between the two arms (HR: 0.417, CI: 0.221– 0.784, p = .007).

**Figure 6: Kaplan-Meier plot of time to date of CD4 test done, from date of HIV testing for HIV positive patients with CD4 test records, by study arm**



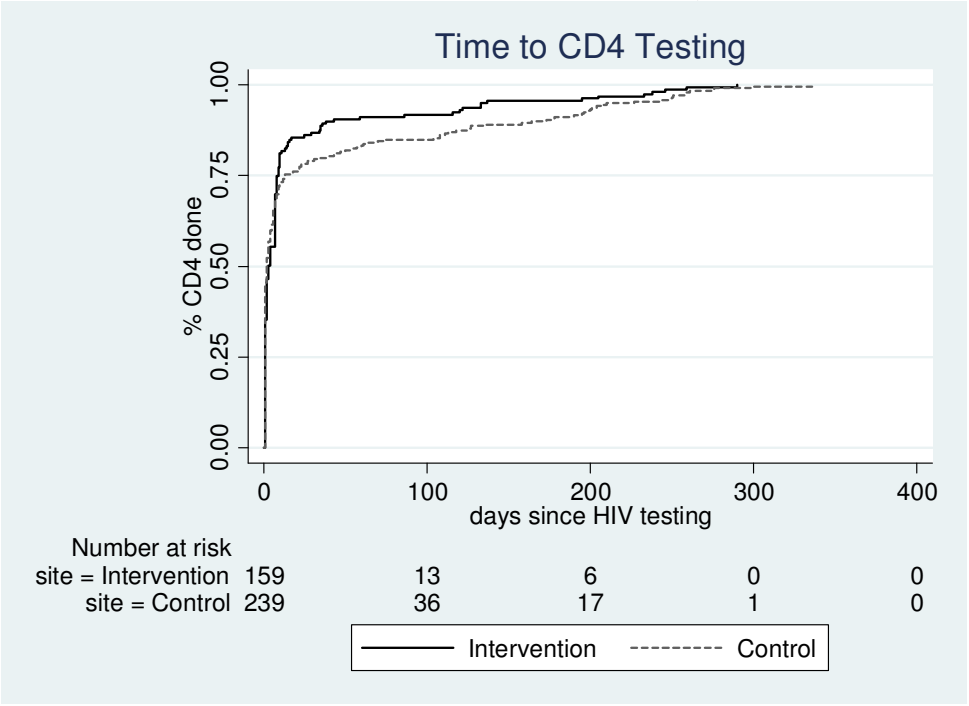


**Figure 7: Kaplan-Meier plot of time to viral load measurement, from CD4 measurement, for HIV positive patients with viral load records, by study arm**

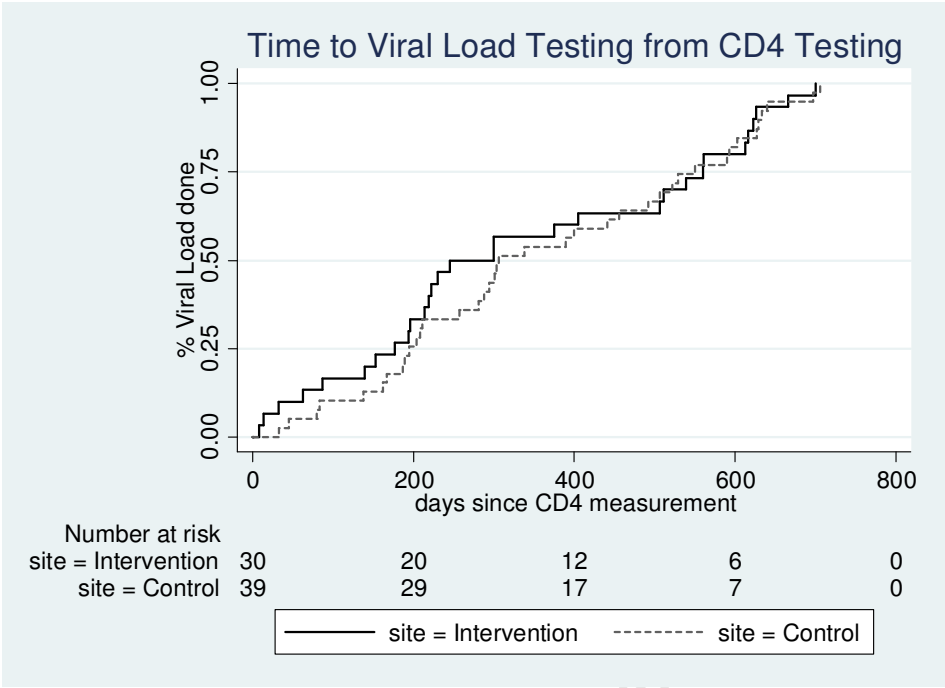
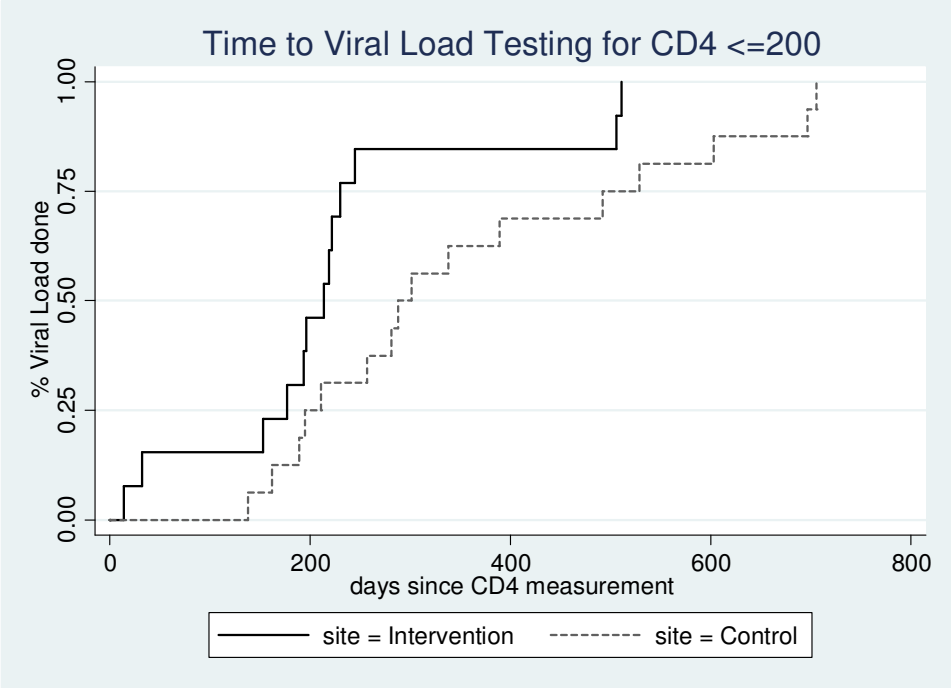



**Figure 8: Kaplan-Meier plot of time from CD4 measurement to viral load measurement for ART-eligible patients, by study arm**



## Discussion

This sub-study examined follow-up care for the 930 HIV-positive patients that were identified in the controlled trial on increasing testing rates (see Chapter 2). The sub-study assessed whether the PITC approach increased access to HIV care for HIV-positive patients in terms of their access to CD4 testing and viral load testing, as compared to HIV-positive patients identified through VCT. Using laboratory records of CD4 and viral load testing as indicators of access to HIV care, the study found that the PITC intervention did not significantly increase access to HIV care, except on one of the indicators. The proportion of HIV positive patients with a record of a CD4 measurement was not significantly greater in the PITC intervention, and the time from HIV testing to CD4 measurement was not quicker for those in the intervention group. In both arms, approximately two-thirds of HIV-positive patients had a record of CD4 testing which was available within 2 to 3 days from HIV testing. Patients in the intervention group also did not have greater access to viral load testing. Less than 15% of all those with CD4 testing had a viral load test done across both arms. For ART-eligible patients (CD4 ≤200 cells/$mm^3$), approximately one third had a viral load test done in the intervention group and about one fifth in the control, but the numbers were too small for a meaningful statistical comparison. Finally, the study found that for ART-eligible patients, the time from CD4 measurement to viral load measurement was significantly shorter in the intervention arm. ART-eligible patients in the intervention arm had viral load testing done on average two and half month's quicker than patients in the control arm.

The findings in this study are in line with the limited evidence available that indicates that there was no decrease in access to ART following the introduction of a PITC approach with antenatal patients in Zimbabwe and Botswana (Chandisarewa et al. 2007; Creek et al. 2007) and access to cotrimoxazole prophylaxis for HIV-positive TB patients in the Eastern Cape province of South Africa (Pope et al. 2008). However, this sub-study is amongst the first to report that ART eligible patients had quicker access to viral load testing. If access to viral load testing is taken as an indicator of patients having been initiated on ART, then this finding would suggest that patients may have been initiated on ART quicker in the clinics with a PITC approach as compared to the clinics with a VCT approach. Thus, PITC may hold the promise of benefiting those HIV positive patients most in need of quick access to ART.

In sum, in this sub-study, patients diagnosed HIV positive via the PITC approach did not have increased access to CD4 and viral load testing (as compared to the VCT approach), but the ART-

eligible patients had quicker access to viral load testing. The findings of no difference between the two arms could also be interpreted as a favourable outcome in terms of scaling up PITC interventions in this setting. What it means is that the increased numbers of patients that tested HIV positive in the PITC arm were not worse off in terms of access to care compared to those who tested in the VCT approach and that in effect, a greater number of HIV positive patients would have been able to access the same level of care as patients in VCT clinics. Nevertheless, others could argue that since PITC aims to diagnose more HIV-positive patients, a finding of equal access to care (or equally limited access to care) still presents an ethical dilemma since a greater number of HIV-positive patients would be exposed to the existing gaps in HIV follow-up care. One could argue, though that this ethical dilemma would, however, not be unique to the PITC approach, but to any HIV testing approach that aims to increase test uptake.

The median CD4 value of patients diagnosed HIV positive in the PITC arm was also not significantly different from that in the VCT arm (intervention CD4 = 386 cells/$mm^3$ and control CD4 = 364 cells/$mm^3$). For instance, for those with CD4 records, similar proportions of patients in both arms were found across CD4 categories, with approximately one fifth being eligible for initiation of ART (CD4 ≤200 cells/$mm^3$). Using the latest WHO CD4 criteria (CD4 ≤350 cells/$mm^3$), close to half in both arms were eligible for ART. These findings suggest that in the PITC intervention, HIV patients were not being diagnosed at an earlier stage of HIV illness as some would have hypothesised. One possible reason is that STI patients are a high-risk group and the high levels of HIV prevalence found in this group may account for the similar CD4 profiles found in this study. The increased test uptake in the PITC trial (reported in Chapter 2 of this thesis) may also not have been large enough to capture a broader and potentially lower-risk patient group.

The proportions found to be ART eligible and the median CD4 counts in this study are similar to those reported in other low-, middle-, and high-income countries (Althoff et al. 2010; Braitstein et al. 2006; CDC 2003; 2009; Connelly et al. 2007; Fairall et al. 2008). The range of CD4 levels in this study is also consistent with those measured in South Africa between 2002 and 2005 that showed 10-22% of participants had CD4 counts below 200 cells/$mm^3$, 19-28% had CD4 counts of 200–349 cells/$mm^3$,and 18-26% had CD4 counts of 350–499 cells/$mm^3$ (Adam & Johnson 2009).

There was no significant difference between PITC and VCT approaches in the time taken from HIV testing to CD4 measurement, with the majority of patients (up to 75%) having a CD4 test

measurement within 7 days of their HIV diagnosis. The median time from HIV testing to CD4 testing in the intervention arm was 3 days and 2 days in the control arm, which indicate that, in the main, staff requested the CD4 test on the same day that the HIV testing was done. Of interest is that the study found that there was significantly less delay in the time between CD4 testing and viral load testing for the ART-eligible patients in the PITC arm, with a difference between the arms of nearly two and a half months. The difference in timing is difficult to interpret given that viral load testing records were a mix of baseline and post-ART-initiation testing. This finding is also based on small numbers at risk and might be due to chance. It would be useful to explore this in future studies of PITC because if confirmed, it would mean that PITC holds the promise of quicker access to care.

Linkage to care immediately or shortly after care has been recommended as one of the strategies to increase access and continuity of care (CDC 2009; Torian et al. 2008). The majority of patients in this sub-study (over two thirds) had CD4 tests done and up to 75% had CD4 measurement within 7 days of testing. It is likely that staff took blood samples for CD4 testing immediately after the patient tested for HIV and this accounts for the CD4 testing rate and the short time period. A cohort study of patients diagnosed HIV positive between 2006 and 2007 in South Africa found that nearly half (45%) were lost to-follow-up (defined as the absence of a CD4 count up to 8 weeks after diagnosis) (Losina et al. 2010). Loss-to follow-up in their study was associated with being ten or more kilometres from a health centre, having a history of TB treatment, and being referred by a health provider for HIV testing rather than being self-referred. The authors suggested that patients who are self-referred for an HIV test may be more motivated to seek follow-up care than those who are referred by a physician and that the latter group may need more time to come to terms with their diagnosis. They also speculated that medically referred patients may be more ill and therefore more likely to have died.

By contrast, another South African study by Kranzer and colleagues found that patients who self initiated HIV testing had the poorest access to CD4 testing compared to other groups that may have more routine access to testing such as antenatal and TB patients and those who might consider themselves high risk like STI patients (Kranzer et al. 2010). Antenatal patients and TB patients who were ART eligible also had better access to ART than STI patients and those learning of their status through the VCT approach which suggest that those testing through more routine clinical care may have an advantage when it comes to linkage to care.

However, this advantage may also be as a result of pregnant women and TB patients having been prioritised for integrated HIV care and not as a result of the approach to HIV testing. Either way, there is a need for health providers to make more effort with linking patients to care with provider-initiated testing approaches such as the one examined in this sub-study. For instance, a recent Thai study reported that over 90% of newly diagnosed HIV-positive patients at a stand-alone HIV testing centre accessed CD4 testing within 1 month of HIV testing, largely due to persistent reminders by staff (Phanduphak 2011).

Another finding is that there was an inverse association between CD4 level and a record of viral load test done, with the lowest CD4 category having a higher likelihood of having a record of viral load testing. Older patients were more likely to have a viral load test done than younger ones. Females were more than twice as likely as males to have a record of viral load testing. This may have to do with the health seeking behaviour of older people and females (Obermeyer & Osborn 2007). The higher viral load testing done for ART-eligible patients compared to those with higher CD4 counts found in this study is reassuring as these patients are sicker and in more urgent need of care. Their increased access to viral load testing might be because of a combination of staff prioritising their referral to ART and their own recognition of the urgency of their health care needs.

The proportions of ART-eligible patients with viral load testing in this study, 33 % in the intervention arm and 21% in the control arm, and the pooled proportion of 28%, is lower than estimates for ART coverage for the Western Cape. Several other estimates of ART coverage (calculated as the number of patients on ART as a proportion of those HIV-positive patients who were diagnosed as being ART eligible) in the Western Cape have come up with significantly higher rates. A study modelling ART coverage in South Africa in 2008 for both the public and private sectors (using CD4 criteria and WHO HIV disease stage IV), estimated a wide range for ART coverage from 26% in the Free State to 72% in Western Cape, with a national average of 38% (Adam & Johnson 2009). Health authorities and researchers jointly estimated a 64% ART coverage for the Western Cape in 2007/08 (University of Cape Town 2008).

There are a few reasons why the 28% figure for ART initiation in this sub-study may be underestimating of the true proportion of ART-eligible patients who initiated ART. Firstly, the study used a laboratory record of a viral load test as an indication of a patient having been initiated on ART and it is likely that this source of information may not be capturing all patients

on ART. A recent review using routine monitoring information of a large South African cohort of patients on ART found that only 80% had a record of a CD4 test and only 60% had a record of viral load testing (Fatti et al. 2010). Secondly, in this sub-study, when someone did not have a record of a CD4 test done, their name was not included in the search for a viral load testing, which could have excluded a number of patients on ART (who may have had missing CD4 but had a viral load record). Thirdly, patients in this study may not have been followed up for long enough. For instance, all ART-eligible patients were followed for a minimum of 12 months after CD4 testing, which is required if one assumes ART initiation 3 months after CD4 testing and a test to ascertain viral load 6-9 months later. This minimum follow-up period, however, may have missed some patients who did receive viral load tests shortly after the prescribed 9 month period.

Using the information on missing CD4 and viral load testing for patients on ART in the Fatti et al. study referred to above, one could assume that this sub-study underestimated the true proportion of patients who may be on ART. This study's numerator (those with CD4 and viral load records) clearly only captures a portion of patients actually on ART. Adjusting this numerator up would bring the ART coverage figure up. When accounting for the drop-off of those not captured due to short follow-up, one could project an even higher estimate, one that would perhaps be closer to the 64% estimate in the Western Cape in 2007/08.

In this sub-study, approximately one third of HIV-positive patients did not have a record of a CD4 test being done. This is similar to the figure reported in a community-wide study of access to care in Cape Town. In 2006, only 62% of those diagnosed HIV positive received a CD4 test within 6 months of diagnosis (April et al. 2009), representing a loss to follow-up care of roughly one third. More critically the study points to a substantial loss to follow-up care for a large group of ART-eligible patients. The Losina et al study (2010) on loss to follow up in the pre-ART period found that nearly half did not have a CD4 count 8 weeks after HIV testing. Failure in linkage to care for the most medically vulnerable patients needs urgent attention as it could have fatal consequences given the high mortality among HIV-positive patients, especially in sub-Saharan Africa (Braitstein et al. 2006; CDC 2003; Cornell et al. 2010; Fairall et al. 2008; Gerver 2008; Lawn et al. 2008; Rosen et al. 2007). The consequences of poor linkage to care is illustrated by a South African study of ART-eligible patients followed up for one year in 2005 in the Free State province that showed that half had died and that most of those who died (86%) had not accessed ART (Fairall et al. 2008). Once on ART, up to 20% of patients died within the first year

of treatment, mainly due to late diagnosis and the severity of AIDS illness (which are also indicators of poor access to testing and poor linkage to ART).

Nevertheless, for those retained in care, studies in South Africa have shown excellent clinical outcomes including significant reduced mortality (Boulle et al. 2008; Cornell et al. 2010; Fairall et al. 2008; Fatti et al.; Rosen et al. 2007). There are, however, indications that the treatment gap may be increasing between those newly diagnosed as ART eligible and those initiated onto ART (University of Cape Town 2008) and that the size and pace of the scale-up may be responsible for increasing rates of loss to follow-up. For instance, enrolments of patients on ART has increased 12 fold over 5 years, 63% of whom enrolled in the last 2 years. The loss to follow-up rates increased annually from 1% in 2002/2003 to 13% in 2006 (Cornell et al. 2010). It is likely that increased HIV case detection through PITC could become a source of increased pressure on HIV follow-up care.

Studies have identified a number of reasons for poor access to HIV care. These include individual patient factors (such as disease stage and health seeking behaviour), structural factors (many due to poverty such as transport, financial and other access barriers) and health systems factors (such as constraints to delivering services). A literature review of utilisation of HIV-related services suggested that utilisation can be enhanced by factors such as health insurance, social support, adequate housing and accessible transportation (Uphold & Mkanta 2005) and other reviews of LMICs support the findings that free access to HIV care services improves retention in care (Braitstein et al. 2006; Rosen et al. 2007).

A range of health systems measures have been recommended to increase access to HIV follow-up care. These include expanding the number of primary health care sites, increasing the service capacity at these sites, increasing human resources for health, task shifting to nurses, strengthening managerial capacity, improving patient tracing and referral mechanisms, and range of strategies to retain patients in care (such as same-day appointments, point of care CD4 testing, reductions in waiting times, reminder notices for visits, and educational programmes to enhance staff friendliness) (Boulle et al. 2008; Losina et al. 2010; Rosen et al. 2007; Schneider et al. 2010; University of Cape Town 2008; Uphold & Mkanta 2005). A recent multi-national study in the US, Canada, Brazil, and Australia reported that social and economic circumstances appeared to have a major impact on HIV treatment outcomes, with women doing worst and black people in the South of the US doing the worst of all (Armstrong & Del Rio 2011). The

authors note that differences in outcome of HIV-related illness were unlikely to have biological causes but are the result of socio-economic circumstances (including access to health services, health behaviours, lifestyle, and environmental factors) that will require multiple strategies that go beyond the health care system.

There are indications that in South Africa, implementation-level factors influence uptake of HIV care. These include those related to managerial leadership of programmes, programme design and flexibility, and effectiveness of monitoring and evaluation systems and partnerships (Schneider et al. 2010). In addition to addressing these broader organisational factors, expanded HIV testing intervention may need to build into their design, steps to promote linkage to care for HIV-positive patients. These could include same-day CD4 testing, facilitating the referral and initial contact with HIV care services (including same day appointments), ensuring that patients are informed of their test results, establishing mechanisms for contacting patients and reinforcing the importance of follow-up care (Losina et al. 2010; Obermeyer & Osborn 2007; Rosen et al. 2007). A large proportion of HIV-positive patients are not eligible for ART and expanded HIV testing should also be accompanied by efforts to retain these individuals in care through education and regular health monitoring (April 2010; CDC 2009; Kranzer et al.; Losina et al. 2010; Richter 2006; Strode et al. 2005).



Strengths and limitations of this sub-study

This was a comparative observational study using clustered data from the controlled trial that was reported in Chapter 2. The trial was not designed to measure access to care as a primary outcome and so the sample sizes did not allow for robust statistical analysis. However, the trial did produce sufficient numbers to evaluate some of the main access to care outcomes reviewed here. There was a potential underestimation of access to ART for those who did not have a record of CD4 testing. The study was not able to examine the differential impact in sub-groups. For example, the sample size for those with viral load tests was too small to allow for a sub-group analysis for the three different CD4 categories. Although the numbers are small, the patients are drawn from the same pool of patients who participated in the non-randomised cluster controlled trial, which improves the general applicability of the findings. The matching process for linking laboratory records to patient names was blind for study arm, which is also strength of the study.

The use of laboratory records as an indicator for access to HIV care could have affected the estimations in this study. Based on the quality checks performed during the data search and matching process, there may also have been a 5% underestimate of CD4 records when searching the NHLS database. Also, evidence emerged subsequent to the study indicating that for a proportion of ART patients, no clinic-based record of viral load testing can be expected (Fatti et al. 2010). This study was not able to distinguish between viral load records at baseline and viral load records for those on ART due to changes in the clinical protocol during the study. This made the findings on viral load testing difficult to interpret.

The follow-up period for observing CD4 and viral load test records was not standardised for each patient which meant some in the study had a shorter follow-up period than others. The follow-up period was adequate to allow for the delivery of CD4 testing (a minimum of 6 months since HIV testing was allowed), but it may not have been long enough to provide a full 9 months of follow-up for all patients diagnosed as ART eligible. The finding that ART-eligible patients had significantly quicker viral load testing done was based on small patient numbers and this issue should be investigated in larger scale studies of PITC.

Finally, the study was not able to ascertain what proportion of patients who had CD4 records returned to get their CD4 test result and was not able to examine the reasons for the loss to follow-up care or the quality of care received. Studies using a longitudinal study design that can track patient care prospectively and/or retrospectively, could address some of the limitations identified in this study.



## Conclusion

The PITC approach did not show a significantly increase in the proportion of HIV positive patients who accessed CD4 and viral load testing compared to the VCT approach. There was also no difference in terms of how early the diagnosis of HIV was made, on the HIV disease profile of the two groups, or on the time between HIV testing and CD4 testing. These findings are in line with the limited available evidence that the routine 'opt-out' HIV testing does not impact on the level of access to HIV care for HIV-positive patients. However, for patients who were ART-eligible, the PITC intervention had a significantly shorter time from CD4 to viral load testing, which suggests these patients may have been initiated on ART quicker than patients in the VCT approach. In

this setting, PITC may therefore hold the promise of additional benefits beyond increased HIV test uptake and this should be investigated on a larger scale.

The study pointed to loss to follow-up care for both arms before accessing CD4 testing and even more so once diagnosed as ART eligible, areas that require increased efforts to improve linkage to care shortly after HIV diagnosis. Expanded HIV testing strategies such as PITC should be designed with explicit steps that can promote follow-up care (including immediate CD4 testing, tracing mechanisms to ensure the test results are communicated, immediate linking to ART services for ART-eligible patients, and constant reinforcing messages on follow-up care).

Although the levels of access to HIV follow-up care are reported here, the study was not able to examine the appropriate levels and quality of care and this could be a topic for future research. Further studies would also be useful to explore which factors (patient, structural, and health systems) are most important at various stages of care in determining loss to follow-up for newly diagnosed STI patients, and to support the development of strategies to improve uptake of HIV treatment, care, and prevention services. In the next two chapters, the ethical implementation of and patient satisfaction with the PITC intervention is explored, issues that are important in themselves, but that might also have a bearing on patient willingness to return for follow-up.

# CHAPTER 4: INFORMED CONSENT AND PROVIDER-INITIATED HIV COUNSELLING AND TESTING

Widespread ethical concerns have been raised about the implementation of PITC and in the previous chapter, one of these concerns, the impact on access to care, was examined. In the next two chapters, these ethical concerns will be examined further in a sub-study evaluating patient informed decision-making. Chapter 4 will provide a literature review and review the methodology of the sub-study and Chapter 5 reports on the findings and conclusion.

## Background

As noted earlier, the WHO/UNAIDS recommendations for the implementation of a provider-initiated HIV testing and counselling (PITC) approach to HIV testing have drawn renewed attention to the ethics of HIV testing. The key concern is whether individual patient rights, and in particular the right to decline testing, would be upheld in settings where issues such as high HIV prevalence, asymmetry of power-relations between health providers and patients, and resource constraints may become pressures that could compromise informed consent (Bayer & Edington 2009; Becker et al. 2009; Crewe & Viljoen 2005; Nieburg et al. 2005; Obermeyer & Osborn 2007; Rennie & Behets 2006; Strode et al. 2005; UNAIDS Reference Group on HIV and Human Rights 2007).



The debate about the ethical application of PITC has been based largely on philosophical, moral, ideological, and legal principles without the benefit of empirical evidence on the ethical implementation of PITC. Several authors who have reviewed literature on HIV testing utilisation and on ethical concerns around expanding HIV testing have called for studies on the application of PITC in practice to allow for an evidence-based bio-ethics to inform the debate (Beardsell & Coyle 1996; Halpern 2005; Jürgens 2006; McQuoid-Mason 2007; Obermeyer & Osborn 2007; Rajkumar 2006; Rennie & Behets 2006; Richter 2006; Strode et al. 2005). As Obermeyer has noted:

> *"The acute need to balance efforts to scale up testing with the protection of individual rights has repeatedly been underlined, and empirical evidence on practices and attitudes*

*in multiple settings is needed to identify innovative ways to adapt ethical principles to local situations."* (Obermeyer & Osborn 2007:1769)

These concerns underscore the need to know more about how the PITC guidelines proposed by WHO/UNAIDS are implemented in practice in different settings. The aim of this sub-study is to examine the implementation of a PITC intervention in a LMIC setting with respect to patient experiences and provider practices. By looking at how PITC is implemented in a routine setting, it will be possible to assess the extent to which the ethical concerns about informed consent are an issue in practice in this setting and also to gain insights into the values and preferences of those involved.

This sub-study examines informed consent from the 'internal perspective' of the patient and the 'external perspective' of the researcher, often referred to in qualitative research as the emic and etic views, respectively (Morris et al. 1999). Using a combination of etic and emic perspectives contributes to the researcher's ability to make judgments about the extent to which the application of PITC observed in this setting is congruent with ethical principles and concerns.

This literature review describes the historical roots of the ethical concerns and the bio-ethical principles that have come to shape the way in which ethical debates on PITC have been conducted. The range of ethical concerns will be described and the focus on informed consent will be clarified. In a review and critique of the empirical studies on informed consent, Meisel and Roth (1983) highlighted the conceptual and methodological difficulties of obtaining and researching informed consent. Their review has proven to be one of the most comprehensive and critical assessments of the informed consent literature. They argued that to improve the quality of investigations into informed consent, they recommended that researchers "must define the concepts they are investigating or at least acknowledge the difficulties of doing so" (Meisel & Roth 1983:338). This literature review identifies some of the conceptual and methodological challenges of studying informed consent in this context in an attempt to avoid some of the pitfalls identified by Meisel and Roth. It concludes by outlining a multi-dimensional conceptual framework of informed decision-making that is then used to guide the analysis and interpretation of the findings of this study in Chapter 5.

Bioethics, informed consent and the rights-based approach

The debate about the ethics of HIV testing is not a new one but it has received renewed attention with the WHO/UNAIDS recommendation for expanded HIV testing. HIV testing has been ethically complex since its introduction in the mid-1980s. As described in Chapter 1, specific features of HIV and AIDS, such as the stigma associated with it, the absence of a cure, and the lack of a legal framework to protect the rights of HIV-positive individuals, created the need for exceptional ethical requirements. Concern about these special features led to the adoption of the 'VCT approach' to testing. VCT emphasised the need for individual protection of autonomy and privacy (including self-initiated testing and heightened requirements for counselling, consent, and confidentiality).

The rapid growth of the epidemic and the advent of ART, however, contributed to a shift towards expanded testing and the 'normalisation' of HIV testing as part of standard medical care. PITC represents one such approach to expanding HIV testing where, as noted earlier, providers offer every patient HIV testing and is geared towards rapidly increasing test uptake rates in medical settings. PITC streamlines the HIV testing approach (by, for example, not requiring pre- and post-test counselling), is routinely offered to all patients, does not require written consent, and requires that the patient 'opt-out' of HIV testing as a standard practice. These elements have elicited a range of concerns about the ethics of PITC. The specific ethical concerns are summarised in Table 9 and will be addressed later.

The ethical debate around PITC is informed by bio-ethical principles that guide medical practice and medical research and that are geared towards protecting patients and research participants from harm or exploitation (Bayer & Edington 2009; Bayer & Fairchild 2006; Jürgens 2006; McQuoid-Mason 2007; Rennie & Behets 2006; UNAIDS Reference Group on HIV and Human Rights 2007). These principles include patient autonomy, beneficence, non-maleficence, and justice (McQuoid-Mason 2007). Patient autonomy relates to upholding the individual's right to have control over their own bodies which would include the right to refuse medical intervention such as HIV testing. The principle of beneficence requires that health professionals do good for their patients by, for example, upholding the patient's right to access health care. Non-maleficence is a related ethical principle that requires that health workers 'do no harm' and could include the right to an environment that is not harmful to the individual. The ethical principle of justice requires that all patients are treated equally and fairly. This would prohibit

discrimination on the grounds of, for example, gender, age, or ethnic origin (McQuoid-Mason 2007).

While these principles are used to ground ethical debates, they do not necessarily assist with resolving the debate, hence the call for evidence on the ethical implementation of PITC (Crewe & Viljoen 2005; Jürgens 2006; Obermeyer & Osborn 2007; Rajkumar 2006; Rennie & Behets 2006). In a discussion of the ethical and legal implications of routine HIV testing in South Africa, McQuoid-Mason (2007) argued that the application of these principles to HIV testing may depend on how different groups interpret the same bio-ethical principles. So, for instance, some would argue that PITC may compromise the ethical principles of autonomy, privacy, and justice (AIDS Legal Network 2005; Bayer & Fairchild 2006; Canadian HIV/AIDS Legal Network 2005; Crewe & Viljoen 2005; Rennie & Behets 2006; UNAIDS Reference Group on HIV and Human Rights 2007) while others argue that by not routinely providing HIV testing in medical settings, the same ethical principles are being violated (especially the principles of beneficence and non-maleficence) because it deprives individuals of the right to health care (April 2010; De Cock & Johnson 1998; De Cock et al. 2003; De Cock et al. 2006; De Cock et al. 2002; Frieden et al. 2005; Koo et al. 2006; Strode et al. 2005).

The key ethical concern about PITC appears to be that informed consent for HIV testing will be compromised. This has been expressed as primarily a concern about upholding an individual's right to autonomy. Autonomy is a guiding principle in international human rights declarations. The individual right to autonomy includes the right for patients to decide for themselves what medical treatment they will choose, even if their choice is not to benefit from interventions that could help them. The Bill of Rights in the South African Constitution also protects this principle of autonomy in its statement of the right to dignity, life, bodily integrity, and privacy (South African Government 1996).

The debate on informed consent in PITC has not only focused on the need for patient autonomy but also on how the individual's right to autonomy should be weighed against the group or public's right to be protected from disease. This is often framed as a debate between an individual human rights perspective (to protect patient autonomy) versus the public health right to be protected from HIV infection. Put another way, the right of the individual not to know their HIV status is being set in relation to the right (and obligation) of health services and governments to develop measures to control epidemic disease and protect public health.

The WHO has also in recent years increasingly argued for the individual's right to know their status (as opposed to their right *not* to know) (World Health Organisation 2003). The argument here is that health personnel should regard offering HIV testing as a positive duty in relation to the ethical imperative of beneficence. From this perspective, not offering HIV screening for a fatal but treatable disease could be considered as medical neglect (April 2010; De Cock & Johnson 1998; De Cock et al. 2003; De Cock et al. 2006; De Cock et al. 2002; Frieden et al. 2005; Koo et al. 2006; Strode et al. 2005).

The WHO/UNAIDS guidelines to scaling up the response to the HIV epidemic have tried to balance these different perspectives and have proposed a 'rights-based' approach to doing so. The guidelines recommend that HIV testing be done in an ethical way that encompasses respect, protection, and fulfilment of human rights norms and standards (World Health Organisation/UNAIDS 2004). The principles of the VCT approach (the three C's of ethical testing: informed consent, confidentiality and counselling) should remain integral to PITC. This 'rights-based' approach to HIV care and HIV testing proposed by WHO/UNAIDS involves five elements as listed in Box 2 below.



**Box 2: Ensuring a rights-based approach to HIV care and HIV testing**

The global scaling up of the response to AIDS, particularly of HIV testing as a prerequisite to expanded access to treatment, must be grounded in sound public health practice and also the respect, protection, and fulfilment of human rights norms and standards. The voluntary nature of testing must remain at the heart of all HIV policies and programmes, both to comply with human rights principles and to ensure sustained public health benefits.

The following key factors, which are mutually enforcing, should be addressed simultaneously:

1. Ensuring an ethical process for conducting the testing, including defining the purpose of the test and the benefits to the individuals being tested; and assurances of linkages between the site where the test is being conducted and relevant treatment, care and other services, in an environment that guarantees confidentiality of all medical information.
2. Addressing the implications of a positive test result, including non-discrimination and access to sustainable treatment and care for people who test positive.
3. Reducing HIV/AIDS-related stigma and discrimination at all levels, notably within health care settings.
4. Ensuring a legal and policy framework within which the response [to AIDS] is scaled up, including safeguarding the human rights of people seeking services.
5. Ensuring that health-care infrastructure is adequate to address the above issues and that there are sufficient trained staff in the face of increased demand for testing, treatment, and related services.

(World Health Organisation/UNAIDS 2004)

The reassurances by WHO (in the above guidelines and in the PITC guidelines) have not satisfied all concerns regarding the ethical implementation of PITC in LMICs. It has been argued that in LMICs, many of which are also high HIV prevalence countries, efforts to increase HIV testing uptake could lead to health care practitioners 'desperately seeking targets' for HIV testing uptake (Rennie & Behets 2006). This may lead to the compromising of autonomy, privacy, and justice. The potential harms that may arise from routine screening include coercion by health personnel, clients fearing negative consequences if they refuse testing, confidentiality breaches, and lack of post-test support (AIDS Legal Network 2005; Becker et al. 2009; Buchanan 2005; Canadian HIV/AIDS Legal Network 2005; Rennie & Behets 2006; Richter 2006; UNAIDS Reference Group on HIV and Human Rights 2007).

There is acknowledgement by some that concerns about informed consent are also relevant in high-income countries because the power imbalance inherent in most medical consultations poses a danger to obtaining informed consent (Obermeyer & Osborn 2007). Nevertheless, ethical concerns regarding PITC have been predominantly focused on its implementation in LMICs for a range of reasons, as noted by Rennie and Behets:

> *"In settings marked by poverty, weak health-care and civil society infrastructures, gender inequalities, and persistent stigmatization of people with HIV/AIDS, opt out HIV-testing policies may become disconnected from the human rights ideals that first motivated the calls for universal access to AIDS treatment"* (Rennie & Behets 2006:52).

The most common reason cited for this focus on the dangers of PITC in LMICs is the perception that the power imbalance between patients and providers is more pronounced in such settings, partly as a result of the social and health system factors noted by Rennie and Behets above. High HIV prevalence countries are faced with poorly functioning health systems and overburdened staff which reduces access to quality health care for patients. The fear is that in such resource-constrained settings, not only is the potential for harm from ethical breaches increased but the harm may worsen as the PITC intervention is taken to scale and as supervision and support for such programmes is reduced (Becker et al. 2009; Evans & Ndirangu 2008; 2009; Jürgens 2006; Nieburg et al. 2005; Rajkumar 2006; Richter 2006; Strode et al. 2005). So, while there appears to be agreement on the need for expanding HIV testing and counselling in high-prevalence

countries, authors have cautioned that this should be monitored systematically through research:

> *"Whenever routine HIV-testing policies are introduced in resource-poor countries…their effect on individuals and communities should be the subject of empirical research, human-rights monitoring and ethical scrutiny"* (Rennie & Behets 2006:52).

The concerns about informed consent have several underlying concerns and critiques of PITC often identify all or some of the following issues. It is feared that the traditional hierarchical power imbalances in the medical encounter may make it difficult for patients to exercise their right to refuse testing when it is offered by a clinician. The manner in which the HIV test is offered (for instance, if providers recommend testing) may unduly influence patients to accept testing. A related fear is that providers may become less conscious of the need for ethical protection, whether because they are overburdened or because of reduced sensitivity to ethical practice. This may then develop into HIV testing becoming mandatory in practice, which all agree is unethical (Bayer & Edington 2009; Jürgens 2006; Obermeyer & Osborn 2007; Rajkumar 2006; Rennie & Behets 2006).



Ethical concerns about PITC – the evidence

The wide range of ethical concerns about PITC, some of which are interrelated, makes it difficult to investigate the ethics of PITC systematically. For instance, to investigate whether individual rights are sufficiently respected, clarity is required about which concerns are being raised in relation to which aspects of the HIV testing process (UNAIDS Global Reference Group on HIV/AIDS and Human Rights 2003). Concerns can relate to the purpose of testing, the implications of the HIV test result, and the implementation of the HIV testing process in practice.

In Table 9 below, the range of ethical concerns is described (and categorised according to the relevant aspect of the HIV testing process) and the available evidence is summarised. Another challenge in resolving these ethical debates is the limited available empirical evidence about the actual implementation of PITC. For an overview of the ethical concerns identified in the table below, see: (AIDS Legal Network 2005; Bayer & Edington 2009; Becker et al. 2009; Canadian HIV/AIDS Legal Network 2005; Crewe & Viljoen 2005; Evans & Ndirangu 2009; Jürgens 2006; McQuoid-Mason 2007; Obermeyer & Osborn 2007; Rajkumar 2006; Rennie & Behets 2006; Richter 2006; Strode et al. 2005; UNAIDS Reference Group on HIV and Human Rights 2007).

**Table 9: Ethical concerns regarding PITC and the evidence available in relation to these**

| Ethical concerns | Evidence |
|---|---|
| **<u>HIV positive patients may not have access to HIV treatment</u>**<br>• This is a concern that relates to both the purpose of HIV testing and implications of testing HIV positive<br>• The aim of expanded HIV testing is to increase the number of people who know their HIV status. Early diagnosis and access to care to reduce morbidity and mortality and HIV transmission. This is the strongest argument for PITC. The concern is that most people diagnosed HIV positive do not have access to HIV treatment and that expanding HIV testing will increase the numbers without access to HIV care, especially in LMICs. The benefits of knowing one's HIV status in the absence of access to ARV treatment is brought into question. | • In terms of the implication of knowledge of HIV positive status, evidence indicates PITC can reduce HIV transmission, especially in sero-discordant couples but the impact is unclear for HIV negative people (Marks et al. 2005; Voluntary HIV-1 Counseling and Testing Efficacy Study Group 2000).<br>• There is evidence that PITC does increase uptake of HIV testing (WHO/UNAIDS 2007) which would result in more people being diagnosed HIV positive. The limited evidence available indicates no difference in access to HIV care based on the approach to HIV testing (Chandisarewa et al. 2007; Creek et al. 2007).<br>• There is a gap in access to ART for HIV positive people globally, but that is higher in LMICs (Braitstein et al. 2006; Uphold & Mkanta 2005). |
| **<u>PITC could increase stigma and discrimination for newly diagnosed patients.</u>**<br>• This is a concern related to the implications of testing HIV positive as well as to how the process of HIV testing is handled by providers.<br>• The concern is about the potential for increased involuntary disclosure of HIV positive results (accidental or intentional disclosure) as well as the potential for negative social impacts of this disclosure on patients. Involuntary disclosure could occur through provider lack of sensitivity, confidentiality breaches or due to partner notification laws. | • The majority of HIV positive women surveyed reported positive outcomes with the disclosure, but there is evidence of disclosure-related violence amongst a minority of women (Jürgens 2006).<br>• Confidentiality breaches with HIV test results have been reported in a minority of cases, but not unique to a particular testing approach (Evans & Ndirangu 2009; Obermeyer & Osborn 2007).<br>• There are no standard legal or medical requirements for patients to disclose their HIV positive status to partners. In a few countries providers can disclose to partners, but there is no evidence on the effects of this (Crewe & Viljoen 2005). |

| | |
|---|---|
| **Routine testing may impede prevention efforts because people will avoid seeking health care**<br>• This is concern about the process of implementing HIV testing.<br>• The argument is that people may avoid seeking health care for fear of being tested against their will and this will negatively affect efforts to prevent HIV. | • The evidence is limited to one study on the introduction of PITC in an antenatal setting in Botswana that showed it did not result in reduced use of services (Creek et al. 2007). |
| **The implementation of PITC will compromise informed consent, especially in LMICs**<br>• This is a concern about the process of implementing PITC.<br>• PITC recommends reduced counselling and informed consent procedures to shorten and integrate the HIV testing process into standard clinical care and to allow more people to test. The fear is that this reduced protocol will result in less informed patients who will be ill-prepared for a testing decision and less able to make a voluntary choice. It is suggested that informed consent will be more difficult to achieve in poorly resourced and poorly functioning health services where patients are less empowered to assert their right to decline HIV testing. | • The evidence about ethical practice of HIV testing is mixed. Some studies reported incidents of patients feeling they were tested against their will and other studies reported that patients felt they were not coerced to test (Evans & Ndirangu 2008; 2009).<br>• Studies have indicated positive patient perceptions of PITC in both high and LMIC countries (Obermeyer & Osborn 2007). |
| **Routine testing will lead to mandatory testing.**<br>• This is a concern about the process of HIV testing.<br>• The concern is that limited resources and power imbalances will result in reduced sensitivity about protecting individual patient rights and that coercion of individuals could become standard practice in LMIC settings. This would amount to "outing" of HIV positive individuals, which would constitute a violation of individual right to autonomy. | • There is evidence of limited resources and overburdened staff in relation to HIV testing services as well as evidence of ethical breaches in a minority of cases in both high income and LMIC settings, as indicated above (Evans & Ndirangu 2008; 2009).<br>• Mandatory testing applies mostly to testing of blood products and organ donors. Private hospitals in India are reported to do mandatory HIV testing on surgical patients (Obermeyer & Osborn 2007). |

Despite the many concerns listed above, there is growing evidence of the acceptability of PITC. Studies on PITC have shown increased test uptake and this has been used as an indication of patient acceptance. As reported in Chapter 2, the size of the absolute increases varied, from 5% to over 50% in places. Although limited in number, the studies on patient acceptance have also been positive. Antenatal patients in the UK expressed no undue anxiety and a preference for routine strategies as compared to self-initiated methods (Simpson et al. 1998; Wanyenze et al. 2008). Studies including hospital patients in the US as well as studies in Botswana and the Congo also showed a preference among patients for PITC (Evans & Ndirangu 2009; Obermeyer & Osborn 2007).

Few studies have specifically investigated the ethical implementation of PITC and most studies of PITC focus on increased testing rates as their main outcome. This might be because it is a relatively new approach and investigation of the ethical handling of PITC is difficult to conduct. Available evidence (see Table 9) on whether patients feel coerced to test for HIV in a PITC approach is mixed. A recent review on nursing implications of PITC in sub-Saharan Africa (Evans & Ndirangu 2009) reported that a few studies indicated that patients felt coerced to test. For example, Medley and colleagues reported in 2006 that their qualitative evidence showed that many patients at 10 antenatal sites in Uganda felt coerced to test (Medley et al. 2006). Patients at an antenatal hospital in South Africa expressed a similar feeling of coercion though this study assessed their participation in an antenatal surveillance study (Abdool Karim et al. 1998). Other studies on PITC, however, have indicated that patients did not feel coerced to test in antenatal and community-based settings (Evans & Ndirangu 2009). The results from a community-based study on perceptions of PITC in Botswana point to the complexity of the issue. The majority of people (81%) were in favour of PITC despite most (68%) acknowledging they would not be able to decline HIV testing if it was recommended by a health provider (Weiser et al. 2006). While many people are thus in favour of PITC, they also acknowledge the difficulty of declining testing in many clinical contexts.



Factors influencing HIV test utilisation

A number of studies have identified a range of factors that influence the utilisation of HIV testing. Against the background of the debate about expanding HIV testing and counselling, Obermeyer and Osborn (2007) reviewed the evidence on the multiple social and behavioural influences on the utilisation of HIV testing, and its implications for testing programmes. The authors highlighted the importance of the personal dimensions, the local context, and the social

context. Factors influencing test utilisation is of relevance for this sub-study as it can help identify potential influences on informed decision-making for HIV testing. This information will be reviewed below drawing heavily on the Obermeyer and Osborn review.

On the individual patient level, gender is a factor as more females than males test for HIV. Psychological factors such as a strong cognitive intention to test and a sense of self-efficacy (to access testing) have also been identified as important (Obermeyer & Osborn 2007). In terms of the local and social context, high HIV awareness and willingness to consider HIV testing has been found in South African surveys but these did not necessarily translate into large numbers accessing HIV testing. Surveys in South Africa and Botswana also pointed out that increased familiarity with HIV (through previous testing or being personally acquainted with an HIV-positive person) was associated with less stigmatising attitudes (Kalichman & Simbayi 2003; Pettifor et al. 2005; Shisana et al. 2005; Shisana et al. 2009; Weiser et al. 2006).

Several studies found that the major barriers to test utilisation across settings were the underestimation of personal risk for HIV, fears of an HIV-positive result, and confidentiality concerns (Jürgens 2006; Obermeyer & Osborn 2007; Weiser et al. 2006). In addition, in LMICs, negative perceptions of the health services were found to negatively influence test utilisation (Evans & Ndirangu 2009; Obermeyer & Osborn 2007) and in European countries, provider reluctance to offer the test was also considered a barrier (Deblonde et al. 2010).

In the health system context, patient-provider interaction has been identified as a major determinant of HIV testing behaviour. In a randomised controlled trial of various routine HIV testing strategies, patients' perceptions of their interactions with staff had a larger influence on test uptake than whether the strategy was routine or not (Simpson et al. 1998; Simpson et al. 1999). Provider characteristics like gender and ethnic group, provider attitudes, and the patient's level of trust in the provider appear to be influential (Anderson et al. 2005; Evans & Ndirangu 2008; 2009; Jürgens 2006; Obermeyer & Osborn 2007).

The manner in which the HIV test process was conducted was also found to influence the effectiveness of HIV test uptake. For instance, personalised interaction about HIV and especially individualised discussion of risk and of the benefits and risks associated with testing was found to increase willingness to test (Anderson et al. 2005; Van Dyk & Van Dyk 2003; Worthington & Meyers 2002). According to Obermeyer and Osborn (2007), this information is consistent with

research that shows that patients need to apply abstract information about risk and uncertainty to themselves for it to influence their decision-making.

These authors also found that staff attitudes and behaviours were a deterrent to test utilisation. For example, negative perceptions of staff attitudes and confidentiality breaches have been identified as reducing patients' willingness to test and to seek follow-up HIV care. In a multi-country Asian study, 34% of health workers reported confidentiality breaches and in European countries, 10-20% of respondents were reportedly tested without their knowledge (Obermeyer & Osborn 2007). A recent review of provider-initiated HIV testing practices in sub-Saharan Africa also reported a mixed picture of ethical practice (Evans & Ndirangu 2009). Lastly, the review reported that barriers to access for testing are reduced by new testing technologies (such as rapid testing), providing testing at convenient places (such as work, community based, health care and mobile settings), and different approaches to testing (such as provider-initiated testing) (Obermeyer & Osborn 2007).

These findings on test utilisation show the multi-faceted nature of the influences on patient test taking behaviour in general but there are no studies focussing on assessing the ethical implementation of PITC. This is partly because of inadequate research on PITC but also because of the conceptual and methodological challenges of evaluating ethical dimensions such as informed consent. Beardsell and Colyle in a 1996 review of research on the nature and quality of HIV testing services concluded that to develop testing services, research should be able to identify and describe the factors that might lead to various outcomes of testing, from the perspective of the client and the provider (Beardsell & Coyle 1996). According to the authors, this would require in-depth examination, through process-based studies, of the various elements of HIV testing, including making a decision to be tested; the process of obtaining clients' informed consent for testing, the ways in which test results are conveyed to clients, post-test strategies aimed at behaviour change, and which professional groups are most suitable to deliver HIV testing. This sub-study will examine elements of the HIV testing process, test decision-making, and informed consent procedures from the perspective of both patients and providers.



