FACTORS AFFECTING ANTENATAL POINT OF CARE TESTING FOR SYPHILIS, ANAEMIA AND HIV IN PRIMARY HEALTH CARE CENTRES IN SEDIBENG DISTRICT, SOUTH AFRICA

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ABSTRACT

Background

Point of Care Testing (POCT) refers to qualitative or quantitative tests done in health facilities where the patient is being attended to (on-site), and not in the conventional hospital laboratory setting. As a consequence of many developing countries not having access to conventional laboratory services (with trained laboratory personnel), diagnostic testing often relies on the availability of valid POC tests. All pregnant women attending antenatal care clinics in the Sedibeng District Primary Health Care (PHC) centres should be screened for syphilis, anaemia and HIV. This can be done by means of POC testing, which is easy to perform. These POC tests provide results promptly allowing treatment to be commenced immediately, if required. Despite this highly desirable benefit of POCT, there is circumstantial evidence which suggests that staff is choosing to send specimens to the laboratory for testing, instead of doing POCT themselves. The extent to which this happens and the factors contributing to this practice are not clear.

Aim

The aim of this study was to assess the prevalence of screening for syphilis, anaemia, and HIV amongst pregnant women during their first antenatal care visit to PHC facilities in the Sedibeng District, and to establish the factors affecting the prevalence of appropriately using POCT for screening tests.

Methodology

Study design: A quantitative, analytical, cross-sectional study was conducted.

Study Population and Sample: Patient registers, staff expected to perform POCT and facility managers. 33 District's health care workers expected to perform POCT on pregnant

women during the first ANC visit and 30 facility managers from these facilities; 360 patient records (these were collected from a total of 7 200 patients' records). The data was collected over a six month period (from 1st July 2012 to 31st December 2012).

Data collection: Data was collected from 360 patient records to determine the rate, appropriateness and mechanism of screening for syphilis, anaemia and, HIV in pregnant women on their first antenatal visit. Interviewer-administered closed-ended questions was asked from 30 antenatal care clinic staff tasked with performing POC tests and from 30 PHC facility managers to determine the factors affecting the rate of conducting POCT.

Data analysis: Data was analysed using univariate, bivariate and multivariate analyses.

Ethical considerations: No harm was anticipated to anyone participating in the study or from the findings of the study. A major benefit of the study was that clarity on the factors affecting the rate of screening and the use of POCT was gained. This will hopefully facilitate the implementation of evidence–based interventions to improve POCT uptake if required.

Results

***Evaluation of the prevalence of screening*:** A total of 360 patients' records were examined. 328 (91 %, 95% CI 0.88 - 0.940) pregnant women were screened for syphilis during their first ANC to the Sedibeng ANC facilities. 304 (84%, 95% CI 0.8 – 0.88) women were screened for anaemia, and 345 (96%, 95% CI 0.93 – 0.98) were screened for HIV during this visit.

***Evaluation of POCT Done*:** A total of 87 (27%, 95% CI 0.22 – 0.31) pregnant women's samples were examined for syphilis using RPR POCT, 265 (87%, 95% CI 0.84 - 0.91)

samples were tested for anaemia using Hb POCT, while 343 (100%, 95% CI 0.98 – 1.00) women were screened for HIV using POCT. ***Factors affecting the rate of screening:*** The following variables yielded statistically significant associations with multivariate logistic regression analyses: **Hb Screening (Type of health facility),** adjusted prevalence odds ratio 0.341 (95% CI 0.182 – 0.638). **Hb Screening (Ability of the manager to produce the MCWH guidelines)**; adjusted prevalence odds ratio **0.744 (95% CI 0.344 – 1.605). Hb POCT (Type of health facility),** adjusted prevalence odds ratio 0.127 (95% CI 0.064 – 0.252); **Hb POCT (Performing of QA before conducting the POCT** adjusted prevalence odds ratio 2.444 (95% CI 1.19 – 5.385); **Hb POCT (Staff views about the availability of sufficient time to perform the POCT),** adjusted prevalence odds ratio 1.949 (95% CI 1.137 – 3.340). **Syphilis POCT (Type of health facility),** adjusted prevalence odds ratio 0.688(95% CI 0.595 – 0.797); **Syphilis POCT (Consistent availability of the POC test kits in the facilities),** adjusted prevalence odds ratio 37.976 (95% CI 5.094 – 283.091); **Syphilis POCT (Availability of sufficient staff to perform the POCT,** adjusted prevalence odds ratio 15.416(95% CI 2.050 – 116.515). All variables not mentioned above did not yield any statistically significant associations.

Conclusion

The study found that despite the high rate of screening of pregnant women for syphilis and anaemia during their first visit to the Sedibeng ANC facilities, less than one third of the women received their syphilis screening results, and more than 10% of the women did not receive the Hb results during the first visit. In addition, the study revealed that 96% of the pregnant women were screened for HIV during their first visit to Sedibeng ANC facilities, with 100% of the screening appropriately done on-site as POCT. Furthermore, with regards to the factors affecting POCT, the study found statistically significant associations for various factors in both the bivariate and multivariate logistic regression analyses for the 3 outcomes

of “antenatal Hb screening”, “antenatal Hb POC testing” and “antenatal Syphilis POC testing”. This study revealed that the major contributing factors that affect the screening of the pregnant women during their first ANC visit to the facilities, and the uptake of POCT by the HCWs were: the type of health of facility that the pregnant women visited, the availability of sufficient staff to conduct syphilis POCT, the availability of POC test kits to conduct syphilis POCT, and having sufficient time to perform Hb POCT.

Key recommendations: A solution to the non-availability of syphilis POC test kits in many of the facilities should be sought and prioritised. The underlying reasons behind the noticeable inadequate performance by Local Municipality facilities with regards to the screening of the pregnant women for anaemia and, for the inadequate conducting of syphilis and Hb POCT by these facilities, needs to be found. Some ANC HCWs seem to require intensive education about how to deal with low Hb POCT results and by implication when to request laboratory investigations.

LIST OF ACRONYMS:

ANC - Antenatal care

CHC - Community Health Care centres

CI - Confidence Interval

DHS - District Health Services

ED - Emergency Department

ELISA- Enzyme Linked Immunosorbent Assay

EQA - External Quality Assurance

FBC – Full Blood Count

Hb- Haemoglobin

HCW - Health Care Workers

HIV - Human Immunodeficiency Virus

IQC – Internal Quality Control

LA - Local Authority

MCWH - Mother and Child and Women's Health

MDG – Millennium Development Goals

NDOH- National Department of Health

NGO – Non Governmental Organisation

NHLS - National Health Laboratory Service

PEPFAR – The United States President's Emergency Plan For Aids Relief

PHC - Primary Health Care centre

POCT- Point of Care Testing

PR- Provincial Government

QA – Quality Assurance

QC - Quality Control

RPR - Rapid Plasma Reagin

SANBS - South African National Blood Transfusion Service

SOP - Standard Operating Procedures

PMTCT - Prevention of Mother to Child Transmission

TAT - Turnaround Times

TPHA - Treponema pallidum haemagglutination assay

UN - United Nations

WHO - World Health Organisation

DEFINITION OF TERMS

Sedibeng Health District:

The Sedibeng Health District is one of the three municipality areas within the Gauteng Province (South Africa), in the southern part of the Province. The District serves a total of 922 052 with 747 771 being uninsured, based on the 2014/15 estimate. The District is demarcated into three sub-districts.

Provincial Government facilities (PR):

These are facilities administered by the Sedibeng District Health Services (which is part of the Gauteng Provincial Health department). The laboratory tests requested by these facilities (conducted by the NHLS) are also paid for by the Sedibeng district health services (DHS).

Local Authority facilities (LA):

These are facilities administered by the Sedibeng Local Municipality, and although their staff is remunerated by the Municipality itself, the laboratory tests (which are conducted by the NHLS) are paid for by the Sedibeng District Health Services.

National Health Laboratory Service (NHLS):

The NHLS is a public health laboratory service with over 300 laboratories across the South Africa's nine provinces and serves approximately 80% of the South African population. It is a diagnostic pathology service which performs laboratory testing for the national and provincial department's provincial and district hospitals, primary healthcare clinics and other state institutions.

Rapid plasma reagin (RPR):

RPR is a non-treponemal serological technique which detects active syphilis. Different studies indicate that the test has a sensitivity which ranges from 56% to 86%; whilst its specificity is reported range from 94% to 100%. This POCT technology is used to screen pregnant mothers for syphilis (during their first ANC visit) by the Sedibeng district ANC facilities.

Non-treponemal syphilis serological tests:

These tests are designed to detect antibodies to non-specific antigens that are produced in most patients with syphilis. Examples of non-treponemal tests include the rapid plasma reagin (RPR) and the venereal disease research laboratory (VDRL) assays. These tests have demonstrated good performance over the years, but can show low sensitivity in very early or late disease. Importantly, these tests usually revert to negative after successful treatment, and so they can be used to monitor response to therapy.

Treponemal syphilis serological tests:

The treponemal syphilis assays are designed to detect antibodies against specific antigens from Treponema pallidum (the spirochete is which is the causative organism for syphilis). Examples include fluorescent treponemal antibody (FTA) and the newer generation assays such as enzyme immunoassays. Although these tests are typically more specific than non-treponemal assays, they will remain positive for years despite treatment.

HemoCue Hb POCT:

The HemoCue Hb POC technology is a method used for the determination of the total amount of haemoglobin in whole blood system. It is used for quantitative diagnostic determination of haemoglobin in blood using a specially designed photometer, HemoCue Haemoglobin analyzer and specially designed HemoCue haemoglobin microcuvettes. The methodology is reported by different authors to have a sensitivity which ranges from 96% to 100%; whereas its specificity is reported to range between 94% and 100%. This POCT technology is used to screen pregnant mothers for anaemia by the majority of the Sedibeng district ANC facilities.

Sensitivity:

This refers to the likelihood of a test to correctly identify individuals who do not have a particular disease.

Specificity:

This refers to the likelihood of a test to correctly identify individuals who have a particular disease.

Positive predictive value (PPV):

This refers to the extent to which being diagnosed as positive predicts the presence of disease.

Negative predictive value (NPV):

This refers to the extent to the proportion of people with a negative test result who do not have the disease.

DECLARATION

I declare that: *Factors affecting antenatal point of care testing for syphilis, anaemia and HIV in primary health care centres in Sedibeng district, South Africa* is my own work, and that it has not been submitted for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged by complete references.

Full name: Nombuto Gloria Mpotulo Date: December 2014

Signed.....

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DEDICATION

I dedicated this work to my daughter Nwabisa and all her cousins with whom we share our home: thank you for understanding that I needed to temporarily neglect you throughout this study period.

TABLE OF CONTENTS PAGE

LIST OF TABLES **PAGE**

CHAPTER 1

1.1 Introduction

Antenatal care (ANC) screening is a critical component of evaluating the health status of pregnant mothers as many of the conditions which afflict them during their pregnancy can be detected and treated early, thereby curbing preventable complications to both the mother and the baby.

To achieve efficient and timely antenatal care screening, point of care testing (POCT) is commonly performed by health care facilities. The most significant value of POCT is that rapid turn-around time is guaranteed and the test results are available promptly, which allows for early treatment if required. Pai, Vadnais, Denkinger, Engel, and Pai, (2012) reiterate that the convenience of POCT to patients and care providers mainly derives from the fact that the POC diagnostic process is completed in the same clinical episode as compared to conventional laboratory testing, for which the patients may not come back for test results or for further testing. Consequently, the availability of valid and good quality POCT technologies in health care facilities is crucial. It is equally important to adequately train health care personnel to manage and operate these technologies, particularly in resource-limited primary health care (PHC) settings (such as the Sedibeng ANC facilities), which often have no access to the expertise of conventional laboratories.

Accordingly, the 37 ANC sites in the Sedibeng District PHC facilities offer a variety of selected and mandatory screening tests to pregnant women. The World Health Organisation (WHO) clinical guidelines on antenatal care stipulates that anaemia, syphilis, HIV, proteinuria, blood group and bacteriuria be screened for during the pregnant mother's first visit (Lincetto, Mothebesoane-Anoh, Gomez, & Munjanja, 2006). These screening tests are low cost and are typically implemented in primary level care facilities in Africa. In line with the above-mentioned WHO guidelines, the South African Guidelines for Maternity Care stipulate that all pregnant women visiting antenatal care facilities must receive screening for syphilis, using a Rapid Plasma Reagin (RPR) POCT: a non-treponemal serological technique which detects active syphilis (Guidelines for Maternity Care in South Africa, 2007; Peeling and Htun, 2004). The rest of the mandatory screening is for HIV (rapid screening test); diabetes (glucose screening); anaemia (screening for haemoglobin [Hb]), and Rhesus test blood group typing (for blood group type determination). These tests are traditionally

conducted by suitably qualified staff, working in the hospital-based National Health Laboratory Service (NHLS) and the South African National Blood Service (SANBS) laboratories.

To strengthen POCT utilisation at facility level, the National Department of Health (NDOH) established an interim POCT policy which specifies which of the routine screening tests should be performed in health facilities (National Department of Health, 2008).The broad aim of this policy was to promote and regulate on-site testing of a selected number of key screening tests, so as to facilitate quicker turnaround times and easier access to testing for patients visiting PHC facilities, which for economic and logistic reasons have no access to the hospital-based conventional NHLS and SANBS laboratories. The POCT technologies endorsed for use in PHC facilities by the NDOH are mostly sanctioned by the WHO and are primarily tailor-made and evaluated for ease of utilisation by non-laboratory trained personnel.

According to recent crude estimates reported to the Gauteng Provincial Health department by the Sedibeng district's Mother Child and Women's Health (MCWH) unit, less than 10% of RPR syphilis screening tests are performed on site. In addition, an observation of NHLS data over a consecutive 18-month period (from September 2010 to March 2012) revealed that higher than expected volumes of RPR and Hb screening tests were being performed at NHLS laboratories. This is in stark contrast to HIV screening tests for which the NHLS database shows minimal volumes, implying that the majority of HIV screening is as expected, done as POCT in the facilities (National Health Laboratory Services, 2012). RPR testing has always been done at conventional laboratories but is now expected to be performed as POCT by the facilities. On the contrary, Hb testing has always been done as a combination of POCT and laboratory testing with the laboratory results accepted as more accurate. In addition, the laboratory provides further testing in the form of a 'full blood count', a more extensive test that includes a Hb result. With regards to screening for HIV, this test was originally introduced as POCT in most facilities and although some facilities initially did this test via the laboratory, it was shortly moved to POC testing. The Hb and HIV POC testing is widely regarded as being relatively easy to perform, whilst RPR testing may be considered to be slightly more cumbersome, as specimen manipulation is required before and during the actual testing.

The previously mentioned data observations suggest that too few POC tests for syphilis and anaemia but paradoxically potentially appropriate POC testing for HIV is in place. Only positive and indeterminate RPR tests should be sent to the NHLS laboratory for the (confirmatory) quantitative Treponema Pallidum Haemagglutination Assay (TPHA) to be done. In addition, haemoglobins of below or above predetermined cut-off values should be sent to the NHLS laboratory for a full blood count (FBC) to be done. The (possibly) inappropriate management of antenatal care POC tests raises major concerns, because when screening tests for syphilis and anaemia are (unjustifiably) processed by off-site NHLS laboratories, the pregnant women do not receive the results of their screening tests during the first visit, thereby compromising initiation of treatment if warranted. Secondly, the observable cost of performing these screening tests on-site is considerably lower than that of similar testing by NHLS laboratories. For example, the NHLS's cost of one RPR test has been recently estimated to be six rands, which is approximately eleven rands higher than that of an on-site RPR POC test. The NHLS charges the state seventeen rands and three cents for one RPR screening test (West Rand District Health Information System, 2011/2012; National Health Laboratory Service, 2012). It is difficult to compare the cost of Hb testing with that of the NHLS as the cost of its POCT varies widely depending on the suppliers chosen by the facilities.

Similar to other resource-limited settings, clinicians working in the Sedibeng District PHC facilities have no formal training in clinical laboratory techniques, but have for several years been expected to perform screening tests for syphilis (RPR), anaemia (Hb), HIV, and Rhesus blood group typing, on site. The clinicians required to perform the POCT are largely the nursing staff who, (depending on the facility) comprise of professional nurses, enrolled nurses and (at times), auxiliary nurses.

The Sedibeng District Health Service is comprised of 3 Sub-Districts. Based on the 2014/15 estimates, this district serves a population of 922 052, of which 747 771 are the uninsured population. The District consists of 30 Primary Health Care (PHC) facilities, four Community Health Care centres (CHCs) which in addition comprise of maternal and obstetrics units (MOUs) and three Community Day Care centres (larger clinics without MOUs). All 37 facilities above include antenatal care clinics (ANCs). An average of 1200 pregnant women per month present to ANC facilities for their first antenatal visit (Sedibeng District Health Information System, 2014/15).

1.2 Problem Statement

All pregnant women attending antenatal care clinics in the Sedibeng District PHC centres should be screened for syphilis, anaemia and HIV by means of POC testing, which is easy to perform. Syphilis and anaemia POCT has been available for approximately 5 years in the district, whilst HIV POCT has been available for about 3 years. These POC tests provide results within minutes allowing treatment to be commenced immediately if required. Despite this highly desirable benefit of POCT, and the fair number of years facilities have been exposed to syphilis and Hb POCT technologies, there is circumstantial evidence suggesting that the HCWs are choosing to send specimens to the laboratory for testing, instead of doing POCT themselves. The factors that contribute to this (apparent) inadequate utilisation of POCT by the ANC facilities, and the extent to which it occurs, is not clear.

1.3 Purpose

This study aimed to evaluate the rate of screening for syphilis, anaemia and HIV of pregnant women during their first ANC visit to Sedibeng facilities, and to identify factors affecting the uptake of antenatal POCT for the specified antenatal care tests.

CHAPTER 2

Literature review

2.1 Introduction

Point of care testing (POCT) is a form of decentralised clinical laboratory testing conducted close to the site of patient care, which shortens the time between sample acquisition and analysis (Luppa, Muller, Schlichtiger and Schlebusch, 2011). Since many developing countries do not have access to conventional laboratory services, laboratory diagnosis depends on the availability of valid POC tests (Peeling and Mabey, 2010). These POC tests need to be easy to do and interpret and are typically done by trained laboratory staff. The situation in the Sedibeng District PHC centres is similar to other developing countries, in that facilities in this district do not have access to on site conventional laboratory services or trained laboratory personnel, hence the facility staff have to perform the POC testing.

It is stated that in the beginning, all laboratory tests were performed near the patient by clinical staff. As early as 1500 BC, one of the earliest diagnostic practices done near the patient site was uroscopy, in which urine was visually examined and assessed for sweetness by tasting. Between 1800 and the early 1900's testing moved to central laboratories with more and more advanced testing technologies being gradually developed. Shifts from central laboratory testing back to POCT with the steady growth in type and volumes of POC tests, have been fuelled by among other issues, technological advancements; demand for faster turnaround times; testing platforms to facilitate care in divisions like intensive care units and the need for simple and robust testing, which do not require laboratory infrastructure, in developing countries and remote sites (Bowman, Hamill and Dale, 2012). Subsequently, POCT technologies are nowadays widely available and extensively utilised. With regards to the adoption of valid POCT in resource-limited settings in particular, the technology is in general intended to be simple, whilst still comparable in quality to that of conventional laboratory testing and with adequate training the technology should be operated by non-laboratory trained personnel, with relative ease.

In addition, the screening of pregnant women for syphilis and HIV is recommended policy for most countries (Mabey, Peeling, Ballard, Benzaken, and Galbán, 2012). Syphilis and HIV screening in pregnancy (especially in resource –limited settings), has received much attention in the literature, because of the risk these conditions pose with regards to cross infection to the baby, the ease with which syphilis can be treated, the need for ongoing lifelong HIV

treatment and the risk of contracting further sexually transmitted infections (Benzaken *et al*, 2011; Peeling, Holmes, Mabey, and Ronald, 2006; Peeling and Mabey, 2010).

Another important dimension worth highlighting is that although conventional laboratory testing mostly guarantees quality assured and accurate results, it is disadvantaged by long turnaround times (TAT) when it comes to the management of samples from the Sedibeng PHC facilities. This is due to the extended length of time it takes to transport these samples from PHC facilities which are often located long distances from the hospital-attached laboratories. Furthermore, the laboratories generally prioritise hospital samples (to which the laboratories are attached) over those from off-site PHC facilities. An added challenge is that delaying the processing of these samples might compromise the quality of the specimens (hence, the quality of patients' results). A further contributing factor to prolonged TAT is that PHC facilities in Sedibeng do not have access to computerised laboratory results and therefore rely on the NHLS to hand-deliver the results to the facilities.

