



TITLE OF DISSERTATION: A study to assess adherence to HIV testing guidelines among HIV exposed paediatric inpatients at Princess Marina Hospital, Gaborone, Botswana

Master of Medicine (MMed), Paediatrics and Adolescent Health

Dissertation

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Date of submission: 30th March 2020

CANDIDATE'S DECLARATION

“The work contained in this dissertation was completed by the author at the University of Botswana between March 2019 and December 2019 and it is original work except where due reference is made and neither has been nor will be submitted for the award of any other University”. Any part of the dissertation that relates to work previously done in connection with another qualification or award shall be declared. The candidate shall state the extent to which he/she has availed himself/herself of the work of others.

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ACKNOWLEDGEMENTS

I am grateful to my supervisor's Dr Tonya Arscott-Mills, Dr Loeto Mazhani and Dr Thuso David for their help, support, encouragement and patience in guiding me from the initial stage of this research study until its completion.

I am thankful to my family for their love and support that kept me strong and am very appreciative of their tolerance and understanding when I was unable to spend quality time with them. Above all, I thank God for making all this possible.

ABSTRACT

Background: Despite well-established prevention of mother to child transmission (PMTCT) programmes, Human Immunodeficiency Virus (HIV) infected children still get missed and present late for diagnosis and antiretroviral therapy (ART). Botswana's HIV testing guidelines recommend using deoxyribonucleic acid-polymerase chain reaction (DNA-PCR) as early as four weeks old. Timely HIV testing will improve early infant diagnosis (EID).

Objectives: To determine the percentage of children under the age of five years that were HIV exposed at birth ,who got admitted to Princess Marina hospital (PMH) at paediatric medical ward (PMW) and paediatric surgical ward (PSW) with a documented HIV test at four to eight weeks and at 17-24 months of age which would indicate testing according to national HIV testing guidelines. This data will be compared to the national testing rate.

Methods: This was a clinical audit of 139 HIV exposed inpatients under the age of five years who were, admitted to PMH paediatric wards(PSW and PMW) from 1st March 2019 to 15th August 2019. The HIV testing rates of the cohort at 4-8 weeks and at 17-24 months before admission was assessed and compared to the national HIV testing rates. The proportion of children who were tested before admission and the proportion of those without a prior HIV test who were tested in the hospital was determined. Among the enrolled cohort, baseline characteristics, caregiver characteristics and testing between the two wards were compared for those with a documented test and those without a documented test. Caregiver characteristics were also assessed for association to testing.

Results: One hundred and thirty-nine(139) participants were enrolled for the study. The HIV testing rates for the admitted cohort was 6% less for the six weeks testing and 21% less for 18 months testing compared to the national HIV testing rate. Twenty-seven (19.4%) of the admitted cohort did not have a documented HIV test, and the majority 23 (85%) of them got

tested in the wards. More participants were tested in paediatric medical ward (PMW) compared to paediatric surgical ward (PSW) but with no statistical significance ($p = 0.144$). Outcome of ward HIV testing was as follows: 17 (77%) – negative, three (14%) – positive, one (4.5%) – pending, one (4.5%) – had missing results. The majority of participants (79%) had Deoxyribonucleic Acid-Polymerase Chain Reaction (DNA-PCR) test at more than two months of age. No associations between caregiver characteristics and DNA-PCR testing was found. Thirty-six(26%) had no documentation of HIV exposure or status in the under-five child welfare card.

Conclusions: This study shows a lower HIV testing rate within the sick cohorts with known exposure at birth compared to the national HIV testing rate. More emphasis on testing paediatric inpatients is needed to improve HIV testing rates and outcomes.

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LIST OF ABBREVIATIONS

ART	Antiretroviral Therapy
ARC	AIDS related Complex
DBS	Dried Blood Spot
DNA-PCR	Deoxyribonucleic Acid-Polymerase Chain Reaction
EID	Early Infant Diagnosis
ELISA	Enzyme-linked immunosorbent assay
HIV	Human Immunodeficiency Virus
HRDC	Human Research and Development Committee
IPMS	Integrated Patient Management System
PI	Principal Investigator
PMH	Princess Marina Hospital
PMTCT	Prevention of Mother to Child Transmission
MTCT	Mother to Child Transmission
PMW	Paediatric Medical Ward
PNC	Postnatal Care
PSW	Paediatric Surgical Ward
RHT	Rapid Human Immunodeficiency Virus test
RNA	Ribonucleic acid
RSA	Republic of South Africa
U5	Under-five child welfare cards

DEFINITIONS

- a) Caregiver – Person staying with the child in the hospital who has access to the under-five child welfare cards and outpatient cards.
- b) HIV exposed – Children born to mothers with a documented positive HIV test results before pregnancy, during pregnancy or at birth.
- c) Guideline testing age range –DNA-PCR test at four to eight weeks of age and rapid HIV test (RHT) at 17-24 months.
- d) HIV exposure unknown – Children born to mothers with an unknown HIV test results by the time of birth.
- e) HIV unexposed – Children born to mothers with a documented negative HIV test results during pregnancy and at birth.
- f) Transmission rate – The number of secondary infections per member of the group per unit time.
- g) Unknown HIV status – Children who have never had an HIV test or those who tested but with no documentation of the test result and those with pending HIV test results.

1.1 INTRODUCTION

Early Human Immunodeficiency Virus (HIV) testing of HIV exposed infants before they become symptomatic is vital for identification of children who need therapy¹. Without treatment, it is estimated that by 12 months of age, 35.2% of infected children would have died, compared with an estimated 4.9% of uninfected children and at two years of age, an estimated 52.5% of infected and 7.6% of uninfected children would have died².

For testing to be done early, World Health Organization's (WHO) infant HIV testing guidelines recommend using deoxyribonucleic acid-polymerase chain reaction (DNA-PCR) on whole blood or dried blood spot (DBS) as early as four weeks old³. Botswana, like many other African countries has also adopted the WHO infant HIV testing guidelines⁴. Diagnosing those infected is a major challenge for the prevention of mother to child transmission (PMTCT) programs in resource limited countries in which most paediatric infections occur⁵.

Both clinicians and caregivers have roles in adherence to HIV testing guidelines⁵. Clinicians are responsible for informing the caregivers about the specific times for testing and testing the children in time^{5,6}. Caregivers are responsible to bring the children to hospital at the recommended times and collect the test results when available^{5,7,8}.

In Princess Marina hospital (PMH) all HIV exposed children admitted to paediatric medical ward (PMW) and paediatric surgical ward (PSW) without any documented HIV test are to be tested and the results documented on the under-five child welfare cards, but sometimes clinicians do not adhere to the recommendations due to various reasons.

The aim of this study is to assess adherence as per Botswana HIV testing guidelines within the sick population that gets admitted to PMW, PSW and to determine if further work is

needed to improve adherence to testing for HIV to bridge the gap and improve PMTCT in Botswana.

1.2 LITERATURE REVIEW

1.2.1 Human immunodeficiency virus and acquired immunodeficiency syndrome

HIV is a lentivirus that causes HIV infection and over time Acquired Immunodeficiency Syndrome (AIDS)⁹. AIDS was first discovered in 1981 amongst homosexual men in United States of America^{9, 10}.

Worldwide, there are two types of HIV: HIV-one and HIV-two. HIV-one, the most prominent type, is further divided phylogenetically into different groups and subtypes¹¹. The main clinical implications of these different types of HIV are that infection with HIV-two appears to have a more indolent natural history than HIV-one and is intrinsically resistant to certain antiretroviral agents¹¹. HIV has several targets including dendritic cells, macrophages, and CD4+ T cells¹¹.

HIV infection is usually acquired through sexual intercourse, exposure to infected blood, or perinatal transmission¹⁰. Risk factors for HIV transmission include high viral load, certain sexual behaviours, presence of ulcerative sexually transmitted infections, lack of circumcision, as well as certain host and genetic factors¹⁰.

The WHO case definition of HIV infection includes 1) a positive result on a HIV antibody test confirmed by a positive result on a second, different HIV antibody test and/or 2) a positive virological test confirmed by a second virological test¹². The WHO classification system for staging established HIV infection uses both immunologic or clinical criteria¹². HIV infection can be divided into the following stages: 1. Viral transmission, 2. Acute HIV infection (also called primary HIV infection or acute seroconversion syndrome)

seroconversion, 3. Chronic HIV -Asymptomatic ,early symptomatic HIV infection (previously known as AIDS-related complex [ARC], AIDS characterized by a CD4 cell count <200 cells/microL or the presence of any AIDS-defining condition and advanced HIV infection characterized by a CD4 cell count <50 cells/microL¹².

1.2.2 Human Immunodeficiency Virus infection worldwide and in Botswana

Across the world 36.9 million (31.1 million–43.9 million) people are infected by HIV¹³. HIV infection is the leading cause of mortality and morbidity in eastern and southern Africa, which is home to 53% of the world's people living with HIV¹³. In eastern and southern Africa, 19.6 million [17.5–22.0 million] people live with HIV and out of those about 12.9 million [11.4–13.4 million] (all ages) were on antiretroviral drugs by the end of 2017¹³.

AIDS-related mortality declined by 42% from 2010 to 2017 in eastern and southern Africa, reflecting the rapid pace of treatment scale-up in the region¹³.

About 1.8 million [1.3 million–2.4 million] children (<15 years) were living with HIV at the end of 2017, and in 2017 there were 180 000 [110 000–260 000] new infections globally¹³.

In 2017 there were 110 000 [63 000–160 000] HIV related deaths in children¹³.