Conceptual and methodological challenges of studying informed consent

Despite the widespread acceptance of the principle of obtaining informed patient consent in medical decision-making, there is no consensus on how this could feasibly be obtained in

practice or how it should be measured (Bekker et al. 1999; Meisel & Roth 1983; Sachs et al. 2003; Siminoff et al. 2004; Sugarman et al. 1999). For instance, while the general bio-ethical principles of informed consent can provide guidance on how to obtain informed consent in practice, it does not deal with the specifics of how medical decisions are made and what would enhance informed decision-making (Siminoff et al. 2004). Sugarman and colleagues described this dilemma in their bibliography of empirical research on informed consent as follows:

> *" … despite broad agreement about the need to obtain informed consent, there is some uncertainty about how or whether meaningful consent is achieved in practice, whether theoretical understandings of informed consent are useful or practical, and what practices help enhance the possibility that patients and subjects in fact meaningfully consent to treatment or participation in research"* (Sugarman et al. 1999:S1).

The literature on informed consent is vast and stretches across many disciplines ranging from law to medicine (including both research and clinical practice) and the many branches of the social sciences. The term is also understood and defined differently across various disciplines, professions, and theoretical models. Some theoretical approaches to the concept of informed consent give more importance to its value than others (with a few questioning its feasibility in busy medical settings) (Doyal 2001; Irwig et al. 2006; Jones et al. 2004; Kirby 1983).

Other approaches recommend adapting the requirements for obtaining informed consent according to different medical settings and different medical conditions (Braddock et al. 1999; Corrigan 2003). According to several reviews of informed consent literature, the expansiveness of the literature, the multiple concepts, and the methodological problems associated with studying informed consent make it difficult to synthesise findings on informed consent in practice (Bekker et al. 1999; Meisel & Roth 1983; Sugarman et al. 2005; Sugarman et al. 1999). Meisel and Roth, the authors of a critical review of empirical studies of informed consent, went as far as questioning the value of informed consent studies owing to their inherent conceptual and methodological difficulties (Meisel & Roth 1983).

The first challenge with studying informed consent is the absence of an agreed definition. In law, the term 'informed consent' is used to indicate that a person gave permission for certain actions to be taken and that this permission or consent met certain minimum standards. Consent is usually considered as 'informed' if the person is able to understand the facts and implications of

the action to which they are consenting. An important distinction in clarifying the concept is that informed consent seeks to regulate the manner in which a decision is made (autonomously or not) but not the outcome of this decision (Meisel & Roth 1983). For example, when faced with a decision to undergo invasive surgery or not, informed consent does not seek to regulate the choice the patient makes (whether the surgery is accepted or declined). The focus is on studying the way the decision was made; whether the patient had adequate understanding to make a choice; and whether the choice was made autonomously.

Despite the absence of a widely accepted definition, most authors suggest that informed consent can be captured by an umbrella of at least five common components (though there might be disagreements about how these should be characterised) (Irwig et al. 2006; Meisel & Roth 1983; Sugarman et al. 1999). These components, drawn from Meisel and Roth, are listed below and provide a starting point for investigating informed consent in this study:

1. Competency (or decision-making capacity): This is the legal presumption of the patient's capacity to comprehend information provided by a health care provider and to make a decision. The method for ascertaining legal competency is not clear but the assumption is that the patient's decision should be considered legally valid. Children and the mentally handicapped may be considered not to be legally competent in this situation.
2. Information (or disclosure): This is the information that the clinician is expected to disclose to the patient related to the alternatives, risks, and benefits of the medical intervention about which a decision is required.
3. Understanding (or comprehension): Related to the above element is the expectation that the patient understands the information provided by the clinician and that they understand the nature of the decision they are expected to make. This is different from competency in that it relates understanding the information pertinent to the particular decision rather than having the ability to comprehend information generally.
4. Voluntariness: This refers to the manner in which the patient makes the decision about the options presented. The decision should be made freely and without undue pressure or coercion.
5. Decision (or authorisation): The patient is expected to express their choice regarding the medical decision. The methods and requirements for obtaining the authorisation may differ (e.g. whether verbal and/or written).

These above five components are useful for analytical purposes but present several challenges for studying informed consent in practice. Firstly, these multiple (and overlapping) components are difficult to separate in the context of medical decision-making in a clinical encounter. Secondly, they are difficult to measure precisely and comprehensively. Thirdly, it is difficult to investigate the inter-relatedness of the components. For instance, the relationship between disclosure and understanding, or between disclosure and authorisation, would be important to understand in evaluating informed decision-making (Bekker et al. 1999; Meisel & Roth 1983; Siminoff et al. 2004).

In the field of medicine and public health, the majority of studies of informed consent address participation in research but there is also a large body of research on informed consent for clinical decision-making. The latter focuses on how informed consent is handled in major medical decisions such as invasive surgery and decision-making about medical screening tests. These studies are approached from a variety of conceptual perspectives, creating an array of overlapping concepts that relate to studying informed consent (or elements of it). The range of concepts includes informed choice, informed decision-making, shared decision-making, patient-participation, and patient empowerment. Drawing mainly from definitions provided by Trevena and colleagues (Trevena & Barratt 2003), Table 10 below describes these concepts of informed consent and illustrates some of the overlap between them.



**Table 10: Summary of the range of concepts related to informed consent**

| Concept | Definition |
|---|---|
| Informed decision-making | "An informed decision is one where a reasoned choice is made by a reasonable individual, using relevant information about the advantages and disadvantages of all the possible courses of action, in accord with the individual's beliefs" (Bekker et al. 1999:1). |
| Informed choice | A term that is often used synonymously with the term "informed decision-making". |
| Informed participation | The term was used to describe the need for patients to have evidence-based information on risks and alternatives when participating in health care initiatives such as medical screening, immunisation campaigns, and clinical trials (Raffle 2001). |
| Patient participation | The term used for describing patient involvement in making health care decisions. |
| Patient empowerment | The term used for some interventions aimed at increasing the level and quality of patient participation in health care decision-making within a clinical context (and in terms of taking responsibility for their health outside the clinical context) (Trevena & Barratt 2003). |

| | |
|---|---|
| Shared decision-making | Decision-making characterised by a sharing of information by both parties, and discussion about the preferred management. The term "informed shared decision-making" is often used synonymously (Trevena & Barratt 2003). |
| Evidence-based choice | This is described as the provision of research evidence on the pros and cons of one or more health care options along with the promotion of active patient involvement in clinical decisions (Entwistle et al. 1998). |
| Integrated decision-making | A new term proposed by Trevena and Barratt that they argue integrates both use of evidence and shared decision-making. Integrated health care decision-making should include 5 dimensions: 1) nature of the health issue, 2) patient preference, 3) practitioner recommendations and responsibility, 4) research evidence and 5) clinical evidence (Trevena & Barratt 2003). |
| Interactive decision-making | This is a framework for studying patient decision-making in medical settings that identifies three domains as important and focuses attention on the interactions between these domains. Factors in the three domains relate (1) to the clinical problem, (2) patient related factors, and (3) contextual factors related to the medical setting (Pierce & Hicks 2001). |



The multiple terms and overlapping meanings in Table 10 illustrate the range of approaches to, and the complexity of, studying informed consent in practice. Some approaches focus on the type of information that is disclosed in the process of making a medical decision (e. g. whether it is evidence-based) and the manner in which this is done (e.g. it should be provided in a non-directive way). Others focus on the interactions between users and health care providers (and the health system more broadly) with respect to the level of involvement of the patient in decision-making (e.g. shared decision-making, patient participation, patient empowerment). Some of the concepts refer specifically to medical decisions in which informed consent should be obtained (e.g. medical interventions or screening tests) whereas others refer also to a patient-centred approach to managing health care in general. For example, shared decision-making would imply involving patients in decisions about how best to manage their treatment for diabetes but it is not expected that informed consent be given for every decision in this regard.

This growing interest in patient involvement has occurred largely because of an ideological shift towards promoting and protecting individual rights (Corrigan 2003; Pierce & Hicks 2001; Siminoff et al. 2004; Woolf et al. 2005; Zussman 1997). Liberal individualist philosophies promote the importance of protecting individual rights and argue for a reduction in the power of institutions and governments in order to promote a more free and democratic society. Feminism has drawn attention to the imbalance in gender power dynamics and to power imbalances in other sectors of society (Zussman 1997). The need to 'democratise' relationships has also been applied to traditional hierarchical doctor-patient relationships which have been characterised as

paternalistic and disempowering for patients (Corrigan 2003; Meisel & Roth 1983; Pierce & Hicks 2001). These ideological shifts are reflected in tensions between population and individual interests in terms of health gains in medical screening programmes (and whether high uptake should be prioritised over individual autonomy of choice) (Austoker 1999; Bayer & Edington 2009; Entwistle 2001; Entwistle & Watt 2006; Jones et al. 2004; Jones & Bayer 2007; Parker 2001; Raffle 2001).

Meisel and Roth in their critical review, highlight a range of problems with studies of informed consent that will be outlined below (Meisel & Roth 1983). One of the main critiques of studies of informed consent is that they are one-dimensional. The difficulty is not only with defining and measuring elements considered crucial to informed consent but also with understanding the relations between these elements in a predictive way. For instance, studies often fail to investigate the complex relationships between elements such as the information received, the patient's comprehension of this knowledge, the way this knowledge was used in the decision-making, and the level of autonomy involved in making the decision (Bekker et al. 1999; Meisel & Roth 1983). Theoretical literature and empirical studies point to a complex relationship between disclosure and what the patient understands of the information (as well as between disclosure, patient participation, and patient satisfaction with decision-making) but these studies are not able to investigate these relationships dynamically. A common difficulty is that disclosure is often assessed through measuring patient recall of the information that was disclosed by the clinician. As Meisel and Roth point out, such studies are unable to account for the influence of normal memory lapses on information recall. More importantly, these studies often do not investigate whether the participants understood the information and if, or how the information was used in their decision-making (Agre et al. 2003; Braddock 1998).

Although there is agreement that providing information is important, little is known about what information should be provided, how much, how to best provide it, who should provide it, and how to frame the information to improve informed decision-making (Agre et al. 2003; Austoker 1999; Bayer & Edington 2009; Bekker et al. 1999; Entwistle 2001; Siminoff et al. 2004). For instance, a review of five randomised controlled trials of interventions aimed at improving informed decision-making in cancer screening found that there was no evidence of impact on knowledge, beliefs, risk perceptions, or satisfaction with the screening decision (Rimer et al. 2004).

It has been pointed out that if the goal of informed consent is to have autonomous authorisation, it would be essential to find ways to assess this component of informed consent (Braddock et al. 1999; Meisel & Roth 1983; Parker 2001; Sugarman et al. 2005; Woolf et al. 2005). Yet even less is known about the voluntariness or the autonomy of a patient's medical decision-making. Evaluating patient autonomy in decision-making presents a challenge for study design as it is a difficult concept to operationalise. For instance, it is not always clear what is exactly is meant by patient autonomy, how it will be measured, and what the criteria for success are in evaluating patient autonomy (Entwistle et al. 1998; Meisel & Roth 1983; Parker 2001). It is also not clear if more patient involvement in decision-making leads to more autonomous authorisation or more satisfaction with the medical decision-making (Rimer et al. 2004).

Several reviews have found that a range of interventions aimed at improving quality of communication can improve aspects of the patient-provider interaction. These intervention can result in more information being received and/or increased patient involvement (Rao et al. 2007). Similarly, a Cochrane review found that training providers on patient-centred care led to increases in the quality of communication and increased patient satisfaction (Lewin et al. 2001) but it remained unclear, for instance, how this might have impacted on patient informed decision-making. Another systematic review of trials to improve the interaction between patients and providers looked at the effect these kinds of interventions on self-reported and objective health outcomes (such as blood pressure). It found that provider-patient interactions can be improved and health outcomes might even be improved, though the evidence from these RCTs on health outcomes was equivocal (Griffin et al. 2004).

What is known indicates that obtaining informed consent in practice falls short of what is envisaged in the legal or bio-ethical conceptions of informed consent. Patients commonly have significant gaps in their recall of treatment information. Decision-making also tends to not be in the rational manner of weighing the risks and benefits of treatment options that legal conceptions of informed consent contemplate (Meisel & Roth 1983; Pierce & Hicks 2001; Rimer et al. 2004; Siminoff et al. 2004; Woolf et al. 2005). Patients may have cognitive and emotional challenges in dealing with the complexity of decisions and not all patients want an increased role in clinical decision-making. Patient may also over-simplify the decision-making process by, for example, assessing risk based on personal experiences. Providers do not provide comprehensive information on harms, benefits, and alternative options for treatment (Siminoff et al. 2004; Woolf et al. 2005). A systematic review of interventions aimed at increasing uptake of screening

tests found that changing the format of informed choice interventions did not affect the knowledge, satisfaction, or decision about the screening test (Jepson et al. 2000). From the review and other studies it remains unclear if informed choice affects test uptake (for example, whether more informed patients are more likely to accept or decline screening tests).

Provider barriers to ensuring informed decision-making include having too little time for detailed information, limitation to their own knowledge base, and limited communication skill to facilitate an individualised approach to patient decision-making. Providers also tend to inevitably convey their biases when discussing treatment options (Braddock et al. 1999; Irwig et al. 2006; Meisel & Roth 1983; Woolf et al. 2005). There may also be health systems barriers to promoting informed decision-making, such as limited availability of quality information and an institutional culture of discouraging patients from asking questions and expressing their preferences (Braddock 1998; Braddock et al. 1999; Woolf et al. 2005).

The difficulties reviewed above in intervening to improve informed choice might indicate that providing information is not enough to change the decision-making process. Some authors have suggested that more attention be paid to the attitudes, skill, and working patterns of providers as this may play a key role in determining the level of patient informed decision-making (Emery 2001; Entwistle 2001; Entwistle & Watt 2006; Trevena & Barratt 2003). A qualitative study of the views and practice of 24 general practitioners in the UK in 2000/01 showed that while the physicians understood and were supportive of ethical principles requiring patient involvement, their practice was not congruent with their belief. The main reason they gave for this was the limited time availability (Jones et al. 2004). The review by Rimer et al. also suggested that further research is required on how informed consent procedures can be better integrated into the clinical consultation (Rimer et al. 2004).

Some have characterised the problem of obtaining and studying informed consent as being due to legalistic and procedural conceptions of informed consent. One element of this is the underlying assumption of many studies that equal partnership exists in the clinical encounter and informed consent should operate as conceived of in bioethical and legal principles. These studies assume a balance of power between patient and provider and that the goal of effective informed decision-making is to 'democratise' the medical interaction through, for example, shared decision-making between patient and provider (Jones & Bayer 2007; Meisel & Roth 1983). Others have challenged this, arguing that studying informed consent is complicated by

the unique power dynamics that characterise patient-provider relationships; where patient vulnerability and provider expertise result in strong asymmetries of power (Corrigan 2003; Lupton 1997; Meisel & Roth 1983). It would seem that part of the problem is that there is a lack of a clear consensus on what it means for patients to be 'involved' in health care decision-making and what constitutes adequate involvement (Entwistle et al. 1998; Entwistle & Watt 2006; Meisel & Roth 1983).

The patient-provider power dynamic involves not simply the power of the provider to control a situation or offer or withhold a service; it also involves more subtle psychological interactions. Lupton and colleague characterised the clinical consultation as a place where the patient's experience of illness requires him or her to invest in the authority of the doctor in the clinical context of a mutually trusting relationship (Lupton 1997). The high level of vulnerability and dependency in a situation of illness means that this trust relationship is always characterised by feelings of ambivalence, uncertainty, anxiety, and risk taking. The role of emotion and trust in the traditional patient-provider relationship has received increased attention. This has gone as far as the delivery of interventions to promote trust between providers and patients and a Cochrane concluded that there was insufficient evidence on these interventions (McKinstry et al. 2006).

Lupton argues that the doctor-patient dynamic is too complex to be defined by one ideology such as that of 'democratising' patient-provider relationships. Meisel and Roth's critical review of empirical studies on informed consent noted that studies were limited by 'consumerist notions of informed consent'. The authors noted that studies incorrectly assumed that the rules of the free market operated in a way that allowed patients free choice when selecting their health care options. They characterised such studies as attempting to "make the free market system work in a political economy characterised by massive inequalities of information" (Meisel & Roth 1983:268). These underlying notions of the nature of the medical encounter, they suggest, is what makes it difficult for studies to reflect meaningfully what happens in practice and to identify what is possible to enhance informed consent practices.

In a review of theory and studies of informed consent, Siminoff and colleagues suggested that while the bio-ethical principles around informed consent can provide general principles for obtaining informed consent in practice, it does not adequately deal with what happens with actual processes of decision-making (Siminoff et al. 2004). They suggested that decision-making

theory and communication studies provide useful guidance for studying informed consent since they examine the various influences on decision-making and consequently, on informed decision-making (Bekker et al. 1999; Entwistle & Watt 2006; Pierce & Hicks 2001; Politi et al. 2007; Sugarman et al. 1999; Trevena & Barratt 2003). In particular, there is a need for conceptual frameworks that can account for the influence of social context on decision-making (such as the patient-provider relationship and cultural dimensions) as this is thought to be understudied (Bekker et al. 1999; Corrigan 2003; Entwistle & Watt 2006; Meisel & Roth 1983; Sachs et al. 2003; Siminoff et al. 2004). The next section of this literature review will propose the use of a decision-making framework as a guide in the analysis and interpretation of findings in this sub-study on informed consent.



Informed decision-making: a multi-dimensional approach to studying informed consent

This literature review has so far described several challenges to the study of informed consent: the lack of conceptual clarity in the field, the difficulty of measuring the extent to which consent is informed, and the gaps in knowledge about informed consent in practice. The review also pointed to the problems with the one-dimensionality of evidence on informed consent and the need for a multidimensional and dynamic approach to studying this process. The conceptual and methodological challenges outlined above make it difficult to identify exactly the optimal focus of a study on 'informed decision-making'.

Meisel and Roth (1983) conclude that the available studies have not provided a comprehensive assessment of informed consent in practice and that this would require examining the entire medical decision process in different settings. They suggested a list of areas that would need to be studied in a comprehensive study on informed consent. These are listed below:

- what information was disclosed, by whom, and under what circumstances,
- what information patients already had prior to their decision,
- the extent to which patients understood the information provided,
- the basis of the decision made, including if and how patients used the information provided in arriving at their decision and whether consultations with others were involved, and;
- what pressures were brought to bear on patients in the process of making the medical decision, and what was the source of such pressures? To what extent did these affect the way the patients made the decision (Meisel & Roth 1983:333).

The above components illustrate the multi-dimensional nature of informed decision-making in practice. The authors of the review and others (Bekker et al. 1999; Sugarman et al. 2005) acknowledge that conducting such comprehensive studies would be a challenge. For instance, it may require multiple research techniques (such as interviews, observations, questionnaires) and continuous data collection over time and with several roleplayers (staff, patients, and other influential people). In this sub-study, some, but not all, of the elements listed above will be investigated, with the help of multiple sources of data collection and a multi-dimensional conceptual framework to guide the investigation.

Although the concept of "informed decision-making" aims to take a multi-dimensional view of informed consent, it still suffers the same methodological challenges outlined earlier. For instance, there is a need to study informed decision-making not as a static outcome but as a series of events or a process that unfolds over time in the clinical encounter (Siminoff et al. 2004). The need to view decision-making as process was also raised for studies evaluation HIV testing behaviour (Beardsell & Coyle 1996). Just as with the concept of informed consent, there is no agreed definition on what constitutes informed decision-making. Below a compromise definition is presented from an annotated bibliography of informed decision-making studies that can provide a reference point for this sub-study. The authors acknowledge that decision-making in practice may not occur in the rational way suggested by their definition.

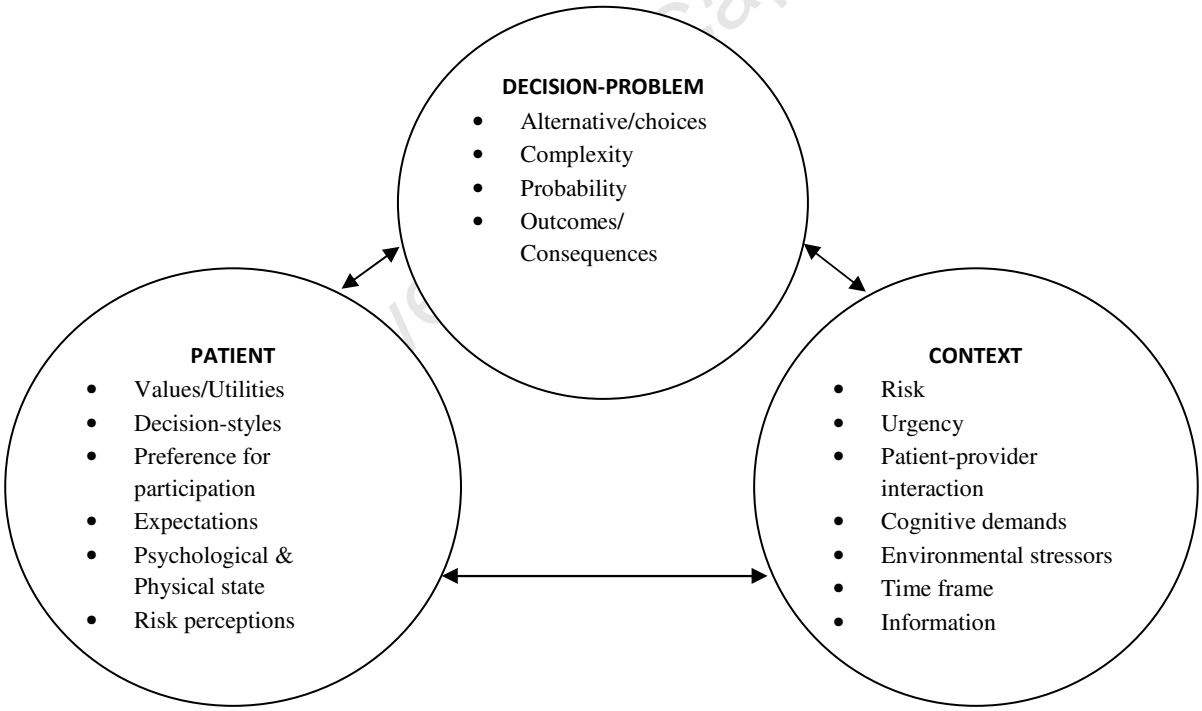
> *"An informed decision is one where a reasoned choice is made by a reasonable individual, using relevant information about the advantages and disadvantages of all the possible courses of action, in accord with the individual's beliefs" (Bekker et al. 1999:1).*

The "Interactive decision-making framework" (IDM framework) is an applied conceptual model that characterises decision-making as a dynamic and multi-dimensional process of interaction between the patient, the nature of the medical decision (decision-problem), and the health care and broader environmental context (including the provider-patient interaction). The elements of the framework are listed in Figure 9 and will be described in more detail below, drawing on the key paper by Pierce and Hicks where they describe the model as an emerging paradigm for nursing science (Pierce & Hicks 2001) as well as earlier papers by the lead author (Pierce 1993; 1996).

This framework was chosen to guide the analysis of the practice of informed consent in this study since it captures individual, social, clinical, and contextual elements that have been referred to in the literature as influential in decision-making. It draws attention to the interactions between these domains, an important element in studying informed consent as a dynamic rather than static process.

The framework was synthesised from evidence derived from a review of theoretical literature and of empirical studies on informed decision-making. This review included evidence from qualitative studies, conducted by the lead author of the IDM framework, on patient decision-making in practice. These were studies in a clinical setting where patients were making decisions on treatment for breast cancer and cardiovascular disease (Pierce 1993; 1996) and the author identified various types of patient decision-making styles. This framework fits well with the content and methodology of this study which considers decision-making in a natural clinical setting using qualitative methods.

**Figure 9: Framework for Interactive Decision-Making (Pierce & Hicks 2001)**




The IDM framework aims to describe the potential interactions between three domains. The domains are factors related to the nature of the medical decision (referred to as the 'decision-problem' domain), patient factors, and contextual factors that relate to the clinical setting and the broader environment. The authors define "decision processes" as "complex cognitive,

perceptual, and affective activities that are multidimensional and often inaccessible to direct observation" (Pierce & Hicks 2001:270). The discussion below explains in detail these three domains.

*Decision problem domain*

The decision-problem is defined as the "act or options among which one must choose, and the possible outcomes or consequences of these acts" (Pierce & Hicks 2001:268). The authors outline four elements of a decision that can influence the nature of the decision-problem and a patient's experience of it. These include the complexity of initial options (alternatives or choices), values (worth, utility, or attractiveness), uncertainties (or probabilities), and possible consequences (of choosing a particular option) (Pierce & Hicks 2001:268).

For example, having to choose between treatment options for breast cancer (e.g. mastectomy or chemotherapy) could be considered a more complex decision-problem than choosing whether to take a screening test for breast cancer. The seriousness of the medical condition and the outcome of the decision about cancer treatment (including the urgency of the medical treatment) and the risks, uncertainties, and probabilities for the available options would all potentially shape the nature of the decision-problem. In the discussion section of this chapter, these dimensions of the HIV test decision-problem will be discussed with reference to how the complexity level of the decision may be shaping the patient experience and the implications for evaluation of informed decision-making.

*Patient domain*

In the patient domain, individual patient values, decision style and preference for participation, and psychological or physical state are among the factors that would interact with the nature of the decision-problem. One way to evaluate if a decision was informed is to assess if the decision was consistent with the patient's values and preferences which involves examining the patient's level of satisfaction with their decision-making process. However, defining and measuring personal values and preferences in a practice setting is a challenge.

In this framework, the authors define "value" as a "measure of attractiveness" and patient preference for (or "liking") a particular option. The framework suggests that "decision-conflict" can emerge when there is a disjunction between patient values and the health care decision they made and in this sub-study, patient satisfaction with their test decision will be explored.

Factors that were identified earlier in this literature review as influencing HIV testing (such as gender, socio-economic status, and patient perception of stigma and of the health system) are not explicitly addressed in this framework. These significant omissions could be considered secondary characteristics in the framework and as potential influences on both patient and contextual levels. For example, gender might influence the patient's values and preferences around HIV testing so in exploring patient reasons to test, these issues would be indirectly examined.

A patient-level factor found to be a major influence on decision-making processes is individual patient decision-making style. As mentioned earlier, the desire to become involved with health care decision-making varies among patients. Pierce found that decision-making style in natural settings varied on a continuum from avoidance (which includes deferring responsibility to the provider) to engagement with the decision problem (which includes actively seeking out information in and outside of the consultation). The predominant style was of patients making a rapid, apparently intuitive decision without seeking further information and with little anxiety about their choice, even when faced with serious life-threatening medical decisions (Pierce 1993; 1996). Although this study was not designed to assess patient decision-making style, the study might be able to gain some insights regarding this from observing the decision-making process in the clinical consultation.

Patients' perceptions of their own risk for a particular outcome can also influence how they decide on a particular option. The individual's judgment of the probability of a certain outcome of a medical decision is seen as the result of interaction between the nature of the decision problem (e.g. the available information about risks) and the patient's individual responses to assessing risk. Little is known about how individuals judge the likelihood of the outcome of a medical decision though over-optimistic judgment is considered to pose a "decision-hazard" for informed decision-making. This is because it could prevent the patient from engaging with other relevant information required for making a more realistic judgment.

For example, it is not clear whether the rapid decision-making style identified by Pierce in his studies on breast cancer intervention is an indication of over-optimistic decision-making where patients may have an unrealistically positive appraisal of risk (Pierce 1993). In the case of HIV testing, for example, while there is evidence of under-estimation of risk for HIV in the general

population, it is not known if this unrealistic appraisal of risk operates when patients are faced with deciding about HIV testing in a routine health care situation. The patient's physical and psychological state (for example, anxiety levels or vulnerability owing to illness) can also influence their perception of risk, their uncertainty regarding options, and their expectations of the medical encounter. These issues will be explored in this study to some degree, by examining patients' reasons for their test decision-making and whether there are elements of over-optimistic decision-making (for instance, whether they had contemplated the possibility of an HIV positive test outcome or not).

*Context domain*

The third domain in the framework refers to health care contextual factors and includes clinical issues that overlap with the other two domains. For instance, the review by Pierce and Hicks found that health service setting (e.g. an in-patient or outpatient situation), the type of health decision (e.g. the seriousness and urgency of the clinical problem), and the role of the health provider (e.g. values and professional socialisation) all interact to influence the context of patient informed decision-making.

The context also interacts with the patient's experience or familiarity with the medical decision. Acute illness, for example, would require rapid decision-making and this may involve stressful emotion and little information about the options for treatment. This could pose a potential decision-hazard in terms of facilitating effective decision-making. Similarly, in complex and high risk situations such as neurosurgery, there may be difficulties due to the urgency and uncertainty of the degree of risk. On the other hand, with chronic care management, patients may become familiar with the treatment and decision-making options and adapt their choices to their lifestyles. Other influential factors include the health care setting (for instance, in hospital or primary care) and the time frame for decision-making (e.g. short consultation times in general practice).

Patient-provider interaction has been identified in this review (and in other studies, as mentioned above) as a particularly important element shaping the context of patient decision-making in the IDM framework. The attitude and demeanour of the provider and the level of trust are considered important in shaping patients' experience of the clinical encounter and their decision-making. The authors of the IDM framework make reference to the provider role as also posing a potential decision-hazard. For example, the provider's position means that they can

promote or “frame” a particular option as preferable which could unduly influence the patient’s decision and could lead to “decision-conflict” (that may be as a result of having made a poorly considered decision).

There is often a lack of congruence between what information providers believe patients need to know, what patients actually want to know, and what clinicians provide. For example, in some studies, patients wanted to know about the course and likelihood of cure for their disease and the available treatment options (Pierce & Hicks 2001). It is not only the amount of information but the manner in which it is presented, including whether the explanation was at the right level for the patient, which can affect patient preferences. Entwistle, in making the case for a broader decision-making framework, emphasised the importance of the provider role. She noted that “attempts to educate, train, and support clinicians to promote patient involvement in decision-making will need to consider clinicians’ underlying motivation and attitudes as well as communication skill sets”(Entwistle & Watt 2006:276).

In conclusion, this literature review described the background to the debate surrounding the ethics of PITC, laid out the various ethical concerns and reviewed what is known and not known about HIV testing behaviour and about informed consent and informed decision-making. The conceptual and methodological challenges to studying informed consent in practice were highlighted and the need for a multi-dimensional and dynamic approach to studying informed consent was described. The review concluded by describing a decision-making conceptual framework, the Interactive Decision-Making (IDM) framework that will serve as a guide for the analysis and interpretation of this sub-study.



## Methods

Study design

A qualitative approach was used that included individual interviews and observation of clinical practice to examine patient informed decision-making from an insider (emic) and outsider (etic) perspective (Morris et al. 1999). The rationale for using qualitative methods is that not enough is known about the how patient informed consent processes unfold in practice and even less is known about this in the context of PITC. The study aims to explore how these multi-dimensional processes unfold in practice and qualitative methods are considered appropriate for studying

the multi-dimensional nature of patient experiences and health care practices (Green & Thorogood 2004).

Study sampling and recruitment

The study population was comprised of patients who were offered HIV testing and nurses who participated in delivering the PITC intervention as part of their STI clinical consultations. Patients and nurses were sampled from four of the seven clinics that participated as intervention clinics in the controlled trial of the PITC intervention. The four clinics were purposively chosen as they were the largest and busiest clinics (based on routine data about their STI patient load), which meant that logistically, the researcher could have easier access to STI consultations and patients. These clinics also provided an operational setting where the high workload and time constraints could provide a realistic picture of the stresses that nurses and patients experience in busy clinical settings.

*Individual interviews with patients*

A purposive approach was used to design the overall sample for interviews with individual patients who had been offered HIV testing by nurses. The sample was selected to include both those patients who had declined and those who accepted the offer of HIV testing. Of those who accepted testing, the sample needed to include both HIV-negative and HIV-positive adult patients.

Recruitment of patients for interviews was done by a nurse, in a private setting, usually in the context of an STI or an HIV clinical consultation. A combination of systematic and convenience sampling was used for recruitment. Nurses were asked to recruit patients systematically which meant each eligible patient (any new STI patient) who was seen by the nurse on the particular day of the researcher's visit was asked if they were willing to be interviewed at the end of their clinic visit that day. It was decided beforehand that, for ethical reasons, patients who tested positive on the day of their STI consultation would not be interviewed. If the patient agreed to be interviewed in the consultation and they had declined HIV testing, they would be interviewed immediately after their STI consultation (3 patients). If the patient agreed and they tested HIV negative, the patient would be interviewed after they received the test result from the lay counsellor (11 patients). If the patient agreed and they tested HIV positive, the lay counsellor would inform the patient that they would not need to participate in the research interview out

of consideration for their need to focus on managing their HIV diagnosis. Two patients out of those approached for an interview declined, one for reasons of time and the other for unknown reasons.

Patients who had tested HIV positive through the PITC intervention were recruited via the specialist HIV care services that were available at each of these clinics. The HIV care nurses were asked to recruit HIV patients who were referred to them via the STI nurse at the clinic. This was convenience sampling as recruitment depended on who was available and willing to be interviewed. Six HIV-positive patients were recruited via this method. The time between their HIV diagnosis and the interview ranged from a few days to two months. One exception was a patient who had tested seven months earlier. Despite the length of time that had passed since his HIV diagnosis, this patient could provide a clear account of his experience of the STI consultation seven months earlier.

A total of twenty individual interviews with patients were conducted. Interviews lasted approximately 45-60 minutes. Patients were given R50 to cover any expenses that they incurred such as travel to the clinic for the interview.

*Observations of STI consultations*

Systematic sampling was applied to determine which of the STI consultations were to be observed. The process typically involved the researcher setting an agreed date with nurses to conduct the observations. On arrival at the clinic, consecutive STI consultations would be observed. This meant that the researcher was able to observe consultations without these being 'pre-selected' by the nurses, each of whom had given written permission to be observed. One nurse declined to be observed, citing performance anxiety as her reason.

Each patient observed in the clinical consultation needed to give verbal consent for observation. At the start of their consultation, the nurse used a standard script to indicate what the study was about and to ask the patient's permission for the researcher to observe the consultation. The script emphasised the patient's right to decline. No patients declined to have their consultation observed. A copy of the script used to recruit patients for participation is provided in Appendix 5 and copies of the patient and staff consent forms are included in Appendix 6 and Appendix 7, respectively. A total of thirteen clinical consultations were observed. Eight of these patients were also interviewed individually.

Data collection

The study utilised three sources of data. The main two sources of data were patient interviews and observations of consultations. The third source was notes on informal observations of the general clinic environment. These notes provided information about the organisation of care processes on a broader clinic level (such as the patient flow) and the social dynamics in the clinic reception and waiting room areas. Participants (patients and health care providers) were told that the general aim of the study was to examine experiences of provider-initiated HIV testing and they were unaware of the particular focus on evaluating the ethical application of PITC.

Data collection was done using an iterative approach where initial data informed later data collection strategies - a standard approach in qualitative data analysis (Miles & Huberman 1994). Data collection occurred over a period of 10 months in three intervals: November 2007, February/March 2008, and August/September 2008. These data collection periods were interspersed with periods of data analysis.



*Individual patient interviews*

Interviews were conducted with individual patients in the clinic setting using a semi-structured interview schedule. The initial interview schedule was changed soon after the start of the investigation to a less structured one as it became evident that richer data could be obtained from asking patients to reflect more broadly on their experience in the consultation. For example, rather than asking directly about their HIV testing experience, the interview process was changed to start off by asking patients to tell the researcher the story about how they came to be at the clinic and what happened during their clinic visit. See Appendix 8 for the original semi-structured interview schedule and the subsequent questions that became the focus in interviews.

The interview focused on the patients' experiences and perceptions of their STI consultation and of HIV testing. This included exploring key elements of their test decision-making, such as the reasons for their HIV test decision, their level of HIV awareness and attitude to HIV testing, appraisal of the voluntariness of the testing, their appraisal of their HIV risk before and during the consultation, and their responses to their test decision and their HIV test result. The most common first language of participants was isiXhosa, an indigenous African language. Initial interviews were conducted in English (the second language of most participants) but it soon

became evident that this presented a communication barrier. The rest of the interviews were done in isiXhosa with the help of an interpreter.

The interviews were audio recorded and transcribed by a professional agency. For the earlier interviews, the transcription was done only for the dialogue in English. This meant that only the researcher's questions (in English) and the translator's version of the patient's responses (in English) were transcribed and not the isiXhosa verbal exchanges between the translator and patient. On the whole, the translations provided by the translator in the room were found to be adequate but, at times, the richness of the patient's response was lost in translation. For a selected sample of interviews (just under half), comprehensive transcription was therefore conducted and involved a double translation process that will be described below. As the financial cost of this was prohibitive, the interviews that were selected for comprehensive translation were those where the most value could be added. This included those with more dense narratives and those where the meaning of responses needed to be clarified further.

For the comprehensive transcription, all audio-recorded verbal communication was transcribed, including communication in English and other languages and both patient speech and summaries of patient responses that were provided by the translator. The isiXhosa exchanges that were transcribed were then translated into English by a professional translator. This expanded the original English transcript to include the patient's verbatim responses in isiXhosa and the translators' isiXhosa version of the interviewers' questions. The benefit of this process was twofold. Firstly, it gave the researcher direct access to the verbatim responses of the patient, which provided a richer source of information than could be provided by the translator in the room. Secondly, it provided the researcher with two translated versions of the patient's responses which were used as an independent quality check of the translation done in the interview setting.

*Observations*

Observations were designed to examine the actual implementation of the PITC intervention in the consultation room, including how nurses implemented the clinical protocol and how the clinical and social context may have shaped patient experiences and perceptions of informed decision-making. The observations were open-ended so as to gain a general sense of the time and style of patient-provider interaction and of the level of confidence providers had with

integrating the HIV testing tasks into the STI consultation and with applying the ethical requirements of informed consent.

The observations of clinical consultations generated two types of data. The first were collected through physical observation of consultation undertaken by the researcher in the consultation room and recorded as notes. These data captured both verbal and non-verbal communication. The second type of data from observations was based on audio-recordings of the consultation and these provided information on the verbal content of communication and processes in the clinical encounter.

Initially, the researcher intended to observe all the consultations in person but this was changed for methodological and practical reasons. In some cases, where the patient that was observed had also agreed to be interviewed, it was felt that it would be helpful for the researcher not be present in the consultation to allow the patient to see her as an independent interviewer. In these cases, the observations were recorded. The added advantage was that nurse practice could be observed under different conditions, with and without the physical presence of the researcher. All the observations were audio recorded and ten out of thirteen were also physically observed.

In three cases, the physical observations were extended to include observing the post-test counselling delivered by the lay counsellor to allow the researcher to observe the entire HIV testing process from beginning to end. The patient flow of the HIV testing intervention is described in the methodology section of Chapter 2 and is illustrated by the PITC patient flow diagram in Appendix 4.

The majority of the STI consultations were conducted in isiXhosa which was the first language of all patients observed (except for one patient who was from elsewhere in Africa and who spoke English). One nurse, who was English speaking, conducted her consultations in English. The patients seen by this nurse had varying levels of English fluency. The researcher conducted the clinical observations herself even though she could not understand the isiXhosa language in which most of the consultations were conducted. This option was preferred by both the researcher and the nurses to using a Xhosa-speaking research assistant. From the researcher's perspective, given the qualitative nature of the investigation, the level of skill of the observer would be an important issue in the quality of the research especially given the need to be

observant of non-verbal communication in the consultation. The researcher is a trained clinical psychologist and a skilled qualitative researcher which made it preferable for her to do the observations herself. It was also the expressed preference of the staff participants that the researcher to do the observations herself given her familiarity with the project as an external evaluator.

Observed consultations ranged between 20 and 35 minutes. A professional transcribing agency was used to transcribe all the audio-recorded consultations including translation of the entire consultation from isiXhosa to English (which was a requirement for 9 of the 13 consultations).

Data analysis

The aim of qualitative analysis is to provide a "believable portrayal" of the phenomena under study to the interested parties through developing an "holistic overview" of the context and using this understanding of the context to help explain the phenomena observed (Piantanida & Garman 2009).

As with the data collection process, data analysis was iterative, moving between interim analyses as the data were collected, refining the questions, and pursuing further avenues of enquiry. For instance, the process of defining and refining the research question was ongoing. The general question was to understand more about patients' perceptions of PITC but it was not clear early on whether the ethical appraisal of PITC should be the key focus of the enquiry. The research question moved between an initial concern to provide a general description of the patient's experience of a new approach to HIV testing (and to extrapolate about the ethical application of PITC) to a more narrow focus on how informed consent was experienced by patients and applied by staff (by focusing on assessing elements of informed consent more directly).

A potential danger of a narrow focus on informed consent was loss of an understanding of how individual patient and contextual factors might be influencing the shaping of informed consent. For example, trying to assess whether patients thought they had adequate information and if they thought the testing was voluntary would represent a narrow interpretation of two elements of the informed consent as it does not include an understanding of what other factors may be shaping their perceptions of informed consent.

The challenges of finding a dynamic and multi-dimensional approach to assessing informed consent was described in the literature review section of this chapter. The IDM framework assisted with examining and identifying the multiple influences on the shaping of patient-informed decision-making and it offered criteria against which to evaluate the level of patient informed decision-making observed in the study. Process-tracing techniques were also used as a tool to provide a more dynamic way of analysing data from the clinical observations. Process tracing techniques are recommended for studying patient decision-making as a process (rather than a static outcome) and are described in more detail below when reviewing the observation data analysis (Bekker et al. 1999).

*Interview data analysis*

Thematic content analysis was used to analyse the transcripts of the individual patient interviews. Analysis was done deductively and inductively. For example, deductive analysis was done by following the topics introduced in the interview guide, such as identifying responses to questions about the reasons for their HIV test decision and their appraisal of voluntariness. Inductive analysis was done by examining both manifest (obvious) and hidden (latent) content of interviews (Graneheim & Lundman 2004).

The first level of analysis involved reading and rereading interview transcripts, identifying and describing the main ideas, and coding these ideas. The codes were related to the main topics under study, such as the reasons patients gave for their testing decision and their perceptions of various elements of their testing experience. Coding was done for each interview and the main codes were distilled at the end of each interview in the following areas of interest: reasons for testing, perceptions of voluntariness of HIV testing, experience of waiting for the test result, and responses to the test decision (including reaction to the test result and intentions about disclosure and prevention).

The next level of analysis involved comparing and contrasting codes to develop themes in a cross-case analysis. Data extracts from interviews are provided to illustrate themes and key issues emerging from the interviews. Elements of the IDM framework also contributed to the development of the themes as they helped to identify issues that could be shaping informed decision-making.

A detailed example of a within-case data display and analytic process is provided in Appendix 10b. The case study of an interview is used to demonstrate how the content of one interview contributed to identifying codes and generating themes. Extracts from the individual interview are presented in a way that shows both the conversation and process flow of the interview, providing the verbatim responses of the patient, and where required, also that of the interviewer to contextualise the responses in the interview.

In the case study example, the code is indicated by a heading, followed by an extract from the interview that relates to that code. This is then followed by comments from the researcher to show how the coded data link to broader themes identified in the data and how the concepts from the decision-making framework were used for interpreting the data. At the end of the case study, there is a summary of the coded content and its links to the themes. Such a within-case display is considered a useful step in the data analysis process to compress and order data as one step in the process of drawing conclusions in a coherent fashion (Miles & Huberman 1994: Chap. 5).

*Observational data analysis*

The analysis of observations had two overlapping objectives. One was to understand how the PITC intervention was implemented in practice, especially with respect to the ethical handling of HIV testing and the efficiency of executing the intervention. This could provide an outsider's perspective for evaluating the ethical implementation of the PITC intervention. The second objective was to gain insights into how the clinical and social context of the PITC intervention may be shaping the patient's experience of informed decision-making.

Patient decision-making in a clinical setting is considered a complex issue to examine and has been described as potentially uncontrolled, ambiguous, and dynamic (Pierce & Hicks 2001). Thematic content analysis was used in combination with elements of process tracing in analysing the observations. The combination of these two techniques assisted with providing a multi-dimensional and dynamic analysis of what was observed in the clinical encounter.

Process tracing is one of a broader range of analytical techniques used to capture the complexity of decision-making processes and is useful in qualitative research to identify the social and contextual factors in decision-making behaviour (Woods 1993). Process tracing can provide a sense of events unfolding over time and assist with analysing elements relating to the

longitudinal nature of a clinical consultation. For example, it can focus on the sequencing of tasks and conversation to analyse what and how information was used in decision-making.

Process-tracing techniques are particularly useful for analysing audio–recorded transcripts of 'real time' decision-making in the clinical encounter and content analysis of transcripts that are based on verbal protocols of patients thinking aloud about their decision-making processes (Bekker et al. 1999; Pierce & Hicks 2001; Woods 1993). In this study, process tracing was used to scrutinise the sequence of events, communication, and interaction to analyse the manner in which the HIV testing process was implemented and to examine what factors in the clinical encounter may have contributed to the patient's perceptions of informed consent.

From reading and re-reading the transcripts of consultations, the researcher was able to identify common patient responses to interview questions. The focus of this analysis was to trace the process of the interactions between provider and patient throughout the consultation and to gain insights into not only the content (with respect to HIV testing in particular) but also the social and clinical dynamics of the patient-provider interaction. Themes that emerged related to the level of patient-provider interaction, the communication and interpersonal style of the nurse, and the level of clinical skill with integrating the HIV tasks within the STI consultation.

A within-case analysis of a transcript of a clinical consultation is presented in Appendix 10a that demonstrates how the data from one clinical observation were coded and shows how broader themes were identified across all observations. Here, again, as for the within-case analysis of the interview transcript, the headings represent the first level of coding (where the main responses are identified) followed by extracts from the consultation that related to that particular code. The case study ends with a summary of the main codes and the discussion also indicates how the codes contribute to the themes that were explored across all the observations.

To complement this open-ended approach to the analysis of observations, another level of analysis was applied that represented a more technical assessment of the HIV testing procedure. Here the steps required in the PITC clinical guideline used by the health services were used to analyse to what extent the required components were implemented in practice, especially with respect to the ethical requirements. This allowed for a more focused assessment and judgments about the quality of the ethical handling of the PITC intervention.

An example of how this consultation was assessed against the required elements of the HIV testing intervention is shown in Appendix 11. Areas analysed included when and how the test offer was introduced, whether specific information was provided on general HIV awareness, the purpose and benefit of HIV testing, the voluntariness of HIV testing, the confidentiality, whether test readiness was assessed, and whether written informed consent was obtained. The level of integration with and efficiency of delivering other STI tasks were also examined.

The findings from observations of the clinical consultation are presented first as a summary of the main themes across all thirteen observations and then as case examples that illustrate the particular elements of informed decision-making findings in more depth. In the case examples, extracts from the transcripts of selected consultations are presented in as much detail as is required to convey a sense of the clinical and social context of the STI consultation. Insights from the analysis of the interviews were used together with the information from observations to reflect on factors that may have shaped patient experience and perception of informed decision-making. To assist the researcher to make an external judgment of the ethical handling of intervention, the findings from these two sources of data were assessed against the criteria for informed consent that emerged from the literature. The findings are presented and discussed in the following chapter (Chapter 5).

# CHAPTER 5: INFORMED CONSENT AND PROVIDER-INITIATED HIV TESTING AND COUNSELLING: FINDINGS

The previous chapter examined ethical concerns about provider–initiated HIV testing and counselling, the literature surrounding the issue of patient informed consent and the conceptual and methodological challenges of studying informed consent in practice. The chapter described the Interactive decision-making framework that was used to guide the analysis and interpretation of the findings presented in this chapter. The qualitative methodology of this sub-study on patient informed consent is also described in detail in the previous chapter. This chapter will report on the main themes that emerged from the observation of the clinical consultations and from the patient interviews. The chapter then discusses the key factors that were identified as influential in shaping the patient's experience of informed decision-making using the IDM framework as a guide. It also reviews the strengths and limitations of the study.



## Background

This chapter presents findings on the evaluation of informed decision-making in the context of a PITC intervention. These findings emerge from observations of provider practice and interviews about patients' experiences and perceptions. The STI clinical consultation was observed to evaluate if PITC was implemented ethically and to identify the factors that may be facilitating or hindering patient informed decision-making. In the interviews, patients were asked to describe their experience of their STI consultation and the HIV testing process, the reasons for their decision to test, and their perceptions of the voluntariness of the testing process. This information contributed to an evaluation of the ethical handling of the HIV testing process. The Interactive decision-making (IDM) framework outlined in Chapter 4 was used as a conceptual guide for evaluating factors that might have shaped the patient's experience of informed decision-making.

### Characteristics of participants

The demographics of the patients who were interviewed and observed are presented in Table 11 below. The consultations of five STI nurses were observed, providing a sample of 13 clinical

sessions. A total of 20 adult patients were interviewed: 8 males and 12 females.[1] The interview sample included 11 patients who tested HIV negative, 6 patients who tested HIV positive, and 3 patients who had declined HIV testing. As shown in the table, seven of the 20 patients interviewed were also observed during their consultation with the STI nurse (these are marked with an asterisk in the table).

The low socio-economic background of patients in this sample is typical of patients in the public sector health services, with most living in the poorest areas, often in informal housing. Patients who were not in school were either unemployed or in vulnerable employment situations. All the patients except one were black African[2] and Xhosa-speaking, with English as their second language. One patient was Malawian and English speaking. Four of the 5 nurses observed were black and they conducted their consultations mostly in Xhosa. One nurse was white and English speaking.