Ultimately, the poor POCT uptake in the Sedibeng District Health ANC services was demonstrated by the much larger than expected RPR and Hb test volumes observed in NHLS data implying that clinicians sent these screening tests to NHLS laboratories for processing, instead of performing them as POCT as expected. Monthly analysis of NHLS samples received from the Sedibeng PHC facilities, persistently showed that the syphilis-screening RPR and Hb tests were part of the top ten tests performed in the NHLS laboratories. However, if all the RPR and Hb tests were performed by facilities as POCT and as mandated by the MCWH guidelines and NDOH policies, the NHLS data was expected to show minimal or zero volumes of these tests, much like the observation of minimal (or often zero) HIV screening tests sent to the laboratories as demonstrated in the monthly NHLS statistics (Guidelines For Maternity Care in South Africa, 2007; National Department of Health, 2008; National Health Laboratory Services, 2012) The above assertion is also supported by the recent admission by the district's MCWH unit that indeed, probably less than 10% syphilis screening tests are performed as POCT.

2.2 The value of POCT

2.2.1 General POCT

The value of POCT may be discussed in relation to speed of testing, economic benefit and patient/treatment outcomes. The most critical elements of POCT are the rapid turn-around

time and hence quicker communication of results to guide clinical decisions, and allowing the completion of testing and follow-up action in the same clinical encounter (Pai *et al*, 2012).

Some authors argue that POC testing is usually more expensive than that performed in a conventional laboratory. This is because of the greater cost of POCT consumables, coupled with the fact that point-of-care tests are performed one at a time. It is argued therefore, that the economies of scale afforded by high-volume automated testing cannot be achieved (Lee-Lewandrowski and Lewandrowski, 2009). The latter assertion implies that POCT is in fact, more expensive. However, with regards to the cost of on-site RPR POCT a recent crude comparison made by the West Rand District PHC Services (South Africa), revealed that the cost of the on-site RPR POCT is approximately eleven rands lower per test than that of similar testing by NHLS laboratories. The cost of an RPR screening test according to the NHLS is seventeen rands and three cents (West Rand District Health Information System, 2011/2012; National Health Laboratory Service, 2011).

Additionally, POCT reduces the number of clinic visits, lessens the hospital length of stay, leads to fewer unnecessary admissions and less inappropriate treatment, reduces the utilisation of blood and blood products, and leads to improved quality of life (Mabey *et al*, 2006).

With regards to antenatal screening, it has been affirmed that POCT can be conducted in a single visit with the potential to significantly reduce perinatal mortality (Bronzan, Mwesigwa-Kayondo, Narkunas, Schmid, and Neilsen, 2007).

2.2.2 Syphilis screening and POCT

Regarding the value of syphilis POCT, a number of studies unveil interesting and comparable findings. An economic evaluation comparing the cost and the associated outcomes for syphilis POC strategies in seven studies was conducted between 2006 and 2008. The studies were conducted amongst pregnant women attending routine antenatal care in South Africa, Tanzania, Mozambique, Haiti, Bolivia, Italy and in high risk populations of adults in sexually transmitted disease infections clinic attendees in Brazil (these countries are differently categorised as lower and middle income settings).The studies revealed that the cost per disability adjusted per life year (DALY) suggests that interventions to add syphilis POC screening to routine antenatal care are very cost effective. In addition, the strategies were cost

effective for both pregnant women attending ANC clinics and the adults attending STI clinics (Ako-Arrey, Johri, Jafari, and Pai, Undated).

The argument which states that POCT permits for testing and treatment to be conducted in a single visit is particularly true with regards to management of maternal syphilis, as this condition relies on early serological screening in pregnancy (Bronzan *et al*, 2007). This is because treatment of maternal syphilis with a single-dose of injectable penicillin is effective in preventing adverse outcomes to both the mother and the baby (Watson-Jones *et. al*, 2005).

Furthermore, it has been argued that antenatal screening and treatment for syphilis in particular, are among the most cost-effective health interventions available, and that POCT for syphilis especially in areas without laboratory infrastructure, makes it even more cost effective (Peeling *et al*, 2006; WHO, 2012).

The WHO (2012) states that new POC tests, which can use whole-blood samples from a finger prick and provide results that allow for treatment of maternal syphilis at a single visit, are available. These technologies can be used in all health-care settings, even in the face of limited electricity, refrigeration or skilled laboratory staff. The Organisation further affirms that existing tests such as the RPR can also be used successfully in settings with sufficient laboratory capacity and minimal quality control processes. The recognition that successful RPR POCT testing requires appropriate systems to be in place is concerning for the quality of results from the Sedibeng facilities that perform this test onsite. This is because these facilities have no laboratory capacity, as well as no quality control processes at their disposal. The report concludes that with a combination of these two diagnostic options, programmes can achieve universal access to syphilis screening in pregnant women. It is worth mentioning that the latter method is not yet available in the Sedibeng districts (and in other Gauteng districts).

In order to evaluate the validity of the RPR POCT, it is important to consider the issue of its sensitivity and specificity. However, there seems to be disagreement about particularly, the sensitivity of this methodology amongst various authors. For example, Larsen and Creighton (1998) wrote extensively about the RPR card test, detailing important factors (such as the principles of the test, interpretation of the results including the performance of the test by stage of untreated syphilis, and the limitations of the test) and reported the following results

with regards to the validity of the test: sensitivity of the test for primary syphilis - 77% to 99%, and for latent syphilis the sensitivity was reported to range between 95 and 100%. In addition, the specificity of the test was reported to range between 93 and 99%. However, these authors further state that a negative RPR test with clinical evidence of syphilis may be observed in early primary syphilis and in certain cases of late syphilis. They argue that consequently, a negative RPR test does not rule out an 'incubating syphilis infection'. Although the authors do not mention anything about proceeding to treat these patients based on the clinical evidence of syphilis, and/or advising that their screening results should be confirmed with a superior laboratory test, the implicit message is that clinicians should have a higher index of suspicion when dealing with these patients. Peeling and Htun (2004) concur with the above-mentioned authors, stating that the RPR POCT has a sensitivity of 86 - 100% and a specificity of 93 - 98%. These authors state furthermore that in pregnant women, as much as 28% of positive RPR tests maybe biological false positives. Conversely, Montoya *et al* (2006) report that in their study of 4428 pregnant women attending ANC facilities in Mozambique, they found that the sensitivity and specificity of the RPR POCT were 56.6% and 97.5% respectively; while the positive predictive value and the negative predictive value were 75.4% and 94.2% respectively in their setting. Although these authors lament the low sensitivity of the RPR as compared to the other syphilis screening methodologies they researched in their study, they do not mention any requirement to confirm the negative tests with a better laboratory test. Moreover, Anque *et al,* (2005) validated the RPR POC test against the Venereal Disease Research Laboratory (VDRL) syphilis serology test, and found the results to be as follows: sensitivity 56.3% specificity 96.5%; predictive value of a positive test 41.2%; and the predictive value of a negative test 98.1%. Because of the broad disagreement displayed in literature about the levels of sensitivity of the RPR screening tests, it is difficult to make a definitive argument about whether or not the test is valid. The fact that even the authors who report that the RPR technology has a sensitivity of 75% and higher, additionally indicate that this methodology displays wide ranges of sensitivity, makes it difficult to give an informed view about the validity of the test. The reason behind the wide ranges of sensitivity for the RPR test reported by the above-mentioned authors can perhaps be explained by the reality that reading of the test results is essentially a subjective measure, as the reading is done by the naked eye. Castro *et al* 2012, who evaluated a new digital instrument which was developed to read RPR results, agrees with this. These researchers state that their motivation for evaluating the results of the reader against those of positive RPR tests was because the visual readings of the tests are considered to be inherently

subjective. Young (2014) concurs with this view, stating that although the test is cheap and simple to perform, it is labour intensive and the (visual) manner in which the test results are interpreted is subjective. Moreover, the above-mentioned author adds to the previously reported variability of the RPR test sensitivity, stating that the sensitivity of the test is approximately 70% - 85% in the primary stages of the disease, while the sensitivity can potentially reach 100% in the secondary stage of syphilis. However, virtually all the literature examined in this review emphatically assert that the RPR has for several years, been the methodology of choice for the screening of patients for syphilis, and despite the above-mentioned challenges, the recommendation has been (and is still) to treat the patients on the basis of the positive POC test, and by implication, to accept the negative results without conducting a superior and confirmatory laboratory test. This recommendation to treat for syphilis based on a positive result via POCT RPR without doing confirmatory tests, despite the low positive predictive value of the test (from 41% to 75%) and hence the high percentage of false positives, is included in the South African Maternal Child and Women's Health guidelines (SA MCWH, 2007), and the WHO guidelines (WHO, 2012). The SA MCWH guidelines (2007) specifically state: 'A rapid card test done by the antenatal clinic staff, gives a result before the mother goes home, this allows immediate treatment of the RPR-positive women; specific treponemal tests such as FTA-Abs and TPHA are not normally used in the management of syphilis in pregnancy in South Africa'. The guidelines go further to state that 'all pregnant women with positive RPR, irrespective of the titre values should be treated'. The guidelines then proceed to detail what kind of treatment the women should receive.

It is unclear why, despite the low positive predictive value of the POC test (implying that a large percentage of those people who are declared by the POC test as having syphilis, will in fact not have syphilis), that both the South African and WHO guidelines recommend treating for syphilis based on a positive RPR POC test only. This means that a large percentage of those treated on this basis would be treated for syphilis even though they don't have syphilis. The lack of explanation as to why guidelines from authoritative bodies should knowingly recommend treatment of a large proportion of patients who do not have syphilis is perplexing. It is usually prudent and indeed standard good clinical practice to confirm a positive result via a definitive test, if the test that identified it initially as positive has a low positive predictive value. In the absence of a clear explanation for this strange recommendation of treating for syphilis without a confirmatory test, it is unlikely that those

clinicians who are aware of the low positive predictive value of the POC test would actually follow the advice to treat. It is indeed highly likely that clinicians who are aware of the low positive predictive value of the POC test, would request a confirmatory test before they commence treatment for syphilis, as was done in a recent study in China (Yang *et al*, 2013). Conversely, those clinicians who are unaware of the low positive predictive value of the POC test and who trust the authorities issuing the guidelines, would probably treat for syphilis based on the POC test positive result alone, and hence they would inevitably (although unknowingly by themselves) provide treatment for syphilis to many people who do not have syphilis.

Despite, as previously stated, there being broad agreement in the literature about the high specificity of the RPR POCT, implying that the test will have a low negative predictive value (from 94% to 98%), because of the low sensitivity of the test (from 56% to 85%) there will be a large actual number of false negatives (although as a percentage they would be low), thus suggesting that many people that the POC test labels as negative, would actually have syphilis. This low validity of the RPR POC test and specifically the low sensitivity, with the resultant large number of false negative results (implying that many people who actually have syphilis will be labelled as not having syphilis by the test), creates quite a dilemma, as one is faced with the difficult decision of whether to recommend definitive testing for all those who test negative, in order to properly identify the false negatives and treat them for their syphilis infection. Of course recommending this, which is strictly speaking the best clinical practice, results in the problematic situation of recommending a confirmatory test for those who test POCT negative *and* for those who test POCT positive (due to the low positive predictive value with a large proportion of false positives, as discussed above). It is then highly problematic as irrespective what the result of the POC test is, one would still proceed to do a definitive test, raising the question as to what the point of doing the POC test is then. So due to the low validity of the RPR POC test one is left questioning what value it adds, as acting solely on both its positive and negative results has serious adverse effects for many of the patients tested. In this scenario it is a difficult and contestable decision as to whether the RPR POC test should be used or not, with managers mainly concerned about improving overall efficiency of service provision probably accepting it (with its in-built adverse consequences for many patients) and clinicians mainly concerned about the well-being of their individual patients (and hence unwilling to accept its in-built adverse consequences for many patients) probably rejecting it.

2.2.3 Hb screening and POCT

The value of Hb POCT is widely acknowledged by various authors, and is written about in diverse literature. For example, the findings of a study of 815 pregnant women, whose objective was to determine the prevalence of anaemia among pregnant women attending antenatal clinics in south-eastern Nigeria, revealed that the prevalence of anaemia (Hb <11.0 g/dl) was 76.9%, and 15 (1.8%, 95% CI 0.9 - 2.7) had severe anaemia: Hb <7.0 g/dl (Uneke, Duhlinska and Igbnedion, 2007). The above-mentioned findings highlight the importance of adopting systems that support performance of good quality Hb POCT on pregnant mothers attending the clinics for their first ANC visit.

Obse, Mossie and Gobena (2013) state that the magnitude of anaemia in pregnant women, as indicated in the WHO's reports, both in developed and developing countries is quite alarming. The WHO (2008) estimates that the global prevalence of anaemia in pregnant women is 68%, whilst the prevalence of anaemia in Africa is estimated to be 66.8%. The effects of anaemia in pregnancy include still-birth, low birth weight and pre-term births, reduced work capacity, decreased mental performance, low tolerance to infections, death from anaemic heart failure and maternal deaths due to uncontrolled bleeding (McLean, Cogswell , Egli , Wojdyla and de Benoist, 2009). Not surprisingly therefore, the screening of pregnant women for anaemia (Hb) during every first ANC visit, at 28 weeks and again at the 36 weeks' visit to South Africa's antenatal care facilities is mandatory (Guidelines for Maternity in South Africa, 2007).

Furthermore, Kalaivani (2009) asserts that with regards to the impact of anaemia in pregnancy, early detection and effective management of anaemia in pregnancy can lead to improved pregnancy outcomes, substantial reduction in under nutrition in childhood, adolescence and improvement in adult height. This assertion highlights the importance of good quality screening for anaemia in pregnancy, which can be successfully done using Hb POCT.

To strengthen the argument for the importance of high quality Hb POCT, Sanchir-Gomar, Cortell-Ballister, Pareja-Galeano, Banfi and Lippi (2012) from the Universities of Valencia (Spain) and Milan (Italy) conducted some very important research on the value of Hb POCT. The authors did this by reviewing ten studies which had compared the performance of the (conventional) haematology automated analysers with that of the hand-held HemoCue Hb

POCT devices (these POCT devices are [seemingly] commonly used worldwide, and most importantly, are used extensively in the Sedibeng district). The researchers were prompted by the discrepancies they had noted in published literature about the devices. Consequently, they resolved to attain an overview and hence finality about the devices' performance. The following considerations emanated from their review: (1) the use of these POCT devices in laboratory and clinical practice should be supported as it addresses the critical issue of saving time where an accurate and rapid Hb measurement is required to make immediate therapeutic decisions within the shortest possible turnaround time. This is especially true in cases where a traditional laboratory is very far away; (2) the availability of rapid Hb POCT assessment is valuable due to the minimal amount of blood required by these devices**.** Most importantly, the accuracy and reproducibility of the devices for Hb determination was compared with a standard haematology instrument (the XE 2100) in 256 arterial blood samples of children undergoing major surgery. Subsequently, it was concluded that the HemoCue instrument showed reliable results in the intra-operative setting. In addition, the accuracy of the instrument in patients receiving antiviral therapy after liver transplantation was determined, leading the authors to conclude that the instrument displayed optimal reproducibility and good correlation with the standard method (r = 0.89). Moreover, its accuracy for determining anaemia was found to be excellent. However, on assessing the devices to determine Hbs of critically ill patients, the unfavourable findings led the authors to advise against the use of these for critically ill patients and especially in the presence of oedema they noted one should not use capillary blood to assess Hb, due to the diluting effect of the oedema on capillary blood. The authors conclude by lamenting that one limitation of their review is that some of the cited publications lack a suitable statistical method when comparing the HemoCue devices.

In addition, the issue of the sensitivity and specificity of the HemoCue POCT instruments has been examined by some authors. These include Briggs, Kimber and Green (2012), from the Department of Haematology, University College of London, who conducted a review of clinical studies from primary health care settings, which validated the use of these instruments. From the review, the authors highlight the outcome of a 2005 study comprising 247 capillary and venous samples which were analysed using a conventional (automated) haematology analyser versus a HemoCue POCT instrument. The findings of the study revealed that although there was no significant difference between venous and capillary haemoglobin levels, the venous Hb (by HemoCue) correlated better with the conventional

analyser than with capillary Hb, producing 100% sensitivity and specificity. On the contrary, capillary HemoCue produced 96.4% sensitivity and 94.4% specificity. Furthermore, a much older (1987) study from the same review, demonstrated that when the HemoCue was used by laboratory-trained clinicians, its results correlated remarkably well with those of the automated analyser (correlation coefficient [*r]* = 0.99), whereas when the device was used by the non-laboratory trained clinicians the results were disappointing, giving a poor correlation (r = 0.66) with the conventional laboratory analyser. The authors attributed this inconsistent outcome to possible poor specimen manipulation techniques by the non-laboratory trained clinicians. The high validity of the Hb POC test makes it highly applicable to and easy to recommend for using as an anaemia screening test for pregnant women. This should be contrasted against the difficult trade-offs encountered when deciding whether to recommend the RPR POC test for use in screening of pregnant women for syphilis, due to its low validity, as discussed above.

2.2.4 HIV screening and POCT

With regards to HIV POCT, Arora, Maheshwari, and Arora (2013) argue convincingly that, this technology attempts to address delays in the detection of the HIV status of patients by providing preliminary HIV-antibody results. The authors add that performing HIV POCT can be most useful in resource-limited settings in which there is lack of well-trained laboratory personnel, poor infrastructure, extreme climate and lack of uninterrupted power supply, all of which have a negative impact on onsite testing. Moreover, the authors state that the rapid HIV screening test kits are designed to deliver results within approximately twenty minutes of a sample being drawn, enabling the availability of results within a single consultation. It is worth noting that in Sedibeng ANC facilities many of the above conditions are present.

Bassett and Walensky (2013) seem to support the abovementioned observation, indicating that very high rates of HIV test uptake have been documented in routine antenatal care and labour room testing programs in South Africa, Uganda, Malawi, Zimbabwe, Brazil, and India. Ultimately, the existence (and adoption) of applicable MCWH policy guidelines (Guidelines for Maternity in South Africa 2007) by the South African NDOH bears testimony to the acknowledgement by government that POCT plays a pivotal role in patient management, particularly in resource limited settings.

Another important consideration when examining the value of HIV POCT is the technology's sensitivity and specificity. Weekes (2013) argues that there is substantial evidence from

studies in many countries that the sensitivity and specificity of rapid tests are similar to those of the standard ELISA. The author explains further that although in settings with a low HIV prevalence, even a test with high sensitivity and specificity may not have a sufficient positive predictive value (PPV); meaning that there is a higher chance of obtaining a false-positive result. The author further states that as prevalence increases, the proportion of the POC test yielding false positive results decreases, but the probability of obtaining false negative results increases. She affirms this assertion by illustrating that it has been shown that for settings with an HIV prevalence of 1%, the negative predictive value (NPV) is 100%, and the positive predictive value is 50%. As the (HIV) prevalence increases to 10%, the NPV decreases slightly to 99.9% whilst the PPV increases to 92%. %. It should be noted here that in Sedibeng, the latest incidence of HIV amongst pregnant women in their first ANC visit is 17.4% (Sedibeng District Health Plan 2013/14**).** Additionally, the WHO (2013) reports that the outcome of the evaluation of five different rapid HIV test assays versus the traditional ELISA showed sensitivity and specificity of 99% to 100%. Importantly, in Sedibeng a second (and different) HIV POC test is used to test all samples that test positive on the first HIV POC test. This practice is in line with assertions by experts who argue convincingly that when choosing a confirmatory test it is important to select one that involves the use of different antigens, and that which demonstrates appropriate levels of specificity and sensitivity (WHO, 2004). The likelihood of two false positives is extremely low as it is the multiplicative product of the likelihood of a false positive in each of the two tests.

2.3 Problems with POCT

2.3.1 General POCT

POCT appears to be beset with widespread challenges with various studies unveiling divergent and yet interesting findings.

