Infant feeding choices of HIV - positive mothers and its impact on the mother-to-child transmission (MTCT) of HIV infection

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Abstract

For many years HIV - positive mothers were advised against breastfeeding their babies because of the high concentration of the HIV virus in breast milk. However the WHO in its 2010 PMTCT guidelines now advice HIV-positive mothers to breastfeed their infants but under ARV prophylactic cover for both the mothers and their infants. This has sparked fears of possible increase in MTCT of HIV infection. This study was designed to ascertain the infant feeding choices of HIV positive mothers and its impact on mother - to - child transmission (MTCT) of HIV infection in Eastern Nigeria. About one hundred and four (104) pregnant HIV positive mothers attending the PMTCT ante-natal clinic were counseled during their pregnancy through their labor and breastfeeding period and recruited for the study after obtaining their consent. They were also counseled on the new PMTCT guidelines of exclusive breastfeeding of infants by HIV positive mothers under ARV prophylactic cover for both mothers and infants during pregnancy, at delivery and throughout the duration of breastfeeding. A data collection form was also designed and used to collect and record relevant information/data on the mothers and their infants as well as results. It was found out that most of the mothers (63%) chose the exclusive breastfeeding (EBF) option, 23% chose the exclusive formula feeding (EFF) option while 14% of them chose the mixed feeding (MF) option. Out of the 104 infants only 6 of them (6%) gave a positive HIV PCR test result while 98 (94%) of them tested negative. The MTCT rate was lowest (5%) among the EBF group strangely followed by the MF group (7%) and the EFF group (8%). The study thus concluded that exclusive breastfeeding of infants born to HIV positive mothers by their mothers under prophylactic cover for both mother and infant during pregnancy, at delivery and throughout the breastfeeding period reduces MTCT of HIV infection.

Keywords: Breastfeeding, HIV-positive mothers, Mother-to-child transmission (MTCT), HIV/AIDS, Breast milk

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1. Introduction

The human immune deficiency virus (HIV) is a virus (retrovirus) which causes acquired immune deficiency syndrome (AIDS). AIDS is characterized by vigorous viral replication, CD4+ lymphocyte depletion and profound immune deficiency making the infected individual highly susceptible to all manner of infections which the individual hitherto could resist (Nwaozuzu et al., 2013). HIV/AIDS is possibly the biggest challenge facing the global health care system today.

One of the global strategies for controlling, and preventing the spread of HIV/AIDS is the prevention of mother - to - child transmission of HIV/AIDS (PMTCT) program. PMTCT aims at preventing HIV infection of the infant during pregnancy, labor and breastfeeding and has been very successful since its inception. It remains the best way of preventing paediatric HIV infection (Mukhtar-Yola et al., 2009).

One of the paediatric HIV infection mode targeted by PMTCT is breastfeeding and this is because of the significant HIV content of breast milk. Breast feeding has also been associated with a high level of paediatric infection. The transmission associated with it (breastfeeding) is high during primary maternal HIV infection as mirrored by a high but transient peak in breast milk HIV load (Humphrey et al., 2010). A fear for breast milk thus developed among counselors and HIV - positive mothers and this challenged the well established [breastfeeding] culture which called for public health action (Koricho et al., 2010).

It also prompted the initial PMTCT global strategy of avoiding breastfeeding of HIV - exposed infants by HIV - positive mothers. But breastfeeding has always been recognized globally as the best means of infant nutrition as it contains all the nutritional requirements for the child’s immunity, growth and development. Thus the strategy of avoiding breastfeeding of HIV - exposed infants sparked off a wide range of socio-cultural nutritional and medical arguments. It was also observed that HIV - exposed infants tends to experience frequent growth faltering which suggested the need for vigilance in recognizing infant [growth] stunting in PMTCT programs (McGrath et al., 2012). This growth faltering is worse for the non-breastfed infant. It has been shown that infant feeding patterns affect MTCT of HIV (Adjeuyigbe et al, 2008). Exclusive breastfeeding however has been associated with reduced postnatal transmission of HIV from mother to child more than mixed breastfeeding (Lunney et al, 2010). Also formula feeding has been associated with higher risk of infant mortality than breastfeeding (Kagaayi et al., 2008). But early exclusive breastfeeding on the other hand has been associated with significant reduction in sick clinic visits especially those due to diarrhea (Koyanagi et al, 2009). These imply that despite the risk of HIV infection, breast milk is still too important for the survival of the HIV - exposed infant. Fortunately, research has shown that breastfeeding of HIV – exposed infants can be made considerably safer in resource-constrained settings (Like ours in Nigeria) through the provision of maternal highly active antiretroviral therapy (HAART), maternal short-course antiretrovirals and extended infant antiretroviral prophylaxis (Saloojee and Cooper, 2010).

