Early infant breastfeeding practices, and predictors of breastfeeding cessation, in HIV-uninfected and HIV-infected mothers on anti-retroviral treatment: a prospective cohort study

Helene Cornelia Theunissen (WTTHEL004)

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Master of Public Health

School of Public Health and Family Medicine

Faculty of Health Sciences,

University of Cape Town

DECLARATION

I, Helene Cornelia Theunissen, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Signature: Signed by candidate

Date: 6 August 2020

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I am deeply grateful to my heavenly Father for this opportunity and without Whom none of this would have been possible.

To my husband Andrew, I am truly grateful and appreciative of you. I would not have been able to have completed this without your encouragement, support and love.

I would like to extend my sincere gratitude to my supervisor Dr Stanzi le Roux. Thank you for guiding me through the dissertation process and thank you for your continued support and expertise.

Thank you to my mother, siblings and rest of the family, I am so thankful for every phone-call and word of love and support.

Thank you to my friends and colleagues, your encouragement, support and advice were invaluable in this journey.

I would like to dedicate this mini dissertation to my father. I wish you had been granted more time to have been able to read it.

Abstract

Background: Optimal breastfeeding promotes child health and survival globally. Pro-breastfeeding HIV infant feeding policy changes in 2010, and the roll-out of universal maternal anti-retroviral therapy (ART) since 2013, have created an opportunity for re-establishment of breastfeeding among HIV-exposed infants in resource-limited settings. Yet data are limited on breastfeeding practices under these policies. This study aimed to evaluate breastfeeding practices and predictors of breastfeeding cessation among women living with HIV (WLHIV) receiving universal ART, and a comparator group of HIV-negative (HIV-) women in Cape Town, South Africa.

Methodology: This secondary data analysis used deidentified data from two parallel, prospective cohort studies conducted at the Gugulethu Midwife and Obstetric Unit between 2013 and 2017; the unit is certified as Baby-Friendly. Utilizing the same research staff, measurement tools and procedures, the studies followed pregnant women (HIV-; and WLHIV initiating universal ART) through delivery. HIV-exposed infants received nevirapine and co-trimoxazole prophylaxis. At the early neonatal visit (± 7 days), breastfeeding mother-infant pairs were eligible to continue follow-up (visits at 6 weeks; 3, 6, 9, 12 months). At each study visit, trained field workers administered 24-hour recall questionnaires to assess infant feeding and asked about changes in feeding practices since the preceding visit. Exclusive breastfeeding (EBF) was defined as feeding infants no other food or drink other than breastmilk, except for medicines, vitamins and minerals. Breast feeding (BF) was censored at last visit with reported BF. We used Cox proportional hazards regression to assess factors associated with cessation of exclusive and all breastfeeding among HIV-negative children of both groups of women (HIV-exposed uninfected, HEU and HIV-unexposed, HU children), expressed as crude (HR) or adjusted hazard ratios (aHR).

Results: Overall, 872 breastfeeding mother-infant pairs (HEU, n=461; HU, n=411) contributed 925 person-years of follow-up. All WLHIV initiated ART in pregnancy (at ART initiation, median HIV viral load 3.97 log10 copies/mL; median CD4 cell count, 354 cells/uL); 352/461 (76%) of WLHIV had viral load <50 copies/mL at the time of delivery. Median (inter-quartile range, IQR) gestation at birth was 39 (38-40) weeks, and birthweight, 3180 (2820-3460) grams; 424 (49%) of infants were boys. Early initiation of breastfeeding (EIBF, < 1 hour; overall, 788/867, 91%) was more common among HU than HEU infants (95% vs 87%, p<0.0001). Among infants who ever received EBF (754/872, 86%), median EBF duration was 1.4 (0.2-3.1) months. HEU vs HU infants were more likely to ever EBF (91% vs 81%, p<0.0001), with longer durations of EBF (median 1.5 vs 1.4 months, p=0.01; HR for EBF cessation, 0.78 [95% CI 0.67-0.9]). The overall median duration of any breastfeeding was 6.0 (IQR 1.5-12.0) months, with earlier cessation among HEU (median 3.9 months) than HU infants (median 9.0 months); HR for BF cessation 1.87 (95% CI 1.56-2.24). Lactation issues (for example cracked nipples or engorgement) were common in the first 6 weeks postpartum (reported by 143 of 872, 16%), with greater risk among WLHIV than HIV- women (20% vs 12%, p=0.003). Lactation problems (vs none reported) were associated with increased relative hazard for EBF cessation among both HEU (HR 1.48, 95% CI 1.13-1.96) and HU infants (HR 1.63, 95% CI 1.17-2.26); and for BF cessation among HEU infants (HR 2.45, 95% CI 1.85-3.24). Study limitations include reliance on maternal recall, and inability to assess exact date of breastfeeding cessation.

Conclusion: Breastfeeding practices remain poor among both WLHIV and HIV- women, despite pro-breastfeeding HIV policy changes. An alarmingly high proportion of WLHIV reported lactation problems including cracked nipples. These data highlight an urgent need for lactation support among peri-urban women in our setting, especially those living with HIV, both to improve overall breastfeeding practices to maximize child health and to prevent breastmilk-associated transmission of HIV.

Part A: The study protocol was submitted for departmental and ethical approval and contains the background and methodology for this Masters in Public Health mini-dissertation.

Part B: The journal-ready manuscript is presented according to the author guidelines for the Journal of Maternal and Child Nutrition.

Part C: The appendices include all additional documentation necessary for the presentation of the Masters in Public Health mini-dissertation.

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PART B: MANUSCRIPT

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ABBREVIATIONS

AUDIT	Alcohol Use Disorders Identification Test
AUDIT-C	Alcohol Use Disorders Identification Test-Consumption
ART	antiretroviral therapy
DAG	Directed Acyclic Graph
CUM-IRB	Columbia University Medical Centre Institutional Review Board
BF	breastfeeding
EBF	exclusive breastfeeding
EIBF	early initiation of breastfeeding
EPDS	Edinburgh Postnatal Depression Scale
HCW	Health care workers
HEU	HIV-exposed, uninfected
HIV	human immunodeficiency virus
HREC	Human Research Ethics Committee
HU	HIV-unexposed
HU2	HIV-Unexposed Uninfected Mother and Infant Cohort Study
MCH-ART	Maternal and Child Health Antiretroviral Therapy Cohort Study
MOU	midwife and obstetrics unit
MTCT	mother-to-child-transmission
PMTCT	prevention of mother-to-child transmission
VAW	violence against women
WLHIV	women living with HIV
WHO	World Health Organization

PART A: PROTOCOL

1. Background

Breastfeeding and HIV

Globally, exclusive breastfeeding is regarded as the optimal form of nutrition for infants during the first five to six months of life, where after breastfeeding should ideally be continued through the first 2 years of age alongside nutritionally sufficient complementary feeding practices. (1-8) Optimal breastfeeding practices have short and long-term health benefits, for both infant and mother. (8) Child health benefits include improved survival, protection against common childhood infections, increased intelligence levels as well as decreased risks of later-life non-communicable diseases including obesity and diabetes. (9)

Although breastfeeding benefits extend to both HIV-infected and -uninfected children, postnatal transmission of HIV may occur via breastfeeding, especially in the context of mixed feeding (provision of both infant formula and breastmilk in the first 6 months of life). (10) Prior to the availability of triple agent antiretroviral therapy (ART), breastfeeding was often avoided by HIV-infected mothers to reduce the risk of vertical transmission. (10,11) In this context, the absence of breastfeeding in high infectious burden settings resulted in high rates of death and infectious morbidity among HIV-exposed infants. (6,7) However, in the context of HIV viral suppression on ART, HIV-infected women can breastfeed safely, with minimal risk of transmission. (12) Since 2010, the World Health Organization has recommended breastfeeding for all HIV-exposed children living in areas with high infectious disease burdens, provided mothers are virally suppressed on ART. (7,13) This recommendation is also reflected in recent changes to the stance of the South African health sector, whereby in 2011, policies were changed to promote and support breastfeeding as the default feeding method for

infants exposed to HIV. (6,11) However, policy changes alone may be insufficient to address the previously reported poor breastfeeding rates of both HIV-infected and HIV-uninfected women in South Africa. (14)

Infant and young child feeding practices

Optimal feeding practices constitute continued breastfeeding up to the age of two years, with the timely introduction of safe, adequate and appropriate complementary foods. (4,5,7,15,16) Optimal feeding practices among infants and young children (0-24months), in their so-called critical window of opportunity (15), are crucial for good developmental, health and survival outcomes. (4,5,7,15,16) Not only is it the time in their life in which they are most vulnerable to acute respiratory tract infections and diarrhoeal disease, but at the same time, they are experiencing rapid growth and development. (5) Nutritional deficiencies and sub-optimal feeding practices during this period in life potentially leads to stunting, increased risk of obesity, compromised cognitive development, impaired educational performance and ultimately lower economic productivity. (4,15,16)

The importance of optimal infant feeding practices is highlighted by the high infant and young child mortality rates that are prevalent in South Africa. (7) Here, mortality rates among infants and young children are commonly attributable to undernutrition as well as pneumonia and diarrhoea. (7,13) For these reasons, improvement of the previously reported poor infant feeding practices among both HIV-infected and HIV-uninfected women should be a public health priority.

Policy changes: breastfeeding and HIV

To date, optimal breastfeeding practices in the context of postnatal Prevention of Mother to Child Transmission (PMTCT), have been hampered by confusion regarding optimal infant feeding practices. (17) This confusion was largely driven by rapidly changing sets of the World Health Organisation (WHO) published feeding guidelines in the context of HIV over time. (18) Between 2001 and 2011, these guidelines called for the avoidance of breastfeeding and for substitution with breastmilk substitutes, in an era when antiretroviral therapy was not widely available in Southern Africa. In this period in South Africa, free infant formula was distributed to most HIV-exposed infants up to the age of 6 months. (17,19) This promotion of the avoidance of breastfeeding in context of HIV was driven by concerns of HIV transmission via breastfeeding. However, several pivotal studies demonstrated markedly reduced risks of breastfeeding-associated HIV transmission in the context of maternal and/or infant use of antiretroviral agent. (20-22) Consequently, WHO infant feeding policies were changed in 2010; in turn, breastfeeding was subsequently promoted as the infant feeding practice of choice in the context of PMTCT in South Africa. (17,19) Contemporaneously, the WHO incorporated antiretroviral-based approaches to minimize breastfeeding related transmission. In 2013, South Africa adopted the so-called "Option B/B+" PMTCT policy, which requires all pregnant and breastfeeding HIV-infected women to receive triple agent antiretroviral therapy (ART) – in Option B+, the ART is continued lifelong. Option B+ PMTCT policies were introduced in the Western Cape in 2014; ART guidelines were subsequently updated to a "test-and-treat" policy for all people living with HIV. (23) Unfortunately, these rapidly changing policies and guidelines created confusion among feeding counsellors, while also creating a loss of confidence and trust in breastfeeding by mothers in general, as well as in healthcare providers and feeding

counsellors. Subsequently, this translated into confusing breastfeeding advice and support provided to mothers in PMTCT, and in turn, poor progression in the aim to improve actual feeding practices. (18,24) Indeed, data from soon after the implementation of the 2010 feeding policy changes indicated that breastfeeding rates continued to be poor (14). Without actual improvements in breastfeeding rates, the optimum child health benefits of Option B+ cannot be realised.

Conclusion

Optimal breastfeeding practices are critical to child health. After a decade of vacillating guidelines and poor infant feeding practices, recent changes in HIV-related feeding and treatment guidelines have the potential to improve infant health and survival in South Africa. However, data are needed to assess the success of updated infant guideline implementation, and to identify potentially modifiable factors that continue to limit this potential success. To optimize successful implementation of these guidelines, a better understanding is required of the obstacles and facilitators of best feeding practices among both HIV-infected and HIV-uninfected women, under current breastfeeding promotion and ART policies.

2. Importance & Benefits of the proposed Study

The results obtained from this study will contribute to a better understanding of obstacles and facilitators of optimal breastfeeding practices among HIV-infected and uninfected mothers in the Western Cape Province, South Africa, in the light of current ART and breastfeeding policies. In turn, a better understanding of these factors will enable improved support offered

to women in this setting. The results of this study will be published in the public domain and shared with local provincial groups, with the eventual aim of improving breastfeeding practices of infants in this, and similar peri-urban settings through science and advocacy.

3. Research Question, Objective & Aims

What are the breastfeeding practices, and predictors of early breastfeeding cessation, among HIV- infected and HIV-uninfected mothers and their infants in a peri-urban South African setting under "Option B+" PMTCT policies?

4. Objective

The main objective of this study is to describe and compare breastfeeding practices and predictors of early breastfeeding cessation of HIV-infected and HIV-uninfected mothers and their infants at the Gugulethu Midwife and Obstetric Unit (MOU), during the first 3 years following introduction of Option B+ PMTCT policies in the Western Cape.

Aims

1. To describe breastfeeding practices using three related measures:
    a. WHO core indictors for breastfeeding in the first year of life, specifically:
        - Proportion of children who were put to the breast within one hour of birth

- Proportion of children exclusively breastfed until 6 months of age
- Proportion of children who were still breastfeeding at age of 12 months

b. Duration of any breastfeeding

c. Age at introduction to complementary feeding

2. To identify potential risk and facilitation factors that influence breastfeeding practices, including investigation of the effects of
    a. Lactation problems
    b. Maternal factors such as education, psychosocial and behavioural challenges
    c. Infant factors such as preterm birth
3. To assess variation in the above (1 and 2), by maternal HIV status

Hypotheses

While Aims #1 and #2 are hypothesis-generating, the following hypotheses underly Aim #3: HIV-infected women have less optimal breastfeeding practices, and more risk factors for early breastfeeding cessation, than HIV-uninfected women, specifically

- HIV-infected women have shorter durations of breastfeeding than HIV-uninfected women
- HIV-infected women introduce complementary feeds at an earlier age than HIV-uninfected women
- HIV-infected women face more challenges to successful breastfeeding, with a higher prevalence of risk factors for early breastfeeding cessation

5. Methodology

5.1. Study Design

The primary researcher proposes to address these objectives, based on secondary data obtained from two parent studies, which have been approved by the UCT HREC committees previously; MCH-ART (UCT HREC reference 451/2012, Appendix A) and HU2 (UCT HREC reference 567/2014, Appendix B).

Both the "Maternal and Child Health Anti-Retroviral Therapy (MCH-ART) and the "HIV-unexposed uninfected (HU2) mother and infant" study are prospective cohort studies, examining amongst others health outcomes of HIV-exposed (MCH-ART) and unexposed (HU2) infants. Data collection commenced in March 2013 and September 2014 respectively. Both studies aimed to follow up for at least 12 months. The MCH-ART cohort is a multi-phase study, which recruited pregnant, HIV infected women sequentially at their first antenatal booking visit. Similarly, HU2 recruited participants sequentially at their first antenatal booking visit, however it recruited pregnant HIV-uninfected women seeking antenatal care.

Phase 1 of MCH-ART enrolled HIV-infected, pregnant women attending their first antenatal visit at the Gugulethu MOU; for Phase 2, women from phase 1, eligible for ART initiation were followed as part of an observational cohort, while Phase 3 constituted a randomized trial of different methods of ART delivery to these postpartum women. In HU2, pregnant, HIV-uninfected women attending their first antenatal visit at the Gugulethu MOU were enrolled and followed in an observational cohort antenatally and then postnatally.

Data for this research will be derived from both baseline and longitudinal questionnaires regarding maternal demographics, infant feeding, psychosocial-behavioural factors and socio-economic status.

5.2. Study Setting

Data for this secondary data analysis is obtained from the above-mentioned parent studies, set at the Gugulethu MOU on the premises of the Gugulethu Primary Healthcare Centre, which serves a population of roughly 350 000. It is located in Gugulethu, a low-income peri-urban township located in the Klipfontein sub-district of Cape Town, characterised by a high antenatal prevalence of HIV, close to 30%. (25) The Gugulethu MOU is a certified "baby-friendly" hospital, in terms of the Baby Friendly Hospital initiative. Breastfeeding support counsellors are available on the premises. (26)

5.3. Study Population & Sampling

Study population

The participants for this study, will be drawn from the MCH-ART (Phase 2 & 3) as well as the HU2 cohort studies. The study populations for both cohorts were recruited from the Gugulethu MOU and followed up with their infants until these were at least 12 months old, and all had initiated breastfeeding after delivery. For the current analyses, children who were eligible for longitudinal follow-up will be included, except those who acquired HIV in the postnatal period. That is, the current analysis will be restricted to HIV-negative infants who

initiated breastfeeding after birth and were followed in the postnatal aspects of the parent studies, to obtain longitudinal measures.

Please see Appendix C for a detailed list of inclusion and exclusion criteria for the parent studies.

Sample size calculations

This secondary data analysis will use the available sample of mothers and children; sample size for the main study was based on the primary objectives for the main studies. All results will be presented with 95% confidence intervals to indicate achieved precision of the estimates; no post-hoc power calculations will be done.

5.4. Data collection

All data used for the purposes of this study were collected at a study research site on the premises of the Gugulethu MOU for both parent studies. Study procedures and measures were identical for both studies, except for HIV-related measurements in the MCH-ART study.

Measurement tools

Data was obtained through Clinical record forms (CRFs), and questions were administered by trained interviewers in private rooms. CRFs were translated from English into isiXhosa and subsequently back-translated by isiXhosa speaking staff members, with validation certification. For the purposes of this study, data derived from the "Infant feeding

intentions/practices" questionnaire (Appendix D) will be used to evaluate breastfeeding practices. This questionnaire was administered in both parent cohorts during post-natal follow up visits at approximately <7 days, 6 weeks, 3,6,9 and 12 months. Additionally, selected data derived from the "Maternal Demographics & Medical History Questionnaire" will be used, as well as the Edinburgh Postnatal Depression Scale (EPDS) (Appendix L), the Kessler-10 (Appendix M), the Trauma/Abuse Assessment (Appendix N) and the Alcohol Use Disorders Identification Test- (AUDIT) (Appendix O). The HU2 questionnaire (Appendix E) was an appropriately shortened version (so as not to enquire about HIV/ART related information) of that of MCH-ART. (Appendix F)

Measurement methods

Exploratory analysis will evaluate breastfeeding and weaning practices, as well as reported reasons for breastfeeding cessation among both HIV-infected and HIV-uninfected mothers. These will be evaluated in the light of (including but not limited to) work commitments, lactation-problems, pressure from family or health care workers and maternal mental health. Please see Appendix G for a Directed Acyclic Graph.

6. Statistical Analysis & Data management

Data capturing, safety and monitoring

All data have been captured as part of the conduction of the parent cohort studies, at the Gugulethu Research Site of the University of Cape Town, School of Public Health and Family

Medicine. As per study protocols, all participant data was kept anonymous with no personal identifiers attached to participant files and with only systematically assigned identification numbers. Database files are stored on password protected external hard drives which in turn are stored in locked safes at the University of Cape Town and at the research site.

Data analysis

This study involves secondary data analysis of data derived from the two parent prospective cohort studies, as discussed above.

All data analysis will be performed by the primary researcher and analysis will be conducted using Stata, Version 14.0.

Proposed statistical tests include but are not limited to:

Table 1: Proposed Statistical tests

	Data type	**Statistical approach and/or test**
Descriptive & summary statistics	Categorical Data	Frequencies, percentages & proportions Bar graphs, mosaic plots
	Numerical Data	Mean (Standard Deviation), compared using t-tests, or Median (Inter Quartile Range) * Box-and-whiskers plots, scatterplots
Correlation coefficients, comparisons & basic tests	Categorical Data	ANOVA, Chi-Square or Fishers exact test*
	Numerical Data	Wilcoxon sum rank or T-tests*
Associations & Hypothesis testing	Generalized Linear Models (link function dependent on distribution of outcome) will be used to assess factors associated with early feeding practices Survival analysis and Cox proportional hazards regression models will be used to assess duration of exclusive, and any, breastfeeding, and predictors of early cessation	

*Normality dependant

7. Ethical & Legal considerations

Both parent studies obtained ethical approval from the University of Cape Town Faculty of Health Services Research Ethics committee (UCT-HREC) and (MCH-ART specifically) from the Columbia University Medical Centre Institutional Review Board (CUMC-IRB). This includes study protocols, informed consent forms and data collection tools. Both parent studies proceeded with full ethical approval.

This sub-study will commence only with the ethical approval from UCT-REC and will only include data from participants who have provided informed consent.

Since this is a secondary data analysis of previously collected, anonymous data, it is anticipated to pose minimal risks to the participants. No direct benefit will be incurred by participants for taking part in this study, however information derived may feed into further research and infant feeding education campaigns and projects.

Informed consent

For the purposes of this sub-study using secondary data analysis, no further consent is needed. Participants were consented through the MCH-ART and HU2 consent process, by a trained interviewer, in isiXhosa making use of standardized consent forms (Appendices H-K). Participation was entirely voluntary. During the consent process, participants were informed of the purpose and procedures of the studies and were given the opportunity to ask questions

Privacy and confidentiality

Data privacy, anonymity and confidentiality will be ensured always, as discussed in "Data capturing, safety and monitoring" above. For the purposes of this research study, no contact will be established with study participants.

8. Logistics & Time schedule

Table 2: Gannt Chart of Actions and Timelines

Year	**2013 - 2017**	**2018**		**2019**		**2020**
Month		**November**	**December**	**January - April**	**May - December**	**January - March**
Actions						
Data Collection						
Protocol Finalization						
UCT-REC Submission & Feedback						
Data Processing						
Data Analysis						
Thesis write up						
Submission						

9. Budget

The primary researcher will receive no funding for the analysis of this data. No funding is required for the conduction of this sub-study.

10. List of Abbreviations

ART	antiretroviral therapy
EBF	exclusive breastfeeding
BF	breastfeeding
HIV	human immunodeficiency virus
HU2	HIV-unexposed uninfected mother and infant cohort study
MCH-ART	maternal and child health antiretroviral therapy cohort study
MOU	midwife and obstetrics unit
PMTCT	prevention of mother-to-child transmission
WHO	World Health Organisation

11. References

1. World Health Organization (WHO). Indicators for assessing Infant and Young Child Feeding Practices: Part 1 Definitions. Geneva, World Heal Organ Dep Child Adolesc Heal Dev. 2008;1:1–26.

2. World Health Organisation (WHO). Indicators for assessing Infant and Young Child Feeding Practices: Part 2 Measurement. Geneva, World Heal Organ Dep Child Adolesc Heal Dev [Internet]. 2010;2:1–91. Available from: http://whqlibdoc.who.int/publications/2010/9789241599290_eng.pdf

3. World Health Organization (WHO). Indicators for assessing Infant and Young Child Feeding Practices part 3: Country Profiles. World Heal Organ [Internet]. 2008;http://www:19. Available from: http://whqlibdoc.who.int/publications/2008/9789241596664_eng.pdf%5Cnhttp://www.unicef.org/programme/breastfeeding/innocenti.htm%5Cnhttp://innocenti15.net/declaration.pdf.pdf%5Cnhttp://whqlibdoc.who.int/publications/2010/9789241599757_eng.pdf

4. Kimani-Murage EW, Madise NJ, Fotso JC, Kyobutungi C, Mutua MK, Gitau TM, et al. Patterns and determinants of breastfeeding and complementary feeding practices in urban informal settlements, Nairobi Kenya. BMC Public Health. 2011;11.

5. Kapur D, Sharma S, Agarwal K. Dietary Intake and Growth Pattern of Children 9-36 Months of Age in an Urban Slum in Delhi. Indian Pediatr. 2005;42.

6. Nieuwoudt S, Manderson L, Norris SA. Infant feeding practices in Soweto, South Africa: Implications for healthcare providers. South African Med J. 2018;108(9):756–62.

7. World Health Organization. Guideline: updates on HIV and infant feeding. Who Publ [Internet]. 2016;59. Available from: http://www.who.int/about/licensing/copyright_form/index.html

8. Victora CG, Bahl R, Barros AJD, França GVA, Horton S, Krasevec J, et al. Breastfeeding in the 21st century: Epidemiology, mechanisms, and lifelong effect. Lancet. 2016;387(10017):475–90.

9. Ramokolo V, Lombard C, Chhagan M, Engebretsen IMS, Doherty T, Goga AE, et al. Effects of early feeding on growth velocity and overweight/obesity in a cohort of HIV unexposed South African infants and children. Int Breastfeed J. 2015;10(1):1–11.

10. Mofenson LM. Review Antiretroviral drugs to prevent breastfeeding HIV transmission.

2010;553:537–53.

11. Kuhn L, Kroon M Breastfeeding and the 2015 South African guidelines for prevention of mother-to-child transmission of HIV. South Afr J HIV Med. 2015; 16 (1) 1–5.

12. White AB, Mirjahangir JF, Horvath H, Anglemyer A, Read JS. Antiretroviral interventions for preventing breast milk transmission of HIV (Cochrane Systematic Review). 2014;(10) 1-88.

13. Rollins NC, Ndirangu J, Bland RM, Coutsoudis A, Coovadia HM, Newell ML. Exclusive breastfeeding, diarrhoeal morbidity and all-cause mortality in infants of HIV-infected and HIV uninfected mothers: An intervention cohort study in KwaZulu natal, South Africa. PLoS One. 2013;8(12):1–10.

14. Doherty T, Sanders D, Jackson D, Swanevelder S, Lombard C, Zembe W, et al. Early cessation of breastfeeding amongst women in South Africa : an area needing urgent attention to improve child health. Bio Med Cent Pediatr. 2012;12(105):1471–2431.

15. Plessis L Du, Kruger H, Sweet L. Complementary feeding: A critical window of opportunity from six months onwards. South African J Clin Nutr [Internet]. 2013;26(3):S129–40. Available from: http://www.ajol.info/index.php/sajcn/article/view/97850

16. Sayed N, Schönfeldt HC. A review of complementary feeding practices in South Africa. South African J Clin Nutr [Internet]. 2018;0(0):1–8. Available from: https://www.tandfonline.com/doi/full/10.1080/16070658.2018.1510251

17. Moland KMI, van Esterik P, Sellen DW, de Paoli MM, Leshabari SC, Blystad A. Ways ahead: Protecting, promoting and supporting breastfeeding in the context of HIV. Int Breastfeed J. 2010;5:2–5.

18. Moland KMI, de Paoli MM, Sellen DW, van Esterik P, Leshabari SC, Blystad A. Breastfeeding and HIV: Experiences from a decade of prevention of postnatal HIV transmission in sub-Saharan Africa. Int Breastfeed J. 2010;5:1–7.

19. Ijumba P, Doherty T, Jackson D, Tomlinson M, Sanders D, Persson LÅ. Free formula milk in the prevention of mother-to-child transmission programme: Voices of a peri-urban community in South Africa on policy change. Health Policy Plan. 2013;28(7):761–8.

20. Shapiro R, Hughes M, Ogwu A, Al. E. Antiretroviral Regimens in Pregnancy and Breast-Feeding in Botswana Antiretroviral Regimens in Pregnancy and Breast-Feeding in Botswana. N Engl J Med. 2010;362:2282–94.

21. Chasela C, Hudgens M, Jamieson D, Al E. Maternal or Infant Antiretroviral Drugs to Reduce HIV-1 Transmission. N Engl J Med. 2010;362(24):2271–81.

22. Kesho T, Study B. Triple antiretroviral compared with zidovudine and single-dose nevirapine prophylaxis during pregnancy and breastfeeding for prevention of mother-to-child transmission of HIV-1 (Kesho Bora study): a randomised controlled trial. Lancet Infect Dis.. 2011;11(3):171–80. Available from: http://dx.doi.org/10.1016/S1473-3099(10)70288-7

23. Department of Health R of SA. IMPLEMENTATION OF THE UNIVERSAL TEST AND TREAT STRATEGY FOR HIV POSITIVE PATIENTS AND DIFFERENTIATED CARE FOR STABLE PATIENTS. Pretoria, Republic of South Africa; 2016.

24. Blystad A, van Esterik P, de Paoli MM, Sellen DW, Leshabari SC, Moland KMI. Reflections on global policy documents and the WHO's infant feeding guidelines: Lessons learnt. Int Breastfeed J. 2010;5:2–4.

25. Myer L, Philips T, Manuelli V, McIntyre J. Evolution of antiretroviral therapy services for HIV-infected pregnant women in Cape Town, South Africa. J Aquired Immune Defic Syndr. 2015;69(2):57–65.

26. Henney N. Western Cape Government: Breastfeeding Seminar. Mother and Baby friendly initiative. 2013.

12. Appendices (see PART C, Appendix 1 for protocol appendices)

Appendix A - MCH-ART study HREC approval

Appendix B - HU2 study HREC approval

Appendix C - MCH-ART & HU2 inclusion/exclusion criteria

Appendix D - Infant feeding intentions/practices questionnaire

Appendix E - HU2 Maternal Demographics & Medical History Questionnaire

Appendix F - MCH-ART Demographics & Medical History Questionnaire

Appendix G - Directed Acyclic Graph (DAG)

Appendix H - MCH-ART Phase 2 informed consent form

Appendix I - MCH-ART Phase 3 informed consent form

Appendix J - HU2 Informed consent form, Antenatal Phase

Appendix K - HU2 Informed consent form, Postnatal Phase

Appendix L - Edinburgh Postnatal Depression Scale (EPDS)

Appendix M - Kessler-10 (K-10)

Appendix N - Trauma / Abuse Assessment (WHO VAW Questionnaire)

Appendix O - Alcohol Use Disorders Identification Test (AUDIT)

Appendix P - Data management plan

PART B: MANUSCRIPT

This manuscript is written in accordance with the Instructions for Authors of the Journal of Maternal & Child Nutrition. Instructions are included as Appendix 5. The journal requires that figures and tables be supplied separately to the main text of the manuscript: these have been inserted in the main text of the manuscript for dissertation purposes. The journal requires that the APA referencing style be used, for dissertation purposes, the Vancouver referencing style was used.

Early infant breastfeeding practices, and predictors of breastfeeding cessation, in HIV-uninfected and HIV-infected mothers on anti-retroviral treatment: a prospective cohort study.

Helene Theunissen (BSc (Med) (Hons))1§*

1Division of Epidemiology and Biostatistics, School of Public Health & Family Medicine, University of Cape Town, Cape Town, South Africa

§Corresponding author
Address: Division of Epidemiology and Biostatistics
School of Public Health & Family Medicine
University of Cape Town, Falmouth Building
Anzio Road, Observatory
Cape Town, 7925
South Africa

Email: wtthel004@myuct.ac.za
Telephone: +27 21 650 6713

Keywords: Anti-retroviral treatment, breastfeeding, exclusive breastfeeding, Women living with HIV, HIV-uninfected, HIV-exposed uninfected, HIV-unexposed, Prevention of mother-to-child transmission (PMTCT), HIV/AIDS, South Africa

Trial registration
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As per MPH dissertation guidelines, co-authors are not listed on the journal ready manuscript. The contribution of supervisors and collaborators is listed in Appendix 3, the acknowledgments section of this dissertation.