[1] A 16-year-old male was included with special permission from the ethics committee. His true age was only established after the interview was concluded.

[2] The terms to describe different race groups, as black and white originate from pre-democratic era of racial classification and are still used in South Africa to varying degrees for identification purposes.

**Table 11: Gender, age, and occupational status of patients interviewed and observed**

| **Interviews** | | |
|---|---|---|
| **Tested HIV negative** | **Tested HIV positive** | **Declined testing** |
| Phakama, male, 19, scholar | Phindi, female, 36, unemployed | Lester, male, 23 unemployed |
| Sihle, male, 16, scholar | Banele, male, 20, scholar | Winston, male, 36, welder, part-time employment* |
| Ntombi, female, 27, shop assistant * | Brenda, female, 28 | Nono, female, 23 * |
| Thando, male, 25, labourer * | Nosipho, female, 31, domestic worker | |
| Funeka, female, 23 unemployed | Andile, male, 23 factory worker | |
| Mandi, female, 25 | Ayanda, female, 24, unemployed | |
| Busi, female, 21, scholar * | | |
| Henry, male, 20+, casual labourer * | | |
| Adeline, female, 21, unemployed * | | |
| Sibonele, female, 19, scholar * | | |
| **Total: 11** | **Total: 6** | **Total 3** |
| **Observations** | | |
| Dumi, male, 18 | Vusi, male, 31 | |
| Vuyo, female, 31 | Bonani, male, 42, gardener | |
| Luyanda, male, 24 | | |
| **Total: 9 (including 6 patients with asterisks above)** | **Total 2:** | **Total: 1 (patient with asterisk above)** |



## The STI consultation and informed decision-making in practice

This section will examine how providers implemented HIV testing in their STI consultation room. The aim is to gain insights into how the HIV testing process is applied and how this may have shaped patient informed decision-making. General trends will be identified and factors that may have played a role in facilitating or hindering informed decision-making will be explored across all providers. The section also provides a fairly brief summary of the STI consultation process.

The three case examples, presented later in this chapter, will provide much greater detail about the practice of three different nurses. In this section, issues of particular interest in assessing informed decision-making will be examined including:

- How did the provider make the test offer and how did the patients respond? For example, how was the test offer framed and could this have unduly swayed the patient's test decision?
- What information was shared with patients – for example, were patients informed of the nature of the test decision?
- Was the voluntary nature of the test offer conveyed and how? For instance, were patients aware of their right to refuse HIV testing?
- What decision-hazards could be identified that may have limited patients' ability to make an informed decision? What factors might have facilitated their informed decision-making? For example, what role did the patient-provider interaction play in shaping the patient's decision-making experience?

The themes that emerged from the observations of the clinical consultations are presented below. This section will be followed by detailed case examples top illustrate elements of these themes.



<u>The efficiency of integrating HIV testing into the STI consultation</u>

On the whole, providers followed the clinical guideline that was designed to assist them to implement the PITC intervention. A copy of the clinical guideline is included in Appendix 3. The steps followed in the consultation usually involved starting with an assessment of the presenting complaint, obtaining a history of recent unprotected sexual practice, and providing the STI diagnosis (based on the presenting symptoms). The nurse then provided health education to explain STIs and HIV and addressed the need to use condoms for prevention. Providers asked screening questions to detect TB, made the offer of HIV testing, performed the rapid test for HIV if the patient accepted testing, and drew blood for syphilis testing. Consultations usually included a physical examination, explanation of sexual partner notification, issuing of partner notification slips, and issuing medication for STI treatment. Most consultations with females also assessed female contraceptive needs and all consultations discussed and/or issued condoms.

Nurses differed in their ability to integrate the HIV testing tasks efficiently with the other components of their consultation. They differed in how successful they were at balancing the additional ethical requirements of HIV testing, how smoothly they were able to make the transition between HIV and other STI tasks, and how effectively they used HIV health education. Differences in clinical communication skills and interpersonal style also affected integration and efficiency. For instance, the timing of the HIV test offer was commonly at the beginning of the consultation (while doing an assessment of the history of the STI complaint) and this helped to integrate it with other tasks. Some providers left the actual offer of HIV testing till much later (after they had provided health education on HIV) and this sometimes made for less efficient integration of HIV testing tasks.



Hierarchical patient-provider interactions that pose a threat to informed decision-making

The patient-provider interaction in the consultation was characterised by unequal power dynamics. The communication was one-sided and there was little participation from the patient. The provider was in the role of professional expert who gave advice and the patient mostly listened and responded to questions. Questions were usually directed at eliciting symptoms and the health education was mainly about HIV and about prevention of STIs. Occasionally, the nurse asked open-ended questions, mostly to establish the patient's awareness of HIV and leading up to making the HIV test offer.

The hierarchical relationship observed in this clinical setting seemed to be normative, and in keeping with the experience and expectations of providers and patients. This may make it difficult for patients to easily express their ambivalence or refusal of testing as will be illustrated with the case example of Nurse B later in the chapter. Asymmetrical power relations may be the norm in most medical settings, given the imbalance in knowledge and expertise and the vulnerability associated with having an illness and seeking care (Lupton 1997).

However, as discussed in Chapter 4, several authors have expressed concern that this power differential may be even greater in LMIC settings where patients are less empowered and staff resources may be overburdened (Jürgens 2006; Rennie & Behets 2006). In situations such as was observed in this study, the authority role of the provider, the one-way communication, and the passive role of the patient are factors that could be considered to pose a threat to patient informed decision-making. Patients may not expect to be consulted on their treatment options and even if they are, they may find it hard to go against the advice of the provider. The next

section examines the ways providers engaged patients around HIV testing, ways that might not be characteristic of the standard patient-provider interaction.

Introducing the HIV test offer: asking or telling?

Despite a traditional hierarchical patient-provider relationship, there were elements that contributed positively to patient informed decision-making. For example, the way the issue of HIV testing was introduced was important for conveying the voluntariness (or otherwise) of the testing offer. Providers usually explained that HIV testing was recommended as part of standard STI treatment but that the patient's permission was required to proceed with testing. The link between STIs and HIV was made with nurses explaining that HIV was another type of STI and that screening for all STIs was recommended. Providers commonly talked about the benefits of HIV testing such as having certainty about one's HIV status and having access to HIV treatment. The provider's preference was usually made clear when they explained the benefits of testing. Health education also included information about the routes of HIV transmission, the window period, and how the HIV virus weakened the immune system.

Patients were usually informed directly or in a circuitous way that their permission was required. Direct communication included telling the patient that they had the right to refuse and that they were required to sign a consent form, or that they were required to make a choice about HIV testing. Sometimes this was explained in a roundabout way, by spending a disproportionate amount of time on talking about HIV and HIV testing or referring to the need for 'a talk' or 'counselling'. This was in sharp contrast to, for example, the syphilis testing, where the patient was merely informed that the test was required and will be performed. In most cases patients were explicitly asked to express their preference. Asking patients to express their preference can convey the message of voluntariness and is an important part of autonomous authorisation (Braddock et al. 1999). This is different from other 'opt-out' approaches that are standard in public health screening tests, where patients are told that they will be tested unless they explicitly decline, as was the case with syphilis testing (Bayer & Edington 2009; Braddock et al. 1999). The following data extracts show the different ways in which providers introduced the HIV test offer and how they tried to elicit the patient's preference. They also illustrate how provider communication and interpersonal style can facilitate or detract from conveying a sense of voluntariness.

*Nurse B:*

The nurse introduced the test offer:

> *"Now HIV is a STI. We encourage you to test for HIV as well."*

And later in the session:

> *"Now, I will give you time to think about it, whether you want it or not. You say 'yes' or 'no'."*

*Nurse C:*

> *"With HIV and STI you get infected in the same way, so that is why we need to test you for HIV when you come for STI. Is that clear?"*

The communication style of Nurse C was more direct and authoritarian than other nurses but this varied across the session. For instance, later, after lengthy HIV health education, her tone softened and became more patient-centred when she elicited the patient's preference regarding HIV testing:

> *"Now that we have spoken about HIV, how do you feel about a nurse testing you for HIV?"*

*Nurse D:*

This nurse introduced the HIV test offer by linking it to other STIs:

> *Nurse: Right, then. Here it is important for us to let you know more about what made you come here. The STI means sicknesses affecting your private parts, example being gonorrhoea and others, okay? HIV is also included, like you hear around people talking about HIV and AIDS, especially nowadays.*
>
> *Patient: Yes.*

*Nurse: Okay, you must understand that these sicknesses like HIV, STI and TB are all related. They are like cousins, if you understand what I mean. How are they related?*

In response to her own question, the nurse gave a lengthy and colourful explanation about the sexual transmission of HIV and how the virus works in the body. She made the HIV test offer much later in the session and explicitly elicited the patient's preference in the following way:

*"Okay, so now that I have explained everything to you, would you be interested to be tested today?*

*Nurse E:*

Here the HIV test offer is introduced in a slightly different way, without much pre-test health education:

*Nurse: You haven't had an HIV test, hey.....?*

*Respondent: No.*

*Nurse: ...for a long time.* [Paging through the patient's record]. *Do you mind if we do one today? Because that can also be part of the problem….*

The patient said she was not sure and the nurse then discussed the benefits of testing. She tried to normalise HIV by describing it as another type of chronic disease that is not curable but treatable. Later in the session, she asked the patient to express her preference, using fairly patient-centred language:

*"And now, how do you feel about doing the HIV test?"*

Except for a few cases, patients made the decision to accept the test fairly rapidly and without hesitation, usually immediately after being offered the test. They generally did not seek further information from the provider and did not engage with the provider as part of making the decision. The apparent ease with which the patients made the test decision and the lack of

deliberation, on the one hand, may be an indication that patients exercised their preference in an efficient way in response to a familiar decision-problem.

However, such rapid decision-making can also be a result of patients not feeling empowered to exercise their choice to decline. For instance, the patient may not want to go against the advice of an authority figure, for a variety of reasons, including personal decision style, fearing negative consequences, or where the norm is not to be consulted on clinical decisions. This is difficult to judge without information from the perspective of the patient. As I will show later, based on patient interviews, patients did not feel that they were coerced in any way in their test decision-making and the reasons for this will be examined.



Providing the patient with adequate information to make an informed decision

As mentioned above, providers explained the purpose of HIV testing and highlighted the benefits. When comparing the information provided in these consultations with that recommended by the WHO PITC guidelines for pre-test information, some gaps can be identified. Providers did not address the potential harms of HIV testing such as anxiety and stigma. In most cases, the preference of the provider (for HIV testing) was also made clear. Not discussing the harms of HIV testing and framing the HIV test offer as the preferred option could both be considered potential hazards for informed decision-making. Data from the interviews, however, indicate that patients valued the nurse's advice about HIV testing and felt it contributed positively to their test decision.

Nurses provided health education about HIV but with varying degrees of success. The health education went beyond what was required to describe the nature of the decision problem. It was often elaborate, delivered indiscriminately (irrespective of whether the patient needed it), and it sometimes confused rather than clarified issues. Health education also took up a disproportionate amount of time compared to the rest of the STI consultation and could account for why the PITC intervention took longer than nurses had anticipated (discussed further in Chapter 6). One of the reasons for their focus on health education may have been that nurses equated health education with 'counselling' and that they regarded some form of counselling as a necessary component to ensure informed consent. This issue was not directly explored with nursing staff but is based on the impression created by references they made in the consultations about needing to have 'a talk' with patients. A more direct illustration can be found in an extract from the case example of Nurse C below, where she referred to 'counselling'

as a pre-requisite for the test. This uncertainty about the role of counselling and how much information was required to ensure informed consent also emerged during the PITC training.

In their HIV education, providers emphasised the link between HIV and STIs, which was one way of normalising HIV testing in this clinical context. This explanation may have personalised patients' risks of contracting HIV and influenced their test decision. This idea will be explored further when discussing data from the patient interviews.

Over-optimistic decision-making is considered a hazard to informed decision-making and the observations examined whether patients had considered the possibility of an HIV-positive result. The clinical guideline posed a series of questions to prepare patients to face an HIV-positive test result and on the whole, nurses asked patients to reflect on how they would react to a positive test result. This meant that patients had an opportunity to engage with a potentially devastating outcome of their test decision.



Conveying the voluntariness of the test decision

As mentioned above, by the way in which they introduced the HIV test offer, nurses managed to convey a sense of the voluntariness of the decision to test (e.g. explicitly eliciting patient preference). The providers were clearly conscious of the need to obtain informed consent and they made efforts to ensure this, in direct and indirect ways and with varying degrees of success. Some nurses conveyed the voluntariness of the test decision by informing patients of their right to refuse testing while others did this indirectly through the way they communicated the test offer and through creating an atmosphere in which the patient was encouraged to express their preference.

To convey a sense of voluntariness, nurses tried to balance a predominantly directive style with elements of a more facilitative style in their communication with patients (as was shown in the data extracts under the heading 'Introducing the HIV test offer' above). Not all nurses struck this balance, though. The directive communication style of one nurse had an almost interrogating tone and this may have made it more difficult for patients to decline testing for fear of going against this nurse's advice.

Nevertheless, despite the variation in clinical communication skills and interpersonal style, what was striking was that nurses were all able to convey a sense of compassion and concern for the

patient's well-being. On the whole, they appeared to be fairly professional and non-judgmental in their handling of sensitive personal matters about sexuality and intimacy. In the case of one nurse though, Nurse C below, there were indications of a more authoritarian style and judgemental overtones, especially in relation to the patient not using condoms.

Despite their obvious position of authority, nurses often found ways of conveying a sense of caring through light social banter or using terms of endearment (even though these were usually infantilising, such as 'my child' or 'my baby'). Another way of showing caring was that nurses often appealed to the patient's sense of self preservation when advising them and sometimes pleading with them to practise safe sex. These types of interactions may have contributed to patients feeling a greater sense of trust in the judgment of the nurse and perhaps in following her advice. This may account for the positive perceptions they had of their testing experience (as described later in this chapter) despite the unequal power dynamics and the limited patient participation that was observed. Rather than seeing it as interfering with their autonomy to decide, patients particularly valued the nurse advising them to test. It is likely that the nurses' professionalism and their caring demeanour may have softened the potential negative effects of the unequal power dynamics in the clinical relationship.

The final method of conveying the voluntary nature of the HIV test was through the requirement of written consent. Written consent cannot be equated with patient-informed decision-making. It could be become part of ritualised process that has little to do with informed decision-making (Doyal 2004). Patients may still not have adequate information and may still not feel free to exercise their autonomy. Nevertheless, this provided a formal route for obtaining evidence of informed consent and it could have reinforced patients' perceptions of the voluntariness of the test offer.

In sum, it was evident from the observations that the dimensions of the STI consultation that shaped informed decision-making went beyond the mere presence or absence of information about the test decision. Informed decision-making was also shaped by the demeanour of the provider and the patient's interaction with the clinical setting. Despite the unequal power dynamics, most nurses showed awareness of the need for patient informed consent and they made efforts towards achieving this. Nurses were able to explain adequately the nature of the decision and actively elicited patient preference. These are considered key elements to ensure a fully informed decision (Braddock et al. 1999; McQuoid-Mason 2007; Meisel & Roth 1983;

Siminoff et al. 2004). However, there was variation in their ethical practice and nurses seemed to struggle with the efficient integration of HIV testing into their STI consultations. The difficulty seemed to lie in the balancing of the extra ethical requirements for HIV testing (pre-test information, written informed consent, and preparation for a HIV positive result) with the existing tasks of the STI consultation.

**Case examples of factors shaping informed decision-making in the context of PITC**

The case examples below demonstrate how the informed consent processes unfolded in individual clinical encounters. They reveal in more detail how the various factors summarised above may shape informed decision-making in the clinical context. The three examples included here represent the practice of three different nurses and show their typical approaches to introducing the HIV test offer and handling informed consent processes. The case examples also illustrate variations in communication and interpersonal style (and, to some extent, their skill in integrating the tasks efficiently) and the way these shape the sense of the voluntariness of the testing offer.

All the case examples also illustrate the obvious hierarchical patient-provider interaction and the limited patient interaction (considered normative in this public sector setting) and the potential of this reality for limiting autonomous authorisation. The first case example was selected to illustrate where a provider was relatively efficient about integrating the HIV testing processes into the rest of the STI consultation. Compared to other nurses, this nurse did little health education, timed the HIV test offer well, and was able to limit the extra time taken without detracting from the level of informed consent. In the second case example, the patient declined testing and the case examines what factors may have contributed to the patient exercising her right to refuse despite the decision-hazards present. The case also demonstrates the over-emphasis on HIV health education that was common in these consultations. The third case was selected to illustrate how the voluntary nature of the test decision can be jeopardised when the communication and interpersonal style is more authoritarian and when there is poor integration of tasks. This case and the second case also show the challenges of implementing routine 'opt-out' HIV testing efficiently if there is uncertainty about the minimum requirements to obtain informed consent.

Case example: Nurse A

Nurse A, a professional nurse in her mid-thirties, consulted with Luyanda, a 24-year-old man who presented with an STI. This patient accepted the HIV test offer and tested HIV negative. The nurse started with an assessment of the problem and made a diagnosis of STI based on the symptoms presented.

*Nurse: Listen right; what you have is an infection that is transferred through having sex, right. There are diseases that are known as … when they are all collected together they are called STIs, right. Which are diseases that are transmitted through sexual intercourse. So it is not common for a person to get it if they did not sleep with anyone, you see. Through all that, you do use a condom?*

*Patient: No, I do not use it.*

*Nurse: Mm, how many partners do you have?*

The patient indicated that he had only one partner and the nurse then explained that he can still get an STI from a single partner. She then asked if he and his partner had ever tested for HIV. He said that they had not. The nurse continued:

*Nurse: You have never tested? Have you heard about HIV?*

*Patient: Yes.*

*Nurse: E…, HIV is… the same as the other diseases that is transferred through sex. If you are able to get this disease that is transferred via sexual intercourse, it is easy that you could get HIV because you do not use a condom, you see. So it is important for you to come…to get treated. We must test for HIV and test for other diseases that is known as syphilis. Have you heard about syphilis?*

*Patient: Yeah, I have heard about it.*

*Nurse: Yes, so we have to test both of them in the blood. It is important that you bring your partner to the clinic and get tested together before you can think of not using a condom... How do you feel about testing for HIV?*

*Patient: No, I could test, there is no problem.*

This is where the patient consented to testing. The provider then moves on to HIV health education.

*Nurse: Okay, do you know what HIV is?*

*Patient: Yes I do know.*

*Nurse: Are you sure that you know about it?*

*Patient: Yes I'm sure.*

*Nurse: Okay, what is it?*

*Patient: It's AIDS.*

*Nurse: [Giggles]. It is not AIDS, it is a virus. AIDS is when it has the results of diseases, it is a collection of diseases that you would get, then that is where we say it is AIDS. But if it is still a virus that is in the body we call it HIV, do you see the difference? Do you see the difference?*

*Patient: Yes, so do you mean that it is curable?*

*Nurse: It is not curable, it's a virus that is not curable, it is different from the other infections, like the one you have now, you see.*

*Patient: Mm...*

*Nurse: This one is curable and it disappears but the HIV is not curable but it is possible to make it mild in the body. You see what causes this … the virus, when this virus has entered, it suppresses those white blood cells that you have. The body's soldiers are the natural ones that we were born with to fight off diseases that are present, you see. They have not found pills that make it go away, you see?*

Despite the patient indicating that he had a basic understanding of what HIV is, the nurse proceeded with a rather elaborate and somewhat confusing explanation about how the HIV virus attacks the immune system. Later in the consultation, while preparing to do the syphilis blood test and the rapid test for HIV, the nurse returned to the issue of HIV testing. She elicited the patient's understanding of the rationale for testing and prepared him to deal with an HIV-positive test result. She encouraged disclosure and checked if he had social support. In an apparent attempt to get the patient's participation, she asked an open-ended question about why he thought it was important to test for HIV:

*Nurse: Why is it important for a person to get tested for HIV?*

*Patient: Yeah it is important so that the person could treat themselves as soon as possible.*

*Nurse: Mm….let us say for example that you are told that you have it, this virus, what would you say?*

*Patient: Eh, no, there is nothing that I can do. But I will do whatever it is that I am told to do, I will go to the clinic, you see?*

*Nurse: Okay, that is the most correct thing because, yes, you would be shocked but you must try and do whatever it is that you are told to do, seriously. What would you do? Would you weep, would you cry, what would you do?*

*Patient: I won't be frightened.*

*Nurse: Are you a person who does not scare easily?*

*Patient: E… I would not be shocked really.*

*Nurse: Why won't you be shocked?*

*Patient: Because it has been a long time that people have been having it* [HIV].

*Nurse: O… who would you tell?*

*Patient: Yuh! No, that one is difficult. I won't be telling anyone.*

*Nurse: [Giggles] It is important though that there be someone you could tell because who will be supporting you? You know when some other things become too much for you; it would be nice if you could tell someone. Won't you tell anyone?*

*Patient: No.*

*Nurse: In the family?*

*Patient: I would tell the brother with whom I live.*

*Nurse: Mm, that would be something really nice because this would be something that you think about in your head. So it is better that you have someone that you tell. Do you think that the brother would be able to support you if he would know?*

*Patient: Yes.*

*Nurse: Okay, can you please sign here for me so that we can do it. You write your name here and you sign here.* [Paging through papers]. *If we treat you it is important that we also treat the 'Mrs.', right?*

The patient was then asked to sign the consent form. The nurse discussed the need for the patient to inform his partner to come for treatment (but she does not clarify whether she means STI treatment or HIV testing). She did the finger prick for the rapid HIV test (while drawing blood for the syphilis test) and informed the patient that he would receive the HIV test result from the

lay counsellor after the STI consultation and would need to return a week later for the syphilis test result. The nurse and patient then exchanged light banter about which rural villages they both originated from. This last interaction is an example of the camaraderie that was sometimes shown in the patient-provider relationship in these case examples. The consultation ended with the nurse explaining how the patient should take the medication for his urinary discharge.

Comment

The consultation shows a mixed picture with elements that can contribute to and that can hinder patient informed decision-making. As with all the consultations, the patient-provider communication here is one-sided with little participation from the patient. There are also gaps in information, for instance about the negative aspects of HIV testing and about the patients' right to refuse testing. In her initial introduction of the test, the voluntariness of the offer is not spelt out. The nurse's choice of words (*"We must test for HIV and test for other diseases*…") might even create the impression that it is a standard requirement, or an 'opt-out' testing, similar to syphilis testing. These issues could be considered potential hazards to informed decision-making.

Nevertheless, there are other elements of this consultation that could be seen as facilitating informed decision-making. The demeanour of the nurse in this encounter was one of a clinically skilled and caring professional with reasonable interpersonal skills. It is likely that these provider characteristics contributed to the patient's sense of trust in the judgment and advice of the provider. The nurse normalised HIV testing by framing it as part of standard screening for other STIs. This normalising of HIV testing could have contributed to the patient's willingness to test. Despite the nurse perhaps giving a mixed message about the voluntary nature of testing at the start, she nevertheless elicited the patient's preference when she asked him: "How do you feel about testing for HIV?" This is an important component of facilitating autonomous authorisation. The patient indicated his acceptance of the offer clearly and without hesitation.

The patient's rapid decision-making may also be related to his decision-making style and his past experience of decision-making in a clinic context. These elements are difficult to assess from observing a single clinical consultation. There are indications that this patient did not engage in over-optimistic decision-making in the sense that he was able to contemplate the possibility of an HIV-positive test outcome. He also seemed to view HIV as a common disease. This may have made it easier for him to accept the HIV test. Even though the potential negative consequences

of testing were not discussed, the patient seemed to be well aware of social stigma (when he expressed his hesitation about disclosing his status).

Finally, compared to the other nurses observed, this nurse was relatively efficient with integrating HIV testing. She introduced the topic early, was able to balance the demand of HIV testing with other STI tasks, and did not provide a disproportionate amount of HIV health education. As a result, her consultation time was at least 5 minutes shorter than the average time (of around 25 minutes) spent by other nurses.

Case example: Nurse B

In this case example, the patient declined the offer of an HIV test. Nurse B, a middle-aged, experienced professional nurse consulted with a 23-year-old woman called Nono. From the transcript, it was not clear whether this patient had been tested for HIV before. The nurse started with an assessment of the patient's presenting symptoms and then informed the patient that she had an STI. She asked her if she had heard about STIs. The patient said this was her first STI and the nurse proceeded with the following explanation of STI:

> *Nurse: Okay, if you do not use protection, condoms that is. Now the abdominal pains that you are complaining about is a symptom of STI. The word STI stands for "Sexually Transmitted Infections" right, when we translate it "Sexually" means to have sex, "Transmitted", to infect during sex with viruses such as diseases of the private parts. So that is what STIs are and now you have come to an STI clinic. Do you understand what I am saying?*
>
> *Patient: Yes I do.*

The nurse then made mention of syphilis and gonorrhoea as types of STIs and talked about the importance of prevention. She introduced the topic of HIV and asked the patient to explain what the routes of HIV transmission were. After a brief and incomplete explanation from the patient, the nurse explained the link between HIV and STIs.

> *Nurse: Yes, but most of the time people get it from being exposed through sex. You get it when you are bruised and its soft down there and there might be ulcers that are exposed. You know that there are some fluids that come out, so that is how*

*one can get HIV in that manner. If I could say HIV is also an STI, would you agree with that? Okay, we have just discussed about HIV and explained more about it and you knew about it. So now I take HIV and say that it is an STI……you said yourself that is being infected through sex and HIV also gets in through that same manner, do you agree?*

*Patient: Yes.*

The nurse then offered the HIV test. She conveyed in her own way the message that the HIV test was voluntary:

*Nurse: So HIV, it's not curable, but there are medicines to suppress the virus. It's important for people to check for HIV, but we don't force people for testing. We are putting it strong but we don't force people to test. You also need to know if there is a change in your body so you can notice what is going on. When you say 'yes' to test, it's strong and also to say 'no', it's quite strong from your side. Seeing that we don't force people, we listen to your input - your 'yes' and your 'no' is strong.*

The nurse asked the patient if she had anything to say and the patient asked:

*Patient: If I can treat the STI now, and then go and sleep with my boyfriend without a condom, am I going to have an STI again?*

The nurse explained in some detail that the patient's partner or partners also needed to be treated for STI. She then first assessed the patient's contraceptive needs before returning to the issue of HIV testing:

*Nurse: So now I would like to know about the blood testing …do you want to have your blood drawn and tested or you don't want to.*

*Patient: [inaudible]*

*Nurse: Why don't you want to?*

*Patient: I am so scared.*

*Nurse: What are you scared of?*

*Patient: Not now…*

*Nurse: What are you scared of?*

*Patient: Ugh…..I am not sure if I have it* [HIV]*. At least once I have completed writing…*

*Nurse: What are you writing?*

*Patient: Final exams…*

*Nurse: Okay, so you're facing exams, you don't want to test, that's good. Okay baby, I'll take that, it's your decision, I respect that, but you know, you still owe yourself to test after you've been exposed, so after your exams, give yourself time, hey?... I wish you pass all of them, neh, but stay practising safer sex and don't forget your date for contraception …. "*

The nurse was affirming of the patient's decision to decline the HIV test. She urged the patient in a respectful and caring manner to consider testing at another time. The nurse then asked the patient to sign the consent form to indicate that she has been informed about HIV testing and that she declined. The consultation continued with a discussion of contraceptive needs, including female condoms, blood testing for syphilis, and a physical examination.



Comment

In this case example, the patient declined the HIV test and was thus able to exercise her right to refuse. The patient declined the test against a background of a traditional hierarchical patient-provider relationship that may ordinarily have made it hard for her to go against the advice of an authority figure and it is worth examining what may have enabled her to do so.

The provider tried to convey the voluntariness of the test decision, using her own peculiar way of expressing this: "*Seeing that we don't force people, we listen to your input - your 'yes' and your 'no' is strong".* This unconventional way of conveying voluntariness may also have to do with language issues, either in the way this idea of voluntariness is expressed in isiXhosa or in the way it translates into English. Nevertheless, this way may have been more accessible and easier for the patient to understand.

In terms of facilitating informedness (another key element of informed decision-making), the nurse provided a range of information about STIs in general and about HIV in particular. She emphasised two messages that were geared towards ensuring the patient understood the nature of the test decision and that advocated for the testing option. One was that HIV is another type of STI which may have had the effect of normalising it. The second message was that HIV is treatable: "*So HIV, it's not curable, but there are medicines to suppress the virus."*

As mentioned before, 'framing' HIV testing as the preferred option, as was done in all these consultations, could be considered a decision-hazard since it could sway the patient towards making a decision that is not consistent with their own preference. Despite the framing of a preferred option and the asymmetry in the power dynamics between patient and provider, the patient nevertheless declined the offer of HIV testing, which was clearly her preference. Still, she was not able to express this decision clearly, perhaps fearing the provider's response. It required the provider to recognise the patient's reluctance and to enable her to express her preference to decline testing. The nurse's communication style and professionalism in this interaction were important elements that enabled this. After briefly exploring her reasons, the nurse not only accepted but also affirmed the patient's choice to decline HIV testing. Her response conveyed a sense of caring about the patient's well-being (even if it was done in a paternalistic way).

It is likely that the provider's clinical communication skills and interpersonal style contributed to an initial environment in which the patient was able to decline the HIV test more easily. For example, at the same time as motivating the patient to test, the provider also conveyed that the patient had a choice. She also actively elicited the patient's preference when she asked: "*So now I would like to know about the blood testing…do you want to have your blood drawn and tested or you don't want to."* It should be noted that this was in contrast to the procedure for syphilis

blood testing where the patient's consent is assumed. Providers regard other STI blood tests as routine practice and asking for consent for HIV clearly sets it apart from routine practice.

There were also some fragmentation of HIV tasks which may have resulted in inefficiency of implementation and potential confusion for the patient. Based on the above data extracts and from reviewing the full transcript of the consultation, the manner in which the HIV testing offer was introduced appeared to be less efficient and more fragmented than in the first case example. For example, in this case, the topic of HIV is raised and the actual HIV test offer is made a little later. The patient was not asked to make a decision when the offer of HIV testing was first made but much later, when the nurse needed to take blood for the syphilis test. This lack of efficient integration of the HIV testing could have caused patients to be confused about how HIV testing fitted into the rest of the consultation and what level of priority it had. Such lack of clarity on the part of the patient could have reduced the patient's sense of the voluntariness of the testing offer.

This case showed that despite the presence of factors that could potentially inhibit patient informed decision-making, the patient nevertheless could decline the test offer. What this illustrates is that achieving patient autonomous authorisation relied not only on the prescribed processes for obtaining informed consent but also the commitment of the provider to create an environment in which the informed consent can be achieved. In this case, the provider used her authority in a positive way and she had the communication skills and professionalism to facilitate informed decision-making.



Case example: Nurse C

In the final case example, the communication style of the nurse was more authoritarian compared to the other nurses observed and the nurse was also less efficient at integrating the HIV tasks. This example explores the influence these issues might have on shaping patient informed decision-making.

Nurse C, a middle-aged, experienced professional nurse was consulting with Sibonele, a 19-year-old female and a high school student. In this consultation, the patient accepted HIV testing and tested HIV negative. The nurse started the consultation by asking the patient's demographic details and then introduced the HIV test offer:

*Nurse: The sister in this room does STIs and there are certain rules that we follow. Understand? When you come to the STI room, we also ask you to do an HIV test. The reason is because you slept with someone without a condom. The other reason is you can get an STI because of that. There are some other infections like syphilis and gonorrhoea. If the other person has it, you can also get it. Maybe you might wonder why the sister is talking about HIV when you come to the STI room, but we have to explain it.*

Before the patient could respond, the nurse asked the patient's age and how she could be of help. She proceeded with an assessment of the presenting symptoms, including enquiring about condom use.

*Nurse: Do you actually use a condom, are you are not using it?*

*Nurse: Why don't you use a condom?*

*Patient: Uhm...*

*Nurse: Why you don't use a condom? Why you don't use a condom?*

*Patient:* [mumbles response]

*Nurse: Do you have a reason?*

*Patient: No.*

*Nurse: When did you get your last period, my child?*

The directive style of the communication in the above exchange took on an almost interrogating tone. The nurse did not give the patient an opportunity to respond and the patient may not have felt free to be honest about her lack of condom use for fear of being scolded by the nurse. The nurse softened her tone for the rest of the session and took on more of a 'teacher-like' role in addressing the patient.

The nurse seemed to struggle with integrating the normal STI tasks with the new HIV-related tasks and this resulted in her taking longer to deliver the intervention compared to her colleagues. The flow of the session was fragmented as the nurse made sudden shifts from one topic to another. She enquired, for example, about contraceptive use, dropped this topic, and then raised it again later in the session. She also provided an excessive amount of HIV health education without checking if the patient needed it. For example, when she established that the patient had previously been tested for HIV, she proceeded to talk at length about the window period for HIV testing. As illustrated below, she tended to view HIV health education as a discrete task which she seemed to equate with 'counselling' for HIV testing:

> *Nurse: Now, what we are going to do, before we examine, my baby, hey. We start with the history and then, because we spoke about HIV and AIDS, we don't test for HIV without being counselled first. Before we do an examination, we talk about the HIV, and we give you all the information about the HIV.*

There were indications that the nurse was not confident about integrating the HIV test offer into the rest of her STI consultation. At one stage, she needed to refer to the PITC clinical guidelines to check if she had covered all the required steps. This added to the disjointedness of the session. The discussion below about confidentiality, for example, seemed out of place in the flow of tasks. Because of this poor sequencing of tasks, she created the impression that confidentiality was specific to HIV issues.

> *Nurse: Now, there are questions here that are specifically concerning about HIV and AIDS. Then after that we are going to examine but there are questions that are here, that I need to ask you and you need to answer. You know when you come here for HIV and AIDS it is confidential, between you and me. Because here we are working as a team – you have to go to the sister* [nurse] *and she has to open up a folder for you. Your partner doesn't see what is in your folder. When you come out here, you go to a sister – and if your partner asks the sister – "what is Sibu's results?" He is not going to find out.... Do you know what is HIV?*
>
> *Patient:* [non-verbal response]

The above exchange was followed by further health education about HIV. Here the nurse changed approach slightly as she tried to elicit patient participation while giving information about the transmission routes of HIV and the link with STIs.

*Nurse: HIV is a virus, when he gets to the immune system of a human being, it changes into AIDS. HIV is a collection of viruses and that leads to AIDS. AIDS is a collection of all the viruses, like pneumonia, TB, meningitis and all those things. Do you understand HIV now?*

*Patient:* [non-verbal confirmation]

*Nurse: Is it, hey? How does a person get infection by HIV?*

*Patient:* [inaudible response but something like] *"Sleeping without a condom."*

*Nurse: Sleeping without a condom, yes. What other means?*

*Patient: When you touch somebody's blood, when you have a cut and touch without gloves on.*

*Nurse: The other one is when you are a mother who is HIV positive and then, pregnant, and the mother is likely she can transmit the viruses to the baby. Another virus from your blood could go straight to your baby, hey, right. So now you know of the ways of transmission, hey. Now, I told you the link between TB and HIV and STI. I said HIV is an?*

*Patient: … an STI.*

*Nurse: Yes! HIV is an STI, hey? So TB, when you are HIV positive, your body is easy to get infection by TB, hey? When you're HIV positive, HIV is doing all the antibodies that protects you from TB. And that will make your body become very weak. And TB you can pass on to someone else, when you cough, is easy to get TB, in an open area where people cough.*

As the data extracts below will show, the HIV tasks were not well sequenced. Before the nurse made the actual offer of an HIV test, she focused on calculating a date for retesting (after the window period) and on preparing the patient for dealing with an HIV-positive result. She then returned to enquiring about STI symptoms and finally asked the patient if she wanted to test for HIV.

> *Nurse: Now how do you feel that you came for STI and Sister talk to you about a test for HIV and AIDS?*
>
> *Patient: I don't have any problem.*
>
> *Nurse: You don't have any problem, hey?*

And later:

> *Nurse: Now, you are being tested and the sister tells you are HIV positive, how would you feel?*
>
> *Patient: I wouldn't feel bad.*
>
> *Nurse: You wouldn't feel bad. Why?*
>
> *Patient: This disease is the same as other diseases, like sugar diabetes and other diseases.*
>
> *Nurse: Uh-uh. So, you say you won't feel bad.*
>
> *Patient:* [confirm]
>
> *Nurse:* [writing and repeating] *'not feel bad'.*

The patient informed the nurse that she had previously been tested for HIV. This presented a good opportunity to offer the test directly but the nurse then proceeded with several bursts of health education, talking about the mechanisms of HIV transmission and the window period. The

nurse returned to the HIV test offer much later but only after she checked the patient's support system. The patient accepted the HIV test offer without hesitation.

> *Nurse: We finished our talk. I'm coming back to you now, Sibu, what is your decision about testing?*
>
> *Patient: I'm going to test.*
>
> *Nurse: You want to test?*
>
> *Patient: Yes.*
>
> *Nurse: All right* [pause, writing]*…Now, sign in the two blocks here. If you agree or don't agree, you still need to sign.*



Comment

The STI consultation was characterised by poor integration of the HIV testing process with the rest of the STI consultation and inefficiency in delivering the intervention. For example, the HIV testing process was fragmented and there was poor sequencing of tasks, duplication, and lengthy health education. This fragmented work style was also observed (though to a lesser extent) in her other two consultations. Partly as result of this work style, the consultation lasted nearly 10 minutes longer (about 35 minutes) than the average for other nurses. The communication style of the nurse in this case also differed from her colleagues in that she was more directive and almost interrogating at times. This communication style had the effect of reinforcing the imbalance of power between patient and provider. In such a setting, the opportunity for a patient to express her preference to decline testing may be diminished.

Despite the authoritarian element to her interaction with the patient, the nurse was nevertheless able to convey a sense of caring about the patient's well-being, even if this was expressed in a somewhat paternalistic tone. For instance, she occasionally used endearing terms for the patient like 'my child' or 'baby'. Despite the fragmentation of tasks, she was nevertheless thorough in her clinical duties and appeared to provide a fairly comprehensive consultation that included a physical exam, TB screening, HIV testing, dealing with family planning needs, advising on condom use and dispensing condoms, and doing a pregnancy test

(the latter test also contributed to the longer consultation time). Showing concern for the patient's well-being in this way in her professional role might have been influential in shaping the patient's positive perception of the testing experience (as reported in this patient's interview), even in the presence of an authoritarian communication style.

The health education that the nurse provided took up a disproportionate amount of the consultation time. The value of the information provided was uncertain, especially as the patient indicated that she had been tested for HIV before. She would presumably have understood the nature of the test decision and would not have required such detailed HIV information. As mentioned earlier, there were indications that the nurse might be equating the provision of health education with pre-test counselling when she said: "*…we don't test for HIV without being counselled first. Before we do an examination, we talk about the HIV, and we give you all the information about the HIV".* Nurses in all observations seemed to convey this sense of needing to provide detailed health education as part of ensuring informed consent.

Providing health education may have offered nurses a familiar 'script' that allowed them to feel they were doing the required 'counselling' to ensure informed consent. Although nurses were told that pre-test counselling was being dropped, they were also told that they had to ensure patient informed consent and they may have been uncertain about the implication of this for their practice. This issue will be explored further in Chapter 6 when reflecting on how uncertainty about the minimum ethical requirements of the PITC intervention may have affected nurse practice and the outcome of the trial results.

Taken together, the findings provide empirical data on factors that may shape patient informed decision-making in practice and, in particular, those related to the clinical context and the patient-provider interaction. A key observation is that assessing the ethical handling of HIV testing needs to go beyond looking at the presence or absence of pre-test information and should consider the communication and inter-personal style of the provider in conveying a sense of voluntariness. An important component of facilitating patient informed decision-making seemed to be the providers' awareness of the need for informed consent and their ability to facilitate this effectively.

The findings also demonstrate the importance of assessing informed consent as a process that unfolds across a series of events in a clinical consultation. Many of the insights shared above

were only possible because the researcher had access to the full transcript of the consultation and could therefore consider the context and flow of the interaction more fully. The findings also illustrate the complexity of making an external judgment of informed consent in this context.

## Informed decision-making: key themes emerging from patient interviews

The interpretation and evaluation of informed consent from the observational data presented thus far is complemented below with data from patients about their experience of the HIV testing intervention, their decision-making processes, and their perceptions of the voluntariness of the process.



Positive belief in the value of HIV testing

Patients were asked about the reasons for their decision to test. Those who accepted testing usually responded by saying they wanted to know their HIV status. This seemed an obvious reason for testing and so their answers were probed for more detail on the underlying reasons. Nevertheless, their responses pointed to the matter-of-fact way that patients viewed their test decision-making. It would seem that patients made the test decision almost intuitively, without much hesitation and with little deliberation with themselves or with the provider. When their initial response was probed, respondents generally provided two sets of reasons for their decision to test. These related to individual-level factors and to contextual factors associated with the STI consultation.

On the individual level, patients cited the medical benefits of HIV testing as the main reason for their test decision. They felt that taking the test would enable them to access HIV care early and so help to avoid HIV-related illness and to prolong life. Patients acknowledged that despite them seeing the value of HIV testing, they had no intention of testing for HIV before they came to the STI consultation. In fact, when asked why they had not tested earlier, a common response was the fear of an HIV-positive result. This fear was expressed even by those individuals who had tested HIV negative in the past. It seemed as if patients accepted the HIV test in this clinical setting, in spite of their fear, due to a belief in the medical benefits of knowing one's HIV status and also simply because the opportunity to test had been presented. The extracts below describe one patient's rationale for testing, where access to HIV care featured prominently.

Phakama, a 19-year-old scholar explained:

> *"I think it's best for me to know my status so that I will take the right precautions to treat it. Because if I don't test and go on not knowing my status, that could affect me badly in my life."*

Funeka, a 23-year-old woman, shared a similar sentiment:

> *"I made a decision because I wanted to know my status beforehand, before I become sick …by the time I become sick it will be too late for me to know."*

As did Sihle, 16-year-old male scholar:

> *"It's no use not to do the HIV test. If you don't do the test, you can become ill and when you come back later, it may be too late – so it's good that you just do it now...."*

For Banele, a 20-year-old high school student, knowledge of his HIV status went beyond the medical benefits alone, to issues of prevention. He explained:

> *"I just thought since I was there already…I thought that I needed to know what kind of person I was… and the nurse advised me in that way…that I would be able to know that I do not have HIV, so that I could protect myself from contracting it…and if I had it I should know, so I would prevent spreading it."*

In the above extract, he also refers to the opportunistic nature of the HIV test decision. Being offered the HIV test in the clinical consultation was considered as presenting an opportunity, one that had few barriers to accepting testing. His decision was seemingly a spur of the moment one (*'since I was here already'*). Here the clinical context could be regarded as a contextual factor contributing to his test-decision-making. A few others referred to this reason for testing. One put it plainly, saying:

> *"Seeing I was around…I decided to test."* [Adeline, 21-year-old, female]

In the data extract below, Banele again referred to the clinical consultation as an opportunity to test. He also described how the interaction with the provider helped him to move beyond his fear to focus on the perceived benefits, a contextual factor that will be discussed in more detail later. Banele explained:

> *"Yes, I knew I could refuse, but what made me brave was being here already, you see? I was advised to leave here knowing my status and I chose that. Because knowing that you have it means to know how to further protect yourself, and if you do not have it you would know how to totally prevent it….So that made me to stop being afraid…and I changed my mindset."*

This positive view of the benefit of knowing one's HIV status was widely expressed by nearly all of the respondents, even those who declined HIV testing. The one exception was Lester, a 23-year-old man, who said he did not see the benefit of knowing one's HIV status. In fact, he thought it might be hazardous to his health to know if he was HIV positive. Lester explained that having witnessed the painful death of someone with AIDS made him more fearful of HIV testing. Because he was worried about how he would cope with a HIV diagnosis, he declined the offer of testing:

> *"…. So by my own way of thinking, I wouldn't like to know that I've got HIV. I would rather get sick first and then do the test. … If I know I've got the virus, I would worry about when I might be getting sick."*

Other individual-level factors that may have played a role in their decision-making were patients' prior experience with HIV testing and their high level of awareness of HIV illness. The majority of respondents in the study (about two thirds) had previous experience of HIV testing. Some had had multiple HIV tests in their lifetime. Female respondents had mostly tested for HIV in the context of the prevention of mother-to-child transmission (PMTCT) programme while others had accessed HIV testing out of a sense of personal risk.

One respondent had tested as a prerequisite for becoming a blood donor. Another had tested as a requirement for entering the circumcision school (where traditional rituals are practised as part of the process of circumcision of young Xhosa men). Two young women indicated that they

tested regularly for HIV because of their concern about being exposed to HIV in their relationships with their steady boyfriends whom they suspected of having other sexual partners.

The social context in which the HIV test was being offered is characterised by high levels of awareness of HIV and HIV testing as well as exposure to HIV illness. Respondents seemed to be affected by their close contact with people living with AIDS. Several respondents volunteered information about family members and friends who were HIV positive or who had died from AIDS. This high level of awareness of HIV illness may be normalising HIV testing in their minds and may have contributed to them accepting HIV testing more readily.

South African studies have shown that knowing someone with HIV does reduce the stigma of HIV (Kalichman & Simbayi 2003; Pettifor et al. 2005). Being a witness to the suffering of friends and family with HIV seemed to have left a deep impression on respondents. For most, this appeared to have increased their willingness to test. However, for a few respondents, it reinforced their fear of HIV testing. Ayanda, a 24-year-old woman who had tested HIV positive at her STI consultation a few days prior to being interviewed, explained how she was affected by her experience with HIV illness:

> *"I also have family who passed away because of HIV. So that's what made me scared …that I'm going to look like them…that I'm going to go through all that pain. But when I came here at the clinic, they [the staff] were convincing me that: 'No, if you're HIV positive, that doesn't mean you're going to die … you can live for longer'… but I was still scared…"*

A particularly tragic example of being affected by HIV is that of Sibonele, a 19-year-old female scholar, who had witnessed the death of both her elder and younger sister within the space of 18 months. Their deaths had left two small children orphaned. She had also recently learnt that her mother was living with HIV. Sibonele had a fairly fatalistic view of her chances of getting HIV and expressed the view that HIV was a common disease that she might not be able to avoid. Similar fatalistic views were expressed by a few female respondents in this study.

In sum, patients appeared to make rapid and apparently intuitive decisions about accepting the test. Individual-level factors that were influential in their test decision-making included the patient's belief in the medical value of HIV testing, their previous experience of HIV testing, and

their high level of awareness of HIV and HIV illness, factors that could also be considered to be part of the social context in which HIV testing is taking place. Despite their fear of HIV testing, the context of the clinical setting seems to have provided an opportunity for testing to which patients responded readily. The potential influences of this clinical setting on shaping patient decision-making will be explored next.

Provider advice and personalising risk in the clinical setting

To further explore their test decision-making process, respondents were asked to describe the experience of the STI session with regard to the HIV testing offer. In addition to valuing the benefits of HIV testing, respondents pointed to the role of the clinical context and the patient-provider interaction as being influential in their decision-making. They reported that information and advice from the provider motivated them to test. One piece of information that made a particularly strong impression on patients was being reminded of the link between HIV and STIs in terms of the common sexual transmission route. The message that HIV is a treatable disease also featured prominently in patients reasons for testing. Phakama, 19, described how the nurse linked STIs and HIV:

> *"She [the nurse] told me that...hmm…STI is similar to HIV because you get it when you're having unprotected sex … Yeah, she asked me do I want to test or not…"*

Characterising HIV as an STI seemed to both normalise HIV testing and personalise the patient's risk of exposure to HIV. Given that patients were presenting with STI symptoms, they were aware on some level that unsafe sex was the common route of transmission for STIs and HIV. However, this did not necessarily translate into a personalised appraisal of their risk for HIV. Being reminded about the link between HIV and STIs, together with being advised by professionals to take the HIV test, seemed to have personalised the link between STIs and HIV more. This may have had the effect of increasing their willingness to consider testing in this clinical context. Henry, 20, explains how his awareness of the link between STIs and HIV became more acute in the consultation:

> *"Yeah, according to her explanation and according to my knowledge, you can get these STIs through sexual intercourse, without protection, you know? And HIV, you can get it through the same way…because before this, I looked at STIs like it was not relating to AIDS."*

Ayanda, 24, female, explained how her STI symptoms cause her to be concerned about HIV, especially since this was her second episode with an STI:

> *"She [the nurse] asked me what I came for and I told her for a discharge and stuff. Then she asked me since when it started…and if I ever tested for HIV….Yeah, she told me that you are at high risk when you have STI, of getting HIV. So that's why I had to test, because she said if I'm having STI then I might as well [might also] have HIV/AIDS. I can get HIV through STIs…that's why I decided to test. … She asked me, so I said: 'Yes, I want to'."*

Ayanda had been trained as a HIV peer counsellor and reported that, despite her high level of awareness of HIV, she had in the past avoided HIV testing for fear of a positive test result. Her concern about her STI symptoms, together with the provider's advice in the clinical encounter, motivated her to test in spite of her continued fear of testing HIV positive.