Botswana has the third highest HIV prevalence rate in the world¹⁴. Botswana's HIV prevalence in the general population was 18.4% and paediatric transmission rate was 1.2% by the end of 2013¹⁵. Ninety percent of all paediatric HIV cases globally are acquired through mother to child transmission¹. PMTCT was introduced in Botswana in 1999 and national rollout of the program was achieved by 2001¹⁶. In 1999 mother to child HIV transmission rate was estimated at 35-40%^{16, 17}. This number has declined significantly to 1.2% by the year 2013^{15, 18} and currently at 0.67% (end of 2018)¹⁹. With the new treat-all strategy more women would be on ART (antiretroviral therapy) before pregnancy and fewer children will be

positive, but at this point HIV infant testing guidelines have not changed that is, maybe they might change and mostly target infections acquired postnatally.

1.2.3 HIV Testing in Infants and Young Children

In infants born to HIV-infected women, maternal anti-HIV antibodies cross the placenta and persist in infant blood for up to 18 months. When detected in young infants, these antibodies usually represent exposure to maternal HIV rather than true infant HIV infection. Antibody-based tests can therefore be accurately used only to exclude infant infection after 12 months of age, or to confirm infant infection after 15-18 months of age. Despite the recommended age of antibody-based testing by WHO, a study done in Florida by Marvel Gutierrez et al found out that 14% of the children had persistence of HIV antibodies at or beyond 18 months of age. Accurate early infant diagnosis (EID) before 12-18 months of age therefore requires detection of viral components in infant blood (virological testing), including cell-free Ribonucleic acid (RNA), Deoxyribonucleic acid (DNA) integrated into host cells, or the viral capsid p24 antigen²⁰⁻²³.

Studies from eastern and southern African countries show that adherence to testing for HIV in young children is still poor. A study by Nyandiko et al on outcomes of HIV exposed children, showed that adherence to HIV testing protocols, in Western Kenya was less than 50% hence the need to strengthen the HIV testing for early infant diagnosis²⁴. Motswere and colleagues did a study on the follow-up of infants diagnosed with HIV in Nyangabgwe Referral hospital - Francistown, Botswana in 2005-2012 and identified that the overall HIV testing rate of the HIV exposed infants was 71%²⁵.

Botswana has made significant progress in the PMTCT program but there is still the 0.67 % HIV infection transmission rate¹⁹, and these cases need to be diagnosed as early as possible in order to initiate therapy to prevent morbidity and mortality. Braun et al in Lilongwe- Malawi

did a study that revealed that late HIV diagnosis and late initiation of ART in HIV infected infants are related to high subsequent mortality rates in HIV infected infants and children²⁶. Botswana's national guidelines requires that all HIV exposed babies complete deoxyribonucleic acid- polymerase chain reaction (DNA-PCR) testing by six weeks of age²⁷. However, testing can be done from four weeks of age if the HIV exposed infant present at a health facility with an illness. Dried Blood Spot (DBS) is the preferred specimen collection method. "The sensitivity of a single HIV DNA-PCR test performed at ≤ 48 hours of age is less than 40% but sensitivity increases to more than 90% by two to four weeks of age"⁴. All children identified as negative by six weeks, who do not breastfeed, must undergo rapid HIV testing at 18 months²⁷. All children identified as negative by six weeks, who are breastfed, should have repeat HIV testing six weeks after cessation of breastfeeding (if < 18 months use DNA-PCR (DBS) if ≥ 18 months use HIV rapid tests)²⁷. If the DNA-PCR test result is positive a repeat DNA-PCR test is repeated to confirm the positive test and the infant is referred for ART initiation²⁷. ART can reduce mortality by 76% if initiated in the first three months of life²⁵. The Botswana national HIV program reports an infant testing rate of 73% by six weeks and 86% retested at 18 months by December 2015²⁸.

Advantages to the afore mentioned Botswana paediatric HIV testing guidelines are that DNA-PCR is highly sensitive and highly specific if performed at two to four weeks of age²⁹. DNA-PCR using DBS is easy to do and requires minimal training²⁹. It can be performed at any clinic and transported without refrigeration to laboratories making it accessible in remote areas³⁰.

Disadvantages of Botswana paediatric HIV testing guidelines are that the period between the six weeks of age test or the test six weeks after cessation of breastfeeding and a confirmatory test at 18 months is a lot of time, that is if infection occurs maybe postnatally, it will be picked up late. There is evidence that the six weeks HIV PCR test yields false-negative results

in the presence of maternal and/or infant antiretroviral prophylaxis³¹, but there is no evidence on how often this occurs. DNA-PCR is an expensive test and only a few laboratories are equipped (machinery and personnel) to run the tests³². Thus, tests are sent to the central labs and patients must wait for results to be returned to the local health facility before they can get the test results. Thus, some results are lost or never returned to the facility and infants must be re-tested which is costly³². Some of the children who get tested are lost to follow-up because caregivers end up not going back for the test results due to long waiting periods^{32, 33}. A study by Rosemary et al in Nigeria estimated the mean turnaround time DBS-PCR collection to return of results to health facility to be 25 days³⁴. Locally the only data that's available is Harvard laboratory turnaround time of seven days³⁵, but more research needs to be done to look at the turnaround time from DBS-PCR collection to return of results to health facilities.

Despite advances in ART globally and in our setting, there is continued mother to child transmission (MTCT) because women present in pregnancy late for antenatal care (ANC) hence testing is also done late and PMTCT is started late as well. Women who test negative during pregnancy and after birth who are breastfeeding do not test for HIV every three months as recommended, so infants who get exposed postnatally are often identified very late. Poor adherence to ART by the expectant mothers leads to high viral loads and hence transmission of infections to their children. The other reason for continued MTCT in Botswana is due to non-citizen population who did not have access to free ART's in Botswana, but as of 19th September, Botswana introduced a new policy that provides free antiretrovirals to non-citizens³⁶.

1.2.4 Clinical practice guidelines

Clinical practice guidelines are “systematically developed statements to assist physicians and patient decisions about appropriate health care for specific clinical circumstances”³⁷.

1.2.4.1 Use of guidelines

There are five major purposes for guidelines, which are: (1) assisting clinical decision making by patients and physicians; (2) educating individuals or groups; (3) assessing and assuring the quality of care; (4) guiding allocation of resources for health care; and (5) reducing the risk of legal liability for negligent care³⁷. They may offer concise instructions on which diagnostic or screening tests to order, how to provide medical or surgical services, how long patients should stay in hospital, or other details of clinical practice³⁸.

1.2.4.2 Implementation of guidelines

The use and how guidelines are accepted by practitioners depends on the way they are developed and implemented³⁹. Their implementation depends on their quality, credibility and other factors like: (1) financial support for circulating and executing the guidelines; (2) the support and motivation for the guidelines to be used by health care providers (3) the accessibility, scope, accuracy, and timeliness of a variety of intra- and interorganizational information systems; and (4) the ability of multiple stakeholders to plan and execute the various steps needed to implement guidelines³⁷.

There is no single approved way to make sure guidelines are used in clinical practice⁴⁰.

Organizations must come up with ways of circulating and implementing guidelines⁴⁰.

Strategies on implementation are chosen looking at the resources at hand, identified barriers to providing care and evidence based research about how effective and efficient different strategies are⁴⁰. Some of the strategies include interventions to improve quality of care like

continuing medical education, audits, feedback, financial incentives for practitioners and regulation of healthcare⁴⁰.

1.2.4.3 Barriers to adherence to clinical guidelines

Physician adherence is critical in turning recommendations in to improved outcomes. Studies show that despite the importance of clinical practice guidelines being implemented to improve outcomes, many practitioners do not use them⁴¹. There are several barriers that influence the clinician's adherence to guidelines. A study by Michael et al on why Physicians do not follow clinical practice guidelines found out that lack of awareness, lack of familiarity, lack of agreement, lack of self-efficacy and reluctance to change previous practice by physicians also has a role in non-adherence to guidelines⁴². Other barriers can be patient related (for example, patient not showing up on time for a test, patients preferring a certain medication or procedure over the one recommended by the guidelines, refusal to consent to an HIV test and poverty, that is lack of money to travel to clinics for an HIV test and stigma especially if mothers have not disclosed their HIV statuses⁴³). Guidelines related barriers : when guidelines are not easy and not convenient to use physicians end up not using them and it has been found that it is easier to follow recommendations that adds a new behaviour than one that gets rid of accustomed behaviour. There are environmental factors that affect guidelines adherence- some recommendations requires acquiring new resources for implementation⁴².

Specific barriers to testing children for HIV is that children are unable to give consent and children may be brought to the clinic or hospital by a caregiver who is unable to give consent³¹. Unavailability of DBS cards, lack of trained personnel who can collect DBS specimens can delay EID and also affect adherence to guidelines poorly as the testing would be done later than required even if they had presented to the health facility on time.

Centralisation of DNA-PCR testing is also a barrier to testing children for HIV as specimens

must be transported to the testing laboratories and at times they get lost⁶. Long turn-around time for results can also be discouraging for parents to go back to health facilities.

1.2.4.4 Strategies to improve adherence to testing guidelines

A rapid point-of-care test for infant HIV diagnosis would get rid of the need to transport samples or to return to a clinic to get the test results and cut the long waiting periods for results which would improve early infant diagnosis programs in resource limited areas^{29, 32}. Introducing rapid HIV test at nine months of age integrated into the EPI (extended program on immunizations) on top of the six weeks testing would improve testing with better identification and early treatment of HIV infected infants. This could also improve monitoring postnatal transmission rates^{31, 43} rather than waiting for the 18 month test, particularly because post-weaning and the 18 months HIV testing uptake is very poor³¹. This would also be cost effective as it will reduce the number of DNA-PCR performed between the six weeks testing and 18 months testing especially for breastfed infants, DNA-PCR would be done on those with a positive rapid HIV test only³¹. Other strategies have included regular audits and feedback to improve adherence to clinical guidelines⁴⁴.