Abstract

Background: Optimal breastfeeding (BF) promotes child survival. Little is known about BF practices among women living with HIV (WLHIV) in the era of universal maternal antiretroviral therapy (ART). We investigated BF practices and predictors of cessation among WLHIV receiving universal ART in peri-urban Cape Town, South Africa.

Methodology: Two parallel, prospective cohort studies (2013-2017, primary care setting) enrolled breastfeeding mother-infant pairs at ±7days postpartum. We evaluated BF practices (24-hour recall, at 6 weeks; 3, 6, 9, 12 months) among WLHIV (HIV-exposed uninfected, HEU infants) versus HIV-negative women (HIV-unexposed, HU infants). We used Cox proportional hazards regression to compare predictors of BF cessation.

Results: Overall, 872 mother-infant pairs (n=461 HEU; n=411 HU) breastfed for a median (interquartile range, IQR) of 6.0 (IQR 1.5-12.0) months; median exclusive BF (EBF) duration was 1.4 (0.1-3.0) months. Early initiation of breastfeeding (<1 hour from birth) was more common among HU vs HEU infants (95% vs 87%, *p*<000.1). A larger proportion of HEU vs HU infants ever EBF (91% vs 81%, *p*<000.1), or were still EBF at 6 months (54% vs 15%, *p*<000.1). BF cessation occurred earlier among HEU than HU infants, (BF at 12 months, 39% vs 50%; *p*=0.01). Lactation problems were common and predicted cessation of EBF vs. no lactation problems, (HR 1.46, 95% Confidence Interval [CI] 1.17; 1.81) and BF (HR 1.98, 95% CI 1.56; 2.51).

Conclusion: Breastfeeding practices remain poor among WLHIV and HIV-negative women, despite pro-breastfeeding HIV policies. This data highlights an urgent need for improved lactation support among women in this setting.

Key messages

- Although national policies promote breastfeeding (BF) in the context of HIV and universal maternal antiretroviral therapy (ART), recent data are lacking on BF practices in South Africa
- Using data from a prospective cohort of peri-urban breastfeeding mother-infant pairs in Cape Town, South Africa, we report inappropriately early cessation of both exclusive and all BF, regardless of maternal HIV status
- We identify lactation problems and maternal employment as major obstacles to optimal breastfeeding in our setting
- Urgent improvements in lactation support are required, and structural interventions at the workplaces of breastfeeding women require exploration

Introduction

Exclusive breastfeeding (EBF) is considered nutritionally complete and the best form of nutrition for infants in the first five to 6 months of their life. (1–9) Breastfeeding and appropriate complementary feeding practices should ideally continue beyond the first,(1) through to the second year of a child's life. (2–10)

Breastfeeding is beneficial to both infant and mother, both in the long- and short term. (7) It is associated with increased intelligence, reduced risk of developing diabetes and overweight as well as reduced infectious illness and mortality. (7,11–13) While benefits are applicable to both HIV-uninfected as well as HIV-infected infants and young children, breastmilk-associated HIV transmission can occur, especially in the context of mixed feeding. (9)

For this reason, historically, breastfeeding was avoided by most women living with HIV (WLHIV) in an attempt to reduce the risk of vertical transmission. (9,14) However, across sub-Saharan Africa including South Africa, breastfeeding avoidance resulted in high levels of infectious disease morbidity and deaths among HIV exposed infants. (5,6) In recognition of these risks, the World Health Organization (WHO) adopted a pro-breastfeeding policy change for resource-limited settings with high infectious burden in 2010. (6) At this time, breastfeeding was re-instated as the HIV infant feeding practice of choice in Prevention of Mother to Child Transmission (PMTCT) programmes. (15,16) Nevertheless, confidence in breastfeeding was lost in the era of distributing breastmilk substitutes in the context of HIV in South Africa, and was not easily restored despite the WHO policy changes. (15,17) Breastfeeding rates remained suboptimal in South Africa among both WLHIV and HIV-negative mothers. (18)

Strong evidence of the protective effects of maternal antiretroviral therapy (ART) to reduce breastmilk-associated HIV transmission (19–21) led to the introduction of "universal" (no restrictions) ART for all pregnant and breastfeeding women ("Option B/B+"), promoted since 2013. Subsequently, South Africa introduced the "Option B/B+" PMTCT policy. (19,20,22)

Of note, the potential health benefits associated with Option B+ cannot be realized without improvements in breastfeeding rates. (23) However, data on breastfeeding practices since the pro-breastfeeding policy change, in the context of Option B/B+, is limited. Studies conducted in the transition period from exclusive formula to EBF policies indicated suboptimal feeding practices in the Western Cape (24), however improvements were seen nationally in early EBF despite low EBF prevalence. (25) Hence, more research is necessary to identify barriers and facilitators of optimal breastfeeding practices in the context of both ART and pro-breastfeeding policies.

The aim of this study is therefore to describe, explore and compare breastfeeding practices and identify predictors of early breastfeeding cessation among WLHIV and HIV-negative women in Gugulethu, in the first three years after the introduction of Option B+ policies in the Western Cape. We attempted to highlight focus areas that should be addressed to restore confidence in breastfeeding and promote better breastfeeding practices among both WLHIV and HIV-negative mothers for the ultimate benefit of mother-infant pairs.

Methods

We conducted a secondary analysis of data from two linked, prospective cohort studies conducted in parallel at the Gugulethu Midwife Obstetric Unit (MOU), a primary care centre in Cape Town, South Africa. Study participants comprised WLHIV who initiated universal ART in pregnancy, and their HIV-exposed, uninfected (HEU) infants from the "Maternal and Child Health Anti-Retroviral Therapy" (MCH-ART) study; and HIV-negative mothers and their HIV-unexposed, uninfected infants (HU) of the "HIV-Unexposed Uninfected" (HU2) mother and infant study. (26) While MCH-ART was conducted from 2013 to 2016, HU2 ran from 2014 to 2017; both studies used the same staff, measurement tools and were based at the same research site. (26) Both studies screened and enrolled women at their first antenatal visit, with follow-up through delivery to the first postnatal visit. (26) At the first postpartum study visit (within 7 days postpartum, window to 28 days for MCH-ART and 6 weeks for HU2), breastfeeding mother-infant pairs were screened and enrolled for further postnatal follow-up. (26)

Postnatal follow-up visits for breastfeeding mother-infant pairs were scheduled at 6 weeks and three, 6, 9 and 12 months postpartum. The current analysis focuses on the longitudinal breastfeeding practices of mother-infant pairs participating in the postnatal phase. As determinants of breastfeeding duration among HIV-infected children may be different to those for HIV-uninfected children of WLHIV, we excluded the breastfeeding data of infants who became HIV-infected from this analysis. Details of mother to child transmission in these cohorts have been published elsewhere. (27)

Measurement

Trained study field workers administered structured questionnaires at all study visits. These included infant feeding intentions and practices questionnaires, validated in previous Prevention of Mother to Child Transmission PMTCT studies. (3) Questionnaires were identical in both parent studies, except for HIV-related questions. Additionally, selected data on maternal demographic and health information, such as for e.g. pregnancy planning, as well as psychosocial and behavioural measures including depression (Edinburgh Postnatal Depression Scale, EPDS)(28), psychological distress (Kessler-10 scale)(29), intimate partner violence (WHO Violence against women questionnaire)(30) and alcohol use (Alcohol Use Disorders Identification Test-Consumption AUDIT-C)(31) were used in the analysis.

Study setting

Research was based at a research unit adjacent to the Gugulethu MOU on the premises of the Gugulethu Primary Healthcare Centre. The unit is certified as baby-friendly. (32) The facility is located in Gugulethu, a low income, peri urban township in the Klipfontein district of Cape Town, which provides services to a population of roughly 350 000 people, (33) with estimated 30% antenatal HIV seroprevalence (16). Since 2013, universal maternal antiretroviral therapy (ART without CD4 cell count restrictions) has been provided by the antenatal care section of the MOU to all pregnant or breastfeeding WLHIV.

Statistical methodology

Sample size calculations were based on primary outcomes for the parent studies, published elsewhere. (26,34). For the purposes of this secondary analysis and in accordance with international epidemiological recommendations, a post-hoc power calculation was not indicated. (35,36) Throughout, results are presented with 95% confidence intervals (CI) to demonstrate achieved precision. Data were analysed using Stata 14.0 (Statacorp, College Station, Texas USA); *p*-values are two-sided.

Breastfeeding practices were described using three WHO core indicators for breastfeeding. (2,3,10) These included 1) prevalence of early initiation of breastfeeding (EIBF, put to the breast within the first hour of life) (2,3,10); 2) prevalence of infants exclusively breastfed (EBF, feeding infants no other food or drink other than breastmilk, except for medicines, vitamins and minerals) for the first 6 months of life (2,3,10); and 3) prevalence of any breastfeeding at 12 months of age. (2,3,10) The primary outcomes for this analysis were duration of a) exclusive and b) any breastfeeding. We estimated duration of EBF and BF and timing of introduction of complementary food using both 24-hour recall at each visit and maternal report of feeding practices since the last visit. We allocated the EBF and BF date as the date of the last study visit at which the mother reported these; similarly, complementary food introduction was allocated as the first date the mother reported this. The exact date of breastfeeding cessation and complementary food introduction was not determinable. The primary comparison for this analysis was between WLHIV and HIV-negative women, using Cox proportional hazards regression analysis to generate crude (HR) and adjusted (aHR) hazard ratios. We further described age of introduction to complementary feeding, and maternal reports of lactation problems and reasons for cessation of breastfeeding, in exploratory

analysis. We assessed factors associated with breastfeeding practices among WLHIV and HIV-negative women separately, with a focus on the consequences of lactation problems.

Potential third variables were identified *a priori* using a directed acyclic graph based on the available literature regarding breastfeeding in the context of HIV (7) (Supplementary Figure1). Potential confounders of the maternal HIV status – breastfeeding relationships included socio-economic status, psychosocial- and behavioural factors (see footnotes, Table 1).

Ethical considerations

Both MCH-ART and HU2 were approved by the Human Research Ethics Committee of the University of Cape Town (UCT-HREC 451/2012; 567/2014). MCH-ART is registered at ClinicalTrials.gov (NCT01933477).

Results

Between 5 June 2013 and 5 April 2016, a total of 1087 mother-infant pairs were screened at the first postnatal study visit (MCH-ART, n=587; HU2, n=500), of whom 203 were excluded from further follow-up (study flow and reasons for exclusion in supplementary figure 2). Postnatal follow-up was concluded for all participants by 28 March 2017, excluding 12 infants who acquired HIV during follow-up. The combined cohort of 872 mothers and their HIV-negative infants [n=461 HIV-exposed uninfected children (HEU) from MCH-ART and n=411 HIV-unexposed children (HU) from HU2] contributed a total of 925 person-years of follow-up. The median (interquartile range, IQR) follow-up time was 12.1 (IQR 12.0: 17.7) months, with MCH-ART mother-infant pairs completing longer median follow-up time than HU2 (17.0 IQR 11.9; 18.0 vs 12.1 IQR 12.0; 12.3 months, p<0.0001).

Maternal and infant characteristics

Overall, 31% (270/872) of pregnancies were planned; fewer WLHIV had planned their pregnancy compared to HIV-negative women (28% [131/461] vs 34% [139/411], p=0.09) and most women were neither married nor cohabitating (57% [499/872]), with a median maternal age of 28 (IQR 24; 32) years. The latter two characteristics did not vary significantly by maternal HIV status (Table 1). WLHIV reported substantially worse socio-economic environments than HIV-negative women, with a lower proportion living in homes with all amenities, including running water, electricity and a toilet. (27 % [125/461] vs 40% 164/411], p<0.0001). WLHIV also had a lower prevalence of secondary education attainment compared to HIV-negative women (25% [114/461] vs 45% 184/411],

p<0.0001) and employment (39% [182/461] vs 47% [194/411], *p*=0.02). At postnatal enrolment visit, WLHIV (vs HIV-negative) reported a greater prevalence of psychosocial and behavioural difficulties including postnatal depression (10% [46/461] vs 7% [29/411], *p*=0.12), intimate partner violence (22% [101/461] vs 8% [32/411], *p*<0.0001) and risky drinking (25% [117/461] vs 7% [30/411], *p*<0.0001). The classification of psychosocial and behavioural difficulties is defined in the footnote of Table 1.

The median birthweight of infants born across both cohorts was 3180 (IQR 2820; 3460) grams. HEU infants were born with a slightly lower birthweight (vs HU infants) with a median of 3130 (IQR 2760; 3400) vs 3220 (IQR 2850; 3510) grams, *p*=0.01. The median gestation at birth was 39 (IQR 38; 40) weeks with 11% (94/872) of infants born prematurely (<37 weeks) and 13% (113/872) of infants being born small for their gestational age (SGA). These birth outcomes did not vary significantly by maternal HIV status (Table 1).

TABLE 1: Maternal and Infant Characteristics of HIV-exposed (HEU) and HIV-unexposed (HU), breastfed infants					
	Combined Cohort n= 872	**Women Living with HIV and their Infants (n=461, 53%)**	**HIV-Negative Mothers and their infants (n=411, 47%)**	***p*-value**	**Data missing**
Maternal Characteristics					
Maternal age (years)	28 (24; 32)	28 (24; 32)	28 (23; 32)	0.13	n=0
Completed secondary and or tertiary schooling[1]	298 (34%)	114 (25%)	184 (45%)	<0.0001	n=0
Employed[2]	376 (43%)	182 (39%)	194 (47%)	0.02	n=0
Married/cohabitating[3]	373 (43%)	189 (41%)	184 (45%)	0.26	n=0
Planned pregnancy[4]	270 (31%)	131 (28%)	139 (34%)	0.09	n=0
Normal vaginal delivery[5]	578 (67%)	323 (70%)	255 (62%)	0.01	n=0
Breast infection/problems at 7 days and or 6 weeks[6]	143 (16%)	92 (20%)	51 (12%)	0.0003	n=0
Lives in formal housing with a toilet, running water and electricity[7]	289 (33%)	125 (27%)	164 (40%)	<0.0001	n=0
Postnatal depression[8]	75 (9%)	46 (10%)	29 (7%)	0.12	n=0
Intimate partner violence[9]	133 (15%)	101 (22%)	32 (8%)	<0.0001	n=0
Risky drinking behaviour[10]	147 (17%)	117 (25%)	30 (7%)	<0.0001	n=2
Psychological distress[11]	228 (26%)	27 (6%)	201 (49%)	<0.0001	n=2
Diagnosed HIV-positive during this pregnancy[12]	-	262 (57%)	-	-	n=0
Log10 HIV viral load at ART initiation	-	3.97 (3.35; 4.54)	-	-	n=0

TABLE 1: Maternal and Infant Characteristics of HIV-exposed (HEU) and HIV-unexposed (HU), breastfed infants					
	Combined Cohort n= 872	**Women Living with HIV and their Infants (n=461, 53%)**	**HIV-Negative Mothers and their infants (n=411, 47%)**	***p*-value**	**Data missing**
CD4 count at ART initiation (cells/uL)	-	354 (249; 527)	-	-	n=12
Viral suppression at delivery[13]	-	352 (76%)	-	-	n=0
Infant and Delivery Characteristics					
Male sex[14]	424 (49%)	228 (50%)	196 (48%)	0.17	n=3
Gestational age at birth (weeks)	39 (38; 40)	39 (38; 40)	39 (38; 40)	0.42	n=0
Birth weight (grams)	3180 (2820; 3460)	3130 (2760; 3400)	3220 (2850; 3510)	0.01	n=0
SGA[15]	113 (13%)	67 (15%)	46 (11%)	0.15	n=3
APGAR <7 @ 5 minutes[16]	7 (1%)	5 (1%)	2 (1%)	0.32	n=0
Prematurity[17]	94 (11%)	56 (12%)	38(9%)	0.17	n=0
Place of birth					
Primary care	344 (39%)	181 (39%)	163 (40%)		
Hospital care	514 (59)	167 (58%)	247 (60%)	0.01	n=0
BBA[18]	14 (2%)	13 (3%)	1 (1%)		
Duration of hospital stay after birth (days)	0 (0; 3)	0 (0; 2)	0 (0; 3)	0.04	n=0
Trimester of entry into antenatal care					
First (≤12 weeks)	112 (13%)	49 (11%)	63 (15%)		
Second (>12, <28 weeks)	566 (65%)	308 (67%)	258 (63%)	0.12	n=0
Third (≥28 weeks)	194 (22%)	104 (23%)	90 (22%)		

†Results are n (column %) with bivariate comparisons obtaining p-values from the chi-squared test. Median with interquartile range (IQR) with p-value from Wilcoxon rank sum test for 2 sample comparisons and Kruskal Wallis test for >2 sample comparisons for non-normally distributed variables.

[1]As compared to having attained less than secondary education.
[2]As compared to unemployed
[3]As compared to not married / cohabitating
[4]As compared to current pregnancy was not planned
[5]As compared to a caesarean section
[6]As compared to not having had breast infections/ problems at 7 days and 6 weeks
[7]As compared to not living in formal housing with a toilet, running water and electricity
[8] Postnatal depression is defined as Edinburgh Postnatal Depression Scale (EPDS) score ≥13, at enrolment visit. As compared to having an EPDS score of <13, at enrolment visit.(28)
[9] Intimate partner violence defined as physical, sexual or psychological violence as per World Health Organization violence against women questionnaire, at enrolment visit. As compared to not having experienced intimate partner violence, at enrolment visit.(30)
[10] Risky drinking behaviour is defined as Alcohol use disorders identification test (AUDIT-C) score ≥3, at enrolment visit. As compared to having an AUDIT-C score of <3, at enrolment visit.(31)
[11] Psychological distress is defined as Kessler Psychological Distress Scale (K10) score ≥21.5, at enrolment visit. As compared to having a K10 score of <21.5, at enrolment visit. (29)
[12]Timing of diagnosis during this pregnancy as compared to during a previous pregnancy.
[13]Viral suppression defined as a viral load of <50 copies per millilitre (copies/mL)
[14]Male sex, as compared to female sex.
[15] SGA refers to Small for Gestational Age defined as weight below the 10th percentile for gestational age.
[16]As compared to having an APGAR score of ≥ 7 at 5 minutes.
[17]Prematurity refers to Gestational Age of less than 37 weeks. As compared to term delivery.
[18] BBA refers to Born before arrival, defined as infants born at home or on route to a delivery centre, without the presence of a skilled birth attendant.

Summary of infant feeding practices overall and by maternal HIV status

Breastfeeding practices differed by maternal HIV status (Table 2). While an overall 91% (788/867) of infants received EIBF, this was only 87% (400/459) among HEU vs 95% (388/408) among HU infants (p<0.0001). Overall, 34% (156/461) of infants were exclusively breastfed through age 6 months, with significantly higher proportions among HEU (54%, 120/221) than HU infants (15%, 36/240), p<0.0001. Furthermore, while a total of 44% (317/719) of infants were breastfed at 12 months of age, only 39% (142/366) of HEU infants were still being breastfed, while half (50%, 175/353) of the HU infants were still breastfed (p=0.01).

The duration of any breastfeeding across both cohorts was a median of 6.0 months (IQR 1.5; 12), with HEU infants breastfed for shorter compared to HU infants, with a median of 3.9 months (IQR 1.4; 12.0) vs 9.0 months (IQR 3.0; 12.05) (p<0.0001). Among infants who were ever exclusively breastfed, HEU infants were exclusively breastfed for markedly longer with a median duration of 1.5 months (IQR 0.3; 5.3), as compared to HU infants with a median of 1.4 months (IQR 0.2; 3.0), p=0.01. The median duration of exclusive breastfeeding among both cohorts was 1.4 (IQR 0.1; 3.0) months.

Overall, 62% (448/722) of infants were introduced to complementary feeding at the WHO recommended age of 6 months; this was no different between HEU and HU infants. However, while substantially fewer HEU compared to HU infants were introduced to complementary foods at younger than 4 months (6% [22/376] vs 14% [48/346], p<0.0001) and between 4 and 6 months (7% [27/376] vs 17% [60/346], p<0.0001), more HEU vs HU infants were introduced to complementary foods later than the recommended 6 months of age (25% [93/376] vs 7% [24/346], p<0.0001).

TABLE 2: Infant feeding including breastfeeding outcomes, stratified by maternal HIV status				
	Combined Cohort n= 872	Women Living with HIV and their Infants (n=461, 53%)	HIV-Negative Mothers and their infants (n=411, 47%)	p-value
Early initiation of breastfeeding	788/867 (91%)	400/459 (87%)	388/408 (95%)	<0.0001
Ever Exclusively breastfed	754/872 (86%)	421/461 (91%)	333/411 (81%)	<0.0001
Exclusively breastfed at				
7 days	753/118 (86%)	420/460 (91%)	333/411 (81%)	<0.0001
6 weeks	494/740 (67%)	295/373 (79%)	199/367(54%)	<0.0001
3 months	353/577 (61%)	205/255 (80%)	148/322 (46%)	<0.0001
6 months	156/461 (34%)	120/221 (54%)	36/240 (15%)	<0.0001
Breastfed at				
7 days	872/872 (100%)	461/461 (100%)	411/411 (100%)	-
6 weeks	740/822 (90%)	373/434 (86%)	367/388 (95%)	<0.0001
3 months	577/734 (79%)	255/366 (70%)	322/368 (88%)	<0.0001
6 months	461/747 (62%)	221/401 (55%)	240/346 (69%)	<0.0001
9 months	382/712 (54%)	174/382 (46%)	208/330 (63%)	<0.0001
12 months	317/719 (44%)	142/366 (39%)	175/353 (50%)	0.01
Duration of any breastfeeding *(months)*	6.0 (1.5; 12.0)	3.9 (1.4; 12.0)	9.0 (3.0; 12.05)	<0.0001
Duration of Exclusive breastfeeding *(months)*	1.4 (0.2; 3.1)	1.5 (0.3; 5.3)	1.4 (0.2; 3.0)	0.01
Age of introduction to complementary food[1]				
<4 months	70/722 (10%)	22/376 (6%)	48/346 (14%)	
≥4, <6 months	87/722 (12%)	27/376 (7%)	60/346 (17%)	<0.0001
6 months	448/722 (62%)	234/376 (62%)	214/346 (62%)	
>6 months	117/722 (16%)	93/376 (25%)	24/346 (7%)	

†Results are n (column %) with bivariate comparisons obtaining p-values from the chi-squared test. Median with interquartile range (IQR) with p-value from Wilcoxon rank sum test for 2 sample comparisons and Kruskal Wallis test for >2 sample comparisons for non-normally distributed variables.

[1] Complementary food defined as semi-solid or solid foods, added to a milk-based diet, reported at the 12month visit.

Summary of lactation problems

WLHIV compared with HIV-negative women were substantially more likely to report having experienced breast infections or problems in the first 6 weeks postpartum, with 20% (92/461) of WLHIV and only 12% (51/411) of HIV-negative women having reported breast related issues (p=0.003) (Table 1). The most common complaints across cohorts were cracked nipples and breast engorgement (Figure 1A and 1B). A breakdown of reported breast and lactation problems in the first 6 weeks postpartum is included as Supplementary Table 1.

Figure 1A: Specific lactation issues reported by women living with HIV and HIV-negative women, approximately 7 days postpartum

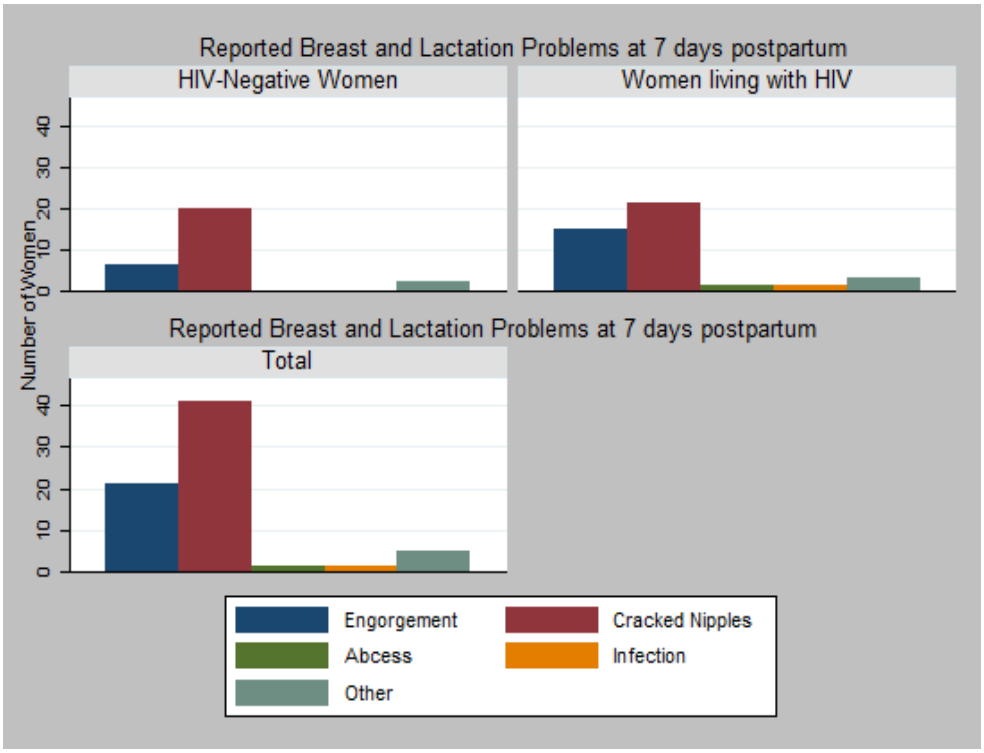

Figure 1A:
HIV-Negative Women: Engorgement 1% (6/411); Cracked Nipples 5% (20/411); Other 0.5% (2/411)
Women living with HIV: Engorgement 3% (15/461); Cracked Nipples 5% (21/461); Abscess 0.2% (1/461); Infection 0.2% (1/461); Other 1% (3/461)
Total Cohort: Engorgement 2% (21/872); Cracked Nipples 5% (41/872); Abscess 0.1% (1/872); Infection 0.1% (1/872); Other 1% (5/872)
[‡]Other lactation problems women indicated included itchiness, painful nipples, pain when breastfeeding and painful breasts

Figure 1B: Specific lactation issues reported by women living with HIV and HIV-negative women, approximately 6 weeks postpartum

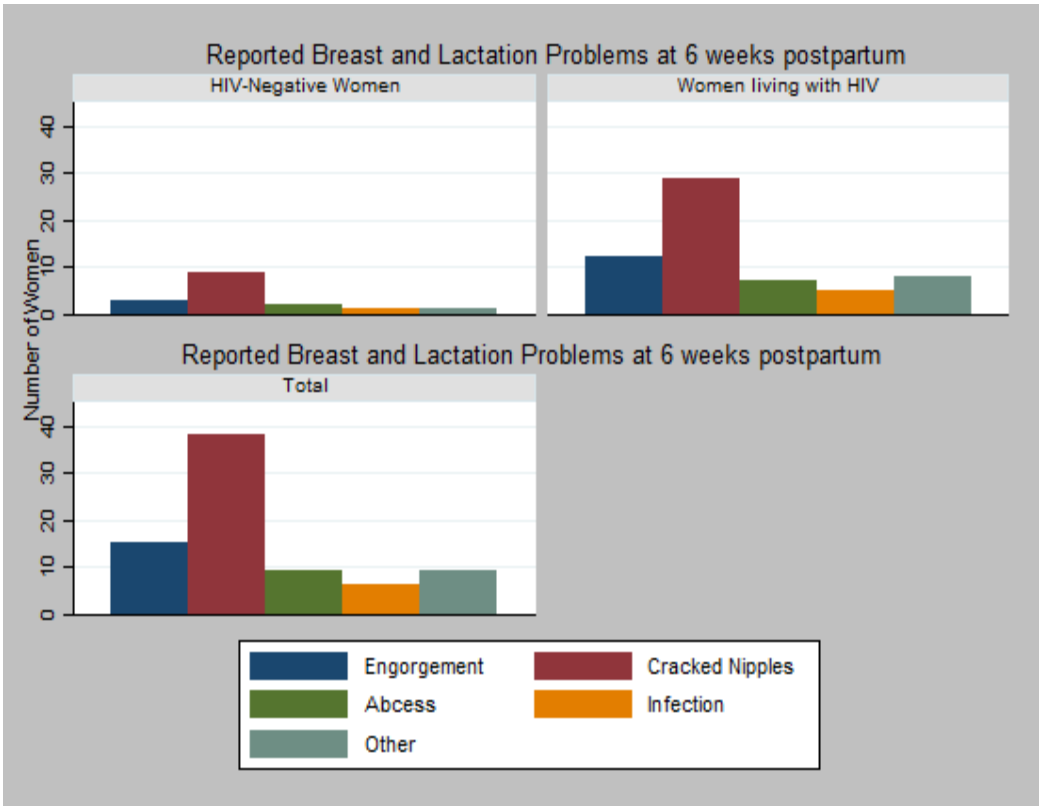

Figure 1B:
HIV-Negative Women: Engorgement 1% (3/411); Cracked Nipples 2% (9/411); Abscess 0.5% (2/411); Infection 0.2% (1/411) Other 0.2% (1/411)
Women living with HIV: Engorgement 3% (12/461); Cracked Nipples 6% (29/461); Abscess 2% (7/461); Infection 1% (5/461); Other 2% (8/461)
Total Cohort: Engorgement 2% (15/872); Cracked Nipples 4% (38/872); Abscess 1% (9/872); Infection 1% (6/872); Other 1% (9/872)
[§]Other lactation problems women indicated included bleeding nipples, empty breasts or not enough breastmilk.

Reasons for breastfeeding cessation

Across the cohort, 13% (111/824) women reported breastfeeding cessation at the second postpartum visit at 6 weeks. (Supplementary Table 2). The main reasons for breastfeeding cessation at this visit were lactation problems (20%, 22/111), followed by perceived insufficient breastmilk supply (16%, 18/111) and work-related commitments (11%, 12/111). Notably, while 27% (22/78) of WLHIV indicated lactation problems to be the reason for BF cessation at the 6-week postpartum visit, 0% (0/33) of HIV-negative women reported this to be the reason for BF cessation at this visit.

Overall, most women reported breastfeeding cessation since the last visit at the infants' three- (18%, 135/737) and six-month visit (18%, 134/749). From the three-months' through to the 12-months' visit, work related commitments were the main reason women indicated for breastfeeding cessation (24%, 131/552).