Banele, the young man referred to earlier, had tested HIV positive at his STI consultation a few weeks prior to the interview. He described how his testing decision was motivated by a combination of factors, including his own awareness and the provider's advice about treatment availability:

> *"She [the nurse] convinced me that it was not the end of my life. Having HIV did not mean that my life had ended. …That I can continue living, you see….And that if I take my treatment, well nothing will go wrong."*

And later:

> *"This thing [HIV] is all over the place out there, and I did not know my status, I only suspected that I could be having it because I was doing anything, anyhow, and I did not like using the condom."*

A few patients were concerned that they may already be HIV positive. Their need to have certainty about the underlying cause of their ill health is what seemed to motivate them to test. For example, Brenda, a 28-year-old mother who had tested HIV positive a few weeks prior to

being interviewed, had suspected she might be HIV positive. Her boyfriend had been treated for an STI and he had an HIV test. He told her he was negative but she did not believe him. Her awareness of her risk for HIV, together with the provider's advice, was influential in her test decision-making, as she explained here:

> *"What made me aware was that my boyfriend had a genital infection, he had a rash. So when he came back he gave me a card [partner notification for STI treatment card] that instructed me to go and test as well at a clinic closest to me. I came here. I did everything… I tested and then discovered that I am HIV positive."*

And later:

> *"She [the nurse] had already told me that when you come for that type of consultation [STI] you should test for HIV. It could happen that you come for one thing and yet you have other diseases as well, like being HIV positive. I then realised that there was a chance to be tested, and I then became willing to test."*

Phindi, a 36-year-old mother of two, also tested HIV positive. She had been concerned about her ailing health and had even intended to make an appointment for HIV testing the same day as her STI consultation visit. She regarded the HIV test offer as an opportune moment to take the test:

> *"I heard about the symptoms of HIV again, that maybe your body is full of pains and you could start to lose weight… Seeing that the Sister [nurse] advised me and because I [had] started to lose weight and [was] having abdominal pains…That's why I decided to come and test, because I had those suspicions that I might be HIV positive."*

And later:

> *"I felt that seeing that I had lost weight, I could have a big problem. I felt that I could be at high risk [for HIV] if I treat the abdominal pains alone rather than putting the two things together to know what is actually going on in my body."*

Phindi told of the relief she felt at finally knowing why she continued to be ill. At the time of the interview, which was 3 weeks after she tested HIV positive, she was preparing to go on antiretroviral treatment.

Both Brenda and Phindi had suspected that their partners were HIV positive, even when the partners themselves denied this. A number of women spoke openly of their distrust of their partners. This awareness of their exposure to HIV risk would perhaps have contributed to their test decision.

In summary, most respondents did not intend to seek out HIV testing at their STI clinic visit, nor did they anticipate being offered HIV testing as part of their STI treatment. Yet, the apparent ease with which they agreed to the test gave the impression that they regarded HIV testing as a reasonable option. The clinical context was important in their test decision-making as it normalised HIV testing. Contextual factors that influenced their test decision included increased awareness of the HIV-STI link, being reassured about the availability of treatment for HIV, and being advised by the provider to consider testing. This, together with the patients' individual-level concerns about their STI symptoms, seemed to contribute to a re-appraisal of risk for HIV. The interaction of these individual and contextual factors seemed to have provided a compelling motivation for many patients to accept HIV testing in this clinical context.



Satisfaction with HIV test decision-making

Patient satisfaction with testing experience can provide insights into the quality of patient informed decision-making. The IDM framework identified possible decision hazards that could lead to decision conflict and reduce patient satisfaction with their test decision. For instance, patients may experience decision conflict because their decision was not consistent with their values. In the case of HIV testing, a patient may regret having accepted HIV testing, either because they were not able to exercise their right to refuse or perhaps because they were over-optimistic about the test outcome. This section examines patients' perceptions of the voluntariness of their test decision, their general level of satisfaction with the PITC intervention, the extent to which they experienced decision-conflict, and whether their judgment of the likelihood of an HIV-positive test outcome was realistic.

*Patient perceptions of the voluntariness of HIV testing*

Respondents were asked in direct and indirect ways about whether they perceived the HIV testing as voluntary. Questioning revolved around assessing if they had knowledge of their right to refuse, whether they felt they could exercise this right, whether their permission was requested, and whether they felt coerced in any way to accept HIV testing. In response to this line of questioning, patients conveyed the sense that they were aware they could decline the HIV test, that their permission was sought, and that they did not feel coerced to test. They noted that providers used various phrases to convey voluntariness, such as "*It's your choice*", *"You can say 'Yes' or 'No'",* and *"It's okay to say 'No'."* A respondent described her sense of the voluntariness of the HIV test offer more directly:

> *"Yeah, you feel free, she [the nurse] doesn't force you when she tells you…you can test or not, it's your choice. I felt I could say 'no' if I wanted to, but because I wanted to [test], I didn't say 'no'."* [Phakama, 19, male]

The option to accept testing in a clinical setting appeared to be the obvious choice for most patients. Several respondents described scenarios where they persuaded themselves to take the test because they felt personally at risk:

> *"Yeah, I had two options. I could say 'yes' or I could say 'no'. But seeing that there's a lot of people out there that are infected with HIV....and I was not taking care of myself, so I had no option to say 'no'. I wanted to know my status. Lucky enough I know my status now....."* [Banele, 20, male]

And another:

> *"Yes, I knew that I had a choice, that I could say 'yes' or 'no' but I preferred personally to get tested."* [Brenda, 28, female]

The apparently intuitive and easy way with which the test decision was made is illustrated by the respondent below. It seems the attractiveness of the HIV test option made it hard for him to decline the offer.

> *"If I could, I would have [declined]…but, because in my heart I was thinking that, yeah, whatever she [the nurse] was going to say - it was there in my heart to say, I must go for the test*." [Henry, male, 20+ years old]

There were other ways in which providers conveyed the sense of voluntariness, for instance, by giving the patient the option to consider testing at another time. As one patient explained:

> *"[She said] if I'm not feeling free, then she can cancel it and I can come some other time. I can think about it if I want to, and come again if I want to…. She gave me choices. I said: 'Okay, no problem'."* [Ayanda, 24, female]

Another way to approach the question of voluntariness would be to examine the responses of those who declined HIV testing. Their responses could provide insight into the factors that enabled them to exercise their right to refuse testing, especially in a situation of substantially unequal power between patient and provider. During the quantitative evaluation of the impact of PITC on HIV testing rates, more than a quarter of those offered the HIV test declined to test (see Chapter 2). This could be taken as indirect evidence that a substantial proportion of patients were able to exercise their right to decline HIV testing but it does not tell us anything about the conditions under which this occurred.

Like those who accepted testing, patients who declined reported that they felt that the testing offer was voluntary. They declined testing for various personal reasons but all related to not feeling emotionally equipped to deal with the possibility of an HIV-positive outcome. One young woman, Nono, whose consultation was described in the case example with Nurse B, declined testing because she did not want to the risk of dealing with the anxiety of an HIV-positive test result before writing her college exam. Winston, a 36-year-old married man, also declined the HIV test because he felt ill-equipped to deal with the potential emotional complications associated with an HIV-positive test result. He reported that he had contracted an STI from a casual sexual partner and was struggling with the guilt associated with his infidelity. He expressed being fearful about the damage to his marriage should his wife learn of the affair. Another complication was that his wife was pregnant. Lester, 23, who also declined the HIV test, explained that he wanted to first concentrate on getting his presenting complaint treated:

*"I said 'No, I don't want the HIV test', because I wasn't coming for that. … I told myself that I want to fix my STI stuff first."*

The HIV testing process also required that patients give written consent for accepting the test and sign when they declined the test (the latter was to confirm they had been offered but had declined testing). This formal written consent requirement may have also strengthened the patients' perception of the voluntariness of the HIV testing offer.

Overall, then, it would seem that patients were aware that they had a choice about HIV testing, they were required to explicitly express their acceptance, and they had to give written consent. In describing the reasons for their testing and their experience of the test offer, patients conveyed the sense that they were able to express their personal preference for or against HIV testing. It should be noted their positive perceptions of voluntariness may also be influenced in part by their past experience and expectations of the health system, where they are not normally consulted about medical decisions (Pierce & Hicks 2001). They may have fairly low expectations regarding informed consent processes in a consultation.

On the other hand, public information campaigns about HIV testing and patients' past testing experience would have increased their awareness of the exceptional ethical requirements for counselling, confidentiality, and consent around HIV testing in South Africa. Thus patients may also be comparing their PITC experience with these higher ethical requirements and found it to be acceptable.



*Decision-conflict and realistic judgments of the test outcome*

As mentioned earlier, over-optimistic expectations of an HIV-negative test outcome can pose a decision-hazard for informed decision-making. A patient who decided to accept testing with an unrealistic assumption that he or she will test HIV negative may suffer decision-conflict if the test result is HIV positive. Such decision-conflict could be a sign of poor initial decision-making.

To explore whether respondents considered the probability of an HIV-positive outcome during the HIV testing process, they were asked to describe what was going through their minds while waiting for the test result. The question elicited a range of animated responses as respondents recounted their anxious wait, with obvious relief that these stressful moments were now behind them. All patients worried about the possibility of being diagnosed HIV positive, even those who

had tested for HIV before. Some patients described how they anxiously contemplated the possible negative health and social implications of testing HIV positive after they agreed to test. Two young men, both of whom tested HIV negative, described these anxious moments. The first, Banele, had tested for HIV once before:

> *"If ever I become positive, what am I going to do - am I going to live a life? Yuh!.....I was imagining my life, how my life is going to change…but if I'm negative, how am I going to make sure that I stay negative all the time? These were the things I was thinking when I stayed there, yeah…in a way, it was difficult."*

The second young man, Sihle, 16, had not had an HIV test before. His biggest fear was social rejection and isolation from his peers:

> *"… you can lose everything, everything will change, even your friends, everyone at school, people who know you…I was scared of that, I can't manage that … I was scared, I think of people who have HIV, I see them and I think of myself – what will happen to me ... then at the same I tell myself I will be strong ... and listen to results."*

As described earlier, a few patients considered themselves to be at high risk for HIV and anticipated an HIV-positive result. Two women who both tested HIV positive (Brenda and Phindi, mentioned above) and another who tested negative described how they weighed the probability of an HIV-positive test outcome.

> *"…I had that feeling that the results might become positive because of my boyfriend's genital ulcers… I was so scared but I preferred to know my status."* [Brenda, 28, female]

> *"I was just thinking that the results might come positive or negative. It's because I don't trust my partner.....because we were not using a condom."* [Phindi, 36, female]

> *"Yuh, yuh, yuh…* [expressing relief]*. The reason I was scared is because sometimes I'm not using a condom and I do not trust my boyfriend…"* [Ntombi, 27, female]

It would seem that most patients had been able to contemplate the possibility of an HIV-positive test outcome. This could be taken as an indication that they were not over-optimistic in their

test decision-making. There was one exception, however, where the patient did not fully engage with the possibility of an HIV-positive test result. Andile, a 23-year-old man, had tested HIV negative a few months prior to his STI visit. He was deeply shocked that he tested HIV positive at his STI consultation. He only believed it when the result was confirmed by another HIV test at his workplace. Although Andile struggled to cope at first, he was able to disclose his status to his girlfriend and he encouraged her to take the test. When she also tested HIV positive, he felt he needed to be a support for her and this also helped him to cope better. He explained:

> *"I was in a bad state. I was worried, I thought that I'm going to die now, I'm going to die….I didn't handle it actually. I cried with my girlfriend. She was also positive, because I told her and she also went for a test… but then I had to be strong because she was crying all the time..."* [Andile, 23, male]

Finally, respondents were asked about their perceptions of the provider-initiated approach as a whole. None of the patients expressed regrets about having accepted HIV testing. Those who tested positive acknowledged being shocked at first but mostly they were relieved to know their status and to be able to access care. Banele, 20, explained his reaction to the news of his HIV-positive result:

> *"My spirit went down, but I suspected that I might have this thing* [HIV] *for quite some time now, though I was not aware of it. Now that I finally know it, it should not change me. … Knowing will help me to further protect myself. Otherwise I do not have a problem with it."*

All patients, including those who declined HIV testing, were satisfied with the PITC approach to HIV testing. They felt this approach reduced some of the barriers associated with VCT, such as the lack of self-motivation and concerns about privacy and long waiting times. Similar positive perceptions of the PITC intervention were expressed in a survey that investigated patients' satisfaction with the PITC approach with the same population (Wills 2007).

In summary, the findings from patient interviews point to a range of factors that may have influenced patient informed decision-making. Patient-level factors included a belief in the value of testing, prior testing experience, and a high level of awareness of HIV and HIV illness. The clinical context provided a range of contextual factors that were influential in their test decision-

making and in shaping their perceptions of informed consent. These included the sense of merely responding to the opportunity to test and interactions with the provider that contributed to personal appraisal of HIV risk. Patients expressed satisfaction with the voluntariness of the test decision and did not appear to have any conflict about the choice they made to accept or decline testing.

## Discussion

This sub-study set out to examine the ethical implementation of the PITC approach to HIV testing in a LMIC setting by examining the influences on patients' test decision-making. The work makes two key contributions. Firstly, it provides empirical evidence on the ethical implementation of the PITC intervention from both a patient perspective as well as from observing practice. Secondly, it demonstrates the usefulness of a multi-dimensional approach to studying informed consent, both in terms of using a decision-making conceptual model and in terms of using multiple sources of information. In Figure 10 below, the findings of this sub-study are applied to the IDM framework to illustrate the usefulness of the framework in identifying and categorising the multiple influences on informed decision-making in a clinical context. The key findings in each of the three dimensions of the framework are reviewed and discussed below.

**Figure 10: Applying the Interactive Decision-Making framework to provider-initiated testing and counselling (PITC)**

(Adapted from Pierce and Hicks 2001)

Patient factors

Patients acknowledged their ambivalence about HIV testing prior to the STI consultation but nevertheless accepted the test offer with apparent ease. The patient's prior beliefs about the value of HIV testing, their high levels of awareness of HIV and HIV illness, and their past test experiences were influential in their test decision-making.

This study was not able to describe the potential influence of the patient's decision-making style, other than observing the rapid and apparently intuitive manner in which patients made the decision to accept HIV testing. Rapid decision-making can raise concerns about the quality of informed decision-making but it has been suggested that in certain clinical settings, it may be an efficient response to a familiar decision-problem (Pierce & Hicks 2001). Patients may, through their prior understanding the nature of the test decision, assess the situation as not requiring deliberation and opt for a quick response. The patients' physical and psychological state associated with presenting with STI symptoms would also have been influential in their decision-making and this is discussed as a part of the clinical context below.

Two studies on respondent decision-making in clinical settings in a high-income country setting (involving breast cancer treatment and a surgical intervention for cardiovascular disease) found that this type of rapid and apparently intuitive decision-making was common in over 40% of respondents interviewed about their decision-making processes (Pierce 1996). While making decisions about these serious medical conditions, patients did not seek out further information to assist their decision-making and showed little distress regarding their decision choice (Pierce 1996). Similarly, respondents in this study did not seek out further information, had no apparent distress about their test decision, and expressed satisfaction with the HIV testing process.

Other quantitative and qualitative studies in both high-income and LMIC settings found that patients responded well to provider-initiated HIV testing (Bokhour et al. 2009; Chandisarewa et al. 2007; Creek et al. 2007; Jürgens 2006; Obermeyer & Osborn 2007; Simpson et al. 1998; Weiser et al. 2006). The findings presented here are also supported by South African studies that show high levels of HIV awareness, openness to HIV testing, and patient awareness of treatment availability (Johnson & Lewis 2008; Pettifor et al. 2005; Shisana et al. 2005; Shisana et al. 2009; Shisana & Simbayi 2002).

Contextual factors

The study identified a range of contextual factors related to the clinical context that could have shaped patient decision-making and their experience and perception of informed consent in this setting. Contextual factors include the normative clinical environment of hierarchy, the way the provider implemented the PITC intervention interaction, and the ways patients responded to this and to the clinical context of the STI consultation.

The HIV test offer was made in a context of traditional hierarchical patient-provider relationships and some would argue that patient informed consent is not possible in this environment as it precludes autonomous decision-making (Canadian HIV/AIDS Legal Network 2005; Crewe & Viljoen 2005). This setting is characterised by unequal power dynamics including the authority position of the provider, the limited patient participation, and framing the HIV test offer as the preferred option; factors that according to the literature, would have limited the opportunity for patients to make an autonomous decision (Obermeyer & Osborn 2007; Richter 2006). As discussed in Chapter 4, some consider this an inevitable feature of the unique dynamics of a medical consultation where patients give up their autonomy to professionals with the expectation that they will receive competent care (Abdool Karim et al. 1998; Corrigan 2003; Lupton 1997; Meisel & Roth 1983). Others argue that a more democratic relationship is possible and can facilitate shared medical decision-making (Doyal 2001; 2004; Elwyn et al. 2000; Kirby 1983; Towle & Godolphin 1999).

Nevertheless, there were indications that patient expressed their preferences for and against testing and that they were satisfied with their test decisions. There were elements of the implementation of the PITC intervention that seemed to promote informed decision-making and this may partly explain why patients perceived their testing experience as voluntary despite the power differences. Providers seemed to have an awareness of the need to obtain informed consent and then took steps, beyond their normal practice, to try and achieve this. The way the test offer was made conveyed a sense of voluntariness (by asking rather than telling patients the test will be performed), they provided detailed information about the nature of the test decision, and they asked patients to explicitly express a choice for or against testing.

Other factors that may have influenced test decision-making include the issue of patients presenting with STI symptoms and the personalisation of their sense of risk for HIV. These aspects of the testing processes contributed to achieving the key elements of informed decision-making, informedness and autonomous authorisation. Despite the hierarchical relationship,

providers maintained a professional and caring demeanour and this may have added to the patients' positive experience of the HIV testing process.

The written consent requirement was an additional formal process that may have shaped patient's perception that their decision-making was voluntary. This was in sharp contrast to the standard practice for screening for other STIs. For syphilis testing, the patient was told the test would be done, in some cases information was provided, and in all cases, consent was considered implicit. Although this study went some way towards assessing both key components of informed decision-making, it was not able to make a definitive judgement of the level of autonomy that patients were able to exercise. The complexity of the concept of autonomy and the difficulty with operationalising it remain challenges for future studies of this nature.

On the whole, providers were able to deliver the intervention ethically though through different means and with different levels of efficiency. Providers struggled with aspects of the implementation of the PITC intervention and this could also have presented obstacles to informed decision-making. For example, there were gaps in information on the patient's right to refuse and excessive and ineffectual use of health education as well as inefficiencies in integrating the intervention into the STI consultation.

Besides the extra time that HIV testing added to the consultation, it also required providers to take a more patient-centred approach in their interaction with the patient. From observing their clinical practice, some nurses were less efficient than others in integrating the additional criteria required for informed consent for HIV testing. According to the PITC clinical guidelines, nurses were required to share a range of HIV-related information with the patient; they had to ensure that the patient could exercise their right to refuse; they had to get written consent; and they had to prepare the patient for dealing with a HIV-positive result. In effect, nurses were trying to integrate a patient-led decision-making process and a provider-led decision-making process within the context of one STI consultation, a phenomenon also reported by Evans (2009) in their review of nurses' experiences of PITC. Later in this chapter and in Chapter 6 this issue is discussed further when looking at the feasibility of the ethical requirements of the PITC intervention.

It is likely that there was confusion among nurses about the minimum requirements for ensuring patient informed consent. Although providers were told that pre-test counselling was not required to ensure patient informed consent, they may have been unsure of what this meant in practice. During their PITC training, nurses were also given mixed messages about the role of pre-test counselling and about HIV health education (see Chapter 6 for more on this). It is therefore not surprising to find that nurses resorted to doing excessive HIV health education and that they may have equated this with providing pre-test counselling. Health education may have been a more familiar and task-orientated response to their lack of clarity about what was required to ensure informed consent as well as being a safety net for ethical practice.

In a medical setting like this, difficulty in distinguishing counselling from providing information and advice may be common, even for specially trained lay counsellors. The fundamental difference between the two is that with counselling, the aim is for people to make or act on their own choices, irrespective of the providers' preference, whereas with advice-giving, the aim is to influence the choice (Egan 1990). As mentioned earlier, even with their commitment to ensure informed consent, staff often did not have the communication skills required to facilitate this and/or to do so efficiently. Another South African study evaluating the training of nurses on integrated HIV and TB care observed a similar struggle, with nurses showing commitment to patient-centred care but struggling to implement this in practice (Stein et al. 2008).

It could be argued that in effect the aim of counselling is also incompatible with the current practice of using specialist HIV lay counsellors in South Africa. For example, it would be difficult for them to remain neutral about the option of HIV testing in a clinical setting where the aim is to increase HIV test uptake and where their performance is measured (formally and informally) by high test acceptance rates. 'Motivational interviewing' is widely regarded as an acceptable and evidence-based strategy for combining the principles of counselling and motivation for positive behaviour change in medical settings. This will be discussed further in Chapter 7 when examining the feasibility of up-scaling PITC-type interventions.

Findings on the way nurses delivered the PITC intervention resonate with findings from another qualitative study that examined best practice for HIV testing. The Worthington and Meyers (2002) study found that providers viewed counselling as largely educational and that individualising HIV risk was considered a key intervention to increase willingness to test. Other South African studies have reported a sense of optimism and hope among nursing staff involved

with HIV testing and HIV care. Nurses saw testing as making a contribution to fighting the epidemic and as promoting patient-centred care (Evans & Ndirangu 2008; 2009; Penn-Kekana et al. 2005; Stein et al. 2007; Stein et al. 2008).

Nurses in other LMICs have remained positive despite the increase in workload but, perhaps unsurprisingly, have requested ongoing counselling, training, and support for dealing with the emotional demands of HIV care, especially in the context of the devastating effects of poverty on patients' lives (Evans & Ndirangu 2009; Stein et al. 2007; Stein et al. 2008). Similar contextual findings were reported in a qualitative study of staff and patient perceptions of routine opt-out HIV testing at two Veterans Affairs medical treatment centres in the US (Bokhour et al. 2009). Patients in the US study thought that making HIV testing routine contributed to destigmatising HIV. Nevertheless, they considered it important that providers ask for their permission rather than tell them the test will be performed. The authors also noted similar constraints on providers as found in this study such as the time it takes and the challenge of ensuring a patient-centred approach within the context of a busy clinical setting.

The findings on the professional care shown by nurses in this study are in contrast to other studies from the South African context which have highlighted unfriendly, sometimes abusive, attitudes on the part of the providers. Reasons for the difference in nurse practice in this study may involve the context of shifting HIV testing paradigms. The human rights and counselling paradigm around HIV testing is still prevalent even as we are moving towards normalising testing and providers may be cautious about how far they can shift towards standard public health practices for screening tests. In addition, nurses were made aware of the importance of informed consent and seemed to be committed to achieving this as best as they could within the context of a busy clinic consultation. Further, nurses were involved in the design and planning phase of the implementation of this intervention and this may have increased their motivation to adhere to the ethical requirements of the clinical protocol (an element that has been highlighted as important in increasing nurse buy-in in implementation of interventions (Walker & Gilson 2004).

A process evaluation of a South African trial comparing different approaches to training primary health care nurses on integrated HIV and TB care also reported on the positive effects of increased nurse involvement in their own training (Stein et al. 2008). STI nurses had clinical autonomy similar to that of physicians (being able, for example, to diagnose, do physical

examinations, and prescribe medicine) and it is possible that this level of autonomy may have contributed to the level of buy-in nurses had in wanting to enhance their clinical practice.

The decision-problem

As discussed in Chapter 4, there are various characteristics of the decision problem that may shape patient decision-making, including the seriousness of the health condition, the clinical setting, the consequences of the choice, and how the options are valued by the patient (Braddock et al. 1999; Pierce & Hicks 2001; Siminoff et al. 2004; Woolf et al. 2005). In Figure 10 at the end of this chapter, the elements of the IDM framework were applied to the HIV test decision. This sub-study was able to assess to some extent how patients viewed the decision-problem and how this may have influenced the ease with which they appeared to make their decision to accept testing. High levels of patient knowledge and past experience would have reduced the complexity of the decision for patients. There was also a high level of confidence in the accuracy of the test outcome given that the specificity and sensitivity of the HIV test is known to be high. These elements would have reduced the requirement for detailed explanation of the decision-problem.

It has been suggested that informed consent criteria should be adjusted according to the level of the complexity of the medical decision (Braddock et al. 1999; Pierce & Hicks 2001). Braddock and colleagues investigated the nature and completeness of patient informed decision-making in routine office visits to both primary care physicians and surgeons in the US. In their audio-taped consultations, they found that less than 10% of medical decisions met the full criteria for informed consent and that decisions with lower complexity were more complete in terms of the criteria (Braddock et al. 1999). They made two key recommendations. One was that medical decisions should be categorised according to the level of complexity and the other was that a minimum set of criteria be introduced for evaluating patient informed decision-making. Determining and agreeing on the level of complexity of HIV testing could provide a conceptual and methodological contribution to the debate about the ethical handling of PITC. One way to determine the level of complexity of the HIV test decision is explored below. The issue is raised again in Chapter 7 when discussing the practice implications of the findings in this study.

Complexity of the decision to test for HIV and implications for informed consent

Braddock et al. (1999) categorised medical decisions into three levels of complexity: basic, intermediate, and complex. Their categories are divided into three domains based on the effect on the patient, whether there was medical consensus on the value of the intervention, and on the level of uncertainty about the outcome of the intervention (see Table 12 below). Using their examples, a routine laboratory test would be a basic decision while a choice of medication might be an intermediate decision. A complex decision would be where there are complex choices to be made, where there are high levels of uncertainty about risks and benefits, and where the consequences of the choice may have serious health consequences (e.g. choosing between invasive surgery and alternative treatment options for breast cancer).

The authors also list seven criteria to determine the completeness of informed decision-making which they base on a synthesis of the literature in bioethics and on professional consensus on the important elements of informed decision-making (Braddock et al. 1999:99). The seven elements are that the provider discusses with the patient the following: (1) the patient's role in decision-making, (2) the nature of the decision, (3) the alternative options available, (4) the pros (benefits) and cons (risks) of the alternatives, (5) the uncertainties associated with the decision, (6) an assessment of the patient's understanding of the decision, and (7) an exploration of the patient's preferences (Braddock et al. 1999:2315).

Their quantitative evaluation of patient decisions showed that only 9% of decisions met their criteria for completeness. The element of informed decision-making that occurred most frequently was discussion of the nature of the intervention (71%) and, least frequently, was an assessment of the patient's understanding of the decision-problem (1.5%). The authors conclude that informed consent in practice falls short of the general criteria set by bio-ethical principles. They recommend that one should expect less extensive discussion of the decision-problem when the decision is considered to be less complex.

In Table 12 below, the researcher has applied Braddock's framework for determining the complexity of a medical decision to the HIV testing decision-problem. While some domains may be easier to categorise, such as the medical consensus and the nature of the test outcome, judging the effect of HIV testing on the patient is more controversial. Most people would probably agree that there is medical consensus about the value of HIV testing and that the

outcome of HIV testing is reliable and can be understood quite easily (putting the decision in the 'basic' category).

The key sticking point is the effect of HIV testing on the patient. Determining the level of complexity of the HIV test decision would require that public health officials and human rights advocates reach consensus on how beneficial or harmful it is for patients to become aware of their HIV status. As shown in Chapter 4, this issue is controversial because of the ideological debates surrounding HIV exceptionalism and the polarisation of the debates around protecting individual human rights and public health rights. The implication of classifying HIV testing as a basic decision would be that less complex informed consent criteria could then be applied. This, in turn, has implications for the content of testing interventions.

**Table 12: Applying Braddock's framework for determining the complexity of a medical decision to HIV testing (based on Braddock et. al 1999)**

| | **DOMAIN** | | |
|---|---|---|---|
| **Decision category** | **Effect on the patient** | **Medical consensus** | **Nature of the outcome** |
| **Basic** | ***Minimal***<br>The outcome of the test is knowledge of HIV status. The medical test is not complex in that that the result is easy to understand. There are treatment, care, and prevention services available. | ***Consensus***<br>There is consensus that knowledge of HIV status is beneficial especially as it is prerequisite for access to medical care. | ***Clear, singular***<br>The test result reveals the presence or absence of the virus in one's blood.<br>The sensitivity and specificity of the test is high which reduces the number of false negative and false positive results. |
| **Intermediate** | ***Moderate***<br>Being diagnosed with HIV means having to cope with the stress of having a fatal disease. Negative consequences may involve stigma & discrimination and a lack of access to HIV care. This should be weighed up against the fact that HIV is treatable and that knowledge of HIV-positive status can improve health, prolong life and reduce risk behaviour. | ***Wide support***<br><br>Not applicable | ***Moderately uncertain***<br><br>Not applicable |
| **Complex** | ***Extensive***<br>Implications of an HIV diagnosis | ***Controversial*** | ***Uncertain, multiple*** |

| | | | |
|---|---|---|---|
| | may have devastating emotional, social and economic consequences. This should be weighted up against the potentially fatal consequences of undetected HIV (including the unknowing spreading the disease). | Not applicable | Not applicable |

Even in the absence of agreement on the level of complexity of the HIV testing decision, it should still be determined what the minimum ethical requirements should be for HIV testing. The WHO guidelines for PITC dropped the requirements for pre-test counselling and written consent, listed the minimum information that should be shared, and gave reminders about the importance of the confidentiality and consent. But they give no guidance about how this should translate in practice in the clinical consultation. Braddock and colleagues recommended that, irrespective of the complexity of a medical decision, there should be a 'moral minimum' set of criteria to facilitate informed decision-making for all medical decisions. They suggest that two specific criteria (out of their list of seven elements of informed consent mentioned earlier) should constitute a 'moral minimum' ethical requirement. The two elements are: explaining the nature of the test decision (element 2) and eliciting the patient's preference (element 7). When applying this to HIV testing, the 'moral minimum' for an HIV test offer in the clinical consultation could be captured in the following script:

> *"We recommend HIV testing to all our patients because knowledge of your status can help you access treatment and prevention [Explaining the nature of the decision, element 2]. Would it be okay to do an HIV test today?" [Exploring patient preference, element 7].*

If this script is used to evaluate retrospectively the delivery of PITC in this study, one could conclude that HIV testing was handled ethically and that, in places, ethical handling exceeded these 'moral minimum' requirements. This concise way of introducing the HIV test offer may also make it more manageable for providers to integrate PITC into their standard clinical practice, which, in turn, may increase their motivation to offer the test.

Nevertheless, as has been shown throughout this study, the ethical handling of HIV testing may not only depend on the presence or absence of written consent or being told of one's right to refuse testing. Ethical implementation depends to a large extent on the conduct of the provider and the extent to which they were sensitised to the importance of patient informed consent. At

the same time, implementing the ethical requirements to share a range of information in an efficient manner remained challenging. With increasing pressure to normalise HIV testing and to deliver increased numbers tested, providers may be tempted to give up any attempts at improving the quality of informed consent for HIV screening if they feel that the requirements cannot be feasibly implemented. Ethical requirements that cannot be easily integrated with standard clinical practice may in themselves pose a threat to future ethical implementation as staff may end up doing it badly or not at all or they may avoid offering HIV testing altogether. The 'moral minimum' script suggested above may be able to assist providers in their efforts to facilitate informed decision-making in a way that can be implemented feasibly in a clinical setting. Providers can also be reminded that informed consent is also important because patient autonomy in the test decision may hold concrete clinical benefits for patients' adjustment to their HIV-positive status and their motivation to return for follow-up care (Abdool Karim et al. 1998; Rennie & Behets 2006; Strode et al. 2005).



Strengths and limitations of this sub-study

Studying informed consent in practice is complicated by a number of conceptual and methodological challenges that were described in the literature review in Chapter 4. This study has addressed some of these challenges but not all. For example, it was able to move beyond a one-dimensional approach to studying informed consent and with the help of a conceptual framework, was able to identify multiple factors that may have been influential in the shaping of informed decision-making. Nevertheless, the study was not able to study all of the components of informed decision-making or examine the interactions between them.

The study methodology has a number of limitations. First, the selection of HIV-positive respondents from among those who returned for follow-up care could have introduced bias towards a more positive perception of the intervention as these patients were drawn from a pool of patients who had returned to the clinic to access HIV care. HIV-positive patients who did not access HIV care may have been less positive about the PITC intervention. Further work with this group is needed.

Second, the study used direct observation of clinical consultations, a method that can be biased by the so-called Hawthorne effect (Wright 1994). Providers who are conscious of being observed may change their behaviour to reflect a more positive picture of their practice. This may be an inevitable consequence of the observation of any practice. However, it does not detract from

the benefit of this method compared to, for example, interviewing patients about their experience of provider practice or interviewing providers about their practice (Braddock et al. 1999). The use of multiple observations of individual providers is a strength of this study as this may have reduced the Hawthorne effect because the clinician may not be able to sustain the change of behaviour across all consultations over time.

Third, the study relied on a translator and on English transcripts that were translated from isiXhosa and translated data may be less rich and nuanced than the original. The researcher addressed this challenge by having a selection of transcripts re-translated by an independent translator. This helped to enrich the meaning for sections of the interviews and observations and it also helped to confirm the accuracy of the original translations.

Fourth, the researcher was the only person responsible for data collection and for analysing the data. The findings are therefore interpreted through the filter of the researcher's professional and personal background, beliefs, and assumptions. While the researcher's background as a clinical psychologist provided a professional level of skill for analysing the findings, it is acknowledged that this does not remove the potential blind spots that are part of one individual's analysis.

Finally, the study was done as a qualitative sub-study nested within a controlled trial that compared PITC with VCT. Extending the qualitative examination to the control group would have added a valuable comparative perspective but this was not feasible for reasons of time and resources.

There are two further issues that should be kept in mind when interpreting the patients' perceptions of their test experience. The first issue is that being interviewed in a health clinic setting may have inhibited them from expressing more honest or more negative views about the service they received. The researcher made it clear that she was not a clinic staff member through her dress and wearing a university name card but positive reporting biases may still be a consideration. The second issue is that patients' past experience of the lack of participation in decision-making may mean that they have relatively low expectations of the health services. Although the study was not able to judge fully the effect of these factors on patient perceptions, the observations of the clinical consultation provided a valuable complementary source of

information to evaluate what might have shaped the patients' experiences and perceptions of informed decision-making.

It could be argued that the Western Cape Province (in which Cape Town is situated) is particularly well-resourced and well-managed compared to other health care settings in South Africa and that this may limit the transferability of these findings to other health care settings in South Africa or other LMICs. While this may be so to some extent, it could be argued that the findings are highly transferable because it described dynamics of the clinical encounter which have universal elements. Sociological studies point to the stability of the clinical encounter and indicate that little of its structure and dynamics has changed over the last 30 years (May 2006). The use of a theoretical framework also provides conceptual generalisability as it offers the opportunity for comparing the findings of this study to other studies where informed consent practices are evaluated.

It should be added that given how important it is to evaluate informed consent in the context of a patient and provider interaction, a more in-depth discursive analytical approach, such as conversation analysis used in the work of David Silverman (Silverman 1997), might have given different insights and understanding of patient informed decision-making in this study.



**Conclusion**

Provider-initiated testing and counselling has raised widespread ethical concerns among human rights advocates, ethicists, and some public health professionals about compromising patient informed consent, especially in LMICs. This sub-study provided empirical evidence on the ethical practice of PITC in a LMIC setting, from both patient and a practice perspective. The study also contributed evidence to a broader body of knowledge about patient informed decision-making in practice, an area that is understudied in LMIC settings.

Using the Interactive Decision-Making framework, the study identified a range of factors influential in shaping informed decision-making, on the individual patient level, the contextual level, and issues specific to the nature of the HIV testing decision-problem. The findings indicate that patient informed consent is possible in a busy clinical setting (in spite of the hierarchical power dynamics), though this may be dependent on providers that are sensitised to the importance of the ethical requirements for HIV testing. Expanded HIV testing in the South

African setting takes place against a background of high awareness of HIV and HIV illness and of the availability of ART, openness (and ambivalence) towards HIV testing, as well as awareness of the ethical requirements about testing. This social context, together with the clinical contextual factors (especially the way the intervention was delivered, the patient's risk appraisal and the professional demeanour of providers) were shown to be influential in shaping the patient's experience and perceptions of informed decision-making.

This study was conducted at the start of a shift in views in South Africa and globally towards normalising HIV testing and this shift has continued to gain momentum (Bayer & Edington 2009; Bayer & Fairchild 2006). Recent changes in South African policy on HIV testing have embraced the shift by inclusion of provider-initiated HIV testing in the new HIV counselling and testing policy (National Department of Health 2010a). The findings from this study are therefore highly relevant because they draw attention to the interaction between the design of the PITC intervention, the feasibility of the ethical requirements, the efficiency of delivering the intervention, and the role of provider commitment in achieving informed consent in busy practice settings. Up-scaling PITC in LMIC settings would need to pay attention to how these elements could be balanced to ensure the efficient, ethical, and sustainable expansion of provider-initiated HIV testing, especially with increased pressure to expand testing services. The study made a novel contribution to such efforts by suggesting how the PITC intervention could be streamlined using minimum ethical requirements appropriate to the setting and the nature of the medical decision. In the next chapter, the impact of the intervention design and the implementation context on both its ethical and efficient delivery will be explored further.

To conclude this chapter, the key practical implications of this sub-study on informed consent are summarised below:

1. Policy makers and implementers should engage with the concerns expressed about the ethical implementation of PITC with the understanding that in medical settings, there are indeed challenges posed to autonomous patient decision-making. Although this concern should not be considered exclusive to opt-out testing approaches, one should acknowledge that the dangers may be increased with PITC. As PITC becomes more widespread in its implementation, the offer of HIV testing and the uptake, could become more normalised, but this also runs the risk of 'normalising' informed consent practices. This may mean that in some settings the minimum criteria for informed consent will not be adhered to and this

should be addressed pro-actively, by identifying ways to increase provider awareness and practices around informed consent.

2. The challenge of how to balance the dual goals of patient support and promoting test uptake is a tension inherent in most screening programs and policy makers and implementers need to show awareness of this. Ethical implementation could be facilitated by removing real and perceived implementation barriers for health providers. This means that implementers should tailor the PITC intervention to provide the shortest and most efficient ways of integrating HIV testing into their clinical practice. For instance, expecting providers to share detailed pre-test information may cause inefficiencies and ineffective practices that could also compromise informed consent, so it becomes more critical to clarify what the minimum requirements are for ethical practice (as was shown in the discussion on Braddock's framework earlier in this chapter).
3. The adaptation of expanded testing strategies should take the local context of high HIV prevalence and high awareness of HIV testing into account. PITC in this South African setting was characterised by patients with high levels of awareness of the benefits of HIV testing as well as ambivalent feelings towards accessing HIV testing on their own initiative. In this context, PITC in a clinical setting seemed to reduce the level of ambivalence and increase patient willingness to test for HIV, with a minimum level of information and motivation from the health provider. This makes it more important to ensure that the voluntariness of HIV testing is conveyed at the start of the test offer and that patients are reassured about the confidentiality of test results and of the availability of access to care.
4. To successfully roll-out PITC, policy makers and implementers may need to pay closer attention to a range of implementation and health systems factors. PITC was perceived by health providers as an opportunity to provide a more comprehensive clinical service to STI consultations, despite the increased workload and emotional burden associate with delivering HIV testing services. Nevertheless, the willingness of clinical staff to integrate HIV testing into their standard practice may be depended on factors independent of the PITC intervention itself. In the next chapter, these factors (such as tailoring the intervention to address local barriers and good management, organisational and supervision support), will be discussed when examining the process and context of implementing the PITC intervention.

# CHAPTER 6: A PROCESS EVALUATION OF THE PROVIDER-INITIATED TESTING AND COUNSELLING INTERVENTION USING THE NORMALISATION PROCESS MODEL

Although research evidence reviewed in the previous chapters may support the effectiveness of interventions such as PITC, its successful implementation may present a challenge. We need a deeper understanding of which implementation strategies are suited for particular types of health care interventions (Damschroder et al. 2009; Greenhalgh et al. 2004; Grol et al. 2002; Grol & Grimshaw 2003; Grol & Wensing 2004; Lavis & Lewin 2009; Lewin et al. 2009; Oakley et al. 2006). This sub-study focuses on understanding the factors that were influential in the implementation of the PITC intervention.



## Background

South Africa is considered a middle-income country but it has health outcomes that are worse than many low-income countries, including for HIV (Coovadia et al. 2009). Leading public health officials, researchers, and scholars agree that the key challenge for improving health care delivery is the need for leaders and managers to improve implementation and monitoring and evaluation of policies and programmes (Chopra et al. 2009; Coovadia et al. 2009). Studies of changes in health care practice use a variety of conceptual and theoretical models, including change management, leadership and organisational management, total quality management, sociological approaches, and patient empowerment (Grol & Wensing 2004). Evidence from these studies often indicates that the implementation of interventions could have been improved and that successful implementation is not only related to the quality of evidence underlying the intervention but also to a complex interaction of factors on multiple levels (Damschroder et al. 2009; Greenhalgh et al. 2004; Grol et al. 2002; Grol & Grimshaw 2003; Grol & Wensing 2004).

In general, four dimensions have been identified as being influential in implementation. These include the characteristics of the intervention itself (such as its acceptability and feasibility), patient-related factors (such as patient needs and expectations), the organisational context (including provider-related factors and organisational culture and constraints), and the broader socio-economic context (such as poverty and socio-cultural norms) (Damschroder et al. 2009;

Davis & Taylor-Vaisey 1997; Greenhalgh et al. 2004; Grol et al. 2002; Grol & Grimshaw 2003; Grol & Wensing 2004; Post et al. 2009).

It has been suggested that process evaluations alongside controlled trials could improve our understanding of the organisational and technical processes of implementation, yet few trials include such evaluations (Calnan & Ferlie 2003; Damschroder et al. 2009; Davis & Taylor-Vaisey 1997; Greenhalgh et al. 2004; Grol et al. 2002; Grol & Wensing 2004; Lewin et al. 2009; Oakley et al. 2006). Process evaluations are used to complement the quantitative findings on the outcome of trials and to help with the interpretation of the trial results. Process evaluations typically examine issues like the reach of a programme, the degree to which the intervention components were implemented as planned, whether it met agreed quality standards, and the acceptability and relevance of the intervention (Calnan & Ferlie 2003; Lewin et al. 2009; Oakley et al. 2006; Parry-Langdon et al. 2003). In a review of barriers and incentives for change in health care practice, Grol and Grimshaw commented that, "in the absence of this knowledge, the success or failure of the implementation of interventions may well be left to chance" (2003).

Process evaluations can benefit from the use of a theoretical model that provides an interpretative framework, for example, by structuring the enquiry to provide a deeper level of explanation (Calnan & Ferlie 2003; Grol & Wensing 2004; Lewin et al. 2009). Theory can be used to provide propositions for investigation or to provide additional explanations of what was observed and it can offer a source of external validity (Calnan & Ferlie 2003). In this study, the Normalisation Process Model (NPM) will be used as a guiding framework for the analysis and interpretation of the findings.

The NPM takes a sociological perspective on implementing change in health care delivery by focusing attention on those dynamic processes through which complex health interventions are made 'workable' and 'integrated' to the point of becoming embedded as normal practice (or 'normalised') (May 2006). The NPM has been described as a robust conceptual model as its starting point was a systematic re-analysis of qualitative findings from a range of studies of change in clinical practice from which the authors developed cross-cutting analytic constructs and propositions (May 2006; May & Finch 2009; May et al. 2009; May et al. 2007b).

The NPM has been found to be useful for improving understanding of factors influencing implementation in various medical settings. The model has been applied in clinical trials on the

delivery of problem-solving therapies for psychosocial distress and for nurse-led clinics for heart failure (May et al. 2007b), the use of telehealthcare services (May 2006), the use of decision-making tools in shared decision-making (Elwyn et al. 2008), and collaborative care in managing depression (Gask et al. 2010).

In the NPM, the term 'complex intervention' is used to refer to "a deliberately initiated attempt to introduce new, or modify existing, patterns of collective action in health care" (May et al. 2007a:3). The model identifies four constructs—interactional workability, relational integration, skills-set workability, and contextual integration—which influence the normalisation of an intervention. Each construct has two dimensions: 'co-operative attributes' describe formal and informal agreements amongst participants and 'executive' attributes' describe the efforts towards enactment of these agreements in practice.

The benefit of using the NPM is not only that it provides an organising framework for analysing and interpreting the findings but also that it provides a coherent language to describe the factors and the relationships between them, thereby contributing to the transferability of the findings. The model also provides propositions about how each construct would contribute to normalisation. Table 13 provides a summary of the constructs, their dimensions, and the propositions of the NPM. The model is described in more detail in the Normalization Process Theory On-line Users' Manual and Toolkit (www.normalizationprocess.org) (May et al. 2010).

The process evaluation in this chapter uses the four constructs of the NPM to examine and analyse factors that influenced the normalisation of the PITC intervention. The rationale for using this model is that it is evidence-based and has an explicit focus on theorising the dynamics of implementation processes. It attempts to unravel the complex realities of the implementation process, phenomena that is not always well covered by other social science theories. As such, the model provides a set of concepts and ideas to help the researcher to examine more closely the complexities of the implementation process.

**Table 13: Constructs and dimensions of the Normalisation Process Model (NPM)**

Adapted from (May et al. 2007a; May et al. 2007b)

| | **Interactional workability** | **Relational integration** | **Skills-set workability** | **Contextual integration** |
|---|---|---|---|---|
| | ***How does a complex intervention affect interactions between people and practice?*** | ***How does a complex intervention relate to existing knowledge and relationships?*** | ***How is the current division of labour affected by a complex intervention?*** | ***How does a complex intervention relate to the organisation in which it is set?*** |
| **Co-operative attributes** | **a. Congruence** Congruence requires shared expectations of normal conduct and purpose of the clinical encounter | **a. Accountability** Accountability requires agreement about the validity and expertise of knowledge and role divisions underpinning the work. | **a. Allocation** Allocation requires agreement on the formal and informal rules about the assignment of tasks, beliefs about ownership and appraisal of skills, rewards linked to roles and how work is monitored. | **a. Execution** Refers to the organisational factors influencing practical implementation and monitoring of the intervention. This includes decisions about distributing responsibility, power and resources and linkages to organisational structures |
| **Executive attributes** | **b. Disposal of work** This requires an investigation into the level of agreement about the meaning and consequences of the work and of expectations about its goals. | **b. Confidence** Confidence requires agreement on the credibility and utility of the knowledge and expertise and the criteria by which it is evaluated. | **b. Performance** Performance requires the ability of the organisation and people to deploy the intervention as planned and includes agreement about the tasks, boundaries, responsibility and autonomy of participants. | **b. Realisation** Realisation is made possible by agreement about the value of the intervention, policies about procurement, delivery of personnel and equipment and mechanisms for modifying organisational objectives. |
| **Proposition** | "A complex intervention is disposed to normalisation if it confers an interactional advantage in flexibly accomplishing congruence and disposal." | "A complex intervention is disposed to normalisation if it equals or improves accountability and confidence within networks." | "A complex intervention is disposed to normalisation if it is calibrated to an agreed skills-set at a recognisable location in the division of labour". | "A complex intervention is disposed to normalisation if it confers an advantage on an organisation in flexibly executing and realising work." |

The sections below describe these constructs in more detail and how these might apply to the PITC intervention and draws on the two main texts.

Interactional workability

The first construct, interactional workability, refers to the question of whether the complex intervention promotes ease and efficiency of interaction between people and practice. In the PITC intervention, a key question is the extent to which the intervention disrupted, maintained, or enhanced patient and staff norms and expectations of the clinical encounter. Trust and expertise are considered two of the factors that provide the 'glue' for interactional workability and that allow for the flexibility required to achieve a high degree of interactional workability. The model proposes that a complex intervention will more likely be normalised if the intervention maintains and/or enhances the existing norms and social relations.

Relational integration

In relational integration, the issue under investigation is the extent to which the complex intervention can be integrated with existing knowledge, practices, and relationships. Integration can be achieved through mechanisms that promote accountability for and confidence in the intervention. For instance, concerns about the safety of an intervention may reduce confidence in the intervention among participants (May et al. 2007a). In examining the PITC intervention, the role of leadership, governance structures, and operational support will be explored for their contribution to achieving internal integration. Disagreements about the scope of the work and the required skills are also of relevance here. The NPM proposes that normalisation of a complex intervention is more likely if it maintains or improves the accountability and confidence within existing professional networks and practices and if it legitimises the knowledge on which this relationship is built.

Skills-set workability

The construct of skills-set workability is concerned with how the current division of labour is affected by the intervention, the capacity of participants to deploy the required tasks, and how the quality of the work is monitored. For instance, for the dimension of accountability, one would examine whether the task is more appropriately allocated to doctors or to nurses, what

the formal and informal beliefs are about ownership of these skills-sets, how internal disputes about the role-division are minimised, and how resources are used to achieve the tasks. Under the performance dimension, the model would examine issues related to the ability to deploy the intervention, such as competencies and scope of work, autonomy of those tasked with deploying the intervention, and quality expectations about the work. In the PITC intervention, the nurses' perceptions of the intervention and their performance on the level of the clinical consultation are examined. The model proposes that normalisation of a complex intervention is more likely if the intervention has a good fit with an actual or realisable division of labour (May 2006).

Contextual integration

Contextual integration focuses on how the organisation uses its capacity and resources in the normalisation of a complex intervention. This includes examining the availability and management of required resources (such as finances and equipment), decisions about costs and risks, and the evaluation mechanisms. The realisation dimension of the model examines how the ownership and responsibility for the implementation is allocated and how the organisation values the intervention. For example, when deciding on adopting and integrating an intervention into normal practice, managers might undertake a formal or informal cost-benefit analysis that may influence the extent to which the intervention is normalised. In the PITC intervention, the timing of the intervention, the capacity for managing change and the allocation of resources to the intervention are among the issues examined. The fourth and last proposition of the model is that a complex intervention is more likely to be normalised if the organisation is able to be responsive and flexible in "executing and realising work" (May 2006:93).



