A CASE-CONTROL STUDY ON NON-DISCLOSURE OF HIV POSITIVE STATUS TO A PARTNER AND MOTHER-TO-CHILD TRANSMISSION OF HIV

by

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Student number: 48109916

D E C L A R A T I O N

I declare that **"A CASE-CONTROL STUDY ON NON-DISCLOSURE OF HIV POSITIVE STATUS TO A PARTNER AND MOTHER-TO-CHILD TRANSMISSION OF HIV"** is my own work, and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references. I further confirm that this work has not been previously submitted for any other degree at any other institution.

31 January 2015

_____ _____

SIGNATURE **DATE**

Joram Lawrence Nyandat

A CASE-CONTROL STUDY ON NON-DISCLOSURE OF HIV POSITIVE STATUS TO A PARTNER AND MOTHER-TO-CHILD TRANSMISSION OF HIV

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ABSTRACT

Background: Non-disclosure of HIV positive status to a partner threatens to reverse gains made in prevention of mother-to-child transmission (PMTCT) in resource limited settings. Determining the association between non-disclosure and infant HIV acquisition is important to justify focussing on disclosure as a strategy in PMTCT programmes.

Objective: To determine the association between non-disclosure of HIV positive status to a partner and mother-to-child transmission (MTCT).

Methods: Using a matched case-control design, we compared 34 HIV positive infants to 146 HIV negative infants and evaluated whether the mothers had disclosed their HIV status to their partner.

Results: Non-disclosure was more frequent among cases (overall, 16.7%; cases, 52.8%; controls 7.6%), $p<0.001$ and significantly associated with MTCT (aOR 8.9 (3.0-26.3); $p<0.0001$), with male partner involvement partially mediating the effect of non-disclosure on MTCT.

Conclusions: There is a need for PMTCT programmes to focus on strategies to improve male partner involvement and partner disclosure without compromising the woman's safety.

KEY WORDS

Non-disclosure; MTCT; vertical transmission; male partner involvement; matched case-control study; HIV status.

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Dedication

To my dear wife, Jackie, whose love, tolerance and unwavering support gave me the determination to complete the study, and to my loving daughter Claire, who always reminded me, by pointing, that I needed to open the computer.

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LIST OF ABBREVIATIONS

AIDS	Acquired immune deficiency syndrome
ARVs	Anti-retroviral drugs
EMTCT	Eliminating mother-to-child HIV transmission
HAART	Highly active antiretroviral therapy
HIV	Human immunodeficiency virus
MTCT	Mother-to-child transmission
PCR	Polymerase chain reaction
PMTCT	Prevention of mother-to-child HIV transmission
SPSS	Statistical Package for Social Sciences
UNAIDS	United Nations Program on HIV/AIDS
WHO	World Health Organization

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CHAPTER 1

ORIENTATION TO THE STUDY

1.1 INTRODUCTION

"The world has a unique opportunity for an AIDS-free generation.
We owe this to our children".

Michel Sidibé, UNAIDS Executive Director

A heartrending outcome of HIV infection in women is the ability of transmitting the virus from the mother to the child. The above statement by the United Nations Program on HIV/AIDS (UNAIDS) Director is a reminder, and a call for everyone to take advantage of the opportunity to right an injustice that nature bequeathed upon innocent children.

Although the global community has committed itself to accelerate progress in the prevention of mother-to-child HIV transmission (PMTCT), and a lot of achievements made with a 58 percent reduction in the number of new HIV infections among children between 2002 and 2013 globally, cases of children being infected by their mothers still abound. In 2013 alone, more than 240,000 children were infected with HIV, an equivalent of 700 new infections every day (UNAIDS 2014:8). The high incidence of HIV among children, especially in sub-Saharan Africa has contributed to the increased infant and child mortality, and is credited with the reversed gains realised in child health and survival in the last decade (United Nations Children's Fund 2008:7), clearly demonstrating the need and importance of eliminating mother-to-child HIV transmission (EMTCT) (United Nations Program on HIV/AIDS 2013:28).

Antenatal HIV testing and counselling and partner disclosure are pillars of PMTCT. These two strategies empower HIV positive women to make early decisions regarding their health and that of their baby, which promotes adherence to PMTCT interventions (Baggaley, Hensen, Ajose, Grabbe, Wong, Schilsky, Lo, Lule, Granich & Hargreaves 2012:653). Whereas the uptake of antenatal HIV testing and counselling has been high, partner disclosure has remained low, raising concern about the possibility of non-disclosure of positive HIV status by pregnant women to their partners being a hindrance

to EMTCT (Villar-Loubet, Bruscantini, Shikwane, Weiss, Peltzer & Jones 2013:264). The concern is validated by the adoption of a "combination HIV prevention strategy" by the World Health Organization (WHO) due to synergistic roles of biomedical, behavioural, structural and supportive risk factors in MTCT (World Health Organization 2013:84).

While a lot of studies have focussed on determining the association between clinical risk factors and MTCT, evaluation of the impact of behavioural risk factors particularly non-disclosure of positive HIV status to a partner on MTCT has not been extensively investigated. The study therefore determined, using a case-control study, the nature of association between non-disclosure of positive HIV status to a partner and MTCT.

1.2 BACKGROUND INFORMATION ABOUT THE RESEARCH PROBLEM

1.2.1 Source of the research problem

Working as an improvement advisor in maternal, neonatal and child health led to the conceptualisation of this study. It was noted that in addition to many HIV positive pregnant women in rural health facilities in Kenya being unaware of their partner's HIV status, the majority of them were also not being accompanied by their partners during clinic visits as a show of support. In 2012, less than 4.5% of HIV positive pregnant women in Kenya were accompanied by their partners to the clinic, and less than 3% were unaware of their partner's HIV status (National AIDS Control Council 2014:14, 21). The two observations begged the questions of whether a HIV positive woman would willingly disclose her status to her partner despite being unaware of his status. Would the poor show of support by the male partners be explained by non-disclosure? And since in most rural African settings men are still the primary decision makers and as such determine the health seeking behaviours of their women and children, would the non- disclosure and lack of male partner support impact on MTCT?

Preliminary literature searches identified an information gap. While rates, barriers and effects of disclosure have been extensively studied, to my knowledge, no study in Kenya, and very few studies globally have directly evaluated the association between non-disclosure of HIV positive status to a partner and MTCT, and whether the

association is indirectly mediated through lack of male partner support. Therefore the necessity and importance of this study is evident.

1.2.2 Background to the research problem

MTCT is responsible for more than 90% of HIV infections in children (The Independent Expert Panel 2010:3), and can occur during pregnancy, childbirth, or through breast feeding (Ahmad 2011:982). Without any intervention the risk of transmission is 15-30% in non-breastfeeding populations and 20-45% in breastfeeding populations (World Health Organization 2013:84). However, the risk of transmission can be reduced to less than 1% through PMTCT interventions as demonstrated in high income countries (Frange & Blanche 2014:692; Townsend, Cortina-Borja, Peckham, De Ruiter, Lyall & Tookey 2008:978). Unfortunately, many countries in sub-Saharan Africa still experience high MTCT rates. For example, the MTCT rate in Kenya stands at 16% (Kenya National AIDS and STI Control Programme 2013:17).

In sub-Saharan Africa, lack of partner support for HIV positive women attending antenatal clinic is one of the obstacles in the elimination of MTCT (Aluisio, Richardson, Bosire, John-Stewart, Mbori-Ngacha & Farquhar 2011:80). Male partner support is crucial as it enhances optimal uptake of PMTCT services (Njunga 2008:68; Villar-Loubet et al 2013:266). However, for support to be offered, disclosure must happen (Bachanas, Medley, Pals, Kidder, Antelman, Benech, DeLuca, Nuwagaba-Biribonwoha, Muhenje, Cherutich, Kariuki, Katuta & Bukuku, for PWP study group 2013:429).

The benefits of partner disclosure are well known. In addition to the public health benefits of expanded awareness of risk that may lead to decreased sexual risk-taking and ultimately decreased transmission of HIV, there are potential benefits on MTCT. Overall, males who take part in healthcare processes (antenatal PMTCT or HIV testing) have more knowledge of, and involvement in, their families' health and subsequently better support women to prevent infant HIV infection (Aluisio et al 2011:81). Specifically, disclosure increases the uptake of antiretroviral drugs for PMTCT, including early initiation of HAART and enhanced uptake of infant prophylaxis (Aluisio et al 2011:80; Jasseron, Mandelbrot, Dollfus, Trocmé, Tubiana, Teglas, Faye, Rouzioux, Blanche, Warszawski & Trocme 2013:492). Moreover, as Stirratt, Remien, Smith, Copeland, Dolezal, Krieger and Team (2006:490) explain, patients are more likely to default on

medication to avoid potential communication of their positive HIV status. Disclosure also encourages uptake of appropriate infant feeding options as it encourages exclusive breastfeeding by releasing pressure from the mother on early initiation of mixed feeding usually advocated for by the extended family in an African setup (Madiba & Letsoalo 2013:8). Additionally, a woman whose spouse is aware of her HIV positive status is more likely to deliver at a health facility where they are likely to receive appropriate measures to lower the risk of MTCT (Kibera 2011:4572; Turan, Hatcher, Medema-Wijnveen, Onono, Miller, Bukusi, Turan & Cohen 2012:e1001295). Finally, disclosure may enable HIV positive individuals gain access to appropriate treatment, motivate them to change risky behaviour patterns, and encourage their sexual partners to seek counselling and testing services. In a polygamous set up, disclosure may also protect the other spouses from being infected. These actions may ultimately lower the number of children being infected through their mothers. (Medley, Garcia-Moreno, McGill & Maman 2004:304; Nkya, Davies, Nzioka & Mithwani 2010:3).

Due to these benefits, HIV positive clients, including those attending antenatal clinic, are routinely encouraged and supported to disclose their status, especially to their sexual partners (Jasseron et al 2013:495). However, this does not always happen, and is reflected in the varied disclosure rates among different populations and settings in Africa which range from as low as 16.7% to as high as 95% (Medley et al 2004:304). Comparing countries, the rates of disclosure are notably lower in developing countries. As reported by Maman and Medley (2011:6), in developing countries, the rates range from 16.7% to 86%, with an average rate of disclosure of 49%, a rate considerably lower than the 79% average rate reported from studies conducted in the developed world. This variance is also demonstrated in women, where those from developed world have an average rate of 71% compared to 51% in the developing world (Maman & Medley 2011:5). Importantly, and of direct impact to PMTCT is that the vital sub-group of pregnant women attending antenatal clinic are less likely to disclose their HIV status to their partners, as compared to the general population (Bachanas et al 2013:427).

Considering the importance HIV status disclosure plays in promoting access, uptake, and adherence to PMTCT interventions, and the low partner disclosure rate among pregnant women attending antenatal clinic, it was paramount to conduct a study to determine whether an association exists between non-disclosure of positive HIV status to a partner and MTCT. Addressing partner non-disclosure, in the setting of an

association between non-disclosure and MTCT, could have an enormous impact on the spread of HIV among children considering MTCT accounts for 90% of childhood HIV infections.

A review by Medley et al (2004:305) confirms that many studies on disclosure have focussed on patterns, fears and barriers to disclosure. The few studies that have directly focussed on the impact of non-disclosure to partners on MTCT have given conflicting and inconclusive results (Aluisio et al 2011:80; Bucagu, Bizimana, Muganda & Humblet 2013:10; Jasseron et al 2013:494; Roxby, Matemo, Drake, Kinuthia, John-Stewart, Ongecha-Owuor, Kiarie & Farquhar 2013:35) This study was therefore conducted against the background of these inconclusive results, and paucity of data on the association between non-disclosure of HIV status to partners and MTCT.

1.3 STATEMENT OF THE RESEARCH PROBLEM

While significant steps have been taken towards PMTCT, non-disclosure of a HIV positive status to male partners by women threatens the success of PMTCT programmes. The low rates of HIV status disclosure reported among women in antenatal settings have several implications for PMTCT programmes as the optimal uptake and adherence to such programmes is difficult for women whose partners are either unaware or not supportive of their participation (Aluisio et al 2011:81). Studies have documented that disclosure rates remain low in developing countries (Bachanas et al 2013:427; Jasseron et al 2013:494; Maman & Medley 2011:5). While rates, barriers to, and outcomes of disclosure have been widely studied, few studies have assessed the association between non-disclosure of HIV status to partners and MTCT. The question that therefore arose was: Is there an association between non-disclosure of HIV positive status to a partner, and MTCT at 6 weeks of age of the baby?

1.4 PURPOSE AND OBJECTIVES OF THE STUDY

1.4.1 Research purpose

The purpose of the study was to determine, using a case-control study, whether a direct association exists between non-disclosure of HIV positive status to a partner and MTCT.

1.4.2 Research objectives

The study sought to

- determine the proportion of mothers who did not disclose their HIV positive status to their partner among mothers of HIV exposed infants who turned positive at 6 weeks of age (case)
- determine the proportion of mothers who did not disclose their HIV positive status to their partner among mothers of HIV exposed infants who remained negative at 6 weeks of age (control)
- compare the proportion of exposure (non-disclosure of HIV positive status) between cases and controls in order to determine the association between non-disclosure of HIV positive status to a partner, and MTCT at 6 weeks of age
- determine whether male partner involvement mediates the effect of non-disclosure on MTCT
- recommend strategies for disclosure and male partner involvement as part of PMTCT

1.4.3 Research hypotheses

- Among HIV exposed infants, infants who turn positive at 6 weeks are more likely to have a mother who has not disclosed her HIV positive status to her partner as compared to HIV exposed infants who remain negative.
- Male partner involvement mediates the effect of non-disclosure on MTCT.

1.5 SIGNIFICANCE OF THE STUDY

The findings of this study inform the current body of research regarding the association between non-disclosure of positive HIV status by women to their partners and MTCT, providing suggestions on how to improve male partner involvement, and better disclose positive HIV status among pregnant women, without compromising on their safety and confidentiality. These contributions, will contribute to the overall reduction in MTCT. Finally, this study exemplifies how a case-control study can be used to show

association between two factors while demystifying the notion that a case-control study is too complex to be conducted by novice researchers.

1.6 DEFINITION OF KEY CONCEPTS

1.6.1 Partner

Free Merriam-Webster Dictionary (2014) defines a partner as someone's husband or wife or the person someone has sexual relations with. In this study, a partner was referred to any male designated by the mother as the father to the baby, or one who she has a sexual relationship with and is involved in the care of the baby.

1.6.2 HIV positive status

A HIV positive person is one who is HIV infected based on a positive HIV antibody test (rapid or laboratory-based enzyme immunoassay), confirmed by a second HIV antibody test (rapid or laboratory-based enzyme immunoassay) relying on different antigens or of different operating characteristics (Baveewo, Kamya, Mayanja-Kizza, Fatch, Bangsberg, Coates, Hahn & Wanyenze 2012:154). In this study, any mother who is reported as HIV positive based on the outcome of HIV tests conducted at a health facility was deemed to be HIV positive.

1.6.3 HIV exposed infant

A HIV exposed infant is defined as infants and children aged less than 18 months born to mothers living with HIV (Sugandhi, Rodrigues, Kim, Ahmed, Amzel, Tolle, Dziuban, Kellerman & Rivadeneira 2013:s187). In this study, a HIV exposed infant was taken as a baby born to a HIV positive mother between January 2013 and June 2014, and who met the eligibility criteria of the study.

1.6.4 Non-disclosure

The definition of non-disclosure by Maman and Medley (2011:3) as failure of informing another person or persons of ones HIV positive status was adapted in this study as failure of a mother with a baby born between Jan 2013 and June 2014 to disclose her positive HIV status to her partner.

1.6.5 Male partner involvement

In the context of PMTCT, a male partner is involved if he accompanies his pregnant spouse to antenatal clinic, receives counselling for HIV either individually or together as a couple and discloses his status to the partner, or provides financial assistance for partner's hospital visits (Kalembo, Zgambo, Mulaga, Yukai & Ahmed 2013:e66517). In this current study the variable used as a proxy for male partner involvement was male partner attendance at antenatal clinic with his partner.

1.7 CONCEPTUAL FRAMEWORK

The study focussed on the relationship between an infant's HIV status at 6 week of age and their mother's disclosure of positive HIV status to her partner, with infant HIV status being the outcome variable and mother's disclosure of positive HIV status to partner the predictor variable. Male partner involvement was hypothesised to affect the relationship between non-disclosure and infant HIV status, and was therefore the mediator variable (figure 1.1). Variables associated with the outcome and with a likelihood of being unevenly distributed between the cases and controls were measured: length/duration of relationship, parity of the mother, couple testing during pregnancy, awareness of partner's HIV status and disclosure to other people.

