

**THE ACCEPTABILITY AND EFFICIENCY OF  
ROUTINE “OPT-OUT” HIV TESTING IN A SOUTH  
AFRICAN ANTENATAL CLINIC SETTING.**

By

Dr Erika van Wyk (Drewes)

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Supervisors:

Dr J. Giddy

Dr C.B. Roberts

Prof S.S. Naidoo

## **Declaration**

I declare that this master thesis, *Acceptability and efficiency of routine "opt-out" testing in a South African antenatal setting*, is my own work and that all the sources used or quoted have been acknowledged by means of complete references and that this thesis was not previously submitted by me for any other degree at any other university. My role in this study was that of principal investigator.

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Dr E van Wyk (Drewes)

## **D e d i c a t i o n**

This study is dedicated to

My Saviour, Jesus Christ;

My wonderful husband, Helmut for his unwavering support;

My son Felix;

Arlys and Johan, my parents, who always motivated and encouraged me.

## **A c k n o w l e d g e m e n t s**

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## **Abbreviations**

**AIDS.** Acquired immunodeficiency syndrome

**ANC.** Antenatal Clinic

**ARV.** Antiretrovirals

**ART.** Antiretroviral treatment

**AZT.** Zidovudine

**CDC.** Centers for Disease Control and Prevention

**DOH.** Department of Health

**HBV.** Hepatitis B Virus

**HIV.** Human immunodeficiency virus

**NSP.** National Strategic Plan 2007-2011

**NVP.** Nevirapine

**PMTCT.** Prevention of mother-to-child transmission

**Rh.** Rhesus Factor

**UNAIDS.** Joint United Nations Programme on HIV/AIDS

**UNICEF.** United Nations Children's Fund

**VCT.** Voluntary Counselling and Testing

**VL.** Viral Load

**WHO.** World Health Organization

## **A b s t r a c t**

Key words: *PMTCT; Routine testing; Opt-out testing; VCT; Exceptionalism; Staff experiences; Acceptability; and Efficiency.*

### **Background and Objectives**

The improved uptake of antenatal Opt-out testing has been documented internationally. In South Africa little is known about the efficiency and the acceptability of Opt-out testing. This study compared VCT with Opt-out testing by measuring the efficiency (defined as uptake of testing, number of women identified as HIV positive and consultation duration of the testing approach) and the acceptability to patients and staff.

### **Methodology**

We conducted a prospective, quasi-experimental equivalent time-samples clinical trial in which we enrolled a consecutive sample of women who presented at the McCord Hospital antenatal clinic from June to August 2006. The study consisted of 2 phases. During the 6 week intervention period women were offered HIV testing with the Opt-out method. During the 6 week control period women were offered midwife-provided VCT. Efficiency was measured in each phase, with 150 participants in the VCT arm and 150 in the Opt-out arm. Participants also completed a survey questionnaire. In depth interviews were conducted with 9 purposefully selected participants from each arm. Two focus group discussions were held with staff. The staff focus group findings were followed-up and validated by conducting in-depth interviews with the staff members who participated in the focus groups 18 months later.

### **Results**

The uptake of HIV testing during the VCT period was 134/150(89.3%) compared to 147/150(98.0%) in the Opt-out period ( $p<0.001$ ). The percentage of women identified as being HIV positive during the VCT period was 7.33% (11/150) vs. 12.6% (19/150) during the Opt-out period ( $p=0.133$ ). Time was saved as a decrease in the duration of midwife

consultations from 34 min (VCT) to 26 min (Opt-out) was found with  $p < 0.001$ . Qualitative analysis revealed Opt-out testing to be an acceptable way of testing. Patients found Opt-out emotionally less distressing than VCT ( $p < 0.05$ ). Staff reported that Opt-out decreased the burden on human resources (only one person needed to facilitate the group and shorter consultations) while it identified more women infected with HIV.

### **Conclusion**

Opt-out testing is significantly more efficient and acceptable than VCT. Opt-out testing should include a group pre-test information session, adequate and ongoing post-test counselling, to be effective and acceptable.

## 1 Introduction

Voluntary Counselling and Testing (VCT) has been the recommended testing approach since the early years of the human immunodeficiency virus (HIV) epidemic in South Africa, as in other parts of the world. However, its implementation has faced many obstacles in the antenatal setting internationally as well as locally. This is because VCT is labour intensive, time consuming and despite efforts from stakeholders, uptake has not met the testing targets in order to achieve good treatment coverage. One group of international researchers has concluded that VCT cannot be seamlessly and fully integrated into optimal antenatal service delivery.<sup>1</sup> This lack of full integration is problematic as it is widely accepted that the gateway to effective HIV treatment is through a testing strategy that is able to diagnose patients early and efficiently. The inefficiency of VCT has also been attributed to the “exceptionalised” way in which HIV testing is done. In other words, HIV is diagnosed differently to other medical conditions. No other common medical condition exists that involves such extensive counselling before a patient may be tested. Because HIV testing is treated differently by healthcare workers it gives patients the impression that HIV infection is somehow different (or abnormal) to other illnesses. It has been reported that this “exceptionalism” has added to stigma and may be perceived by patients as a barrier to testing, as outlined by de Kock et al “Our philosophical and technical approaches to HIV/AIDS prevention must interrupt HIV transmission, mitigate the epidemic’s clinical and social effects, reduce stigma and vulnerability, and promote the rights and wellbeing of HIV-infected and uninfected people. We believe that HIV exceptionalism cannot achieve these goals in Africa and suffers from inherent contradictions.”<sup>2-4</sup>

The low uptake of testing in antenatal clinics directly impact how well Prevention of mother-to-child transmission (PMTCT) treatment interventions can be applied. Since improved PMTCT treatment regimens are now widely available, public health proponents have advocated that alternative testing approaches should be considered in order to improve the

coverage of care.<sup>5</sup> In South Africa HIV positive pregnant women are able to receive life-saving antiretroviral treatment (ART) and antiretroviral prophylaxis that will protect their unborn children from HIV infection.

The Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) have adopted Opt-out testing as the recommended testing approach in response to the problems that was experienced with VCT.<sup>7</sup>

### **1.1 Motivation to do the study**

Opt-out testing is defined as an approach to HIV testing which informs pregnant women that, together with all other routine antenatal blood tests, they will be tested for HIV, as part of routine obstetric care unless they specifically decline.<sup>8</sup> The term “routine testing” was initially used to refer to this testing approach.

In May 2007 the WHO officially modified its testing policy to recommend Opt-out testing internationally as the preferred testing approach.<sup>7</sup> The widely reported success of Opt-out testing in Botswana demonstrated that Opt-out testing could be implemented successfully in developing countries.<sup>10</sup> However despite this evidence and endorsement by international health organizations (WHO and CDC) there is still scepticism in South Africa about the Opt-out testing approach.<sup>11</sup> This scepticism arises from fears about the way in which patient consent is obtained with Opt-out. It has been stated that Opt-out testing could lead to patients feeling coerced into testing. Sceptics feel that it could be detrimental to those who were found to be positive and not “ready” to know their HIV status.<sup>11</sup> By possibly not meeting the legal requirements for informed consent Opt-out testing could potentially violate human rights. In addition, concern has been expressed that less information prior to testing could lead to poor health education, which in turn, could lead to high-risk health behaviour.<sup>12</sup> So, Opt-out may not be an acceptable way of testing despite its successful proven record with improved uptake. South African stakeholders have made it clear that the Opt-out approach will only be considered if there is local evidence based on local research that it is an efficient and

acceptable method of testing. In 2008 the South African National Department of Health released the new PMTCT policy guideline which recommends provider initiated VCT and not Opt-out testing as the testing approach to be implemented. <sup>14</sup> Provider initiated VCT means VCT offered routinely to all pregnant women as opposed to client initiated VCT.

The way in which Opt-out testing is implemented varies and depends largely on the socio-economic context, the country, available resources and the perceived risk to the patient population. For example, in some first world countries where patients are more educated and where HIV is less stigmatized, Opt-out pre-test education consists of an information leaflet that is mailed to the patients prior to the booking visit. <sup>15</sup> Botswana utilizes group education, flip charts and posters. <sup>10</sup> In the South African antenatal context, there are no published reports about the practicalities involved in implementing Opt-out testing.

Given the excellent uptake of HIV testing with Opt-out testing demonstrated in the literature, a study that measured the efficiency and acceptability of Opt-out testing in the South African antenatal setting was warranted.

## **1.2 McCord Hospital PMTCT Context**

McCord Hospital is a state aided hospital in Durban, KZN, where women pay subsidized fees for obstetric care. McCord serves a mixed demographic population, and approximately 1820 women book for antenatal care per year.

The McCord PMTCT program is linked to the provincial PMTCT program.

Prior to this study, the testing approach used at McCord antenatal clinic was VCT. All pregnant women were offered VCT routinely on their first antenatal visit. VCT resulted in 100% counselling coverage, while the uptake of testing ranged from 85-88% per month.

Midwives were trained in VCT and did the rapid testing during the first visit. The same midwife who did the pre-test counselling did the initial post-test counselling for positive patients. The HIV counsellors became involved once patients were diagnosed HIV positive

and provided ongoing support and counselling and preparation for ART throughout pregnancy and delivery. The process of VCT was labour intensive with the midwives having to do pre-test counselling, testing and initial post-test counselling. This resulted in lengthy consultations. The VCT testing approach as done in the McCord setting was therefore not very efficient.

The PMTCT team decided that it would be ideal to test all patients who book for delivery in order to provide the best care to the HIV infected mothers and their babies. The PMTCT team was advised by the PMTCT provincial manager that it would be better to implement this idea initially as a research project, because of the potential ethical issues involved.

Thus a study comparing the efficiency and acceptability of Opt-out testing as compared to VCT was designed.

### **1.3 Hypothesis and Objectives**

Hypothesis: Opt-out testing would be more efficient and acceptable to patients and staff in the antenatal clinic than VCT.

The objectives of the study were the following:

- To compare the efficiency (uptake of testing, time and human resource cost, number of HIV positive women identified during the study arms) of provider initiated VCT with Opt-out testing;
- To compare the acceptability to patients of each of the testing approaches in terms of deciding to test, and their feelings, thoughts , perceptions and attitudes associated with HIV testing;
- To compare the acceptability to staff in terms of their, beliefs, fears, and attitudes; and

### **1.4 Key terminology**

- Opt-out testing

- VCT
- Efficiency
- Acceptability
- Exceptionalism
- PMTCT

#### **1.4.1 Opt-out testing**

When the study protocol was written in 2005, “Opt-out testing” was not yet used as a recognized term to describe this testing approach. There are several different terms that are used to describe this approach to HIV testing. These include: Batch testing, routine testing and provider initiated testing in the “Opt-out” way.<sup>16,17</sup> The Opt-out term originated from the way in which patients are prepared to consent to test. Patients are informed that an HIV will be done but that they have the right to refuse or “opt-out” of testing.<sup>8</sup> The study title refers to routine testing. With this, it was intended to measure routine offer of HIV testing in the “Opt-out” way. The rest of this thesis will make reference to “Opt-out testing” and not “routine testing” as Opt-out is now a recognized term that is more specific and clear in its meaning.

#### **1.4.2 VCT**

Voluntary counselling and testing (VCT) is currently used in most antenatal settings in South Africa. It is the testing approach against which Opt-out testing was compared. Until recently, the VCT approach was “client initiated.” This meant that patients had to approach health care workers to ask for an HIV test. However, this approach has been adapted to be “provider initiated” to offer testing to more people. Recently, the National Department of Health has included what is called: “provider initiated counselling and testing” in the new PMTCT policy guideline.<sup>14</sup> This means HIV testing is offered routinely to patients as they book for antenatal care. This is different from Opt-out testing in that Opt-out testing educates patients about all the antenatal tests including HIV. With VCT, patients are counselled for HIV in groups and then also individually. Provider initiated counselling and testing is thus VCT that is offered



routinely. At the time of starting this study, VCT was also offered routinely to all patients who booked for antenatal care at McCord. Therefore the Opt-out approach was measured against “provider initiated VCT.”

#### **1.4.3 Efficiency**

Efficiency of the testing approach was measured by comparing three outcomes common to both approaches: Uptake of testing; time cost of the testing approach and finally, the HIV prevalence diagnosed in the clinic with each testing approach.

#### **1.4.4 Acceptability**

One of the main advantages of Opt-out testing was reported to be reduction of stigma as HIV testing is offered in a non-exceptionalized way. Therefore the study included questions on how patients perceived each testing approach in an attempt to understand how the Opt-out approach influences stigma. As the analysis of this data progressed, it became clear that the patients’- and staff’s responses did not reflect their perceptions of stigma in general as much as their perceptions of acceptability of the testing approach. It is thus more appropriate to refer to acceptability of the testing approach rather than stigma. Acceptability includes aspects concerning perceptions of stigma and elements of HIV knowledge, past HIV testing experiences, emotional responses and attitudes to HIV testing. Therefore the researcher will refer to the acceptability of the testing approach and not stigma specifically as was previously indicated in the study title.

#### **1.4.5 HIV Exceptionalism**

This term was coined by researchers to refer to the exceptionalised way in which public health strategies approached HIV testing. It has since become a widely used term in the HIV testing debate. It refers to the VCT testing approach and how HIV is tested and diagnosed differently to other medical illnesses. The HIV epidemic was not dealt with in the standardized way in which epidemics have always been approached, which includes routine testing, case detection and case notification. For example, consider how the Severe Acute

Respiratory Syndrome (SARS) was approached. Instead, with the HIV epidemic, the VCT approach was adopted, in which patients had to choose to present themselves to test of their own accord. Patients were given extensive counselling and were then invited to test. In this way an unprecedented approach to this epidemic was taken. By avoiding the standard public health management of epidemics it set the stage for a silo approach to the subsequent management of HIV. This approach became known as HIV exceptionalism. This thesis will present the reasons why HIV exceptionalism developed and then debate its current relevance in the Discussion Chapter.

#### **1.4.6 PMTCT**

The aim of testing in the antenatal setting is to identify HIV positive pregnant women in order to offer prevention of mother-to-child transmission treatment options. Therefore the effectiveness of the testing approach would directly impact to what extent PMTCT care can be offered to those patients identified through testing.

The next chapter deals with relevant national and international research.

## **2 Literature Review**

The literature review is presented according to the following main themes.

- Introduction: The impact of public health response on the HIV epidemic
- The severity of the South African HIV epidemic
- The impact of undiagnosed and untreated HIV in the South African antenatal context
- Voluntary counselling and testing as a testing approach.
  - Background to the VCT approach
  - The National PMTCT policy and its revised VCT testing approach
  - HIV exceptionalisation, VCT and how it influences patients' testing choices
  - VCT in the antenatal context
  - VCT and behavioural change
  - The sensitivity of VCT as a testing approach
- Opt-out testing as a testing approach.
  - Opt-out testing: International Policy
  - How the Opt-out approach is implemented
  - Acceptability of Opt-out testing to patients
  - The problems with Opt-out testing to staff and patients
- Ethical and legal issues around HIV testing including informed consent
- The benefits of knowing one's HIV positive status
- Chapter summary

### **2.1 Introduction: The impact of the public health response to the HIV epidemic**

With the outbreak of the HIV epidemic, routine testing and case detection (that has traditionally been part of standard public health responses to epidemics) was not applied.<sup>2</sup>

Instead the testing approach that was implemented relied on patients electing to seek HIV testing at health care facilities of their own accord (this is a client-initiated testing approach).

Such patients would have to receive extensive HIV pre- and post -test counselling in order to have the HIV test. This approach to testing was named voluntary counselling and testing (VCT). The literature discussion on the reasons for the implementation of VCT is presented in section 2.4 of this chapter.

Thus VCT differs from the standard testing approach used in communicable disease epidemics, namely, routine testing. Routine testing (which is a provider -initiated testing approach) is used in a public health setting where all patients who attend a health care facility are regarded as “at risk” of being infected, and thus screening testing is routinely offered to them. The use of VCT in countries where HIV is a defined epidemic, has led to obstacles in early diagnosis, and therefore may have hampered the containment of the epidemic.<sup>19</sup>

In 2002, a group of CDC researchers based in Kenya argued that the response to the threat of HIV/AIDS in Africa has been inappropriate in terms of the devastation that the epidemic has caused.<sup>2</sup> They maintained that VCT as a uniform, global approach to testing might not be the most appropriate action given the geographic and epidemiological differences in Africa. In addition, acquired immunodeficiency syndrome (AIDS) prevention strategies in Africa have largely been under -funded and therefore Western approaches to testing (such as VCT) might not be optimal. <sup>22</sup> The emphasis on human rights in HIV testing has reduced the importance of public health and social justice.<sup>2</sup>

In an effort to understand the South African context, one needs to look at the severity of the HIV epidemic and how it relates to the selection of a testing approach.

## **2.2 The severity of the South African HIV epidemic**

To address the growing HIV epidemic, the South African government released the new National Strategic Plan (NSP) in 2007.

The NSP<sup>23</sup> states that: “Although the rate of the increase in the prevalence has slowed down, the country (South Africa) still has to experience a reversal of the trends. There are still too many people living with HIV, too many still getting infected. The impact on individuals and households is enormous.”

There is an estimated 5.54 million people living with HIV in South Africa today. The country’s adult population is worst affected, with 18.8% affected in the 15-49 year age group.<sup>23</sup> In this age group, women make up 55% of those infected. Most infected women are in the peak of their reproductive years with the ages 25-29 being the worse affected. The province of KwaZulu- Natal is the province worst affected by HIV with 39% of pregnant women in antenatal care being infected.<sup>23</sup>

The UNAIDS and WHO use prevalence and population affected by HIV to determine the scope of epidemics in affected countries. If >1% of an antenatal population are found on consistent measurement to be HIV infected, this is considered to be a generalized epidemic. By this definition it is clear that South Africa has a major HIV epidemic. Currently South Africa has one of the largest antiretroviral programmes in the world with approximately 300 000 patients on treatment.

The new National Strategic Plan (NSP) acknowledges the problem of late testing by infected individuals as a key area that needs a fresh approach.<sup>23</sup>

The NSP includes the following targets for the period of 2007-2011:

- To reduce the rate of new infections by 50%;
- To increase the number of eligible HIV positive pregnant women enrolled in the antiretroviral programme to 95% by 2011;
- To increase the number of pregnant women who present for an HIV test from 25% to 90% by 2011.

Currently the NSP suggests that VCT remains the testing approach of choice, though the NSP does mention that the testing approach should be “provider initiated” rather than “client initiated”. This implies that the health care provider would routinely offer VCT to all patients on their first attendance at the antenatal clinic.

### **2.3 The impact of undiagnosed and untreated HIV in the South African antenatal context**

Undiagnosed and therefore untreated HIV in the South African antenatal context is having a major impact on the health of mothers and infants.<sup>23,26,19</sup>

The main cause of maternal deaths in South Africa for the period 2002-2004 was found to be AIDS related.<sup>27</sup> The Saving Mothers and Babies Report<sup>27</sup> is the result of a confidential enquiry into the factors contributing to maternal deaths over the period of 2002-2004. The findings and recommendations of this report is distributed by the Department of Health to all obstetric care facilities countrywide. The recommendations, if implemented, should result in improved obstetric care and a decrease in the maternal mortality rate.

The 2006 Saving Mothers and babies report estimated that the maternal death rate in South Africa is currently one in a thousand.<sup>27</sup> This report also states that there are more maternal deaths attributable to AIDS than were reported to the commission. The reason for this was that more than half of the maternal deaths, which were investigated in the report, had no known HIV test result documented. Significantly, 78% of the number of cases with a known HIV test result was positive. Therefore it was likely that the HIV prevalence in the unknown result group was also high. In addition, AIDS was the stated cause of death in 50% of the maternal deaths included in the report.<sup>26</sup> The report classifies only 9% of the non-pregnancy related infections as avoidable and goes on to say: “ Few of the non-pregnancy related infections were thought to have been avoidable by the assessors, although deaths due to non-pregnancy related infections are potentially preventable,” implying that had these women been diagnosed and treated earlier in their infection, they might not have died.<sup>27</sup>

The problem of maternal deaths is escalating. According to a report from Statistics South Africa the death rate from maternal conditions more than doubled between 1997-2004.<sup>29</sup>

It is clear that from the report on the confidential enquiry into the causes of death of pregnant mothers that undiagnosed and therefore untreated HIV/AIDS in pregnancy is a serious challenge facing South Africa.<sup>26</sup>

UNICEF (United Nations Children’s Fund) demonstrates the importance of an effective testing approach in a report on the implementation of Prevention of Mother-to-child transmission (PMTCT) services.<sup>32</sup> The South African and Botswana data are summarized in Table 1 below. Botswana uses Opt-out antenatal testing and South Africa uses VCT as antenatal testing approach.

Table 1: PMTCT coverage: South Africa compared to Botswana 2005<sup>32</sup>

<b>Country</b>	<b>% of women who have access to ANC</b>	<b>Estimated no of HIV +ve pregnant women</b>	<b>% of all pregnant women counselled on PMTCT</b>	<b>% of all pregnant women who received an HIV test</b>	<b>HIV prevalence in ANC setting</b>	<b>% of all HIV positive pregnant women who received ART prophylaxis</b>
<b>Botswana</b>	97	21,445	73.5	73.5	30.2	50.4
<b>South Africa</b>	94	271,939	19.4	19.4	27.9	22.1

In South African clinics, where VCT is the testing approach, only 19.9% of women are counselled and tested. In contrast, Botswana clinics (where Opt-out testing is implemented) 73% are counselled and tested. The above UNICEF data conflicts (possibly due to the use of a different data collection method with UNICEF relying on self-validated data from each provincial health department) with the data released by the National Department of Health in the latest PMTCT Policy and Guideline. This document reports 70% coverage of HIV counselling and testing in South Africa’s antenatal clinics of which 26% of pregnant women tested positive. According to this document 60% of those who tested positive received PMTCT treatment.<sup>14</sup>

In another study in Malawi, a similar trend of progressive loss to follow-up was noted.<sup>34</sup> It is due to these data trends that authors such as Bassett<sup>35</sup> argue that a testing approach should aim for 100% coverage of all pregnant women because with each step in the VCT process, the number decreases. Of the number of women who book for antenatal care, not all tested for HIV; of those tested not all are given results; and of those who are found to be HIV positive, not all access PMTCT services.

The problem of the low coverage of HIV testing in South Africa's antenatal population is illustrated by Schuklenk & Kleinschmidt<sup>36</sup>, who predicted that by increasing the HIV testing rate with 25%, an increase in the HIV prevalence of 7.5% can be expected in the South African antenatal context. If these 7.5% new cases were all to be offered PMTCT treatment using dual therapy (Zidovudine and Single dose Nevirapine), it would lead to a decrease of 1.5% in the current perinatal transmission rate.<sup>36</sup>

Thus undiagnosed, untreated maternal HIV infection leads to an increased transmission rate to their infants.

## **2.4 HIV testing in general**

### **2.4.1 Background to the VCT approach**

The early years of HIV testing were linked to the first case reports of the disease in the USA among men who had sex with men.<sup>37</sup> A fear of this unknown, deadly infectious disease was born. This fear, fuelled by "homophobia," (stigma and discrimination) was extreme and intense.<sup>12</sup> Therefore the standard public health measures that deal with infectious disease were overwhelmed by the social need to protect the rights of sufferers from stigma and discrimination. <sup>37</sup> The new testing approach (VCT) did away with the standard public health approaches of disease notification, contact tracing and most importantly, routine case detection.<sup>2</sup>



Instead, medical confidentiality was replaced with anonymity. Mass education was advocated together with counselling and the right to privacy. This approach became the international global norm of testing.<sup>2</sup>

The VCT approach, as implemented in South Africa, consists of health care professionals or counsellors who do individual pre-test counselling. If the patient gives consent to test, the test is done followed by post-test counselling. The content of the pre-test counselling session consists of the following basic elements <sup>39</sup>:

- Giving information on HIV and the HIV test to patients;
- Discussing the meaning of a HIV positive test result, including the practicalities of care and treatment;
- Assessing the patient's personal risk of infection;
- Discussing strategies for safe sex;
- Discussing how to cope with a positive test result and disclosure issues. (In some sources this issue is addressed with the question: "How would you react if you test positive today?" <sup>40</sup>; and
- Giving patients time to think whether they would like to test or not.

After pre-test counselling, informed, written consent is obtained and then the HIV test is done. Rapid HIV test kits are most commonly used and are done by pricking the patient's finger to obtain blood that is dropped onto the test strip. The test takes about 15 minutes to complete. The person doing the test can interpret the results at this time. Usually, if one test is positive, a confirmatory test is done before the patient can be diagnosed as positive.<sup>14,40</sup>

After the test results are given, patients receive post-test counselling. The person who gives the result usually does the post-test counselling. Post-test counselling consists of the following elements:

- Giving the result. Making sure that the patient understands the result;

- Discussing low risk behaviour, for example, condom use and avoidance of multiple partners. (This discussion is aimed at promoting low risk behaviour);
- Discussing the psychological, medical and social implications and perceptions if a test is positive; and
- Assisting the patient to cope with the result by ongoing counselling and support, assisting disclosure and helping patients to access further medical care.<sup>40</sup>

The National PMTCT policy was revised in 2008 to adjust the testing approach:

#### **2.4.2 The National PMTCT policy revised VCT testing approach**

In the National Department of Health released its updated policy and guidelines for PMTCT in 2008.<sup>14</sup> According to the guideline, VCT remains the testing approach of choice but has been adjusted to increase counselling coverage to all patients. It makes reference to this approach as “Provider Initiated VCT” and recommends that VCT should be offered to all new antenatal patients. The standard content of VCT pre-test counselling should be given to all new patients in groups in a “Group Information Session.” Then, following the group session, patients are given information individually. In the individual session the health care worker must ensure that the patient understood the information that was given in the group session. If the patient indicates that they understand the information, they are asked to give verbal and written consent for a HIV test.<sup>14</sup>

The intention with VCT is that it protects human rights by allowing patients to make an informed choice. VCT also allows for an opportunity for health education in which positive health behaviour such as using condoms can be promoted.<sup>12</sup>

This approach to HIV testing sets it apart from the routine ways in which other infectious diseases or sexually transmitted diseases are screened. There is no other disease, infectious or not, which has this amount of counselling made mandatory. Therefore the term “HIV

exceptionalism” has been used to refer to the exceptionalised way in which HIV testing has been entrenched.<sup>12,4,2,3</sup>

This exceptionalisation of HIV testing is central to the argument against the use of VCT as a universal testing approach in South Africa.<sup>41</sup>

### **2.4.3 HIV exceptionalisation, VCT and how it influences patient’s testing choices**

In his speech at the Ronald Louw Memorial lecture Cameron<sup>4</sup> spoke about the stigma that exists around HIV testing and diagnosis. He stated that Ronald had been ill for a long time and he only tested for HIV six weeks prior to his death in 2006. He had advanced AIDS- and he was diagnosed too late to receive effective treatment with antiretrovirals. As an educated, informed and socio-economically empowered individual the question was asked: “Why did he not test in time?” Cameron<sup>4</sup>, in an attempt to answer this question, distinguished between internal and external stigma and the role each played in influencing Louw not to test. External stigma refers to the negative perceptions of HIV in the community. This could lead to discrimination such as being victimized, ostracized and could even lead to those infected not receiving adequate health care.<sup>37</sup>

Internal stigma indicates the self-repulsion, fear and self-loathing that a person experiences internally when he/she realizes that he/she may have contracted HIV.<sup>4</sup> These internal emotions disempower the infected individual who may then choose not to seek medical care. Internal stigma thus makes it difficult for individuals to access testing and treatment. This stigma may be further fuelled by the exceptionalism of the VCT approach.<sup>4</sup> Thus, patients who are already victims to internal stigma may subconsciously or consciously experience the VCT process as stigmatizing and will therefore avoid testing.<sup>42</sup>

Several authors have referred to this stigmatizing effect of VCT.<sup>36,12,4,8,35</sup>

Sometimes, internal stigma can be stronger than external stigma and could lead to the patient delaying HIV testing and hence diagnosis.<sup>4</sup> Eventually, this would result in a death that could

have been avoided.<sup>43,44</sup> The phenomenon of “late testing” for HIV has been widely reported on in the international literature.<sup>43,44</sup> Although the true reason for patients’ testing late cannot be ascribed to stigma alone, the data does indicate that stigma has some influence in patients choosing to test or not. In 2006 there was a report on AIDS related deaths in the United Kingdom. It was found that in 25% of cases, death could have been avoided if these patients had tested sooner for HIV.<sup>43,44</sup> In the context of HIV treatments being made available and accessible, there are many researchers who have advocated that HIV testing policy should be revised in order to reduce the barriers to testing so that as many patients as possible can be diagnosed and treated.<sup>7,4,8,35</sup>

When VCT was implemented at first in the USA, human rights protection was a pressing need due to the high prevalence of discrimination against those infected with HIV<sup>12,46,45</sup>, and the fact that the disease was prevalent in a marginalized community.