In summary clinical guidelines are important because they provide a guide for systematic and universal management of specific patient conditions. The implementation of guidelines can be determined by several factors, that is practitioner factors, patient factors and guideline related factors. The specific barriers to EID have been the prolonged turnaround time for DBS DNA-PCR testing which require testing kits to be sent to a centralized location. A rapid point of care testing for infant testing could overcome this barrier ensuring that all test results reach the patients and are acted on appropriately. An introduction of rapid HIV at nine months into the EPI program could bridge the gap of the poor testing rates post weaning and at 18 months.

1.3 STUDY RATIONALE

Every opportunity to test those children who were not tested at guideline times must be used and some countries such as Malawi, Kenya, South Africa, Tanzania, Zambia have adopted routine paediatric HIV testing in inpatient wards, immunization clinics, primary health-care clinics, school-based testing campaigns, community-based case findings, task-shifting and screening for HIV in emergency departments⁵. Testing in all these areas have been shown to improve early infant HIV diagnosis and early initiation of treatment which is associated with less HIV related mortality^{24, 45-50}. HIV testing, and documentation of results is important for identification of patients requiring ART initiation. Poor documentation of testing done can result in re-testing which is costly, time wasting and lead to late initiation of treatment. Thus, it is also very important to have the test results properly documented⁸.

HIV exposed children admitted to PMH we do not know what percentage have had HIV testing as per national guidelines and of those not tested as per guidelines what proportion are tested during their admission.

As this is a sick population, we postulate that the adherence to national guideline testing will be lower than the national testing rate. There are no previous studies examining testing in a HIV exposed sick cohort compared to national cohorts of exposed children to guide an estimated difference in testing. However, we hypothesize that a sick admitted cohort may have a lower testing rate compared to the national cohort since overall hospitalized children may not have benefited at the same level from preventative care activities. A study by Daniel et al has shown that testing for HIV on inpatients, assumed to be sicker, diagnosed more HIV infections than in outpatient, less sick, setting⁴¹.

Thus, this study will document the testing per guidelines of admitted HIV exposed children under the age of five years at PMH. Documenting whether there is less than expected testing

in accordance with guidelines is the first step in assessing guideline use. If the study determines that admitted children are not tested per guidelines next steps would be to explore the reasons for this both from the health system, clinicians and caregivers.

1.4 STUDY AIM

To assess testing as per Botswana HIV national testing guidelines in HIV exposed children under the age of five years admitted to PMH.

1.5 OBJECTIVES

1.5.1 Primary objective

To determine the percentage of children under the age of five years that were HIV exposed at birth ,who got admitted to PMH at PMW and PSW with a documented HIV test at four to eight weeks and at 17-24 months of age which would indicate testing according to national HIV testing guidelines. This data will be compared to the national testing rate.

1.5.2 Secondary objectives

- To determine the percentage of HIV exposed children under the age of five years who are not documented as tested who get tested during the admission.
- To compare the percentage of HIV exposed children under the age of five years who are not documented as tested who are tested between the two wards (PMW and PSW).
- To determine the outcome (percentage positive and negative) of HIV exposed children under the age of five years who undergo testing while admitted.
- To determine the percentage of HIV exposed children under the age of five who are documented as tested but not at six weeks and eighteen months as per guidelines.

- To explore the factors associated with failure to test.

2.1 METHODOLOGY

2.1.1 Study design

Clinical audit.

2.1.2 Study setting

This was a single centre audit undertaken at PMH, Gaborone, in the southern part of Botswana. PMH is one of the two main referral hospitals in Botswana, the paediatric wards have a bed capacity of 60 with an average of 2700 admissions per year. Data was collected prospectively from under five welfare cards and inpatient records (registers, files, integrated patient management system (IPMS)) of children admitted to the paediatric medical and surgical wards.

In PMH, PMW the average number of admissions is 110 per month and 22% of the admissions are HIV exposed infants and in PSW the average number of admissions is 84 per month and 17.8% of the admissions are HIV exposed (unpublished departmental data).

During admission in PMW if there is no documentation of HIV exposure for those less than 18 months of age the standard is to do the parallel rapid HIV test on the mother as per the national guidelines. If the result is negative the infant is unexposed, and no further HIV testing is done unless clinically indicated by the child's illness. However, if it is positive a DNA-PCR is done on the child. For children, over 18 months without any previous HIV test a parallel rapid HIV test is performed on the child. However, clinician's adherence to this recommendation is not known.

2.1.3 Study population

The study enrolled children admitted to the paediatric medical and surgical wards between 1st March 2019 and 15th August 2019.

2.1.4 Inclusion criteria

The study enrolled HIV-exposed children under the age of five years admitted to PMW and PSW at PMH with under-five child welfare card (including non-citizens who were born in Botswana with a Botswana under-five child welfare card). HIV unexposed children are those children born to mothers with a documented negative HIV test results during pregnancy and at birth.

2.1.5 Exclusion criteria

- Patients whose caregivers decline to consent to participate in the study.
- Children less than one month of age.

2.1.6 Sample size

In Botswana, the HIV exposed paediatric population was 11799 from January to December 2015²⁸. The testing rate for 2015 at six weeks was 73% and at 18 months was 86%. Sample size was calculated using Stata Sampsi version 15.1 for estimated sample size for one-sample comparison of proportion to hypothesized value, which is the testing rate for six weeks testing, that is 73%. We hypothesize that a difference of 15 percent would indicate a clinically significant difference from the national cohort for the adherence to national guidelines for infant testing by six weeks and 18 months of age. Thus, we estimated that the testing at six months and 18 months of this admitted population will be lower by 15% than the nationally recorded testing rate of 73% at six weeks of age, and of 86% at 18 months of age. The study was powered to detect this 15% difference. The study was powered at 80% to detect a 15%

lower testing rate, that is 62% instead of 73 % at six weeks of age and 73% instead of the 86% at 18 months of age , using relative percentage reduction. The sample size for six weeks testing was 139, which is what was used as it was larger than the 18 months testing.

In PMH, PMW the average number of admissions is 110 per month and 22% of the admissions are HIV exposed infants. Thus, over six months we had anticipated approximately 240 HIV exposed infants to be admitted. We enrolled until we reached our sample size of 139.

2.1.7 Recruitment and Data collection

The study used convenience sampling given the constraints on the investigator availability. This was a clinical audit with prospective data collection. Recruitment was started on the 1st of March 2019 and continued until the 15th August 2019 when desired sample size was reached. Under five welfare cards for all the children admitted to PMW and PSW were screened for HIV exposure. Caregivers of those that were found to be HIV exposed and under the age of 5 years were approached for consent. Caregivers were informed about this study individually in the counselling rooms in the wards and consent was obtained. After caregiver consent, under five welfare cards and inpatient records on all HIV exposed children under five years who are admitted in PMW and PSW were screened for documentation of HIV status and testing. Initial enrolment data was collected from under five welfare cards, where there is a page specifically for recording the mother's HIV status and the HIV tests done on the children, and for those without HIV exposure documentation verbal confirmation was taken from the caregiver, only if the caregiver was the parent. Documentation of HIV testing on this page or in the outpatient or inpatient record was used to determine if a child was HIV exposed. Initially we screened all children already admitted in the wards (PMW and PSW) and enrolled those eligible and subsequently, new admissions were screened for eligibility and

those eligible were enrolled. Screening during the week was done twice a day, in the morning for overnight admissions and in the evening for day admissions. Screening during the weekends was done in the mornings only because most discharges are done in the afternoon after ward rounds. However, we acknowledge that we might have missed some patients who came and were discharged before recruitment occurred. Other information was collected from the patient inpatient records that is, age, gender, date of admission and admission diagnosis. Caregiver's age, marital status, educational background and place of residence was also captured on the data collection form. For those who were identified as exposed but not previously tested, and who were tested during the admission, their HIV test results were retrieved from inpatient records and IPMS. See appendix A for sample data collection form. Due to ethical considerations we recommended to the teams to test and facilitate testing when needed when we found a case that needed testing.

2.2 SUMMARISING DATA AND ANALYTIC PLAN

Data gathered from the study was de-identified and entered into Microsoft excel; the data was entered as numerical variables. Data gathered was analyzed using Stata version 14.2 and was summarized in tables, charts and flow diagrams. Baseline characteristics of cohorts and their caregivers were summarised by standard descriptive summaries. Median and interquartile range was used for skewed data. Dichotomous variables/categorical data (for example, gender) was analysed for association with testing using the Chi-square test and Fisher exact test. Fisher exact test was used over Chi-square test when the expected cell frequencies were less than five. Categorical variables were reported using numbers and percentages. Wilcoxon Rank Sum test was used for non-parametric continuous variables (for example, age) and we reported median and interquartile range. Yield of positive results was compared by assessing the point estimate and 95% confidence intervals to assess if the 95% confidence intervals

overlap (non-significant difference) or do not overlap (significant difference at the 5% level). For objective two, a secondary analysis, we compared the number of children who were documented as tested vs not tested between the two wards (PMW and PSW) and test for statistical significance using Fisher's exact test. For objectives three and four we calculated the basic percentages. For objective five due to low numbers of children who had both PCR and RHT in guideline timeframe we just explored caregiver characteristics with testing on time for PCR only and data was analyzed using logistic regression. Independent variables for caregiver's characteristics were age, marital status, educational background and place of residence (how far they live from a health facility), these factors were chosen as they are some of the challenges that caregivers mentioned and were also from the principal investigator's (PI) observation.

