

CHAPTER II
METHODOLOGY

2.1. Introduction

Parent to Child Transmission (Mother-to-child transmission/MTCT) of HIV is the most common mode of HIV-1-infection in the child. The prevalence of HIV-1 among pregnant women is highest in developing countries, and in the absence of therapy, approximately one-third of the mothers transmit HIV-1 to their infants. In the absence of breastfeeding, 70 per cent of MTCT occurs in the intrapartum period. Antiretroviral drugs during pregnancy and delivery, caesarean section and artificial feeding have almost eliminated MTCT in the developed world. Unfortunately, these interventions are difficult to implement in developing countries because of socio-economic, societal, logistical and financial limitations, and poorly functioning health systems. To start with, the above mentioned interventions require individual testing and pre-test counselling which is a major burden on the already overstretched healthcare systems. Hence, there is an urgent need to develop interventions that are effective, feasible, affordable and easy to implement Prevention of Mother-to-Child Transmission (PMTCT) programme. Since a substantial proportion of MTCT takes place during labour and delivery, effective intrapartum interventions could have an impact on MTCT.

In the previous chapter, an in-depth literature study was done on HIV/AIDS scenario in global and India specific, knowledge of HIV/AIDS, Prevention to Parent to Child Transmission (PPTCT), infant feeding practices, risk factors on MTCT and infant feeding practices, decision-making, disclosure of HIV, behaviour and attitudes. This chapter presents a comprehensive methodological approach that has been used in conducting the study. It covers the research design, description of the area studied and justification for its choice, data collection methods and tools for data collection, sampling techniques, ethical consideration and informed consent, data analysis techniques and field experience and challenges.

2.2. Study Design

A cross sectional and explorative study using both quantitative and qualitative methods have been designed for this study. It is cross-sectional because the information which is gathered at one point of time. Since there is no follow-up, fewer resources were required to conduct it. The basic data used to fulfil its objectives have been collected both from the primary and secondary sources. Primary data have been collected through questionnaire method from the women diagnosed as HIV infected who came to the hospital during the

antenatal stage and delivery care. The information was also collected from health care providers such as doctors and counsellors in PPTCT programme. On the other hand, secondary information was gathered from ‘HIV positive women line list’, ‘ANC registration form’, ‘ANC check-up and follow-up form’, ‘infant follow-up form’, ‘monthly summary report’, and ‘ICTC/PPTCT registers. The treatment records, medical information and child growth have been collected from selected ART centres in these hospitals.

2.3. Selection of Sites

The study has been carried out in high HIV prevalence ‘A’ category and medium prevalence ‘B’ and “C” category districts of Odisha as per the National AIDS Control Programme Phase-III categorization. As per the definition, there are four districts which fall into ‘A’ category where more than 1 per cent HIV prevalence at Antenatal Care (ANC) in any site in the last three years. There are four districts (Anugul, Bolangir, Bhadrak and Ganjam) which fall in this category. In Medium Prevalence category ‘B’ districts there is less than 1 per cent of ANC in all sites and more than 5 per cent prevalence is in any High Risk Groups (HRG) sites for the last three years. Three districts (Baleswar, Khordha and Koraput) fall in this category. Category ‘C’ has been categorized as less than 1 per cent ANC prevalence in all sites during the last three years with less than 5 per cent in all HRG sites with known hot spots (migrants, truckers, large aggregation of factory workers, tourists, etc). There are 18 districts which fall in this category. Category ‘D’ has been categorized as less than 1 per cent ANC prevalence in all sites during the last three years with less than 5 per cent in all HRG sites with no known hot spots or no or poor HIV data. Five districts fall in this category (NACP-III, 2007).

One district has been selected from each category, namely, Ganjam, Khordha and Cuttack. The categorization has been given below:

Table 2.1 Categories of districts based on HSS, 2004-06

Category 'A' (4 districts)	Category 'B' (3 districts)	Category 'C'(18 districts)	Category 'D' (5 districts)
Anugul, Bolangir, Bhadrak and Ganjam	Baleswar, Khordha and Koraput	Baudh Cuttack Debagarh Jagatsinghapur Jajapur Kalahandi Kendrapara Keonjhar Malkangiri Mayurbhanj Nawarangpur Nayagarh Nuapada Puri Rayagada	Bargarh Dhenkanal Gajapati Jharsuguda Kandhamal

Source: Computerized Management Information System, NACO.