Currently there is a challenge to this approach with some authors arguing that VCT itself could be violating human rights by being perceived as an artificial barrier that has to be overcome before patients can actually access the HIV test.<sup>47,4</sup> The exceptionalism of VCT could thus deter patients from accessing treatment and care.

Cameron<sup>4</sup> states: “But still we remain very far from treating AIDS as just an ordinary disease. And the question I raise is whether the continued exceptionalisation of AIDS from the human rights point of view is not undermining human rights. Ronald’s death shows us that the struggle to normalise AIDS is not just against stigma’s external manifestation, but against its internalisation in those who have, or fear they have, HIV – the shame and disempowerment and self-disabling ignominy they all too often feel. And this forces us to ask whether the medical protocols and procedures that surround diagnosis with HIV and treatment for AIDS reinforce the internal manifestation of stigma and thus impede access to treatment.”

Other public health researchers, for example Bassett<sup>35</sup> have echoed this sentiment: “HIV diagnosis differs from any other diagnostic process. This process emerged at a time when

therapeutic intervention was uncertain. It stressed ensuring the patient's autonomy and asked the counsellor to take a neutral stance- to be accepting of unwillingness to be tested and unwillingness to learn the result. This situation has changed with the advent of effective, available interventions. Should health workers- particularly in the developing world, where HIV is prevalent- remain neutral?"<sup>35</sup>

It is ironic that by striving for the protection of human rights in HIV testing policies, the exceptional approach to HIV could instead, strengthen the stigma and fear surrounding the testing and diagnosis of HIV. Thus, it is important to realize that while laws and testing strategies can protect people from discrimination, it does little to protect them against stigmatization.<sup>2</sup>

In the antenatal context, VCT, as a testing approach has implications for the effective delivery of thorough health care.<sup>1</sup>

#### **2.4.4 VCT in the antenatal context**

From as early as 1999 it has been clear that the provision of VCT as a testing approach in antenatal clinics would create a problem in the delivery of PMTCT care to infected women, especially in countries that were facing a significant HIV epidemic.<sup>35</sup> The problem is that not only does VCT cause bottlenecks to efficient delivery in antenatal clinics, but also to be implemented effectively, it is cost and labour intensive.<sup>48</sup> In high HIV prevalence areas, such as in the Kenyan Machakos district, routine VCT (VCT offered to every woman) has led to burnout of staff due to the increased workload.<sup>22</sup> Furthermore, the evidence suggests that the uptake of VCT remains low in smaller antenatal contexts such as in midwife obstetric units (MOUs), despite otherwise good antenatal care.<sup>49</sup>

“ In a model presented by Elliot Marseille and colleagues, a strategy offering counselling, testing and for those who were found to be positive – antiretroviral drugs, was twice as expensive as mass treatment, where all pregnant women would receive antiretroviral drugs without learning their HIV status.”<sup>35</sup>

VCT is also less effective at reaching HIV-infected women than mass treatment. In a large systematic review, of the acceptability of VCT in the context of clinical trials, it was shown that VCT had a median overall acceptability of 69%.<sup>50</sup> Similarly, in a study in Tanzania the “acceptability” (read: uptake of testing) of VCT among pregnant women was studied, and the outcome was that out of 10 010 pregnant women, 7647 (76.4%) agreed to be tested for HIV.<sup>51</sup>

One fifth of women in Zambia decline HIV testing with VCT.<sup>52</sup>

These results demonstrate that VCT consistently produces a smaller uptake of testing than Opt-out testing.<sup>16</sup>

VCT as assessed by the above reviews is problematic as there are inevitable dropouts at each step of the VCT process. In reality not all women are offered an HIV test, of those who are offered a test, not all accept a test, of those who test positive not all accept the PMTCT intervention.

Bassett<sup>35</sup> identifies two barriers to VCT:

A) Health Services; and

B) Social Barriers

#### **2.4.4.1 Health Services**

If the aim is to provide 100% coverage in a clinic, then VCT is labour -intensive. Many clinics are under-resourced with respect to staffing. Relying on health care providers to do VCT on all patients is only possible if lay counsellors are available to provide counselling capacity.

Supervised lay-counsellors have been demonstrated to be effective in many clinics, improving the capacity to provide VCT.<sup>35</sup>

Similarly, in an article evaluating a pilot PMTCT programme in a district hospital in rural Zimbabwe, the challenge of integrating HIV testing into routine antenatal care was debated by the authors: “In our experience, individual counselling remains the only aspect of the

overall cascade of activities for prevention of mother to child transmission of HIV that cannot be fully integrated within routine antenatal clinics owing to lack of human resources.”<sup>1</sup> They go on to recommend routine Opt-Out testing as a possible solution to the problem.

Similarly, the Machakos District Hospital, that has an HIV prevalence of 57%, has introduced group pre-test counselling, due to the lack of trained counselling staff. In a meeting, hosted by the President’s Emergency Plan for AIDS Relief (PEPFAR), where these issues were discussed the representatives concluded: “So in order to scale-up testing and treatment, HIV programmes may have no choice but to abandon lengthy pre-test counselling.”<sup>22</sup>

#### **2.4.4.2 Social Barriers**

Bassett<sup>35</sup> discusses acceptability barriers in the clinic setting. These are two-fold: Patient acceptability issues and health care worker acceptability issues.

Patient issues relate to the fear of stigma - the cost of an HIV test is high for many women who are not empowered in their relationships with men. Less than 50% of HIV positive, pregnant women disclose their status to their partners.<sup>35</sup>

Health care workers may be reluctant to promote VCT for a number of reasons. Promoting VCT may be difficult due to difficult working conditions<sup>22</sup> and relate to the health care workers’ personal views of HIV.<sup>42</sup> They are often underpaid and work in clinics that are not well-equipped. Health care workers working under such difficult conditions, especially in the context of HIV, often have low morale. Until recently, antenatal services have had only the limited option of single dose NVP for HIV infected pregnant women with high CD4 counts.

Few staff members have personally experienced VCT and may not be convinced that VCT for their clients is the best option. Moreover in settings where the HIV prevalence is high, a positive test result is likely. Thus, staff may be less inclined to test clients for fear of communicating a positive test result. Steinberg<sup>42</sup> writes: “It is perhaps trite to point out that nurses are both medical personnel and people. To what extent did they simply carry into the

wards a sense of scandal from the outside?" In support of this claim, consider the following dialogue between a counsellor and a patient:

"From a counsellor: *"Once HIV is diagnosed, death comes more quickly."*

During a discussion with a client, a counsellor speaks in a normal voice about the advantages and disadvantages of HIV testing. Then, in a whispered voice, the counsellor asks: "So do you want an HIV test?"

Client: *"I would like to have an HIV test."*

Counsellor: *"Are you sure?"*"<sup>35</sup>

Similarly, a study in Zambia surveyed 225 health care providers about their perceptions toward HIV screening, HIV infection and the use of anti-retroviral medications. Its findings were that doctors, and providers located in urban Lusaka and providers with research affiliations were more likely to offer HIV testing. Only thirty percent (30%) of respondents routinely prescribed antiretrovirals for the prevention of MTCT of HIV.<sup>53</sup>

In another study, 90% of health care providers were likely to counsel pregnant women with known risk factors to be tested but, only 34% were likely to counsel pregnant women without risk factors to test.<sup>54</sup> Thus the social barriers to HIV testing are often maintained by health care worker-related perceptions and stigma.

#### **2.4.5 VCT and behavioural change**

Does a testing approach influence behavioural change? There is evidence that VCT does not have this desired effect.

Supporters of VCT, as a testing approach, often argue that VCT educates patients and therefore decreases high-risk behaviour (for example, having unprotected sex) through education.<sup>12,22</sup> However, the literature does not support this claim. In a study evaluating the uptake of VCT and the impact on sexual behaviour and HIV incidence in Zimbabwe, it was



reported that people who previously underwent VCT had the same rate of HIV infection as people who weren't tested during the previous three years.<sup>55</sup> By implication this means that patients who received VCT pre-test counselling had the same high risk behaviour as those who did not receive VCT counselling.

A similar finding was reported in a Ugandan study that found that VCT had no impact on behaviour.<sup>56</sup> It was noted that individuals who had knowledge of their HIV status and who chose to receive their results from population sero-prevalence testing displayed the same risk behaviour as those who chose not receive their result. These findings indicate that pre-test counselling does not always have the impact on health behaviour that health care providers intend it to have.

It would appear that VCT does not promote low risk behaviour in individuals who are counselled, as was previously thought.<sup>57</sup> A review of the literature around the impact of VCT has showed that risky behaviour of patients after receiving a negative HIV test result, increased. Similarly it has been consistently demonstrated that patients who agree to test through VCT are mostly risk averse (do not partake in risky behaviour.)<sup>52,59,58</sup>

Sensitivity of a testing approach in detecting HIV positive patients is an important criterion for the choice of a testing approach and is relevant when discussing the advantages of VCT.

#### **2.4.6 The sensitivity of VCT as a testing approach**

When the uptake of VCT for HIV is compared to the sero-prevalence of the population being tested, it is evident that women who are at risk of HIV infection often decline VCT.<sup>52,58-60</sup>

The literature consistently demonstrates that the HIV prevalence is high amongst women who do not agree to test with VCT.<sup>36,60</sup> It has been found in an antenatal population in a Johannesburg hospital (where the estimated HIV prevalence is 29%) that with anonymous testing of those women who declined VCT on attendance, the estimated prevalence increased to 44%.<sup>36</sup> A retrospective audit of HIV screening uptake in women with Hepatitis B (HBV)

infection (Routinely done in the UK antenatal clinics) had similar findings.<sup>61</sup> The study was carried out in order to analyze the differences between those who accepted testing and those who refused: “The overall uptake rate of HIV screening in the West Midlands population served by the National Blood Service was 60% in 2001 and 74% in 2002. The prevalence of HBV infection was found to be twice as high (0.39%) in those who had refused an HIV test compared with those who had accepted a test (0.21%) (p = 0.022).”<sup>61</sup> The researchers concluded that women who refuse HIV testing are more likely to be at risk of having other sexually transmitted illnesses than women who accepted an HIV test as they were found to have an increased prevalence of Hepatitis B.

In another study, Hladik et al.,<sup>60</sup> compared universal, anonymous testing (UAT), as a surveillance tool for HIV prevalence, with VCT using data from Uganda, Thailand, Kenya and Botswana. Universal anonymous testing is the method by which all pregnant women are tested for HIV using blood samples that are taken for routine antenatal care. Thus the women are unaware of the test and the result. However, the sero-prevalence of the clinic can be calculated accurately by using this method.

The authors investigated if VCT could replace UAT as a statistical surveillance tool: “In most ANC surveillance systems, the ANC client is unaware that her left-over blood, taken for routine care is tested for HIV. When HIV testing is based on informed consent, such as in PMTCT programmes, individuals refusing testing more often have a higher risk of HIV infection than consenters, a phenomenon well documented in many testing populations.”<sup>60</sup> The authors conclude that VCT could not replace UAT because clients who are at high risk refuse HIV testing through VCT.

Thus it is clear that there are often unidentified proportions of HIV positive women who decline VCT testing in the antenatal context. Although the uptake of VCT can be more than 70% in some clinics, the women who refuse to test with VCT appear to be those more at risk of HIV infection.<sup>51,50</sup>

In a study looking at the individual predictors of women electing to test in Zambia, it was found that women with a low self-perceived risk were more likely to choose to test than women who saw themselves being at risk of infection ( $p < 0.001$ ).<sup>52</sup> In this study 99% of antenatal attendees were pre-test counselled and only 65% agreed to test. Therefore VCT is not a sensitive testing approach to efficiently and consistently identify women who are at risk of being HIV infected. It is important to consider the background of Opt-out testing, if this is to be recommended as an alternative (discussed below).

## **2.5 Background to Opt-out testing as a testing approach**

With the advent of better treatment options available to pregnant HIV positive women, the testing debate has now shifted and the emphasis has moved to identifying those most at risk as early as possible as not only the rights of the woman but also that of the unborn fetus need to be considered.<sup>44,41,4,5</sup> In the recent years the implementation of Opt-Out testing in antenatal settings has been reported in several studies to increase the uptake of HIV testing.<sup>64,63,16,62</sup> This research has indicated that increased testing uptake would lead to increased numbers of infected pregnant women accessing care. These studies have been ground breaking in demonstrating increased uptake of testing with the Opt-out method, but it is recommended that further work is needed to evaluate fully all the effects of Opt-Out testing when it is implemented.<sup>12,64,57</sup>

In 2004 the MMWR reported on a study undertaken in four antenatal clinics in Botswana where a statistically significant increase in HIV testing uptake was demonstrated after the introduction of Opt-out testing. There were 314/347 (91%) of patients who tested after the introduction of Opt-out testing. This was a significant increase ( $p < 0.001$ ) from the 381/506 (75%) who tested previously with VCT.<sup>16</sup> The strength of the Botswana study was that it was done under operational conditions.

Similar findings were reported in Malawi where VCT was compared to Opt-out testing in an operational research study. The uptake of testing with VCT was 79% which increased to 99% with the introduction of Opt-out testing <sup>65</sup>.

Internationally, the increased uptake of testing with the Opt-out approach has also been described.<sup>64,17</sup> A retrospective study conducted between 1998-2000 amongst the antenatal attendees at Denver Health Medical Centre, Colorado presented evidence that the uptake of Opt-out testing was found to be 98.2% (CI = 97.9-98.4%) <sup>63</sup>

In September 1998, the state of Alberta in Canada adopted Opt-out testing as a routine testing in antenatal care. The data was collected on pregnant women screened for HIV between September 1, 1998 and Dec. 31, 2000. There was a sustained 28% annual rate increase of HIV testing amongst females with Opt-out testing, as opposed to a 9% annual rate increase with VCT.<sup>62</sup>

Similarly, in Newfoundland and Labrador a 98% testing rate was found after the implementation of Opt-out testing. In the USA Tennessee reported a testing rate of 85% with Opt-out testing. Arkansas reported improvements in the testing rates from 57% prior to Opt-out testing to 71% after Opt-out testing was introduced.<sup>17</sup>

Clearly, the Opt-out approach has been shown to increase uptake of testing in diverse antenatal settings. This is an important attribute for a testing approach. For the many HIV positive women identified through an effective testing approach, the antenatal clinic would be the entry-point through which they could access treatment: "Pregnancy is a critical time to identify women with HIV infection and to link them and their families to ongoing care and treatment. In addition to providing perinatal prevention intervention, pregnancy serves as an entry point into the health-care system."<sup>66</sup> Uniquely prevention and treatment of HIV can be managed together through the antenatal clinic.

### **2.5.1 Opt-Out testing: International Testing Policy**

In 2006 the CDC released a revised recommendation on the testing of pregnant women with Opt-Out testing. The guideline reads as follows:

“These guidelines reiterate the recommendation for universal HIV screening early in pregnancy but advise simplifying the screening process to maximize opportunities for women to learn their HIV status during pregnancy, preserving the woman's option to decline HIV testing, and ensuring a provider-patient relationship conducive to optimal clinical and preventive care. All women should receive HIV screening consistent with the recommendations for adults and adolescents. HIV screening should be a routine component of preconception care, maximizing opportunities for all women to know their HIV status before conception.”<sup>8</sup>

The CDC<sup>8</sup> states that the following conditions must be met when implementing Opt-Out testing: “All pregnant women in the United States should be screened for HIV infection;

- Screening should occur after a woman is notified that HIV screening is recommended for all pregnant patients and that she will receive an HIV test as part of the routine panel of prenatal tests unless she declines (Opt-out screening);
- HIV testing must be voluntary and free from coercion. No woman should be tested without her knowledge;
- Pregnant women should receive oral or written information that includes an explanation of HIV infection, a description of interventions that can reduce HIV transmission from mother to infant, and the meanings of positive and negative test results and should be offered an opportunity to ask questions and to decline testing;
- No additional process or written documentation of informed consent beyond what is required for other routine prenatal tests should be required for HIV testing; and
- If a patient declines an HIV test, this decision should be documented in the medical record.”<sup>8</sup>

On 30 May 2007 the World Health Organization (WHO) and UNAIDS announced the adoption of Opt-out testing as the preferred strategy for testing for HIV in a generalized HIV epidemic.<sup>7</sup> However, it was stressed that testing must remain free of coercion. The WHO still advocates that consent is taken prior to testing. In addition, the following guidelines are given

“All testing must be voluntary;

- A patient’s right to decline should be respected;
- Pre- and post-test counselling and informed consent should be provided;
- There must be access to care and treatment after testing;
- Opt-out testing does not endorse compulsory/mandatory testing;
- A supportive social, legal and policy framework should be in place before Opt-out is implemented; and
- Monitoring and evaluation is integral to Opt-out testing.”<sup>7</sup>

### **2.5.2 How to implement the Opt-out testing approach**

According to the CDC <sup>8</sup>, Opt-out testing means informing pregnant women that an HIV test, together with all the routine antenatal blood tests, will be done, unless she specifically declines. Each patient receives adequate information and explanation about the importance of all the tests, including (but not exceptionalising) HIV. This information can be presented in a group talk or individual sessions. General medical consent for all the tests is regarded as sufficient. Patients are tested in individual sessions and then receive individual post-test counselling after the test <sup>8</sup>.

Thus in the antenatal setting HIV testing is grouped together with haemoglobin, syphilis and Rhesus tests. Opt-out is similar to VCT in that it still informs patients about each test, and the test is still voluntary as patients have the right to decline.

The differences between Opt-out and VCT are:

- 1) Written specific consent for HIV is not required with Opt-out testing;

- 2) Everyone is tested unless they specifically decline an HIV test with Opt-out;
- 3) Intensive, individual pre-test counselling is not provided with Opt-out testing.

Note: As with VCT, full individual post test counselling must be provided.

### **2.5.3 Acceptability of Opt-out testing**

There has been little qualitative data published about the acceptability of Opt-out testing to patients and staff in an African antenatal setting.<sup>64</sup> However some studies provide proxy indications of acceptability.<sup>67,68</sup>

A Botswana study demonstrated that the numbers of patients who linked to care after the HIV test did not change much from the numbers of patients who normally linked with follow-up care during VCT.<sup>10</sup> This gives the impression that this form of testing does not dissuade patients from attending the clinic and may be a proxy indication of acceptability.

A cross sectional survey done in Botswana (where Opt-out testing is done routinely) found that 94% of participants were in favour of routine testing.<sup>67</sup> Ninety-six percent of patients felt they were treated with respect and 90% were comfortable with confidentiality. The conclusion was that there was an overall high rate of awareness and acceptability of Botswana's HIV testing programme which has resulted in high rates of testing.<sup>67</sup>

Some studies utilize quantitative methodology to measure acceptability of Opt-out testing.<sup>69,64</sup>

Some authors look at numbers of patients attending the clinic before and after the introduction of Opt-out and also the numbers that link to care after the HIV test. A study in Malawi demonstrated that the uptake of HIV testing increased from 75% to 99% when Opt-out testing was introduced.<sup>65</sup> The authors concluded that Opt-out testing was acceptable to patients as they claimed that it reduced stigma to offer the test to everyone routinely.<sup>65</sup>

In a cross sectional survey of women attending a post-natal clinic in 6 rural districts, the attitudes women had to Opt-out testing were examined.<sup>69</sup> The overall outcome was that 463/520 (75%) patients indicated that they would accept HIV testing if it was offered

through the Opt-out approach.<sup>69</sup> Both these approaches do give one an impression of acceptability, but does not accurately reflect what patients experience through Opt-out testing.<sup>22</sup>

Difficulties of the Opt-out testing approach are discussed below.

#### **2.5.4 The problems with Opt-out**

It is clear from most of the sources consulted that more research in the developing world is needed to ascertain the impact of Opt-out testing on acceptability, stigma and risk behaviour in patients.<sup>12,64,36,11</sup>

Most criticism of Opt-out testing is rooted in concerns about adverse outcomes of implementing it on a larger scale. There is little evidence that Opt-out does have such adverse effects. One such author writes: “ While it may be true that treatment roll-out (after routine testing) will reduce HIV-related stigma and discrimination by turning HIV into a treatable and chronic, rather than a deadly disease, it is also possible that increased testing- especially testing of the “routine/Opt-out” or mandatory kind, will increase HIV related stigma.”<sup>11</sup>

A fear around the introduction of routine Opt-out testing is that it will not be conducted with proper understanding of the social and cultural lives of the people whom governments hope to test.<sup>12</sup>

Though research in African countries has demonstrated that HIV positive pregnant women may experience negative life events, such as breaking up of marriages and domestic abuse <sup>70</sup>, positive life events (mainly in the form of increased emotional support) after disclosure of HIV positive status has also been reported. In addition, research done in Uganda demonstrated that the fear of disclosing one’s HIV status was often much more exaggerated than the actual stigma experienced when disclosure occurred.<sup>36</sup>



The gap in the availability of literature considering these issues, suggests that further studies need to be done. The ethical and legal implications of testing approaches need to be taken into consideration when choosing a testing approach.

## **2.6 Ethical and Legal considerations around HIV testing strategies**

### **2.6.1 Informed Consent and routine testing**

The ethical and legal issues around the Opt-out approach can be weighed within the basic framework of biomedical ethical principles, namely, patient autonomy; beneficence; non-maleficence and justice.<sup>47</sup>

### **2.6.2 Patient Autonomy**

Patient autonomy refers to the principle that patients have a right to decide ultimately what they want to do or have done to their bodies.<sup>71</sup>

There have been several ethical and legal questions about the implications of an Opt-out approach to HIV testing. An objection against the use of Opt-out is that it undermines the “voluntariness” of the HIV test and that, due to the decreased counselling, the prevention benefits of testing would be lost.<sup>22</sup> Some authors have even gone as far as to state that Opt-out testing leads to patients being coerced into testing.<sup>12,11</sup> Specifically, the Opt-out approach uses “group information sessions,” in which pre-test information is routinely given to patients in groups. The information session gives less HIV related information than pre-test counselling and therefore the question arises if this limited information leads to diminished informed consent and thus undermines the voluntariness of the test.

The question of whether routine Opt-out testing influences informed consent being obtained has been studied in international settings: A study evaluating the responses and perceptions of pregnant women to routine HIV testing was conducted in a Central London Hospital and 32 women were interviewed upon their first antenatal visit. In this study there was a good uptake of testing with only 6 women declining to test. However the study found that only 9 of

the women who tested had a good understanding about the reasons to test for HIV. Although there is no control group against which the findings were measured, the study suggests that routine testing does limit informed consent.<sup>15</sup>

The National Department of Health <sup>39</sup>, the Health Professions Counsel of South Africa <sup>45</sup>, and the South African Medical Association (SAMA) have all advised that in order to obtain legally acceptable informed consent, individual counselling needs to be done.<sup>39</sup> However the new PMTCT policy <sup>14</sup> has included “group information” sessions that include basic information about HIV pre-test counselling. Group pre-test counselling (VCT to groups) is widely seen as acceptable in the face of shortage of counselling staff to do individual pre-test counselling.<sup>22</sup>

It has been argued that to satisfy the principle of autonomy, Opt-out testing can be implemented if patients receive sufficient information about the nature, effects and consequences of testing HIV in order for them to make an informed decision.<sup>72</sup> In such a case, group counselling, pamphlets and posters may be sufficient to enable patients to make an informed decision. Such is the case for any other dreaded disease (like malaria, tuberculosis and cancer) where patients are tested after being briefed unless they specifically opt-out.<sup>47</sup> In addition, the right to confidentiality must be assured.

### **2.6.3 Beneficence**

Beneficence refers to the ethical principle that doctors have to do good to their patients.<sup>71</sup> Cameron<sup>4</sup> states:“ ...But where diagnosis could lead to treatment, to the preservation of the patient’s life – and where continued ignorance will surely hasten death – the health carer’s duty of beneficence to the patient demands that accurate, early diagnosis of the treatable condition should be encouraged. Where possible, diagnosis should be a routine and uncontroversial element in the patient management process.”

Because Opt-out testing is a routine testing approach, it satisfies the principle of beneficence as it assists in the early detection of HIV infection thereby allowing patients to access care before they fall ill with Opportunistic Infections.<sup>47</sup>

#### **2.6.4 Non-maleficence**

This principle requires that doctors do no harm to their patients while they treat them.<sup>71</sup>

This is reflected in the Constitution of South Africa where it states that everyone has the right to access emergency care and everyone has the right to an environment that is not harmful to their health and well-being.

In terms of prevention of mother-to-child transmission of HIV (PMTCT), this principle was upheld by the high court in a judgment where the South African Department of Health was forced to provide single dose Nevirapine during delivery to all HIV infected mothers to prevent transmission of HIV to their unborn infants.<sup>14</sup>

In pregnancy, a positive HIV test constitutes an emergency to prevent the unborn infant from being infected with HIV. It has been demonstrated that early treatment with antiretrovirals during pregnancy results in a decline of the HIV infection rate of infants.<sup>73</sup> Late treatment or no treatment can lead to the infection of babies.<sup>5</sup> Women who do not know their HIV status could breastfeed their babies thereby increasing the risk of postnatal transmission of HIV. These babies born to HIV infected mothers have the right to an environment that is not harmful to their health and well-being.<sup>47</sup>

Thus, routine testing of women who attend antenatal clinic could ensure that more women are tested in time to access care not only for their unborn babies but also for themselves thereby satisfying the principle of non-maleficence.

#### **2.6.5 Justice**

This principle requires that all patients be treated equally and fairly.<sup>71</sup> McQuoid-Mason<sup>47</sup> states that: "It can be argued that HIV positive people are not being treated equally or fairly compared with other people afflicted with deadly diseases that can be controlled through routine testing and medication."

By implication this would mean weighing the disadvantages of an Opt-out testing approach against the benefits it offers. <sup>4,47</sup> In the case of Opt-out testing, the disadvantage is that patient autonomy may be restricted by requiring that a patient specifically has to decline the HIV test rather than request it. The benefit that is gained by the Opt-out approach is that more patients know their HIV status and can access life-saving drugs. “ The Constitution provides that fundamental rights in the Constitution can only be limited if such a limitation is of general application to the people concerned, and is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom.” <sup>47</sup>

Thus, when the detriments versus the benefits are weighed it could be strongly argued that the benefits of Opt-out testing outweigh the damage it potentially causes (by causing women to know their status when they may not be emotionally ready to know) and is therefore justifiable in terms of the Constitution.<sup>36,47,4</sup>

## **2.7 The benefits of knowing one’s HIV positive status**

In addition to the benefit of being able to access antiretroviral treatment (ART), if indicated, another benefit of knowing one’s HIV positive status is the changing of high-risk health behaviour.<sup>12</sup> High-risk health behaviour refers to behaviours that promote the spread of HIV infection such as having unprotected sex and having multiple partners. <sup>74</sup>

A meta-analysis done on eleven studies, found that the prevalence of high-risk sexual behaviour was between 53-68% lower in HIV-positive individuals who were aware of their status than in HIV-positive individuals who are unaware of their status.<sup>74</sup> All the data included in the study were from the United States. It compared a group of individuals who were aware of their HIV positive status with a control group of whom the individuals were all unaware of their status. The methods included measuring the behaviour of sero-converting individuals before and after receiving an HIV positive diagnosis. The study was based on measuring the occurrence of insertive or receptive anal intercourse, unprotected vaginal

intercourse and/ or consistency of condom use during sexual intercourse before and after having done an HIV test and receiving the HIV positive result.

