ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF NURSING AND MIDWIFERY
DEPARTMENT OF NURSING AND MIDWIFERY
POSTGRADUATE PROGRAM

DETERMINANTS OF SEVERE ACUTE MALNUTRITION AMONG HIV POSITIVE CHILDREN RECEIVING HAART IN PUBLIC HEALTH INSTITUTIONS OF NORTH WOLLO ZONE, NORTHEASTERN ETHIOPIA, 2019: UNMATCHED CASE-CONTROL STUDY

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ADVISORS: Mr. GIRUM SEBSBIE (MSc, Asst. Prof.)
Mrs. FIKRTEMARIAM ABEBE (MSc)

A RESEARCH PROPOSAL SUBMITTED TO SCHOOL OF NURSING AND MIDWIFERY, COLLEGE OF HEALTH SCIENCES, ADDIS ABABA UNIVERSITY, FOR THE PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF SCIENCE (MSc) IN PEDIATRICS AND CHILD HEALTH NURSING.

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Full title of the study:	Determinants of Severe Acute Malnutrition among HIV positive children receiving HAART in Public health institutions of North Wollo zone, Northeastern Ethiopia, 2019: Unmatched Case-control study
Study period:	From March to May /2019
Study area:	Public health institutions of North Wollo zone
Total cost of the study	26,550 ETB

February, 2019

Addis Ababa, Ethiopia

DECLARATION

By my signature below, I declare and affirm that this proposal is my own work. I will follow all ethical principles of scholarship in the preparation, data collection, data analysis and completion of this proposal. All scholarly matter that is included in the proposal has been given recognition through citation. I affirm that I have cited and referenced all sources used in this document. Every effort has been made to avoid plagiarism in the preparation of this proposal. This proposal is submitted in partial fulfillment of the requirement for a graduate degree from the Addis Ababa University at College of Health Sciences, School of Nursing and Midwifery. I solemnly declare that this proposal has not been submitted to any other institution anywhere for the award of any academic degree, diploma or certificate.

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Principal Investigator:

Name: Melaku Bimerew Sign_____ Date _____

Advisors:

1) Girum S. (Asst. prof)
   (Principal Advisor) Sign_____
   Date_____

2) Fikrtemariam A. (MSc)
   (Co-Advisor) Sign_____
   Date_____

CERTIFICATE OF APPROVAL

I, the undersigned MSc student, affirm that I have submitted my original thesis proposal, entitled as "**Determinants of Severe Acute Malnutrition among HIV positive children receiving HAART in Public health institutions of North Wollo zone, Northeastern Ethiopia, 2019: Unmatched Case-control study,"** to School of Nursing and Midwifery of Addis Ababa University for examination.

Submitted by: Melaku Bimerew _____ _____
(Student's name) (Signature) (Date)

This thesis proposal work has been submitted for examination with my approval as an advisor.

Advisors: **Girum S. (Asst. prof)** _____ _____
(Principal Advisor) (Signature) (Date)

Fikrtemariam A. (MSc) _____ _____
(Co-Advisor) (Signature) (Date)

I, the undersigned below, had examined and accepted the research proposal entitled as in the above as a satisfying proposal in its present form, and recommended to School of Nursing and Midwifery of Addis Ababa University, for its acceptance as a partial fulfillment for the award of Master of Science (MSc) in Pediatrics and Child health nursing:

Examiners: Name: Birhanu Wordofa_____ _____
(Internal Examiner) Sign Date

Advisors: **Girum S. (Asst. prof)** _____ _____
(Principal Advisor) (Signature) (Date)

Fikrtemariam A. (MSc) _____ _____
(Co-Advisor) (Signature) (Date)

Department Head: _____ _____ _____
(Name) (Signature) (Date)

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ACRONYMS AND ABBREVIATIONS

AOR:	Adjusted Odds Ratio
ART:	Anti-Retroviral Therapy
CD4:	Cluster of Differentiation 4
COR:	Crude Odds Ratio
HAART:	Highly Active Anti-Retroviral Therapy
MAM:	Moderate Acute Malnutrition
NAIDS:	Nutritional Acquired Immuno-Deficiency Syndrome
SAM:	Severe Acute Malnutrition
SPSS:	Statistical Package for Social Science

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SUMMARY

Background: Malnutrition and HIV/AIDS are common problems in sub-Saharan countries including Ethiopia. They are closely interlinked conditions. Their combined effect is more severe in children and is a cause for greater morbidity and mortality in those children. In children with severe malnutrition, the risk of death is three to four times higher in HIV-infected children.

Objective: The aim of this study is to assess determinants of Severe Acute Malnutrition among HIV positive children receiving HAART in Public health institutions of North Wollo zone, Northeastern Ethiopia, 2019.

Methodology: Institutional based unmatched case-control study will be conducted on 204 HIV positive children (68 cases and 136 controls). Data will be collected retrospectively (secondary data) and by interviewing of attendants (primary data) from March to May/ 2019 and will be entered to Epi Data Version 4.2.0. Binary and multiple logistic regressions will be employed by SPSS version 23 and results will be presented by narration, tables, graphs and charts.

Budget plan: a total of 26, 550 ETB will be needed to accomplish this research.

Key words: HIV positive children, Severe acute malnutrition, Determinants

CHAPTER ONE

1. INTRODUCTION

1.1. Background

Malnutrition is a condition where an individual's function or body form is impaired and can no longer maintain normal body performance due to inadequate or unbalanced diet. It is a state of deficiency (Under-nutrition), or excess (Over-nutrition) of nutrients causing measurable adverse effects on body forms (1). But in resource limited countries like Ethiopia, and in HIV infected individuals over-nutrition is not a public problem and malnutrition is commonly used to denote under-nutrition (2). Under-nutrition occurs when an individual fails to take or absorb enough amounts of essential nutrients due to different underlying factors including infection as in HIV/AIDS. It manifests in three forms— as Acute (wasting), chronic (stunting) or Micronutrient deficiency. The Acute form of under-nutrition is again classified as Mild, Moderate or Severe forms (3, 4).

Severe Acute Malnutrition (SAM) in children is defined by the World Health Organization (WHO) as a weight-for-height/length (WFH/L) Z-score of less than –3, or a mid-upper arm circumference (MUAC) of less than 11.5 cms for children aged 6 to 59 months, or BMI-for age- Z-score of less than -3 for children >5 years and present as non-edematous (marasmus) or bilateral edematous disease (kwashiorkor or marasmic-kwashiorkor) (3, 5).

Malnutrition is a global trouble causing extensive morbidity and mortality for both adults and children worldwide (6, 7). In developing countries, an estimated of 19 million children are severely wasted and malnutrition is responsible for 11% of the total global disease burden. It is also responsible for 35% of childhood deaths worldwide. In some regions particularly in sub-Saharan Africa including Ethiopia, HIV infection poses an added challenge to the case of malnourished children (8).

HIV/AIDS is also a leading killer disease globally and it is a primary cause of death in Africa, especially sub-Saharan Africa. Global statistics for 2017 estimated the number of children (age <15years) living with HIV on average to be 1.8 million (9).

