

# Incidence and Predictors of Loss-to-follow-up Among Pregnant and Breastfeeding Women on Option B+ PMTCT Program in Northwest Ethiopia: a Retrospective Follow-up Study.

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## Research

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# Abstract

**Background:** Although Ethiopia is implementing an option B+ program for the last seven years, lost to follow-up among HIV positive women remains the major problem for ART treatment. The study was conducted on lost to follow-up among human immunodeficiency virus infected pregnant and breastfeeding women after Option B+ modality since there was a scarcity of literatures in Northwest Ethiopia. The result is also expected to strengthen the effort to eliminate mother-to-child transmission of HIV to 5%.

**Methods:** A retrospective follow-up study was conducted among 403 pregnant and breastfeeding women between June 2013 and December 2019 at the University of Gondar comprehensive specialized Hospital. Cox proportional hazards regression model was used for identifying predictors of lost-to-follow-up. Results were reported as hazard ratios with 95% confidence interval at a significance level of  $p=0.05$ .

**Results:** The overall incidence rate of loss to follow-up was 9.4 per 1000 person-months of observation (95% confidence interval (CI): 7.4–11.9). According to the multivariable Cox regression, rural residency (adjusted hazard ratio(AHR): 2.30; 95% CI:1.08–4.88), being Muslim religion follower (AHR: 2.44; 95% CI:1.23–4.81), having no baseline viral load measurement (AHR: 4.21; 95% CI:2.23–7.96, being on ART before enrolment (AHR: 0.30; 95% CI:0.15–0.62), having drug side effects (AHR: 1.82; 95% CI:1.01–3.33), same day ART initiation (AHR: 3.23; 95% CI:1.53–6.84) and having sub-optimal adherence level (AHR: 3.96; 95% CI:2.18–7.19) were significant predictors of lost to follow up.

**Conclusion:** The incidence of lost to follow-up is lower as compared to evidence from most African countries but slightly higher than the WHO target. It is better to strength and expand viral load measurement for all women and giving attention to those women who are residing in a rural area and having fair/poor adherence level.

## Background

Globally, there were an estimated 180,000 new pediatric infections every year in 2018(1). Of which, Mother-to-child transmission (MTCT) accounts 90% of these new pediatric infections, which might be transmitted in utero, labor, delivery or breastfeeding. Without any intervention, MTCT ranges from 15% to 45%. However, antiretroviral treatment and other interventions can reduce this risk to below 5% in breastfeeding women and 2% in non-breast-feeding women (2-4).

The Joint United Nations Program on HIV/AIDS set a target for member states to have virtual elimination of MTCT to less than 5% and 90% reduction of new HIV infections among young children by 2015 and moved the global commitment to eliminate MTCT by 2020 and HIV epidemic in 2030(1). Moreover, World Health Organization recommends the Option B+ program to prevent MTCT transmission of HIV infection. An Option B+ program started in 2013 and became expanded for the provision of universal, lifelong ART for all HIV-infected individuals regardless of CD4 count and WHO clinical staging as “Test and Treat” approach in 2016(2, 5-7). The above strategies directly related to an increment in coverage of

antiretroviral medicines taking by pregnant women living with HIV from 51% in 2010 to 80% in 2017 to prevent MTCT(1). In addition to this, these programs contributed to reduction of maternal mortality by 44% between 1990 and 2015(8) and for the averted of 1.4 million new child infections since 2010(1).

Even though the presence of efforts, loss to Follow-up (LTFU) and poor adherence to drugs are still a major challenge to achieve virtual elimination of MTCT of HIV especially in Sub-Saharan Africa (12). Loss to Follow-up in PMTCT program had impact on women's access to HIV care and treatment, which leads advanced HIV stage, increases maternal HIV/AIDS related morbidity and mortality, enables the vertical transmission of HIV to newborn and facilitates the development of drug resistance, missed opportunities to family planning(2, 9). Moreover, LTFU had a consequence for future pregnancies of child health and survival and increases risk of transmission if the partner is sero discordant(2).

Different studies indicated incidence rate of LTFU among HIV positive pregnant and lactating mothers on PMTCT program varied in different countries. A prospective cohort study in Brazil showed that the rate of LTFU among mother-child pairs in PMTCT program was 15.4% (10). Another retrospective cohort study in Myanmar showed that pregnant women's LTFU rate was 7 per 1000 person-years under option B+ PMTCT programs(11). A retrospective follow-up study in different African countries showed that the incidence of LTFU among pregnant and lactating mothers under option B+ program were still high which ranges from 16% to 53.7(12-26). Previous studies in Ethiopia showed that the rate of LTFU among women under Option B+ program varied region to region. A retrospective follow-up study at different public health facilities in Northeast regions of Ethiopia showed that cumulative incidence LTFU was 16.5% (29). Similar finding also revealed that cumulative incidence of LTFU was 15.4% with incidence rate of 9 per 1000 person-months in western Ethiopia(30) and 18.2% in Southern Ethiopia (31).

Various literatures reported that LTFU can be affected by various factors, including socio-demographic and economics, behavioral and clinical variables. Reports from Africa indicated that, maternal age less than 25 years (12, 13, 15, 21, 26, 27, 32), less than 26 years (33), and less than 30 (23) were statistically significant positive predictor for LTFU. Moreover, Educational status (15, 28), Marital status(19), unemployment status(34), number of pregnancies(13), religious reasons, and partner HIV status(12, 16) were a significant predictor for LTFU. In addition, studies showed that the baseline low CD4 cell counts and high viral load measurement were positively associated with LTFU among women in PMTCT services (36, 37). Moreover, advanced WHO clinical stages ( III/IV) was positively significant risk factors for poor retention of care(23).

Even though, there are studies on LTFU among general adult population on ART care, there is no published studies on the incidence of LTFU and its predictors among HIV positive pregnant and lactating mothers on ART treatment since Option B+ program started. As a result, current study determined the incidence of LTFU and its predictors among women initiating ART at University of Gondar comprehensive specialized Hospital after Option B+ PMTCT program, Northwest Ethiopia from June,2013 to December,2019. Hence, the finding from this study will help health institution managers and programmers for developing evidence-based interventions to promote retention in care for both mothers

and infants because early identification of the magnitude and factors helps to identify vital sites and improving women with HIV by enhancing viral suppression. This study also fills information gap in the area. The findings of this study also assist policy makers and programmers to focus on the major identified risk factors of LTFU among HIV positive women to improve PMTCT services and to eradicate HIV as planned in 2030.