## 2.8 Chapter Summary

HIV exceptionalism was regarded as the norm prior to the availability of ART when public health approaches to HIV testing were considered in order to manage the HIV epidemic in Africa.<sup>12,5,37</sup> There was an emphasis on the protection of human rights because the early years of HIV infection in Africa saw many instances of the violation of human rights.<sup>2,37</sup> Thus, it was deemed inappropriate to approach the epidemic with the standard public health strategies.<sup>46</sup> Instead the proposed approach was aimed at protecting the rights of the individual during the testing procedure, as its foremost objective. Voluntary counselling and testing largely rested on the principle of the “Three C’s” of Counselling, Consent and Confidentiality. Voluntary counselling and testing was intended to protect those infected with HIV, from stigma and discrimination.<sup>12,40</sup> With VCT, the way in which HIV was diagnosed was different from the way in which other medical conditions were approached. The term “HIV exceptionalism” was coined to describe this exceptional way of approaching the public health dilemma that was HIV.<sup>2,36</sup>

By making VCT the normal method of testing for HIV, the following effects have been demonstrated:

- Voluntary counselling and testing acts as a barrier to patients testing.<sup>4,5,35</sup>
- Pregnant women who are at risk of sexually transmitted infection are less likely to test with VCT.<sup>60,61,51</sup>
- Voluntary counselling and testing is time-consuming and labour intensive<sup>69,49</sup>; and
- It is a burden for health care workers to test in this way. The result is that too few people are being tested or that health care providers actively avoid recommending the HIV test to their patients.<sup>22,75,35</sup>

The effect of VCT as a testing approach is that many people are not tested in time because the process of testing is so complicated.<sup>75</sup> It discourages patients from testing.<sup>4</sup> By exceptionalising HIV testing, the message the patient gets is that HIV infection is abnormal and different from other illnesses like TB and Cancer. This leads to patients being discriminated against because they have been discouraged from learning their status and as a result have been prevented from accessing life-saving treatment.<sup>4,47</sup>

Opt-out testing normalizes HIV testing thereby making it easier for patients to test <sup>4,5</sup>. The implementation of Opt-out testing in countries like Botswana has been shown to reduce public resistance to HIV testing and to increase the uptake of testing.<sup>67</sup> An increased number of HIV infected patients diagnosed, in turn, leads to more patients accessing antiretroviral treatment before they become too ill.<sup>44</sup>

In the pre-ART era, a human rights-centred testing approach like VCT was appropriate as patients, who were newly diagnosed with HIV often faced an uncertain future, no effective treatment in most cases, and stigma. With ART now being made freely available and accessible it is appropriate to review the universal VCT testing approach. The literature indicates that new approaches to HIV testing should be considered, as no single one approach is appropriate and feasible in all contexts.<sup>36,5,12</sup>

A new approach should lead to increased case finding, respect for human rights and be integrated into routine care without creating an extra burden on the (already strained) public health sector. At present the literature suggests that there is more and more support for the Opt-out testing approach to achieve this goal, especially in antenatal settings.<sup>36,12,16,5,7</sup>

Opt-out testing has improved uptake of testing in many different international contexts. However, its efficiency and acceptability to staff and patients needs to be researched in the South African setting.

## **3 Methodology**

### **3.1 Study Design**

To enable the researcher to achieve more comprehensive insight into each testing approach, a mixed method, prospective, quasi-experimental equivalent time-samples clinical trial was designed i.e. quantitative and qualitative methodology was used. The intention was that this would lead to an understanding of both the quantitative aspects of each testing approach, as well as a fuller insight into patients' and staff's subjective experiences during each of the interventions. The context of testing is shaped on a micro-level by what happens between a patient and a nurse before the HIV test in the consulting room. On a macro-level, the context is shaped by what is experienced by the whole patient population and the health care worker population in the social and hospital environment. Both groups (patients and staff) add to this context with their own personal beliefs, fears, stigma and knowledge.

Therefore the use of mixed methods in the study design would make the study more reliable, comprehensive and rich in its findings.

### **3.2 Selection of methods**

In order to objectively compare the two testing approaches ideally they needed to be implemented in the same patient population in parallel. This would ensure that the two groups did not differ much in demographic profile and would thus be completely comparable.

However, logistical obstacles in the day-to-day operation of the antenatal clinic made it impossible to implement both testing approaches in parallel. The biggest constraints were lack of office space and lack of staff to implement and measure VCT and Opt-out testing concurrently. The best alternative was to implement the two approaches sequentially:

- a) Phase one: VCT (6 weeks)
- b) Phase two: Opt-out testing (6 weeks)

Demographic data in each phase was collected to ensure that there were no major differences between the groups. Fortunately the antenatal patient population at McCord hospital is very stable in terms of both demographic profile and of the uptake of testing prior to commencement. Therefore it was felt that this design would still allow the researcher to compare the two testing approaches reliably.

The two phases occurred in a close time period (2 weeks) apart, so ensuring that there were not too many differences, as the service otherwise remained the same.

The same methods were used in both phases to measure efficiency and acceptability. It was intended that the outcomes and staff-feedback would guide the decision of whether to continue with the new testing approach (Opt-out) or to go back to the original testing method (VCT) at the conclusion of the study.

### **3.3 Research Procedure**

The study was divided into two phases that took place sequentially:

**Phase 1** measured the standard VCT testing approach. The approach was implemented as discussed in Chapter 2. Demographic data was collected together with acceptability data on the questionnaires.

*Efficiency* was examined by:

- Collecting data measuring the uptake of testing.
- The time cost of the testing approach: The time it took per women at the midwife station (where testing took place) was measured.
- The prevalence was measured for this phase.

*Acceptability* was examined:

- By collecting data from questionnaires that was completed by all the study participants.



- In-depth interviews were conducted with 9 of the participants.
- Focus group discussions were held with the staff providing VCT.

VCT was discontinued after the study sample size was achieved for phase 1. Thereafter, Opt-out testing was introduced. Phase 2 (measuring Opt-out testing) was initiated after a brief delay of two weeks between the two phases. In this break period the midwives who performed VCT, were trained on how to do the Opt-out testing. Once the midwives and the researcher were satisfied with the midwives' ability to offer the Opt-out testing method, data collection for phase 2 was started.

**Phase 2** measured efficiency and acceptability for Opt-out exactly the same as was described for phase 1.

Qualitative methods (in-depth interviews and focus groups) were used together with the quantitative methods (measurement of efficiency and questionnaires) to ascertain the acceptability of each testing intervention for staff as well as patients. Therefore each phase of the study measured the efficiency and the acceptability of the testing interventions to staff as well as patients.

To validate the findings of the focus groups, the midwives who conducted the testing were followed up by doing in-depth interviews 18 months after introducing Opt-out testing.

### **3.4 Study population**

The total sample size for each phase was determined to be  $n=150$  (as discussed in section 3.8). Participants were enrolled consecutively at the first antenatal visit. Participants were asked to complete the consent form after reading the patient information document (Appendix 1).

Data on demographics and efficiency of the testing approach was collected on this population. In addition, a structured questionnaire was applied to each participant in this population.

During each phase of the study in-depth interviews were conducted (participants were selected as a subset of the 150 participants in each phase). There were 9 participants interviewed during the first phase and 9 participants during the second phase. The participants were purposefully selected, information-rich clients and the number of interviews was determined to be 9 when, on analysis, recurring themes could be clearly identified. Selection occurred after the HIV test on the first visit when participants were tested. Information-rich participants were identified and recruited by the research team after the first visit interview with the midwife and after the HIV test was completed. The interviews were conducted anytime from 3 days after the test-result to 6 weeks after delivery.

The staff focus groups had the same 4 participants in each group (the clinic only employed 4 First visit midwives at the time of the study). They were the four midwives who performed the HIV counselling and testing.

### **3.5 Inclusion and exclusion criteria**

All pregnant women who booked for their first visit during the study period were invited to enroll in the study.

Women who could not speak English or Zulu were excluded. Women who were illiterate were assisted by the study volunteers to complete the form. 99% of the antenatal patient population can speak either Zulu or English. Therefore the exclusion of non-English and non-Zulu speakers would not have influenced the findings.

For the individual in-depth interviews it was decided to purposefully recruit at least 50% HIV positive participants who enrolled in each study arm because most testing interventions are aimed at diagnosing HIV positive women in an ethical, legal and acceptable way. Therefore the opinions and experiences of this group of participants were considered important to

evaluate it comprehensively. Thus 50% of the participants interviewed in each study arm were HIV positive.

HIV negative women would have different experiences of being tested to HIV positive women. While the prevalence in the clinic is only about 16%, the researcher wanted a balanced view from each group of patients.

### **3.6 Method of performing the Opt-out testing approach**

The staff were familiar with the flow of the clinic during the VCT phase. The enrollment for Phase 1 occurred without any changes to the established flow of the patients.

Several meetings with the staff of the general Antenatal clinic (ANC) and the PMTCT team were held from 2005 to 2006 to prepare them for the implications of this operational research study. Staff needed to understand the study and agree to participate in both phases of the research otherwise the smooth flow clinic may have been compromised.

No formal models or policies for implementing Opt-out testing in an ANC in South Africa existed at the time of the study, however descriptions of the Opt-out approach in the developed world existed and the CDC had released a policy and definition. The CDC approach to Opt-out was used in this study.

By performing a patient flow analysis of the clinic, and then adjusting it to accommodate the new testing approach, helped keep the clinic operational throughout.

The CDC recommends a brochure and informing women of the routine batch tests for the purposes of pregnancy care as a minimum form of information sharing. Such a brochure was designed (Appendix 8) by the research team. The brochure briefly described each recommended antenatal blood test and it included information on HIV testing. In so doing, HIV was not exceptionalised to patients as being “different” from other illnesses that can be diagnosed in pregnancy. Staff were not willing to abandon documented consent as is

suggested in the CDC's definition of Opt-out testing. Thus a form was designed to incorporate space to document the women's consent/refusal for the batch tests. (Appendix 6).

Posters were designed advising patients about the change in the flow (see Figure 1) of the women for the Opt-out approach before the second phase was implemented. These posters were enlarged and laminated and displayed in the ANC. The buy-in of the staff to the research project was obtained by promising that the final decision, of which testing approach would be used after the study, would be taken by their vote at the end of the study. This created an atmosphere of trust and teamwork that was crucial to the successful completion of the research project.

The revised clinic flow-chart for Opt-out testing was as follows:

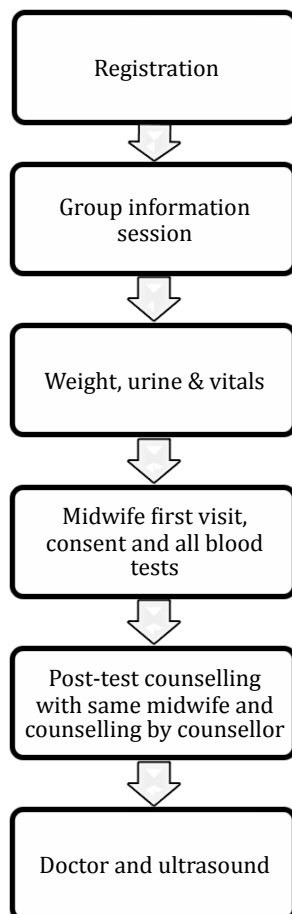


Figure 1, Revised flow of patients with Opt-out testing (A figure showing the flow of patients during VCT can be seen in Appendix 10).

Posters and flip charts were designed and laminated to use as prompts (for staff) and visual educational tools (for patients). The staff were trained in the skills of facilitating a Group session between Phase 1 and Phase 2. The training was done by the researcher and a nurse educator who helped as a volunteer. The content of the group information talk can be studied in Appendix 9.

They practiced facilitation techniques in the staff group and gave each other feedback. The system was piloted before enrollment resumed. The staff were given feedback by the researcher, Dr Roberts (HOD Obstetrics and Gynaecology & supervisor) and the Nurse Educator (Anne Moys). Patients were being tested in the Opt-out way between the two phases of the study.

The system was running smoothly when enrollment resumed.

The contents of the group information session included information about all the routine antenatal blood tests: Haemoglobin (FBC), Rhesus blood grouping (Rh), HIV test and Syphilis (RPR). A midwife presented the talk to the women in groups of 2-6 (including partners, if present) at a time. Information on the importance of each of the tests, how the samples are obtained, which treatments were available for each positive test and the implications of testing HIV positive or negative, was given. Participants were informed of their right to refuse any of the tests.

Women were then given an opportunity to ask questions. After the group session, women were seen individually by the midwives and written consent for all the tests was obtained. Women were also given opportunity to ask questions at the midwife station that they may have been uncomfortable to ask in the group. Women who refused an HIV test were offered VCT. The midwife performed the HIV rapid testing and initial post-test counselling. Patients who required further counselling were referred to the counsellor. Participants who declined testing with Opt-out were offered VCT. This meant that when a woman indicated at the

midwife station that she did not want an HIV test, the midwife would then proceed with individual pre-test counselling as per VCT and then offer the test once again.

### **3.7 Ethical approval**

The study protocol was submitted to the McCord Research Ethics Committee (MREC) and the Biomedical Research Ethics Committee at the University of KwaZulu-Natal (UKZN). Both approved the protocol in 2006. In addition, the UKZN Post-graduate Education Committee, the McCord Hospital management and the KZN Department of Health also supported the study.

### **3.8 Biostatistical support**

Ms Tonya Esterhuizen provided expert biostatistics support for the study from the College of Health Sciences, UKZN. Based on the research question and hypothesis the sample size was determined to be  $n=150$  for each phase (Total sample  $n= 300$ ) to achieve 80% power when comparing uptake, time and time duration of each testing approach. Sample size was calculated based on the following:

- The average number of first antenatal attendees were about 40 patients per week;
- The approximate uptake of HIV testing was about 85% before the study;
- The number of HIV positive women identified per month was about 9% and
- The time taken by a midwife for a first visit was approximately 40 minutes.

The data were captured on Microsoft Excel™. After the quality control was done the data was converted into SPSS™ and analysed. SPSS version 13(SPSS Inc., Chicago, Illinois, USA) was used to analyze the individual level data that was collected from the questionnaires and time sheets. Data collected at an aggregated level was analysed using EpiCalc 2000 version 1.02.

Independent 2 sample t-tests were used to test the first null hypothesis of no time difference between study groups. Cross tabulations and Pearson chi square tests or Fisher's exact tests

as appropriate were used to test the hypothesis involving categorical dependant variables (HIV uptake and HIV positivity). A p value of  $<0.05$  was considered as statistically significant.

### **3.9 Data collection methods and tools**

#### **3.9.1 Method of collecting efficiency data**

Data for uptake and prevalence was taken from the *PMTCT statistical record*, routinely kept by the PMTCT staff in the clinic.

**Uptake of HIV** testing was measured by the number of women who agreed to test out of the total antenatal population during the study period. The number of women who declined testing was also measured.

**Prevalence** in each phase was measured to compare the case finding ability of each of the testing approaches. The period sero-prevalence of HIV infection was calculated for each phase in the study. The prevalence was calculated by adding the number of positive patients who booked knowing their HIV status and the number of patients who tested positive at the first antenatal visit.

**Time cost of each testing approach:** After enrollment and obtaining informed consent, each patient was given a data collection sheet (Appendix 7) and a pencil and they were asked to record how long it took to complete each station. During Phase 1 (VCT), the data analyzed was from the “Time taken at the midwife” station. During Phase 2 (Opt-out), the midwife who conducted the Group Information sessions recorded the length of each session. The data for this phase was measured by adding the time in the group session to the “Time taken at the Midwife” to get the total time of the Opt-out intervention. The total time of a booking visit was also measured for each participant.

The same staff performed the counselling and testing during both the VCT phase and the Opt-out phase.

### **3.9.2 Method of collecting acceptability data**

*Acceptability* of the testing approaches was studied in both patients and the antenatal staff.

#### **3.9.2.1 Patients**

##### **Questionnaires**

Each participant was given a questionnaire (Appendix 2) to complete after the HIV test.

The questionnaire was designed to collect data about the participants' demographics and how acceptable participants found the testing approach to be. In addition to the questionnaire, it was decided that acceptability is not optimally measured by questionnaires only. Therefore qualitative methods were also used.

#### **3.9.2.2 Method of data collection for in-depth interviews**

The researcher decided not to perform the interviews as she was the PMTCT clinician at the time of the study, and her role as a clinician might have biased the research findings. Firstly, it could have influenced the participants agreeing to be interviewed (selection bias) and secondly, how they responded in the interviews.

As this was not a funded study, the budget constraints limited the investigator to the use of informally trained volunteers and available staff. The interviewers were 2 psychology interns and 2 volunteers who worked at the hospital in 2006.

Each interviewer was given instructions on how to administer the semi-structured questionnaire (Appendix 3) prior to the interviews. The instruction to the interviewers was given by the researcher and with the guidance of Tamaryn Crankshaw (an experienced ethnographer who was working at the HIVAN centre for research based at McCord hospital) and Dr Janet Giddy (Supervisor of the study and experienced in qualitative research). Their first interviews (2 per interviewer) were critically reviewed and each received feedback to improve their method of interviewing. (These first interviews were not included in the data-analysis.)



All questionnaires, patient information sheets consent forms and interview guides were written in English and professionally translated into Zulu.

### **3.9.2.3 Antenatal Staff**

*Focus groups* were held with the antenatal staff to measure acceptability of each of the testing approaches to staff members. There were two groups. The first took place during phase one, prior to the commencement of phase two (Opt-out). And the second took place one month after starting phase two. The same staff members were involved in both groups as mentioned previously.

For the same reasons as mentioned previously, the researcher decided not to facilitate these groups so as to avoid introducing bias.

A staff member who was also a nurse educator facilitated the groups after she was given some training on how to facilitate such a group. Instruction was given by the same team who instructed the volunteers who did the interviews and was needed as the nurse educator had limited experience in facilitating a group for research purposes. The facilitator conducted the groups using an interview guide (Appendix 4 and 5) which measured data on how the midwives perceived the two testing approaches and how efficient and acceptable they found each to be. The focus group interviews were recorded and analyzed by researcher who identified recurring themes and responses.

The findings of the groups were validated by performing in-depth interviews with all the staff eighteen months after Opt-out testing was implemented(Appendix 5). The interviews were conducted by a professional field worker who was trained in qualitative methodology and who was available to help. The same interview guide was used as in the focus groups. The purpose of these interviews was to validate the findings from the focus groups.

### **3.10 Method of data analysis**

#### **3.10.1 Analysis of quantitative data**

The *quantitative* data (uptake of testing, prevalence, time measurement, demographics) was collated and analyzed using SPSS. Field workers captured the data from the questionnaire and the *PMTCT statistical record* during and after the data collection period onto Microsoft Excel. The data was checked and cleaned afterwards to ensure good quality control. The quality controlled data was then exported to SPSS where it was analyzed. Several meetings with the biostatistician were held to interpret the results appropriately.

The questions in the acceptability questionnaire were formulated so that the researcher could assess not only if patients felt comfortable during the testing approach, but also if patients were conscious of the fact that they have been counselled/informed and tested for HIV. This would demonstrate if patients were coerced into testing. Other questions pertained to the patients feelings during the test; their attitudes to knowing their status; their attitudes to partners knowing their status and general HIV knowledge. Free text responses were limited but some were included after a “yes/no” question to help limit unreflective responses. Patients were asked to qualify why they answered “yes” or “no”. On analysis, the free text responses were collated, coded thematically and then captured in Excel. The thematic coding of the data was done by the researcher (with guidance from the research team members with qualitative experience.) Responses were grouped into themes and then coded and captured. The data was then exported to SPSS from where it was analyzed.

The study supervisors were also involved in the discussion of the data interpretation.

#### **3.10.2 Analysis of qualitative data**

The *qualitative* data was analyzed as follows:

The *in depth interviews* were digitally recorded and then were transcribed by a field worker.

For the purposes of the analysis, a group of people with experience and training in qualitative

research methodology were asked to assist with the analysis of a subset of the data to optimize validity. This group comprised of the researcher and members of research team who had training in qualitative analysis. The group met twice over a month period to read and analyze the emerging themes in the transcribed interviews. Recurring themes were noted and summarized as they emerged.

The *focus group discussions* were also digitally recorded at the time. The groups were analyzed while listening to the recordings. Emerging themes were noted as the analysis proceeded.

*In-depth interviews* with staff were recorded, transcribed and analyzed thematically. These interviews were used to validate the findings of the earlier focus groups thereby strengthening the findings of the study.

## 4 Results

### 4.1 Demographics of the study population

Table 2, Demographic Summary

Demographic Detail (N=150 in each study group)	VCT	Opt-Out	Pearson Chi-square	p-value
1) Median age	23(range=17-38)	24(range=19-39)		
2) Education			3.51	0.31
Number of missing answers	57	22		
Up to Grade 7	4/93 (4.3%)	1/128 (0, 8%)		
Up to Grade 10	9/93 (9.7%)	15/128 (11, 7%)		
Matric (Grade 12)	42/93(45.2%)	54/128 (42, 2%)		
Higher Education	38/93(40, 9%)	58/128 (45, 3%)		
3) Employment Status			4.68	0.30
Number of missing answers	32	17		
Employed	78/118 (66, 1%)	70/133 (52, 6%)		
Unemployed	40/118 (33.9%)	63/133 (47, 4%)		
4) Employment Details			0.20	0.90
Full Time	44/58 (75, 9%)	51/67 (76, 1%)		
Part Time	9/58 (15, 5%)	9/67 (13, 4%)		
Casual	5/58 (8, 6%)	7/67 (10, 4%)		
5) Unemployment details			1.78	0.41
House wife	31/38 (81, 6%)	41/59 (69, 5%)		
Student	6/38 9 (15, 8%)	15/59 (25, 4%)		
Casual	1/38 (2, 6%)	3/59 (5, 1%)		
6) Marital status			9.32	0.02
Number of missing answers	27	10		
Married	65/123 (52, 8%)	80/140 (57, 1%)		
Single	44/123 (35, 8%)	30/140 (21, 4%)		
Engaged & Living with partner	6/123 (4, 9%)	16/140 (11, 4%)		
Not living with partner	8/123 (6, 5%)	14/140 (6, 5%)		
7) Ethnicity			5.40	0.24
Number of missing answers	21	6		
Asian	60/129 (46, 5%)	65/144 (45, 1%)		
White	8/129 (6, 2%)	8/144 (5, 6%)		
African	56/129 (43, 4%)	55/144 (38, 2%)		
Coloured	5/129 (3, 9%)	15/144 (10, 4%)		
Other	0/129 (0%)	1/144 (0, 7%)		
8) Religion			2.86	0.72
Number of missing answers	44	49		
Hindu	25/106 (23, 6%)	28/101 (27, 7%)		
Christian	55/106 (51, 9%)	51/101 (50, 5%)		
Other Christian	7/106 (6, 6%)	7/101 (6, 9%)		
Muslim	13/106 (12, 3%)	13/101 (12, 9%)		
Zulu	1/106 (0, 9%)	1/101 (1, 0%)		
Other	5/106 (4, 7%)	1/101 (1, 0%)		
9) Total Household income/month			0.82	0.97
Number of missing answers	73	30		
<R1000/month	5/77 (6, 5%)	8/120 (6, 7%)		
R2000-4000/month	36/77 (46, 8%)	50/120 (41, 7%)		
R4000-6000/month	17/77 (22, 1%)	30/120 (25, 0%)		
R6000-8000/month	10/77 (13, 0%)	15/120 (12, 5%)		
R8000-10 000/month	3/77 (3, 9%)	7/120 (3, 9%)		
>R10 000/month	6/77 (7, 8%)	10/120 (8, 3%)		

There was no statistically significant difference between the two study groups in education level, employment details, ethnicity, religion or income. The groups did differ on marital status where there was a significant result with more women (57%) married during Opt-out than during VCT (53%)  $p= 0.02$ . Not all participants completed the questionnaires in full. The numbers of missing responses are reported in Table 2.

#### **4.2 Demographics of the subset interviewed**

Table 3 presents the demographic profile of the subset of participants who were selected for interviews.

There were 11/18 African participants (61%), 1/18 Coloured (6%), 3/18 Indian (17%) and 3/18 White (17%) participants. 61% (11/18) participants were HIV infected health care workers working in other institutions.

The demographics of the interviewees show that the interviewees were ethnically representative and balanced in terms of HIV status in both groups.

Table 3, Demographics of Interviewees

Phase	Participant No	Ethnicity	Age	Parity	HIV status
VCT	1	Coloured	25	0	Negative
VCT	2	African	29	3	Positive
VCT	3	White	23	1	Negative
VCT	4	African	30	1	Positive
VCT	5	African	31	2	Positive
VCT	6	African	31	1	Positive
VCT	7	African	28	1	Positive
VCT	8	Indian	22	0	Negative
VCT	9	White	19	1	Negative
Opt-out	1	African	33	1	Positive
Opt-out	2	Indian	35	3	Negative
Opt-out	3	African	30	1	Positive
Opt-out	4	African	24	0	Positive
Opt-out	5	White	34	0	Negative
Opt-out	6	Indian	25	0	Negative
Opt-out	7	African	28	1	Positive
Opt-out	8	African	22	0	Positive
Opt-out	9	African	22	1	Positive

### 4.3 Efficiency

*The efficiency of the testing approach was measured by the uptake of testing, the time cost of the testing approach and the prevalence of the testing approach.*

#### 4.3.1 Uptake of testing

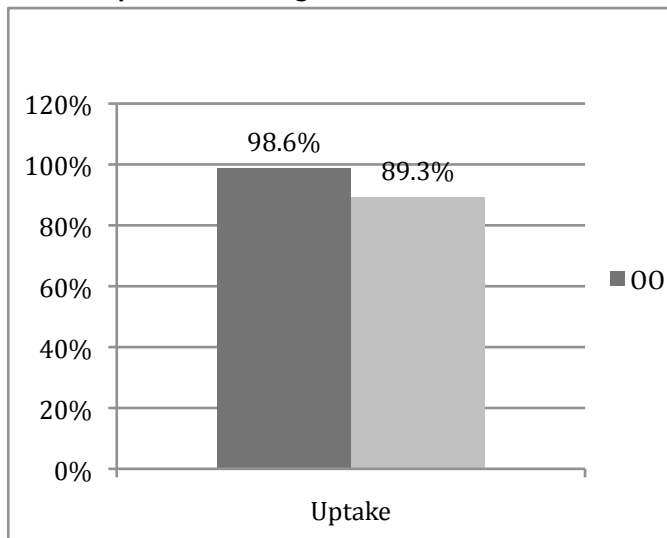


Figure 2, Uptake of testing in two groups

The uptake of HIV tests during VCT was 134/150 (89.3%) during the VCT approach. With Opt-out testing uptake increased to 147/150 (98.0%). This difference was statistically significant  $p < 0.001$  and confirmed the hypothesis that Opt-out testing would increase the

Figure 2).

#### 4.3.2 Time cost of each testing approach

The time cost of the testing approaches was assessed by measuring the length of time a participant spent in the midwife-consultation and also the total time the patient spent in the clinic.

##### 4.3.2.1 The length of the midwife consultation

The time participants spent with the midwife decreased during Opt-out testing with the difference between the two groups being statistically significant ( $p < 0.001$ ). On average the midwife consultation during VCT took 8 minutes longer per participant than Opt-out testing on average. The average visit time was 34 minutes during VCT and 26 minutes during Opt-out testing.

Figure 3 demonstrates the differences between the two groups below.