Complex association exists between malnutrition and HIV infection. The two potentiate each other. Because, untreated HIV infected children tend to have repeated episodes of infections which contribute to loss of appetite and difficulty in eating. In turn, loss of appetite and difficulty of eating leads to reduced food intake; predisposing the child to malnutrition. On the other hand, malnutrition, especially SAM, causes oxidative stress and nutritional-acquired immune deficiency syndrome (NAIDS) which increases the risk of progression of HIV infection to AIDS. Indeed, Rapid progression to AIDS stage is more common even in well-nourished children, since they have physiologically immature immunity (2, 10, 11). In children with SAM, physiological and nutritional-acquired immune deficiency will act synergistically leading to acceleration of HIV progression and increased morbidity. Again, increased morbidity results in increased nutritional requirements. This complex association between those two sufferings will continue by creating vicious cycle and the end result will be death of the sufferer (12).

So, prevention, early identification and management of SAM are an important component of care in a child with HIV to limit the vicious cycle and death. However, prevention of SAM in HIV positive children requires identification of its predisposing factors. Therefore, this study is intended to identify determinants of SAM among HIV positive children receiving HAART in Public health institutions of North Wollo Zone, Northeastern Ethiopia.

1.2. Statement of the problem

HIV infection and malnutrition are major public health problems in children (4, 13). In 2015, about 1.8 million under-fifteen children were infected with HIV worldwide (4), and more than 90% of them were found in sub-Saharan Africa (14). Similarly, malnutrition is estimated to contribute to more than 20 million childhood morbidity and mortality. Moreover, malnutrition is a major problem for HIV-infected children and HIV has increased the prevalence of severe acute malnutrition (15). Because being infected with HIV has a substantial impact on nutritional status, especially in children; due to increased energy requirements, loss of appetite, decreased absorption and other related impairments (13, 16, 17). This makes the global prevalence of malnutrition in HIV infected children to be as high as 40% (12), but this prevalence reaches as high as 68.7% in resource limited countries (4). HIV/AIDS can also increase the severity of pre-existing mild and moderate under-nutrition cases (18). Consequently, over half of children living with HIV/AIDS would also suffer from SAM especially in countries having food insecurity like Ethiopia (19, 20).

HIV/AIDS and nutritional problems in Ethiopia are of large magnitude. The exact prevalence of HIV in Ethiopian children is not known, but an estimated of over 160,000 under-fifteen children were living with HIV/AIDS by 2013 (21). Data on the prevalence of malnutrition in under-fifteen Ethiopian children is also limited, but in under-five children it reaches as high as 40% with 15% being severe forms in Ethiopia (22). The prevalence of Malnutrition among HIV positive Ethiopian children is not abundantly investigated, but it is assumed to be high especially in rural parts of the country (23).

Different countries across the world including the Ethiopian Ministry of health are on implementing integrated Nutritional and HIV care to improve nutritional status of infected individuals (14, 24). Despite some progress being made towards HIV/AIDS and Malnutrition through those integrated approaches, both continues to be significant causes for death of children (15). Combined effect of HIV/AIDS and malnutrition greatly weakens the immune system and provides a fertile ground for opportunistic infections. Their combined effect is more severe in children and is a cause for greater morbidity and mortality in those children (4, 25).

In HIV positive children, SAM is an indicator of severe disease that is associated with worse prognosis and impaired immune recovery even on Anti-Retroviral Therapy (ART) alarming extensive medical attention for this population (12). It will decrease adherence to ART, reduce effectiveness of ART, increase risk of opportunistic infections, facilitate HIV progression and shorten survival (26, 27). Thus, among children with severe malnutrition, the risk of death is three to four times higher in HIV-infected children (28, 29).

Improving nutritional status is a key strategy to reduce the progress of HIV and to prolong survival in HIV infected children (1). So, identifying determinants of SAM among HIV positive children will aid for proposing appropriate preventive and therapeutic strategies to improve nutritional status, increase effectiveness of ART and to decrease morbidity and mortality in those children. Despite this only few studies were conducted to address the issue particularly in Ethiopia. Besides, most of the studies conducted in other countries were not specific to SAM. Additionally, most of the studies were conducted with cross-sectional study design which fails to identify the chicken-egg dilemma for the occurrence of malnutrition and HIV—meaning it fails to identify whether HIV leads to malnutrition or malnutrition occurs before HIV—so, it may not address HIV related factors that lead to Malnutrition.

Moreover, SAM is still a cause for morbidity and mortality of HIV positive children in Ethiopia particularly in rural parts of the country. Due to these reasons, the investigator believes that there is a need to further investigate determinants of SAM among HIV positive children with a case- control study which will fill the gaps identified above. So, the purpose of this study is to assess determinants of SAM among HIV positive children receiving Highly Active Anti-Retroviral Therapy (HAART) in Public health institutions of North Wollo zone located in Northeastern Ethiopia.

1.3. Significance of the study

Since this study will reveal determinants of SAM among HIV positive children, it will increase existing knowledge of health professionals on determinants of SAM among HIV positive children. This will in turn help health care workers working in ART clinic to provide evidence based factor oriented preventive strategies to prevent SAM and its effect on HIV positive children. Additionally identifying determinants of SAM will help health care workers working in ART clinic to give more attention for risky children and to take appropriate measures before they develop the condition.

This study will also help caregivers of HIV infected children to aware factors that lead to malnutrition and to take appropriate measures before their child develops the condition. It will also help planners and policy makers to develop evidence based factor oriented strategy to reduce exposure of HIV infected children for determinants of SAM which in turn will help to reduce SAM among HIV positive children. It will also be used as a source of data for any concerned governmental or non-governmental organization for developing interventional projects towards improving nutritional status of HIV positive children in the study area. Moreover, this study will be used as a source for further researchers who are interested in the same or related areas of investigation.

CHAPTER TWO

2. LITERATURE REVIEW

2.1. Prevalence of Severe Acute malnutrition among HIV positive Children

Despite the efforts tried to reduce Malnutrition in HIV infected children through the availability of treatment and various nutritional programs, malnutrition remains highly prevalent in those individuals, with variable prevalence being recorded (20, 30).

A retro prospective record based study carried out from January 2013 to December 2015 in the Antiretroviral therapy (ART) Centre of Dr. Stm Forest Hospital in Haldwani-India on 107 under-fifteen children showed that the prevalence of Severe Acute malnutrition (wasting with Z-score less than -3) to be 13.04% (31).

A descriptive study performed in the CNHU-HKM Pediatrics and Medical Genetics Clinic from September 15, 2014 to August 28, 2015 in Cotonou on under-fifteen children revealed that the prevalence of SAM to be 11.5% (32).

A retrospective study carried out on a cohort of HIV-infected children, aged 0-5 years at initiation of ART and regularly followed at the HIV Care and Treatment Center of Laquintinie hospital, Douala, Cameroon from January 2002 to December 2015 revealed that the prevalence of SAM to be 10.6% (4).

A three year prospective study (April 2011 to March 2014) on children with diagnosis of severe acute malnutrition conducted in the pediatric medical ward (PMW) of the University of Abuja Teaching Hospital (UATH) revealed that Marasmus to be the commonest type of SAM in HIV positive children with prevalence of 80.9% (7).

Institution based cross-sectional study conducted on 301 conveniently selected HIV positive children aged 6 months to 14 years (median 7 years) in the Pediatric ART clinics of Felege Hiwot and Gondar referral hospitals, Northwest Ethiopia, between April 30 and June 15, 2009 revealed that the prevalence of SAM to be 10.3% (23). Another study conducted in Adama Hospital Medical College, Ethiopia had showed the prevalence of acute malnutrition among under-fifteen HIV positive children to be 21.8% (33).

