First-time- and repeat testers for HIV: a demographic and HIV prevalence comparison amongst clients at mobile HIV Counselling and Testing sites in Tshwane, South Africa

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Abstract

There has been significant debate, specifically within the African context, regarding the validity of using HCT data as part of routine surveillance data for the HIV epidemic. The use of HCT data in tracking the prevalence of HIV, as well as in estimating incidence rates for HIV, has been applied in some African countries, and may offer opportunities to strengthen surveillance in the Gauteng Province, South Africa. Literature suggests HCT data are biased as a result of the high proportion of repeat testers, where repeat testing may be related to high risk sexual behaviour. (1–8) It has been suggested that HCT data be separated into first-time- and repeat tester data in prevalence or incidence estimations. (9)

The aim of this research was to determine if there are demographic and HIV prevalence differences between first-time- and repeat testers, as suggested in the literature. (9) Existing mobile HCT unit data was used from the Foundation for Professional Development (FPD). The data was collected in the Tshwane Metropolitan Municipality, Gauteng Province, South Africa. An observational, cross-sectional study design was applied. A systematic random sample of 400 first-time testers and 400 repeat-testers was drawn and analyzed.

The findings of this study indicated an overall 10.0% (n=80) HIV prevalence rate. When compared to the Gauteng adult prevalence (15+) of 14.4%, the study prevalence is lower. (10) When looking at the characteristics of the first-time tester and repeat tester groups, there was an HIV prevalence rate of 12.5% (n=51/407, p=0.0152) in the first-time tester group, and 7.4% (n=29/393, p=0.0152) HIV prevalence rate in the repeat tester group. Although literature suggests that repeat testers are the more at risk population, the finding in this study clearly demonstrates that there is a difference in HIV prevalence between first-time- and repeat testers. When first-time/repeat tester was used as the dependent variable, it was found that
females are 0.6 less times likely to be a first-time tester compared to males (OR=0.6, p=0.001).

The finding of a difference in HIV prevalence between first-time- and repeat tester groups was consistent with three other studies in Ethiopia, Uganda and Kenya. In these studies, HIV prevalence in first-time testers was slightly higher than in that of repeat-testers. (3,11,12) It was found that there is a difference in the HIV and demographic profile between those who test for HIV for the first time and those who are repeat testers.

The perceived risk and vulnerability to HIV plays a heavy role in motivating individuals to test once, or repeatedly. In regards to disease surveillance, this study did not prove that the population that utilises mobile HCT are representative of the Tshwane population. This study highlighted the need to better understand the sub-groups and characteristics of those who test for the first-time and those who test repeatedly for HIV.

In conclusion, this study has provided evidence that there is a difference between the HIV prevalence of first-time- and repeat testers. However, there is good reason to doubt that the prevalence rate of first-time testers is genuine.

**Keywords:** HIV, counselling and testing, first-time, repeat, prevalence, disease surveillance, mobile testing units
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Chapter 1 - Introduction

1.1. Background

Effective disease surveillance and health information systems are integral to understanding growth patterns and distribution of new disease in South Africa. Regarding HIV, ample statistical information regarding HIV prevalence exists both nationally and provincially, but there is little data available at local municipality and community level. In South Africa, HIV is not a notifiable disease and HIV testing is voluntary. HIV incidence and prevalence estimates in Africa have been derived in the past, predominately from longitudinal cohort studies or from mathematical modelling using sentinel or age specific quantification. (13–15) Annually, sentinel antenatal clinic (ANC) data are carried out at municipal level by the South African National Department of Health (NDOH), under the name of the National HIV and Syphilis Prevalence Survey South Africa. (16) An alternative is to carry out longitudinal studies. Several longitudinal cohort studies have been conducted in other countries such as Uganda and Rwanda; yet these studies are challenging and expensive. This demonstrates that alternative forms of HIV disease surveillance methodologies must be investigated. (17–19)

With ART treatment widely available in South Africa, there is now a focus on HIV prevention. As social and environmental factors have a correlation with HIV risk, a focus on social and behavioural interventions increases the understanding of disease patterns within communities.(10,20) This information strengthens HIV prevalence data and assists in determining the effectiveness of interventions. Community-specific data are being used, with ANC data as an example of this. Limitations of this data are acknowledged. HIV infection patterns are different in women of reproductive age compared to the general population. Although mathematical models are applied to manipulate ANC data to achieve representativeness of the general population, the preferred methodology for determining HIV prevalence would be through conducting sample surveys among the general population. Disease surveillance using HIV Counselling and Testing (HCT) site data may be an alternative or complementary source of data. (1) The collection of disease surveillance data would be optimal in the HCT environment
because of the wide availability of HCT testing sites, making it possible to draw representative samples.

There has been significant debate, specifically within the African context, regarding the validity of using HCT data as part of routine surveillance data for the HIV epidemic. The use of HCT data in tracking the prevalence of HIV, as well as in estimating new incidence rates for HIV, has been applied successfully in some African countries, and may offer opportunities to strengthen surveillance in the Gauteng Province, South Africa. Since 2002, the Human Sciences Research Council (HSRC) in South Africa, has released several HIV reports including prevalence and incidence data. The methodology used to determine HIV prevalence in these HSRC reports is the analysis of dried blood spot (DBS) specimens, collected through finger-prick testing. (10) It should be mentioned however, that literature suggests that HCT data are biased as a result of the high proportion of repeat testers. (1–8) Therefore the data itself raises questions about their validity and reliability. More must be understood about the potential bias of HCT data because of the high proportion of repeat testers.

Rapid HIV test kits being used in Africa have been shown to have acceptable specificity and sensitivity if used correctly; supporting the use of rapid testing as an appropriate measurement tool. (14,21) It is important to recognise that although the measurement tool is effective, the data collection process must also be effective in order to deliver true results that can deemed to be reliable. One must consider the systematic challenges that impact the quality of the data collected at HCT sites. Reporting systems throughout Africa are considered weak, unreliable and lack consistency. (21) When considering opportunities to collect data, it is also essential to consider those who will be the data capturers. Additional work load on clinic staff may compromise the quality of the data collection, but may also compromise the level of care in a clinic. (9,22,23) It is integral to the formation of public health strategies to work through the reporting limitations that exist in Africa. While acknowledging barriers, solutions must be explored that are epidemiologically sound as well as appropriate for the African context. HCT data could be an alternative or additional data source for HIV surveillance and health information system reporting.
mechanisms, but more needs to be understood about the trustworthiness of HCT data.

The literature regarding HCT as a source of disease surveillance data focuses on repeat HIV testing as a potential source of bias. (9,22,23) Much research has been done around understanding the motivation of people to voluntarily test. More needs to be understood about why people choose not to test. This includes the impact of stigma on HIV testing, as well as the confidence individuals have in the health system to provide appropriate treatment. (22) It has been suggested that HCT data be separated into first-time- and repeat tester data in any prevalence or incidence estimations. (9)

Studies regarding the use of HCT data have not been carried out in South Africa to date, and yet the results of such investigations would be crucial in the debate around whether or not data from HCT sites could provide unbiased estimates of HIV prevalence. Based on literature available, understanding demographic and HIV prevalence profiles of first-time- and repeat testers will assist in determining the potential use of HCT data for disease surveillance. It will also contribute to better understanding the profile of those who test voluntarily, which will also contribute to the development of HIV testing strategies and ‘know your HIV status’ interventions. With the launch of the National HCT Campaign in South Africa by the Minister of Health, Dr Aaron Motsoaledi in April 2010, the role of HIV testing in programmes for prevention, HIV awareness and primary health care has become vital. With the mass availability of HCT to the South African population, this may be an appropriate source of data. HCT data could provide an appropriate indication of HIV prevalence that is representative of the South African population. With the re-engineering of primary health care in South Africa, including a major focus on improving the quality of information in the District Health Information System (DHIS), this presents an ideal time to present alternate data sources such as HCT. (24)

1.2. Problem Statement

Literature regarding HCT as a source of disease surveillance data focuses on repeat HIV testing as a potential source of bias. (9,22,23) It has been suggested that HCT
data be separated into first-time- and repeat tester data in any prevalence or incidence estimations. (9) If repeat testers are excluded, a potential variance between this group and first-time testers could exist. Studies regarding the use of HCT data have not been carried out in South Africa to date, and yet the results of such investigations would be crucial in the debate around whether or not data from HCT sites could provide unbiased estimates of HIV prevalence. Based on the literature available, understanding the demographic and HIV prevalence profiles of first-time- and repeat testers will assist to determine the potential use of HCT data in disease surveillance and health information system reporting mechanisms.

1.3. Aim and Objectives of the Study

The aim of this research is to examine and determine if there are demographic and HIV prevalence differences between first-time- and repeat testers, as suggested in the literature. (9) This is an important initial step, because if a difference is determined between first-time and repeat testers, further research can be conducted to determine if first-time testers are a potential source of data for HIV disease surveillance. Therefore this research will aim to determine if there are differences between these two groups.

The first objective in this study is to estimate the prevalence of HIV among first-time-testers and repeat testers at mobile HCT units in Tshwane, Gauteng Province, South Africa. This will determine if there is a difference between the two groups. The second objective is to record the HIV test result as well as sex, age and population group of first-time- testers and repeat testers to better understand the basic demographic profile of these two groups. The third objective is to obtain population demographic data and HIV prevalence data through existing sources for Gauteng Province for reference purposes. This will add value to the final objective that is to compare the overall profile of mobile HCT users (first-time- and repeat testers) in Tshwane with the Gauteng Province profile. This comparison will determine if the sample population of this study was similar to the general population profile of Gauteng Province.
1.4. Rationale

Literature is available to support the view that there are demographic differences between first-time- and repeat testers. There are two studies regarding first-time- and repeat tester in Sub-Saharan Africa. The first is a cross-sectional study published in 2011 which looks at the correlation of HIV with repeat HIV testing among women in Ethiopia. The findings in this study indicate that 40% of the total sample (n=2027) were repeat testers and that high-risk sexual behaviour was associated with repeat testing. (11) The second is a prospective randomized trial conducted over 5 years (1994-1999) in Uganda regarding the control of Sexually Transmitted Diseases (STD) for purposes of HIV prevention. All those enrolled in the trial were initially HIV negative. The study based on this trial was published in 2007 and explored the relationship of high-risk sexual behaviour in first-time- and repeat HIV testers. Again, a 40% repeat-tester proportion was found within the total sample of first-time- and repeat-testers (n=4083), and again there was a relationship between high-risk sexual behaviour and repeat-testers.(12) What was most interesting from both studies is that the prevalence and incidence of HIV in first-time testers was slightly higher than in that of repeat-testers. It would be expected that those who are practicing high-risk sexual behaviour would have a higher HIV prevalence. While the Ethiopian study showed that first-time testers were a lot younger in age than the repeat-testers, the Ugandan study did not show this. In regards to sex, the Ugandan study had a fairly equal proportion of males (49.5%) and females (50.5%) in the combined first-time- and repeat tester groups. It is helpful to understand if the South African population that tests voluntarily for HIV in Tshwane, Gauteng Province has similar sex and age proportions in the first-time- and repeat tester groups. It is also important to understand the HIV prevalence in both of these groups.

HIV incidence and prevalence estimates in Africa have been derived, in the past, predominately from longitudinal cohort studies or from mathematical modelling using sentinel or age specific quantification. (13–15) Several of these studies have been conducted in Uganda and Rwanda. With longitudinal cohort studies being both challenging and expensive, there is a need to investigate alternate disease surveillance methodologies. (15,17–19) The inability to effectively measure new infection rates restricts the ability for effective public health interventions. Incidence
is an important monitoring tool for understanding the epidemic. A methodology called serological testing algorithm for recent HIV seroconversion (STARHS) is often applied when determining HIV incidence. In a cohort study in Buenos Aires and Montevideo, this methodology was applied to measure incidence levels in at-risk populations over a five-year period. This disease surveillance methodology was able to detect an emerging epidemic within the heterosexual community. (25) A rise in incidence may also be linked to an increased uptake of HCT. A study conducted in the UK over a seven-year period also used the STARHS methodology and indicated an incidence increase in the men who have sex with men (MSM) population. The increase was later determined to be statistically insignificant and the study concluded that the increased incidence was related to an increased uptake of HCT. (26) It is estimated that worldwide less than 1 000 HIV cases are diagnosed in the first month of infection, although they often present themselves with STI coinfections. (27) Although measurement of incidence is a major challenge for HIV epidemiology, prevalence also presents challenges as well. There are many people infected who are unaware of their status and the more at-risk people feel, the less inclined they are to test. (3) The population that is most at-risk are likely to have a higher infection rate and may have been excluded from the prevalence calculation because they are hesitant to test or do not know their status. This is where understanding the testing profile of those who test for the first-time and those who test repeatedly may shed light upon the characteristics of those who would be included in South Africa’s prevalence numerator.