In another study, prophylactic antiretroviral therapy in mothers and babies gave a marked reduction in mother–to–child transmission (MTCT) rates while feeding with BMS (Breast milk substitute) conferred a superior protection against MTCT than EBF (Ugochukwu and Kanu, 2010).
Nevertheless, there is hope that perinatal HIV transmission may be greatly reduced in breastfeeding populations worldwide through a combination of behavioural interventions that encourage exclusive breastfeeding and pharmacological interventions with antiretrovirals for mothers and or their infants (Slater et al, 2010). Studies have also confirmed that HAART for mothers effectively reduces the risk of infant HIV infection while preserving the breastfeeding option for mothers (Kouanda et al, 2010). However, complimentary breastfeeding (combination of breastfeeding and replacement (formula) feeding) represents an important source of risk of HIV infection for infants born to HIV-infected mothers and the WHO recommends that infants born to HIV-positive mothers receive either exclusive breastfeeding (EBF) or exclusive replacement feeding (ERF) in addition to early weaning though the acceptability and feasibility of the two options among the rural populations of sub-Saharan Africa remains to be seen (Hoffman et al, 2009). This is because it has been observed that in some settings many women still chose and practiced formula feeding despite the premium placed on breastfeeding in their locality and despite receiving infant feeding counseling (Oladokun et al, 2010).

This apparent ability or inability of HIV-positive mothers to adopt the recommended infant feeding options have been linked to several factors which impinge on their decision-making processes and perceptions and these factors includes a strong socio-cultural value in favour of breastfeeding linked to historical traditions and contemporary state and international development discourses (Van Hollen, 2011).

Thus beyond the clinical and epidemiological debate and given the socio-cultural importance attributed to breastfeeding and the prevailing poverty in most developing countries (like Nigeria), it may be more acceptable and more feasible to promote EBF followed by early weaning than [promoting] replacement feeding (Hoffman et al, 2009).

2. Methods

This is part 1 of 3 presentations from a study carried out using the method described below. The other parts will also be subsequently published in this journal. The study is both prospective and retrospective in nature. Ethical approval for the study was sought for and obtained from the management of the centre where the study was done (Appendix 1). About 104 HIV-positive mothers who just delivered their babies (during the month the study was carried out) were individually counseled on the importance of the new PMTCT guidelines of exclusive breastfeeding of the infant under ARV prophylactic cover for both mother and infant during pregnancy, delivery and breastfeeding. They were then recruited into the study after seeking and obtaining informed consent from them to use data collected from them, their medical records and laboratory test results for the study. A copy of the consent form is shown in Appendix 2. A proforma (data collection form – Appendix 3) was also designed and used to collect/ document relevant information from the HIV-positive mothers participating in the study and from their hospital records. Then, the new mother-child pairs were now followed up with ARVs and nutritional support and counseling. At three (3) months of age, dry blood samples (DBS) of the infants were prepared and screened for HIV using the HIV Ribonucleic Acid Polymerase Chain Reaction test (HIV - RNA PCR Test). The data collected was then collated and analyzed.
3. Data analysis

Two methods were used in the analysis of the data, namely:

1) Method of percentage
2) The chi-square

The method of percentage was used to show the extent of relationship among variables. The Chi-square ($X^2$) was used to determine the probability that differences in the expected and deserved number of cases falling in each cell of the table occurred because of sampling variations (Thirkette, 1976). It is a non-parametric inferential statistical method used in the analysis of frequencies of nominal data (Nnadozie, 1980).