2.2. Factors associated with malnutrition among HIV positive Children

Different factors may contribute for the development of malnutrition in HIV positive children (19).

A single-centered, retrospective, cross-sectional survey conducted on HIV-infected children aged 2-18 years at the Bamrasnaradura Infectious Diseases Institute (BIDI) in Thailand revealed that malnutrition was significantly associated with severity of HIV (WHO stages 3 and 4) (OR=184.50, 95%, CI=35.72-952.73, p= 0.000), Protease Inhibitor (PI) based HAART (OR= 5.38, 95% CI=1.97-14.67, p= 0.001) and being non-orphan (parent as caregivers) (OR= 0.56, 95% CI=0.34-0.92, p= 0.023); while adherence, CD4 count and viral load were not associated with malnutrition (34). Similarly, a study conducted in Dr. Stm Forest Hospital in Haldwani-India among HIV infected children showed that malnutrition was not associated with sex and CD4 count (31).

A mixed- design (quantitative and qualitative) study among 748 children aged 6 months-14 years attending ART centers in Tanga region, Tanzania, showed that wasting was associated with age (b=0.20, p=0.009) and HIV clinical stage (b=20.25, p=0.001)—Younger children were more likely to experience wasting, and an increase in child's HIV clinical stage from early to advanced was more likely to be associated with severity of wasting (35). Another study conducted among ART-treated HIV-positive children in Dar es Salaam, Tanzania, revealed that diarrhea (AOR = 22.49, 95% CI= 3.38 149.61, p = 0.001), household food insecurity (AOR= 8.64, 95% CI= 1.26, 59.23 p= 0.028 and feeding frequency (AOR = 0.03, 95% CI= 0.01, 0.21, p< 0.001) were factors associated malnutrition (19).

According to a cross-sectional study conducted from September to December 2011 among HIV-infected children aged 2–19 years old, enrolled in central and west Africa HIV-care programs—in Benin, Burundi, Cameroon, Cote d'Ivoire, Mali, Chad and Togo, acute malnutrition was associated with male gender (AOR= 2.27 with 95% CI of 1.52–3.41), and severe immunodeficiency (AOR= 2.07 with 95% CI of 1.25–3.42); while being Orphan-hood and cotrimoxazole prophylaxis were not associated with malnutrition (36). Another retrospective study carried out on a cohort of HIV-infected children, aged 0-5 years at initiation of ART and regularly followed at the HIV/CTC of Laquintinie hospital Douala, Cameroon from January 2002 to December 2015, Oropharyngeal candidiasis was a risk factor

independently associated with severe wasting (with OR = 5.1, 95% CI: 1.5-17.1, p = 0.007), while Age and Sex was not associated with Severe wasting (4).

A case-control study conducted in Bushbuckridge District, Limpopo Province, South Africa from April 2003 to March 2004, identified that parental death/ orphanhood (AOR=38.0, 95% CI =3.8–385.3, p= 0.002), male sex (AOR= 2.7, 95% CI =1.2–6.0, p=0.014), and diverse food intake (AOR= 0.53, 95% CI =0.41–0.67, p= 0.000) to be factors statistically associated with malnutrition (37). Another study conducted in Agincourt sub-district of Mpumalanga Province, northeast South Africa, showed existence of association between malnutrition and area of residence (AOR= 2.2, 95% CI= 1.1, 4.3, p= 0.024) (38).

A quantitative descriptive study conducted at pediatric wards of Parirenyatwa Group of Hospitals on 30 conveniently selected under-five children with weight-for-age below 80 % of expected weight and who were HIV positive identified that contributing factors to malnutrition were presence of other illnesses such as diarrhea, pneumonia and tuberculosis and coming from a family with more than 5 dependents/ family size (15).

As per a study conducted in Pediatric ART clinics of Felege Hiwot and Gondar referral hospitals, Northwest Ethiopia, malnutrition was significantly associated with duration of follow-up at ART clinics (AOR=3.33; 95% CI =1.37, 8.11), presence of eating problem (AOR= 2.14; 95% CI =1.40,4.40) and Age of the child (AOR= 4.10; 95% CI=1.22,13.76); while sex and presence of opportunistic infections were not associated with malnutrition (23).

According to an institutional based comparative cross-sectional study conducted on 372 under-fifteen HIV positive children in three public hospitals of east and west Gojjam zones, in Amhara Regional State from February 20 to April 20/ 2017, sex of child (being male) (AOR= 2.37, 95% CI= 1.34, 4.20), age of the child (being age of 10- 15 years) (AOR= 0.05, 95% CI= 0.01, 0.25), oral ulcer (AOR= 2.30, 95% CI= 1.41, 7.60), and diarrhea (AOR= 3.30, 95% CI= 1.41, 7.72) were found significantly associated with malnutrition (39).

Another institution based cross sectional study conducted in 2017 on 412 Under-fifteen HIV positive children who were on chronic ART care and support in Adama Hospital Medical College had revealed that male sex (AOR= 1.99, 95% CI= 1.19, 3.32), existence of eating problems (AOR, 2.2; 95% CI: 1.19, 4.11), age greater than 10 years (AOR= 0.24; 95% CI= 0.08, 0.73) and monthly income of the caregivers (AOR= 0.40; 95% CI= 0.20, 0.79) to have a significant association with acute malnutrition (33).