## Methodology

Study design

The aim of this sub-study is to identify the factors that influenced the normalisation of the PITC intervention, drawing on the NPM as an analytical tool. The study was a process evaluation of the implementation of the PITC intervention. The design is a longitudinal observational case study based on research conducted over the two years of the implementation of the controlled trial. Process evaluations typically use a variety of methods for data collection (Lewin et al. 2009; Oakley et al. 2006; Parry-Langdon et al. 2003). In this study, a range of qualitative methods was used including focus groups with staff and management and participant

observation of the implementation process (see Table 14 for further details). The study also draws on findings from Chapters 2, 3, and 5 of this thesis where quantitative and qualitative methods were used.

This study examined the implementation processes of the PITC intervention and evaluated these against the four constructs of the NPM to understand what factors may have contributed to the intervention becoming embedded in practice and made routine in the study sites. Normalisation is, therefore, studied as both a process and an outcome. It has been suggested that normalisation as an outcome occurs when an intervention or programme is formally taken up by an organisation and scaled-up for wider implementation (May 2006). Though this sub-study examines implementation within the context of a relatively small pragmatic controlled trial, the NPM does help in understanding how this new intervention was accommodated within routine practice at Cape Town STI clinics.



Population and sampling

The study population for this chapter comprised all the role-players who were involved in and affected by the PITC intervention. This included the patients who received the PITC intervention, the nursing staff and lay counsellors who implemented it, the project leadership team, clinic facility managers, the TB/HIV/STI clinical supervisors, and the HIV trainers. All of these role-players were represented on a project steering committee (PSC) that had the task of planning and co-coordinating the implementation and evaluating its success.

Data collection

Data for this sub-study were collected from multiple sources during the researcher's work as an external evaluator of the PITC controlled trial, including from the other sub-studies that make up this thesis. These include the findings of the controlled trial on increasing uptake of HIV testing and the secondary study examining access to HIV care for those who tested HIV positive. The data also included qualitative findings from the study on patient informed decision-making (from patient interviews and observation of clinical consultations). Table 14 provides a summary of the data sources.

Another source of data was focus groups conducted with staff and management (see Appendix 9a and 9b for focus group schedules). Separate focus groups were conducted with nurses and

lay counsellors around the beginning and end of the implementation period (5 months and 17 months into the implementation period, respectively). A separate focus group was also conducted at 17 months with facility managers from the intervention clinics. In addition, a focus group was conducted with the project leadership after the intervention was concluded. This group included the original team leader (who had by then resigned), the new team leader, and the project manager.

The aim of the focus groups was to examine the experiences and perceptions of the participants. The focus groups used similar semi-structured interview guides that focused on their understanding of the intervention, the acceptability of the intervention, and the strengths and challenges of implementation. Focus groups were facilitated by the researcher (with a co-facilitator in two of the earlier groups), were conducted in English, and were audio-recorded and transcribed. Participants provided written informed consent for their participation. Copies of the interview schedule and of the consent form are provided in Appendices 7b, 9a, and 9b.

Data were also derived from participation in the implementation over a period of more than 3 years. This included being a participant observer in the last four months of the planning and training, the 21 months of the implementation, and the months following the review and evaluation phase. Observing the implementation phase involved accompanying the project manager on supervisory visits and attending the regular monitoring and evaluation meetings. Data sources included written material generated such as interviews and focus group reports, the researcher's notes, minutes of meetings, management progress reports, and training programme information. Other data were gathered from interactions with participants outside of the above forums and did not necessarily get recorded in writing. All the data collection was done at intervention sites except for two interviews with clinic management teams that were conducted at control sites. These interviews were conducted with the project manager to examine the reasons for those two control clinics achieving higher testing rates than the intervention sites.

**Table 14: Data collection methods and the participants of the process evaluation**

| Methods | Number of participants |
|---|---|
| Focus groups with staff, 5 months into the trial:<br>• One focus group with HIV Lay counsellors<br>• One focus group with STI nurses | <br>8<br>8 |
| Focus groups with staff, 17 months into the trial:<br>• One focus group with HIV lay counsellors<br>• One focus group with STI nurses<br>• One focus group with facility managers | <br>5<br>7<br>11* |
| Focus group with project leadership after completion of the study | 3 |
| Participant observation (general) over more than 3 years from planning to the end of the project | Multiple planning and monitoring meetings and supervision visits |
| Participant observation of training: First round of training for both STI nurses and lay counsellors and selected follow-up training | 10 STI nurses (& clinical supervisors)<br>12 lay counsellors |
| Interviews with patients (Findings reported in Chapter 5) | 20 |
| Observation of clinical consultations (Findings reported in Chapter 5) | 13 observations |
| Interviews with the facility manager, the HIV/TB clinical supervisor and the district manager at two control sites | Three interviews involving a total of 5 team members |

**Some facilities were jointly managed by the municipal and provincial health authority and facility managers from both authorities attended.*



Data analysis

Thematic content analysis was used to identify elements of the implementation process (Miles & Huberman 1994). Transcripts of focus groups were read and re-read to identify the common responses in relation to the key areas and these contributed to development of the main themes. Themes that emerged from the patient interviews and observation of clinical consultations became additional themes, for instance, on patient and provider perceptions of the interventions.

Information from participant observation of the implementation process contributed to the themes on staff and patient responses to the intervention, how it was promoted, and the main obstacles encountered. The NPM was used at the end stage of the analysis to group the themes under the headings of the four constructs and to assist with the interpretation of the findings. The NPM helped, for example, to reflect on the dynamic relationship between the organisational and leadership processes (that promoted integration) and the factors influencing the workability

of the intervention in the clinical encounter. Table 15 provides an example of how the NPM constructs were used to group, analyse, and interpret the findings.

To improve the credibility of the data, the researcher asked the original team leader and the project manager to read and comment on a draft of the findings. Both thought it a fair reflection of the implementation process of the PITC intervention.

**Table 15: Examples of the analysis process and application of the NPM constructs to the findings**

| Data items | Data source | Theme | NPM dimensions | NPM construct |
|---|---|---|---|---|
| Patient reasons for HIV testing consistent with their positive belief regarding the value of HIV testing & preference for PITC | Findings from patient interviews (Chapter 5) | Patient satisfaction with clinical encounter | Congruence achieved between patient experience and expectations. | Interactional workability was high because the intervention did not disturb the standard practice and expectations of the clinical encounter. |
| Trainers and management disagreed on content of the intervention and, as a result, the clinical protocol had to be adjusted | Observation of planning meetings & document review of clinical protocol | Disputes regarding clinical protocol related to ethical concerns that were (partially) resolved by compromise | Disputes about accountability and confidence challenged relational integration of implementation. | Achievement of relational integration required shifting of expectations on both sides. |
| Management identified operational support and monitoring and evaluation mechanisms as key to effective implementation | Management focus group & observation of implementation processes | There was a high level of operational support. Supervision and monitoring and evaluation are facilitative factors | Accountability and confidence were enhanced by operational support mechanisms. | Relational integration was facilitated by operational support mechanisms. |
| Nurses were positive about PITC, but concerned about the burden of work. The duration of the clinical consultation was increased. There were problems with how to integrate HIV testing into the STI consultation efficiently. | Findings from clinical observations (Chapter 5) & focus groups | Positive nurse perceptions. Challenges with practical implementation. | Re-allocation of roles was successfully achieved. Performance at the level of clinical encounter highlighted some problems with balancing the additional HIV testing tasks. | Challenges with achieving skills–set workability. |

## Results

The table below provides a description of the stages and activities involved in the implementation process and it is these activities that will be examined more closely, through the lens of the NPM.

**Table 16: Stages and activities during implementation of the PITC intervention 2005/06 to 2009**

| Year | Activity | Detail |
|---|---|---|
| 2005 | Conceptualising, designing and project governance | • The health department HIV manager identified a gap in HIV testing uptake for STI patients and rallied a few colleagues to motivate for the PITC intervention.<br>• The PITC intervention was proposed and accepted by top health department management.<br>• The PITC intervention was adapted to suit local needs: nurses offer and do the HIV test and lay counsellors give the result and do post-test counselling.<br>• A project governance structure called the Project Steering Committee (PSC) was set up to guide planning and implementation and to obtain the collaboration of stakeholders. The HIV manager who initiated the project became the team leader and chairperson of the PSC.<br>• The planning process was a 'start and stop' process due to disagreements among stakeholders. This delayed implementation by approximately six months. |
| 2006 | Planning, redesign and training. Project management and monitoring and evaluation put in place | • Disagreements amongst stakeholders were resolved to allow continuation of the project.<br>• The PITC intervention was redesigned to increase feasibility and acceptability.<br>• Detailed operational planning was done and facilities were prepared for implementation.<br>• A project manager was identified from within the health department to coordinate and support implementation.<br>• STI nurses and lay counsellors were trained on the PITC intervention by trainers from an HIV counselling training unit within the health department..<br>• Regular monitoring and evaluation mechanisms were put in place (cluster and quarterly evaluation meetings ) |
| 2007 | Implementation continued. Monitoring and evaluation | • More nurses and counsellors were trained at the intervention clinics.<br>• A patient satisfaction survey was done.<br>• Regular monitoring and evaluation continued.<br>• The team leader resigned from position as HIV manager and left the health authority.<br>• The PITC intervention was continued even though the team leader had resigned. |

| | | |
|---|---|---|
| 2008 | Final review, termination of demonstration project. | • New HIV manager provided support until the final review meeting where it was concluded that the demonstration project had achieved its goal of demonstrating success and feasibility, although the increase in testing was not as great as was anticipated.<br>• After the intervention project was formally concluded, there were a few months spent waiting for management to reach a decision about continuing the PITC intervention. During this time, STI nurses in the intervention clinics were given the option to continue using the PITC method, which some chose to do. |
| 2009 | *Formal uptake, roll-out and policy change | • After a few months while the health authority explored the feasibility of a broader roll-out, the new HIV manager led the process of formalising uptake and roll-out of the PITC intervention.<br>• After final health authority approval, the PITC intervention was now to be applied to all clinic patients, not just STI patients. The PITC intervention was redesigned and further streamlined to allow for better integration with routine clinical care.<br>• The roll-out was first applied to one sub-district and then it was implemented across the city at all the clinics.<br>• External donor support was used to provide training and project management support<br>• Plans were put in place to change city and provincial policy to integrate PITC into routine care, alongside the VCT approach to HIV testing. |

**The formal uptake and rolling-out of provider-initiated HIV testing does not form part of this study.*



<u>Interactional workability: How did the PITC intervention affect interactions between people & practice?</u>

*Congruence: To what extent were the expectations of the intervention congruent with current practice?*

Within the PITC intervention, nurses were asked to offer HIV testing to all their STI patients as part of standard clinical care. The standard practice at that time was that specially trained lay counsellors were providing the service for patients who self-initiated or who were medically referred for HIV testing. PITC therefore represented a paradigm shift from viewing HIV testing as a specialised counselling service to viewing it as part of a standard clinical service. Providing the HIV testing service also required upward task shifting from lay counsellors to nurses. Such upward task shifting would ordinarily not be considered feasible in the context of a LMIC health system where the norm is often downward task shifting from doctors to nurses to lay health workers (Dohrn et al. 2009; World Health Organisation 2007; Zachariah et al. 2009). The implementation of the PITC intervention had to overcome potential resistance to changing the current role-division between lay counsellors and nurses around HIV testing that had been in

place for many years, as well as the potential resistance from nurses to taking on additional work when they are already considered over-burdened.

The conceptual change underlying the paradigm shift can be characterised as moving from HIV exceptionalism (which underpins the current VCT approach) towards normalising HIV testing (by including it in standard clinical care). The need for this shift was articulated by the team leader at the stage of conceptualising the intervention—she thought the paradigm shift was essential to facilitate a change in attitude and practice towards HIV testing among staff. In an extract from a published interview prior to the implementation of the intervention, the team leader explained the paradigm shift underlying the PITC intervention:

> *"Treating HIV testing in this exceptional way contributes to the secrecy and stigma associated with HIV, discourages HIV testing and limits access to the credible treatment options available. Changing the status quo requires two major mindset shifts. The first is that HIV testing needs to be normalised. Within a medical context this translates to more routine, service provider-initiated HIV testing as part of the standard of care provided in a range of services including the management of sexually transmitted infections, antenatal, reproductive health and TB services amongst others. The second shift is that HIV needs to be framed within a chronic disease model. The emphasis should be on a range of care and support interventions that commence early in the disease and promote wellness"* (Naidoo 2006).



The leadership motivated for the PITC intervention by framing it as an intervention that would improve the comprehensiveness of clinical care and that could feasibly be integrated into nurse practice. Nurses shared the belief with management that the PITC intervention was congruent with their existing activities in the STI consultation and that the intervention only required a small shift in their practice. They also saw the potential benefits by increasing the comprehensiveness of STI care and reducing barriers to HIV testing:

> *"This is to be able to treat STI fully. It will ensure that clients are offered all services, even HIV testing… we want to offer complete care and treatment."* [STI nurse]

And another nurse commented:

> *"With me, even though there wasn't this project, whenever I was treating an STI, I always talked about HIV. So is not a new thing. The only opportunity I have now is that I have to do the HIV test. When I used to refer them for VCT, they always say: 'Oh, How long will I have to wait? Do I have to see a counsellor?' That was always an issue. They would say: 'I am willing to take the test, but if I have to go to the lay counsellor, I'm not going to test'... it's too time consuming for them…"* [STI nurse]

Not everyone agreed that PITC would provide an advantage over current practice and there was some resistance to the idea of normalising HIV testing. In particular, the HIV trainers and some lay counsellors had concerns about the ethics of the intervention and they questioned whether nurses were adequately skilled to implement it. These issues were discussed in Chapter 5 and will be elaborated on later in this chapter.

*Disposal of work: To what extent was there agreement on the meaning and consequence of the work?*

Although the intervention achieved its aim to increase HIV testing rates, there were challenges that may have affected the disposal of work and that could, if not addressed, affect the ability of the intervention to deliver better results. For instance, the PITC intervention had a significantly higher HIV test uptake compared to the VCT sites but the 14% increase was disappointing compared to the 20% difference anticipated by the project leadership. On average, the intervention sites implemented the offer of an HIV test with 75% of their new STI patients whereas it was envisaged that 100% of new STI patients would be offered the test. There were concerns among nurses with the increase in workload associated with offering HIV testing though this did not detract from their support for the intervention:

> *"There are limitations, like the time constraints, but we should go ahead. We should integrate routine screening to all parts of medical care."* [STI nurse]

The 100% test offer rate, however, was not clearly articulated as a target and may have been unrealistic. A large proportion (27%) of patients declined the test offer, more than double that found in the control sites, which also raises questions about the effectiveness of implementation. There was also wide variation in the performance across intervention sites

(although less than in control sites) which was not fully examined and was difficult to explain. Further, some control clinics performed better than the intervention clinics which pointed to the influence of local management and supervision issues that were independent of the approach to HIV testing.

Qualitative findings indicated a high level of patient satisfaction with the intervention. Nurses were generally positive and were able to apply HIV testing ethically although there were indications of challenges with efficient implementation at the level of the clinical encounter. The disposal of work might have benefited from more specific targets, for example, for proportions offered testing, for those who accept testing, and for those who declined. Although a rough target was set to achieve a 20% increase in testing compared to the control sites, the absence of a baseline testing rate meant that intervention sites did not have a clear target to aim for.



Relational Integration: How did the PITC intervention relate to existing knowledge and relationships?

*Accountability: To what extent was there agreement about the validity and expertise of knowledge and role divisions underpinning the work?*

As mentioned earlier, nurses largely felt that the paradigm and practice shifts required for the PITC were congruent with their current clinical practice. In practice, the PITC intervention required changes in the accountability for HIV testing that involved a re-alignment of roles. Nurses were required to take on tasks previously performed by lay counsellors, who were then required to give up some of their tasks.

This change in accountability (which also concerned the issue of confidence in the intervention) posed a challenge to the implementation and normalisation of the intervention. The leadership capacity, governance structures, and operational support mechanisms played a key role in strengthening the accountability and confidence in the intervention through creating a project governance structure that allowed for stakeholder involvement and for identifying and resolving disputes that threatened the implementation. Key to this was involving representatives on the project steering committee (PSC) in the planning process at an early stage. The planning phase was a lengthy process and was stopped and restarted several times as a result of disagreements among stakeholders. The team leader was a member of the top management team and this high

level of support and the representivity of the PSC would also have increased the confidence that participants had in the intervention.

The PSC played a valuable role in providing legitimacy, authority, motivation, and continuity. These contributed to the positive perception and uptake of the project by critical role-players such as facility managers, clinical supervisors, the STI nurses, and HIV trainers. The PSC also became the forum where disagreements among stakeholders (about the scope of work and the skills required) were identified and resolved. Some of the planning activities that increased relational integration included developing ownership through stakeholder involvement in the PSC, agreeing on the need for project management support and for additional training of nurses, and detailing monitoring and evaluation mechanisms to assess progress. The monitoring and operational support mechanisms included quarterly progress review meetings involving review of the overall project and quarterly supervision and 'cluster' meetings geared to provide supportive supervision in smaller groups of facilities.

STI nurses usually receive supervisory support and support from HIV/TB/STI co-ordinators, in addition to their line management support from the facility manager. These forms of support continued in both the intervention and control sites. Additional operational support for implementation was provided by a part-time project manager who was a senior clinical manager. She was responsible for overseeing the implementation and monitoring and providing additional support supervision. This, together with the quarterly review and support mechanisms, facilitated greater accountability and confidence among staff. The key contribution of the project manager was identifying and responding to the support needs of the staff in a timely way and ensuring the continuous monitoring of the intervention. The project manager provided operational support on multiple levels including purely technical or administrative assistance, ensuring that more STI nurses were trained in PITC, co-ordinating the cluster meetings for supportive supervision, conducting facility-based supervisory visits, facilitating the collation of routine information required for monitoring, and checking the quality of the information.

For example, she successfully addressed the shortage in trained nurses by arranging for more training courses to be conducted throughout the intervention period. Another example of operational support was that the project manager facilitated quarterly meetings (in smaller clusters of 2-3 facilities) that regularly monitored progress and provided peer support. Both the

team leader and the project manager felt that these 'cluster' meetings were central to the implementation of the intervention. The project manager explained:

> *"The cluster meetings were the 'engine' of the implementation process. It was used to share best practice and staff made it their responsibility to bring information to the meeting. They reviewed their monthly and quarterly statistics, they did problem solving and it was considered a team approach."* [Project manager]

In addition, the intervention relied on the accountability of facility managers. They participated in the planning via the PSC and they were asked to extend their regular monitoring and evaluation functions to include the PITC intervention. The team leader thought that the involvement of the facility managers was essential as their line management authority helped to maintain accountability. She noted:

> *"Facility managers wanted to deliver results - and they knew they were being monitored. People are more responsive when having to report regularly."* [Team leader]

*Confidence: To what extent was there agreement on the credibility and utility of the knowledge and expertise and about the criteria by which it is evaluated?*

There was a high level of agreement between management and the nurses (who were the main implementers) about their roles, about the utility of the intervention, and about the credibility of the knowledge requirements. The credibility of the intervention was enhanced by the fact that it was a highly experienced and respected senior manager who was leading the project. The PITC intervention also had the recognition of a global body such as WHO, which may have added to the level of confidence of all involved.

Staff acknowledged that the intervention was addressing a gap in service delivery for STI patients and they accepted the rationale that nurses should be used to address this gap. This shared understanding of the problem and participative planning process may have enhanced nurse compliance with implementation, a factor identified as important by Walker and Gilson (2004). Using service data on nurse and lay counsellor workload, the leader was able to show that the shift in roles and accountability was justified. Nurses and management also concurred about the feasibility of adding HIV testing to the standard STI treatment. For example, nurses agreed that their STI consultation already dealt with several elements of the HIV testing process,

such as sexual risk assessment, prevention education, and condom distribution. The quote below expressed a common sentiment among nurses about their comfort with the increased responsibility in practice:

> *"I think that we always did talk about HIV. People know it's a virus, they know it has to do with sexual transmission. But I think we spend more time now pointing to the benefit to the patient of testing. Previously we would refer them to VCT and because we weren't really involved with the testing, we didn't go into depth* [such as discussing]*, 'How this is going to benefit you. What services is available for an HIV positive patient, whether they know how they can prolong their life'."* [STI nurse]

One of the main challenges to achieving relational integration was a dispute about the scope and skills required to implement PITC. The HIV trainers and lay counsellors expressed their concerns about dropping the pre-test counselling component and a related concern was that patients would feel coerced into taking the test:

> *"Already overburdened staff may jeopardise the objectives of this new model because they have a lot of other things to do and the patient may not feel they can refuse."* [HIV trainer]

The dispute centred around two issues—the scope of the clinical guideline that nurses would be using in the consultation and the duration of the training required to implement the intervention. The disputes were resolved through compromises in which both sides had to adjust their expectations. In the first issue, HIV trainers were concerned that the clinical guideline was too short and would result in patients not being adequately prepared for potentially devastating news of an HIV-positive test result. The project leadership and nurses showed appreciation of the need for patient informed consent but they did not think this required specialist counselling skills. They were more concerned with the practical challenge of how to integrate HIV testing tasks efficiently with the rest of the STI consultation.

After much negotiation, the project leadership agreed to extend the number of questions nurses would explore with patients to ensure the patient was prepared for an HIV-positive test result. The extract from the clinical guideline in Box 3 below shows that in addition to having to share a range of HIV-related information with the patient (see the full clinical guideline in Appendix 3),

nurses were now required to explore six different questions after the patient accepted testing. Initially, only the first question ('How do you feel about having an HIV test?') and a question about whether the patient would have support if needed were included in the clinical protocol but trainers and lay counsellors thought this was insufficient.

**Box 3: Extract from PITC clinical and consent guideline**

| |
|---|
| How do you feel about having an HIV test? |
| What are the benefits of having an HIV test? |
| How would you feel if the HIV test result is positive? |
| How will you react/cope if the HIV test is positive? |
| Who would you tell if you are HIV positive? |
| Would they be able to support you? |
| **Explain that the HIV test is confidential. Client will need to consent to test. Client can refuse to have the test. Comments:** |



In the second issue, stakeholders agreed about the need for additional training for nurses and lay counsellors and that this was important for promoting confidence in the intervention. However, there was disagreement and a lack of clarity about what skills were required for nurses to implement the intervention. This led to a dispute with the training institution about the length and the content of the training for nurses.

HIV counselling training was provided by a semi-autonomous unit within the health department and they were asked to design a customised course for the PITC intervention. Their standard training for HIV counsellors lasts 20 days but this was thought to be inappropriate because nurses were not expected to provide pre-test or post-test counselling. The unit designed a 5-day course but the project leadership would not agree to this saying that it was not feasible to release nurses for this length of time. The training was eventually reduced to three days and, subsequently, to a course lasting only two days. The trainers were also asked to change the focus of the training to concentrate more on how to ensure that nurses obtained informed consent and less on counselling and providing HIV health education.

The leadership was successful in minimising these disputes, which threatened to derail the intervention. The downside was a protracted, 'start-stop' planning process that lasted more than a year and delayed implementation. The underlying reasons for these disputes appeared to

be related to the different expectations (and uncertainties) that arose from the shift in paradigm from HIV exceptionalism to normalising HIV testing. These uncertainties about the scope of practice, the ethical requirements, and the skills required, were also evident in the nurses' practice at the level of the clinical encounter as will be highlighted under the performance dimension of the skills-set workability construct (and as was described in detail in Chapter 5).

Skills-set workability: How is the current division of labour affected by the PITC intervention and how was the intervention deployed?

*Allocation: To what extent was there agreement on tasks and roles and the skills required for implementing the intervention?*

The PITC intervention was adapted to make it more feasible for local implementation. Usually, it is expected that the same provider will do the full HIV testing process, from offering the test, performing the rapid test, and giving the test result and post-test support. Previously, lay counsellors were providing pre- and post-test counselling (although the rapid test was performed by the nurse). In the adaptation of PITC to this setting, the re-allocation of roles involved nurses taking on the pre-test component and performing the test in their clinical consultation. The post-test component (giving the test result and support) remained a lay counsellor task and the nurse referred the patient to them after completing the STI consultation.

According to the management, the PITC intervention was split between these two providers for strategic and practical reasons. Most nurses were willing to offer the test but not to do the post-test counselling (for reasons of time and because some felt this required specialist counselling skills). This local adaptation made it more attractive for nurses to take on the intervention initially. The intervention was also adapted to increase the role of lay counsellors in the follow-up counselling for HIV positive patients. Lay counsellors, who were initially concerned about their job security, felt reassured by their increased involvement in providing follow-up care services. In reality, this increased role did not materialise as patients did not return for follow-up care services to the degree that was anticipated. Nevertheless, lay counsellors were satisfied with the opportunities for closer collaboration with nurses and became less concerned about the quality of the testing service that nurses provided. A study on integrated assessment of HIV, TB, and STI care in Cape Town clinics also reported low rates of return for follow-up care among HIV

and STI clients (Scott et al. 2010) and this remains a challenge irrespective of the HIV testing approach used.

To summarise, nurses were enthusiastic about the intervention from the start; they remained positive throughout and appeared to have internalised the paradigm shift to normalising HIV testing. It was mentioned earlier that they perceived HIV testing as a logical extension of the work they were doing with STI patients. Although not explicitly stated, another possible reason for their response may be that PITC addressed some of their frustrations about their work. For example, nurses conveyed a sense of helplessness in relation to their lack of involvement with HIV. They also expressed some frustration with STI patients with recurrent episodes of STI who were unaware of their HIV status. A nurse gave an example of a patient whom she had seen 13 times for STI treatment in recent years and who steadfastly refused to go for VCT but who accepted an HIV test when she offered it. Another source of frustration was the inconsistency in the availability of lay counsellors in the past as this meant that nurses could not always refer STI patients for VCT. The PITC intervention was regarded by many nurses as an opportunity to address these frustrations.

Nurses thought that the benefit of the PITC intervention was that they could offer a more comprehensive clinical service to STI patients but also a more holistic service by building rapport with patients through discussing behavioural and emotional issues:

> *"I think it boils down to the fact that we are actually spending more time with each client… as you're talking you win their trust and they are perhaps giving you information that they wouldn't have given before."* [STI nurse]

A nurse illustrated how having a discussion about HIV can lead to deepening of rapport with the patient:

> *"I asked 'How are you gonna feel if you're HIV positive?' and he said 'Ugh, I don't want to think about it', and I asked 'What do you think you'd do?' And he said 'I don't know'. I said 'How have you dealt with stress before in your past?' and he said 'I tried to commit suicide' and he describes this horrific personal life with an abusing father who is still abusing his mother… And you know, he was in tears… that someone cared enough to feel about his problems and to try to do something about it."* [STI nurse]

The team leader and project manager both thought that the nurses had been able to internalise the paradigm shift towards normalising HIV testing. They felt that without this paradigm shift, the practice shift would not have been possible. The initial exposure of nurses to offering HIV testing in the clinical consultation was thought to have increased their willingness to continue with the intervention. The team leader explained:

> *"I think it is due to HIV becoming more of an important issue in the sites. It raised staff awareness. When staff deals with HIV themselves, instead of others dealing with it, it makes then more aware of the urgency of testing and this awareness increased staff willingness to deal with HIV testing. "* [Team leader]

This sentiment was echoed by the project manager who also pointed to the benefits of staff feeling more empowered:

> *"I think staff felt empowered to deal with HIV which was a 'no-go' area for them previously and the responsibility of a different category of staff. Being allowed to offer HIV testing empowered them and made them feel they could deal holistically with patients."* [Project manager]

And later:

> *"For me, it's actually impacting very positively because we are dealing with the client only once, so at the end of the day the client is managed holistically…"* [Project manager]

One of the challenges of taking on HIV testing was that nurses felt the emotional burden of dealing with HIV on a daily basis. In particular, they struggled with their emotions when someone tested HIV positive:

> *"When you do the test, you pray: 'Please God, it mustn't be this one'… You have to take a deep breath when you are still waiting for the result and you pray."* [STI nurse]

This was particularly hard when young people were involved:

> *"Sometimes when they come and they are young, vibrant and the result is HIV positive, and you say 'Oh God' and you take a deep breath and you don't want anyone to be HIV positive. So when you get the result, you think, 'I can't do this, somebody else has to do this* [give the test result]*'. It's not nice, even in your tea-time, you think about these children and you wonder, how can I take the ignorance away from them? How can I get them to be bold and to say: 'I want to use a condom' when they are sexually active. I don't know if we are failing them with our education, I don't know, it's frustrating me…"* [STI nurse]

Another nurse described the emotional burden of the work:

> *"It depends on the history of the patient….There is this patient I saw on Tuesday. She attended in November last year and was negative and again in March this year, she was negative. So I was giving her education and she told me: 'You know, there is a friend of mine who is HIV positive and I found out she is having an affair with my husband…they just made it public now. Then my husband came back to me and I refused to sleep with him without a condom and he will swear at me in front of my children. So I ended up sleeping with him without a condom'. Then I tested her and she was HIV positive. …Sometimes it does affect you, in a way it is hard to do this work…"* [STI nurse]

Involvement with HIV also made nurses feel more vulnerable on a personal level. Nurses were sometimes asked by patients if they themselves knew their own HIV status. One nurse said she responds by telling the patient she is HIV negative. Nurses seemed to be aware of their own ambivalence about HIV testing although this sensitive issue was mentioned only once in the focus group discussions. In a moment of candour, a nurse says she raised the issue in the staff tearoom:

> *"One day in the tearoom I said: 'Why can't we as health workers go for VCT?' All of us should go, so when we talk to patients we know we are negative, because not all of us know. Some of us say: 'I will never go for VCT unless I am just sick, sick, sick...' This is what we are saying… it's true."* [STI nurse]

In the focus group, this comment met with lots of nervous laughter and acknowledgement from her colleagues but they did not purse the topic, perhaps due to its personal nature.

Nurses also remained ambivalent about providing the patient with the HIV test result themselves. A few nurses became more confident and had even shifted their practice to giving the HIV test result themselves. Other nurses were against the idea, citing time constraints and a lack of counselling training. The latter group also did not want to have the associated emotional burden of dealing with the reactions of HIV-positive patients. It is worth noting that when the PITC intervention was eventually scaled up, nurses also provided the test result and gave brief, post-test support. The management felt that the initial adaptation made it possible for nurses to later become more comfortable with the idea of providing the full HIV testing service.

*Performance: To what extent was the organisation and people able to deploy the intervention as planned? Could staff implement the PITC intervention?*

In terms of outcomes, the PITC intervention achieved its aim of increasing HIV testing rates. As described in Chapter 5, patients responded positively to the intervention and felt it was implemented ethically. They seemed to value the role played by the nurse in offering them the HIV test and advising them of the link between HIV and STI. They also accepted HIV testing in greater numbers than STI patients at VCT sites, which could be considered another indicator of patient acceptance. As discussed in Chapter 5, patients' positive perceptions appear to be related to their belief in the value of HIV testing, their high level of awareness of HIV illness, and their appreciation for the role of the provider in advising them to test for HIV.

From observations of clinical consultations, nurses did relatively well with implementing the intervention ethically given the busy clinic setting. However, as noted earlier (under the disposal of work dimension), both quantitative and qualitative findings indicate that performance could have been improved. Specifically, the average degree of improvement was small and there was wide variation in the performance of intervention sites (although this variation was less than in the control sites. Also, the intervention took longer to implement than was planned. When asked what the biggest limitation was of the PITC intervention, nurses reiterated their earlier concern that it took too long to implement. The amount of information they were required to convey was a problem as they were trying to balance patient participation with the need for efficiency:

*"We have a lot of information to discuss with them and the clients are also asking a lot of questions."* [STI nurse]

Another respondent explained this plainly:

*"We have to do too much talking and writing."* [STI nurse]

In Chapter 5, the nurses' performance on the level of the clinical encounter was examined in detail. The main findings that emerged were that nurses showed a willingness to implement the intervention ethically but that they struggled to do so in an efficient way. Part of the reason for this was their level of clinical and communication skills but another component was related to the requirements of the PITC intervention (having to provide more information and engage more with the patient in order to fulfil the increased ethical requirements of HIV testing). As part of ensuring informed consent, nurses were required to share a range of information about HIV with the patient and they were expected to ask a range of open-ended questions to prepare the patient for a HIV-positive test result. The approach to getting informed consent also encouraged a more patient-centred decision-making process and this may have been difficult to balance with the standard provider-led approach to working with patients.

These two processes required more time than nurses anticipated and made it difficult for nurses to integrate HIV testing efficiently into the rest of their STI consultation. The additional questions added to the adapted clinical guideline increased the demands on nurses and would have made it more difficult to shorten the time taken. It may also have added to confusion about what counselling role they were expected to play in the consultation. The nature of the training did not necessarily clarify this dilemma, as explained in an earlier discussion on training issues (in relation to the accountability construct above). In fact, the emphasis on HIV information giving and counselling may have added to the confusion on what the minimum requirements were for ethical application of HIV testing and how this could be feasibly achieved in the consultation.

Contextual integration: How does the PITC intervention relate to the organisation in which it is set?

*Execution: To what extent did organisational factors influence implementation and monitoring of the intervention?*

At the time of the design and implementation of the PITC intervention, there was already a global shift away from HIV exceptionalism towards normalising HIV testing and this shift provided a favourable socio-political environment for the implementation of PITC. On a national level, though, it should be noted that VCT was the predominant approach and that there has been resistance to PITC (though there were signs of this position softening). The National VCT policy was being re-drafted at the time of the implementation of this PITC intervention but the Western Cape Province went ahead with exploring ways to feasibly implement PITC. This led to the demonstration project that forms the basis of the evaluation in this study. The final HIV Counselling and Testing (HCT) policy in 2010 accepts provider-initiated testing but unlike in the WHO PITC guidelines, pre-test counselling remains a prerequisite (National Department of Health 2010a). The high level of patient awareness of HIV illness and the increased availability of ARVs in the South African context may also have contributed to a favourable environment for patient and staff acceptance of the PITC intervention.

Organisational-level factors may also have played a role in the variation found in uptake of HIV testing between intervention and control clinics. The underlying reasons for the variation between control arms were never fully examined. However, it is possible that some of the reduced variation found in intervention sites may have been brought about by the additional surveillance and support provided. Supportive monitoring and teamwork were also identified as the underlying reasons why two clinics in the control arm performed better than the highest performing clinics in the intervention arm. Successful up-scaling of the intervention may require, at least in the beginning, some form of additional operational support. This raises a question about whether similar positive outcomes can be expected in the absence of additional project management support. It remains to be seen whether the success of implementing a new intervention such as PITC may be dependent on a health system in which management, supervision, and monitoring systems are relatively well-functioning.

*Realisation: To what extent was the organisational environment and resources able to support the realisation of the intervention's objectives?*

The Cape Town health authorities responsible for implementing this intervention had a track record of successful management of projects to improve quality of care and this environment may have enhanced the chances of successful implementation. For instance, they were involved in the roll-out of ARVs ahead of the rest of the country and implemented a systematic approach to improving TB care outcomes. They also have developed an innovative approach to promoting the integration of HIV, TB, and STI services by monitoring the quality of these services through an integrated assessment tool (Scott et al. 2010).

The normalisation of the intervention was also supported by a high level of management support and the provision of an appropriate level of resources. It was determined from the start that no extra nurses would be made available as the intervention had to be tested in a realistic operational setting where additional clinical resources would be limited. Nevertheless, the organisation was able to make available the part-time services of a mid-level clinical manager who provided the project management support that was, as argued above, critical to the success of the intervention.

The PITC intervention achieved effectiveness in terms of the increased HIV testing rates and achieved 'ecological success' in terms of workability and integration. In the NPM, ecological success refers to the embedding of the intervention into routine practice without it necessarily achieving clinical or cost effectiveness (May et al. 2007b:2). Nevertheless, an evaluation of contextual integration remains incomplete in the absence of information that weighs the cost of additional nurse time used in the implementation. Such an evaluation would also need to take cognisance of potential opportunity costs such as the impact of the PITC intervention on the integration and workability of other services being delivered by the clinic (for instance, examining the effect of increased consultation time on patient flow and efficiency of the clinic).

Finally, the intervention was dependent on identifying spare capacity among nursing staff and on nurses agreeing to shift practice. This is something that may be difficult to achieve in an environment where nurses are over-burdened and have low morale, as has been described in some LMICs, including South Africa (Atkins et al. n.d.; Jewkes et al. 1998). Nevertheless, the results from this study showed that even in a resource-constrained environment, the PITC

intervention could be normalised, although this was in the presence of facilitating factors such as strong management capacity and support.

Table 17 below shows how the NPM was applied to the PITC intervention and summarises the factors that facilitated normalisation.

**Table 17: Factors affecting the normalisation of the PITC intervention**

| Interactional workability | Relational integration | Skills-set workability | Contextual integration |
|---|---|---|---|
| **Congruence**<br>The intervention required both a mind shift towards normalising HIV testing and upwards task shifting. Despite this, there was congruence with patient and nurses' experience and expectations of the existing clinical practice. | **Accountability**<br>Shifts in accountability and practice were successfully achieved through high levels of leadership, planning, operational support and monitoring and evaluation. Accountability was challenged by disagreements about the roles and expertise required for the work. | **Allocation**<br>There was agreement on and successful re-allocation of tasks for all participants. Nurses internalised the paradigm shift that was required for implementation, even where this meant an increase in workload. | **Execution**<br>Facilitating factors were the social and organisational contexts favouring normalising HIV testing, a receptive patient population and organisational capacity for implementing quality improvements. |
| **Disposal of work**<br>The intervention achieved its aim to increase testing rates but disposal of work and outcomes could have been improved. Monitoring targets may not have been sufficiently detailed. | **Confidence**<br>Leadership and nurses shared had a high level of confidence in the intervention, stemming from its international and organisational endorsement. However, HIV trainers challenged the credibility and utility of this knowledge. Disagreements were resolved by adapting the clinical guideline and reducing the duration of training. | **Performance**<br>Patients and nurses found the intervention acceptable. Nurses could implement the intervention, but ethical requirements were challenging to implement efficiently. | **Realisation**<br>Organisational mechanisms and responsive and appropriate resourcing enhanced the realisation of the intervention (and improves its sustainability). Limitations are that the intervention depends on identifying spare nurse capacity and there is no information of cost-effectiveness. |

## Discussion

The study identified a number of issues affecting the normalisation of the intervention. The main facilitating factors were that nurses embraced the intervention and that the management and operational support enhanced the implementation processes. Nurses appeared to have internalised the paradigm shift and the shift in practice required for implementation of the PITC intervention. Nurses welcomed the intervention as a way of enhancing their clinical work with STIs and HIV despite the increased time and emotional burden this represented. The characteristics of the intervention (which were seen as congruent with their clinical practice) and its timing (against the background of a global shift towards normalising HIV testing) further contributed to its normalisation.

The high quality of the leadership, operational management, and supervision were also influential in the success of the intervention. In addition, patients had a positive response to the intervention which was related to their beliefs about the benefits of HIV testing and their experience of the clinical encounter. The literature on drivers of successful implementation of health care changes identified similar factors related to the characteristics of the intervention, patient-level factors, and the clinical and organisational context (Grol & Wensing 2004). A recent South African study pointed to implementation level differences (other than financing and human resource capacity) as the reason for the differential uptake of ARV treatment at sites in three different provinces (Schneider et al. 2010). The factors identified as influential in the implementation were similar to those identified in this study and included political and managerial leadership, programme design, the effectiveness of monitoring and evaluation systems, and the extent of external programme support.

The PITC intervention required a shift in practice amongst nurses, and this was achieved by adapting the new intervention to the local setting, by, for example not expecting nurses to deliver the post-test counselling component. Another aspect was that the normal clinical encounter between nurse and patient was largely kept intact, which minimised disruption to their normal clinical routine. These adaptations allowed the intervention to be tailored to the local needs of health care practitioners which may have contributed to the successful shift in their practice. A Cochrane review of 26 studies assessed the effectiveness of tailoring interventions to address barriers to change in professional practice. The review concluded that tailoring interventions to address local barriers may have greater likelihood of success in

changing professional practice, though not enough is known about the types of tailoring interventions that work best (Baker et al. 2010).

As mentioned earlier, although the intervention required a shift in practice on the part of nurses, the normal clinical encounter between nurse and patient was kept intact, while merely adding layer of complexity to the interaction between the patient and the health provider. Keeping the clinical encounter intact has been identified as an important factor in normalising interventions. Evidence from sociological studies points to the stability of the clinical encounter across different kinds of health services and in different cultures since the 1930s (May 2006:90). Clinical staff usually have a traditional level of autonomy associated with clinical practice which is problematic for management oversight at this micro-level (Elwyn et al. 2008). However, as shown in this study, evaluation of the clinical encounter is important in process evaluation since we need to understand how and why implementation differs from intended policy and training.

Normalisation was challenged by disagreements about the accountability of roles and confidence in the intervention but these were resolved at the planning stage. The challenges that remained relate to the workability of the intervention. Although nurses were positive about PITC, they struggled to implement the intervention efficiently and this may, in part, explain the limited impact on testing rates and the variable performance of clinics. The PITC intervention, even though streamlined, still required more pre-test information for HIV screening than is usually required for screening for other STI tests. The local adaptations made to the clinical guideline increased the demands on nursing staff, both in terms of time and requiring a more patient-centred approach.

Nurses seemed to be committed to ensuring informed consent but there were ambiguities about what this entailed in practice, which may have caused them to spend more time than was required. They may have over-compensated for this uncertainty by focusing on HIV health education. They also struggled to balance the more patient-centred decision-making for HIV testing with their standard practice of provider-led decision-making on screening tests.

Other studies have shown enthusiasm among nurses about taking on additional HIV-related duties, even if this meant an increase in workload. The reasons for this enthusiasm include a sense of hopefulness about being able to contribute to fighting the HIV epidemic and satisfaction about providing a more comprehensive and better quality health service (Bernays et

al. 2007; Evans & Ndirangu 2009; Penn-Kekana et al. 2005; Rhodes et al. 2009; Stein et al. 2007). Nevertheless, high workloads and high stress levels limit the potential of nurses to respond to the counselling needs of HIV-positive patients. Nurses have called for more training and support to enable them to fulfil this role (Dohrn et al. 2009; Evans & Ndirangu 2008; 2009). Future PITC interventions and up-scaling would need to pay attention to the need to balance the requirements for ethical implementation of HIV testing with the need for efficient and integrated delivery of HIV testing in the clinical setting.

It should be noted that despite the challenges identified with implementing the PITC intervention, the health authorities formally accepted PITC for up-scaling on a provincial level, mainly because of evidence on its acceptability, impact, and feasibility. In the provincial rollout, HIV testing was offered to all primary health care patients, not only STI patients. For this purpose, the PITC intervention was further streamlined and nurses also provided the test result and post-test support (Dr K. Jennings, HIV manager, personal communication, 2009).

Drawing on the findings of this process evaluation, a list of recommendations concerning wider implementation and normalisation of PITC follow in Table 18. The recommendations highlight the importance of the design of the intervention for achieving congruence and the need for accountability mechanisms and shared confidence in the intervention (and the role of leadership, governance and stakeholder involvement in achieving this). It also focuses attention on the skills and tasks required to achieve workability, such as agreement on re-allocation of roles and mechanisms to ensure successful performance (including operational support and monitoring and evaluation). Finally the recommendations point to the importance of a favourable organisational environment and the organisation's capacity for realising implementation through appropriately resourcing and support services.



Strengths and limitations of this sub-study

The process evaluation used a range of qualitative methods that was able to examine both micro and macro-level implementation issues and it drew on quantitative trial findings. This multiple-method approach produced a robust design and comprehensive evaluation of the intervention. Another strength was the use of an theoretical framework for the analysis and interpretation of the findings for improving the depth of the analysis and, through conceptual generalisation, improving the transferability of the results (Green & Thorogood 2004). This study also points to

the importance of evaluating the clinical encounter in practice as it generated insights that would have been hard to gain from other sources of information.

The NPM proved useful in identifying the factors that contributed to the PITC intervention becoming part of routine practice. The model was useful for analysing the implementation process as it helped to identify influential factors and drew attention to the dynamic interaction between various dimensions. The factors identified in this study do not appear to differ substantively from those identified in other studies using the NPM with regard to the stability of the clinical encounter and the roles of different role-players (Elwyn et al. 2008; May et al. 2007b). However, this is only the second study applying the NPM in a LMIC setting, the other being a study examining the normalisation of a patient-centred TB treatment model in a similar setting in South Africa (Atkins et al. n.d.). One challenge of applying the NPM was how to avoid duplication that resulted from the overlap between the various constructs of the model. For example, the management made a number of adaptations to the PITC approach to address potential barriers and it was difficult to decide whether such efforts would best be considered examples of the concept of interactional workability, relational integration or skill-set workability as all three the concept were potentially applicable because of its common focus on the fit between the intervention and the current context.

One challenge of applying the NPM was how to avoid duplication that resulted from the overlap between the various constructs of the model. For example, the management made a number of adaptations to the model to address potential barriers and it was difficult to decide whether such efforts would best be considered examples of the concept of relational integration, relational integration or skill-set workability. All three these concepts were potentially applicable because of its common focus on the fit between the intervention and the current context.

A limitation of this process evaluation is that the qualitative research could have been more closely linked to explaining the outcomes and variation in the trial findings, a limitation that has been identified in other process evolutions as well (Lewin et al. 2009). The qualitative research was done in parallel implementing the trial which has the benefit of observing implementation in real time but as the trial results were not available at the time, it was more difficult to focus the investigation onto factors underlying the trial findings, thus limiting the explanatory value of the process evaluation. This dilemma was recently acknowledged by authors who conducted a process evaluation of an RCT of an unsuccessful school-led health promotion intervention where

the process evaluation was limited in its ability to explain the trial findings (Munro & Bloor 2010). The use of multiple methods, focussing on multiple stakeholders, while producing a more comprehensive evaluation, may have had the limitation of diluting the potential impact of the qualitative investigation. For instance, individual interviews with nurses to learn more about their perceptions of the ethical requirements may have generated more in-depth insights as compared to the data from the follow-up focus groups. The process evaluation in this study could have also benefited from investigation of HIV testing practices in control sites as it may have generated useful insights for a comparative analysis. Finally, the review of the implementation of this intervention could have been more extensively discussed in relation to implementation of new practices in health care, for example, by drawing on evidence from Cochrane and other reviews on successful implementation strategies (although the evidence for LMICs remains limited (Lewin et al. 2008)).



**Table 18: Recommendations concerning wider implementation and normalisation of the PITC intervention**

| Construct | Recommendations |
|---|---|
| Interactional workability | • Local adaptation of the PITC intervention is required and this should ensure that the intervention is congruent with the current clinical practice. Changes to the clinical encounter should be limited.<br>• The disposal of work could be improved by setting process targets in addition to outcome targets. For instance, targets such as the percentage of patients offered and declining testing, the level of patient and staff acceptance and how the ethics of implementation will be measured. |
| Relational integration | • There should be strong leadership and governance mechanisms that can facilitate stakeholder involvement and ensure that accountability.<br>• Leaders need to show management skills to resolve disputes that may arise and to ensure that stakeholders feel ownership of the intervention.<br>• Operational management support and regular monitoring and evaluation were central to normalisation. |
| Skills-set workability | • The workability of PITC may depend on the extent to which role-payers are able to internalise a paradigm shift towards normalising HIV testing. Re-allocation of roles and responsibility for HIV testing must ensure that the intervention is adapted to fit within standard clinical practice. Streamlining PITC should ensure both ethical and efficient implementation. This will require a careful balance of exceptional requirements for ethical HIV testing and standard screening practice. |

| | |
|---|---|
| | Training should include both a conceptual component to understand the ethical requirements and a practical component that teaches how to integrate HIV testing with other clinical tasks.<br>• Monitoring on the level of the clinical encounter is required to assess the extent to which the intervention is implemented as planned, especially to assess the quality of informed consent practices. |
| Contextual integration | • There is a favourable social and organisational environment favouring normalising of HIV testing (more so since the new HCT policy) that provides an increasingly receptive environment for PITC amongst patients and staff. Implementers should find ways to optimise this.<br>• Successful implementation of PITC will nevertheless require organisational capacity for managing change, appropriate resourcing and monitoring of the impact and quality of delivering HIV testing.<br>• A cost-effectiveness analysis of PITC in the SA context would add useful additional information for making decisions about policy and practice shifts. |



**Conclusion**

This study examined the implementation of the PITC intervention in a LMIC setting using the Normalisation Process Model as a theoretical framework and identified factors that were considered influential in its normalisation. Although the intervention challenged existing roles and practices around HIV work, it was nevertheless normalised. The results pointed to the importance of ensuring congruence between the design of the PITC intervention and the practice and expectations of the standard clinical consultation and for promoting accountability through strong leadership and governance mechanisms. Achieving workability of the intervention required an attitudinal shift towards normalising testing, acceptability of the intervention amongst providers and staff, operational support, and continuous monitoring and evaluation. A supportive organisational context and capacity as well as responsive and appropriate resourcing not only promoted success, but also improved the organisation's ability to up-scale the PITC intervention. Finally, improving the performance and normalising the PITC intervention will require attention to further streamlining the intervention and providing not only practical guidance but also conceptual guidance about the importance of ensuring patient informed consent.