Relative hazard of EBF cessation comparing WLHIV to HIV-negative women

In the overall cohort, maternal HIV-status (positive vs negative) was significantly associated with a reduced relative hazard of EBF cessation (HR 0.78, 95% CI 0.67 – 0.90; Table 3a). Potential confounders of the maternal HIV status-EBF cessation relationship such as higher maternal age and low birth weight (birthweight <2500g) were significantly associated with a reduced relative hazard of EBF cessation. Conversely, any lactation problems in the first 6 weeks postpartum (defined as reported at either of 7 days' or 6 weeks' study visit) and maternal psychological distress were significantly associated with increased relative hazard of EBF cessation across cohorts (Table 3a). After adjusting for employment, maternal age and confounders such as living in housing with all amenities, as well as risky drinking behaviour,

maternal HIV status was persistently associated with a reduced hazard of EBF cessation (aHR: 0.76 CI: 0.65 – 0.89).

Relative hazard of all BF cessation comparing WLHIV to HIV-negative women

In the overall cohort, maternal HIV-status was associated with an increased relative hazard of all BF cessation (HR 1.87 CI 1.56 – 2.24, Table 3b). In addition, lactation problems in the first 6 weeks postpartum, employment and risky drinking behaviour were significantly associated with increased relative hazard of all BF cessation across cohorts. Low birth weight, EIBF and late entry into antenatal care (defined as entering antenatal care after 28 weeks' gestation), were associated with a markedly reduced relative hazard of BF cessation (Table 3b). After adjusting for employment, maternal age and potential confounders including living in a house with all amenities, as well as risky drinking behaviour, maternal HIV-status was persistently associated with an increased hazard of BF cessation (aHR: 1.85 CI:1.53 – 2.24). Therefore, while the time to EBF cessation was longer in WLHIV, time to all BF cessation was longer in HIV-negative women (Supplementary Figure 3A and 3B).

TABLE 3. Factors associated with cessation of (a) exclusive breastfeeding or (b) all breastfeeding among women living with HIV compared to HIV-negative women: crude and adjusted hazard ratios from Cox proportional hazards regression

	(a) Relative hazard for cessation of exclusive breastfeeding‡				(b) Relative hazard for cessation of any breastfeeding			
	Crude Hazard Ratio (95% Confidence Interval)	p-value	Adjusted Hazard Ratio (95% Confidence Interval)	p-value	Crude Hazard Ratio (95% Confidence Interval)	p-value	Adjusted Hazard Ratio (95% Confidence Interval)	p-value
Maternal characteristics								
HIV-Positive[1]	0.78 (0.67 – 0.90)	0.001	0.76 (0.65 – 0.89)	0.001	1.87 (1.56 – 2.24)	<0.0001	1.85 (1.53 – 2.24)	<0.0001
Breast infection/problems at 7 days and or 6 weeks[2]	1.46 (1.17 – 1.81)	0.001	-	-	1.98 (1.56 – 2.51)	<0.0001	-	-
Employed[3]	1.11 (0.96 – 1.29)	0.16	1.10 (0.95 – 1.23)	0.20	1.28 (1.07 – 1.53)	0.01	1.40 (1.17 – 1.67)	<0.0001
Maternal age (years)	0.99 (0.97 – 1.00)	0.01	0.99 (0.97 – 0.99)	0.02	0.99 (0.98 – 1.01)	0.98	0.99 (0.98 – 1.00)	0.27
Completed secondary and or tertiary schooling[4]	1.05 (0.91 – 1.23)	0.49	-	-	0.97 (0.80 – 1.16)	0.71	-	-
Lives in formal housing with a toilet, running water and electricity[5]	1.11 (0.95 – 1.29)	0.18	1.07 (0.91– 1.25)	0.42	0.94 (0.78 – 1.14)	0.54	0.99 (0.82 – 1.20)	0.92
Postnatal depression[6]	1.27 (1.00 – 1.62)	0.05	-	-	0.92 (0.65 – 1.30)	0.65	-	-
Intimate partner violence[7]	0.97 (0.79 – 1.19)	0.78	-	-	1.22 (0.96 – 1.54)	0.11	-	--
Risky drinking behaviour[8]	1.08 (0.90 – 1.30)	0.40	1.20 (0.91 – 1.25)	0.07	1.58 (1.28 – 1.96)	<0.0001	1.35 (1.09 – 1.69)	0.01
Psychological distress[9]	1.31 (1.11 – 1.54)	0.001	-	-	0.83 (0.68 – 1.03)	0.09	-	
Infant and Delivery Characteristics								
Gestational age at birth								

TABLE 3. Factors associated with cessation of (a) exclusive breastfeeding or (b) all breastfeeding among women living with HIV compared to HIV-negative women: crude and adjusted hazard ratios from Cox proportional hazards regression

	(a) Relative hazard for cessation of exclusive breastfeeding‡				(b) Relative hazard for cessation of any breastfeeding			
	Crude Hazard Ratio (95% Confidence Interval)	p-value	Adjusted Hazard Ratio (95% Confidence Interval)	p-value	Crude Hazard Ratio (95% Confidence Interval)	p-value	Adjusted Hazard Ratio (95% Confidence Interval)	p-value
≥37 Weeks	1.00	(Ref)	-	-	1.00	(Ref)	-	-
≥34 Weeks, <37 Weeks	0.81 (0.63 – 1.04)	0.10	-	-	1.04 (0.76 – 1.41)	0.81	-	-
<34 Weeks	0.91 (0.67 – 1.23)	0.53			1.22 (0.81 – 1.83)	0.35		
Birth weight (grams)								
≥ 2500	1.00	(Ref)	-	-	1.00	(Ref)	-	-
<2500	0.80 (0.66 – 0.97)	0.02	-	-	1.08 (0.84 – 1.40)	0.53	-	-
Birth weight (kilograms)	1.12 (1.00 – 1.26)	0.05	-	-	0.86 (0.74 – 0.99)	0.04		
SGA[10]	0.88 (0.73 – 1.06)	0.19	-	-	1.08 (0.84 – 1.40)	0.53	-	-
APGAR <7 @5min[11]	1.32 (0.66 – 2.60)	0.43	-	-	1.23 (0.48 – 2.65)	0.78	-	-
Put to breast within 1 hour of birth[12]	1.04 (0.82 – 1.32)	0.74	-	-	0.67 (0.52 – 0.87)	0.01	-	-
Place of birth								
Primary Care	1.00	(Ref)	-	-	1.00	(Ref)	-	-
Hospital care	1.03 (0.88 – 1.19)	0.73	-	-	0.93 (0.77 – 1.12)	0.43	-	-
BBA[13]	0.88 (0.57 – 1.35)	0.57	-	-	1.00 (0.56 – 1.81)	0.99	-	-
Entry into antenatal care								
Early (<28 Weeks)	1.00	(Ref)	-	-	1.00	(Ref)	-	-
Late (≥28 Weeks)	0.99 (0.84 – 1.18)	0.93	-	-	0.77 (0.62 – 0.97)	0.03	-	-

TABLE 3. Factors associated with cessation of (a) exclusive breastfeeding or (b) all breastfeeding among women living with HIV compared to HIV-negative women: crude and adjusted hazard ratios from Cox proportional hazards regression

	(a) Relative hazard for cessation of exclusive breastfeeding‡				(b) Relative hazard for cessation of any breastfeeding			
	Crude Hazard Ratio (95% Confidence Interval)	p-value	Adjusted Hazard Ratio (95% Confidence Interval)	p-value	Crude Hazard Ratio (95% Confidence Interval)	p-value	Adjusted Hazard Ratio (95% Confidence Interval)	p-value
Male Sex[14]	0.89 (0.77 – 1.03)	0.12	-	-	0.93 (0.78 – 1.11)	0.42	-	-

†Analysis based on a) 754 observations; 1726.02 months total analysis time and b) 870 observations; 6132.60 months total analysis time

‡Exclusive Breastfeeding analysis was restricted to infants who were ever breastfed.

[1] Reference category: HIV-negative

[2] Reference category: not having had breast infections/ problems at 7 days and 6 weeks

[3] Reference category: being unemployed

[4] Reference category: having attained less than secondary education

[5] Reference category: not living in formal housing with a toilet, running water and electricity

[6] Postnatal depression is defined as Edinburgh Postnatal Depression Scale (EPDS) score ≥13, at enrolment visit. (28)
Reference category: having an EPDS score of <13, at enrolment visit

[7] Intimate partner violence defined as physical, sexual or psychological violence as per World Health Organization violence against women questionnaire, at enrolment visit.
Reference category: not having experienced intimate partner violence, at enrolment visit.(30)

[8] Risky drinking behaviour is defined as Alcohol use disorders identification test (AUDIT-C) score ≥3, at enrolment visit. (31)
Reference category: having an AUDIT-C score of <3, at enrolment visit

[9] Psychological distress is defined as Kessler Psychological Distress Scale (K10) score ≥21.5, at enrolment visit.(29)
Reference category: having a K10 score of <21.5, at enrolment visit

[10] SGA refers to Small for Gestational Age defined as weight below the 10th percentile for gestational age.
Reference category: Weight above the 10th percentile for gestational age

[11] Reference category: APGAR ≥ 7 @ 5 minutes

[12] Reference category: Not having been put to the breast within 1 hour after birth

[13] BBA refers to Born before arrival, defined as infants born at home or on route to a delivery centre, without the presence of a skilled birth attendant

[14] Reference category: female sex

Predictors of EBF and all BF cessation among WLHIV

In analysis restricted to WLHIV (Table 4), lactation problems were associated with an increased relative hazard of both EBF and BF cessation ([HR 1.48 CI 1.13 – 1.96] and [HR 2.31 CI 1.73 – 3.08]). While older maternal age was associated with a decreased relative hazard of EBF cessation, postnatal depression and psychological distress were associated with an increased relative hazard of EBF cessation. After adjusting for maternal age, postnatal depression, EIBF and low APGAR scores at birth, lactation problems remained significantly associated with EBF cessation in WLHIV (aHR: 1.54 CI: 1.16 – 2.03).

Older maternal age and late entry into antenatal care (≥28 Weeks) were associated with a reduced relative hazard of BF cessation among WLHIV, while employment and risky drinking behaviour were associated with an increased relative hazard of BF cessation. After adjusting for maternal age, employment, postnatal depression and EIBF, lactation problems persisted to be associated with increased risk of BF cessation (aHR: 2.45 CI: 1.85 – 3.24). The adjusted hazard for employment (Table 4) indicated a 41% increased hazard of BF cessation among mothers who were employed compared to those unemployed after considering lactation problems and other potential confounders (aHR: 1.41 CI: 1.11 – 1.78).

Predictors of EBF and all BF cessation among HIV-negative women

In analyses restricted to HIV-negative women (Supplementary Table 3), lactation problems remained predictive of EBF cessation (aHR: 1.62 CI: 1.15 – 2.27) but the association with any BF was attenuated among HIV-negative women (aHR: 1.44 CI: 0.91 – 2.27). The most marked predictors of all BF cessation were employment (HR: 1.35 CI: 1.01 – 1.79), psychological

distress, (HR 1.37 CI 1.03 – 1.83) and low birth weight (HR 0.72 CI 0.57 – 0.92). Results were similar after adjusting for potential confounders (Supplementary Table 3b).

TABLE 4. Factors associated with cessation of (a) exclusive and (b) all breastfeeding among women living with HIV: crude and adjusted hazard ratios from Cox proportional hazards regression analysis

	(a) Relative hazard for cessation of exclusive breastfeeding‡				(b) Relative hazard for cessation of any breastfeeding			
	Crude Hazard Ratio (95% Confidence Interval)	p-value	Adjusted Hazard Ratio (95% Confidence Interval)	p-value	Crude Hazard Ratio (95% Confidence Interval)	p-value	Adjusted Hazard Ratio (95% Confidence Interval)	p-value
Maternal characteristics								
Breast infection/problems at 7 days and or 6 weeks[1]	1.48 (1.13 – 1.96)	0.05	1.54 (1.16 – 2.03)	0.01	2.31 (1.73 – 3.08)	<0.0001	2.45 (1.85 – 3.24)	<0.0001
Employed[2]	1.05 (0.86 – 1.28)	0.64	-	-	1.36 (1.08 – 1.71)	0.01	1.41 (1.11 – 1.78)	0.01
Maternal age (years)	0.98 (0.97 – 1.00)	0.02	0.98 (0.97 – 1.00)	0.03	0.98 (0.97 – 0.99)	0.01	0.99 (0.97 – 1.01)	0.51
Completed secondary and or tertiary schooling[3]	0.93 (0.74 – 1.18)	0.57	-	-	1.10 (0.85 – 1.42)	0.46	-	-
Lives in formal housing with a toilet, running water and electricity[4]	1.08 (0.87 – 1.34)	0.48	-	-	0.97 (0.75 – 1.25)	0.81	-	-
Postnatal depression[5]	1.40 (1.01 – 1.92)	0.04	1.46 (1.11 – 1.93)	0.01	0.97 (0.64 – 1.46)	0.87	0.93 (0.59 – 1.46)	0.75
Intimate partner violence[6]	1.01 (0.79 – 1.27)	0.97	-	-	0.94 (0.71 – 1.24)	0.64	-	-
Risky drinking behaviour[7]	1.15 (0.94 – 1.42)	0.18	-	-	1.30 (1.02 – 1.68)	0.04	-	-
Psychological distress[8]	1.30 (1.02 – 1.67)	0.04	-	-	0.92 (0.55 – 1.51)	0.73	-	-
Infant and Delivery Characteristics							-	-
Gestational age at birth **≥37 Weeks**	1.00	(Ref)	-	-	1.00	(Ref)	-	-

TABLE 4. Factors associated with cessation of (a) exclusive and (b) all breastfeeding among women living with HIV: crude and adjusted hazard ratios from Cox proportional hazards regression analysis

	(a) Relative hazard for cessation of exclusive breastfeeding‡				(b) Relative hazard for cessation of any breastfeeding			
	Crude Hazard Ratio (95% Confidence Interval)	p-value	Adjusted Hazard Ratio (95% Confidence Interval)	p-value	Crude Hazard Ratio (95% Confidence Interval)	p-value	Adjusted Hazard Ratio (95% Confidence Interval)	p-value
≥34 Weeks, <37 Weeks	0.97 (0.71 – 1.33)	0.85	-	-	0.95 (0.63 – 1.43)	0.80	-	-
<34 Weeks	0.98 (0.74 – 1.29)	0.88	-	-	0.88 (0.53 – 1.46)	0.62	-	-
Birth weight (grams)								
≥ 2500	1.00	(Ref)	-	-	1.00	(Ref)	-	-
<2500	0.89 (0.73 – 1.10)	0.30	-	-	0.89 (0.65 – 1.22)	0.47	-	-
Birth weight (kilograms)	1.01 (0.87 – 1.17)	0.95	-	-	1.10 (0.89 – 1.34)	0.37	-	-
SGA[9]	0.95 (0.75 – 1.21)	0.70	-	-	0.93 (0.67 – 1.29)	0.67	-	-
APGAR <7 @5min[10]	1.30 (0.56 – 3.00)	0.55	0.83 (0.32 – 2.14)	0.70	1.36 (0.76 – 2.44)	0.30	-	-
Put to breast within 1 hour of birth[11]	0.95 (0.74 – 1.22)	0.70	0.96 (0.73 – 1.26)	0.76	0.71 (0.54– 0.95)	0.02	0.70 (0.52 – 0.94)	0.02
Place of birth								
Primary Care	1.00	(Ref)	-	-	1.00	(Ref)	-	-
Hospital care	1.08 (0.88 – 1.32)	0.45	-	-	0.95 (0.76 – 1.21)	0.71	-	-
BBA[12]	1.18 (0.76 – 1.82)	0.47	-	-	0.89 (0.50 – 1.57)	0.68	-	-
Entry into antenatal care								
Early (<28 Weeks)	1.00	(Ref)	-	-	1.00	(Ref)	-	-
Late (≥28 Weeks)	0.99 (0.80 – 1.23)	0.96	-	-	0.73 (0.55 – 0.97)	0.03	-	-
Male Sex[13]	0.89 (0.73 – 1.08)	0.23	-	-	0.82 (0.65 – 1.02)	0.08	-	-

†Analysis based on a) 421 observations; 1090.26 months total analysis time and b) 461 observations; 2987.99 months total analysis time

ǂExclusive Breastfeeding analysis was restricted to infants who were ever breastfed.

[1] Reference category: having attained less than secondary education

[2] Reference category: not having had breast infections/ problems at 7 days and 6 weeks

[3] Reference category: being unemployed

[4] Reference category: not living in formal housing with a toilet, running water and electricity

[5] Postnatal depression is defined as Edinburgh Postnatal Depression Scale (EPDS) score ≥13, at enrolment visit. (28)
Reference category: having an EPDS score of <13, at enrolment visit

[6] Intimate partner violence defined as physical, sexual or psychological violence as per World Health Organization violence against women questionnaire, at enrolment visit.
Reference category: not having experienced intimate partner violence, at enrolment visit.(30)

[7] Risky drinking behaviour is defined as Alcohol use disorders identification test (AUDIT-C) score ≥3, at enrolment visit. (31)
Reference category: having an AUDIT-C score of <3, at enrolment visit

[8] Psychological distress is defined as Kessler Psychological Distress Scale (K10) score ≥21.5, at enrolment visit.(29)
Reference category: having a K10 score of <21.5, at enrolment visit

[9] SGA refers to Small for Gestational Age defined as weight below the 10th percentile for gestational age.
Reference category: Weight above the 10th percentile for gestational age

[10] Reference category: APGAR ≥ 7 @ 5 minutes

[11] Reference category: Not having been put to the breast within 1 hour after birth

[12] BBA refers to Born before arrival, defined as infants born at home or on route to a delivery centre, without the presence of a skilled birth attendant

[13] Reference category: female sex

Discussion

In this observational cohort study, we observed suboptimal breastfeeding practices among WLHIV and HIV-negative mothers, despite pro-breastfeeding policy changes and universal ART use among the former. Our study findings are similar to those of another study which reported suboptimal breastfeeding practices between 2012 and 2013 in the Western Cape, during the transition period from exclusive formula feeding to exclusive breastfeeding policies in the context of HIV and prior to the widespread availability of universal ART. (24) That is, our data suggests that guideline changes alone did not translate into improved breastfeeding practices.

We found that while EIBF, was less common in HEU infants, considerably more HEU compared to HU infants were exclusively breastfed for 6 months. However, the duration of any breastfeeding was shorter in HEU- compared to HU infants. Results regarding EBF from other South African studies show quite the opposite, in that EBF rates were lower among WLHIV at 14 weeks postpartum (37) and at all times up until 6 months postpartum. (38) These differences may be explained by the fact that the first study was conducted in a rural setting, prior to the pro-breastfeeding policy change, while the latter study, though conducted in an urban setting, post the policy change, had a small sample size.

We found that maternal HIV status was a substantial threat to optimal BF duration. A study conducted in northwest Ethiopia found similar results in that the duration of all BF was shorter by 3.4 times in WLHIV compared to HIV-negative mothers. (39) We found psychosocial-behavioural adversities to be particularly common among WLHIV, with postnatal depression associated with early EBF cessation among WLHIV. These findings are corroborated by a Nigerian study (40), and highlight the importance of psychosocial-behavioural problem

screening and referral structures to be put in place in the antenatal care setting, particularly for WLHIV.

Despite all study participants attending antenatal care at a "Baby-Friendly" hospital, lactation problems were commonly reported in our study, and strongly predictive of both EBF and BF cessation. Lactation problems, usually indicative of incorrect positioning and latching (41) are known to predict suboptimal breastfeeding (18,42) and are largely preventable through adequate breastfeeding support. (41) In the context of maternal HIV, concerns should extend to increased risks of vertical HIV transmission, especially related to bleeding and inflammation. (43) Clearly, pro-breastfeeding guideline changes are inadequate without also improving breastfeeding support for WLHIV. In order to both prevent mother-to-child transmission (MTCT) and optimize HEU child health, an urgent upscaling of the BF support services is imperative in our context. Studies in South Africa and Kenya have reported the key roles health care workers (HCW) play in providing breastfeeding support (44–46), while simultaneously highlighting issues around the training of and advice given by HCW. (44–49) This highlights the need for building HCW knowledge and competency in providing feeding advice and support. However, it is increasingly evident that BF support by HCW is inadequate, and broader-based community outreach projects have shown great promise in providing the additional support women require in the vulnerable first few weeks after delivery. (50–52)

An additional threat to optimal BF duration that emerged in our analysis is maternal employment, an issue evident for both WLHIV and HIV-negative women. This finding aligns with data from Nigeria, Kenya, rural KwaZulu-Natal and urban Botswana, where employment was observed to be associated with suboptimal EBF, regardless of HIV status (39,40) and strongly associated with early weaning (37), particularly among WLHIV. (53) Reasons for this

are likely complex and combine issues such as informal employment, no job protection, lack or duration of maternity leave and being the main breadwinner of a household. (54) This highlights the need for workplace and structural interventions around issues such as paid maternity leave, job protection and availability of lactation rooms to enable mothers to continue breastfeeding while retaining their employment. It also highlights the role that HCW could play in providing tailor-made lactation advice for working mothers. More interventions should focus on supporting mothers who return to work. (55)

Our data demonstrate that despite advances in policies towards promoting breastfeeding, real-life and "on the ground" implementation remains suboptimal. Mothers are faced with a multitude of challenges, including difficulties with lactation, socio-behavioural struggles and the need to return to work, all of which affect BF practices negatively. (13)

Since both lactation problems as well as employment remained strong predictors of EBF and BF cessation in this analysis, it is crucial that interventions address these, to improve EIBF, EBF and BF for reduced child morbidity and mortality. (7) Health systems need to ensure regular contact with postpartum women and HCW – extending to community supporters - should be skilled to provide tailor-made breastfeeding advice, lactation support (48), and screening for psychosocial behavioural issues, within the context of appropriate referral structures.

HCW based interventions that have shown promise include regular hospital based follow-ups and breastfeeding support as seen in northern Ethiopia, demonstrating improvements in breastfeeding practices from the first week to six months post-partum. (56)

Another low-cost intervention that could be considered, would be the training of peer counsellors. Despite South African sites reporting mixed results for promoting EBF among

WLHIV, (50,51) this intervention has improved EBF duration and initiation in low and middle income countries. (50)

Interventions combining community and interpersonal communication activities at scale, similar to the Alive and Thrive initiative in rural, low-income Burkina Faso (52) may have the potential to improve breastfeeding outcomes and increase breastfeeding related knowledge. (52) However, the financial implications of such interventions may limit their implementation. (55)

The findings of this study should be interpreted in the light of several study limitations and strengths. This study is an observational study, thereby at risk for bias and confounding. Although we attempted to address these in both the study design and analysis, some issues to internal validity may have persisted, including recall bias. Our wide and intensive measures of maternal psycho-social wellbeing provide unique insight into early postpartum breastfeeding obstacles, but data are lacking on the precise details of HCW lactation support and the exact dates of EBF and BF cessation. Our findings might not be generalizable to other peri-urban settings in South Africa, nor to rural areas where breastfeeding practices may differ substantially. Nonetheless, we provide robust data that illustrate a convincing picture of ongoing suboptimal breastfeeding practices that require urgent attention in our setting.

Future research should focus on a combination of interventions that best support breastfeeding mothers. These should include, but not be limited to, upskilling HCW to provide regular and up to date breastfeeding support, as well as work-place interventions on various levels, from the individual company to policy level, to give the structural support needed by mothers to successfully breastfeed.

Conclusion

We found the matter of suboptimal breastfeeding practices in the South African context to be complex and multifaceted, even more so in the light of HIV. Since policies supportive of breastfeeding have been implemented in South Africa, it is crucial that HCW who provide feeding support and counselling receive the necessary training and knowledge to provide pro-breastfeeding advice and intensified, hands-on lactation support. Furthermore, referral channels for psychosocial and behavioural adversities should be in place and HCW should be familiar with these, especially in the context of WLHIV. It is important to strengthen continuity of care for mother-infant pairs throughout pregnancy and postnatal journey. This will help to address any feeding related issues early. Additionally, workplace interventions need to be put in place to provide structural breastfeeding support. Ultimately, this will help improve overall breastfeeding practices and subsequently will be beneficial to maternal and child health and help prevent transmission of HIV through breastmilk.

Declarations

The secondary analysis of MCH-ART and HU2 data was approved by the University of Cape Town Human Research Ethics committee (HREC Ref: 732:2019) (Appendix 2) for submission for a Master of Public Health, mini dissertation.

Consent for publication

Not applicable

Availability of data and material

The datasets generated in this analysis are not publicly available, however are available from the Principle investigators (PI's) on reasonable request.

Competing interests

The authors of this paper have no competing interests to declare.

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References

1. Mallampati D, Maclean RL, Shapiro R, Dabis F, Engelsmann B, Freedberg KA, et al. Optimal breastfeeding durations for HIV-exposed infants: The impact of maternal ART use, infant mortality and replacement feeding risk. J Int AIDS Soc. 2018;21(4):1–10.

2. World Health Organization (WHO). Indicators for assessing Infant and Young Child Feeding Practices: Part 1 Definitions. Geneva, World Heal Organ Dep Child Adolesc Heal Dev. 2008;1:1–26.

3. World Health Organisation (WHO). Indicators for assessing Infant and Young Child Feeding Practices: Part 2 Measurement. Geneva, World Heal Organ Dep Child Adolesc Heal Dev [Internet]. 2010;2:1–91. Available from: http://whqlibdoc.who.int/publications/2010/9789241599290_eng.pdf

4. Kimani-Murage EW, Madise NJ, Fotso JC, Kyobutungi C, Mutua MK, Gitau TM, et al. Patterns and determinants of breastfeeding and complementary feeding practices in urban informal settlements, Nairobi Kenya. BMC Public Health. 2011;11.

5. Nieuwoudt S, Manderson L, Norris SA. Infant feeding practices in Soweto, South Africa: Implications for healthcare providers. South African Med J. 2018;108(9):756–62.

6. World Health Organization, UNICEF. Guideline: Updates on HIV and infant feeding. WHO Publications. Geneva; 2016. 1–68 p.

7. Victora CG, Bahl R, Barros AJD, França GVA, Horton S, Krasevec J, et al. Breastfeeding in the 21st century: Epidemiology, mechanisms, and lifelong effect. Lancet. 2016;387(10017):475–90.

8. Ramokolo V, Lombard C, Chhagan M, Engebretsen IMS, Doherty T, Goga AE, et al. Effects of early feeding on growth velocity and overweight/obesity in a cohort of HIV unexposed South African infants and children. Int Breastfeed J. 2015;10(1):1–11.

9. Mofenson LM. Antiretroviral drugs to prevent breastfeeding HIV transmission. Antivir Ther. 2010;15(4):537–53.

10. World Health Organization (WHO). Indicators for assessing Infant and Young Child Feeding Practices part 3: Country Profiles. World Heal Organ [Internet]. 2008;http://www:19. Available from: http://whqlibdoc.who.int/publications/2008/9789241596664_eng.pdf%5Cnhttp://www.unicef.org/programme/breastfeeding/innocenti.htm%5Cnhttp://innocenti15.net/declaration.pdf.pdf%5Cnhttp://whqlibdoc.who.int/publications/2010/9789241599757_eng.pdf

11. Rollins NC, Ndirangu J, Bland RM, Coutsoudis A, Coovadia HM, Newell M-L. Exclusive breastfeeding, diarrhoeal morbidity and all-cause mortality in infants of HIV-infected and HIV uninfected mothers: an intervention cohort study in KwaZulu Natal, South Africa. PLoS One. 2013;8(12):e81307.

12. Thior I, Lockman S, Smeaton LM, Shapiro RL, Wester C, Heymann SJ, et al.

Breastfeeding plus infant zidovudine prophylaxis for 6 months vs formula feeding plus infant zidovudine for 1 month to reduce mother-to-child HIV transmission in Botswana - A randomized trial: The Mashi study. J Am Med Assoc. 2006;296(7):794–805.

13. Bode L, Raman A, Murch S, Rollins N, Gordon J. Understanding the mother-breastmilk -infant "triad." Science (80-). 2020;367(6482):1070–3.

14. Kuhn L, Kroon M. Breastfeeding and the 2015 South African guidelines for prevention of mother-to-child transmission of HIV. South Afr J HIV Med. 2015;16(1):1–5.

15. Moland KMI, van Esterik P, Sellen DW, de Paoli MM, Leshabari SC, Blystad A. Ways ahead: Protecting, promoting and supporting breastfeeding in the context of HIV. Int Breastfeed J. 2010;5:2–5.

16. Ijumba P, Doherty T, Jackson D, Tomlinson M, Sanders D, Persson LÅ. Free formula milk in the prevention of mother-to-child transmission programme: Voices of a peri-urban community in South Africa on policy change. Health Policy Plan. 2013;28(7):761–8.

17. Blystad A, van Esterik P, de Paoli MM, Sellen DW, Leshabari SC, Moland KMI. Reflections on global policy documents and the WHO's infant feeding guidelines: Lessons learnt. Int Breastfeed J. 2010;5:2–4.

18. Doherty T, Sanders D, Jackson D, Swanevelder S, Lombard C, Zembe W, et al. Early cessation of breastfeeding amongst women in South Africa: an area needing urgent attention to improve child health. BMC Pediatr. 2012;12.

19. Shapiro RL, Hughes MD, Ogwu A, Kitch D, Lockman S, Moffat C, et al. Antiretroviral regimens in pregnancy and breast-feeding in Botswana. N Engl J Med. 2010;362(24):2282–94.

20. de Vincenzi I, Kesho Bora Study Group. Triple antiretroviral compared with zidovudine and single-dose nevirapine prophylaxis during pregnancy and breastfeeding for prevention of mother-to-child transmission of HIV-1 (Kesho Bora study): a randomised controlled trial. Lancet Infect Dis. 2011 Mar;11(3):171–80.

21. Flynn P, Taha E, Cababasay M, Fowler M, Mofenson L, Owor M, et al. Prevention of HIV-1 Transmission Through Breastfeeding: Efficacy and Safety of Maternal Antiretroviral Therapy Versus Infant Nevirapine Prophylaxis for Duration of Breastfeeding in HIV-1-Infected Women With High CD4 Cell Count (IMPAACT PRO MISE): A Random. J Acquir Immune Defic Syndr. 2018 Apr 1;77(4):383–92.

22. Chasela CS, Hudgens MG, Jamieson DJ. Maternal or Infant Antiretroviral Drugs to Reduce HIV-1 Transmission. N Engl J Med. 2010;362(24):2271–81.

23. Arikawa S, Rollins N, Jourdain G, Humphrey J, Kourtis AP, Hoffman I, et al. Contribution of Maternal Antiretroviral Therapy and Breastfeeding to 24-Month Survival in Human Immunodeficiency Virus-Exposed Uninfected Children: An Individual Pooled Analysis of African and Asian Studies. Clin Infect Dis. 2018 May;66(11):1668–77.