As per the National AIDS Control Programme, there are 184 Integrated Counselling and Testing Centres (ICTCs and PPTCTs) and nine Antiretroviral Treatment (ART) Centres available for providing counselling, testing and treatment services in Odisha. For the study three centres have been selected purposively where PPTCT centres have been integrated with ART centre and have a number volume of ANC clients. In this connection, one centre has been selected for each district. The selected centres are served as a centre of excellence for providing health care and HIV care in the particular districts. These centres are the Govt. medical colleges. The names of the centres have been kept as confidential. These three hospitals have been providing counselling, testing and treatment services and ANC prevalence is more than 1 per cent in them.

2.4. Sampling Design

As for the sampling design, a random sample of women living with HIV/AIDS is difficult to obtain as enumeration of the entire population of HIV infected women is not possible. Therefore, this study is based on a purposive selection of the respondents. It was restricted to only those HIV positive mothers who are identified as HIV positive during ANC and delivery care and came for post-test counselling and follow-up stage. In all 290 HIV

positive deliveries took place during 2011-13 in these hospitals. Of 290 deliveries, 152 HIV positive mothers who came for ANC check-up and post-natal follow-up visit to the hospitals were included as sample. All of them were interviewed with the help of standard structured questionnaire method. HIV counsellors and research investigator were trained as to collect the required information through face to face interview. Socio-economic and demographic profile, medical history and intention and practice of infant feeding have been captured. In-depth interviews were conducted with 40 HIV positive mothers (33 from Ganjam district, five from Cuttack district and two from Khordha district) to obtain qualitative information. These positive mothers were counselled for infant feeding practices and having some experience of infant feeding practices.

Table 2.2 PPTCT coverage, 2009-2013

Indicators	Ganjam	Cuttack	Khordha	Total
No of pregnant women counselled	13219	11850	66071	91140
No of pregnant women tested	12938	11775	62456	87169
No. of pregnant women identified HIV +ve	233	94	42	369
No. of partners of pregnant women counselled	1031	3729	966	5726
No. of partners of pregnant women tested for HIV	1031	3729	966	5726
No. of positive women delivered	213	55	22	290
No. of life birth	207	52	20	279
No. of pregnant women who received prophylaxis (Sd BVP)	185	45	19	249
No. of infants who received prophylaxis (Sd NVP)	185	45	20	250
No. of -mother-baby pair who received prophylaxis (Sd NVP)	185	45	18	248

Source: Computerized Management Information System, NACO.