2.3 LEGAL AND ETHICAL CONSIDERATIONS

Written informed consent was obtained from a caregiver of each child (see Appendices E and F). The discussion for consent was done in the counselling room in the wards. The consent forms clearly state that participation in this study is voluntary and refusing consent will not affect the care that the child would receive from healthcare workers. The potential participants were also assured that they could withdraw consent at any time during the study and would not be required to give any explanation. There was no form of compensation or incentives as a way of recruiting patients into this study and this was clearly communicated with caregivers. The data collection forms do not include any personal identifiers. Only the student PI, research assistant and the University of Botswana supervisors were dealing with data that is directly linked to the patients. Approval to conduct the study was obtained from the Human Research and Development Committee (HRDC) of the Ministry of Health in Botswana and ethics committees of Princess Marina Hospital in Gaborone and the University of Botswana. The

principal investigator is a salaried employee at the Ministry of Health of Botswana, and she got funding from the training unit to cover the costs of the study. The costs of the study included stationery (pens and papers), printing and payment of the research assistant.

3.1 RESULTS

3.1.1 Study cohort

A total of 139 (90%) out of 153 potentially eligible participants were enrolled for the study with baseline characteristics as illustrated in table 1. The participants were further divided in to two age groups, group one for less than 17 months and group two, greater than or equal to 17 months. Group one had 76 (55%) participants and group two had 63 (45%). The majority 101 (73%) of participants were from PMW. There were 14 (9%) participants who were eligible but refused to consent

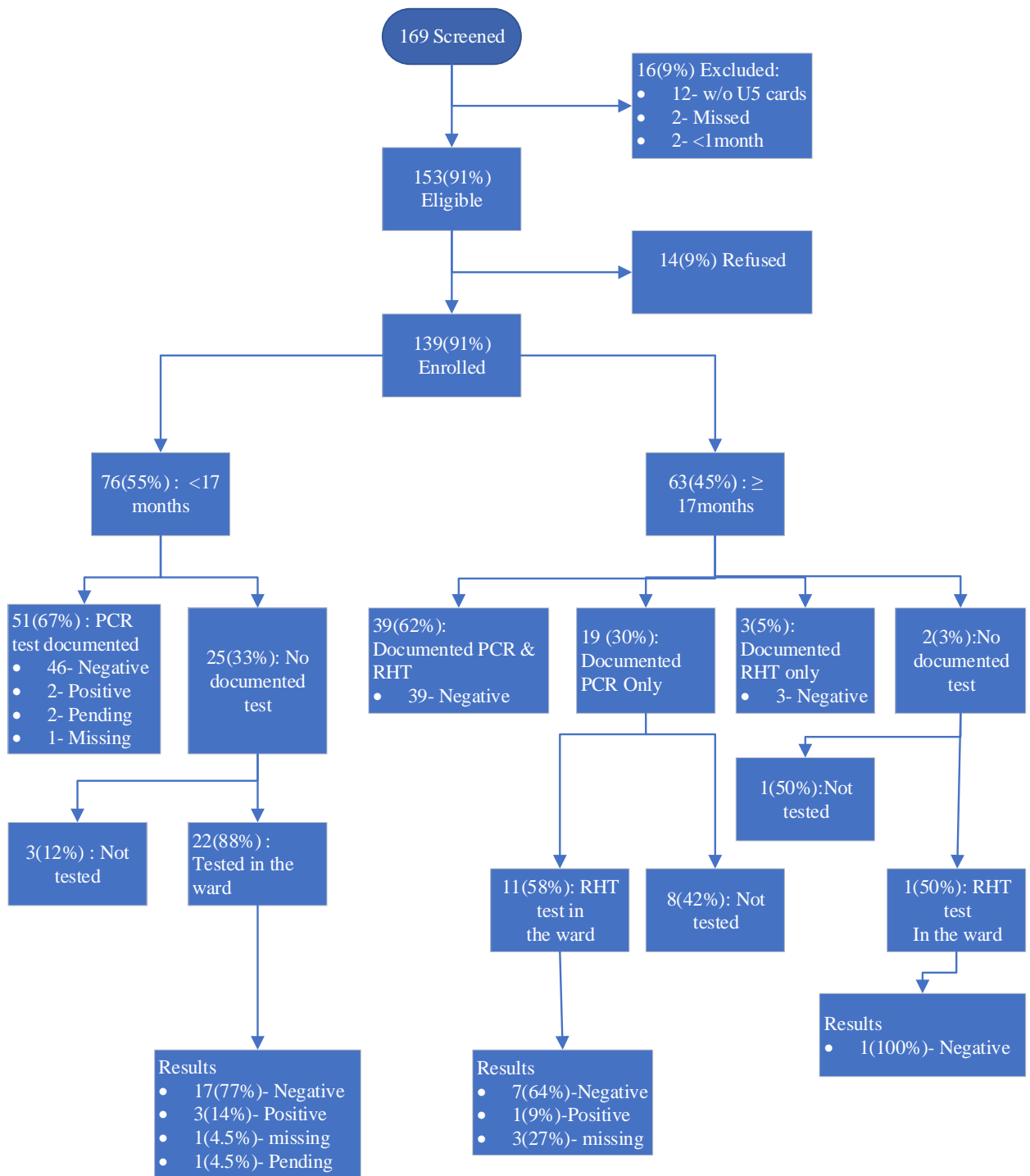


Figure 1: Study flow diagram

Tested - Children with documentation in their cards. Abbreviations: U5-Under five child welfare cards ; RHT- Rapid HIV test ;PCR- Polymerase Chain Reaction

Table 1: Baseline characteristics of cohorts

Characteristics	Total (n=139)	Tested (n=112)	Not tested (n=27)	P-value
Age (months), median (IQR)	14 (5-32)	18 (8-35)	3.5 (1.63 -9)	<0.001
Gender, n (%)				
Male	81	67(60)	14(52)	0.451
Female	58	45(40)	13(48)	
Place of residence, n(%)				
Political district				0.735
Southern	50	41(37)	9(33)	
Kweneng	35	27(24)	8(30)	
Central	24	20(18)	4(14)	
North-east	8	7(6)	1(4)	
South-east	7	4(4)	3(11)	
Kgalagadi	5	4(4)	1(4)	
Kgatleng	4	4(4)	0(0)	
Ngami-land	3	3(2)	0(0)	
Ghanzi	3	2(1)	1(4)	
Chobe	0	0(0)	0(0)	
Feeding method, n (%)				
Formula	106	83(74)	23(85)	0.298
Breast	30	27(24)	3(11)	
Mix	3	2(2)	1(4)	
Subspecialty, n (%)				
Gastrointestinal	30	21(18)	9(33)	0.109
Neurology	27	22(19)	5(19)	
Pulmonology	26	20(17)	6(21)	
Cardiology	12	12(10)	0(0)	
Orthopaedics/Trauma	9	9(8)	0(0)	
Infectious disease	9	4(4)	5(19)	
Urogenital	5	5(5)	0(0)	
Toxicology/ Burns	5	5(5)	0(0)	
ENT	5	4(4)	1(4)	
Metabolic/endocrine	3	3(3)	0(0)	
Haematology/Oncology	2	2(2)	0(0)	
Renal	2	1(1)	1(4)	
Plastic surgery	2	2(2)	0(0)	
Ophthalmology	1	1(1)	0(0)	
Maxillo-facial	1	1(1)	0(0)	
Ward admitted, n (%)				
PMW	101	79(71)	22(82)	0.252
PSW	38	33(29)	5(18)	

Abbreviations: IQR- interquartile range, ENT- Ear Nose and Throat.

The median age was 14 months and those who were not tested were statistically significantly younger ($p < 0.001$). There were no admissions from Chobe district.

Table 2 : Baseline characteristics of caregivers of the cohorts

Characteristics	Total	Tested n=112	Not tested n=27	Unadjusted P-value	Adjusted Odds Ratio	
					OR	95% CI
Age, years, n (%)						
<18-24	11	8(7)	3(11)	0.439	0.89	0.49, 1.60
25-34	59	49(44)	10(37)			
35-44	61	50(45)	11(41)			
>45	7	4(3)	3(11)			
Unknown	1	1(1)	0(0)			
Marital status, n (%)						
Unmarried	122	97(87)	24(89)	0.866	0.91	0.22, 3.67
Married	17	14(13)	3(11)			
Education background, n (%)						
Primary	20	17(15)	3(11)	0.106	1.08	0.69, 1.71
Junior	56	42(38)	14(52)			
Secondary	43	35(31)	8(30)			
Tertiary	16	16(14)	0(0)			
None	4	2(2)	2(7)			
Distance from local health facility, km, n (%)						
10/<	135	110(98)	25(93)	0.101	0.46	0.09, 2.22
11-20	3	1(1)	2(7)			
>20	1	1(1)	0(0)			