24. Zunza M, Esser M, Slogrove A, Bettinger JA, Machekano R, Cotton MF, et al. Early Breastfeeding Cessation Among HIV-Infected and HIV-Uninfected Women in Western Cape Province, South Africa. AIDS Behav. 2018;22:114–20.

25. Jackson D, Swanevelder S, Doherty T, Lombard C, Bhardwaj S, Goga A. Changes in rates of early exclusive breast feeding in South Africa from 2010 to 2013: Data from three national surveys before and during implementation of a change in national breastfeeding policy. BMJ Open. 2019;9(11):1–8.

26. Myer L, Phillips TK, Zerbe A, Ronan A, Hsiao N-Y, Mellins CA, et al. Optimizing Antiretroviral Therapy (ART) for Maternal and Child Health (MCH): Rationale and Design of the MCH-ART Study. J Acquir Immune Defic Syndr. 2016 Aug;72 Suppl 2:S189-96.

27. le Roux S, Abrams EJ, Nguyen KK, Myer L. HIV incidence during breastfeeding and mother-to child transmission in Cape Town, South Africa. AIDS. 2019;33(8):1399–401.

28. Cox J, Holden J, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. Britihish J Psychiatry. 1987;150:782–6.

29. Kessler R, Barker P, Colpe L, Epstein J, Gfroerer J, Hiripi E. Screening for serious mental illness in the general population. Kessler Psychological Distress Scale (K10). Arch Gen Psychiatry. 2003;60(2):184–9.

30. Garcia-Moreno C, Jansen H, Ellisberg M, Helse L, Watts C. WHO Multi-country Study on Women's Health and Domestic Violence against Women. World Health Organization. Geneva; 2005.

31. World Health Organization (WHO). AUDIT: The Alcohol Use Disorders Identification Test: Guidelines for use in primary care. Geneva; 2001.

32. Henney N. Western Cape Government: Breastfeeding Seminar. Mother and Baby friendly initiative. 2013.

33. Myer L, Phillips TK, Manuelli V, McIntyre J, Bekker L-G, Abrams EJ. Evolution of antiretroviral therapy services for HIV-infected pregnant women in Cape Town, South Africa. 2016;69(2).

34. le Roux SM, Abrams EJ, Donald K, Brittain K, Phillips TK, Zerbe A, et al. Infectious morbidity of breastfed, HIV-exposed uninfected infants under conditions of universal antiretroviral therapy in South Africa: a prospective cohort study. Lancet Child Adolesc Heal. 2020;4(3):220–31.

35. Levine M, Ensom MHH. Post hoc power analysis: An idea whose time has passed? Pharmacotherapy. 2001;21(4):405–9.

36. Hoenig JM, Heisey DM. The abuse of power: The pervasive fallacy of power calculations for data analysis. Am Stat. 2001;55(1):19–24.

37. Ghuman MR, Saloojee H, Morris G. Infant feeding practices in a high HIV prevalence rural district of KwaZulu-Natal, South Africa. South African J Clin Nutr. 2009

Jun;22(2):74–9.

38. West NS, Schwartz SR, Yende N, Schwartz SJ, Parmley L, Gadarowski MB, et al. Infant feeding by South African mothers living with HIV: implications for future training of health care workers and the need for consistent counseling. Int Breastfeed J. 2019;14:11.

39. Hunegnaw MT, Gelaye KA, Ali BM. Factors associated with the time to cessation of breastfeeding among mothers who have index children aged two to three years in Debre Markos, northwest Ethiopia: A retrospective follow up study. BMC Pediatr. 2018;18(1):1–8.

40. Coetzee B, Tomlinson M, Osawe S, Amibiku A, Kagee A. Barriers to and Facilitators of Adherence to Exclusive Breastfeeding Practices Among HIV Infected and Non-Infected Women in Jos, Nigeria. Matern Child Heal J. 2017 Apr;21(4):953–60.

41. World Health Organization (WHO). Trainer's guide. WHO, Geneva. Breastfeeding counselling: a training course. 1993;

42. Rollins NC, Ndirangu J, Bland RM, Coutsoudis A, Coovadia HM, Newell ML. Exclusive breastfeeding, diarrhoeal morbidity and all-cause mortality in infants of HIV-infected and HIV uninfected mothers: An intervention cohort study in KwaZulu natal, South Africa. PLoS One. 2013;8(12):1–10.

43. Lunney KM, Iliff P, Mutasa K, Ntozini R, Magder LS, Moulton LH, et al. Associations between Breast Milk Viral Load, Mastitis, Exclusive Breast-Feeding, and Postnatal Transmission of HIV. Clin Infect Dis. 2010;50:762–9.

44. Horwood C, Jama NA, Haskins L, Coutsoudis A, Spies L. A qualitative study exploring infant feeding decision-making between birth and 6 months among HIV-positive mothers. Matern Child Nutr. 2019 Apr;15(2):e12726.

45. Lang'At PC, Ogada I, Steenbeek A, Macdonald NE, Ochola S, Bor W, et al. Infant feeding practices among HIV-exposed infants less than 6 months of age in Bomet County, Kenya: An in-depth qualitative study of feeding choices. Arch Dis Child. 2018;103(5):470–3.

46. Jama NA, Wilford A, Masango Z, Haskins L, Coutsoudis A, Spies L, et al. Enablers and barriers to success among mothers planning to exclusively breastfeed for six months: A qualitative prospective cohort study in KwaZulu-Natal, South Africa. Int Breastfeed J. 2017;12(1):1–13.

47. Ijumba P, Doherty T, Jackson D, Tomlinson M, Sanders D, Persson L-A. Social circumstances that drive early introduction of formula milk: an exploratory qualitative study in a peri-urban South African community. Matern Child Nutr. 2014 Jan;10(1):102–11.

48. Doherty T, Horwood C, Haskins L, Magasana V, Goga A, Feucht U, et al. Breastfeeding advice for reality: Women's perspectives on primary care support in South Africa. Matern Child Nutr. 2019 Jul;e12877.

49. Mphasha MH, Skaal L. Infant and Young Child Feeding Policy: do primary health care nurses adhere to the HIV breastfeeding recommendations in Limpopo province? South African J Clin Nutr. 2019 Sep;32(3):70–5.

50. Reimers P, Israel-Ballard K, Spies L, Tanser F, Thior I, Scott Gordon W, et al. A Protocol for a Cluster Randomized Trial on the Effect of a "feeding buddy" Program on adherence to the Prevention of Mother-To-Child-Transmission Guidelines in a Rural Area of KwaZulu-Natal, South Africa. J Acquir Immune Defic Syndr. 2016 Aug;72 Suppl 2:S130-6.

51. Tylleskär T, Jackson D, Meda N, Engebretsen IMS, Chopra M, Diallo AH, et al. Exclusive breastfeeding promotion by peer counsellors in sub-Saharan Africa (PROMISE-EBF): A cluster-randomised trial. Lancet. 2011;378(9789):420–7.

52. Cresswell JA, Ganaba R, Sarrassat S, Somé H, Diallo AH, Cousens S, et al. The effect of the Alive & Thrive initiative on exclusive breastfeeding in rural Burkina Faso: a repeated cross-sectional cluster randomised controlled trial. Lancet Glob Heal. 2019;7(3):e357–65.

53. Ogwu A, Moyo S, Powis K, Asmelash A, Lockman S, Moffat C, et al. Predictors of early breastfeeding cessation among HIV-infected women in Botswana. Trop Med Int Health. 2016 Aug;21(8):1013–8.

54. Bhan G, Surie A, Horwood C, Dobson R, Alfers L, Portela A, et al. Informal work and maternal and child health: A blind spot in public health and research. Bull World Health Organ. 2020;98(3):219–21.

55. Rollins N, Doherty T. Improving breastfeeding practices at scale. Lancet Glob Heal. 2019;7(3):e292–3.

56. Genetu H, Yenit MK, Tariku A. Breastfeeding counseling and support are associated with continuous exclusive breastfeeding from one week to six months of age among HIV exposed infants in north Gondar zone, Ethiopia: A cross-sectional study. Int Breastfeed J. 2017;12(1):1–8.

PART C: APPENDICES

APPENDIX 1: Protocol Appendices

Contents

APPENDIX A

- **MCH-ART Study HREC Approval –**

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal - 5 OCT 2016

HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

HREC office use only (FWA00001637; IRB00001938)
This serves as notification of annual approval, including any documentation described below

☑ Approved	Annual progress report	Approved until/next renewal date	30.10.2017
☐ Not approved	See attached comments		
Signature Chairperson of the HREC	Signature Removed	Date Signed	7/10/16

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	03 Oct 2016		
HREC REF Number	451/2012	Current Ethics Approval was granted until	30 OCT 2016
Protocol title	Strategies to optimize antiretroviral therapy services for maternal & child health: the MCH-ART study		
Protocol number (if applicable)	N/A		
Are there any sub-studies linked to this study?	✓ YES		
If yes, could you please provide the HREC Ref's for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.	**HREC REF 194/2013** Estimation of delivery dates using obstetric ultrasound in the MCH-ART study **HREC REF 550/2015** Childbearing, family planning and relationships among women living with HIV in Gugulethu, Cape Town.		
Principal Investigator	Prof Landon Myer		
Department / Office Internal Mail Address	CIDER, School of Public Health and Family Medicine, Faculty of Health Sciences		

1.1 Does this protocol receive US Federal funding?	✓ Yes	☐ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval?	☐ Yes	✓ No

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

APPENDIX B

- HU2 Study HREC Approval -

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30 05 2020
☐ Not approved	See attached comments		
Signature Chairperson of the HREC	Signature Removed	Date signed	22/5/2019

Comments to PI from the HREC
Thank you for the declaration document

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	22 May 2019		
HREC REF Number	650/2015	Current Ethics Approval was granted until	30 November 2018
Protocol title	Growth, infectious morbidity and neurodevelopment of HIV-exposed and HIV-unexposed infants in the context of lifelong maternal antiretroviral therapy and breastfeeding: a prospective cohort study (PhD Candidate – Dr S le Roux) Sub-study linked to 567/2014 and 451/2012		
Protocol number (if applicable)	Version 1.2		
Are there any sub-studies linked to this study?	☒ Yes ☐ No		
If yes, could you please provide the HREC Ref's for all sub-studies? Note: A seperate FHS016 must be submitted for each sub-study	This study is a sub-study of 567/2014 and 451/2012		
Principal Investigator	Professor Landon Myer		
Department / Office Internal Mail Address	Landon.Myer@uct.ac.za		

1.1 Does this protocol receive US Federal funding?	☒ Yes	☐ No

(Note: Please complete the Closure form (FHS019) if the study is completed within the approval period)

HUMAN RESEARCH ETHICS COMMITTEE
22 MAY 2019
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

APPENDIX C

- MCH-ART (HEU) and HU2 (HU) inclusion and exclusion criteria -

Phase 1: Inclusion criteria: antenatal

For both groups, inclusion criteria will include:

- First antenatal booking for index pregnancy
- Maternal age of 18 years or older
- Confirmed pregnancy
- Able to provide informed consent for research
- HIV-testing conducted at least once during current pregnancy, with results available

a. *Specific to HEU group:*
    - Booking HIV test positive in index pregnancy
    - Initiating ART during index pregnancy

b. *Specific for HU group:*
    - Booking HIV test negative in index pregnancy

Phase 2 & 3: Inclusion criteria: postnatal

For both groups, inclusion criteria will include:

- Had breastfed at any point during the first week post-delivery
- Willingness to return for postnatal study visits
- Able to provide informed consent for research

c. *Specific for HEU group*
    - Had been enrolled and seen for at least one antenatal MCH-ART study visit
    - Willingness to allow minimally invasive infant blood sampling at 12 months

d. *Specific for HU group*
    - Had been enrolled and seen for at least one antenatal HU2 study visit

Exclusion criteria: antenatal and postnatal

Individuals meeting any of the following exclusion criteria at any point in either study will be excluded:

- Not currently pregnant (antenatal phase) or loss of pregnancy/neonate (postnatal phase) at the time of eligibility determination
- Intention to relocate out of Cape Town permanently during the study period
- Any medical, psychiatric or social condition which in the opinion of the investigators would affect the ability to consent and/or participate in the study (all phases),

e. *Specific for HEU group*

Infants who test HIV-positive at any point during postnatal follow-up will not be excluded from the study but their outcome measures will be analysed separately.

f. Specific for HU group

Women who seroconvert and subsequently test HIV-positive after enrolment will continue study follow-up where possible; the maternal and infant health outcomes of this group will be analysed separately.

APPENDIX D

- **MCH-ART Infant feeding intentions/practices Questionnaire -**

Visit Date: __ __/__ __ __/__ __ __ __	Visit number	6 weeks	3 months	6 months	9 months	12 months

Ukukhumbula indlela zokondla usana
Infant feeding recalls:

1.	Uyaluncancisa ibele usana lwakho kude kube ngoku *Are you currently breastfeeding your baby*	Hayi *No* = 0 Ewe *Yes* = 1→ Gqithela ku-7 *SKIP to Q7*
2.	Uluncancise ibele usana lwakho ixesha elingakanani *For how long did you breastfeed your child?*	Iintsuku:_____ *Days* Liveki:_____ *Weeks* Andiyazi =9 *Do not know*
3.	Zeziphi izizathu ezibangele uyeke ukuluncancisa usana/okanye ungaluncancisi *What were your reasons for stopping to breastfeed/not breastfeed your child?* *Read all, circle all that apply*	a. Umsebenzi *Work* b. Imfundo *Education* c. Ukugula,ngaphandle kwengxaki zokuncancisa *Illness, other than lactation problems* d. Ingxaki zokuncancisa *Lactation problems* e. Usana alukhuli kakuhle *Child not grow well* f. Usana lukhala kakhulu *Child crying a lot* g. Ubisi lwebele alwanelanga *Not enough breast milk* h. Andifuni ukumosulela ngentsholongwane *Did not want to give my baby HIV infection* i. lingcebiso/ukunyanzeliswa ngabanye *Advice/pressure from others* j. Ezinye,cacisa:_____ *Other, specify*
4.	Uyeke njani ukuncancisa? *How did you stop breastfeeding?*	Ndimlumlile kancinci ndamnika olunye ubisi emva kwentsuku ezimbalwa=1 *Gradually changed to other replacement milk over a period of days* Ndimlumlile kancinci ndamnika ubisi emva kweveki ezimbalwa=2 *Gradually change to other replacement milk over a period of weeks* Ndimlumlile kancinci ndamnika ubisi mva kwenyanga ezimbalwa=3 *Gradually change to other replacement milk over a period of months* Ndiluhambisile usana iintsuku ezimbzlw=4 *Sent the child away for some days* Ndiqabe into ebeleni usana alwalifuna ibele=5 *Put something on breast to make child refuse breast* Ndiluncancise ebusuku kuphela=6 *Only breastfed at night* Ndifumene iyeza ekliniki lokunqamla ubisi=7 *Got medicine from clinic to stop milk* Ndisebenzise iyeza lesi Xhosa lokunqamla/irati yokunqamla=8 *Took traditional medicine/remedy medicine to stop milk* Lingcebiso/uxiizelelo ngabaye=9 *Advice/pressure from others* Ezinye=10,cacisa:_____ *Other , specify*
5.	Ikuthathe ixesha elingakanani ukumyekisa umphelo? *How long did it take you to stop all breastfeeding?*	Iintsuku:_____ *Days*

Initials of counsellor: _____

6.	Uceba ukuluncancisa olu sana kaphinda? *Are you planning on breast feeding this baby ever again?*	Hayi *No* = 0 Ewe *Yes* = 1 Andazi=9 *Don't know*
7.	Aye acandeka aphuma ubumdaka amabele, okanye wanengxaki emabeleni oko uhte walubeleka usana? *Have you had any infection, or problem with your breasts since we last saw you?*	Hayi *No* = 0 → Gqithela ku- 10 "dietary 24 hour recall" *SKIP to Q10* Ewe *Yes* = 1
8.	Ukuba ewe,ngxakini le? ***If yes**, what problem did you have?* Funda zonke , urhangqe ezenzekileyo *Read all, circle all that apply*	a. Ukudumba kwamabele *Engorgement (swollen painful breasts)* b. lingono ezichachambileyo *Cracked nipples* c. isilonda ebeleni *Abscess (sore on the breast)* d. ulosuleleko *Infection* e. Uqhaqho *Operation* f. Umothuko *Trauma* g. Ezinye, cacisa *Other, specify:* _____
9.	Usana lwakho belunangaphi ukwenzeka kwa le nto? *How old was your baby when this occurred?*	lintsuku :_____ *Days* Liveki:_____ *Weeks*
Dietary 24hr recall *We will now ask you some questions about your baby's feeding over the last 24 hours*		
10.	Ukuvuka kwakho izolo ekuseni kude ibe kukuvuka kwakho namhlanje ekuseni uye waluncancisa usana? *From the time you woke up yesterday morning till you woke up this morning did you breastfeed your baby?*	Hayi *No* = 0 → Gqithela ku-13 *SKIP to Q13* Ewe *Yes* = 1
11.	Ukuvuka kwakho izolo ekuseni wade walala ebusuku ,uluncancise kangaphi usana? *From the time you woke up yesterday morning till you went to bed last night, how many times did you breastfeed?*	a. _____ amaxa *# of times* b. _____ usana lulilela ibele *# of on demand feedings*
12.	Ngelixesha uya kulala izolo kwade kwaba kukuvuka kwakho namhlanje ekuseni,uluncancise kangaphi usana? *From the time you went to bed last night till you woke up this morning, how many times did you breastfeed?*	c. _____ amaxa *# of times* d. _____ usana lulilela ibele *# of on demand feedings*

Initials of counsellor: _____

13.	Ukuvuka kwakho izolo ekuseni kude kube kukuvuka kwkho namhlanje ekuseni:Ulunikile usana ezinye zezi zinto. Rhangqa zonke omnike zona. *From the time you woke up yesterday morning till you woke up this morning: Did you give any of the following items to the child?* ***Read ALL; please circle all that apply.*** Ukuba umnikile ,sixelele umnike kangaphi? *And if you did, will you please tell how many times you gave it?*	a. Amanzi *Water, #____* b. Amanzi aneswekile *Any water with sugar or glucose, #____* c. Ijusi yeziqhamo *Any fruit juice, #____* d. Ingcambu emanzini *Any herbs in water, #____* e. Iti engenabisi *Any tea without milk, #____* f. Iti enobisi *Any tea with milk, #____* g. amanzi erayisi *Rice water, #____* h. Ubisi lwenkomo oluxutyiweyo *Diluted cow's milk, #____* i. Ubisi lwenkomo olungaxutywanga #____ *Non diluted cow's milk,* j. Ubisi olungumgubo labantwana *Infant formula, #____* k. Olungolunye ubisi olungumgubo #____ *Other powdered milk,* l. Ezinye izinto njenge yogati,itshizi,ikhrim #___ *Any other dairy product like yoghurt, cheese or cream,* m. Ubisi lwebhokhwe *Goat's milk* #___ n. Ipapa yabantwana,ipapa,okanye isonka *Cereals, porridge or bread, #____* o. Iziqhamo/vegi *Any fruits/vegetables, #____* p. Inyama ,intlanzi *Any meat or fish, #____* q. Amaqanda *Eggs, #____* r. iGripe water *Gripe water, #____* s. Amayeza abhalwe ngugqira *Any prescribed medicine, #____* t. Amayeza angabhalwanga ngugqira *Any non-prescribed medicine, #____* u. Into ebutywalara njenge bhiya,umqombothi *Any alcohol like beer or brew, #____* v. Ezinye, cacisa:_____ #_____ *Other, specify* w. Nanye kwezi zikhankanywe ngentla *None of the above*
Formula Feeding *We would also like to ask you some questions about using infant formula milk*		
14.	Umnika umntwana ubisi lomgubo? *Is the mother formula feeding?*	Hayi *No* = 0 → Gqithela ku-32 "leaving the child" *SKIP to Q32* Ewe *Yes* = 1
15.	Yeyiphi indlela eqhelekileyo yokunika usana ubisi lomgubo? *What is the usual way that you feed the child formula milk?* Mthundeze xa iyimfuneko. *Prompt when necessary.*	Ibhotile = 1 *Bottles* Ikomityi necephe=2 *Cup and spoon* Ikomityi evulekileyo asele=3 *Open cup and drinking* Ikomityi enomngxunya wokusela=4 *Cup with drinking spout* Ezinye=5 *Other* Andazi=9 *Don't know*

Initials of counsellor: _____

16.	Zingaphi ezinye zezi zinto onazo ezisetyenziselwa ukondla usana? *How many of each of the following items do you have that are for infant feeding?* Nika inani lonazo ngento nganye. *Provide a number for each item that applies.*	a. Ibhotile *Bottles*: # _____ b. Ikomityi *Cups* :#_____ c. Ikomityi zokondla ezinemingxuma yokusela *Feeding cups with drinking spouts*: #_____ d. Itiiti *Teats*: #_____ e. Ezinye, cacisa into : _____ #_____ *Other, specify item*
	Kuyakhuthazwa ukuxuba/ulungise isidlo esinye sobisi lomgubo ngexesha, kwaye ungalugcini olushiyeluley ubisi, kodwa abanye omama bafumanisa kulula kwaye kungabizi ukuxuba ubisi olungu mgubo lwabantwana olwanele ngaphezu kwesidlo esinye, banika inxenye yobisi kwisidlo esinye kwaye bongele isininzi sobisi isidlo esilandelayo. Ngoku sizakubuza eminye imibuzo malunga nokuba ukukhetha ukuxuba kwaye utyise ngayo umntwana wakho amaxesha amaninzi: *It is recommended to only mix/prepare one feed of formula milk at a time, and not store left over milk. However, some mothers find it easier, and cheaper, to mix enough formula for more than one feed; they give some of the milk for one feed and save the rest of the milk for the next feed. We are now going to ask some questions about how you choose to mix and feed your baby most of the time:*	
17.	Kukangaphi ngemini (iiyure ezi -24)ulungisa ubisi lomgubo xa usana luza kuncanca. (Kukangahpi uxuba ubisi lomgubo,hayi amaxa omncancisa ngawo) *How many times during a day (i.e. in a 24 hour period) is the formula normally **prepared** for the child? (Number of times the formula is mixed, **not** number of times given)*	_____ amaxesha *times*
18.	Lubisi olungakanani lomgubo wabantwana oqhele ukululungisa ngexesha elinye (hayi ubungakanani obutyisa umntwana kwisidlo esinye)?*How much formula is normally prepared at one time (not how much is fed to the baby in one feed)?* Mthundeza xa kuyimfuneko *Prompt when necessary.*	75ml 100ml 125ml (1/2 yebhotile=1bhotile encinci)) 150ml 175ml 200ml 250ml (1 bhotile enkulu) 500ml 1 litre Eminye, cacisa :_____ (mls) *Other, specify* Andazi/ *Don't know* = 9
19.	Umncancisa ubisi lomgubo olungakanani ngexesha? *How much formula is fed to the child each time?*	_____ (mls)
20.	Xa ubisi lomgubo wabantwana selulungisiwe (luxutyiwe), ulubekaphi ubisi oselulungisiwe kude ube uyamtyisa umntwana/phakathi kokutyisa umntwana?*When the formula has been prepared (mixed), where is the prepared formula stored until/between feeding the baby?* Mthundeze xa kuyimfuneko. *Prompt when necessary.*	Egumbini: lugqunyiwe=1 *Room; covered* Egumbini ;lungagqunywanga=2 *Room; uncovered* Kwisikhencisi=3 *Refrigerator* Eflaskini lupholisiwe=4 *Flask: cooled first* Andilugcini,ndilunika ngoko=5 *Do not store, give it directly* Ezinye=6 cacisa:_____ *Other, specify* Andazi=9 *Don't know*

Initials of counselor: _____

21.	Anjani amanzi owenza ngawo ngesiqhelo ubisi? *How was the water you use for the child's formula feeds normally prepared?* Aphendule kubekanye ungamthundezi *One response only, do not prompt.*	Billisa phambi kokunika usana=1 *Boil before each feed* Bilisa kanye ngemini agcinwe:egqunyiwe=2 *Boil once a day and store it: covered* Hluza=3 *Filter* Linda acwenge=4 *Allow to settle* Galela iblitshi=5 *Bleach* Andenzi nto=6 *Nothing* Bilisa,gcine amanzi ashushu eflaskini=7 *Boil, store hot water in flask* Ezinye=8 cacisa:_____ *Other, specify* Andazi=9 *Don't know*
22.	Ubisi lomgubo ulufumana esibhedlele /kliniki losana lwakho? *Are you currently receiving formula milk from the hospital/clinic for your infant?*	Hayi *No* = 0 →SKIP to Q25 Ewe *Yes* = 1
23.	Ukugqibela kwethu ukubonana nawe, ukhe wayokuthatha ubisis wafumanisa ukuba baphelelwe lubusi? *Since we last saw you have you been to the clinic to collect milk and found that they were out of stock?*	Hayi *No* = 0 → Gqithela ku-25 *SKIP to Q25* Ewe *Yes* = 1
24.	Yenzeke kangaphi lonto emva kokuba sigqibele ukubonana nawe? *How many times has this happened since we last saw you?*	_____ amaxesha # *times*
25.	Ukugqibela kwethu ukubonana nawe, ukhe wamthengela umntwana wakho ubisi olungumgubo lwabantwana? *Since we last saw you, have you purchased any formula milk for your infant?*	Hayi *No* = 0 Ewe *Yes* = 1
26.	Ukugqibela kwethu ukubonana nawe, ukhe waphelelwa lubisi lomntwana olungumgubo? *Since we last saw you, have you ever run out of formula milk?*	Hayi *No* = 0 → Gqithela ku-29 *SKIP to Q29* Ewe *Yes* = 1
27.	Ithathe ixesha elingakanani? *How many days did this last?*	Iintsuku :_____ *Days*
28.	Uluncancise ntoni usana ngeli xesha? *What did you feed the baby during this time?* Rhangqa zonke omnike zona *Circle all that apply*	a. Ubisi lwebele *Breast milk* b. Ipapa *Porridge* c. Amanzi *Water* d. Amanzi aneswekile *Sugar and water* e. Iti *Tea* f. Ndiluthengile *Purchased formula* g. Ijusi *Juice* h. Ezinye,cacisa:_____ *Other, specify*
29.	Unalo ubisi lomgubo namhlanje endlini? *Do you have any formula in the house today?*	Hayi *No* = 0 Ewe *Yes* = 1

Initials of counsellor: _____

30.	Ukugqibela kwethu ukuonana nawe, ukhe wamncancisa umntwana ibele, umz: ukumlalisa ebhedini ngokuhlwa xa lila? *Since we last saw you, have you ever put your baby to the breast e.g. to go to sleep, in bed at night time, when crying?*	Hayi *No* = 0 Ewe *Yes* = 1
31.	Ukugqibela kwethu ukubonana nawe, ukhe wabona iintengiso ezibhengeza ubisi lwabantwana olungumgubo kuyo naphi na iKliniki? *Since we last saw you, have you seen adverts at any health clinic advertising formula milks?*	Hayi *No* = 0 Ewe *Yes* = 1
Questions about leaving the child		
32.	Wakhe wohlukana nosana lwakho oko saqgibela ukubonana, wade umntana watyiswa ngomnye umntu? *Have you ever been separated from your child since we last saw you, so that someone else has fed the child?*	Hayi *No* = 0 → Gqithela ku-34 *SKIP to Q34* Ewe *Yes* = 1
33.	Luye lwancanciswa ntoni usana oku kokugqibela ungekho? *What did they feed the child the last time you were away?* Rhangqa zonke ezenziweyo *Circle all that apply*	*a.* Umxube wamanzi *Water based liquids* *b.* Umxube wobisi/ukutya okuthambileyo *Milk based liquids/semi-solid feeds* *c.* Ubisi lwam lwebele ebendilukhamile *My own expressed breast milk* *d.* Usana beluncanciswe ibele ngomnye umdlezana *The child was "wet nursed" (breastfed by another woman)* *e.* Ubisi lomgubo *Formula milk* *f.* Ukutya ebendikuhlafunile kosana *Food that I chewed for the baby* *g.* Andazi *Do not know* *h.* Enye,cacisa : _____ *Other, Specify*
Last questions about formula and breastfeeding: *We will now ask you five more questions about milk feeding*		
34.	Ngawaphi kulamayeza atyiwa lusana lwakho: Which of these medicines is your baby currently receiving: *Please show the mother a range of possible medicines: multivitamins, iron drops, nevirapine, cotrimoxazole, TB treatment and antibiotics* Rhangqa zonke ezenziweyo *Circle all that apply*	a. Multivitamins (eg Kiddivite) b. Iron drops c. Zinc syrup d. Nevirapine e. Co-trimoxazole (or Bactrim/ Trimethoprim-Sulphamethoxazole / Resmed / Iantibiotic ukukhusela ulwasuleleko lwesifuba (antibiotic to prevent chest infection)) f. TB drugs g. Antibiotics h. Enye,cacisa Other – specify_____ i. Umntwana akanamayeza awatyayo *Baby is not currently receiving any medicine*

Initials of counsellor: _____

35.	Ebengakanani umntwana ukuqala kwakho ukumnika ezinye izinto ngaphandla kwebisi lebele okanye amayeza? Ngamany'amazwi, ebengakanani yena xa wayeqala ukufumana amanzi okanye ukutya okanye ubisi lomgubo wabantwana? *How old was the baby when you FIRST gave him/her anything other than breast milk or medicine? In other words, how old when he/she first had any water or food or formula milk?*	# weeks old _____ OR zange ndamnika enye into umntwana ngaphandle kwebisi lwebele= 0; →Phela apha/ *END* *Have never given the baby anything other than breast milk and medicine* Unsure = 9 →Phela apha/ *END*
36.	Ukusuka kwixesha ovuke ngalo kusasa izolo kude kuye ekuvukeni kwakho kusasa nje, ubukhe wamnika umntwana wakho ubisi olungumgubo lwabantwana? *From the time you woke up yesterday morning till you woke up this morning did you give your baby any formula milk?*	Hayi *No* = 0 → Gqithela ku-39 *SKIP to Q39* Ewe *Yes* = 1
37.	Ukusuka kwixesha ovuke ngalo kusasa izolo kude kubelixesha lakho lokulala, umncancise kangaphi umntwana wakho ubisi olungumgubo lwabantwana? *From the time you woke up yesterday morning till you went to bed last night, how many times did you feed your baby formula milk?*	_____ amaxa *# of times*
38.	Ngelixesha uya kulala izolo kwade kwaba kukuvuka kwakho namhlanje ekuseni, umncancise kangaphi umntwana wakho ubisi olungumgubo lwabantwana? *From the time you went to bed last night till you woke up this morning, how many times did you feed your baby formula milk?*	_____ amaxa *# of times*
Questions about introduction of complementary foods *We will now ask you about feeding your baby food other than milk*		