# CHAPTER 7: CONCLUSIONS AND RECOMMENDATIONS

This thesis is based on an impact and process evaluation of a provider-initiated HIV testing and counselling intervention aimed at increasing HIV testing uptake among STI patients in Cape Town, South Africa. The previous chapters have provided the background to the problem and described the findings from the four sub-studies. In this concluding chapter, the research objectives and findings will be briefly reviewed. The chapter will then examine some of the main themes that emerged and their policy, practice and research implications. It concludes with a review of overall study strengths and limitations.

## Review of the main findings

The provider-initiated testing and counselling approach (PITC) emerged out of widespread recognition of the need to expand HIV testing to increase access to HIV treatment and prevention. Concerns were raised, however, about its feasibility and ethical implementation, especially in LMIC settings. The objectives of this thesis were to assess the impact of a PITC intervention on HIV test uptake and on access to HIV care, to evaluate the extent to which ethical principles were upheld in the implementation, and to examine the factors influencing routine implementation of the intervention.

Although there was a range of evidence about effectiveness of PITC in increasing testing rates, at the time of starting this research, the quality of the evidence on PITC was variable. Wide variation in the absolute effect sizes had been reported and most of the evidence was from antenatal and TB patient populations. Apart from one study in Botswana (Creek et al. 2007), no studies in LMIC settings had investigated the impact of PITC on STI patients, a target group that is particularly vulnerable to HIV risk.

This study contributed evidence about the effectiveness of the PITC with STI patients, a high-risk target group, in a LMIC setting, using a controlled trial methodology. The main study finding on the impact of PITC on testing rates was that PITC had three successes; it significantly increased the offer of testing (and thus the access to testing), the uptake of testing, and the consistency of clinic performance with respect to testing uptake. These findings are line with other studies in other settings that found that PITC increased testing rates. The increase in HIV testing rates

through PITC in this study is not as large as those reported for PITC in other LMIC settings, such as Botswana, Zimbabwe, and Uganda (Evans & Ndirangu 2009; Jürgens 2006; Obermeyer & Osborn 2007). There may be a range of reasons (reviewed in Chapter 2) for this, including difference in setting and baseline testing rates.

Up-scaling of PITC in South Africa would benefit from more research on the impact of PITC on the broader patient population as this will increasingly be the target group for expanded testing. The general population may be different in their response to routine testing than, for instance, high-risk groups like antenatal, TB, and STI patients. A district-based randomised controlled trial using PITC could, for example, provide useful information about the impact of expanded testing with the general primary care patient population. Research on PITC with hospital patients would also be useful as this may represent a different kind of setting and high-risk population.

The purpose of expanded testing strategies is not only to increase HIV testing rates but also to enable earlier diagnosis and linkage to HIV treatment, care, and prevention (WHO/UNAIDS 2007). Ethical concerns have been raised about the ability of health systems in LMIC countries to link increased numbers of HIV-positive patients to HIV follow-up care (Rennie & Behets 2006). The limited available evidence suggests that PITC does not decrease access to HIV-related care (Chandisarewa et al. 2007; Creek et al. 2007; Obermeyer & Osborn 2007; Pope et al. 2008) and the sub-study in Chapter 3 is in line with this evidence.

The sub-study on access to care is one of only a few that has examined the extent to which improved access to HIV follow-up care was realised in the context of expanded HIV testing. The study found no difference between PITC and VCT sites in the proportions of HIV-positive STI patients who accessed follow-up care for HIV. Across both arms, over two-thirds of patients had a record of CD4 testing (an indicator of HIV care). For those who were considered ART eligible (based on a low CD4 count), the study found equally low levels of viral load testing across arms, with less than one-third of eligible patients having a record of viral load testing. The study also found that there was less delay in accessing viral load testing for ART-eligible patients in the PITC sites compared to control sites but this would need further confirmation through a larger study. There was no difference between PITC and VCT in the illness stage of patients diagnosed HIV positive, with patients from both sites having equally low median CD4 counts.

A recent study in Cape Town compared the routine records of 885 randomly selected adult patients who tested HIV positive at 3 different testing sites between January 2004 and March

2009 (Kranzer et al. 2010) and found that access to CD4 testing was better for patients who tested via antenatal and STI services than patients who tested via self-initiated VCT services. This finding points to the possibility that testing approaches can influence access to care (discussed further below). More research studies are needed that are robust enough to study access to HIV care as the primary outcome of competing approaches to expanded testing.

This study found that less than one-third of ART-eligible patients across both arms had initiated ART within the minimum of 12 month observation period (as measured by presence of a viral load test record). Even if this estimate of ART initiation is an underestimate (as discussed in Chapter 3), these figures still represent a substantial gap in access to care for ART-eligible patients. There is growing concern and evidence about the loss to follow-up care of patients once on ART. This is a vital issue but we also need to know much more about failure to retain people in care after HIV testing but before ART initiation (April et al. 2009; Bartlett et al. 2008; CDC 2009; Kranzer et al.; Obermeyer & Osborn 2007; Pope et al. 2008; 2000) Expanded HV testing methods may need to build in clear mechanisms that increase linkage to follow-up care immediately after HIV testing, especially for ART-eligible patients.

This thesis also addressed concerns that PITC would compromise informed consent and result in coercive and mandatory testing practices, especially in resource-poor settings (Rennie & Behets 2006; UNAIDS Reference Group on HIV and Human Rights 2007). At the beginning of this research, a few studies have reported that patients and community members found PITC acceptable (which could be taken as a proxy for ethical implementation and informed decision-making) but no evidence was available on the actual implementation of PITC. Patient reports on their experience of the ethical implementation of HIV testing were mixed with some reporting feeling coerced and others experiencing testing as voluntary. Further investigation of the ethics of testing practices was thus required (Evans & Ndirangu 2008; Jürgens 2007; Obermeyer & Osborn 2007; Rajkumar 2006; Rennie & Behets 2006; Richter 2006).

The sub-study in Chapter 5 provided systematic evidence, from a patient and practice perspective, of the extent to which the ethical principles of informed consent were upheld in the implementation of PITC. The study identified elements of the STI consultation, such as the traditional hierarchical patient-provider relationship, that pose a hazard for informed decision-making in any medical setting. There were also gaps in the information nurses conveyed (such as only focussing on the benefits of testing) and they did not always inform patients about their

right to refuse. Despite these hazards, STI patients expressed satisfaction with their PITC test experience and did not perceive their test decision-making to be coercive in any way. A fair proportion of these patients declined the offer of testing which could also be taken as an indicator of patients exercising their right to refuse.

Part of the reason nurses were able to deliver the test offer appropriately is that they were sensitised to the need to ensure informed consent through the PITC training and through participating in the adaptation of the intervention. For the most part, they informed patients of the nature of the test decision, conveyed the voluntariness of the test offer, and provided patients with the opportunity to explicitly express their preference, all key elements of informed decision-making. Although nurses seemed committed to getting patient informed consent, they also seemed to struggle with how to achieve this in practice. The difficulties seemed to revolve around wanting to be more facilitative and patient-centred in their communication and needing to balance this with their more provider-led communication style and clinical priorities. This meant that nurses weren't always successful in explicitly conveying the voluntariness of the testing intervention. There was also reduced efficiency in implementing the intervention, with providers spending more time on HIV health education than necessary, in turn making the consultation time longer than was required. The feasibility of implementing the additional ethical requirements of PITC will be discussed below.

Finally, studies on the implementation of new and complex health interventions such as PITC point to a gap between the intervention effects in research settings and effects of these interventions in real-world (practice) settings (Grol & Wensing 2004). This gap points to the need to better understand the influence of specific implementation contexts on the outcomes of intervention trials. This study used a multi-method process evaluation to examine the implementation process of the PITC intervention from its planning and design phase through to its training, implementation, and evaluation phases. Despite the PITC intervention requiring upwards task shifting of HIV testing from lay counsellors to nursing staff, the intervention nevertheless became successfully embedded in routine practice. The Normalisation Process Model (NPM) helped to identify areas where the PITC intervention was usefully adapted to existing clinical practice and skills-sets (thus enhancing its workability). For instance, even though HIV testing represented an additional task for nurses, the intervention was designed to be integrated into the STI consultation in a way that would require little extra time. The model also helped to highlight the critical role played by management and staff in ensuring the

intervention was well received by various stakeholders and well integrated into existing professional and organisation practices (relational and contextual integration). Key to normalising the intervention was the high level of operational support and the regular monitoring and evaluation. This support was facilitated by strong leadership, responsive management, and the availability of additional project management resources.

## Key themes and the policy, practice and research implications

This next section discusses key themes that emerged across the research findings in the four sub-studies and reviews some of their implications for policy, practice, and research.



Beyond the numbers: lessons for expanding HIV testing in South Africa

Expanded testing is being rolled out across high-income and LMIC countries and it is likely that there will be growing pressure on health systems to provide HIV testing as a standard part of care. Increasingly, the goal of expanded testing will not simply be to increase the numbers of patients testing for the first time but also to provide for regular retesting. Regular retesting is now being recommended as an important cost-effective intervention for both high- and low-risk patient populations in the sub-Saharan region (Waters et al. 2011).

PITC may be one effective way to respond to this need. The findings from the controlled trial in this thesis suggest that PITC, when introduced in a busy primary health care setting in South Africa, can increase access to HIV testing while maintaining existing levels of access to care. The qualitative investigation found that testing can be delivered to this increased number of patients in an ethical manner. The implementation sub-study identified a range of barriers and enablers to PITC but, in the main, PITC also appears to be a feasible and possibly sustainable programme for the public health system in South Africa.

However, the relatively small effect size of the PITC intervention in this pragmatic setting suggests that PITC may not deliver the large increases in HIV testing numbers that would be required for managing the epidemic in a high-prevalence setting. Other testing strategies that are showing promise include mobile and community-based testing services, home-based testing, and self testing (April 2006). Efforts to expand testing will also require more research on the effectiveness, impact on access to care, feasibility, and acceptability of these other strategies

since they are likely to be as complicated ethically and operationally as PITC. Given the wide variety in the type of PITC interventions reported, it would be useful to have a systematic review of the evidence for PITC, especially for LMIC settings.

The goal of expanding HIV testing, however, should not just be to increase the numbers who know their status but also to link individuals to care, treatment, and prevention at an earlier stage of the disease (Rennie & Behets 2006; WHO/UNAIDS 2007). There is evidence of a growing gap between newly-diagnosed HIV-positive patients and access to HIV care, particularly in LMICs (UNAIDS/WHO/UNICEF 2010). This is true regardless of the approach to HIV testing. The key question then becomes how to increase linkage to care for newly-diagnosed HIV-positive patients, especially for ART-eligible patients who need urgent care.

The literature has not been explicit about exactly how expanded testing approaches may be able to increase linkage to care. As mentioned in Chapter 3, a few studies have suggested generic ideas for how to improve access to HIV care such as improved tracing and referral systems, expanding the number of service points to increase physical proximity to ART sites, point of care CD4 count testing at time of HIV diagnosis, integrated TB and HIV services, and ensuring patients understand the importance of follow-up care (Cooke et al. 2010; Cornell et al. 2010; Fairall et al. 2008; Kranzer et al. 2010; Losina et al. 2010).

While PITC may increase the numbers of people diagnosed and in need of care, there could be ways in which it may also improve linkage to care. For example, by having nurses provide an HIV test as part of a batch of other clinical investigations, active clinical follow-up of cases may become more routine and efficient. The medicalised clinical context may also make it easier for patients to see HIV testing and follow-up care for HIV as a more routine aspect of medical care. Policy makers and implementers need to pay closer attention to the ways PITC interventions could be expanded to include components that promote such linkages to care.

Further research is needed on the impact of different testing approaches on all the various steps in the health care process that link HIV-positive patients to appropriate care. For example, home-based testing might be an effective way to increase the numbers of people who access HIV testing (an initial requirement for accessing care). But there is a question about how effective it would be in linking those diagnosed positive to clinical assessment and treatment.

Finally, strategies to expand HIV testing in South African and other LMIC settings should aim not only to expand the different forms of testing and their linkage to care but also to ensure that the quality of the HIV testing process is assured. A recent presentation by Strategic Evaluation, Advisory and Development Consulting (www.sead.org.za) reported on research currently being written up on the quality of HIV testing in South Africa (meeting of the HIV Clinicians Society, Cape Town, January 2011). Their data indicated adequate pre-test procedures but poor management of the testing process, such as running out of test supplies, not using the correct equipment, not following test specifications like correct waiting time, and inadequate safety precautions. Performance across provinces was especially poor for using the confirmatory rapid test and for providing post-test counselling.

Expanding HIV testing effectively, as part of standard care, therefore requires attention not only to the ability of testing approaches to generate greater numbers of people testing. It also requires attention to the differing impacts of various testing approaches on access to care once diagnosed and to the need for continued quality assurance of the testing process.



How contextual factors may shape the ethical implementation of PITC

Though PITC's effectiveness, feasibility, and impact of access to care have been demonstrated in a range of studies (including this one), it is the ethical implementation of this testing model that has generated the greatest debate. This study has provided evidence for how PITC can be implemented ethically in a pragmatic LMIC setting. Perhaps more importantly, however, than establishing that it *can* be implemented ethically is this study's recognition of the importance of context in determining what ethical implementation looks like in practice. A number of authors have argued that ethical implementation requires knowledge of local context and appropriate translation of abstract bio-ethical principles into practice (Braddock et al. 1999; Corrigan 2003; Musschenga 2005).

This thesis has provided several examples of how the context in which HIV testing is offered can shape both the patient's and the provider's experience and understanding of informed consent in HIV testing. Drawing on the Interactive Decision-Making model, the study identified a range of individual, social, organisational, and environmental factors that shaped how testing was offered and how patients experienced the test decision-making and the process of informed consent. Findings indicate that patients had a high level of awareness of the nature and importance of HIV testing, many had been personally affected by relatives and friends with HIV,

and many had past experiences of HIV testing. One of their main reasons for testing was their belief in the medical benefits of HIV testing, including access to ART. The interaction with the provider in the clinical setting and the fact that their clinical complaint was related to unsafe sex also resulted in a more personalised appraisal of their own risk for HIV, further contributing to their willingness to test. These findings describe local reasons for how informed patients already were about testing and how willing they were to consider testing in a clinical setting.

Local context, however, may not always promote informed consent. Patients in this particular setting may have little sense of their right to refuse testing given the normative clinical encounter where they are not consulted and where their consent for screening tests is usually assumed. In this intervention, this aspect of local context was adjusted for by having providers ask patients to explicitly make a choice about HIV testing. This request may have been unusual for patients and may have strengthened their sense of the voluntariness of the test offer. In this particular context, then, informed consent best practices might need to be adjusted in several ways; on one hand, reducing the amount of information shared about the nature of HIV testing and its potential harms while on the other hand maintaining a higher standard than normal for eliciting expressed consent.

Such calculations are not always easy to make, though. The dilemma of how far to go in normalising HIV testing and adapting it to local contexts is reflected in both the WHO guidelines for PITC and the new National HIV Counselling and Testing (HCT) guidelines of South Africa (National Department of Health 2010a). The WHO guidelines for implementing PITC are faced with potential challenge on conceptual and practical levels. The guidelines call for a streamlined HIV testing protocol which includes dropping pre-test counselling and the need for written consent. Yet it still calls for a more stringent standard for informed consent practice than standard public health screening practice, including a pre-requisite set of pre-test information. This could be causing confusion in the minds of providers about what the nature of 'normalised' testing is and how it differs from their normal practice. Providers may also struggle to translate such guidelines into practice due to its incongruence with their normal clinical practice.

This dilemma of the potential incongruence between HIV testing requirements and normal practice has been identified by Evans et al (2008) as an important challenge to address in the implementation of PITC strategies. In this study, for example, standard practice in STI consultations was to inform patients (often in passing) that they would be screened for syphilis.

This screening test was often accompanied by little to no information and consent was assumed. Syphilis screening was dramatically different, however, from the way nurses offered HIV testing. Here, they made efforts to convey the message that the test was voluntary, they provided a range of HIV-related information, and they asked the patients, with varying degrees of effectiveness, to explicitly give their permission.

The question that presents itself is whether this approach to routine HIV testing strikes an appropriate balance between clinical and human rights imperatives and whether it can be effectively integrated with standard clinical practice. We might also ask if we should be improving upon standard practice and supporting test decision-making for other conditions in the same way this intervention does for HIV. This study cautions, however, that nurses struggled to effectively implement the ethical and operational requirements of this particular PITC approach. This suggests that the balance between normalising and exceptionalising HIV testing may need to shift even more towards standard practice. The next section offers another way of thinking about how we might achieve this without sacrificing the ethical gains that have been achieved around patient autonomy (Bayer & Edington 2009).



Getting back to basics: reassessing the counselling paradigm around HIV testing

Concerns about informed consent are neither new nor unique to HIV testing. Questions about whether and how medical screening tests can achieve public health goals in an ethical way have been long debated and are unlikely to be resolved soon (Bayer & Edington 2009; Bayer & Fairchild 2006; Bayer & Jones 1991). This is partly because of the ideological and philosophical differences underlying these arguments. There is disagreement, for example, on the extent to which the patient-provider relationship can or should be democratised (Corrigan 2003; Lupton 1997; Meisel & Roth 1983). In addition to philosophical disputes, however, there is also insufficient evidence to resolve areas of disagreement and there are considerable conceptual and methodological challenges to producing such evidence (as discussed in Chapters 4 and 5).

Chapters 1 and 4 review the ways that these issues have played out in the debates over HIV testing. In South Africa, the outcome of these debates has meant that VCT was the official policy for two decades. This policy emerged out of a heightened sensitivity to the importance of protecting the human rights of those with HIV. What this means, however, is that until this PITC intervention was introduced, the majority of nurses in the public sector in the Western Cape have had little opportunity to be involved with the HIV counselling aspect of HIV testing. As

mentioned when describing the PITC intervention and the VCT approach in Chapter 2 of this thesis, counselling was considered a non-negotiable aspect of HIV testing in the VCT approach and it was generally considered the domain of a specially trained cadre of HIV lay counsellors.

In the classical view of psychological counselling, espoused by the VCT approach, the counsellor remains neutral and empowers the client with information and other decision-making skills in order to help them make an informed decision. Strictly speaking, in this client-centered approach, the outcome of the decision to test or not is immaterial as the role of the counsellor is not to advise on a particular option, but to lay out the advantages and disadvantages of various options and to support a healthy decision-making process (Stein n.d.). In South Africa, in the VCT policy, the VCT approach has a dual goal; it is expected to be both client-centered and to deliver on public health outcomes such as high uptake of HIV testing (Strode et al. 2005; van Rooyen et al. 2011). This duality of HIV counselling, creates a tension, theoretically and in practice, about how one balances the client support and public health imperative for test uptake in HIV counselling (Buskens & Jaffe 2008; Silverman 1997; van Rooyen et al. 2011), when the public health imperative is to increase uptake of HIV testing. In the South African VCT policy, for instance, the emphasis is on client-centered support, by reinforcing the importance of pre-test counselling, but the policy is not explicit about how high uptake of testing could be achieved within client-centered counselling.

The use of such a classic psychological counselling approach to HIV counselling and testing, may have been appropriate in an earlier era of HIV, where the disease was heavily stigmatised and there were no treatment options available. However, against the scale of an epidemic of this size and with the advances made with HIV treatment, care, and prevention options, it may be time to review the counselling doctrine the underlies many exceptionalist approaches to HIV testing.

The classical psychological approach to counselling is to some extent incompatible with medical practice in a public health context. Medical practice in this setting usually aims to motivate people to make choices that are geared towards promoting health. If the purpose of testing is to promote health, it would follow that providers would want to recommend HIV testing as the health-promoting option, rather than remain neutral on the issue. Indeed, in a discussion paper on the patient, clinical practice, and health systems barriers to informed decision-making, Woolf

and colleagues (2005) examined three different ways of facilitating decision-making in medical settings and concluded that:

> *"Finally, despite the best informed-choice training, clinicians may still have difficulty shedding conflicts of interest, biases, and preferences when presenting options." (269)*

This conflict between neutrality and promotion was also identified in a review of the implications of PITC for nurses. They expressed a conflict between the counselling ethos and their perceived professional role as clinical experts and advisors for patients (Evans & Ndirangu 2008; 2009).

This dilemma of how to effectively motivate patients to make healthy choices while still respecting their autonomy is addressed in a growing body of literature on the use of 'motivational interviewing' in medical settings. Motivational interviewing is a brief counselling approach that allows the provider to recommend a preferred option while acknowledging that patients are at different levels of change. It recognises that different types of motivation and communication techniques may be required to move patients along the continuum of change (Miller & Rollnick 1991; Rubak et al. 2005). Motivational interviewing is grounded in the key elements of counselling including respect for the client's autonomy, the need for them to take responsibility for the choice, and a belief in the client's ability to change when ready. Motivational interviewing, however, also provides communication techniques that are brief enough to be integrated into everyday clinical practice (see Rubak (2005) for a systematic review of motivational interviewing in the medical context). Shifting the current doctrine of specialist pre-test counselling towards a motivational interviewing approach may provide a model that is more compatible with medical practice while still avoiding unethical practice.

Motivational interviewing, however, may still be difficult to implement in settings without access to proper training and/or without the organisational or professional culture to support it. Other mechanisms should be employed to simplify HIV testing in ways that staff can implement easily and where the minimum ethical requirements are adhered to. Chapter 5 suggested one strategy for striking this balance: streamlining the HIV test offer to a two-line script that nurses could use to introduce the test offer. This script is based on framework proposed by Braddock and colleagues (1999) who argued that HIV testing should be considered a basic medical decision (as opposed to an intermediate or complex decision). They argued that, in this context, the moral

minimum for ethical HIV testing included two key elements: explaining the nature of the test decision and explicitly eliciting the patient's preference. Their script, adapted for the HIV testing context, is repeated below for ease of discussion:

> *"We recommend HIV testing to all our patients because knowledge of your status can help you access treatment and prevention. Would it be okay to do an HIV test today?"*

Such a script resembles current public health practice for screening in terms of the ease with which it can be integrated into standard clinical care. However, it increases the opportunity for patient autonomous authorisation by asking explicitly for the patient to express their preference, an element that is not often part of health screening practice.

Policy makers and managers should of course be cautious of depending solely on written guidelines or scripts like this to ensure providers apply HIV testing ethically. Guidelines may not be worth the paper they are written on if health providers do not understand why it is so important that patients explicitly choose to take the test and how, as providers, they can facilitate such patient autonomous authorisation. Training for providers should focus on clarifying what the minimum criteria are for obtaining informed consent. They should be reassured that ensuring respect for patient autonomy should not require lengthy counselling or specialised skills but a commitment to enabling those patients who want to refuse to be able to do so without fear of negative consequences. They can also be reminded of the benefits to ensuring patient informed consent for future patient care (such as encouraging follow-up care and adherence to treatment) (Richter 2006). Finally, health systems factors that are supportive of ethical practice by providers—such as regular monitoring and effective supervision—also need to be encouraged.

The power of legal protections should also not be discounted. The public health system in Australia, for example, has been able to achieve some of the highest testing rates in the world for at-risk populations by both designing *and* enforcing legal protections for patients. These laws compel health workers to protect patient confidentiality and ensure informed consent in testing and they are matched by effective and accessible means of legal redress for patients whose rights have been violated (Buchanan 2005). Creating the environment for ethical testing requires engaging on a number of different levels both inside and outside the clinic and health system context. Policy makers need to consider how best to promote an environment in which

people want to be tested, are provided with ample opportunity to do so, and trust that they will receive the appropriate treatment care and support they need (Evans & Ndirangu 2009; Kalichman & Simbayi 2003).

## Strengths and limitations of the study

The use of conceptual frameworks

One strength of this study is that it used two conceptual frameworks, the Interactive Decision-Making framework and the Normalisation Process Model, to help guide the analysis and interpretation of the qualitative findings. These conceptual frameworks provided a mechanism for organising the findings and seeing the relations between different variables and between the findings of this study and the broader literature. They also provided a common and coherent language for reflecting on the findings which may make it easier to compare these findings with those from other settings.

Studies of informed consent in practice can benefit from using a multi-dimensional conceptual and methodological approach. Using a decision-making theoretical framework produced a more dynamic and comprehensive appraisal of informed consent in practice. This, and the use of multiple data sources (especially observations of clinical consultations), allowed the researcher to study informed consent as a process that unfolded over time in the STI consultation. This contrasts with the narrow approach taken in many studies, where informed consent is conceptualised as an outcome or event rather than as a series of events or a process (Bekker et al. 1999; Meisel & Roth 1983). The study also tried to move beyond the limited focus of many studies on the information component of informed consent and address the question of the voluntary nature of the testing experience as well.

Similarly, the use of the NPM to examine implementation of the PITC intervention allowed the researcher to identify and describe the interactions between different components of the implementation process. For instance, the analysis was able to focus in on how changes in one area (expanding the clinical guideline in an effort to improve integration) created a challenge in another dimension (by reducing the workability of the intervention and limiting its efficient implementation).

One limitation of this research is that the usefulness of these conceptual frameworks was perhaps not fully realised. These frameworks emerged during the implementation of the study and were used mainly to guide the analysis and interpretation of data but not to guide the intervention or research design. Using theory to inform the intervention and study design may have resulted in a tighter fit between the conceptual frameworks, data collection and analysis, and the study findings.

Most work on patient decision-making models comes from high-income countries (Bekker et al. 1999). To this researcher's knowledge, this is the first time that the Interactive Decision-Making framework has been applied in a LMIC setting. There weren't any real difficulties, however, in translating the model from a high-income to an LMIC setting since the three main components of the model were fairly generic and could be applied to a wide range of medical settings. The NPM is a relatively new model and still being developed and tested. This is only the second application of the NPM in a LMIC setting. The NPM was also generic enough to prove useful in analyzing implementation of this complex intervention. Some of its constructs, however, were not sufficiently distinct from each other, creating challenges in making consistent use of the model.



Methodological design

A key strength of this study is that it used a mixed method evaluation approach that included a controlled trial and an in-depth qualitative process evaluation, providing a robust evaluation design. This mixed method approach extended the evaluation beyond the quantitative impact of the intervention to an exploration of the micro-level issues of implementation at the level of patient-provider interactions. The study also considered macro-level issues influencing uptake of the intervention into routine practice in a busy primary health care setting.

Process evaluations in the context of controlled trials have been recommended as a means of improving understanding of the mechanisms and the effects of the intervention (Calnan & Ferlie 2003; Damschroder et al. 2009; Davis & Taylor-Vaisey 1997; Greenhalgh et al. 2004; Grol et al. 2002; Grol & Grimshaw 2003; Sanson-Fisher 2004). A recent review of the use of qualitative evaluations alongside trials indicates that these methods can be used for different purposes, such as assisting with the design of an intervention, describing implementation processes, and examining the reasons for the effects of the trial (Lewin et al. 2009). The reviewers expressed concern about the methodological rigour of some of these qualitative investigations. They also

noted that the majority of these studies were done prior to the implementation of the trial, limiting their ability to contribute to an understanding of the quantitative trial findings.

This study provides an example of how qualitative investigation can be used effectively alongside a controlled trail of a complex health intervention. In this process evaluation, the qualitative investigation took place before (in the design, planning, and training phases) and during the implementation and evaluation of the trial. This allowed the researcher to study the intervention over its entire life-span which strengthened and deepened understanding of important implementation factors.

The study was also able to investigate the different perspectives of those involved in the delivery and receipt of the PITC intervention. This addresses a gap in the research on informed consent in that the majority of studies on consent in practice rely on patient accounts only, limiting the richness of their findings (Bekker et al. 1999; Meisel & Roth 1983). This study engaged with project leaders, patients, trainers, nurses, lay counsellors, and facility managers. It also combined observations of clinical consultations with patient interviews, providing a more comprehensive investigation of the study question.

The trial was pragmatic in nature in that it was initiated, designed, planned, and implemented by the health authority. It was conceived of as a demonstration project to investigate the effectiveness, feasibility, and acceptability of PITC in a real-life operational setting and was therefore not strictly conceived for research purposes. The health management requested a rigorous external evaluation to be done (alongside their routine monitoring of the project) but only after the initial design of the intervention was completed.

The pragmatic design of the trial strengthened the applicability and relevance of the evaluation as the results can be seen as more applicable in real-life operational settings than for a more controlled research setting**.** The primary outcomes of the trial and of the qualitative study were chosen to be of specific relevance to the local and provincial health authorities who were interested to know how to improve testing rates for STI patients in their setting. The intervention lasted 21 months and the research evaluation period for the trial was for a period of 6 months in the middle of the trial, which was sufficient to take account of the influence of normal health systems fluctuations.

There were, however, a number of key methodological limitations in the design of this study. A key limitation was that the researcher was not able to randomise the allocation of clinics to intervention or control. Although baseline comparisons indicated no important differences between intervention and control clinics, the lack of randomisation could be seen to reduce the strength of the evidence due to the increased risk of bias (Higgins et al. 2008). Another limitation of any complex health intervention trial is that it is not feasible for staff participants to be blinded, making it difficult to account for confounders such as staff enthusiasm, belief in the intervention, or optimism about its effects. The health managers involved in compiling and collecting the data to evaluate the progress of the intervention were also not blinded. However, data from the routine monitoring data systems were used which would have prevented any manipulation of outcome data and data quality checks of routine data were performed, which limited the potential biases emanating from the lack of blinding of the assessors.

The pragmatic approach meant the researcher had less control over the study environment. A case in point, described in Chapter 2, was that control clinics may have received an incentive to increase their performance midway through the trial. A further difficulty was that the health authority management had specific operational goals they wanted to evaluate that were not always compatible with the research-oriented focus of the evaluation. This required careful negotiation of the boundaries of the external evaluation.

One limitation of the process evaluation was that it may not have optimised the contribution of the qualitative investigations. For instance, it would have been helpful if it was determined at the start how the qualitative findings would be contributing to the trial findings, improving the integration of the process evaluation findings. Poor integration of process evaluation findings in trials of complex interventions was identified as a limitation in other process evaluation studies (Lewin et al. 2009). Part of the challenge in this study was that the process evaluation was done in parallel with the trial. This has its benefits but since the trial outcome was not known until much later, it was difficult to focus the process evaluation to investigate specifics dimensions. One example of an issue that could not be investigated was why there was so much variation in the performance of participating clinics and why this variation was not seen in intervention clinics.

A second limitation of the process evaluation's design was that using multiple methods and covering several perspectives may have diluted the focus of the qualitative investigation at the

expense of in-depth analysis. On the other hand, qualitative investigation was not extended to observing practice and exploring the perceptions at control sites. This would have provided a valuable comparative perspective but would have been difficult to manage in terms of resource and logistical constraints.

There were a range of other technical methodological limitations in the qualitative components of the study. Firstly, HIV-positive respondents were recruited for interviews from among those who returned for follow-up care and this could have introduced bias towards a more positive perception of the intervention. HIV-positive patients who did not access HIV care may have been less positive about the PITC intervention. Further work with this group is needed. Secondly, patients were interviewed in the clinic setting. The setting may have inhibited their ability to be critical of the health service and staff and in this context they may have also regarded the researcher as being aligned with the clinic. The researcher made efforts to convey the message that she and the translator were not clinic staff members and to stress the confidentiality of findings but this may not have been enough to change patient perception.

Thirdly, the data from observations of clinical consultations may have been influenced by the so-called Hawthorne effect (Wright 1994). Providers who are conscious of being observed may change their behaviour to reflect a more positive picture of their practice. This may be an inevitable consequence of observation of any practice but does not detract from the benefit of this method compared to, for instance, interviewing patients about their experience of provider practice or interviewing providers about their practice (Braddock et al. 1999). The Hawthorne effect in this study may have been reduced by the use of multiple observations of individual providers because the clinician may not have been able to sustain changes in behaviour across all consultations over time.

Fourthly, the study relied on data translated from isiXhosa into English. Although the researcher made efforts to ensure that translation was of a professional quality, translated data may be less rich and nuanced. There were also challenges in working with a translator when doing interviews as it was difficult to decide what method worked best to get the richest data. For example, initially the researcher opted for immediate verbatim translations of patient responses which allowed for a variety of follow-up questions to explore meaning. While this worked well with some patients, with others, it interrupted the flow and produced material that lacked depth. The researcher decided to allow the patient to provide a longer narrative in isiXhosa and

for the translator to provide the English translation only at the end of such a narrative. While this approach had the benefit of providing more continuity and depth to the patient's narrative, its value was limited by the ability of the translator to accurately convey the detail and it also reduced the opportunity to explore multiple angles.

As explained in Chapter 4, for a selection of the interviews, a full translation was done of the isiXhosa sections during the transcription of the digital recording. This provided the researcher with two translated versions of the patient's responses and an independent quality check of the translation provided in the interview setting. It also gave access to richer material in some of the interviews. The researcher chose to do the interviews herself with a translator rather than recruiting a Xhosa-speaking research assistant to conduct the interviews. In retrospect, the study might have benefited from using both options to address some of the language and translation challenges of working in a cross-cultural setting like this.

The last technical methodological concern is that the researcher was the only person responsible for data collection and for analysing the data. The findings are therefore interpreted through the filter of the researcher's professional and personal background, beliefs and assumptions. While the researcher's background as a clinical psychologist and as a public health worker and researcher provided a professional level of skill for analysing the findings, it is acknowledged that this does not remove the potential blind spots that are part of one individual's analysis (this is discussed in more detail below in the section on reflexivity).

Finally, there are a number of gaps in the scope of the research study's objectives that, if filled, could have strengthened the overall evaluation of the intervention. For example, the research did not examine in-depth the issue of confidentiality or the experiences of lay counsellors who had to shift their practice in the PITC intervention. The evaluation also did not include an economic evaluation of the intervention. A cost-effectiveness evaluation would have been able to provide information on the relative costs of using nurse time and may also have been able to investigate the important question of opportunity costs (such as the impact of PITC on other activities in the clinic, information important for policy decisions on the up-scaling of PITC). Economic evaluations of new health care interventions are reportedly often omitted (Grol & Grimshaw 2003).

Applicability

Lavis and colleagues (2009) have identified several key criteria against which to assess the applicability of research findings in a health systems context, including differences in the setting in terms of constraints, health systems arrangements, and other baseline conditions that may affect the feasibility and the acceptability of the intervention elsewhere. These criteria help to identify a range of issues relating to the applicability of these findings to other settings.

The design of the PITC intervention and health systems arrangements, such as the level of resources, the baseline testing rates, and the management capacity for implementation are all elements that might affect the applicability of this study's findings to other settings. The study was conducted with STI nurses in Cape Town who were working mainly in local health authority clinics. This could be considered a relatively well-resourced and managed health service compared to other South African and LMIC settings and may also limit the applicability of the findings. This may be true to varying degrees for some, but not all the findings. For instance, the quantitative findings may be particularly applicable to the other five metropolitan cities in South Africa where similar levels of health system resources are in place.

The intervention was adapted to respond to the local situation where lay counsellor capacity for expanding the HIV testing service was limited and where it was considered feasible to integrate HIV testing into the STI care provided by nurses. Changes to the design of the PITC intervention and the available nurse and lay counsellor capacity may affect the impact of the intervention in other settings. For instance, the intervention used an abbreviated HIV testing protocol that could more easily be integrated into the STI consultation but did not require nurses to provide the test result and post-test support. Post-test support was still being provided by HIV lay counsellors after the STI consultation. Study findings might be less applicable if, for example, shifts in policy required nurses to provide post-test support in addition to offering the test. Similarly, in this study, the intervention was offered only to new STI patients. Offering PITC more broadly, to all patients attending the clinic, could also affect the applicability of these findings.

The PITC intervention was delivered by public sector STI nurses as part of their standard STI care. The intervention did not use any additional clinical resources and relied on the existing nurse capacity at the intervention clinics and the intervention limited the duration of nurse training to two days, factors that might be considered as increasing the applicability of study findings to similar resource-constrained setting. However, the implementation of the intervention was

supported by a part-time project manager, a component that, if dropped, may reduce the applicability to other settings.

The level of clinical autonomy of nurses is another important element of the specific context of this research study and may not be more generally applicable. Nurses were able to diagnose and prescribe treatment for STI. Management and nurses also came to mutual agreement on the feasibility of adding a few minutes to their consultation time. Nurses with less clinical autonomy and in situations of greater workloads may react differently when faced with the increased demands of HIV testing.

Differences in baseline characteristics between this setting and others may also influence the impact of the PITC intervention. The baseline testing rate for new STI patients in this study in 2006 was an estimated 30%, which was thought to be higher than what could be expected in other settings in South Africa and other LMICs. Studies in LMIC countries with low baseline testing rates appeared to have larger absolute effects (Chou et al. 2005a; Evans & Ndirangu 2008; Jürgens 2006). It is likely that baseline testing rates in other settings might yield different absolute and relative effects.

Qualitative findings on the patients' perceptions of the PITC intervention and findings based on the clinical consultations may hold more potential for applicability to other settings. This is because the structure, organisation, and expectations of the clinical encounter have been shown to be relatively stable over the last 30 years and across different medical settings (May 2006). Conceptual generalisations based on the study findings may therefore have wider application to settings elsewhere, in both high-income and LMIC settings. As mentioned above, using conceptual frameworks in these qualitative studies provided a common and coherent language to analyse and interpret the findings and this contributes to a greater transferability of results (Green & Thorogood 2004).



Reflexivity

Qualitative investigations in particular require a high level of reflexiveness on the part of the researcher (Green & Thorogood 2004). The researcher aimed to provide a coherent, plausible, and credible account of the perspectives of stakeholders and of the implementation processes but acknowledges that this account is influenced by the researcher's own experience and assumptions. She is both a mental health professional and a public health researcher and

practitioner. These professional frameworks would have both shaped her understanding of the data as well as the ways she was perceived in the research context.

Nevertheless, the researcher was able to increase the reflexiveness of the analysis through various strategies including: being explicit about the methods used and the limitations thereof; considering the ways in which the data are shaped by the social setting of the research (including the challenges posed by translation); and being aware of the larger context of the research such as who requested it and how this required balancing different aspects of the research.

The researcher has had to balance her roles as an external evaluator, a participant-observer, and fellow colleague. This often required a fine balance between contributing as a colleague in health systems management (when asked to contribute technical expertise to improve the intervention) and as an external evaluator assessing the intervention. One example of such a situation was when the researcher was asked to help redesign and conduct the PITC training for a new batch of STI nurses to be trained because the project management team felt the previous training did not have sufficient practical focus and was too long. Although this was stepping out of the researcher role and into the role of a team member, the researcher agreed to do so and formed a training team with the project leader for one round of training. Based on this experience, the researcher then facilitated discussion between the project management team and the original trainers that resulted in them continuing with future training. This involvement in a training capacity may have complicated the researcher's role as an external evaluator. It had some benefits in that it provided the researcher valuable insights about the communication skills of the nurses. However, the experience may have also have signalled a particular alliance between the researcher and the management team in the eyes of the nurses.

The issue of race and language in South Africa influences relationships on many levels. In this case, the researcher is of Coloured (mixed-race) descent and was able to speak English and Afrikaans but not isiXhosa. The majority of the staff and patients were black African and Xhosa speaking and this language barrier was particularly hard to overcome in relation to patient interviews (as described above). It also meant that the researcher was sitting in on a clinical consultation that was conducted in a language she could not understand (though the transcripts were subsequently translated). During the design of the research methodology, providers were given a choice in the method of observation and they expressed a preference for this approach

rather than having a Xhosa-speaking research assistant do the observations. Part of the reason for their choice may be to do with the fact that the researcher was regarded as more of a team member at this stage of the project and staff may have felt more comfortable with a familiar person doing the observation. Staff were also aware that the researcher was a clinical psychologist by profession and this may have been another source of influence in their choice.

Finally, it was not always easy to contend with the potential biases of one's own professional background when it comes to analysing and interpreting data. The dual professional background of the researcher provided some balance between sometimes competing paradigms around individual and health systems perspectives but it does not necessarily eliminate biases from personal and professional assumptions. The governance structure that was set up for the implementation project via the Project Steering Committee provided some opportunity against which to test the researcher's interpretation of events which may have helped to limit the extent of biases associated with personal and professional assumptions.

**Conclusion**

Provider-initiated HIV testing and counselling is likely to be rolled out globally in the next few years and it remains important to look at its impact and process in different settings (Evans & Ndirangu 2009). Ongoing debate about the feasibility and ethical implementation of PITC in low- and middle-income countries may be needed to remind governments and policy and public health officials of the individual, social, economic, and political complexities that surround HIV testing. Some of these ethical dilemmas cannot be resolved through research and need to be resolved through debates based on bio-ethical and human rights principles. Where evidence can be generated, however, the debate should be grounded in the empirical realities that such evidence presents (Halpern 2005).

This study has presented evidence that PITC can be an effective and feasible intervention for increasing HIV test uptake in a busy primary health care setting in Cape Town. It did not negatively affect access to follow-up care for HIV-positive patients and it could be implemented ethically. Uptake of testing with PITC may not be as large as required to effectively manage the epidemic in LMICs and a variety of strategies for expanding testing may be required. Efforts to improve linkage to HIV care should be up-scaled along with expanded testing approaches. Successful and ethical up-scaling of PITC in LMIC settings may be dependent on how well the intervention can be integrated into standard care and on broader health systems support

mechanisms. It will also depend on how well the balance is struck between exceptionalising and normalising imperatives in HIV testing strategies. The research makes practical recommendations for how this balance might be achieved.

# APPENDIX 1: STANDARD OPERATING PROCEDURE FOR RESEARCH

## Standard Operating Procedure for evaluation of the impact of the routine HIV screening for STI pilot intervention, 2007

The main operational research objectives for this evaluation are:

1. To assess if the routine HIV screening for STI clinics increases HIV testing rates of new STI clients in intervention clinics as compared to the standard VCT approach in control clinics.
2. To determine if clients who are diagnosed HIV positive and who have a CD4 count of 200 or less, are accessing the recommended HIV follow-up services within a 3-month period after diagnosis.
3. To explore the decision-making processes involved with test uptake behaviour in routine HIV screening.
4. To again an understanding of the health system factors that affect test uptake rate and which need to inform policy about routine HIV screening in South Africa.

The following procedures will be followed in the quantitative data gathering and management processes to ensure confidentiality of patient identifying and clinic identifying data.

1. Confidentiality agreements to be signed by the research co-ordinators, data manager and data capturer.
2. There are 7 intervention and 14 control clinics. Quantitative data capturing of the VCT register will take place off the clinic premises for practical reasons of time, convenience and saving costs.
3. The TB/HIV co-ordinators will be asked to make copies of the relevant Q1, 2007 VCT register pages (and if need be Q2, 2007 at a later stage). These will be collated by Dr. Jennings at her head office and collected by Dr. Naidoo.
4. Dr Naidoo would then turn the VCT register pages into linked anonymous data before passing it on to the data capturer for entry. This will be done in the following way:
    a. Given that patient names will only be needed for Objective 2 above, two databases will be created, one without any patient names for assessing Objective 1 (testing rates) and one with linked patient names, for assessing Objective 2
    b. To create the first, anonymous database, all the patient names will be blanked out by sticking dense black packing tape over the patient names on the hard copies of the relevant VCT register pages. These altered VCT register sheets will then be passed on to the data capturer who will enter anonymous data, using only patient folder numbers.
    c. Clinic names will be coded C1-C21 from the start of data entry, to remove identifying clinic data.
    d. Initial quality checks will be performed by the research co-ordinators Ms Leon and Dr. Naidoo. Detailed quality control checks of a sample of the data will be performed by and independent person, Mr. Schoeman.
    e. For Objective 2, only the names of those with and HIV positive result in the VCT register will be required for the second database as this will enable the researchers to assess whether those with low CD4 counts are receiving follow-up care. The names of patients with an HIV positive test result will then be linked to their patient folder numbers and these names will be entered by the

Dr. Naidoo and Ms Leon. This will be treated as a highly confidential database and the two co-ordinators will ensure that there will be no further distribution of this information (either in paper-based or electronic form), except for quality control purposes. Mr. H. Schoeman will once again do the quality control.

5. The data capturer will enter the anonymous VCT register data into an excel database set up with the relevant research variables.
   a. The data capturing will be done at Ms Brown's home in Montana, Belville, on a password-protected laptop. As mentioned earlier, the patient folder numbers and no names will be entered. As patient folder numbers will be used, confidentiality measures will still have to be ensured.
   b. As soon as Ms Brown has completed entering data from the coded VCT register pages, she will lock up the relevant pages in a draw in her desk, to which she is the only one with a key.
   c. Once she has completed data entry for the first clinic, she will back up the information on CD and email the excel spreadsheet to Dr. Naidoo and take the VCT register pages to her for quality control checks and storage. Access to her laptop computer will also be password protected.
   d. Dr. Naidoo will also store the VCT register pages in a lockable file cabinet at her home to ensure confidentiality. The VCT register pages will be handed back to Dr. Jennings at the end of the research process, once the database has been completed, quality checked, fully backed up and data has been analysed.
   e. The process of and confidential entry of anonymous data, continuous quality checks and backing up data, will continue until data base one has been completed consisting of all those new STI clients tested in Q1 2007, in all the 21 clinics.
   f. Completed datasets will be sent to Dr. Naidoo and Ms Leon via e-mail and back-up CDs- to be stored in lockable cabinets that ensure confidentiality.
   g. Dr. Naidoo & Ms Leon, will then use database number one to develop the second database and do data entry of names for those with HIV positive results, using the unique linked patient code. (See 4.e above). The second database will only be available on the password-protected computers of the two researchers.
   h. Data analysis and interpretation will be done jointly with the assistance of Mr. Schoeman.
   i. Dr. Naidoo will access clinic- specific laboratory reports for CD4 blood counts via the laboratory either electronically or paper copies and kept in a locked cabinet at her office. Ms Leon and Dr. Naidoo will enter the data and do the analysis to generate a list of patients whose clinic folders will need to be reviewed to assess access to care.
   j. Ms Leon and Dr. Naidoo will enter clinics to do clinic folder reviews and tracking of patient referrals for those STI patients with CD4 counts of 200 or less to determine what percentage of clients have accessed the following HIV services: a follow-up clinic visit to be informed of their low CD4 status, a referral to a specialist HIV clinic for clinical assessment, an assessment for eligibility for ARV treatment, commencement of ARV treatment if found to be suitable.
   k. At the end of the data gathering, analysis and interpretation process, all unnecessary electronic copies of the data base will be destroyed.
   l. Any reporting on results will protect the confidentiality of the clinics and of patients.
6. The qualitative data gathering and management will follow the ethical guidelines of confidentiality and anonymity as outlined in the relevant consent forms.