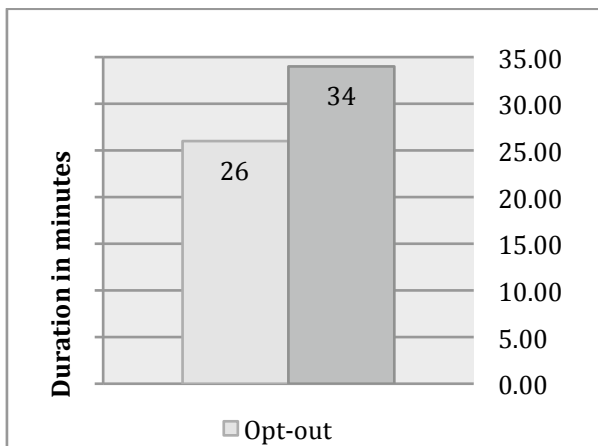


Figure 3, Time spent with midwife

##### 4.3.2.2 The total length of time of a booking visit during each phase

The total length of time that each participant spent during the first antenatal visit (booking visit) was measured to see what the operational impact of the various testing approaches was on the clinic's efficiency. There was a statistically significant difference between the two groups ( $p < 0.05$ ) with VCT having a longer mean time (4 hours and 35 minutes) than Opt-out (4 hours and 21 minutes). Figure 4 depicts the differences between the two groups. The

findings of the time it takes per participant at the midwife and in total confirms the hypothesis that Opt-out testing would shorten the duration of the time spent at the antenatal clinic.

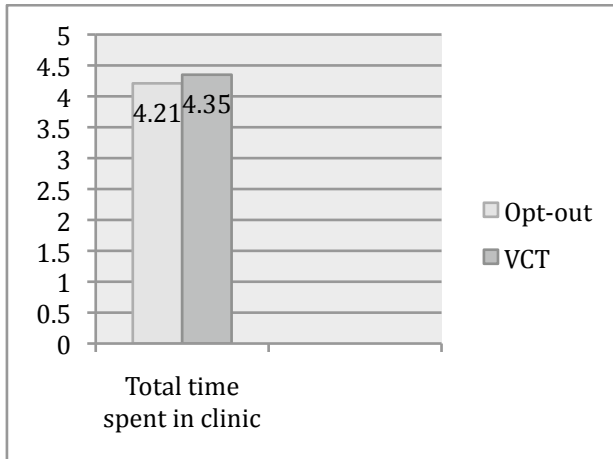


Figure 4, Total time spent in clinic

#### 4.3.3 Prevalence: The Sensitivity of the testing approach

The difference in the HIV prevalence during each phase in the study population was statistically significant with  $p=0.046$ . Opt-out testing showed an increased case finding of HIV positive women with 23/150 (15.3%) testing positive. In comparison 14/150 (9.3%) of women tested positive during VCT. Figure 5 depicts the difference in prevalence between the two study phases.

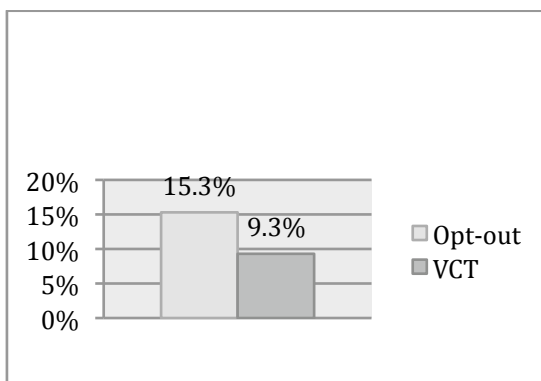


Figure 5, Prevalence during each study phase

During VCT 25% and Opt-out 21.5% of patients booked having been recently tested in the previous 3 months. The prevalence for patients who agreed to test at their first Antenatal



visit at McCord Hospital would be a more accurate measurement when the impact of the testing approach is studied. Therefore the prevalence in those who tested at McCord (the testing approach measurement) and those who tested elsewhere (those who booked knowing their status and therefore not impacted by the testing approach used) will now be presented.

#### **4.3.3.1 Prevalence in participants tested at McCord**

The prevalence in the Opt-out group (12.6%) was higher than that in the VCT group (7.3%) with  $p=0.13$ . The relative risk of testing positive in the Opt-out group when compared with the VCT group was 1.64 times more likely. However the overlap with 0 by the 95% confidence interval indicated a non-significantly increased risk.

#### **4.3.3.2 Prevalence for those who tested elsewhere**

Similarly there was an increased non-significant risk of testing positive in the Opt-out group compared with the VCT group ( $p = 0.12$ ) in those who tested elsewhere. With VCT 14% tested positive and with Opt-out, 26%.

Thus when the two groups were combined to increase statistical power, there was a significant difference in the proportion of participants testing positive between the Opt-out and the VCT groups ( $p = 0.046$ ) as depicted in Figure 5. The relative risk was 1.67 times higher in the Opt-out group than in the VCT group.

## **4.4 Patients' evaluation and experience of testing approach**

The findings that relate to how participants evaluated and experienced each testing approach would indicate the acceptability of each testing approach and is presented below.

### **4.4.1 Past experiences and education regarding HIV**

Questions (See Appendix 2) that related to previous testing experiences were:

- *Were you counselled for an HIV test before today?*

Significantly, more than 50% of participants in each group had previous HIV counselling experience. There were 61.1% (55/90) during VCT, and 55.7% (68/122) during Opt-out that affirmed that they had been counselled for an HIV test on previous occasions. The Pearson chi-square value was 0.61 with  $p= 0.433$  showing that there was no significant differences between groups. (Missing responses were  $n=60$  with VCT and  $n=28$  with Opt-out.)

- *If you were counselled before- indicate how many times?*

Those who had been counselled before showed no significant difference in the number of times they have been counselled between the study groups. The Pearson chi-square value was 5.63 with  $p=0.433$ .

Table 4 below presents these findings.

Table 4, Frequency of prior counselling

	<b>Once before</b>	<b>Twice before</b>	<b>4-5 times before</b>	<b>More than 5 times before</b>
<b>Opt-out (n=65)</b>	43.1%(28)	26.2%(17)	10.8%(7)	20%(13)
<b>VCT (n=53)</b>	47.2%(25)	35.8%(19)	7.5%(4)	9.4%(5)

The findings to the questions above were further analyzed to correlate ethnicity with the number of previous counselling episodes.

- *Was there a correlation between ethnicity and previous counselling experiences?*

There was no significant difference between the different ethnic groups and their responses. However, there was a significant difference when African participants' responses were compared to the sum of the other ethnicities. More Africans (68%), compared to the other ethnicities (50.4%), indicated that they had been counselled on prior occasions ( $p=0.10$ ). Significantly, the majority of African participants (36%) had in fact been counselled 2-3 times before with  $p=0.036$ .

- *What are the main sources of information about HIV?*

Participants were asked to indicate the main sources from where they learn HIV-related knowledge (See Appendix 2, question 11).

The results are summarized in

Table 5 to Table 11:

**Table 5, Percentage of patients who received their info from *Television***

<b>Opt-out (n=149)</b>	68.5% (102)
<b>VCT (n=94)</b>	39% (37)

Pearson chi-square: 19.93 with p = 0.000 (p< 0.001).

The only statistical significant difference (p<0.001) between the study groups was found when the Opt-Out group indicated that 68% (102) of them got most of their information from television compared to the VCT group 39%(37). It is unclear why there was such a difference between groups with this indicator.

**Table 6, Percentage of patients who received their information from *Radio***

<b>Opt-out (n=150)</b>	48.7%(73)
<b>VCT (n=94)</b>	50.0%(47)

Pearson chi-square: 0.041 with p =0.84.

**Table 7, Percentage of patients who got information from *Magazines***

<b>Opt-out (n=150)</b>	49.3%(74)
<b>VCT (n=94)</b>	48.9%(46)

Pearson chi-square: 0.004 with p= 0.53.

**Table 8, Percentage of patients who got information from *School***

<b>Opt-out (n=150)</b>	23.3%(35)
<b>VCT (n=94)</b>	26.6%(25)

Pearson chi-square: 0.332 with p= 0.53

**Table 9, Percentage of patients who got information from *Health Care Workers***

<b>Opt-out (n=150)</b>	32.7%(49)
<b>VCT (n=94)</b>	39.4%(37)

Pearson chi-square: 1.135 with p= 0.28

Table 10, Percentage of patients who got information from *Friends and Family*

<b>Opt-out (n=150)</b>	30.7%(46)
<b>VCT (n=94)</b>	25.5%(24)

Pearson chi-square: 0.745 with p= 0.38.

Table 11, Percentage of patients who got information from *other sources* than were listed

<b>Opt-out (n=149)</b>	9.4%(14)
<b>VCT (n=94)</b>	7.4%(7)

Pearson chi-square: 0.277 with p=0.59.

Although there were no other differences in the rest of the groups, the most popular sources for both groups can be listed. They were Television, Radio, Magazines and Health Care workers.

#### **4.4.2 Acceptability of each testing approach (n=150)**

The questions relating to the acceptability to participants of each testing approach include the following The possible coercive nature of the testing approach; the voluntariness of the consent; the subjective experiences and attitudes after testing and their reactions to finding out their status after testing., ( Appendix 2). Some responses were missing as patients did not complete all the questions in the questionnaires.

##### **4.4.2.1.1 Possible Coercive aspects of testing approach**

If participants are not counselled or informed adequately about being tested, it could possibly be construed as “coercive testing”.

Participants’ responses indicating awareness that they had been counselled to have a HIV test are shown in Figure 6.

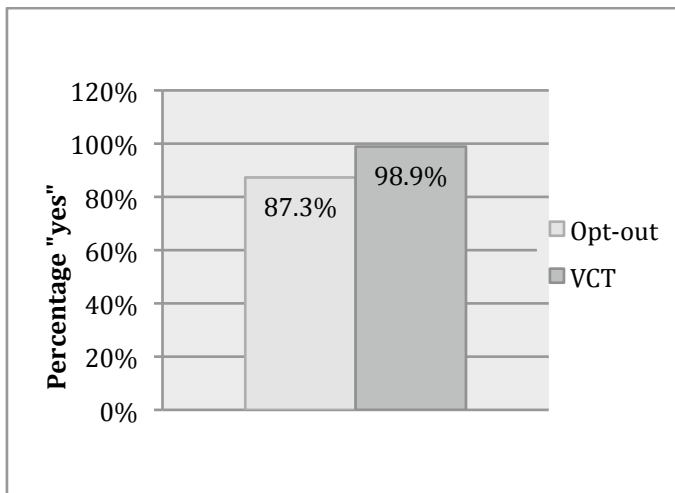


Figure 6, Women aware that they were counselled

The difference between groups was statistically significant (Pearson chi-square = 9.85,  $p=0.002$ ) with 87.3% (110 responses obtained) of participants in the Opt-out group indicating that they were counselled compared to 98.9% (90 responses obtained) in the VCT group. These findings must be compared with the findings of the same question that was also posed during the in-depth interviews.

#### 4.4.2.2 *The voluntariness of the consent*

The voluntariness of the consent can be assessed if participants indicate that they had agreed to be tested when asked. The findings to the following question: "Did you agree to test for HIV? Y/N" is presented below (Appendix 2: Question 2).

In the Opt-Out group 87.2% (109 responses obtained) compared to 85.2% (75 responses obtained) in the VCT group said that they agreed to test. There was no significant difference between the groups (Pearson chi-square = 0.17,  $p= 0.679$ ).

#### 4.4.2.3 *Interview findings regarding the possible coercive nature of the testing approach and the voluntariness of the consent*

These findings were similar to the findings of the questionnaire where all the participants in the VCT phase indicated that they were aware of the pre-test counselling. One participant in the Opt-out phase seemed confused when she was asked whether she had been given counselling about HIV and testing (See discussion and limitations in Chapter 5). Most patients

during Opt-out were also aware of the pre-test information session and thus indicated that they were asked to do an HIV test. The in-depth interviews demonstrated that most patients (60%) arrived expecting an HIV test to be offered and the majority of these (>50%) had already made a decision regarding the testing choice they would make before they had arrived at the clinic.

#### 4.4.3 Emotional experience of the testing approach

The emotional experience of participants was assessed with the questionnaire (Appendix 2: Question 8) as well as the in-depth interviews (Appendix 3). The question required participants to indicate how they felt emotionally during each testing approach. The results were statistically significant ( $p=0.003$ ) with participants experiencing more negative emotions during VCT than during Opt-Out testing.

These findings are presented below in Figure 7.

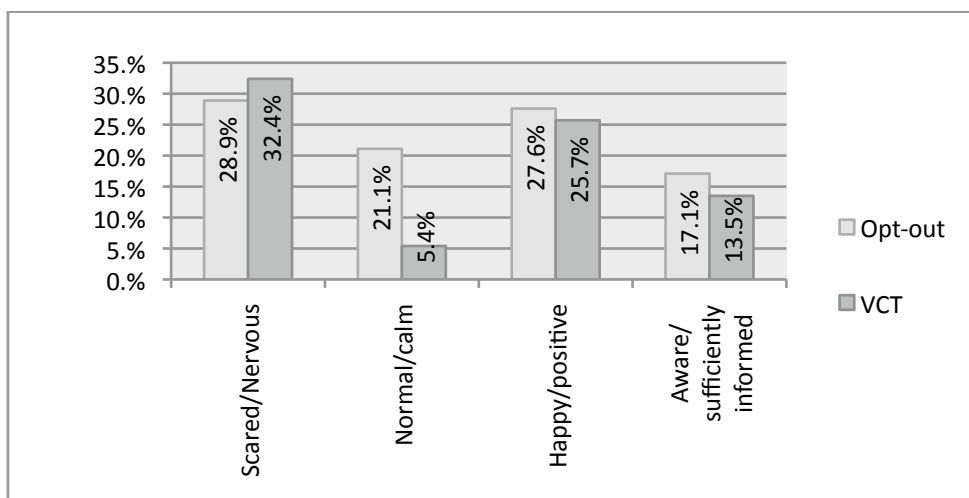


Figure 7, Feelings experienced during testing

The responses in each phase of the study can be reported as follows:

##### 4.4.3.1.1 VCT

- Scared/Nervous comprised the biggest group with 32%.
- Happy/positive comprised 26% of the group.
- Participants who felt aware or sufficiently informed comprised 14% of the group.

- The smallest part of the group (5%) had neutral feelings that were described as normal or calm.

#### 4.4.3.1.2 Opt-out

- Participants who felt scared or nervous comprised 29%.
- Participants who felt happy or positive comprised 28%
- The group of participants who felt aware or sufficiently informed was greater with Opt-out at 17%.
- The group of participants who had neutral feelings of normal/calm was also bigger during Opt-out at 21%.

### 4.4.4 Reaction and responses to testing

#### 4.4.4.1 Reaction and responses to VCT

This data was mainly collected during the in-depth interviews. The responses of the participants who experienced VCT and then those who experienced Opt-out are presented below.

Almost all the participants felt a degree of fear when they were given pre-test counselling the first time however 7 participants indicated feeling less fearful when they received their results. These participants also agreed that they found the counselling to be acceptable.

Most participants agreed to be tested, however the two participants who verbalized feeling terrified in the counselling, were unsure when they were confronted with the choice of testing.

- Participant 1: *It is something we all have to face... you have to deal with it.*
- Participant 3: *A test is a test. If it needs to be done, it has to be done.*
- Participant no 6 said that there was a “ringing in her ears” and couldn’t concentrate while she was being counselled. She verbalized being “*very, very scared.*”

Participants 6 and 7 felt that the HIV test was compulsory. Interestingly, these two participants (6 & 7 had negative emotional experiences that could be directly connected with a specific question unique to pre-test counselling: *“How would you feel if you tested positive?”*

- Participant 6 related in the interview that her response to the above question was: *You know me, I don't know, but I can be very angry for myself, and maybe I can kill myself.*
- Participant 7 felt very scared and declined testing at the first visit: *They said you must take a blood test, and I refused because I was afraid.* She decided to return on the following visit and agreed to be tested then. She said that she realized after leaving the first time that it was in the best interest of the baby that she tested, and concluded *“I counselled myself.”*

On a return visit she was asked again how she would feel if she tested positive she responded: *Hey, I can do nothing. I can accept it.* And when the test turned out to be positive, the patient said: *Ok, its fine.* But: *She (the nurse) didn't believe me.* (That she was fine).

#### **4.4.4.2 Attitudes to knowing HIV status with VCT**

Most participants were aware that they would be offered and HIV test when they arrived at ANC before they were counselled. Six of the participants indicated that they arrived at the clinic with the intention to test. One participant indicated that she intended to decline the HIV test (however she did not). Two participants were uncertain prior to the first visit and VCT whether they would test or not.

Participants 1, 2, 3, 4, 5, 8 & 9 were said they felt comfortable during the initial counselling. Participant 3 said although she was comfortable during the counselling, she did get confused with the “big words” that the counsellors used.



Five participants were HIV positive. Most participants felt they had accepted their status by the time of the interview though all of the positive patients related feeling traumatized/upset at the initial diagnosis.

- Participant 6: *So it was positive. Woo! I was I, cried! and then later while crying: No, I can't, I can't tolerate this burden!*
- Participant 2 stated: *I have accepted it, but I hide it at times.*
- Participants 5, 6 and 7 indicated that what made them accept their status was the realization that there was a future with treatment for HIV: *Even if you have this, you can be treated.*
- Participant 5: *Ok, it's not me only. And if you can understand the treatment you can live with it.*
- Participant 6: *That's why, I'm free. Even now I'm good. I accept.*

The participants 5, 6 & 7 also indicated that the post-test counselling helped them come to terms with their status.

- Participant 6: *It was good cause even now, I haven't told anybody that I am HIV positive, but due to their (the counsellors) help that I got from them, I'm right; I'm fine.*
- Participant 7: *They took me to the counsellors. Yes, they talking to me, they give me more "power" so, I accept because I can't change anything now.*

#### **4.4.4.3 Reactions and responses to Opt-out testing**

Participants also responded positively to the way in which the information session was conducted and agreed that the testing was acceptable when they were asked for their perceptions.

- Participant 8: *I felt it was just information and it was very good. I only realized it's a good way of counselling people because sometimes - the horror when you are counselled on your own, because actually you feel that maybe you have the disease she's talking about.*

Four participants (2, 5, 6 and 8) felt “normal” or “neutral” during the information session:

- Participant 5: *I didn't feel like I was going for an HIV test. She kept talking to us and explaining to us and while she was talking she was explaining the charts and talking to us normally.*
- Participant 6: *Normal, just like when somebody wants to teach you about something, or advice or something. They were willing to hear you speaking.*
- Participant 8: *I felt that it was just information and it was very good.*

Participant 2 was critical of the information in the group session and had a problem with the group. She identified herself as Islamic and because of her religion she cannot show her face or fully participate if there is another man (not her partner) present in a group scenario. She also felt the session could have included more on screening for congenital abnormalities. In terms of consenting for the antenatal batch test she said: *I didn't object to it because it's a routine thing.* In addition to the group session content she said: *I think most of us know what's going on. But I think they should stress more the treatment for those who are positive.*

- Participant 8 revealed in the interview that she used to decline the HIV test on prior occasions. When asked why she agreed after Opt-Out she said: *I don't know, but this time I felt I had to take it. That I had no choice- I'm a pregnant woman. Yeah, because now that I have a better understanding. It is better if I find out earlier than later.*

#### **4.4.4.4 Attitudes to knowing status with Opt-out**

Three participants said they felt afraid during the information session and the test, but came to terms with their results soon after:

- Participant 1: *Yes it is very scary. It's painful. I thought it's painful to get a result, "you're positive" but now it is no problem. I'm relaxed.*
- Participant 3: *It is painful to go through, but everyone must face it at some time.*
- Participant 4: *When I get tested I feel scared before I knew the results- now I'm fine.*

Three participants (No 3, 7 and 9) arrived at the clinic already knowing their status- and so no 7 and 9 didn't give any impression of their feelings prior to testing at the group session. Participant 3 was actually a qualified HIV counsellor - her opinion was that the session was of a good quality but didn't include much new information to her.

#### 4.4.5 Informative value of testing approach

Participants were asked to indicate the informative value of each testing approach (Appendix 2, question 3 and 4; Appendix 3). Findings in Figure 8 demonstrate if participants felt they learnt any new knowledge in the counselling.

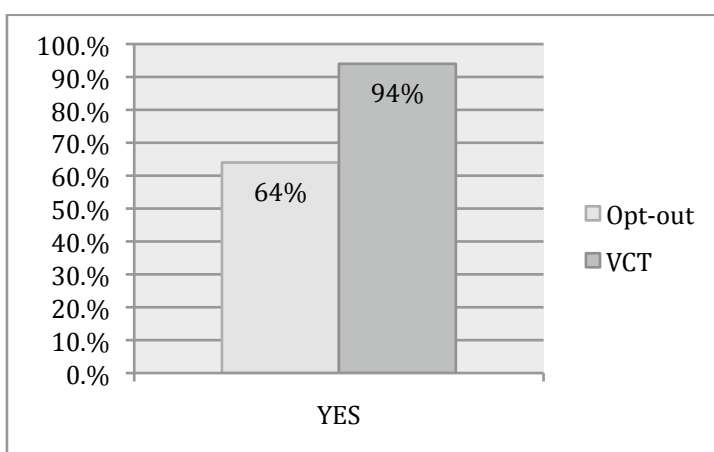


Figure 8, New knowledge gained

In the VCT group 94% (n=141/150) said they learnt new information. In the Opt-out group 64% (n=96/150) felt they learnt something new. This finding was statistically different with  $p < 0.001$ . This finding was correlated with age, education level and ethnicity to see if these variables influenced the outcome.

##### 4.4.5.1 Correlation with age and if anything new was learned

On further analysis there was found to be a statistically significant difference (with  $p < 0.001$ ) in the correlation for age and whether participants learnt anything new. The difference showed that older participants (average age 27 years) felt they learnt less new information during the counselling sessions than younger participants (average age 22 years).

#### **4.4.5.2 Correlation with level of education and if anything new was learned**

The difference between education levels and this question was not statistically significant with  $p=0.64$ . The results of this analysis are presented in Table 12 below.

Table 12: Education and what was learned

<b>Educational level</b>	<b>Percentage of patients who learnt something new (total= 181)</b>
<b>Up to standard 5</b>	100% (n= 5/5)
<b>Up to standard 8</b>	80% (n= 12/15)
<b>Matric</b>	75.9% (n= 63/83)
<b>Higher education</b>	76.1% (n=67/88)

#### **4.4.5.3 Correlation with ethnicity and if they learnt anything new**

Analysis of this question showed no statistically significant difference between ethnic groupings with  $p=0.143$ . The highest percentage of participants was 81.6% (71/87) of Asians who felt they had learnt something new in the counselling session. The other ethnic groups also had high positive responses with 63.6% (7/11) of Whites, Africans 79.0% (64/81) and Coloured 66.7% (12/18) responding that they learnt something new in the counselling session.

#### **4.4.5.4 What new information was learnt?**

**Questionnaire findings:** Patients also had to identify what new knowledge they gained during each testing approach. When the responses between the two groups were compared there was no statistical difference between the participant responses in Opt-Out and VCT ( $p = 0.52$ ). However this borderline result warrants a closer look at the trends (Figure 9 and Figure 10) depict the difference between the two groups' responses in terms of themes.

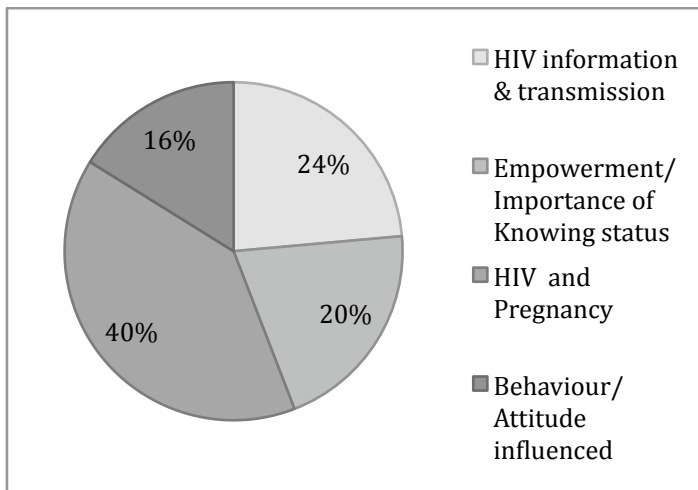


Figure 9, What did they learn? – VCT

- The biggest group of patients (40%) indicated that they learned new information about HIV and pregnancy.
- 24% learned about general HIV information and how HIV is transmitted.
- 20% indicated that the new knowledge they gained was to be empowered through knowing their status.
- 16% felt the counselling influenced their attitude to HIV and health behaviour.

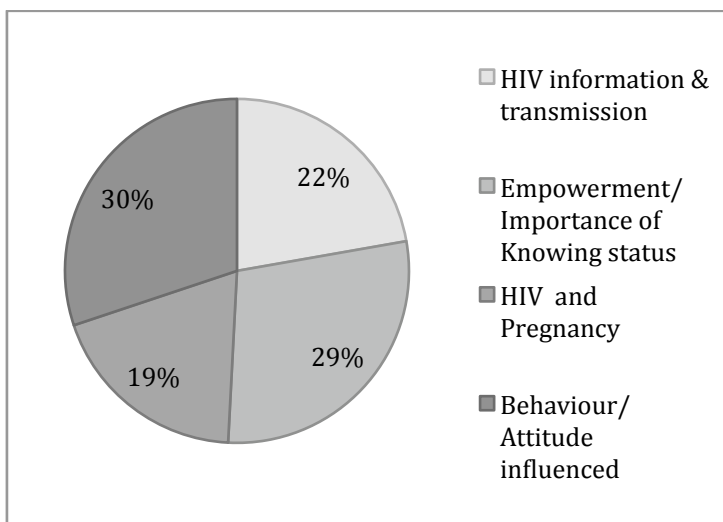


Figure 10, What did they learn? - Opt-out

- The biggest group of patients (30%) indicated that the testing approach influenced their attitude to HIV and their health behaviour.

- Significantly 29% indicated that the testing approach empowered them and made them realize the importance of knowing their HIV status.
- 22% indicated that they learnt general HIV information and how HIV was transmitted.
- 19% indicated that they learnt new knowledge about HIV and pregnancy.

#### 4.4.5.4.1 Interview findings on value of pre-test information

##### **VCT**

Participant 1 highlighted she learned that even though she was HIV negative, she needs to re-test after 3 months. She also learnt that knowing one's status is important for both mother and baby's health.

Participant 2 indicated that the information she learnt was about the availability of treatment to prevent Mother-to-child transmission of HIV.

Participant 2, 3, 4, 5, 6, 8 & 9 all indicated that the counselling taught them information about protecting the baby from HIV infection and using condoms. Participants 4, 5, 6 also indicated that they learnt information about the promotion of the mother's health through doing CD4 counts, adherence to ARV's and treatment.

##### **Opt-out**

- Participant 1: Learnt that HIV testing was very important for the sake of the baby and that HIV is a chronic disease: *Because if I am like HIV positive and you are having Diabetes, cancer and all. Cancer, Diabetes and AIDS one and the same- because there is no cure, so I'm free now." Also, "It's very important for a baby, for the sake of the baby.*

Participant 2: Indicated that she learnt about why the full blood count and an iron rich diet were important. She also learnt about HIV in pregnancy.

Participant 3, 4, 5 and 9: Learnt about how the baby can be protected against vertical transmission.

- Participant 6 and 7: *It can be treated if it's known earlier.* And also about the ARV's that can prevent transmission.

Thus the findings from the interviews are similar to the questionnaire findings for the two testing approaches.

#### **4.4.6 Ideas regarding HIV testing in the two groups**

##### **Understanding of the term “counselled”**

It was clear from the interviews that subjects did not use or perhaps understand the word “counselled”, as health care providers do. From the responses it can be seen that subjects would refer to the group-information session, pre-test counselling and post-test counselling all interchangeably, as “being counselled.”