Plebani (2009) concurs, reporting that studies conducted for the Centres for Medicare and Medicaid Services National Survey involving 436 laboratories in eight states in the United States of America, unveiled quite remarkable sources of errors in POC testing, although the study does not list the range of the POC tests involved. The author reveals that sources of error were categorised into the following: **operator incompetence** - the studies revealed that 19% of personnel performing POCT had neither been trained or evaluated for the testing they were conducting and in 32% of the cases, the same staff could not locate test instructions; **non-adherence to procedures** - 25% of the same staff failed to follow operator instructions,

with 7% not performing the necessary POCT instruments calibrations; **use of uncontrolled reagents/equipment -** 32% of the staff did not perform the necessary quality control(QC) procedures and 6% of test reagents were used beyond the expiry date. Furthermore, the POCT reagents were reported to be degraded by humidity and by improper lighting and heating. The researchers also noted that the same defective reagents continued to be used for testing, inevitably resulting in inaccurate POC test results, due to the lack of implementation of the QC program. Finally, the author argues that certain studies have shown that clinicians' mindsets have not moved in line with the rapid availability of test results made possible by POCT. To support this argument, the author reports that a United Kingdom(UK) hospital study revealed that 52% of clinicians wait for laboratory confirmation of potassium results done in a blood gas POC analyser, whilst only 48% based their decision on the POCT results alone**.**

Carraro and Plebani (2009) conducted a study to examine POCT post-analytical errors of 1966 blood glucose determinations in a University hospital in Italy, in which POCT data was manually transcribed onto patients' records. The authors found that 12.1% of the results were not reported in patients' files, the time of testing was imprecisely recorded in 7.2% of cases and there were transcription errors in 3.2% of the cases, although in all these cases, no adverse events were attributed to these errors. These findings can be directly attributed to the practice of manually recording patients' results by the clinicians.

There is agreement in some literature regarding the nature of POCT obstacles, with two senior specialist clinicians from an anaesthesia and critical care department of a UK hospital echoing that POCT is expected to eliminate challenges, such as lack of transport for specimens and distribution of results from the core laboratory back to the requesting wards/units. However, these clinicians caution that the POCT service is fraught with challenges, such as increasing demands on clinical staff, non-adherence to testing procedures, operator non-competence, inadequate documentation of POC test results, and use of uncontrolled reagents and equipment. The authors suggest that haemoglobin-A1c, glucose, electrolytes and blood gases are some of the tests that should be targeted by the hospital's POCT programme. These clinicians insist that ultimately, POC devices should be electronically linked to a clinical information system so that clinical results can be integrated into the patients' record, in order to avoid some of the potential errors mentioned above(Kumar and Arrowsmith, 2006).

In response to discussions around published statistics relating to the performance of antenatal care services in general, it has been argued that measuring ANC services' coverage alone does not provide information on quality of care, and that poor quality in ANC clinics does correlate with poor service utilisation and that this is a common problem in Africa. The authors relate this to insufficient numbers of skilled providers (particularly in rural and remote areas), lack of standards of care and protocols, few supplies and drugs, and poor attitudes of health providers (Lincetto *et al*, 2006). The difficulties put forward by the aforementioned authors are noticeably similar to those observed at the Sedibeng facilities, particularly with regards to the screening of pregnant mothers using POCT methodologies.

2.3.2 Syphilis screening and POCT

The WHO (2012) bemoans the fact that although RPR POCT is simple and cheap, the technology requires basic laboratory capacity and quality controls that may not be available in remote or resource limited facilities with limited infrastructure. In addition, the organisation states that laboratory staff is sometimes opposed to the idea of training nurses and midwives to do a task that had traditionally been done by trained laboratory scientists, especially in countries with excellent laboratory services. This goes against the critical need for the laboratory staff to become involved in the training and supervision of the non-laboratory trained clinicians. This should be done during testing, and in setting up quality assurance programs to monitor the HCW for proficiency during POC testing. The challenge relating to serious shortage of trained staff is also known to prevail in many countries and even in adequately staffed facilities, the dilemma relating to high staff turnover is said to persist. In addition, the organisation bemoans the fact that trained HCW are often transferred to new facilities without training the remaining HCW on POCT utilisation.

Mabey *et al* (2012) reiterates the importance of sustained training in quality assurance for non-laboratory trained HCW and how the lack of training can be problematic, leading to these clinicians compromising the quality of patients' results. The authors reveal that six months into an eighteen-month HCW training program for syphilis proficiency testing in Geita District in Tanzania, the percentage of facilities failing the proficiency testing rose to 65%. This was after initial success was achieved by the program, resulting in less than 20% of the facilities failing the proficiency testing. In several of these clinics, the staff members performing the tests were not the ones who had been trained to do so.

Some literature highlights and contrasts the abovementioned non-treponemal RPR POCT technology with the newly introduced treponemal POCT technology. The non-treponemal tests are designed to detect antibodies to nonspecific antigens that are produced in most patients with syphilis, the RPR being the most prominent example thereof. The most prominent feature of these tests is that they usually revert to negative after successful treatment hence; they can be used to monitor response to therapy. Conversely, the treponemal assays are designed to detect antibodies against specific antigens from Treponema pallidum *(*the spirochete which is the causative organism for syphilis). Although the latter tests are typically more specific than the non-treponemal assays, they will remain positive for years despite treatment **(**Theel, 2012**).** The authors concur that although the RPR POCT has the advantage of being able to distinguish active and past syphilis infection, the technology's disadvantage is that it requires electricity for a refrigerator to store the reagents; it also requires a rotator and a centrifuge. Additionally, testing cannot be conducted with whole blood, and false negative results can occur when this is done. In contrast, the treponemal rapid POCT syphilis test has the advantages that it can be used with whole blood, serum or plasma, and can be transported and stored at temperatures below 30ºC, whilst its disadvantage is that it cannot distinguish between active and past treated infection as antibodies to treponemal antigens are retained for years (Peeling, 2006; Singh and Peeling, 2012). The RPR POCT technology is the method of testing used in the Sedibeng facilities. Consequently, the problems highlighted by the literature regarding this technology are noted with interest to this study**.**

2.3.3 HIV screening and POCT

With regards to problems that may be experienced with HIV POC testing, Arora *et al* (2013) express these emphatically**.** The authors argue that with regards to HIV POCT, the standard requirement of pre and post counselling may be difficult to attain, this is especially true in the case of patients in labour where detailed pre-test counselling may be difficult. In these cases an informed consent from the patient would be a minimum requirement. Moreover, they point out that pre-test counselling is critical for preparing patients for the implications of a reactive test result which include ensuring that they return for their confirmatory test results. The authors remind us about the other challenges that may be encountered with HIV POCT namely:

- Quality assurance difficulties may be faced by non-laboratory trained HCW especially when they have not been trained sufficiently or there is inadequate

resources. They correctly state that these factors are critical in ensuring proper administration of the test and the correct interpretation of the test result.

- HIV POCT requires regulatory approval which necessitates that these test kits should be licensed for use in the country
- Rapid test devices are generally satisfactory for the detection of uncomplicated HIV infection or its absence, but are less sensitive than the laboratory-based enzyme linked immunosorbent assay (ELISA) methodology for detecting of early infection. HIV POCT may therefore not be reliable for detecting the very important 'window period'.
- The ease of the POC testing may lead to a deviation from ethical considerations which may result in HCWs not seeking patients' voluntary, specific and informed consent. This is a particular risk when patients are in labour, are anaesthetised or otherwise lack capacity to make decisions.
- Lastly, the authors state that a small number of HIV POCT may produce a false positive result which necessitates that all reactive test results be confirmed with a laboratory-based confirmatory test.

2.3.4 Hb screening and POCT

There are several problems that might be experienced when Hb POCT is performed by non-laboratory trained clinicians.

Byrkit *et al* (2013) contend that the difficulty in utilising POC testing for haemoglobin lies in the methodology's requirement for blood samples to be drawn, the need for maintenance of equipment (by non-laboratory trained HCWs), and the need for recurrent testing kits' supplies, which limits these devices' use in resource-poor settings. These authors argue convincingly that in general, PHC settings should aim for tests that are easy to use and have lower costs, because they do not have highly trained staff or the resources needed to support expensive, more accurate and complicated tests. However, the authors concede that clinicians in these settings may have to compromise on screening test accuracy due to the above-mentioned constraints.

In a recent review of POCT in haematology, Briggs *et al* (2012) maintain that Hb POCT devices should generate results that are comparable to the local reference laboratory, internal quality control (IQC) measures must be available in all POCT instruments to identify

significant deviations from acceptable performance and that this IQC should be analysed daily. The authors add that ideally there should be an objective external method of quality assurance (EQA).

Schapkaitz and Mahlangu (2011), who are both South African-based haematologists, concur that there is a need for adherence to the abovementioned quality assurance measures, if good quality Hb POCT is to be attained. Regrettably, the aforementioned levels of quality assurance seem not to be achieved by the Sedibeng ANC facilities, and one might add, through no fault of theirs as structures to support these objectives are yet to be established by the relevant government departments.

2.4 Introducing POCT to workers previously used to laboratory-based testing services

2.4.1 General POCT

The practice of introducing POCT to non-laboratory trained personnel requires the adoption, implementation and monitoring of government policy that facilitates regulation and strengthening of these services. One of the key reasons these measures are required is that the clinicians' normal scope of practice is vastly different from the skills required to conduct POC testing. Consequently, clinicians may find it cumbersome to carry out the POCT.

Some authors have suggested that POCT education should be included in medical and nursing school curricula, and that continuing medical education should be provided to clinicians, with updates on diagnostics, similar to those for drugs provided by the pharmaceutical industry (Peeling and Mabey, 2010).

Moreover, there is broad consensus that the issue of training of clinicians on POCT utilisation is critical for these services' sustainability (Junker, Schlebusch, and Luppa, 2010).

Arguments for non-laboratory trained personnel performing POCT to have access to a competent medical laboratory service that could be relied upon for guidance and advice are made frequently, with some of the researchers proposing specifically that there should be committed involvement of laboratory trained scientists to address the issue of safety and quality in POCT (Peeling *et al*, 2006).

The important finding from the previously mentioned United Kingdom hospital study that 52% of clinicians await laboratory confirmation before acting on blood gas analyser-potassium (POCT) results, underscores the fact that the uppermost issue in clinicians mindsets is the validity of test results, rather than their rapid availability or their immediate therapeutic implications (Plebani, 2009).

Contrary to some findings, a few studies have reported success on introduction of POCT to non-laboratory trained personnel: A before-and-after study conducted by a large New York university-based emergency department (ED) demonstrated that after nurses commenced bedside troponin-one (a cardiac marker) POCT on patients with chest pain (and admitted in the ED), TAT and ED length of stay were significantly reduced: (5.2 hours [95% CI 4.6 to 5.8 hours] versus 7.1 hours [95% CI 6.6 to 7.7 hours]). Unsurprisingly, the authors attribute this success to the unit's reliance on cooperation between ED staff and the central laboratory, which is responsible for training, oversight, and quality control (Singer, Ardise, Gulla and Cangro, 2005).

Furthermore, substantial POCT success was reported with non-laboratory trained clinicians (who were doctors) working in a remote New Zealand rural hospital. The findings in this study revealed that POC testing on 269 tests (the majority of which were urea, electrolytes, glucose and haemoglobin), significantly increased diagnostic certainty ($p < 0.01$)), and altered treatment allocation for 43% of patients ($p < 0.01$), by reduced transfers to a base hospital by 62% and increased discharges by 480%. Substantial treatment change was reported in 75% of cases, some change in 22%, and no change in 3%. Moreover, considerable financial benefits were reported. These translated into a net benefit of 452 360 New Zealand dollars to the District Health System over one year. The authors conclude by affirming that their study has shown that rural hospitals can readily adopt new POC technology using it to improve patient care and to reduce hospital admissions and inter-hospital transfers with consequent savings to the health care system (Blattner, Nixon, Dovey, Jaye and Wigglesworth, 2010).

2.4.2 Syphilis screening and POCT

With regards to the introduction of accessible and good quality syphilis POCT to non-laboratory trained HCWs, researchers in Tanzania conducted a cohort study using 2099 blood samples, comparing a new POCT method with two laboratory-based technologies, which

includes the RPR technology was performed in a conventional laboratory. The method uses whole blood and therefore samples do not need centrifuging and it takes only fifteen minutes to complete. These researchers argue that although the samples tested with the new POCT method (and conducted by trained clinicians) yielded lower sensitivity but higher specificity (59.6% and 99.4% respectively) compared to the two laboratory-based methodologies (95.3% and 97.8% respectively), the new method's greater accessibility and the fact that treatment can be given on the same day, would result in a higher proportion of syphilis positive women being treated promptly than with the other two methods (Smit *et al*, 2013). The lower sensitivity (59.6%) demonstrated by the new method in the latter study suggests that the method yielded lower volumes of false positive test results.

The WHO (2012) states that rapid and improved POCT which enables on-site diagnosis and prompt treatment of women who screen positive for syphilis is increasingly possible, even in remote settings. Although the organisation does not specify which methodologies these are, it does stress that these diagnostics allow syphilis-infected women to be diagnosed and treated in a single antenatal visit. It goes without saying that any evidence-based method that could make it easier for the non-laboratory trained HCW to conduct syphilis POCT proficiently is extremely desirable for the Sedibeng district's ANC facilities.

Finally, the following factors have been cited as being critical to the introduction of new syphilis POCT: engagement of policymakers and stakeholders, identifying champions to promote syphilis screening, training and technical assistance, positive feedback to the HCWs, and keeping motivation high among the teams (Peeling *et al*, (2013).

2.4.3 HIV screening and POCT

As previously mentioned, examination of the NHLS database by the student shows that minimal volumes of HIV screening tests were processed at these laboratories, implying that the majority of HIV screening is as expected, done as POCT in the Sedibeng facilities (National Health Laboratory Services, 2012). If this is observation is indeed true for most PHC facilities in South Africa, it suggests that HIV POC testing has lead to drastic improvement in the surveillance of HIV in endemic settings such as South Africa.

Alemnji, Nkengasong and Parekh (2011) assert that the advantage of HIV POCT over other technologies include, clinical decision making made at the patients' point of care, testing

performed with minimal training, costly equipment not required, rigorous sample preparation and acquisition eliminated, and that reagent use is minimised thereby reducing costs significantly. In addition, these authors state that minimal blood volumes are used requiring minimal expertise and eliminating the risk of transporting potentially infectious materials. Moreover, they argue that some of the HIV POCT equipment is portable and battery operated and very suitable for rural settings where electricity is a major challenge.

Parekh, Kalou, Alemnji, Ou, Gershy-Damet, and Nkengasong (2010) concur with the latter assertions, affirming that HIV POCT is indeed largely low-cost and that transport and storage requirements for this methodology have become flexible. The abovementioned statements concur with the observations from the Sedibeng ANC facilities, which seem to indicate that HIV POC testing is performed and managed with relative ease by the non-laboratory trained personnel. As previously mentioned, adequate training of staff not accustomed to performing laboratory testing is vital.

2.4.4 Hb screening and POCT

In the student's own assessment, introducing Hb POCT to non-laboratory trained HCWs appears to be a manageable process as the technologies used are (seemingly) straightforward and thus relatively easy to operate.

Dunning, MacGinley, and Ward (2012) concur with this assertion. The authors conducted a study for which outpatient nursing staff were rigorously trained, and were observed by the supplier of the Hb POCT instruments as they conducted screening for anaemia on 554 patients. The testing happened over a three-month period. The authors report that the nurses operated the analysers accurately and with relative ease. However, three key considerations in the positive outcome of the study warrant mentioning, these are: the nurses were rigorously trained (as previously mentioned), the trainer stayed with the nurses for the first week to provide advice and support, and lastly, the analysers were subject to routine quality assurance testing by the hospital laboratory staff during the study, to ensure they read the results within the recommended reference range.

In addition, Briggs *et al* (2008) suggest that training protocols for POC testing be established and that all potential operators must achieve an adequate level of competence. The content of the training programme and the knowledge/skill level assessment should be documented in a

training manual. The authors further suggest that with regards to the quality control of instruments such as the hand held haemoglobin metres, liquid controls should be used at least once weekly. These controls should be used when there is a new lot number of a test strip, a new delivery of strips, when there is any doubt about the storage condition of strips, or when unexpected high or low analytic values are detected. Unfortunately, there is no evidence which suggests that the above-mentioned trainee-support and quality control measures are in place in the Sedibeng ANC facilities.

2.5 Factors affecting the uptake and provision of high quality POCT

2.5.1 General POCT

A variety of factors contribute to the uptake and provision of high quality POCT. One envisages that acceptability of POCT to non-laboratory trained personnel should feature quite prominently as one of the factors that would contribute to uptake and provision of high quality POCT.

Reid (2012) argues that developing POCT for resource limited settings requires a convincing and empirical argument that the proposed methodologies will improve individual and public health. She asserts that this will facilitate an uninhibited flow of adequate resources and the political will for the programs to succeed. Moreover, the author emphasizes that the quality control in POC testing is critical as an incorrect result may result in delayed treatment, stigma and failure to detect or control a disease outbreak. Consequently, the author argues that any POCT should come with a comprehensive quality assurance plan. Furthermore, the author crucially argues that the time and cost of consistently performing quality control before POC testing should be considered, as end-users may be in the difficult position of choosing between testing more patients and fulfilling quality control requirements. In addition, the author stresses that the concept that POC test results are meaningless if quality control is neglected, should be a core component of user training, adding that training materials must be developed with the non-laboratory HCWs in mind.

Wagar, Yasin and Yaun (2008) from the Los Angeles Clinical Laboratories, offer a broader perspective to the latter discussion. Upon considering their review of 20 years of POCT practices, the authors insist that the vast majority of clinical staff members involved in POCT are primarily focused on clinical care and are much more variable in their knowledge of the POC testing processes and quality control requirements. In addition, these authors assert that training and ongoing competency maintenance for clinicians performing POCT can be

overwhelming to manage. They suggest that to achieve successful POCT management a multidisciplinary organisational approach should be adopted by health care institutions and this should include the creation of a clearly defined organisation that has designated authority, responsibility and accountability. In addition, the authors advise that standard operating procedures and a POCT quality programme should be developed and carried out in all areas.

Junker *et al* (2010) concur with the latter suggestions, affirming that for POCT to be successfully implemented, it is absolutely essential that suitable management structures be put in place. The authors propose furthermore, that POCT activities should be coordinated from a conventional laboratory to facilitate quality management, and that there should be information systems with a centralised computer network to allow for reliable documentation of results, optimisation of quality and proper calculation of POCT cost-effectiveness. It is worth noting however, that the latter authors make their assertions about POCT from a First World (German) perspective. Consequently, their expectations about certain requirements (such as the proposal for the availability of a centralised computer network) for successful POCT implementation might be unrealistic for a resource-limited setting such as the Sedibeng district.

Interestingly, Kavsak, Zielinski, Li, McNamara, and Khosrow (2007) reveal that a neonatal intensive care unit of a children's hospital in Canada reported a low uptake in glucose POCT, which was demonstrated by the unexpected increase (21%) in neonatal blood glucose tests performed by the core laboratory after the introduction of blood glucose POCT in the unit. This is despite the fact that the clinicians (nurses) were trained in utilisation of the glucometers prior to the introduction of the POCT. In addition, a statistically significant (p = 0.016*)* difference in the POCT test results amongst operators was reported, (discovered on comparing their POC test results with the ones done in the core laboratory instrument). The authors observed that the operators performing the POCT more frequently produced results that were comparable to the core laboratory. Consequently, they pondered whether the observed differences in the quality of the operators' glucose POCT could in future be resolved through additional training and monitoring. The latter is another illustration of the need for sustained training and monitoring of non-laboratory trained clinicians if high quality POCT outcomes are to be achieved.

An assessment of user issues impacting the uptake and adoption of cardiac enzyme POCT, involving100 HCWs (which included doctors, nurses and laboratory scientists) from 15 United Kingdom and Northern Ireland National Health Service major hospitals, revealed various concerns in relation to factors affecting uptake of POCT by non-laboratory trained clinicians. These included the following: ability to adhere to the required quality assurance practices, clinical governance issues, test-costs and consumables-costs issues, and the levels of training required to perform the POCT (FitzGibbon, Huckle and Meenan, 2010). The issues raised in the latter survey regarding barriers to POCT are very similar to those highlighted elsewhere in this review, but the fact that HCWs' views about POCT issues were sought is noteworthy. Furthermore, concerns around quality assurance and training are very similar to those faced by clinicians working in the Sedibeng districts' ANC facilities.

Tirimacco's (2012) assertions concur with many of the afore-mentioned factors that could affect uptake and provision of high quality POCT, adding that POCT methodologies could potentially be incompatible with methods used in the local laboratories. Although the article does not specify how POCT methods could be incompatible to those used in local conventional laboratories, one envisages that some POC test methods could possibly be unavailable or dissimilar to an equivalent method used in the local (and referral) conventional laboratory leading to an inability by the laboratory to conduct requisite confirmatory testing.