Studies regarding the use of HCT data in South Africa have not been carried out in South Africa to date, and yet the results of such investigations would be crucial in the debate around whether or not data from HCT sites could provide unbiased estimates of HIV prevalence. Based on the literature available, understanding the demographic and HIV prevalence profiles of first-time- and repeat testers will assist in determining the use of HCT data in disease surveillance. It will also contribute to better understanding the profile of those who test voluntarily, which will also contribute to the development of HIV testing strategies and ‘know your HIV status’ interventions.
Chapter 2 - Literature Review

2.1. Introduction

The formation of strategic information through epidemiology is invaluable in public health. In order to respond effectively to public health challenges, decision makers need to have information that assists them: to understand the prevalence and incidence of diseases in a population; to identify potential relationships or correlations; and to determine the effectiveness of potential public health interventions. Moreover, another challenge is to make maximum use of existing data sources.

Current disease surveillance practices in HIV include population sampling and the use of ANC sentinel data. The aforementioned methodologies are applied to determine HIV prevalence. Determining HIV incidence is a challenge and is currently, for the most part, determined through mathematical modelling. (15) Additional sources of data should be explored and understood. As HCT services are widely available throughout South Africa, coupled with the push from government to encourage widespread HCT use, HCT is an obvious potential source of data.

The aim of this research is to examine and determine if there are demographic and HIV prevalence differences between first-time- and repeat testers, as suggested in the literature. (9) This is an important initial step, because if a difference is determined between the first-time- and repeat tester population, further research has to be conducted to determine if first-time testers are a potential source of data for HIV disease surveillance. This research will aim to determine if there are differences between these two groups.

The literature review will investigate five key areas related to this study. The first is to explain HCT operationally, including the assessment of HIV rapid test kits as an effective measurement tool. Secondly, the literature review will also explore the various approaches used to increase HCT uptake effectively, ensuring adequate participation throughout the population. To be used as a potential source of HIV surveillance and health information data, there needs to be a wide uptake of HCT to ensure population representativeness.
The third area the literature review will cover is to summarise existing methods to determine HIV prevalence and incidence in South Africa. This section describes the existing data sources and identifies the need to explore additional data sources and approaches to determining HIV prevalence and incidence. The fourth area the literature review will evaluate is HCT as a potential data source, as there are many factors that inhibit participation in HCT, such as stigma. The fifth area the literature review will explore is the characteristics of those who test for HIV for the first time (first-time testers) and those who test for HIV repeatedly (repeat testers). These are the areas of interest in this study and the aim of the study is to understand the complexities of each area. Lastly, the literature review will conclude key areas of interest specific to this study.

2.2. HIV rapid test kits as an effective measurement tool

HIV tests originated with the enzyme-linked immunosorbent assay (ELISA) test that is still used in laboratory settings to detect HIV antibodies. Additional testing methodologies have since been created, making HIV testing possible much earlier after onset of infection. As the testing methodologies have evolved they have been grouped into first-, second-, third- and since 2009 a fourth-generation of HIV tests. The evolution of HIV testing, as well as the ability to effectively deliver an HIV test outside of a clinical setting has improved efficiency, while significantly reducing the cost of testing. The majority of HIV rapid test kits currently used in South Africa have a sensitivity of at least 99% and a specificity of 98%, further supporting the effectiveness of the rapid test as a measurement tool. The rapid test kit has made it more appropriate to be used for wide-scale HIV testing campaigns.

HIV rapid test kits have improved over time. However, determining new infections using these test kits still remains a challenge. First- and second-generation test kits detect immunoglobulin G antibodies. Using these test kits, immunoglobulin G antibodies are only detectable after 45-60 days.(28) Third-generation tests have definitely improved on this, but it is fourth-generation tests that are now able to ascertain the HIV-1 p24 antigen that appears sooner in a new infection than immunoglobulin G antibodies. (28) This allows for identification of new infections without doing blood tests in the laboratory. However, the window period to test for new infections is limited using rapid HIV test kits. Individuals would need to test
weekly for a period of time to identify a new infection, and this is not realistic in the HCT environment, as even annual testing is not adhered to.

After the HIV test, post-test counselling is provided and the result of the HIV test is revealed immediately. Those who test positive and negative are given counselling on how to reduce HIV risk as well as how to disclose the test result to their partner. (29) If the result is negative, the client is encouraged to test every 6-12 months. If the result is positive, another rapid test kit of a different brand is used to confirm the positive result. If the result of the second test is also positive, the client is referred to an HIV clinic, or Primary Health Clinic in the area where the client lives. An ELISA blood test is then performed at a public health site, where there is access to laboratory facilities. The result is confirmed and a CD4 count is provided, as this will determine the viral load of the patient and potential need for Antiretroviral Therapy (ART).

The introduction of the rapid HIV test kit has allowed for mass testing campaigns, specifically in resource-limited areas. Rapid test kits are inexpensive, have acceptable sensitivity and specificity, are easy to use and do not necessarily require a healthcare professional to conduct the test. This allows HIV testing to be done on a wide-scale, as well as reach rural and remote populations in resource-limited areas. (21) In resource-limited areas, post-test counselling may include provision of information and support on how to cope living as an HIV positive person. (29)

The introduction of mobile HCT units has also made HCT more readily available in resource-limited areas. Although mobile HCT units have additional costs that a clinic-based HCT does not have, it has been found that they are more cost-effective. Moreover, as an HIV prevention strategy, mobile HCT has been found to be as cost-effective as prevention of mother to child transmission (PMTCT) HCT programmes. (30) HIV testing has been scaled up significantly in South Africa due to the National HCT Campaign in 2010, initiated by Minister of Health, Dr Aaron Motsoaledi. HCT has long been an entry point into HIV treatment, care and support. Prior to the HCT Campaign in South Africa, HCT was available in designated fixed-sites, such as primary health clinics and hospitals. HCT is now available in all primary health
facilities throughout South Africa as well as in civil sector organisations and private businesses. Most services are free of charge, or there is a nominal fee.

The entire HCT process takes approximately 30-40 minutes and involves a lay counsellor as well as a nurse. Since 2010 there has been a change in the Human Tissue Act, allowing lay counsellors in South Africa to conduct finger-pricks. A nurse is no longer required in the HCT process. (31) Because of the human resources for health challenges in South Africa, there are simply not enough nurses to provide effective coverage of HIV testing. Another recent change in the provision of HCT is the introduction of Provider-initiated testing and counselling (PITC) to include expansion of opt-out testing. Opt-out testing is where HIV testing is routinely implemented unless patients state they do not wish to be tested. PITC has been effective in routine HCT in PMTCT programmes. A South African study showed that PITC increased overall HCT uptake by 13.8%. (32) This is relevant to this research as the aforementioned changes to the delivery of HCT demonstrate the potential of HCT as a data collection methodology.

There are South African National Department of Health (NDOH) policies in place dealing with the implementation of HIV, following guidelines from both UNAIDS and the WHO. According to the 2004 UNAIDS/WHO policy statement on HIV testing and the South African NDOH policy on HIV testing, HIV testing must always be provided confidentially; be accompanied by counselling; and informed consent must be in place to ensure that individuals participate freely and are provided with information. HCT uses formal guidelines to ensure consistency and effective delivery.

2.3. Increasing uptake of HCT – necessary for disease surveillance

It is important to explore various mechanisms of HCT delivery, because it allows to address the complexities of an individual’s decision to have an HIV test. The outcome of this should be: to increase the number of people participating in HCT; to increase annual testing for those who test negative; and to ensure referral to appropriate services when necessary. This is relevant for research as an increased uptake allows for better quality data. Research into HCT methodologies should also assist to identify the characteristics of HCT populations.
If uptake increases in the general population, with annual testing for those who are negative, then HCT data would be an ideal data source. The motivation for a person to test includes two main aspects. This first is the extent of satisfaction of the participants with the operational aspects of the HCT service. This would include availability of supplies, cleanliness, professionalism, confidentiality and respect they received from the service provider. The second is the emotional preparedness of the participants to have an HIV test. This is where culture, stigma and other social aspects play a determining role in whether someone will agree to have an HIV test. A study in Swaziland describes how gender-based violence, community and culture contribute to stigma of HIV. (33) This is also supported by a study in Uganda that identified stigma, gender positions, HIV knowledge and the role of the HCT provider as playing a role in the decision to participate in HCT. (34) Expansion of HCT sites will not necessarily improve uptake of HCT. A study in Mpumalanga Province, South Africa indicated that men are less likely to test compared to women. This is supported by other literature as well. (10,35)

HCT has been expanded due to the inclusion of more sites and the use of various approaches to HCT provision. Previously, HCT had been provided at dedicated, fixed sites inside of clinics and hospitals. This method of HCT delivery is now discouraged, as HIV testing is encouraged to be mainstreamed into all clinics and hospitals where HIV testing can be offered in conjunction with other medical testing and interventions. This is due to the hesitance of individuals to be seen at sites that only offer HIV testing. Testing should be integrated and offered throughout the healthcare system to reduce stigma and increase uptake. Mobile HCT units have provided a unique opportunity for individuals to test at a convenient location, in hard to reach areas, or at events. Mobile HCT units have been encouraged to provide additional health services such as blood pressure monitoring, blood glucose readings and other services that will increase usage and opportunity to offer an HIV test.

The expansion of HCT site availability has created multiple opportunities for the public to be tested, with the introduction of opt-out testing through PITC increasing the uptake of HCT even further as demonstrated in PMTCT and STI studies.
(32,36,37) Opt-out HCT applied to the general population increases HIV testing uptake and is effective in resource-limited areas where ongoing communication and awareness programmes are costly. (29) Routine testing has been implemented in many countries successfully. In South Africa, this is generally only provided for pregnant women. Due to the success of HCT uptake in the PMTCT programme in South Africa, it is clearly documented that routine testing can impact uptake and reduce stigma and discrimination as it is offered to everyone in the clinic. (38,39) In Botswana, routine opt-out testing has been well received with 81% (n=1 268) of participants choosing routine opt-out testing in a cross-sectional study. (40) Another study conducted in Botswana found that those most at risk were least willing to test. (41) Home-based HCT has led to significant uptake of HCT. In a Zambian study, acceptance of HCT in the home was 4.7 times higher than when offered at a clinic. This was attributed to the perception of poor services in the clinic, increased confidentiality at home and also easy access to HCT. (42) Studies in Uganda and Malawi have also shown increased uptake in home-based HCT. (38,43)

With HIV testing, there is an element of stigma that cannot go unmentioned. The stigma is not limited to HIV, but extends to sexually transmitted infections (STIs). It impedes health-seeking behaviour and prevents patients from being truthful with healthcare professionals regarding their sexual behaviour. In a South African study of pregnant women attending antenatal clinics, the reasons given for refusing an HIV test was the opinion that there was no access to HIV treatment, so testing for HIV appeared futile to them. Two other reasons mentioned were more emotionally motivated, where stigma around HIV and apprehension of knowing their status were reasons not to test for HIV. Knowing their status was a deterrent to test, as they may then have to disclose this to others. It was suggested that those who refused an HIV test were aware of the likelihood of being positive because of known HIV exposure. It was determined that women were knowledgeable regarding HIV, although independently made the decision not to test. (44) In a study based in Kenya, uptake of HCT was higher when clients were certain: HCT services were confidential; clients would be respected and provided dignity; and service providers would conduct themselves in a professional manner. (45) Successful HCT programmes have
included these best practices, whether routine testing or voluntary testing. Increased HCT uptake will occur when a client-centered approach is applied. (46)

Opt-in testing is the standard delivery method for HCT in South Africa. Clients interacting with the public health system may or may not be given the option to be tested for HIV. Opt-out HIV testing is where HIV testing is routinely included, unless the client states they do not want to be tested. In South Africa there is much discussion about opt-out HIV testing for the general population, although it is currently not policy to do so. (47) Internationally, antenatal clinics appear to be documented as the earliest example of applying opt-out testing strategies. This has shown a much higher HCT uptake in the US, leading to a national change in policy in that country in 1999. (48) This opt-out methodology has now been recommended for PMTCT programmes by both the Centre for Disease Control (CDC) and UNAIDS/WHO. Opt-out testing is currently standard protocol in South African PMTCT programmes. HIV testing is routinely implemented for pregnant women unless they state they do not wish to be tested.