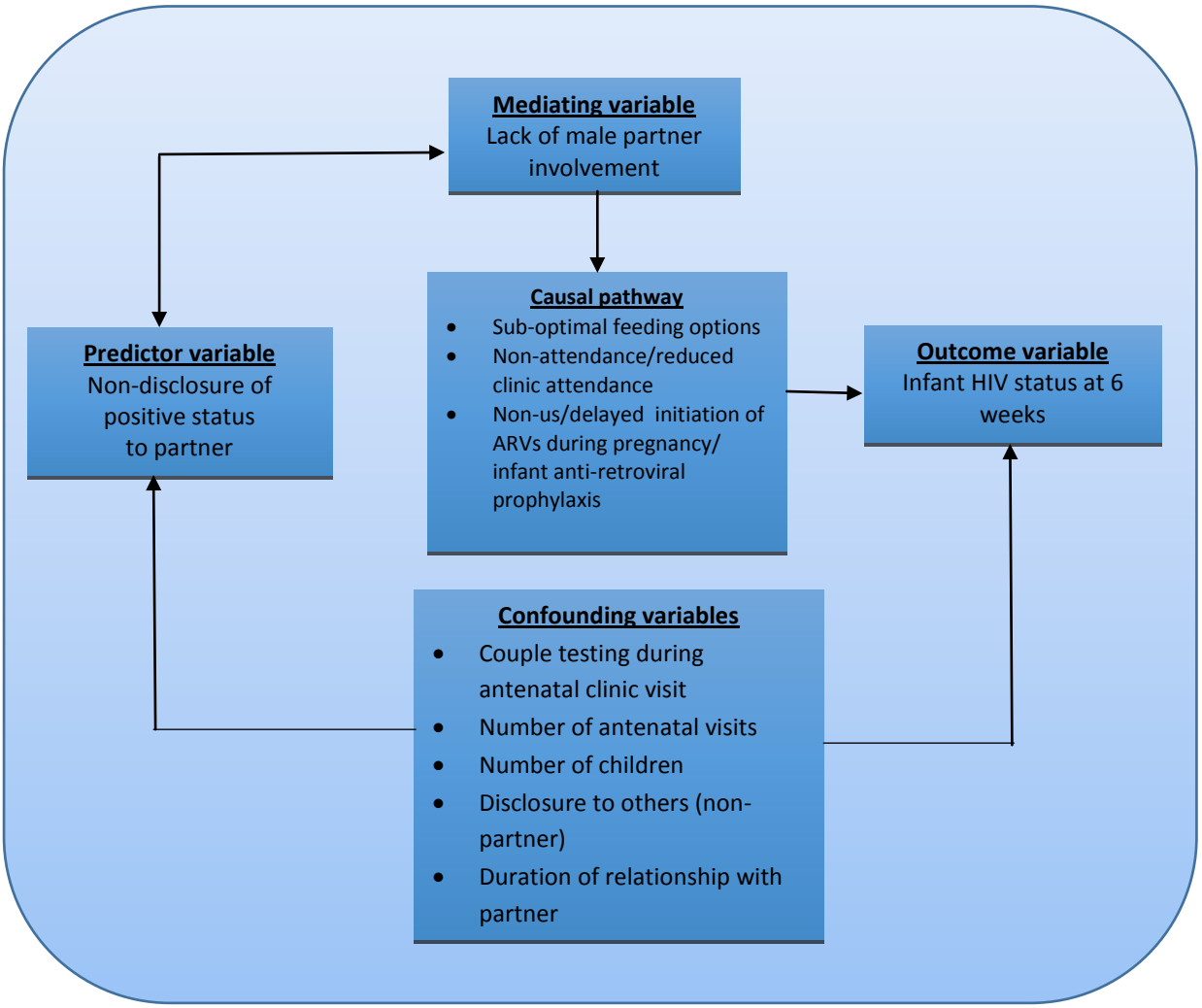

Figure 1.1: Relationship among variables

1.8 RESEARCH DESIGN AND METHOD

The section outlines the research design and methodology used in this study, with a more detailed description presented in chapter 3.

1.8.1 Research paradigm

To enable the researcher to test the hypothesis of whether an association between non-disclosure of HIV positive status and MTCT exists, the positivist research paradigm was selected. The paradigm assumes a reality independent of human observation exists, a reality that can be measured objectively using an orderly disciplined procedure to test the researchers hypothesis about the nature of the phenomena being studied and the relationship among them (Polit & Beck 2012:15). The paradigm ultimately led to

adoption of the quantitative approach which studies phenomena by way of precise measurement and quantification involving a rigorous and controlled design (Weaver & Olson 2006:460).

1.8.2 Research design

A 1:4 matched case-control study, a type of analytical observational design which measures the exposure and disease occurrence without intervening (Polit & Beck 2012:224) enabled the researcher compare the exposure level (non-disclosure of positive HIV status) between HIV positive and negative infants.

1.8.3 Population

1.8.3.1 Study population

The study population was defined as HIV positive women and their exposed infants delivered between January 2013 and June 2014 in line with the definition by Curtis and Drennan (2013:236) study population being the total number of units from which data can potentially be collected from.

1.8.3.2 Target population

The target population from whom the researcher gathered information and generalised findings to were HIV positive women aged 15-49 years and their exposed infants on follow up at a HIV comprehensive care centre in the developing world.

1.8.3.3 Accessible population

The accessible population, defined as the aggregate of cases that conform to designated criteria and that are accessible as subjects for the study (Polit & Beck 2012:274) was HIV positive women and their exposed infants, who were born between January 2013 and June 2014 and who had their HIV status determined by polymerase chain reaction test at 6 weeks of age, and were on follow up at a HIV comprehensive care centres within Siaya County, Kenya.

1.8.4 Sample and sampling procedure

Sampling is the process of selecting a group of subjects for a study in such a way that the individuals represent the larger group from which they were selected. This representative portion of a population is called a sample (Polit & Beck 2012:275). A sampling frame on the other hand refers to the source material from which a sample is drawn. It is a list of all those within a population who can be sampled, and may include individuals (respondent sampling), households or institutions (site sampling) (Katzenellenbogen & Joubert 2007:106; Polit & Beck 2012:275).

A list of all health facilities offering HIV comprehensive care in Siaya County served as the health facilities' sampling frame, from which referral health facilities from each sub-County was selected and included in the study. For respondent sampling, all HIV exposed infants in the year 2013/2014 on care at the selected facilities were identified from the HIV exposed infants cohort registers. For every case identified, four controls were identified by random sampling from the same register.

1.8.5 Data collection

Data collection is the capturing and translating of data so that the data can be analysed (Polit & Beck 2012:367). For this study the structured data collection approach was selected. The structured approach ensured that data were quantifiable by the use of numerical values.

Review of records involves use of data collected routinely as part of patient care, and for this study, the HIV exposed infants database was used to identify HIV exposed infants, and the PCR test result at 6 weeks used to classify them as cases or controls.

Self-reports was used to gather information from the respondents due to its ability to gather retrospective data about events occurring in the past hence specifically ideal for case-control studies (Katzenellenbogen & Joubert 2007:106).

The data collection instrument of choice for this study was a structured questionnaire. A self-administered questionnaire, consisting of closed ended questions was used to collect information from respondents in this study. This questionnaire was pre-tested

using ten mothers from a hospital in Kisumu County to test the reliability, validity and cultural sensitivities of the questions.

1.8.6 Data analysis

The research was designed and analysed as a matched case-control study. In the analysis, the primary question considered was the degree of association between risk of MTCT and non-disclosure of positive HIV status, the extent to which the observed associations may have resulted from bias, confounding and/or chance, and the extent to which they may be described as causal.

1.8.7 Validity and reliability

Reliability is the extent to which measurements are repeatable when different persons perform the measurements, on different occasions, under different conditions (Drost 2011:106). The use of a pre-test was a measure put in place to ensure reliability of the data collection tool.

Validity on the other hand refers to whether the instrument is measuring what it was supposed to measure (Drost 2011:114). To develop strong support for the validity, the researcher extensively reviewed existing literature prior to the questionnaire design to ensure broader subject matter knowledge on the research topic. The questionnaire was designed and discussed with the study supervisor, and the questionnaire reviewed by a statistician to confirm the information that will be collected could be analysed.

1.9 ETHICAL CONSIDERATIONS

Ethical considerations refer to the protection of the rights of all those involved or affected by the research study. To protect the rights of the respondents, the three ethical principles of autonomy, beneficence/non-maleficence, and justice were upheld. The right to self-determination and full disclosure was ensured as well as the respondents' right to fair treatment and privacy.

To protect the institution, ethical clearance was granted by the Research and Ethics Committee, Department of Health Studies, UNISA on 29 October 2013 (see annexure

1). Local ethical approval was obtained from Moi University, College of Health Sciences Research and Ethics Committee on 3 March 2014 (see annexure 2). Permission to conduct the study in Siaya County was sought and granted by the County Director of Health (see annexure 3 and annexure 4). All facilities received a copy of the research proposal and copies of the ethical clearance certificates together with the request for permission to conduct the study at the institution. Additional verbal permission was obtained from the in-charges of the various health facilities.

1.10 SCOPE AND LIMITATIONS OF THE STUDY

The study focussed on determining whether non-disclosure of a positive HIV status to a male partner can have an impact on 6 week MTCT rates. The accessible population included HIV positive mothers and their babies who were born after January 2013, and had their 6 week PCR status determined.

As with all research, this study had several limitations. As a case-control study, the focus is more on determining an association and as such generalisation of results to a broader population must be done with caution. There is also the risk on any self-reported assessment that the results may be vulnerable to the reporting of socially desirable responses. The intended behaviour reported by the subjects, especially for those variables that are culturally sensitive such as infant feeding practices, mutual disclosure of HIV status and individual socio-economic characteristics may not be consistent with their real-life actions. In order to moderate these potential limitations, the respondents were assured anonymity and were encouraged to give honest responses.

1.11 STRUCTURE OF THE DISSERTATION

This dissertation is organised in chapters, each with a specific focus. The first chapter provides the background to the study, significance of the study and study question and objectives. It also described the research methodology, a brief literature review, study limitations, and an overview of ethical considerations. Chapter 2 is a review of the literature on HIV partner disclosure and MTCT. A summary of the related literature provides a framework for proceeding with the current study. The third chapter explains the methodological aspects, study design, data collection and the instruments used in

the study. Results of the study are discussed in chapter 4. Chapter 5 provides a summary and interpretation of the findings, limitation and recommendations.

1.12 CONCLUSION

HIV disclosure among pregnant women is an important element in PMTCT as it allows women to make informed decisions regarding their babies and their own health. This chapter has provided background information on the study, clearly justifying the need for the current study. Additionally, the chapter provided a summary of the research process followed by the researcher, including the selection of a matched case-control analytical research design, and use of a structured self-administered questionnaire as the data collection instrument of choice. The chapter that follows is a detailed review of some of the literature available on non-disclosure and MTCT.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

Chapter 1 gave a summary of the key features of the study, in addition to providing a framework for the dissertation. This chapter provides an overview of previous research on non-disclosure and mother-to-child transmission, while explicating the mechanism through which non-disclosure impacts on MTCT.

Research success depends to a large extent on how effectively the literature review is conducted. Not only does a well-conducted review create justification for the study, but also builds a solid understanding of the research area in terms of what has been done before, and the relationship among the various study variables. Moreover, the review allows for establishment of a conceptual framework and methodological focus (Curtis & Drennan 2013:54; Randolph 2009:2). Therefore, a literature review is "an evaluative report of studies found in the literature related to a given proposed research area" (Boote & Beile 2005:3).

The procedure followed during a review is as important as the outcome, and the strategy should be adequately described in detail to the point where, if the strategy was to be reused, the same literature sources would be identified. For that reason, the step by step strategy adopted in this review is briefly described.

To begin with, the research question for the literature review was framed: "From previous literature, does non-disclosure of a positive HIV status to a partner have an influence on MTCT?" Eligibility criteria of literature sources was then determined. Any study that reported results on at least one of the two study variables; disclosure of HIV status and MTCT was included. Additionally, the literature must have been written in English language not earlier than 2003 in line with the recommendation of Burns and Grove (2011:190) of obtaining documents for the previous ten years. Since the literature search began in January 2013, the search went back to January 2003. Nevertheless,

literature written prior to January 2003 were included if they were considered classic documents related to either the literature review topic or the methodology. The next step involved using the key terms; non-disclosure or disclosure and MTCT or vertical transmission, both singly and in combination to search for relevant documents (articles, books and teaching materials) using CINAHL, PubMed, and Google scholar. The search was conducted between January 2013 and April 2014. All identified documents were examined by reviewing the title and abstract, and those found relevant were retrieved for inclusion in the review. Reference lists of retrieved documents were additionally reviewed to identify additional publications that were relevant. The process of reference review was repeated until no new documents could be retrieved.

The causal pathway adopted in this study is that HIV testing counselling and testing creates awareness of HIV status among pregnant women. The awareness thus created should enable the woman maximise PMTCT. While this is true, it is additionally necessary to secure the support of the male partner, which requires disclosure of HIV positive status by the pregnant woman. It is posited that with the full support of the partner, the woman will then be able to optimise PMTCT interventions, an action that will ultimately lower the risk of mother-to-child transmission of HIV.

Therefore, this review is structured to first present background information on the burden of HIV among women and children in sub-Saharan Africa, aimed at demonstrating the importance of the research focus area. Antenatal HIV counselling and testing, male partner involvement and disclosure of HIV status, as strategies to reduce MTCT are followed by a demonstration of how the three strategies are linked to MTCT. Finally, a review of the case-control study design will be undertaken to demonstrate the appropriateness of the design in studying the problem area.

At the end of this chapter, it is hoped that the structured discussion of the aforementioned literature areas will not only facilitate a critical understanding of the linkage between non-disclosure of positive status and MTCT, but also enable the reader to appreciate the focus and justification for this research.

2.2 HIV INFECTION AMONG WOMEN AND CHILDREN

A lot has changed since the documentation of the first case of Acquired Immune Deficiency Syndrome (AIDS) among children in the early 1980s. The epidemiology of pediatric HIV transmission has been demystified, and it is now recognized that more than 90% of childhood infections are as a result of MTCT (The Independent Expert Panel 2010:7). The burden of the HIV epidemic has shifted towards women and female adolescents, with women constituting nearly half of all HIV/AIDS infections worldwide, 58% of whom live in sub-Saharan Africa (Abdool Karim, Sibeko & Baxter 2010:S122). Furthermore, this burden is disproportionately distributed to young women aged 15-24 years as compared to young men in the same age group. Out of the total number of people aged 15-24 years who are HIV infected, 71% are females representing a HIV burden 3-7 fold higher in adolescent women (Abdool Karim et al 2010:s122; Gouws, Stanecki, Lyerla & Ghys 2008:S5; Shetty 2013:81). As theorised by Breu, Guggenbichler and Wollmann (2012:1), the HIV epidemiologic shift towards women can only serve to increase new paediatric infections since MTCT is the most common source of HIV infection among infants and children.

In 2012, an estimated 1.4 million pregnant women infected with HIV gave birth globally, with approximately 297,000 children born being newly infected with HIV; 91% of whom were in sub-Saharan Africa (Anoje, Aiyenigba, Suzuki, Badru, Akpoigbe, Odo, Odafe, Adedokun, Torpey & Chabikuli 2012:1). In Kenya, studies have reported MTCT rates of between 4% and 7% (Nyandiko, Otieno-Nyunya, Musick, Bucher-Yiannoutsos, Akhaabi, Lane, Yiannoutsos & Wools-Kaloustian 2010:44; Roxby et al 2013:35). However, these figures are thought to be underestimates owing to low HIV testing rates among HIV exposed infants. A recent nationwide survey reported a 16% rate among all the infants tested (Kenya National AIDS and STI Control Programme 2013:12). Due to these high rates, a lot of attention has been directed towards decreasing perinatal HIV transmission, with a goal of eventually eliminating MTCT.

2.3 SOCIO-BEHAVIOURAL PMTCT STRATEGIES

2.3.1 Antenatal HIV testing and counselling

Maternal antenatal HIV testing is considered one of the core PMTCT interventions as it creates awareness of HIV status among pregnant women which is essential in providing

an entry point into PMTCT programme, an action considered the starting point for achieving low rates of mother-to-child transmission. (Aluisio et al 2011:79). Consequently, efforts to control vertical transmission have been directed first at increasing HIV status awareness among pregnant mothers.

The “opt out” approach in HIV testing and counselling adopted by many countries has contributed to an increase in the number of pregnant women being tested and being aware of their HIV status (Baggaley et al 2012:637; Chandisarewa, Stranix-Chibanda, Chirapa, Miller, Simoyi, Mahomva, Maldonado & Shetty 2007:843). In this strategy, all pregnant women attending antenatal clinic are counselled and tested, unless they decline. Wettstein, Mugglin, Egger, Blaser, Vizcaya, Estill, Bender and Collaboration (2012:2367) review on the uptake of antenatal testing in 44 countries in sub-Sahara Africa using the opt out approach reported an average testing rate of 94%, an observation supported by two separate studies done in south Africa and Uganda where testing rates in both settings were above 90% (Byamugisha, Tumwine, Ndeezi, Karamagi & Tylleskär 2010:54; Horwood, Vermaak, Butler, Haskins, Phakathi & Rollins 2012:171). In Kenya, a National survey revealed that out of the 96% pregnant women who attended antenatal clinic between 2007 and 2012, ninety-two percent had been tested for HIV (Kenya National AIDS and STI Control Programme 2013:17).The high uptake of antenatal HIV counselling and testing has resulted in increased HIV status awareness among pregnant women attending antenatal care.

2.3.2 HIV positive status disclosure

Optimal utilisation of all PMTCT interventions presents a much higher transmission risk reduction, and often depends on social support offered to HIV positive women. In patrilineal societies where male heads are still the primary decision makers, partner social support impacts on utilisation of health services (Gourlay, Birdthistle, Mburu, Iorpenda & Wringe 2013:8). However, for the support to be offered by the partner, disclosure must happen.