Unfortunately, details about the factors leading to the substantial success in the uptake and provision of high quality POCT reported by the previously mentioned New Zealand rural hospital study are lacking (Blattner, Nixon, Dovey, Jaye and Wigglesworth, 2010).

Pai *et al* (2012) put forward a compelling assertion as far as the South African context of POCT programs is concerned, revealing that South African experts are wary of the fact that the NHLS cannot control or provide oversight to any (POC) testing outside the NHLS laboratory network. This is certainly the case with regards to any quality assurance challenges that might be experienced with POC testing in the Sedibeng ANC facilities, as non-laboratory trained clinicians (mainly nurses) have the overall responsibility of managing all aspects of onsite testing of pregnant mothers for syphilis, anaemia and HIV, with no access to the expertise of laboratory trained personnel.

2.5.2 Syphilis screening and POCT

WHO (2012) specifies that the barriers to the elimination of mother-to-child elimination of syphilis include: **(among health care service providers) -** lack of awareness of or training in the appropriate intervention, lack of commodities appropriate to the setting, insufficient logistical support for the intervention; **(among programme managers) -** syphilis being accorded a low priority compared with other problems, there is lack of resources for effective interventions, lack of awareness of the cost effectiveness of the interventions, lack of clarity regarding roles, responsibility and accountability and poor planning, coordination and monitoring of programmes**; (among policy makers and decision makers) -** lack of awareness of true disease burden, lack of awareness of the cost effectiveness of the intervention and little external pressure to adopt or implement policies.

Remarkably, Peeling *et al* (2013) argue that country programmes have difficulty in implementing RPR POCT even though it is rapid and affordable. The reasons given are that: the test is designed for ten reactions per card, requiring the patient results to be batched; the test can only be used with serum and the instrumentation requires electricity to operate; HCW who are not laboratory trained often find the test difficult to interpret. Moreover, these authors stress that most clinics lack the capacity to offer screening consistently due to shortage of personnel, supply chain failures for test cards, gloves and other consumables.

Watson-Jones *et al* (2005), in their quest to determine the operational reality of syphilis POCT screening, conducted observations, interviews and facility audits in health facilities within nine districts in Tanzania. The findings of their study were quite revealing with regards to the RPR POCT's operational challenges experienced by the health care workers. These include the findings which reveal that often only one HCW was trained in RPR POCT at each site, trained staff were transferred before a replacement was trained, there was no cover for leave or illness, no refresher training was conducted, there was lack of understanding of the rationale behind the screening, the screening was unpopular and time-consuming, no quality control procedures were in place, storage of RPR test kits was inadequate and there was lack a of supervision of HCWs performing the POCT. The latter findings are strikingly similar to a general observation made by the student about RPR POC testing at the largest CHC in the Sedibeng district.

Mabey *et al* (2012) demonstrated in all the 6 lower to middle income countries (Tanzania, Uganda, Zambia, Peru, Brazil and China) chosen for their study, that rigorous training of HCWs in syphilis POCT utilisation, as well as training them in quality assurance and in supply chain management, are vital in promoting good uptake and provision of high quality POCT. The researchers reported significant accomplishments in syphilis POCT utilisation (with over 100 000 pregnant women reportedly screened for syphilis). These include an increase in the proportion of pregnant women diagnosed with syphilis treated on the same day exceeding 90% in all countries, and successfully screening 55% of the sexually active population in a remote setting in Brazil (exceeding the originally set target of 30% to 40%). However, some of these gains were reversed, as six months after the initial training workshops facilities failing proficiency testing rose to 65%, clearly demonstrating that POCT utilisation by non-laboratory trained HCWs will deteriorate drastically, if training programmes are not sustained.

As previously highlighted by Pai *et al* (2012), the reality is that non-laboratory trained HCWs may lack the knowledge and training required to implement even the simplest POC technologies, and this would erode the health system's faith in POCT. These authors also mention staff shortages and high workload as barriers that contribute to inadequate uptake of POCT.

The findings of the Sedibeng study which revealed that 91% of pregnant women screened for syphilis during their first ANC visit are in line with the WHO's Millennium Development Goals (MDG), which seeks to eliminate mother-to-child transmission of syphilis by having more than 90% of women tested and treated for syphilis by 2015 (Newman, et al., 2013). The aforementioned authors conducted a study (using a health service delivery model) to collate and assess the national syphilis seropositivity data from 97 countries and the burden of syphilis related adverse pregnancy outcomes from 147 countries for 2008. These researchers assert that the vast majority of the (adverse) outcomes such as stillbirths or early foetal deaths, neonatal deaths, preterm or low birth weight infants and infected newborns, that occurred in 2008, could have been prevented had the women received quality early ANC services that include syphilis testing and access to effective therapies, if they test positive for syphilis. In addition, the researchers found that an estimated 1.4 million pregnant mothers had active syphilis infections, with an estimated 39% of the mothers (being the highest of all the regions) residing in Africa.

A Chinese study revealed that syphilis POCT was successfully used to screen 27 150 pregnant women in rural areas of South China. The study was done to address the reported lack of syphilis testing in rural regions which lead to uncertainty about the extent of the syphilis epidemic among rural pregnant women in this region (Yang *et al,* 2013). There are three factors pertaining to the screening of pregnant women for syphilis between the above-mentioned Chinese and the Sedibeng District study that are worth highlighting: 1) contrary to the practices stipulated in the South Africa's NDOH guidelines, the researchers highlight the fact that the Chinese national plan lacks emphasis on the importance of early antenatal screening, 2) all the Chinese women screened in their study received their syphilis POC results on the same day, whilst as previously mentioned, only 27% of the pregnant women visiting the Sedibeng District facilities received this benefit; however, because the Chinese women who had tested positive with syphilis POC were treated only after three days (which was when the confirmatory results were received from the referral laboratory), the potential benefit of POCT on early treatment was lost, 3) all the positive POC tests from the Chinese study were confirmed by a referral laboratory, presumably because of the low positive predictive value of the POC test. The South African Mother and Child and Women's Health guidelines (2007) do not have this requirement, and indeed, some facilities treat the pregnant mothers based on the positive syphilis POCT result. Interestingly, the Sedibeng study revealed that one of the three facilities that perform on-site syphilis screening indicated that it refers all syphilis positive POC samples to the laboratory for confirmation, with the basis for their decision being the HCWs' discomfort with labelling the pregnant women as having syphilis and treating them for syphilis based on the POCT result. It is unclear whether this discomfort is due to their awareness of the low positive predictive value of the POC test as none of the respondents mentioned this specifically and it therefore seems more likely that they might just be suspicious of a POCT test which is relatively new to them and which is not yet widely used.

2.5.3 HIV screening and POCT

A United Nations (2009) report argues that thirty decades after the discovery of the first HIV antibody test, only about 26% of the 126 million pregnant women in lower and middle income countries learn their HIV status prior to child birth.

Furthermore, Madhivanan *et al* (2013) lament the fact that India is among the top ten countries in the world with the highest burden of paediatric HIV infections. They state that

the low rates of HIV testing have been found to be closely associated with a lack of accessible and affordable healthcare. However, the latter situation differs markedly with that observed by the student in the Sedibeng ANC facilities, as evidence gleaned by the student from the ANC facilities' records, together with data from the NHLS suggests that substantial numbers of pregnant women do receive screening for HIV during their first ANC visits by means of POCT (National Health Laboratory Services, 2012).

In one study to determine the feasibility and acceptability of HIV POCT in community outreach programs, it was discovered that although HCWs were accepting of a newly introduced HIV POCT technology in 6 selected health care services in the North West of England, their principal concern was that performing the procedure would impact upon their regular duties. This overlapped with the HCWs' concerns (in the same study), that POCT for HIV could distract them from core service provision (MacPherson *et al*, 2011).

Additionally, Arora *et al* (2013) reiterate that appropriate training on the use of kits, reading of test results, quality assurance, detection of errors, counselling and regular assessment of staff performing POCT are important requirements for providing high quality HIV POCT. These factors also affect the uptake of the technology.

Remarkably, the findings of the Sedibeng study are a demonstration of the success of the huge drive by the South African government to actively expand the Prevention of Mother to Child Transmission (PMTCT) of HIV coverage to pregnant women (Guidelines for Maternity Care, 2007). The success of the PMTCT programme is reflected in the South African National Department of Health 2011/12 – 2013/14 Annual Performance Plan, which reported a rise in the percentage of pregnant women who were tested for HIV from 80.3% in the 2007/8 reporting period to 86.5% in 2008/09, to 92.7% in the 2009/10 period. The report estimated that the performance of the PMTCT programme for screening of pregnant women for HIV for the 2011/12 would rise to 96.2%. In addition, the estimated (medium term target) PMTCT coverage to pregnant women for the 2013/14 was expected to be at 100% (SA NDOH, 2011). The Sedibeng PMTCT of HIV coverage to pregnant women for the 2011/12 and 2013/14 reflect that 100% of the women were tested for HIV during their first ANC visit over these 2 periods, although the actual patient registers over the study period reflected slightly less coverage (Sedibeng District Health Plan 2011/12, 2013/14

2.5.4 Hb screening and POCT

Even though the previously mentioned studies (Sanchir-Gomar *et al,* 2012; Byrkit *et al,* 2013; Briggs *et al,* 2012; Schapkaitz and Mahlangu, 2011; and Dunning *et al,* 2012) suggest that less difficulties can be expected with conducting Hb POCT, they nevertheless indicate that issues such as adequate training of the non-laboratory trained HCW and adherence to strict quality assurance measures, are vital for the adequate uptake and provision of good quality Hb POCT.

With regards to the previously mentioned HemoCue Hb POCT devices, Sanchir-Gomar *et al* (2012) caution that the blood test results obtained by venous and arterial sampling are more accurate than those obtained with capillary blood and should therefore be preferred whenever possible.

In addition, Schapkaitz and Mahlangu (2011) compared the HemoCue device with an automated laboratory analyser using 100 venous blood samples They concluded that the device can be used to provide accurate and reliable Hb measurements with improved turnaround time and long-term cost saving. It is worth highlighting that capillary blood samples were not used in comparing the two methods in the latter study.

However, Adam, Ahmed, Mahmoud, and Yassin (2012) disagree with the latter studies, stating that results of their study of 108 samples taken from ANC patients in Khartoum Hospital (Sudan), indicate that haemoglobin concentration assessment by HemoCue using either venous or capillary blood samples does not have an acceptable agreement with the automated haematology analyser. Although the issue of using capillary blood for conducting Hb POCT when utilising the abovementioned device is clearly discouraged by these and the other previously mentioned authors, it might be difficult to implement the use of venous blood samples for conducting Hb POCT in the Sedibeng PHC facilities, as one of the major reasons for opting for POCT is that the methodology does away with the time-consuming practice of drawing blood from patients.

As previously mentioned, Lincetto *et al* (2006) discuss several factors that may lead to lack of provision of high quality care to pregnant mothers. Likewise, these may easily affect provision of high quality Hb POCT. These include: competition for resources as well as poor communication with other programs (e.g. HIV and emergency obstetric care), lack of updated

standard protocols and weak monitoring systems, poor regulatory systems or insufficient capacity to enforce regulations, and that staff may not have the required skills to provide all components of antenatal care.

The Sedibeng study revealed that the rate of screening of the pregnant women for Hb during their first ANC visit was 84.4%, which was the lowest of the three screening tests. However, the above findings are to a large extent, comparable to those of a 2007 study conducted in twenty three Zimbabwean rural areas. That study was a randomised control trial of 13 517 pregnant women which was conducted with the objective of comparing the value of a five-ANC visits (newer and WHO-approved) model with that of a standard model, (an older [1929] fourteen–visit ANC model), which was recommended by the British Department of Health. The study revealed that 88% of the pregnant women sampled in the trial as part of the new (five-visit ANC model) were screened for anaemia during their first ANC visit. The study also found that the likelihood of haemoglobin testing was higher in the new model (Odds Ratio 1.5; 95% CI 1.0-5.7). Correspondingly, 81% of the pregnant women who were studied as part of the older (fourteen-visits standard ANC model), were screened for anaemia during their first ANC visit. A pertinent observation from this study is that all the pregnant women received the Hb screening results during their first ANC booking. However, it is not clear whether the women's Hb samples were processed as POCT (by non-laboratory trained staff), or if the testing was conducted in a conventional laboratory. Another noteworthy observation from the study is that the researchers were not able to retrieve 22% of the data, reportedly due to incomplete information in the patients' records. This was (apparently) because the midwives had to prioritise certain functions at the expense of thorough record keeping (Majoko, Munjanja, Nystrom, Mason and Lindmark, 2007). Unfortunately, it was not clear how in the above mentioned Zimbabwean study, the researchers were able to distinguish the 22% of the patients with incomplete information due to poor record keeping, from those who had not been screened. The latter observation is significant, as it puts a spotlight on the previously mentioned finding of this study with regards to how the quality of record keeping in Sedibeng facilities could have impacted the finding that a significant number the pregnant women were not screened for anaemia during their first ANC visit.

2.6 Conclusion

This literature review revealed comprehensive and broad information about the prevalence of screening of the three specified ANC tests and the factors affecting antenatal point care testing for syphilis, anaemia and HIV in both the developing and developed world, thus giving the review a broader global context. In many instances the outcomes of the several studies and articles with the ensuing discussions, could largely be linked to those of the Sedibeng study. The review has thus enabled the student to gain a 'world view' on the topic, thereby broadening her knowledge base on this important subject. However, the student discovered that the topic was much less-charted than expected. Consequently, she struggled somewhat to find specific literature that directly relates to the topic, both locally and globally.

CHAPTER 3

Methodology

3.1 Aim and objectives

3.1.1 Aim

The aim of this study was to assess the prevalence of screening for syphilis, anaemia, and HIV amongst pregnant women during their first antenatal care visit to PHC facilities in the Sedibeng District, and to establish the factors affecting the prevalence of appropriately using POCT for screening tests.

3.1.2 Objectives

- To evaluate the prevalence of any type of screening for syphilis, anaemia and HIV of pregnant women during their first ANC visit
- To evaluate the prevalence of POC testing for syphilis, anaemia and HIV
- To identify the factors affecting the rate of screening and POC testing for syphilis, anaemia and HIV
- To examine the appropriateness of laboratory tests requested for syphilis, anaemia and HIV

3.2 Study Design

A quantitative, analytical, cross-sectional study was conducted. This study design was appropriate for the research topic because it was suspected that POCT services were minimally and inefficiently utilised by clinicians in Sedibeng PHC facilities, yet little was known about the magnitude and causes of this low uptake. In addition, this study design allowed one to relatively easily establish the size and distribution of the POCT uptake in Sedibeng in a relatively inexpensive manner and within a short space of time.

3.3 Population and Sampling

There were 3 study populations in this study, namely:

a) **ANC registers of** approximately 7 200 pregnant women who attended PHC facilities for their first antenatal care visit over a six month period (from 1st July 2012 to 31st December 2012).
b) **All the facility staff** expected to perform the ANC POCT screening tests: these were either professional nurses or enrolled nurses.
c) **Facility managers**: All the managers of the 37 PHC facilities in the Sedibeng district.

3.3.1 Sample size

The sample size for the patient records was calculated using a desired level of power of 80%. This is the ability of the study to detect the actual effect, with an error margin of 3%. The Epi Info statistical programme was used to calculate a sample size of 360 patients' records using the above criteria.

3.3.2 Sampling procedure

For registers of patients on their first ANC visit: Systematic sampling was conducted. Patient numbers were selected from the ANC register according to the predetermined sampling interval. For this study a population of about 7200 pregnant women's records was expected. To obtain a sample of 360 a sampling interval of 20 was used.

Staff expected to perform POCT: 30 nursing staff working in the 30 facilities (one per facility) who were expected to perform the POCT screening tests on patients attending the clinics for their first ANC visit, were included in the sample. These were a mix of professional nurses and enrolled nurses tasked with performing the POCT. If more than one staff member tasked with performing POCT was present at the facility at the time and date of data collection, then one was randomly selected. However, in all instances, a registered nurse was selected over an enrolled nurse, if both performed POCT.

Facility managers: 30 facility managers from the 30 PHC facilities from which the patient data was sampled (Note that ANC first assessment services were only available at 30 of the 37 PHC facilities in Sedibeng district).

3.4 Data collection methods

Data extraction form for patient folders: The ANC first visit registers were examined to determine if for each patient the RPR, Hb and HIV screening tests were done **(*see Appendix A*)**.

To establish **the mechanism of the testing**: the ANC first visit registers were examined to establish the method of syphilis, anaemia or HIV screening used. This was determined by checking the kind of test results documented on the register, i.e. was POC testing done, or was the sample sent to the NHLS laboratory for processing.

To obtain data from staff performing POCT: Interviewer-administered closed-ended questionnaires were used. The staff members tasked with performing the POCT were questioned about their knowledge, attitude and practice of POCT. In addition, questions were asked regarding the HCWs knowledge about which ANC screening tests appear in the

MCWH guidelines and about their knowledge about the availability and contents of the provincial POCT list. The staff members were additionally asked questions about how they were trained to perform the POCT, whether they perform quality assurance prior to conducting the testing, and about the ease of performing POCT. Finally, these HCWs were asked questions about whether they were able to interpret the POCT results and if they trusted these results ***(see Appendix B).***

To obtain data from facility managers: Interviewer-administered closed-ended questionnaires were utilised. The managers were questioned about the availability of relevant policy documents, the presence of different standard operating procedures (SOPs), consistent availability of staff to perform POCT, availability of test kits, working condition of testing material, equipment procurement procedures, and the availability of written procedures to communicate with the NHLS laboratories when the need arises (***see Appendix* C).**

3.5 Data analysis

Questionnaires were checked for completeness and internal consistency.

Data was analysed using univariate, bivariate and multivariate analyses.

3.5.1 Univariate analysis

The rate with its corresponding 95% confidence interval (CI) of screening for anaemia, syphilis, and HIV was calculated individually, and the rate and the 95% CI of having all three screening tests done were calculated. A similar analysis was done for syphilis POCT, anaemia POCT and HIV POCT, as well as for laboratory tests for syphilis, anaemia and HIV.

It is worth highlighting that 'Appropriateness' was determined by a mix of POCT and laboratory tests in the following manner:

(a) <u>For RPR</u> – All the testing should have been conducted as POCT as indicated in the guidelines, therefore all samples processed at the NHLS were done so inappropriately (Guidelines for Maternity Care, 2007). Even though the literature noted the low validity of the syphilis RPR POC test, the South African guidelines which staff in Sedibeng health district are expected to follow, recommends that RPR POCT only be done, and that no further laboratory testing is required irrespective of whether the POC test is positive or negative.

(b) <u>For Hb</u> – A laboratory test is required if the result from the POC test showed a low Hb value [Hb < 10.9g/dl] (Guidelines for Maternity Care, 2007).

(c) For HIV – All the screening for HIV should have been conducted as POCT since, as indicated in the guidelines if a POC test is positive then a second and different of POC test should be done to confirm HIV positivity. Therefore all samples processed at the NHLS were done so inappropriately (Guidelines for Maternity Care, 2007).

Although laboratory testing could quite reasonably be deemed to be appropriate if POC test kits were not available in the facility, that criterion was not used in this study, as unavailability of POC test kits is itself deemed to be inappropriate given the policy of prioritising POCT.

3.5.2 Bivariate analysis

In the bivariate analysis prevalence ratios were calculated in which the prevalence in one group was compared to another group with different exposure levels to various factors that might affect the POCT uptake. For example, the prevalence ratio of POCT for syphilis amongst those patients seen at facilities that have SOPs for POCT was compared to the prevalence ratio amongst those patients at facilities that do not have SOPs. The same analysis was done for anaemia and HIV. The potential factors affecting the use of POCT for screening included the knowledge, attitudes and practice of staff performing the POC testing, and how they were trained to perform the POCT. Bivariate analysis was also done on the prevalence of screening and the appropriate use of POCT.

3.5.3 Multivariate analysis (adjusted prevalence ratios)

For multivariate analysis all the factors were compared together to control for confounding. The analysis was adjusted for confounding to assess the individual effect of any potential causative factor. Confounding might occur when another exposure factor exists in the study population and is associated both with the outcome and the exposure being studied.