Abbreviations: KM- kilometers

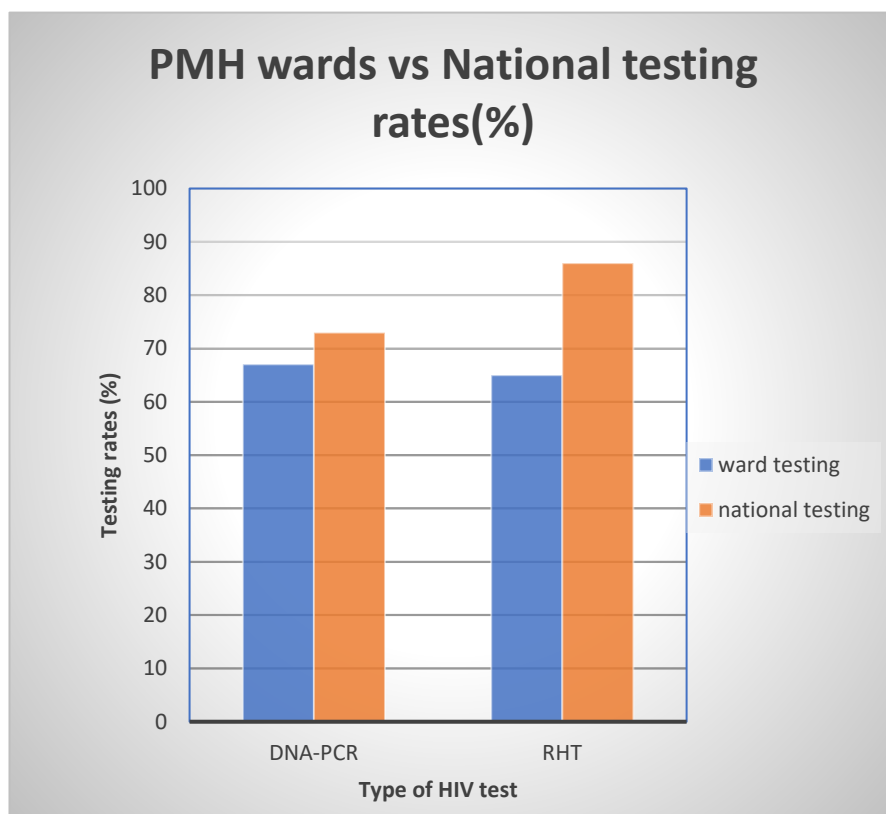
None of the caregivers was a widow/widower.

*Adjusted- only for those with PCR results and multivariate model used was logistic regression.

3.1.2 HIV testing rates on admission vs national testing rates

Testing rates assessed before admission in the ward for DNA-PCR at four to eight weeks of age was 67% vs national testing rate of 73% and for RHT at 17-24 months was 65% vs 86%.

Figure 2: Princess Marina wards vs national HIV testing rates



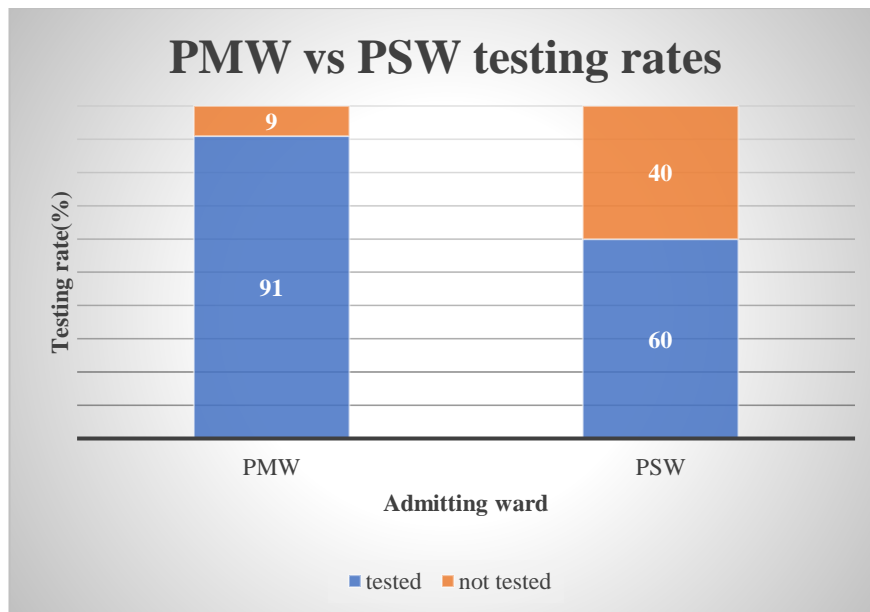
3.1.3 PMH ward HIV testing rates

Overall a total of 27 (19.4%) participants were admitted without any HIV tests and 23 (85%) got tested in the wards while four (15%) were not tested.

3.1.4 PMW vs PSW testing rates

Figure 3 below shows testing in each ward: More patients admitted to PMW without a documented HIV test were tested during their admission compared to PSW, but it was statistically not significant ($p = 0.144$). PMW had 20 (91%) participants who got tested and two (9%) who did not get tested, while PSW had three (60%) participants who got tested and two (40%) did not get tested during admission. From those that were not tested for DNA-PCR, one was from PMW who demised before test could be done and the other two participants were admitted in PSW. For RHT one participant was missed by clinicians in PMW. Sixty percent (60%) of those who got tested in PSW during their admission were all under 17 months and they got tested because the PI did the test herself at the parent's request.

Figure 3: HIV testing rates between PMW and PSW

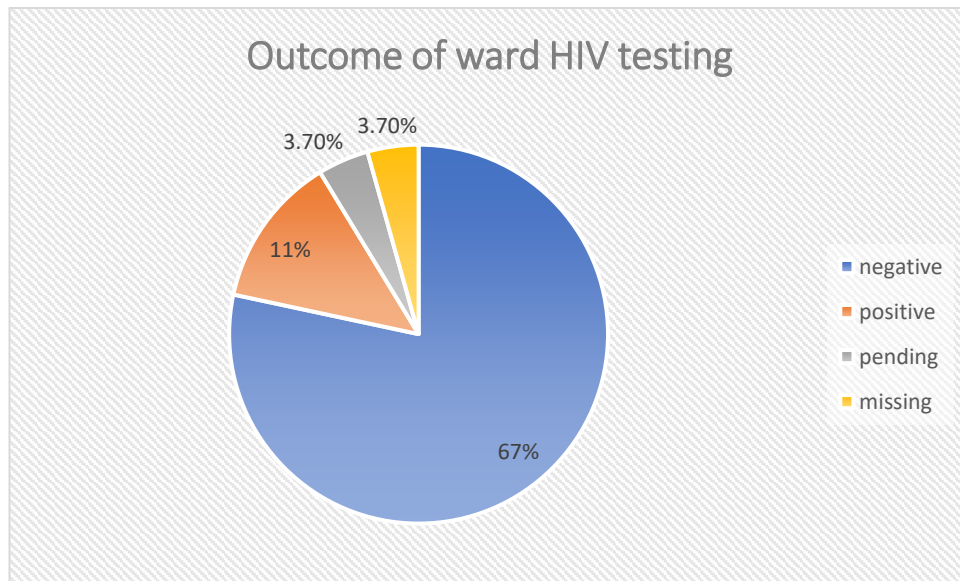


3.1.5 Outcome of ward HIV tests

From the 27 (19.4%) who got admitted without any documented test 23 (85%) got tested in the wards and their results are as follows: 18 (66.6%) – negative, three (11.0%) – positive,

one (3.7%) – pending, one (3.7%) – had missing results as shown below in figure 4. One (3.7%) participant whose results were pending had an initial DNA-PCR done during the admission and was indeterminate hence the repeat which was pending at the time the study was conducted. For the other one (3.7%) participant who had missing results the DNA-PCR was done at accident and emergency and the card was never received at the laboratory.

Figure 4: Outcome of ward HIV testing



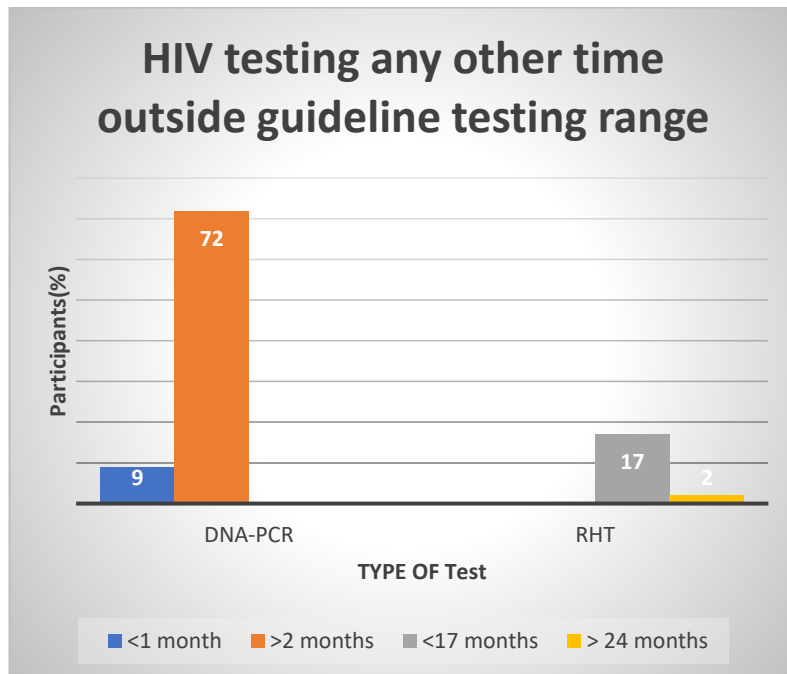
There were other participants 20 (32%) who were more than 17 months who came with PCR results only but were eligible for RHT. The wards tested 12 (60%) for RHT and the results are as follows: eight (40%) were negative, one (5%) positive, three (15%) with missing results and eight (40%) were not tested.