Opt-out HIV testing has been implemented in other Sub-Saharan countries, where results show a much improved uptake of HCT for pregnant woman. A study in rural Malawi (n=4528) showed a 46% increase in HCT uptake, resulting in a 98.8% HCT coverage. (36) In Botswana, the change in policy resulted in a 91% uptake of HCT, compared to previous reporting of a 75% uptake. In Uganda, between 2002 and 2009, uptake of HCT at antenatal clinics increased from 3.3% to 94.5% as the policy moved from opt-in to opt-out. (37) The findings in the Ugandan study suggest that the opt-out methodology was seen as ‘standard of care’ and increased the acceptability to participate. (37) In a study conducted in 2003-2004 in a rural South African community, 12323 women attending antenatal clinics were offered HCT. Some were offered a rapid test with the results revealed the same day, while others were offered an ELISA test where they would return in two weeks time for their test results. Although there was an HCT uptake of 9134 (74.6%) women overall, only 57% of those returned for their results. Interestingly, only 3.4% of those who took a rapid test requested their results on the same day. (47) Another study in Uganda also showed that 25% of HCT clients did not return for their HIV test results. (49) In
a Zimbabwean study, limited uptake of HCT results was also identified as a challenge. (50) This highlights the need to not only measure uptake, but also to ensure that results are revealed. The low number of women willing to accept same-day HIV test results demonstrates the need for women to be emotionally prepared to receive their results. It also emphasizes the need to provide good quality pre-test counselling.

Pre-test counselling has been shown to increase uptake of HIV testing. (51) In some countries HCT is offered in the home. This delivery method has shown a higher uptake of HIV testing as opposed to clinic-based HCT. (52) HCT for couples has also been initiated in many Sub-Saharan countries, where male partners are asked to attend antenatal clinic appointments with their female partners. Given the nature of HIV transmission, this protocol makes sense and ensures that partners are equally informed, as well as be made aware of the status of their partner. A Ugandan study achieved a 100% HCT uptake in male partners at antenatal clinics. (37) Because of the often unequal power relationships between men and women, caution is needed when applying couple testing in the African context. Couples counselling may also be influenced by individuals suspicious of infidelities. This is something to consider when initiating couples counselling as opposed to individual counselling. HCT has been modified in many resource-limited settings to ensure widespread availability. This has also included the move from one-to-one pre-test counselling, to group counselling. This allows a faster uptake of HCT for larger numbers, while utilizing minimal human resources.

2.4. Determining the severity of HIV in South Africa

To effectively manage a public health challenge, it is integral to fully understand the depth of the challenge. Health situations that: cause disability or are fatal; have a high prevalence; are communicable; are preventable and/or have an economic impact on the country, are in most instances considered for disease surveillance. The purpose of disease surveillance is to monitor the incidence and prevalence of diseases for the purpose of responding with public health interventions to reduce or eliminate diseases. Most disease surveillance systems are created to monitor notifiable diseases that are typically linked to the International Health Regulations, to
monitor diseases that could impact global health security. Additional diseases are included in surveillance systems in countries for the purposes of monitoring immunization programmes, understanding unique disease patterns within their society and for strategic planning purposes.

In some countries HIV is a notifiable disease. In South Africa, this is not the case. The decision not to include HIV as a notifiable disease in South Africa has long been debated by public health specialists and advocacy groups. In 1999, the National Department of Health had planned to make HIV a notifiable disease, but it was later abandoned, because of pressure from advocacy groups. (53) The rationale of the advocacy groups was that because of poor infrastructure, a disease surveillance system for HIV would be difficult to implement and data quality would be poor. The high level of HIV stigma that exists in South Africa would place individuals who are HIV positive at risk. Moreover, data on HIV prevalence from antenatal clinics was readily available and it was determined this would provide adequate statistics on HIV. (53) Countries such as Australia, France and the US have included HIV on their list of notifiable diseases. However, a study from the Netherlands in 2007 determined that making HIV a notifiable disease does not increase HIV testing or contribute more effectively to the success of prevention programmes. (54)

In South Africa, there are currently several main sources of data on HIV prevalence. First, the National Department of Health releases the *National HIV & Syphilis Antenatal Sero-Prevalence Survey in South Africa*. (16) This study uses ANC data, a common approach to determine HIV prevalence in the broader population. The use of ANC data is not the ideal methodology, as there are concerns regarding the true population representativeness of antenatal surveys. Secondly, the Actuarial Society of South Africa (ASSA), also produces HIV data using modelling techniques. Thirdly, population based HIV surveys have been conducted by the Human Sciences Research Council (HSRC). (10) Population based surveys are considered as being more representative of the South African population than using antenatal data or modelling techniques. The population based survey conducted by the HSRC, also uses HIV testing data retrieved voluntarily from survey participants to determine HIV prevalence. (10)
South Africa has the DHIS that collects facility-based data. This system allows for data capturing of human resources, patient load, diagnosis, treatment provided, chronic care, births and deaths in each facility. The data are captured from patient files and recorded on a data grid by a nurse. The data are then given to a data capturer at the district health level to load into the DHIS. This data are consolidated at a provincial level and once again at a national level. Although this is an ideal system for burden of disease and surveillance methodologies, it is fair to state that there is significant scepticism within the public health community in South Africa that the DHIS is a reliable source of public health data.

Measurement of HIV incidence remains elusive as it is difficult to determine new infections. Data on HIV prevalence trends are currently utilised in South Africa, but may not reflect incidence trends. The literature also states that incidence must be considered, specifically with respect to mature epidemics. Identifying recently HIV infected individuals would contribute greatly to monitoring HIV in populations \( (1,15) \) To determine the usefulness of HCT as a data collection source for disease surveillance, an evaluation of the ability to collect both prevalence and incidence data are imperative.

HIV incidence estimates can be derived from longitudinal cohort studies or from mathematical modelling using sentinel or age specific quantification. \( (13–15) \) Such studies have been conducted in Uganda and Rwanda, and are expensive and challenging. Alternatively, less expensive forms of disease surveillance methodologies need to be investigated. \( (1,17–19) \) Using immunoassay methodology such as the BED Capture Enzyme Immunoassay (BED-CEIA) or the Enzyme Immunoassay for Recent Infection (EIA-RI), it is possible to determine new incidence. These methods have been applied and used in countries where HIV is a notifiable disease and where data on newly diagnosed cases is available. \( (55,56) \) In South Africa, BED-CEIA was used by the HSRC in the 2005 South Africa national HIV household survey to determine incidence estimates. \( (15) \)
It is documented that very few people worldwide are diagnosed within the first month of infection, making the determination of incidence from those newly diagnosed a challenge. (27) There is still limited focus on earlier identification of HIV infection. If annual HCT uptake increased, as recommended by the CDC, this would significantly reduce this challenge. (57,58) It is also estimated that in Sub-Saharan Africa, 90% of those who are HIV positive are unaware of their status. (39) In the US, it is estimated that 54-70% of new infections occur in those who do not know their HIV status. (58) These statistics provide significant limitations for estimation of prevalence and incidence derived from existing data.

The literature also refers to the high transmission rates amongst those who are undiagnosed. In the US it was estimated that transmission rates in those who are undiagnosed can be as much as three and a half times higher than those who are diagnosed. (59) This indicates that there is an undiagnosed population that has an incidence rate different from those who are diagnosed. Therefore, modelling methodology should be able to take this into consideration. A study conducted in France from 2003-2007 used the EIA-RI methodology to look at national incidence rates and found that the sensitivity of the methodology was different for populations from different geographic origins. (56) This is an important finding as it highlights that demographic stratification of populations is an important step to determine HIV incidence as well as prevalence.

In 1995, it was suggested by Brookmeyer and Quinn that the most appropriate HIV incidence approach would be through diagnostic testing for the p24 antigen, which appears in the blood prior to the production of antibodies and seroconversion. (60) The window period for the p24 antigen is estimated at 20-30 days which is a short space of time in order to confirm a new HIV infection through laboratory tests. There are fourth-generation HIV rapid test kits that also detect the p24 antigen. Considering that the window period to test for new infections is so short, testing would need to be conducted weekly over a period of time. HCT programmes are therefore not a realistic data collection point for incidence data, as most people do not even test annually at HCT sites.
2.5. **Evaluating HCT data as a disease surveillance source**

There has been substantial debate, specifically in Africa, regarding the validity of using HCT data as part of routine surveillance data of the HIV epidemic. With HCT programmes that are by now widespread throughout South Africa, HCT data are a unique source of existing data. Rapid HIV test kits being used in Africa have been shown to have acceptable specificity and sensitivity if used correctly, which supports the use of rapid testing as an appropriate measurement tool. (14,21) The literature however, also suggests that HCT data are biased as a result of the high proportion of repeat testers, where repeat testing is indicative of high risk sexual behaviour. (1–8)

Reporting systems in Africa are generally considered weak, unreliable and lack consistency which may compromise surveillance reporting. (21) Additional work load on clinic staff may compromise the quality of the data collection, but may also compromise the level of care provided in a clinic. (9,22,23) It is integral to the formation of public health strategies to work through the reporting limitations that exist in Africa and - while acknowledging barriers - to come up with solutions which are epidemiologically sound as well as appropriate for the African context. HCT data could be an alternative or additional data source for HIV surveillance; however more needs to be understood about both strong and weak points.

Much research has been done around understanding the motivation of people to test voluntarily. Whether people choose not to test because of stigma or lack of appropriate treatment if they do test positive for HIV, there is still much uncertainty about the relationship between stigma and HIV testing. (22) It has been suggested that HCT data be separated into first-time- and repeat tester data in any prevalence or incidence estimations. (9) If repeat tester data are excluded, a potential difference between this group and first-time testers remains undetermined.

2.6. **Repeat-testing and high-risk sexual behaviour**

There is conflicting literature regarding repeat-testers. They have been shown in several African studies to have a higher self-reported behavioural risk for HIV
compared to first-time testers. (3,5–8,61) However the behaviour and motivation of repeat-testers is both complex and poorly understood. (62) Therefore to disregard HCT data due to repeat testers may be premature, specifically due to the findings in several studies where a lower HIV incidence and prevalence is found when repeat testers are compared to first-time testers. (3,11,12) A study conducted in the UK, also highlighted the need to understand if repeat testing is linked to high-risk behaviour, or if it is a risk reduction strategy. (63) There is an urgent need for analysis of sub-groups in both repeat-testers and those who are testing for the first-time.

Literature suggests that HCT data are biased as a result of the high proportion of repeat testers, where repeat testing is indicative of high risk sexual behaviour. (1,2,64) Literature also highlights that there are not only repeat-testers, but also routine-testers who are those who regularly plan to have an HCT test. (64) This raises the question if repeat testing is linked to high-risk behaviour and if it is utilised as a strategy to reduce risk. (63) This demonstrates that in the group of repeat-testers, there are also sub-groups that need to be further defined. Characteristics of these sub-groups would have an impact on the need to test repeatedly. More needs to be known about the unique characteristics of these sub-groups.

Repeat-testers have been shown in several African studies to have a higher self-reported behavioural risk for HIV compared to first-time testers. (3,5–8,61) Reviewing studies that investigated this behaviour, there are contradicting findings. In a study based in Zimbabwe, sexual behaviour was not linked to HCT uptake. It was also found, however, that those who tested HIV negative were more likely to engage in risky sexual behaviour. (50) Another study in the UK showed no difference in sexual risk behaviour between first-time- and repeat testers. (63) Studies in both Ethiopia and Uganda, where HIV prevalence and incidence were determined in the two groups, a lower HIV incidence and prevalence was found in repeat testers when compared to first-time testers. (11,12) A recent cross-sectional, population-based study in Kenya also confirmed this, where of those who tested HIV positive, 64% were first-time testers. (3) The profile of first-time- and repeat testers is also most likely very different in Western countries compared to African countries due to socio-
economic and gender inequalities. The conclusion that can be drawn is that there is a need for analysis of sub-groups in both repeat-testers and those who are testing for the first-time.