3.6 Validity

Precision is reasonably assured as the sample size calculation of this study was calculated using the required level of significance. Selection bias did not occur in this study as systematic random sampling was conducted to select samples from ANC first visit registers. Staff selection bias is unlikely, as the entire population of facility managers were included and a representative selection of clinic staff performing POCT, were sampled. The language

used and questions posed in the questionnaires were relevant and clear. A multivariate analysis of all the factors was conducted to control for confounding.

3.7 Generalisability

The rate of screening was unique to Sedibeng district. The findings of this study regarding factors affecting screening and POCT may be generalised to other PHC facilities in South Africa as they are similarly resource-limited and have a similar history and similar practices to those in Sedibeng district. These findings of the study may not however, be generalised to facilities with onsite conventional laboratories and to adequately-resourced facilities.

3.8 Ethical considerations

No harm was anticipated to anyone participating in the study or from the findings of the study. A major benefit of the study was that clarity on the factors affecting the rate of screening and the use of POCT was gained. This will hopefully facilitate the implementation of evidence–based interventions to improve POCT uptake if required. With regards to the PHC staff that was requested to answer the interviewer-administered questions, a participant information sheet was provided. This explained the purpose of the study; the benefits entailed in the study and assured the staff of strict confidentiality. Informed consent was sought and signed by all those agreeing to participate in the study. They were assured that there would be no adverse consequences for the staff who decided not to participate. Participants could at any stage withdraw from the study without the need to explain their withdrawal. Only numbers were used to identify patients from the first ANC visit-registers (no patient names were used). The UWC Senate Research Committee approved the study and issued an ethics clearance letter. Permission to conduct the study was thereafter, sought from the Gauteng Province's Planning and Research Directorate, who subsequently approved the study. Finally, the office of the Director of the Sedibeng DHS approved the study and issued a letter permitting the student to conduct the research in the district's facilities.

(Participant Information Sheet - see Appendix - D; Informed Consent Sheet - see Appendices E, F and G).

CHAPTER 4

Results

The results are presented in the following categories:

- Sample realisation
- Comparison of the prevalence of screening between Local Municipality and Provincial government facilities
- Comparison of screening mechanisms between Local Municipality and Provincial government facilities
- Comparison of appropriateness of Laboratory screening between Local Municipality and Provincial government facilities
- Description of factors affecting POCT utilisation: responses by Staff Performing POCT
- Description of factors affecting POCT utilisation: responses by Facility Managers
- Bivariate analysis assessing potential factors affecting the rate of screening for syphilis, anaemia and HIV; and the rate of POCT testing of RPR (syphilis), Hb (anaemia) and HIV
- Multivariate logistic regression analysis on the 3 outcomes of "antenatal Hb screening"; "antenatal Syphilis POC testing" and Hb POC testing" was conducted. Only these outcome variables were selected based on the results of the bivariate analysis, which indicated that for these three outcomes several independent variables yielded statistically significant associations

4.1 Sample realisation

The sample size of 360 for patient data was obtained. However, the student was able to collect data from only 30 of the 37 facilities. This was because six of the facilities do not offer first-visit ANC services to pregnant women, as these services have been outsourced to surrounding clinics, to save human resource costs and other costs. Due to initial misinformation as to whether 30 or 31 facilities provided first-visit ANC services (the student had been informed that only 30 facilities provided first visit ANC services, however it transpired that 31 facilities provided these services), the sample size of 360 was obtained by the 30th clinic, which prompted the student to stop and not proceed to the 31st (and final) clinic. The process of collecting data from the patients' registers from each clinic was done on the same day as that of interviewing the facility managers and the staff performing POCT. This was done to enable the student to ask clarity seeking questions that could arise from the data extraction from the patients' registers on the same day. Furthermore, the student decided not to proceed to interview staff from the 31st clinic, as patient data had not been collected from this facility. In addition, data could not be collected for the employment, marital status and education variables as these were not recorded in the patients' registers. Moreover, some of the expected screening tests results were missing from these registers. This was particularly true for HIV screening, as the student was told that those patients that had previously tested positive for HIV would not be re-screened when they came for their first ANC visit (only confirmatory testing for CD4 count and other relevant testing would be done).The fact that some of the patients had been previously screened and had tested positive was not evident from the ANC records though, as the student noted that some of the screening results slots were merely left blank (instead of being marked as known HIV positive), giving an impression that these patients had in fact not been screened. However, the student did not manage to verify from the individual patient records if an HIV positive result was recorded in them, as the pregnant women were told to take the folders home.

4.2 Evaluation of the prevalence of screening between Local Municipality and Provincial government facilities

As eighteen of these health care facilities in the Sedibeng district are managed by the Sedibeng Local Municipality and twelve of the facilities by the Provincial government, the screening practices of the pregnant women who attended facilities under these two entities warrant closer scrutiny.

The results of a comparison between Local Municipality and Provincial government managed facilities for the rate of syphilis; anaemia and HIV screening are tabulated below.

TABLE 1 Evaluation of the PREVALENCE of screening: a comparison between Local Municipality and Provincial government facilities (with 95% Confidence intervals)

Facilities Type	**Syphilis: (*n* = 360)**	**95% Confidence intervals**	**Hb (*n* = 360)**	**95% Confidence intervals**	**HIV (*n* = 358)**	**95% Confidence intervals**
Patients Screened: Local Municipality	167/192 (87%)	0.82 – 0.92	145/192 (75.5%)	0.69 –0.82	182/190 (95.8%)	0.93 – 0.99
Patients Screened: Provincial Govt	161/168 (95.8%)	0.93 – 0.99	159/168 (94.6%)	0.91 – 0.98	161/168 (95.8%)	0.93 –0.99
TOTAL	**328/360 (91.1%)**	**0.88 – 0.94**	**304/360 (84.4%)**	**0.80 – 0.88**	**343/358 (95.8%)**	**0.93 – 0.98**

Comment

Two patients were known to be HIV positive and hence it would have been inappropriate to screen them for HIV. This therefore reduced the sample size for HIV screening from 360 to 358. It should be noted that more patients might have been HIV positive and hence ineligible for screening, but whether this was the case or not was not reflected in the records. Hence the point prevalence for HIV screening is at the very least 95.8% but is in reality probably higher.

4.3 Evaluation of screening mechanisms between Local Municipality and Provincial government facilities

Screening mechanisms for the three screening tests conducted at the Local Municipality and Provincial government facilities were compared, and are tabulated below. None of the samples were tested as *both* POCT and via the laboratory.

TABLE 2

Evaluation of POCT DONE: Proportion of antenatal screening done as POCT stratified by type of facility [Local Municipality and Provincial government facilities], (analysed with 95% Confidence intervals)

Facilities	**Syphilis done as POCT (*n* = 328)**	**95% Confidence intervals**	**Hb done as POCT (*n* = 303)**	**95% Confidence intervals**	**HIV done as POCT (*n* =343)**	**95% Confidence intervals**
Local Municipality	1/167 (0.6%)	(-)0.01 – 0.02	120/145 (82.7%)	0.71–0.89	182/182 (100%)	97% – 100%
Provincial Government	86/161 (53.4%)	0.46 – 0.61	145/158 (91.8%)	0.87 – 0. 96	161/161 (100%)	
TOTAL	**87/328 (26.5%)**	**0.22 – 0.31**	**265/303 (87.5%)**	**0.84 – 0.91**	**343/343 (100%)**	**0.98 – 1.00**

4.4 Evaluation of appropriateness of screening between Local Municipality and Provincial government facilities

All the screening test samples which were sent to the laboratory were sent there without a POC test being done first. Since no initial POC testing was done, all the samples sent to the laboratory were inappropriately sent there (see methodology section for details on appropriateness of laboratory tests). Hence inappropriate laboratory testing is as follows:

Syphilis: **241/328 = 73.5%**

Hb: **38/303 = 12.5%**

HIV: **0%**

4.5 Evaluation of factors affecting POCT utilisation: responses by Staff Performing POCT

Staff members tasked with performing POCT and working in the 30 facilities, from which the patient data were collected, were asked various questions about their knowledge of applicable MCWH guidelines and about their POCT utilisation practices when attending to pregnant women, during their first visit to ANC centres. Their responses are shown in Tables 3 and 4.

TABLE 3

Evaluation of factors affecting POCT utilisation: responses by staff performing POCT: (*n* = 30)

Description	**Number and percent with correct answer**
Know about the availability MCWH guidelines at Facility	30(100%)
Usually perform quality assurance before testing POC samples	25(83%)
Always check and record fridge temperatures	23(76.7%)
Always use control reagents provided in the test kits	15(50%)
Staff trained to perform POCT	30(100%)
Always sufficiently trust of POCT results	6(20%)
Always sufficient time to perform POCT	18(60%)
Always sufficient staff to perform POCT	11(36.7%)
Sufficient knowledge about when to send POCT samples to the NHLS	30(100%)

TABLE 4

Evaluation of factors affecting POCT utilisation: responses by staff performing POCT: (*n* = 30)

Number and percentage with correct answer

Description	**RPR**	**Hb**	**HIV**
Believe test appears in MCWH guidelines	29(96.7%)	30(100%)	30(100%)
Tests done as POCT at Facility	3(10%)	30(100%)	30(100%)
Believe it is always easy to perform POCT	3(100%)	30(100%)	30(100%)
Believe it is always quick to perform	2(66.7%)	30(100%)	30(100%)
Always perform tests as POCT	3(10%)	26(86.7%)	29(96.7%)
Is always able to interpret POCT results	3(100%)	28(93.3%)	27(90%)
Believe test kits are always available at Facility	3(10%)	19(63.3%)	29(96.7%)

4.6 Circumstances reported by staff in which they would send samples to the NHLS laboratory for testing

The circumstances under which staff would send RPR samples to the laboratory varied from the vast majority (90%) mentioning the unavailability of POC test kits as the reason, to one staff member (33.3%) stating that the samples would be sent to confirm a positive POC titre, the other one referring samples to the laboratory if the screening results do not correlate with the clinical picture, and one staff member stating that the sample would be forwarded for confirmatory testing if the RPR POC test is positive. With regards to referring HIV samples, all the staff correctly stated that they would send these samples to the laboratory either to clarify discordant results, or to refer HIV positive samples for staging tests. The circumstances under which staff would request a confirmatory laboratory Hb test after having done an initial POC test were quite varied, but using the listed POCT protocol criteria strictly all of them were incorrect (see previous description of the criteria). Using more lax criteria (response closest to that which the criteria stipulates) only 4 staff (13%) provided the correct response as per protocol. However, all the responses except one (never send) were clinical protocol ones, rather than POCT protocol ones. See tables 5 and 6 for more details.

TABLE 5

Reasons provided by staff for requesting laboratory tests after POCT: Syphilis and HIV screening (*n* = 30)

Test	**Reasons**	**Correct Reason**
RPR	Unavailability of test kits	27(90%)
HIV	To clarify discordant results; For staging tests to be conducted	30(100%)

TABLE 6

Hb POCT values and reasons provided by the staff for requesting confirmatory laboratory tests

Reason	**Sums of similar responses**	**Correct Reasons**
Hb values below 10	4(13.3%)	4(13.3%)
Hb values below 8.5	3(10%)	0
Hb values below 8	7(23.3%)	0
Hb values below 7	9(30%)	0
Hb values below 6	2(6.7%)	0
Hb values below 5	1(3.3%)	0
When patient on AZT	1(3.3%)	1(3.3%)
No correlation with clinical picture	2(6.7%)	2(6.7%)
Never send: refer all low haemoglobins to hospital	1(3.3%)	0
Non-functioning instrument	1(3.3%)	1(3.3%)
Never	1(3.3%)	0
TOTAL	**32(107%)**	**8(27%)**

***Total percentage adds up to greater than 100% as staff could provide more than one answer.**

4.7 Evaluation of factors affecting POCT utilisation - responses by Facility Managers: (*n*=30)

Facility managers from whose facilities the patient data was gathered, responded to various questions, which were sought to determine what and how POCT management issues could affect the technologies' utilisation by the staff tasked to perform the onsite screening. Table 7 below illustrates the managers' responses stratified according to whether they work for Local Municipality or Provincial government facilities.

TABLE 7

Evaluation of factors affecting POCT utilisation: responses by Facility Managers: *(n*=30)

Description	**Local Municipality: *n* = 18***	**Provincial government: *n* = 12***	**TOTAL *n* = 30***
Clinic reports possession of the MCWH guidelines	18(100%)	10(83.3%)	28(93.3%)
Manager could produce the guidelines	17(94.4%) ***n* =18**	8(80%) ***n* =10**	25(89.3%) **n= 28**
Clinic in possession of the Provincial POCT list	0	0	0
RPR POCT equipment consistently available and fully functional	0	3(25%)	3(10%)
Hb POCT equipment consistently available and fully functional	15(83.3%)	11(91.7%)	26(86.7%)
HIV POCT equipment consistently available and fully functional	17(94.4%)	12(100%)	29(96.7%)
RPR POC test kits consistently available	0	3(25%)	3(10%)
Hb POC test kits consistently available	16(88.9%)	12(100%)	28(93.3%)
HIV POC test kits consistently available	18(100%)	12(100%)	30(100%)
SOPs for procurement and maintenance of POCT equipment and material available	0	0	0
Sufficient staff trained to routinely perform POCT available	13(72.2%)	11(91.7%)	24(80%)
Written procedures to communicate with the NHLS available	3(16.7%)	1(8.3%)	4(13.3%)
Manager could produce the NHLS communication procedures	2(66.7%)	0	2(50%)

*** Unless otherwise indicated the *n* value listed here applies to each of the variables**

4.8 Bivariate analysis

The bivariate analyses of association of socio-demographic, staffing and facility factors with the outcomes of: "antenatal Syphilis, Hb and HIV screening"; and "antenatal Syphilis, Hb and HIV POC testing" was conducted, and are shown in tables 8 and 9 respectively.

Table 8: Bivariate analysis of association of socio-demographic, staffing and facility factors with antenatal Syphilis, Hb and HIV *SCREENING*

The following independent variables were assessed for an association with the performance of the above screening tests:

a. **Demographic factors**: Gestational age, place of residence, patient's age, and type of health facility.
b. **Staff performing POCT:** Adequacy of knowledge of MCWH guidelines.
c. **Facility managers:** Availability of the MCWH guidelines in the clinics, whether the managers could find the guidelines, availability of SOPs for procurement and maintenance of POCT equipment and material, availability of written procedures to communicate with the NHLS, and whether the facility managers could find the aforementioned procedures.

Table 9: Bivariate Analysis of association of socio-demographic, staffing and facility factors with Antenatal Syphilis, Hb and HIV *POCT Tests Done*

The following independent variables were assessed for an association with the performance of the above POC tests:

a. **Demographic factors**: Gestational age, place of residence, patient's age, and type of health facility.
b. **Staff performing POCT:** Adequacy of knowledge of MCWH guidelines, adequacy of knowledge of POC tests appearing in the guidelines, conducting of the three screening tests as POCT, performing of quality assurance as required, checking and recording of fridge temperatures, utilisation of control reagents provided in test kits, assessment of whether staff were trained, the ease and quickness of performing the POCT on the three screening tests, how frequently the staff performed POCT on the three tests, ability of staff to interpret POCT results, availability of POC test kits for the three tests, whether staff trusted the POCT results, and whether there was sufficient time and staff to perform POCT. Moreover, the knowledge by the HCWs about why they would send POCT samples to the NHLS laboratory was assessed.

c. **Facility managers:** Availability of the MCWH guidelines, whether the managers could find the guidelines, whether the clinics were in possession of the Provincial POCT list, the consistent availability of fully functional POC equipment, the consistent availability of the three POC test kits, availability of SOPs for procurement and maintenance of POCT equipment and material, whether the clinics had sufficient staff trained to perform POCT, availability of written procedures to communicate with the NHLS , and whether the facility managers could find the aforementioned procedures.

TABLE 8

Bivariate Analysis of association of: socio-demographic, staffing and facility factors with antenatal Syphilis, Hb and HIV *SCREENING* with the Prevalence Ratio and 95% Confidence Intervals shown

Variable Name	Variable Value	Syphilis Screening Prevalence Ratio and 95% CI	Hb Screening Prevalence Ratio and 95% CI	HIV Screening Prevalence Ratio and 95% CI
Gestational Age:	Gestational stage ≤16 weeks	1.007 (0.94 – 1.078)	0.984 (0.892 – 1.087)	0.986 (0.946 – 1.028)
	Gestational stage >16 weeks			
Place of Residence:	Resident in suburb	1.091 (1.036 - 1.149)	0.92 (0.796 – 1.063)	0.934 (0.857 – 1.017)
	Resident not in suburb			
Patients' Age:	Age ≤20 years	0.906 (0.818 – 1.004)	0.957 (0.851 – 1.077)	0.985 (0.93 – 1.044)
	Age >20 years			
Type of health facility:	Local municipalityty facilities	0.908 (0.852 – 0.967)	0.798 (0.731 – 0.872)	0.958 (0.958 – 1.044)
	Provincial government facilities			
Facility Managers: Availability of MCWH guidelines in the facilities	Clinic in possession of MCWH guidelines for all	1.447 (0.924 – 2.262)	1.166 (0.81 – 1.679)	1.056 (0.875 – 1.274)
	Facility not in possession of MCWH guidelines for all			
Manager could produce the MCWH guidelines	Manager could produce MCWH guidelines for all	0.937 (0.881 – 0.996)	0.829 (0.788 – 0.872)	0.983 (0.93 – 1.04)
	Manager could not produce MCWH guidelines for all			
Availability of written procedures to communicate with the NHLS	Communication procedures with NHLS available	0.925 (0.809 – 1.058)	0.876 (0.728 – 1.053)	1.020 (0.965 – 1.077)
	Communication procedures with NHLS not available for all			
Manager able to produce the NHLS procedures	Manager could produce NHLS procedures for all	0.896 (0.703 – 1.142)	1.179 (0.756 – 1.838)	0.964 (0.898 – 1.035)
	Manager could not produce NHLS procedures for all			

TABLE 9

Bivariate Analysis of association of socio-demographic, staffing and facility factors with antenatal Syphilis, Hb and HIV *POCT Tests done* with the Prevalence Ratio and 95% Confidence Intervals shown

Variable Name	Variable Value	Syphilis POCT Prevalence Ratio and 95% CI	Hb POCT Prevalence Ratio and 95% CI	HIV POCT Prevalence Ratio and 95% CI
Gestational Age:	Gestational age ≤16 weeks	0.698 (0.458 – 1.07)	0.945 (0.859 – 1.04)	0.992 (0.976 – 1.008)
	Gestational age >16 weeks			
Place of Residence:	Resident in suburb	1.369 (0.903 – 2.083)	1.05 (0.917 – 1.203)	1.007 (0.997 – 1.017)
	Resident not in suburb			
Patients' Age:	Age ≤20 years	0.869 (0.536 – 1.411)	0.969 (0.864 – 1.086)	0.99 (0.962 – 1.018)
	Age >20 years			
Type of health facility:	Local municipality facilities	0.011 (0.002 – 0.079)	0.902 (0.826 – 0.984)	0.989 (0.974 – 1.004)
	Provincial government facilities			
The following variables apply to questions posed to Staff tasked with performing the POCT:				
QA performed before testing POCT samples	QA performed for all	16.421 (2.308 – 113.76)	1.310 (1.084 – 1.585)	1.039 (0.985 – 1.096)
	QA not performed for all			
Fridge temperatures checked and recorded	Fridge temps checked and recorded for all	23.714 (9.029 – 45.271)	1.150 (1.002 – 1.311)	1.026 (0.99 – 1.06)
	Fridge temps not checked and recorded for all			
Control reagents provided in test kits used	Control reagents used for all	32.045 (8.02 – 128.011)	1.122 (1.021 – 1.233)	1.001 (0.985 – 1.01)
	Control reagents not used for all			
Staff trained to perform POCT	Staff trained	1.330 (0.228 – 7.756)	1.021 (0.752 – 1.385)	0.994 (0.985 – 1.002)
	Staff not trained			