Questions about introduction of complementary foods
We will now ask you about feeding your baby food other than milk

39.	Ukhe umnike umntwana wakho okunye ukutya okanye ukutyana okulula ngaphandle kwebisi lwebele? *Do you give your baby any meals or snacks besides milk?*	Hayi *No* = 0 →Phela apha/ *END* Ewe *Yes* = 1
40.	Ebengakanani umntwana wakho ukumqalisa kwakho ukutya nakuphi na ukutya, okanye ukutyana okulula ngaphandle kwebisi lebele? *At what age did you FIRST give your baby any meals or snacks besides milk?* Khetha ibenye *Choose one option*	a. Kwiveki yokuqalaWithin 1 week of birth b. 1-4 iiveki ubudala 1-4 weeks old c. 1-2 iinyanga1-2 months old d. 2-3 iinyanga 2-3 months old e. 4-5 iinyanga 4-5 months old f. 6 iinyanga 6 months old g. Ebemdala kunenyanga eziy6 iinyanga zobudala *Older than 6 months*, # months age: _____ h. Andiqinisekanga *Unsure*
41.	Umpha kubekangaphi ngemini umntwana wakho ukutya ngaphandle kwebisi lwebele okanye ubisi olungumgubo lwabantwana? *How many times PER DAY do you usually feed your baby food other than milk? (both snacks and meals)*	#_____times per day

Initials of counselor: _____

42.	Umphe kangaphi ukutya umntwana wkaho izolo ngaphandle kwebisi lebele? *How many times did you give your baby food other than milk yesterday? (both snacks and meals)*	#_____ times per day
43.	Uqhele ukutya okungakanani umntwana wakho ngexesha lesidlo? *How much food (other than milk) does your baby usually eat per meal?** Please show mother the study-specific cups (full cup, half cup, quarter cup) and teaspoon*	a. A teaspoon or less b. ¼ - ½ cup c. ½ - 1 cup d. >1 cup e. *Enye,cacisa* Other, specify: _____ f. Andiqinisekanga *Unsure*

Date completed: __ __ /__ __ __ / __ __ __ __ Signed counsellor completing CRF: _____

Date of QC: __ __ /__ __ __ / __ __ __ __ Signed measurement nurse: _____

Initials of counsellor: _____

APPENDIX E

- **HU2: Maternal Demographics & Medical History Questionnaire -**

HU2: Maternal Demographics & Medical History, visit A1 PID: 5 - __ __ __ __ - __ __

Xhosa-English Version 2.1, 2nd October 2014

		Visit Date: __ __/__ __ __/__ __ __ __
Phambi kokuba uphendule uyacelwa ugqibezele iinkcukacha apho unokufunyanwa khona xa ufunwa. *Before completing this questionnaire please remember to complete the locator information form.* Siza kubuza imibuzo embalwa *We are now going to ask you a few questions:*		
SECTION A: Maternal demographics		
1.	Mingaphi iminyaka yakho *What is your age?*	*Age:* _____Iminyaka/*years*
2.	Ulohluphi uhlanga *What population group do you belong to?*	UmAfrika African = 1 Indiya *Indian* = 2 Umntu webala *Coloured* = 3 Umlungu *White* = 4 Olunye = 5, cacisa: _____ *Other specify*
3.	Uthetha oluphi ulwimi ekhayai? *What language do you speak at home?*	isiXhosa = 1 isiZulu = 2 isiBhulu *Afrikaans* = 3 isiNgesi *English* = 4 Olunye = 5, cacisa: _____ *Other specify*
4.	Lelephi elona banga liphezulu oliphumeleleyo? *What is the highest level of schooling/education that you have completed?*	Umgangatho/*Grade*:_____ Okanye/*or* Ibanga/ *Standard*:_____ Imfundo enomsila/ *Postsecondary*:_____
5.	Ngoku uyasebenza okanye uyafunda *Are you currently working and /or studying?*	Hayi *No* = 0 → Gqithela ku Q7 **SKIP to Q7** Ewe *Yes* = 1
6.	Ukuba nguEwe, yeyephi kwezi zilandelayo echaza, bhetele ukuba wenza ntoni? *If yes, which of one the following best describes what you do?* Khetha ibenye */Choose one only*	Ndiphangela isigxina = 1 *Employed full-time* Ndiphangela mangqaphangqapha = 2 *Employed part-time* Ndiphangela izingxungxo/ ndingumatheng 'ethengisa = 3 *Informal job/hawker* Uhamba isikolo/ ungumfundi = 4 *Attending school/learner* Uhamba isikolo semfundo enomsila = 5 *Attending tertiary education facility*

Initials of counsellor: _____

7.	Ngowuphi owona mthombo wemali kwikhaya lakho? *What is the MAJOR source of income for your household?* Khetha ibenye */Choose one only*		Ayikho =0 *None* Umsebenzi osisigxina =1 *Full-time employment* Umsebenzi wamaangqaoha-ngqapha =2 *Part-time employment* Umsebenzi wezingxungxo/ umthengisi =3 *Informal employment* Imali yesibonelelo sokukhuba zeka karhulumente= 4 *Disability grant* Imali yesibonelelo karhulumente =5 *Social grant* Umhlala phantsi =6 *Pension* Olunye imali yesibonelelo =7 *Other grant* chaza: _____ *specify type* Olunye =8 *Other* Chaza: _____ *specify* Andazi = 9 *Don't know*
8.	Uhlala kwikhaya elinjani? *What kind of home do you live in?*		Ityotyombe/ uhlaliso olungahlelwanga = 1 *Shack/informal dwelling* Indlu yesitena = 2 *Formal house* Ifleti/ indlu kamaspala = 3 *Flat/council home* Enye = 4, chaza:_____ *Other, specify*
9.	Ingaba indlu yakho inazo ezi zinto zilandelayo: *Does your house have the following:* *Read and answer for all*	a. Indlu yangasese *A toilet inside*	Hayi/*No* =0 Ewe/*Yes* =1
		b. Amanzi abalekayo empompo *Running water inside*	Hayi/*No* =0 Ewe/*Yes* =1
		c. Umbane *Electricity inside*	Hayi/*No* =0 Ewe/*Yes* =1
		d. Isikhenkcisi *A refrigerator*	Hayi/*No* =0 Ewe/*Yes* =1
		e. Umnxeba *A telephone*	Hayi/*No* =0 Ewe/*Yes* =1
		f. Umabona kude *A television*	Hayi/*No* =0 Ewe/*Yes* =1
10.	Bangaphi abantu abahlala kule ndlu bedibene nawe(abadala,abancinci)? *Including yourself, how many people (adults and children) live in your house?*		Inani labantu: _____ # *of people:*
11.	Bangaphi abadala (iminyaka-16 nangaphezulu)bedibene nawe abahlala kule ndlu? *How many adults (aged 16 or older), including you, live in your house?*		Inani labadala:_____ # *of adults*
12.	Bangaphi abantwana (iminyaka -15 nanganeno) abahlala nawe? *How many children (aged 15 and under) live in your house?*		Inani labantwana:_____ # *of children*
13.	Ukhulelwe kangaphi (kudibene nesi isisu)? *How many times have you been pregnant (including current pregnancy)?*		inani lokukhulelwa: _____ # *of pregnancies:*

Initials of counsellor: _____

14.	Ingaba ubuzama ukuba nosana ngelixesha ufumanisa ukuba ukhulelwe (Kwesi isisu)? *Were you trying to have a baby when you found out you were pregnant (in this pregnancy)?*	Hayi/*No* = 0 Ewe/*Yes* = 1 Andazi/*I don't know* = 9
15.	Bangaphi abantwana obazeleyo? *How many children have you given birth to?*	Inani labantwana:_____ *# of children* **Ukuba = 0,** Gqithela ku Q20 ***If 0, SKIP to Q20***
16.	Bangaphi kwaba bantwana abaphilayo? *How many of these children are living?*	Inani labantwana:_____ *# of children*
17.	Bangaphi kwaba bantwana abahlala nawe ngoku? *How many of these children currently live with you?*	Inani labantwana:_____ *# of children*
18.	***Not applicable***	
19.	***Not applicable***	
20.	Uya thandana ngoku? *Are you currently in a relationship?*	Hayi/*No* = 0→ **Gqithela ku Q25** ***SKIP to Q25*** Ewe/*Yes*= 1
21.	Ungaluchaza njani uthando lwakho? *How would you describe your current relationship?*	Utshatile = 1 *Married* Anditshatanga ,ndiya hlalisana =2 *Not married, living together* Nditshatile, asihlali kunye = 3 *Married, not living together* Anditshatanga, asihlali kunye = 4 *Not married, not living together* Enye = 5, cacisa:_____ *Other, specify*
22.	Lileshe ellingakanani unobudlelwana nalomntu? *How long have you been in a relationship with this person?*	Ixesha Inyanga *Months*_____ *Duration in:* Iminyaka *Years*_____
23.	Ingaba eli qabane lakho ngutata womnye wabantwana bakho(kunye nalo umkhulelweyo)? *Is your current partner the parent of any of your children? (including current pregnancy)*	Hayi/*No* = 0 Ewe/*Yes* = 1
24.	***Not applicable***	
25.	Ubukhe wabelana ngesondo nabanye abantu ingenguye lomntu uthandana naye? *In the last 12 months have you had any sexual relationships/sexual partners? (if in a relationship then other than this partner)*	Hayi/*No* = 0 → **Gqithela ku Q51** ***→ SKIP to Q 51*** Ewe/*Yes* = 1
26.	Bunjani ubudlelwanebakho namanye amaqabane ngaphandle kweqabane lakho langoku ukuba akhona? *What is the nature of your relationship(s)? (other than current partner if applicable)* Rhangqa konke okungqamene nawe. *Mark all that apply.*	a. Umlingane/nditshatile *Spouse/ married* b. Iqabane lam *Boyfriend* c. Iqabane lethutyana *Casual Partner/One Night Stands* d. Omnye ,cacisa:_____ *Other, specify*
	Questions 27 to 50 are not applicable	
51.	Ubukhe watshaya isagarethi kulenyanga iphelileyo? *Did you smoke cigarettes in the last month?*	Hayi *No* = 0 → ***Gqithela ku Q. B1*** ***→ SKIP to Question B1*** Ewe *Yes* = 1
52.	Utshaya isigarethi ezingaphi ngemini? *How many cigarettes do you smoke in a day?*	#_____ cigarettes

Initials of counsellor: _____

SECTION B: Maternal medical history		
1.	Uze njani ekliniki namhlanje? *How did you get to the clinic today?*	Uqeshe imoto = 1 *Hired car* Uze ngemoto yakho=2 *My own car* Uze ngetaxi=3 *Taxi* Ngebhasi=4 *Bus* Ngenyawo=5 *Walk* Olunye =6,cacisa:_____ *Other, specify*
2.	Uthathe ixesha elingakanani ukuza ekliniki namhlanje? *How long did it take you to get to the clinic today?*	Imizuzu*/Minutes:* _____ Iyure*/Hours:* _____
3.	Uhlawule malini ngesithuthi? *How much did you pay for transport?*	*Rand:* _____
4.	Uthathe ixesha emsebenzini ukuza apha? *Did you take time off of work to come here?*	Hayi/*No* =0 Ewe/*Yes* =1
5.	Kuye kwafuneka wenze isivumelwano nabantu bajonge umntwana/abantwana? *Did you have to make special arrangements for people to watch your child/children?*	Hayi *No* = 0 → Gqithela ku Q7 *SKIP to Q7* Ewe *Yes* = 1 Andinabantwana = 2 → Gqithela ku Q7 *Don't have any children SKIP to Q7*
6.	Kuye kwafuneka uhlawule umntu oza kujonga usana ngelixesha uze ekliniki? *Did you pay someone to watch your child so you could come to the clinic?*	Hayi/*No* =0 Ewe/*Yes* =1
7.	Usakhulelwe? *Are you still pregnant?*	Hayi/*No* =0 → ***END contact SC to complete termination CRF*** Ewe/*Yes* =1
8.	Uneveki ezingaphi ukhulelwe? *How many weeks pregnant are you?*	Iiveki/ *Weeks:* _____ *okanye/or* Iinyanga */Months:* _____
9.	Kolu umitho ingaba, ugqira okanye unesi uthe une-TB? *During your current pregnancy, has a doctor or nurse told you that you have TB?*	Hayi *No* = 0 → Gqithela ku Q14 *SKIP to Q14* Ewe *Yes* = 1
10.	Uxelelwe nini ngoku kugula? *When did you receive this diagnosis?*	Umhla:____ Inyanga:_____ Unyaka:_____ *Day Month Year*
11.	Uxelelwe phi ngoku kugula? *Where did you receive this diagnosis?*	Igama lekliniki *:* _____ *Name of clinic*
12.	Iphi emzimbeni wakho le TB? *Where in your body was the TB (eg, lungs, other location)?*	Indawo emzimbeni *:* _____ *Place in body*
13.	Uye wafumana unyango lwayo? *Did you receive treatment for TB?*	Hayi/*No* =0 Ewe/*Yes* =1
14.	Ngaphandle koku kukhulelwa ,ugqira okanye unesi bakhe bakuxelela ukuba une-TB? *Other than during this pregnancy has a doctor or nurse ever told you that you have TB?*	Hayi *No* = 0 → Gqithela ku Q20 *SKIP to Q20* Ewe *Yes* = 1

Initials of counsellor: _____

HU2: Maternal Demographics & Medical History, visit A1 PID: 5 - __ __ __ __ - __ __

Xhosa-English Version 2.1, 2nd October 2014

15.	Waxelelwa nini ngoku kugula kuqala ingekuko ngoku ukhulelwe? *When did you receive this diagnosis the last time (not during this pregnancy)?*	Umhla:____ Inyanga:_____ Unyaka:_____ *Day Month Year*
16.	Waye walufumana unyango ngoko? *Did you receive treatment for TB the last time?*	Hayi/*No* =0 Ewe/*Yes* =1
17.	Kungamaxesha amangaphi ewonke ufumana unyango lweTB? *How many times in total have you been treated for TB?*	Amaxesha:_____ # *of times* Ukuba ngu-0 Gqithela ku Q20/*If 0, SKIP to Q20*
18.	Walufumana phi unyango lwe TB? *Where did you receive your TB treatment?*	Igama lekliniki :_____ *Name of clinic*
19.	Lixesha elingakanani ufumana unyango lweTB ukugqibela kwakho ukunyangelwa yona? *How long did you receive treatment for TB the last time you were treated for TB?*	6 nyanga=1 *6 months* 8 nyanga=2 *8 months* 9 nyanga=3 *9 months* Iyaqhubekeka=4 *On-going* Amanye=5,cacisa:_____ *Other, specify* Andazi=9 *Don't know*
20.	Wakhe whacitha ubusuku esibhedlele? *Have you ever spent the night in hospital?*	Hayi *No* = 0 → Gqithela ku Q22 *SKIP to Q22* Ewe *Yes* = 1
21.	Ukuba nguEwe, cacisa ngezantsi ulaliso ngalunye *If yes, list details for each admission below:*	

	a. Isizathu *Reason for admission*	b. Ulaliswe nini? *Date of Admission*	c. Isibhedlele/kliniki *Hospital/ Clinic*	d. Wawukhulelwe *Were you pregnant at the time of this admission?*
i.		Umhla: Day Inyanga Month Unyaka Year		Hayi/*No* =0 Ewe/*Yes* =1
ii.		Umhla: Day Inyanga Month Unyaka Year		Hayi/*No* =0 Ewe/*Yes* =1
iii.		Umhla: Day Inyanga Month Unyaka Year		Hayi/*No* =0 Ewe/*Yes* =1
iv.		Umhla: Day Inyanga Month Unyaka Year		Hayi/*No* =0 Ewe/*Yes* =1
v.		Umhla: Day Inyanga Month Unyaka Year		Hayi/*No* =0 Ewe/*Yes* =1

Initials of counsellor: _____

22.	Kolu mitho ubukhe wathunyelwa kwesinye isibhedlele kuba uguliswa kukukhulelwa (Mowbray,okanye Groote Schuur) *During this pregnancy, have you been referred to any other health facility for pregnancy-related care (eg, Mowbray or Groote Schuur)?*	Hayi *No* = 0 → Gqithela ku Q23 *SKIP to Q23* Ewe *Yes* = 1
a.	Ubuthunyelwe phi? *Where were you referred?*	Igama lendawo: _____ *Location*
b.	Wawusithini umhla wokuthunyelwa kwakho? *What was the date of the referral?*	Umhla:____ Inyanga:_____ Unyaka:_____ *Day Month Year*
c.	Yintoni isizathu sokuthunyelwa kwakho? *What was the reason for the referral?*	Isizathu: *Reason*
d.	Ingaba wafumana unyango olutsha/ amayeza? *Did you receive any new treatment or medications as a result of this referral?*	Hayi/*No* =0 Ewe/*Yes* =1 Ukuba nguEwe, cacisa:_____ *If Yes, specify*
23.	Kolu mitho ingaba uye wathunyelwa kwesinye isibhedlele ngenxayokugula(Jooste,Groote Schuur) *During this pregnancy, have you been referred to any other health facility for other medical care (eg, GF Jooste or Groote Schuur)?*	Hayi *No* = 0 → END Ewe *Yes* = 1
a.	Ubuthunyelwe phi? *Where were you referred?*	Igama lendawo: _____ *Location*
b.	Wawusithini umhla wokuthunyelwa kwakho? *What was the date of the referral?*	Umhla:____ Inyanga:_____ Unyaka:_____ *Day Month Year*
c.	Yintoni isizathu sokuthunyelwa kwakho? *What was the reason for the referral?*	Isizathu: *Reason*
d.	Ingaba wafumana unyango olutsha/ amayeza? *Did you receive any new treatment or medications as a result of this referral?*	Hayi/*No* =0 Ewe/*Yes* =1 Ukuba nguEwe, cacisa:_____ *If Yes, specify*
Questions 24 to 38 are not applicable		

Date completed: __ __ /__ __ __ / __ __ __ __ Signed counsellor completing CRF: _____

Date of QC: __ __ /__ __ __ / __ __ __ __ Signed measurement nurse: _____

Initials of counsellor: _____

APPENDIX F

- **MCH-ART: Demographics & Medical History Questionnaire -**

		Visit Date: __ __/__ __ __/__ __ __ __
1.	Mingaphi iminyaka yakho *What is your age?*	*Age:* _____Iminyaka/*years*
2.	Uloluphi uhlanga *What population group do you belong to?*	UmAfrika African = 1 Indiya *Indian* = 2 Umntu webala *Coloured* = 3 Umlungu *White* = 4 Olunye = 5, cacisa: _____ *Other specify*
3.	Uthetha oluphi ulwimi ekhayai? *What language do you speak at home?*	isiXhosa = 1 isiZulu = 2 isiBhulu *Afrikaans* = 3 isiNgesi *English* = 4 Olunye = 5, cacisa: _____ *Other specify*
4.	Lelephi elona banga liphezulu oliphumeleleyo? *What is the highest level of schooling/education that you have completed?*	Umgangatho/*Grade*:_____ Okanye/*or* Ibanga/ *Standard*:_____ Imfundo enomsila/ *Postsecondary*:_____
5.	Ngoku uyasebenza okanye uyafunda *Are you currently working and /or studying?*	Hayi *No* = 0 → Gqithela ku Q7 **SKIP to Q7** Ewe *Yes* = 1
6.	Ukuba nguEwe, yeyephi kwezi zilandelayo echaza, bhetele ukuba wenza ntoni? *If yes, which of one the following best describes what you do?* Khetha ibenye */Choose one only*	Ndiphangela isigxina = 1 *Employed full-time* Ndiphangela mangqaphangqapha = 2 *Employed part-time* Ndiphangela izingxungxo/ ndingumatheng 'ethengisa = 3 *Informal job/hawker* Uhamba isikolo/ ungumfundi = 4 *Attending school/learner* Uhamba isikolo semfundo enomsila = 5 *Attending tertiary education facility*
7.	Ngowuphi owona mthombo wemali kwikhaya lakho? *What is the MAJOR source of income for your household?* Khetha ibenye */Choose one only*	Ayikho =0 *None* Umsebenzi osisigxina =1 *Full-time employment* Umsebenzi wamaangqaoha-ngqapha =2 *Part-time employment* Umsebenzi wezingxungxo/ umthengisi =3 *Informal employment* Imali yesibonelelo sokukhuba zeka karhulumente= 4 *Disability grant* Imali yesibonelelo karhulumente =5 *Social grant* Umhlala phantsi =6 *Pension* Olunye imali yesibonelelo =7 *Other grant* chaza: _____ *specify type* Olunye =8 *Other* Chaza: _____ *specify* Andazi = 9 *Don't know*

Initials of counsellor: _____

8.	Uhlala kwikhaya elinjani? *What kind of home do you live in?*		Ityotyombe/ uhlaliso olungahlelwanga = 1 *Shack/informal dwelling* Indlu yesitena = 2 *Formal house* Ifleti/ indlu kamaspala = 3 *Flat/council home* Enye = 4, chaza:_____ *Other, specify*
9.	Ingaba indlu yakho inazo ezi zinto zilandelayo: *Does your house have the following: Read and answer for all*	a. Indlu yangasese *A toilet inside*	Hayi/*No* =0 Ewe/*Yes* =1
		b. Amanzi abalekayo empompo *Running water inside*	Hayi/*No* =0 Ewe/*Yes* =1
		c. Umbane *Electricity inside*	Hayi/*No* =0 Ewe/*Yes* =1
		d. Isikhenkcisi *A refrigerator*	Hayi/*No* =0 Ewe/*Yes* =1
		e. Umnxeba *A telephone*	Hayi/*No* =0 Ewe/*Yes* =1
		f. Umabona kude *A television*	Hayi/*No* =0 Ewe/*Yes* =1
10.	Bangaphi abantu abahlala kule ndlu bedibene nawe(abadala,abancinci)? *Including yourself, how many people (adults and children) live in your house?*		Inani labantu: _____ *# of people:*
11.	Bangaphi abadala (iminyaka-16 nangaphezulu)bedibene nawe abahlala kule ndlu? *How many adults (aged 16 or older), including you, live in your house?*		Inani labadala:_____ *# of adults*
12.	Bangaphi abantwana (iminyaka -15 nanganeno) abahlala nawe? *How many children (aged 15 and under) live in your house?*		Inani labantwana:_____ *# of children*
13.	Ukhulelwe kangaphi (kudibene nesi isisu)? *How many times have you been pregnant (including current pregnancy)?*		inani lokukhulelwa: _____ *# of pregnancies:*
14.	Ingaba ubuzama ukuba nosana ngelixesha ufumanisa ukuba ukhulelwe (Kwesi isisu)? *Were you trying to have a baby when you found out you were pregnant (in this pregnancy)?*		Hayi/*No* = 0 Ewe/*Yes* = 1 Andazi/*I don't know* = 9
15.	Bangaphi abantwana obazeleyo? *How many children have you given birth to?*		Inani labantwana:_____ *# of children* **Ukuba = 0,** Gqithela ku Q20 ***If 0, SKIP to Q20***
16.	Bangaphi kwaba bantwana abaphilayo? *How many of these children are living?*		Inani labantwana:_____ *# of children*
17.	Bangaphi kwaba bantwana abahlala nawe ngoku? *How many of these children currently live with you?*		Inani labantwana:_____ *# of children*
18.	Bangaphi kwaba bantwana ekufumaniseke bakho ukuba baphila nentsholongwane? *How many of your children have tested HIV-positive?*		Inani labantwana abaphila nentsholongwane:_____ *# of HIV-positive children*
19.	Bangaphi kwaba bantwana baphila nentsholongwane abasaphilayo? *How many of these children who have tested HIV- positive are currently living?*		Inani labantwana abaphila nentsholongwane abaphilayo ngoku: _____ *# of HIV-positive children currently alive*

Initials of counsellor: _____

20.	Uya thandana ngoku? *Are you currently in a relationship?*	Hayi/*No* = 0→ **Gqithela ku Q25** ***SKIP to Q25*** Ewe/*Yes*= 1
21.	Ungaluchaza njani uthando lwakho? *How would you describe your current relationship?*	Utshatile = 1 *Married* Anditshatanga ,ndiya hlalisana =2 *Not married, living together* Nditshatile, asihlali kunye = 3 *Married, not living together* Anditshatanga, asihlali kunye = 4 *Not married, not living together* Enye = 5, cacisa:_____ *Other, specify*
22.	Lileshe ellingakanani unobudlelwana nalomntu? *How long have you been in a relationship with this person?*	Ixesha Inyanga *Months*_____ *Duration in:* Iminyaka *Years*_____
23.	Ingaba eli qabane lakho ngutata womnye wabantwana bakho(kunye nalo umkhulelweyo)? *Is your current partner the parent of any of your children? (including current pregnancy)*	Hayi/*No* = 0 Ewe/*Yes* = 1
24.	Ulichazele na iqabane lakho ngesimo sakho sentsholongwane? *Have you disclosed your HIV status to your current partner?*	Hayi/*No* = 0 Ewe/*Yes* = 1
25.	Ubukhe wabelana ngesondo nabanye abantu ingenguye lomntu uthandana naye? *In the last 12 months have you had any sexual relationships/sexual partners? (if in a relationship then other than this partner)*	Hayi/*No* = 0 → **Gqithela ku Q28** ***→ SKIP to Q 28*** Ewe/*Yes* = 1
26.	Bunjani ubudlelwanebakho namanye amaqabane ngaphandle kweqabane lakho langoku ukuba akhona? *What is the nature of your relationship(s)? (other than current partner if applicable)* Rhangqa konke okungqamene nawe. *Mark all that apply.*	a. Umlingane/nditshatile *Spouse/ married* b. Iqabane lam *Boyfriend* c. Iqabane lethutyana *Casual Partner/One Night Stands* d. Omnye ,cacisa:_____ *Other, specify*
27.	Ubaxelele aba bantu wabelana nabo ngesondo ukuba uphila nentsholongwane? *Have you disclosed your HIV status to any of these other sexual partners?*	Hayi/*No* = 0 Ewe/*Yes* = 1
28.	Ubuqala ukufumanisa ukuba unentsholongwa kagawulayo kolumitho okanye phambi kokuba ukhulelwe? *Did you first test HIV positive in this pregnancy or before this pregnancy?*	Koku ukukhulelwa =1 → Gqithela ku Q32 *In his pregnancy* ***SKIP to Q32*** Phambi koku ukukhulelwa =2 *Before this pregnancy*
29.	Kwakunini ukuqala kwakho ukufumanisa ukuba unentsholongwane kagawulayo? *When did you 1st test HIV-positive?*	Umhla:___ Inyanga:_____ Unyaka:_____ Day Month Year
30.	Kwakutheni ukuze oluhlolo lwenziwe? *Why was this test conducted?*	Ndivavanywe ngelixesha ndikhulelweyo = 1 *Tested during pregnancy* VCT/Ndandifuna ukuvavanywe =2 *VCT/Wanted to be tested* Ndafunyaniswa ndinesifo sephepha (TB) = 3 *Diagnosed with TB* Ndangeniswa esibhedlele = 4 *Admitted to the hospital* Enye = 5, cacisa:_____ *Other, specify*

Initials of counsellor: _____

31.	Ingaba wawukhulelwe ukuqala kwakho ukufumane ukuba unentsholongwane kagawulayo? *Were you pregnant when you first tested HIV-positive?*	Hayi/*No* = 0 Ewe/*Yes* = 1
32.	Wakhe wanazo iziphumo ezingena chaphaza kuvavanyo lwentsholongwane kagawulayo? *Have you ever tested negative on an HIV test?*	Hayi/*No* = 0 →Gqithela ku Q36 ***SKIP to Q36*** Ewe/*Yes* = 1
33.	Ugqibele nini ukuba neziphumo ezingenachaphaza zovavanyo lwentsholongwane kagawulayo? *When did you last test HIV-negative?*	Umhla:___ Inyanga:_____ Unyaka:_____ Day Month Year
34.	Kwakutheni ukuze uvavanywe ngelo xesha? What was the reason for you doing the HIV test? *Why did you test at that time?*	Ndivavanywe ngelixesha ndikhulelweyo = 1 *Tested during pregnancy* VCT/Ndandifuna ukuvavanywe =2 *VCT/Wanted to be tested* Ndafunyaniswa ndinesifo sephepha (TB) = 3 *Diagnosed with TB* Ndangeniswa esibhedlele = 4 *Admitted to the hospital* Enye = 5, cacisa:_____ *Other, specify*
35.	Wawukhulelwe ngeloxesha uvavanyelwa intsholongwane? *Were you pregnant at the time of that test?*	Hayi/*No* = 0 Ewe/*Yes* = 1
36.	Wakhe waxelela nabanina ukuba unentsholongwane kagawulayo? *Have you told anyone that you are HIV-positive?*	Hayi/*No* = 0 →Gqithela ku Q39 ***SKIP to Q39*** Ewe/*Yes* = 1
37.	Ngawaphi amlungu osapho lwakho owaxeleleyo ngesimo sakho sentsholonwane? *Which of your family members have you told about your HIV status?* Nceda phendula lombuzo ngelungu ngalinye losapho oludweliswe ngezantsi. *Please answer this question for each of the family members listed below.* Wamxelele u_ _ _ _ _ _ _ ukuba unentsholongwane kagawulayo? *Have you told your _____ that you are HIV positive?*	
a.	Umyeni/*iqabane* *Husband/partner/boyfriend*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
b.	Umama *Mother*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
c.	Utata *Father*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
d.	Udade *Sister*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
e.	Umtakwenu *Brother*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
f.	Intombi *Daughter*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
g.	Unyana *Son*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
h.	Umalume *Uncle*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
i.	U-anti *Aunt*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9