There are many studies that have investigated the impact of HCT on reducing risky sexual behaviour. Pre- and post-counselling during HCT is a method for prevention through use of behaviour change interventions. The information and support provided allows individuals to review their sexual practices, identify what they can or cannot control and find support on how they may decrease or manage their sexual risk behaviour. Post-counselling including prevention messaging that has been shown to be ineffective for behaviour change. (64) Most studies on the effect of HCT on prevention are based on self-reported sexual behaviour. Overall, these studies demonstrate a self-reported reduction in sexual risk behaviour. The effect of post-test counselling is minimal in reducing risk behaviour. The minimal effect of post-test counselling has been predominately found in women; those who are HIV positive; and serodiscordant couples. (65,66) With mounting pressure for prevention programming, this feeds the debate regarding the redirection of resources to fund prevention programming rather than scale up HCT.

The issue of social behavioural change to impact HIV infection rates is complex and literature has encouraged to use units of analysis such as communities, rather than individuals or couples. (65) This can be applied to HCT testing strategies, as the motivation of a person to test for HIV is also complex involving both operational and emotional aspects. This is why new approaches to behaviour change are focusing on social marketing and media, instead of individual one-to-one style counselling that has been applied to HCT until now. (67,68)

2.7. Conclusion

The literature review has determined that HCT as a measurement tool has been proven to be accessible, cost-effective and has the appropriate sensitivity and specificity. It is also clear that the uptake of HCT is influenced by the ability to provide effective pre- and post-test counselling, as well as confidentiality and referral to appropriate treatment. Recognizing that the motivation to have an HIV test has
significant social and behavioural components, individuals are more confident to test for HIV when HCT services are provided in a professional way. Encouraging an increased uptake of HCT is integral to the use of HCT data for disease surveillance purposes. The increasing research into effective HCT methodologies such as PICT and opt-out testing is integral to better understand the characteristics and motivations of those who voluntarily test for HIV.

It is recognised that HIV prevalence is a realistic measure to be used in HIV disease surveillance, while HIV incidence holds additional challenges. HCT may not necessarily be an effective methodology to determine HIV incidence. When looking at the groups of interest, there was literature suggesting there is a difference in HIV prevalence between first-time- and repeat testers. It is clear from the literature review that repeat testers self-report increased sexual risk at a higher rate than first-time testers. Knowledge around the demographic profile of these two testing groups is until now fairly unknown, specifically in Southern Africa.

As there was limited information on the two testing groups while developing the research protocol, and limited literature specific to South Africa, the hypothesis used in this study is that there is no difference in the demographic characteristics and HIV prevalence of those who are first-time testers and those who are repeat testers.
Chapter 3 - Methodology

3.1. Aim(s) and objectives

3.1.1. Study aim

The aim of this research was to determine whether there is a difference in the demographic characteristics and HIV prevalence of those testing for the first-time and those testing more than once; and whether there are differences in HIV prevalence between first-time- and repeat testers.

3.1.2. Study objectives

i. To estimate the prevalence of HIV among first-time testers and repeat testers at FPD mobile HCT sites in Tshwane;

ii. To record the HIV test result, sex, age and population group of first-time testers and repeat testers;

iii. To obtain population demographic data and HIV prevalence data for Gauteng Province for reference purposes; and

iv. To compare the overall profile of mobile HCT users (first-time- and repeat testers) in Tshwane with the Gauteng Province profile.

3.2. Study design

This was an observational study, as there was no intervention. A cross-sectional study design was used with random proportional sampling, to compare first-time testers and repeat testers. Sampling was done from existing HCT client records, and the data was also used for determining HIV prevalence for both groups.

The data was collected from existing data of the FPD mobile HCT units in Tshwane, Gauteng Province. There are limitations to using existing data, as data collection and quality control mechanisms cannot be changed. The variables being used for this study are easily understood as they are standard demographic characteristics such as age, sex, population group and whether they are a first-time- or repeat tester. All
records, including HIV status were filled in by FPD trained counsellors and nurses, who have received training regarding the definition of the above mentioned variables. The variable of first-time- or repeat tester was self-reported, therefore this must be considered with caution.

Descriptive analysis was used to describe the demographic characteristics and HIV prevalence of those who voluntarily test for HIV (for both first-time- and repeat testers). Statistical tests of significance were used (chi-square) to analyse the relationship between variables. To evaluate the determinants of HIV status, multiple logistic regression was applied by test group (first-time- and repeat tester), adjusted for sex, age and population group.

3.2.1. Study setting

The study setting was in the Tshwane Metropolitan Municipality in Gauteng Province, and mobile HCT unit data from FPD was used. FPD is registered with the Department of Education as a private institution of higher education. FPD runs an extensive HIV testing programme, funded by the USAID PEPFAR programme and in cooperation with the Gauteng Provincial Department of Health. This programme is well-established in the Tshwane Metropolitan Municipality area and consists of both stationary HCT sites based in public clinics, as well as mobile HCT units which move daily throughout the municipal area. The data collected by the programme is used for reporting on numbers of people tested as well as HIV status, but is currently not analysed for demographic characteristics. FPD has four mobile HCT units, which run five days a week from 8:30 am-3:00pm at various public sites throughout the City of Tshwane. The nurses and counsellors in the mobile HCT units are highly trained and the programme has been running in Tshwane since 2007. For the purposes of this research, only the mobile HCT unit data was utilised.

3.2.2. Study population and sampling

The sampling frame included all individuals who had voluntarily agreed and signed an informed consent for HCT at an FPD mobile HCT unit throughout Tshwane since
December 2010. The sampling method was systematic random sampling for those who have had an HIV test for the first time and those who have had repeat HIV tests.

The inclusion criteria for this research were those who, since December 2010, had voluntarily agreed to HCT and have signed an informed consent at an FPD mobile HIV testing site in Tshwane. The exclusion criterion was anyone under the age of 18. Only individuals who are at or above the age of 18 were included in this research as they are considered adults and do not need the permission of a parent or guardian for HCT as indicated in the South African Child Act. (69)

Within the mobile HCT programme, FPD conducts an average of 2 000-4 000 HIV tests per month making this data an acceptable pool of sample data. It was estimated from existing data collected in December 2010 and January 2011 that there is a 6% HIV prevalence (n=4 913) from the data collected from the FPD mobile HIV units. It was also found that 20% (n=966) of all those who test are first-time testers. The indication of first-time tester is a relatively new variable, which has been initiated by the National Department of Health into all HCT data collection systems since the announcement of the National HCT Campaign, by the Minister of Health in April 2010. At the time of drawing the sample, there was few data to determine accurately a proportion of first-time testers and for this reason samples drawn were of equal size. The sample was drawn systematically from the total data set, from December 2010 onwards.

3.2.3. Sample size

The sample size was determined in consultation with a biostatistician and epidemiologist. In view of the consideration mentioned in the above section regarding sampling method, it was recommended to detect a 10% difference between all variables, with a power of 80%. The desired sample size was determined to be 400 for those who were first-time HIV testers and 400 for those who were repeat testers.
3.2.4. Measurements

The measurement tools used in this research were demographic and HIV testing data gathered from FPD mobile HCT unit data since December 2010, and collected by the FPD HCT Department.

The HIV tests used for all HCT conducted by FPD were HIV rapid tests that are approved for use and funded by PEPFAR-USAID. The rapid test kit included the testing strip, a lancet and capillary tube to draw the blood and the chase buffer when using whole blood. Using the lancet to prick the finger, the blood was drawn into the capillary tube and placed on the testing strip. The chase buffer was added to the testing strip and the result was ready to read in approximately 15-20 minutes, depending on the test kit used. Each HIV rapid test that is determined as positive was then confirmed with a second rapid test of another brand. According to donor requirements, all HIV rapid tests must have documentation from the manufacturer stating a sensitivity of at least 99% and a specificity of 98%. All HIV rapid tests being used must also have had reliable evaluations from one or more independent institutions which are internationally recognized, that can confirm sensitivity and specificity are within 95% +/-2% CI of that established in the manufacturers studies. (70)

The three rapid tests that were used in 2010-2011 at all FPD mobile HCT units can be seen below in Table 1.

**Table 1. Sensitivity and specificity of HIV rapid test kits used within the Tshwane study.**

<table>
<thead>
<tr>
<th>HIV Rapid Test Kit Name</th>
<th>Manufacturer</th>
<th>Sensitivity*</th>
<th>Specificity*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Double Check Gold™ HIV1&amp;2</td>
<td>Inverness Medical Innovations, Inc./Orgenics</td>
<td>100%</td>
<td>99%</td>
</tr>
<tr>
<td>First Response® HIV 1-2.0</td>
<td>Premier Medical Corporation</td>
<td>100%</td>
<td>99%</td>
</tr>
<tr>
<td>EZ-TRUST™ Rapid Anti-HIV (1&amp;2) Test</td>
<td>CS Innovation</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

(70)
The HIV rapid tests were administered by trained professional nurses employed by FPD, and confidentiality agreements were signed by all FPD staff. All information collected was securely stored by FPD in a document warehouse. The primary researcher had also signed a confidentiality agreement with FPD.

3.3. Quality assurance

3.3.1. Validity and reliability

Previous research has established that appropriate sensitivity for HIV rapid tests is a minimum of 99% and the specificity minimum is 98%. (70) As indicated in Table 1, all HIV rapid test kits used for the duration of this Tshwane study met the sensitivity and specificity requirements.

3.3.2. Quality control

In regard to quality control, all nurses were trained in the proper use of rapid tests for HIV in the HCT environment. HIV testing protocols have been developed and are applied. The HIV testing protocol states that if a positive HIV result is received on the first test kit, an additional test kit of a different brand must be used to confirm the positive result. All test kits were sealed and the expiration date was confirmed to ensure the test kit was still viable. All test kits were opened in front of the participant to be tested. Participants were asked to fill out an informed consent explaining the HIV test and guaranteeing confidentiality. All documentation was completed by one staff member, confirmed and signed by the participant. All documentation was then securely stored for data entry. As the data being used for this study is basic demographic information, the margin of error is small. The head of the HCT unit supervises all data collection and the collection of data are monitored by a monitoring and evaluation specialist in FPD through a reporting mechanism.

The sampling of the data was done by the primary researcher and all identifiers were removed and an id number was allocated to each file. The data was then entered into a database using EpiData, and a double entry method was applied to reduce data entry error.
3.3.3. Data management and analysis

EpiData was used for initial data entry, using a double entry method. Data entry and storage was done on one computer, with an external back up designated for this research. The computer used was password protected, including a finger print scan to ensure that the data are secure. The clean data set was exported to STATA version 11 which was used for analysis. A statistician was also consulted on the methodology applied. The dataset used will be stored for 15 years on a secure electronic file stored at FPD, in line with FPD policy of storing and securing data.

3.4. Variables

Id (##) – to replace any identifiers, an id number will be assigned.
tester (f/r) – first time or repeat tester.
sex (m/f) – male or female.
age (##) – age in years at last birthday.
population group (b,w,c,i) – race is black, white, coloured, indian.
HIV+ (RR,NR) – HIV status as positive (RR) or negative (NR).

3.5. Analysis Plan

Using the study aim and objectives as a framework, the research design was both descriptive and analytical; differences in values of variables for first-time testers and repeat testers are described and compared. For hypothesis testing, the probability of a Type I error was set at 0.05 ($\alpha$). All variables used were categorical and nominal.

3.5.1. Descriptive analysis

Cross-tabulations of the relationships of the variables sex, age and population group with first-time- and repeat tester were used. Likewise, cross-tabulations were made of the relationships of the variables sex, age, population group and first-time- and repeat tester with HIV status. The strength of the relationships has been determined by comparing percentage distributions and means, as well as odds ratios.
3.5.2. Analytical statistics

The main outcome variable was HIV status and the correlates of this outcome was determined for sex, age and population group. For continuous data (age), the data was transformed into categorical data using standard age categories by intervals of five years. For variables already defined as categorical data (sex, population group and HIV status), the chi-squared significance test was applied. Analysis also included multiple logistic regression to evaluate the impact of determinants of HIV status by testing group (first-time- and repeat tester), adjusted for sex, age and population group. Testing behaviour (first-time- and repeat tester) was also used as the outcome in multiple logistic regression. However, the main outcome of interest remained HIV status.