Disclosure of HIV positive status is defined as revelation by a HIV positive person of his or her status to another person, usually of significance to him/her such as a sexual partner (Maman, Mbwambo, Hogan, Weiss, Kilonzo & Sweat 2003:375). Among HIV positive women, disclosure has been shown to provide emotional and psychological

support which increases acceptance, uptake, and adherence to PMTCT interventions resulting in increased survival and follow up among HIV exposed infants (Aluisio et al 2011:81; Farquhar, Kiarie, Richardson, Kabura, John, Nduati, Mbori-Ngacha & John-Stewart 2004:1625; Msuya, Mbizvo, Hussain, Uriyo, Sam & Stray-Pedersen 2008:705). Additionally, disclosure enables sexual partners to make informed reproductive health choices that may ultimately lower the number of unintended pregnancies among HIV positive and discordant couples which ultimately decreases the risk of HIV transmission to the unborn child (Maman et al 2003:377).

In spite of the benefits of disclosure on MTCT, some pregnant women may decide to keep their positive HIV status a secret. Indeed, in women, disclosure of positive HIV status has been linked to several risks such as blame of infidelity, abandonment, separation and divorce, physical and emotional abuse, discrimination and stigma, as well as loss of custody of children and property (Masupe 2011:50). Such risks make decision to disclose one's status a difficult one, more so in the context of opt out testing where the burden of disclosure is left on the infected woman (Masiye & Ssekubugu 2008:343). Still, HIV positive pregnant women, as part of antenatal counselling and testing are routinely advised to disclose their HIV status to their partners (Roxby et al 2013:33; Sendo, Cherie & Erku 2013:768). But as Bachanas et al (2013:429) pointed out, disclosure in antenatal settings does not always happen.

Medley, Garcia, Moreno, McGill and Maman (2004:304) in their systematic analysis reported that disclosure rates varies greatly between 16.7% and 86%, a variability that has persisted beyond 2004. Low disclosure rates have been demonstrated in several countries: 41% in Tanzania (Kiula, Damian & Msuya 2013:436), 49% in Kenya (Roxby et al 2013:34), and 66% in Zimbabwe (Mucheto, Chadambuka, Shambira, Tshimanga, Gombe & Nyamayaro 2011:53). Conversely, some countries have demonstrated high disclosure rates including 90% in Nigeria, 97% in Zimbabwe, 80% in Namibia, Tanzania, and Ethiopia (Igwegbe & Ugboaja 2010:298; Reda, Biadgilign, Deribe & Deribew 2012:3; Udigwe, Mbachu, Oguaka, Onyegbule, Udegbunam & Umeononihu 2013:338). The variability in disclosure rates illustrated supports the singling out of non-disclosure as one of the important non-chemo prophylactic factors that if not adequately tackled will continue to hamper efforts in the elimination of vertical transmission of HIV (Torpey, Mandala, Kasonde, Bryan-Mofya, Bweupe, Mukundu, Zimba, Mwale, Lumano & Welsh 2012b:e42859).

Several factors promote partner HIV status disclosure among women attending antenatal clinic. Couple testing by default removes the burden of disclosure on the woman as this approach assures mutual partner disclosure (Msuya et al 2008:707; Farquhar et al 2004:1625). If couple testing is not possible and the woman has been tested individually, it has been shown that repeated encouragement for disclosure at every clinic visit increases the chances of disclosure taking place (Sendo et al 2013:769). Involvement and awareness of the partner status in the testing process also strongly influences the decision to disclose (Reda et al 2012:3).

Other factors that enhance disclosure include nature of relationship with the partner. Women who are married and in a stable relationship are more likely to disclose (Osinde, Kakaire & Kaye 2012:63; Seid, Wasie & Admassu 2012:102) , especially if the partners are open to each other and the woman is aware of the partner's status (Seid et al 2012:103). For example, Kassaye, Lingerh and Dejene (2005:129), in a cross-sectional study found that the respondents who did not know the partner's HIV status were 98% less likely to disclose to the partner. They also reported that women are additionally more likely to disclose to their partner if they have been in the relationship for a longer duration and are the primary partners.

Characteristic of the woman can also impact on disclosure. A younger woman, more so if she has no other children is less likely to disclose (Kassaye et al 2005:125; Kiula et al 2013:4; Olagbuji, Ezeanochie, Agholor, Olagbuji, Ande & Okonofua 2011:487). Kassaye et al (2005:125) also showed that less educated women were more likely to disclose their test results to sexual partners than more educated women. However, this varies by setting. For example, Osinde et al (2012:63) demonstrated that in Burkina Faso, women with higher education are more likely to disclose their HIV test result to their sexual partner than women who are illiterate.

Another determinant of disclosure is duration of status awareness, with women aware of their status for a longer period of time being more likely to disclose (Kassaye et al 2005:128). Finally, a woman who is currently on ARVs is more likely to have disclosed her status due to the fact that prior to being initiated on ARVs, disclosure for purposes of creating a support system is emphasised as part of adherence counselling (Stirratt et al 2006:488).

2.3.3 Male partner involvement

Men are the decision-makers in many African countries where PMTCT services are offered (Kalembo et al 2013:e66517), and their involvement is crucial in the optimisation of PMTCT services. Many reports point to the beneficial effect of male partner support in antenatal HIV services on prevention of paediatric infections (Morfaw, Mbuagbaw, Thabane, Rodrigues, Wunderlich, Nana & Kunda 2013:8), and as Auvinen, Suominen, Valimaki & Välimäki (2010:308) point out, increased pregnant women's commitment to PMTCT interventions depends on the male partner's support and commitment in all the phases of the PMTCT interventions. This support has been linked to optimisation of PMTCT services including, *inter alia*, attendance to antenatal clinic, use and adherence to maternal and infant ARVs, adherence to infant feeding method selected, and increased follow up among HIV exposed infants (Jasseron et al 2013:488; Laher, Cescon, Lazarus, Kaida, Makongoza, Hogg, Soon, Miller & Gray 2012:94; Msuya et al 2008:705; Roxby et al 2013:35; Varga, Sherman & Jones 2006:955). Ultimately, all these positive outcomes contribute to a lower vertical HIV transmission (Aluisio et al 2011:76; Villar-Loubet et al 2013:265).

Moreover, male partner involvement has been shown to increase acceptance of HIV testing and the results thereof (Bolu, Allread, Creek, Stringer, Forna, Bulterys & Shaffer 2007:s85). Men involvement also allows for shared responsibility for preventing HIV transmission to the unborn child, and adoption of safer sex practices (Medley et al 2004:305), while also playing the crucial role in supporting HIV positive pregnant women, by assisting them to get to clinics or hospitals where chances of safe delivery are higher (Haile & Brhan 2014:66).

2.3.3.1 PMTCT clinics attendance

Antenatal clinic attendance is crucial in early detection of HIV infection among pregnant women, and the male partner is key in ensuring this happens. The male partner will not only determine whether a pregnant woman attends antenatal clinic, but will also influence whether the first antenatal visit will be attended early in pregnancy and whether the woman will honour subsequent clinic appointments (Brusamento, Ghanotakis, Tudor, Van-Velthoven, Majeed & Car 2012:5; Kebaabetswe 2007:357;

Jasseron et al 2013:492). For example, in Uganda women who were economically dependent on their male partners had challenges in attending antenatal clinic (Duff, Kipp, Wild, Rubaale & Okech-Ojony 2010:39). Therefore, as demonstrated by Bobrow (2008:1), gaining support of the male partner for the HIV pregnant woman is key in ensuring initial and subsequent PMTCT clinic attendance.

2.3.3.2 Uptake of infant and maternal prophylaxis

Early and consistent use of anti-retroviral drugs (ARVs) is known to dramatically lower the risk of MTCT (Ahmad 2011:980; Koye & Zeleke 2013:402). However, several factors including non-disclosure of positive status to a male partner tends to inhibit the use of ARVs. Indeed it is believed that the strong association noted between non-disclosure of positive HIV status and poor use of maternal and infant ARV prophylaxis may partly reflect the difficulties experienced due to absence of male partner support (Jasseron et al 2013:494; Kuonza, Tshuma, Shambira & Tshimanga 2010:4). Several studies have confirmed that non-disclosure could deter HIV positive women from obtaining, using or storing ARVs for maternal prophylaxis and from seeking/ administering infant prophylaxis (Delvaux, Elul, Ndagije, Munyana, Roberfroid & Asiimwe 2009:227). As Duff et al (2010:42) discusses, non-disclosure of HIV positive status is a major barrier to accessing and accepting highly active antiretroviral therapy (HAART) by HIV positive mothers. Varga et al (2006:954) affirms this by reporting that most women who choose to disclose do so anticipating that the disclosure will reduce the barrier on the use of ARVs for maternal and infant prophylaxis, since hiding of HIV status makes taking of ARV medicine a challenge (Kasenga, Hurtig & Emmelin 2010:29). Msuya et al (2008:704) also demonstrates that support of male partner is directly linked to higher use of nevirapine for infant prophylaxis, a fact further supported by Koye and Zeleke (2013:398) and Gourlay et al (2013:13). Additionally, non-disclosure is associated with higher rates of non-completion of PMTCT regimens (Jasseron et al 2013:491; Kirsten, Sewangi, Kunz, Dugange, Ziske, Jordan-Harder, Harms & Theuring 2011:4). This pattern reflects the impact keeping HIV infection status secret has on compliance with antiretroviral therapy.

2.3.3.3 Adherence to safe infant feeding options

Compared to mixed feeding, exclusive breast feeding is an affordable, culturally acceptable, and effective means of lowering the risk of post-natal transmission while maintaining the overwhelming benefits of breastfeeding (Anoje et al 2012:4; Coutsoudis, Kwaan & Thomson 2010:1165; Kumwenda, Hoover, Mofenson, Thigpen, Kafulafula, Li, Mipando, Nkanaunena, Mebrahtu, Bulterys, Fowler & Taha 2008:124). Consequently, HIV positive mothers are usually advised to observe exclusive breastfeeding. However, in African settings, mothers are known to introduce supplementary feeds as early as when the baby is one months old substantially increasing the risk of HIV transmission (Madiba & Letsoalo 2013:8).

Mothers aware of this risk usually strive to observe exclusive breastfeeding, but usually receive pressure from either the partner or other family members to introduce other foods. This makes exclusive breastfeeding in an area of HIV secrecy to be difficult due to familial pressure. As Msuya et al (2008:705) reported, women receiving support of their partners are more likely to avoid mixed feeding and adhere to the infant feeding method selected. Moreover, Muluye, Woldeyohannes, Gizachew and Tiruneh (2012:243 also found out that husband's preference was influential in the choice of infant feeding adopted, where if support was present, the mother was more likely to breastfeed.

2.4 PARTNER NON-DISCLOSURE AND MTCT

Few studies investigating the direct relationship between partner involvement and non-disclosure of positive HIV status to a partner and MTCT exists and warrant in-depth discussion (Aluisio et al 2011; Bucagu et al 2013; Jasseron et al 2013; Roxby et al 2013; Torpey et al 2012b:e42859).

Aluisio et al (2011) were the first to document the benefits of male partner involvement in prevention of infant HIV acquisition. Through a prospective study of 456 women conducted between 1999 and 2005 in Nairobi, Kenya the researchers were able to demonstrate that male partner involvement significantly lowered risk of HIV acquisition. The researchers attributed the reduced risk to better adherence of antiretroviral medicine and more uptake of formula feed for infants. They also suggest that the reduced risk could be attributed to increase financial, physical and/or psychosocial

support for the HIV infected pregnant woman and her infant. One limitation though was that the sampling strategy was not adequately described to enable determination of the power of the study.

Bucagu et al (2013) findings were similar to that of Aluisio et al (2011). They reported that non-disclosure of HIV status to partner emerged as an important factor for MTCT. In this prospective cohort study conducted at Muhima Health Centre in Kigali, Uganda, 8,669 pregnant women who attended antenatal visits and screened for HIV were followed between May 2007 and April 2010. One limitation with the study was, as with all longitudinal studies, long time passage since cohort accrual might confound the association between the variables under study.

A study in Zambia by Torpey et al (2012b:e42859) support studies by Aluisio et al (2011) and Bucagu et al (2013). In their analysis of DNA Polymerase Chain Reaction (PCR) results and client information on all dried blood samples from perinatally exposed infants 0 to 12 months of age sent to a central PCR laboratory between September 2007 to January 2009, they reported that HIV status among infants was significantly associated with disclosure of HIV status to partner both at 6 weeks and 6 months of age. However the association did not exist where both mother and infant received intervention. The only limitation to the study by Torpey, Kabaso, Weaver, Kasonde, Mukonka, Bweupe, Mukundu and Mandala (2012a:27) is that they excluded infants not brought to facilities for their immunisation, and this could result in selection bias.

Roxby et al (2013), however, contradicts the findings of the three aforementioned studies. In their study conducted in Nairobi, Kenya, HIV positive pregnant women HIV transmission risk was comparable between those who disclosed as compared to those who did not disclose to their partners. The study's conduct within a primary study not designed to assess disclosure as a primary outcome could have limited the findings as the intervention of the primary study could have confounded the association between non-disclosure and MTCT resulting in a generally better adherence of PMTCT interventions as compared to those not in the study. In addition, exclusion of respondents who did not have Herpes simplex virus-2 (HSV) could have resulted in exclusion of HIV positive women and a possible selection bias. Finally, the small number of transmission events in the study made it impossible to exclude anything due to associated low statistical power.

To further complicate matters, despite finding an association between non-disclosure and non-optimal PMTCT (late initiation of antiretroviral therapy, detectable viral load at delivery and lack of neonatal prophylaxis), Jasseron et al (2013) in their French Perinatal Cohort study of HIV infected pregnant women reported no difference in transmission rates based on disclosure status. Interestingly, the lack of association between non-disclosure and MTCT was explained by the economic independence of the women, higher level of care and availability of ARVs factors. Consequently, the authors cautioned on generalisation of these findings to a developing country setting. On a downside, as with the aforementioned studies, the 1.0% MTCT rate might have nulled the non-disclosure-MTCT effect.

The above-mentioned studies have identified several other points of interest to this current study: The mechanism through which non-disclosure influences MTCT, and factors which could independently be associated with either MTCT and/or non-disclosure, and therefore act as possible confounders in this current study. These factors will be briefly discussed to give the reader insight into why these factors are important in the current study.

2.5 CLINICAL AND BIOLOGICAL RISK FACTORS FOR MTCT

Several studies have demonstrated that MTCT is strongly associated with several maternal factors. These factors include: stage of HIV infection, represented by CD4 count and viral load, use of HAART, and route of delivery (Ahmad 2011:981; Mucheto et al 2011:4). Maternal viral load remains the major biological determinant of MTCT , with total viral suppression (below 40 copies/mL) providing the most protective effect against MTCT (Charurat, Datong, Matawal, Ajene, Blattner & Abimiku 2009:9). In areas where viral load is not available, Maternal CD4+ count has been found to be associated with increased MTCT (Bucagu et al 2013:8; Toro, Katyal, Carter, Myer, El-Sadr, Nash & Abrams 2010:515). As a result, use of antiretroviral therapy (ART) during pregnancy decreases HIV replication, thus reducing rates of virus transmission (Ahmad 2011:981).

Great controversy still exists regarding the best route of delivery in HIV infected pregnant women. Caesarean delivery has been shown to offer significant reduction in the risk of MTCT as compared with vaginal delivery (Brocklehurst 2002:102). However,

more recently, Torpey et al (2012a:29) demonstrated that vaginal delivery did not have a higher risk of transmission when both the mother and baby received ARV prophylaxis. However, if Invasive delivery procedures, for example episiotomy, are undertaken the risk of transmission is increased (The Independent Expert Panel 2010:12).

Regarding the newborn, failure to receive oral zidovudine/nevirapine in the neonatal period, low birth weight, small for gestational age, late enrolment to the follow up clinic and home delivery are considered to present an increased risk of transmission (Charurat et al 2009:10; Delicio, Milanez, Amaral, Morais, Lajos, e Silva & Cecatti 2011:40; Koye & Zeleke 2013:397).

2.6 CONCLUSION

Review of literature has demonstrated that non-disclosure of HIV positive status by a HIV positive mother to her partner is a real challenge and if not adequately addressed could hamper efforts in the elimination of MTCT. The review has also highlighted how non-disclosure could influence MTCT, through male partner support, which determines optimal utilisation of essential PMTCT interventions. The few studies that have evaluated the association between non-disclosure and MTCT were reviewed. All of them were limited by low transmission events that eventually impacted on the power of the studies. Moreover, the results were conflicting, creating need for further research that evaluates the direct association of non-disclosure and MTCT. Therefore, an empirical research using a case-control design which is appropriate for studying diseases with low disease outcome was adopted.

The next chapter will detail the research methods used to capture the empirical data, including details on the research strategy to be adopted, data collection techniques and sample selection procedures used.

CHAPTER 3

RESEARCH DESIGN AND METHOD

3.1 INTRODUCTION

The previous chapter discussed at length previous studies touching on the current research problem. The design and methodology used to determine whether an association between non-disclosure of positive HIV status to a partner and MTCT exists is discussed in this chapter. The chapter covers the research paradigm, the strategy for inquiry, study population and sampling technique used, data collection method and instrument, ethical considerations, validity and reliability, and data analysis plan.

3.2 RESEARCH DESIGN

The research paradigm, strategy for inquiry, and the methods all contribute to a research design that tends to be quantitative, qualitative, or mixed (Creswell 2014:7). The quantitative design, adopted in this study is explored in this section.

3.2.1 Research paradigm

Weaver and Olson (2006:460) define a research paradigm as “a set of beliefs and practices which regulates inquiry within a discipline by providing lenses, frames, and processes through which an investigation is accomplished”, and although not commonly expressly stated in the literature world, Creswell (2014:3) defines a research paradigm as “a set of beliefs and practices which regulates inquiry within a discipline by providing lenses, frames, and processes through which an investigation is accomplished”, and although not commonly expressly stated in the literature world, the author advises researchers to make explicit the larger philosophical ideas they espouse as this information explains why a given research approach was adopted.