2.3. Conceptual framework

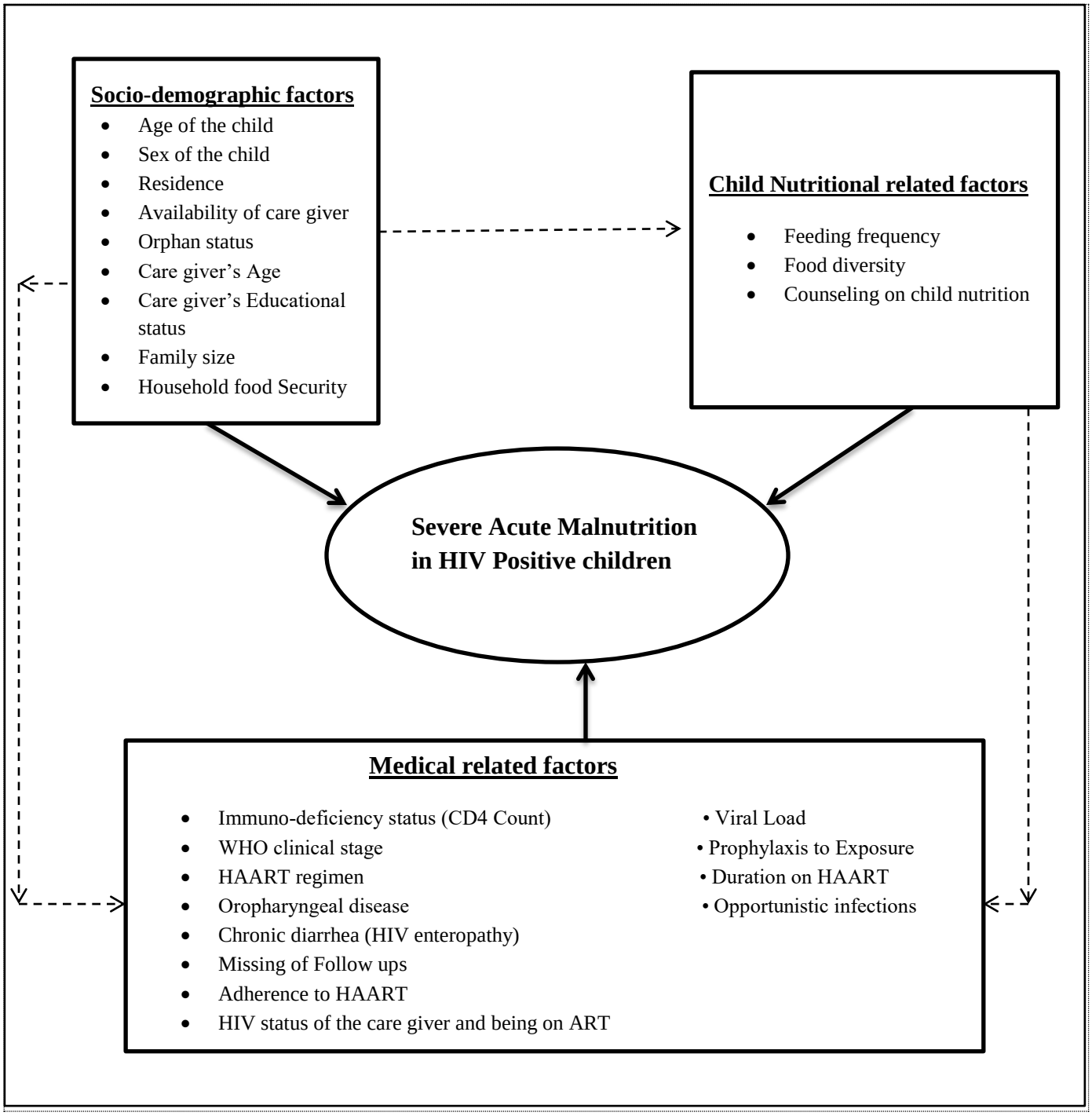

Figure 1: Conceptual framework showing determinants of Malnutrition (SAM) among HIV positive children, 2019 *(Source: adapted from previous study,(1))*

CHAPTER THREE

3. OBJECTIVES

3.1. General objective

- To identify determinants of Severe Acute Malnutrition among HIV positive children receiving HAART in Public Health Institutions of North Wollo zone, Northeastern Ethiopia, 2019.

3.2. Specific objectives

1. To identify socio-demographic related determinants of SAM among HIV positive children by assessing exposure differences for selected socio-demographic variables among cases and controls.
2. To identify medical related determinants of SAM among HIV positive children by assessing exposure differences for selected medical related variables among cases and controls.
3. To identify nutritional related determinants of SAM among HIV positive children by assessing exposure differences for selected nutritional related variables among cases and controls.

CHAPTER FOUR

4. METHODS AND MATERIALS

4.1. Study Area and Period

The study will be conducted in Public health institutions that provide ART service (ART clinics) in North Wollo Zone, Amhara region, Northeastern Ethiopia located around 521 Kms far from Addis Ababa. North Wollo Zone is one among 10 zones of the Amhara Region which is bordered on the south by South Wollo, on the west by South Gondar, on the north by Wag Hemra, on the northeast by Tigray Region, and on the east by Afar Region (40). According to the 2007 Census conducted by the Central Statistical Agency of Ethiopia (CSA), this Zone has a total population of 1,500,303; of whom 752,895 are men and 747,408 women; with an area of 12,172.50 square kilometers (41).

In this zone there are 19 public health institutions that provide ART service for children. In those institutions there are an estimated of 637 children receiving HAART in a monthly/ an every two months routine follow up (40). So, this study will be conducted in ART clinics of those public health institutions from March to May/ 2019.

4.2. Study design

Institution based Unmatched Case-Control study will be conducted.

4.3. Population

4.3.1. Source population

- All HIV positive children receiving HAART in public health institutions/ ART clinics in North Wollo Zone.

4.3.2. Study population

- **Cases:** will be all HIV Positive children with SAM receiving HAART in selected Public Health Institutions in North Wollo Zone and passed the inclusion and exclusion criteria.
- **Controls:** will be all HIV Positive children without SAM receiving HAART selected in Public Health Institutions in North Wollo Zone and passed the inclusion and exclusion criteria.

4.4. Inclusion and Exclusion criteria

4.4.1.Inclusion criteria

Cases:

- HIV Positive children who had history of SAM (MUAC < 11.5 cms, or Weight for height/ length Z-score < -3, or bilateral pitting edema of other causes excluded with or without severe wasting, or BMI Z-score < -3) will be included as cases.

Controls:

- HIV Positive children who had not history of SAM (MUAC ≥ 11.5 cms, or Weight for height Z-score ≥ -3, or no any history of nutritional related bilateral pitting edema or severe wasting, or BMI Z-score ≥ -3) will be included as controls.

4.4.2.Exclusion criteria

- Children who had developed SAM before the diagnosis of HIV, children who were on ART for less than six months, children who had history of MAM that did not progressed to SAM, medical records with deceased children and medical records with missed significant information will be excluded from cases and controls.
- If more than one HIV positive children found within the same household, only one will be selected randomly to be included in the study.

4.5. Sample size determination and sampling procedure

4.5.1.Sample size determination

Sample size is determined using a formula for two population proportion and calculated with Open Epi version 7.2.0.1 statistical software package.

$$n_{case} = (\frac{r+1}{r}) \frac{(\bar{p})(1-\bar{p})(Z_{\beta} + Z_{\alpha/2})^2}{(p_1 - p_2)^2};$$

$$n_{control} = r(n_{case}); and \quad N = n_{case} + n_{control}$$

Where, n_{case} = Sample size in the case group

r = Ratio of control to case

$(\bar{p})(1-\bar{p})$ =A measure of variability

Z_{β} = The desired power (0.84 for 80% power)

$Z_{\alpha/2}$ = The desired level of statistical significance (1.96)

$(p_1 - p_2)$ = Effect size (the difference in proportions)

p_1 = percent of cases exposed = $p_1 = \frac{OR(p_2)}{p_2(OR-1)+1}$

p_2 = percent of controls exposed

$n_{control}$ = sample size for control group

N = total sample size

By considering the following assumptions from a study conducted in South Africa, the sample size required for this study is as follows (37):

Variable	**Proportion of controls exposed**	**Odds ratio**	**Power**	**Confidence level**	**Case to control ratio**	**Initial sample size**	**10% for non-response rate**	**Final sample size**
Sex (Male)	51%	2.72	80%	95%	1:2	177	18	**195**
Weaning practice	22%	3.04	80%	95%	1:2	150	15	165
Orphan-hood	49%	38.01	80%	95%	1:2	38	4	42

So, the calculated sample size required for this study was 195 (65 cases and 130 controls).
Sampling method and procedure

1. From the total 19 ART clinics, first the investigator will choose 5 ART clinics with simple random sampling technique.
2. Medical Registration Number (MRN) of HIV positive children receiving HAART in those Selected ART clinics will be filtered from computerized Health information management system (HIMS) and all medical records/ charts of HIV positive children receiving HAART in those Selected ART clinics will be extracted from Medical registration department.
3. Counting of medical records of all HIV positive children receiving HAART in those 5 ART clinics will be made.
4. Simultaneously with assessment for fulfilling the inclusion and exclusion criteria, identifying SAM (cases) and non-SAM (controls) children will be carried out.
5. Simple random sampling technique will be used to select cases and controls.