## Methods

### Study design and setting

A retrospective follow-up study was conducted from February to April, 2020 among pregnant and breastfeeding women on option B+ PMTCT program. The study was conducted at University of Gondar comprehensive specialized Hospital in Northwest Ethiopia. The Hospital is located in Gondar Town in the Amhara regional state which is 748 km far from Addis Ababa. It is one of the referral hospital in Northwest Ethiopia providing service for over 5 million people in the catchment area (39). The Hospital is also providing HIV chronic care, including PMTCT services for clients since 2005 as one component of comprehensive HIV/AIDS care and support program. It began Option B+ PMTCT program in 23 June 2013, and since then 1049 women with HIV were enrolled for PMTCT services and treatment.

### Population and sampling

This retrospective follow-up study was conducted among pregnant and breastfeeding women in option B+ PMTCT program who enrolled for PMTCT service and treatment from 23 June 2013 to December 31, 2019. Data were extracted from February to April, 2020. Pregnant and breastfeeding women on the PMTCT program from 23 June 2013 to December 31, 2019 were considered for the study. Those women with incomplete maternal cohort outcome, data inconsistencies about ART confirmation and initiation of option B+ program were excluded. A total of 403 pregnant and breastfeeding women charts was selected using the simple random sampling from the PMTCT register based on inclusion criteria.

### Measurements

Pregnant and breastfeeding women under Option B+ PMTCT program were followed until December 31, 2019. Outcomes such as loss to follow-up, death, transferred-out, treatment completed, and on-treatment were measured at the end of the follow-up. Loss to follow-up (LTFU) from Option B+ PMTCT program is defined as for women who missed 90 days after the last documented visit, as per the recently developed simplified tools to measure retention in care in ART program (40, 41). Women who missed at least 3 months after the last documented visit under Option B+ PMTCT and not recorded as 'dead', 'retained' or 'transferred-out' on patient PMTCT logbook or medical cards were considered as event (4), while patient who did not develop an event or LTFU which can be death, transferred-out, treatment completed, and

receiving treatment when the study was reported as censored. Time to LTFU was calculated in months using the time between the date of treatment initiation (Option B+ PMTCT program) and the date of the event (LTFU). Drug adherence level was evaluated according to the percentage of drug dosage calculated from a monthly total dose of ART drugs, and further classified as good, fair and poor. The adherence classification was based on the WHO classification and good adherence was defined if the percentage of missed (equal to or greater than 95% or  $\leq$  missing less or equal to 2 out of 30 doses or missing 3 or less from the 60 doses), **fair** (85-94%) adherence or missing 3–5 doses out of 30 tabs or 3–9 tablets from 60 doses), or **poor** (less than 85% or missing  $\geq$  6 tablets out of 30 tabs or  $>$  9 tabs from 60 tabs (42). Functional status of women defined based on WHO criteria as follows. **Working**: able to perform usual work inside or outside home. **Ambulatory**: able to perform activity of daily living. **Bedridden**: not able to perform activity of daily living(43).

## Data Collection Procedure

Data were extracted from the ART intake forms, HIV care follow-up and the PMTCT register using the data extraction check-list. The component of the check-list is socio-demographic characteristics, immunologic, treatment, clinical, behavior, follow up related and outcome variables. Records of patients were extracted in the last 7 years after Option B+ program based on the inclusion criteria. Six Data collectors and two supervisors were recruited to extract the data from PMTCT service records at the University of Gondar comprehensive and specialized Hospital. The data reviewers were trained BSc midwives who are working in PMTCT clinic. They extracted the data using a structured extraction tool prepared for the study. The data extraction tool for chart review was prepared based on the information contained within the patient registration and follow-up card according to national guidelines.

## Statistical Analysis

The collected data were cleaned, coded and entered in Epi Data version 4.6.0.0. Then it was exported to STATA version 14 (StataCorp, College Station, TX, USA) for further analyses. An incidence rate was computed using person-month observations by adding the amount of time contributed by study participants in the follow-up period. The Kaplan–Meier non-parametric survival analyses were calculated for estimating cumulative survival probability of LTFU at specific time after PMTCT program and Nelson–Aalen method was used to generate a cumulative hazard function. Univariate Cox proportional hazards were fitted for predictors of LTFU among women on the Option B+ PMTCT program for complete data. Potential predictors that were significantly associated with LTFU in univariate models ( $P < 0.25$ ) were evaluated in a multivariable model. To identify the combination of factors that best predict LTFU, backward stepwise Cox proportional hazards model evaluated the inclusion or exclusion of potential predictors at each step. The model with the highest loglikelihood was chosen and checked for individual variation using the univariate frailty model. The proportional hazard assumption and fit of the model were checked by Schoenfeld global test and Cox-Snell residuals plot respectively. Finally, results were

reported as hazard ratios with 95% CI and examined at a significance level of  $p=0.05$  (two-sided test) using multivariable Cox proportional hazard model.

## Results

### Socio-demographic and maternal related characteristics

A total of 416 randomly selected HIV positive women who started ART under Option B+ PMTCT service at the University of Gondar Comprehensive specialized Hospital between 23 June 2013 and 31 December 2019 were reviewed. Of these, 13 (3.1%) were excluded from the study due to data inconsistencies, resulting in a final total of 403 (96.9%) women for further analysis. The mean ( $\pm$  standard deviation (SD)) age of mothers was  $27.6 \pm 4.7$  years. Overall, 98 (24.3%) women were in the age group of 15–24 years. The majority of the study participants 248 (61.5%) were urban dwellers. Large proportion 186 (46.1%) of participants were housewife. Of 403 observations, 359 (89.1%) women were pregnant during enrollment to ART treatment and 169 (41.9%) women were newly enrolled in ART treatment. About 70 (17.4%) women had MUAC measurement below standard ( $<23$  cm) level. Overall, 222 (55.1%) of the partner were positive for HIV (Table 1).

### Clinical, laboratory, and treatment related characteristics

The mean CD4 count was 419.1 cells/ $\text{ml}^3$  with standard deviation of  $\pm 224.0$ . A total of 238 (59.1%) HIV positive women has CD4 counts greater than 350 cells/ $\text{mm}^3$  at baseline. Of the total study participants, 344 (85.4%) were classified as WHO Clinical Stage one followed by WHO clinical stage-II 37 (9.2%). A combination therapy, *AZT-3TC-EFV* was the second predominant regimen prescribed during enrollment for 105 (26.1%) women, next to *TDF-3TC-EFV* for 239 (59.3%). Overall, 132 (32.8%) women during enrollment were anemic. The majority (83.6%) of the women had good adherence levels, and 72 (17.9%) women developed side effects related ART treatment during PMTCT enrollment. Overall, 279 (69.9%) women had at least one recorded viral load measurement within three months of PMTCT enrollment (Table 2).

### Survival status of study participants

Overall, 6.8% (95%CI: 13.5–20.8) women were LTFU to ART treatment, and five (1.2%) women were died during the course of ART treatment of PMTCT. About 403 study participants were followed for a mean time of 17.9 (SD $\pm$  7.2) months. Of the total observations, 12(2.9%), 31(7.7%), 53(13.2%) and 68 (16.8%) women were LTFU by the end of 6, 12, 18 and end month of the PMTCT program, respectively. Three hundred thirty-five (83.1%) observations were censored (retained, transferred out or died) at the end of the enrollment (Fig 1).