3.6. Ethical and legal considerations

The protocol for this study was vetted by the Academic Advisory Committee of the School of Health Systems and Public Health (SHSPH), University of Pretoria. Ethics approval was obtained from the University of Pretoria, Faculty of Health Sciences, Ethics Committee. All University of Pretoria, Faculty of Health Sciences ethics protocols were followed as outlined by the Faculty of Health Sciences. (UP ethics approval no. 80/2011)

All data used for this study is existing data, where all participants had received pre-test counselling and had signed an informed consent to participate voluntarily in HCT. In the process of communication between the person who requests the test and the HCT staff, all participants were informed of the benefits and resources available to them. All participants understood that by giving consent the data collected may be used for research without disclosing their name or personal information (see Appendix B). For the purposes of this research, no personal identifiers were used and id numbers were assigned. Participants had the opportunity to ask questions during both the pre- and post-test counselling and all participation was voluntary; refusal and withdrawal could take place at any time. As the primary researcher did not work in the HCT department, she signed a confidentiality agreement with FPD.
Those who voluntarily agree to an HIV test received pre- and post-test counselling, (See Appendix C). If the test is HIV positive, participants were referred to an ART clinic close to them where they could have further counselling and CD4 testing. Those who had a CD4 test that was low enough, were deemed eligible and were enrolled on antiretroviral therapy; those who were not eligible for ART at that time had the option of being enrolled in a wellness programme.

Completion of all informed consent forms took place in a private enclosed space. All hard copy records are being kept in a secure locked document storage facility for 15 years, following to policy for storing and securing data in FPD. The results of the study will be placed in the public domain by means of a peer reviewed publication. The results will also be lay-communicated to the public at large on a poster, copies of which will be distributed to FPD mobile HCT units and FPD associated stationary clinics for a period of one year.

The study has been conducted with the permission of the Foundation for Professional Development (FPD), who has been conducting HIV testing and collecting the data since 2007. The permission letter is attached in the appendices (see Appendix A).

The primary researcher was solely in charge of data processing and storage was protected by password and fingerprint scan. All data was backed up on a password protected external hard drive.

3.7. Logistics and time schedule

The study was started in May 2011, once ethical approval was received. Existing retrospective data was used to collect the sample. Analysis was completed in June to August 2011 with the final report writing commencing from December 2011 to March 2012.
3.7.1. Budget and resources

All funds for HCT activities needed for this study have been provided by the Foundation for Professional Development (FPD), through a USAID PEPFAR grant.

3.8. Reporting of results

Annually the Foundation for Professional Development releases a “State of HIV and AIDS in Tshwane” report, in partnership with the University of Pretoria. The findings of this research were to be released within that report, but this could not be realised because of its discontinuation in 2012 due to lack of funding. Other potential reporting opportunities include article submissions to the South African Medical Journal (SAMJ) and the Southern African Journal of Epidemiology and Infection (SAJEI). International journal submissions will be considered as well as abstract submissions to national and international conferences specific to this area. The primary author of this research is Ms J Mitchell, while the secondary author is Prof J van Ginneken. There are no other authors.
Chapter 4 - Results

4.1. Introduction

The aim of this research was to determine if there were demographic differences, as well as HIV prevalence differences between those testing for HIV for the first-time and those who are repeat testing. The public health importance of this research is to better understand the profiles of those who test for HIV. This improved understanding will assist in determining the effectiveness of HCT as a data source for disease surveillance. As HCT is widely available throughout South Africa, with large numbers of people testing, HCT data are a potential source for disease monitoring, as well as evaluating prevention programmes and other interventions over time. Within the African context, HCT data are ideal as infrastructure is currently in place and data are already being collected in various public and private sectors.

This study was conducted in the City of Tshwane Metropolitan Municipality, in the Gauteng Province of South Africa. The Foundation for Professional Development (FPD) provides mobile HCT testing throughout the municipality, through funding provided by PEPFAR-USAID and in partnership with the local and provincial health authorities. In April 2010, the Minister of Health, Dr Aaron Motsoaledi, launched a National HCT Campaign that encouraged all South Africans to be responsible and know their HIV status, by encouraging South Africans to test for HIV. As the National HCT Campaign was launched, an indicator was also added to all data-collection forms to identify people testing as a first-time tester. Because this indicator was added, this research was made possible as records now included the first-time tester indicator.

Records from December 2010 to April 2011 were used to draw the sample total (n=800), divided into first-time testers (n=407) and repeat testers (n=393). The data was analysed and the following demographic and HIV prevalence findings were determined.
4.2. Descriptive Analysis

Demographic variables included in this study were sex, age and population group. For comparative purposes, Table 2 indicates the population distribution by age and sex for those eighteen years and older, in both the City of Tshwane Metropolitan Municipality and Gauteng Province. Only those above the age of eighteen were eligible to participate in this study, therefore these are the ages of interest for comparative reasons. The following will compile the descriptive analysis of the study findings.

4.2.1. Population Estimates of Gauteng Province and Tshwane Municipality

The estimated Gauteng population is derived from the mid-year population estimates for 2011, released by Statistics South Africa in July 2011. (71) The estimated Tshwane population is derived from the Statistics South Africa, Community Survey 2007. (72) The Community Survey 2007 is used, as this is the only recent document in South Africa with population estimates available by age below provincial level. It is acknowledged that since 2007 there has been population growth in Tshwane. Using the difference between mid-year population estimates for 2007 and 2011, a Gauteng population growth percentage was derived and applied to the Community Survey 2007 population estimates, by age category, to determine a 2011 population estimate for Tshwane.
Table 2. Estimated Tshwane and Gauteng Population Distribution Proportions (15+ years) by age category and sex, 2011

<table>
<thead>
<tr>
<th>Age Category</th>
<th>Estimated Tshwane Population</th>
<th>Estimated Gauteng Population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>15-19</td>
<td>11.5</td>
<td>11.1</td>
</tr>
<tr>
<td>20-24</td>
<td>13.6</td>
<td>12.8</td>
</tr>
<tr>
<td>25-29</td>
<td>11.9</td>
<td>11.5</td>
</tr>
<tr>
<td>30-34</td>
<td>12.2</td>
<td>11.6</td>
</tr>
<tr>
<td>35-39</td>
<td>13.7</td>
<td>12.6</td>
</tr>
<tr>
<td>40-44</td>
<td>10.1</td>
<td>9.8</td>
</tr>
<tr>
<td>45-49</td>
<td>7.5</td>
<td>7.9</td>
</tr>
<tr>
<td>50+</td>
<td>19.4</td>
<td>22.7</td>
</tr>
<tr>
<td>Total</td>
<td>100.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

4.2.2. Age

Age was collected as continuous data; however the data was allocated into age categories for the purpose of aligning the analysis and reporting with the age categories that are most utilised in public health. These age categories also align with South African reporting on HIV prevalence by age category, allowing ease of interpretation and comparison to existing reporting. The age category 50+ was included, as there were low numbers in the sample above 50 years of age. By combining the age categories 50 and above there is a sufficient amount of data (>n=30) to be statistically significant.

Table 3 illustrates the age distribution of the total study sample. The age span of the study sample was from 18 to 66 years of age. The largest participation in HCT by age are those 20 to 24 years, with a proportion of 30.4% (n=243) of the total sample. The next largest participation by age category are those 25 to 29 years, with 17.8% (n=142) of the total sample. The third largest participation are those aged 30-34, with 13.5% (n=108) of the total sample. Combined, the top three age categories, which span from age 20 to 34, indicate 61.7% (n=493) of the total sample. Those under the age of 20 are the next largest age category in the sample with 9.3% (n=74) of the total sample. Combined with the largest three age categories, those aged 18 to 34 years are 70.9% (n=567) of the total sample.
Table 3. Age Distribution of the Total Sample

<table>
<thead>
<tr>
<th>Age Group</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;20 (18-19)</td>
<td>74</td>
</tr>
<tr>
<td>20-24</td>
<td>243</td>
</tr>
<tr>
<td>25-29</td>
<td>142</td>
</tr>
<tr>
<td>30-34</td>
<td>108</td>
</tr>
<tr>
<td>35-39</td>
<td>66</td>
</tr>
<tr>
<td>40-44</td>
<td>45</td>
</tr>
<tr>
<td>45-49</td>
<td>41</td>
</tr>
<tr>
<td>50+</td>
<td>81</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>800</strong></td>
</tr>
</tbody>
</table>

It is important to note that this Tshwane study collected data from those 18 years and older. The population estimates available in the public domain for Tshwane and Gauteng did not provide data disaggregated by age; the data are available for the age category of 15 to 19. Keeping in mind the differences in data available for the under 20 age category, Table 4 shows the age distribution of the sample of this study, compared to Tshwane and Gauteng age distribution of the population.

Table 4 compares the age distribution between the sample for this Tshwane study and the estimated population of Tshwane and the Gauteng Province. It is estimated that 36.8% of the Tshwane population (15+) are between the ages of 20 to 34. This is very close to the Gauteng Province, where 37.7% of the population (15+) are estimated to be between the ages of 20 to 34. Overall, the age distribution in Tshwane is close to that of the Gauteng Province. However, the sample for this study in Tshwane was much larger with an age distribution of 61.7% between the ages of 20 to 34 years.

Table 4 indicates that there is significant variation between the sample and the estimated Tshwane population in most age categories. The largest variation is seen in the age category of 20 to 24 years, and 50+ years of age. Therefore the sample drawn for this study does not have a similar age distribution of either the estimated Tshwane or the Gauteng Province populations. However, the sample distribution does potentially indicate that those aged 20 to 29 are more likely to have an HCT
test; more likely to be available for an HCT test; and/or are more targeted by HCT staff.

Table 4. Sample age distribution compared to estimated population distribution in Tshwane and Gauteng Province

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Sample Total (18+) %</th>
<th>Estimated Tshwane Population Distribution (15+) %</th>
<th>Estimated Gauteng Population Distribution (15+) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-19</td>
<td>9.3</td>
<td>15-19 11.3</td>
<td>10.8</td>
</tr>
<tr>
<td>20-24</td>
<td>30.4</td>
<td>20-24 13.2</td>
<td>11.4</td>
</tr>
<tr>
<td>25-29</td>
<td>17.8</td>
<td>25-29 11.7</td>
<td>12.7</td>
</tr>
<tr>
<td>30-34</td>
<td>13.5</td>
<td>30-34 11.9</td>
<td>13.6</td>
</tr>
<tr>
<td>35-39</td>
<td>8.3</td>
<td>35-39 13.2</td>
<td>12.8</td>
</tr>
<tr>
<td>40-44</td>
<td>5.6</td>
<td>40-44 9.9</td>
<td>9.0</td>
</tr>
<tr>
<td>45-49</td>
<td>5.1</td>
<td>45-49 7.7</td>
<td>7.5</td>
</tr>
<tr>
<td>50+</td>
<td>10.1</td>
<td>50+ 21.1</td>
<td>22.3</td>
</tr>
<tr>
<td>Total</td>
<td>100.0</td>
<td>Total 100.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

4.2.3. Sex

The data for sex (male, female) was dichotomous. Statistics South Africa mid-year population estimates of Gauteng Province for 2011 indicate that 50.4% of the Gauteng population are male, while 49.6% are female. Within the total sample for this study, 58% (n=464) were female and 42% (n=336) were male.

4.2.4. Population Group

Data for population group was categorical, aligning with population groups that are standard in South African demographic reporting. Black, coloured, white and indian were the population groups used. The sample group contained 98.8% (n=790) black, 1.1% (n=9) white, 0.1% (n=1) coloured and 0% (n=0) indian. As all groups did not contain a significant number in the sample, it is not possible to provide comparisons between population groups in this study.
4.3. **HIV Prevalence**

Dichotomous HIV data was collected by identifying those who were non-reactive (NR) to the HIV rapid test, indicating that they are HIV negative. Those who were reactive (RR) to the HIV rapid test were identified as HIV positive.