4. Results

The results of the fore-going study are summarized as follows:

- About 54% of the infants involved in the study were males while 48% of them were females.
- About 63% of the mothers exclusively breastfed [EBF] their babies, 23% of them chose the exclusive formula feeding option while 14% of them opted for the mixed feeding (MF) method.
- About 97% of the mothers knew their HIV status before the delivery of their infants while only 3% of them did not know their status before their babies’ delivery.
- About 94% of the babies had a negative HIV PCR test result while only 6% of had a positive result.
- About 67% of the HIV positive infants were females while only 33% of them were males.
- Only three (3) out of the six (6) mothers (whose babies were HIV PCR positive) breastfed their babies exclusively, 2 of them formula-fed their babies exclusively while only one of them mixed-fed her infants.
- Only 54% of the mother-infant pairs adhered with the PMTCT guidelines of exclusive breastfeeding of the infants under ARV prophylactic cover for both mother and infant during pregnancy, delivery and breastfeeding. About 46% of the pairs did not adhere to this PMTCT guideline.
- The adhering mother-infant pairs group accounted for only one (1) of the six (6) HIV PCR positive results.

These findings are summarized in the tables below;

<table>
<thead>
<tr>
<th>GENDER</th>
<th>NO. OF INFANTS</th>
<th>% OF INFANTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>54</td>
<td>52</td>
</tr>
<tr>
<td>Female</td>
<td>50</td>
<td>48</td>
</tr>
<tr>
<td>Total</td>
<td>104</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 1. Gender distribution of the infants involved in the study
Table 1 shows that the number male infants involved in the study [54%] was slightly more than the number of females involved in the study [48%].

Table 2. MTCT rates among the mothers in the different infant feeding options

<table>
<thead>
<tr>
<th>FEEDING OPTION</th>
<th>NO. OF MOTHERS</th>
<th>NO. OF POSITIVE INFANTS</th>
<th>% OF INFANTS WITHIN GROUP</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBF</td>
<td>65</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>EFF</td>
<td>24</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>MF</td>
<td>15</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>TOTAL</td>
<td>104</td>
<td>6</td>
<td></td>
</tr>
</tbody>
</table>

Table 2 shows that MTCT rates was lowest among the EBF group [5%] followed strangely by the MF group [7%] and the EFF group [8%].

Table 3. Distribution of mother’s infant feeding choices

<table>
<thead>
<tr>
<th>INFANT FEEDING</th>
<th>NO. OF MOTHER’S</th>
<th>% OF MOTHERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBF</td>
<td>65</td>
<td>63</td>
</tr>
<tr>
<td>EFF</td>
<td>24</td>
<td>23</td>
</tr>
<tr>
<td>MF</td>
<td>15</td>
<td>14</td>
</tr>
<tr>
<td>TOTAL</td>
<td>104</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 3 shows that most of the mothers [63%] chose the exclusive breast feeding [EBF] option while fewer numbers of them [23%] chose the exclusive formular feeding [EFF] option with only 14% of the mothers choosing the mixed feeding [MF] option.

Table 4. Distribution of number of mothers – infant pairs that adhered to PMTCT guidelines

<table>
<thead>
<tr>
<th>EBF WITH ARV PROPHYLAXIS IN BOTH MOTHER</th>
<th>NO. OF MOTHER - INFANT PAIRS</th>
<th>% OF MOTHER - INFANT PAIR</th>
<th>NO OF HIV PCR POSITIVE INFANTS</th>
<th>% OF HIV POSITIVE RESULT</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>56</td>
<td>54</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>NO</td>
<td>48</td>
<td>46</td>
<td>5</td>
<td>83</td>
</tr>
<tr>
<td>TOTAL</td>
<td>104</td>
<td>100</td>
<td>6</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 4 shows that 54% of the mothers adhered to the PMTCT guidelines of exclusive breastfeeding of the infant with ARV prophylaxis for both mothers and infants throughout the period of breastfeeding. About 46% did not adhere to the above guidelines. It also shows that the non-adherent group accounted for most [83%] of the PCR positive results [i.e. 5 of the 6 positive results]. While the adhering group accounted for just 1 out of the 6 positive results [17%].
Table 5. Distribution of the infants’ HIV PCR test results after 3 months of delivery

<table>
<thead>
<tr>
<th>INFANT HIV PCR TEST RESULTS</th>
<th>NO OF INFANTS</th>
<th>% OF INFANTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive result</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Negative result</td>
<td>98</td>
<td>94</td>
</tr>
<tr>
<td>Total</td>
<td>104</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 5 shows that only 6% of the infants involved in the study seroconverted to HIV-positive status after 3 months of delivery while 94% remained HIV-negative after the same period.