The dialogue from the Opt-out interview with the first participant (she was HIV positive) below illustrates this finding:

Interviewer: *When you came in what did they do for your testing?*

Participant: *They started counselling me because I was scared, the first time I came here.*

Interviewer: *What were all the different things they spoke about in this session?*

Participant: *If you are positive you must be brave because you will live longer. You are like a normal person. Yah they told us a lot of things but what is important is that if you are pregnant you must have a test for the baby, for the sake of the baby not to be infected. They told us a lot of things.*

Interviewer: *Did you learn anything new?*

Participant: *Yes I did, Viral loads. I didn't know about that. And they explain me what is a CD4 count, I didn't know.*

In the above dialogue the participant associated the group session and post-test counselling information with “being counselled.”

This broad understanding of the term, was found repeatedly in the interviews with participants. The impact of how subjects understand the word “counselled” will be discussed in the following chapter.

**4.4.6.1 Perceived need for repeated pre-test counselling**

Participants were asked: *Do you want to be counselled every time before an HIV test?*

(Appendix 2; Question 5).The results showed no statistical difference between the groups (Pearson Chi square = 1.06 and p=0.304) with 60.7% (n=71/117) during Opt-Out and 52.9% (36/68) during VCT saying that they would not like to receive repeat counselling. (There were 33 missing responses with Opt-out and 82 with VCT.) See Figure 11.

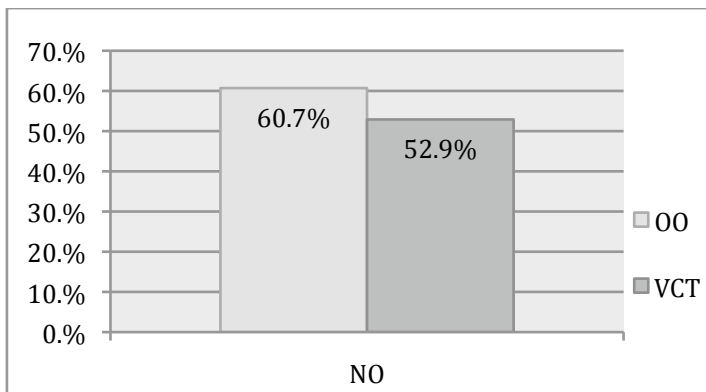


Figure 11, Perceived need for repeated counselling: Not necessary

The findings of the above question correlated significantly with ethnicity.

**4.4.6.2 Correlation between ethnicity and the perceived need for repeated counselling**

There was no significant difference between ethnic groups in the way they responded to this question. But there was a statistically significant difference between African participants and the sum total of other ethnic groupings with 51.9% of Africans preferring to be counselled every time before an HIV test compared to 34.6% of other ethnicities (p= 0.018). Figure 12 presents these findings.



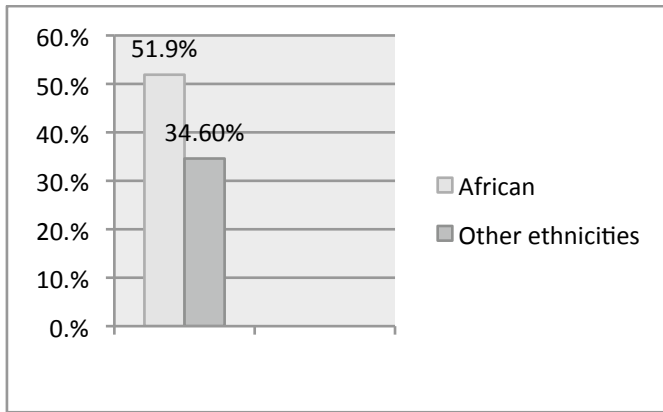


Figure 12, Ethnic group responses on perceived need for repeated counselling

#### 4.4.6.3 Perceived need to know HIV status

##### Questionnaire findings

More participants indicated (Appendix 2, question 6) that all pregnant women should know their HIV status during VCT than Opt-out. There was 91/91 (100%) during VCT (with 59 responses missing) and 118/128(92.2%) during Opt-out (with 22 responses missing). This difference in the findings were statistically significant with the Fischer's Exact test (2 sided) calculated as  $p < 0.05$ . See Figure 13.

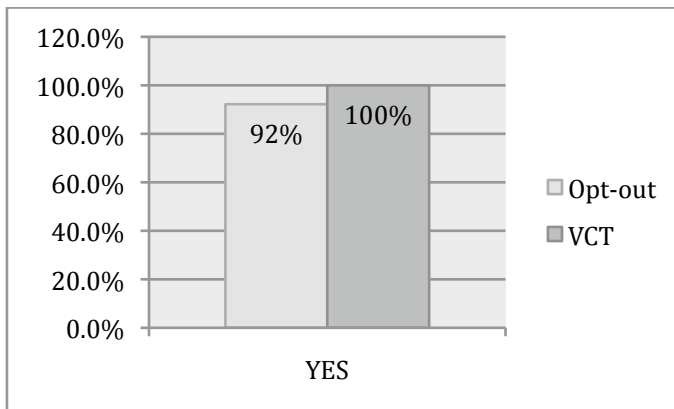


Figure 13, Perceived need to know HIV status during pregnancy

Patients had to qualify why they gave the above responses. The differences between the reasons given for both the Opt-Out and VCT groups can be showed in the Figure 14 and Figure 15:

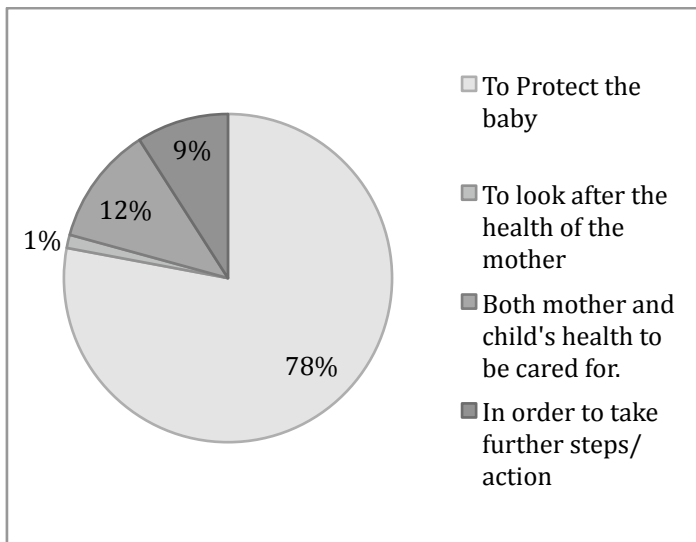


Figure 14: Why pregnant should know their status- VCT

The majority of women (78%) who experienced VCT indicated that women should know their status so as to get treatment to protect the baby. The other reasons women should know their status are that were given by participants during the VCT phase can be summarized as follows:

- To care for both the mother and child's health (12%);
- To be able to take further steps/action once the status is known (9%) and
- In order to look after the health of the mother (1%).

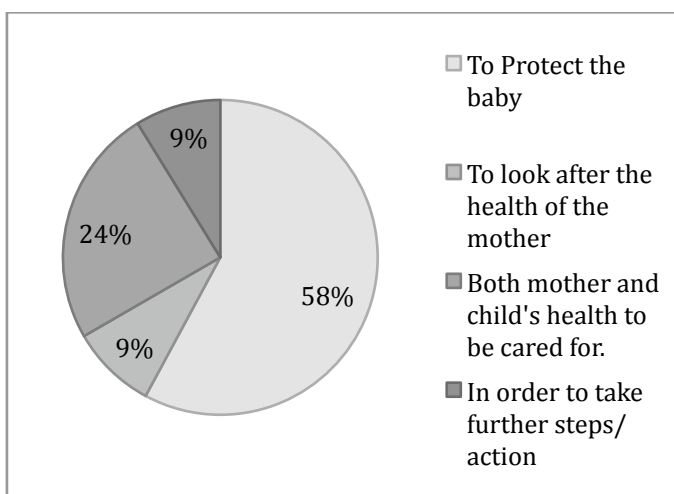


Figure 15: Why pregnant women should know their status- Opt-out

The women who experienced the Opt-out testing phase of the study responded differently from the VCT participants in that bigger proportions of the group indicated that women should know their status in order to:

- Look after the health of the mother and the baby (25%);
- Look after the health of the mother (9%) and
- Take further steps/action once their status is known (9%); and
- Protect the baby from HIV infection (57%)

The differences in the responses between groups were statistically significant with Pearson chi-square 13.41 and  $p= 0.009$ .

### **Interview Findings**

#### VCT

Interestingly, when asked if it is important that pregnant women knew their HIV status most patients replied that it was important. These responses were consistent irrespective of HIV status but there was a noticeable focus on the baby's health being a recurrent reason to know one's status.

- Participant 6: *It is very important cause that you help me, the mother, to take my medications.*
- Participant 7: *Ooh- It is very important! I can't, it's very important to know their status because of the baby. I don't care about the moms; I care about the baby.*
- Participant 5: *Because it is important for yourself, it's especially important for the baby. Yeah, it's very important because you can save another person's life instead of yours, because that's important.*

Opt-out

Most participants felt that pregnant women should know their status. Participant 3 pointed out that *“everyone should know their status.”* The main reason given for this in the interview recurred throughout the interviews as it being important to know to protect the baby.

- Participant 4: *Yeah, I think it's important to know because of the sake of the baby. You have to know and deal because life is one lesson.*
- Participant 6 felt that knowing one's status helps you to take action: *So that if you are HIV positive they can do something.*

#### **4.4.6.4 Perceived need to disclose status to partner**

VCT

Four participants out of nine agreed that disclosure to your sexual partner is important.

Three of these had already disclosed their status by the time of the interview.

One participant indicated that though disclosure is important, she wasn't ready to do so. She indicated fear of her partner's reaction as the reason why she did not disclose:

- Participant 2: *He's a man. He's a man who always speaks his rights, you know. She was worried he would blame her: He told me 'oh no, I don't have that thing; I don't have AIDS. If I do have it then I can kill somebody. 'Cause the only thing he believes is that we are the women, the females, we are the ones who transmit this thing. So if he finds out I am HIV positive...'*

Opt-out

Most participants felt that disclosure is important.

- Participant 1: *It's important (to inform your partner) because maybe my partner is negative and I am positive...sometimes the Zulus don't understand if I'm positive, he will think that maybe I'm the one who carried that virus, he may think that I'm the one who gave it to him..*

Participant 2 and 3 felt that disclosure to one's partner depends on the state of communication in the relationship that exists between partners:

- Participant 3: *It depends on the relationship. They should tell their partners because of what if their partner is negative so that they don't spread it on to him. If it's caused from the partner then they should as a couple be able to communicate together, be able to speak to each other.*
- Participant 6: *Yes they should, and they should be honest with their partners. I think they should because they need to know.*

There was only one participant (9) who indicated that she did not intend to disclose her status because she feared rejection.

## **4.5 Staff evaluation and experiences of the testing approaches**

### **4.5.1 Results from the first focus group during VCT**

The group lasted about 40 minutes. All the midwives participated and asked questions of one another. There were three midwives who participated in this session: JL, JK and JH. Another midwife, LP was ill at the time of the group and couldn't attend. They were at ease and were open about their opinions. The body language was slightly closed- some of them sat with their arms folded across their chests. As the group progressed, they participated more enthusiastically. The facilitator used a semi-structured questionnaire to coordinate the discussion (See Appendix 4).

#### **4.5.1.1 Beliefs about VCT in pregnancy**

All of the midwives agreed that HIV testing in pregnancy is important for not only the protection of the baby, but also the care and treatment of the mother.

- JL: *Most of our babies are negative if we start them early.*
- JK: *If you (a patient) are positive you can start treatment early.*

All three of the midwives agreed that they find it difficult to counsel, test and give results to patients.

- *JH: It is very difficult in the beginning especially if they are positive, but I am slowly getting used to it.*

A strong theme emerged when they talked about giving patients a positive diagnosis after pre-test counselling. They agreed that the pre-test counselling was important not only to prepare the patient for an HIV test result, but also serves to help the midwife prepare herself for the patient's initial reaction to a positive result. This preparedness was achieved through the content of pre-test counselling. They expressed the belief that it was the information that enabled patients to decide to test and cope with a positive diagnosis.

- *JK: VCT is our safety blanket. We feel "naked" if we have to test patients without it.*

The midwives spoke about feeling ill at ease if they would be expected to give a positive test result without any in-depth pre-test counselling. On deeper exploration of the theme it seemed that this feeling related to not being able to anticipate how a patient would respond to the outcome of a positive test.

- *JK: It's important to ask patients how they would feel should they test positive before you test them.* JK proceeded to indicate she would probably be inclined to persist with pre-test counselling even though the Opt-out group session would be introduced.
- *JK: Patients accept their status when they have had good counselling and when they know there is treatment available.*

Another theme that emerged was that they were noticing a change in the attitudes patients have to testing.

- *JH: Patients are more relaxed about testing these days. It is not like before, because they know there is treatment available.*

- *JL: They accept now that having HIV is just like having any other incurable disease like Diabetes and Hypertension.*

#### **4.5.1.2 Attitudes to Opt-Out testing**

##### 4.5.1.2.1 Concerns

The midwives voiced some concerns when the group started talking about the Opt-out phase of the study. They were concerned that giving information in groups would lead to patients not retaining the information as well as they believed they did with VCT.

- *JK: I am worried about how good the patients will retain the information if we put them in groups.*
- *JL: We are already doing health education to the waiting room (in groups), but when the patients come to us individually, they do not even know what we are talking about.*
- *JK: We are not just counselling to give them information, we want them to go out and educate people at home.*

The fears of how well patients would retain the information given in the group session related to the belief that it is the information given in the counselling that:

- a) Convinces patients to test;
- b) Helps them accept their status; and
- c) It is a form of public health education.

As the information about HIV was more limited in the Opt-out session than with VCT, they predicted that more patients would decline testing during Opt-Out testing.

There was the opinion that the group would inhibit patients to participate in groups.

- *JK: I am worried that patients won't feel free to talk in group.*

Another fear that was mentioned was when one of the midwives asked what would happen if a patient opts out of all the antenatal tests. How would they be able to deal with such a patient?

- JL: *How are we going to deal with a pregnant mother? She must have a FBC, she must have a WR, and she must have a blood group done!*

The mood of the group changed when they realized that they would have to change the way patients flow from the phlebotomist in order to accommodate “batch consent” at the midwife consultation. It would be there when a patient accepts or declines all the routine tests. The group became quiet and reserved and the interviewer couldn’t draw them to participate to the extent they had earlier. They seemed to feel a lack of confidence when confronted with trying the Opt-out intervention.

In addition, there was a concern that Opt-out would take longer to complete than the VCT and there were fears that this could negatively impact the rest of the clinic flow. Although they were sceptical about Opt-out, they weren’t totally opposed to the idea. They did see the benefit of doing the study.

- JL: *But we’ll give group sessions a go, see how it goes.*
- JH: *You can’t say VCT is the best before you haven’t compared it with Opt-out.*

#### 4.5.1.2.2 Hopes

The midwives did mention one positive aspect they hoped would be achieved with Opt-out testing. They indicated that it would be good if HIV could be treated as a normal illness.

- JK: *We need to treat HIV like any other disease.* JK related she knew about many people in her community living in the fear that they might have been infected with HIV, and that this fear causes stress to these individuals. *There are people dying of stress out there and yet they never come to test. They will never know their status even if they are negative.* The other midwives concurred with her.



The summary of the session was that though they had identified many potential concerns with the Opt-out testing intervention, they realized the benefit of studying it to gather evidence. They also agreed that they themselves needed to change the way they think about change.

- JH: *We are going to have to change our mindsets.*

#### **4.5.2 Results of second staff group discussion during Opt-out**

This group was done three weeks into the Opt-out phase of the study. At this group there were three midwives present: JK, LP and JL. JH was on leave at the time. This group lasted 30 minutes. All of the midwives participated in the group discussion, though this group was not as lively as the first group. Appendix 5 contains the semi-structured questionnaire the facilitator used to co-ordinate the group.

##### **4.5.2.1 Negative attitudes to Opt-out testing**

The midwives raised the issue of the limited information again. They felt that patients who were diagnosed HIV positive during Opt-out were less informed and therefore less prepared for the impact that HIV would have in their care during pregnancy. They felt that this part of the process flowed better during VCT.

- JK: *We are giving less information to them. If they are negative it doesn't matter, but if they are positive it is a problem.*
- JL: *Information is important not only to help patients make better health choices, but also to pass on the information to others.*

When the midwives were asked if this would be a reason to go back to VCT, they disagreed:

- JK: *No, I don't want to go back- I just want to voice my concern.*

##### **4.5.2.2 Experiences of Opt-out testing**

###### **4.5.2.2.1 Efficiency**

JL: *It's really working, yes. It's working very well.*

JK: *It's working really well.*

The group agreed that Opt-Out testing worked well because of two things:

- 1) It saves one time on the patients who are negative.
  - 2) It is efficient as it involves fewer staff members. If it is quicker for the midwives to complete the first visit consultation, the whole clinic flows better.
- LP: *Last week we had a really busy day with more than 20 first bookers. In the past we would have been complaining about that day for weeks! No, it is really much better.*

The midwives agreed unanimously that they would prefer to continue with Opt-out testing after completion of the study.

#### 4.5.2.2.2 Acceptability

The midwives found Opt-out to be acceptable as it was efficient and it did not exceptionalise HIV testing.

- LP: *The way they are being given the information means when they come to you, it's all there. Everything is in one. Nothing's special like: "Oh, so now we are coming to the HIV test.*

They indicated that Opt-out helps to normalize HIV testing.

- JL: *The message that HIV is like any other illness it getting through.*

They agreed that the patients are more at ease when they come to them for testing.

- LP: *Like yesterday I had a patient, a positive patient and she was fine when I gave her the diagnosis, seriously.*

When they were asked about how the groups are working they indicated that the small groups are working:

- JL: *No, they (the patients) do ask questions in the group. They are free to ask questions in the group.*

The group unanimously agreed that Opt-out testing should be the continued testing approach used in the antenatal clinic.

#### **4.5.3 Validation in-depth interviews with the Staff**

These interviews were done 18 months after Opt-out testing had been adopted as the routine testing approach in the antenatal clinic.

Six staff members participated in these interviews. The original four midwives (JH, LP, JK and JL) were interviewed as well as two new staff members, a midwife (PL) and counsellor (PM), were included. (Appendix 5 contains the semi-structured questionnaire that was used in the interviews.)

The following themes emerged during the follow-up interviews:

##### **4.5.3.1 Reflections on the change in testing approach**

It was clear during the follow-up interviews that the staff had had sufficient time to familiarize themselves with, and reflect on the differences of the two testing approaches. They acknowledged their initial reluctance to change to a new testing approach, but agreed that it was a process they were now happy to have gone through. The positive findings of the second focus group was strongly validated with the staff being more specific and clear about the reasons why they preferred doing Opt-out testing. The following reflections indicate the tone of the interviews:

- LP: *I mean really if you are asking me, I really don't think anybody (the staff) wanted to do it. You know people had been doing VCT for so long. They didn't see why we had to change now although we were getting a higher rate of refusals.*
- JL: *Ja, it has been a process. Even when we were doing one to one, it was very difficult. They would refuse to test because they were not used to it. Now it is spoken about all over and they know this thing is there to stay.*
- LP: *No it wasn't glamorous or anything like that, but I think people got more used to doing it. If you go and sit with JK you will see people ask questions. They come out of*

*their shells. If they come for the first time some do sit there and keep quiet or whatever. So I think maybe initially it would have been a slower process and people had to build their confidence but when you have been doing it for so long, there is no problem with it at all.*

The following themes emerged when the staff talked about their experiences with Opt-out testing:

- Increased uptake of testing leads to increased job satisfaction.
- Time saving promotes efficient service delivery
- The Opt-out way of approaching HIV puts patients at ease and informs them comprehensively

Some comments (and conflicting opinions) on how patients respond to Opt-out testing

- The Opt-out way of approaching HIV puts patients at ease and informs them comprehensively
- Opt-out allows patients to reflect adequately before they are tested.
- VCT or Opt-out approach does not differ in how positive patients react when they get their results.

Some cautionary reflections and criticism

- Space is a problem in the antenatal clinic and impacts efficiency.
- Strong post-test counselling is a crucial part of the Opt-out approach.

#### **4.5.3.2 Increased uptake of testing improves job-satisfaction**

It was clear from the comments that the staff were satisfied about the increased uptake of testing. They were aware of the impact increased uptake has on promoting PMTCT care coverage and thus communicated feelings of satisfaction in being able to achieve this goal.

- *PM: Most of our patients test. I would say 99% test now. They come forward and test. If they are negative, we encourage them to stay negative. Some come with their partners and we find that one partner is negative while the other is positive. We sit down and talk to them. I think Opt-out is wonderful. It is really reaching its goal.*
- *JK: The goals were to have less positive people. We were there from the beginning with the patient and the end product was good. I feel our output in doing this Opt-out is working very well. So many babies are negative. So I think the program is going well.*
- *LP: I will give you the last statistics, 2007. We tested here 1296 patients on Opt-out, not people that came with their results, but people we tested. That was 1296. The total number of people refusing was 22 per year. In 2006 we tested 1310 and we had maybe 100 people refusing to test, using the VCT method. Remember we had gone to Opt-out in July, so from that point onward you can see. I will take you to 2005 were we tested 1186 people. 220 refused using proper VCT. The refusal rate as you can see is much higher using VCT than as of now. Things now look normal as people take this now as just another test.*

*JK: Generally I would say with Opt-out I would say we have a much more number of patients that test. About 99% of our patients are testing now.*

#### **4.5.3.3 Time saved improves overall clinic efficiency**

In addition to the increased uptake of testing, the staff also strongly approved of the time saving in going through the testing approach. It became clear that they felt released from having to counsel patients individually and by rote. This is also a factor that appears to increase job-satisfaction.

- *LP: So I think from a time point of view, like we see the patients until 1pm, these people don't want to be sitting the whole day waiting for the midwife. But during this Opt-out, the minute they finish they come to your room. You give them a consent form and you ask them if there are any of the tests they don't want and they would say: "I don't want*

*HIV or I don't want that." That is a refusal. It is not time consuming and much more economical in terms of time.*

- *JH: What I like is that we don't have to keep repeating one and the same thing with every patient.*
- *JK: In that you don't have, like you know when we used to do VCT, we had to explain the whole thing to the patient, go through everything individually on a one to one basis, whereas maybe you will find the patient that has been in a group information session, they have already got the answers from what she wanted to know. She will only want to know how long the HIV test will take, whether she will know the results today. That is the only thing. We don't get people asking lots and lots of questions while they are here. So time factor is quick, and I mean you have got a lot of patients to see. So at least with the timing, it is not that bad. They can go home quicker.*
- *JK: You see VCT took a lot of time with each one of us. If you remember, you would see a patient and go through all that with them, start with pre-test counselling and tell them about post-test counselling and then you must test and then you must do all that. So you can see how much time we took you know, with one patient. It was like hectic. At least now we are sharing the load. One person does Opt-out counselling and when they come here they already know what they want to ask.*
- *PL: I think with VCT it is more longer. It takes more time. You deal with the specific person's emotions, which can drag on and also, I think too much information before you do the test. Patients take what they want and they forget what you tell them. So with VCT it is too long, too much information and with Opt-out it is more straight to the point. You tell them what they need to know and you work on what the patient needs to know from you, based on what you said.*

#### **4.5.3.4 The Opt-out way of approaching HIV puts patients at ease and informs them comprehensively**

Staff attributed the increased uptake of testing to the group and to the normalized way in which HIV was included in the antenatal batch test information. They also indicated that the provider-initiated approach (as opposed to client-initiated) improves the uptake of testing. They observed that these factors lead to patients feeling more at ease with the process of testing.

- JH: *Another good thing is that it is no longer common to find people who refuse to test because it is done in a group and everybody is there and they can see that everybody sees that everybody did not object during the session. There are no longer people who are afraid to do the test.*
- PM (counsellor): *I think it is much easier, like it is not that we offer Opt-out and not helping them afterwards, because when we like, in the mornings when we are doing the Opt-out session, we explain to them about all the bloods they need to take, especially with HIV, we also emphasise that. I don't do the tests. It is the sisters that do the tests. So they also mention the importance of the blood tests. If for instance your results are positive, we help you. So it makes people comfortable to come forward and do it rather than VCT. I think Opt-out is working much better.*
- LP: *Well we are taking in a lot of people. We take a group of people and we tell them what is HIV and we tell them what is syphilis and we are going to do these blood tests on you. What is Rhesus factor and the reason why we are doing these tests is explained. Why are we doing HIV/AIDS? Because if you are positive, we can help you prevent transmission to your baby. So everything is explained nicely in that Opt-out session to them. So when you are grouped together like that, not making it special, like 'come I want to talk to you quietly about HIV.*
- PL: *O.K. from the time I came to the clinic, and I started and I observed the Opt-out and then I said to myself, I think it is a good idea, why because you are talking to a group of people and you are including HIV. You are not saying, 'listen you are doing your pre-test*

*and your post-test and 'and then they become more anxious. It is more friendly. It is more giving you information. This is what we do and these are tests we are doing. So it is more informative and if you function as a group they feel more included and not isolated. So I feel there is big advantage and patients are encouraged to do the test and we haven't had anyone that has refused.*

- *JK: So we did have a few refusals (at the outset), but at that time people were not so open about HIV. You find that people know when they come to the clinic they are very open about this and they would ask questions, but at that time they were not so open about it because of lack of information. Now we are giving them that information and it is quite informative because we are not only dwelling on HIV. We are talking about other aspects as well. We are not just hammering one thing. We talk about the RH; we talk about HP and things like that. So people are comfortable. Everything is included, not only HIV.*

#### **4.5.3.5 Comments on how patients respond to Opt-out**

The staff commented on how the Opt-out testing approach had impacted the way patients react to the offer of HIV testing.

##### **4.5.3.5.1 Opt-out allows patients to reflect adequately before they are tested**

The staff commented that patients were changing in their attitude to being asked to do an HIV test. Patients appeared to be better informed when they arrive at the clinic to book. In addition, the time-gap between the group session and the actual test helps patients to reflect on the new knowledge they have gained before they decide to test.

- *JL: Opt out gives a client more time to think, because we do them individually as well, not like when she is coming in here, now you are counselling her and now you want her to test at the same time. It gives more time so that when she is from there she goes back to register and she is still thinking about this and it depends on the way how you put it.*



- JL: *I mean, probably they know now that being HIV positive is not a death sentence. They hear it on radio and everywhere. In fact they are beginning to accept that they have to test. So that is why they are comfortable. They know they are not the first ones.*

#### 4.5.3.5.2 VCT and Opt-out approaches do not differ on how positive patients react when they get the result

The staff were asked to comment on if they perceived the women to react differently to a positive test result after Opt-out than how they reacted with VCT. Did the changed testing approach impact how the positive patient receives bad news? All the staff agreed that the changed testing approach has not impacted the way patients respond to bad news. They attributed most of the reaction to bad news to the emotional make-up of the patient and her expectations of the outcome. However, they did point out that post-test counselling is very important in assisting patients to absorb and work through bad news (see later in the chapter).