### Incidence rate of LTFU

We calculated incidence rate by taking the denominator as person-months (PM) because the study is a dynamic cohort. During the follow-up time, a total of 7215 person-months' time risk was observed with an overall incidence rate of lost-to-follow-up (LTFU) 9.4 per 1000 person months (95% CI (7.4–11.9) by the end of follow-up. The incidence proportion of LTFU was dramatically declined from 38% at the initiation of the program in 2013 to 6.8% in 2019 (fig.2). The Kaplan–Meier method for the time to LTFU after ART initiation during PMTCT follow-up period showed that close to 80% of the participants were still in care after 12 months of follow-up (Fig.3). The cumulative hazard estimate of LTFU has shown difference among enrolment status of PMTCT. The cumulative hazard of LTFU among HIV positive women of breastfeeding status was higher than pregnancy status during PMTCT enrollment (Fig. 4).

## **Incidence of LTFU among different levels of predictor variables**

Overall, the incidence rate was higher for women who were residing in rural areas (19.3 per 1000 person months) and it was lower for mothers who were residing in urban dwellers (4.1 per 1000 person months). The Log-rank test also shows that women had a significant difference of LTFU between rural and urban. Moreover, it shows that incidence of LTFU was significantly different according to the patient's marital status, religion, status of women during enrolment, enrolment type, MUAC level, anemia status, adherence level, CD4 cell count, ART initiation time, drug side effects, and baseline viral load so that these variables were included to binary cox regression (Table 3).

## **Factors affecting lost to follow up from PMTCT service**

Predictors included in multivariable Cox regression analysis were those with a p-value < 0.25 in bivariable analysis and 21 variables were selected in the first step of model buildings. After running backward stepwise variable selection and by considering multicollinearity, the first group was selected as the best model from LLH ratio, which includes full (17) variables in multivariable analysis.

According to the multivariable Cox regression analysis, being a rural residency were 2.30 higher risk of LTFU (AHR:2.30; 95% CI:1.08–4.88) as compared to urban residency. Muslim religion followers were 2.44 times higher risk of LTFU (AHR: 2.44; 95% CI: 1.23–4.81) as compared to Orthodox Christian religion followers. The risk of LTFU for participants who started ART on the same day as the HIV diagnosis was 3.23 times more likely than latter initiation (AHR: 3.23; 95% CI: 1.53–6.84). Participants who were on ART before PMTCT enrollment had a 70% increased risk of LTFU as compared to newly enrolled (AHR: 0.30; 95% CI: 0.15–0.62). During the last of PMTCT follow-up, LTFU among participants who had drug side effects was 82% higher as compared to their counterparts (AHR: 1.82; 95% CI: 1.01–3.33). Participants with sub-optimal adherence status (fair/poor) had 3.96 times higher risk of LTFU (AHR: 3.96; 95% CI: 2.18–7.19) than participants with good adherence. Lastly, the risk of LTFU among women who had no viral load measurement was 4.21 times higher than those who measured for viral load during enrollment (AHR:4.21; 95% CI :2.23–7.96) (Table 4). The global test results showed  $p > 0.05$  thus we do not have a violation of the proportional assumption.

## Discussion

Lost to follow up is a major challenge in PMTCT program which leads advanced stage of HIV, increases maternal HIV/AIDS related morbidity and mortality, enables the vertical transmission of HIV to newborn and facilitates the development of drug resistance, missed opportunities to family planning(40). Nationally, there was a target for fulfilling 90-90-90 strategy as percentage of currently receiving antiretroviral therapy among all adults and children living with HIV to be 90% which is to decrease LTFU to less than 10% (5). Therefore, this retrospective record review was conducted to determine the incidence and predictors of LTFU among pregnant and breast-feeding women on Option B+ PMTCT program at Gondar university comprehensive specialized hospital.

The overall incidence density of LTFU in the current study was 9.4 per 1000 person-months by the end of PMTCT follow-up time. This finding is agreed with previous study conducted in Nekemte Hospital, western Ethiopia ( 9 per 1000 person-months observations) (30). This is due to the similarity in study time at which nationally different strategies were adopted to increase ART coverage and adherence. Among these, ART drug refill and clinical follow-up, including laboratory investigation, took place in advance at ART/PMTCT clinic. In addition, Case managers, who are trained lay workers and most of whom are PLHIV, provide adherence and psychosocial services at these ART health facilities in order to decrease interruption from services(44, 45). On the other hand, this finding is lower than studies reported from Northeast Ethiopia (14.8 per 1000 person-months observations) (29). This difference might be due to the difference in the study time that the study was initiated. The current study includes the recent year data at which most strategies as a country level were implemented to decrease LTFU like bringing services closer to communities by expanding ART sites to above 1,500 Health facilities, increasing service provision by expanding trained health personnel in order to decrease waiting times at the facility than the previous study(2013, 2014 and 2015).The variation could also be explained by the difference in study setting, since this study was conducted at one referral hospital whereas, a study conducted in Northeast Ethiopia was done in four hospital and ten health centers. Studies showed that magnitude of lost to follow up varied according to level of health institutions(23, 29). Moreover, the lower incidence of LTFU in the current study might be due to the fact that different programs/measures were implemented in the country in recent years to decrease the rate of LTFU among HIV infected women. Among these measures, increasing trained human power including midwives, frequent follow-up schedule and better drug preparation (fixed dose ART treatment) by giving better consideration for mothers to implement the program effectively(40). The current study finding is also lower than studies conducted in different African countries such as Uganda(15, 16, 18), South Africa(24), Malawi(14, 46) and Kenya(19).This discrepancy might be due to the difference in study time, operational definition of the outcome variable, and characteristic of study participants. For example, the study period for a study conducted in Malawi was 3-years record review(14) whereas the current study incorporated recent years' data which had better improvement ART coverage. Another explanation for discrepancy of incidence rate was characteristics of study participants that the study in Uganda incorporated 92% of the population with rural place of residence(16) compared to only 38.5% in the current study. The operational definitions of studies in Kenya and south Africa (28,33) were missing 6 months till last follow up visits compared to three months

to the current study. Furthermore, the rate of LTFU on the current study was lower than the study done in Myanmar which was 7 per 1000 person-years(11). This difference might be due to the reason that study in Myanmar included only pregnant women. Pregnancy related symptoms and signs during ante-natal care clinics (ANC) follow-up have chance of dropping out from the PMTCT clinic(47).