Table 6. Gender distribution of the HIV PCR positive infants

<table>
<thead>
<tr>
<th>GENDER</th>
<th>NO OF INFANTS</th>
<th>NO OF PCR HIV POSITIVE INFANTS</th>
<th>% OF POSITIVE INFANTS</th>
<th>% OF CORRESPONDING GENDER POPULATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>54</td>
<td>2</td>
<td>33</td>
<td>4</td>
</tr>
<tr>
<td>Female</td>
<td>50</td>
<td>4</td>
<td>67</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>194</td>
<td>6</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

Table 6 shows that most of the infants [67%] that seroconverted to HIV-positive status were females while 33% of them were males.

Table 7. Distribution of mothers’ knowledge of their HIV status prior to pregnancy or delivery

<table>
<thead>
<tr>
<th>KNOWLEDGE OF HIV STATUS</th>
<th>NO OF MOTHERS</th>
<th>% OF MOTHERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>101</td>
<td>97</td>
</tr>
<tr>
<td>No</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>104</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 7 shows that most of the mothers involved in the study (97%) knew their HIV status prior to their pregnancies and deliveries while only few of them (3%) did not know their status.

5. Test of hypothesis

Here we conduct statistical analysis using the chi-square method to validate some of the above results that are related to our hypotheses.

_Hypothesis 1_

_Ho_: Exclusive breastfeeding of infants is not practiced by HIV positive mothers in Eastern Nigeria.

_Ha_: Exclusive breastfeeding of infants is practiced by HIV positive mothers in eastern Nigeria.
**Decision rule**

Accept null hypothesis if the value of the chi-square calculated is less than the chi-square table value and reject the alternative hypothesis, otherwise accept the alternative hypothesis if the value of the chi-square calculated is greater than the chi-square table value and reject the null hypothesis. Mathematically, the above decision rule is stated as follows:

Accept $H_0$ if $X^2 \text{(Cal)} < X^2 \text{(tab)}$

Accept $H_a$ if $X^2 \text{(Cal)} > X^2 \text{(tab)}$

For this hypothesis, we use table 3 for the analysis and adjust the options in the table to give the following table;

<table>
<thead>
<tr>
<th>INFANT FEEDING OPTIONS</th>
<th>NO OF MOTHERS</th>
<th>% OF MOTHERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBF</td>
<td>65</td>
<td>63</td>
</tr>
<tr>
<td>EFF + MF</td>
<td>39</td>
<td>37</td>
</tr>
<tr>
<td>TOTAL</td>
<td>104</td>
<td>100</td>
</tr>
</tbody>
</table>

The chi-square statistic (formula) is given as;

$$X^2 = \frac{\text{[Observed frequency (F_o) - Expected frequency (F_e)]^2}}{\text{Expected frequency F_e}}$$

Now, degree of freedom (DF) = (R-1) (C-1)

$$= (2-1) (2-1)$$

$$= 1 \times 1$$

$$= 1$$

Then from Chi-Square table,

DF 1 at 95% confidence level = 3.84.

i.e. $X^2 \text{Cal} = 6.92$ and

$$X^2 \text{Tab} = 3.84$$

Therefore based on our decision rule, we reject $H_o$ and accept $H_a$ since $X^2 \text{Cal} (6.92)$ is > $X^2 \text{Tab} (3.84)$ and conclude that exclusive breastfeeding (EBF) is practiced by HIV-positive mothers in Eastern Nigeria.
Hypothesis 2

**HO:** Exclusive breastfeeding by HIV-positive mothers results in an increase in the MTCT rates of HIV in Eastern Nigeria.

**HA:** Exclusive breastfeeding by HIV-positive mothers does not result in an increase in the MTCT rates of HIV in Eastern Nigeria.