- LP: *Well that doesn't make any difference whether it is Opt-out testing or VCT. The patient is still given time concerns. So if they are positive, whether it is VCT or Opt-out, it doesn't really make any difference, they remain positive, because you are not twisting anybody's arm. Your job is going to come as a midwife. They come to you and you have to talk to them more about everything and about their fears and all that. You know even though we are not only doing HIV counselling, we supply information. That is what pre-test counselling is all about, information, education and that sort of thing. So when a patient tests, they have, in a way been pre-test counselled because they have been given information and they have been told all about it and what will happen if they are positive and what will happen if they are negative. At that stage you have got to counsel. You know we get different people and the whole attitude towards HIV, I find, of late, when you say, 'Were you shocked?' They will say, 'Oh you know 88% of people have it in South Africa and I am having sex. I can't be shocked. Then you get another lady. The other day she was almost hysterical, trying to give her sugar water. She couldn't even*

*hold it. I mean she was so shocked. So I don't think whether it is VCT or Opt-out, if it will make any difference. Even with VCT a woman can leave here and throw herself onto a truck on the road. Then you cannot let that person ever go but it is the same thing if you are doing Opt-out, you have to inform them and then they are post-test counselled.*

- *PL: I don't think so. I don't think it makes any difference. Speaking from my own experience I have heard patients that have tested positive. Every person is individual and I think you can't say, because it is Opt-out it is going to affect the way the patient reacts because at that time the patient is coming to terms. So no matter what you said then (during pre-test counselling) and how you said it is not going to make a difference. The point is that they think it is the end of the world. So I don't think it has an effect.*

#### **4.5.3.6 Some cautionary reflections and criticism**

The staff were asked to comment on any short comings of the Opt-out approach. The comments were quite varied with some commenting on the lack of space to handle bigger groups and others commenting on the need to strengthen post-test counselling. One of the staff members felt the Opt-out talk was too rigid and would have liked to have more freedom to add to it and tailor it to the needs of the group. In addition, two staff members indicated that they would prefer it if even more information of HIV and pregnancy was included. One would have liked to add a tour of the labour ward to the end of the talk.

##### **4.5.3.6.1 Space is a problem**

- *PL: I am feeling nice. It is working. Time has changed. Things could be good, but for now it is O.K. The only problem is space because we have got big groups like today and you have to cut them down into three groups and at times we have to battle in these consulting rooms. It is not too much of a bad thing but we manage.*
- *JL: This place is too small. Like as it is here. Next door there is wound care. So it is so congested. Our clients sit here and also clients for the dressing room also sit here. We don't have much space to put our clients.*

#### 4.5.3.6.2 Strong post-test counselling is needed

- *PL: However I feel post-test counselling would be more beneficial. I have had few patients where I felt I had to do more. I am saying what I have to do and I have to do and say goodbye. I spoke to you in the beginning and I explained everything. I want to know where you are after you have got your results. How are you because you were broken? Who did you speak to? How are you feeling today, now because you have had your results? Maybe we couldn't do everything with her then, and then she is going to come back another day and it is broken service for me, from the patient and the midwife.*
- *JL: You make sure that they have received the proper post – test counselling so that they can be able to face other clients outside. You take your time really when you see that she is breaking down. So we leave everything, and concentrate on her until you see that at least she is composed and can go out there and face the world. We even pray with her to make her comfortable.*

#### **4.5.3.7 Summary of interviews**

The follow-up interviews were found to validate the findings of the earlier focus groups with the staff. The staff were more comprehensive in their comments about Opt-out testing and how they perceived the differences from VCT approach. The final findings were that the staff still found Opt-out and acceptable approach and perceived patients to find it acceptable as well. Strong post-test counselling was crucial in securing the success and acceptability of the Opt-out testing approach.

## 5 Discussion

### 5.1 Research Methods

A study design that combined quantitative and qualitative methodologies was appropriate to give a comprehensive assessment of the efficiency and acceptability of the two testing approaches. Quantitative methodology was used to measure the efficiency of the HIV testing approach. For this study, efficiency was defined as the uptake of testing, the time required for each testing approach and the HIV prevalence in the clinic. Acceptability was measured by administering a questionnaire, which collected data on how participants experienced each testing approach. In addition, the acceptability of the testing approach was studied by doing in-depth interviews with a subset of participants as well as focus group interviews with antenatal clinic staff. The use of mixed methods was justified in that literature has shown that Opt-out testing has mainly been studied quantitatively and few studies exist that have examined acceptability directly.<sup>68</sup>

The uptake of HIV testing in antenatal clinics has increased with the introduction of an Opt-out testing approach.<sup>64,10,16</sup> It has also been well documented that HIV testing in the South African antenatal context is inefficient due to the complicated VCT testing approach that is implemented at present.<sup>75,49</sup> However, before an alternative HIV testing approach can be considered, its overall efficiency in the antenatal setting should be compared with that of VCT. In addition, the researcher wanted to discover if Opt-out testing would produce similar results in a local antenatal context. Thus, a study examining efficiency was needed to ascertain if Opt-out testing would be an effective testing strategy in the South African antenatal context. No study has been published examining Opt-out testing in a South African antenatal context. Therefore this study set out to measure uptake of testing, prevalence and time taken, as study outcomes.

The literature made it clear that in order to gain sufficient understanding of the acceptability of Opt-out testing, quantitative methodology methods alone would be less comprehensive. The acceptability of Opt-out testing and VCT in research studies has largely been measured by means of quantitative methodology.<sup>10,64,69,16</sup> These studies aimed to demonstrate acceptability indirectly by measuring the uptake of testing in the antenatal clinic. The numbers of participants who agreed to test would, according to this strategy, have proven the acceptability of Opt-out testing. However, critics have argued that a high uptake rate may mean that participants are being coerced into testing and thus the uptake of testing cannot be assumed to indicate acceptability.<sup>11,12,15</sup> Only a few studies have used qualitative methodology (interviews) to evaluate acceptability of Opt-out testing.<sup>68</sup> Thus, acceptability could only be studied comprehensively by using mixed methods (for example questionnaires and in depth interviews).

The use of mixed methods contributed to the reliability and validity of the findings.

## **5.2 Reliability & Validity**

The use of mixed methods has assisted/facilitated triangulation of the results and contributed to the reliability and validity of the findings. The internal comparison between the various qualitative methods used (in-depth interviews and focus groups) also compared well. Gaining a more holistic understanding of the acceptability of the testing approach was one of the key aims when choosing a mixed method design for the study. This choice proved to be very valuable in contributing to the reliability of the findings regarding acceptability. Figure 16 demonstrates how the acceptability data compared and supported validity and reliability. In addition, the findings of the patient in-depth interviews and staff focus groups were cross-validated by doing follow-up in-depth interviews with staff 18 months after the introduction of Opt-out testing into the antenatal clinic.

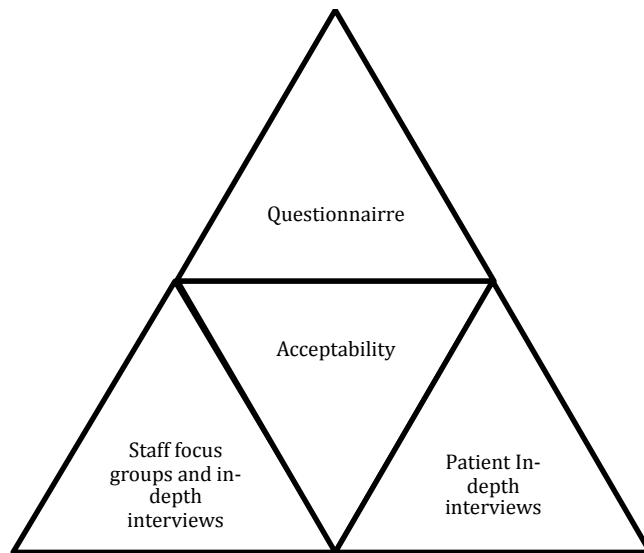


Figure 16: Triangulation of acceptability data

### 5.3 Discussion of the findings

#### 5.3.1 Demographics of the study population

The groups were compared and found not to differ significantly in any of the variables except for unemployment details. The mean age of the participants during VCT was 22 years and during Opt-out the mean age was 25 years. The demographic were mixed with most participants being of Asian (46% during VCT and 45% during Opt-out) and of African (43% in VCT and 38% in Opt-out) ethnic grouping. Most participants were well-educated with 45% (VCT) and 42% (Opt-out) having matriculated and 40% (VCT) and 45% (Opt-out) having higher education. In VCT 66%, and in Opt-Out 52% were employed. The largest group of the participants who were employed (75%, VCT and 76%, Opt-out) indicated that they were employed full time. The biggest group of participants, who were unemployed, indicated that they were housewives. The representation of housewife groups were statistically significantly different with the 81% in VCT and 69% in the Opt-out group ( $p=0.02$ ). Ninety-five percent (95%) of the both the groups earned more than R2000 per month with the average income being between R2000-R4000 per month.

The demographics of the study population may not be the same as those in a Department of Health Antenatal clinic. The ethnicity, income levels and educational levels may differ and this may limit how the findings are generalised.

#### **5.3.1.1 Discussion of demographics of the in-depth interview subjects**

The HIV prevalence in the total antenatal clinic population is 17%; however 61% of participants in the in-depth interviews were HIV positive, and were purposively chosen. The responses of the HIV positive participants were of particular interest, as they are the ones who are most affected by the testing intervention. The ethnicity of the interviewees differed from the total study population with African patients making up 61% of the group. This selection was intentional as the African ethnic group is most affected by- and infected with HIV at the McCord Antenatal clinic. Therefore it was appropriate to ensure that this group was well represented in studying the acceptability of the testing approaches.

### **5.4 Discussion of the findings of efficiency**

The following findings are based on the outcomes of the measurements of efficiency of the testing approach and the outcomes of the in-depth interviews and focus groups.

#### **5.4.1 Uptake of testing**

The data of the testing uptake was taken from the PMTCT *Statistical Record*, routinely kept on all patients by the antenatal staff. The uptake of Opt-out testing increased by 10% from 89.3% during VCT to 99% during Opt-out ( $p > 0.001$ ). This is a significant finding given that the uptake of VCT at McCord was considered good before the introduction of Opt-out.

This finding is consistent with the literature on international results and proves that the Opt-out approach has the same effect on uptake in a South African antenatal population. <sup>10,68,64</sup>

Interestingly, the new PMTCT policy guideline<sup>14</sup> recommends “Provider Initiated VCT” in an effort to increase coverage and uptake of HIV testing in the antenatal context. Provider initiated VCT is defined as the routine offer of VCT to all pregnant women as they book for

antenatal care. Importantly, provider initiated VCT is the testing approach against which Opt-out testing was measured in this study. Therefore, the increased uptake of testing found with Opt-out was measured against the routine offer of VCT and thus adds to the significance of this finding. Opt-out still provided significantly better uptake of testing than routinely offered VCT.

During the in-depth interviews the midwives strongly supported Opt-out because it resulted in increased uptake of testing. It was clear, during the interviews, that this also created a sense of service satisfaction as the midwives felt that they were achieving their goals in enhancing the coverage of PMTCT care:

- *PM: Most of our patients test. I would say 99% test now. They come forward and test. If they are negative, we encourage them to stay negative. Some come with their partners and we find that one partner is negative while the other is positive. We sit down and talk to them. I think Opt-out is wonderful. It is really reaching its goal.*
- *JK: The goals were to have less positive people. We were there from the beginning with the patient and the end product was good. I feel our output in doing this Opt-out is working very well. So many babies are negative. So I think the program is going well.*

The staff experiences of VCT and Opt-out testing will be discussed in greater detail later in this chapter.

#### **5.4.2 Time cost of each testing approach**

VCT has been reported to be time consuming and labour intensive.<sup>35</sup> Alcorn<sup>22</sup> reported that VCT has been difficult to implement in limited resource settings due to shortage of human resources. Researchers reported that VCT is the only PMTCT intervention that could not be fully integrated into routine antenatal care because it is labour intensive and time consuming.<sup>1</sup> Several researchers<sup>76</sup> reported that pregnant women were more likely to accept HIV testing after at least 3 minutes of talking to the midwife prior to testing. The



impact of the testing approach on the consultation length with the midwife would influence its demand on human resources. The demand on human resources would impact on the acceptability and feasibility of the testing approach.

Opt-out testing resulted in a statistically significant shorter consultation with the midwife (mean of 34 minutes during VCT and 26 minutes during Opt-out) with  $p < 0.001$ . This finding is further validated by the finding that the time of a full first visit was shorter during Opt-out (4 hours and 21 minutes) compared to VCT (4 hours 35 minutes)  $p < 0.05$ . During the second focus group, the midwives verbalized that they preferred Opt-out to VCT because it is more efficient and saves time:

- LP: *Last week we had a really busy day with more than 20 first bookers. In the past we would have been complaining about that day for weeks! No, it is really much better.*

This response was also validated during the follow-up in-depth interviews with the midwives where they confirmed that Opt-out is efficient and saves time not only from a care-provider point-of-view, but also from the patients' point-of-view:

- PL: *I think it is easier because personally if you have got 25 mothers in one day and you have to get through every single person and you have to tell them the same thing over and over, it is time consuming and you are going to miss out a few points and you are not going to be interested at the end of the day. Whereas if you are talking to a group of people and you are giving them information they need and anything that needs to be discussed is done here with the midwife.*
- LP: *So I think from a time point of view, like we see the patients until 1pm, these people don't want to be sitting the whole day waiting for the midwife. But during this Opt-out, the minute they finish they come to your room. You give them a consent form and you ask them if there are any of the tests they don't want and they would*

*say: "I don't want HIV or I don't want that." That is a refusal. It is not time consuming and much more economical in terms of time.*

This finding that significant time is saved in the process validates the midwives' opinion that the Opt-out approach saves time. Opt-out decreased the time spent on consultation and only one staff member was needed per day to coordinate the information sessions, thus this finding correlates with similar findings from a Zimbabwean study where Opt-out testing was also shown to decrease the burden on human resources <sup>68</sup>.

(Although the introduction of Opt-out testing resulted in a shorter total clinic time, the average visit time was still long. An incidental finding was found to be the delay caused by the waiting time for ultrasound service. The average waiting time for ultrasound was 1, 5 hours. An additional ultrasound service has subsequently been added to the antenatal service and has increased the overall clinic efficiency.)

#### **5.4.3 The influence of the testing approach on HIV prevalence & who is tested**

Research suggests that women who decline VCT are at greater risk of being infected with HIV and other sexually transmitted infections.<sup>36,61,51,50</sup> This study supports this view in that the total HIV prevalence at the clinics was shown to increase with the introduction of Opt-out testing with the prevalence being 9% during VCT and 15% during Opt-out ( $p < 0.05$ ).

Importantly the 9% prevalence during VCT was a stable figure that did not change prior to the study period. This indicates that a significant new number of HIV positive ("at risk") women were being identified with the Opt-out approach. The uptake of VCT during the study was 89, 3%, but compared to the uptake of Opt-out was 99% a statistically significant difference ( $p < 0.001$ ). (Interestingly, one would not expect that the prevalence would differ by as much as 6% given that only a 10 % increase in the uptake of testing occurred).

Unfortunately not all the women who participated in the study tested for HIV at McCord, as some participants had been tested at other sites. Therefore, measuring the prevalence of the

sub-group of patients who tested at McCord would more accurately reflect the prevalence impact of each testing approach. This measurement showed the population prevalence for each group was 7, 33% during VCT and 12, 6% during Opt-out ( $p=0.13$ ). Chandisarewa, Stranix-Chibanda & Chipara <sup>68</sup> reported similar findings when the population prevalence in a Zimbabwean cohort increased from 16.8% during VCT to 20.4% during Opt-out testing ( $p<0.001$ ).

Thus, Opt-out testing is a sensitive testing approach that is able to identify individuals who are at increased risk of HIV infection but would otherwise have declined VCT. The routine availability of testing to a high risk population is an effective way of avoiding late testing.<sup>44</sup> Given the importance of scaling up PMTCT coverage and addressing the issue of maternal deaths in South Africa, this attribute of the Opt-out approach is very valuable.

## **5.5 How patients evaluated and experienced the testing approaches**

This topic will be discussed according to the findings of the questionnaire, the patient- and staff interviews and relevant literature.

### **5.5.1 Possible Coercive Aspects of Testing**

Participants were asked to indicate if they were aware that they had been counselled to test for HIV. Participants had to indicate if they had agreed to a test or not in the question: “Were you counselled for an HIV test today?” (Appendix 2). There was a statistically significant difference ( $p=0.002$ ), between VCT (98.9%) and Opt-out (87, 3%) although the majority of participants affirmed that they were counselled for an HIV test. This finding is consistent with the literature that Opt-out testing does somewhat reduce pre-test information and therefore limits informed consent.<sup>12,11,15</sup> However, during the interviews, the majority of participants who experienced Opt-out acknowledged receiving HIV pre-test information.

A limitation to this finding can be found in the use of the word “counselled” in the Opt-out questionnaire. The word used should rather have been: “Were you given

information/education on testing for HIV today?" For example, during the Opt-out interviews participants would say that they were not counselled, but would remember the group session content clearly. Importantly, the majority (87%) of participants still indicated awareness that this "counselling" took place before they tested. Participants could also indicate what new information they received during the pre-test counselling and information sessions. Therefore the researcher concluded that a decrease in informed consent was present: however it was limited.

Further study is needed to confirm this finding.

#### **5.5.1.1 The Voluntariness of Consent**

Participants were asked to indicate if they consented to having an HIV test on the booking visit. This finding would also indicate if patients were coerced into testing.

The questionnaire results (87% during VCT and 85% during Opt-out) showed no statistical difference between groups and indicated that the majority of participants in both groups were aware of consenting to having an HIV test. This finding demonstrated that both groups reacted similarly ( $p=0,679$ ). This disproves the arguments of certain authors who claim that the Opt-out approach significantly diminishes informed consent.<sup>12,11</sup> Instead, findings proving the acceptability of the Opt-out approach are validated.<sup>68,69</sup>

#### **5.5.1.2 The testing approach and informed consent**

The Opt-out testing approach informs patients that an HIV test is routinely done, unless they decline. Critics of Opt-out testing have cautioned that this way of obtaining consent might result in patients being "coerced" into testing without being fully informed of the implications of an HIV test.<sup>15,12,11</sup> This study has found that patients are informed and aware of consenting to test during the Opt-out approach. De Zulueta & Boulton <sup>15</sup> reported that, through routinely recommending an HIV test, consent is still obtained in a coercive manner as it gives patients the impression that they cannot decline. VCT does not recommend HIV testing as such. It is

designed to give HIV-related information after which patients are invited to test. Therefore the impact of the Opt-out approach on informed consent must briefly be discussed.

Medical legal experts agree that it's the doctor's responsibility to inform patients of risks, benefits, limitations and alternatives to make a true choice on tests and treatment.<sup>72,47,71</sup>

Modern medical ethics has seen the doctor-patient relationship develop from a "traditionally paternalistic philosophy" to a "partnership relationship" between the medical practitioner and patient.<sup>77</sup> The modern Family Medicine description of the doctor-patient relationship is a "therapeutic alliance" in which both the doctor and patient share the responsibility of the decision-making process.

"True informed consent is more than a signature on a piece of paper. True informed consent involves helping patients make an informed choice through shared decision making."<sup>72</sup>

The model of shared decision making has been shown to improve adherence, improve patient satisfaction and lead to better health outcomes.<sup>72</sup> The nature of the shared decision-making process allows for patients not only to be informed of the "objective facts" that are important to know before a decision is made, but also allows the health care worker to express a professional opinion about any specific route of action that would lead to the best possible health outcome. The findings of this study validates this approach as patients who underwent Opt-out testing were found to be informed of the implications of an HIV test and were found to feel less anxiety during the test, perhaps because it was integrated into routine care, rather than exceptionalised. (The emotional outcomes of the study will be discussed later in this chapter). Chandisarewa, Stranix-Chibanda & Chirapa<sup>68</sup> demonstrated that more patients accessed PMTCT care and more were retained in antenatal and postnatal care during Opt-out than during VCT.

Significantly, De Zulueta & Boulton<sup>15</sup>, in a study of the impact of Opt-out testing on informed consent, reported that the pregnant women did not meet the full criteria of informed consent before they tested. Twenty percent of the women did not know that they had been tested for

HIV. However, in this study women were not given a pre-test information session prior to testing. This result highlights the fact that general pre-test information session is crucial to obtaining informed consent in Opt-out testing.

Should an HIV test then be *recommended* as part of routine care, as opposed to “offered”, like an optional extra?

The transmission of HIV infection to a baby is preventable with adequate, early treatment<sup>73</sup>.

Women who test early will not only have access to such PMTCT-treatment but also themselves benefit from better care.<sup>78</sup> Adequate antiretroviral treatment has been made widely available in South Africa since 2004. The new national PMTCT policy has been expanded to include dual therapy with AZT, thereby enhancing the success of PMTCT care.<sup>14</sup> In the light of this, it is clear that for a medical professional to *not* recommend HIV testing can infringe on a patient’s rights. It has been suggested by a senior medico-legal expert in South Africa, that to neglect recommending an HIV test can be viewed as infringing patients’ rights as beneficence, and non-maleficence would be limited.<sup>47</sup> This means that doctors who do not routinely recommend an HIV test during pregnancy are not meeting their medical obligation to pregnant women and their babies. Thus, the routine recommendation of a test is an essential step in the shared decision-making process and should not be seen as coercion.

The implication of being diagnosed with a dread disease such as HIV/AIDS often has drastic implications for a patient. However the negative impact of a HIV/AIDS diagnosis is outweighed by that, with the knowledge of their HIV status, pregnant women can access life-saving treatment for themselves and their babies.<sup>47,4</sup>

### **5.5.2 HIV testing experiences and educating about HIV**

Participants were questioned about previous HIV testing experiences and education regarding HIV. They had to indicate:

- whether they had been HIV counselled;

- how many times had they been counselled; and
- where had they gained information about HIV.

These questions aimed at gaining insights regarding HIV testing history and level of knowledge.

There was no difference in results between groups ( $p= 0.433$ ) in responding to this question with 61.1% (55/90) of VCT participants, and 55.7% (68/122) during Opt-out indicating they had been counselled for an HIV test previously. It is significant that the majority of participants in each group had been counselled before. Most (43.2% with VCT and 47.1 % with Opt-out) were counselled at least once before, with a smaller percentage (35.8% with VCT and 26.2% with Opt-out) having been counselled more than once before.

More Africans (68%) than participants of other ethnicities (50.4%) indicated that they had been counselled on prior occasions ( $p= 0.10$ ). The majority of African participants (36%) had in fact been counselled 2-3 times before with  $p < 0.05$  compared to other ethnicities. This finding is important and its impact on future testing behaviour, health behaviour and informed consent is discussed later in this section.

Although most participants indicated that television, radio and magazines are their main sources of HIV information, health care workers have an important role in educating the public with 30% of patients indicating that this was a source of information for them.

Therefore the time spent at an antenatal clinic *is* an educational opportunity. It has been shown that during pregnancy, women are more motivated to receive health related information.<sup>79</sup> Therefore this is an ideal “teachable moment” in which essential public health education can take place.

#### 5.5.2.1.1 The impact of past testing experiences and education on informed consent

It would appear from studies that in settings where HIV testing is offered routinely, women are aware in advance that a test will be offered when they book for care.<sup>80</sup> In contrast,

patients in a large London hospital were unaware and uninformed of the reasons for HIV testing in pregnancy despite testing being offered routinely.<sup>15</sup>

More than 50% of patients acknowledged that they had been counselled to test for HIV on previous occasions prior to their antenatal booking visit. In the whole cohort more than 40% had been counselled once before with another third indicating they had been counselled twice before. Moreover, 77% of participants indicated, during the in depth interviews, that they arrived at the antenatal clinic intending a specific testing choice for example, intending to agree or intending to decline an HIV test, even before they had been offered a test (McCord antenatal as been offering HIV testing routinely for at least 5 years).

These findings are consistent with work done in antenatal populations for example, in the UK where HIV tests are offered routinely. Sherr, Bergenstrom & Hudson<sup>80</sup> reported that 77% of women who attended 4 antenatal clinics in London believed they would be offered an HIV test at first booking. The findings contrast with the findings of De Zulueta & Boulton<sup>15</sup> where pregnant women seemed unaware that an HIV test would be offered at their booking visit.

This study supports the finding that most women knew that an HIV test would be offered at the first booking visit.<sup>80</sup> This finding is significant as awareness that a test would be offered presents the “ideal conditions” in which true informed consent can be obtained. Patients have had time (between the group information session and the consultation with the midwife) to consider their decision to accept or decline testing. In the interviews with staff this finding was confirmed:

- JL: *Opt out gives a client more time to think, because we do them individually as well, not like when she is coming in here, now you are counselling her and now you want her to test at the same time. It gives more time so that when she is from there she goes back to register and she is still thinking about this and it depends on the way how you put it.*



- JL: *I mean, probably they know now that being HIV positive is not a death sentence. They hear it on radio and everywhere. In fact they are beginning to accept that they have to test. So that is why they are comfortable. They know they are not the first ones.*

This finding conflicts with the argument that by shortening the pre-test information-giving phase as Opt-out testing does, patients are being “coerced” into testing due to not having enough time to reflect <sup>47,12,11</sup>.

However, on further analysis of the interviews, a smaller percentage of women (13%), though aware that a test would be offered, did not have a clear intention to test or not. In these cases the pre-test counselling/information could possibly influence testing behaviour.

It is important to establish to what extent pre-test information influences behaviour.

### **5.5.3 The impact of the information given during HIV testing on patient behaviour**

The information value that participants received with each of the testing approaches needed to be compared. In addition it was important to see if the amount of knowledge participants acquire during pre-test counselling influenced their decision to test for HIV or not. The value of pre-test information will be discussed according to:

- the impact it has on educating patients about HIV;
- the impact on testing behaviour; and
- the impact on modifying high risk behaviour.

#### **5.5.3.1 The educational impact of pre-test information**

There was a statistically different response to this question (*Did you learn anything new in the counselling session?*) with more respondents feeling that they had learnt something new during VCT (94,3%) than during Opt-out (64,5%) with  $p < 0.001$ .

Importantly, this finding highlights the strength of one-on-one VCT. When individual counselling takes place patients are able to gain more new HIV knowledge from the counselling session. A group session limits patients’ access to specific information in the

context of a general information package (which is not all HIV related). However, patients may have interpreted the question to mean new “HIV-related knowledge” and thus, this could be seen as a potential limitation when interpreting the result.

It was expected that people with a higher level of education would gain less knowledge than people with less education. This was confirmed on further analysis, but the outcome was not statistically significant with  $p=0.64$ . There was no correlation between ethnicity and whether patients felt they had learnt anything new.

Age influenced the response to this question with older women (average=27yr) indicating that they had not learned anything compared to younger women (average 22=yr) ( $p<0.001$ ).

Question 4: *What did you learn in the counselling session?* (Appendix 2). The responses between VCT and Opt-out were not statistically significant with  $p=0.052$ . However, given this borderline result, the differences need to be discussed in more detail.

The groups responded similarly regarding gaining knowledge about HIV information and transmission (VCT = 24% and Opt-out =22%). Empowerment/Importance of knowing your status indicated a bigger difference between groups with VCT =21% and Opt-out 29%.

Interestingly, the results reveal that VCT content focuses largely on the impact of HIV during pregnancy with 39% compared to 19% during Opt-out.

The amount of information on the role HIV in pregnancy was less in the group information session, and therefore participants who experienced Opt-out did not indicate learning new information about this. The knowledge participants identified during Opt-out was about being influenced in their health behaviour and changing their attitude to HIV infection (30%) compared to 16% in VCT.

These differences in responses could be accounted for by the differences between the content of the information session and the content of the pre-test counselling. The group information session was designed to cover routine antenatal care, general information about pregnancy

and all the blood tests. VCT pre-test counselling focuses on the impact of HIV during pregnancy. Thus, Opt-out testing has led to balanced education of patients with knowledge acquisition of not only HIV in pregnancy, but also of how participants respond to HIV diagnosis and the importance of the health of the mother with HIV infection.

The non-exceptionalized presentation of the HIV test as “just another medical condition” that has to be excluded in pregnancy, accounts for the participants’ acknowledgement of attitudinal/behavioural change towards HIV. This finding was supported by the findings from the in depth interviews. The influence of the testing approach on patients’ attitudes is discussed at length later in this chapter.

This finding indicates that the group information session in Opt-out may be more effective to make women aware of the importance of caring for their own health and not only the health of their babies. It has been reported that the health of the mother is closely and significantly connected to the health of the baby.<sup>14,78</sup>

#### 5.5.3.1.1 The impact of pre-test information on testing behaviour

Interestingly, despite the history of previous HIV testing, the majority of the women (during both testing approaches) indicated that they did indeed learn something new during HIV testing counselling and even indicated specifically what new knowledge they gained.