3.1.6 HIV Testing rates outside the normal testing age range

Some participants had documented test results, but the tests were done outside the guideline expected testing age that is, for DNA-PCR testing: less than one month of age – (9%) , more

than two months of age – (72%) and for RHT testing: less than 17 months of age – (17%), more than 24 months of age – (2%) as shown in figure 5 below.

Figure 5: HIV testing rates outside the guideline testing age range



3.1.7 Factors associated with failure to test

Factors that were looked at which could be associated with failure to test were caregiver’s age, level of education and marital status then the distance between place of residence and local facility. We used a multivariate model to assess for caregiver factors associated with PCR testing. None of the factors included in the model were statistically associated with testing.

3.1.8 Documentation

There were 103 (74%) of participants who had documentation on the designated PMTCT page in the under-five child welfare card and 36 (26%) had no documentation. Out of the 103

(74%) participants with documentation 44 (43%) were under 17 months of age and had DNA-PCR results. For those over 17 months 19 (18%) had DNA-PCR results only, 3 (3%) had RHT results only and 37 (36%) had both DNA-PCR and RHT results documented on the PMTCT page. The ones with no documentation included those who had records in any other page in the under-five child welfare card and those without documentation at all.

CHAPTER 4

4.1 DISCUSSION

This study demonstrated a lower HIV testing rate for DNA-PCR and RHT within the sick cohort admitted to PMH compared to national HIV testing rates as we had anticipated. The results of this study are 5% more than the 62% for DNA-PCR and 8% less than 73% for RHT test as hypothesized. Although not as high as hypothesized the lower testing rates support the hypothesis that HIV exposed hospitalized children tend to have lower routine HIV care, including HIV testing according to guidelines. There are no studies that compare testing between those who are admitted and the national testing rates but there is a study by A. Dramowski et al done at Chris Hani Baragwanath, where they had 54.1% of the cohort being newly diagnosed in the hospital and 92% of them had advanced disease. They also reported that 87.5% had delayed DNA-PCR testing⁵¹. This just shows that the incidence of HIV in admitted population is quite high hence the need for continuous testing in the paediatric wards. Another study done in Kenya also showed poor adherence to HIV testing guidelines with the HIV testing rate of less than 50%⁵².

The baseline characteristics of the cohorts were similar except for age in the documented vs undocumented test which is significant ($p = <0.001$). The median age for those with undocumented test was three months and two weeks, this could explain the age difference since some participants were admitted before PCR test was due and some before collection of results due to long turn-around time of PCR results.

The majority of participants who came without any documented test got tested in the ward and for PSW, more than half of those who got tested during their admission were all under 17 months and they got tested because the PI did the test at the parent's request. The PI facilitated the testing in PSW, and this might have affected findings of the study, that is testing

rates in PSW would have been lower. Despite monitoring participants that needed testing and recommending testing to the clinicians, fifteen percent (15%) of all the participants who came without a documented test were discharged without any HIV test done in the ward. Some of the reasons when the clinicians were asked and from observation by the PI were: they got admitted and discharged over the weekend or holidays, just missed by doctors and in PSW clinicians do not think it is their primary concern so they do not bother checking the children's HIV exposure and testing, and the designated staff that do RHT in the wards did not show up when they were called for testing.

Although it was not statistically significant due to small numbers PSW had low testing rates. This could be because HIV testing is perceived as primarily the physician's responsibility and the PI observed that the surgeons do not include nor screen for HIV exposure as there was no documentation of such in the inpatient's files. Maybe if PSW had large numbers the difference between the two wards would have been statistically significant. This is an area that could be further explored. A study done in a paediatric emergency department in South Africa concluded that surgeons fail to recognise HIV infected children and only 5% of their cohort got tested for HIV and 55% of those tested were HIV positive⁵³. Auditing wards and other entry points where HIV tests should be done and giving feedback, organising regular HIV testing training for new staff and training nurses on doing the DNA-PCR test and allowing laboratories to do RHT or send whole blood for DNA-PCR rather than only waiting for personnel trained to do DNA-PCR could improve testing in the wards.

The majority of the tested participants were negative (74%) which is as expected as Botswana currently has a lower MTCT rate of 0.67%¹⁹. The percentage number of women who receive ART during pregnancy is more than 95 % which is more than the United Nations target of 90% thus most women should have a known HIV status by delivery⁵⁴. Even though testing in the ward in this study only diagnosed HIV in 4.5% of the cohorts who were admitted without

any HIV test, there are reports that there is significantly higher prevalence of HIV in the hospital setting than PMTCT programmes, hence the need for routine HIV testing in inpatients⁵⁵. A study done in Kenya showed that HIV-exposed infants tested in hospital were four times as likely to be HIV-infected as those tested in the PMTCT clinic⁵⁵ and they concluded that hospital-based testing was more likely to detect an HIV infant than PMTCT testing⁵⁵. The PMTCT rate for Kenya in 2016 was 8.3%⁵⁶ which is much higher than Botswana's PMTCT rate, this could explain the different results. Given the higher yield of inpatient testing and given Botswana's PMTCT rates it's difficult to know if the findings of these studies would be the same in Botswana therefore more exploration is needed in this population.

All the participants who tested positive were non-citizens and were all under 17 months of age and had the first DNA-PCR test at five months when they got admitted. This is expected as during the time this study was conducted non-citizen did not have free access to ART in Botswana unlike the citizens. Including non-citizens in this study increased the newly diagnosed cases in the paediatric wards and this is a population we had to include because they do not have access to free PMTCT but once the children are sick they get admitted to the wards and treatment has to be arranged for them. Now Botswana government has introduced free ART to non-citizens since September 2019³⁶, so the HIV rates in this paediatric population should decrease.

One of the participants who tested positive, on admission had PCR results which were missing, the test was done at the local clinic and no results documented and child was more than 17 months of age. Currently it is not easy to follow up tests done from local clinics because they do not have the IPMS that district and referral hospitals use.

Most participants had the DNA-PCR test late. The late testing affects goals of EID negatively as those who are HIV infected would be diagnosed late and it means the health personnel are not adhering to testing guidelines. The good thing is that it also shows that the health care workers are recognising the children who were missed at the six weeks testing and testing them. Healthcare workers know the guidelines but other barriers to testing needs to be explored. Those who were tested before one month of age (9%) were enrolled in a study for birth PCR with Botswana Harvard Partnership Institute. Two percent (2%) of the patients had the RHT after two years of age, this could also have a negative impact on EID and lead to late diagnosis and initiation of ART²⁰. For the who were not tested on time or not tested at all, the barriers in this population needs to be studied. With great PMTCT rates in Botswana ,specific groups need to be targeted, that is offer birth PCR testing for the high risk or those who do not have access to PMTCT programmes⁵⁷. Birth PCR could be offered to babies whose mothers were not on PMTCT and non-citizen babies born to mothers who were not on PMTCT as this would aid in diagnosing prenatally acquired HIV and initiation of treatment will be done early.

None of the caregiver's characteristics were associated with late PCR testing despite studies showing some of these factors to be obstacles to HIV testing. A study by E.W. Murange found some of these factors to be structural barriers affecting health care access⁷, and from the PI's observation and talking to the parents they mentioned lack of transport money as a major issue when it comes to going for testing or going back to get test results. Another study by Camille Ndongki et al in Code d'Ivoire found poverty as one of the barriers in testing for HIV as well⁴³. Findings for this study being different from the other studies could be that in this study the majority of the cohort lived in close proximity to healthcare facilities and Botswana has good access to free healthcare. For the study done by E.W. Murange the study

population was in a rural area and cohorts were randomly selected. In addition, their age range was one to five years and over half of the caregivers had no formal education.

We also looked at documentation of HIV exposure and results in the under-five child welfare cards. The study found out that there is poor documentation of the either HIV exposure or results in the PMTCT page, this makes it difficult for health care workers to identify children who need testing. Documentation of the test results can help prevent unnecessary re-testing and reduce the financial burden in the health system. There is need to improve the way HIV test results are given to patients, for example use of the message system⁵⁸ to let the parents know that the results are at the facility, rather than expecting caregivers to go back to facilities when there is no guarantee that they will find the results. This could improve turn-around time and documentation. Decentralisation of DNA-PCR and establishing a rapid point of care could reduce the turn-around time for results³².

4.2 Study limitations

We acknowledge that the study has limitations. The study relied on a sample size in a single referral hospital and the results might not be generalisable to the whole population of children under the age of five years in Botswana. We included some non-citizens as part of the cohort which the national testing rates excludes although those born in Botswana should be following local guidelines. We also acknowledge that some participants were missed, especially those that did not stay in the wards for more than a day. During screening, because of poor documentation of the HIV exposure status on the under-five child welfare card, we had to rely on mother's word of mouth about their HIV status during pregnancy, and we acknowledge that we might have missed some participants. Reinforcing importance of documentation of maternal status and children's test results if done could help.

Despite using prospective data, the PI had to go back to check for test results of RHT done during admission. RHT results are documented in the inpatient files and not the electronic lab system and some inpatient files were missing when the participants were already discharged. The candidate tested and encouraged teams to test and this could have diluted the findings on the post-admission testing rate, but we felt it was unethical to not to do it.

4.3 Conclusion

This study shows a lower HIV testing rate within the sick cohort with known exposure at birth compared to the national HIV testing rate. Majority of the participants who were admitted without previous HIV tests were tested in the wards. More emphasis on the importance of testing admitted children for HIV and proper documentation needs to be made as a way of bridging the gap with the missed opportunities, particularly for wards where it is less routine such as surgical wards. Caregiver and healthcare related barriers to paediatric HIV testing needs to be explored to help improve EID and we recommend further studies to explore these barriers.