For the current study the positivist paradigm was adopted for several reasons. First, the positivist paradigm believes in determinism where causes determine an outcome, a

feature that resonated well with the study problem area, allowing the determination of whether non-disclosure contributes to MTCT. Secondly, the paradigm allowed the researcher to breakdown the broad concept of MTCT and only study the effect of non-disclosure owing to the reductionism principle that ideas can be reduced into small discrete sets of ideas to test. Besides, the researcher had control over the choice of the research problem, research methodology, and variables to be studied, and had control over the effect of extraneous variables, all which are acceptable in the positivist view. Logical, deductive reasoning that involves generating conclusions from a sample was invoked to generalise findings from a subset of HIV positive women and their babies to a larger population. Finally, structured data collection and statistical analysis, both which appeal to the researcher were possible in positivism (Creswell 2014:7).

3.2.2 Strategies of inquiry

Philosophical assumptions are operationalised by adoption of specific strategies of inquiry which provide specific direction for procedures in a research design. Three strategies espouse the positivist worldview: true experiments, quasi-experiments and correlational studies (Creswell 2014:15).

The researcher chose a non-experimental approach since for the research problem, it would be morally unacceptable and undesirable to manipulate any part of the study. Moreover, it was desirable to capture the phenomenon as it occurred without any intervention. Consequently, the researcher observed HIV positive mothers and their babies without manipulation of the independent variable.

3.2.2.1 Case-control study

Vanderbroucke and Pearce (2012:1480) and Marshall (2004:612) explain a case-control study as an investigation to the extent in which persons selected because they have a specific disease (the cases) and comparable persons, who do not have the disease (the controls) have been exposed to the disease's possible risk factors in order to evaluate the hypothesis that one or more of these risk factors is a cause of the disease. For this study, the design was used to compare the exposure level (non-disclosure of positive HIV status to a partner) between HIV exposed infants who turned positive at 6 weeks

(cases) and those who remained negative at 6 weeks (controls), to determine whether partner non-disclosure of positive HIV status to a partner is a risk factor for MTCT.

The case-control design was selected for this study due to the strengths it offers. Foremost is that the case-control design enabled the researcher to study MTCT, which is a rare outcome, more so with the success of PMTCT interventions. Secondly, since the case-control design can be used to study a variety of exposures, it allowed for the study of non-disclosure of positive HIV status, which is a behavioural risk factor. Another advantage of the case-control design was its efficiency. The researcher was able to study the association in a short time and with minimal costs because the outcome of interest was already present and time was not spent waiting for an outcome to occur. Besides, only pre-existing data was gathered on relatively few subjects (Sayed 2007:346). Lastly, the ability to match in case-control studies allowed the researcher to increase the power of the study to achieve a higher precision of the estimate measure by allowing the confounding variable be evenly distributed in both cases and controls.

On the other hand, despite its practicality, the researcher was aware of the inherent limitations in the design which makes a case-control study one of the most challenging to design and conduct. The threats to validity were well anticipated and addressed as discussed in the enhancing research rigour section. Though in summary, the first major area where a case-control study presents a difficulty is in the selection of cases and controls. It becomes a problem if for some reason, cases (or controls) are included in (or excluded from) a study because of some characteristic they exhibit which is related to exposure to the risk factor under evaluation. In the current study, the sensitivity and specificity of the PCR testing currently being used to test for HIV in infants makes it less likely to classify cases as controls or vice-versa (Shah 2006:198).

Another difficulty in case-control studies involves the measurement of exposure information. Cases often remember exposures to putative risk factors differently than controls. This differential recall (recall bias) can lead to information bias which could potentially generate an exaggerated relation between exposure and disease. The time period of exposure in this study was limited to less than 2 years to reduce the chance of differential recall of exposure in cases and controls. Bias from data gatherers presents further difficulties. If the individuals gathering information know the case or control status of the respondents, they might delve more deeply into a case’s background than

a control's to obtain a hypothesised exposure. The data collectors were masked on the status of the respondents. Moreover the fact that the questionnaire was self-administered also mitigated against this potential bias (Schulz & Grimes 2002:432).

3.2.3 Research methods

The third major element in the research design is the specific research methods that involve the forms of data collection, analysis, and interpretation that researchers propose for their studies. The quantitative methodology shares its philosophical foundation with the positivist paradigm and was consequently adopted for the purpose of predicting an association between the two key variables in this study.

3.2.3.1 Research setting

The study was conducted in Kenya within Siaya County. Kenya is one of the East African Countries lying between 5° north and 5° south of the equator. It is bordered by Ethiopia to the North, Somalia to the Northeast, Tanzania to the south, Uganda and Lake Victoria to the west, and Sudan to the northwest. The Indian Ocean borders it on the East. The country is divided into 47 counties within a total area of 582,646 square kilometres.

Siaya County is one of the 47 counties in Kenya with a total surface area of 2,530 km^2. It is located in the western parts of Kenya, bordering Lake Victoria to the East (figure 3.1). It is divided into six administrative sub-counties namely; Gem, Ugunja, Ugenya, Siaya, Bondo and Rarieda. The country has a total population of 885, 762 persons comprising 419,227 males and 466,535 females, with 65.3% of the population being below 24 years.

Siaya country has some of the worst HIV indicators in the country with a HIV prevalence rate of 19.1% and a MTCT rate of 15% (Kenya National AIDS and STI Control Programme 2013:4). The current child mortality rates for the county (NNMR 39/1000 live births, IMR 111/1000 live births, U5MR 159/1000 live births) are among the highest in the country, with majority of these deaths being as a result of HIV/AIDS and malnutrition.

The major health care provider in Kenya is the Ministry of Health. The public delivery system is organised in a traditional pyramidal structure. First-level care is provided at dispensaries and medical clinics. The next level comprises health centres and sub-County referral hospitals. Third-level care is provided at County referral hospitals, with two National Hospitals offering the highest level of care. Siaya County has one County referral hospital, six sub-County referral hospitals, 38 health centres, 98 dispensaries, and 12 clinics (Siaya County Health Strategic and Investment Plan 2013:7).

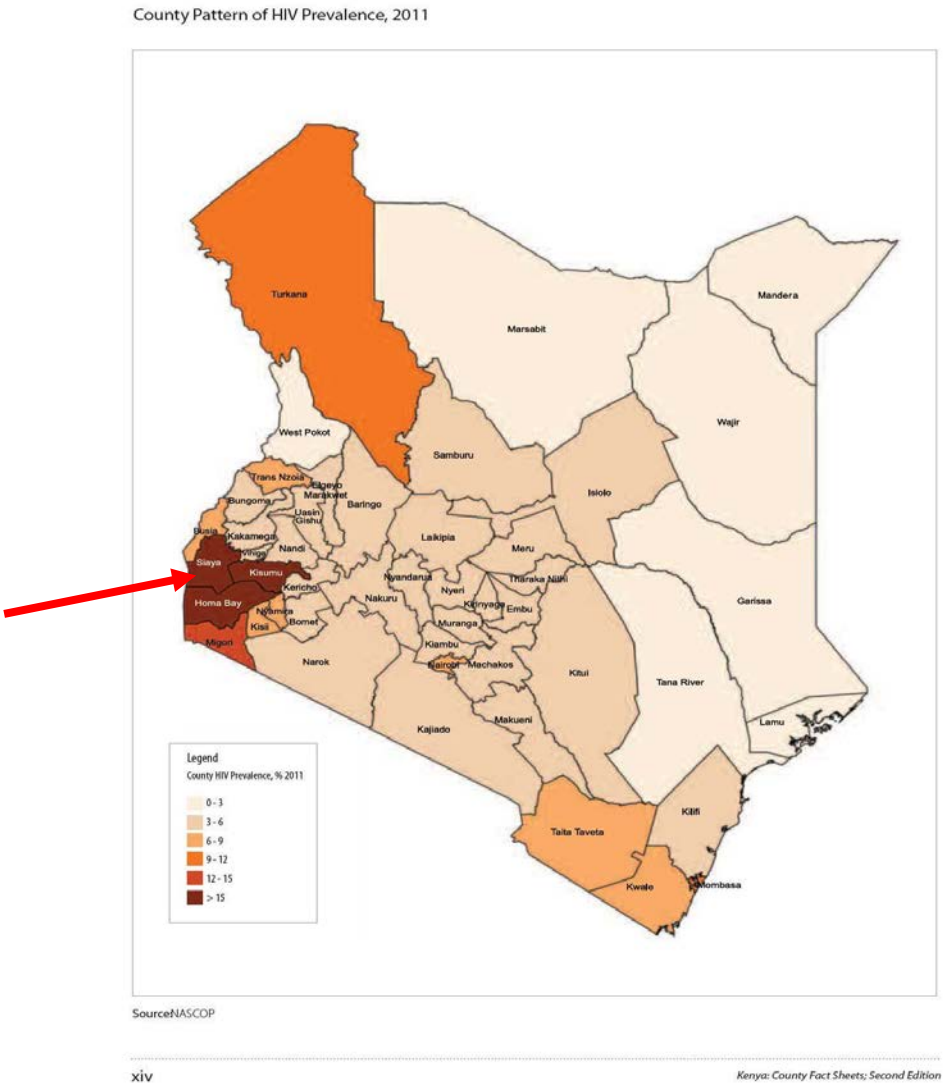

Figure 3.1: Map of Kenya showing Siaya County

3.2.3.2 Population

The target population refers to a complete set of elements (persons or objects) to whom the researcher would like to generalise the study's findings (Polit & Beck 2012:274). The

findings in this study were generalised to HIV positive women and their exposed infants receiving HIV care and treatment at a health facility.

The accessible population on the other hand is a set of persons from where respondents taking part in the study are selected from (Polit & Beck 2012:274). For the study, the accessible population was HIV positive mothers and their infants receiving care and treatment at a health facility within Siaya County.

3.2.3.3 Eligibility criteria

The eligibility criteria for the study population included the following:

- HIV positive mother who gave birth to a baby between January 2013 and June 2014.
- The mother should have been in a relationship with a person of the opposite sex, either during pregnancy or for any period after delivery of the baby.
- The mother-baby pair was receiving HIV care and treatment at a public health facility in Siaya County.
- The mother-baby pair was resident in Siaya County.
- The HIV exposed infant had the 6 week polymerase chain reaction (PCR) test done and results are available.

3.2.3.4 Sampling

According to Polit and Beck (2012:275), sampling is the process of selecting a group of subjects for a study in such a way that the individuals represent the larger group from which they were selected, usually done by selecting from a list of all those within a population who can be sampled, and may include individuals (respondent sampling), households or institutions (site sampling) (Katzenellenbogen & Joubert 2007:106). This representative portion of a population constitutes a sample.

3.2.3.4.1 Site sampling

Siaya County was stratified into six zones in line with the administrative sub-County divisions. From each of the sub-Counties, the sub-County referral health facility was

selected and included in the site sample. The approach was adopted since the referral facilities' catchment population covers the entire county, and majority of HIV positive women seek care from these high volume facilities (Siaya County Health Strategic and Investment Plan 2013:7).

3.2.3.4.2 Individual sampling

HIV exposed infants born between January 2013 and June 2014 in the six selected facilities were identified by reviewing Government of Kenya HIV exposed infants' cohort register which captures all infants born to HIV positive mothers. The registers are available at the facility level. The identified HIV exposed infants provided the sampling frame.

- **Selection of case and control groups**

Incidence density purposive sampling was used in the selection of cases (Curtis & Drennan 2013:241). Purposive sampling allowed for conscious and deliberate identification of infants who were HIV positive and fulfilled the eligibility criteria. Since the cases were newly diagnosed, they represented incident cases for the study period. A case consequently was identified as an infant born to a HIV positive mother within January 2013 to June 2014, and who had a positive PCR result at 6 weeks of age.

Simple random sampling was used to select "potential" controls from the sampling frame. A control was defined as an infant born to a HIV positive mother within the same time period, and who had a negative PCR result at 6 weeks. For every case identified, four controls were included from the same facility to increase power in the analysis.

- **Sample size**

In order to be able to detect statistically significant results, it is important to power the study adequately by determining the number of respondents required for the level of power desired (Curtis & Drennan 2013:156; Sayed 2007:346). In the current study, a difference in proportions formula for matched case-control studies was used. The formula considers type I and Type II errors, prevalence of exposure to the risk factor, and the odds ratio that one regards as important to detect. The following formula was

used to calculate the minimum required sample size (Edwardes 2001:13; Kim, Xue & Du 2006:929).

$$n = (\frac{r+1}{r}) \frac{(\overline{p})(1-\overline{p})(Z_{\beta} + Z_{\alpha/2})^2}{(p_1 - p_2)^2}$$

Where; n= Sample size in the case group

r=ratio of controls to cases

Z_{β} = represents the desired power

α=Represents the desired level of statistical significance

(P_1-P_2) =Effect Size

For this study the following assumptions were made in the calculation of the sample size;

- Power of 0.80, with an equivalent Z_{β} of 0.84
- Significance level of 0.05, with a Z_{α} of 1.96
- Least extreme odds ratio to be detected of 2
- Ratio of control to cases of 4:1
- The proportion exposed in the control group is 15%
- The Proportion of exposed in the case group used was 40%
- Average proportion exposed = $(P_{caseexp} + P_{controlsexp})/2$=0.275

$$N = \frac{(2+1)}{2} (0.275) \frac{(1-0.275)(0.84+1.96)^2}{(0.40-0.15)^2}$$

$$=1.5x0.275\ (0.725)\ (7.84)/0.0625$$

=36 pairs (36 cases and 144 controls) matched in the ratio 1:4

3.2.4 Data collection

Data Collection is an important aspect of any type of research study. This is because inaccurate data collection can impact the results of a study and ultimately lead to invalid results. Data can be obtained from primary or secondary sources, both of which were utilised in the current study (Polit & Beck 2012:293).

The data for this study was gathered retrospectively, with the use of a questionnaire which was developed to achieve the research aim and objectives (see annexure 6).

Primary data was obtained from respondents while secondary data included data from health facility records collected for routine care of patients.

3.2.4.1 Data collection instrument

Following a rigorous literature review, it was determined that no instrument could be used to adequately address the research purpose and objectives. Consequently, the researcher resolved to develop a new tool for eliciting the required information from respondents.

The questionnaire, defined as a "printed self-report form designed to elicit information" (Burns & Grove 2011:353) was developed by following a defined process (Rattray & Jones 2007:235). The process involved making a decision on the information required, deciding on the question content, developing question wording, ordering the questions in meaningful order and format, pre-testing the questionnaire and development of the final questionnaire.

3.2.4.1.1 Development

The first step in questionnaire development was to decide the information that the researcher required to get from the respondents in order to meet the study's objectives. The researcher had an idea about the kind of information to be collected, but sought additional help from secondary data. This review focussed on work that had been done on the same or similar problems area, identifying factors that had not yet been examined. Further, the researcher's interaction with the respondents gave insight onto what information could be required.

3.2.4.1.2 Compilation of the questions

The information needed was then translated into questions that could elicit the desired information. A mix of open- and closed-ended questions was developed. Each potential question was screened with respect to (1) how the answers will be analysed (2) the anticipated information provided and (3) how the ensuing information would be used.

Next, the questions were assessed for their administrative viability or how respondents might react to them by considering three key questions: (1) Can respondents understand the question? (2) Can respondents answer the question? and (3) Will respondents answer the question? The focus was that the questions be amenable to being self-administered.

The questionnaire was then structured, guided by the study problem, purpose and objectives. The questions were ordered in a logical sequence to allow for meticulous documentation of events. The language of communication was English and the same tool was used for all the subjects.

3.2.4.1.3 Piloting the questionnaire

After development, the questionnaire was subjected to a pre-test to enable the researcher to determine:

- whether the questions as worded would achieve the desired results
- whether the questions had been placed in the best order
- whether the questions were understood by the respondents
- whether additional questions were needed or whether some questions should be eliminated

A small number of respondents, from a neighbouring County, with similar socio-demographic profile as Siaya County was selected for the pre-test. Following the pre-test, modifications were made in the grouping, sequencing, and coding of the questions. The final questionnaire was divided into the following sections (see annexure 6):

Section A: Personal characteristics
Section B: Infant characteristics
Section C: Disclosure and HIV status

3.2.4.2 Ensuring rigour of the study: reliability and validity

In the following section the validity and reliability as applied to this research is discussed.

3.2.4.2.1 Validity

The conclusion drawn from studies is based on information collected using a data collecting instruments. Therefore, ensuring the quality of these instruments is critical (Curtis & Drennan 2013316; Fraenkel & Wallen 2003:158). Validity in research addresses the issue of whether the findings of a study is believable and true and whether it evaluated what it was supposed to evaluate (Drost 2011:114; Rattray & Jones 2007:238).

There are several different types of validity. Content validity (or face validity) refers to expert opinion concerning whether the scale items represent the proposed domains or concepts the questionnaire is intended to measure. Face validity refers to face judgement on whether the items in the questionnaire appear to represent the construct and whether the test or the instrument looks valid (Curtis & Drennan 2013:186; Mostert 2007:339).

Validity in the current study was assured by undertaking a thorough conceptualisation of the key constructs by conducing of a thorough literature review to ensure the questionnaire captured the full content domain and to ensure that the researcher had a broader knowledge on what has already been studied on the subject. The constructed questionnaire was additionally reviewed by a biostatistician, the ethical review panels, and the researcher's supervisor to ensure content validity.