Initials of counsellor: _____

j.	Umza wesikhomo *Male cousin*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
k.	Umza wesikhomokazi *Female cousin*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
l.	Enye indoda yalapha *Other male family member*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
m.	Esinye isikhomokazi *Other female family member*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
38.	Ngaphandle kwabantu bakowenu aba badweliswe ngentla,ngubani omnye umntu owamxelelyo ukuba uphila nentsholongwane?(funda uphendule yonke imibuzo) *Aside from family members listed above, who else have you told about your HIV status? (read and answer for all)*	
a.	Amanesi/ogqira *Health professionals*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
b.	Iqumru lenxaso labantu abaphila nentsholongwane *Support group*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
c.	Umntu owabelana naye ngesondo ongahlali naye *A sexual partner who does not live with you*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
d.	Isihlobo *Friends*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
e.	Inkokheli ngokwa kwamoya *Spiritual leader*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
f.	Umntu okuqashileyo/wayekuqashile *Current or former employer*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
g.	Ukuchaza esidlangalaleni *Public disclosure/ community*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
h.	Abanye, chaza: _____ *Other, specify*	Hayi/*No* = 0 Ewe/*Yes* = 1 N/A = 9
39.	Wakhe wakhulelwa phambi koku ukukhulelwa? *Have you ever been pregnant before this pregnancy?*	Hayi/*No* = 0 →Gqithela ku Q45 ***SKIP to Q45*** Ewe/*Yes* = 1
40.	Ngokuya ubukhulelwe ngaphambi koku ukukhulelwa wawuke wanikwa amayeza okhusela usana lungosuleleki yintsholongwane (ezeku khusela umntwana hayi amachiza okutho malalisa intsholongwane wobomi bonke) *When you were pregnant before this pregnancy have you ever been given medication at the clinic to keep your baby from getting HIV infected? (prophylaxis NOT lifelong ART)*	Hayi/*No* = 0 →Gqithela ku Q45 ***SKIP to Q45*** Ewe/*Yes* = 1
41.	Ukuba nguEwe, zingaphi izisu ufumane la machiza ngesisizathu? *If yes, during how many pregnancies have you received medication for this purpose?*	Inani lezisu:_____ *# of pregnancies*

Initials of counsellor: _____

42.	Kwezi zisu siyi____ofumene kuzo amachiza, zingaphi izisu otye kuzo iipilisi ngelixesha ubelekayo qha? *For the ___ pregnancies that you received medication, For how many pregnancies did you take pills while you were pregnant and for how many pregnancies did you take pills only at delivery?*	Ngoku wawubeleka *Only at Delivery (Nevirapine) #:*_____ Ngelixesha ukhulelwe *While you were pregnant (AZT)? #:* _____
43.	Bekunini ukugqibela kwakho ukufumana la machiza ngesisizathu? *When was the last time that you received medication for this purpose?*	Umhla:___ Inyanga:_____ Unyaka:_____ Day Month Year
44.	Uwafumene phi la machiza ukugqibela kwakho? *Where did you receive the medication the last time?*	Igama lekliniki:_____ *Name of clinic:*
45.	Wawuke wawathatha amachiza okuthomalalisa intsholongwane (awobomi bakho bonke) *Have you ever taken triple drug antiretroviral therapy (lifelong ART)?*	Hayi/*No* = 0 → Skip to Q51 Ewe/*Yes* = 1
46.	Ukuba nguEwe, ingaba wawafumana amachiza okuthomalalisa intsholongwane ukugqibela kakho? *If yes, where did you receive ART the last time?*	Igama lekliniki:_____ *Name of clinic:*
47.	Uqale nini ukutya la machiza okuthomalalisa intsholongwane kagawulayo? *When did you start taking ART?*	Umhla:___ Inyanga:_____ Unyaka:_____ Day Month Year
48.	Usawatya amachiza okuthomalalisa intsholongwane kagawulayo? *Are you still on ART?*	Hayi/*No* = 0 Ewe/*Yes* = 1→ SKIP to Q51
49.	Ukuba nguHayi,uyeke nini ukuwatya amachiza okuthomalalisa intsholongwane kagawulayo? *If No, when did you stop taking ART?*	Umhla:___ Inyanga:_____ Unyaka:_____ Day Month Year

Initials of counsellor: _____

50.	Uyekele ntoni ukutya amachiza athomalalisa intsholongwane? *Why did you stop taking ART?* (rhagqa zonke ezibhekisa kuwe) *Circle all that apply*	a. Ndaphelelwa ngumchiza andaya ukuyakuwalanda *I ran out of medicine and didn't go for refills* b. Anencasa embi *The medicine tastes bad* c. Ndulibala *I just forgot* d. Bendikhathazwa yimiphumela yawo *I was worried about the side effects* e. Bendingafuni abanye bandiqaphele ukuba nditya amachiza *I did not want others to notice me taking the medicine* f. Ndandigula *I was ill* g. Ndacinga ukuba andisawafuni nganto *Didn't think I needed it anymore* h. Bendicinga ndingahlala ndiphilile ngaphandle kwawo *Can stay healthy without it* i. Bendicinga ukuba lamayeza anganobu ngozi kum. *I felt the medicine might be harmful to me* j. Ndizive ndinoxinizelelo *I felt depressed* k. Ndandiphilile *I was well* l. Ebemaninzi la machiza ekufuneka ndiwathathe *There was too much medicine to take* m. Bendingekho ekhaya *I was away from home* n. Bendixakekile zezinye izinto *I was busy with other things* o. Ndiye ndafunda ukuba zikho ezinye iindlela endinganyanga okanye ndiphilise intsholongwane kagawulayo *I learned that there are other ways to treat or cure HIV* p. Enye, cacisa: _____ *Other, Specify*
51.	Ubukhe watshaya isagarethi kulenyanga iphelileyo? *Did you smoke cigarettes in the last month?*	Hayi *No* = 0 → END Ewe *Yes* = 1
52.	Utshaya isigarethi ezingaphi ngemini? *How many cigarettes do you smoke in a day?*	#_____ cigarettes

Date completed: _ _ /_ _ _ / _ _ _ _ Signed counsellor completing CRF: _____

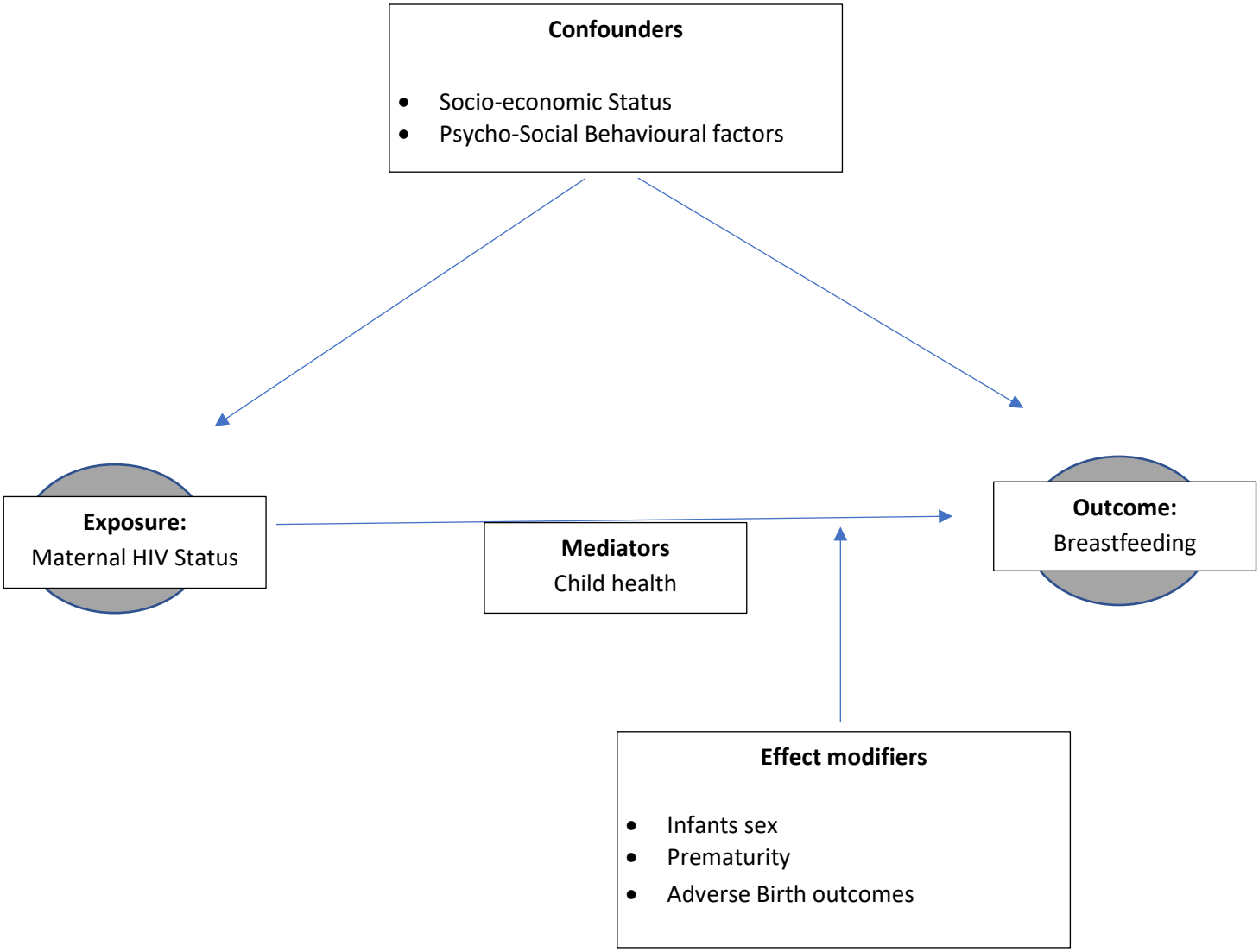
Date of QC: _ _ /_ _ _ / _ _ _ _ Signed measurement nurse: _____

Initials of counsellor: _____

APPENDIX G

- Directed Acyclic Graph (DAG) -

Directed Acyclic Graph



APPENDIX H

- MCH-ART study informed consent form, Phase 2 -

TITLE OF RESEARCH: **Strategies to optimize antiretroviral therapy services for maternal & child health: the MCH-ART study**

WHAT IS THE PURPOSE OF THIS STUDY?
We are from the University of Cape Town and ICAP at Columbia University. You are being asked to take part in a study that is being conducted at the Gugulethu Midwife Obstetric Unit (MOU). The purpose of this study is to understand how to improve health care services for HIV-positive women during their pregnancy and after they deliver the baby.

We know that it is important for their own health as well as the health of their baby, that HIV-positive women receive the HIV care and treatment that they need both during and after delivery. Information learned in this study will help us to improve HIV services for pregnant women.

You are being asked to take part in this study because you are a pregnant woman with known HIV infection who is about to start taking HIV drugs (antiretroviral therapy) and you took part in the first phase of the study. The purpose of this consent form is to give you information to help you decide if you want to take part in the next phase of this study.

WHAT DO I HAVE TO DO IF I AGREE TO TAKE PART?
If you agree to take part, you will come in for up to 3 visits. These visits will take place today while you are in the clinic, when you are getting close to delivering your baby and within one week of delivering your baby. These study visits are separate from the usual clinic visits that you will have for your pregnancy and HIV care. Study visits will be timed so that they take place on the same days that you come in for your usual pregnancy and/or HIV care.Each visit will take about 30-45 minutes.

At the two visits that are conducted *while you are pregnant*, you will do the following:

- Answer questions about your recent pregnancy- and HIV-related health care, HIV disclosure, and use of HIV drugs (including side effects and adherence).
    - At different visits, we will ask you additional questions about HIV, stigma, social support, infant feeding practices, family planning, experiences of partner violence, and mental health (including drug and alcohol use).
- Have 5mLs (1 teaspoon) of blood drawn from your arm each time

One-week after delivery
One week after you give birth to your baby, you will come to the clinic for a visit that will include the following:

- Answer questions about your recent pregnancy- and HIV-related health care, HIV disclosure, and use of HIV drugs (including side effects and adherence).
    - At this visit, we will ask you additional questions about family planning after delivery, how you felt about the HIV care that you received, infant feeding practices and infant health and health care.
- Have 5mLs (1 teaspoon) of blood drawn from your arm

NOTE: The blood that is drawn today will be stored and used to check your viral load (this is the amount of HIV in your blood) at a later time. Results from these tests will not be available to you, the clinic, or the study staff. When the health care providers at the clinic need to check your viral load, they will take a separate blood specimen. When it is stored, your blood and test results will not have your name or any other way of identifying you attached to it.

Follow-up of missed visits
You will be asked to provide contact information so that we may get in touch with you during the study. Study staff will talk with you about the best way to contact you. In the event that you miss one of the scheduled study visits, a member of the study staff will contact you in order to find another day and time to complete your visit. If you repeatedly miss study visits or the staff is unable to contact you using the information that you provide, it may be necessary to visit you at home in order to reschedule the missed study visit.

Contact for future study
After the completion of the visit one week after delivery, *it is possible that we will contact you again at your next clinic visit or at another time in the future to take part in additional research studies. At that time, you would be asked to review and sign another consent form. You can choose to not take part in any future studies if you are asked.* You will be asked to provide contact information so that we may get in touch with you regarding additional research studies. Study staff will talk with you about the best way to contact you.

WHAT ARE THE POTENTIAL RISKS?
You may feel uncomfortable about some of the personal questions you are asked. You may refuse to answer any question that you do not want to answer. There is some risk in sharing personal and medical information. We will be careful to keep all your information as private as possible.

Drawing blood is normally done as part of routine medical care and presents a slight risk of discomfort. Experienced staff will draw blood under sterile conditions in order to protect you against these risks.

WHAT ARE THE POTENTIAL BENEFITS?
There is no direct benefit to you if you take part in this study. The information gained in this study may help to improve ART services for HIV-infected pregnant women in Cape Town, the Western Cape Province, and across South Africa.

WHAT ARE THE ALTERNATIVES TO TAKING PART?
The alternative to taking part in this study is to continue with your usual care at the MOU.

WHAT ABOUT CONFIDENTIALITY?
If you agree to take part, all information collected during the study will be kept strictly confidential. Your name will not be written on the study forms and will not be used in connection with any information or lab specimens that are collected as part of the study.

All study materials will be stored in locked filing cabinets. Only study staff and personnel involved in routine audits will have access to these materials. All staff involved in data collection and management will get specific training in confidentiality.

Even with these procedures in place, if the study staff learns that you are a risk to yourself or someone else or of possible child abuse and/or neglect, study staff will tell the proper authorities.

WILL I BE GIVEN ANYTHING FOR TAKING PART?
At the end of each visit, you will be given R20 in cash to cover the transport cost to your next scheduled study visit, and anR80grocery voucher. You will also receive a small gift for the first visit after birth and refreshments will be provided at all visits.

ARE THERE ANY COSTS?
There is no cost for being in this study.

CAN I LEAVE THE STUDY?
You have the right to decide not to not take part in the study, to refuse to answer any questions, or to withdraw from the study at any time without any penalty. It will have no effect on the care that you receive at the Gugulethu MOU or any other health facility.

FUTURE USE OF SPECIMENS:
If you agree, any leftover blood from the samples you have provided for this research project may be used for future HIV related research. It is possible that these stored samples may be tested to see if the HIV in your blood is resistant to any types of HIV medications or to look at other questions related to HIV.

At this time, we cannot provide details of when this testing may be conducted. However, additional testing will not be done using these stored samples without the approval of the appropriate ethics committees involved in this research.

If you agree to let us keep your stored samples for future research, they may be kept in a locked freezer for up to 5 years. If we do use your samples in the future, your name or other identifiers will not be included with this information (as with the rest of the information we collect for this study).

Please initial below to indicate whether or not you give permission for your specimens to be used for future research. You may still remain in the study, no matter which you choose.

_____ (initial) I agree to have my blood stored for future research.

_____ (initial) I agree to have my blood stored for future research related to this study ONLY.

_____ (initial) I do NOT agree to the storage of my blood for future use.

DO YOU HAVE ANY QUESTIONS?
If there is anything that is unclear or if you need further information, please ask us and we will provide it.

Do you have any questions?

FOR ADDITIONAL INFORMATION:
If you have any questions or have any problems while taking part in this research study, you should contact:

Dr Landon Myer
School of Public Health and Family Medicine
Faculty of Health Sciences, University of Cape Town
Tel: 021 406 6661
Email: Landon.Myer@uct.ac.za

Dr Elaine Abrams
ICAP, Columbia University
Mailman School of Public Health
College of Physicians and Surgeons
Tel: +1 212 342 0543
Email: eja1@columbia.edu

If you have any questions about your rights as a research participant, you may contact the following member of the ethics committee:

Prof Marc Blockman
Chair, Human Research Ethics Committee
Faculty of Health Sciences, University of Cape Town
Tel: 021 406 6338

Columbia University Medical Center IRB
Tel: +1 212 305 5883

Phase 2 Informed Consent Form

CONSENT STATEMENT:
I have read this form, or someone has read it to me. I have been offered a copy of this consent form. I was encouraged and given time to ask questions. I agree to be in this study. I know that after choosing to be in this study, I may withdraw at any time. My being in the study is voluntary. I understand that whether or not I participate will not affect my health care services received today, or at any time in the future.

Please indicate your consent with your signature.

Volunteer's name _____

_____
Signature of Volunteer Date

Staff member's name _____

_____
Signature of study staff Date

If the volunteer is unable to read or write the entire counselling process must be observed by an independent witness who can then confirm the procedure once the she has given consent.

Fingerprint of volunteer:

Witness:
I confirm that I am independent of the study and that I witnessed the entire informed consent counselling process in the home language of the volunteer

Name:_____

Signature: _____

Date: _____

Thank you.

APPENDIX I

- MCH-ART study informed consent form, Phase 3 -

TITLE OF RESEARCH: **Strategies to optimize antiretroviral therapy services for maternal & child health: the MCH-ART study**

WHAT IS THE PURPOSE OF THIS STUDY?
We are from the University of Cape Town and ICAP at Columbia University. You are being asked to take part in a study that is being conducted at the Gugulethu Midwife Obstetric Unit (MOU). The purpose of this study is to compare two different ways of providing HIV treatment to women after they deliver a baby.

We know that it is important for their own health as well as the health of their baby, that HIV-positive women receive the HIV care and treatment that they need both during and after delivery. Information learned in this study will help us to improve HIV services for pregnant women.

You are being asked to take part in this study because you are woman with known HIV infection who is currently breastfeeding a baby and who is taking HIV drugs. In addition, you have taken part in the previous phases of this study. The purpose of this consent form is to give you information to help you decide if you want to continue to take part in the last phase of this study.

WHAT DO I HAVE TO DO IF I AGREE TO TAKE PART?
If you agree to take part, you will be randomized (like a flip of a coin) to one of two places to receive your ART, as described below:

1. MCH-focused ART services group: Women assigned to this group will continue to receive HIV care and medicines here, at the MOU, as they did during their pregnancy. Their babies will also receive their routine baby care here at the MOU. When they have stopped breastfeeding, women in this group will be referred to their nearest general ART clinic, and their babies to their nearest City of Cape Town clinic for routine baby care

2. General ART services group: Women assigned to this group will be referred to the nearest ART clinic for HIV care and to continue their HIV medicines. Their babies will be referred to their nearest clinic for routine baby care.

   This is currently the standard of care for all HIV-positive woman and their babies attending the MOU.

"Randomized" means that you will have a 50% chance of being in the group that will stay at the MOU to receive care. You will also have a 50% chance of being in the group that gets referred to an ART clinic. Neither the study staff nor you can choose which group you will be assigned to. The decisions are made by a computer and put into an envelope. The staff does not know which group is in each envelope.

This randomization will occur today and you and your baby will then come in for up to 6 additional study measurement visits at 6 weeks after delivery and 3, 6, 9, 12 and 15 months after delivery. These study visits are separate from the usual clinic visits that you will have for your postpartum and HIV care. Study visits will be timed so that they take place on the same days that you come in for your usual postpartum and/or HIV care. Each visit will take about 30-60 minutes.

These visits will include the following:

- Answer questions about your recent pregnancy- and HIV-related health care, HIV disclosure, and use of HIV drugs (including side effects and adherence).
    - At selected visits, we will ask you additional questions about HIV, stigma, and mental health (including drug and alcohol use), family planning, infant feeding practices, infant health and health care and how you feel about the HIV care that you have received.
- Have 5mLs (1 teaspoon) of blood drawn from your arm
- Measurement of weight, length, head circumference and mid-upper arm circumference of your baby.
- Measurement of your height at the first visit and your weight and mid-upper arm circumference at all study visits

NOTE: The blood that is drawn at each visit will be stored and used to check your viral load (this is the amount of HIV in your blood) at a later time. Results from these tests will not be available to you, the clinic, or the study staff. When the health care providers at the clinic need to check your viral load, they will take a separate blood specimen. When it is stored, your blood and test results will not have your name or any other way of identifying you attached to it.

At both the 12 and 15 month visits, we will also draw blood from your baby:

- Baby will undergo a blood draw to collect up to 5ml of blood (no more than 1 teaspoon).
- This blood will be used to check your baby's HIV status.
    - We will return the results of this test to you as soon as it is available.

Follow-up of missed visits

You will be asked to provide contact information so that we may get in touch with you during the study. Study staff will talk with you about the best way to contact you. In the event that you miss one of the scheduled study visits, a member of the study staff will contact you in order to find another day and time to complete your visit. If you repeatedly miss study visits or the staff is unable to contact you using the information that you provide, it may be necessary to visit you at home in order to reschedule the missed study visit.

Contact for future study

After the completion of your last visit at **15 months postpartum**, it is possible that we will contact you again at your next clinic visit or at another time in the future to take part in additional research studies. At that time, you would be asked to review and sign another consent form. You can choose to not take part in any future studies if you are asked. You will be asked to provide contact information so that we may get in touch with you regarding additional research studies. Study staff will talk with you about the best way to contact you.

WHAT ARE THE POTENTIAL RISKS?
You may feel uncomfortable about some of the personal questions you are asked. You may refuse to answer any question that you do not want to answer. There is some risk in sharing personal and medical information. We will be careful to keep all your information as private as possible.

Drawing blood is normally done as part of routine medical care and presents a slight risk of discomfort. Experienced staff will draw blood under sterile conditions in order to protect you against these risks.

WHAT ARE THE POTENTIAL BENEFITS?
There is no direct benefit to you if you take part in this study, but if we identify any health care problem for you or your baby during the course of the study, we will make sure you are referred to the appropriate health care services. In addition, the information gained in this study may help to improve ART services for HIV-infected pregnant women in Cape Town, the Western Cape Province, and across South Africa.

WHAT ARE THE ALTERNATIVES TO TAKING PART?
The alternative to taking part in this study is to continue with the standard of care for all HIV-positive pregnant women, which means you will be referred from the MOU to your nearest general ART clinic, and your baby will be referred to your nearest clinic for routine baby care, as soon as possible.

WHAT ABOUT CONFIDENTIALITY?
If you agree to take part, all information collected during the study will be kept strictly confidential. Your name will not be written on the study forms and will not be used in connection with any information or lab specimens that are collected as part of the study.

All study materials will be stored in locked filing cabinets. Only study staff and personnel involved in routine audits will have access to these materials. All staff involved in data collection and management will get specific training in confidentiality.

Even with these procedures in place, if the study staff learns that you are a risk to yourself or someone else or of possible child abuse and/or neglect, study staff will tell the proper authorities.

WHAT ABOUT INSURANCE?
There are no experimental medicines being used in this study. Therefore no insurance has been obtained. However you will be protected in terms of the study staffs' personal malpractice insurance or that of the university in the event of injury or illness that is caused by you taking part in this study.

If you sign this form, you do not give up any of the legal rights that you and your child have as research participants.

WILL I BE GIVEN ANYTHING FOR TAKING PART?
At the end of each visit, you will be given R20 in cash to cover the transport cost to your next scheduled study visit, and an R80 grocery voucher. Refreshments will be provided at all visits. You will also receive a small gift, up to the value of R50, at the final study visit when your baby is 12 months old.

ARE THERE ANY COSTS?
There is no cost for being in this study.

CAN I LEAVE THE STUDY?
You have the right to decide not to not take part in the study, to refuse to answer any questions, or to withdraw from the study at any time without any penalty. It will have no effect on the care that you receive at the Gugulethu MOU or any other health facility.

FUTURE USE OF SPECIMENS:
If you agree, any left over blood from the samples you have provided for this research project and the sample taken from your baby at the 12 and 18 month study visit, may be used for future HIV and maternal and child health related research. It is possible that these stored samples may be tested to see if the HIV in your blood is resistant to any types of HIV medications or to look at other questions related to HIV. It is also possible that the stored blood from you and your baby may be used to look at other questions related to maternal and child health.

At this time, we cannot provide details of when this testing may be conducted. However, additional testing will not be done using these stored samples without the approval of the appropriate ethics committees involved in this research.

If you agree to let us keep your and/or your baby's stored samples for future research, they will be kept in a locked freezer for up to 5 years. If we do use the samples in the future, your name, your baby's name or other identifiers will not be included with this information (as with the rest of the information we collect for this study).

Please initial below to indicate whether or not you give permission for your and/or your baby's specimens to be used for future research. You may still remain in the study, no matter which you choose.

Consent for storage of your blood:

_____ (initial) I **agree** to have my **blood stored for future research.**

_____ (initial) I **agree** to have my **blood stored for future research** related to this study ONLY.

_____ (initial) I **do NOT agree** to the storage of my blood for future use.

Consent for storage of your baby's blood taken at the 12 and 18 month visit:

_____ (initial) I **agree** to have my baby's **blood stored for future research.**

_____ (initial) I **agree** to have my baby's **blood stored for future research** related to this study ONLY.

_____ (initial) I **do NOT agree** to the storage of my baby's blood for future use.

DO YOU HAVE ANY QUESTIONS?
If there is anything that is unclear or if you need further information, please ask us and we will provide it.
Do you have any questions?

FOR ADDITIONAL INFORMATION:
If you have any questions or have any problems while taking part in this research study, you should contact:

Dr Landon Myer
School of Public Health and Family Medicine
Faculty of Health Sciences, University of Cape Town
Tel: 021 406 6661
Email: Landon.Myer@uct.ac.za

Dr Elaine Abrams
ICAP, Columbia University
Mailman School of Public Health
College of Physicians and Surgeons
Tel: +1 212 342 0543
Email: eja1@columbia.edu

If you have any questions about your rights as a research participant, you may contact the following member of the ethics committee:

Prof Marc Blockman
Chair, Human Research Ethics Committee
Faculty of Health Sciences, University of Cape Town
Tel: 021 406 6338

Columbia University Medical Center IRB
Tel: +1 212 305 5883

Phase 3 Informed Consent Form

CONSENT STATEMENT:
I have read this form, or someone has read it to me. I have been offered a copy of this consent form. I was encouraged and given time to ask questions. I agree to be in this study. I know that after choosing to be in this study, I may withdraw at any time. My being in the study is voluntary. I understand that whether or not I participate will not affect my health care services received today, or at any time in the future.

Please indicate your consent with your signature.

Volunteer's name _____

_____
Signature of Volunteer Date

Staff member's name_____

_____
Signature of study staff Date

If the volunteer is unable to read or write the entire counselling process must be observed by an independent witness who can then confirm the procedure once the she has given consent.

Fingerprint of volunteer:

Witness:
I confirm that I am independent of the study and that I witnessed the entire informed consent counselling process in the home language of the volunteer
Name: _____

Signature: _____

Date: _____

Thank you.

APPENDIX J

- HU2 study informed consent form, Antenatal Phase -

TITLE OF RESEARCH: **Growth, morbidity and development of HIV-unexposed infants: a prospective cohort study**

WHAT IS THE PURPOSE OF THIS STUDY?

We are from the University of Cape Town. You are being asked to take part in a study that is being conducted at the Gugulethu Midwife Obstetric Unit (MOU). The purpose of this study is to investigate how babies grow and learn during their early life, and to identify possible ways to help mothers so that their babies can grow and learn at their best. This study will also help us to understand possible reasons for any differences seen between babies whose mothers have HIV infection and babies whose mothers are HIV negative.

We know that the mother's health during pregnancy, after delivery and during breastfeeding can affect how babies grow and learn during the first year of life. You are being asked to take part in this study because you are an HIV-negative pregnant women receiving antenatal care at the Gugulethu MOU. The purpose of this consent form is to give you information to help you decide if you want to take part in this study.

WHAT DO I HAVE TO DO IF I AGREE TO TAKE PART?

If you agree to take part, you will come in for up to 3 visits. These visits will take place today while you are in the clinic, when you are getting close to delivering your baby and within one week of delivering your baby. These study visits are separate from the usual clinic visits that you will have for your pregnancy and infant care. Study visits will be timed so that they take place on the same days that you come in for your usual pregnancy and/or other care. Each visit will take about 30-60 minutes.

At the two visits that are conducted *while you are pregnant*, you will do the following:

- Answer questions about your recent pregnancy- and general health care
    - At different visits, we will ask you additional questions about social support, infant feeding plans, family planning, experiences of partner violence, and mental health (including drug and alcohol use).
- Have an ultrasound ("scan") test to help us to work out how old your unborn baby is, and to evaluate the growth of your baby during pregnancy

One week after delivery:
Within one week after you give birth to your baby, you will come to the clinic for a visit that will include the following:

- Answer questions about your recent pregnancy and delivery
- Answer questions about family planning after delivery, infant feeding practices and infant health and health care.

Review of medical records
As part of this study, we will also be looking at and taking information from your antenatal, obstetric, laboratory and pharmacy records. From these records, we are interested in learning about the pregnancy care you received as well as information about your delivery. We also want to learn about any tests, procedures or treatment that you received after delivery. Finally, we want to learn about your baby's health status after delivery as well.