CHAPTER 5

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6.1 APPENDICES

Appendix A: Data collection form

HIV Test Data Collection Form

Study Number.....

Age D.O.B/...../..... Gender: M /F Place of Residence.....

Date of admission (DD/MM/YYYY)/...../..... Admit ward: PMW/PSW

Main admission diagnosis Feeding: breast/ formula/ mix

Type of Test	date test done& age test done	Tested in the ward (Y/N)	Outpatient records(Y/N)		Inpatient records(Y/N)			
			Under 5 card	General OPD card	Inpatient file	Discharge summary	IPMS	
DNA-PCR								
Double RHT								
DNA-PCR results								
RHT results								

Caregiver's information

Age (years)	
<18	
18-24	
25-34	
35-44	
45-54	
55-64	
65 and older	

Marital status:

Single Married Divorced Widowed

Education Background:

None Primary Junior Secondary Tertiary

Distance from local health facility:

10km/ < 11 – 20km >20 km

Appendix B: Health Research and Development Committee, Ministry of Health and Wellness

PRIVATE BAG 0038
GABORONE
BOTSWANA
REFERENCE:



REPUBLIC OF BOTSWANA

MINISTRY OF HEALTH AND WELLNESS

TEL: (+267) 363 2500
FAX: (+267) 391 0647
TELEGRAMS: RABONGAKA
TELEX: 2818 CARE BD

REFERENCE NO: HPDME: 13/18/1

01 September 2017

Health Research and Development Division

Dr Unami Elias
University of Botswana
Private Bag 00708
Gaborone

Dear Dr Unami Elias

PERMIT: ADHERENCE TO HIV TESTING GUIDELINES AMONGST HIV EXPOSED PEDIATRIC INPATIENTS IN PRICESSE MARINA HOSPITAL

Your application for a research permit for the above stated research protocol refers. We note that your proposal has been reviewed and approved by University of Botswana Review Board.

Permission is therefore granted to conduct the above mentioned study. This approval is valid for a period of 1 year effective 01 September 2017.

This permit does not however give you authority to collect data from the selected site(s) without prior approval from the management. Consent from the identified individuals should be obtained at all times.

The research should be conducted as outlined in the approved proposal. Any changes to the approved proposal must be submitted to the Health Research and Development Division in the Ministry of Health and Wellness for consideration and approval.

Furthermore, you are requested to submit at least one hardcopy and an electronic copy of the report to the Health Research, Ministry of Health Wellness within 3 months of completion of the study. Approval is for academic fulfillment only. Copies should also be submitted to all other relevant authorities.

Thank you for your cooperation and your commitment to the protection of human subjects in research.

Yours faithfully


Ms S. Mosweunyane
for /PERMANENT SECRETARY



Vision: *A Healthy Nation by 2036.*
Values: *Botho, Equity, Timeliness, Customer Focus, Teamwork, Accountability*



Appendix C: University of Botswana IRB approval



Office of the Deputy Vice Chancellor (Academic Affairs)

Office of Research and Development

Corner of Notwane
and Mobuto Road,
Gaborone, Botswana

Pvt Bag 00708
Gaborone
Botswana

Tel: [267] 355 2900
Fax: [267] 395 7573
E-mail: research@mopipi.ub.bw

Ref: UBR/RES/IRB/BIO/GRAD/014

24th August 2017

Permanent Secretary
Ministry of Health and Wellness
The Permanent Secretary
Private Bag 0038
Gaborone, Botswana

RE: REQUEST FOR EXPEDITED REVIEW OF A RESEARCH PROPOSAL SUBMITTED BY DR UNAMI ELIAS

Since it is a requirement that everyone undertaking research in Botswana should obtain a Research Permit from the relevant arm of Government, The Office of Research and Development at the University of Botswana has been tasked with the responsibility of overseeing research at UB including facilitating the issuance of Research permits for all UB Researchers inclusive of students and staff.

I am writing this letter in support of an application for a research permit by Dr Unami Elias, a graduate student at the Faculty of Medicine at the University of Botswana. Dr Elias has proposed to conduct a study titled "Adherence to HIV testing guidelines amongst HIV exposed paediatric inpatients in Princess Marina Hospital". The overall objective of the proposed study is to assess testing as per Botswana HIV national testing guidelines in HIV exposed children under the age of 5 years admitted to PMH. It is hoped that the findings of this study will inform the paediatric department on how it is doing at catching vulnerable children on HIV testing and if the admitted population is a group that has missed the scheduled routine testing more than the general population. This will allow the department to develop interventions to assist this group if needed.

The Office of Research and Development is satisfied with the process for data collection, analysis and the intended utilisation of findings from this research.

We will appreciate your kind and timely consideration of this application.

We thank you for your usual cooperation and assistance

Sincerely,

Dr M. Kasule

Assistant Director for Research Ethics, Office of Research and Development



Appendix D: Princes Marina Hospital IRB approval

PLOT 1836 HOSPITAL WAY
TELEPHONE: 3621400
FAX: 3673776



RE PUBLIC of BOTSWANA

PRINCESS MARINA HOSPITAL
P. O. BOX 258
GABORONE
BOTSWANA

REF: PMH 5/79(325-2-2017)

6 September 2017

Dr Unami Elias
University of Botswana

Dear Dr Elias

RE: Adherence to HIV Testing Guidelines amongst Paediatric Inpatients in Princess Marina Hospital

The Research and Ethics Committee (REC) of Princess Marina Hospital met and discussed your request to conduct a study with the aforementioned title. **Full approval has been granted.**

Please observe the following:

1. Ask for permission from the head of department that you will be doing your research in.
2. Please ask for informed consent at all times where it is needed.
3. You will not change any aspect of your research without permission from the REC.
4. You need to report any unforeseen circumstances including the termination of the study to the REC.
5. You must allow the REC access to the study at anytime for purposes of auditing.
6. This permit is valid for one year; from 6 September 2017 to 5 September 2018.
7. At the end of the study you should give the research and ethics committee a hard copy and soft copy of your report.

Thank you

Sincerely,

A handwritten signature in blue ink, appearing to read 'Gladness O. Tlhomelang'.

Gladness O. Tlhomelang
Secretary Research and Ethics Committee

Appendix E: Informed English consent form

PROJECT TITLE: A study to assess adherence to HIV testing guidelines for HIV exposed pediatric inpatients in Princess Marina Hospital, Gaborone, Botswana.

Principal Investigator: Dr Unami Elias

Phone number(s): 3621414/ 72893288

What you should know about this research study:

- We give you this informed consent document so that you may read about the purpose, risks, and benefits of this research study.
- You have the right to refuse to take part or agree to take part now and change your mind later.
- Please review this consent form carefully. Ask any questions before you decide.
- Your participation is voluntary.

PURPOSE

You are being asked to allow your child to participate in a research study of assessing adherence to HIV testing guidelines for HIV exposed pediatric inpatients in Princess Marina Hospital, Gaborone, Botswana.

The purpose of the study is to contribute to improvement of early diagnosis of HIV in children. Your child was selected as a possible participant in this study because he/she fits the requirements to participate. Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over.

PROCEDURES AND DURATION

If you consent to your child participating in the study, you will be asked brief questions regarding the health status of the child. These questions are related to HIV and will take

between 5 and 10 minutes of your time. In addition, you are giving permission for the study team to review your child's health records, both outpatient and inpatient and lab records.

RISKS AND DISCOMFORTS

The main risk that can happen to your child is a disclosure of personal information. This can cause other people to have information regarding your child. As the study team we will do all we can to ensure that this information is kept confidential and others outside the team do not have access to personal information. Information about your child will be stored in a computer, which will be kept by one of the research team, and, will require a security password to access it. The password will only be known by the investigators. Your child's information will not be shared with anyone except the investigators. In addition, any paper records will not have identifiable information and will be kept in a locked cabinet in a locked office.

BENEFITS AND/OR COMPENSATION

This research study will help assess in some detail if your child was exposed to HIV and whether the child was tested for HIV at 6 weeks or and at 18 months. There is a chance that the study may discover that your child was never tested for HIV as they should have been and if this happens, the study team will let your doctor and nurse know so that they can test and treat your child correctly. There will be no form of compensation for allowing your child to participate in his study

The study will also add knowledge to healthcare workers about the benefit of HIV testing in children admitted to the ward and inform our ward policies.

CONFIDENTIALITY

The data from this investigation will be stored in a computer, which will be kept by one of the research team, and, will require a password to access it. The password will only be known by

the investigators. Your child’s information will not be shared with anyone except the investigators. None of these will be used for commercial use. We will be asking permission to look on the child’s outpatient card, inpatient card for HIV exposure or what is available on admission. The data collection forms will be stored in a locked cabinet in a locked office.

VOLUNTARY PARTICIPATION

Participation of child in this study is voluntary. If you decide not to allow your child to participate in this study, your decision will not affect the care that your child will receive in the hospital as an in-patient or in the future. If you decide to allow your child to participate, you are free to withdraw your consent and to discontinue participation at any time without penalty.

AUTHORIZATION

You are deciding whether or not to participate in this study. Your signature indicates that you have read and understood the information provided above, have had all your questions answered, and have decided to participate.