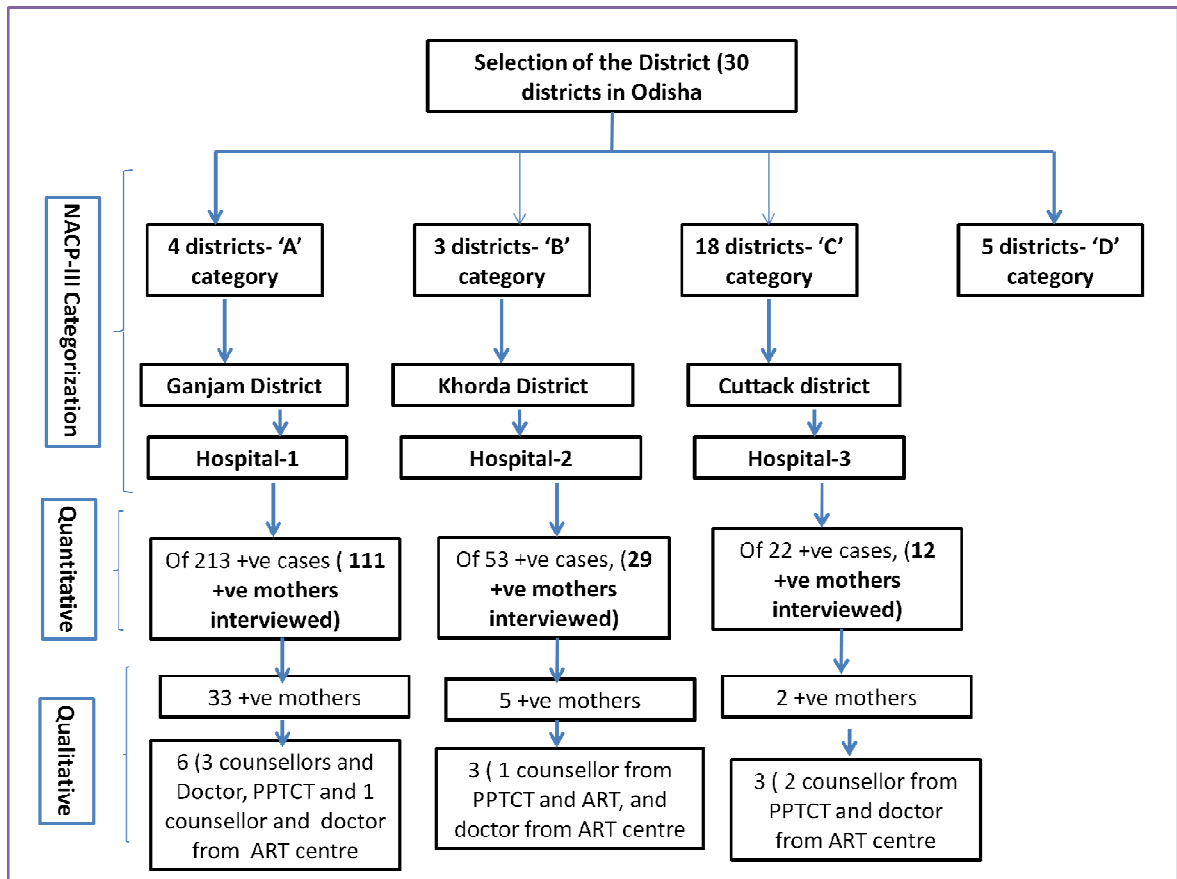
2.5. Selection of HIV positive women: HIV infected women/positive mothers who were willing and consented for participation were included in the study.

2.6. Selection of Health Care Providers: Doctors and counsellors who are particularly appointed for the PPTCT programme were interviewed using in-depth interview guide consent for their role in providing PPTCT services, infant feeding practices and challenges. In this regard, 12 health care providers were interviewed.

2.7. Exclusion criteria

HIV positive mothers who refused to participate after explanation about the purpose of the study, those who were too sick to participate in it and health care providers (doctors and counsellors who were not currently working with the hospitals) were not interviewed. Those health care providers who were not present at the time and refused to participate are also excluded from it.

Figure 2.1 Sampling frame of the study



2.8. Ethical consideration and informed consent

The practice of requiring informed consent and ethical consideration for HIV/AIDS research is an obligatory policy in India following the stigma attached to HIV disease. In this context, the researcher followed the process of ethical clearance. The ethical review committee and Ph. D. advisory committee of the Gokhale Institute of Politics and Economic (GIPE), Pune, approved the study for ethical and scientific merit. It has also received approval of the Department of AIDS Control, National AIDS Control

Organization, and Union Ministry of Health & Family Welfare. The proposal was submitted to the Department of AIDS Control, National AIDS Control Organization, and Union Ministry of Health & Family Welfare for seeking the permission for this study. The researcher was presented at Department of AIDS Control, Ministry of Health & Family Welfare. The proposal was reviewed by the technical committee and approved for the study.

The purposes of the study were explained to all potential participants (HIV-positive mothers, counsellors, lab technician and doctors). The participants gave verbal consent to participate in it. The study opted for oral consent from the HIV-positive mothers. It was also clarified that the informants could decline from answering particular questions or could withdraw from the study at any point of time freely.