# APPENDIX 2: PITC TRAINING PROGRAMME

## 2 DAY HIV AND AIDS COURSE FOR NURSES

DATE: 14 & 15 JUNE 06
VENUE: ATICC

| DAY 1 | | | WEDNESDAY 14 JUNE 06 |
|---|---|---|---|
| 09h00 | - | 09h30 | WELCOME AND INTRODUCTION<br>GOALS, EXPECTATIONS<br>GROUP CONTRACT |
| 09h30 | - | 10h00 | THE NEW HIV TESTING MODEL<br>- Aims & Objectives<br>- Background Information<br>- How the model works |
| 10h00 | - | 10h20 | TEA |
| 10h20 | - | 11h20 | RECAP<br>- Medical facts<br>- Legal Facts<br>- Safer Sex |
| 11h20 | - | 12h30 | RECAP COMMUNICATION SKILLS<br>RISK REDUCTION THEORY |
| 12h30 | - | 13h00 | LUNCH |
| 13h00 | - | 13h30 | OVERVIEW OF SUPPORTIVE COUNSELLING SESSIONS<br>- NEGATIVE RESULT<br>- POSITIVE RESULT<br>- FOLLOW-UP SESSION |
| 13h30 | - | 14h30 | INFORMED CONSENT SESSION (THEORY) |
| 14h30 | - | 16h00 | ROLE PLAYS |

| DAY 2 | | | THURSDAY 15 JUNE 06 |
|---|---|---|---|
| 09h00 | - | 10h30 | ROLE PLAYS |
| 10h30 | - | 10h50 | TEA |
| 10h20 | - | 12h30 | ROLE PLAY AND EVALUATION |
| 12h30 | - | 13h00 | LUNCH |
| 13h00 | - | 16h00 | ROLE PLAY AND EVALUATION |

## 3 DAY HIV/AIDS COUNSELLING COURSE FOR NURSES

DATE: FEBRUARY 06
VENUE: ATICC

DAY 1

| | | | |
|---|---|---|---|
| 09h00 | - | 10h00 | WELCOME AND INTRODUCTION<br>GOALS, EXPECTATIONS<br>GROUP CONTRACT |
| 10h00 | - | 10h20 | TEA |
| 10h20 | - | 11h30 | THE NEW HIV TESTING MODEL<br>- Aims & Objectives<br>- Background Information<br>- How the model works |
| 11h30 | - | 12h30 | RECAP MEDICAL FACTS<br>- Basic immunology<br>- Disease progression<br>- WHO stages<br>- Link between HIV & TB<br>- Link between HIV & STI |
| 12h30 | - | 13h00 | LUNCH |
| 13h00 | - | 14h00 | RECAP MEDICAL FACTS CONT. |
| 14h00 | - | 15h00 | RECAP SAFER SEXUAL PRACTICES |
| 15h00 | - | 16h00 | RECAP LEGAL AND ETHICAL ISSUES |

DAY 2

| | | | |
|---|---|---|---|
| 09h00 | - | 10h00 | RECAP COUNSELLING SKILLS |
| 10h00 | - | 10h20 | TEA |
| 10h20 | - | 11h30 | INFORMED CONSENT COUNSELLING SESSION (THEORY) |
| 11h30 | - | 12h30 | OVERVIEW OF SUPPORTIVE COUNSELLING SESSIONS<br>- NEGATIVE RESULT<br>- POSITIVE RESULT<br>- FOLLOW-UP SESSION |
| 12h30 | - | 13h00 | LUNCH |
| 13h00 | - | 16h00 | ROLE PLAY AND EVALUATION |

DAY 3

| | | | |
|---|---|---|---|
| 09h00 | - | 15h30 | ROLE PLAY AND EVALUATION |
| 15h30 | - | 16h00 | EVALUATION AND CLOSURE |

**5 DAY HIV/AIDS COUNSELLING COURSE FOR VCT/MTCT LAY COUNSELLORS**

DATE: FEBRUARY 06

VENUE: ATICC

DAY 1

| | | | |
|---|---|---|---|
| 09h00 | - | 10h00 | WELCOME AND INTRODUCTION<br>GOALS, EXPECTATIONS<br>GROUP CONTRACT |

| | | | |
|---|---|---|---|
| 10h00 | - | 10h20 | TEA |
| 10h20 | - | 11h30 | THE NEW HIV TESTING MODEL<br>- Aims & Objectives<br>- Background Information<br>- How the model works |
| 11h30 | - | 12h30 | RECAP MEDICAL FACTS<br>- Basic immunology<br>- Disease progression<br>- WHO stages<br>- Link between HIV & TB<br>- Link between HIV & STI |
| 12h30 | - | 13h00 | LUNCH |
| 13h00 | - | 14h00 | RECAP MEDICAL FACTS CONT. |
| 14h00 | - | 15h00 | RECAP SAFER SEXUAL PRACTICES |
| 15h00 | - | 16h00 | RECAP LEGAL AND ETHICAL ISSUES |
| | | | |
| DAY 2 | | | |
| 09h00 | - | 10h00 | RECAP COUNSELLING SKILLS |
| 10h00 | - | 10h20 | TEA |
| 10h20 | - | 11h00 | INFORMED CONSENT COUNSELLING SESSION |
| 11h00 | - | 12h30 | SUPPORTIVE COUNSELLING SESSION<br>- NEGATIVE RESULT (THEORY) |
| 12h30 | - | 13h00 | LUNCH |
| 13h00 | - | 14h00 | SUPPORTIVE COUNSELLING SESSION<br>- NEGATIVE RESULT (PRACTICAL) |
| 14h00 | - | 15h00 | SUPPORTIVE COUNSELLING SESSION<br>- POSITIVE RESULT (THEORY) |
| 15h00 | - | 16h00 | SUPPORTIVE COUNSELLING SESSION<br>- POSITIVE RESULT (PRACTICAL) |
| | | | |
| DAY 3 | | | |
| 09h00 | - | 10h30 | SUPPORTIVE COUNSELLING SESSION<br>- FOLLOW-UP SESSION (THEORY) |
| 10h30 | - | 10h50 | TEA |
| 10h50 | - | 12h00 | SUPPORTIVE COUNSELLING SESSION<br>- FOLLOW-UP SESSION (PRACTICAL) |
| 12h00 | - | 12h30 | LUNCH |
| 12h30 | - | 16h00 | ROLE PLAY AND EVALUATION |
| | | | |
| DAY 4 | | | |
| 09h00 | - | 16h00 | ROLE PLAY AND EVALUATION |
| | | | |
| DAY 5 | | | |
| 09h00 | - | 13h00 | ROLE PLAY AND EVALUATION |
| 13h00 | - | 13h30 | EVALUATION AND CLOSURE |

# APPENDIX 3: ADAPTED COUNSELLING AND CONSENT CLINICAL GUIDELINES

The standard of care guildeines for HIV testing are appended beginning on the next page.

## STANDARD OF CARE HIV TESTING RECORD

| | | | | | |
|---|---|---|---|---|---|
| Name of Client: | | | | | |
| Client code / folder number: | Age: | | Sex: | Male | Female |
| **INFORMATION FOR CONSENT** | **Date:** | | | | |

**Explain:** Role of nurse is to provide treatment for the condition. HIV testing is a routine part of treating this condition. Nurse will take informed consent and do HIV test. HIV test result will be provided by the counsellor.

| | | | |
|---|---|---|---|
| Confidentiality discussed? | Yes | No | |

| **HIV Education** | | **Risk Assessment** | | | |
|---|---|---|---|---|---|
| 1. What is HIV? | | Previous treatment for an STI | Yes | No | When? |
| 2. Effect of HIV on the immune system | | Practicisng safer sex | Yes | No | If yes, frequency |
| 3. Modes of transmission | | Last unprotected sexual encounter | | | |
| 4.Link between HIV and STI/TB | | Client in the window period | Yes | No | If yes, explanation of the window period |

| **FP Screen N/A** | | | **TB Screen N/A** | | | **STI Screen N/A** | | |
|---|---|---|---|---|---|---|---|---|
| Currently on reliable FP method | Yes | No | Cough | Yes | No | Vaginal discharge | Yes | No |
| If female: | | | Weight loss | Yes | No | Urethral discarge / Dysuria | Yes | No |
| At risk of unwanted pregnancy | Yes | No | Fever | Yes | No | Genital ulcers | Yes | No |
| No FP with LMP > 4 weeks ago | Yes | No | Night sweats | Yes | No | Lower abdominal pain | Yes | No |

| **PMTCT Education N/A** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 1. Transmission to baby | Yes | No | 3. NVP to mother | Yes | No | 5. Bactrim to baby | Yes | No |
| 2. Feeding options | Yes | No | 4. NVP to baby | Yes | No | 6. Testing of baby | Yes | No |

How do you feel about having an HIV test?

What are the benefits of having an HIV test?

How would you will feel if the HIV test result is +?

How will you react / cope if the HIV test is + ?

Who would you tell if you are HIV+?

Would they be able to support you?

**Explain that the HIV test is confidential. Client will need to consent to test. Client can refuse to have the test. Comments:**

| | | | | | | |
|---|---|---|---|---|---|---|
| Test decision: | Consents | Declines | | Test procedure explained? | Yes | No |

**CONSENT TO HIV TESTING**

I hereby consent to having blood taken for HIV testing. I understand the consequences of the outcome as I have received counselling regarding the disease. I understand that I may need further testing.

Ndiyavuma okokuba igazi lam lingahlolelwa isifo sengculazi (HIV/AIDS). Ndiyazi ukuba iziphumo zithetha ntoni kuba ndicaciselwe malunga nesi-sifo. Ndiyaqonda ukuba ndingaphinda ndihlolwe kwakhona.

Hiermee magtig ek die neem van bloed monsters vir HIV toetsing. Ek dra kennis oor die nagevolge van die uitslae soos verduidelik aan my gedurende die voorligting sessies. Ek verstaan dat verdere toetse nodig mag wees.

| | |
|---|---|
| Name/Igama/Naam: | |
| Signature/Usayine/Handtekening: | Date/Umhla/Datum: |
| Witness 1 (Nurse) Name: | |
| Signature/Usayine/Handtekening: | Date/Umhla/Datum: |
| **HIV TEST RESULT** | **Date:** |

Test performed / blood specimen taken by:

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Screening test | Neg | Pos | Confirmatory test | Neg | Pos | ELISA | Neg | Pos |

Date to return for ELISA result if necessary:

**POST-TEST SUPPORT: NEGATIVE / INDETERMINATE RESULT**

| | | | | | | |
|---|---|---|---|---|---|---|
| Role of counsellor explained | | Confidentiality discussed | | Is client ready to receive HIV test result? | Yes | No |
| If no, explore reasons: | | | | If yes, provide HIV test result | Result given | Result not given |

Does client understand the test result?

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Window period discussed | Yes | No | Date to return for repeat test if in window period: | | | | | |
| Risk assessment completed | Yes | No | Risk Profile | High | Medium | Low | | |
| Triggers identified | Yes | No | Management of triggers: | | | | | |
| Safer sex discussed | Yes | No | Condom demonstration done | Yes | No | Condoms dispensed | Yes | No |

Counsellor's Comments and Signature:

**If result is indeterminate, date for ELISA result:**

**POST-TEST SUPPORT: POSITIVE RESULT**

| | | | | | | |
|---|---|---|---|---|---|---|
| Role of counsellor explained | | Confidentiality discussed | | Is client ready to receive HIV test result? | Yes | No |
| If no, explore reasons: | | | | If yes, provide HIV test result | Result given | Result not given |

Does client understand the test result?

How does client feel?

What are clients concerns?

Explore how concerns will be addressed

What will client do after leaving the clinic?

Where will client go after leaving the clinic and who will be there?

Will client be able to speak to this person about their result?

Will this person will be able to support client?

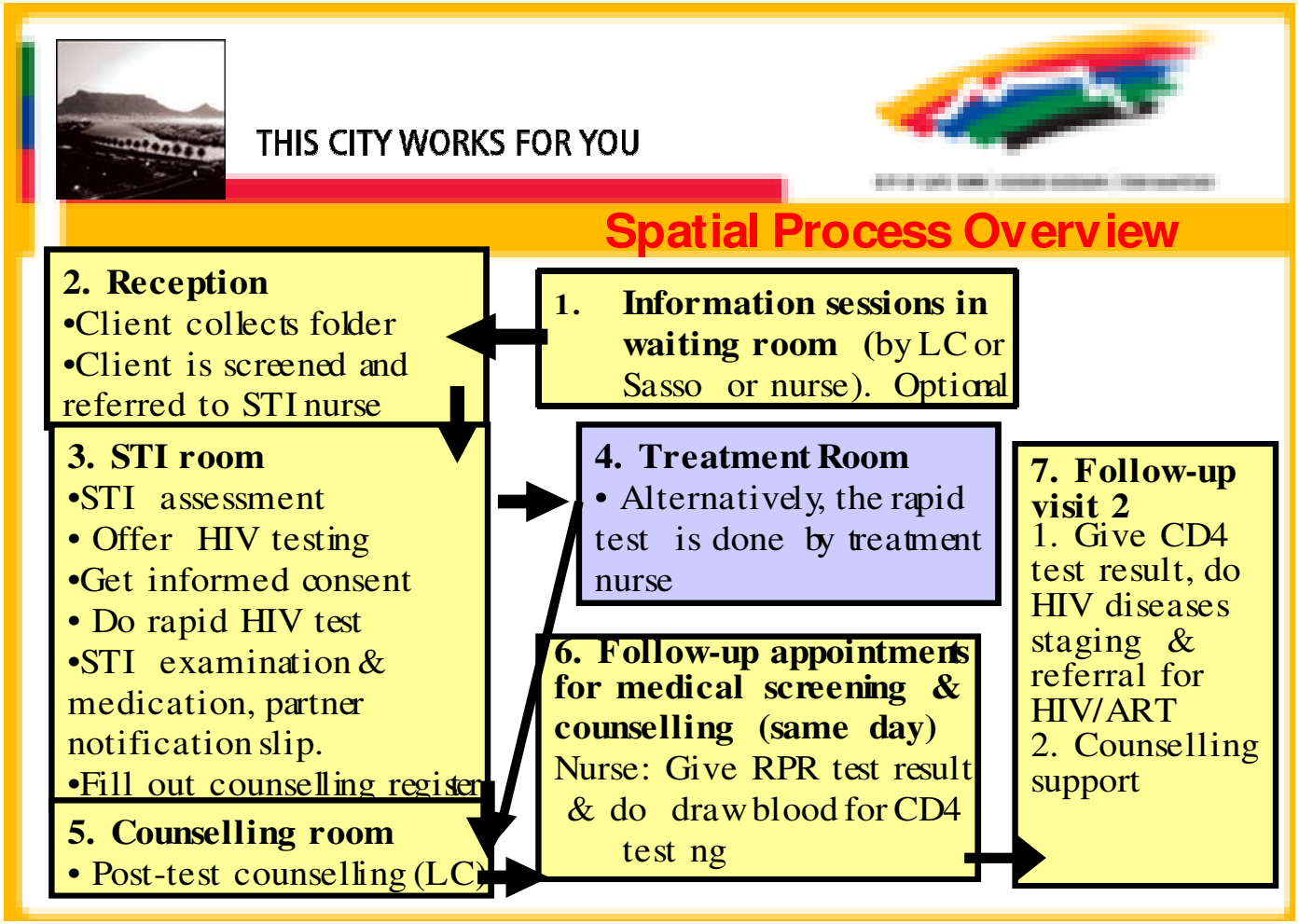
| | | | |
|---|---|---|---|
| Will client be able to discuss the result with their partner? | Yes | No | If no, explore reasons |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Plan for disclosure: | | | | | | | | |
| Safer sex discussed | Yes | No | Condom demonstration done | Yes | No | Condoms dispensed | Yes | No |
| Counsellor's Comments and Signature: | | | | | | | | |
| Date for follow-up counselling: | | | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **ONGOING COUNSELLING 1** | | | | | | | **Date:** | | |
| How has client been coping since last visit? | | | | | | | | | |
| What are main concerns? | | | | | | | | | |
| How will these be dealt with? | | | | | | | | | |
| Link between HIV/AIDS | | HIV and the immune system | | Disease progression | | Clinical care | | | |
| Risk assessment completed | Yes | No | Risk Profile | High | Medium | Low | | | |
| Triggers identified | Yes | No | Management of triggers: | | | | | | |
| Safer sex discussed | Yes | No | Condom demonstration done | Yes | No | Condoms dispensed | Yes | No | |
| Has client disclosed test result (and to whom)? | | | | | | | | | |
| Date for follow-up counselling session 2 and baseline clinical examination: | | | | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **ONGOING COUNSELLING 2** | | | | | | | **Date:** | | |
| How has client been coping since last visit? | | | | | | | | | |
| What are main concerns? | | | | | | | | | |
| How will these be dealt with? | | | | | | | | | |
| If no disclosure previously, has client disclosed test result (and to whom)? | | | | | | | | | |
| Nutrition | | Rest and stress management | | OI's | | CD4 | | Family planning | |
| Exercise | | Clinical care | | Antiretrovirals | | Viral load | | Safer sex | |
| Follow-up plan: | | | | | | | | | |

## APPENDIX 4: PATIENT FLOW DIAGRAM



# APPENDIX 5: PATIENT RECRUITMENT SCRIPT

## SCRIPT FOR NURSES AND LAYCOUNSELLORS TO OBTAIN VERBAL CONSENT FROM CLIENTS FOR OBSERVATION OF STI CONSULTATIONS

UKUJONGA/UKUBUKELA UTHETHATHETHWANO LWEMIBHALO/IZIKRIPTHI ZEZIFO ZANGAPHANTSI (STI) EZISENTYENZISWA NGAMANESI KUNYE NABACEBISI UKUFUMANA IMVUME KUBAGULI

- WE HAVE A PhD STUDENT FROM THE UNIVERSITY OF CAPE TOWN HERE TODAY, NATALIE LEON, WHO IS STUDYING THE STANDARD OF CARE FOR STI PATIENTS. SHE WOULD LIKE TO SIT IN OUR CONSULTATION OR TO TAPE RECORD THE DISCUSSION.
- SINOMFUNDI OFUNDELA PhD OSUKA KWIDYUNIVESITHI YASEKAPA NAMHLANJE, UNATALIE LEON, OPHICOTHA IZINGA LOKUNAKEKELA ABAGULI ABANEZIFO ZANGAPHANTSI. UYAKUTHANDA UKUBA ABENGOMNYE KUTHETHATHETHWANO LWETHU OKANYE ASHICILELE INGXOXO LE.

- THE INFORMATION WILL REMAIN CONFIDENTIAL AND YOUR REAL NAME WILL NOT BE USED.
- ULWAZI/ YONKE INTO EFUNYENWEYO IYAKUHLALA IYIMFIHLELO KWAYE IGAMA LAKHO LOKWENYANI ALISAYI KUSETYENZISWA.

- YOU ARE FREE TO SAY 'NO' AND THERE WILL BE NO NEGATIVE CONSEQUENCES FOR YOUR TREATMENT.
- UVUMELEKILE UKUBA "UNGALA" KWAYE AKUSAYI KUBAKHO ZIPHUMO ZIMBI UKUPHATHWA KWAKHO.

- CAN I HAVE YOUR PERMISSION FOR MS.LEON TO OBSERVE OR TO TAPE RECORD OUR CONSULTATION?
- NDICELA IMVUME YAKHO YOKUBA UNKOSAZANA LEON AJONGE OKANYE ASHICILELE UKUDIBANA KWETHU KWANAMHLANJE?

THANK YOU. ENKOSI.

# APPENDIX 6: PATIENT CONSENT FORM

## Consent Form: CONSENT TO PARTICIPATE IN RESEARCH

**Evaluation of Routine Services for STI clients in Cape Town**

You are asked to participate in a research study conducted by Natalie Leon from the University of Cape Town.

### 1. PURPOSE OF THE STUDY

The aim of the study is to get a better understanding of how patients and staff experience routine STI services.

### 2. PARTICIPATION AND WITHDRAWAL

If you volunteer to participate in this study, I would ask you to do the following things:

-You will be asked to be interviewed by a trained researcher. She/he will ask you some questions about how you experienced the offer of routine screening tests when it is included as part of the STI treatment.
-The interview will take approximately 30-40 minutes and your participation is completely voluntary.
-You may refuse to answer some questions and you may withdraw from the interview at any point. Your withdrawal will not have any negative effects on the health service you receive.
-The interview will be done immediately after your clinic treatment, in a private part of the clinic or a more convenient time and place can be arranged.

### 3. CONFIDENTIALITY

I would like to tape record the interview with your permission, to help me make notes afterwards. This information will be kept confidential and anonymous (without using real names). The information collected will not become part of your medical records. The information will only be used anonymously for recommendations and in an academic paper. One exception to the confidentiality rule is if I find out you are in danger of harming yourself or others, I will have to report it to the appropriate authority.

### 4. POTENTIAL BENEFITS TO PARTICIPANTS

There are no direct benefits to participants for participating in the research, but indirectly you are contributing to a better understanding of how the health services work. You may also benefit from talking with a professional about your health service experiences. If you want to talk more about the topic of STI, including about HIV, I can assist you or refer you to the appropriate health worker.

## 5. POTENTIAL RISKS AND DISCOMFORTS

There are no direct risks to participation in this study. You will not experience any physical discomfort from being interviewed. There may be sensitive information that come up in the interview that may worry you. All information is kept confidential and I would be glad to discuss any concerns you have arising from the interview.

***Please note: If you have any concerns about your welfare as a research subject, please contact Professor Marc Blockman, Chairperson of the UCT Human Research Ethics Committee at 021 -4066496.***

## 6. PAYMENT FOR PARTICIPATION

There will be no payment for participation in the study, but you will be offered R50 as compensation for travel and other expenses you may have incurred.

## 7. IDENTIFICATION OF INVESTIGATORS

If you have any questions or concerns about the research, please feel free to contact Natalie Leon (contact details below)

*Natalie Leon*
Phone: 021-4477605
Cell: 083-4548 567
Email: natalie.leon@mrc.ac.za



**SIGNATURE OF RESEARCH SUBJECT**

**I hereby consent voluntarily to participate in this study. I understand the information in this form.**

_____

**Name of Participant**

_____ _____

**Signature of participant** **Date**

Thanking you for your participation
Natalie Leon

- **I agree that I received R50 towards my expenses**

  **Signature_____**

# APPENDIX 7A: STAFF CONSENT FORM FOR OBSERVATIONS

## CONSENT FORM TO OBSERVE STI NURSE CONSULTATIONS

EVALUATION OF ROUTINE HIV SCREENING FOR STI CLIENTS:
MEDICAL RESEARCH COUNCIL, 2007/08

### ELIGIBILITY

As a nurse involved in piloting a new model of HIV testing, you are kindly asked to participate in the evaluation of the routine HIV screening intervention for STI clients. This form provides you with information about the purpose and procedure of the evaluation and asks for you to give written consent for your participation.

### PURPOSE

The study involves the OBSERVATION OF STI CONSULTATIONS AND OR TAPE RECORDING where routine HIV screening is implemented in order to better understand the experience of the nurse and client. Natalie Leon, **AN EXTERNAL EVALUATOR FROM THE MEDICAL RESEARCH COUNCIL**, will do the observations. The evaluation will help the health services to review the pilot intervention and to make decisions about future routine HIV screening services. The evaluation will also contribute towards Ms. Leon's PHD study.

### WHAT DO I NEED TO DO?

We are asking you to agree to a trained observer (Ms. Natalie Leon) sitting in and observing a series of your STI consultations that involve HIV screening. The observer will not interfere in the session and will be as unobtrusive as possible. The observer will assess the content and steps of the session. Clients will be asked to give permission for the observation prior to the observer sitting in. The observer will, on request, provide constructive feedback to the nurse after the observations.



We are asking your permission to observe a series of your STI consultations (2-3 sessions).

**If you agree to your consultations being observed, we are also asking that you seek verbal permission, USING THE SCRIPT, from your clients for the observation. Staff and client participation must be voluntary, SO PLEASE REASSURE CLIENTS THAT THEY ARE FREE TO SAY 'NO'. Staff refusal to participate will not have any negative consequences for your work. Clients should be reassured that refusal to be observed will not negatively affect the service to the client.**

### ARE THERE ANY RISKS TO ME?

We do not think that participating in this study will harm you or your clients. Initially staff may have worries about being observed or they may worry that clients will find it unacceptable. Where observational assessments have been used, researchers found a much higher

acceptance by clients than anticipated. Staff also felt more comfortable and reassured that the observations were of benefit for them in improving their skills.

Staff and client participation is anonymous and confidential in that names will not be linked to the assessments. Names will not be mentioned in the writing up of any reports or in the feedback to staff and management. You are free to decline participation in this study and if you accept, you are free to change your mind at any time.

Please note: If you have any concerns about your welfare as a research subject, please contact Professor Marc Blockman, Chairperson of the UCT Human Research Ethics Committee at 021 4066496.

**WHAT AM I GETTING OUT OF THESE OBSERVATIONS?**

The observations give you a chance to share your experience in implementing a new HIV testing model. This information will contribute to developing the services. You will receive confidential feedback on the observations that will be of benefit to your work. Clients will receive indirect benefit only in that they are assisting the evaluation that can contribute to improving services.

**DO I HAVE ANY QUESTIONS?**

Do you have any questions or worries about the study? Have your questions been answered? Please could you write your name and clinic and sign next to it to indicate that you consent to participate?

***NAME:***

***SIGNATURE:***

***CLINIC:***

***DATE:***

***THANKING YOU FOR YOUR PARTICIPATION***

***NATALIE LEON (083 45 48 567), MEDICAL RESEACH COUNCIL (021-9384054)***.

# APPENDIX 7B: STAFF CONSENT FORMS FOR FOCUS GROUPS AND INDIVIDUAL INTERVIEWS

## FOCUS GROUP & INDIVIDUAL STAFF CONSENT FORM

EVALUATION OF ROUTINE HIV SCREENING FOR STI CLIENTS:
MEDICAL RESEARCH COUNCIL, AUGUST/SEPTEMBER 2007

### ELIGIBILITY

You have been asked to participate in this FOCUS GROUP or INDIVIDUAL INTERVIEW today because you are a manager, nurse or a counselor involved in routine HIV screening as a standard of care for STI clients. This form provides you with information about the purpose and procedure of the focus group or interview and asks for you to give written consent for your participation.

### BACKGROUND

These focus groups and interviews with nurses, lay counsellors and managers are part of an evaluation of the pilot routine screening in seven clinic sites in the Metro. The evaluation was requested by the health department, via the Steering Committee of this project. An external evaluator from the Medical Research Council, Natalie Leon, will co-ordinate the evaluation as a research project for her PhD studies.

### PURPOSE

We would like to talk with you so we can better understand your experience, ideas and opinions about implementing routine HIV screening for STI clients at your clinic. What you tell us will help the health services to review the pilot intervention and to make decisions about future routine HIV sreening services. The information will also contribute towards a PhD study.

### WHAT DO I NEED TO DO?

We are asking you to answer some questions about your experience with routine HIV screening at your clinic so far. We are also asking your permission to allow us to tape record and to take notes on this discussion so we can remember what is said. This group discussion will last approximately 90 minutes and the individual interviews 60 minutes.

### ARE THERE ANY RISKS TO ME?

We do not think you will become upset as a result of participating in this focus group today. Your participation is anonymous and confidential in that your names and clinic names will not be mentioned in the writing up of any reports or in the feedback to staff and management.

If you do not want to answer a certain questions you do not need to answer it. You are free to leave this focus group or terminate the interview at any time. Leaving/termination will not have negative consequences for your work.

Please note: If you have any concerns about your welfare as a research subject, please contact Professor Marc Blockman, Chairperson of the UCT Human Research Ethics Committee at 021 4066496.

**WHAT AM I GETTING OUT OF THIS FOCUS GROUP?**

This interview gives you a chance to share your ideas and feelings after participating in the implementation of a new routine HIV screening intervention in your clinic. We will share what we learn from the group with the Steering committee, clinic managers, and other public health partners who do counseling and testing in South Africa. This information may be used to improve the services.

**DO I HAVE ANY QUESTIONS?**

Do you have any questions about what I have just said? Have your questions been answered? Please write your name and clinic and sign next to it to indicate that you consent to participate.

***NAME:***

***SIGNATURE:*** ***DATE:***

***CLINIC:***

***THANKING YOU FOR YOUR PARTICIPATION***

***NATALIE LEON (083 45 48 567), MEDICAL RESEACH COUNCIL (021-9384054)***

# APPENDIX 8A: DRAFT PATIENT INTERVIEW SCHEDULE

**Implementing routine HIV screening for STI clients in Cape Town: An evaluation of test-uptake behaviour**

***Draft Interview questions***

**We would like to stress that your replies will be treated in the strictest confidence and will not be used for any purpose other than that stated in the consent form. Your name will not be recorded anywhere on this form so your views cannot be linked to your name.**

**You gave your permission to participate in this research project when you signed the consent form. Are you still happy to continue with this interview?**

| | |
|---|---|
| **Name of the Interviewer:** | **Date of the interview:** |
| **Location:** | |

## SECTION A - PERSONAL DETAILS

***Have you tested for HIV before? If Yes- terminate interview. (Not the case if HIV +ve pt)***

**We would like to start by asking you some questions about yourself.**

A1. How old are you? ☐ M ☐ F

A2. Where do you live? (Probe formal or informal housing)

A3. Which statement best describes your working or domestic circumstances?

| | | | |
|---|---|---|---|
| In paid work or self-employed - **full-time** | ☐ | Unemployed | ☐ |
| In paid work or self-employed - **part-time** (less 30 hrs/ week) | ☐ | Looking after the home or family | ☐ |
| Permanently sick or disabled and not able to work | ☐ | Going to school, | ☐ |
| Other (Please specify) | ☐ | Going to college or university | ☐ |

**A4. Which statement best describes you at present?**

| | | | |
|---|---|---|---|
| Married | ☐ | Involved in two or more relationships | ☐ |
| Not in a relationship | ☐ | Cohabiting/living with a partner | ☐ |
| Casual relationship | ☐ | In a relationship but not living together | ☐ |

**A5. What school educational level did you complete?**

| | | | |
|---|---|---|---|
| Below primary school (below grade 7/Std.5) | ☐ | Grade 10-11(Std 8-9) | ☐ |
| Primary school (grade 7/Std.5) | ☐ | Matric/Std. 10/Grade12 | ☐ |
| Grade 8-10 (Std 6-7) | ☐ | Tertiary (post-matric) (Specify) | ☐ |

## SECTION B – Clinic visit

**B1. What time did you arrive at the clinic today?**

**B2. How long did it take to get to the reception?**

**B3. Time to get to the STI consultation or treatment consultation?**

**B4.How long did it take to have the STI consultation and the HIV test together?**
(From when you got into the nurse's room till your left the nurse's room)
TICK ONE BOX ONLY

| | |
|---|---|
| 5-10 minutes | ☐ |
| 10 – 30 minutes | ☐ |
| 30 minutes – one hour | ☐ |
| One hour or more | ☐ |
| Can't remember | ☐ |

**B5. In the last year, how often did you attend this clinic?**

| | | | |
|---|---|---|---|
| First time | ☐ | Once a month | ☐ |
| Once a year or less | ☐ | More than once a month | ☐ |
| A few times a year | ☐ | | ☐ |

B6. Do you recall what was the reason for your STI visit on the day you attended the clinic?) PLEASE TICK ALL THAT APPLY

| | | | |
|---|---|---|---|
| Had pain, itch, discharge | ☐ | Came for family planning | ☐ |
| Thought I had an STI | ☐ | Came for VCT | ☐ |
| My partner suggested I come | ☐ | Other: Plse specify…… | ☐ |
| A follow-up visit for a previous STI | ☐ | Don't know | ☐ |
| | ☐ | Refuse to answer | ☐ |

## SECTION C – STI VISIT AND HIV SCREENING

**Now I will ask you some questions about your experiences with the HIV screening and the STI consultation.**

**1. PLSE COULD YOU TELL ME ABOUT WHAT HAPPENED IN THE STI CONSULTATION ROOM.**
**What did you discuss and what steps was taken? What tests were discussed and done?**

**Explore**

- Pre-test counseling,
- HIV test
- Post-test counselling

**2. WHAT MADE YOU DECIDE TO TAKE THE TEST/NOT TAKE THE TEST?**
**What was your experience of being offered a HIV test as part of your STI treatment?**
**What was going through your mind when you were asked about testing?**
**Explore**

- Role of information
- Previous intention to test

- Perception of confidentiality of process
- Staff –patient relationship
- Process of testing

**Specific probes after open ended narrative given.**
**3. At your STI visit:**

| | | | |
|---|---|---|---|
| *a)* Did the nurse tell you that you have an STI? | **Yes** | **No** | **Don't know** |
| b) Do you know the name of the STI? *(Write the name in the 'Yes' box)* | **Yes** | **No** | **Don't know** |
| **c) Did the nurse explain to you that HIV is an STI?** | **Yes** | **No** | **Don't know** |
| **d) Did the nurse offer you an HIV test during your STI visit?** | **Yes** | **No** | **Don't know** |
| **e) Did you have enough information to make up your mind about whether to take the test or not?** | **Yes** | **No** | **Don't know** |
| **f) Did you understand that the test was voluntary and that you can refuse the test?** | **Yes** | **No** | **Don't know** |
| g) Did you accept (say Yes) or refuse (say No) to the test? (*If No, continue from q. C1.q) below)* | **Said Yes** | **Said No** | |
| **h) Did you have a chance to think about how you would react if you got an HIV positive result?** | **Yes** | **No** | **Don't know** |
| i) Did you understand that signing the 'Informed Consent' form meant that you gave written permission to be tested? | **Yes** | **No** | **Don't know** |
| j) Did the nurse prick your finger for the HIV test? | **Yes** | **No** | **Don't know** |
| **k) Was there enough privacy when the rapid test was done?** | **Yes** | **No** | **Don't know** |
| **l) Did you feel your test result would be confidential?** | **Yes** | **No** | **Don't know** |
| m) Did the nurse give you the test result in a supportive manner? | **Yes** | **No** | **Don't know** |
| n) Did you understand the meaning of your HIV test result? | **Yes** | **No** | **Don't know** |
| o) Do you feel that the nurse answered your questions about your test result? | **Yes** | **No** | **Don't know** |
| **p) Did the nurse tell you about the "window period" and that you would have to test again in 3 months if you are HIV negative?** | **Yes** | **No** | **Don't know** |
| q) *Did the nurse examine you to check for an STI? | **Yes** | **No** | **Don't know** |
| r) *Did the nurse tell you that you have an STI? | **Yes** | **No** | **Don't know** |
| s) ***Did the nurse take blood from your arm for a syphilis/venereal disease test? (RPR test) and a CD4 Test?** t) | **Yes** | **No** | **Don't know** |
| u) *Were you given any medication? | **Yes** | **No** | **Don't know** |
| v) *Did the nurse tell you what the medication was for? | **Yes** | **No** | **Don't know** |
| **w) *Did the nurse tell you how to prevent getting an STI in future?** | | | |
| **x) *Were you offered free condoms?** | **Yes** | **No** | **Don't know** |
| **y) Were you given a partner notification slip?** | **Yes** | **No** | **Don't know** |

**Do you mind sharing your HIV status with me? Remember the information is confidential.**

Yes ☐
No ☐
Not sure ☐

*If "Not sure", probe if there are anything you can do to address his/her concern and then accept the final response. Do not pressurise the client to disclose in anyway.*

**4. What has happened since you were offered the test? (whether client tested or not)**

**Explore**

**Access to care**

- Intention to test/not to test in future
- Regret or positive response to decision to test or not
- Feeling/attitude to the health service/staff
- Change in relationships & sexual practice

**After detailed narrative, explore the following areas:**

**Before the nurse offered you an HIV test, *how much did you know* about it?**

| | |
|---|---|
| I've never heard of an HIV test before | ☐ |
| I have heard of HIV testing but did not know what it means | ☐ |
| I understood what an HIV test is | ☐ |
| I knew a lot about HIV testing | ☐ |

**Before the nurse offered you an HIV test, *what was your feeling* about HIV testing?**

| | |
|---|---|
| I never thought about getting an HIV test before | ☐ |
| I thought I would get a test some time in the future | ☐ |
| I was unsure about getting an HIV test | ☐ |
| I was scared to get an HIV test | ☐ |

4. **How do you feel about talking to family and friends about having tested /or not? ?**

5. **What would you tell them ?**

6. **What would you recommend to friends?**

7. **If client agreed to share status & tested HIV negative:**
   Explore perceptions of routine offer of testing as per question 1, 2 and 3 in more detail- to determine how their HIV status may be affecting their attitude to routine HIV screening.

8. **If client agreed to share status & client tested HIV positive:**
   Explore perceptions of routine offer of testing as per question 1, 2 and 3 in more detail- to determine how their HIV status may be affecting their attitude to routine HIV screening
   HIV testing services at this health clinic?

Additional questions to explore

**SERVICE IMPROVEMENTS**

***. Do you have any suggestions for improvement or any other general comments about the STI service and HIV testing?***

……

……

……

……

**There are no more questions.**
**Do you have any questions or concerns?**

**Thank you for taking part in this research interview.**

# APPENDIX 8B: REVISED VERSION OF PATIENT INTERVIEW SCHEDULE

## EXTENDED QUESTIONS FOR INDIVIDUAL INTERVIEWS ON HIV TEST DECISION-MAKING

### Demographics

Gender, age employment status, educational level, children, intimate relationship (type, duration, age of partner/s), living arrangements

### Experience of STI treatment and HIV testing

- What was your experience of the health service today? (or on the day of HIV test offer) Could you tell me what happened from when you arrived here this morning until you came to interview.
- **Tell me what happened in the consultation room**
  - Trying to establish to what extent their experience of the health services may be influencing their decision to test or not. This may include issues like long waiting times, attitude of staff, satisfaction with service, use of other services such as private and traditional. In particular if and how the attitude of the nurse, the content and communication in the consultation, incl the specific process of offering the test, my have influenced the testing decision.
  - Try to establish whether their experience today was any different from their past experience.

- **Testing history and attitude to testing**
  - Previous attitude to testing, changes in attitude and reasons (How did you feel about HIV testing in the past and has this changed at all?/What made you test before or what stopped you before? )
  - Perceptions of readiness to test
  - Concerns, thoughts while waiting for the test result
  - Feeling post-testing, regrets re decision
  - What made you decide to take the HIV test or not to take the test?
  - Have you ever tested before? Why and how was that experience?
  - Tell me all the thoughts that went through your mind while you were waiting for the test to finish
  - What was your view/attitude about HIV testing before?
  - What stopped you before? (and why did you make a change today?)
  - What about the way the HIV test service was done made it easier or more difficult to decide.
    - Did you have enough information to decide?
    - How did the nurse communication/attitude affect your decision?
    - How ready would you say you were to take the test today?
    - Would you have liked more or less counselling before testing?
    - How was the post-test counselling?
    - Would you have preferred it if the nurse gave you the result?
    - What about the waiting time involved –is it worth the time?

- **Perceptions of own risk for HIV & changes**
    - What do you think your risk is of getting HIV?
    - Explore issue of safe sex, condom use
    - Explore issue of multiple partners and nature of trust (of self and partner)

- **Attitude and intentions about disclosure of testing and of test result**
    - Presence of emotional and social supports and responsibilities
    - Quality of intimate relationships
    - Would you tell anyone that you tested today? Who, why and what would you say?
    - Do you know people who are HIV positive? How are they being they been treated by others?

- **Views on the future – whether knowledge of status makes any difference to ideas and plans for the future**
    - How does knowing your status make a difference to your plans and ideas about the future?
    - Explore if pt has the intention to retest after the widow period and if they understand the need for safe sex during this period.
    - If testing was declined, whether the offer of testing has made any difference to ideas about HIV, testing and future plans

- **If positive, how has he/she been coping?**

- **What has been the experience of access to care?**
    - Knowledge of CD4 count & clinical stage, clinical follow-up, counselling follow-up
    - Obstacles and facilitators of follow-up care

- **Previous and current experience of the health services**
  (Repetition of some of the questions above)
    - Experience of informed consent and of confidentiality
    - Knowledge about harms /risks of HIV testing/What are the negative side of taking an HIV test?
    - Adequacy of knowledge /information re HIV test in relation to making a decision (Do you feel you had enough info to make the decision?)
    - What HIV information was gained in the STI consultation
    - Knowledge gaps: What do you understand by “window period?
    - What do you think of the way the HIV testing was included into the STI treatment?
    - What would you recommend to your family and friends when it comes to HIV testing at this clinic?

# APPENDIX 9A: STAFF FOCUS GROUP SCHEDULE FOR LAY COUNSELLORS, STI NURSES AND FACILITY MANAGERS

**Staff and lay counsellor second round focus group questions**

ROUTINE HIV SCREENING FOR STI CLIENTS
FACILITY MANAGERS

Researcher**: Natalie Leon, Medical Research Council. 083 45 48 567**

**INTRODUCTION**

The purpose of this focus group discussion is to review the implementation of routine HIV screening for STI clients. Your experiences and opinions since the last focus groups are valuable in terms of evaluating the implementation and progress of the pilot project. There are no right or wrong answers and I would like to encourage you to speak as freely as possible so that we can hear a range of opinions.

Your participation is anonymous in that your names and clinic names will not be mentioned in the writing up of any reports. The consent form you signed will be kept as a separate record for administrative purposes only. The session is scheduled to last 90 minutes and as mentioned in the consent form, will be recorded to allow me to transcribe the discussion and to analyse the information. A co-facilitator may be present to participate and to assist with making notes. The project steering committee will be given verbal and written feedback on the final evaluation and they will decide if further feedbacks should be arranged.

Any questions before we start the discussion?



**QUESTIONS**

FACILITY MANAGERS

1. Involvement of FM with the project implementation so far
   incl . How informed are they re-the goals of the project

2. Monitoring and evaluation role
   -what is their role e.g. monthly M& E.
   -how well is it working
   -what are the obstacles; suggestions

3. Managing the STI service & project
   Managing staff changes: How they provide backup for an absent STI nurse/for a trainee absent STI nurse (are STI pts deferred?)

4. What is their assessment of the STI Pns work regarding this project?

-does it add value

-are staff able to execute it well enough to add value?

- What if any problems are you experiencing?
- What about the time factor? VCT vs. Routine for the staff and for the pt?

4. Training

How should this have been done? (Only STI, over a longer period? method)

5. Communication regarding the project

6. Suggestions for the future of this project

**General questions to start off with:**

1. Since we last spoke, how do you feel the routine HIV screening pilot program has been going?
   - (Plse comment broadly: planning, training, implementation, supervision, monitoring and evaluation)
   - Check all along if experiences of those who had the full ATTIC training and those who got the shortened training differ.

2. What do you think has gone particularly well and why?
   - Plse give specific examples.

3. What do you think has not gone well and why?
   - Plse give specific examples.

Explore their experience of the following specific areas:

4. How comfortable are the PN/s with getting Informed consent?
   - How long does it take? /How and when is it introduced? Given that in practice, not 100% of STI pts are offered, what determines whether you offer or do not offer the test?

5. How well is the patient flow proceeding?
   - For instance in terms of waiting times at different stations (esp. where the treatment room PN is doing the test), and post-test counselling & CD4 blood test
   - What role does the PN play in facilitating the pt. Flow? E.g. does she call the L/C or take the pt to the LC or the VCT waiting area?
   - Are there follow-up counselling sessions and how well is it working?

6. Do PNs sometimes have to give the result? If so how is that going? If not, how is it going? (For instance, when the LC is not available, does it mean the PN does not offer the test?)

7. To what extent do you think the pilot achieved its goals?
   - Probe: Elaborate and give examples in terms goals of:

-Increasing HIV testing rates for STI clients? Compare and discuss the rates in routine screening and VCT clinics.

-Increasing the focus on access to care and support for HIV positive people? (Incl. counselling *and social support)*

-Increasing the focus on prevention of HIV transmission? *(Opinion of how HIV _ people are responding e.g., a 2nd chance?; and HIV +ve; what about recurring STIs with people who know their status?)*

8. How adequate do you feel the routine model is in terms of:

- Whether the client understands the reasons and benefits of HIV testing?
- Is the client adequately prepared to make an informed decisions whether to test or not (In other words, to what extend may clients be feeling coerced into HIV testing in this model?)
- Is the client adequately prepared to receive an HIV positive result?
- Do they understand what a HIV positive result means?
- Are the clients getting enough time and support after an HIV positive result is given? (Compared for instance to the VCT model?)
- Are the clients getting enough information about how to prevent acquiring HIV (if HIV-ve) or spreading HIV (if HIV+ve)?
- What kind of access to care and support are being provided for HIV +ve clients in this model (Compared for instance to the VCT model?)

9. In general, what do you feel about the importance of people being tested for HIV? Has your clinical practice been influenced in any way with this new intervention of offering HIV testing? *(Mainly for nurses?)*

10. What are the main practical & logistical issues that are important in the implementation of this project?
(Explore what happens to STI pts and to the offer of testing when the trained STI PN is not available)

11. What are the main emotional and attitudinal issues that are important in the implementation of this project?

12. What specifically do you feel about the routine HIV screening model in terms of the following issues?

- The role of the STI nurse
- (and the role of the Treatment room nurse where applicable)
- The role of the lay counsellor
- The role of the peer educator (applicable to youth and NAFCI clinics only)
- The role of health promoter educator (where applicable)

13. To conclude I would like you to tell me how you think this routine model can be improved.
For instance, can we deliver the STI service everywhere in this new model?
Also, if we were moving to an integrated STI service where all PNs were offering the service and not only a designated PN- could this model still be used?

- Please give specific examples. Comment on planning, training, implementation, supervision, monitoring and evaluation)
- What about staff support?
- Should this model be continued, expanded or stopped? Why
- Who should have routine HIV screening? (If it should be upscaled, to whom should it be upscaled e.g.? To all health clinics for all STI clients, to F/planning? All clients attending health facilities? Why
- If in future, L/Cs were permitted to perform the HIV test, would you still recommend the pilot model where PNs offer it as standard of care or not. Explain

14. Is there anything else that you would like to share with us about your experience of using this routine screening model in your clinic?

**Thank you very much for your participation in this focus group. Feedback will be given at the next Steering committee meeting.**
**Natalie Leon, PhD Fellow, Medical Research Council**

# APPENDIX 9B. INTERVIEW SCHEDULE FOR INTERVIEWS/FOCUS GROUPS FOR MANAGEMENT

**Semi-structured interview questions for managers**

PROCESS EVALUATION OF IMPLEMENTATION FACTORS ASSOCIATED WITH THE OUTCOME OF THE INTERVENTION

**INTRODUCTION**

- Consent signatures
- Tape recording and note making
- Scheduled time 90 minutes- check ending time with group

**PURPOSE OF THE DISCUSSION:**

To explore the process and context issues that may have contributed to the impact of the intervention in order to improve our understanding of how the intervention worked.

**INTERVIEW QUESTIONS:**

1. Did the intervention achieve its goals? In which ways did it work and which ways did it not work?

Probes
What were the main goal and secondary goals and to what extend were these achieved?
Issues to explore:

- Size of the increase compared to expectation of 20%;
- Coverage of rate of test offered (76% as compared to aim of 100%)
- Compared to estimated baseline of 30%
- Issue of increasing consistency of clinic performance;
- Level of HIV diagnosis/detection rate
- Gender balance compared to the gender composition of STI patients?
- Follow-up care for HIV positive patients

2. What factors do you think contributed to the outcome of this intervention? (How and why did it work?)

Probe:
Review the processes involved in the intervention and identify which factors contributed and which factors were obstacles to the success of the intervention.
Issues to explore for each area below:

- What was done, what were the success factors and challenges (& how was it addressed)?
- How may this have affected the implementation and outcome?

- How would you refine these issues if the intervention were to be up-scaled?

Areas to review should include

- **Design**
- **Planning**
- **Training:**
- **Preparation and Implementation processes**:

-was the intervention standardized; how did it differ at sites and could this have affected outcome

-patient flow issues; who does the rapid test, where and when

-ways of integrating testing into STI care:

-how much 'counselling' needed & how much persuasion?

-application of informed consent procedure

-health education sessions

-recording in the VCT register

- **Monitoring and supervision**

-initial support and how this may have changed over time

-managing collection and use of routine data

-review meetings

-steering committee meetings

- **Evaluation and research**
- operational and research goals –how did it work
    - issue of research methods e.g. randomization, baseline data, baseline comparison
    - site selection issues
    - management of data collection and quality
        - use of and quality of routine STI data
        - accessibility and quality of baseline data
        - data analysis issues (re incl or excl province stats)
        - feedback of findings

-Role of the research and of the researcher- what balance needed?

-response of role-players to research component



## Policy and decision-making

- Policy and practice shift during implementation

-NDOH changes in STI recording

-DOH targeting of HIV testing for STI

- How were the research findings communicated?

-What decisions were made and why?

(E.g. why roll-out decision and how was this decision linked to the pilot study findings?)

-How do the roll-out processes and outcomes compare with this intervention?

-What lessons can be learnt from comparing the new roll-out and this pilot PITC intervention?

Other questions to explore:

3. What if any were the unanticipated effects of this intervention?

4. What concerns did you have about the intervention and how did it play out?

- Issues to explore:
    - Quality of STI care may be compromised
    - Acceptance issues
        - Amongst nurses/attitude to the intervention (How and why did nurses agree to take on extra work?)
        - ethical applications
        - patient attitude
    - Feasibility issues
      Use of scare clinical/nurse resources
      Opportunity costs- effects of focus on new intervention
      And increasing nurse workload

5. What are the conditions and factors needed to achieve successful outcomes of PITC elsewhere in South Africa?

6. How applicable is this intervention resource constrained and high prevalence settings?

Thanking you

# APPENDIX 10A: WITHIN-CASE DATA DISPLAY AND ANALYTIC PROCESS (OBSERVATION)

## Case Study 1: Observation of STI consultation

Dumi is a 18 year old scholar, who was well groomed and fashionably dressed. He was offered and accepted the HIV test in the STI consultation. His HIV test result was negative.

Presenting complaint and risk assessment for STI

The observation of the consultation started with the nurse introducing the researcher to the client, after she had obtained his verbal consent for the consultation to be observed. She addressed the patient in Xhosa and encouraged him to continue speaking in his native tongue (as agreed), even if the researcher could not understand the language. It was agreed for privacy reasons that the researcher would leave the consultation at the start of the physical examination.

The first part of the consultation focused on the nurse assessing the clinical problem that the patient presented with.

> *Sr. "What do you want to say, what do you feel? Just talk like you would normally talk in Xhosa….. don't worry, then I will respond."*
> *Pt: "Well what I feel is that when I urinate, the urine burns, and I have a something like puss (discharge)."*

She enquired about the date of the onset of his symptoms and then about sexual partners:

> *Nurse: " Do you have a partner with whom you are sleeping with Dumi? How many partners? I would like you to answer honestly and freely, you are not held unwillingly here. …because if you answer honestly and freely I can also relax and I become honest, I am able to advise you better, you understand. So how many partners do you have?"*

He indicated that he had two partners and the nurse responded with a pragmatic question about his sexual risk behaviour.

> *Nurse : "There are two, okay. Do you use condoms for both of them?"*

He said that he only used condoms with one partner and the nurse enquired about the reason:

> *Nurse: "And for the other one you don't use it. Why aren't you using it for the other one..why are you doing that? Just out of curiosity "*

The patient said that he ran out of condoms. The nurse then continued with assessing the history of his health complaint:

> *Nurse: "Sorry for asking these questions, the reason is,……I know this is personal but it helps me in a way that I know exactly what type of danger you are in, you understand? The fact that I am asking about the exact date, it's not that I am probing."*

*Commentary*

In this first phase of the consultation, the nurse gathered information about the presenting complaint including the patient's symptoms, the type and duration of the symptoms as well as information about his sexual risk behaviour. Her communication style reflected an attempt to build rapport with the patient. For instance, she tried to put the patient at ease by encouraging him to speak freely. She also showed sensitivity and respect for privacy by explaining why she needed to ask personal question. She tried to enlist is co-operation by encouraging him to be honest about his responses. When she asked about the reason for his selective condom use, she added the phrase: "Just out of curiosity", almost as if she wanted to make sure not to sound too judgemental. Of interest is how the nurse tries to create opportunities for patient participation by asking a few open-ended questions. Despite this communication remained one-sided., as I will show later.

The nurse then made the STI diagnosis and checked if the patient understood.