According to the data released by Statistics South Africa in the mid-year population estimates 2011, the estimated HIV prevalence nationally for the total population (all ages) in South Africa is 10.6%. HIV prevalence is estimated to be 16.6% for the adult population (15-49 years). (71) In the South African National HIV Survey 2008, conducted by the Human Sciences Research Council (HSRC), the national HIV prevalence for the age category of those 25 years of age and older was 16.8% (n=7191). HIV prevalence estimates for provinces are also provided in the National HIV Survey 2008 (ages 2+), with Gauteng Province having an HIV prevalence of 10.3% (n=2093). Those aged 25 and older in Gauteng Province have an HIV prevalence of 14.4% (n=1057), while the adult population (15 to 49 years) have an HIV prevalence of 15.2% (n=1274). (10)

The South African National HIV Survey 2008 also identifies those populations most at risk of HIV. African females aged 20 to 34 are the most at risk population with an HIV prevalence of 32.7% (n=1395), while African males aged 25 to 49 are the second highest at risk population with an HIV prevalence of 23.7% (n=944). Males 50 years of age and older are the third highest at risk population, with an HIV prevalence of 6.0% (n=946). (10)

The findings of this Tshwane study indicated an overall 10.0% (n=80) HIV prevalence rate (18+ years). As the Tshwane study sample is 18 years of age and older, when compared to the Gauteng adult prevalence (15 to 49 years) of 15.2%, or the Gauteng HIV prevalence (15+ years) of 14.4%, this Tshwane HCT study HIV prevalence is lower. (10)

Table 5 shows HIV prevalence data disaggregated by sex and age category. HIV prevalence is highest in the 40 to 44 age category for males (26.7%). In females, the
30 to 34 and 35 to 39 age categories are highest (17.2% and 17.4% respectively). HIV prevalence is slightly higher in males (10.3%), than in females (9.5%).

**Table 5. HIV Prevalence by Age Category and Sex**

<table>
<thead>
<tr>
<th>Age Category</th>
<th>&lt;20</th>
<th>20-24</th>
<th>25-29</th>
<th>30-34</th>
<th>35-39</th>
<th>40-44</th>
<th>45-49</th>
<th>50+</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>HIV+ %</td>
<td>0.0</td>
<td>3.7</td>
<td>7.0</td>
<td>16.5</td>
<td>20.9</td>
<td>26.7</td>
<td>13.8</td>
<td>6.6</td>
</tr>
<tr>
<td>Total</td>
<td>N</td>
<td>29</td>
<td>107</td>
<td>86</td>
<td>79</td>
<td>43</td>
<td>30</td>
<td>29</td>
<td>61</td>
</tr>
<tr>
<td>Female</td>
<td>HIV+ %</td>
<td>6.7</td>
<td>5.9</td>
<td>16.1</td>
<td>17.2</td>
<td>17.4</td>
<td>0.0</td>
<td>8.3</td>
<td>10.0</td>
</tr>
<tr>
<td>Total</td>
<td>N</td>
<td>45</td>
<td>136</td>
<td>56</td>
<td>29</td>
<td>23</td>
<td>15</td>
<td>12</td>
<td>20</td>
</tr>
</tbody>
</table>

Figure 1 below compares the sample HIV prevalence by age category (20 to 50+) and sex with South African HIV prevalence data from the HSRC. (10) The female HIV prevalence for the age categories 20 through to 39 years in the sample is lower compared to the National HIV prevalence pattern. For both males and females, compared to the National HIV prevalence, the sample has a lower HIV prevalence pattern in the age categories of below 34.

**Figure 1. HIV Prevalence by Age Category and Sex – Sample compared to National HIV Prevalence patterns.** (10)
4.4. First-time/Repeat tester profiles

Individuals participating in HIV testing were asked if this was their first HIV test. Those who indicated ‘yes’, were identified as first-time testers. Those who indicated ‘no’, were identified as repeat testers. This variable was dichotomous.

The total proportions of those who are first-time- and repeat testers cannot be compared, as equal samples were drawn based on these criteria. Therefore the sample has equal proportions of first-time- (n=407) and repeat testers (n=393). The slight variation of fourteen cases between the two groups was simply a counting error and was not identified until the data was already electronically captured. As the variation is small, it is seen as insignificant considering the size of the sample.

When first-time- and repeat tester groups are disaggregated by sex, Table 6 shows that for males, there are more first-time testers (53.7%) while for females, there is a lower proportion of first-time testers (47.0%). However the difference between first-time- and repeat testers by sex was not proven to be statistically significant (p=0.0637) in the sample.

<table>
<thead>
<tr>
<th>Sex</th>
<th>First time</th>
<th>Repeat</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>53.7%</td>
<td>46.3%</td>
<td>100.0%</td>
</tr>
<tr>
<td>Female</td>
<td>47.0%</td>
<td>53.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td>Total</td>
<td>50.9%</td>
<td>49.1%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

(Chi2 test of significance, p=0.0637)

Figure 2 shows that the highest proportion of total HIV testers was in the age category of 20 to 24, and the lowest being in the 45 to 49 age category. Both first-time- and repeat testers follow a similar age distribution pattern, peaking in the age category of 20 to 24 and falling until the age category of 50+ where the proportion rises slightly. Differences between first-time- and repeat testers were found to be statistically significant only in the age category of 18 to 20 (p=0.0000) and 40 to 44 (p=0.0008).
Table 7 shows that a high percentage of first-time testers were HIV positive (12.5%), compared to repeat testers (7.4%). This is very different from those whose status was HIV negative; 87.5% of first-time testers and 92.6% of repeat testers. The difference in HIV status between those who are first-time- and repeat testers was found to be statistically significant (p=0.0152).

Table 7. HIV status of first-time- and repeat tester

<table>
<thead>
<tr>
<th>Tester</th>
<th>HIV+</th>
<th>HIV-</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>First time</td>
<td>12.5</td>
<td>51</td>
<td>87.5</td>
</tr>
<tr>
<td>Repeat</td>
<td>7.4</td>
<td>29</td>
<td>92.6</td>
</tr>
<tr>
<td>Total</td>
<td>10.0</td>
<td>80</td>
<td>90.0</td>
</tr>
</tbody>
</table>

(Chi² test of significance, p=0.0152)

Table 8 shows the HIV prevalence of first-time- and repeat testers by age category. It can be seen that the percentage of HIV positive repeat testers peaks in the age category of 30 to 34. The second highest percentage for repeat testers is in the age category of 40 to 44.
This is in contrast with first-time testers, where the percentage who is HIV positive peaks in the age category of 35 to 44. First-time testers have an increased HIV percentage in all age categories, except for those aged 50+. Repeat testers have a larger percentage of HIV positive in the 50+ age category.

Table 8. HIV prevalence of first-time- and repeat testers, by age category

<table>
<thead>
<tr>
<th>Age Category</th>
<th>Tester HIV status</th>
<th>&lt;20</th>
<th>20-24</th>
<th>25-29</th>
<th>30-34</th>
<th>35-39</th>
<th>40-44</th>
<th>45-49</th>
<th>50+</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>First-time</td>
<td>HIV+ %</td>
<td>5.2</td>
<td>6.0</td>
<td>14.1</td>
<td>18.8</td>
<td>33.3</td>
<td>33.3</td>
<td>26.3</td>
<td>5.1</td>
<td>12.5</td>
</tr>
<tr>
<td></td>
<td>Total N</td>
<td>58</td>
<td>134</td>
<td>64</td>
<td>48</td>
<td>33</td>
<td>12</td>
<td>19</td>
<td>39</td>
<td>407</td>
</tr>
<tr>
<td>Repeat</td>
<td>HIV+ %</td>
<td>0.0</td>
<td>3.7</td>
<td>7.7</td>
<td>15.0</td>
<td>6.1</td>
<td>12.1</td>
<td>0.0</td>
<td>9.5</td>
<td>7.4</td>
</tr>
<tr>
<td></td>
<td>Total N</td>
<td>16</td>
<td>109</td>
<td>78</td>
<td>60</td>
<td>33</td>
<td>33</td>
<td>22</td>
<td>42</td>
<td>393</td>
</tr>
</tbody>
</table>

4.5. Analytical Statistics

Logistic regression analysis was performed with HIV status as the dependent variable, to determine the effect of other variables on HIV status. Age, although a continuous variable, was modified into age categories; altering the data into categorical data. Logistic regression analysis was also performed with the first-time- and repeat tester as the dependent variable using age and sex as the independent variables.

4.5.1. HIV Status

Logistic regression analysis was applied with HIV as the outcome variable and sex, age, first-time- and repeat tester as the explanatory variables. In Table 9, Model 1 shows a statistically significant relationship between being HIV positive and being a first-time tester (OR=1.8, p=0.016). When adjusted for sex and age, the odds ratio and statistical significance increase (OR=2.4, p=0.001, Model 3). A first-time tester, is 2.4 times more likely to be HIV positive than a repeat tester. In regards to sex, it is clear that this does not have a statistically significant relationship with being HIV positive (p=0.822, Model 2). In Model 3, those in the age categories of 30 to 34 (OR 2.7, p=0.051), 35 to 39 (OR 3.0, p=0.037) and 40 to 44 (OR 3.3, p=0.041) are more likely to be HIV positive compared to other age categories.
Table 9. Logistic regression with HIV as the outcome variable and adjusted by first-time/repeat tester, sex and age.

<table>
<thead>
<tr>
<th>HIV+</th>
<th>Model 1</th>
<th></th>
<th>Model 2</th>
<th></th>
<th>Model 3</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR</td>
<td>p-value</td>
<td>OR</td>
<td>p-value</td>
<td>OR</td>
<td>p-value</td>
</tr>
<tr>
<td>First-time</td>
<td>1.8</td>
<td>0.016</td>
<td>1.8</td>
<td>0.017</td>
<td>2.4</td>
<td>0.001</td>
</tr>
<tr>
<td>tester</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repeat tester</td>
<td>1.0</td>
<td>—</td>
<td>1.0</td>
<td>—</td>
<td>1.0</td>
<td>—</td>
</tr>
<tr>
<td>Female</td>
<td>—</td>
<td>—</td>
<td>0.9</td>
<td>0.822</td>
<td>1.3</td>
<td>0.257</td>
</tr>
<tr>
<td>Male</td>
<td>—</td>
<td>—</td>
<td>1.0</td>
<td>—</td>
<td>1.0</td>
<td>—</td>
</tr>
<tr>
<td>&lt;20</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>0.4</td>
<td>0.187</td>
</tr>
<tr>
<td>20-24</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>0.6</td>
<td>0.276</td>
</tr>
<tr>
<td>25-29</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1.5</td>
<td>0.440</td>
</tr>
<tr>
<td>30-34</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>2.7</td>
<td>0.051</td>
</tr>
<tr>
<td>35-39</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>3.0</td>
<td>0.037</td>
</tr>
<tr>
<td>40-44</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>3.3</td>
<td>0.041</td>
</tr>
<tr>
<td>45-49</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1.8</td>
<td>0.383</td>
</tr>
<tr>
<td>50+</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1.0</td>
<td>—</td>
</tr>
</tbody>
</table>

4.5.2. First-time- and repeat testers

Table 10 shows logistic regression analysis using first-time- and repeat testers as the outcome variable and adjusted for sex and age. It is interesting that the association of first-time- and repeat tester with sex is statistically significant after controlling for age. Females are less likely to be first-time testers compared to males (OR=0.6, p=0.001). Those aged under 20 are 5.0 times (p=0.000) more likely to be first-time testers, while those aged 40 to 44 are 0.4 times (p=0.013) less likely to be first-time testers when compared to the age group of 50+. The relationship of first-time- and repeat tester with age was found to be statistically significant in the age category of under 20 (18 to 20 years) and those 40 to 44.
Table 10. Logistic regression with first-time- and repeat tester as the outcome variable adjusted by sex and age.

<table>
<thead>
<tr>
<th></th>
<th>Model 1</th>
<th>Model 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adjusted by sex</td>
<td>Adjusted by sex and age</td>
</tr>
<tr>
<td><strong>First-time tester</strong></td>
<td><strong>OR</strong></td>
<td><strong>p-value</strong></td>
</tr>
<tr>
<td>Female</td>
<td>0.8</td>
<td>0.064</td>
</tr>
<tr>
<td>Male</td>
<td>1.0</td>
<td>—</td>
</tr>
<tr>
<td>&lt;20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-24</td>
<td>1.6</td>
<td>0.094</td>
</tr>
<tr>
<td>25-29</td>
<td>1.0</td>
<td>0.854</td>
</tr>
<tr>
<td>30-34</td>
<td>0.9</td>
<td>0.637</td>
</tr>
<tr>
<td>35-39</td>
<td>1.1</td>
<td>0.707</td>
</tr>
<tr>
<td>40-44</td>
<td>0.4</td>
<td>0.026</td>
</tr>
<tr>
<td>45-49</td>
<td>1.0</td>
<td>0.896</td>
</tr>
<tr>
<td>50+</td>
<td>1.0</td>
<td>—</td>
</tr>
</tbody>
</table>

4.6. Conclusions

The results above demonstrate that those who utilise mobile HCT units, are different from the population of the Tshwane Municipality, or the Gauteng Province by age and sex. It is also clear that mobile HCT units are almost exclusively utilised by the black population group in Tshwane, due to the low representation of white, coloured or indian population groups in the sample. Sites targeted by the mobile HCT units may be predominately located in areas inhabited by the black population.