2.9. Confidentiality

My name is Ananta Basudev Sahu working for PhD at Gokhale Institute of Politics and Economics, Pune. I am interviewing the HIV positive mothers and health care providers to study the infant feeding practices and challenges. The research is being carried out after the formal approval of the Department of AIDS Control. Yours participation in this study will be very useful. If you are willing to participate, I would like to tell you about the right time of the interview. Firstly, your participation is purely voluntary. You can refuse to answer any particular question and also withdraw from the study without giving any reason. You also have the right to seek clarification and information about any aspect of the research topic. I would like to assure you that all the information provided by you will be kept confidential and in safe custody. No identification, particularly your name, etc., will be revealed in the thesis or elsewhere. I would appreciate if you will be willing to participate in this study.

2.10. Data collection process

Mixed method approach was used during data collection process by using both quantitative and qualitative methods. The basic data used to fulfil the objectives of the study have been gathered from both the primary and secondary sources. A structured questionnaire method was adopted for collecting socio-economic and demographic profiles and knowledge, attitude and practices about Prevention of Parent to Child Transmission of HIV (PPTCT) and infant feeding practices among HIV positive women.

For qualitative information, in-depth interviews were conducted with HIV positive women and health care providers at the post-natal clinic and ART centres. These interviews included guidelines and open ended questions related to their knowledge of different infant feeding practices, infant feeding decision by HIV positive women, reasons for choosing a particular feeding option, challenges of infant feeding practices, disclosure of their HIV serostatus and household environment. In-depth interview has also been conducted to obtain required related information from health care providers, i.e., counsellors, doctors, and lab technicians who provide counselling and treatment services in the selected hospitals.

The National AIDS Control Programme has adopted a strong monitoring and evaluation framework in phase III of the NACP. Along with the primary information, information has been captured from medical records such as 'HIV positive women line list', 'ANC registration form', 'ANC check-up and follow-up form', 'infant follow-up form', 'monthly summary report' and 'ICTC/PPTCT registers. The treatment records, medical information and child growth have been collected from selected ART centres in these hospitals.

The study analyses the feeding practices of HIV positive women. As per the policy of the Government of India, every study needs to be permitted by the Department of AIDS Control (DAC), National AIDS Control Organization (NACO) and ethical consideration from the Institute. In this context, the researcher took formal permission from Department of AIDS Control and ethical clearance from the University. The proposal was presented to the data sharing committee of DAC on February, 2012. The proposal was reviewed by the technical committee and approved for the study. The institutional ethics board of the university approved the ethical clearance on 1st August, 2012. With the approval of DAC and the ethical clearance of the Institute, the field work was started. Its duration was almost one year from November, 2012 to September, 2013.

2.11. Field experiences and challenges

The utmost challenge is to identifying the HIV positive pregnant women at the respected health facilities. After approval of DAC, NACO and the Institute, the researcher has interacted with State AIDS Control Society (SACS) official. With their help, researcher interacted with the counsellors, doctors and lab-technician at the facility. All the counsellors and lab-technicians were cooperative during the interviews. With the help of

counsellors and out-reach workers interacted and interviewed with HIV positive women. It was a combination of sorrow and adventure to work directly with HIV positive women primarily when they were diagnosed during pregnancy and delivery. In general, the trust generated between the researcher and respondents ensured a degree of openness to discuss the sensitive issues in their life, infant feeding practices and challenges they faced for adopting a particular feeding option. They also disclosed the status to their partners and in-laws.

Most of the women were curious to know the best infant feeding options and prophylaxis available for both mother and infant. Exclusive breastfeeding is recommended for the initial six months. However, HIV virus could be transmitted through breast milk which creates a major public health dilemma for the promotion of breastfeeding in resource limited settings. The confusion is not only for HIV positive women but also for health care providers. Some of the HIV positive women were confident of their child not getting infected as they had delivered with medicines and practised formula/replacement feeding. The HIV positive women were probed whether they were asked by relatives for not breastfeeding what explanation normally they gave for it. Some of the positive women were not able to purchase the formula/replacement feeding for their babies due to lack of money. It is also sad to observe that when they found that their children were HIV positive after tests, they burst into tears. .