**Decision rule**

Accept null hypothesis if the value of the chi-square calculated is less than the chi-square table value and reject the alternative hypothesis, otherwise accept the alternative hypothesis if the value of the chi-square calculated is greater than the chi-square table value and reject the null hypothesis. Mathematically, the above decision rule is stated as follows:

Accept $H_0$ if $X^2_{(Cal)} < X^2_{(tab)}$

Accept $H_a$ if $X^2_{(Cal)} > X^2_{(tab)}$

For this hypothesis, we use Table 2 for the analysis and adjust the options in the table to give the following table;

<table>
<thead>
<tr>
<th>FEEDING OPTION</th>
<th>NO. OF MOTHERS</th>
<th>NO. OF POSITIVE INFANTS</th>
<th>% OF INFANTS WITHIN GROUP</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBF</td>
<td>65</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>EFF+MF</td>
<td>39</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>TOTAL</td>
<td>104</td>
<td>6</td>
<td></td>
</tr>
</tbody>
</table>

Here the expected frequency ($F_e$) is 50/50 since the chance probability is half (1/2).

As such,

$$X^2_{cal} = \frac{[F_o - F_e]^2}{F_e} = \frac{(65 - 50)^2}{50} + \frac{(39 - 50)^2}{50} = 4.5 + 2.45 = 6.92$$

Now, degree of freedom (DF) = (R-1) (C-1)

= (2-1) (2-1)

= 1 X 1

= 1

Then from Chi-Square table,

DF 1 at 95% confidence level = 3.84.
i.e. $X^2_{\text{Cal}} = 65$ and

$X^2_{\text{Tab}} = 3.84$

Therefore based on our decision rule, we reject $H_0$ and accept $H_a$ since $X^2_{\text{Cal}} (65)$ is $> X^2_{\text{Tab}} (3.84)$ and conclude that exclusive breastfeeding (EBF) by HIV-positive mothers does not result in an increase in MTCT rates in Eastern Nigeria.

6. Discussion

The results of the fore-going study shows a near equal number of male infants and females infants delivered by the HIV positive mothers involved in the study. This result further underscores the already known ratio (near equal ratio) of male to female HIV patients.

Also about 63% of the mothers exclusively breastfed their babies while 23% of them exclusively formula fed their babies and this could also have been the reason for the low HIV transmission rates since exclusive breastfeeding or formula feeding of infants (under prophylactic cover) is known to reduce the likelihood of HIV transmission to infants. Only 14% of the mothers mixed-fed their babies. Again the fact that 97% of the mothers in the study knew their HIV status during or prior to their pregnancies could also have contributed to the low HIV transmission rates as these mothers could have taken precautions to protect their babies from HIV infection.

An analysis of the HIV PCR test results reveal a very low incidence of HIV transmission to the infants involved in the study as only 6% of them tested positive while 94% of them tested negative. A further analysis of the HIV PCR positive results show that 67% of HIV PCR positive infants were females while 33% of them were males.

In terms of breastfeeding, only three (3) out of the six (6) mothers whose infants tested positive fed their babies exclusively, two (2) of the mothers formula-fed their infants exclusively while only one (1) of the mothers here mixed-fed her infant which is a risk factor and could have contributed to the infection of this infant. Mixed feeding is also associated with increased risk of mother-to-child transmission of HIV infection (Emem, 2006). The exclusive formula feeding of the two (2) positive infants could also have been a factor as the infants may have been denied of the immune boostingcolostrums and other health and developmental benefits of breast milk which could have increase their susceptibility and exposure to HIV infection.

In addition to the above findings, a general assessment of the adherence of the mother–infant pairs to PMTCT guidelines of exclusive breastfeeding of infants under ARV prophylactic cover for both mothers and infants during pregnancy, delivery and breastfeeding, shows that only 54% of the mother-infant pairs adhered to the guidelines while 46% of the pairs did not adhere to PMTCT guidelines. This degree of adherence is low and could predispose infants to HIV infection from their mothers. This is underscored by the fact that the adhering mother-infant pairs (54%) group accounted for only one (1) out of the six (6) HIV
PCR positive infants while the remaining five (5) HIV PCR positive infants came from the non-adhering (46%) group.

7. Conclusion

The rate of infant breastfeeding among the HIV positive mothers involved in the present study was fairly high (63%) and this could have accounted for the low rate of mother-to-child transmission of HIV infection observed in the study. Thus breastfeeding (exclusive) of infants by HIV positive mothers (under prophylactic cover for both mother and child) reduces the rate of mother-to-child transmission of HIV infection. This is contrary to the fears expressed by some medical practitioners and HIV positive mothers and their relatives that encouraging breastfeeding of infants by HIV positive mothers will increase MTCT rates and hence destroy the successes of the PMTCT program over the years. However, the level of adherence to breastfeeding under joint prophylactic cover for both mothers (PMTCT guideline) and infants was just above average.