3.2.4.2.2 Reliability

It is essential that the reliability of a questionnaire be demonstrated. Reliability is the extent to which measurements are repeatable when different persons perform the measurements, on different occasions, under different conditions (Drost 2011:106). To reinforce and assess the reliability of the instrument in this research, evaluating test-retest reliability assessed stability. The same questionnaire was used twice and a comparison of the responses assessed. The majority of respondents (90%) responded in the same manner to more than 95% of the questions. This was deemed adequate.

3.2.4.3 Data collection approach and method

The researcher relied on a combination of two methods to gather information: use of instruments and collection of existing data from medical records.

3.2.4.3.1 Review of records

Review of records involves the use of data collected routinely as part of patient care. Following ethical approval, and after obtaining consent from the Director of Health, the County HIV exposed infants' database was accessed and used to classify exposed infants into either cases (positive HIV status at 6 week) and controls (negative HIV status at 6 weeks). Medical records of the potential respondents were then extracted to enable the researcher get contact details of the potential respondents.

A major limitation of records is that completeness and accuracy may be compromised because the information is being recorded for other purposes. However, due to sensitivity of the research focus (mother-to-child transmission [MTCT]), the HIV exposed infant registers and individual records are usually well completed, and as such the researcher had confidence in the accuracy and completeness of the records.

3.2.4.3.2 Questionnaire

Once the respondents were identified, mothers to the infants (both cases and controls) were contacted to arrange for collection of exposure information. The respondents were presented with a list of questions to which they were to respond to. They were guided by the researcher, where necessary. Information collected included demographic details of the mother, disclosure of HIV status to the partner, disclosure to others who is not a partner, whether couple testing was done during clinic visits, whether the HIV status of the partner is known, and the duration of the relationship with the partner.

The use of a questionnaire was favoured due to the increased reliability of information collected since data is collected in a structured manner (Curtis & Drennan 2013:300; Parahoo 2006:148). In addition, it allowed for quick data collection in an inexpensive and standardised manner (Rattray & Jones 2007:234). On the other hand, the researcher was aware that the respondents may report inaccurate information in

questions involving embarrassing or socially unacceptable behaviours. A questionnaire offers anonymity which can help towards obtaining candid results (Katzenellenbogen & Joubert 2007:106). Moreover, the researcher identified a private location in each health facility for respondents to fill the questionnaire, prior to which they were assured of anonymity and confidentiality of the data collected. Refer to section 4.3.1 for response rate.

3.2.5 Data analysis

The research was designed and analysed as a case-control study. In the analysis, the basic question considered was the degree of association between an infant's risk of being HIV positive at 6 weeks of age and non-disclosure of positive HIV status to a partner, with consideration being made on the extent to which the observed associations may have resulted from bias, confounding, and/or chance, and the extent to which they may be described as causal. The steps followed in the analysis of data are presented below.

3.2.5.1 Exploratory data analysis

Before onset of analysis, editing and cleaning of the data was undertaken to minimise data errors. This was based on the explanation by Heagerty, Kung-Yee and Zeger (2013:6) on the importance of exploratory data analysis, as it not only allows one to visualise patterns in data and therefore be able to identify unusual observations, but also aids in detection of missing data on exposure, outcome, and other relevant variables. Moreover, exploratory analysis assists in the discovery of systematic relationships that are relevant to the study hypothesis. Once the errors were corrected, the analysis was directed towards determining the data distribution by plotting normality graphs for continuous variables for both case and control groups. The results of the analysis are shown in the results section.

3.2.5.2 Univariate and multivariate analysis

After exploratory data analysis, univariate analysis was performed to identify differences between the case and the control groups using Student's t-test (continuous data) or the chi-square test (categorical variables) as appropriate. Mantel-Haenszel summary odds

ratio and 95% confidence intervals for the odds ratio for the matched-pair data was calculated for each 2X2 table and Cochran-Mantel-Haenszel chi-square test used to test for its significance according to the formulas:

$$OR_{MH} = \frac{\sum_i \frac{a_i d_i}{T_i}}{\sum_i \frac{bc_i}{T_i}} \qquad \chi^2_{CMH} = \frac{\left(\sum_i a_i - \sum_i \frac{N_{1i} M_{1i}}{T_i}\right)^2}{\sum_i \frac{N_{1i} N_{0i} M_{1i} M_{0i}}{T_i^2 (T_i - 1)}}$$

Statistical significance was defined as $p<0.05$. Conditional logistic regression was used to control for variables shown to be significant in the univariate analysis, and not in the causal pathway. The conditional logistic regression is similar to CMH Chi-square, in that it stratifies on the matched sets using the conditional maximum likelihood estimation (Fidler & Nagelkerke 2013:e58327). The advantage of using conditional logistic regression over the McNemar test or the CMH Chi-square test, is that covariates can be included in the model that are not in the list of the matching variables.

3.2.5.3 Testing for mediation

Mediation is a hypothesised causal chain in which one variable affects a second variable that, in turn, affects a third variable (Anon [s.a.]). It was hypothesised in this study that the effect of non-disclosure on MTCT is mediated by male partner involvement. To determine mediation, presence of four conditions were assessed (figure 3.2) by performing three separate regression analyses (Kenny 2014):

- The independent variable (non-disclosure) is significantly related to the dependent variable (MTCT) (path c).
- The independent variable is significantly related to the Mediator variable (male partner involvement) (path a).
- The mediator variable is significantly related to the dependent variable (path b).
- When controlling for the effects of the mediator variable on the dependent variable, the effect of the IV on the DV (path c) is no longer significant (path c').

The significance of the mediation was tested using the Sobel test (Preacher 2010).

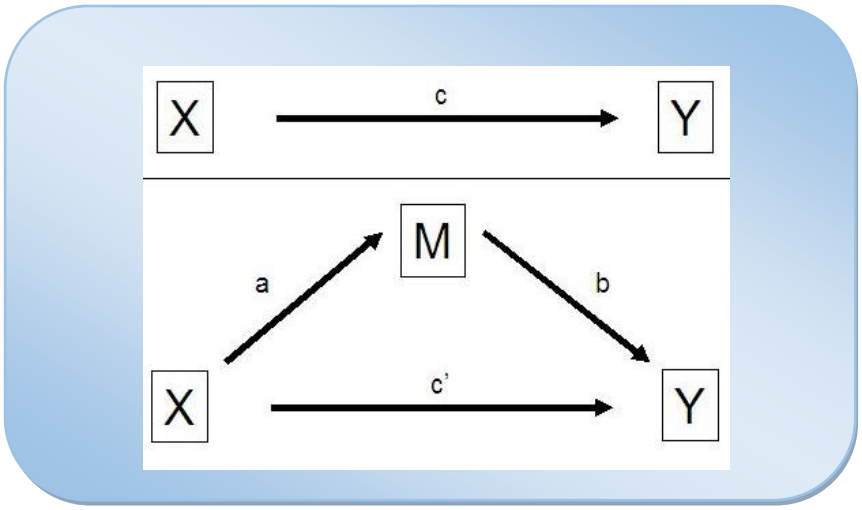

Figure 3.2: Framework for mediation analysis

3.2.5.4 Statistical software

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) version 22.0 for Windows.

3.2.6 Ethical considerations

Ethical considerations refer to the protection of the rights of all those involved or affected by the research study. To protect the rights of respondents, the three ethical principles of autonomy, beneficence/non-maleficence, and justice were upheld. The right to self-determination and full disclosure was ensured. The researcher ensured the respondents' right to fair treatment and privacy.

To protect the institution, ethical clearance was granted by the Research and Ethics Committee, Department of Health Studies, UNISA on 29 October 2013 (see annexure 1) and local ethical approval wasobtained from Moi University, College of Health Sciences Research and Ethics Committee on 3 March 2014 (see annexure 2). Permission to conduct the study in Siaya County was sought and granted by the County Director of Health (see annexure 3 and annexure 4). All facilities received a copy of the research proposal and copies of the ethical clearance certificates together with the request for permission to conduct the study at the institution Additional verbal permission was obtained from the In-charges of the various health facilities.

3.2.6.1 Ethical considerations in data collection

Any study involving human respondents is bound by certain ethical principles when it comes to data collection. Considerations of these principles is necessary, among the significant issues considered were voluntary participation, confidentiality and data protection. Voluntary participation is operationalised by obtaining of an informed consent from the respondents (see annexure 5), which involves the respondent knowing the purpose and nature of the study, the nature of his or her participation, and the potential risks and benefits involved. Implicit in this definition, however, is the belief that potential respondents will understand the information they are given. In this study, all these aspects were considered. The exact nature of the study was explained in a manner and language understandable to the respondent. Additional time was given to consider the information provided before making a decision to participate. To avoid undue influence, the respondents were not given any incentive to participate in the study.

Personal information collected by researchers may be damaging to respondents if disclosed to a third party, especially with HIV/AIDS. Stigmatisation, discrimination, and other social or physical harms may occur if they are identified as different in some way from a larger community. The researcher ensured that information was collected in a confidential manner by identifying a room within the health facility where the questionnaire was filled. No identifier information was collected, and all information collected was entered into a database which was password protected.

3.2.6.2 Ethical considerations in sampling

In this study, steps were taken in ensuring that the respondents selected from the population were done in such a way that they accurately portray characteristics of the population. Health facilities sampled were the sub-County referral hospitals, which attend to HIV positive women from every corner of the sub-County. The respondents were further selected on a random basis, with selection being done on different days over a whole month to ensure representation of the population. Further, the effect of refusal to participate in the study was analysed to determine whether those who refused

to take part, differed significantly from those who participated. It was determined they had not differed significantly.

Sample size estimation is a key component of empirical research as the sample size influences the quality and accuracy of the research. In general, increased sample size is associated with decreased sampling error. Accordingly, researchers should focus on determining the smallest necessary sample size. This, as shown in section 3.2.3.4, was undertaken to arrive at the minimum required sample size.

3.3 SCOPE OF THE STUDY

The study focussed on determining whether non-disclosure of a positive HIV status to a male partner can have an impact on 6 week MTCT rates. The accessible population included HIV positive mothers and their babies who were born after January 2013, and had their 6 week PCR status determined.

3.4 CONCLUSION

The purpose of this chapter was to describe the research methodology of this study, explain the sample selection, describe the procedure used in designing the instrument and collecting the data, and provide an explanation of the statistical procedures used to analyse the data.

Chapter 4 will present the results derived from the study.

CHAPTER 4

ANALYSIS, PRESENTATION AND INTERPRETATION OF THE RESEARCH FINDINGS

4.1 INTRODUCTION

As mentioned in section 1.4, the purpose of this study was to determine whether an association exists between non-disclosure of a positive HIV status to partner and MTCT. Consequent to an association being found, the study further purposed to determine whether the effect of non-disclosure on MTCT is mediated by male partner involvement. The final objective was then to make recommendations for disclosure and male partner involvement as part of PMTCT.

In order to realise these objective, a 1:4 matched case-control study design was implemented with relevant data being collected using a questionnaire developed purposefully for this study. SPSS statistical software version 22 was used to analyse the data collected. These details were presented in the previous chapter.

This chapter reports and describes the results of the response rate, distribution of data, sample characteristics, and the association between non-disclosure and MTCT. Tables and diagrams have been used to facilitate a simplistic reader-friendly writing. Finally, a summary to the chapter is provided.

4.2 DATA MANAGEMENT AND ANALYSIS

4.2.1 Data management

Data collection resulted in accumulation of data, primarily quantitative. An electronic database was created in excel 2013, following which the data was cleaned and edited to minimise data errors. The dataset was then exported to SPSS version 22. Examination of ranges and distributions of the variables was done to ensure all the values of all variables in the dataset are legitimate. Exploration of missing data revealed

no missing data. An analysis of the response rate and distribution of data are described below.

4.2.1.1 Analysis of non-response bias

Non-response is an important potential source of bias in a study as it could affect the magnitude and direction of measures of association (Barclay 2002:105; Curtis & Drennan 2013:188). When only a subset of respondents provides follow-up information on exposures and outcomes, the participating subset may not be representative of the original sample. Owing to this importance, non-response bias analysis was performed first by examining the response rates among respondents and non-respondents. To test the null hypothesis that there was no difference between estimates for respondents and non-respondents, three variables (mother's age, child birth weight, and disclosure status) were compared using a two-tailed, two-sample t-tests for continuous variables and chi-square for categorical variable.

4.2.1.2 Assessing for normality of data

When analysing differences between groups using parametric tests, a common assumption is that the dependent variable is approximately normally distributed for each group of the independent variable. When this assumption does not hold, it is impossible to draw accurate and reliable conclusions about reality (Ghasemi & Zahediasl 2012:486). In order to determine the applicability of parametric tests in this study, continuous data was assessed for normality using Shapiro-Wilk's test, and to ensure no outliers were present, an inspection of the box-plot was performed.

4.2.3 Descriptive analysis

The purpose of conducting a descriptive analysis is to characterise the respondents to better understand the composition of the sample. The characteristics of the sample population can be described using measures of central tendencies and dispersion. Central tendency gets at the typical score on the variable, while dispersion gets at how much variety there is in the scores. In this study, normally distributed data was represented by means and standard deviation while skewed data was presented using

mean and interquartile range as a measure of central tendency and dispersion respectively.

4.2.4 Inferential statistics

Univariate analysis was performed to identify differences between the case and the control groups using paired student's t-test (continuous data) or the chi-square test (categorical variables) as appropriate (Gerstman 2008:204). Mantel-Haenszel summary odds ratio and 95% confidence intervals for the odds ratio for the matched-pair data was calculated and Cochran-Mantel-Haenszel chi-square test was used to test for its significance (Tripepi, Jager, Dekker & Zoccali 2010:c318). Conditional logistic regression was then used to control for variables shown to be significant in the univariate analysis (Langholz & Goldstein 2001:67).

4.3 SAMPLE CHARACTERISTICS

4.3.1 Response rate

Out of the 50 potential cases and 200 potential controls identified through a desk review of the HIV exposed infants register of the six sub-County referral hospitals in the County, 36 and 144 respectively were included in the analysis. The overall response rate was 72%. The numbers of cases and controls initially identified, reasons for exclusion, and numbers included in the analyses are shown in figure 4.1.

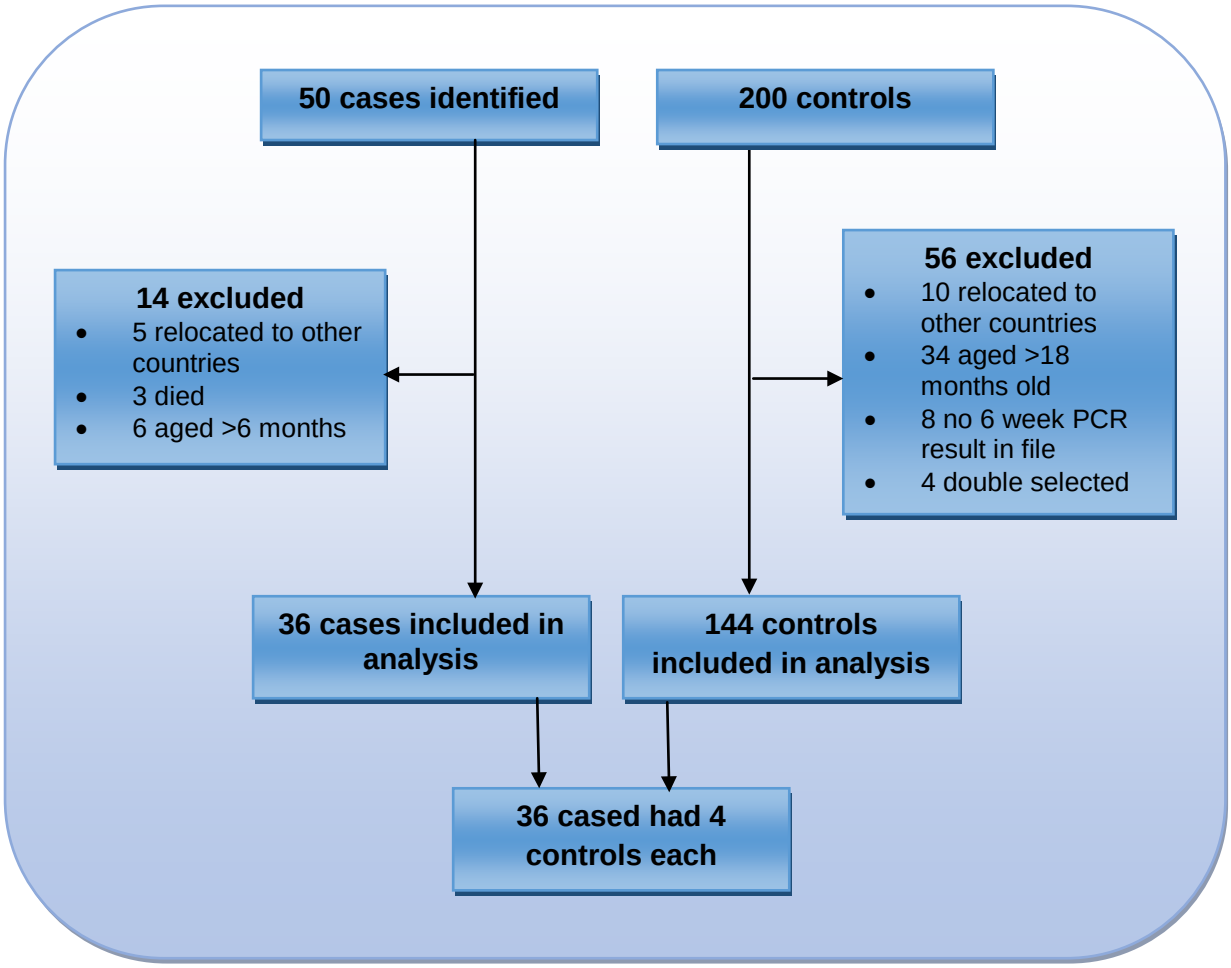

Figure 4.1: Number of potential cases and controls identified, excluded, and included in study

The comparison of the mean mother's age and child's birth weight and disclosure status showed no statistical differences between respondents and non-respondents (table 4.1).