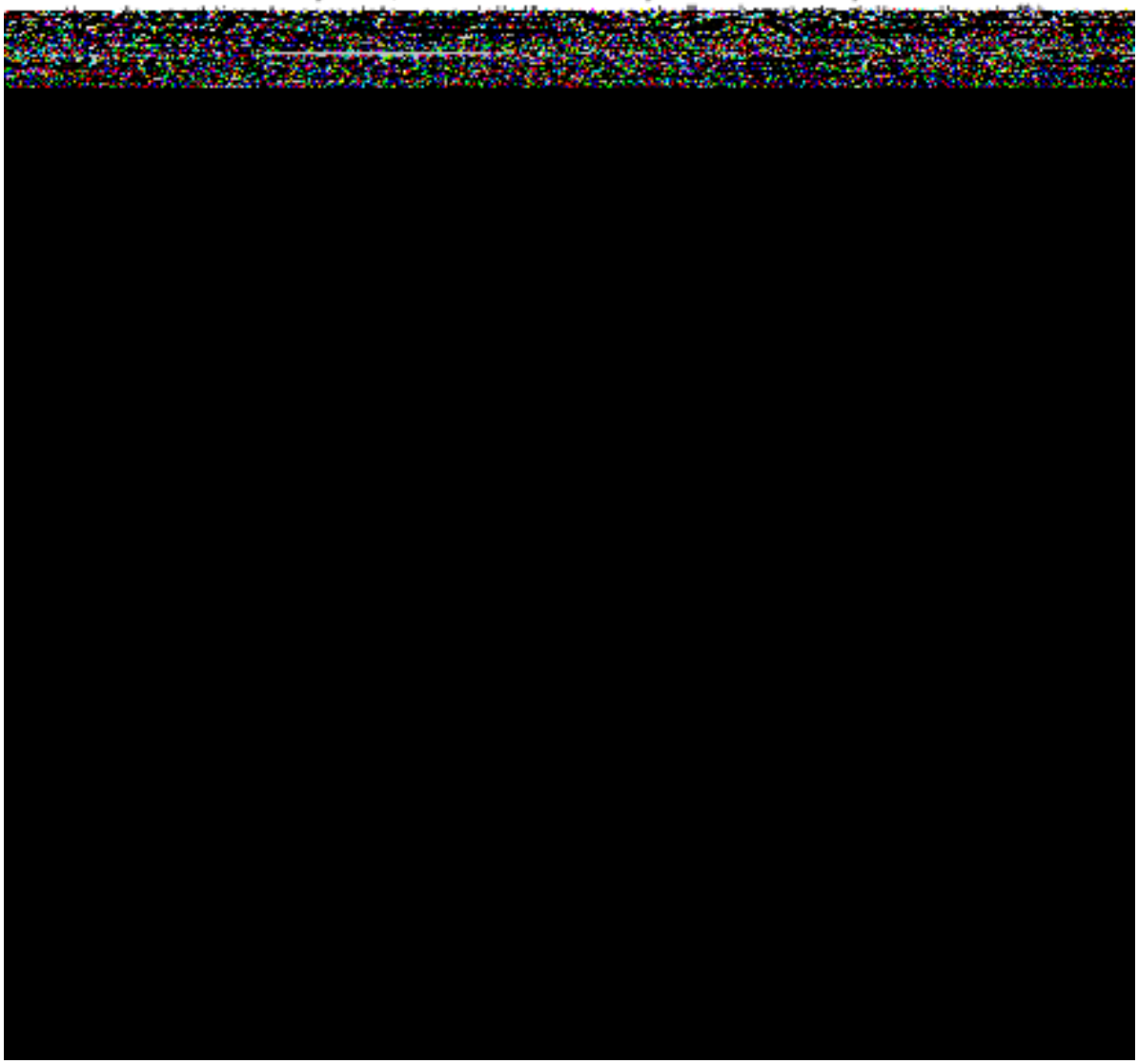
Ultrasound measurements

Fetal ultrasound is commonly used to determine the duration of the pregnancy (how old the unborn baby is), the expected delivery date, to find problems with the development of the baby, and to see if there are any pregnancy complications. When you have an ultrasound, the sonographer (person doing the scan) places a small amount of gel onto the skin of the abdomen (stomach area), and uses a rounded, hand-held device to transmit sound waves into the body through the skin. The sound waves are reflected off the body, and turned into a picture on the monitor. The ultrasound test takes between 10-30 minutes, and is safe for you and your baby.

These ultrasound scans in no way replace the routine antenatal care that you receive at Gugulethu MOU. If your health care providers at the MOU need an ultrasound scan, they will do this during your routine care. However, if during a research scan, we detect any problems or abnormalities, you will be immediately referred to your usual antenatal care providers for further tests and treatment.

Follow-up of missed visits

You will be asked to provide contact information so that we may get in touch with you during the study. Study staff will talk with you about the best way to contact you. In the event that you miss one of the scheduled study visits, a member of the study staff will contact you in order to find



WHAT ABOUT CONFIDENTIALITY?
If you agree to take part, all information collected during the study will be kept strictly confidential. Your name will not be written on the study forms and will not be used in connection with any information or lab specimens that are collected as part of the study.

All study materials will be stored in locked filing cabinets. Only study staff and personnel involved in routine audits will have access to these materials. All staff involved in data collection and management will get specific training in confidentiality.

Even with these procedures in place, if the study staff learns that you are a risk to yourself or someone else or of possible child abuse and/or neglect, study staff will tell the proper authorities.

WILL I BE GIVEN ANYTHING FOR TAKING PART?
At the end of each visit, you will be given R20 in cash to cover the transport cost to your next scheduled study visit, and an R80 grocery voucher. After the ultrasound measurements, you will be given a small black and white print of the picture of your unborn baby. You will also receive a small gift for the first visit after birth and refreshments will be available at each visit.

ARE THERE ANY COSTS?
There is no cost for being in this study.

CAN I LEAVE THE STUDY?
You have the right to decide not to not take part in the study, to refuse to answer any questions, or to withdraw from the study at any time without any penalty. It will have no effect on the care that you receive at the Gugulethu MOU or any other health facility.

DO YOU HAVE ANY QUESTIONS?
If there is anything that is unclear or if you need further information, please ask us and we will provide it.

Do you have any questions?

FOR ADDITIONAL INFORMATION:
If you have any questions or have any problems while taking part in this research study, you should contact:

Dr Stanzi le Roux
School of Public Health and Family Medicine
Faculty of Health Sciences, University of
Cape Town
Tel: 082 925 8259
Email: stanzi.leroux@gmail.com

If you have any questions about your rights as a research participant, you may contact the following member of the ethics committee:

Prof Marc Blockman
Chair, Human Research Ethics Committee
Faculty of Health Sciences, University of Cape
Town
Tel: 021 406 6338

CONSENT STATEMENT:
I have read this form, or someone has read it to me. I have been offered a copy of this consent form. I was encouraged and given time to ask questions. I agree to be in this study. I know that after choosing to be in this study, I may withdraw at any time. My being in the study is voluntary. I understand that whether or not I participate will not affect my health care services received today, or at any time in the future.

Please indicate your consent with your signature.

Volunteer's name _____

_____
Signature of Volunteer Date

Staff member's name _____

_____
Signature of study staff Date

If the volunteer is unable to read or write the entire counselling process must be observed by an independent witness who can then confirm the procedure once the she has given consent.

Fingerprint of volunteer:

Witness:
I confirm that I am independent of the study and that I witnessed the entire informed consent counselling process in the home language of the volunteer

Name: _____

Signature: _____

Date: _____

Thank you.

APPENDIX K

- **HU2 study informed consent form, Postnatal Phase -**

TITLE OF RESEARCH: **Growth, morbidity and development of HIV-unexposed infants: a prospective cohort study**

WHAT IS THE PURPOSE OF THIS STUDY?

We are from the University of Cape Town. You are being asked to take part in a study that is being conducted at the Gugulethu Midwife Obstetric Unit (MOU). The purpose of this study is to investigate how babies grow and learn during their early life, and to identify possible ways to help mothers so that their babies can grow and learn at their best. This study will also help us to understand possible reasons for any differences seen between the babies whose mothers have HIV-infection and the babies whose mothers do not have HIV infection.

We know that the mother's health during pregnancy, after delivery and during breastfeeding can affect how babies grow and learn during the first few years of life. You are being asked to take part in this study because you are woman known to have been HIV-negative during pregnancy, and who is currently breastfeeding a baby. In addition, you have taken part in the previous phase of this study. The purpose of this consent form is to give you information to help you decide if you want to continue to take part in the second phase of this study.

WHAT DO I HAVE TO DO IF I AGREE TO TAKE PART?

If you agree to take part, you and your baby will come in for up to 6 additional study measurement visits at 6 weeks, and 3, 6, 9 and 12 months after delivery. These study visits are separate from the usual clinic visits that you and your baby have in the area where you live. Each visit will take about 60 minutes, except the 12 month visit, which will take about 2-3 hours.

These visits will include the following:

- Answer questions about your recent pregnancy-related and general health
- Answer questions about your baby's health and how he/she is feeding
- Measurement of weight, length, head circumference and mid-upper arm circumference of your baby.
- Measurement of your height at the first visit and your weight and mid-upper arm circumference at all study visits
- Assessment of your baby's development at 12 months of age

Review of medical records
As part of this study, we will also be looking at and taking information from your antenatal, obstetric, laboratory and pharmacy records. From these records, we are interested in learning about the pregnancy care you received as well as information about your care and treatment during and after delivery. Finally, we want to learn about your baby's health status after delivery as well.

Neurodevelopmental assessment at 12 months
Between the ages of 11 and 13 months, your baby will be assessed by a trained developmental assessor (a doctor or occupational therapist), in a room separate from the main clinic. You and your baby will be given a snack, and the interviewer will ask you some questions about your baby. Then the developmental assessor will use a developmental test, called the "Bayley Scales of Infant and Toddler Development (3rd edition)". This involves asking some more questions,

and playing with the baby using specific toys and books. The toys are all designed for young babies and are safe.

Follow-up of missed visits
You will be asked to provide contact information so that we may get in touch with you during the study. Study staff will talk with you about the best way to contact you. In the event that you miss one of the scheduled study visits, a member of the study staff will contact you in order to find another day and time to complete your visit. If you repeatedly miss study visits or the staff is unable to contact you using the information that you provide, it may be necessary to visit you at home in order to reschedule the missed study visit.

Contact for future study
After the completion of your last visit at 12 months postpartum, it is possible that we will contact you again at your next clinic visit or at another time in the future to take part in additional research studies. At that time, you would be asked to review and sign another consent form. You can choose to not take part in any future studies if you are asked. You will be asked to provide contact information so that we may get in touch with you regarding additional research studies. Study staff will talk with you about the best way to contact you.

WHAT ARE THE POTENTIAL RISKS?

You may feel uncomfortable about some of the personal questions you are asked. You may refuse to answer any question that you do not want to answer. There is some risk in sharing personal and medical information. We will be careful to keep all your information as private as possible.

Your baby may become unsettled during the developmental assessment. The assessors are however experienced in dealing with small children, and if your baby shows signs of being upset (such as crying, whining or refusing), the test will be interrupted for 5-10 minutes. If the baby still remains upset, testing will discontinue and we will arrange another date for the assessment. We will not do developmental testing on your baby if he/she is ill, but will reschedule the visit.

WHAT ARE THE POTENTIAL BENEFITS?

There is no direct benefit to you if you take part in this study, but if we identify any health care problem for you or your baby during the course of the study, we will make sure you are referred to the appropriate health care services. If the developmental assessment identifies any significant delay in your baby's development we will refer you to the developmental clinic at Red Cross War Memorial Children's Hospital. In addition, the information gained in this study may help to improve health care for pregnant women and their babies in Cape Town, the Western Cape Province, and across South Africa.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

The alternative to taking part in this study is to continue with the standard of care mother and child health services, which are the clinics and referral centers you would normally attend.

WHAT ABOUT CONFIDENTIALITY?

If you agree to take part, all information collected during the study will be kept strictly confidential. Your name will not be written on the study forms and will not be used in connection with any information or lab specimens that are collected as part of the study.

All study materials will be stored in locked filing cabinets. Only study staff and personnel involved in routine audits will have access to these materials. All staff involved in data collection and management will get specific training in confidentiality.

Even with these procedures in place, if the study staff learns that you are a risk to yourself or someone else or of possible child abuse and/or neglect, study staff will tell the proper authorities.

WHAT ABOUT INSURANCE?

There are no experimental medicines being used in this study. Therefore no insurance has been obtained. However you will be protected in terms of the study staffs' personal malpractice insurance or that of the university in the event of injury or illness that is caused by you taking part in this study.

If you sign this form, you do not give up any of the legal rights that you and your child have as research participants.

WILL I BE GIVEN ANYTHING FOR TAKING PART?

At the end of each visit, you will be given R20 in cash to cover the transport cost to your next scheduled study visit, and an R80 grocery voucher. Refreshments will be provided at study visits. You will also receive a small gift, up to the value of R50, at the final study visit when your baby is 12 months old.

ARE THERE ANY COSTS?

There is no cost for being in this study.

CAN I LEAVE THE STUDY?

You have the right to decide not to not take part in the study, to refuse to answer any questions, or to withdraw from the study at any time without any penalty. It will have no effect on the care that you receive at the Gugulethu MOU or any other health facility.

DO YOU HAVE ANY QUESTIONS?

If there is anything that is unclear or if you need further information, please ask us and we will provide it.

Do you have any questions?

FOR ADDITIONAL INFORMATION:

If you have any questions or have any problems while taking part in this research study, you should contact:

Dr Stanzi le Roux
School of Public Health and Family Medicine
Faculty of Health Sciences, University of
Cape Town
Tel: 0829258259
Email: stanzi.leroux@gmail.com

If you have any questions about your rights as a research participant, you may contact the following member of the ethics committee:

Prof Marc Blockman
Chair, Human Research Ethics Committee
Faculty of Health Sciences, University of Cape
Town
Tel: 021 406 6338

CONSENT STATEMENT:

I have read this form, or someone has read it to me. I have been offered a copy of this consent form. I was encouraged and given time to ask questions. I agree for my baby and I to be in this study. I know that after choosing to be in this study, we may withdraw at any time. Our being in the study is voluntary. I understand that whether or not we participate will not affect the health care services we receive today, or at any time in the future.

Please indicate your consent with your signature.

Volunteer's name _____

_____

Signature of Volunteer Date

Staff member's name_____

_____

Signature of study staff Date

If the volunteer is unable to read or write the entire counselling process must be observed by an independent witness who can then confirm the procedure once the she has given consent.

Fingerprint of volunteer:

Witness:
I confirm that I am independent of the study and that I witnessed the entire informed consent counselling process in the home language of the volunteer

Name: _____

Signature: _____

Date: _____

Thank you.

APPENDIX L

- Edinburgh Postnatal Depression Scale (EPDS) -

EPDS

Visit Date: __ __/__ __ __/__ __ __ __	**Visit number** *Please circle appropriate visit*	1st Antenatal (booking) visit	6 weeks postnatal visit	12 months postnatal visit

Sifuna ukwasi ukuba ubuziva njani kwiveki ephelileyo. Sicela ukhethe iimpendulo ezikufutshane nendlela ozive ngayo kwi veki edlulileyo, hayi nje indle oziva ngayo namhlanje.

We would like to know how you have been feeling in the past week. Please choose the answer that comes closest to how you have felt in the past week, not just how you feel today. Please read all the options for each statement.

		0	1	2	3
EPDS -1	Ndibenako ukuhleka nokubona icala lezinto ezinga lunganga. *I have been able to laugh and see the funny side of things*	Njengokuba ndihlala ndisenza *As much as I always could*	Hayi Kangako *Not quite so much now.*	Ngokuqinisekileyo akukho kangako ngoku *Definitely not so much now.*	Hayi azange *Not at all.*
EPDS -2	Izinto ndizijonge ndinolonwabo *I have looked forward with enjoyment to things*	Njengokuba bendihlala ndisenza *As much as I ever did.*	Kancinci kunokuba bendihlala ndisenza *A little less than I used to.*	Kancinci kakhulu kunokuba bendisenza *Much less than I used to.*	Kungqabile ukuba kubenjalo. *Hardly at all.*
EPDS -3	Bendizigxeka xa izinto zingandihambeli kakuhle ngaphandle kwesizathu. *I have blamed myself unnecessarily when things went wrong*	Ewe, ixesha elininzi *Yes, most of the time.*	Ewe, ngamanye amaxesha *Yes, some of the time.*	Hayi kangako *Not very much.*	Hayi azange *No, never*
EPDS -4	Bendinxunguphele ndinexhala ngaphandle kwesizathu *I have been anxious or worried for no good reason*	Hayi konke konke *No, not at all.*	Kungqabile ukuba kubenjalo *Hardly ever.*	Ewe, ngamanye amaxesha *Yes, sometimes.*	Ewe kakhulu *Yes, very much.*
EPDS -5	Ndizive ndisoyika ndinexhala ngaphandle kwesizathu *I have felt scared or panicky for no very good reason*	Ewe kakhulu *Yes, quite a lot.*	Ewe, ngamanye amaxesha *Yes, sometimes.*	Hayi kangako *No, not much.*	Hayi konke konke *No, not at all*
EPDS -6	Izinto bezindongamela *Things have been getting on top of me*	Ewe, ixesha elininzi bedingakwazi ukuphumelela tu *Yes, most of the times I haven't been managing at all.*	Ewe, ngamanye amaxesha bendingakwazi ukuphumelela njengesiqhelo *Yes, sometimes I haven't been managing as well as usual.*	Hayi, ixesha elininzi bendiphumelela kakuhle kakhulu *No, most of the time I have managed quite well.*	Hayi, benoliphumelela njengesiqhelo *No, I have been managing as well as ever.*
EPDS -7	Bendingonwabanga ndifumane ubunzima xa kufuneka ndilele *I have been so unhappy that I have had difficulty sleeping*	Ewe, ixesha elininzi *Yes, most of the time.*	Ewe, ngamanye amaxesha *Yes, sometimes.*	Hayi kangako *Not very much.*	Hayi konke konke *No, not at all.*
EPDS -8	Ndiziva ndilusizi okanye ndingxunguphele *I have felt sad or miserable*	Ewe, ixesha elininzi *Yes, most of the time.*	Ewe, ngamanye amaxesha *Yes, sometimes.*	Hayi kangako *Not very much.*	Hayi konke konke *No, not at all.*
EPDS -9	Bendingonwabanga ndisoloko ndilila *I have been so unhappy that I have been crying*	Ewe, ixesha elininzi *Yes, most of the time.*	Ewe, ngamanye amaxesha *Yes, sometimes.*	Hayi kangako *Not very much.*	Hayi konke konke *No, not at all.*
EPDS -10	Ingcinga yokuzenzakalisa ithe yandifikela *The thought of harming myself has occurred to me*	Ewe kakhulu *Yes, quite a lot*	Ngamanye amaxesha *Sometimes*	Kungqabile ukuba kubenjalo. *Hardly ever*	Zange *Never*

Date completed: __ __ /__ __ __ / __ __ __ __ Signed counsellor completing CRF: _____

Date of QC: __ __ /__ __ __ / __ __ __ __ Signed measurement nurse: _____

Initials of counsellor: _____

APPENDIX M

- Kessler-10 (K-10) -

KESSLER-10				
Visit Date: __ __/__ __ __/__ __ __ __	**Visit number** *Please circle appropriate visit*	1st Antenatal visit (booking)	6 weeks postnatal	12 months postnatal

Le mibuzo ilandelayo ilishumi ikubuza ukuba ubuziva njani na kule nyanga idlulileyo. Ngombuzo ngamnye yakha isangqa phantsi phantsi kwalo mpendulo ichaza ngokupheleleyo ubungakanani bexesha obuvakalelwa ngalo ngolo hlobo.

The following ten questions ask about how you have been feeling in past month.

Kule nyanga iphelileyo, oku kukuthi, ukususela [xela inyanga enye edlulileyo] ukuyo kutsho izolo, ikuba kukangaphi uziva:

That is, from [date one month ago] to yesterday, about how often did you feel: (Circle the option that best describes the amount of time that you feel that way.)

		Akukhange kubehki xesha *None of the time*	**Kubekhona ixeshana** *A little of the time*	**Abekhona amanye amaxesha** *Some of the time*	**Kubekho amaxesha amaninz** *Most of the time*	**Ibilixesha lonke** *All of the time*
K10 -1	Udiniwe ngaphandle kwesizathu? *During the past month, about how often did you feel tired out for no good reason?*	1	2	3	4	5
K10 -2	Uphakuphaku? *During the past month, about how often did you feel nervous?*	1	2	3	4	5
K10 -3	Uphakuphaku kangangokuba kungekho nto inokukuthomalalisa? *During the past month, about how often did you feel so nervous that nothing could calm you down?*	1	2	3	4	5
K10 -4	Uphelelwa ngamathemba? *During the past month, about how often did you feel hopeless?*	1	2	3	4	5
K10 -5	Ungazinzanga okanye ugungqa? *During the past month, about how often did you feel restless or fidgety?*	1	2	3	4	5
K10 -6	Ungazinzanga de ugugqagungqe xa uhleli? *During the past month, about how often did you feel so restless you could not sit still?*	1	2	3	4	5
K10 -7	Ulusizana udakumbile? *During the past month, about how often did you feel depressed?*	1	2	3	4	5
K10 -8	Yonke into ibiyimigudu? *During the past month, about how often did you feel that everything was an effort?*	1	2	3	4	5
K10 -9	Udakumbile kangangokuba kungekho nanye into engakonwabisayo? *During the past month, about how often did you feel so sad that nothing could cheer you up?*	1	2	3	4	5
K10 -10	Ungena xabiso? *During the past month, about how often did you feel worthless?*	1	2	3	4	5

Date completed: __ __ /__ __ __ / __ __ __ __ Signed counsellor completing CRF: _____

Date of QC: __ __ /__ __ __ / __ __ __ __ Signed measurement nurse: _____

APPENDIX N

- Trauma / Abuse Assessment (WHO VAW Questionnaire) -

WHO VAW QUESTIONNAIRE				
Visit Date: __ __/__ __ __/__ __ __ __		**Visit number:** *Please indicate the visit*	1st Antenatal visit	Postnatal visit 12 months
Siza kubuza imibuzo embalwa malunga nokuhlukunyezwa kwako liqabane lako. *We are going to ask you a few questions relating to partner violence.* Kwezi nyanga zi-12 zidlulileyo ukhe wafunyanwanzezi zilandelayo *In the last 12 months, have you experienced any of the following?*				
UHLUKUMEZO LWENGQON *Psychological Violence*			Ewe *Yes*	Hayi *No*
1.	Iqabane lakho likhe lakuthuka okanye wasiva ungalunganga? *Has your partner insulted you or made you feel bad about yourself?*		1	0
2.	Likhe lakwenza wasifumanisa ukuba usithobile isidima sakho phambi kwabanye abantu? *Has he belittled or humiliated you in front of other people?*		1	0
3.	Likhe laoyikisa lakuphatha kakubi ngabom *Has he done things to scare or intimidate you on purpose?*		1	0
4.	Likhe lakugrogrisa ngokonzakalisa okanye umntu omnakekelayo? *Has he threatened to hurt you or someone you care about?*		1	0
UHLUKUMEZO LOMZIMBA *Physical Violence*			Ewe *Yes*	Hayi *No*
5.	Likhe lakuqhwaba ngempama okanye wakugibisela ngento enokwenzakalisa? *Has he slapped you or thrown something at you that could hurt you?*		1	0
6.	Likhe lakutyhala okanye lakunyola? *Has he pushed or shoved you?*		1	0
7.	Likhe lakubetha ngenqindi okanyengento enokonzakalisa? *Has he hit you with a fist or with something else that could hurt you?*		1	0
8.	Likhe likukhabe,likurhuqe okanye likubethe? *Has he kicked you, dragged you or beaten you up?*		1	0
9.	Likhe likukrwitshe okanye likutshise ngabom? *Has he choked or burnt you on purpose?*		1	0
10.	Likhe likugrogrise okanye lisebenzise umpu,imela okanye nasiphi isixhobo kuwe? *Has he threatened to use or actually used a gun, knife or other weapon against you?*		1	0
UHLUKUNYEZO NGOKWABELANA NGOCANTSI *Sexual Violence*			Ewe *Yes*	Hayi *No*
11.	Likhe likunyanzele ngokwabelana ngocantsi wena ungafuni? *Has he physically forced you to have sexual intercourse when you didn't want to?*		1	0
12.	Wakhe wabelana naye ngocantsi ungafuni kuba uloyika umazi angenza ntoni? *Did you ever have sexual intercourse when you didn't want because you were afraid of what he might do?*		1	0
13.	Likhe likunyanzele ngokwebelana ngocantsi ngendlela ofumanisa ukuba ukuthathela phantsi okanye uyakwenyelisa? *Has he forced you to do something sexual that you found degrading or humiliating?*		1	0

Date completed: __ __ /__ __ __ / __ __ __ __ Signed counsellor completing CRF: _____

Date of QC: __ __ /__ __ __ / __ __ __ __ Signed measurement nurse: _____

APPENDIX O

- Alcohol Use Disorders Identification Test (AUDIT) -

AUDIT	**Please mark relevant visit number:**	1st Antenatal visit (booking)	12 month visit	**Visit Date**: __ __/__ __ __/__ __ __ __		
Ngoku sizakubuza imibuzo ngokusebenzisa kwakho utywala. Ncede urhangqe impendulo engqamene nawe: *We are now going to ask you some questions about your use of alcohol. Please circle the relevant answer for each question bellow:*						
		0	1	2	3	4
AUDIT -1	Ubusela kangakanani utywala? *How often do you have a drink containing alcohol?*	Zange *never*	Kanye ngenyanga nangaphantsi *Once per month or less*	Kabini ukuya kwisine enyangeni *2-4 times a month*	Kabini ukuya kwisithathu evekini *2-3 times per week*	Kane nangaphezulu evekini *4 times or more per week*
AUDIT -2	Zingaphi iglasi zesiselo esinxilisayo oziselayo ngemini? *How many standard drinks containing alcohol do you have on a typical day when drinking?*	1 okanye 2 *1 or 2*	3 okanye 4 *3 or 4*	5 okanye 6 *5 or 6*	7 ukuya 9 *7 to 9*	10 okanye ngaphezulu *10 or more*
AUDIT -3	Kukangaphi usela iglasi ezintandathu nangaphezulu ngexesha? *How many times do you have six standard drinks or more at time?*	Zange *Never*	Ngaphantsi kwenyanya *Less than monthly*	Ngenyanga *Monthly*	Ngeveki *Weekly*	Ngosuku okanye malunga nosuku *Daily or almost daily*
AUDIT -4	Kunyaka ophelileyo kukangaphi, ufumanisa ukuba awukwazi ukuyeka ukusela xa sele uqalili? *During the past year, how often have you found that you were not able to stop drinking once you had started?*	Zange *Never*	Ngaphantsi kwenyanya *Less than monthly*	Ngenyanga *Monthly*	Ngeveki *Weekly*	Ngosuku okanye malunga nosuku *Daily or almost daily*
AUDIT -5	Kulo nyaka uphelileyo kukangaphi ungakwazi ukwenza into ubumele ukuyenza ngenxa yokuba ubusela? During the past year, how often have you failed to do what was normally expected of you because of drinking?	Zange *Never*	Ngaphantsi kwenyanya *Less than monthly*	Ngenyanga *Monthly*	Ngeveki *Weekly*	Ngosuku okanye malunga nosuku *Daily or almost daily*

AUDIT -6	Kulo nyaka uphelileyo kukangaphi ufuna ukusela utywala ekuseni kuba ufuna ukuqala usuku lwakho kakuhle? During the past year, how often have you needed a drink in the morning to get yourself going after a heavy drinking session?	Zange *Never*	Ngaphantsi kwenyanya *Less than monthly*	Ngenyanga *Monthly*	Ngeveki *Weekly*	Ngosuku okanye malunga nosuku *Daily or almost daily*
AUDIT -7	Kulonyaka uphelileyo kukangaphi uzifumanise unesazela okanye uzisola emva kokuba usele? During the past year, how often have you had a feeling of guilt or remorse after drinking?	Zange *Never*	Ngaphantsi kwenyanya *Less than monthly*	Ngenyanga *Monthly*	Ngeveki *Weekly*	Ngosuku okanye malunga nosuku *Daily or almost daily*
AUDIT -8	Kulo nyaka uphelileyo ukhe wazilibala izinto ebezenzekile ngezolo ngenxa yokuba ubusele? During the past year, have you been unable to remember what happened the night before because you had been drinking?	Zange *Never*	Ngaphantsi kwenyanya *Less than monthly*	Ngenyanga *Monthly*	Ngeveki *Weekly*	Ngosuku okanye malunga nosuku *Daily or almost daily*
AUDIT -9	Ukhe wonzakala okanye omnye umntu wonzakala ngenxa yokuba ubusele? Have you or someone else been injured as a result of your drinking?	Hayi *No*	Ewe, kodwa hayi kunyaka ophelilieyo. *Yes, but not in the past year*	Ewe, kunyaka ophelilieyo. *Yes, during the past year*		
AUDIT -10	Sikhona isizalwana sakho, okanye isihlobo,ugqira okanye umntu osebenzela ezempilo obekhathazekile ngendlela osela ngayo waza wakucebisa ukuba uthobe isantya? Has a relative or friend, doctor or other health worker been concerned about your drinking or suggested you cut down?	Hayi *No*	Ewe, kodwa hayi kunyaka ophelilieyo. *Yes, but not in the past year*	Ewe, kunyaka ophelilieyo. *Yes, during the past year*		

Date completed: __ __ /__ __ __ / __ __ __ __ Signed counsellor completing CRF: _____

Date of QC: __ __ /__ __ __ / __ __ __ __ Signed measurement nurse: _____

APPENDIX P

- **Data Management Plan -**

DATA MANAGEMENT PLAN

Institution: University of Cape Town

1. PROJECT NAME

Early infant breastfeeding practises and predictors of breastfeeding cessation in HIV-uninfected and HIV-infected mothers on anti-retroviral treatment: a prospective cohort study

2. LEAD PRINCIPAL INVESTIGATOR(S)/GRANT HOLDER

Dr Stanzi le Roux, Supervisor of Helene C Theunissen

3. DATA COLLECTION/GENERATION

This study involves secondary data analysis only.
Data was obtained through Clinical record forms (CRFs), and questions were administered by trained interviewers in private rooms. CRFs were translated from English into isiXhosa and subsequently back-translated by isiXhosa speaking staff members, with validation certification.

For the purposes of this study, data derived from the "Infant feeding intentions/practices" questionnaire (Appendix D) will be used to evaluate breastfeeding practices. This questionnaire was administered in both parent cohorts during post-natal follow up visits at approximately <7 days, 6 weeks, 3,6,9 and 12 months. Additionally, selected data derived from the "Maternal Demographics & Medical History Questionnaire" will be used, as well as the Edinburgh Postnatal Depression Scale (EPDS) (Appendix L), the Kessler-10 (Appendix M), the Trauma/Abuse Assessment (Appendix N) and the Alcohol Use Disorders Identification Test (AUDIT) (Appendix O). The HU2 questionnaire (Appendix E) was an appropriately shortened version (so as not to enquire about HIV/ART related information) of that of MCH-ART. (Appendix F).

4. DATA STORAGE

As per study protocols, all participant data was kept anonymous with no personal identifiers attached to participant files and with only systematically assigned identification numbers. Database files are stored on password protected external hard drives which in turn are stored in locked safes at the University of Cape Town and at the research site.

APPENDIX 2: University of Cape Town Human Research Ethics Committee (HREC) Approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone (021) 406 6492
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

07 November 2019

HREC REF:732/2019

Dr S le Roux
Division of Epidemiology & Biostatistics
Entrance 5, Level 5
Falmouth Building-FHS

Dear Dr le Roux

PROJECT TITLE: EARLY INFANT BREASTFEEDING PRACTICES, AND PREDICTORS OF BREASTFEEDING CESSATION IN HIV-UNINFECTED AND HIV-INFECTED MOTHERS ON ANTI-RETROVIRAL TREATMENT: A PROSPECTIVE COHORT STUDY (MPH DEGREE - MRS H C THEUNISSEN)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 November 2020.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: Mrs H Theunissen will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC 732/2019

NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

APPENDIX 3: Authors contributions and Acknowledgements

Authors' contributions

Helene Theunissen conducted the data analysis for this paper and drafted the protocol as well as the manuscript. Dr Stanzi le Roux was the supervisor for this mini-dissertation, was co-investigator of the child health aspects of MCH-ART study and co-principal investigator of the HU2 study. Professors Elaine Abrams and Landon Myer were principal investigators of the MCH-ART study and co-principal investigators for the HU2 study. Dr Kirsty Brittain was responsible for overall data management of both studies, while Dr Tamsin Phillips was the study coordinator for the MCH-ART study and assisted with data management. Kelly Nguyen was the study coordinator for the HU2 study. Allison Zerbe was responsible for overall study administration. All authors contributed to and approved the final manuscript for submission.