The respondents' confidentiality was a challenge for the researcher. So proper care was taken to maintain it and not to disclose their HIV status to their family members, relatives and friends. Some of the mothers-in-law who had not been informed about the HIV status inquired about the reasons for not breastfeeding the child. In the health facility and during counselling every positive woman was encouraged to disclose the HIV status to the husband and bring him for testing.

Though the researcher presented the proposal to DAC and NACO and obtained permission to collect data from the field, he faced the challenges in collecting secondary information from the field. As per the guidelines of NACO, PMTCT programme captures the information of HIV positive women and maintains the HIV positive line list to track the HIV positive women. Most of the information, i.e., socio/economic and demographic profile has not been captured. There were incidences where hand written scripts were not legible or left blank. Follow-up register, prophylaxis registers (MB pair register) and ANC note were not well maintained by the counsellor and out-reach worker. Data from such

forms could not be retrieved. It is understandable that doctors are occupied with professional works to undertake on daily basis, leaving the chances open for such omissions. The women who were identified as HIV positive were referred to ART centre for treatment. Their Management Information System (White Card) is maintained as per the direction of NACO. HIV positive women were tracked through a White Card and their medical history captured. In the health facility it is difficult to track the HIV positive women in PPTCT centre and ART centre as they do not maintain a different registration code for such women.

The researcher faced the challenge of interviewing the HIV positive women at the health centre. Interviewing them at the post-natal clinic and isolated corner invited unnecessary attention of others who visited the OPD. Interviews were conducted in the morning hours. Counsellors helped in providing the necessary information about the respondents prior to the interview and they also helped in the interviewed process.

2.12. Validity and reliability:

Variables were created based on their use in other studies and experts in the field reviewed the questionnaire. It was administered in languages understood by both respondents and interviewers. A research assistant was trained on how to ask questions and record the answers in order to ensure standardisation and to avoid interviewer's bias. Quality control checks on data were done in the field as well as before and during the data processing for completeness and consistency.

2.13. Statistical Methods used for Data Analysis

Data were entered into and analyzed using SPSS database programme. Univariate, bivariate and multivariate techniques were employed to analyse data. Univariate analysis has been used for the computation of frequency and number of cases that determines the variation between or among different categories of a given variable. Through bivariate analysis, association between variables were determined. The Chi-square test was used to measure the strength of associations between variables, a p-value and significant level of <0.05 was considered to be statistically significant. Multivariate analyses were carried out using logistic regression methods. Logistic regression method was used to understand the level of effect of different background factors on outcome variable. To understand the effect of background or independent variables on dependent or outcome variable, these outcome variables such as knowledge of HIV/AIDS, knowledge of prevention of

HIV/AIDS transmission from mother to her baby, knowledge of intention of exclusive feeding and formula feeding, etc., have been included in the binary logistic regression model. In order to fit into the model all the outcome variables were coded binary as '1' for Yes and '0' for 'No', creating dummy variable for more than two categories. The predicted variables included in the logistic regression model are place of residence, age, education and occupation of women and their husbands, family income and type of family to understand their effect on knowledge on HIV/AIDS and PPTCT. Adjusted Odds Ratios (ORs) were calculated to understand the factors affecting the infant feeding practices. Further, analysis of qualitative method was used for interpreting the infant feeding challenges of HIV positive women.

2.13. A. Chi square

Most commonly used test of significance for finding out the association between two nominal variables is chi square (χ^2) test. If two variables have a non-zero relation, then to test whether the relation is statistically significant, chi square test is applied. The chi square equation is written as:

$$\chi^2 = \frac{\sum (O - E)^2}{E}$$

Where

O = observed frequency

E = Expected frequency

This test compares the observed and expected (assuming the relation is zero) frequencies in each category. The larger the summed difference between observed and expected values as a ratio of expected values, the larger is the value of chi square and the greater is the likelihood that the relationship is statistically different.

Following table shows the data, method, variables, topic and main analysis conducted for the respective chapters.