Table 4.1: Differences in characteristics of respondents vs. non-respondents

Variable	Respondents, n=180		Non-respondents, n=70		P value
	N (%)	Mean (SD)	N (%)	Mean (SD)	
Mother's age (years)	-	27.4 (5.4)	-	26.9 (4.2)	0.327
Child's birth weight (kg)	-	3.2 (0.6)	-	2.9 (1.3)	0.289
Disclosure status* (yes)	150 (83)	-	55 (78)	-	0.642

* Disclosure status for non-respondents was obtained from medical records at the facility

The response rate of 72% reported in this study was deemed adequate (Curtis & Drennan 2013:188; Baruch 1999:421; Choung, Locke, Schleck, Ziegenfuss, Beebe, Zinsmeister & Talley 2013:93) especially as the minimum sample size required to give the study a power of 0.80 was achieved. Important too was the fact that the case and control groups did not significantly differ with regard to sample variables assessed. Therefore the researcher was confident of minimal errors in the estimations of exposure and association measures (Bjertness, Sagatun, Green, Lien, Søgaard & Selmer 2010:602).

4.3.2 Socio-demographic characteristics

This section describes the socio-demographic characteristics of the respondents who took part in this study. Information on age, gender and birth weight of the infant was collected. Information of the age, marital status, number of siblings, and educational level was collected from the mother.

4.3.2.1 Infant characteristics

4.3.2.1.1 Child age

The child age was normally distributed for both cases and controls as assessed by Shapiro-Wilk's test ($p>0.05$). However, the distribution histogram of the case group reveals a bi-modal age distribution (figure 4.2). There were no outliers in the data, as assessed by inspection of the box-plot (figure 4.3). The overall median (min, max) age was 10 (1, 18) months. The Wilcoxon signed-rank test (Curtis & Drennan 2013:369) determined that there was no significant difference between the case and control median ages (10.5 (1, 18) vs. 9.5 (1, 18); P=0.703).

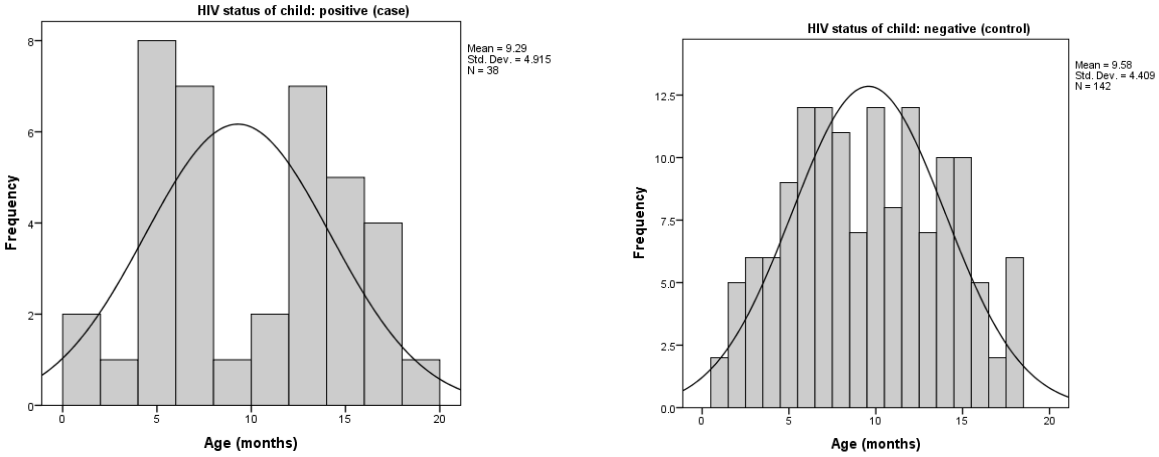

Figure 4.2: Age distribution for cases and controls

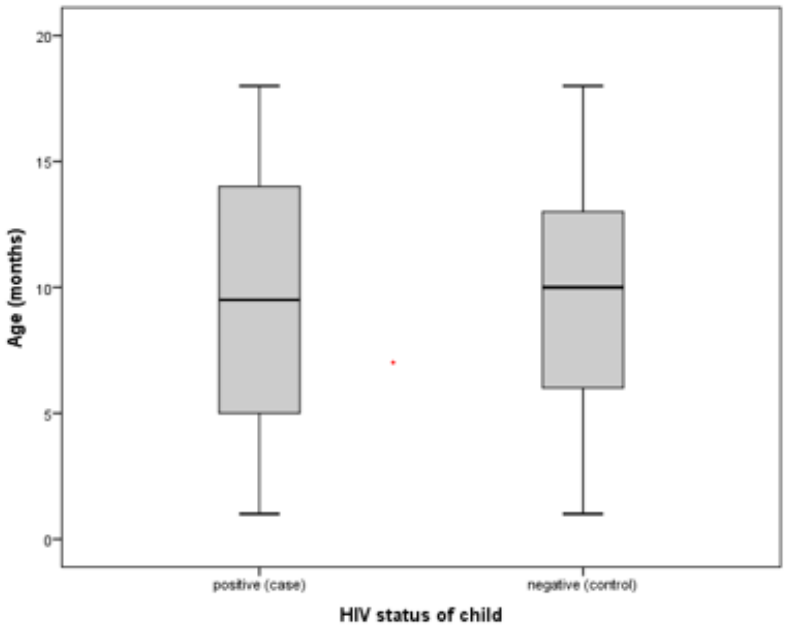

Figure 4.3: Box-plot of cases and controls

4.3.2.1.2 Child birth weight

The birth weight of the babies were approximately normally distributed for cases and controls as assessed by Shapiro-Wilk's test ($p>0.05$). There were several outliers in the control data, as assessed by inspection of the box-plot (figure 4.4). The overall mean (SD) birth weight was 3.2 (0.6) kg. The differences in mean birth weight between cases and controls However was statistically significant, with controls having a higher mean birth weight, M=0.35 (95% CI, 0.13 to 0.56), t (178)=3.163, p=.002. Birth weight was controlled for in the multi-variate analysis.

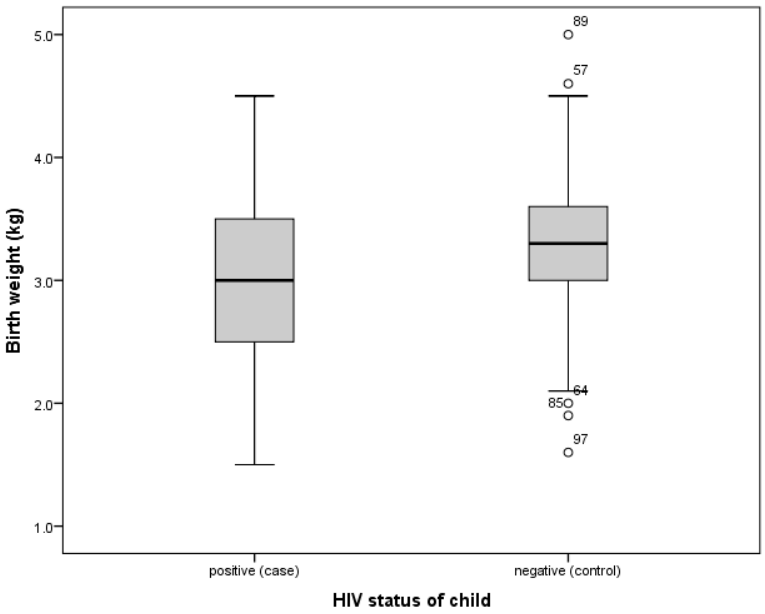

Figure 4.4: Box-plot distribution of cases and controls

4.3.2.1.2 Sex

Overall, 43% (n=43) of the respondents were female, with no significant difference between males and females in the two groups (cases: 61% vs. 39%; p=0.467; controls: 56% vs. 44%; p=0.341).

4.3.2.2 Maternal characteristics

4.3.2.2.1 Mother's age

The data on the maternal age approximated a normal distribution as assessed by Shapiro-Wilk's test (p>0.05). There were no outliers as shown in the box-plot (figure 4.5). The mean (SD) maternal age for the entire sample was 27.4 (5.4), with no significant difference in mean maternal age between cases and controls, M=1.5 (95% CI, -0.4 to 3.5), t (178)=0.041, p=0.139).

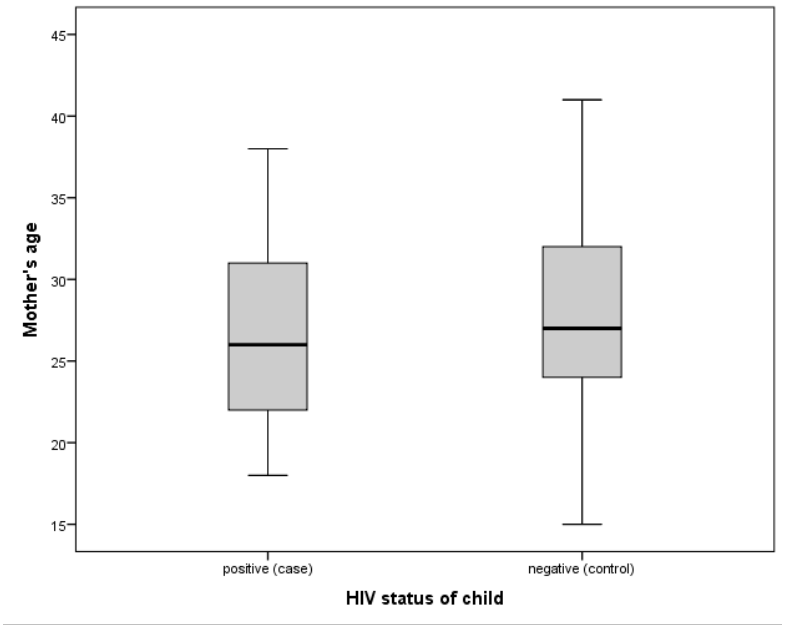

Figure 4.5: Box-plot distribution of cases and controls on mother's age

4.3.2.2.2 Mother's marital status

Most (n=119, 66.0%) of the mothers were married in a monogamous relationship, with a significant proportion (n=29, 16.0%) being in a polygamous relationship. The proportions did not significantly differ between cases and controls (p=0.447) as shown in table 4.2 in section 4.4.

4.3.2.2.3 Mother's educational level

The majority of the respondents (n=141, 78.3%) has basic level of education, with only 21.6% (n=39) having obtained post-primary education. The proportions did not significantly differ between cases and controls (p=0.640) (table 4.2).

4.3.2.2.4 Number of children

A visual analysis of the box plot (figure 4.6) shows there were several outliers with the histograms showing a positive skew for both cases and controls, with a skewness of 1.56 (0.20) and 1.45 (0.39) respectively. The overall median (min, max) number of children was 3 (1-12), which did not significantly differ across the two groups: 2 (1-8) vs. 3 (1-12); p=0.447.

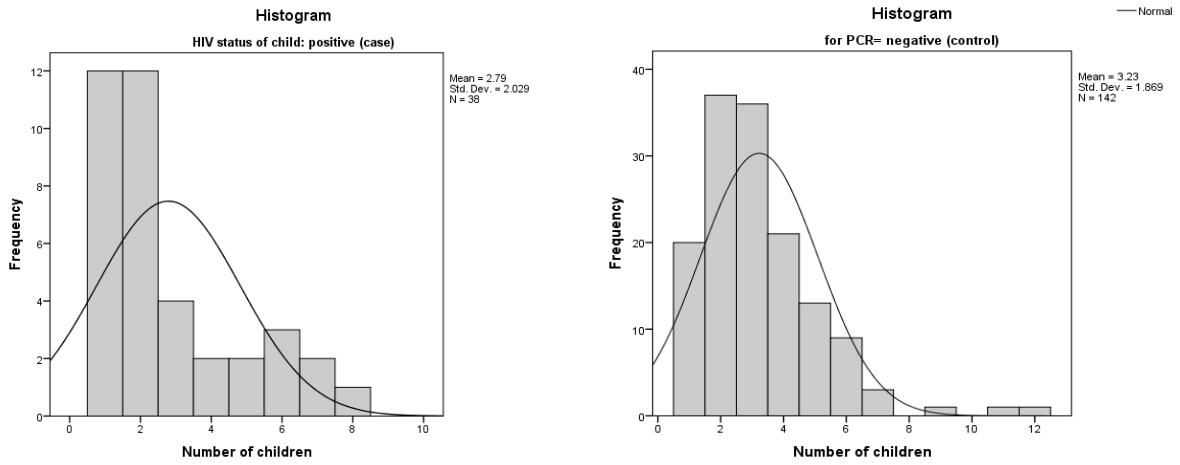

Figure 4.6: Distribution of number of children for cases and controls

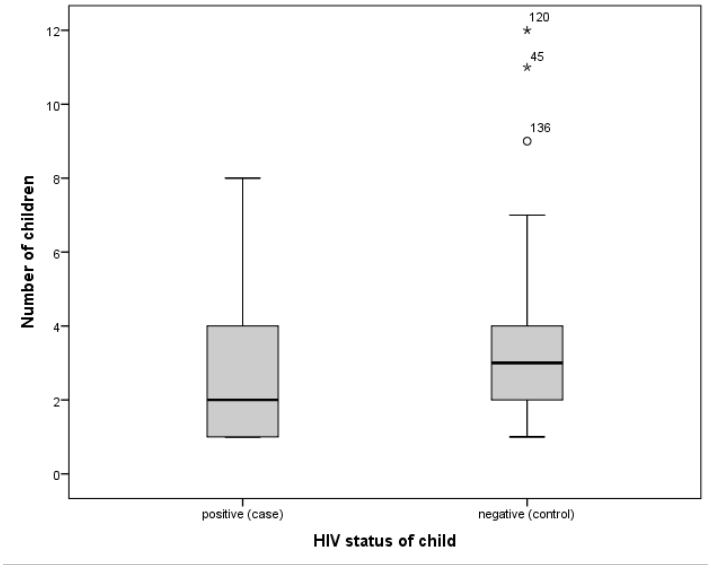

Figure 4.7: Box-plot distribution of cases and controls

4.3.2.2.5 Relationship duration

The duration of a relationship with a partner had a right tail skew, with a Shapiro-Wilk's test of $p<0.001$. An analysis of the box-plots (figure 4.8) shows there were no outliers for both cases and controls. The median relationship duration for both cases and controls was 1 year.

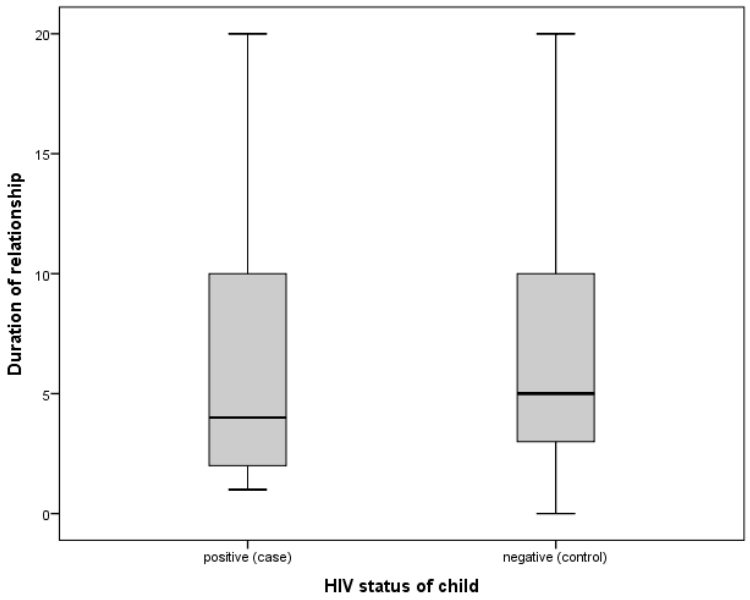

Figure 4.8: Box-plot of duration of relationship

4.3.2.2.6 Duration aware of status

The duration of time aware of one's status had a right tail skew, but no outliers (figure 4.9). Shapiro-Wilk testing the null hypothesis that your data's distribution is equal to a normal distribution was <0.001. The overall median (min, max) time aware of one's status was 16 months (1-24), which did not significantly differ across the two groups: 17 (1-20) vs. 19 (3-24); P=0.627.