8. Recommendations

Based on the results of the foregoing study we recommend that:

1. All countries and states of the world as well as their health agencies and institutions and their medical practitioners should adopt and implement this new PMTCT guideline of exclusive breastfeeding of infants by HIV positive mothers under ARV prophylactic cover of both the mothers and infants during pregnancy, at delivery and throughout the period of breastfeeding of the infant.
2. All HIV positive mothers and their relatives should be educated on the benefits of exclusive breastfeeding of infants (under prophylactic cover for both mother and infant) and encouraged to practice it especially as it reduces rather than increase the likelihood MTCT of HIV infection.
3. Government and other responsible agencies and organizations should step up efforts at providing ARV’s, antibiotics and other medicines and logistics needed to ensure the global success of the PMTCT and other HIV/AIDS related programs of the WHO and their related and affiliated organizations.

Acknowledgement

I wish to thank the Project Officer of the HIV clinic at the Federal Medical Centre, Owerri Dr (Mrs.) Eugenia Ufondu and the HOD of the Paediatrics Department Dr. Emeka Nwolisa for their understanding and cooperation during this study. I also wish to thank the paediatric doctors at the HIV clinic who collected and prepared the dry blood samples and Mr Donald Ozuzu of the records unit for their assistance.
I am also grateful to the Federal Medical (Specialist) Centre, Owerri (where I was born) for the privilege to work there and the permission to carry out this study. May God continue to sustain us all.

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Appendix 1. Ethical approval for the study

FMC/OW/P/910/pg209A

Pharm. Nwacuzu Ezeudo E.
Pharmacy Department
Federal Medical Centre
Owerri

U.f.s:
Head of Pharmacy Department

Dear Pharm. Nwacuzu,

APPLICATION FOR APPROVAL TO CONDUCT RESEARCH
RE: BREAST FEEDING AMONG HIV-POSITIVE MOTHERS AND ITS IMPACT ON MOTHER-TO-CHILD (MTC)
TRANSMISSION OF HIV INFECTION.

Your application for approval for the conduct of your research project titled as stated above and dated 14th September, 2012 refers.

I am directed to convey approval for you to conduct the study.

It is hoped that you would abide by the methodology detailed in your research proposal.

Dr T. C. Osuagwu
HEAD OF CLINICAL SERVICES
For MEDICAL DIRECTOR

19th October 2012
Appendix 2. Consent form for study participants

I, ........................................ of .................................. hereby consent to this study; I acknowledge that I have been fully counseled on the purpose and benefits of the study. I also acknowledge that I have been informed on the confidentiality of any information given by me.

I understand that the study is to be carried out solely for that purpose on the understanding that I shall be entitled to withdrawal of my consent at any time.

Date ................................ Signed ...........................................

(Patient)

I confirm that I explained to the patient the purpose and nature of the study and the fact that refusal to participate will not in any way affect his/her normal care by me or any member of this institution. I know the consequences of any false declaration on this or any other form.

Date .................................. Signed ........................................

(Pharmacist/Research).
### Appendix 3. Study proforma (data collection form)

<table>
<thead>
<tr>
<th>S/N</th>
<th>Patient Name</th>
<th>Folder No</th>
<th>Patient Address</th>
<th>Patient Phone No</th>
<th>Patient email</th>
<th>Patient ART Regime</th>
<th>Patient CD4 count at delivery</th>
<th>Feeding option</th>
<th>Patient no of deliveries</th>
<th>Infant sex</th>
<th>Infant Prophylactic Regim-en</th>
<th>Infant HIV status at IIWeek</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Feeding option: EBF, EFF, MF
- Infant HIV status at II Week: 0, 14, 28, 84, 168
Appendix C. Chi – square distribution table

<table>
<thead>
<tr>
<th>n</th>
<th>x²</th>
<th>0.025</th>
<th>0.010</th>
<th>0.005</th>
<th>0.0025</th>
<th>0.001</th>
<th>0.0005</th>
<th>0.00025</th>
<th>0.00005</th>
<th>0.0001</th>
<th>0.00001</th>
<th>0.000005</th>
<th>0.0000005</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.00</td>
<td>0.0005</td>
<td>0.0025</td>
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