(dd/mm/yyyy)

Name of Research Participant (caregiver) (please print)

Date

(dd/mm/yyyy)

Signature of Staff Obtaining Consent

Date

If the caregiver consents but is unable to read or sign their name, the following signature line should also be placed under the area for the subject’s name and signature:

Name of Witness to Subject Mark or Consent	Signature of Witness to Subject Mark or Consent	Date/Time
---	--	-----------

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, the rights as a research participant; or if you feel that you have been treated unfairly and would like to talk to someone other than a member of the research team, please feel free to contact the Office of Research and Development, University of Botswana, Phone: Ms Dimpho Njadingwe on 355-2900, E-mail: research@mopipi.ub.bw, Telefax: [0267] 395-7573 Name: Mr. Moremi, Acting Chief Research Officer, Head of Health Research Unit, Ministry of Health, Private Bag 0038, Botswana: (+267) 3632775 Fax: (+267) 3910646

APPENDIX F: Setswana consent form

Mokwalo wa dintlha tsa tumalano

SETLHOGO SA DIPATLISISO: Thuto-tshekatsheko tse di sekasekang tshalo morago ya melawana ya itlhatlhobelo mogare wa HIV mo baneng ba amaneng le one, ba robaditsweng mo kokelong kgolo ya Princess Marina, Gaborone, Botswana.

Motlhotlhomise Mogolo: Dr Unami Elias

Megala: 3621414/72893288

Se o tshwanetseng go se itse ka dipatlisiso tse:

- Re lo neela bukana e faphegileng ya go itse ditumalano gore lo bale ka maikaelelo, diphatsa, le mosola wa dipatlisiso.
- O na le tshwanelo ya go dumelana kgotsa go gana go tsaya karolo, gape o letlelesegile go fetola mogopolo wa morago.
- Tswee-tswee bala ka kelotlhoko fomo e ya ditumalano. Botsa dipotso pele fa o ka tsaya tshwetso.
- Go tsaya karolo ga gago ke boithaopo.

MAIKAELELO

O kopiwa go letlelela ngwana wa gago go tsaya karolo mo thuto-tshekatsekong, e sekasekang tshalo morago ya melawana ya itlhatlhobelo mogare wa HIV mo baneng ba amaneng le one, ba robaditsweng mo kokelong kgolo ya Princess Marina, Gaborone, Botswana. Maikaelelo a dithuto tse ke go tsenya seabe mo go tokafatseng go tshwara mogare nako e santse e le teng mo baneng. Ngwana wa gago o tlhopilwe go ka nna motsaya karolo mo thuto-tshekatshakong ka gore o lekane ditsetlana tsa go tsaya karolo. Pele ga o baya monwana mo fomong, tswee-tswee

botsa dipotso ka karolo ngwe le ngwe ya thuto-tshekatsheko e, e tsietsang. O ka tsaya nako yotlhe e o e tlhokang go ikakanya.

DITSAMAISO LE SEBAKA SA NAKO

Fa o letlelela ngwana wa gago go tsaya karolo mo thuto-tshekatshekong e, o tla botswa dipotso ka boripana mabapi le botsogo jwa ngwana. Dipotso tse di amana le mogare wa HIV mme di tla tsaya metsotso e le tlhano go ya ko go e lesome mo nakong ya gago. Mo godimo ga moo, o tlaa bo o fa tetla ya gore ba dirang thuto-tshekatsheko e, ba ka lebelela ditshupo tsa botsogo jwa ngwana tsa fa a bonwa ko kokelong le tsa fa a robaditswe mo sepatela.

DIPHATSA LE TLHOKO PHUTHULOGO

Tekeletso kgolo e ka tsenyang ngwana mo diphatseng ke fa kitso ka ga gagwe e ka ntshetswa mo mpepeneng. Se ka baka gore batho ba bangwe ba nne le kitso mabapi le ngwana wa gago. Re le setlhopha sa baithuthuntshi re tla dira ka bojotlhe go rurifatsa fa kitso e e tla bewa sephiri le gore ba ditlhopha tse di kwa ntle ga ba na kamano epe le kitso ka ngwana wa gago. Kitso ka ngwana wa gago e tla bolokelwa mo sebaleng-makgolo, se se tla bong se tshwerwe ke mongwe wa setlhopha sa dipatlisiso, mme se tla tlhoka nomoro ya sephiri go tsena mo go sone. Nomoro e ya sephiri e tla itsewe fela ke batlhotlhomisi. Go tlaleletsa, tshupo e e mo pampiring e tla nna le kitso e e sephiri e e tla bewang mo kobotlong e e lotletsweng mo ofising e e lotletsweng.

MOSOLA LE PHIMOLO DIKELEDI

Patlisiso e e tla thusa go sekaseka ka botlalo fa ngwana wa gago a ka tswa a ne a amane le mogare wa HIV le gore a ngwana o ne a tlhatlhobelwa mogare wa HIV a le dibeke tse thataro kgotsa dikgwedi tse di lesome le boferabobedi. Go na le kgonagalo ya gore thuto-tshekatsheko e ka lemotsha fa ngwana wa gago a ise a tlhatlhobelwe mogare wa HIV jaaka go ne go tshwanetse, mme fa se se ka diragala, setlhopha sa thuto-tshekatsheko se tla bolelela ngaka le

mooki gore ba ba tlathlobe, a bo ba ka alafa ngwana ka fa go tshwanetseng. Go tla bo go sena phimolo dikeledi ya mofuta ope fa o letlelela ngwana go tsaya karolo mo thuto-tshekatshekong e. Thuto-tshekatsheko e tla oketsa kitso ya babereki jwa lephata la botsogo ka bo mosola jwa go tlathloba mogare wa HIV mo baneng ba ba robaditsweng mo kokelong le go ba itsise melawana ya kokelo.

TSHIRELETSO YA DIKITSO TSA GAGO

Motlhokomedi wa ngwana o tla itsisiwe le go kopiwa tetla go tsaya karolo mo thuto-tshekatshekong mo ofising ya tshidilo maikutlo ko bana ba robaditsweng teng. Dikitso tsothe tsa tlhotlhomiso e di tla bolokelwa mo sebaleng-makgolo, se se tla bong se tshwerwe ke mongwe wa setlhopha sa dipatlisiso, mme se tla tlhoka nomoro ya sephiri go tsena mo go sone. Nomoro e ya sephiri e tla itsewe fela ke batlhotlhomisi ba mmadikolo. Kitso ka ngwana wa gago ga e kake ya bolelelwa ope kwa ntleng ga batlhotlhomisi. Sepe sa dipatlisiso se tla dirisetswa kgwebo. Re tla kopa tseletso go bona karata ya ngwana wa molwetse ya ko kokelong, le karata ya ngwana yo mo kokelong yo amaneng le mogare wa HIV kgotsa sepe fela se se leng teng ka nako ya ngwana a robadiwa. Difomo tsa dipatlisiso di tla bewa di lotleletswe mo kobotlong, mo ofising e e lotletsweng.

GO TSAYA KAROLO GA BOITHAOPPO

Go tsaya karolo ga ngwana mo thuto-tshekatshekong e, ke boithaopo. Fa o ka tsaya tshwetso ya go gana gore ngwana a tseye karolo mo dipatlisisong tse, tshwetsho ya gago ga e ka ke ya ama tlhokomelo e ngwana wa gago a ka e bonang mo kokelong jaaka molwetse kgotsa mo nakong e e tlang. Fa o ka tsaya tshwetso ya go letlelela ngwana go tsaya karolo, o a letlelelega go gogela morago tetlelelo le go emisa go tsaya karolo ka nako ngwe le ngwe ntle le kotlhao epe.

TETLELELO

O tsaya tshwetso ya go dumela kgotsa go gana go tsaya karolo mo thuto-tshekatshekong e. Monwana wa gago o kaya fa o badile ebile o tlhalogantse mokwalo yo o filweng fa godimo, dipotso tsotlhe tsa gago di arabilwe, le gore o tsere tshwetso go tsaya karolo.

_____ (DD/MM/YYYY)

Leina la motsaya karolo mo patlisisong (kwala)

_____ Letsatsi

_____ (DD/MM/YYYY)

Leina la mosupi

Monwana wa mosupi

Letsatsi/Nako

Monwana wa modiredi yo tsayang tumalano

_____ Letsatsi

Fa motlhokomedi a dumalana mme a sa kgone go bala le go baya monwana, tselana ya peo monwana e e latelang e tshwanetswe go bewa ka fa tlase ga kgaolwana ya leina le monwana ya motsaya karolo:

O TLA FIWA SEKAO SA FOMO YA TUMALANO GO SE IPEELA.

Fa o na le dipotso mababi le patlisiso e, kgotsa o na le dipotso ka fomo ya tumalano go feta fa motlhotlhomisi a emeng teng, ga mmogo le dipotso ka patlisiso, tshwanelo tsa gago o le motsaya karolo wa patlisiso, kgotsa o ikutlwa eketse ga wa tsewa sentle mme o eletsela go ka buwa le mongwe yo eseng leloko la setlhopha sa dipatlisiso, tsweetswee phuthologa go ka

itshwaraganya le ofisi ya dipatlisiso le ditlhabololo, kwa mmadikolo wa Botswana le ba lephata la botsogo. Leina la yo o ka ikgolaganyang le ene: Mme Dimpho Njadingwe, Mogala: 355-2900, E-mail: research@mopipi.ub.bw, Telefax: 395-7573

Leina: Mogolwana wa tsa dipatlisiso, Mogolwane wa lephata la dipatlisiso tsa botsogo, Lephata la Botsogo, Private Bag 0038, Botswana: (+267) 3632775, Fax: (+ 267) 3910646