Quickness of performing POC testing	Always quick to perform POCT on all	1.038 (0.963 – 1.123)	N/A	N/A
	Not always quick to perform POCT on all			
Frequency of performing POCT by staff	Always perform POCT on all	N/A	1.198 (0.955 – 1.504)	0.994 (0.985 – 1.002)
	Do not always perform POCT on all			
Ability of staff to interpret POCT results	Always able to interpret results on all	81.333 (26.41 – 250.246)	1.410 (0.998 – 1.993)	0.993 (0.983 – 1.003)
	Not always able to interpret results on all			
Availability of POCT kits in the facilities	Test kits always available for all	81.333 (26.41 – 250.426)	1.006 (0.918 – 1.102)	0.994 (0.985 – 1.002)
	Test kits not always available for all			
Trust of POCT results by staff	Always trust POCT results for all	0.058 (0.008 – 0.406)	0.693 (0.569 – 0.845)	0.986 (0.953 – 1.021)
	Do not always trust POCT results for all			
Availability of sufficient staff to perform POCT	Sufficient staff always available to perform POCT for all	67.260 (16.848 - 268. 546)	1.090 (1.004 - 1.183)	1.009 (0.996 - 1.022)
	Sufficient staff not always available to perform POCT for all			
Time to perform POCT at every ANC first visit	Always sufficient time to perform POCT for all	N/A	1.309 (1.178 – 1.454)	1.003 (0.985 – 1.02)
	Not always sufficient time to perform POCT for all			

The following variables apply to questions posed to Facility Managers:

Variable Name	Variable Value	Syphilis POCT Prevalence Ratio and 95% CI	Hb POCT Prevalence Ratio and 95% CI	HIV POCT Prevalence Ratio and 95% CI
Availability of MCWH guidelines in the clinic	Clinic in possession of MCWH guidelines for all	N/A	7.159 (1.144 – 44.80)	0.994 (0.986 – 1.002)
	Clinic not in possession of MCWH guidelines for all			
Ability of manager to produce the guidelines	Manager could produce guidelines for all	0.333 (0.242 – 0.457)	0.935 (0.858 – 1.018)	1.024 (0.971 – 1.079)
	Manager could not produce guidelines for all			
Consistent availability of POC test kits in the facility	Test kits consistently available for all	81.333 (26.41 – 250.426)	2.111 (1.510 – 2.951)	N/A
	Test kits not consistently available for all			
Consistent availability of fully functional POC equipment	Equipment consistently available and functional for all	81.333 (26.41 – 250.426)	3.023 (1.892 – 4.831)	0.994 (0.986 – 1.002)
	Equipment not consistently available and functional for all			
Availability of SOPs for procurement and maintenance of POCT equipment and material	SOPs for procurement and maintenance of POCT equipment available for all	0.100 (0.015 – 0.699)	1.032 (0.909 – 1.173)	1.007 (0.997 – 1.016)
	SOPs for procurement and maintenance of POCT equipment not available for all			
Availability of sufficient staff trained to routinely perform POCT at every first ANC visit	Sufficient staff trained to perform POCT available for all	N/A	1.105 (0.931 – 1.312)	0.993 (0.983 – 1.003)
	Sufficient staff trained to perform POCT not available for all			
Availability of written procedures to communicate with the NHLS	Communication procedures with NHLS available for all	0.100 (0.015 – 0.699)	1.032 (0.909 – 1.173)	1.007 (0.997 – 1.106)
	Communication procedures with NHLS not available for all			
Ability of manager to produce the NHLS procedures	Manager could produce NHLS procedures for all	N/A	0.864 (0.731 – 1.02)	1.000
	Manager could not produce NHLS procedures for all			

4.9 Multivariate analysis

The multivariate logistic regression analyses of the association of several staffing and facility factors with the outcomes of: “antenatal Hb screening”, “antenatal Hb POC testing” and “antenatal Syphilis POC testing” were conducted, and are shown in Table 10. Only these outcome variables were selected as on bivariate analysis only these three outcomes yielded statistically significant associations with more than one independent predictor variable. Moreover, in order to arrive at the adjusted prevalence ratios the independent variables which showed statistically significant association on bivariate analysis with the above 3 outcomes were included in the multivariate logistic regression analysis, using a backward stepwise regression model. The final outcome of the multivariate logistic regression analysis is shown in Table 10 below. Table 11 lists the variables initially included in the multivariate logistic regression model but which were then excluded from the analysis due to a high degree of collinearity and/or due to a lack of statistical significance.

Table 10: Multivariate Analysis of the association of staffing and facility factors with Antenatal Hb screening, Hb POCT and Syphilis POCT

Description of Independent variables.		Hb Screening Adjusted Prevalence Odds Ratios (95% CI)	Hb POCT Adjusted Prevalence Odds Ratios (95% CI)	Syphilis POCT Adjusted Prevalence Odds Ratios (95% CI)
Type of health facility	Local municipality facilities	0.341 (0.182 – 0.638)	0.127 (0.064 – 0.252)	0.688 (0.595 – 0.797)
	Provincial authority facilities			
Managers' ability to produce the MCWH guidelines	Could produce the guidelines	0.744 (0.344 – 1.605)		
	Could not produce the guidelines			
Performance of quality assurance before testing POCT samples	Performed QA		2.444 (1.1.9 – 5.385)	
	Did not perform QA			
Perceived availability of sufficient staff to perform POCT	Thought sufficient staff available			15.416 (2.050 – 116.515)
	Thought insufficient staff available			
Staff feel they have sufficient time to perform POCT at every ANC first visit	Feel that they have sufficient time		1.949 (1.137 – 3.340)	
	Feel that they do not have sufficient time			
Consistent availability of POC test kits in the facility	Test kits always available			37.976 (5.094 – 283.091)
	Test kits not always available			

TABLE 11: List of variables initially included in the multivariate logistic regression that were subsequently dropped due to collinearity and/or lack of statistical significance

Hb POCT:	**Syphilis POCT:**
Staff responses	Staff responses
	QA performed before testing POCT samples
Fridge temperatures checked and recorded	Fridge temperatures checked and recorded
Control reagents provided in test kits used	Control reagents provided in test kits used
Ability of staff to interpret POCT results	Ability of staff to interpret POCT results
	Trust of POCT results by staff
Availability of sufficient staff to perform POCT	
Facility managers' responses	Facility managers' responses
Availability of MCWH guidelines in the facility	
Consistent availability of fully functional POCT equipment	Consistent availability of fully functional POCT equipment
	Availability of SOPs for procurement and maintenance of POCT equipment and material
Consistent availability of POC test kits in the facility	
	Availability of written procedures to communicate with the NHLS
Ability of manager to produce written procedures to communicate with the NHLS	

CHAPTER 5

Discussion

5.1 HIV screening and HIV POCT

The findings which reveal that 96% of the pregnant women were screened for HIV during their first ANC visit are by far the best performance by the Sedibeng facilities (as compared to syphilis and Hb screening). This statistic could actually be higher as women who had previously tested positive for HIV, would not be re-tested when they present to the facilities for their first ANC visit. Interestingly, the Sedibeng District findings concur with (and exceed) findings from a systematic review of eight studies. Two of the studies in the review were conducted in Scotland and were published in 1998 and 2001 respectively, one was conducted in Kenya and was published in 2005, one was conducted in Botswana and published in 2007, with the other one conducted in Zimbabwe and published in 2007. A more recent study evaluated in the systematic review was conducted in Uganda and was published in 2010. The objective of the systematic review was to assess the contribution of provider-initiated HIV testing and counselling toward achieving universal HIV testing of pregnant women. The interventions included the introduction of provider-initiated HIV testing, the ultimate aim being the achievement of universal testing of pregnant women in the aforementioned countries. The review revealed that HIV testing uptake increased to greater or equal to 85% after the intervention (Hensen *et. al,* 2012). The finding that significantly higher numbers of pregnant women were tested for HIV in the Sedibeng district study, is a marked improvement on an earlier (2008) United Nation report which states that only about 26% of the 125 million pregnant women in lower and middle income countries learn their HIV status prior to child birth (United Nations, 2009). As mentioned above, the South African Annual Performance Plan revealed that the PMTCT of HIV coverage to pregnant women had rapidly expanded since 2007/8, however just before then in the years prior to 2006 the coverage was below 50% reflecting the South African health department's reluctance to implement PMTCT, ostensibly due to the South African president's questioning of whether HIV caused AIDS (SA NDOH, 2011; Barron *et al,* 2013). Furthermore, although this current study revealed that 4.2% of the pregnant women were not screened for HIV during their first ANC visit, it was interesting to discover on closer examination, and after inquiring from the ANC clinicians tasked with performing POCT, that the reason for the absence of some of the HIV screening records may possibly be because some of these patients were known to be HIV positive and hence there was no need for an additional HIV

screening test, when they were attending the ANC clinics for their first visit. However, it was difficult to quantify what proportion of the 4.2% (unscreened) pregnant women were known to be HIV positive, due to incomplete record keeping.

This study revealed that 100% of the pregnant women's HIV samples were done as POC tests by the Sedibeng clinicians. Much like the findings pertaining to HIV screening, these results are by far the best of the three POC tests. There are three possible reasons for HIV POC testing's massive success: (a) conducting HIV screening as POCT is the most recent policy of the SA NDOH (of the three), (b) as mentioned above, the programme has largely been the most supported by the South African government during the past five to six years, and (c) HIV screening was from the start conducted using POCT, with laboratory tests only being used for confirmation of the POCT results. The level of HIV POC testing on the pregnant women in this study is much higher than that revealed by a (2011) Ugandan study of 300 pregnant women who had attended ANC facilities which found that 76% of the women received on-site HIV testing with the screening being done by the ANC HCWs ((Kwapong, Boateng, Agyei-Baffour, and Addy, 2014). However, there is a difference in the manner in which the sample was collected in the Ugandan study, as the researchers targeted pregnant women who had attended ANC two or more times, and had received HIV testing and counselling (HTC) during one of the visits. Butsashvili *et al* (2014) report that in Georgia the coverage of HIV testing among pregnant women was estimated to be 87% in 2010, a finding which is almost consistent with the SA PMTCT estimate (which was 92.7%) for HIV screening for the equivalent period.

The findings which reveal that the vast majority of pregnant women were successfully screened for HIV during their first visit to Sedibeng district facilities should be applauded; as it indicates that non-laboratory trained personnel are able to conduct POCT successfully, if all the appropriate support mechanisms are put in place. These include the adequate and sustained training of HCWs in POCT utilisation, improved and simplified POC technologies that can be easily used by non-laboratory trained HCWs, and ensuring the consistent availability of POC kits and equipment in all health care facilities. The abovementioned enabling mechanisms were reportedly, massively availed to all the Sedibeng facilities when the PMTCT of HIV to pregnant women was strengthened. In addition, the current HIV POCT technology used in the district is considered to be relatively simple to use (by non-laboratory trained HCWs). Another important consideration alluded to above in the success of HIV

POCT, is that HIV screening was from the start done as point-of-care testing by the Sedibeng facilities, hence sending samples to the laboratory is not a norm in the HIV programme. Given that the screening for HIV has only been done using POCT in Sedibeng, staff have accepted it as a usual care component of clinical functioning. This is because the testing is considered to be easy and quick to do, the results are easy to interpret, and most importantly, the HCWs accept and trust the validity of the HIV POCT.

Finally, the success of the HIV screening programme is probably in large part due to the overwhelming global response to the HIV epidemic, which meant that lower to middle income countries received significant political, social and financial support to curb the spread of the disease. With regards to Sedibeng health care centres, this support included funding, logistical supply support, training, mentoring and provision of clinical protocols by global organisations such as the United States President's Emergency Plan For Aids Relief (PEPFAR) and the WHO (Steven, Gous, Ford and Scott, 2014). Moreover, the practical aspects of HIV POCT form part of the nursing curriculum in South Africa, as second and third year nursing students are required to observe, train and conduct some HIV POC testing in primary health care centres during their in-service training (NDOH R425 Nursing Curriculum, 2010).

5.2 Syphilis screening and Syphilis POCT

Syphilis screening, which the study found to be at 91%, had an intermediate prevalence between the 3 ANC screening tests in the Sedibeng health facilities. It is worth highlighting however that although the 91% syphilis screening prevalence found in the Sedibeng District study, is somewhat higher than the more than 90% coverage - 2015 target set by the WHO, the finding that only 27% of these pregnant women received their syphilis screening test results during their first ANC visit, is worrisome. This low percentage receiving their test results at the first visit is possibly, a direct consequence of 73% of these samples being sent to an offsite NHLS laboratory for processing. In addition, the latter finding implies that the pregnant women who tested positive for syphilis did not receive the required treatment during the same day of testing, as it takes a minimum of three days to receive the syphilis test result from the NHLS laboratory. The usual practice after receiving a positive result for syphilis screening from a NHLS laboratory is that the clinic will trace the mother for the purpose of administering the required treatment. The latter situation is highly undesirable as it deviates even further from the previously mentioned (in the literature review) NDOH policy and

WHO guidelines of treating syphilis positive pregnant women immediately, and runs the risk of several syphilis infected pregnant women not being treated, or being treated too late to prevent sequalae in the foetus (Guidelines for Maternity Care, 2007; Peeling *et al.*, 2013; Mabey *et al.*, 2012).

The finding that 73% of syphilis screening was inappropriately conducted at off-site NHLS laboratories is nonetheless not surprising, as this study also revealed that both the staff performing POCT (90%) and their facility managers (more than 85%) reported that some facilities never stocked the syphilis screening POC test kits**.** Interestingly, 100% (3) of the staff who conduct syphilis screening on-site indicated that the POC testing was easy to perform. However, it was difficult to corroborate this assertion of ease of testing as these three clinicians who had actual experience of conducting syphilis POCT screening, represent only 10% of the staff designated to conduct the screening. Moreover, the unavailability of the syphilis screening POCT test kits and equipment in many facilities does not seem to be linked to a lack of knowledge about relevant ANC guidelines, as 97% of the staff performing POCT indicated that they knew that first time pregnant mothers need to receive syphilis screening during the first ANC visit. This suggests that the foremost reason the facilities send syphilis screening samples to off-site NHLS laboratories for processing, could indeed be that test kits were not available for them to screen the pregnant mothers via POCT. A key question that was not asked in this study is the reason why these syphilis POC tests were not available in the Sedibeng ANC facilities. Moreover, Pai *et al.* (2012) has, as previously stated (in the literature review), expressed discomfort at South African experts in the NHLS not being able to provide oversight to any POC testing in the country. One envisages that the oversight by the NHLS would include using the organisation's expertise to advise PHC facilities on how to manage the quality assurance aspects of POCT, and on the crucial issue of procuring the most appropriate syphilis technology to use by non-laboratory trained clinicians. However, it is important to note that the availability of test kits in the facilities does not guarantee that the required levels of onsite screening of pregnant women during their first ANC visit will occur, although it does increase the chances of it happening.

Furthermore, it is difficult to link the important finding that 80% of the staff indicated that there was sufficient personnel to perform POCT, when the vast majority of the facilities did not conduct the syphilis POCT (and syphilis POCT as noted in the literature review is the

most time-consuming POCT) screening of pregnant mothers. There was indeed some level of agreement between the staff and the facility managers with regards to the latter finding, as 73% of the managers reported that there was sufficient staff trained to perform POCT in their facilities. Since the (few) staff members that successfully conducted syphilis POCT reported that they found it easy to do, it implies that if test kits were availed in the rest of the facilities, their colleagues would probably have a similar experience. Despite the assertions by the staff and their managers that there is sufficient staff to perform syphilis POCT routinely, there is a level of unease by the student with the glaring reluctance to procure these test kits by the majority of the facilities, that this could be related to the apparent cumbersomeness of the RPR POCT, and the level of expertise required to conduct and interpret the test. These include: centrifugation of the blood sample, requirement of test reagents to conduct the test, correctly operating the sample rotator, expertly reading the result of the test, conducting titres of the serum samples if the tests are positive, the expectation of the HCWs to correctly interpret the titre, reading of the test results which one needs to base treatment on; most of which is not required for conducting Hb and HIV POCT. Several authors have previously (in the literature review), listed similar factors to those mentioned above as significant hindrances to the successful utilisation of RPR POCT by non-laboratory trained staff (WHO 2012; Peeling 2006; Singh and Peeling 2012; Peeling *et al* 2013). When one adds to these problems the appropriate discomfort by one clinic (from the three that actually conduct RPR POCT), to accept and act on a positive RPR test, without a laboratory confirmed result, it might be best to seek a more appropriate and user-friendly syphilis POC technology, which requires less expertise from the non-laboratory trained personnel and which has higher validity. This would hopefully, lead to a drastic improvement in the uptake of syphilis POCT by the ANC facilities.

One of the justifications for this poor syphilis POCT uptake may be due to the fact that conducting on-site syphilis screening is a relatively new POCT policy as for decades syphilis testing has been conducted exclusively in laboratories. As a result, the staff members are used to routinely sending syphilis test samples to the laboratory. Accordingly, this new policy requires a change in a long standing practice.

Ultimately, all the issues surrounding the inadequate screening for syphilis of pregnant women during their first ANC visit to Sedibeng facilities should be carefully examined by the relevant authorities**.** These include: the involvement of role-player with the relevant expertise

such as the Provincial Laboratory and Blood Services unit in strengthening POCT utilisation in the district by: advising PHC management with regards to the adoption of the most appropriate and evidence-based syphilis POC technology that is suitable for utilisation by non-laboratory trained clinicians, (especially those who work in resource-limited settings); by ensuring that the applicable SOPs are written and adhered to; by overseeing the training of the non-laboratory trained HCWs in POCT utilisation, and that the training is sustained; and by ensuring that quality assurance aspects of POCT are known and adhered to by these HCWs. Furthermore, effective and efficient management of the latter processes by the Sedibeng district's senior management is vital**.** This includes effective leadership by facility managers to ensure that: the screening of pregnant women for syphilis during their ANC visit is adhered to and is not compromised and, overseeing the efficiency of procurement processes for syphilis POCT and other relevant first ANC visit screening equipment. The importance of adopting appropriate interventions which are known to have a positive impact on the uptake of syphilis POCT by non-laboratory trained clinicians has been extensively discussed and addressed in the literature review (Watson-Jones et al, 2005; Peeling, 2006; Mabey, et al, 2012; Pai et al, 2012; Singh and Peeling, 2012; Theel, 2012; WHO, 2012; Peeling et al, 2013; Smit *et al*, 2013). However, with regards to adopting improved technologies that are geared to address the shortcomings of the RPR POC test (which hopefully also address the contentious issue of the low validity of the test), and those more appropriate to be utilised by non-laboratory trained HCWs, there are promising signs that the WHO the has started to endorse more user-friendly technologies (WHO, 2012; Smit *et al*, 2013). Most significantly, there are indications that these technologies will, in the near future be made available to the Sedibeng's PHC facilities.

5.3 Hb screening and Hb POCT

Screening for Hb is the lowest prevalence of the 3 ANC screening tests conducted by the Sedibeng ANC facilities, with 84.4% of the pregnant women being screened for anaemia during the first ANC visit. This finding is somewhat disappointing as the implication is that a considerable number of pregnant women were not screened for anaemia during their first ANC visit. The following four considerations are important when discussing Hb screening uptake in the district: firstly, testing for haemoglobin via both the laboratory and as POCT has been conducted for a while, and is a long established component of antenatal care both in South Africa and globally. Consequently, better levels of screening of the pregnant women for anaemia were expected. However, the finding is not surprising, as only 63% of the staff

tasked with performing the screening reported that the Hb test kits were always available in the facilities. This is hugely different from the findings which revealed that 93% of facility managers stated that the test kits were always available. Secondly (and perhaps most importantly), the reasons for the HCWs not screening the pregnant women cannot be simply attributed to the absence of POCT kits in the facilities, as the HCWs had an option of sending the samples to be processed at the off-site NHLS laboratories. Whilst it is not clear why the HCWs did not perform the screening, and considering the adverse impact of not screening the pregnant women for anaemia on both mother and baby, the HCWs' conduct is concerning. Thirdly, a pertinent question not investigated by this study is the reasons why the Hb POC test kits were not available in the facilities. Fourthly, the screening for anaemia using a POC test is ostensibly a simple process of performing a finger prick on the patient and inserting the drop of blood into a hand-held Hb POC instrument (much like that for HIV screening), therefore, it is difficult to attribute the apparent lack of screening of 16% of the pregnant women to any cumbersomeness in the procedure (in contrast to the syphilis screening scenario). One is however limited in the boldness with which one can comment about how unacceptable the level of Hb screening is in Sedibeng district, as it was impossible to confirm that the gaps that appeared in the patient registers (and were recorded in this study as screening not done), reflected the reality that HCWs did not conduct the screening for anaemia on the women; (i.e. it couldn't be reliably determined that the gaps that appeared in the patients' registers were a result of screening not being conducted, or whether these were a consequence of poor record keeping by the HCWs).