> *Nurse: "Do you know that what you have is called STI? Have you heard about STI? What is STI?"*
> *Pt: "They say it's a drop"*
> *Nurse: "Do they say its drop?"*

The nurse then proceeded with a detailed explanation of what STI is and she structured her explanation by using the 3 letters of the word "STI" : Here is an excerpt of this explanation.

> *Nurse: "STI is being infected through sex, the "S" stands for sexually, right ?, as in having sex with someone. 'Transmitted', is infecting each other. When you sleep with someone and you are not using a condom, there are some fluids from one person that goes into the other person, there is that kind of transmission."…*

She continued:

> *Nurse: "If you have an STI like syphilis and you slept with someone who has this you get infected. So when you say that you have "drop" and when you explain it, you see some yellow fluid coming from you private organ that means you contracted one of these STIs. You got infected with one of them and so it's important to be treated. So it's also important that your partners should be treated with STI. "To prevent STI, practice safer sex, always use condoms every time you slept with someone. It is important to treat yourself and sleep with one partner. I can't say don't sleep with your partners, but it is important to use the condom. The reason for STI – you got infected by sexual intercourse*

*without a condom. I won't stop you from having sex your body is matured and it's telling you to have sex, but it is important to use a condom and practise safer sex. Do we understand each other?*

*Pt: Yes.*

*Sr: So you understand how you get STI and how it gets transmitted?*

*Pt: Yes*

*Sr: And what can you do to prevent you from not having an STI again?*

*Pt: (No opportunity for response)*

*Commentary*

In the above interaction, the nurse provided information about several of the standard elements of STI treatment. These included information about the transmission of STIs, the need for partner notification and treatment and the way to prevent contracting STIs through condom use. The STI information she provided was fairly comprehensive and clear, even though it was somewhat disorganised in its flow and idiosyncratic in the use of certain phrases.

In terms of her communication style, she started off by presenting the information in a creative and accessible way. She was able to link to the patient's own explanation about 'drop'. In this way, she seemed to be personalising the information about preventing STIs. This personalisng was laos done by her referring to what the patient can do personally, to prevent contracting STI. The nurse seemed to be making an attempt not to be authoritarian and directive in her manner at this stage. For instance, she framed her role as an advisor and not as one who is prescribing to him. At the same time, the communication is fairly one sided and the questions at the end of her statements seemed to be more pedagogical than directed at eliciting real patient participation. Also, she did not give him much chance to respond to questions, as illustrated in the last interaction above.

**Introducing the HIV topic**

Following on the above interaction, the nurse introduced the topic of HIV.

*Nurse : " There is something called HIV. Have you heard about it?"*

*Pt: "Yes."*

*Sr: What do they say, just tell me the way you heard it, don't worry?*

*Pt: When you slept with someone without a condom, you can get HIV.*

*Sr: That's how you get it, can you explain a little bit?*

*Pt: When you've got a drop, you can get HIV. If you don't have a drop, you can get it.*

The nurse acknowledged the patient's answer about the sexual route of HIV transmission, but she launched into a further long explanation about the sexual and other transmission routes of HIV. In the extract below, she explained the rationale for testing for HIV and tried to convey the message that an STI poses an increased risk for HIV infection, but the message got lost along the way. The explanation is provided here in full:

*Nurse: " Let's say when you slept with someone, you are right you can get it. When someone you slept with has it or else you have it, you will pass it to the other person. You will get it if that person has it, you understand, especially when the some bruising, fluids come out, both of you can get from each other's fluids. You can also get it through blood infections for instance; you can get it even from a cut through blood, but mostly, likely from sexual intercourse. Most of the time infection comes from sexual intercourse, bruises, cuts, [unclear recording], ulcers where there is scrapes of skin off the penis and vagina. When you have many partners you find that the other partner, you do use condoms right, did not use a condom and the partner has another partner likely you can infect the other one who in turn infects another person. You find that you are in a cycle of ± 10 or 8 – you might have 2 partners, and 1 has 1 to make 3 and the other has 2 you make 5 then you get many people being infected with this disease and then the STI spread with the group. And if it happens that one of you has HIV, you will infect each other and it spread. So we encourage people to use a condom. Are your girls on contraceptives?"*

*Nurse (continues) ….And if it happens that one of you has HIV, you will infect each other and its spread. So we encourage people to use a condom. Are your girls on contraceptives?*

*Pt: I don't know.*

The nurse rechecks his age, that he is 18, and explains her concern about contraception:

*Nurse: You do not want to be a father or do you want to be a father at this age?*

*Pt: Not sure. [Mumbling]*

*Sr: It's your responsibility/duty to ask regarding contraceptives so you won't be able to support babies. Do you understand?*

*Pt: Yes.*

<u>*Commentary*</u>

With respect to basic information about HIV, it would seem that the patient was aware that unsafe sex is the route of transmission for HIV. The nurse expanded on the patient's explanation and made the link between HIV and STI more explicit. In the above interaction, the nurse was able to get the patient to participate and he responded twice in a short space of time. This was in part facilitated by her asking an open-ended question : "… *can you explain a little bit*". The patient responded by providing an explanation that linked directly to his presenting complaint. This gives and indication of how the clinical context provides an opportunity for personalising the discussion of HIV risk.

The nurses' explanation about HIV included information about routes of transmission, how multiple partner's increases transmission and how condom use cut down on the spread of the virus. She also gave details on how STI can increase the risk of HIV (although her explanation was not always concise). Her explanation contains several examples of personalising the HIV message. For instance, on a content level, she refers to symptoms of STI that the patient is experiencing and she refers to his having multiple partners. In her communication style, she

tried affirm the patient's contribution to the discussion, by responding: …*'you are right you can get it (when you sleep with someone)".*

The interaction between the nurse and patient about how HIV and STI are linked, seemed to have contributed to a more personalised reflection of risk behaviour and exposure to HIV. Whilst personalising the HIV message has been found to increase willingness to test in a clinical setting, there is also the danger that such information can be skewed to unduely influence the patient's test decision-making. . For instance, in this case, the impression could be created that that the patients' STI symptoms, were in fact, symptoms of HIV, and that this is the reason the patient should test for HIV. A test decision based on this wrong impression could compromise the decision-making process. The patient may decide to test for the wrong reason if, in this instance, he assumed the HIV test was a prerequisite for an accurate diagnosis of his STI complaint.

From the observation data, one can determine what exactly is being said by the provider, but it remains difficult to know what the patient understands by it, and how the patient may be applying the information to themselves and how this might influence his test decision. The patient's explanation of the link between HIV and STI (when he said that one can get HIV, whether you have another STI or not) showed that he was clear about the distinction between presenting with a general STI and the possibility of having contracted HIV as a separate issue.

In terms of communication there are more examples of the nurse employing good communication skills whilst also mixing her professional role with elements of a parental role. For instance, she does not pass any judgement on the fact that he has two partners. She expressed her concern about unplanned fatherhood (although this may have been somewhat patronizing) and reminds him of his responsibility to prevent unplanned children. The patient's responded with unexpected honesty in the face of what appeared to be a rhetorical question on the part of the nurse.

The flow of the STI treatment shifted from gathering information in the first section, into a mode of delivering information (with some, at time haphazard, switching between these two modes,). For instance, her explanation about HIV ended with a sudden switch to asking about contraception of his girlfriends. This might reflect the nurse's uncertainty about how integrate the offer of HIV testing into the flow of the STI consultation.

**<u>Making the link between HIV and STI and recommending HIV testing</u>**

After the brief detour on contraception, the nurse continued to with illustrate how HIV was another type of STI.

> *Sr: So tell me now, it's HIV – HIV is similar to STI, they relate a lot to each other. HIV is an STI?*
> *Pt: Okay.*
> *Sr: Do you understand me? It is STI in the sense that it's transmitted through not using protection, like a condom. We say HIV is an STI. Okay?*

*Pt: Yes.*

*Sr: " Seeing that HIV is part of an STI, and there are (no) medicines to cure HIV but there are medicines that keep it under control. We wouldn't like for someone to get HIV. That is what we want to prevent, the sooner we prevent....people from getting it, the better. Is there anything that you want to ask Dumisani?*

*Pt: No.*

*Sr You don't have any questions, okay? (very small gap left for patient to ask a question)*

*Now with our treatment we have to take blood for syphilis,, then next week you come back we will give you a date over there, but if you cannot come on that date you can come the following day your results will be with us. So from this blood we are going to see whether you don't have syphilis, if you do have syphilis – we take it from there and say "what do we do", but if you are infected we give you a treatment. If you don't have syphilis, we will encourage you to use a condom all the time*

*Sr: Now, HIV is an STI, we encourage to test for HIV as well. So you know whether you have it or not. Then if we test for HIV as well. It's important that you know. If you find that you have it, we can give you the treatment that suppresses HIV. Do you get what I mean?*

*Pt: Yes.*



*<u>Commentary</u>*

In the above exchange, the nurse continued to explain the link between HIV and STI. She stressed the common sexual route of transmission. She also explained that HIV is treatable and she linked this to the need for early diagnosis of HIV (although, again, the explanation was not concise). Leaving the HIV topic, she then shifted to informing him about the need to test for other STIs, like syphilis. She explained what syphilis is, including that is treatable and that a follow-up visit is required. She then shifted back to HIV, and introduced the idea of HIV testing.

The nurse employed a few strategies to introduce the offer of HIV testing, from vague hints initially, to raising the idea of testing for HIV in relation to blood tests for other STIs like syphilis. The offer of testing is preceded by lots of information directed towards framing HIV testing as a standard part of STI treatment. There are also several opportunities in the conversation where the nurse could have directly introduced the offer of testing, but did not. The careful way that the topic of HIV testing is introduced here, might also be reflective of the nurse's struggle to find a smooth and efficient way to integrate HIV testing. The nurses' caution may also be reflecting a hesitation about how to offer HIV testing without being coercive. The importance of ensuring informed consent is stressed during the training of the PITC training, but there was little practical training about how to apply this.

From the interaction, the process and the content so far, the provider preference for testing is made clear. She repeats the information provided earlier, that HIV is an STI and that HIV is treatable. In effect, she is using the STI clinical context to emphasise the clinical reasons for testing, as a way of motivating the patient to consider testing. These are examples of the provider "framing" testing as the preferred option. She was careful to indicate that it is a

recommendation (and by implication, not compulsory) to test, when she stated that *"we encourage to test for HIV as well"*.

In the theory on patient decision-making in naturalistic settings, such positive " framing" of the provider's preference, poses a potential 'decision-hazard' for informed consent as it could unduly influence the patient to make a decision that is not line with their own preferences. An alternative interpretation of 'framing' is that the provider's recommendation is viewed as a useful way to for facilitate decision-making in medical screening. Studies show that in many contexts, the patient may prefer to have the provider give them a professional opinion. They may defer to this professional advice in moments of uncertainty, especially if they have trust in the provider-patient relationship. ( Lupton, ? Simpson). This apparent conflict of ideas will be discussed further in the analysis in Chapter 4.

**The HIV test procedure and informed consent**

*Sr: Now, if you say 'yes', there is no one who will stop you (?from testing or not testing). So we're gonna write here and sign here. (That you agreed). [Explaining taking of blood] I will prick you on your finger, but the one I have to send to the lab I will get from the arm. When we do the prick, we'll put it onto the screening, when your results are through, you'll get the result from the trained counsellor,– seeing that you started with me. (Explaining that he probably won't need to wait in the queue). If you get your results now, we'll tell you what is the way forward. After your results, you get support. If your results are good, we encourage you to use a condom. If your results are positive, we don't throw you out, we give you a support – being referred to someone you can talk to. We would also like to know who will be supporting you, things like that because we can also support you.*

*…. Now, I will give you time to think about it, while I am busy writing your details down,, whether you want to test or not. You say 'yes' or 'no'.*

*[Pause while nurse writes in the file)*

*Sr: You are thinking…?*

*Pt: Yes, I'm thinking…*

*(Pause while nurse continues to write in the file for about half a minute)*

*Sr: You are still thinking about my words? (?Considering)…What are you saying?*

*Pt: No, I can test.*

*Sr: You're gonna test?*

*Pt: Yes.*

*Sr: Okay. Have you understood our conversation about testing?*

*Pt: Yes.*

*Sr: You say you can test? (3rd time)*

*Pt: Yes.*

*Sr: It's a good thing that you know your status when coming out. I'm so glad you eventually made up your mind to test – that is where you're gonna get your help from, you understand?*

*Pt: Yes.*

In this above exchange, one can identify the following elements of the HIV testing process:

- Now the nurse is directly offering the HIV test for the first time.
- The nurse explained that written permission is required for HIV testing.
- She indicated that the patient had a choice about testing, though this is done clumsily saying: "*Now, if you say 'yes', there is no one who will stop you."*
- She explained how the rapid tests for HIV works and that this is different from the blood tests for other STIs like syphilis.
- She explained that the lay counsellor will be giving the HIV test result
- She addressed issues of prevention in the event of an HIV negative result.
- She noted that support will be available should he test HIV positive. (Here the nurse may be unwittingly communicating a value judgement that a HIV negative result is " good" and by implication, that a HIV positive result is "bad. Whilst this may be correct in strictly clinical terms., this phrasing might to the stigma associated with being HIV positive.

*Commentary*

The message about the voluntariness about testing is somewhat obscure in the nurse's communication, but there are indications that she is aware of the need to convey the voluntary nature of testing. For instance, the nurse did not state directly and clearly, that the test is voluntary, but she comes close to doing so with the words: "You say 'yes' or 'no'. She informed him that she will give him time to think about the offer. This implied that he had to consider the option to test but also to decline the offer. She then informed him that written consent was also required. This awkward manner of raising the issue might be indicative of the provider's unfamiliarity with the issue of seeking explicit consent, Seeking explicit verbal and written consent for blood tests is uncommon in this primary health care context (HIV is the exception) as general consent is given as part of the administrative process of admitting the patient.

In the above exchange, there is an omission of the direct words such as 'voluntary' and 'right to refuse', but when examining the exchange in detail, one could argue that the patient was not only made aware of this (albeit in a clumsy way), but also that there opportunities for the patient to exercising his right to refuse testing. Firstly, there is a pause in the conversation while the nurse writes in the patient record, she then asks if he is thinking about her words and he replies that he is still thinking. My general sense of this interaction was that the patient was not being rushed to make a decision. She then asked what his decision was and he said: '*No, I can test'* in a tone that indicated he was deciding *for* something, rather than merely going along with the nurse. (The 'No' in this sentence would be considered a turn of phrase and not a sign of ambivalence.) The nurse then checks three times to confirm that he has agreed to test, presumably to confirm his intention to test. This would have provided a small opportunity for him to change his mind or at least to indicate his ambivalence, which he does not do. The nurse is clearly pleased about the patient's choice to accept HIV testing and she indicates this by affirming his decision. It may have been difficult for the patient to change his mind after the nurse showed such appreciation for his decision to test.

The key point illustrated above, is that when evaluating informed consent in a naturalistic setting such as this, is useful to look not only for how the voluntariness of testing is communicated in words, but also how the clinical context may be shaping the patient's experience of

voluntariness of the test decision. For instance, here the communication dynamics and flow of the STI treatment and the way the HIV test offer was introduced, all indicate that the patient is being asked to express his preference, rather than being told he will be tested. This is different from the process for the syphilis screening test where the patient is told the test will be done and patient's consent is assumed.

**Prevention education and post-test support**

*Sr: You must, I'm encouraging you, you must always use the condom from now on and even your partners, you must use safe sex, understand? They must also keep condoms – you must advise them that there are female condoms available if they don't know how use it, they could come and we will show them how they are used. You as an individual, you know how to use it?*

*Pt: Yes (laughing)*

She comments on the feasibility of the female condoms, which gets a laugh from the patient. She then prepares to do the rapid finger prick test for HIV. While doing so, she addressed the researcher and informed her in English, that the patient had decided to test for HIV. She explained her next steps; that she would proceed with the physical examination, followed by prescribing medicine and arranging a follow-up visit. She continued with getting written consent from the patient:

*Sr: He's going to sign now. ( In English, addressed to the researcher) .*

*Sr: (In Xhosa, addressing the patient) If you are found to have HIV, who are you going to tell, someone whom you know will support you. Who can you tell? …Someone you normally share your problems with?... Because you need to tell someone who will support you, a person who cares for you and comforts you and listens to your troubles and fixes them for you,… you understand?*

*Pt: My mother.*

*Sr: Your mother?... okay.*

*Pt: After now I will do the prick, after this I will look at the tests and give you medicines. It's so important that you finish the whole course of the Rx – even the partners need to be treated. I will now give you two papers, no name written on it. If they stay here in Crossroads, I'd be very much glad if they can come. If not, they can go to the nearby clinic. You can come and sign here, we have spoken in depth about HIV and [sign-unclear] it.*

*Commentary*

As part of an assessment of the patient's readiness to test, the nurse checked if the patient would have emotional support, should he test HIV positive. She then switched to talking about how to take the STI medication and informing him about the need for partner notification and treatment and ended with a request to sign the consent for HIV testing. These sudden switches in communication of information and between the standard STI procedures and HIV related procedures is evident elsewhere in the session and I suggested then it might be due related to lack of efficient integration of STI and HIV processes. This lack of smooth integration holds the

potential danger of confusing the patient about which processes relate to STI and which to HIV. At this stage of the consultation it could have had the effect of undoing some of the clarification the nurse had provided earlier. For instance, the patient may not understand clearly, medicine she is referring to ; whether it was for his current STI condition, for syphilis, should he have it. The same confusion could creep in about partner notification: is for STI or for HIV or perhaps for both? Lack of clarity in communication such detail may have deleterious effects on the effectiveness of STI treatment and follow-up.

**Getting written consent and performing the rapid HIV test**

*(Pause – as patient signed the consent form.)*
*[busy with the testing] . (Interruption at door)*
*(Trying to get blood)*
*Sr. …You know that this one is for the HIV test (indicates the rapid test kit)…. Which arm do you want me to do this on? Alright roll up your jacket fully.( (referring to the need to draw blood from his arm).*
*Pt: Is this one for Aids?*
*Sr: "Its not for Aids, we don't say that its Aids, we say its HIV, you understand that Aids comes after a long time. You first start and see what is happening then name it that. Do you want it here, it does not matter which finger it is…, this one is for HIV (pricking).*
*Pt: Its stinging…*
*Sr: Is it stinging? Sorry, press on it….While we are still waiting for this one (referring to the rapid HIV test), then we should take one that will go…and the results will be here within a week (refers to drawing blood from his arm for the syphilis test)*

*Commentary*
The nurse made a running commentary of her actions while taking blood. She even consulted him about which arm and finger to draw blood from. At the end the two of them were laughing together when she struggled to draw blood from him and jokingly called him a coward, which he denied. This bantering provided for a lighter moment, at a time, when the patient might have been quite anxious about the outcome of the HIV test. These interactions illustrates a level of rapport and camaraderie, even when there was very little participation from the patient's side. Of note in the above interaction is that the patient asked his first and only question when he wanted to clarify which test was for HIV. The nurse responded, although the explanation is again rather clumsy and difficult to follow. It could even confuse, if the patient is familiar with AIDS but not HIV.

The tape recording was stopped and the researcher left the room. The STI consultation continued for another 10 minutes and would typically have included the physical exam, final diagnosis, providing medication and making a follow-up appointment for the syphilis test result. During this time, the rapid HIV test result would have been processed and the test, together with the patient's folder would be handed over to the lay counsellor. After the completion of the STI consultation, the patient then proceeded to the lay counsellor's room where he would have received the test result and post test counselling. The nurse informed the researcher afterwards that the patient had tested HIV negative.

The total time of the STI consultation was approximately 25 minutes which is reportedly 5 to 7 minutes longer than the standard STI consultation without the offer of HIV testing.

**Conclusion**

In this analysis of one consultation, the researcher pointed to the issues and questions that will be explored in more depth across the analysis of the observations. Some of the issue will also require theoretical framing and this will be done in the literature review and in Chapter on the overall findings.

The analysis of the observation case study provided a description of the HIV testing process and how it was integrated into the STI treatment consultation. It detailed the information provided by the nurse and how it was used to motivate the patient to test. It also showed how the informed consent procedures were applied. This initial showed the dynamic process of HIV testing procedure within the STI consultation by describing the patient provider relationship, the communication style of the provider, the level of patient participation and engagement of the provider and the patient with the clinical issues.

In terms of the social dynamic of the consultation, there was clear power imbalance with minimal patient participation, a situation that is not untypical in this context. Despite this, the communication and clinical skill of the provider and her caring demeanour seemed to contribute to an environment where informed decision-making was possible. Her communication style conveyed the impression of an experienced and professional nurse who was authoritative, but not authoritarian in her manner. She appeared to use the clinical context of the STI consultation appropriately to motivating the patient to test: using information about the HIV and STI link, noting the benefits of testing, personalising the patient's risk for HIV and recommending testing as a preferred option. In the process, the provider's preference for testing was made clearly 'framed", but there is little evidence to suggest that this compromised the patient's autonomy in the decision-making process. However, given the one-sidedness of the communication, it may be difficult for the nurse to fully assess the patient's preferences.

The nurse showed an awareness of the need for informed consent and applied the procedures for informed consent appropriately, even if this was not done in a systematic way. The way the HIV test was introduced conveyed the message of voluntariness, The patient is asked to express his preference,. This is a subtle but importance difference with other approaches 'opt-out' testing where patients are told the test will be performed unless they explicitly decline.

One problem was that the HIV testing process flow was at times fragmented and inefficient and this poses a potential risk of confusing the patient. The information provided was not always comprehensive or concise, but on the whole it seemed adequate, especially against a background of high levels of awareness about HIV.

The data from the observation case study was able to show in more detail the role the nurse played in motivating the patient to test and it was able to show the outcome of the patients'

decision. It was not able to show the cognitive and affective processes of the patient's test-decision-making.

# APPENDIX 10B: WITHIN-CASE DATA DISPLAY AND ANALYTIC PROCESS (INTERVIEW)

## Case study 2: Individual interview

Banele is a 20-year-old male scholar who was repeating grade 11. He has steady intimate partner for the past 2 years with whom he has a 6 months old baby. He accepted the offer of HIV testing and tested HIV positive at a STI consultation, one week prior to the research interview. The interview was conducted upon his return for his first HIV follow-up care visit at the same clinic.

The interview started with introductory conversation about his family background and his career plans. Banele mentioned that he was repeating grade 11 in order to improve his maths and science marks as he intended to study medicine. He arrived at the clinic 7.00 am in the morning when the clinic was still closed and had to join a long queue. He left and returned at 8.00 am and was seen by a nurse at 10.00 am for a 30-minute clinical assessment. This is an unusually short waiting time for this setting, and probably due to the clinic having a dedicated HIV care service on site. This patient indicated at some point in the interview that he had tested for HIV before.



<u>Reasons for testing</u>

After some introductory conversation, I asked Banele about his girlfriend. He explained that he had a steady girlfriend for the past 2 years and a 6-month-old baby with her. He added that he felt bad about not being able to support the baby financially because of still being at school. When asked if he had other girlfriends, he described openly his multiple casual sexual relationships:

> *Participant: 'Sometimes I do get some of them…. Like I meet a person in a shebeen where people buy and drink alcohol…And she is just a person I want to be with at that time you see? …The following day we are no longer in the same boat. So I am not able to count them because most of the time it is possible to find these people you see?'*

Banele conveyed the sense that such casual sexual encounters was a common occurrence in the taverns where he socialised. His candid response may have been partly facilitated by the fact that he had just completed a HIV clinical assessment where such personal information may have been requested.

Banele had a STI consultation the week before and I wanted to know more about his experience at the time, especially what his perceptions were about the HIV testing procedures. I started by asking about his knowledge of STI:

*Interviewer: 'Did you…..do you know what STI means? When you think back, did the sister explain to you what STI means?'*

*Participant: 'No, she did not explain it to me because she said there was nothing she saw when I came to check myself. When she came to check my blood, ....She noticed then that I was HIV positive.'*

Banele did not answer the question directly and moved straight to the topic of being diagnosed HIV positive. This is understandable given the recent diagnosis and the fact that he had just had a clinical visit related to his HIV. From his response, it is unclear whether Banele meant he was not diagnosed with a general STI at the last STI consultation or whether the nurse did not provide him with an explanation about STI. I continued and tried to clarify what the patient's understanding was of STI and HIV testing.



Health information and provider advice

Part of informed decision-making, is to be aware of the purpose of testing for HIV, for instance, that it can diagnose HIV earlier and therefore facilitate early access to care and prevention. In this setting, one would expect that patients also be informed about why the provider is recommending HIV screening now, in the context of their STI treatment. This is not standard practice, except in some instances, in antenatal and TB care. To explore the patient's understanding, I asked the patient how the nurse introduced the topic of HIV testing:

*Interviewer: 'At the time when you only came for STI last week, did she explain to you why you should check for the AIDS virus as well?' (translated version)*

*Participant: 'She explained to me that the AIDS virus could easily manifest itself….That I must check for HIV because the STI can change into HIV if you do not treat it.'*

The patient refers to information that the nurse provided about the link between HIV and STI and indicates that the nurse used this information to motivate the patient to consider testing for HIV. On the face of it, the nurse's explanation above is unclear, confusing and even inaccurate in places. For instance, she did not make clear the clinical reasons for offering HIV testing in the STI consultation. For example, explaining that the presence of an STI is evidence of unprotected sex and this constitutes risk of exposure to HIV or that that having an STI significantly increases the risk for acquiring and transmitting HIV. It is unclear from he statement: 'STI can change into HIV if you do not treat it', what the patient understood or was told about the clinical link between HIV and STI. This statement could be construed as misrepresenting and exaggerating the clinical connection between HIV and STI, an idea that could result in scaring the patient into testing for HIV. Such a situation could be considered as compromising of informed consent.

At this stage of the interview, it would be premature to make a judgement that informed consent was compromised due to inaccurate information. A more considered appraisal of

information on consent would required based on information from the clinical consultation. One could then unpack the issue of information a little further to determine whether the nurse did not provide correct information, whether the patient misunderstood what the nurse explained, whether the patient understood, but mis-communicated the message to the interviewer, or perhaps a combination of all of these.

Positive belief about HIV testing and familiarity with testing

I wanted to explore the reasons why the patient accepted the HIV test and started by enquiring about how he responded to being offered a HIV test:

> *Interviewer: Okay, and when she offered you the test, Banele, when you had to decide to say 'yes' or 'no', what was going through your mind?*
>
> *Participant: I thought that she had helped me because I did not know my status. I was going to continue doing anything....without caring.*
>
> *Interviewer: Okay, what made you decide to say 'yes' to the test because you came for STI, not for HIV testing?*

When the interpreter translated this question, he took the liberty to extend the question by referring to the patient's right to refuse (an issue that I had raised in previous interviews with patients where the translator was present). The translated question read as follows:

> *Interviewer: 'What made you say 'Yes', because you had the right to say 'No'?'*
>
> *Participant: 'Yeah, I had the right, but I just thought since I was there already,…I thought that I needed to know what kind of person I was… and she advised me in that way… I would be able to know that I do not have it, so that I could protect myself from contracting it……And if I had it (HIV) I should know, so I would prevent spreading it.'*

Enquiring about the reasons patient gave for their testing decision provided some sense of how informed or uniformed the patient's test decision was. Banele identified multiple, interrelated reasons associated with his decision to test for HIV. These included:

- regarding the STI consultation as opportunity to test, simply because he happened to be present at the STI consultation as he puts it; " since I was there already.."
- having the belief that he needed to know his status, when he says: " I thought that I needed to know what kind of person I was.."
- that he was advised and motivated by the provider to take the test; his words were: " and she advised me in that way…"

- having a sense that there are benefits to knowing one's status, both to prevent becoming infected ( "so that I could protect myself from contracting it') and to prevent transmission to others ('so I would prevent spreading it.')

What is evident from the above response is that this **patient has the basic knowledge about the transmission and prevention of HIV** and he has an awareness of the benefits of testing for HIV. The patient most likely had this knowledge prior to his STI consultation, especially since he had tested for HIV before. One could therefore conclude that despite what initially seemed like an inaccurate understanding about the link between STI and HIV testing, that this patient probably had the **minimum information required to make an informed choice.** (Irwig et al 2007).

Adequate knowledge and a belief in the value of HIV testing are two factors that may have contribute to Banele's willingness to test, but this may not be enough for people to take the action of testing, as was shown in the literature review. ( ref). Psychological studies have identified that patients who successfully accessed testing had formed a prior intention to test for HIV. ( Overmeyer) I asked Banele if he may have had a prior intention to test for HIV and he responded saying:

*Participant: 'I had it in my mind but I was scared'.*

Fear of testing HIV positive has been identified as a common reason for avoiding HIV testing. ( ? Obermeryer, Van Dyck). What is striking in this case is that this fear was present even in the case of the patient having tested for HIV before. Banele had tested for HIV a few years earlier as it was a prerequisite for attending a traditional circumcision school. He tested HIV negative then. Since then he had considered HIV testing, but was too scared to act, that is, until he was offered HIV testing in the STI consultation.

This raised the question: 'Why now?', what might have happened to allay the fear of testing at this STI clinic visit? I enquired why he had agreed to test in the STI consultation, when he had no prior intention to do so and in spite of his fear of HIV testing: His response was:

*Participant: No, what made me brave was being here already you see? I was advised to leave here knowing my status and I chose that. Because knowing that you have it means to know how to further protect yourself, and if you do not have it you would know how to totally prevent it….So that made me to stop being afraid.*

*Interviewer: And you decided to change…?*

*Participant: Yeah, I had to change my mind set.*

Banele repeated the reasons for deciding to test. From his account, it seemed that the context of the STI consultation in itself was experienced as a motivating factor. It presented an immediate opportunity for accessing testing and he made a quick decision about making use of the opportunity. In some sense, the decision was made on the spur of the moment, without necessarily intending to do so prior to the consultation and without giving much thought to pre-

existing fears about testing. There did not seem to be much deliberation with himself or with the provider and it would appears as if he gave little thought to the possible harms of choosing to test. One interpretation of this situation is that such rapid decision-making is hazardous for informed choice and it could leave the patient ill prepared to cope with the potentially devastating news of being HIV positive. An alternative interpretation, is that the patient was fully aware of the negative consequences of testing for HIV generally and for himself (given his prior testing experience and his subsequent avoidance of HIV testing), but that his need to know his HIV status was overriding.

There are other elements of decision-making that may have relevance in assessing informed consent here, but they are difficult to study in an interview and an observation context. For instance, one cannot determine if Banele's apparent ease with making the decision and his appreciation of the provider's advice, is perhaps evidence of a **preferred decision-making style**. Pierce pointed out a continuum of individual patient decision-making styles in naturalistic settings, where the majority of **people tended to defer to the provider for direction on what option to consider**.



Assessment of own risk and coping with being HIV positive

In the case of HIV, the nature of the decision or the '**decision-problem** ' as described in the Pierce model), is not a complex one. There are only two options, to test or not to test and most patients know what the meaning is of a HIV positive or negative result. This is different from, for instance a decision-problem such as having to decide about complex surgery that may have uncertain outcomes. Of more relevance in this clinical setting, is how patients **weigh up the probability of a HIV positive or HIV negative outcome**. In the decision-making conceptual framework, a realistic judgment of the outcome of a screening test is desirable. An overoptimistic judgement about a HIV negative test result, may be an indication that the patient may not have engaged with all the information at hand. To get a sense of whether Banele **considered the possibility of an HIV positive outcome** when he agreed to test, I asked Banele how he had felt when he received his test result the previous week:

> *Participant: My spirit went down, but I was convinced that I might have had this thing (HIV) for quite some time now, though I was not aware. …:And that I finally know should not change me….Knowing will help me to further protect myself. Otherwise, I do not have a problem with it.*

From his response, it would seem that the HIV positive test result may not have been totally unexpected. He had some awareness of his risk for HIV, especially given his earlier indication of having unprotected sex with multiple partners. It is likely that the engagement around the assessment for HIV and the nurses' recommendation to test, contributed to a more acute appreciation of his risk and this ***realistic risk assessment became internal motivation factor.***

The patient's post-test appraisal of the test decision, is another source of information about whether the patient felt adequately prepared and whether they felt their decision to test was consistent with their personal preference. Banele acknowledged the initial emotional shock of hearing that he was HIV positive. I explored how was coping emotionally and whether he had had symptoms of depression. He described how was coping:

> *Participant: No, I sometimes forget about it because I am mostly with my friends. I think about it when I am alone or when I am about to go to bed, otherwise I spend most of the time with my friends.*

Understandably, Banele was struggling to adapt to the knowledge of his HIV positive status and socialising with friends helped him to forget about it some of the time. One of his coping strategies was to **reframe the bad news in positive terms**, for example, by telling himself it was better to be aware of it. He appeared to be relieved to know his status and was intent on not allowing it to disrupt his life. Banele had returned to the clinic within one week of is diagnosis for follow-up HIV assessment and care. On the day of the interview, he was informed that his CD4 count is 353 and that he was not yet eligible for ARV treatment. Another example of his good coping skills is is that he was able to disclose his status to his steady girlfriend shortly afterwards. He explained how he encouraged her to get tested as well:

The way he responded shortly after the diagnosis, points to a person with good coping skills.

> *Participant: No, I only told my girlfriend so that she can also check herself…:She did not believe me as she thought I was joking….Her results came back negative so that is why she did not believe me.*

I checked if Banele understood that couples could be sero-discordant and the implications for their sexual practice. He understood and intended to use condoms to ensure his girlfriend stayed HIV negative. I enquired about his plans with his casual partners:

> *Interviewer: Have you thought about how you are going to manage the other girlfriends?*
> *Participant: Yeah, I will use a condom with the others too.*

Banele 's prevention plans does not seem to include cutting down on casual sexual encounters, although he expressed the intention to practice safe sex. He was clearly aware of the need to prevent spreading the virus to others.

<u>Provider's advice, personalised risk and informed consent</u>

One of the factors to look out for when assessing informed consent, is to what extent the provider may have influenced the patient's decision to test. In particular, one would need to have a sense of w**hether the provider's advice and preference may have unduly influenced the patient** to make a decision that was not consistent with his own preference. I returned to this

issue and enquired more directly about what information the nurse provided that may have assisted him to make the test decision. The patient describes how the nurse motivated him to test:

> *Participant: …she convinced me that it was not the end of my life. Having HIV did not mean that my life had ended. …I can continue living, you see….And if I take my treatment, well nothing will go wrong.*

In the above account, the nurse tried to normalise HIV as a chronic disease when she mentioned that there is treatment available, information that probably had a positive influence on the patient's decision test. From this interaction, one could assume that the provider showed that she preferred the option of HIV testing and that the patient was made aware of the provider's preference. This is unlike the VCT approach where the underlying counselling approach calls for the provider to be neutral about the options to test or not to test. In the literature on decision-making in screening tests, the ***'framing' of provider preference*** for one option as opposed to another option, is considered a ***potential hazard for informed decision-making*** (ref). It could have the effect of persuading the patient of an option that may not be consistent with the patient's values and preferences. On the other hand, studies on screening tests also indicate, that the **provider's opinion is often the preferred option** of the patient, as they expect and trust the provider to make make a professional recommendation. ( ref). From the interview, it is difficult to get a comprehensive sense of how the provider's preference for HIV testing may have influenced patient-decision-making and informed consent and this is another issue where it will be **useful to use complementary data from observations**

A key element of assessing informed consent is the awareness of the right to refuse testing or voluntariness of testing. By asking directly whether the patient thought their decision was voluntary, one might be introducing a preconceived notion that may not be entirely shared by the patient, hence the need to complement the information with observations of how informed consent was applied. I nevertheless asked Banele directly whether he was aware that he could refuse testing:

> *Interviewer: During that time the sister was going to… when she was telling you about the HIV virus, what was going on in your mind? Did you know that you had the right to say yes or no? (translated version)*

> *Participant: Yeah I could say yes because (?but) this thing (HIV) is all over the place out there, and I did not know my status, I only suspected that I could be having it because I was doing anything, anyhow and I did not like using the condom.*

Banele gave an incomplete response, but I inferred from his words a sense of awareness about the voluntary nature of testing. He appeared to be justifying why he needed to say 'yes' to the offer of testing, citing how widespread HIV was referring to his suspicion that he could also have the virus.

It would seem that in the context of the STI consultation, his awareness of risk became more acute. Many people have an **inaccurate perception of being at low risk or not at risk for HIV** and this prevents them from testing for HIV. (ref) Even when high sexual risk activity is acknowledged, this does not necessarily lead to testing.( pettifor and others). In this case, it is possible that the context of the STI consultation provided an **opportunity** to facilitate a **realistic and personalised assessment of risk** which may have contributed to the decision to test. It was found that willingness to test is increased when providers are able to personalise the HIV message by conveying the personal gains and losses associated with HIV testing, a situation that is inherent in the STI consultation. (Obermeyer and others)

Preference for HIV testing approach

**Post-test appraisal is another source of evaluating decision-making and indirectly tell us about informed** consent. How the patient responds to the test decision, the test outcome and the acceptability of the testing approach can provide information about the quality of the decision-making process. As shown earlier, even though he had tested HIV positive, Banele expressed relief and gratitude for having had the opportunity to take the HIV test and did not appear to have regret about having made the decision to test.

The patient's appraisal of the provider–initiated approach to HIV testing was also of interest and I enquired about how acceptable he found this. I asked what method of testing he would have preferred and gave him the two options to compare: the client–initiated VCT that he had experienced some time before or the provide–initiated offer of testing that was part of his STI consultation. As it was not easy to describe the details of two models of testing, the translated version of the question is provided in full to show how this was explained to the patient:

> *Interviewer: Which way do you suggest that…. There are two ways one can test for the HIV virus, one is when you have for STI's, and the other is to see the counsellor and make an appointment to come and test for the virus. Which one of these two ways do you think can help the other people? Is it when a person comes just for testing for the HIV virus or when he has come to check for STI's, and then combine that with getting advice on testing for the HIV virus? (translated version)*
>
> *Participant: The better way is when a person has come for STI's and then test for HIV…. In that way he can know if he has the virus or not because people do not want to come just for testing, they do not like that.*

Banele indicated that **he found the PITC approach acceptable** and explained why he thought it was preferable. His reasoning was that people generally shy away from testing for HIV and that the STI consultation provided a good opportunity. This opinion supported his earlier reasoning that the STI consultation provided a ready opportunity for him to test. I asked if there **might be a danger of patients being forced to test, in the PITC method**, but he did not think so and explained why:

*Participant: A person does as he pleases. The nurse is just there to give advice….Therefore, she will never force me.*

Post-test plans for disclosure and practicing prevention

Closer examination of the patient's post–test behaviour provided further examples of coping behaviour and of his preferences. Banele had already indicated earlier that he thought had done the right thing by taking the test and that he felt it will benefit his future adjustment. Nevertheless, he had a realistic appreciation of obstacles facing him. He intended to disclose his status to his family sometime and acknowledged that this would not be and easy task. Tthough his family would be supportive, he was more concerned about causing them to worry about his well-being. He was especially anxious about telling his mother, as he felt he may have disappointed by not preventing HIV. He explained:

*Participant: My mother is old and she has always cared for me and warned me against things like these.*

He said he was considering telling his friends as well, but he did not sound too convincing:

*Participant: I will tell them. I can tell them that I have this but they are scared of coming to test…They do not want it because they are scared.*

As part of concluding the interview, I praised Banele for his adjustment to his HIV status and his mature attitude. I asked if he had any questions and he shared his concern about fatherhood:

*Participant: So I want to know if I will be able to have another child now that I am HIV positive.*

I reassured him that it would be possible and encouraged to discuss the matter with a clinician as it has medical implications. I ended the interview by encouraging him to consider joining a support group at some point.

End of recording/interview

**Summary**

The patient was able to identify a **range of personal reasons** for accepting HIIV testing as well as reasons relating to the **patient –provider interaction**.

- The personal reasons included having a prior belief about the benefits of HIV testing as well as the experience of testing in the past.
- There were reasons for testing that related to the experience of the testing process, starting with regarding the STI consultation as presenting an immediate opportunity to test.
- In the patient –provider interaction, the information and encouragement by the provider played a role in motivating the patient to test.
- The clinical issues relating to the STI seemed to create an environment where the message about HIV could be personalised.
- The patient's decision-making may have been influenced by a personalised and a more acute and realistic assessment of risk for HIV. This was quite possibly facilitated by context where STI as the presenting complaint provided a close clinical and personal link to HIV.
- Post-test responses to the test decision and outcome, about the voluntariness and the acceptability of the HIV testing process all indicate a positive appraisal of the testing experience and of informed consent.

Based on the information above, indications are that the patient made a decision to test based on his own preference for testing in the context of the STI consultation.

There are areas in the interview where complementary information would be useful for a more comprehensive assessment of the testing process and context. One area that need clarity is the quality of the health information about the link between HIV and STI treatment was and secondly, to determine if and how this information may have influenced the quality of informed consent. This area was be explored further by examining the STI consultation and identifying what information the provider delivered in the STI consultation. It was also difficult to get a clear sense of the patient's awareness and appreciation of the voluntary nature of the HIV screening. This is partly because of the obscure nature of the concept of something being 'voluntary. This was especially so in a context where verbal and written consent is seldom explicitly requested in medical treatment at clinic level. In an individual interview, patient may for a range of reasons, be hesitant to identify that they felt coerced into HIV testing. Data from observation of the STI consultation should be able to show how the providers applied informed consent procedures, for instance, how the nurse conveyed the message of the voluntary nature of the HIV test offer. The observations will provide an additional source of complementary information to enable a more comprehensive assessment of informed consent.

# APPENDIX 11: A CROSS-CASE ANALYSIS OF STI OBSERVATIONS

**Analysis of STI Observations:Coding matrix July 2009**

| CODE AREA | No. 5 | No. 8 |
|---|---|---|
| **Background info** | Henry, M, 20+, laborer,. Tested before . | Bona,M 42 |
| **Other Data sources** | Interview ( Engl) | LC |
| **HIV test decision** | ACCEPT; HIV+ve | ACCEPT; HIV +ve, 1st timet tested |
| **Total time STI/HIV** | 13 pgs/7pgs (? 25min/10min) | 11pgs (20min/ |
| **HIV Testing process checklist** | | |
| Introduction of HIV/testing | 1 Early, well integrated. Expl tha STI & HIV assessment done here. ".. A.also doing the counselling for HIV.." | 4;yes- short and sweet: :STI sickness measn affecting your private parts, for examnple, gonorrhea and others. …HIV is also included… |
| Motivating for HIV testing | 1. 1"I don't know is you know that HIV is an STI…. How do you get HIV? " | Extensive HIV info 1st, then much later, pg 7, a good mananer of offrrign the test:"Okay, so now that I have explained everything to you, Would you be interested to be tested today? |
| HIV awareness/education/info | 2;" …but for us to be clear they must all go for counselling and be tested…" | 4; long, colourful expl. Suing analogy of sea and body soldiers |
| *Explaining that HIV is an STI* | 1. Says she should check for HIV, because a sexual partner can have any of the STIs | see above |
| *Expl -STI increases HIV risk* | | Not done |
| *Personalising HIV risk* | | 5. refer to wperiod, apply ot pt's risk, but too long and leave out crucial prt abpout safe sex. |
| *refer to pts STI symptoms* | Yes- says pt could have picked up any STI, incl HIV. It's a fine line i.t.o confusing pts, but PN she does not cross it. | links HIV as another STI |
| *Expl HIV treatment availability* | | Yes= pt mentioned it 1st |
| assess sexual risk behaviour | 1;For STI assessment & elsewhere ;condoms & multiple partners | yes |
| condom use | pg1. 'condoms" used 16 times betw pt and PN. | |
| number of partners | Pt says 1 & gives details. Not sure re partner | yes, says 1, but indicates alchohol as a factor |
| discuss window period | | yes-unnecc detail |
| Benefits of testing | | yes-pt metnioned it first, see below |
| Harms of testing | | |
| Actual test offer | | Extensive HIV info 1st, then much later, pg 7, a good mananer of offrrign the test:"Okay, so now that I have explained everything to you, Would you be interested to be tested today? |
| Test decision & reasons | Pt clear about wanting to test. He welcomes the opportunity . Has tested before. | 7: NB Quote this whole section:"Yes I am because I want to know my status" …"if the results show that I am positive, it would be better to know ..I will get a chance of getting treatment…… |

| | | |
|---|---|---|
| nurse response to decision | double checks, then do extensive test readiness which is unnecc for these pts who tested before | 7; Askse preparation for a +ve result, disclosure, support etc. Good bec not be;laboring the post-test issues. Good rapport, but too much info, though more efficient than previous pt, Good motivation of pt, but it too detailed as pt awoudl have consented at the start, reagardless. Pn regardss info as essential for HIV testing. This causes poor flow, lack of integartion of testting.. But PN has an emphathetic, non-judgemental and careing style which makes up for the ineffiencies in worksstyle |
| **ASSESSMENT re PN role** | Poor communic. Style, Unnecc level of motivation, overemph on info, rapid qs. Inefficient delivery of testing offer & STI care. but PN connect with pts through health educ mode. | |
| assessing test readiness | Overemphasised since pt tested twice before. | |
| Expl test procedure | | |
| Expl post-test counselling | | |
| Expl confidentiality | | 2;early, integrated- but incomplete explanation" "between us only, not allowed to talk about it elsewhere.." |
| Expl right to refuse | | pg 8 Good explanation |
| directly/indirectly | | directly & indirectly, through tone |
| Consent form expl+signed | | pg 8 Good explanation |
| Do HIV rapid test | To be done by different nurse in Rx room, after the STI consult | pg.9 Explain which test is which, so pt cler about which is the HIV test |
| Expl medical f/up/CD4 test | Not checked- ? LC | |
| **ASSESSMENT re Inf Consent** | Not ideal, but there are indictions of IC. Eg. Double checks pts decision to test times! Appears to be aware of need for IC, but sees this as a function of giving HIV info. Written consent | Appropriate applic of IC and little evidence of coercion. But not eficiently done. Pt appear to be willing to test and my have said yes earlier if allowed to do so. Pt is clear about the ned to test and the reasons. This patient, although he said very littleat first, expressed his view of the benfit of testing clearly-and so spoke more thatn other, more communcative pts!(pg7) |
| **Quality of STI Treatment** | | |
| **STI TREATMENT** | | |
| presenting complaint assessed | 1. and in different places- goes back and forth, looses track | 1;extensive STI symptoms, but also ear problems; allowed to elaborate |
| sexual risk assessment | | |
| prevention education | Yes- condoms and one partner. ( Give example of good communic here) | |
| STI education | Yes | 4;yes- short and sweet: :STI sickness measn affecting your private parts, for examnple, gonorrhea and others. …HIV is also included… |
| STI diagnosis | Yes | |
| Syphillis blood test explained & done | Syphilis treatment mentioned, but not clear | |
| Physical examination | | |

| | | |
|---|---|---|
| medication given & explained | | |
| partner treatment explained | 14; Yes - says she will elaborate later | pg 1- Good explanation |
| partner slip (s) issued (No) | 14; Yes - says she will elaborate later | Yes |
| condoms offerred/given | multiple times, but duplication & very haphazard. See pg 8. | Yes- "May I give you another packet? |
| condoms demonstrated | No | No |
| F/up apptment for STI | 14- makes reference to this | yes |
| F/up re HIV treatment | | |
| **Other Screening** | not observed, but referred to TB | Checked complaint re sore ears |
| TB | | Yes |
| Contraception | | |
| Pregnancy | | |
| Papsmear | | |
| **Communication style** | Similar, Inefficient, haphazard, fragmented communic & work style, but more fasciliative . Repeats, looses track, awkward, failed attempts at getting pt participation. | 1; called pt 'son' although an older man. But otherwise a respectful, non-judgemental and easy communcat. Style tha puts pts at ease, allows pt to speak, Only probl is overemhais on HIV and othe r inof, Also, she looses track and repeats questions. |
| **ASSESSMENT re STI Care** | **Comprehensive STI care re Dx, exam, treatment, partner notif- but inefficient** | **Not fully observed, but the observed section indicates a Comprehensive STI care re Dx, exam, treatment, partner notif and comprehensice screening, but could be more efficient** |

| | | |
|---|---|---|
| **SUMMARY** | Similar to previous OBS, but a little less fragmented and chaotic. Though same inefficient patter observed. Pn does seem to connect with pt despite her inefficient communic- asks pt to participate by posing qs- but mainly to continue with her info giving. This pt is more communicative- comfortable in Engl. Pt had tested before= & is keen on testing, so did not need the extensive HIV educ or 'counselling'. Post-test would have been unnec as PN coverd most things in pre-test- another example of the inefficieciency of practice. | Good rapport, but too much info, though more efficient than previous pt, Good motivation of pt, but it too detailed as pt awoudl have consented at the start, reagardless. Pn regardss info as essential for HIV testing. This causes poor flow, lack of integartion of testting.. But PN has an emphathetic, non-judgemental and careing style which makes up for the ineffiencies in worksstyle. Good rapport, but too much info, though more efficient than previous pt, Good motivation of pt, but it too detailed as pt awoudl have consented at the start, reagardless. Pn regardss info as essential for HIV testing. This causes poor flow, lack of integartion of testting.. But PN has an emphathetic, non-judgemental and careing style which makes up for the ineffiencies in worksstyle. it appears that in these cases, the pt would hav consented right at the start, after the 1st expalnation of the HIV -STI link and it could ahve taken less tahtn 5 minutes, even as little as 2-3 minutes to do an effectgive ands an ethical offer. The mian obstacles were the excessive HE and prep for a +ve result. Perhaps more than what the PN actually says and does, it the influence of the STI consultation context - taht pts seems to find this a good opportunity to test. Partner notification reinforced, but lack of clarity could undermine the STI treatment message |

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