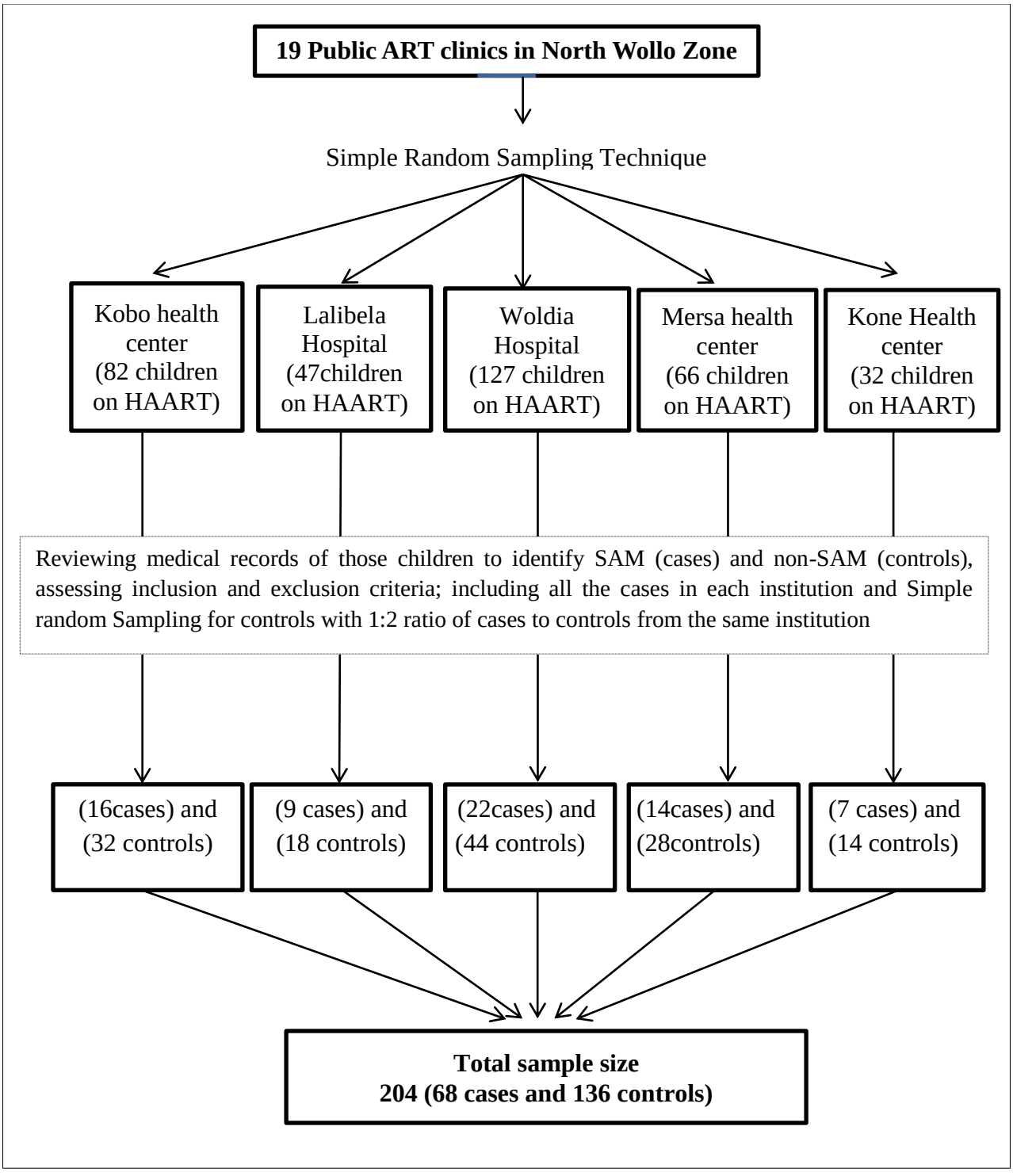

Figure 2: Schematic presentation of sampling procedure to select study participants from North Wollo Zone public ART clinics, 2019

4.6. Study variables

4.6.1. Dependent variable

- Severe Acute Malnutrition

4.6.2. Independent variables

- **Socio-demographic variables** (Age of the child, Sex of the child, Residence, Availability of care giver, Orphan status, Care giver's Age, Care giver's Educational status, Family size, Household food Security).
- **Child Nutritional related variables** (Feeding frequency, Food diversity, Counseling on child nutrition).
- **Medical related variables** (Immuno-deficiency status (CD4 Count), Viral Load, WHO clinical stage, Prophylaxis to Exposure, HAART regimen, Duration on HAART, Missing of Follow ups, Adherence to HAART, Opportunistic infections, Chronic diarrhea (HIV enteropathy), Oropharyngeal disease, HIV status of the care giver and being on ART).

4.7. Operational definitions and definition of terms

- **Severe Acute Malnutrition (SAM):** Medical condition characterized by MUAC less than 11.5 cms, or weight for height (W/H) Z-score less than -3 or by presence of bilateral pitting edema with or without severe wasting (in children aged 6-59 months) or BMI Z-score < -3 (for children 5-15 years) (5).
- **Children:** an individual whose Age is less than 15 full years.
- **Opportunistic infection:** HIV related infections/ cancers other than Chronic diarrhea and Oropharyngeal disease/ candidiasis.
- **Food insecurity:**
  - ✓ Secured: if the attendant responds ≥ 2 for food security checking Analog scale.
  - ✓ Unsecured: if the attendant responds < 2 for food security checking Analog scale.
- **Feeding frequency:**
  - ✓ Adequate: if the child has feeding history of ≥ 4 times per day for age < 5 years or of ≥ 3 times per day for age ≥ 5 years.
  - ✓ Inadequate: if the child feeds < 4 times per day for age < 5 years or < 3 times per day for age ≥ 5 years.

4.8. Data collection

4.8.1.Data collection methods

Data will be collected by extracting available information from participant's medical record and by interviewing the participant's attendants/ participants (mixed primary and secondary data will be used).

4.8.2.Data collection tools

Data extraction checklists and semi-structured questionnaires adapted from previous study (39) will be used. The questionnaire used for interviewing the participant's attendant/ Participants will be first prepared in English version and then translated in to Amharic version and then again translated in to English version with independent language translators.

4.8.3.Data collection procedure

Five data collectors working in ART clinics and five supervisors will be recruited. Medical records of the samples will be coded during sampling procedure and based on this code data collectors will first took the informed consent and/ or assent. Then interviewing of volunteers; and extraction of the required information from the participant's medical record will be conducted.

4.9. Data quality control

The checklist and questionnaire will be pre-tested on 10% of the sample size at Dessie Referral hospital and necessary modifications will be made to increase their quality for the actual data collection. The data collectors and supervisors will be trained. During data collection, data collectors will check the checklist and questionnaire for completeness and if missing information is there, they will take measures to overcome it. Supervisors will also receive, check the completed checklist and questionnaire regularly and will double check the checklist with the participant's medical record accordingly. The principal investigator will also incidentally check the whole process of data collection and lastly the data will be checked during coding, data entry and was cross tabulated before analysis.