Furthermore, somewhat disturbing findings emerged when the HCWs were asked about reasons they would send the samples to the NHLS for confirmatory testing after conducting POCT, as only 27% of them provided 'correct reasons'. The MCWH (2007) guidelines state that all women with mild anaemia (7 to 10.9g/dl) should be investigated for an FBC and a smear to determine the probable cause of the anaemia; those with an Hb of less than 7g/dl should be referred to a hospital, and in addition, have their bloods drawn for an FBC and smear. It was concerning to note that less than a third of the ANC HCWs sampled correctly followed these guidelines.

Notably, the possibility that more than 10% of the pregnant women were not screened for anaemia during their first ANC visit, coupled with the apparent lack of knowledge by some

of the ANC staff about what course of action to follow after mild to severe anaemia was detected in the women, necessitates decisive interventions by the District's MCWH unit.

5.4 Factors affecting the prevalence of screening, and the uptake of POCT by the HCWs

The findings of this study indicated that various factors affect the screening of pregnant women for syphilis, Hb and HIV; and the uptake of POCT for the three screening tests by the HCWs at the Sedibeng ANC facilities. The outcome of the bivariate analysis indicated that only the "antenatal Hb screening", "antenatal Hb POC testing" and "antenatal Syphilis POC testing" yielded statistically significant associations with more than one independent predictor variable. Moreover, the independent effect (measured via adjusted prevalence odds ratios) of the predictor variables which showed a statistically significant associations on bivariate analysis with the above three outcomes, were assessed using multivariate logistic regression analysis. The details of noteworthy findings for the above-mentioned factors are summarised below:

5.4.1 Factors affecting Hb screening

The finding that Local Municipality facilities were less likely to perform Hb screening was corroborated by the outcome of the multivariate logistic regression analysis which indicated a statistically significant negative association. Clearly, the fact that the facility is a Local Municipality one per se` does not result in a low prevalence of Hb screening, hence there must be an underlying reason/s why Local Municipality fare worse than their Provincial government counterparts with regards to this screening test. The reasons behind this inadequate screening of the pregnant women for Hb by the Local Municipality facilities needs to be investigated by the District's management, and perhaps lessons could also be learnt from the demonstrable success of the Provincial government facilities' screening programme.

Interestingly, the previously stated finding that less than a third of the HCWs knew which steps to follow after detecting low to mild anaemia on Hb POCT, could be a result of the HCWs not reading the MCWH guidelines due to the document's unavailability in some of the facilities, but this possibility was not further pursued. However, the ability of the managers to produce the MCWH guidelines yielded statistically significant negative association, indicating the negative impact of the unavailability of the guidelines on the screening of the pregnant women.

5.4.2 Factors affecting syphilis and HIV screening

No statistically significant associations were found with regards to the factors potentially affecting the screening of the pregnant women for syphilis and HIV, which we measured in this study. This is probably due to the study only being able to measure a few potentially causative factors.

5.4.3 Factors affecting syphilis POCT

The findings of this study revealed that pregnant women attending the Local Municipality facilities for their first ANC visit were highly unlikely to receive their syphilis screening results on the same day, as a mere 0.6% of their samples were done on-site. This practice is in considerable contrast to that demonstrated by Provincial government facilities, which showed a 53.4% uptake of syphilis POCT. As with the Hb screening this is an indication of an as yet unknown underlying factor affecting Local Municipality facilities, which negates the performance of syphilis POCT.

Remarkably, the above results (with regards to the performance of the Local Municipality facilities) were corroborated by the outcome of the multivariate logistic regression analysis, which indicated a statistically significant negative association for the type of health facility. In addition, the multivariate logistic regression showed significant statistically significant and strong positive associations for the perceived availability of sufficient staff to perform POCT and for consistent availability of syphilis POC test kits in facilities, an outcome which to a large extent, was to be expected.

5.4.4 Factors affecting Hb POCT

The findings pertaining to the conducting of Hb POCT by the Local Municipality and Provincial government facilities seemed to follow a similar trend to that of syphilis POCT, as the multivariate logistic regression yielded a statistically significant negative association for the 'type of heath facility' variable. Thus yet again, the Local Municipality seems to be the ones that somewhat battle with the management of both POC and laboratory investigations for the pregnant women during their first ANC visit. Additionally, performance of quality assurance before testing POC samples, and staff feeling that they had sufficient time to perform POCT at every ANC first visit indicated statistically significant positive associations with multivariate logistic regression analysis. The outcome of the two latter variables is

somewhat to be expected, and it indicates that the facilities were more likely to perform the Hb POCT if these variables were positively addressed.

5.4.5 Factors affecting HIV POCT

Similar to the factors affecting the screening of the pregnant women for HIV, no statistically significant associations were found with regards to the factors affecting the conducting of HIV POCT by the Sedibeng HCWs due to a large degree of collinearity between the variables.

5.5 Study limitations

Collecting data from patients' registers limits the breadth of useful information to that which the health facilities routinely collect, hence only a few potential causal factors can be amassed via the registers. This was evident in this study, as the student was unable to collect data relating to some of the requisite demographic factors. These were the employment, education and marital status of the patients, which meant that the possible impact of these variables on POCT utilisation could not be measured.

In addition, the student would have liked to assess whether POCT training manuals were available in the ANC facilities, and whether the training of the staff was sustained, mentored and monitored by both senior management in the facilities, and the suppliers of POCT equipment. Furthermore, it would have been worthwhile to assess the impact of the following on POCT utilisation: the lack of access to electronic results, especially considering the remoteness of the Sedibeng facilities from conventional laboratories; the extent of the involvement of the Provincial Laboratory and Blood Services' unit (which employs qualified laboratory professionals at managerial level) in overseeing POCT training, POCT materials' procurement processes, and in overseeing quality assurance aspects of POCT utilisation in facilities. Another key factor that would have assisted in shedding more light on the reasons behind the sometimes less than expected screening of the pregnant women, and the at times poor POCT uptake, would have been to determine why the POC test equipment and test kits were not adequately stocked by the facilities.

A key limitation when assessing factors associated with POCT utilisation is that despite collecting staff data, the student was not be able to assess individual staff factors affecting POC testing, as it was impossible to link individual patients to individual staff members. The student therefore, only managed to assess staff factors at facility level with POCT implementation.

In this study, there was a slight mismatch between the screening of patients and the interviewing of staff, as the interviews were conducted several months after the screening of the patients was done, as records of patients seen previously were used. However, one would not expect staff dynamics or facility circumstances to have changed within this period.

Crucially, the pregnant women's first ANC visit registers are not designed to separately reflect the results of POC testing or those forwarded by the NHLS laboratories to the ANC facilities. Only one column is designated for this purpose. Consequently, the student could not determine which results reflected duplications in testing (samples done both as POCT and sent to the laboratory). Moreover, the results column did not allow HCWs to indicate whether the results were either from a POCT instrument or from the laboratory. In addition, the documentary evidence of the results (slips produced by POCT instruments or the printed results forwarded by NHLS laboratories) seemed to be either destroyed or in the case of the NHLS printouts, poorly kept. The student was forced to rely on the ANC staff's assertions about whether the results were from a POCT instrument or from the laboratory, based on their knowledge about the availability of POC test kits and equipment in their facilities.

With regards to the absence of some patient data, it was impossible to determine for sure if the patients were screened or not, or if these were merely cases of poor record keeping by facilities. Therefore, it was difficult to affirm with absolute certainty that the 8.9% and 15.6% of pregnant women (for syphilis and anaemia screening respectively), whom this study shows not to have been screened, were indeed not screened. This was likewise, true for HIV screening, as the student was told that those patients that had previously tested positive for HIV would not be re-screened when they came for their first ANC visit (only confirmatory testing for CD4 count and other relevant testing would be done).The fact that some of the patients had been previously screened and had tested positive was not evident from some of the ANC records though, as the student noted that some of the screening results slots were merely left blank (instead of being marked as known HIV positive), giving an impression that these patients had in fact not been screened.

Another limitation of this study is that although it would have been worthwhile to examine whether on-site POCT is cheaper than sending the tests to the off-site NHLS laboratories, and especially taking into account the broad disagreement displayed in the literature on this issue. However, investigating the cost-effectiveness of on-site POCT was beyond the scope of this study.

CHAPTER 6

6.1 Conclusion

The study found that despite the high rate of screening of pregnant women for syphilis during the first ANC visit, less than a third of the women received their syphilis screening results during this visit, although these findings were not corroborated by statistically significant associations due to a high degree of collinearity between the variables studied. The findings that were supported by statistically significant associations with regards to performing syphilis POCT include: that less than a third of the pregnant women received their screening results during the visit, the availability POC test kits in the facilities, and the availability of sufficient staff to conduct the POCT. With regards to Hb POCT, the finding that a large percentage of the screening was successfully conducted on-site was corroborated by statistically significant associations. However, this study indicated that despite the finding that a huge majority of the pregnant women were screened for HIV, and all of the testing was conducted on-site, these were not backed by statistically significant associations due to the large degree of collinearity between the variables examined. On the whole, the study revealed that the Local Authority facilities seem to bear the brunt of inadequate screening of the pregnant women for Hb. In addition, the study found inadequate on-site testing of the women for both Hb and syphilis by the latter facilities. Furthermore, this study found an apparent lack of knowledge by some of the ANC staff about what course of action to follow after detecting anaemia when screening the pregnant women using Hb POCT. A key observation in this study is the apparent poor recording of POCT results by some facilities. In addition, the filling of NHLS results was found to be in complete disarray in many facilities.

6.2 Recommendations

- A solution to the non-availability of syphilis POC test kits in many of the facilities should be sought and prioritised. This will hopefully start with the District management considering procuring one of the new user-friendly and higher validity syphilis POC test that are currently being examined by the health department.
- The underlying reasons behind the noticeable inadequate performance by Local Municipality facilities with regards to the screening of the pregnant women for anaemia, together with the inadequate screening of the women using Hb and syphilis POCT (which inevitable leads to the sending of these patients' samples to off-site NHLS laboratories by these facilities), needs to be uncovered by the District management.
- Some ANC HCWs seem to require intensive education about how to deal with low Hb POCT results and by implication when to request laboratory investigations.
- The unavailability of SOPs for the procurement and maintenance of POCT equipment and material in all facilities needs to be addressed by the GDOH's Laboratory and Blood Services unit.
- The Provincial POCT list should be made available to all facilities, and the relevant managers should ensure that the HCWs are familiar with its contents.
- The District's Laboratory and Blood Services coordinator should ensure that the NHLS supplies written procedures to communicate with the organisation to all facilities.
- A solution needs to be found to address the apparent practice of poor record keeping of the POCT results by some facilities.
- In addition, a more efficient system of filling of NHLS results is required by all facilities.

REFERENCES:

Adam, I., Ahmed, S., Mahmoud, M. and Tassin, M. (2012).Comparison of HemoCuehemoglobin-meter and automated hematologyanalyzer in measurement of hemoglobin levels in pregnant women at Khartoum hospital, Sudan, *Diagnostic Pathology*, 7(30).

Ako-Arrey, D., Johri, M., Jafari, Y. and Pai, N. (***Undated***).*Economic Evaluation of Point of Care Testing*. Canadian Institute of Health Research.[Online], Available:www.nitikapantpai.com/documents/workshop/10.pdf. [Downloaded: 11/22/12 08: 20 AM].

Alemnji, G., Nkengasong, J. N., and Parekh, B. S. (2011). HIV testing in developing countries: What is required? *Indian J Med Res,* 134(6): 779–786.

Anque, Y., Yauieb, A., Mola, G., Duke, T. and Amoa, A.B. (2005). Syphilis serology testing: a comparative study of Abbot Determine, Rapid Plasma Reagin (RPR) card test and Venereal Disease Research Laboratory (VDRL) methods. *P N G Med J.;* 48(3-4):168-73.

Arora, D. R., Maheshwari, M. and Arora, B. (2013). *Rapid Point-of-Care Testing for Detection of HIV and Clinical Monitoring*.[Online],Available:http://dx.doi.org/10.1155/2013/287269.[Downloaded: 12/11/131: 00 PM].

Barron. P., Pillay, Y., Doherty, T., Sherman, G., Jackson, D., Bhardwaj, S., Robinson, P., and Goga, A. (2013). Eliminating mother-to-child HIV transmission in South Africa. *Bulletin of the World Health Organization*; 91:70-74.

Bassett, V. I. and Walensky, R. P. (2013).*Integrating HIV Screening into Routine Health Care in Resource-Limited Settings.*[Online], Available: http. [Downloaded: 10/06/149: 00 AM]

Benzakenn, A. S., Sabido´, M., Galban, E., Pedroza, V., Arau´ jo, A. J. G., Peeling, R.W. and Mabey, D. (2011). Field performance of a rapid point-of-care diagnostic test for antenatal syphilis screening in the Amazon region, Brazil. *International Journal of STD & AIDS*, 22: 15–18.

Beaglehole, R., Bonita, R. and Kjellstrom T. (1993). *Basic Epidemiology*. WHO, Geneva.

Blattner, K., Nixon, G., Dovey, S., Jaye, C., and Wigglesworth, J. (2010). Changes in clinical practice and patient disposition following the introduction of point-of-care testing in a rural hospital. *Health Policy,* 96: 7–12.

Briggs, C., Guthrie, D., Hyde, K., Mackie, I., Parker, N., Popek, M., Porter, N. and Stephens, C. (2008).Guidelines for point-of-care testing: haematology. *British Journal of Haematology,* 142, 904–915.

Briggs, C., Kimber, S., and Green, L. (2012).Where are we at with point- of- care testing in haematology? *British Journal of Haematology,* 158, 679–690.

Bronzan, R.N., Mwesigwa-Kayondo, D.C., Narkunas, D., Schmid, G.P. and Neilsen, G.A. (2007). Onsite rapid antenatal syphilis screening with an immunochromatographic strip improves case detection and treatment in rural South African clinics. *Sex Transmitted Diseases*, 34: S55-S60.

Butsashvili, M., Kajaia, M., Kamkamidze, G., Tchendjou, P., Desgrees du Loû, A., Dabis, F. and Orne-Gliemann. J.(2014). Factors Associated with HIV Testing History among Pregnant Women and Their Partners in Georgia: The ANRS 12127 Prenahtest Trial. *AIDS Research and Treatment.* Volume 2014, Article ID 356090.

Byrkit, R., Campbell, C., Dixon, D., Gamazina, K., Larivee, C., Makame, M., Osborne, K., Trangsrud, R., V, T. (2012*). Non-invasive Anaemia Screening: Technology Opportunity Assessment.* Program for Appropriate Technology in Health (PATH).[Online], Available:www.path.org. [Downloaded: 01/04/14 7:00 PM].

Carraro, P. and Plebani, M., (2009).Post-analytical errors with portable glucose meters in the hospital setting.*ClinicaChimicaActa*, 404: 65- 67.

Castro, A.R., Binks, D.D., Raymer, L.L., Kikkert, S. E., Jost, H.E., Park, M.M., Card, D.D. and Cox, D.L. (2012). Evaluation of a Digital Flocculation Reader for the Plasma Reagin Test for the Serological Diagnosis of Syphilis. *Sexually Transmitted Diseases,* (39)3: 223 – 225.

Chopra, M. and Coveney, J., (2012).*Health Systems Research II: Module Guide*. Cape Town: University of the Western Cape.

Christian, P., Shahid, F., Rizvi, A., Klemm, R.D.W., and Bhutta, Z.A. (2009). Treatment response to standard of care for severe anaemia in pregnant women and effect of multivitamins and enhanced anthelminthics. *The American Journal of Clinical Nutrition,* 89:853–61.

Dawson, B., and Trapp, R.G. (2004*). Basic & Clinical Statistics*. Lange Medical Books.

Dunning, T., MacGinley, R., and Ward, G. (2012). Is point of care testing for anaemia (Hb) and microalbumin feasible in people withtype2 diabetes attending diabetes outpatient clinics? *Renal Society of Australasia Journal, 8*(2), 76-81.

Durrheim, K. (2006). Ch – 3 Research design. In M. Terre Blanche, K. Durrheim and D. Painter (eds.) *Research In Practice: Applied Methods For The Social Sciences.* Cape Town: University of Cape Town Press: 35-59.

FitzGibbon, F., Huckle, D. and Meenan, B. (2010).Barriers affecting the adoption of point-of-care technologies used in chest pain diagnosis within the UK National Health Service. *Point of Care,* 9(2):70 -79.

Hensen, B., Baggaley, R., Wong, V. J., Grabbe, K. L., Shaffer, N., Lo, Y. J. and Hargreaves, J. (2012).Universal voluntary HIV testing in antenatal care settings: a review of the contribution of provider-initiated testing &counselling. *Tropical Medicine and International Health,* 17(1): 59-70.

Junker, R., Schlebusch, H. and. Luppa P. B. (2010). Point-of-Care Testing in Hospitals and Primary Care. *DtschArzteblInt,* 107(33): 561–7.

Kalaivani, K. *(2009).* Prevalence & consequences of anaemia in pregnancy. *Indian J Med Res* 130: 627-633. Kamb, M., Sarah Hawkes, S., Gomez, G., Say, L., Seuc, A. and Broutet, N. (2013). *PLoS Med*, (10) 2.

Kavsak, P. A., Zielinski, N., Li, D., McNamara, P.J. and Khosrow, A. (2007). Challenges of implementing Point-of-Care Testing (POCT) glucose meters in a paediatric acute care setting. *Clinica ChimicaActa*, 379: 14–28.

Kwapong, G.D., Boateng, D., Agyei-Baffour, P., and Addy, E.A. (2014). Health service barriers to HIV testing and counselling among pregnant women attending Antenatal Clinic; a cross-sectional study. *BMC Health Services Research.* 14:267.

Kumar, R.N. A., and Arrowsmith, J. E. (2006). Intraoperative and postoperative management: Point-of-care testing. *Surgery*, 24:10.

Larsen, S.A and Creighton, E.T. (1998). *Rapid Plasma Reagin (RPR) 18-mm Circle Card Test.* [Online], Available: www.cdc.gov/std/syphilis/manual-1998. [Downloaded: 28/12/14 7.00 PM].

Lee-Lewandrowsk, E. and Lewandrowsk, K. (2009). Perspectives on Cost and Outcomes for Point-of –Care Testing. *Clin Lab Med*, 29: 479–489.

Lincetto, O., Mothebesoane-Anoh,S., Gomez, P. & Munjanja, S. (2006). Ch – 2 Antenatal Care. In D. Lord, R. Wake, L. Elder, K. Grear, & A. Antayhua (eds.) *Opportunities for Africa's Newborns.* Cape Town: Mills Litho: 51 – 62.

Luppa, P.B., Muller, C., Schlichtiger, A. &Schlebusch, H. (2011).Point-of-care testing (POCT): Current techniques and future perspectives. *Trends in Analytical Chemistry*, 30:6.
Mabey, D.C., Sollis, K.A., Kelly, H.A., Benzaken, A.S., Bitarakwate, E., Changalucha, J., Chen, X., Yin, Y., Garcia, P. J., Strasser, S., Chintu, N., Pang¸ T., Terris-Prestholt, F.,

Sweeney, S., and Peeling, R.W. (2012). Point-of-Care Tests to Strengthen Health Systems and Save Newborn Lives: The Case of Syphilis. *PLoS Med*, 9(6).

Mabey, D., Peeling, R.W., Ballard, R., Benzaken, A.S. and Galbán, E. (2006). A Prospective, multi-centre clinic-based evaluation of four rapid diagnostic tests for syphilis. *Sex Trans Infect*, 82(5): S13-S16.

MacPherson, P., Chawla, A., Jones, K., Coffey, E., Spaine, V., Harrison, I., Jelliman, P., Phillips-Howard, P., Beynon, C., and Taegtmeyer, M. (2011). Feasibility and acceptability of point of care HIV testing in community outreach and GUM drop-in services in the North West of England: A programmatic evaluation. *BMC Public Health*, 11: 419.

Majoko, F., Munjanja, S., Nystrom, L., Mason, E and Lindmark, G. (2007). Randomised controlled trial of two antenatal care models in rural Zimbabwe. *BJOG*, 114:802–811.

McLean. E., Cogswell, M., Egli., I Wojdyla, D., and de Benoist, B. (2009) Worldwide Prevalence of Anemia. WHO Vitamin and Mineral Nutrition Information System, 1993-2005. *Pub Health Nutrition*, 12(4): 444-454.