In the light of their extensive counselling history, this finding could indicate one of two things:

- That patients do not retain what they hear in the counselling sessions and/or,
- That not all pre-test counselling is of a good standard and quality.<sup>55</sup>

This finding indicates that the amount of new knowledge gained does not necessarily lead to women choosing to test. A review of the literature shows conflicting findings regarding testing behaviour. In an antenatal survey conducted in Zimbabwe, it was found that neither knowledge nor previous pre-test counselling influence pregnant women’s decisions to test.<sup>69</sup>

This conflicts with other work done in Zimbabwe where it was found that education and knowledge are the biggest predictors of testing behaviour.<sup>55</sup>

These findings (that women still acquired new HIV related information despite having an extensive history of prior counselling experiences) do seem to indicate that there are other influencing factors rather than “amount of HIV related information” when designing an effective HIV testing approach. The researcher finds no evidence of a correlation between the amount of knowledge gained and testing behaviour as more subjects chose to test during Opt-out where information was limited to basics. If then the quantity of pre-test information does not influence testing behaviour, is it important to retain the pre-test information in order to promote low risk health behaviour? What is the impact of pre-test information on high risk health behaviour?

#### **5.5.3.2 Pre-test information and high risk health behaviour**

Advocates of VCT argue that extensive pre-test counselling is still important to promote less risky health behaviour, for example, having unprotected sex.<sup>12,22</sup> Moreover, one of the main objections against using a testing approach with reduced pre-test information (for example Opt-out testing), has been that the promotion of low risk behaviour is lost due to limited information being given to patients.

However, the literature has consistently shown that pre-test counselling has little effect on future risky sexual behaviour especially if the patient tests negative.<sup>55-57</sup> These studies have found that HIV knowledge impacts on neither risky behaviour nor HIV incidence. Therefore, the relevance of promoting VCT as a means of providing comprehensive HIV related information is questionable.

#### **5.5.4 The emotional impact of the testing approach- How subjective factors influence testing behaviour**

##### **5.5.4.1 Emotional experiences during HIV testing**

A positive emotional testing experience can be interpreted as a proxy indicator of acceptability. It is clear from the literature that very little is known about how patients experience HIV testing. Some authors have argued that VCT could act as an artificial barrier to accessing the HIV test.<sup>4</sup> Few studies, using qualitative means, have assessed the acceptability of Opt-out testing to patients and staff.<sup>68,69,64</sup> Testing approaches cannot be recommended without proper understanding of the emotional experiences patients have when testing for HIV.<sup>12</sup> Therefore, a study question was included to evaluate the emotional experiences of the women as they underwent testing.

There was a statistically significant difference between VCT and Opt-out when the groups are compared. More participants reported positive and neutral emotions during the Opt-out testing approach ( $p < 0.05$ ).

It appears from this outcome that VCT evokes extremes of emotion with most patients either experiencing feelings of “fear or anxiety” or feelings of “happiness/positive feelings”. In contrast to these findings, the majority of participants experienced Opt-out testing as “Normal”, “calm”, “aware” and “informed.” In addition, a smaller group of women (than with VCT) acknowledged feeling “Happy or Positive” and some felt “scared/nervous” during Opt-out. The in-depth interviews reflected similar emotional reactions. Below are some quotes that indicate how participants responded emotionally to the counselling and testing:

#### **VCT**

Two patients verbalized feeling terrified in the counselling session and were unsure when they were confronted with the choice to testing.

- Participant no 6 said that there was a *“ringing in her ears”* and couldn’t concentrate while she was being counselled. She verbalized being *“very, very scared.”*
- Participants 6 and 7 felt that the HIV test was compulsory. Interestingly, these two participants had negative emotional experiences that could be directly connected with a specific question unique to pre-test counselling: *“How would you feel if you tested positive?”* Participant 6 related in the interview that her response to the above question was: *“You know I, I don’t know, but I can be very angry for myself, and maybe I can kill myself.”*

Almost all the VCT participants felt a degree of fear/apprehension when they were given the VCT pre-test counselling the first time, however 7 participants indicated feeling less fearful when they received their results. These participants also agreed that they had found the counselling to be acceptable.

#### **Opt-out**

- Participant 5: *I didn’t feel like I was going for an HIV test. She kept talking to us and explaining to us and while she was talking she was explaining the charts and talking to us normally*
- Participant 6: *Normal, just like when somebody wants to teach you about something, or advice or something. They were willing to hear you speaking.*
- Participant 8: *I felt that it was just information and it was very good.*

Patients in both VCT and Opt-out indicated that they had found the testing approaches to be acceptable, however, two participants during VCT reacted with extremes of negative emotion during their pre-test counselling sessions of VCT after the question: *“How would you feel if you test positive today?”* This question is included as part of many standardized VCT questionnaires.<sup>40</sup> In the latest version of the Health Professions Council of South Africa’s ethical guide to HIV testing it is made clear that prior to testing, patients must contemplate the psychosocial impact a positive test would have. The study shows that specifically this

element in VCT pre-test counselling evoked extreme emotional reactions in these two patients (22%) in contrast to no such reactions in the Opt-out interview participants.

Participants during the Opt-out phase were more neutral in their description of the testing experiences despite being tested and found to be positive.

Emotional stability during counselling is an important indicator of acceptability. It can be concluded from all the data that Opt-out is emotionally less distressing to patients than VCT.

It is important to consider how the subjective (emotional) context influences women's testing choices. The subjective context is informed by the emotional context of the patient and the attitude with which the testing approach is presented.

#### **5.5.4.2 The influence of the subjective context on testing choice**

Research has shown that younger patients are "highly attuned" to healthcare worker's attitudes toward them and that: "patients are more likely to seek out and follow-through with HIV testing at services that they perceive to be non-threatening, non-judgmental and responsive to their individual needs and circumstances."<sup>81</sup>

The questionnaire addressed women's emotional experiences of the testing by asking them to indicate how they felt during the counselling. More respondents felt extremes of emotions during VCT (Anxious and very happy) compared to people feeling neutral and informed during Opt-out  $p > 0.05$ .

In addition, it was clear during the interviews that women did not always base their decisions to test on the information given at the clinic, but on subjective influences. These subjective factors related to personal circumstances and to how they felt emotionally during the counselling. Consider the following story from a patient who initially declined VCT because she felt afraid:

- Participant 7 indicated during the interview that she declined testing at first, when she was asked the question: "*How would you feel if you tested positive*"

*today?" She related feeling scared: "They said you must take a blood test, and I refused because I was afraid." She decided to return on the following visit and agreed to be tested then. She said that she realized after she left on the first occasion, that testing was in the best interest of the baby. She said: "I counselled myself." On a return visit she was asked again how she would feel if she tested positive she responded: "Hey, I can do nothing. I can accept it." And when the test turned out to be positive, the patient said: "Ok, its fine." But: "She (the nurse) didn't believe me." (That she was fine).*

The emotional atmosphere a testing approach creates is often what influences the decision to test. If patients feel threatened it is unlikely that they will proceed with a test.

This finding is consistent with a study in Uganda that found that one of the major reasons patients declined with VCT is because they fear the negative consequences of the test<sup>82</sup>. Thus, by requiring that patients consider the negative outcomes of a test before they are diagnosed leads to an emotional reaction that could result in them declining the test.

Patients and staff indicated that the Opt-out testing approach makes patients more at ease when HIV information is given. They indicate two reasons for this reaction.

- The routine offer of information in groups.
- The non-exceptionalized (normalized) way in which HIV is included in a general antenatal health talk.

Consider the following quotes from participants who experienced Opt-out testing:

- Participant 8: *I felt it was just information and it was very good. I only realized it's a good way of counselling people because sometimes - the horror when counselled on your own, because actually you feel that "maybe I have the disease she's talking about.*



- Participant 8 revealed in the interview that she used to decline the HIV test on prior occasions (VCT). Most significantly, when asked why she agreed after Opt-out she said: *I don't know, but this time I felt I had to take it. That I had no choice- I'm a pregnant woman. Yeah, because now that I have a better understanding. Its better if I find out earlier than later.*
- Participant 5: *I didn't feel like I was going for an HIV test. She kept talking to us and explaining to us and while she was talking she was explaining the charts and talking to us normally*

These findings are further validated when some of the findings in the staff interviews are considered:

- JH: *Another good thing is that it is no longer common to find people who refuse to test because it is done in a group and everybody is there and they can see that everybody sees that everybody did not object during the session. There are no longer people who are afraid to do the test.*
- LP: *Well we are taking in a lot of people. We take a group of people and we tell them what is HIV and we tell them what is syphilis and we are going to do these blood tests on you. What is Rhesus factor and the reason why we are doing these tests is explained. Why are we doing HIV/AIDS? Because if you are positive, we can help you prevent transmission to your baby. So everything is explained nicely in that Opt-out session to them. So when you are grouped together like that, not making it special, like 'come I want to talk to you quietly about HIV.*
- PL: *O.K. from the time I came to the clinic, and I started and I observed the Opt-out and then I said to myself, I think it is a good idea, why because you are talking to a group of people and you are including HIV. You are not saying, 'listen you are doing your pre-test and your post-test and 'and then they become more anxious. It is more friendly. It is more giving you information. This is what we do and these are tests we*

*are doing. So it is more informative and if you function as a group they feel more included and not isolated. So I feel there is big advantage and patients are encouraged to do the test and we haven't had anyone that has refused.*

It can be concluded that Opt-out testing leads to an increased uptake of testing because it is emotionally neutral approach that normalizes HIV testing. This finding is validated by work done by Blake, Jones, Reid & Kosowski <sup>83</sup> who found that patients are more likely to access and stay in care if they perceive health care providers to be supportive and non-judgmental. Several studies report on the increased uptake of testing when the Opt-out approach is used.<sup>68,10,64,17</sup> Researchers in a Zimbabwean study on Opt-out testing <sup>68</sup> , reported that in their study more patients were tested, more accessed PMTCT care, more remained in antenatal care and more attended post-natal follow-up than during VCT. This finding also supports the literature that an exceptionalized approach to HIV testing could act as a barrier to patients who need to be tested for HIV.<sup>3,4,2,35</sup>

#### **5.5.5 The influence of the testing approach on attitudes and beliefs**

The influence the testing approaches had on the attitudes and beliefs of patients and staff can be summarized into four themes. These themes were prominent during the analysis of the questionnaires, in-depth interviews and focus groups:

- The perceived need of repeated pre-test counselling;
- The perceived need for pregnant women to know their status;
- The perceived need to disclose HIV status to partners; and
- How patients accepted their HIV status.

##### **5.5.5.1 Perceived need for repeated pre-test counselling**

Before the findings regarding the need for repeated counselling is discussed, it is important to understand how participants used and seemed to understand, the term “counselling.” It was clear during the in-depth interviews that participants may or may not view the pre-test information session of Opt-out as “counselling.” Moreover, participants often did not

distinguish between pre-test and post-test counselling and referred to all kinds of counselling and information related to HIV as “counselling”. It was often only possible to define what part of the testing process participants referred to by determining where in the testing process, the subjects’ comments originated from. For example:

- Participant 1 (Opt-out): *After the counselling and, oh after the counselling there is a lot of changes, there is a lot of things that the sisters told me about positive people about how they live and so on, and I’ve always seen the people with HIV, they’re still alive, they’re happy, they do everything. They’re okay. They live longer, if they use the safe sex, like even condom, so I know that I can still live long. Because if I’m HIV like and you, having Diabetes, cancer and all; cancer, Diabetes and AIDS one and the same thing. Because there is no cure (for them.) So, I am free now.*

The above statement refers to post-test counselling as the content of the participant’s originates from the content of post-test counselling. Similarly in other places subjects referred to the pre-test session as being “counselled.”

This broad understanding of the word “counselled,” is important to take cognizance of. Therefore, when subjects say they would like to be counselled for HIV in the future, they may not mean formally pre- test counselled, but given information of some kind, or maybe even just informed that they are being tested. Thus, in the following discussion on the need for repeated counselling, the researcher will refer to counselled/given information as if they are interchangeable terms.

(Problems with using the word “counselled” in the study questions are discussed later in the chapter.)

The respondents were asked if they would like to be counselled every time they have an HIV test. In a future study it would be important to define this term more clearly to participants, or use a different word. The reason the question was asked was to assess whether

participants want to be formally pre-test counselled, every time they are tested, given the current reality in South Africa, where pre-test counselling is required every time a person tests, which may be repeatedly. The responses would also indicate how acceptable participants found the two testing approaches. In both groups the majority of participants (60.7% during the VCT group and 52.9% during Opt-out group) indicated that they would prefer not to be counselled/given information again with  $p < 0.305$ . It is significant that the majority of participants did not want to be re-counselled every time they tested.

However, there were still a significant number of participants who preferred to be counselled/ given information again (39.3% with VCT and with 47.1% Opt-out). Therefore it was important to understand the differences between those who wanted repeated counselling and those who did not.

When the answers of all ethnic groups were added collated and compared, one group (African patients) indicated a significant difference with  $p=0.018$ . Interestingly, patients of African ethnicity comprised 51.9% of participants who wanted to be counselled again and the other ethnicities together comprised 34.6%. This indicates that Africans as a sub group preferred repeated counselling /given information. Why would these participants feel they required repeated counselling?

One could argue that participants, who preferred repeated counselling, perceived themselves to be more at risk of HIV infection. However, such a finding is unlikely. Several studies have found that self-perceived risk is a poor indicator of testing behaviour<sup>55,69,56,60</sup>. The majority of African patients also indicated that they had been pre-test counselled on prior occasions ( $p=0.10$ ). Significantly, a third of Africans (36%) indicated having had 2-3 previous pre-test counselling experiences ( $p<0.05$ ). Therefore this finding is probably not related to African ethnicity, but rather to having a history of HIV tests on previous occasions.

This finding is consistent with a study done in Malawi that found that patients who request repeat VCT are often those who had VCT previously. The patients who do not seek repeated testing are those who had never tested before.<sup>56</sup>

Given the findings of this question, repeated pre-test counselling/information should still be regarded as an important step in the HIV testing process. This finding supports World Health Organization recommendations that the only way in which PMTCT coverage can effectively be expanded, is through the routine offer of HIV testing to high risk populations, with patients being clearly informed that they are being tested.<sup>44</sup>

#### **5.5.5.2 Perceived need to know HIV status**

Undiagnosed, untreated HIV during pregnancy is a major cause of maternal deaths in South Africa<sup>27</sup>. While pre-test information during pregnancy usually focuses on the protection of the baby through PMTCT, there has been less focus on making women aware of the importance of their own health to ensure good pregnancy outcomes. Authors like Basset<sup>35</sup> have aptly asked: “Where is the ‘M’ in ‘PMTCT’?” The long-term survival of babies is intrinsically linked to the health of their mothers.<sup>78</sup> At present, evidence suggests that assisting HIV positive women to access care after delivery is the gateway to providing holistic sustainable family care.<sup>84,44</sup> This study also included questions about the attitudes and beliefs regarding knowing one’s HIV status during pregnancy. These responses reflect what messages healthcare providers have been giving their patients in the antenatal setting.

The majority of participants (VCT = 100% and Opt-out 92.8%) agreed that pregnant women should know their HIV status ( $p < 0.05$ ). Given the extent of comprehensive VCT pre-test counselling and the reduced HIV-related content of the Opt-out group information session, this significant difference between groups was not surprising. However, although there were differences, even in the Opt-out group, >90% of women had got the message.

The reasons given for pregnant women knowing their HIV status (Figure 14 and Figure 15) affirmed that the main message pregnant women receive in VCT pre-test counselling, is to

protect the health of the baby(78% with VCT and 58% with Opt-out). This theme emerged throughout the analysis of the different data collection methods.

However, in comparison to the major differences between groups in the questionnaire, all the participants (Opt-out and VCT) in the interviews agreed that knowing their HIV status was important in order to protect the baby from infection. The following responses indicate how women have been educated regarding the importance of testing during pregnancy:

- Participant 7: *Ooh- It is very important! I can't, it is very important to know their status because of the baby. I don't care about the moms; I care about the baby. (VCT)*
- Participant 5: *Because it is important for yourself, it is especially important for the baby. Yeah, it's very important because you can save another person's life instead of yours, because that's important. (VCT)*
- Participant 4: *Yeah, I think it's important to know because of the sake of the baby. You have to know and deal because life is one lesson.(Opt-out).*

In addition, the staff members who participated in the focus groups also indicated that protecting the infant was the main reason why pregnant women should know their HIV status.

The message that the “health of the mother” is important and seems to reach patients better during Opt-out testing (With Opt-out 9% compared to 1% with VCT), however even with Opt-out, the overarching theme was still the health of the baby. This difference between the groups can be ascribed to having different content in the two testing approaches. It would be interesting if this theme emerges at other sites where similar research is conducted.

Although “protecting the baby from HIV infection” is without doubt, a powerful reason for pregnant women to test, the finding of only 10% of women in the total study population who answered correctly, about own health being important, highlights the lack of information given to women about the importance of knowing their HIV status for the sake of their own

health. This is a significant finding. It highlights the importance of women knowing their status early in order to have healthy pregnancy outcomes not only for their babies, but also for themselves. It could also be seen as a contributing factor as to why so few HIV positive mothers link to care after delivery.

#### **5.5.5.3 Perceived need to disclose status to partner**

This theme emerged during the in-depth interviews with patients and was not directly related to acceptability of HIV testing approaches. However, it does reflect how education regarding disclosure during the testing influenced women's attitudes and beliefs. The literature indicates that pre-test counselling does not always influence health behaviour positively.<sup>1</sup>

Without exception all the patients (VCT and Opt-out) indicated that pregnant women ought to disclose their HIV status to their partners. Yet when asked if they had disclosed their status, few had actually done so:

- Participant 2: *He's a man. He's a man who always speaks his rights, you know." She was worried he would blame her: "He told me "oh no, I don't have that thing; I don't have AIDS. If I do have it then I can kill somebody." 'Cause the only thing he believes is that we are the women, the females, we are the ones who transmit this thing. So if he finds out I am HIV positive... (VCT)*
- Participant 1: *It's important (to inform your partner) because maybe my partner is negative and I am positive...sometimes the Zulu's don't understand if I'm positive, he will think that maybe I'm the one who carried that virus, he may think that I'm the one who gave it to him... (Opt-out)*

Disclosure is a major obstacle for HIV positive pregnant women to overcome.<sup>11</sup> Often the fear of disclosing is far worse than the consequences of disclosure.<sup>36</sup> Thus, it was found with both testing approaches, that patients are educated about the need to disclose, but that the pre-test counselling did not always lead to the act of disclosure.

### 5.5.6 The testing approach and the impact of acceptance of HIV status

The theme of acceptance of HIV status emerged strongly during the in-depth interviews with patients, and during the staff interviews.

In the past, VCT- pre-test counselling was intended to prepare HIV positive patients for the result when they first tested in a time where ART was not easily available.<sup>12,2</sup> Moreover, VCT was intended to shield patients from the trauma of a positive diagnosis and the subsequent stigma they would have to face. Proponents of VCT argue that comprehensive pre-test counselling protects patients who are found to be HIV infected from negative experiences after testing.<sup>11</sup> Objections to the use of Opt-out testing is often that patients may be victims of negative life events if they are found to be positive and were not properly emotionally prepared for the result.<sup>12,52,11</sup> However, preliminary work has found that patients find Opt-out testing acceptable with little evidence that events after diagnosis of HIV are worse or better than after diagnosis through VCT.<sup>68,67,69</sup> Thus, the reaction of patients to their status was examined in the light of this literature.

Participants who were diagnosed HIV positive during pregnancy all described being upset or distressed at the time of diagnosis. However, all of them felt less distressed about the diagnosis after some time had passed. Consider some of the responses from participants:

- Participant 2: *I have accepted it, but I hide it at times.*(VCT)
- Participant 3: *It is painful to go through, but everyone must face it at some time.*  
(Opt-out)
- Participant 1: *Yes it is very scary. It's painful. I thought it's painful to get a result, "you're positive" but now it is no problem. I'm relaxed.* (VCT)
- Participant 3: *It is painful to go through, but everyone must face it at some time.*(VCT)
- Participant 4: *When I get tested I feel scared before I knew the results- now I'm fine.* (VCT)



- Participant 1: *Yes it is very scary. It's painful. I thought it's painful to get a result, "you're positive" but now it is no problem. I'm relaxed. (Opt-out)*

Significantly, the women indicated that it was the information and support they received during the post-test counselling period that helped them come to terms with their status. This theme also emerged during the groups and interviews with the antenatal staff.

During the initial focus group session, prior to the introduction of Opt-out, staff expressed concern that women will not be adequately, emotionally prepared to be tested:

- JK: *It's important to ask patients how they would feel should they test positive before you test them.*
- JK: *Patients accept their status when they have had good counselling and when they know there is treatment available.*

What became clear during the first focus group discussion was that the staff supported VCT, as the extensive pre-test counselling allowed for a good rapport with the patient and this helped them to gauge how a particular patient would respond to a positive result:

- JK: *VCT is our safety blanket. We feel "naked" if we have to test patients without it.*

During the second focus group discussion and the follow-up interviews (during Opt-out testing); it was evident that the above perception had changed. All the staff indicated during the interviews that the change in testing approach from VCT to Opt-out, did not lead to women having increased negative experiences after testing:

- LP: *Well that doesn't make any difference whether it is Opt-out testing or VCT. The patient is still given time concerns. So if they are positive, whether it is VCT or Opt-out, it doesn't really make any difference, they remain positive, because you are not twisting anybody's arm. Your job is going to come as a midwife. They come to you and you have to talk to them more about everything and about their fears and all*

*that. You know even though we are not only doing HIV counselling, we supply information. That is what pre-test counselling is all about, information, education and that sort of thing. So when a patient tests, they have, in a way been pre-test counselled because they have been given information and they have been told all about it and what will happen if they are positive and what will happen if they are negative. At that stage you have got to counsel. You know we get different people and the whole attitude towards HIV, I find, of late, when you say, 'Were you shocked?' They will say, 'Oh you know 88% of people have it in South Africa and I am having sex. I can't be shocked. Then you get another lady. The other day she was almost hysterical, trying to give her sugar water. She couldn't even hold it. I mean she was so shocked. So I don't think whether it is VCT or Opt-out, if it will not make any difference. Even with VCT a woman can leave here and throw herself into a truck on the road. Then you cannot let that person ever go but it is the same thing if you are doing Opt-out, you have to inform them and then they are post-test counselled.*

- *PL: I don't think so. I don't think it makes any difference. Speaking from my own experience I have heard patients that have tested positive. Every person is individual and I think you can't say, because it is Opt-out it is going to affect the way the patient reacts because at that time the patient is coming to terms. So no matter what you said then (during pre-test counselling) and how you said it is not going to make a difference. The point is that they think it is the end of the world. So I don't think it has an effect.*
- *JL: You make sure that they have received the proper post – test counselling so that they can be able to face other clients outside. You take your time really when you see that she is breaking down. So we leave everything, and concentrate on her until you see that at least she is composed and can go out there and face the world. We even pray with her to make her comfortable.*

It was clear from the interviews that it is not pre-test counselling that helps patients deal with an HIV positive diagnosis, *but ongoing post-test counselling*. Opt-out testing similarly can only be effective in the presence of adequate, ongoing post-test counselling. This finding illustrates the significance of effective and ongoing post-test counselling.

#### **5.5.7 Further findings that emerged from staff focus group discussions and interviews**

Although staff members were concerned about the impact of Opt-out testing on their daily clinical routine they agreed to participate. They expressed concern in the first focus group discussion that they themselves would not be sufficiently prepared to test a patient without first counselling them individually. It was clear that staff valued VCT pre-test counselling as a means of preparing themselves to test a patient. In addition they singled out one question that does this best. The question was: *“How would you feel if you tested positive today?”* The staff indicated that this was a key question to prepare staff for patient reaction to a diagnosis, as discussed previously in this chapter. This finding contrasts with emotional experiences (often negative) participants shared when this question was posed to them during VCT as discussed previously in this chapter.

In addition the staff were worried that patients would retain less information after the group information session. They communicated the belief that the pre-test counselling would be more likely to convince patients to test and that less pre-test information as with Opt-out would lead to more people declining the test. Reports from several authors <sup>1, 55</sup>; together with the patients' responses and testing uptake contradict this perception.

The staff indicated that although giving someone a positive diagnosis was always difficult, it had become easier since the availability of antiretrovirals. They said that patients were more prepared to deal with a positive result if they were aware of the available treatment.

After the introduction of Opt-out testing the staff unanimously accepted it as the preferred way of HIV testing. They were satisfied that Opt-out testing was more efficient and that patients found it an acceptable way of testing. Since there was improved uptake of testing

with Opt-out than VCT, they acknowledged that their initial belief in the pre-test VCT counselling was not accurate. But they did emphasise that Opt-out could only be adequate if post-test counselling is effective and ongoing. The reason for this was that they felt patients needed more information about living with HIV, antiretrovirals and PMTCT care once they tested positive.

The follow-up interviews done with the midwives validated that staff found Opt-out an acceptable way of testing pregnant women. The staff verbalized that Opt-out improved clinical efficiency by increasing the testing uptake, by saving time and by saving human resources. They expressed a sense of job-satisfaction as Opt-out testing was helping them identify more infected women who could be offered care.

The staff also indicated that Opt-out gave women the opportunity to reflect on their testing choice as there was a time lapse between the information session and the midwife consultation.

The staff did also indicate some aspects to the approach that they still felt could be improved:

All the staff indicated that the group information session facilitated efficiency and normalizing of HIV testing. Some felt that the group situation also facilitated getting women to open up and ask questions. However, this conflicted with the opinions of one staff member who felt that the groups inhibited patient-responses.

- *PL: I think it is working, number one, time factor, it is quicker. You are able to reach more people and in a short space of time. You can get more interaction, limited though. It is more friendlier and more easier with groups. The disadvantages are that other patients or clients aren't able to verbalize personal issues.*

Staff also found that patients responded positively to the group sessions and therefore the number of patients declining the test decreased.

They indicated that lack of space is sometimes an obstacle when big groups of women are booked on a day. They deal with this problem by breaking the group into smaller groups. They also indicated that despite this, they still prefer Opt-out to VCT.

- PL: *I am feeling nice. It is working. Time has changed. Things could be good, but for now it is O.K. The only problem is space because we have got big groups like today and you have to cut them down into three groups and at times we have to battle in these consulting rooms. It is not too much of a bad thing but we manage.*

VCT is labour intensive and time consuming in resource limited settings.<sup>22,1,35</sup> This burden on health care staff has led to VCT not always being offered in an acceptable way.<sup>85</sup> The focus group and interview findings illustrate that through the decreased demand on staff time, Opt-out has improved not only efficiency, but also staff morale. These findings of improved efficiency and acceptability have been confirmed by other research groups in Botswana<sup>67</sup> and Zimbabwe <sup>68,69</sup>.

The interview findings, contradict arguments by Jürgens <sup>12</sup> and Kippax <sup>11</sup> that women are coerced into HIV testing. Opt-out allows for adequate reflection between the group session and the midwife consultation where the test is done. The need for ongoing post-test counselling and the value that patients get from ongoing post-test counselling is also validated by Maman et al<sup>86</sup>.

## **5.6 Limitations of the study**

### **5.6.1 Method of recruitment for total study population**

One of the limitations of the study design was that VCT and Opt-out could not be measured in tandem/parallel during the same period of time. By comparing the two testing approaches in parallel, the study design would have controlled better for variances in the patient demographics. Unfortunately due to limited human resources and space in the clinic this

design was operationally impossible to implement. Therefore a compromised design was used:

- First by measuring VCT and then
- Opt-out testing.

In reality, it is unlikely that there would have been a lot of variance the comparable demographics findings of each group.

### **5.6.2 Limitation in statistical power of sub-groups**

The sample size and allocated time of the study was powered to finding statistical differences in testing uptake, number of women tested and time duration of each testing approach.