The current study showed that risk of LTFU among women who are residing in rural area is higher as compared to women residing in urban. Supportive findings were reported from previous studies in Ethiopia and Brazil(10, 30, 48). Possible explanations for this might be remote area mothers are forced to travel long distances in order to get the nearest hospital, which necessarily involves high costs which leads LTFU(16) and cannot easily get transport services due to poor /lack of road construction, makes women to walk long distances by bare foot, this leads them less likely to adhere to option B+ strategy (31) and resulting in missing the appointments(15, 32). This justification is also supported by the report given that lack of access to health care service leads to poor adherence and LTFU to option B+ PMTCT drugs (15). Although the current study did not assess this, additional explanation for high risk of LTFU that in a rural setting transport is costly because most mothers are farmers and housewife with low socioeconomic status(16).

This study also found that women who had no baseline viral load measurement were more likely to be LTFU as compared with those who had baseline viral load measurement within three-month of PMTCT enrollment. This finding is supported by a study in Nigeria among general population which was missing viral load measurement affects LTFU(49). This might be due to the fact that when viral load measurement took during PMTCT enrolment, the health care provider classified women as high risk with viral load more than 1000 copies/mm<sup>3</sup> and low risk with viral load less than 1000copies/mm<sup>3</sup>. Therefore, those with high risk category will be followed carefully and frequently in order not miss the appointment time since it is a gold criteria to know the women with a good way/ adherence in service provision(40). Another possible explanation for the high rate of LTFU for those who had no baseline viral load measurement is that viral load measurement implemented in advance after 2016 in Ethiopia. Another possible explanation could be that taking viral load measurement at the baseline raises women's HIV-related literacy and awareness and might engage women in care(45).

Moreover, women who had a fair/poor drug adherence level were more likely to be LTFU compared to women who had a good adherence level. This finding is supported by the study conducted in previous studies in Ethiopia(48) and in Malawi (22).This might be due to the fact that poor adherence to drugs is due to the feared side effects resulting in stopping taking ART treatments and lack of knowledge towards the importance of adherence to all appointments lead stopping/missing the schedule of ART treatment(18).

The current study revealed that risk of LTFU for those women who started ART at the same day following HIV diagnosis was higher than those women who started ART latter following HIV diagnosis. This finding is agreed with studies done in Northeast Ethiopia(29) and in Malawi (20).This might be due to the need of sufficient time and information for clients to adjust and preparing themselves lifetime treatment

psychologically, socially and physically. Moreover, the reason for lost follow-up for those women who started in the same day initiation might be due to the combined effect of ART side effects at the time of initiation and pregnancy induced physiological side effects such as; regurgitation, nausea and vomiting leads loss in treatment follow-up. But the study in southern Ethiopia suggests that pregnant women who started ART at the time of HIV diagnosis were more likely to adhere to option B+ ART resulting in increasing retention in HIV care(31) which is against of the finding of this study. The current study is also against to the study in south Africa which showed that same day antiretroviral therapy initiation in pregnancy is not associated with engagement in care(37). This might be due to the difference of study participants in which study in south Africa included only pregnant women.

The risk of LTFU among women who were on ART before PMTCT enrolment was lower than those who enrolled newly to PMTCT. This finding agreed with studies done in in different countries in African region(19, 23, 30). The possible explanations for this might be a known HIV woman and on ART before enrolment had experienced with ART treatment and might have good awareness about ART treatment, drug side effects and drug adherence than a newly enrolled woman. Evidence also showed that a new HIV diagnosis during routine ante-natal screening can be attended by different degrees of shock and denial and may lead to difficulty accepting immediate initiation of lifelong treatment resulting in lost to follow-up(46). This study also supported previous study done in south Africa which stated that being newly diagnosed with HIV were positively significant predictors of disengagement to ART treatment(24).

The finding of the current study also revealed that women who had recent ART side effects during PMTCT follow-up had a higher risk of LTFU than those women who had not ART side effects. The finding of this study supported by the study in Uganda(16) and in Malawi(9, 26, 33). This might be due to less counselling towards side effects of ART, and less support for women experiencing challenges with tolerability, including options to switch regimens(24).

All in all, incidence rate of LTFU was higher in the last month of PMTCT follow up period which gives implication that lack of proper linkage and referral systems between PMTCT services and ART clinics. In addition, in contrary to the current study, variables like educational status, maternal age, and baseline CD4 cell count showed statistically significant association with LTFU among HIV infected women under PMTCT services in the previous studies conducted at different African countries(15, 23, 24, 26, 29, 33). However, these variables are not statistically significant in the current studies. This difference might be due to the fact that predictors of LTFU varied from one geographical area to another geographical area due to the differences in the economic status of the study participants and infrastructure in the health facilities.

Although our study has its own strength to assess incidence of lost to follow-up (LTFU), it is not free from limitations and should be considered before interpreting results. First, as we conducted through the reviewing of records, we didn't include important predictors of LTFU like stigma, distance to Hospital, social support. Second, since this study was conducted only in one hospital it may not enough to generalize to all health facilities in Northwest Ethiopia.

## Conclusion

The current study revealed that the incidence of LTFU was dramatically and consistently decreasing as Option B+ matured from 38% in 2013 to 6% in 2019. The high rate of LTFU occurrence was observed in the last month of PMTCT follow-up. The study also found that there was a lower rate of LTFU among HIV positive women as compared to previous studies but it is slightly higher than WHO target. Place of residence, recent adherence level, baseline viral load measurement, a known HIV status, time of ART initiation, drug side effects, and religion were found to be the predictors of LTFU. Hence, we recommended the Hospital to give more attention for rural dwellers in order to decrease LTFU. Providing information about optimal ART drug adherence, management of drug side effects and regular viral load measurement shall be recommended. Furthermore, we recommend research considering qualitative component of the behavioral and cultural

## Abbreviations

AHR: adjusted hazard ratio; AIDS: acquired immunodeficiency syndrome; ART: antiretroviral therapy; CD4: Cluster of Differentiation T-4 cells ; CHR: crude hazard ratio; CI: confidence interval; CPT: Co-trimoxazole preventive therapy; eMTCT: elimination of mother to child transmission; HIV: human immunodeficiency virus; LTFU: lost to follow up; MUAC: mid-upper arm circumference; OI: opportunistic infections; PMTCT: prevention of mother to child transmission; WHO: World Health Organization.

## Declarations

### Acknowledgements

We would like to thank the University of Gondar for covering data collectors and supervisors per diem. We would also like to thank data collectors and the supervisor.

### Authors' contributions

MMA designed the study, supervised data collection, performed data analysis and interpretation, and drafted the manuscript. AGB assisted in designing the study, did data analysis and interpretation, and critical review the manuscript. MKY assisted in designing the study, did data analysis and interpretation, drafted the manuscript, and substantially revised the manuscript. All authors read and approved the final manuscript and agree to be accountable for all the contents of the work in the manuscript.