Table 2.3 Data method, variables, topic and main analysis conducted for respective chapters

Chapter	Method	Variables	Topics	Main Analysis
IV	QUAN	<p>Independent variables: Age, place of residence, marital status, religion, caste, education and occupation of HIV positive women and income of the family</p> <p>Dependent variables: Knowledge about HIV/AIDS and knowledge about parents to child transmission (PPTCT) during pregnancy, delivery and breastfeeding</p>	<p>1. Socio-Economic and Demographic profile</p> <p>2. Knowledge about HIV/AIDS,</p> <p>3. Knowledge about PPTCT,</p>	<p>1. Bi-variate analysis, Mean, standard deviation,</p> <p>2. Measurement of knowledge on transmission of HIV/AIDS and knowledge of transmission MTCT (Modified Bloom's cut off points)</p> <p>3. Logistic regression on knowledge of PPTCT</p> <p>4. Level of knowledge (Good, Moderate, Poor)</p> <p>5. Logistic regression on knowledge of HIV transmission during pregnancy, delivery and breastfeeding among HIV positive women</p>
V	QUAN and QUAL	HIV counselling, Infant feeding counselling (Exclusive breastfeeding, bottle feeding, supplementary feeding/cow's milk , knowledge of feeding methods, advantages of breast feeding and formula feeding,	<p>1. Knowledge and attitude of infant feeding methods among HIV positive women</p> <p>2. Health care provider's knowledge about infant feeding in the context of HIV/AIDS</p>	<p>1. Univariate analysis</p> <p>2. Bi-variate analysis</p> <p>3. Inductive thematic content analysis</p>
VI	QUAN and QUAL	<p>Independent Variables: Age, Education of women and their husbands, Family Income, Marital Status, Place of residence, Caste, Religion, Type of family, income of the family, received infant feeding counselling, received sd NVP, disclosure of the test report, etc</p> <p>Dependent Variable: Infant feeding intention – exclusive breast feeding, exclusive replacement/formula feeding, Intention of infant feeding practices (Recommended, not recommended)</p> <p>Intention of infant feeding (Exclusive Breastfeeding, Exclusive Replacement Feeding, Mixed Feeding)</p>	<p>1. Intention of infant feeding practices among HIV positive women</p> <p>2. Actual feeding practices among HIV positive women</p>	<p>1. Univariate analysis</p> <p>2. Bi-variate analysis</p> <p>3. Chi-square analysis</p> <p>4. Crude Odds Ratio and Adjusted Odds Ratio</p> <p>5. Inductive thematic content analysis</p>

2.13. B. Odds ratio and Logistic regression

It is a measure of association between an exposure and an outcome. The OR represents the odds that an outcome will occur given a particular exposure, compared to the odds of the outcome occurring in the absence of that exposure. It is most commonly used in case-control studies, cross-sectional and cohort study designs as well (with some modifications and/or assumptions).

When the response variable is dichotomous or binary (0, 1), application of binary logistic regression is appropriate. Any regression other than binary logistic regression would violate the basic underlying assumptions that the line tends to be very poor because the response variable can assume only two values that are 0 or 1. Hence, binary logistic regression technique is quite suitable in which independent variable may be continuous or categorical, or mixture of both (Retherford and Choe, 1993). When a logistic regression is calculated, the regression coefficient (b_1) is the estimated increase in the log odds of the outcome per unit increase in the value of the *exposure*. In other words, the exponential function of the regression coefficient (e^{b_1}) is the odds ratio associated with a one-unit increase in the exposure.

$$p = \frac{1}{1 + e^{-z}} = \frac{e^z}{1 + e^z}$$

where, z is a linear combination of independent (predictor) variable in a multivariate logistic function and e is the base of natural logarithm. Thus,

$$Z = b_0 + b_1X_1 + b_2X_2 + \dots + b_kX_k$$

In other words, the probability of not occurring of an event is

$$1 - p = 1 - \frac{1}{1 + e^{-z}} = \frac{e^{-z}}{1 + e^{-z}}$$

Hence, odds of occurring of an event are:

$$\frac{p}{1 - p} = e^z$$

Clearly $p/1-p$ equals the odds of occurring of an event. The logistic model for log odds of given predictor variable is

$$\text{logit } p = \log \frac{p}{1-p} = \log \text{odds}$$

2.13. C. Adjusted Odds Ratio

When a non-casual association is observed between a given exposure and outcome is as a result of the influence of a third variable, it is termed confounding, with the third variable termed a confounding variable. A confounding variable is causally associated with the outcome of interest, and non-causally or causally associated with the exposure, but is not an intermediate variable in the causal pathway between exposure and outcome (Szklo & Nieto, 2007). Stratification and multiple regression techniques are two methods used to address confounding, and produce “adjusted” ORs.