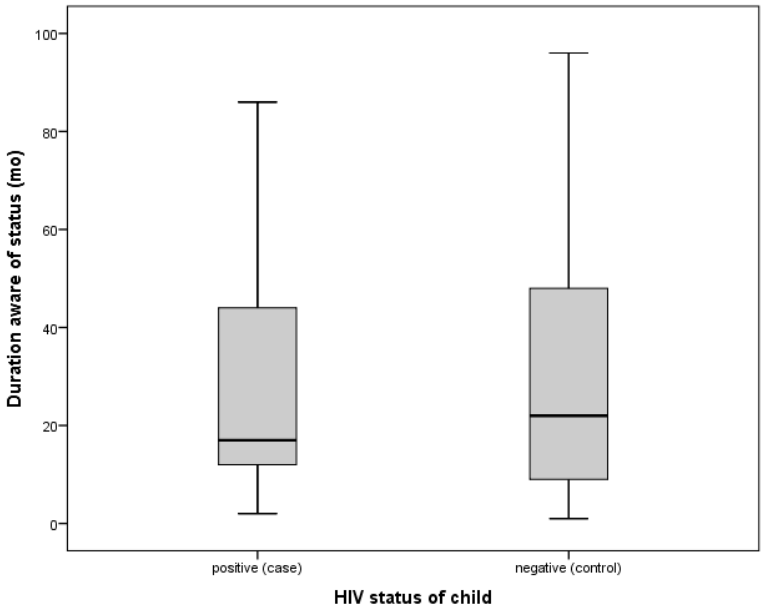

Figure 4.9: Box-plot of duration aware of status

4.4 BIVARIATE ANALYSIS OF OUTCOME AND PREDICTOR VARIABLES

4.4.1 Non-disclosure and MTCT

Overall, the non-disclosure rate to a partner was 16.7% (n=30). Among cases, mothers who had not disclosed to their partners was 52.8% (n=19) as opposed to 7.6% (n=11) among controls, with an odd ratio of 13.5 (95% CI 5.5-33.2), p<0.001 (table 4.2).

Table 4.2: Bivariate analysis of non-disclosure of positive HIV status among cases and controls

Variable		Overall N (%)	Outcome at 6 weeks		Odd ratio (CI)	P value	MH OR (CI)*	P value
			Cases, n (%)	Controls, n (%)				
Non-dis-closure	Yes	30 (16.7)	19 (52.8)	11 (7.6)	13.5 (5.5-33.2)	<0.001	10.1 (4.0-26.0)	<0.0001
	No	150 (83.3)	17 (47.2)	133 (92.4)				

*****Mantel Haenszel odds ratio, matching on health facility

4.4.2 Other predictors and MTCT

Two other variables were significantly associated with HIV status at 6 weeks: Infant prophylaxis and absolute breast feeding in the first 6 months were protective of MTCT OR=0.12 (0-0.9), p=0.005 and 0.19 (0.07-0.48), p=0.001 respectively. An awareness of partner status and male partner involvement were similarly found to be significantly associated with MTCT, OR=0.30 (0.1-0.5), p=0.001 and OR=0.12 (0.1-0.90), p=0.001 (table 4.3).

Table 4.3: Univariate analysis of outcome and clinical predictor variables

Variable		Total, n (%)	Case, n (%)	Control, n (%)	OR (95% CI)	P value
Infant prophylaxis	Yes	174 (96.7)	34 (89.5)	140 (98.6)	0.12 (0-0.9)	0.005**
	No	6 (3.3)	4 (10.5)	2 (1.4)		
Place of birth	Health facility	150 (83.3)	30 (78.9)	120 (84.5)	0.6 (0.3-1.6)	0.350
	Home		8 (21.2)	22 (15.5)		
Type of feeding	Breastfeeding	158 (87.8)	26 (68.4)	132 (93.0)	0.19 (0.07-0.48)	0.001**
	Mixed feeding	22 (12.2)	12 (31.6)	10 (7.0)		
Mode of delivery [a]	No procedure	172 (95.6)	38 (100)	134 (94.4)	-	-
	procedure	8 (4.4)	0 (0)	8 (5.6)		
Antenatal clinic attendance [a]	Yes	179 (99.4)	38 (100)	141 (99.3)	-	-
	No	1 (0.6)	0 (0)	1 (0.7)		
Partner involvement	Yes	33 (18.3)	4 (10.5)	29 (20.4)	0.12 (0.1-0.90)	0.001**
	No	34 (89.5)	34 (89.5)	113 (79.6)		
Maternal prophylaxis	Yes	165 (91.7)	32 (84.2)	133 (93.7)	0.39 (0.13-1.19)	0.097
	No	15 (8.3)	6 (15.8)	9 (6.3)		
Duration aware of status	<1 year	55 (30.6)	9 (23.7)	46 (32.4)	0.7 (0.3-1.7)	0.425
	>1 year	125 (69.4)	29 (76.3)	96 (67.6)		
Duration of relationship with partner	<1 year	155 (86.6)	31 (83.8)	124 (87.3)	0.8 (0.2-2.3)	0.713
	>1 year	24 (13.4)	6 (16.2)	18 (12.7)		
Time of disclosure	Before pregnancy	143 (93.5)	18 (85.7)	125 (94.7)	0.2 (0.1-1.4)	0.112
	After pregnancy	10 (6.5)	3 (14.3)	7 (5.3)		
Time to disclosure	<3 months	116 (75.8)	17 (85)	99 (77.4)	1 (0.2-4.0)	1.000
	>3 months	37 (24.2)	3 (15)	34 (25.6)		
Awareness of partner status	Yes	109 (60.6)	14 (36.8)	95 (66.9)	0.3 (0.1-0.5)	0.001**
	No	71 (39.4)	24 (63.2)	47 (33.1)		
Tested as a couple	Yes	43 (23.9)	6 (15.8)	37 (26.1)	0.56 (0.23-1.36)	0.201
	No	137 (76.1)	32 (84.2)	105 (73.9)		
Disclosed to other people	Yes	135 (75.0)	27 (71.1)	108 (76.1)	0.8 (0.3-1.7)	0.528
	No	45 (25)	11 (28.9)	34 (23.9)		
Encouraged to disclose by health worker	Yes	167 (92.8)	36 (94.7)	131 (92.3)	1.7 (0.3-8.0)	0.494
	No	13 (7.2)	2 (5.3)	11 (7.7)		
Follow-up on disclosure	Yes	160 (88.9)	33 (86.8)	127 (89.4)	0.9 (0.2-2.7)	0.809
	No	20 (11.1)	5 (13.2)	15 (10.6)		

** Significant at p=0.05

4.4.3 Multivariate analysis

At multivariate analysis, using conditional logistic regression, non-disclosure of a positive HIV status to a partner remained a significant risk factor for MTCT of HIV, aOR 8.9 (95% CI 3.0-26.3) after controlling for infant age and awareness of partner status

(table 4.4), which was the only predictor variable not in the causal pathway that was statistically associated with the outcome variable.

Table 4.4: Adjusted OR for non-disclosure according to multiple logistic regression analysis

Variable	Unadjusted OR (CI)	Adjusted OR (CI)	P value
Non-disclosure of positive HIV status	10.1 (4.0-26.0)	8.9 (3.0-26.3)	<0.0001

(Variables included in the analysis were infant age and awareness of partner status)

4.4.4 Testing for mediation

The regression coefficient for the analysis of path c shows that non-disclosure was significantly related to MTCT (path c) (0.37, $p<0.001$), satisfying the first condition for mediation. Similarly, the regression coefficients for the relationship between non-disclosure and male partner involvement (path a) and between male partner involvement and MTCT (path b) were significantly related, 0.51, $p<0.001$ and 0.36, $p<0.001$, satisfying the second and third conditions for mediation respectively. The standardised indirect effect (path c) was substantially reduced [(0.47) (0.36)=0.17 p=0.01] compared to the direct effect coefficient of 0.37. This last condition supports male partner involvement partially mediating the relationship between non-disclosure and MTCT (figure 4.10).

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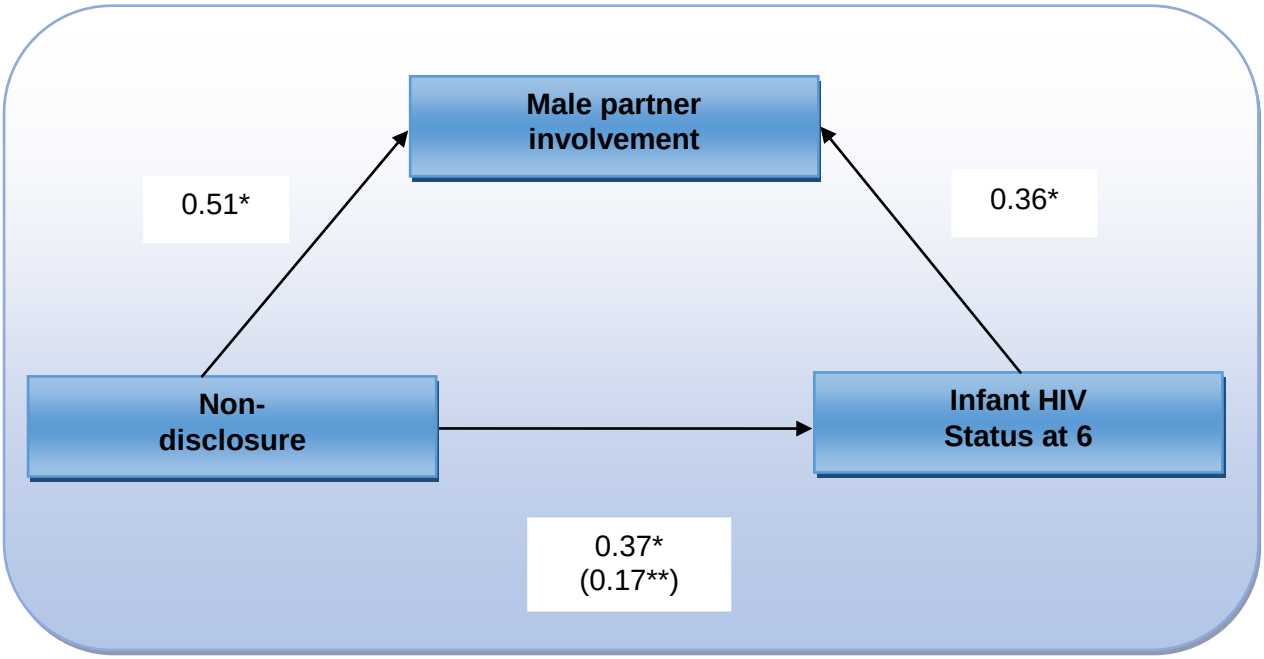

Figure 4.10: Standardised regression coefficients for relationship between non-disclosure and HIV status at 6 weeks as mediated by male partner involvement

(Standard regression coefficient between non-disclosure and outcome controlling for male partner involvement in parenthesis)

Note: *p<0.001; **p<0.01

4.5 OVERVIEW OF RESEARCH FINDINGS

In this study, the overall prevalence of non-disclosure was 16.7%, with non-disclosure being more common among cases (52.8%) as compared to controls (controls 7.6%), resulting in an odds ratio of 13.5 (5.5-33.2).

In the univariate analysis, Infant prophylaxis and absolute breast feeding in the first 6 months were protective of MTCT OR=0.12 (0-0.9), p=0.005 and 0.19 (0.07-0.48), p=0.001 respectively. Awareness of partner status and male partner involvement were similarly found to be significantly associated with MTCT, OR=0.30 (0.1-0.5), p=0.001 and OR=0.12 (0.1-0.90), p=0.001.

In multi-variate analysis, the effect of non-disclosure on MTCT maintained significance after controlling for potential confounders (aOR 8.9 (3.0-26.3); p<0.0001).

A mediation analysis demonstrated that the effect of non-disclosure on MTCT is partially mediated by male partner involvement (0.17, p=0.01).

4.6 CONCLUSION

This chapter discussed procedures employed in the data analysis, and the research findings. The analysis was performed with the help of SPSS version 22.0 statistical software package. Data analysed and presented in this chapter included response rate analysis, demographic characteristics. Findings on bivariate correlation, multiple regression and mediation results were also discussed. Graphs, charts, scatter plots and frequency tables were used along with text description to present and analyse the findings. Chapter 5 will present a summary and interpretation of the findings, while discussing the implications of the findings.

CHAPTER 5

CONCLUSIONS AND RECOMMENDATIONS

5.1 INTRODUCTION

The purpose of the study to determine whether an association exists between non-disclosure of HIV positive status and MTCT was addressed during the course of this dissertation. An association between non-disclosure and MTCT was established and enough evidence provided on the mediation effect of male partner involvement on the association. A summary of the findings and its interpretation is presented below. This chapter additionally draws out the implications of the findings while cognisance is given to the limitations of the study design. Recommendations for disclosure and male partner involvement, as part of PMTCT are then presented.

5.2 RESEARCH DESIGN AND METHODS

A matched case-control study was conducted among HIV positive women and their infants receiving HIV care and treatment at six referral hospitals in Siaya County. Cases were defined as infants who were HIV positive at 6 week of age and controls as infants who were HIV negative. For every case identified by reviews of HIV cohort registers, four controls from the same facilities were also included by random sampling of HIV exposed infants with a negative status. Mothers who accepted to be respondents were invited to complete a questionnaire which collected data on disclosure status among other variables. Data collected were entered on an Excel spread sheet for data cleaning and subsequently transferred to SPSS for analysis.

5.3 SUMMARY AND INTERPRETATION OF THE RESEARCH FINDINGS

Two important findings have stemmed out of this research effort. Primary is that HIV exposed infants whose mothers have not disclosed their positive HIV status to their partners are at a higher risk of HIV acquisition as compared to those who have

disclosed. Secondary is the finding that male partner involvement is a mediator variable in the effect of non-disclosure on MTCT.

The study has also demonstrated infant prophylaxis, absolute breast feeding in the first 6 months, awareness of partner status and male partner involvement to be protective against MTCT.

In the current study, more than two thirds (83.3%) of HIV positive women reported having disclosed their HIV status to their partner. This proportion is similar to those reported in most studies in sub-Sahara, with disclosure proportions ranging from 16.7% to 86% (Medley et al 2004:300). In a study on 3538 HIV positive patients in Kenya, Tanzania, and Botswana (Bachanas et al 2013:427), 80% reported disclosing their status to their partner. These findings were corroborated by a study of 20 HIV positive pregnant women in Kenya (Walcott, Hatcher, Kwena & Turan 2013:1118), in which 70% had disclosed their status to their partner.

The small proportion (16.7%) of non-disclosure in this current study could be an underestimate as disclosure was self-reported. As such, it is possible that some of the mothers who reported disclosing to their partner had not disclosed. But to minimise such reports, the researcher ensured that no single question in the questionnaire was given biased emphasis during data collection to ensure respondents did not feel some of the questions were more important hence requiring them to present themselves in good light. Additionally, the responses were corroborated with disclosure status reported in the patient's file, and where discordance was found or when no response was recorded, the respondent was contacted to clarify the true position.

The first significant finding not reported in any of the earlier studies is the higher proportion of non-disclosure among mothers of HIV positive infants as compared to HIV negative infants. In this study, 52.8% of women with a HIV positive infant had not disclosed their status, compared to only 7.6% among those who had a HIV negative infant, representing an odds ratio of 13.5 (95% CI 5.5-33.2). The association maintained significance even after controlling for infant age and awareness of partner status, which were significantly associated with MTCT. Despite also being significantly associated with the outcome, infant prophylaxis, type of feeding in the first 6 months, and male

partner involvement were not controlled as they were deemed to be in the causal pathway.

Several explanations have been put forth as to why a pregnant woman may be unwilling to disclose her HIV status to her partner. For the woman, disclosure of her HIV infection has far-reaching personal implications. As pointed out by several studies, pregnant women must overcome a number of difficulties when disclosing their HIV status to their partner, including but not limited to the fear of abandonment, discrimination, violence, accusations of infidelity and fear of a loss of economic support from the partner (Farquhar et al 2004:1624; Maman & Medley 2011:377). The fears experienced are valid as exemplified by Farquhar et al (2004:1625) where women who work outside the home or have more sexual experience believe that they are more likely to be blamed for infidelity and do not disclose as a result of this fear, and a lower socioeconomic status is related to an increased likelihood of disclosure to a partner. Past experiences of violence also decreased the likelihood that women would disclose their HIV status to their partners (Medley et al 2004:300). Disclosure is also impacted by issues that relate to the couple's relationship; married women and those who have discussed HIV testing prior to the test are more likely to disclose their diagnosis to their partner (Makin, Forsyth, Visser, Sikkema, Neufeld & Jeffery 2008:913).

Therefore it comes as no surprise that some women choose to remain silent about their HIV infection. The secrecy as demonstrated in this research may increase the risk of MTCT, and the mechanism as explained in several studies include delays in starting ART, poor compliance, lack of post-natal infant prophylaxis or breastfeeding (Aluisio et al 2011:79; Bachanas et al 2013:428) through lack of partner support as shown in this current study.

The second significant finding was the partial mediation of the effect of non-disclosure on MTCT by male partner involvement. Findings in this current research demonstrate that mothers with HIV positive infants have a higher rate of male partner non-involvement (10.5%) compared to 20% among those with HIV negative infants. The mediation analysis earlier presented suggests a possibility of an association between non-disclosure and MTCT being partly mediated by male partner involvement usually through poor compliance with PMTCT interventions (Kalembo et al 2013:40). These include poor attendance to antenatal clinics, non-adherence to maternal and infant

ARVs, non-adherence to infant feeding method selected, and loss to follow up among HIV exposed infants (Aluisio et al 2011:78; Bii, Otieno-Nyunya, Siika & Rotich 2008:158; Jasseron et al 2013:431; Laher et al 2012:94; Msuya et al 2008:706; Nyondo, Chimwaza & Muula 2014:36; Roxby et al 2013:34; Varga et al 2006:955). The overall low rates of male partner involvement (18.3%) are similar to low rates found in Uganda (Byamugisha et al 2010:54) reflecting a need for focussing on male partner involvement.