### Funding

The University of Gondar has covered the costs of data collectors and supervisors per diem. The funded organization has no role in designing the study, data collection, or manuscript preparation.

### Availability of data and materials

All essential data for this study are included in this article. The datasets used to analyze for this study are available from the corresponding author upon reasonable request.

### **Ethical approval and consent to participate**

Ethical clearance was obtained from the Ethical Committee of the institute of public Health at University of Gondar. First formal letter was written from University of Gondar to Gondar comprehensive and specialized hospital. Moreover, Permission for data collection was granted from the hospital. Informed consent was waived as secondary data have been extracted from the chart. Confidentiality of information was maintained through not extracting personal identifiers.

### **Consent for publication**

Not applicable.

### **Competing interests**

The authors declare that they have no competing interests.

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## Tables

Table 1: Baseline Socio-demographic, Maternal related Characteristics of pregnant and breast-feeding women on Option B+ at Gondar University Comprehensive and Specialized Hospital from June 2013 to December 2019, Ethiopia (n=403).

<b>Variables</b>	<b>Category</b>	<b>Frequency (%)</b>
Age in years	mean± (SD)	27.6 ± (4.7)
	15-24	98 (24.3)
	25-29	160 (39.7)
	30-45	145 (36.0)
Place of residence	Urban	248 (61.5)
	Rural	155 (38.5)
Marital status	Single	53 (13.2)
	Married	264 (65.5)
	Widowed	33 (8.1)
	Divorced	53 (13.2)
Religion	Orthodox Christian	328 (81.4)
	Muslim	49 (12.2)
	Others (protestant, catholic)	26 (6.4)
Educational status	No education	126 (31.3)
	Primary	112 (27.8)
	Secondary	110 (27.3)
	Above secondary	55 (13.6)
Occupational status	Housewife	186 (46.1)
	Governmental employee	62 (15.4)
	No-governmental employee	23 (5.7)
	Daily laborer	99 (24.6)
	Others*	33(8.2)
Number of pregnancies	One	147 (36.5)
	Multiple	256 (63.5)
Enrolment Status of women	Pregnancy	359 (89.1)
	Breast-feeding	44 (10.9)
Enrolment type to PMTCT	New	169 (41.9)
	On ART before enrolment	234 (58.1)

Recent MUAC level	≥23 cm	333 (82.6)
	<23 cm	70 (17.4)
Partner HIV status	Positive	222 (55.1)
	Negative	131 (32.5)
	Unknown/not done	50 (12.4)
Disclosure status	Yes	315 (78.2)
	No	88 (21.8)
<b>Total</b>		<b>403(100.0%)</b>

*Key: Others\*=student and merchant*

Table 2: Clinical, laboratory and Treatment related Characteristics of pregnant and breast-feeding women on Option B+ at Gondar University Comprehensive and Specialized Hospital from June 2013 to December 2019, Ethiopia.

<b>Variables</b>	<b>Category</b>	<b>Frequency (%)</b>
TB screening status	Negative	379 (94.0)
	Positive	24 (6.0)
INH prophylaxis	No	351(87.1)
	Yes	52 (12.9)
Comorbidity	Yes	27 (6.7)
	No	376 (93.3)
Initial ART regimen	<i>AZT-3TC-NVP</i>	105 (26.1)
	<i>AZT-3TC-EFV</i>	29 (7.2)
	<i>TDF-3TC-EFV</i>	239 (59.3)
	<i>TDF-FTC-NVP</i>	22 (5.4)
	Others*	8 (2.0)
Change of ART regimen	No	344 (85.4)
	Yes	59 (14.6)
Anemia status	Not anemic	271 (67.2)
	Anemic	132 (32.8)
Adherence level	Good	337 (83.6)
	Fair/Poor	66 (16.4)
Maternal CPT	No	223 (53.3)
	Yes	180 (44.7)
Drug Side effects	No	331 (82.1)
	Yes	72 (17.9)
WHO clinical stage	Early stage (I/ II)	381(94.6)
	Late stage (III/ IV)	22(5.4)
Functional status	Working	355 (88.1)
	Ambulatory/Bedridden	48 (11.9)
Time of ART initiation	Later	144 (35.7)
	Same day	259 (64.3)
CD4 cell count (cells/mm3)	mean± SD	419.1 ± 224.0

	Less than 200	60(14.9)
	200-350	105 (26.1)
	Greater than 350	238 (59.1)
Baseline Viral load taken	Yes	279 (69.2)
	No	124 (30.8)
<b>Total</b>		<b>403(100.0%)</b>

Key:AZT=Zidovudine,3TC=Lamivudine=Nevirapine, EFV=Efavirenz=Tenofovir Disoproxil Fumarate, FTC=Emtricitabine, others=1g(ABC+3TC+NVP), 2f (AZT-3TC-ATV/r), second line treatment, Comorbidity=heart disease and/or renal diseases and/or hypertension, and/or diabetes mellites.

Table 3: Comparisons of LTFU among different levels of baseline predictor variables using log-rank test from pregnant and breast-feeding women on option B+ PMTCT program at Gondar University comprehensive specialized Hospital (June, 2013–December, 2019)

Variables	Category	LTFU		Log rank test	
		IR /1000	PMO	$\chi^2$	P value
Age in years	15-24	7.9	1780	0.84	0.6580
	25-29	9.2	2818		
	30-45	10.7	2617		
Place of residence	Urban	4.1	4675	40.98	<0.0001
	Rural	19.3	2540		
Marital status	Single	21.5	838	17.11	0.0002
	Married	7.2	4866		
	Widowed/Divorced	9.9	1511		
Religion	Orthodox Christian	7.8	6002	10.93	0.0042
	Muslim	19.5	718		
	Others *	14.1	495		
Educational status	No education	13.1	2139	4.26	0.2350
	Primary	7.3	2057		
	Secondary	8.1	1985		
	Above	8.7	1034		
Employment status	Housewife	7.8	3322	5.74	0.2190
	Government employee	9.8	1120		
	Non-government employee	19.8	405		
	Daily laborer	9.5	1789		
	Other*	10.4	579		
Number of pregnancies	Single	9.8	2637	0.11	0.7418
	Multiple	9.2	4578		
Partner HIV status	Positive	8.6	4074	10.61	0.0050
	Negative	7.3	2326		
	Unknown/not done	19.6	815		
Disclosure status	Yes	6.9	5730	17.49	<0.0001
	No	18.9	1485		