4.10. Data processing and presentation

After data collection and assuring of the data quality, the questionnaire will be codded and data will be entered in to Epi Data version 4.2.0. Then the entered data will be exported to SPSS version 23 for analysis. Descriptive analysis will be employed to describe socio-demographic characteristics of study participants and the type of SAM distributed among case groups. To identify determinants of SAM among HIV Positive children, first, binary logistic regression will be used and variables that had a p-value of < 0.25 will be entered into multiple logistic regression for further analysis. Odds ratio with 95% CI will be used to interpret results and a p-value of < 0.05 will be considered as significance difference between cases and controls for the exposure variable under study. Finally, results will be presented in the form of narration, tables, graphs and charts.

4.11. Ethical consideration

Ethical clearance will be obtained from departmental review board of Nursing and Midwifery, College of Health Science, Addis Ababa University before the beginning of data collection. Permission letter will be provided for directors of the selected public health institutions and then attendants of the participant child/ participants will be well-informed about the purpose, risks, benefits and procedure of data collection. Confidentiality and privacy will be ensured by anonymous recording of the participant's information. Furthermore, participation will be based on the willingness of participant's attendant/ the participant and this will be ensured by using informed consent and/ or assent.

4.12. Plan for study finding dissemination

After completion of the study, the result will be disseminated to school of Nursing and Midwifery of Addis Ababa University, public health institutions of north Wollo zone and North Wollo zone health bureau. Additionally manuscripts will be prepared and efforts will be tried for publication.

CHAPTER- FIVE

Work plan

Table 1: Work plan to conduct research on "Determinants of Severe Acute Malnutrition among HIV positive children receiving HAART in Public hospitals of North Wollo zone, Northeastern Ethiopia, 2019"

S. No.	Activities	Responsible body	Time span													Remark
			February			March	April				May				June	
			1st week	2nd - 3rd weeks	4th week	1st - 4th weeks	1st week	2nd week	3rd week	4th week	1st week	2nd week	3rd week	4th week	1st week	
1	Research proposal presentation and defense	PI														
2	Research proposal submission	PI														
3	Pre-test, and modification of the questionnaire	PI														
4	Receiving permission letter and submitting to the selected hospitals	IRB & PI														
5	Subject recruitment, Data collection and process monitoring	PI, CE, DC, & Sup.														
6	Data entry and Data analysis	PI														
7	Thesis draft development and advisor review	PI & Advs.														
8	First draft Research paper submission, Thesis presentation and defense	PI														
9	Last research paper submission and result dissemination	PI														

PI: Principal investigator DC: Data Collectors Sup.: Supervisors
IRB: Institutional Review Board Advs.: Advisors CE: Card Extractors

CHAPTER- SIX

Budget plan

Table 2: Budget needed to accomplish a research on "Determinants of Severe Acute Malnutrition among HIV positive children receiving HAART in Public hospitals of North Wollo zone, Northeastern Ethiopia, 2019"

So.No.	Items and personnel needed	Unit	Quantity (amount needed)	Unit price (Birr)	Total price (Birr)	Remark
	Personnel					
1	Data collectors	Price birr per questionnaire	195	30	5850	
2	Supervisors	Price birr per questionnaire	195	40	7800	
3	Card extractors	No. of persons and No. of days	5 persons & 5 days	220	5500	
	Items					
1	CD	No.	3	25	75	
2	Printing	Page no.	270	2	540	
3	Photocopy	Page no.	1500	1	1500	
5	Note book	Number	16	30	480	
6	Paper	Pack/ desta	1	450	450	
7	Pen	Number	16	7	112	
8	Pencil	Number	16	3	48	
9	Eraser	Number	16	5	80	
10	Marker	Number	5	20	100	
12	Binding materials	Handout no.	4	200	800	
13	For communication	Mobile card for each personnel (No.)	16	50	800	
Total					**24,135**	
10% Contingency cost					2,415	
Grand Total					**26, 550**	

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ANNEXES

1. Dummy tables

Variables		Cases		Controls		Total
		N	%	N	%	N (%)
Child's Age	< 5 years					
	≥ 5 years					
	Total					
Child's sex	Male					
	Female					
	Total					
Orphan status	Orphan					
	Non-orphan					
	Total					
Food security status of the household	Secured					
	Unsecured					
	Total					
Child feeding frequency	Adequate					
	Inadequate					
	Total					
HIV stage	Early (I and II					
	Advanced (III and IV)					
	Total					
Duration on ART	< 6 months					
	≥ 6 months					
	Total					
Adherence to ART	Optimal					
	Sub-optimal					
	Total					

2. Questionnaire and Checklist

INFORMED CONSENT

TITLE OF THE STUDY: "Determinants of Severe Acute Malnutrition among HIV positive children receiving HAART in Public health institutions of North Wollo zone, Northeastern Ethiopia, 2019: Unmatched Case-control study"

1) INTRODUCTION

I, a graduating class student in Addis Ababa university school of Nursing and Midwifery with MSc in child health nursing, kindly requests for you and your child to participate in the research study titled as in the above. Before you decide whether or not to participate in this study, I would like to explain to you the purpose of the study, procedure, any risks, benefits and what is expected of you. Your participation in this study is entirely of your own free will. You are under no obligation to participate; you may choose to participate or not to participate. If you decide not to participate, no privileges will be taken away from you as a client in this ART clinic. If you agree to participate, you will be asked to sign in the space provided below.

2) PURPOSE OF THE STUDY

The purpose of this study is to identify determinants of SAM among HIV positive children.

3) PROCEDURE

After you have signed the informed consent form, and have a chance to ask questions, you will be requested to answer questions asked by the data collectors.

4) RISKS

No risks are involved apart from the use of your time for answering questions.

5) BENEFITS

Agreement to participate will not result any immediate benefits to you. But by taking part in this study, you will be able to provide true information that will help relevant health care providers working in ART clinics to give factor oriented health education, authorities and policy makers to come up with strategies and policies that will help to decrease SAM among HIV positive children. This will in turn benefit children and the community at large.

6) CONFIDENTIALITY

The information that you provide will be confidential to the data collectors only and it will be used for the purpose of this study only.

7) INFORMED CONSENT FORM

The purpose of this study has been explained to me and I understand the purpose, the risks, benefits and confidentiality of the study and also taking part in this study is purely voluntary. So, I am agreed to take part/ participate in this study.