The results above confirm that those who report themselves as a first-time tester are 2.4 times more likely to be HIV positive compared to those who are repeat testers. Sex does not have a relationship with HIV status. However, when first-time/repeat tester is used as the outcome variable females are 0.6 times less likely to be a first-time tester, compared to males. When looking at age categories, those aged 30 to 44 are more likely to be HIV positive compared to those 50+ years of age.
Chapter 5 - Discussion and Conclusion

5.1. Introduction

One of the topics in literature regarding HCT focuses on the use of such data for the purposes of disease surveillance. Repeat testing is frequently mentioned in literature as a potential source of bias. (9,22,23) It has been suggested that HCT data be separated into first-time- and repeat tester data in any prevalence or incidence estimations. (9) Studies regarding HCT data, and the characteristics of those who participate in HCT, have not been carried out in South Africa to date, and yet the results of such investigations would be crucial in the debate around whether or not data from HCT sites could provide unbiased estimates of HIV prevalence. Based on the literature available, understanding the demographic and HIV prevalence profiles of first-time- and repeat testers will assist is determining the potential use of HCT data in disease surveillance.

The aim of this research was to determine whether there is a difference in the demographic characteristics between those testing for the first time and those testing more than once; and whether there are differences in HIV prevalence between first time and repeat testers. The objectives of the study were to: estimate the prevalence of HIV prevalence among first-time testers and repeat testers at FPD mobile HCT sites in Tshwane; to record the HIV test result as well as sex, age and population group characteristics of first-time testers and repeat testers; to obtain population demographic data and HIV prevalence data for Gauteng Province for reference purposes; and to compare the overall profile of mobile HCT users (first-time- and repeat testers) in Tshwane with the Gauteng Province profile.

5.2. Discussion

The overall aim of this study was to understand if there is a difference between the basic demographic profile, as well as HIV prevalence amongst those who are testing for HIV for the first-time and those who are repeat testers. There is a high HIV prevalence in South Africa and with increasing focus on the correlation between social behaviour and HIV, the relevance of this study is to draw attention to the
characteristics of the various sub-groups at risk of HIV and this goes beyond basic population demographics. Therefore, testing behaviour (first-time- vs. repeat-testers) is an area of interest.

In South Africa, HCT is one of the key strategies to ensure that people know their HIV status and to understand how to either stay HIV negative or live well as an HIV positive individual. HIV intervention strategies aim to target specific populations, and with the correlation between social behaviour and HIV, these target populations need to be further understood and defined. To increase uptake of HIV testing, it is necessary to better understand the demographic profile as well as the HIV prevalence of HCT participants. Such studies may help to identify populations who are not participating in HCT and populations with an above average HIV prevalence. Such studies assist to expand HCT programmes to increase effectiveness and overall population uptake.

5.2.1. HIV Prevalence of the HCT sample compared to Gauteng Province

The findings of this Tshwane study indicated an overall 10.0% (n=80) HIV prevalence rate. The Tshwane study includes only those 18 years and older. Compared to the Gauteng adult prevalence (15 to 49) of 15.2%, or the Gauteng HIV prevalence for those ages 15 and older of 14.4%, the Tshwane HCT study prevalence is lower. (10) This indicates that those who test for HIV at mobile testing sites in Tshwane have a lower HIV prevalence than the Gauteng Province. Service at mobile HIV testing sites is relatively quick and is a more accessible option for people moving throughout their day. Mobile testing sites are also helpful for rural and hard to reach areas. According to the DHIS, HIV prevalence at fixed sites in Tshwane, such as primary health clinics and district hospitals, is 22% for the first six months of 2011. It is expected that HIV prevalence will be higher at fixed sites compared to mobile sites, as those who are testing at fixed sites may already be well aware of the possibility of a positive HIV status, or are already showing HIV infection symptoms. This example again highlights the importance of understanding the motivation for individuals to test, as it may indicate what mechanism of HCT delivery is effective in targeted HCT programmes.
5.2.2. HIV Prevalence in First-time- vs. Repeat Testers

When looking at the characteristics of the first-time tester and repeat tester groups, there was an HIV prevalence rate of 12.5% (n=51/407) in the first-time tester group, and a 7.4% (n=29/393) HIV prevalence rate in the repeat tester group. The difference between the two groups is statistically significant (p=0.0152). Although literature suggests that repeat testers are the more at risk population, this finding in this study of first-time testers having a much higher HIV prevalence (OR=2.4, p=0.001) demonstrates that there is a difference in HIV prevalence between the two groups. Three studies carried out in Ethiopia, Uganda and Kenya also found that the prevalence of HIV in first-time testers was slightly higher than in repeat testers. (3,11,12)

Literature suggests that those engaged in high-risk sexual behaviour are also those who are much more aware of the risk. Therefore they test more often as a monitoring mechanism. (3,5–8,61) If you were to follow this group over time, in a cohort study, the expectation would be that the prevalence rate would be higher than in the first-time tester group as their exposure to HIV is increased. As this study had a cross-sectional design, this is not known. It is important to further explore and define the characteristics of the first-time tester group. In addition, it should be mentioned that data on first-time- or repeat testers was self-reported. There may be a tendency to over-report data on testing for the first time. There may be stigma attached to defining oneself as a repeat tester, as it may allude to high-risk sexual behaviour; and/or clients may have misunderstood the question concerning testing for the first-time at this facility. This presents a potential limitation to this study, as it has used self-reported information. However, it was determined that those who reported themselves as a first-time tester have an odds ratio of 2.4 of being HIV positive as opposed to those who reported themselves a repeat tester.
5.2.3. HIV Prevalence - Adjusted for Sex and Age

The sample for this Tshwane study found an HIV prevalence of 16.1% in females aged 25 to 29 years, with females aged 30 to 34 and 35 to 39 having the highest HIV prevalence (17.2%, 17.4%) within the female sample. Compared nationally (Fig. 1), this prevalence is lower than the South African National HIV Survey 2008, where females aged 25 to 29 years had the highest HIV prevalence (32.7%). Nationally, those aged 30 to 34 and 35 to 39 also had higher HIV prevalence rates than the Tshwane study (29.1%, 24.8%). (10)

The Tshwane study found males aged 40 to 44 had the higher HIV positive prevalence (26.7%). This was the highest prevalence rate within the entire sample. Compared nationally (Fig. 1), males aged 30 to 34 had the highest HIV prevalence rate (25.8%) in the male population. Nationally, males aged 40 to 44 had an HIV prevalence rate of 19.2%. (10)

In the Tshwane study sample, males 50 years of age and older had an HIV prevalence of 6.6%. This is consistent with the national prevalence rate of 6.0% in males 50 year and older. (10) While the HIV prevalence of females 50 years and older was slightly higher than the national HIV prevalence in this population group (Fig. 1).

Overall, in the Tshwane study there was no significant statistical relationship found between HIV status and sex. When adjusted for sex and age, and compared to those aged 50 and above, those aged 30 to 34 were 2.7 (p=0.051) times more likely to be HIV positive. Those aged 35 to 39 were 3.0 (p=0.037) times more likely and those aged 40 to 44 were 3.3 (p=0.041) times more likely to be HIV positive.

5.2.4. First-time- and repeat testers - Adjusted for Sex and Age

When first-time- and repeat testers was used as the dependent variable, it was found that females are 0.6 less times likely to be a first-time tester compared to males (OR=0.6, p=0.001). This study also found that those aged under 20 are 5.0 times
more likely to be first-time testers, while those aged 40 to 44 are 0.4 times
(p=0.013) less likely to be first-time testers, compared to first-time testers 50 years
and older. For those under 20 years of age it is reasonable to believe that this is their
first HIV test. This study demonstrates that there is a large population of older
individuals who are testing for HIV for this first-time. It is suggested that strategies to
increase the uptake of HCT does not only focus on the younger age categories.
Older populations should also be targeted for HCT as there may be a lack of
perceived risk of HIV in older populations. This is supported by the findings of the
2005 South African national HIV household survey, conducted by the HSRC. (15)

5.3. Recommendations

Based on the results of this research, the following recommendations are identified
as a way forward:

- Basic demographic indicators, such as sex and age, do not work in isolation of
social aspects that influence increase risk for HIV, as well as uptake of HCT.
Further research into social aspects of HIV risk must be carried out and
combined with epidemiological research.
- There is substantial literature supporting the correlation between repeat testing
and having an increased behavioural risk for HIV. It has been demonstrated in
literature that those who feel more at risk of HIV are less likely to test
repeatedly, while those who feel less at risk are more likely to be repeat
testers. Therefore HCT services targeting those at high-risk of HIV must
consider the social and behavioural aspects that motivates this sub-group to
be tested.
- Self-reported first-time testers are a sub-group that are clearly more at risk for
HIV infection compared to self-reported repeat testers. Appropriate shifts in
HCT programmes should be made to ensure that first-time testers are
identified as a target group with high priority.
- This study and others demonstrate that first-time testers have a higher HIV
prevalence than repeat testers. It is recommended that further research be
done regarding the use of self-reported data. Specifically the classification of
first-time- and repeat testers.
• Emphasis is placed on the number of people who access HCT services. Literature revealed that although individuals participate in HCT, there is a low uptake of people who wait or return for their HIV test results. If the purpose of HCT is to ensure that people ‘know their status’, service providers must record not only the number of HIV tests provided, but the number of results revealed as a monitoring mechanism.

• With the re-engineering of primary health care as a priority in South Africa, it is recommended that more alternative HCT delivery mechanisms be developed, specifically widespread opt-out and home-based HCT. These additional mechanisms for HCT delivery will increase HCT uptake.

5.4. Conclusion

It is clear that there is a difference in the HIV and demographic profile of those who test for HIV for the first time and those who are repeat testers. The hypothesis for this study, as formulated at the end of Chapter 2, has been found to be unsubstantiated. It was found that those who reported themselves as a first-time tester were 2.4 times more likely to be HIV positive as opposed to those who reported themselves a repeat tester. This finding is consistent with three other studies in Ethiopia, Uganda and Kenya where HIV prevalence in first-time testers was slightly higher than in that of repeat-testers. (3,11,12)

It is acknowledged that there could be a tendency for over-reporting of those who have classified themselves as first-time testers, as this data is self-reported. There may be stigma attached to defining oneself as a repeat tester, as it may allude to high-risk sexual behaviour. It is also possible that clients misunderstood the question on whether they had tested for the first-time or not.

Repeat testing does not correlate with increased risk of HIV. A study done in Uganda found that those who would accept repeat testing had a slightly lower HIV incidence than those accepting an HIV test for the first time. (12) An Ethiopian study found that those who felt a high level of perceived risk of HIV were less likely to be repeat testers, while those who had a moderate level of perceived vulnerability were more
likely to be repeat testers. (11) This is substantiated by the higher HIV prevalence in the first-time tester group of this Tshwane study, as well as the other studies that also found a higher HIV prevalence and incidence in first-time testers. Based on the findings of this study, it cannot be concluded that repeat testers are a source of bias due to an increased risk of HIV.