Enrolment status	Pregnancy	8.4	6647	8.05	0.0046
	Breast-feeding	21.1	568		
Enrolment type	New	13.7	2698	8.44	0.0037
	On ART before enrolment	6.8	4517		
Comorbidity	No	8.0	6488	13.51	0.0002
	Yes	22.2	727		
MUAC level	≥ 23 cm	5.6	6203	67.16	< 0.0001
	< 23 cm	32.6	1012		
Anemia status	Not anemic	4.3	5128	48.56	< 0.0001
	Anemic	22.0	2087		
Maternal CPT	No	4.5	4017	23.81	< 0.0001
	Yes	15.6	3198		
Initial ART regimen	<i>AZT-3TC-NVP</i>	10.3	1933	4.58	0.2050
	<i>AZT-3TC-EFV</i>	5.2	582		
	<i>TDF-3TC-EFV</i>	10.5	4091		
	Other	3.3	609		
WHO clinical stage	Early stage(I/II)	8.5	6908	13.06	0.0003
	Late stage (III/IV)	29.3	307		
Functional status	Working	7.2	6538	37.27	< 0.0001
	Ambulatory/Bedridden	31.0	677		
Adherence level	Good	4.4	6310	134.86	< 0.0001
	Fair/Poor	44.2	905		
CD4 cell count in cells/ml	>350	6.0	4340	14.69	0.0001
	200-350	7.8	1917		
	<200	28.2	958		
ART initiation time	Same day	11.5	4707	5.86	0.0155
	Latter	5.6	2508		
ART Side effects	No	5.1	6104	79.40	< 0.0001
	Yes	33.3	1111		

Baseline Viral load taken	Yes	3.1	5196	79.00	<0.00001
	No	25.8	2019		

*Key: Comorbidity included chronic illness, tuberculosis and opportunistic infections, IR=incidence rate of loss to follow-up, PMO=person-month observation, Others\*=student and merchant*

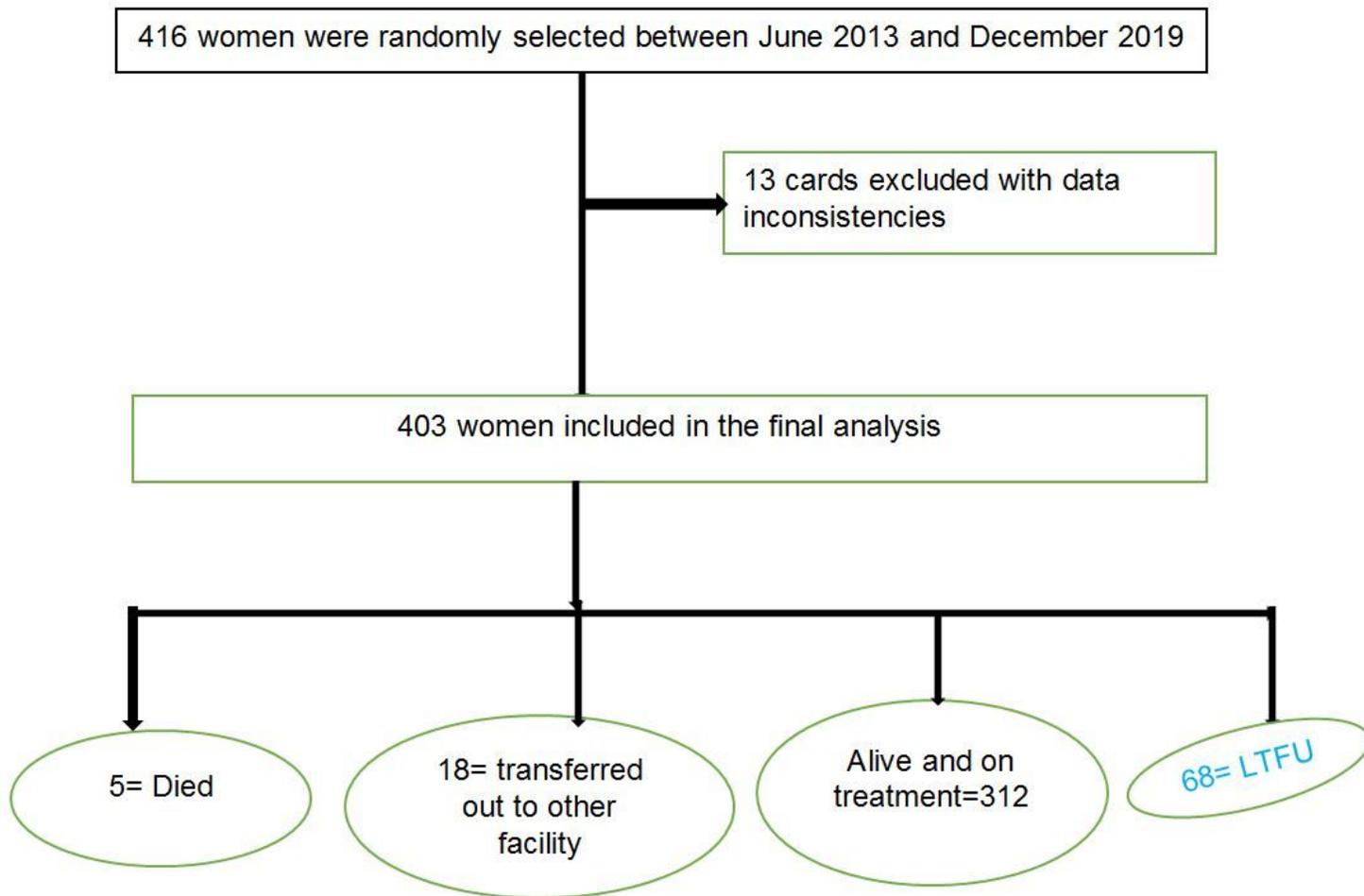
Table 4: Multivariable Cox regression of LTFU among pregnant and breast-feeding women on Option B+ PMTCT program at Gondar university Comprehensive and specialized hospital, northwest Ethiopia from June 2013–December, 2019

Variables		Censored	LTFU	Crude Hazard ratio	Adjusted Hazard ratio
				CHR (95%CI)	AHR (95%CI)
Residence	Urban	229	19	1	1
	Rural	106	49	4.75 (2.79,8.07)	2.30(1.08,4.88) *
Religion	Orthodox	281	47	1	1
	Muslim	35	14	2.52 (1.38,4.57)	2.44(1.23,4.81) *
	Others*	19	7	1.84 (0.83,4.07)	2.33(0.87,6.21)
Marital status	Married	229	35	1	1
	Single	35	18	3.12 (1.77,5.52)	1.57 (0.76,3.23)
	Divorced/widowed	71	15	1.38(0.76, 2.53)	0.77(0.36,1.65)
Disclosure status	Yes	275	40	1	1
	No	60	28	2.67 (1.65,4.34)	0.91 (0.47,1.81)
ART initiation time	Latter	130	14	1	1
	Same day	205	54	2.02 (1.12,3.65)	3.23(1.53,6.84) *
Comorbidity	No	307	52	1	1
	Yes	28	16	2.72 (1.55,4.77)	0.77(0.37,1.59)
MUAC level	Greater or equal to 23 cm	298	35	1	1
	Less than 23 cm	37	33	5.78(3.58,9.33)	1.79(0.91,3.52)
Anemia status	Not anemic	249	22	1	1
	Anemic	86	46	5.04(3.03,8.39)	1.78(0.97,3.26)
Clinical stage	Early stage (I/II)	322	59	1	1
	Late stage (III/IV)	13	9	3.35 (1.66,6.78)	0.87(0.33,2.3)
Functional status	Working	308	47	1	1
	Ambulatory/Bedridden	27	21	4.33(2.58,7.26)	1.51(0.63,3.61)
Maternal CPT	No	205	18	1	1
	Yes	130	50	3.49(2.03,5.98)	1.84(0.95,3.58)
Enrolment status	Pregnancy	303	56	1	1