Acknowledgements

We are grateful to the study staff for their hard work in making the MCH-ART and HU2 studies possible, and to the mothers and infants who participated in this research.

APPENDIX 4: Manuscript Supplementary Tables and Figures

SUPPLEMENTARY TABLE 1: Specific lactation issues reported by women living with HIV and HIV-negative women at approximately 7 days and 6 weeks postpartum

Visit	Lactation issue	Combined Cohort n= 872	Women Living with HIV and their Infants	HIV-Negative Mothers and their infants
7 Days postpartum	Engorgement	21/872 (2%)	15/461(3%)	6/411 (1%)
	Cracked Nipples	41/872 (5%)	21/461 (5%)	20/411 (5%)
	Abscesses	1/872 (0.1%)	1/461 (0.2%)	0/411 (0%)
	Infection	1/872 (0.1%)	1/461 (0.2%)	0/411 (0%)
	Operation	0/872 (0%)	0/461 (0%)	0/411 (0%)
	Trauma	0/872 (0%)	0/461 (0%)	0/411 (0%)
	Other problems[1]	5/872 (1%)	3/461 (1%)	2/411 (0.5%)
6 Weeks postpartum	Engorgement	15/872 (2%)	12/461 (3%)	3/411 (1%)
	Cracked Nipples	38/872 (4%)	29/461 (6%)	9/411 (2%)
	Abscesses	9/872 (1%)	7/461 (2%)	2/411 (0.5%)
	Infection	6/872 (1%)	5/461 (1%)	1/411 (0.2%)
	Operation	0/872 (0%)	0/461 (0%)	0/411 (0%)
	Trauma	0/872 (0%)	0/461 (0%)	0/411 (0%)
	Other problems[2]	9/872 (1%)	8/461 (2%)	1/411 (0.2%)

Results are n(column %)

[1] Other lactation problems women indicated included itchiness, painful nipples, pain when breastfeeding and painful breasts.

[2]Other lactation problems women indicated included bleeding nipples, empty breasts or not enough breastmilk.

Supplementary Table 1 provides a breakdown of reported lactation and breast problems in the first 6 weeks postpartum. The most common problem reported by 5% (41/872) of all women, was cracked nipples at the 7-day postpartum visit, this was no different among WLHIV as compared to HIV-negative women (5%, 21/461 vs 5%, 20/411). This was followed by engorgement, with 3% (15/461) of WLHIV as compared to 1% (6/411) of HIV-negative women reporting this problem at the 7-day postpartum visit.

Cracked nipples and engorgement continued to be the main lactation related problems reported at the 6-weeks postpartum visit. While 6% (29/461) of WLHIV reported having cracked nipples, only 2% (9/411) HIV-negative women reported this problem. Similarly, while 3% (12/461) of WLHIV reported breast engorgement, only 1% (3/411) reported this problem at the 6 weeks postpartum visit.

SUPPLEMENTARY TABLE 2: Maternal reasons for cessation of breastfeeding, by study visit: overall, and stratified by maternal HIV status				
Visit		**Combined Cohort**	**Women Living with HIV and their Infants**	**HIV-Negative women and their infants**
6 Weeks	**Number who attended this visit**	824/872 (94%)	435/461 (94%)	389/411 (95%)
	Number (%) who reported breastfeeding cessation since previous visit	111/824 (13%)	78/435 (18%)	33/389 (8%)
	Reasons given for Breastfeeding cessation			
	No reason given	23/111 (21%)	6/78 (8%)	17/33 (52%)
	Work	12/111 (11%)	10/78 (13%)	2/33 (6%)
	Education	2/111 (2%)	1/78 (1%)	1/33 (3%)
	Non-lactational illness	11/111 (10%)	8/78 (10%)	3/33 (9%)
	Lactation problems	22/111 (20%)	22/78 (27%)	0/33 (0%)
	Poor growth	1/111 (1%)	0/78 (0%)	1/33 (3%)
	Inconsolable crying	6/111 (5%)	3/78 (4%)	3/33 (9%)
	Insufficient breastmilk supply	18/111 (16%)	13/78 (17%)	5/33 (15%)
	Fear of HIV transmission	3/111 (2%)	3/78 (4%)	0/33 (0%)
	External advice/pressure	2/111 (2%)	2/78 (3%)	0/33 (0%)
	Other[1]	11/111 (10%)	10/78 (13%)	1/33 (3%)
3 Months	**Number who attended this visit**	*737/872 (85%)*	*369/461 (80%)*	*368 (90%)*
	Number (%) who reported breastfeeding cessation since previous visit	135/ 737 (18%)	98/369 (27%)	37/368 (10%)
	Cumulative number of women who have stopped breastfeeding	246/872 (28%)	176/461 (38%)	70/411 (17%)
	Reasons given for Breastfeeding cessation			
	No reason given	47/135 (36%)	31/98 (33%)	16/37 (43%)
	Work	31/135 (23%)	22/98 (22%)	9/37 (24%)
	Education	2/135 (1%)	1/98 (1%)	1/37 (3%)
	Non-lactational illness	3/135 (2%)	3/98 (3%)	0/37 (0%)
	Lactation problems	11/135 (8%)	8/98 (8%)	3/37 (8%)
	Poor growth	3/135 (2%)	3/98 (3%)	0/37 (0%)
	Inconsolable crying	4/135 (3%)	2/98 (2%)	2/37 (5%)
	Insufficient breastmilk supply	15/135 (11%)	10/98 (10%)	5/37 (14%)
	Fear of HIV transmission	1/135 (1%)	1/98 (1%)	0/37 (0%)
	External advice/pressure	0/135 (0%)	0/98 (0%)	0/37 (0%)
	Other[1]	18/135 (13%)	17/98 (17%)	1/37 (3%)
6 Months	**Number who attended this visit**	*749/872 (86%)*	*403/461 (87%)*	*346/411 (84%)*
	Number (%) who reported breastfeeding cessation since previous visit	134/749 (18%)	56/403 (14%)	78/346 (22%)

	Cumulative number of women who have stopped breastfeeding	380/872 (44%)	232/461 (50%)	148/411 (36%)
	Reasons given for Breastfeeding cessation			
	No reason given	25/134 (19%)	5/56 (9%)	20/78 (26%)
	Work	46/134 (34%)	17/56 (29%)	29/78 (37%)
	Education	5/134 (4%)	2/56 (4%)	3/78 (4%)
	Non-lactational illness	3/134 (2%)	2/56 (4%)	1/78 (1%)
	Lactation problems	5/134 (4%)	3/56 (5%)	2/78 (3%)
	Poor growth	0/134 (0%)	0/56 (0%)	0 /78 (0%)
	Inconsolable crying	3/134 (2%)	2 /56 (4%)	1 /78 (1%)
	Insufficient breastmilk supply	12/134 (9%)	5/56 (9%)	7 /78 (9%)
	Fear of HIV transmission	2/134 (1%)	2/56 (4%)	0/78 (0%)
	External advice/pressure	0/134 (0%)	0 /56 (0%)	0 /78 (0%)
	Other[1]	33/134 (25%)	18/56 (32%)	15 /78 (19%)
9 Months	**Number who attended this visit**	*714/872 (82%)*	*384/461 (83%)*	*330/411 (80%)*
	Number (%) who reported breastfeeding cessation since previous visit	89/714 (12%)	49/384 (13%)	40/330 (12%)
	Cumulative number of women who have stopped breastfeeding	469/872 (54%)	281/461 (61%)	188/411 (46%)
	Reasons given for Breastfeeding cessation			
	No reason given	14/89 (17%)	2/49 (4%)	12/40 (30%)
	Work	28/89 (31%)	21/49 (43%)	7/40 (17%)
	Education	5/89 (6%)	3 /49 (6%)	2/40 (5%)
	Non-lactational illness	1/89 (1%)	0 /49 (0%)	1 /40 (3%)
	Lactation problems	6/89 (7%)	0/49 (0%)	6/40 (15%)
	Poor growth	1 /89 (1%)	1/49 (2%)	0/40 (0%)
	Inconsolable crying	2/89 (2%)	2/49 (4%)	0 /40 (0%)
	Insufficient breastmilk supply	3/89 (3%)	2/49 (4%)	1 /40 (3%)
	Fear of HIV transmission	1/89 (1%)	1/49 (2%)	0/40 (0%)
	External advice/pressure	0/89 (0%)	0 /49 (0%)	0/40 (0%)
	Other[1]	28/89 (31%)	17/49 (35%)	11 /40 (27%)
12 Months	**Number who attended this visit**	*741/872 (85%)*	*388/461 (84%)*	*353/411 (86%)*
	Number (%) who reported breastfeeding cessation since previous visit	83/741 (11%)	35/388 (9%)	48/353 (14%)
	Cumulative number of women who have stopped breastfeeding	552/872 (63%)	316/461 (69%)	236/411 (57%)
	Reasons given for Breastfeeding cessation			

	No reason given	17/83 (20%)	8/35 (23%)	9/48 (19%)
	Work	14/83 (17%)	5/35 (14%)	9 /48 (19%)
	Education	1/83 (1%)	1/35 (3%)	0/48 (0%)
	Non-lactational illness	2/83 (3%)	1 /35 (3%)	1/48 (2%)
	Lactation problems	4/83 (5%)	0/35 (0%)	4 /48 (8%)
	Poor growth	0/83 (0%)	0/35 (0%)	0 /48 (0%)
	Inconsolable crying	1/83 (1%)	0/35 (0%)	1/48 (2%)
	Insufficient breastmilk supply	8/83 (10%)	0 /35 (0%)	8/48 (17%)
	Fear of HIV transmission	1/83 (1%)	1 /35 (3%)	0/48 (0%)
	External advice/pressure	0/83 (0%)	0/35 (0%)	0/48 (0%)
	Other[1]	35/83 (42%)	19/35 (54%)	16/48 (33%)
Main reason for cessation	Work commitments	131/552 (24%)	75/316 (24%)	56/236 (24%)

Results are n(column %)

[1] "Other" reasons women gave included but are not limited to maternal depression, the child rejecting breastmilk, the child and mother being separated geographically, the child being hospitalized, refusing breastmilk and reduced milk production.

Supplementary Table 2 provides a breakdown of all the reasons women reported for breastfeeding cessation. At the 6-week postpartum visit, the most common reason reported for breastfeeding cessation was lactation problems, 20% (22/111). While 27% (22/78) WLHIV reported lactation problems to be the reason for BF cessation, 0% (0/33) of HIV-negative women reported lactation problems to be the reason for BF cessation.

At the 3-month, 6-month, 9-month and 12-month visits, the most common reason stated by all women for breastfeeding cessation, was work, with 23% (31/135), 34% (46/134), 31% (28/89) and 17% (14/83).

SUPPLEMENTARY TABLE 3: Factors associated with cessation of (a) exclusive and (b) all breastfeeding among HIV-negative women: crude and adjusted hazard ratios from Cox proportional hazards regression analysis.

	(c) Relative hazard for cessation of exclusive breastfeeding‡				(d) Relative hazard for cessation of any breastfeeding			
	Crude Hazard Ratio (95% Confidence Interval)	**p-value**	**Adjusted Hazard Ratio (95% Confidence Interval)**	**p-value**	**Crude Hazard Ratio (95% Confidence Interval)**	**p-value**	**Adjusted Hazard Ratio (95% Confidence Interval)**	**p-value**
Maternal characteristics at first antenatal visit								
Breast infection/problems at 7 days and or 6 weeks[1]	1.63 (1.17 – 2.26)	0.01	1.62 (1.15 – 2.27)	0.01	1.32 (0.86 – 2.02)	0.21	1.44 (0.91 – 2.27)	0.12
Employed[2]	1.15 (0.92 – 1.43)	0.21	-	-	1.35 (1.01 – 1.79)	0.04	1.37 (1.02 – 1.84)	0.04
Maternal age (years)	0.99 (0.97 – 1.01)	0.36	0.99 (0.97 – 1.01)	0.42	0.99 (0.97 – 1.01)	0.42	-	-
Completed secondary and or tertiary schooling[3]	1.08 (0.87 – 1.34)	0.47	-	-	1.10 (0.82 – 1.46)	0.53	-	-
Lives in formal housing with a toilet, running water and electricity[4]	1.06 (0.86 – 1.32)	0.58	-	-	1.07 (0.80 – 1.43)	0.67	-	-
Postnatal depression[5]	1.11 (0.76 – 1.63)	0.60	1.13 (0.80 – 1.61)	0.48	0.67 (0.35 – 1.30)	0.24	-	-
Intimate partner violence[6]	1.21 (0.81 – 1.82)	0.35	-	-	1.38 (0.87 – 2.19)	0.17	-	-
Risky drinking behaviour[7]	1.36 (0.83 – 2.24)	0.23	-	-	1.38 (0.88 – 2.17)	0.16	-	-
Psychological distress[8]	1.15 (0.92 – 1.42)	0.22	-	-	1.37 (1.03 – 1.83)	0.03	1.35 (1.01 – 1.81)	0.04
Infant and Delivery Characteristics								
Gestational age at birth								
≥37 Weeks	1.00	(Ref)	1.00	-	1.00	(Ref)	1.00	(Ref)
≥34 Weeks, <37 Weeks	0.63 (0.42 – 0.95)	0.03	0.66 (0.44 – 0.99)	-	1.12 (0.70 – 1.79)	0.64	0.94 (0.56 – 1.67)	0.90
<34 Weeks	0.85 (0.41 – 1.80)	0.68	0.91 (0.40 – 2.04)		1.75 (0.91 – 3.36)	0.09	1.37 0.57 – 3.25)	0.48
Birth weight (grams)								
≥ 2500	1.00	(Ref)	-	-	1.00	(Ref)	-	-
<2500	0.71 (0.48 – 1.04)	0.08	-	-	1.25 (0.81 – 1.92)	0.32	-	-
Birth weight (kilograms)	1.22 (1.02 – 1.46)	0.03	-	-	0.72 (0.57 – 0.92)	0.01	0.71 (0.52 – 0.97)	0.03
SGA[9]	0.80 (0.58 – 1.10)	0.16	-	-	1.20 (0.81 – 1.78)	0.37	-	-
APGAR <7 @5min[10]	1.67 (1.04 – 2.70)	0.04	1.24 (0.52 – 2.92)	0.62	4.62e-15 (0)	1.00	-	-
Put to breast within 1 hour of birth[11]	1.12 (0.62 – 2.04)	0.70	1.03 (0.58 – 1.82)	0.92	0.96 (0.57 – 1.64)	0.90	1.23 (0.67 – 2.27)	0.50
Place of birth								
Primary Care	1.00	(Ref)	-	-	1.00	(Ref)	-	-
Hospital care	0.93 (0.74 – 1.17)	0.54	-	-	0.88 (0.66 – 1.18)	0.41	-	-
BBA[12]	0.30 (0.24 – 0.37)	<0.0001	-	-	3.17e-14 (0)	1.00	-	-
Entry into antenatal care								
Early (<28 Weeks)	1.00	(Ref)	-	-	1.00	(Ref)	-	-
Late (≥28 Weeks)	1.01 (0.77 – 1.34)	0.92	-	-	0.83 (0.58 – 1.20)	0.33	-	-
Male Sex[13]	0.93 (0.75 – 1.15)	0.50	-	-	1.05 (0.79 – 1.40)	0.70	-	-

†Analysis based on a) 333 observations; 635.76 months total analysis time and b) 411 observations; 3168.62 months total analysis time

‡Exclusive Breastfeeding analysis was restricted to infants who were ever breastfed.

[1] Reference category: having attained less than secondary education

[2] Reference category: not having had breast infections/ problems at 7 days and 6 weeks

[3] Reference category: being unemployed

[4] Reference category: not living in formal housing with a toilet, running water and electricity

[5] Postnatal depression is defined as Edinburgh Postnatal Depression Scale (EPDS) score ≥13, at enrolment visit. (28)
Reference category: having an EPDS score of <13, at enrolment visit

[6] Intimate partner violence defined as physical, sexual or psychological violence as per World Health Organization violence against women questionnaire, at enrolment visit.
Reference category: not having experienced intimate partner violence, at enrolment visit.(30)

[7] Risky drinking behaviour is defined as Alcohol use disorders identification test (AUDIT-C) score ≥3, at enrolment visit. (31)
Reference category: having an AUDIT-C score of <3, at enrolment visit

[8] Psychological distress is defined as Kessler Psychological Distress Scale (K10) score ≥21.5, at enrolment visit.(29)
Reference category: having a K10 score of <21.5, at enrolment visit

[9] SGA refers to Small for Gestational Age defined as weight below the 10th percentile for gestational age.
Reference category: Weight above the 10th percentile for gestational age

[10] Reference category: APGAR ≥ 7 @ 5 minutes

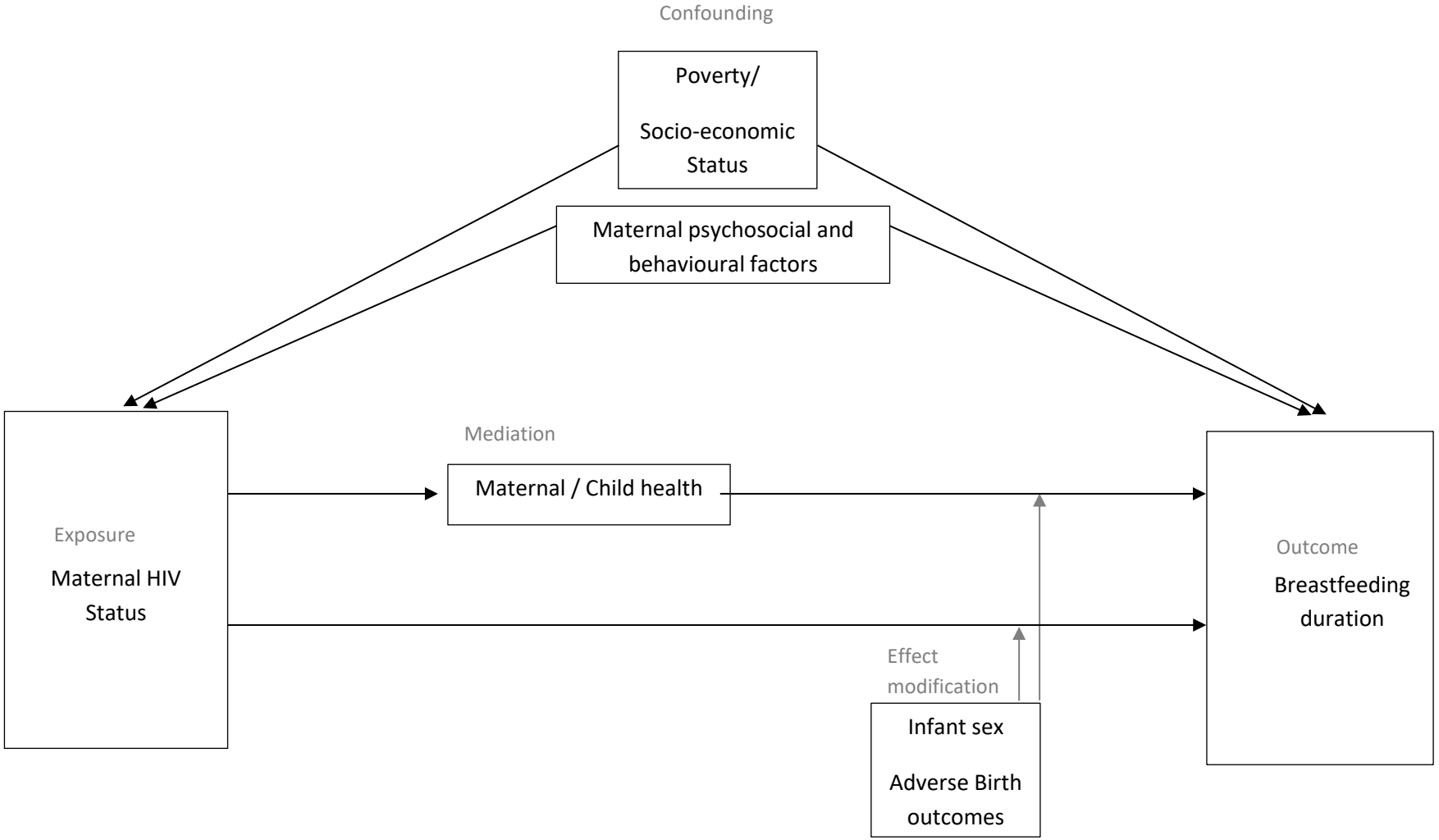
[11] Reference category: Not having been put to the breast within 1 hour after birth

[12] BBA refers to Born before arrival, defined as infants born at home or on route to a delivery centre, without the presence of a skilled birth attendant

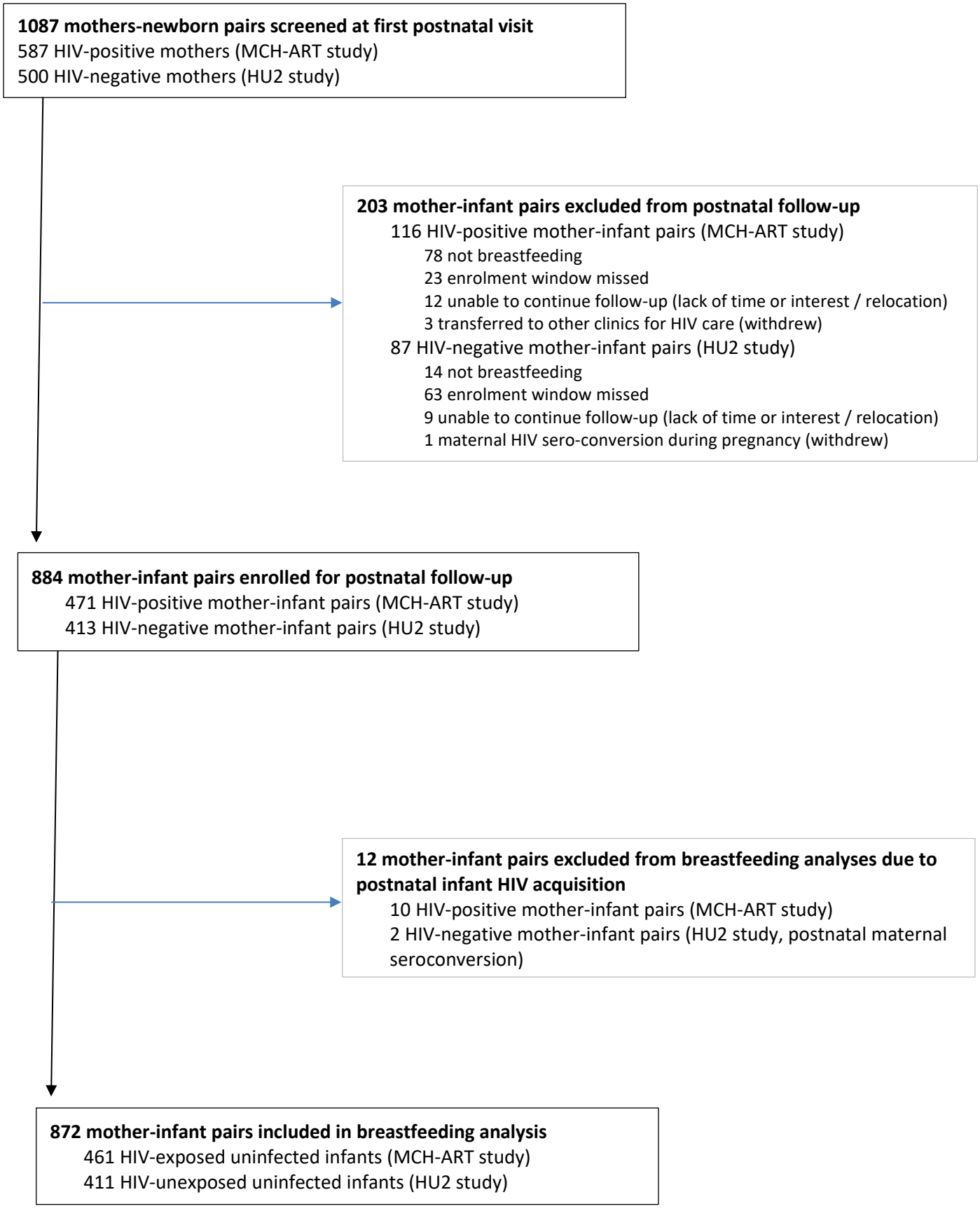
[13] Reference category: female sex

Supplementary Table 3 is indicative of analyses restricted to HIV-negative women. Lactation problems were predictive of EBF cessation (aHR 1.62 CI 1.15 – 2.27), however not significantly predictive of BF cessation (aHR 1.44 CI 0.91 – 2.27). Relative and adjusted predictors of all BF cessation included employment (HR 1.35 CI 1.01 – 1.79), psychological distress (HR 1.37 CI 1.03 – 1.83) and low birth weight (HR 0.72 CI 0.57 – 0.92).

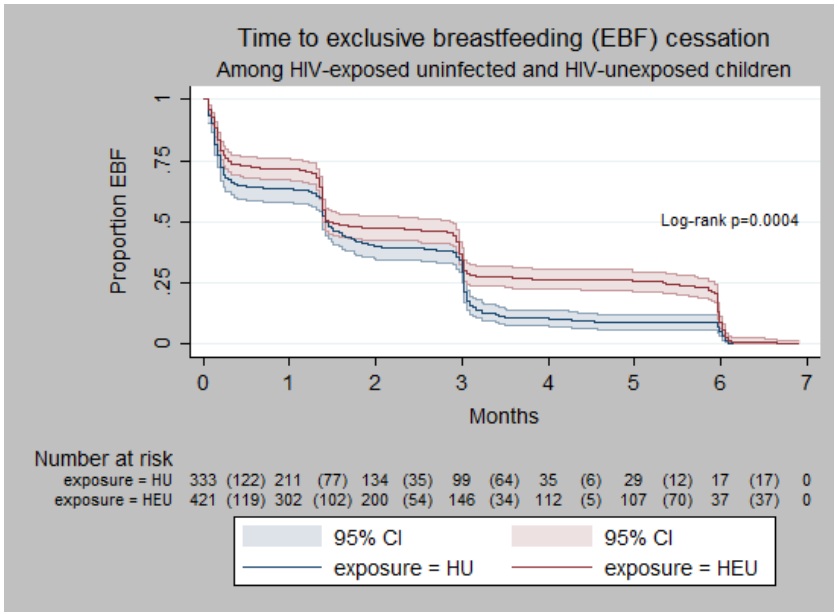
SUPPLEMENTARY FIGURE 1: Directed acyclic graph

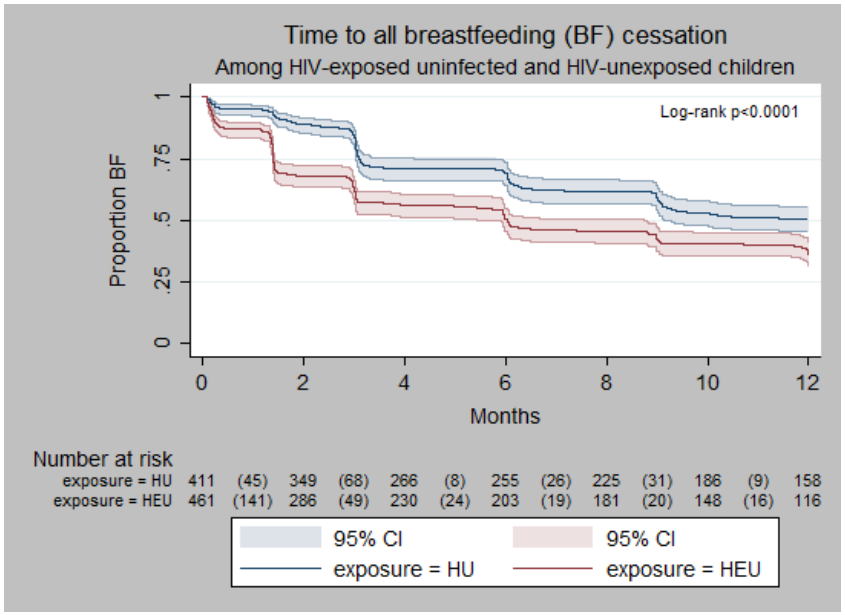


SUPPLEMENTARY FIGURE 2: Study Flow Diagram



SUPPLEMENTARY FIGURE 3: Kaplan Meier curve for breastfeeding cessation, comparing women living with HIV to HIV-negative women





SUPPLEMENTARY FIGURE 3A: Kaplan Meier curve for breastfeeding cessation, comparing women living with HIV to HIV-negative women. Exclusive breastfeeding cessation.

SUPPLEMENTARY FIGURE 3B: Kaplan Meier curve for breastfeeding cessation, comparing women living with HIV to HIV-negative women. All breastfeeding cessation.

The Kaplan Meier curve for exclusive breastfeeding cessation displayed in supplementary figure 3A shows that exclusive breastfeeding duration was consistently longer among WLHIV as compared to HIV-negative women (p=0.0004). The Kaplan Meier curve for (all) breastfeeding cessation displayed in supplementary figure 3B on the other hand, shows that the duration of all breastfeeding was shorter among WLHIV as compared to HIV-negative women.

APPENDIX 5: Authors Guidelines for the Journal of Maternal & Child Nutrition

"Author Guidelines

Contents

1. SUBMISSION

Thank you for your interest in *Maternal & Child Nutrition*. Note that submission implies that the content has not been published or submitted for publication elsewhere except as a brief abstract in the proceedings of a scientific meeting or symposium.

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- Nutritional needs of mothers and their children in health and disease

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- Health Improvement
- Health education
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- Inter-agency initiatives
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- Evaluation of interventions aimed at improving health
- The role of nutrition in both healthy and vulnerable groups
- Development of research methods, validation of measures

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References: Maximum of 100 references.

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Book
Bradley-Johnson, S. (1994). Psychoeducational assessment of students who are visually impaired or blind: Infancy through high school (2nd ed.). Austin, TX: Pro-ed.

Internet Document
Norton, R. (2012, September 6). How to train a cat to operate a light switch [Video file]. Retrieved from **here**.

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Footnotes should be placed as a list at the end of the paper only, not at the foot of each page. They should be numbered in the list and referred to in the text with consecutive, superscript Arabic numerals. Keep footnotes brief; they should contain only short comments tangential to the main argument of the paper and should not include references.

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