In regards to the use of HCT data for disease surveillance, this study did not find that the population utilizing mobile HCT sites is representative of the Tshwane population. This study also highlighted the need to better understand the characteristics of the sub-groups of those who test for the first-time and those who test repeatedly for HIV. This Tshwane study did show evidence that there is a difference in the HIV prevalence between first-time- and repeat testers. However, because of self-reported data there is good reason to doubt that the prevalence rate of first-time testers is genuine.
Chapter 6 - References


Chapter 7 – Appendices

A. Letter of support from FPD – mobile HCT unit

APPENDIX A

FPD

PO Box 7632A, Lynnwood Ridge 0040: Shirley Office Park, East Block, 173 Mary Street, The Willows, 0184, South Africa
Tel +27-12-816 9000, Fax +27-12-807 7165, e-mail foundation@foundations.co.za, website: http://www.foundation.co.za

26 May 2011

Letter of Support/Access to Information: First time and repeat testers for HIV: a demographic and HIV prevalence comparison amongst clients at mobile HIV Counselling and Testing sites in Tshwane, South Africa

Dear University of Pretoria Ethics Committee,

Please accept this letter of support for the research protocol of Ms Janine Mitchell, an MSc Epidemiology student within the School of Health Systems and Public Health, Faculty of Health Sciences. (Student # 28196083)

The Foundation for Professional Development (FPD) is a private higher education institution focusing on education, research and community engagement. FPD currently has an HCT unit which works throughout the City of Tshwane Metropolitan Municipality to provide HCT services across sectors. FPD therefore gives the following support and permissions to conduct the research quoted above:

- Access to information as required
- Support from the appropriate departments responsible for HCT
- Storage of the data from the research for 15 years in a secure location

Ms Mitchell will provide important information regarding the use of HCT as a disease surveillance methodology, as well as assisting to define population characteristics of those who voluntarily test. FPD will support this research project within existing programmes and funding which has already been secured through various international donors.

Sincerely,

Dr GG Wolvaardt
Managing Director

Foundation for Professional Development (Pty) Ltd Registration number 2000/02644/07
External Directors: D. van der Walt (Chairperson), M. Raff, I. Are, N.Y. Dombio
Executive Directors: G.G. Wolvaardt (Managing Director), N.P. Nhlapo
Company Secretary: A. Berman
Registered with the Department of Education as a Private Higher Education Institution under the Higher Education Act, 1997. Registration certificate number 2002/HE31013

A Member of the SAMA Group
B. Existing Informed Consent Form

---

**CONFIDENTIAL AGREEMENT and INFORMED CONSENT**

to undergo HIV RAPID TEST and TB SCREENING

---

**CLIENT INFORMATION**

| Client Name: |  |
| ID Number: |  |

I hereby give written consent to participate in a Voluntary Counselling and Testing programme and I understand the confidential nature of the process.

I further agree to have blood samples collected for the purpose of HIV rapid testing.

I have and understand the nature of an HIV test and its benefits.

I agree / decline to undergo a TB screening by answering the following questions:

**Tick the symptoms that apply to you**

- [ ] Sudden unintentional/unexplained weight loss
- [ ] Cough for longer than 2 weeks
- [ ] Night sweats for longer than 2 weeks
- [ ] Fever for longer than 2 weeks

I agree to be contacted telephonically by a health worker/counselor from FPD call centre on any of the numbers supplied below. Telephonic contact will be initiated in order to assist me with referral to an appropriate healthcare facility for further testing and/or enrolment on a treatment program.

- [ ] Cellular phone no: ____________________________
- [ ] SMS (cell no): ____________________________
- [ ] Landline no: ____________________________

I have been informed and I have understood that:
- All tests and results of these tests will be dealt with, with unrestricted confidentiality towards others, (employer(s))
- All topics discussed before, during and after the counselling session and during HIV Treatment, as well as during the process of Data Management, are equally treated as confidential.
- The results of all tests will be revealed to me only, if so wished.
- I understand, and have given my consent that the data might be used for research without disclosing my name or personal information.

---

**Signature: Client**

**Right Thumb Print: Client**

**Signature: Physician/Name**

**Date**

---

[USAID and related logos]

PRINTING
APPROVED

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C. Participant Information – Pre-Post Test Verbal Counselling

The information on this card is to help lay counsellors remember all the things they need to discuss with a client who wants an HIV test.

<table>
<thead>
<tr>
<th>Step</th>
<th>Instructions</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introduction</td>
<td>Introduce yourself, explain your role and the VCT process</td>
<td>Yes/No</td>
</tr>
<tr>
<td>2. Motivation for testing &amp; risk reduction</td>
<td>Explore reasons for testing and client’s history</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Discuss client’s sexual risk behaviour and risk reduction options</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Advantages and disadvantages of testing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Window period and its impact on results</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Check client understands the above</td>
<td></td>
</tr>
<tr>
<td>3. Basic HIV/AIDS Education</td>
<td>Explain and discuss: How HIV and AIDS are transmitted, PREVENTION, safe sex is</td>
<td>Yes/No</td>
</tr>
<tr>
<td></td>
<td>Symptoms and Myths</td>
<td></td>
</tr>
<tr>
<td>4. Results – Implications</td>
<td>Discuss feelings about possible results</td>
<td>Yes/No</td>
</tr>
<tr>
<td></td>
<td>Discuss imagined consequences of a positive result</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Discuss and identify possible supportive people</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Discuss legal rights (including discrimination, employment, safety)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Discuss disclosure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Referral, wellness and support options</td>
<td></td>
</tr>
<tr>
<td>5. Testing Procedures and readiness to test</td>
<td>Discuss type of test e.g. rapid/laboratory</td>
<td>Yes/No</td>
</tr>
<tr>
<td></td>
<td>- What is measured</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Accuracy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- How and when result will be given</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Discuss readiness to test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Immediate plans after test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Immediate potential support</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Referral options</td>
<td></td>
</tr>
<tr>
<td>6. Consent</td>
<td>Make sure the client understands completely what the test means and what will happen to them in their own terms, not yours!</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>
**POST TEST COUNSELLOR GUIDE**

The information on this card is to help lay counsellors remember all the things they need to discuss with a client who **COMPLETED** an HIV test.

**Preparing the client for the result**
- Re-introduce yourself and confirm personal details of client.
- Confirm that the client is ready to receive HIV test result.
- Clarify the meaning of **NEGATIVE** versus **POSITIVE** result.
- Clarify how the client wants to find out their results: read out by counsellor or read.

### Give HIV result to the client:

<table>
<thead>
<tr>
<th>IF HIV NEGATIVE</th>
<th>IF HIV POSITIVE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>tick</strong></td>
<td><strong>tick</strong></td>
</tr>
<tr>
<td>• Explore client’s reaction to the test result</td>
<td>• Follow client’s reaction, do not control or lead discussion</td>
</tr>
<tr>
<td>• Review meaning of result</td>
<td>• Be there on clients terms. Don’t rush.</td>
</tr>
<tr>
<td>• Does client understand</td>
<td>• Allow client to absorb result.</td>
</tr>
<tr>
<td>• Help client to consider result in terms of most recent risk exposure and remind about window period</td>
<td>• Review meaning of result. Does client understand?</td>
</tr>
<tr>
<td>• Suggest follow up test date</td>
<td>• Acknowledge challenge of dealing with a positive result.</td>
</tr>
</tbody>
</table>

### RE-VISIT HIV/AIDS EDUCATION | MEDICAL ISSUES | BEHAVIOUR ISSUES | PERSONAL SUPPORT | FOLLOW UP |
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td><strong>tick</strong></td>
<td><strong>tick</strong></td>
<td><strong>tick</strong></td>
<td><strong>tick</strong></td>
<td><strong>tick</strong></td>
</tr>
<tr>
<td>• Explain and discuss: What HIV and AIDS are, HIV transmission, <strong>PREVENTION</strong>, safe sex, symptoms and myths.</td>
<td>• Recommend visit to doctor and offer appropriate referrals.</td>
<td>• Risk reduction</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Introduce idea of a health plan.</td>
<td>• Immune compromising behaviour including smoking, heavy drinking, lack of exercise, bad diet and re-exposure to the virus.</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>• Explain relevance of CD 4 test and viral load.</td>
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<tr>
<td></td>
<td>• Discuss ARV’s and how to access them.</td>
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<tr>
<td></td>
<td>• Explain importance of adherence.</td>
<td></td>
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</tbody>
</table>

### RISK REDUCTION & STYING HIV NEGATIVE | **tick** |
<table>
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</thead>
<tbody>
<tr>
<td><strong>tick</strong></td>
<td></td>
</tr>
<tr>
<td>• Emphasis importance of planning to reduce risk</td>
<td></td>
</tr>
<tr>
<td>• Explore practical risk re-duction</td>
<td></td>
</tr>
</tbody>
</table>

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**Supported in part by**

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**FPD**

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D. Author/acknowledgment list

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HCT Unit Staff
Foundation for Professional Development (FPD), South Africa
### USAID List of Approved HIV/AIDS Rapid Test Kits - February 23, 2010

<table>
<thead>
<tr>
<th>Test Kit Name</th>
<th>Supplier</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. ACON® HIV 1/2/0 Tri-line</td>
<td>Inverness Medical Innovations, Inc.*</td>
<td>USAID</td>
</tr>
<tr>
<td>2. Aware™ HIV-1/2 RISP</td>
<td>Calypte Biomedical*</td>
<td>USAID</td>
</tr>
<tr>
<td>3. Biosline HIV 1/2 3.0</td>
<td>Standard Diagnostics</td>
<td>USAID</td>
</tr>
<tr>
<td>4. Bionor™ HIV-1&amp;2</td>
<td>Bionor A/S</td>
<td>USAID</td>
</tr>
<tr>
<td>5. Bundi™ Rapid HIV 1/2</td>
<td>Bundi International Diagnostics Ltd.</td>
<td>USAID</td>
</tr>
<tr>
<td>6. Calypte® Aware™ HIV-1/2 OMT</td>
<td>Calypte Biomedical Corp.*</td>
<td>USAID</td>
</tr>
<tr>
<td>7. Capillus™ HIV-1/HIV-2</td>
<td>Trinity Biotech</td>
<td>USAID</td>
</tr>
<tr>
<td>8. Care Start™ HIV 1-2-O</td>
<td>Access Bio, Inc.*</td>
<td>USAID</td>
</tr>
<tr>
<td>9. Clearview® COMPLETE HIV1/2 (formerly SURE</td>
<td>Inverness Medical Innovations, Inc.*</td>
<td>USAID</td>
</tr>
<tr>
<td>10. Clearview® COMPLETE HIV1/2 - US labeling**</td>
<td>Inverness Medical Innovations, Inc.*</td>
<td>FDA</td>
</tr>
<tr>
<td>11. Clearview® HIV 1/2 STAT-PAK® Assay - US labeling**</td>
<td>Inverness Medical Innovations, Inc.*</td>
<td>FDA</td>
</tr>
<tr>
<td>12. Combines® KS Advantage</td>
<td>Span Diagnostics Ltd.</td>
<td>USAID</td>
</tr>
<tr>
<td>13. Determine™ HIV-1/2</td>
<td>Inverness Medical Innovations, Inc.<em>/Abbott Laboratories</em></td>
<td>USAID</td>
</tr>
<tr>
<td>14. Determine™ HIV-1/2 Ag/Ab Combo Rapid Test Kit</td>
<td>Inverness Medical Innovations, Inc.°</td>
<td>USAID</td>
</tr>
<tr>
<td>15. DPP® HIV 1/2 Screen</td>
<td>Chembio Diagnostic Systems, Inc*</td>
<td>USAID</td>
</tr>
<tr>
<td>16. DPP® HIV 1/2 Screen Assay – Oral Fluid, Whole Blood, Serum</td>
<td>Chembio Diagnostic Systems, Inc*</td>
<td>USAID</td>
</tr>
<tr>
<td>17. Double Check™ HIV 1&amp;2</td>
<td>Inverness Medical Innovations, Inc.°/Organics,</td>
<td>USAID</td>
</tr>
<tr>
<td>18. Double Check Gold™ HIV1&amp;2</td>
<td>Inverness Medical Innovations, Inc.°/Organics,</td>
<td>USAID</td>
</tr>
<tr>
<td>19. EZ-TRUST™ Rapid Anti-HIV (1&amp;2) Test</td>
<td>CS Innovation</td>
<td>USAID</td>
</tr>
<tr>
<td>20. First Response® HIV 1-2-0</td>
<td>Premier Medical Corporation</td>
<td>USAID</td>
</tr>
<tr>
<td>22. HIV 1/2 Gold Rapid Screen Test</td>
<td>Medinostics Int'l *</td>
<td>USAID</td>
</tr>
<tr>
<td>23. HIV 1/2 Rapid Test Kit</td>
<td>Medinostics Int'l *</td>
<td>USAID</td>
</tr>
<tr>
<td>24. HIV 1/2 STAT-PAK® Assay</td>
<td>Chembio Diagnostic Systems, Inc*</td>
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<td>31. INSTI™ HIV Antibody</td>
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<td>32. Multispot™ HIV-1/HIV-2</td>
<td>Bio-Rad laboratories*</td>
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*Parent Company is a United States-based firm.
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