	Breast-feeding	32	12	2.39(1.28,4.49)	0.97(0.95,2.25)
Enrolment type	New	132	37	1	1
	On ART before enrolment	203	31	0.50(0.31,0.81)	0.30(0.15,0.62)**
Side effects	No	300	31	1	1
	Yes	35	37	6.52(4.04,10.52)	1.82 (1.01,3.33)*
ART adherence level	Good	309	28	1	1
	Fair/poor	26	40	10.19(6.26,16.58)	3.96 (2.18,7.19)***
Baseline Viral load taken	Yes	263	16	1	1
	No	72	52	8.29 (4.73,14.52)	4.21 (2.23,7.96)***
Baseline CD4 cell count	<200	33	27	1	1
	200-350	90	15	0.28 (0.15,0.54)	1.19 (0.50,2.83)
	>350	212	26	0.22(0.13,0.37)	1.53(0.67,3.49)

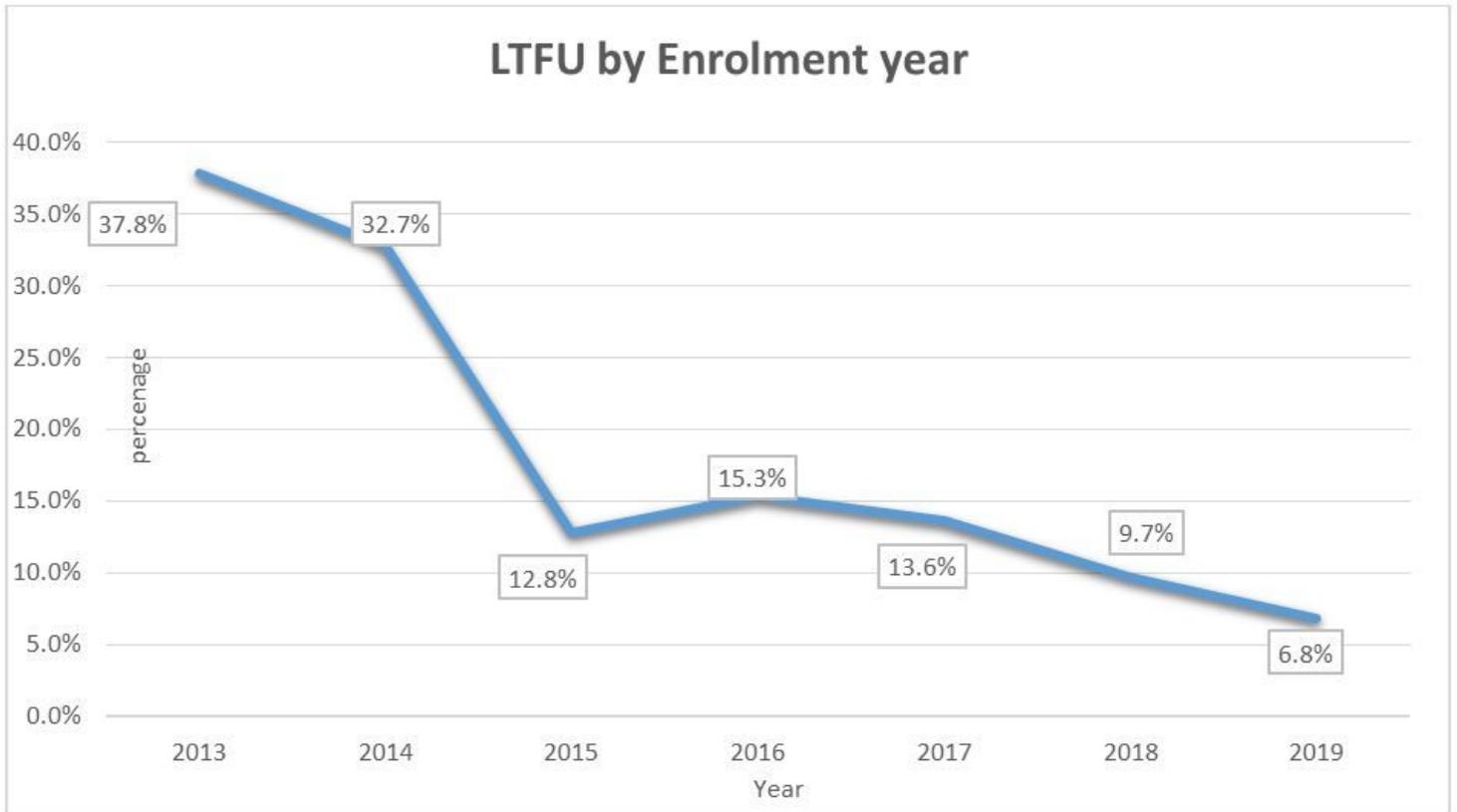
Key: others= protestant and Catholics religions, \*=significant at p value 0.05, \*\*= significant at p value 0.01 and \*\*\*= significant at p value 0.001