- ☐ Yes
- ☐ No

If yes, Sign_____

8) PERSON TO CONTACT FOR PROBLEMS OR QUESTIONS

Melaku Bimerew (Mobile: +251923065826)
Email: mebiget@gmail.com

መጠይቅ

የስምምነት መጠየቂያ ቅጽ

እኔ ተማሪ_____ በ አዲስ አበባ ዩኒቨርሲቲ ጤና ሳይንስ ኮሌጅ በ ነርሲንግ ትምህርት ክፍል ስር በሚገኘው የህጻናት ጤና ነርሲንግ የ 2ኛ ዲግሪ ትምህርቴን በመከታተል ላይ ያለሁ ስሆን የመመረቂያ ጥናታዊ ጽሁፌን በዚህ የጤና ተቋም ውስጥ የህክምና ክትትል ባላቸውና እድሜያቸው ከ 15 ዓመት በታች በሆኑ ህጻናት ላይ ለመስራት ንድፈ–ሃሳብ አዘጋጅቼ በመንቀሳቀስ ላይ እገኛለሁ። የጥናታዊ ጽሁፌ ርዕስ " በ ሰሜን ወሎ ዞን በሚገኙ የመንግስት ሆስፒታሎች ውስጥ የ ኤች. አይ. ቪ /ኤድስ መድሃኒት እየወሰዱ ያሉ እድሜያቸው ከ 15 ዓመት በታች የሆኑ ህጻናትን ለ ከፍተኛ የምግብ እጥረት በሽታ የሚያጋልጡ መንስኤዎች'' ይሰኛል። የጥናቱ ዓላማ የ ኤች. አይ. ቪ /ኤድስ መድሃኒት እየወሰዱ ያሉ እድሜያቸው ከ 15 ዓመት በታች የሆኑ ህጻናትን ለ ከፍተኛ የምግብ እጥረት በሽታ የሚያጋልጡ መንስኤዎችን ለመለየትና እነዚህን መንስኤዎች ለመቀነስ የሚያስችሉ እርምጃዎችን ለማመላከት ነው። በመሆኑም የእርስዎ ህጻን እድሜው ከ 15 ዓመት በታች ስለሆነና በዚህ ሆስፒታ ውስጥ የ ኤች. አይ. ቪ /ኤድስ መድሃኒት እየወሰደ ስላገኘሁት በጥናታዊ ጽሁፌ ተሳታፊ ይሆን ዘንድ እንዲፈቅዱልኝ እርስዎም ለምጠይቅዎት ጥቂት ጥያቄዎች ተገቢውን ምላሽ በመስጠት እንዲተባበሩኝ በአክብሮት እጠይቅዎታለሁ። በጥናቱ ለመሳተፍ የመፍቀድም ሆነ ያለመፍቀድ ሙሉ መብትዎት ሲሆን ፈቃደኛ በመሆንዎ በእርስዎም ሆነ በህጻንዎ ምንም አይነት የጎንዮሽ ጉዳት አያስከትልም፤ የ ኤች. አይ. ቪ /ኤድስ ተጠቂ የሆኑ ህጻናትን ለ ከፍተኛ የምግብ እጥረት በሽታ የሚያጋልጡ መንስኤዎችን ለመለየት የራስዎን ድርሻ ይወጣሉ እንጂ የተለየ እለታዊ ጥቅምም አያገኙም፤ ፈቃደኛ ባለመሆንዎም ምንም አይነት ጉዳት አይደርስብዎትም። የሚሰጡኝ መረጃ ምስጢራዊነቱ የተጠበቀ እንደሚሆንና ለጥናቱ ዓላማ ብቻ እንደሚውል ላስገነዝብዎት እወዳለሁ። በመጨረሻም ፈቃደኛ መሆንዎን ወይም አለመሆንዎን በፊርማዎት ያረጋግጡልኝ ዘንድ በድጋሜ በአክብሮት እጠይቅዎታለሁ።

እኔ የዚህ ህጻን እናት/ አባት / አሳዳጊ ስሆን የዚህን ጥናት ርዕስ እና ዓላማ በተደረገልኝ ገለጻ መሰረት በደንብ ተገንዝቤያሉሁ። በተጨማሪም ለመሳተፍ መፍቀድም አለመፍቀድም ሙሉ መብቴ እንድሆነና ብፈቅድም ባልፈቅድም በእኔና በልጄ ላይ ምንም አይነት ጉዳት እንደማይደርስብኝ፤ የምሰጠው መረጃም ምስጢራዊነቱ የተጠበቀ እንደሚሆንና ለጥናቱ ዓላማ ብቻ እንደሚውል ተረድቻለሁ። በዚህም መሰረት ልጄ በጥናቱ ይሳተፍ ዘንድ እኔም መረጃ ሰብሳቢው የሚጠይቀኝን ጥያቄ በመመለስ አስፈላጊውን ትብብር ለማድረግ

☐ ተስማምቻለሁ

☐ አልተስማማሁም

ተስማምቻለሁ ካሉ ፊርማዎትን ክፍት ቦታው ላይ ያስቀምጡ _____

ለሚጠይቁኝ ጥያቄ ወይም ከጥናቱ ጋር በተያያዘ ለሚደርስብዎት ማንኛውም ነገር ከታች በተቀመጠው አድራሻ ያግኙኝ።

መላኩ ቢምረው (ስልክ +251923065826)

(ኢሜይል mebiget@gmail.com)

A. CHECKLIST (used for extracting data from participant's medical record)

i. Case-control screening questions (code- 1)

Sampling Code: _____

Date_____

Code		Variable/questions	Possible responses	Remark
101	1011	Does the child has history of SAM (MUAC< 11.5 cms or W/H< -3 or nutritional related Bilateral pitting edema with or without severe wasting or BMI Z-score < -3)?	1. Yes 2. No	If No, go to Q. No. 201
	1012	Type of SAM the child diagnosed was____?	1. Edematous i) Kwashiorkor ii) Marasmic-kwash 2. Non-edematous/ marasmus 3. Not specified	

ii. Factor Extraction checklist (Code- 2)

Code		Variables/ questions	Possible responses	Remark
201		Child's Age is		Write the child's age in full years
202		Child's sex is	1. Male 2. Female	
203	2031	Was the HIV transmitted to the child Vertically (mother to child)?	1. Yes 2. No	If no skip to Qn # 204
	2032	If yes, Was the child diagnosed as HIV exposed starting from Birth?	1. Yes 2. No	If no skip to Qn # 204
	2033	If yes, Does the child take any prophylaxis for exposure and/ or for prevention of opportunistic infections? **(for case groups starting from 6 months before the Diagnosis of SAM)**	1. Yes 2. No	
204		Which HAART regimen does the child take? **(for case groups starting from 6 months before the Diagnosis of SAM)**		Write it in the space provided
205		Duration of child's follow up at ART clinic was ____?		Write in full months

206	Does the child had any History of Oropharyngeal candidiasis? **(For case groups starting from the last 6 months before the Diagnosis of SAM)**	1. Yes 2. No	
207	Does the child had any History of Opportunistic infections**? (For case groups starting from the last 6 months before the Diagnosis of SAM)**	1. Yes 2. No	
208	Does the child had any history of HIV enteropathy (chronic diarrhea)? **(For case groups starting from the last 6 months before the Diagnosis of SAM)**	1. Yes 2. No	
209	Does the child had History of missing of follow ups? **(For case groups starting from the last 6 months before the Diagnosis of SAM)**	1. Yes 2. No	
210	The child's Level of adherence to HAART was__? **(For case groups starting from the last 6 months before the Diagnosis of SAM)**	1. Good 2. Fair 3. Poor	
211	Immuno-deficiency Status reached by the child? **(For case groups starting from the last 6 months before the Diagnosis of SAM)**	1. Severe 2. Moderate 3. Not significant	
212	Maximum Viral load of the child is? **(For case groups starting from the last 6 months before the Diagnosis of SAM)**		Write it in the space provided
213	Highest WHO staging (clinical severity of HIV) experienced by the child? **(For case groups starting from the last 6 months before the Diagnosis of SAM)**	1. Early i) Stage I ii) Stage II 2. Advanced i) Stage III ii) Stage IV	