An adjusted odds ratio is an odds ratio comparing two categories of the variable after controlling for the other variables in the model. For example, an adjusted odds ratio comparing two categories of the variable, (X_1) is

$$\widehat{OR}_{X_1=1 \text{ vs } X_1=0} = \frac{\widehat{\text{Odds}}(Y = 1 | X_1 = 1, X_2, \dots, X_k)}{\widehat{\text{Odds}}(Y = 1 | X_1 = 0, X_2, \dots, X_k)} = \frac{e^{\hat{\beta}_0 + \hat{\beta}_1 + \hat{\beta}_2 X_2 + \dots + \hat{\beta}_k X_k}}{e^{\hat{\beta}_0 + \hat{\beta}_2 X_2 + \dots + \hat{\beta}_k X_k}} = e^{\hat{\beta}_1}$$

and its $(1 - \alpha) * 100\%$ confidence interval is

$$e^{\hat{\beta}_1 \pm Z_{1-\alpha/2} * S_{\hat{\beta}_1}}$$

More specifically, its 95% confidence interval is $e^{\hat{\beta}_1 \pm 1.96 * S_{\hat{\beta}_1}}$.

Coefficients, from a multiple logistic regression, estimate the magnitude of each predictor/outcome relationship after adjusting for all other predictors in the model. The estimates can be exponentiated to get associated adjusted odds ratios

2.14. Measurement of Knowledge and Attitude

2.14. A. Knowledge of HIV/AIDS

Knowledge is a measure to understand the level of awareness among HIV positive women. For measuring knowledge, basic questions related to knowledge were assessed using participant's correct responses. The five questions had a total of 16 points. Each correct response was given a score of 1 for 'Yes' response and a wrong response a score of 0 for 'No' response. The points assessed basic knowledge on transmission (5 points – knowledge on transmission of HIV, unsafe blood transfusion, sharing needles with an infected person, mother to child transmission, and unprotected sexual intercourse), risk factors (6 points – knowledge on the risks of HIV transmission, unprotected sexual intercourse with an infected person, multiple sexual partners, having sexually transmitted infections, intravenous drug abuse) and preventive measures (5 points – abstinence, having one faithful sexual partner, using condoms correctly during sexual intercourse, use tested blood, use only newly sterilized needles).

On assessment, Modified Bloom's cut off points were used during analysis which were adopted from Ms Nahida's KAP study (Questionnaire shows original Blooms cut-off points). A score of 75 – 100 per cent, 50 – 74 per cent and less than 50 per cent placed the respondent in good, moderate and poor basic HIV/AIDS knowledge respectively.

Ten questions assessing participants' knowledge on mother to child transmission during pregnancy, labour and delivery and breastfeeding had a total of 26 points and Bloom's cut- off points were used. Therefore, the scores were as follows:

- i) 20 – 26 points = good knowledge
- ii) 15 - 19 points = moderate knowledge
- iii) 0 – 14 points = poor knowledge

2.14 B. Attitude

Attitude was assessed by eight questions. These were put on Likert's scale and respondents were provided with statements to indicate the extent to which they agree with those statements on whether they strongly agree, agree, have no opinion, disagree or strongly disagree with what they were asked. The scoring system used with respect to respondents' responses was as follows: strongly agree scored '5', agree '4', no opinion '3', disagree '2', strongly disagree '1'.

The responses were summed up and a total score was obtained for each respondent. The mean score was calculated and those who scored above the mean and the mean score had positive attitude and scores below the mean meant negative attitude towards prevention of mother to child transmission strategies. The highest score was expected to be 40 and the lowest score was eight.