## Figures



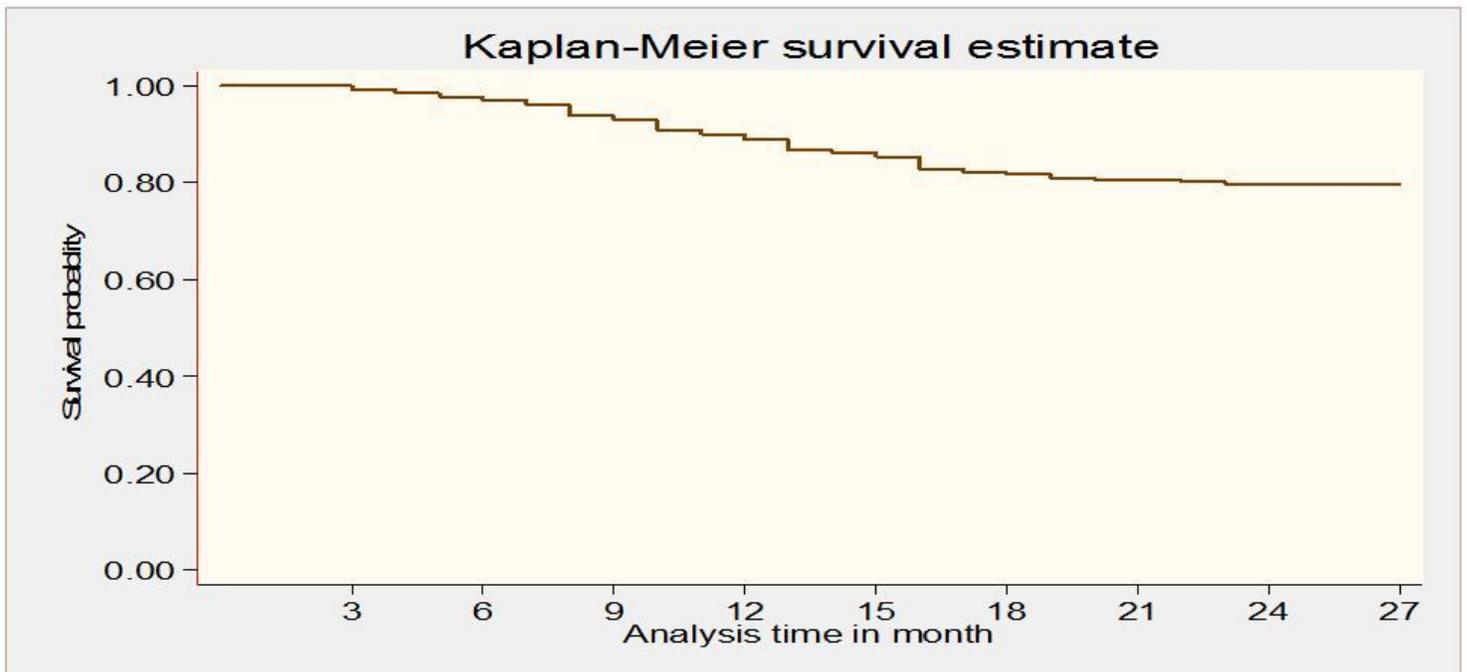
**Figure 1**

Consort diagram with Total number of eligible patients and final number of women included in the analysis.



**Figure 2**

Incidence of LTFU by enrolment year among pregnant and breast-feeding women on Option B+ PMTCT program at Gondar University Comprehensive and Specialized Hospital from June, 2013 – December, 2019.



**Figure 3**

Kaplan-Meier survival estimate of LTFU among pregnant and breast-feeding women on option B+ PMTCT service at Gondar university comprehensive and specialized hospital from June, 2013 to December, 2019

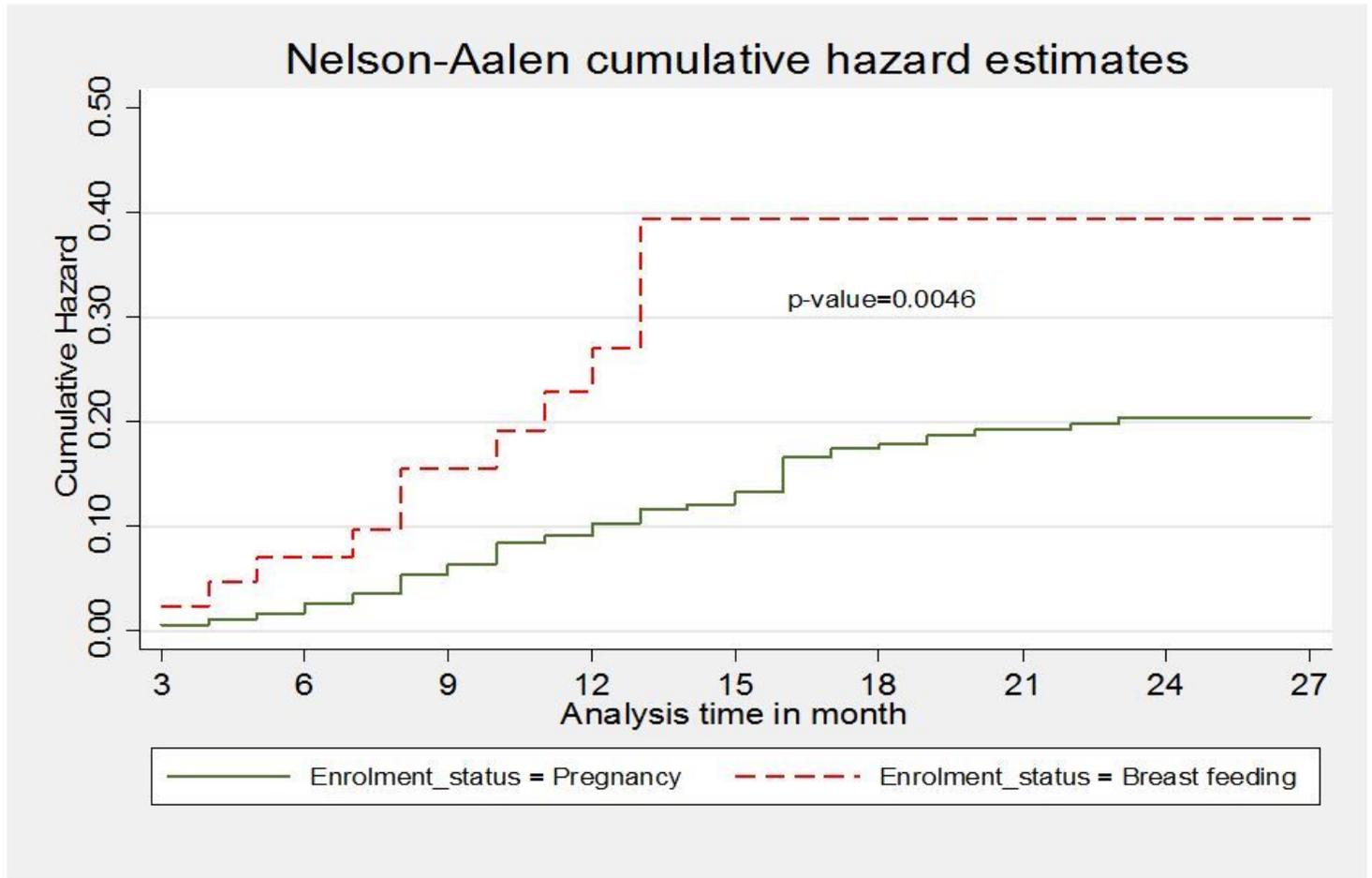


Figure 4

Cumulative hazard estimate of LTFU among pregnant and breast-feeding women on Option B + PMTCT program at University of Gondar comprehensive specialized hospital, Northwest Ethiopia between June 2013 and December 2019 by Enrolment status