However, the limited sample size in the given time frame, did hinder investigation of the interaction and subgroup analysis. This played a role when the acceptability questionnaire was analysed. Fortunately the data and findings from the qualitative methodology (interviews and focus groups) triangulated well with the subset data and could be presented in this thesis.

### **5.6.3 Missing data**

Not all of the participants completed the questionnaires in full. The missing data did decrease the sample size and could have influenced some of the findings. However this effect is limited as the findings were validated by the other data collection methods.

### **5.6.4 Method of recruitment for In-depth interviews**

It was decided that it might be unethical to interview HIV positive participants immediately after they had discovered their status. Therefore it was decided to recruit participants one week after they had been tested. However this proved difficult to achieve in all participants and some were recruited much later in their antenatal experience. Most patients (16) were recruited during the antenatal period but there were 2 participants who were interviewed 6 weeks after delivery. Therefore the later recruitment of some of the participants must be

seen as a study limitation because of the problem of recall bias with participants perhaps not able to remember the pre-test counselling clearly enough to be able to evaluate it. Fortunately, recall bias was proven to be limited as the interview findings were consistent with findings of the questionnaires and focus groups.

#### **5.6.5 The Phrasing of the questions in the questionnaire**

The use of the word “counselled” in the phrasing of questions in the Opt-out questionnaire and in the Opt-out in-depth interviews was probably not the best term to use. The group information session was not a counselling session per se and moreover, patients might or might not have seen it as being “counselled.” Therefore, it would have been more correct to refer to it as an “information session” rather than “counselling”. It was clear during the in-depth interviews, that though participants indicated that they were not “counselled” for an HIV test during Opt-out testing, they did receive information about HIV in the information session. For example, participants would respond negatively to the question: “Were you counselled for an HIV test today?” But then later during the interview, they would refer to the information given in the group session in a different context with good recall of the contents.

This limitation could account for the significant difference in the response of the Opt-out participants versus the VCT participants where more patients indicated that they were counselled during VCT (89.8%) than during Opt-out (87.3%)  $p=0.002$  (Appendix 2; question 1).

Thus, the result of especially question number two in the questionnaire should be interpreted within the context of this limitation.

#### **5.6.6 The limitations of the data collection method**

During the VCT phase of the study participants were “helped” by the midwives to complete the questionnaires. Given the initial “pro-VCT” attitude of the midwives and given that they were providing the pre-test counselling, their “help” could have influenced the way patients evaluated the testing intervention. For example, if participants were asked how they felt

during the VCT session, they would not give an honest response because the midwife (who did the original counselling) was posing the question. Fortunately, this limitation was discovered early in the first phase of the study and the midwives were asked not to complete the questionnaires on behalf of the participants any longer. Thus the effects of this limitation on the findings should be negligible.

The researcher was the PMTCT clinician during the time of the study period therefore, to avoid introducing bias into the data collection, she did not conduct the patient or staff interviews herself. Staff from the hospital Psychology Department, as well as some volunteers, were trained to do the interviews. Four different interviewers, who were not previously experienced in qualitative research, conducted the in-depth patient interviews. (Their training was discussed in Chapter Three.) This led to differences in the interviewing style and could have created a limitation by compromising the uniformity of approach that is obtained by using one trained and experienced interviewer. However, a trained and experienced field worker was used to do the validation follow-up interviews with staff and these findings strongly supported the first interview and focus group findings. Therefore this limitation does not pose a threat to the findings.

Only participants able to speak English were interviewed, as the interviewers were all English speakers. Participants were not interviewed in Zulu, the first language of some of them. This could also have limited their responses and thus the richness of the data. Fortunately, the findings of the patient interviews triangulate well with the findings of the staff focus groups and questionnaires. Therefore this limitation is less significant than previously anticipated.

In addition, the follow-up interviews with staff by an experienced field worker (who was fluent in Zulu and English) have greatly improved the validity of the findings. The findings of the follow-up interviews were consistent with all of the findings of the other methods of data collection.



## 5.7 Discussion

VCT was designed to protect the individual's human rights by allowing them to be thoroughly educated, informed and "counselled" prior to HIV testing. No other medical disease is diagnosed in this way. This approach to testing has been described as *HIV exceptionalism* <sup>4</sup>. Times have changed and lifesaving anti-retrovirals are now widely available to treat HIV. Effective therapy is available and accessible to prevent the transmission of HIV from infected women to their infants. Thus, there is a need to normalise HIV testing in order to facilitate the diagnosis and treatment of HIV.<sup>5</sup>

The aims of this study were:

- To study the efficiency of Opt-out testing versus VCT, which was assessed by measuring uptake of testing; the time cost; and the number of women diagnosed with HIV.
- To study the acceptability to both patients and staff, of Opt-out testing versus VCT.

### 5.7.1 Efficiency

The uptake of testing increased significantly ( $p < 0.001$ ) during Opt-out testing, thereby proving Opt-out testing has similar benefits in a South African antenatal setting to those demonstrated in international studies. In addition, Opt-out was shown to decrease significantly ( $p < 0.05$ ), the time taken to complete a booking visit. The interviews with staff showed that Opt-out decreased the burden on human resources through time saved and the increased uptake of testing. Only one midwife per day allocated to facilitating the group information session resulted in decreasing the burden of work in the clinic.

Most notably the study demonstrated that the number of HIV diagnoses increased, as a result of the increased uptake of testing<sup>10,16</sup> in the clinic population ( $p < 0.05$ ). This demonstrated that Opt-out testing identifies more high risk women, thereby improving PMTCT coverage. This is a significant finding that stake-holders need to take cognizance of.

Poor PMTCT coverage and poor maternal outcomes have been shown to be the result of poor uptake of VCT in antenatal settings.<sup>27,75</sup>

## **5.7.2 Acceptability**

### **5.7.2.1 Coercion and Informed consent**

The participants in both parts of the study were shown to have extensive previous VCT experiences. The majority of participants indicated that they had previously been counselled and that they agreed to an HIV test on a number of occasions. Thus unless VCT is then also seen as a coercive strategy, it can now be concluded that it is unlikely that participants were being coerced into testing with opt-out testing. These findings contrast with findings of several authors<sup>15</sup> who found that women who booked for antenatal care at a London hospital were not fully informed of the HIV test that was done. The difference in these findings can be ascribed to the absence of the pre-test group information session in the London study and given the difference in the context where HIV prevalence in the UK is much lower than in SA. This illustrates the significance of adequate pre-test information in order to obtain informed consent. It is clear from the patient and staff interviews and focus groups that participants did not feel coerced to undergo HIV testing.

Our findings that adequate informed consent can be obtained through group information sessions offering opt-out HIV testing are confirmed by others in South Africa.<sup>4</sup>

### **5.7.2.2 The impact of Pre-test information**

The quantity of pre-test information did not positively impact on the women's testing behaviour. Despite women indicating that with the shorter Opt-out session they learnt less new information than women who had VCT, more women still chose to test with Opt-out testing. In addition, it has been shown that extensive pre-test counselling does not decrease high risk behaviour if patients test negative. These findings cast doubt on whether VCT promotes better health behaviour through education than Opt-out testing.

### **5.7.2.3 Emotional impact of testing approach and HIV exceptionalism**

Opt-out testing is a more emotionally neutral way of informing patients about HIV testing and it normalizes HIV through the group testing approach. The participants who experienced Opt-out indicated it to be acceptable and adequate. The increased uptake of testing and the observations of the staff validate this finding of emotional acceptability. The finding is supported in the literature with work done in Zimbabwe and Botswana.<sup>68,67,69</sup> VCT appears to be a more emotionally distressing experience and could therefore act as a barrier to testing. This concept is supported in the literature.<sup>36,4,2</sup>

### **5.7.2.4 Impact of testing approach on attitudes & beliefs about testing**

The study found that participants perceive a need for repeated pre-test counselling */information* if they had a history of previous testing experiences. This finding is of concern given the low uptake of VCT and the fact that women who decline testing with VCT are often more at risk of HIV infection than those who agree. Thus it is likely that those who decline VCT are those who would not perceive a need for repeated pre-test counselling and thus have low self-perceived risk. This finding is supported by the literature<sup>56</sup>. It also illustrates the point made by several researchers<sup>44</sup> who recommended that improved uptake of testing is only possible if HIV tests are offered routinely to high risk people.

The majority of participants in both study groups agreed that all pregnant women should know their HIV status. The main reason given by participants for this was to protect the health of the baby. This finding was less evident during Opt-out where more women indicated that women need to know their status to manage their own health. Given the problem of loss of follow-up of PMTCT patients many of whom do not link to care in the post-natal period, and given the importance of maintaining maternal health, this is a finding of concern. Women need to be made aware of the importance of knowing their HIV status for the sake of their own health.

Participants were well-educated regarding the need to disclose their HIV status to their partners, but few of them had done or seriously intended to do so. The main reason for this

was the fear of their partners' reaction. Disclosure is regarded as an important step in an HIV positive person's life towards improving support and health. This finding illustrates that pre-test counselling does not always decrease the high risk health behaviour of non-disclosure.

Participants did not differ according to how they were tested, in the way they accepted their status when they were found to be HIV positive. This finding was validated in all the data-collection methods. This contradicts reports that Opt-out testing could lead to patients not accepting their status due to the shortened pre-test information session.<sup>11</sup> This finding supports reports that patients find Opt-out testing an acceptable approach to HIV diagnosis.<sup>68,67</sup>

### **5.7.3 Acceptability to staff**

Staff and patients found Opt-out to be an acceptable way of HIV testing. The staff were initially sceptical of the benefits that Opt-out offered, but unanimously voted to change to Opt-out testing by the end of the study. The follow-up interviews that were conducted 18 months after Opt-out testing validated these findings of acceptability. Staff found Opt-out to be efficient and acceptable. However, they did stress strongly that adequate post-test counselling was imperative to providing a good service. It was clear during the in-depth interviews with patients and staff that they highly valued post-test counselling and they indicated that this support was crucial for them coming to terms with an HIV positive diagnosis.

These findings indicate that the role of the counsellor as a VCT-only service provider must be reconsidered if Opt-out testing is to be implemented. The HIV counsellor should be strongly involved in ongoing post-test support and ongoing counselling.

## **5.8 Conclusion**

Dr Kevin de Cock, HIV Director of the WHO stated: “Without a major increase in HIV testing and counselling in healthcare facilities, universal access to HIV prevention, treatment and care will remain just a noble goal.”<sup>7</sup>

Opt-out testing is an acceptable and efficient testing approach that could lead to dramatic increases in the coverage of PMTCT in the South African antenatal setting. This study supports an accumulating body of work recommending Opt-out as a preferred testing approach in antenatal patients. Opt-out testing is efficient, feasible and acceptable. It has consistently been proven to be more effective than provider initiated VCT, even when this is done routinely. This study provides evidence that can be used by policy makers to reconsider current antenatal HIV testing policies.

# Appendix 1: Patient information Document and Consent

## Patient Information document

Dear Patient,

The staff at the McCord Hospital Antenatal Clinic is doing research on the best possible way to do HIV testing of pregnant women, and we are asking you to participate in this research study.

We will be asking you to fill in two questionnaires, one before and one after being tested. We will be measuring how long it takes for each patient to complete the antenatal visit. We will also be asking some pregnant mothers to participate in interviews.

This research project is being undertaken at McCord Hospital only. It will involve your first visit to the clinic only. The benefit of taking part in this study is that your opinion on HIV testing is heard and you will be helping us improve our service to our pregnant mothers-to-be, like yourself.

**Participation is voluntary** and your refusal to participate will not involve penalty or loss of benefits to which you are otherwise entitled. You can withdraw at any time.

Efforts will be made to keep all personal information confidential, however absolute confidentiality cannot be guaranteed.

### IMPORTANT

This consent document means only that you agree to participate in the research. Consent for blood tests and HIV tests will be obtained at the midwife station.

### INFORMED CONSENT TO PARTICIPATE IN STUDY

You have been invited to participate in this research study.

You were informed by \_\_\_\_\_ what this study entails.

You may contact Dr E van Wyk at Cell: 0827860517 at any time if you have any questions or complaints related to this research project.

You can also contact the Medical Research Office at the Nelson R Mandela School of Medicine at 031-260 4604 if you have questions about your rights as a research subject. Your participation in this project is totally voluntary and you may decide to refuse to participate at any time during the course of the study. This will not lead to any loss of benefits or penalties. If you decide to agree to participate in this research, you will be given a signed copy of this consent form as well as the patient information document. The research study information and the information above have been explained to me orally. I understand this and I voluntarily agree to participate in this project.

Signature of participant

Date Signature of witness

Date

## Appendix 2: Questionnaire

### Survey Questionnaire

Patient study no: \_\_\_\_\_

Please tick your answer in the right block.

Age: \_\_\_\_\_

1. How many children do you have?

1	2	3	4	5 and more
---	---	---	---	------------

2. What level of education do you have?

a) Up to standard 5	
b) Up to standard 8	
c) Matric/ Grade 12	
d) University/college	

3. Are you employed?

Yes	
No	

4. If employed:

Full time		Part Time		Casual	
-----------	--	-----------	--	--------	--

5. If unemployed:

Housewife		Student		Casual	
-----------	--	---------	--	--------	--

6. What work do you do? \_\_\_\_\_

7. Marital status:

a) Married	
b) Single	
c) Unmarried	
d) Have a partner but not living together	



8. Do you regard yourself as?

a) Asian	
b) White	
c) African	
d) Coloured	
e) Other	

9. Religion: \_\_\_\_\_

10. Total monthly household income

a) Less than R1000	
b) R2000- R4000	
c) R4000- R6000	
d) R6000- R8000	
e) R8000- R10000	
f) R10000+	

Please answer the following questions about your HIV test and counselling:

1. Were you counselled to do an HIV test at McCord? Yes / No
2. Did you agree to be tested for HIV today? Yes/ No
3. Did you learn anything new in the counselling session? Yes/ No.
4. If yes, what did you learn?
5. \_\_\_\_\_
6. Do you want to be counselled every time before you take an HIV test? Yes/No
7. Do you think that pregnant women should know their HIV status? Yes/ No
8. Why do you think so? \_\_\_\_\_
9. What feelings did you experience while you were counselled for an HIV test?  
\_\_\_\_\_
10. Have you ever had HIV counselling before today? Yes/ No
11. If yes, how many times? \_\_\_\_\_
12. What is your source of information about HIV?

Media: TV Radio Magazines	
School	
Health care workers	
Friends & Family	
Other _____	

## Appendix 3: Patient In-depth interview guides

### In Depth interviews Interview Guides

Time: \_\_\_\_\_ Date: \_\_\_\_\_ Place \_\_\_\_\_

Patient file no: \_\_\_\_\_

First name: \_\_\_\_\_

Age: \_\_\_\_\_

Cultural group: \_\_\_\_\_

Number of children: \_\_\_\_\_

Special interview circumstances

#### Goals of in depth interviews: (Open)

1. Is patient aware that she was counselled for an HIV test today?
2. How did she perceive the counselling method? Did she find it helpful/acceptable?
3. What subjective feelings/emotions did she perceive during the counselling?
4. What factors (internal/external) influenced her agreeing/declining to test? (Did the counselling persuade/ facilitate her decision in any way or did the counselling not influence her at all?)
5. What are the patients' feelings/opinions about pregnant women knowing their HIV status and the importance of disclosing their status to their partners?

#### Further questions to guide in depth interviews (Closed semi-structured)

1. Were you counselled for an HIV test today? If so, by whom?
2. Did you agree to be tested for HIV today as a result of the counselling (that is, did the counselling in any way encourage you to test) or were you intending to anyway?
3. If anything, did you learn something new today regarding HIV in the counselling session? If so, then what? If not, explore reasons.
4. Do you think the counselling provided enough information about HIV or do you have other questions (based on things you may have heard about HIV) that the counselling did not address? If so, what are these questions?
5. Were you given enough time or opportunity to ask these questions in the counselling session?
6. In what ways do you think the counselling sessions can be improved (explore: length of time, way it is conducted, one on one versus group etc)?
7. Did the way that the counselling sessions handle HIV make you feel scared, nervous or worried in any way? OR How did the counselling session make you feel about going for HIV testing?
8. If you were to take another HIV test in the future, would you want to be counselled again before you took the test? Reasons.
9. Do you think that it is necessary for pregnant women to know their HIV status? Reasons.
10. Do you think that pregnant women should tell their partners what
11. their HIV status is? Reasons?

## **Appendix 4: Focus group questionnaire - VCT**

### ***Guide pre-introduction of routine batch testing***

#### **Goals:**

To ascertain the acceptability of Opt-out vs. VCT in the antenatal setting

Regarding the current system of individual VCT done by the midwives:

1. Why, in your opinion is VCT important?
2. What are your thoughts/feelings/ideas about the current system used? That is- how acceptable do you find VCT? Is it an effective system? I.E Does it accomplish its goals? Why do you think so?
3. Are there any problems with the present system of VCT?
4. Do clients need VCT each time they test for HIV? Why?
5. Does practicing the current system of VCT (individual counselling) make it easier to conduct the rest of the midwife visit? Is it easier for the midwife to test for HIV because of VCT being done? Why do you think so?
6. How do you think clients perceive the current system of VCT? Do you think clients find VCT an effective way of counselling?
7. What are your feelings about substituting VCT with the opt-out approach? Will it work? What are your fears? What are the obstacles?

# **Appendix 5: Focus group and interview guide - Opt-out**

## **Guide for during routine batch testing and follow-up Interviews**

### Goals

To ascertain the acceptability of Opt-out vs. VCT in the antenatal setting

Regarding the current system of Opt-out done by the midwives:

1. Why, in your opinion is Opt-out important? What are your thoughts/feelings/ideas about the current system used? That is- how acceptable do you find Opt-out? Is it an effective system? I.E Does it accomplish its goals? Why do you think so?
2. Are there any problems with the present system of Opt-out?
3. Do clients need counselling each time they test for HIV? Why?
4. Does practicing the current system of Opt-out make it easier to conduct the rest of the midwife visit? Is it easier for the midwife to test for HIV because of VCT being done? Why do you think so?
5. How do you think clients perceive the current system?
6. What are your feelings about substituting VCT with the opt-out approach? Did it work? What are your fears? What are the obstacles?

## Appendix 6: Consent for routine blood tests

### Consent for routine blood tests

A: I, \_\_\_\_\_

A n c / N o: \_\_\_\_\_

Hereby give consent for the following routine blood tests to be done at the antenatal clinic. I have been counselled and informed about all the tests and I know that my choice to test is voluntary.

a) RPR/WR screen

b) Rhesus screen

c) HIV rapid test

d) Haemoglobin

e) Screening Glucose Tolerance test (If indicated) (We may need more blood do confirmatory tests.)

Client's signature \_\_\_\_\_ Printed name \_\_\_\_\_

Counsellor's Signature \_\_\_\_\_ Printed name \_\_\_\_\_

Date \_\_\_\_\_

B: If there are any tests you would like to decline please complete this section.

I refuse to do the following test: \_\_\_\_\_

The reason I refused this test is because:

Signature of Patient \_\_\_\_\_

Signature of counsellor \_\_\_\_\_

Date \_\_\_\_\_

## Appendix 7: Data capture sheet

### Data capture sheet

Patient Study no: \_\_\_\_\_ Time of arrival\_\_\_\_\_ Time of departure\_\_\_\_\_

Station	Time In (From)	Time Out (To)
Arrival time at clinic		
Group session		
Weight & urine testing		
5 Time waiting for Midwife		
6. Time spent with midwife		
8. Time drawing blood		
11 Time waiting for doctor		
12. Time with doctor		
13. Time waiting at ultrasound		
14. Time spent in ultrasound		
15. Time of departure from clinic.		

Total time \_\_\_\_\_ Time at midwife \_\_\_\_\_

- ✓ This form is part of a quality assurance project to improve our service in the antenatal clinic it is also part of the study that you have signed consent for.
- ✓ In order to get the most benefit from this please fill these out as completely and accurately as possible.
- ✓ Your participation is valuable feedback and this sheet will help us deliver a better service to pregnant women like you!
- ✓ Order of the stations may not be the order you are actually seen in.
- ✓ Please try and at least record the arrival and departure time. Hand in the pencils/pens in at the front desk on departure. **If you have any questions please ask for Dr van Wyk**

# Appendix 8: Routine testing brochure

## Routine Care in Pregnancy

Thank you for coming to McCord Hospital and entrusting us with the care of your pregnancy.

Kindly read the information below and feel free to ask any of the midwives or doctors in the clinic should you not fully understand any of the information.

When you attend antenatal clinic we aim:

To see that you have a pregnancy as free from problems as possible;

To help you to have a healthy baby born at the right time.

In order to do this, we do certain things so that we can pick up any possible problems early on.

### Weighing

It is important to weigh you on each visit to be sure the weight gain is normal. Too little weight gain may be a sign of a problem. A sudden increase in weight could be caused by high blood pressure in pregnancy, which needs to be treated early otherwise it can become a serious risk for both mother and baby.

### Blood Pressure

Your blood pressure will be checked at every visit. High blood pressure can cause damage to the placenta which could mean that the baby doesn't get enough oxygen and nutrition. As a result the baby may not grow adequately.

### Urine testing

This is a simple 'dipsticks' test that can show if you might have diabetes or a urinary infection needing treatment. The urine will be tested at each visit. One of the reasons is to look out for protein in the urine which is also a sign of high blood pressure in pregnancy.

### Blood tests

#### *Full Blood Count*

This test looks at the "strength" of your blood. It may show that you are anaemic and need extra iron supplements.

#### *Rhesus factor*

This is a test to determine your blood group type. It will show whether you are Rhesus negative or positive. Most people have the Rhesus factor in their blood (Rh +ve), but about 5% do not (Rh -ve). If you are Rh -ve and your baby is Rh +ve, you could develop antibodies which could damage the red blood cells of a Rhesus positive baby. It is a treatable condition as you can be given an injection after delivery to stop you making these antibodies.

#### *RPR/WR*

This is a test for syphilis. Syphilis, like HIV can be a "silent" infection which might only show on a blood test. If it is not treated it can be passed on to the baby and cause health problems.

### *HIV test*

HIV is a common problem in South Africa. It is a viral infection that can be passed on to the unborn baby. With proper treatment, nearly all babies can be saved from infection. The virus can be transmitted in adults in a number of ways especially by unprotected sexual intercourse. One might not suspect that they are infected however, it is very important to ensure that you have a recent result in order to either:

a) Prevent yourself from getting infected (if result negative)

Or,

b) To ensure optimal treatment of yourself and therefore protection of your unborn baby (if result positive).

If a test result is positive, we will check the strength of the immune system by doing a CD4 count and as well as a viral load. This will enable us to give out the correct medication (antiretrovirals) for the stage of the infection. If the treatment is taken timeously during pregnancy, almost every baby will be protected from infection.

It is also recommended that your partner is tested for HIV. This can be done at our antenatal clinic.

### *Screening Glucose Tolerance Test*

This test will only be done where there is a reason to think a woman might have diabetes – such as finding sugar in the urine, having a family history of diabetes, being of Asian descent or a having a very large baby in a previous pregnancy.

This test requires that you drink a cup of very sweet sugar water and then after one hour blood is tested to check how the body has coped with the “load” of sugar. We will phone you later in the day should there be a problem and ask you to come back as soon as it suits you to do a further test.

### *Ultrasound*

This is a type of scan to check whether the structure of the baby’s body and inner organs is normal.

Ultrasounds are recommended for all women at 18 weeks of pregnancy and may be repeated later in the pregnancy if any complications develop.

The cost per ultrasound is R170.

You will shortly be seen by a midwife who will ask you whether you have any further questions or problems about having any of the routine tests.



# Appendix 9: Opt-out group talk content

## Opt-out testing information session

### Background:

Patients who arrive for first visits will have to be counselled in batches of 6 for phase 2 of the Opt-out study. We aim that this leg of the study will run over a period of 6 weeks.

This is a proposed guideline for the session with each group. At the end of the session the first visits will go to the individual midwives where they will sign consent for the batch tests and indicate whether they will need further individual counselling.

The proposed guideline is as follows:

Welcome to McCord Antenatal Clinic.

The purpose of this session is to inform all first visit mothers of the routine blood tests that we require from you today. We will take some time to explain the different tests and the reason why each test is so important. These tests are voluntary, so if there are any tests that you don't want to take you can sign a refusal document with the midwife.

You can follow in the information leaflet as we go along.

**FULL BLOOD COUNT:** This is an important test we do to measure how 'STRONG' your blood is. Pregnant ladies tend to have low counts of iron in the blood and this makes the blood weak. All of you will receive an iron supplement called Pregamol to help keep the levels normal. Weak blood can lead to abnormal development of the baby while it is still in the womb. A good natural source of iron is green leafy vegetables like spinach and also red meat. If the FULL BLOOD COUNT shows low counts, it means we have to give extra iron tablets in high doses to correct the levels. This test will be performed on more than one occasion in your antenatal time with us.

**RHESUS FACTOR:** This is a finger prick test that we perform to tell us about your blood group. We want to know if you are Rhesus positive or negative. Most of you will be Rhesus positive. A small percentage of you will be Rhesus negative and if your baby is Rhesus positive, your body can develop antibodies against the baby and can damage it. If we test for this factor early in pregnancy we can give an injection which will prevent your body from forming these harmful antibodies.

**RPR/WR:** This is a blood test for syphilis and can be a "silent" infection. A "silent" infection is when you are not aware that you have an infection because it doesn't give any obvious symptoms. Even though you may not feel any symptoms this infection can harm the baby's development. The good news is that if we diagnose this infection, we can treat it effectively and cure it- thus preventing harm to the baby.

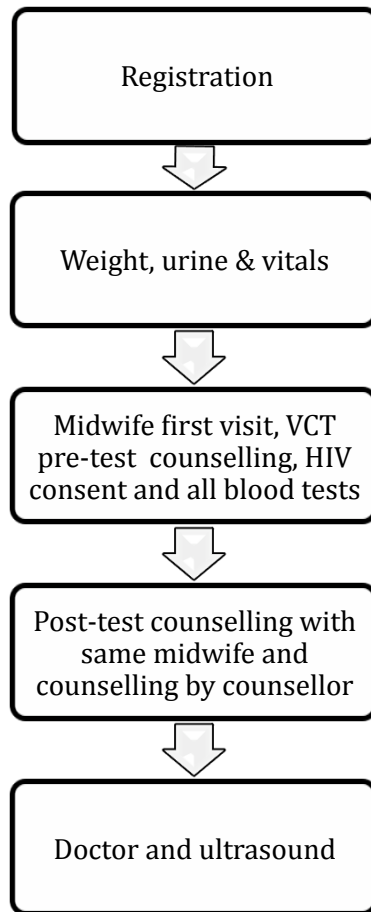
**HIV:** This can be another "silent" infection and it can be transferred from the mother to the baby. Nowadays this is a very treatable condition if diagnosed early and we have an excellent treatment programme in which we provide free treatment to prevent the virus from transmission to the baby. We can save nearly all babies from this infection if we diagnose it early. We strongly recommend that you and your partner take the test together as it is part of our antenatal service to care for the partner as well as the mother. If your test is negative and you feel you are at risk of infection, we recommend that you repeat the test after 3 months as you might be in the window period. If you are found to be positive, we will take more blood to do a CD4 count. This will determine what drugs we will give you to prevent you and your baby from getting sick. With early treatment the chances of having a positive baby are very low.

**SCREENING GLUCOSE TOLERANCE TEST:** We only do this test if you suspect that you might be at risk for Diabetes (High sugar). These risk factors include: Glucose in the urine; having a family history of Diabetes or being over-weight. The test will mean you need to drink a cup of sweet sugary water

after which we will take blood to test the sugar levels. If the levels are high, you might have uncontrolled sugar levels and will need special treatment and follow-up throughout your pregnancy to ensure a healthy baby. High sugar levels can lead to abnormal development of the baby.

Please note that if you feel you need special individual counselling before you take any test, you can inform the midwife who will be happy to spend more time with you. Thank you for your attention.

## Appendix 10: Flow of patients during VCT



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