Madhivanan, P., Niranjan Kumar, B., Shaheen, R., Jaykrishna, P., Ravi, K., Gowda, S., Srinivas, V., Arun, A. and Krupp, K. (2013). *Increasing Antenatal Care and HIV Testing among Rural Pregnant Women with Conditional Cash Transfers to Self-Help Groups: An Evaluation Study in Rural Mysore, India* .Journal of Sexually Transmitted Diseases.[Online], Available: http://dx.doi.org/10.1155/2013/971458.[Downloaded: 12/11/132:00 PM].

Montoya, P. J., Lukehart, S.A., Brentlinger, E.F., Blanco, A. J., Floriano, F., Sairosse, J., and Gloyd, S. (2006). Comparison of the diagnostic accuracy of a rapid immunochromatographic test and the rapid plasma reagin for antenatal screening in Mozambique. *Bulletin of the World Health Organisation.* 2006; 84(97 – 104).

National Department of Health. (2011).*Annual Performance Plan, 2011/12 – 2013/14.*

National Department of Health. (2010). *Diploma in Comprehensive Four Year Course, R425 Curriculum.*

National Department of Health, (2008). *Point Of Care Testing Policy Guidelines.*

National Department of Health (2007).*Guidelines for Maternity Care in South Africa.*

National Health Laboratory Services (2011). *State Pricing Catalogue.*

National Health Laboratory Services (2012). *Customer Detailed Schedule.*

Newman, L., Kamb, M., Hawkes, S., Gomez, G., Say, L.,Seuc, M., Broutet, N. (2013). Global Estimates of Syphilis in Pregnancy and Associated Adverse Outcomes: Analysis of Multinational Antenatal Surveillance Data. *PLoS Med* 10(2).

Nichols, J.H. (2007). Point of Care Testing. *Clin Lab Med*,27: 893–908.

Obse, N., Mossie, A. and Gobena, T. (2013).Magnitude of anaemia and associated risk factors among pregnant women attending antenatal care in Shalla Woreda, West Arsi Zone, Oromia region, Ethiopia. *Ethiop J Health Sci.*, Vol. 23 (2).

Pai, N.P., Vadnais, C., Denkinger, C., Engel, N. and Pai, M. (2012). Point-of-Care Testing for Infectious Diseases: Diversity, Complexity, and Barriers in Low- And Middle-Income Countries. *PLoS Med*, 9:9.

Parekh, B. S., Kalou, M. B., Alemnji, G. Ou, C. Y., Gershy-Damet, G. M., and Nkengasong, J. N. (2010). Scaling up HIV rapid testing in developing countries: comprehensive approach for implementing quality assurance. *American Journal of Clinical Pathology*, 134(4): 573–584.

Peeling, R. W. (2009).Utilisation of Rapid Tests for Sexually Transmitted Infections: Promises and Challenges. *The Open Infectious Diseases Journal* ,3:156-163.

Peeling, R. W. And Htun, Y. (2004).Diagnostic tools for preventing and managing maternal and congenital syphilis: an overview. *Bulletin of the World Health Organisation*,82(6).

Peeling, R. W., Holmes, K., Mabey, D. & Ronald, A. (2006). Rapid tests for sexually transmitted infections (STIs): the way forward. *Sexually Transmitted Infection,* 82(Supplement V):v1–v6.

Peeling, R. W. &**.** Mabey, D. (2010). Point-of-care tests for diagnosing infections in the developing world. *Clinical Microbiology Infect,*16:1062–1069.

Peeling, R.W., Mabey, D., Ballard, R. C. (2013). Introducing new diagnostics into STI control programmes: the importance of programme science. *Sexually Transmitted Infection, 89: 115-119.*

Plebani, M. (2009).Does POCT reduce the risk of error in laboratory testing?*ClinicaChimicaActa*404:59–64.

Plebani M. (2010). The detection and prevention of errors in laboratory medicine.*Ann Clin Biochem* ,47(2):101-10.

Reid, A. (2012*). Developing point of care diagnostics for resource-limited settings.* American Academy of Microbiology.[Online] Available: www.finddiagnostics.org/resource. [Downloaded: 29/03/14 2:00 PM].

Sanchir-Gomar, F., Cortell-Ballister, J., Pareja-Galeano, H., Banfi, G. and Lippi, G. (2012).Hemoglobin Point-of-Care Testing: The HemoCue System. *Journal of Laboratory Automation,* 1- 8.

Schapkaitz, E., and Mahlangu, J. (2011).Point-of-care estimation of haemoglobin concentration in all age groups in clinical practice. *S Afr Fam Pract*, 53(3):271-274.

Sedibeng District Health Information System.(2013/2014). *District Health Plan.*

Sedibeng District Health Information System. (2014/15). *District Health Plan.*

Singer, A.J., Ardise, J., Gulla, J., and Cangro, J. (2005).Point-of-Care Testing Reduces Length of Stay in Emergency Department Chest Pain Patients. *Annals of Emergency Medicine,*45:6.

Singh, A., and Peeling, R. W. (2012). Rapid/Point of Care Testing for Syphilis: Canadian and International Perspectives. *Purple Paper,* 36.

Smit, P, W., Mabey, D., Changalucha, J., Mngara, J., Clark B., Andreasen, A., Toff, J., Urassa, M., Zaba, B., and Peeling, R.W. (2013).The Trade-Off between Accuracy and Accessibility of Syphilis Screening Assays.*PLoS ONE 8(9*).

Theel, E. S. (2012). *Serologic Testing for Syphilis - Comparison of the Traditional and Reverse Screening Algorithms*.[Online], Available: ***http://www.mayomedicallaboratories.com/http://www.mayomedicallaboratories.com***. [Downloaded: 20/06/14 1: 00 PM].

Steven, W., Gous, N., Ford, N. and Scott, L.E. (2014). Feasibility of HIV point-of-care tests for resource-limited settings: challenges and solutions. *BMC Medicine,* 12:173.

Tirimacco, R. (2013). *The Evolving Role of Point of Care Testing.* International Federation of Clinical Chemistry and Laboratory Medicine. [Online] Available: www.ifcc.org/media/.../1.%202012%2011%2019%20R%20. [Downloaded: 29/03/14 4:00 PM].

United Nations Department of Economic and Social Affairs Population Division. (2009).*World Population Prospects: The 2008Revision (CD-ROM Edition).*

Wagar, E.A., Yasin, B., and Yaun, S. (2008). Point-of-Care Testing: Twenty Years' Experience. *Labmedicine,* 39:9.

Watson-Jones, D., Oliff, M., Terris-Prestholt, F., Changalucha, J., Gumodoka, B., Mayaud, P., Semakafu, A. M., Kumaranayake, L., Gavyole, A.,Mabey, D. and Hayes, R. (2005).

Antenatal syphilis screening in sub-Saharan Africa: lessons learned from Tanzania. *Tropical Medicine & International Health*, 10: 934–943.

Weekes, L. (2013). *Rapid HIV testing- better or just faster*? Health News and Evidence. [Online] Available: http://www.nps.org. [Downloaded: 08/11/2014 1:00 PM]

Wood, F., Brookes-Howell, L., Hood, K., Cooper, L., Verheij, T., Goossens, H., Little, P., Godycki-Cwirko, M., Adriaenssens, N., Jakobsen, K. & Butler, C. C. (2011). A multi-country qualitative study of clinicians' and patients' views on point of care tests for lower respiratory tract. *Family Practice*, 28(6):661-9.

World Health Organisation (2004). Rapid HIV Tests: Guidelines for use in HIV testing and counselling services in resource-constrained setting, WHO, Geneva.

World Health Organisation (2006). Prevention of mother-to-child transmission of syphilis: Integrated management of pregnancy and childbirth. WHO, Geneva.

World Health Organisation (2008).Worldwide prevalence of anaemia 1993-2005: WHO global database on anaemia. WHO, Geneva.

World Health Organisation (2012). Investment case for eliminating mother- to- child transmission of syphilis: Promoting better maternal and child health and stronger health systems. WHO, Geneva.

World Health Organisation (2013). HIV Assays: Operational Characteristics. WHO, Geneva.

Yang, L., Tucker, J.D., Liu, F., Ren, X., Hong, X., Wang, C., McLaughlin, M.C., Bien, C.H., Chen, X. and Yang, B. (2013). Syphilis Screening among 27,150 Pregnant Women in South Chinese Rural Areas Using Point-of-Care Tests. *PLOS ONE (8)8.*

Young, H. (2004). *Standard serologic testing for syphilis in individual patients: the European view (paper nr 1).* IUSTI/WHO Europe Workshop on Management of Syphilis: 6 scientific background papers.

APPENDIX A

Questionnaire B: Patient folder

Assessing the Prevalence, Mechanism and Appropriateness of POC testing

Folder Number....(tick √ appropriate answer)

Questionnaire A: Demographic data form: Patient folder

<table>
<tr><td>Patient age</td><td colspan="4"></td><td colspan="2">Unknown</td></tr>
<tr><td>Paragestational age at first visit for this pregnancy</td><td colspan="4"></td><td colspan="2">Unknown</td></tr>
<tr><td rowspan="2">Residence (Tick √ appropriate answer/box)</td><td>Township (indicates living in low socio-economic area)</td><td>Suburb (indicates living in middle to high socio-economic area)</td><td>Informal settlement</td><td>Rural area</td><td>Unknown</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td rowspan="2">Employed (Tick √ appropriate answer/box)</td><td>Formally employed</td><td>Unemployed</td><td>Self-employed</td><td>Student</td><td>Unknown</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Educational level(Tick √ appropriate answer)</td><td>No formal education</td><td colspan="2">Completed primary education</td><td colspan="2">Completed high school education</td><td>Completed tertiary education</td><td>Unknown</td></tr>
<tr><td rowspan="2"></td><td rowspan="2"></td><td>Grade 1 to 3</td><td></td><td>Grade 7 to 9</td><td></td><td rowspan="2"></td><td rowspan="2"></td></tr>
<tr><td>Grade 4 to 7</td><td></td><td>Grade 10 to 12</td><td></td></tr>
<tr><td rowspan="2">Marital status (Tick √ appropriate answer/box)</td><td>Single</td><td colspan="2">Married/Cohabiting</td><td colspan="2">Divorced</td><td>Widowed</td><td>Unknown</td></tr>
<tr><td></td><td colspan="2"></td><td colspan="2"></td><td></td><td></td></tr>
</table>

PREVALENCE: **Does the patient record show that the following tests were done?**			
RPR:	Yes	No	Do not Know
Hb:	Yes	No	Do not Know
HIV:	Yes	No	Do not Know

MECHANISM: **Which method of testing was done?** **Note: POCT results are mostly handwritten;** ***ALL*** **LAB results are included in a clearly marked NHLS test request form** **(more than one method could be used)**	***RPR***	***HIV***	***Hb***	***Mechanism unknown***
	POCT	POCT	POCT	
	LAB	LAB	LAB	

APPROPRIATNESS: **Results of test done as POCT**					
RPR:	Positive	Negative	Indeterminate	Not done	Unknown
Hb (list the actual value obtained):	Lower value	Upper value	Indeterminate	Not done	Unknown
HIV:	Positive	Negative	Indeterminate	Not done	Unknown
Results of tests sent to the lab					
RPR	Positive	Negative	Indeterminate	Not done	Unknown
Hb	Result value	-	-	Not done	Unknown
HIV	Positive	Negative	Indeterminate	Not done	Unknown

APPENDIX B

Questionnaire C: Staff performing POCT

Determine factors affecting prevalence of POCT

(Tick √ appropriate answer)

Questionnaire B :Demographic data on staff

Age		
Gender	Female	Male
Basic qualification		
Yearobtained		
Furthereducation		
Yearsworked in ANC		
Category of nurse		

Q1 Do you know which ANC screening tests appear in the MCWH guidelines	Yes	No	Do not remember
If yes, are the following tests in the list?			
Q2 Urea	Yes	No	Do not remember
Q3 RPR	Yes	No	Do not remember
Q4 Folate	Yes	No	Do not remember

Q5 Hb	Yes	No	Do not remember
Q7 HIV	Yes	No	Do not remember
Q8 Do you know about the presence of the Provincial POCT list?	Yes	No	Do not know
Q9 If yes, are the following tests in the list?			
Q10 RPR	Yes	No	Do not remember
Q11 Bilirubin	Yes	No	Do not remember
Q12 Hb	Yes	No	Do not remember
Q13 Creatinine	Yes	No	Do not remember
Q14 HIV	Yes	No	Do not remember
Q15 Do you perform any POCT?	Yes	No	Do not remember
Q16 If yes, please state which ones?			
Q17 Potassium	Yes	No	Do not remember
Q18 RPR	Yes	No	Do not remember
Q19 Urea	Yes	No	Do not remember
Q20 Hb	Yes	No	Do not remember
Q21 HIV	Yes	No	Do not remember
Q18 Do testing using control reagents provided in the test kit?	Yes	No	Do not remember
Who trained you to perform POCT?			
Q19 Supplier	Yes	No	Do not remember

Q20 Colleague	Yes	No	Do not remember
Q21 Other	Yes	No	Do not remember
Q22 Not trained	Yes	No	Do not remember
How easy is POCT to perform on?			
Q23 RPR	Very easy	Easy	Difficult
Q24 Hb	Very easy	Easy	Difficult
Q25 HIV	Very easy	Easy	Difficult
How quick is POCT to perform on?			
Q26 RPR	Very quick	Quick	Long
Q27 Hb	Very quick	Quick	Long
Q28 HIV	Very quick	Quick	Long
How often do you perform the following POC tests on ANC patients?			
Q29 RPR	Always	Most times	Sometimes
Q30 Hb	Always	Most times	Sometimes
Q31 HIV	Always	Most times	Sometimes
Can you interpret POCT results on? Q32 RPR	Always	Most times	Sometimes
Q33 Hb	Always	Most times	Sometimes

Q34 HIV	Always	Most times	Sometimes
Are POCT kits available for RPR?			
Q35 RPR	Always	Most times	Sometimes
Q36 Hb	Always	Most times	Sometimes
Q37 HIV	Always	Most times	Sometimes
Q38 How often do you trust the results of the POC test?	Always	Most times	Sometimes
Q39 Do you have sufficient time to perform POCT on every patient?	Always	Most times	Sometimes
Q40 Is there sufficient staff to perform POCT for syphilis, anaemia and HIV at every first ANC visit?	Always	Most times	Sometimes
Q41 Do you know when to send POCT samples to the NHLS Lab?	Yes	No	
Q42 If yes, then indicate for each of these tests in the above list when you would send it to the lab after POCT			
RPR			
Hb			
HIV			

APPENDIX C

Questionnaire C: Facility managers

Determine factors affecting prevalence of POCT

(Tick √ appropriate answer?)

Q1 Are you in possession of the MCHW guidelines?	Yes	No	I am not sure
Q2 If yes, could I see which one you have?	Could find it	Could not find it	
Q3 Are you in possession of the provincial POCT list?	Yes	No	I am not sure
Q4 If yes, could I see which one you have?	Could find it	Could not find it	
Q5 Have the following POC test kits been consistently available? RPR	Yes	No	Do not know
Q6 Hb	Yes	No	Do not know
Q7 HIV	Yes	No	Do not know
Q8 Have the POC equipment and testing materials been consistently available and fully functional? RPR	Yes	No	Do not know
Q9 Hb	Yes	No	Do not know
Q10 HIV	Yes	No	Do not know
Q11 Are SOPs for procurement and maintenance of POCT equipment and materials available?	Yes	No	Do not know
Q12 If yes, could I see which SOPs you have?	Could find it	Could not find it	

Q13 Is there sufficient staff trained to routinely perform POCT at every first ANC visit?	Yes	No	Do not know
Q14 Are written procedures to communicate with the NHLS available?	Yes	No	Do not know
Q15 If yes, could I see which procedures you have?	Could find it	Could not find it	

APPENDIX D

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Private Bag X 17, Bellville 7535, South Africa

Tel: +27 21-959 2809, Fax: 27 21-959 2172

E-mail: greagon@uwc.ac.za

CONSENT FORM

Title of Research Project: Prevalence of syphilis, anaemia and human immunodeficiency virus screening and factors affecting antenatal point of care testing for these diseases in primary health care centres in Sedibeng District, South Africa

The study has been described to me in language that I understand and I freely and voluntarily agree to participate. My questions about the study have been answered.

I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way.

Participant's name……..

Participant's signature…….

Witness…….

Date……

APPENDIX E

UNIVERSITY OF THE WESTERN CAPE
Private Bag X 17, Bellville 7535, South Africa
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E-mail: greagon@uwc.ac.za

PARTICIPANT INFORMATION SHEET

Dear Participant

Thank you for your willingness to be informed about this study. What follows is an explanation of the study and your potential involvement. This study is being conducted for a mini-thesis as part of the requirements for a Masters in Public Health degree, which I am completing at the University of the Western Cape. You are free to ask me anything that may be unclear or that you do not understand. My contact details and those of my supervisor can be found at the end of this memo.

TITLE OF RESEARCH: Prevalence of syphilis, anaemia and human immunodeficiency virus screening and factors affecting antenatal point of care testing for them in primary health care centres in Sedibeng District, South Africa.

PURPOSE OF THE STUDY

The study seeks to determine the prevalence, appropriateness and mechanism of RPR, HB and HIV POC testing in the Sedibeng District ANC facilities. This information should help establish the magnitude of inappropriate laboratory-based testing of these crucial antenatal POC tests and should assist in determining the reasons behind the practice. Moreover, this study seeks to contribute to knowledge about issues relating to clinician non-compliance to POCT utilisation for ANC screening tests.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

For this study, patients' records will be examined to determine whether or not the Rapid Plasma Reagin (RPR), haemoglobin (HB) and HIV POC tests were performed. The same will be done to determine the appropriateness of testing, with patients' records checked to establish the test results of samples sent to the National Health Laboratory Services (NHLS). In addition, you will be asked questions about availability of test kits, working condition of testing material and equipment, training of staff and availability of different standard operating procedures.

APPENDIX F

UNIVERSITY OF THE WESTERN CAPE
Private Bag X 17, Bellville 7535, South Africa
Tel: +27 21-959 2809, Fax: 27 21-959 2172

E-mail: greagon@uwc.ac.za

CONFIDENTIALITY

Your name will be kept confidential at all times and I shall keep all records of your participation, including a signed consent form, which I will need from you should you agree to participate in the study, locked away at all times and they will be destroyed after the study is completed.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalised in any way. If you choose to participate, you may choose not to answer particular questions that may be asked. Please feel free to inform me if there is anything that you would prefer not to discuss.

BENEFITS AND COSTS

You may not get any immediate benefit from this study. However, the primary benefit of the study is to establish the magnitude of and the factors affecting the three key antenatal POC tests in the District. The latter information should assist in guiding policy-making by the relevant authorities for the overall benefit of patients and the improved efficiency of the health service. The only costs that will accrue to you for participating in this study is the time you will need to spend in completing the self-administered questionnaires.

INFORMED CONSENT

Your signed consent to participate in this study is required before I proceed to interview you. I have included the consent form with this information sheet.

QUESTIONS

Should you have further questions or wish to know more, I can be contacted as follows:

Ms Nombuto Mpotulo
Tel: 011 933 4471
Cell: 0823201678
nombuto.mpotulo@gauteng.gov.za

APPENDIX G

UNIVERSITY OF THE WESTERN CAPE
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E-mail: greagon@uwc.ac.za

9192 Nonqawe Street
Zone 6 Extension
Pimville
Johannesburg
1809

I am accountable to my supervisor, therefore should you have any concerns regarding this study or wish to report any problems you have experienced related to the study, please contact the study supervisor, or the director of the school or the dean of the faculty.

Study Supervisor:
Dr Gavin Reagon
University of the Western Cape
Private Bag X17, Bellville 7535
Telephone: +27 21 959 2809
Email: greagon@uwc.ac.za

Director School of Public Health:
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Dean of the Faculty of Community and Health Sciences:
Prof Jose Frantz
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This research has been approved by the University of the Western Cape's Senate Research Committee and Ethics Committee.

APPENDIX H

UNIVERSITY of the WESTERN CAPE

OFFICE OF THE DEAN
DEPARTMENT OF RESEARCH DEVELOPMENT

02 August 2013

To Whom It May Concern

I hereby certify that the Senate Research Committee of the University of the Western Cape approved the methodology and ethics of the following research project by
Ms N Mpotulo (School of Public Health)

Research Project: Prevalence of syphilis, anaemia and human immunodeficiency virus screening and factors affecting antenatal point of care testing for these diseases in primary health care centres in Sedibeng District, South Africa

Registration no: 13/6/25

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

The Committee must be informed of any serious adverse event and/or termination of the study.

Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape

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