B. <u>Questionnaire for Primary data from the child/ child's caregiver (Code- 3) (English Version)</u>

Code			Variable	Possible Response	Remark
301			Does the child has a main Caregiver?	1. Yes 2. No	If no skip to 303
302	3021	If yes,	Age of the caregiver is		Write in full years
	3022		Educational status of the care giver is	1. Non Educated at all 2. Up to primary or less 3. Secondary or above	
	3023		Residence of the care giver is	1. Rural 2. Urban	Urban: living in zonal / woreda town Rural: living out of zonal/woreda town
	3024		Caregiver's HIV status is	1. Positive 2. Negative	If negative go to Q. No. 303

	3025	If HIV Positive, Was the caregiver's of the child on ART?	1. Yes 2. No	
303		Orphan status of the child is	1. Orphan i) Mother ii) Father iii) Both 2. Non-orphan	
304		Family size was____?	1. ≤ 3 2. 4- 6 3. ≥ 7	
305		Household food insecurity status was____? (rate your status relatively) 	1. Secured (if the attendant rates at 2 and above) 2. Unsecured (if the attendant rates below 2)	0= unable to get daily foods 1= can get only to feed 2 times per day 2= can get enough food 3= even they have wealth for emergency time (drought…) 4= have permanent capitals and even can help others
306		Most of the time the child takes food that are_____	1. Diversified 2. Non-diversified	**Diversified:** if contains mixture of cereals, meet, egg… **Non-diversified:** if does not contains mixture of foods
307		Feeding frequency for the child? (Ask history of 6 months before the diagnosis of SAM for case groups)	1. Adequate 2. Inadequate	**Adequate:** if ≥ 4 times/day for children Aged less than 5 years or ≥ 3 times/day for Age≥ 5 **Inadequate:** if <4 times/day for children Aged less than 5 years or <3 times/day for Age≥ 5
308		Does the caregiver/ child get nutritional counseling from health care providers?	1. Yes 2. No	Ask only if the child had weaned

Thank You for Your Response!!!

መጠይቅ (ህጻኑን/የህጻኑን የቅርብ ተንከባካቢ ለመጠየቅ የሚሆን (ኮድ-3) (አማርኛ ቅጅ)

ኮድ/መለያ		ጥያቄ	አማራጭ መልሶች	ማስታወሻ
301		ህጻኑን በዋናነት የሚንከባከብ ሰው	1. አለ 2. የለም	መልሳቸው የለም ከሆነ ወደ ጥያቄ ቁጥር 303 ሂድ
302	3021	ህጻኑን በዋናነት የሚንከባከበው ሰው እድሜ (በ አመት)		ክፍት ቦታው ላይ ይሞላ
	3022	ህጻኑን በዋናነት የሚንከባከበው ሰው የትምህርት ደረጃ	1. ምንም ያልተማረ 2. የመጀመሪያ ደረጃ (እስከ 8ኛ) 3. ሁለተኛ ደረጃ እና ከዚያ በላይ	
	3023	ህጻኑን በዋናነት የሚንከባከበው ሰው መኖሪያ ቦታ	1. ገጠር 2. ከተማ	ከተማ= የዞን ዋና ከተማ እና የወረዳ ዋና ከተሞች ላይ የሚኖሩ ከሆነ ገጠር= ከዞን እና የወረዳ ዋና ከተሞች ውጭ
	3024	ህጻኑን የሚንከባከበው (የሚያጠባ/ የሚመግበው) ሰው ቫይረሱ በደሙ ውስጥ	1. አለበት 2. የለበትም	መልሳቸው የለበትም ከሆነ ወደ ጥያቄ ቁጥር 303ሂድ
	3025	ህጻኑን የሚንከባከበው (የሚያጠባ/ የሚመግበው) ሰው ቫይረሱ በደሙ ውስጥ ያለበት ከሆነ የ ኤች አይ ቪ /ኤድስ መድሃኒት በመውሰድ ላይ ነውን?	1. አዎ 2. አይደለም	
303		ህጻኑ ቤተሰብ	1. የሞተበት i. እናት ii. አባት iii. ሁለቱም 2. ያልሞተበት	
304		የቤተሰብ ብዛት ስንት ነው?	1. 3 እና ከዚያ በታች 2. ከ 4- 6 3. 7 እና ከዚያ በላይ	
305		(የቤተሰቡ) የምግብ ዋስትና እንዴት ነው? (ከታች የተቀመጠውን ምስል በማየት የእርስዎ በአንጻራዊ የት ሊሆን እንደሚችል ይናገሩ) 0 1 2 3 4	1. የተረጋገጠ (2 እና ከዚያ በላይ ላይ ካመለከቱ) 2. ያልተረጋገጠ (ከ 2 በታች ላይ ካመለከቱ)	በደንብ ገለጻ ይደረግበት **0**= የዕለት ምግባቸውን ለማግኘት የሚቸገሩና ምንም የሌላቸው 1= በቀን ለ 2 ጊዜ ብቻ ከሚመገቡት በላይ የሌላቸው **2**= ለቤተቡ የፈለገውን ያህል እንዲመገብ የሚያስችል ሃብት ያላቸው **3**= አስቸጋሪ ሁኔታዎች (ድርቅ፣ ረሃብና የመሳሰሉት) ቢፈጠሩ እንኳን መቋቋም የሚያስችል ሃብት ያላቸው **4**= ከራሳቸው አልፎ ሰውን መርዳት የሚያስችል በቂና ቋሚ ሃብት ያላቸው

306	ህጻኑን በቀን ለምን ያህል ጊዜ ይመግቡታል/ ይመገባል? (ህጻኑ የምግብ እጥረት በሽታ የነበረበት ከሆነ ከመታመሙ 6 ወራቶች በፊት ጀምሮ የነበረው ይጠየቅ)	1. በቂ 2. በቂ ያልሆነ	**በቂ**= እድሜያቸው ከ 5 ዓመት በታች ለሆኑ 4 ጊዜና ከዚያ በላይ/ እድሜያቸው 5 ዓመት እና በላይ ለሆኑ 3 ጊዜና ከዚያ በላይ **በቂ ያልሆነ**= እድሜያቸው ከ 5 ዓመት በታች ለሆኑ 3 ጊዜና ከዚያ በታች/ እድሜያቸው 5 ዓመት እና በላይ ለሆኑ 2 ጊዜና ከዚያ በታች
307	ህጻኑ አብዛኛውን ጊዜ የሚወስዳቸው ምግቦች ምን አይነት ናቸው?	1. ተመሳሳይነት የበዛባቸው (ከተለያዩ የምግብ ተዋጾዎች ያልተዘጋጁ) 2. ከተለያዩ የምግብ ተዋጾዎች የተተዘጋጁ (ስጋ፣ ፍራፍሬ፣ ባቄላ፣ እንቁላል... እና የመሳሰሉትን የያዙ)	
308	ለ እርስዎ የህጻናት አመጋገብ ምክር በጤና ባለሙያዎች ተሰጥቶዎት ያውቃል?	1. አዎ 2. የለም	

ለሰጡኝ ምላሽ ከልብ አመሰግናለሁ!!!