5.4 CONCLUSIONS

The non-disclosure rates of HIV positive status in this study were high. However, mothers with HIV positive infants were significantly more likely not to have disclosed their HIV positive status to their partner as compared to those with a HIV negative infant. The non-disclosure of a HIV positive status was found to be significantly associated with MTCT, even after controlling for infant age and awareness of partner status which was the only variable significantly associated with MTCT and was not in the proposed causal pathway. The effect of non-disclosure on MTCT was found to be partially mediated by male partner involvement.

5.5 RECOMMENDATIONS

5.5.1 Recommendations for disclosure

Individuals are motivated by a multiplicity of factors in their decisions regarding disclosure of their HIV status, and thus multiple strategies are warranted to promote safe disclosure to a partner. In sub-Saharan Africa PMTCT guidelines encourage self-disclosure of HIV status, being keener on ensuring confidentiality and privacy. While this is key, placing the burden of disclosure on the women has not yielded high enough disclosure rates in many settings. Recognising the complexities involving disclosure for the women, and the potential negative outcomes following disclosure, strategies to enhance disclosure must be carefully designed to address the fears. One of the most critical is removing the burden of disclosure from the women.

Facilitated HIV disclosure is one such strategy whereby a counsellor is present during the disclosure period to help with understanding and information. This approach has

been shown to receive favour among HIV infected couples as it facilitates disclosure while reducing potential for adverse events (Walcott et al 2013:1116). On the other hand, the approach does not entirely negate potential adverse events that may occur later on after the counsellor has left the couples.

Another strategy that can be adopted is testing for HIV together as a couple. The strategy not only removes the burden of disclosure on any one individual, but also provides a safe environment for disclosure to occur. Another potential benefit of couples testing is in the partner support offered to access and adhere to ART and interventions to prevent mother-to-child transmission of HIV.

Home-based couple HIV counselling and testing with support for mutual disclosure can also be an effective and acceptable method (Walcott et al 2013:1120). However, the strategy can also be predisposed to stigma for the couple and erroneous disclosure to other family members resulting in breach of confidentiality by the health worker.

Importantly, it is worth considering that some of the barriers to disclosure hinge on gender and societal norms whereby in some cultures women are not allowed to have a voice. Women's empowerment programmes can shift gender norms and ultimately facilitate HIV status disclosure to sexual partners. Addressing stigma associated with HIV status through community-based programmes is another way of changing societal norms. The development of support groups for infected women provides another avenue for ongoing support that may help women work through their disclosure processes.

5.5.2 Recommendations for male partner involvement

Strengthening male partner involvement not only reduces MTCT through enhanced adherence, but also presents an avenue for safe disclosure of HIV status. It creates an opportunity for individual men and couple HIV testing, actions that remove the disclosure burden from the woman (Jasseron et al 2013:495). Theuring, Mbezi, Luvanda, Jordan-Harder, Kunz and Harms (2009:96) showed that men actually support and are not averse to being involved in PMTCT and antenatal-clinic services, despite barriers of lack of knowledge, health services representing a female responsibility, and fear of HIV test results. Moreover, the traditional gender roles that empower men to

make decisions regarding their female partners' medical care enable them to determine the success of PMTCT programmes.

A successful intervention aimed at improving male involvement ought to address these barriers. Experiences from programmes working with men on HIV/AIDS-related issues in various African countries attest to the importance of constructively engaging men to address women's uptake of PMTCT interventions (Kalembo et al 2013:40). The first step involves appealing to men to share equal responsibility and participate in joint decision-making with their partners, without necessarily controlling those decisions. Health facilities can facilitate this role by offering services that are welcoming to male clientele with an addition of initiatives that are exclusively for men. Other areas have reported increased male involvement through the use of invitation letters to the male partners to attend either PMTCT or ANC services (Byamugisha et al 2010:54).

Behaviour change and communication through the media may be used to increase the number of men accompanying their female partners to antenatal clinics by changing the gender stereotype and providing more information. One additional strategy that can be used is peer-peer sensitisation of men. This may involve recruiting leaders from the men's support groups to serve as peer discussion leaders to deliver educational sessions to other men in their communities about the importance of men's support and engagement in PMTCT programmes.

5.5.3 Recommendations for future research

From previous publications and this current study, several potential areas of future research have been identified. First, although this study established a significant association between MTCT and three behavioural predictor variables (non-disclosure, awareness of partner status, and male partner involvement), more studies need to be undertaken to comprehensively study other behavioural factors not addressed in the current study. Moreover, while mediation on the effect between MTCT and non-disclosure by male partner involvement was established, it is imprudent not to realise that the model thus tested is very simplistic. More detailed mediation models should be explicated to comprehensively understand the mediation mechanism of the effect of non-disclosure on MTCT.

As a follow up to this study, it would be interesting to replicate the study in a metropolitan area or in a culture where the health seeking behaviour of women and children is not solely determined by men.

5.6 CONTRIBUTIONS OF THE STUDY

This study has provided useful insights in the fight against MTCT of HIV. It has supported findings from other studies of a high rate of disclosure among HIV positive pregnant women. The study has also demonstrated that HIV positive women with a HIV positive child are likely not to have disclosed their status to their partner. Infant prophylaxis and mode of feeding in the first six month has been shown to be still important determinants of MTCT of HIV in the era of universal access to HIV medicines. Additionally, evidence has been provided that awareness of male partner involvement is significant determinants of MTCT of HIV.

Finally, in addition to proposing ways of improving disclosure among HIV positive pregnant women, the study has also demonstrated how to apply a matched case-control design to assess relationships between two variables.

5.7 LIMITATION OF THE STUDY

Despite an important contribution to our existing knowledge about non-disclosure and MTCT, care must be taken in generalising this study's findings. Inasmuch as the study involved all referral facilities in the County, the findings may not be generalised to other settings with varying socio-demographic, cultural and economic characteristics.

Another possible limitation is the possibility of social desirability bias owing to the nature of data collection. Self-reports usually have risk of introducing bias as respondents may lie about themselves to present themselves in good light. This study minimised that possibility by corroborating the reported findings as much as possible with patients' records, and assuring the respondents of data anonymity, privacy and confidentiality.

While every effort was made to ensure the sample of controls was representative of the general population, it is possible that this was not the case as the study was facility-

based. Besides, pregnant mothers not attending ante natal clinics are likely to differ from those who seek care from health facilities.

5.8 FINAL REMARKS

Given the potential for PMTCT interventions to eliminate MTCT, and the evidence emanating from this study suggesting an important association among non-disclosure of HIV positive status, male partner involvement and infant HIV acquisition, which hitherto was unclear, a re-examination of policies on disclosure and male-partner involvement ought to occur in order to address these two behavioural predictors of infant HIV acquisition. While policy on HIV testing and counselling advocate on partner disclosure as part of post-test counselling, very little is done to ensure disclosure indeed happens. This evidence should invigorate efforts to integrate more effective methods that ensure disclosure occurs in a safe environment. Additionally, male partner involvement which serves the dual purpose of increasing awareness of HIV status and enhanced disclosure should be prioritised.

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Annexure 1

The Clearance certificate issued by Health Studies Research and Ethics Committee of UNISA

UNISA university of south africa

UNIVERSITY OF SOUTH AFRICA
Health Studies Higher Degrees Committee
College of Human Sciences
ETHICAL CLEARANCE CERTIFICATE

HSHDC/262/2013

Date:	27 November 2013	Student No:	4810-991-6
Project Title:	A case-control study on non-disclosure of HIV positive status to a partner and mother to child transmission of HIV.		
Researcher:	Nyandat Lawrence Joram		
Degree:	Masters in Public Health	Code:	DLMPH95
Supervisor:	Prof GH van Rensburg		
Qualification:	D Litt et Phil		
Joint Supervisor:	-		

DECISION OF COMMITTEE

Approved [√] **Conditionally Approved** [ ]

pp

Prof L Roets
CHAIRPERSON: HEALTH STUDIES HIGHER DEGREES COMMITTEE

Prof MM Moleki
ACADEMIC CHAIRPERSON: DEPARTMENT OF HEALTH STUDIES

PLEASE QUOTE THE PROJECT NUMBER IN ALL ENQUIRES

UNIVERSITEIT VAN SUID-AFRIKA
PRETORIA
UNIVERSITY OF SOUTH AFRICA

Annexure 2

Moi University Institution Research Ethics Committee approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2014/08
Approval Number: 0001160

7th April, 2014

Dr. Joram Nyandat,
P.O. Box 1058-00300,
NAIROBI-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
07 APR 2014
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Dr. Nyandat,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"A Case-Control Study on Non-Disclosure of HIV Positive Status to a Partner and Mother to Child Transmission in HIV".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1160*** on 7th April, 2014. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 6th April, 2015. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc Director - MTRH
Principal - CHS
Dean - SOM
Dean - SOP
Dean - SON
Dean - SOD

Annexure 3

Permission request letter

19th May 2014

County Director of Health
Siaya County
P.O. Box 592
Siaya.

Dear Sir,

RE: **Permission to conduct a facility based study**

I request to be allowed to conduct a study titled "A case-control study on Non-disclosure of HIV positive status to a partner and mother to child transmission of HIV" in health facilities offering HIV care and treatment in your County. This study is a dissertation towards a Masters of Public Health (MPH) degree from The University of South Africa, and will be conducted under the supervision of Prof Gisela Von Rensburg from the University of South Africa and Dr Peter Gisore from Moi University.

The need for this study is based on the realization that behavioural factors, including non-disclosure of positive HIV status to partner contributes to poor uptake and utilization of key Prevention of Mother to Child transmission interventions, hindering elimination of Mother to Child Transmission of HIV.

The results of this study will provide information on the Mother to Child transmission rates for 2013 and provide information on whether non-disclosure contributes to MTCT, information which may inform policy on disclosure, male partner involvement and HIV testing and counselling.

Upon completion of the study, I undertake to provide a copy of the research report. If you require any further information, please do not hesitate to contact me on 0721802036 or jnyandat@yahoo.com.

Thank you for your time and consideration in this matter.

Yours sincerely,

Dr Joram Nyandat, MPH student
University of South Africa.

Annexure 4

Approval letter by Siaya County Director of Health

COUNTY GOVERNMENT OF SIAYA

MINISTRY OF HEALTH

KNUT Building
Siaya Town
Email: siayachd@gmail.com

COUNTY HEALTH HEADQUARTERS
SIAYA COUNTY
P.O. BOX 597
SIAYA

Our Ref: GN/XIV/VOL1(5)

2nd July 2014

THE SUB COUNTY MEDICAL OFFICER OF HEALTH: SIAYA, UGENYA, UGUNJA, GEM, BONDO, RARIEDA

THE MEDICAL SUPERINTENDENT: SIAYA COUNTY REFERRAL HOSPITAL, UKWALA SUB COUNTY HOSPITAL, AMBIRA SUB COUNTY HOSPITAL, YALA SUB COUNTY HOSPITAL, BONDO SUB COUNTY HOSPITAL, MADIANY SUB COUNTY HOSPITAL

RE: REQUIRED SUPPORT FOR A CASE CONTROL STUDY ON EMTCT

Dr. Joram Nyandat is an MPH student from the University of South Africa and is currently conducting a case control study on EMTCT in Siaya county titled ***"A case-control study on non-disclosure of HIV positive status to a partner and Mother To Child Transmission of HIV"***. The study aims to determine whether an association exists between non-disclosure of HIV positive status to a partner and Mother to Child transmission of HIV.

The study population will be from the Comprehensive Care Clinics in the referral hospitals in each sub-county and will consist of HIV positive women who delivered between July 2013 - June 2014

This case-control study by Dr. Nyandat has been reviewed and approved by the **Higher Degrees Committee of the Department of Health Studies, University of South Africa** and the **Moi University Research and Ethics Committee in Kenya**. The Office of the County Director of Health (Siaya) has likewise given approval for this study to be conducted in Siaya County.

Please give Dr. Nyandat the necessary support required for this study that will inform HTC and EMTCT programming in our county

Dr.Omondi Owino

County Director of Health-SIAYA

2nd July 2014

Annexure 5

Consent form

INFORMED CONSENT FORM

RESEARCH TITLE

A case-control study on Non-disclosure of HIV positive status to a partner and mother to child transmission of HIV

RESEARCHER

Dr Joram Nyandat

INSTITUTION

University of South Africa

PART I: INFORMATION ABOUT THE STUDY

Introduction

I am **Dr Joram Nyandat** doing a research on transmission of HIV from the mother to her baby, which is of great concern in Kenya.

I am going to give you information about the research then invite you to participate. If you have any question or need clarification do not hesitate to bring it up. You do not have to decide today whether or not to take part.

Purpose

Everyone is trying to ensure that the risk of a mother transmitting HIV to her child is eliminated. To do this, we need to understand everything that may contribute to its transmission. In this study we will be concerned with just one aspect which is non-disclosure of a positive HIV status to the partner.

Participant selection

You have been selected due to your HIV status as a result of which your baby is at risk of being infected by the virus.

Voluntary Participation

Your decision to participate in this study is entirely voluntary. You may also choose to change your mind later and stop participating, even if you agreed earlier.

Procedure

If you choose to participate in this study you will be asked to fill a questionnaire, which will ask you a few questions about yourself and your baby.

Duration

It will take you around 30-60 minutes to fill the questionnaire.

Risks

By participating in this research it is possible that you may suffer from emotional strain and your partner or some of your family members may demand certain information from you, especially if they were not aware of your status.

Benefits

Your participation in the study will provide us with valuable information that will help us make recommendations on how to further reduce the chance of a mother transmitting HIV to her baby.

Reimbursements

You will not be provided any incentive to take part in this research.

Confidentiality

The information that we collect from this research project will be kept confidential, and only the researchers will be able to see it. Any information about you or your child will have a number instead of the name.

Who to Contact

If you have any questions you may ask them now or you can ask later, even after the study has started. If you wish to ask questions later, you may contact me on the following: Phone: 0723641271; Email: jnyandat@yahoo.com

This proposal has been reviewed and approved by Higher Degrees' Committee of the Department of Health Studies, University of South Africa (UNISA) and Moi University Research and Ethics Committee in Kenya, which are committees tasked to make sure that research participants are protected from harm. If you wish to find about more about the ethics committee, please call 057-33471

PART II: STATEMENT OF CONSENT

I have read the above information, and have received answers to any questions I asked. I consent to take part in the study.

Name of Participant	Signature/thumb print	Date

PART III: STATEMENT BY THE RESEARCHER

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of Researcher	Signature	Date

Annexure 6

Questionnaire

UNISA

QUESTIONNAIRE

Study number_____
Facility Name_____

(Please go through the questionnaire carefully and fill it to the best of your ability. Tick where appropriate.)

PART A: PERSONAL CHARACTERISTICS

(To be filled by interviewer from hospital records)

What were the mother's most recent CD4 count/viral load during this last pregnancy?
Viral load_____ CD4 count_____ Disclosed status? ☐ Yes ☐ No

(To be filled by the respondent)

1. How old (in years) are you? _____

2. What is your highest school qualification?
☐ Never attended ☐ Primary ☐ Secondary ☐ College ☐ University
☐ Other, please specify_____

3. What is your marital status?
☐ Unmarried ☐ Married/cohabiting (monogamy) ☐ Married/cohabiting (polygamy)
☐ Divorced/separated ☐ Widowed

4. How many children have you had (both alive and deceased) _____

PART B: INFANT CHARACTERISTICS

5. How old (in months) is your baby? _____

6. What is the sex of your baby?
☐ Male ☐ Female

7. What was your baby's birth weight (in kg)? _____

8. What type of feed did you give your baby during the first 6 months?
☐ Absolute breastfeeding ☐ Formula milk ☐ Breastfeeding combined with some other food (mixed feeding)

PART C: DISCLOSURE AND HIV STATUS

9. Have you disclosed to your partner that you are HIV positive?
☐ Yes ☐ No

9.1 If yes, when did you disclose?
☐ Before this pregnancy ☐ During this pregnancy ☐ After delivery of this baby

10. How long (in months) have you known that you are HIV positive? _____

11. How long after first knowing your status did you disclose your HIV status to your partner? _____

12. Did you attend antenatal clinic during the pregnancy that resulted in the delivery of this baby?
☐ Yes ☐ No
If yes,
12.1 How many times did you attend antenatal clinic? _____

12.2 Were you accompanied by your partner to any of the clinic visits?

☐ Yes ☐ No

12.3 Were you advised by a health care provider to disclose your status to your partner?
☐ Yes ☐ No

If yes,
12.3.1 How many times were you encouraged to disclose to your partner before you actually disclosed? _____

12.3.2 Were you asked in any of the subsequent visits whether you had disclosed to your partner?
☐ Yes ☐ No

13. Were you taking any HIV medicines during this last pregnancy?
☐ Yes ☐ No
If yes, specify which ones.....

14. Were you given any medicine to give to your baby to prevent transmission of the HIV virus?
☐ Yes ☐ No

15. How long have you been with your partner?_____

16. Do you know the HIV status of your partner?
☐ Yes ☐ No
If yes,
14.1 Were you tested together with your partner (couple testing) for HIV?
☐ Yes ☐ No

17. Have you disclosed your status to someone else other than your partner?
☐ Yes ☐ No
15.1 If yes, to who?
☐ Sibling ☐ Parents ☐ Neighbour ☐ Friend ☐ Other_____

18. Where did you deliver the baby?
☐ Health facility ☐ Home

18.1 If at a health facility, what form of delivery did you have?
☐ Vaginal without any procedure ☐ Episiotomy was done ☐ forceps/vacuum delivery
☐ Caesarean section (operation)

Thank you for your time!